

**The development and evaluation of individual Cognitive  
Stimulation Therapy (iCST) for people with dementia**

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Thesis submitted for the degree of Doctor of Philosophy

## **Declaration**

I, Lauren Amy Yates, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I can confirm that this has been indicated in the thesis.

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Date

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Lauren Amy Yates

**“And the day came when the risk to remain tight in a bud was  
more painful than the risk it took to blossom”**

*- Anaïs Nin*

## **Abstract**

**Background:** Cognitive Stimulation Therapy (CST) can improve cognition and quality of life (QoL) for people with dementia. However, previously this has only been delivered in a group format.

**Aim:** To develop and evaluate the effectiveness of a home-based, carer-led individual CST (iCST) programme.

**Methods:** The trial followed the Medical Research Council (MRC) framework. The development phase included; assessment of studies of home based cognitive stimulation, consultation with carers, people with dementia and healthcare professionals on the adaption of the CST and maintenance CST (maintenance CST) programmes, focus groups ( $n=32$ ), ten interviews, a period of field-testing ( $n=22$ ), an online survey and a consensus conference. A multi-centre, single-blind, pragmatic, randomised controlled trial (RCT) was conducted. In total, 356 people with mild to moderate dementia and their carers were recruited. Dyads were randomly assigned into the iCST arm (three, 30 minute sessions per week for 25 weeks plus support) or treatment as usual (TAU) control. The iCST training DVD was developed as part of the trial.

**Results:** In the development phase the concept of iCST was well received, and both carers and people with dementia responded positively to the first drafts of materials. Anticipated issues, such as finding time to do sessions and suitability of the carer to deliver sessions were identified in the focus groups and interviews. The field-testing phase demonstrated that implementation of the iCST intervention was feasible. However, the majority of dyads completed fewer than three sessions per week. Identified barriers to participation included, lack of time, illness, and motivation. The training and support package appeared to be suitable as carers were able to deliver the intervention without intensive support. Two drafts of the materials were produced before a final version ready for use in the main RCT. Of the

180 iCST dyads, 134 (74%) were included in the intention to treat (ITT) analysis. There were 178 TAU dyads, of which 139 (78%) were available for analysis. At follow-up 2 (FU2) there were no significant differences between the iCST and TAU groups in the primary outcomes of cognition (Alzheimer's Disease Assessment Scale - cognitive [ADAS-cog], SMD = -0·55, 95% CI -2·00,0·90; p=0·45) and self-reported QoL (Quality of Life Alzheimer's Disease [QOL-AD], SMD = -0·02, 95% CI -1·22,0·82; p= 0·97). People with dementia receiving iCST rated the relationship with their carer more positively (SMD = 1·77, 95% CI 0·26,3·28; p= 0·02). No other secondary outcomes were significant.

**Conclusions:** The rigorous development of the intervention was beneficial as the feasibility of the intervention was explored both in theory and practice. There was no evidence of iCST benefitting either cognition or QoL for the person with dementia. However, it did improve the relationship with the carer. Future work should investigate delivery of iCST by paid carers or professionals and developing the intervention for a computer platform.

## Acknowledgements

Firstly, thank you to Professor Martin Orrell. I cannot begin to express my gratitude that you had enough faith in me to offer me the opportunity to be part of this project in the first place, and for being ever present throughout. When writing this thesis felt like looking up at Everest from base camp, you told me to concentrate on the checkpoints along the way instead of the summit. You would not believe what a difference this advice made! I would also like to thank Dr. Aimee Spector for lending expertise, support, and invaluable feedback on my thesis work and the journal articles we collaborated on.

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I would like to thank the iCST team – Phuong Leung, Fara Hamidi, Dr. Vasiliki Orgeta, and James Sinclair, and all staff across the sites who ensured this study ran like a well-oiled machine. Thank you to the NHS, voluntary organisation, and research networks staff who assisted with recruitment.

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Lastly, thank you to my grandmother, Inge. Though in circumstances I'd never have wanted, you set me on this path. My childhood memories of you are the fondest. I will keep them for us.

## **Statement of contribution**

### **Preliminary work**

My first tasks on the individual Cognitive Stimulation Therapy (iCST) trial were to design activities, source materials suitable for the iCST programme and adapt key principles for iCST. I developed an understanding of the structure of the trial, and previous research into individual cognitive stimulation approaches in the process of converting the protocol into an academic paper (Orrell *et al.*, 2012).

### **Systematic review**

With guidance from my supervisors I developed a research question for the review based on a topic I had interest in, and which I felt would assist in both my understanding of the benefits of mentally stimulating activities, and potentially offer insight into the results of the iCST trial. I conducted the initial title sift and removal of duplicates independently, then collaborated with a University College London (UCL) medical student on further sifts of abstracts and assessment of selected studies for quality.

### **Development phase**

- Organisation, recruitment, and screening of participants for focus groups, interviews, and field-testing.
- Guided participants through the process of providing fully informed consent to participate in the development studies.
- Conducted six of the individual interviews, lead facilitator in five of the focus groups.
- Took field notes in the focus group I didn't lead and transcribed audio recordings of two of the interviews.
- Applied thematic analysis techniques to the data (focus groups, interviews, field-testing).
- Developed the standardised training package trialled in the field-testing phase.
- Trained 11 dyads and provided support to those plus an additional eight dyads.

- Conducted debrief visits
- Presented to delegates at the consensus conference, led a workshop and recorded feedback from participants.
- Reviewed the data at each stage and was involved in the decision making process regarding which suggested amendments should be incorporated into the manual, activity workbook, and the contents of the toolkit.
- Implemented amendments as well as performing checks of formatting, spelling, and grammar in the manual and activity workbook.

### **Main randomised controlled trial (RCT)**

I acted as a blind researcher in the North East London Foundation Trust (NELFT) boroughs, and the unblind researcher for iCST dyads in Barnet, Enfield and Haringey Mental Health Trust (BEHMHT) boroughs. As part of my role I completed the following tasks;

- Collected baseline data for 69 dyads, blind follow up data for 62 dyads, and contributed to data entry into MACRO.
- Trained 30 dyads in the iCST approach, and provided ongoing support via telephone contacts and visits.
- Performed randomisations using the online service.
- Trained and supported staff from the other research sites to deliver iCST, support carers, collect, and enter data onto MACRO. Co-ordinated audits of baseline and follow up data across sites.
- Co-authored the Health Technologies Assessment (HTA) report on the trial.
- Recruited for, and developed the iCST DVD.
- Liaised with Hawker Publications to develop the published version of the iCST package.

### **Other work based on the iCST trial**

Carer outcomes collected as part of the iCST trial are reported in my colleague Phuong Leung's (PL) PhD thesis.

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## Publications

Orrell, M., Yates, L. A., Burns, A., Russell, I., Woods, R. T., Hoare, Z., Moniz-Cook, E., Henderson, C., Knapp, M., Spector, A., & Orgeta, V. (2012). Individual Cognitive Stimulation Therapy for dementia (iCST): study protocol for a randomized controlled trial. *Trials*, 13(1), 172.

Yates, L.A., Leung, P., Orgeta, V., Spector, A., & Orrell, M. (2015). The development of individual Cognitive Stimulation Therapy (iCST) for dementia. *Clinical Interventions in Aging*, 10, 95-104.

Yates, L.A., Orrell, M., Spector, A., & Orgeta, V. (2015). Service users' involvement in the development of individual Cognitive Stimulation Therapy (iCST) for dementia. *BMC Geriatrics*, 15, 4.

Yates, L.A., Orrell, M., Leung, P., Spector, A., Woods, R.T., & Orgeta, V. *Making a Difference 3 Individual Cognitive Stimulation Therapy: A manual for carers*. Hawker Publications; 2014.

Orgeta, V., Leung, P., Yates, L., Kang, S., Hoare, Z., Henderson, C., Whitaker, C., Burns, A., Knapp, M., Leroi, I., Moniz-Cook, E. D., Pearson, S., Simpson, S., Spector, A., Roberts, S., Russell, I.T., de Waal, H., Woods, R.T., Orrell, M. (2015). Individual Cognitive Stimulation Therapy for dementia (iCST): effectiveness and cost-effectiveness pragmatic multicentre randomised trial. *Health Technology Assessment*, 19.

Yates, L.A., Orgeta, V., Spector, A., & Orrell, M. Field-testing phase of the development of individual Cognitive Stimulation Therapy (iCST) for dementia. Submitted to BMC Health Services Research

Yates, L., Ziser, S., Spector, A., & Orrell, M. Cognitive leisure activities, and future risk of cognitive impairment and dementia: Systematic review and meta-analysis. Submitted

Orrell, M., Yates, L., Leung, P., Kang, S., Hoare, Z., Whitaker, C., Burns, A., Knapp, M., Leroi, I., Moniz-Cook, E., Pearson, S., Simpson, S., Spector, A., Roberts, S., Russell, I., de Waal, H., Woods, R.T., Orgeta, V. Individual cognitive stimulation therapy for dementia (iCST): a single-blind, multi-centre pragmatic randomised controlled trial. Submitted

## **Ethical approval and trial registration**

Ethical approval was obtained through the East London 3 Research Ethics Committee (ref no.10/H0701/71) in January 2010, registered as a clinical trial (ISRCTN 65945963) in May 2010, and granted approval in September 2010 (see Appendix 1).

The trial was registered with North East London Foundation Trust (NELFT) Research and Development (R&D) department, University College London (UCL), Barnet, Enfield and Haringey Mental Health NHS Trust (Participant Identification Centre [PIC]), Bangor University, Betsi Cadwaladr University Health Board, Humber NHS Foundation Trust, the University of Manchester, Manchester Mental Health and Social Care Trust, Lancashire Care NHS Foundation Trust, Dorset Health Care University NHS Foundation Trust, Lincolnshire Partnership NHS Foundation Trust, Norfolk and Suffolk NHS Foundation Trust, Devon Partnership NHS Trust and Northern Devon Healthcare NHS Trust.

## Abbreviations

AChEIs	Anticholinesterase inhibitors
ADAS-Cog	Alzheimer's Disease Assessment Scale – Cognitive
AD	Alzheimer's Disease
ADL	Activities of Daily Living
aMCI	Amnestic Mild Cognitive Impairment
ANCOVA	Analysis of Covariance
ANOVA	Analysis of Variance
APA	American Psychiatric Association
BADLS	Bristol Activities of Daily Living Scale
BEHMHT	Barnet, Enfield & Haringey Mental Health Trust
BL	Baseline
BPSD	Behavioural and Psychological Symptoms of Dementia
CAPE-BRS	Clifton Assessment Procedures for the Elderly – Behaviour Rating Scale
CDR	Clinical Dementia Rating
CI	Confidence Interval
CS	Cognitive Stimulation
CSRI	Client Service Receipt Inventory
CST	Cognitive Stimulation Therapy
DEMQoL	Dementia Quality of Life Scale
DeNDRoN	Dementias and Neurodegenerative Diseases Network
DLB	Dementia with Lewy Bodies
DMEC	Data Monitoring and Reporting Ethics Committee
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, 4th Edition
EQ-5D	European Quality of Life – 5 Dimensions
FC	Family Carer
FG	Focus Group
FTD	Frontotemporal Dementia
FU1	Follow-up 1 (13 weeks)
FU2	Follow-up 2 (26 weeks)
GDS-15	Geriatric Depression Scale - 15
HADS	Hospital Anxiety and Depression Scale
HR	Hazard Ratio
HTA	Health Technology Assessment
iCST	individual Cognitive Stimulation Therapy

ISRCTN	International Standard Randomised Controlled Trial Number
ITT	Intention To Treat
IV	Interview
LREC	Local Research Ethics Committee
Maintenance CST	Maintenance Cognitive Stimulation Therapy
MCI	Mild Cognitive Impairment
MMSE	Mini-Mental State Examination
MRC	Medical Research Council
MV1	Monitoring Visit 1 (12 weeks)
MV2	Monitoring Visit 2 (25 weeks)
NELFT	North East London Foundation Trust
NHS	National Health Service
NICE	National Institute of Clinical Excellence
NISCHR-CRC	National Institute for Social Care and Health Research Centre
NPI	Neuropsychiatric inventory
NWORTH	North Wales Organisation for Randomised Trials in Health and Social Care
OR	Odds Ratio
PIC	Participant Identification Centre
PwD	Person with Dementia
QCPR	Quality of the Care giving Relationship
QoL	Quality of Life
QoL-AD	Quality of Life - Alzheimer's Disease
RCT	Randomised Controlled Trial
R&D	Research and Development
REC	Research Ethics Committee
RO	Reality orientation
RR	Risk Ratio
RS-14	Resilience Scale 14
SAE	Serious Adverse Event
SF-12	Short Form-12 health survey
SMD	Standard Mean Difference
SSI	Site Specific Identification
TAU	Treatment As Usual
TI	Treatment Integrity
VaD	Vascular Dementia

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## **Chapter 1**

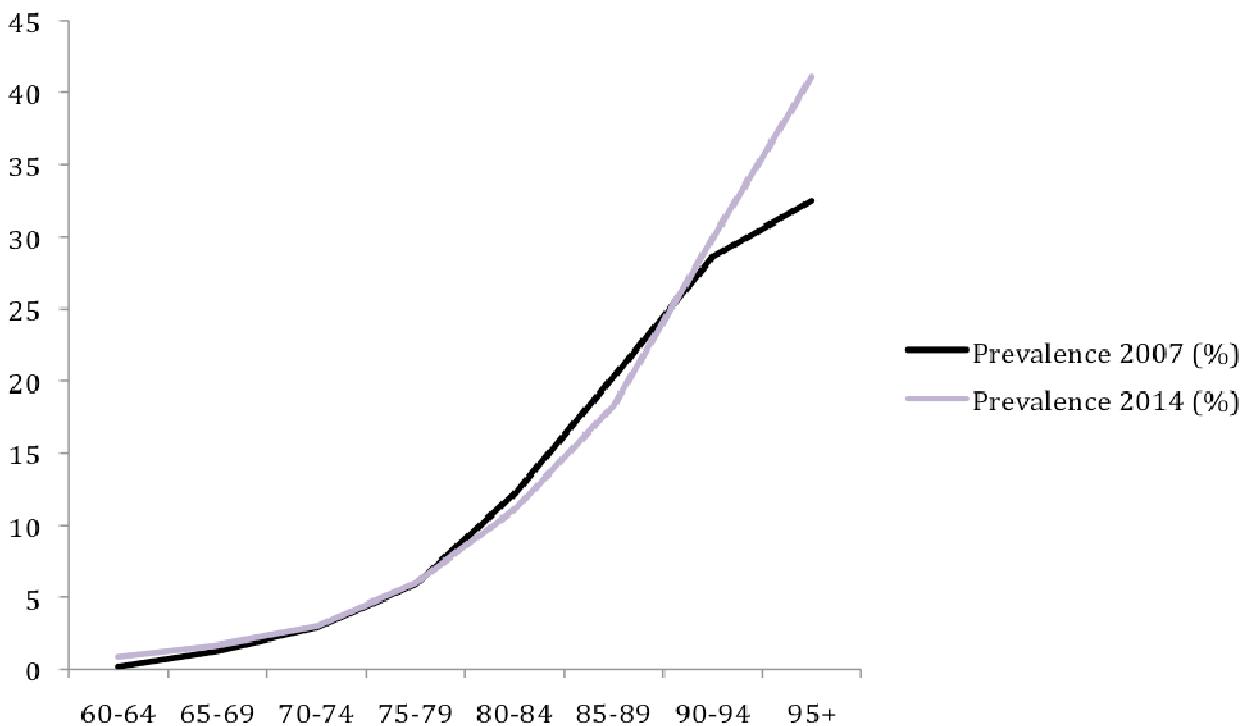
### **Introduction**

#### **1.1 Dementia**

##### **1.1.1 Epidemiology of dementia**

Advances in health care and technology over the past century have increased people's life expectancy dramatically (World Health Organisation Report, 2012). Enabling people to live longer, healthier lives is a remarkable achievement. However, the prevalence of chronic diseases such as dementia has increased alongside the extension of life span. It was estimated that in 2010, 36 million people around the world were living with dementia. Based on the current estimated rate of prevalence, the number of people living with dementia is expected to reach 850,000 in 2015 (Dementia UK: Update, Prince *et al.*, 2014). Prevalence of dementia increases with age, and rates vary slightly between men and women. The prevalence of dementia in men and women aged between 65-69 years is estimated to be around 1.5%, and 1.8% respectively. Between the ages of 75-79 years, prevalence increases to approximately 5.3% in men, and 6.6% in women (Dementia UK: Update, Prince *et al.*, 2014).

The Dementia UK report outlined projections for prevalence of dementia in 2007 (Alzheimer's Society, Knapp *et al.*, 2007). However, the most recent estimations made by an expert consensus group based on new evidence suggest that prevalence of dementia has changed since these figures were published (Figure 1.1). Encouragingly evidence from the Medical Research Council (MRC) Cognitive Function and Ageing Study II suggests there has been a reduction in prevalence in the UK over the last two decades (Matthews *et al.*, 2013). This may reflect a positive shift in health behaviour (e.g., improved cardiovascular health, reduction in negative lifestyle behaviours, such as smoking).



*Figure 1.1 Estimates of dementia prevalence in 2007 vs. 2014 (Knapp et al., 2007; Dementia UK: Update, Prince et al., 2014)*

However, even with a small decrease in incidence and prevalence, the number of people living with dementia world wide is still likely to increase almost two-fold to 66 million by 2030, and 115 million by 2050 as the population ages. Thus dementia presents a great challenge for health and social care systems across the globe (World Alzheimer's Report, Batsch & Mittelman, 2012).

### 1.1.2 Definition of dementia

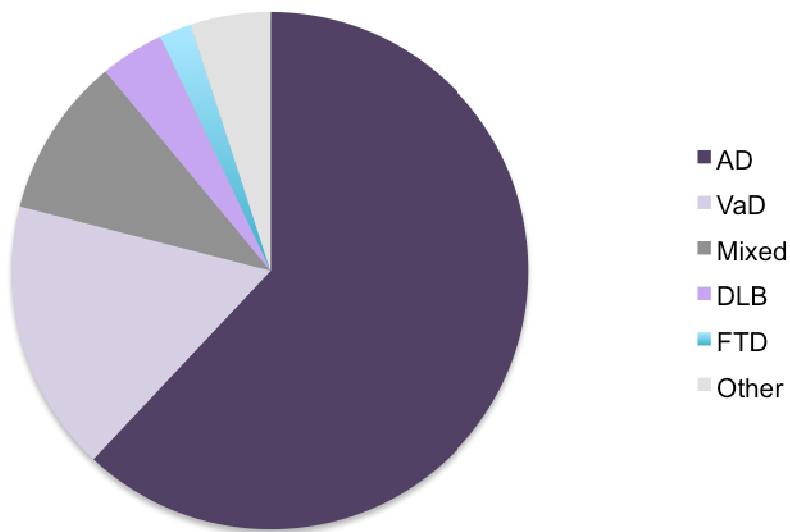
According to the Diagnostic and Statistical Manual of Mental Disorders 4<sup>th</sup> Edition (DSM-IV, American Psychiatric Association [APA], 2000) dementia is a non-specific syndrome characterised by memory impairment, and one or more of the following cognitive disturbances; aphasia, apraxia, agnosia, and disturbance in executive functioning. Symptoms represent deterioration in the person's previous level of cognitive functioning, and have a significant impact on social and occupational functioning. Typically, deficits must persist for a period of at least six months to support a diagnosis.

### **1.1.3 Types of dementia**

Dementia is thought to be a pathological condition distinct from ‘normal ageing’ (Nelson *et al.*, 2011) and is linked to a number of underlying brain pathologies (World Alzheimer’s Report, 2009). In the UK, around 62% of the total cases of dementia are of Alzheimer’s type (Alzheimer’s Society, Knapp *et al.*, 2007; Dementia UK: Update, Prince *et al.*, 2014) (Figure 1.2). Globally, 50-75% cases of dementia are classified as Alzheimer’s Disease (AD). The onset and progression of AD are gradual, and characteristic symptoms include impaired memory, apathy, and depression. The presence of cortical amyloid plaques and neurofibrillary tangles in the brain is linked to AD (World Alzheimer’s Report, 2009). AD can be classified as ‘early’ or ‘late’ onset. ‘Early onset’ AD is clinically symptomatic at 30-65 years of age, and is very rare in comparison with ‘late onset’ AD, which occurs after the age of 65. Vascular dementia (VaD) accounts for 17% of cases of dementia in the UK (Alzheimer’s Society, Knapp *et al.*, 2007), and an estimated 20-30% globally (World Alzheimer’s Report, 2009). VaD is linked to cerebrovascular disease. Although clinical presentation is often similar, in contrast to AD, the progression of VaD is often stepwise, characterised by periods of relative stability in symptoms and sudden deterioration as a result of cerebral infarctions, which cause localised or diffuse damage to brain tissue. Memory tends to be less affected than in AD, however, fluctuations in mood are more prominent. AD and VaD sometimes present together, which is classified as ‘mixed type dementia’, and accounts for 10% cases in the UK (Alzheimer’s Society, Knapp *et al.*, 2007).

Less common types of dementia include dementia with Lewy Bodies (DLB), which accounts for four percent of UK cases (Alzheimer’s Society, Knapp *et al.*, 2007), and less than five percent of global cases (World Alzheimer’s Report, 2009), and Frontotemporal dementia (FTD), which accounts for two percent of UK cases (Dementia UK: Update, Prince *et al.*, 2014), and 5-10% global cases (World Alzheimer’s Report, 2009). People with DLB experience fluctuations in their cognitive ability, visual hallucinations, and Parkinsonism (e.g.,

tremor, rigidity). In terms of neuropathology, DLB is associated with the presence of cortical ‘Lewy bodies’, which are abnormal collections of the protein, alpha-synuclein (World Alzheimer’s Report, 2009).



*Figure 1.2 Proportion of types of dementia in the UK (Alzheimer’s Society, Knapp et al., 2007; Dementia UK: Update, Prince et al., 2014)*

No single pathology is attributed to FTD. Rather, it is caused by damage to the frontal and temporal lobes of the brain. Symptoms include; changes in personality and mood, notably disinhibition and difficulties with language (World Alzheimer’s Report, 2009).

#### **1.1.4 Symptoms of dementia**

##### **1.1.4.1 Cognitive symptoms**

Memory impairment is typically the principle symptom of dementia. Dementia can affect both the episodic and semantic subsystems of explicit memory. In terms of episodic memory, people with dementia often have difficulty acquiring and retaining new information (Albert, 2008). To a lesser extent, and often at a later stage of the disease, they may also demonstrate deficits in semantic memory, including difficulty recalling general knowledge

about the world, meanings, and facts (Patterson, Nestor, & Rogers, 2007). In addition to memory impairment, the following cognitive disturbances might also be experienced:

- Aphasia, which refers to impairment in language. Word finding ability is often most profoundly affected. Language comprehension, and verbal and written expression (dysgraphia) may also be impaired, particularly in the mid to late stages of dementia (McKhann *et al.*, 2011).
- Apraxia, which refers to impaired ability to carry out learned purposeful motor functions despite intact physical ability. This typically leads to functional difficulties such as inability to operate simple implements, or orient clothes to the body (McKhann *et al.*, 2011).
- Agnosia, which refers to impairments in recognition or attribution of meaning to sensory perception despite having a functionally intact sensory system. The person may be unable to recognise objects (visual agnosia), or familiar faces (prosopagnosia), or locate objects in plain view (McKhann *et al.*, 2011).
- Executive dysfunction, which refer to difficulties in reasoning, problem solving, planning, and abstraction. Symptoms include, inability to plan complex or stage-process activities, poor decision-making ability, and inability to anticipate the consequences of actions (McKhann *et al.*, 2011).

#### 1.1.4.2 Non-cognitive symptoms

Non-cognitive symptoms, or behavioural and psychological symptoms of dementia (BPSD), are considered as clinically significant as the cognitive impairments associated with the syndrome (Robert *et al.*, 2005). Non-cognitive features of dementia include; psychotic symptoms (e.g., hallucinations, delusions), depressive features (e.g., sadness, apathy), anxiety, and behavioural disturbances (e.g., agitation, aggression) (Burns, Jacoby, & Levy,

1990). It is estimated that 90% patients with AD experience BPSD during the course of the illness (Frisoni *et al.*, 1999), although the severity, frequency, type, and impact of BPSD varies between individuals. Robert *et al.* (2005) suggested that BPSD are not unitary, but rather several symptoms, or groups of symptoms, each differentially occurring and prevalent, with different biological correlates and psychosocial determinants.

BPSD are often distressing for the person themselves and carers, and can determine the person's lifestyle and management. Indeed, BPSD has been linked to carer burden and stress (Benoit *et al.*, 2003). However, there is evidence to suggest that BPSD can be influenced by caregiver management styles (de Vugt *et al.*, 2004) with inappropriate strategies appearing to foster delusional (Riello, Geroldi, Zanetti, & Frisoni, 2002), aggressive (Hamel *et al.*, 1990), and hyperactive behaviours (de Vugt *et al.*, 2004). In addition to environmental influences, such as caregiver management, pre-morbid personality may also shape which BPSD the person expresses (Osborne, Simpson, & Stokes, 2010). Management of BPSD may be non-pharmacological (e.g., behavioural therapy, eradication of environmental factors that perpetuate BPSD) and/or involve drug treatment (e.g., antipsychotics to reduce agitation) (McKeith & Cummings, 2005).

The presence of BPSD is associated with impairment of instrumental activities of daily living (IADLs), such as managing finances and taking medications (Tekin, Fairbanks, O'Connor, Rosenberg, & Cummings, 2001). McKeith & Cummings (2005) suggest there may be a neuropsychological basis for this, in that neuropsychiatric symptoms and the capacity for complex planning required for performance of IADLs are both mediated by frontal subcortical structures in the brain. Performance of IADLs deteriorates as the illness progresses so that, in the later stages, the person is unable to perform even basic IADLs, such as feeding themselves and personal care.

## **1.1.5 Impact of dementia**

### **1.1.5.1 Economic and societal impact of dementia**

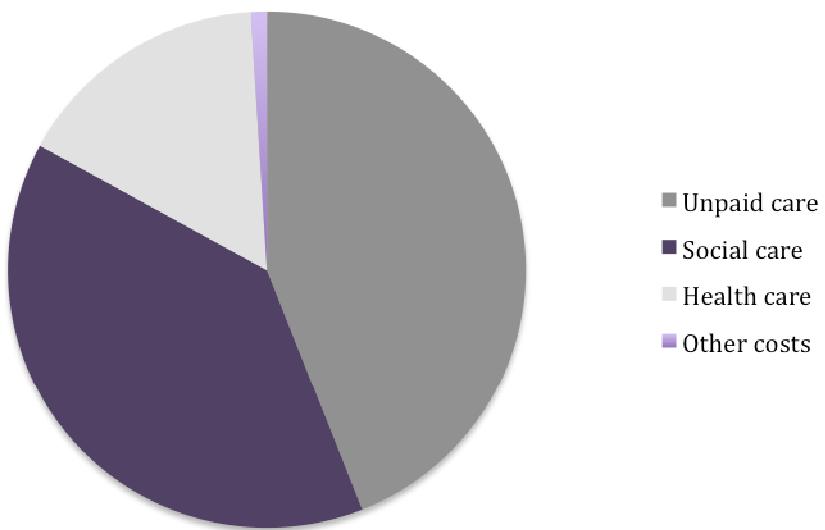
Globally, dementia is the principal cause of dependency and disability among older people. Accounting for 11.9% of years lived with disability, and 1.1% of years of life lost, dementia is the second most burdensome chronic non-communicable disease among people aged 60 years and over. Although the contributions of heart disease and cancer to mortality are much greater than dementia, at 32.9% and 22.5% of years of life lost respectively, the contribution of dementia to disability is much greater (World Alzheimer's Report, 2009). Moreover, data suggest that, in as much as two thirds of all elderly people, loss of independence can be attributed to dementia (Qiu, de Ronchi, & Fratiglioni, 2007). In the face of this loss of independence, people with dementia often rely on family members to provide care. Occupying a caring role can have negative psychological and physical consequences, including the experience of significant psychological illness, impaired immunity, and higher mortality (World Alzheimer's Report, 2009).

The World Alzheimer's Report (2009) urged national governments to prioritise the development of strategies to respond to the needs of people with dementia and their families by providing widely accessible services and support. The report also recommended that services should focus on the following; raising awareness and understanding of dementia, providing accurate and timely diagnosis, providing information and support post diagnosis, increasing the efficiency of the co-ordination and management of care, increasing the availability of community based services for people with dementia living in their own homes, and improving continuing and end of life palliative care.

At £26.3 billion, the annual societal cost of dementia in the UK is greater than that for stroke, heart disease, and cancer combined. This majority of this total is split between healthcare (£4.3 billion, 16%), social care (£10.3 billion, 39%), and unpaid care (£11.6 billion, 44%), with a small proportion spent on 'other costs' (£111 million, 1%) (Figure 1.3). This equates to an

average annual cost per person with late onset dementia of £32,250 (Dementia UK: Update, Prince *et al.*, 2014).

*Figure 1.3 Sources of costs (Dementia UK: Update, Prince et al., 2014)*



#### 1.1.5.2 Personal impact of dementia

Alongside the significant economic and societal costs of dementia, are the personal costs of the illness to both the person and their family. Findings from the World Alzheimer's Report (Batsch & Mittelman, 2012) suggest that many people with dementia experience stigma about their condition, which can lead to avoidance, social isolation, reduced quality of life, low self-esteem, depression, loss of income, and loss of independence. However, in a study of quality of life in early stage dementia by Katsuno (2005) it was evident that, although stigma clearly impacted participants' quality of life, particularly their psychological and social wellbeing, they perceived their lives as good. Quality of life appeared to be firmly rooted in the 'family' domain, with good family support bringing a sense of security. This finding suggests that emphasis should be placed on supporting families in order to maximise their care-giving experience and capacity, in turn this may be instrumental in maintaining a good quality of life for the person with dementia.

There is a wealth of research evidence to suggest that caring for a person with dementia is fiscally, emotionally, and physically challenging (Richardson, Lee, Berg-Weger, & Grossberg, 2013), and can result in the experience of burden. Savundranayagum, Montgomery, & Kosloski (2011) describe how being a carer can interfere with daily life activities and other responsibilities (objective burden), cause strain in the relationship between the care giver and recipient (relationship burden), and create stress and anxiety (stress burden). The extent and presence of subjective burden is mediated by factors such as gender (Schoenmakers, Buntinx, & Delepeleire, 2010), relationship to the care recipient (Etters, Goodall, & Harrison, 2008), and culture (Adams, Aranda, Kemp & Takagi, 2002).

Experience of burden can increase the risk of psychological and physical health problems for the carer. In terms of mental health, depression is common amongst dementia carers (Richardson *et al.*, 2013). Indeed Joling *et al.* (2010) found that spousal carers are four times more likely to have depression than non-carers. Spousal carers may also experience cognitive decline, and are at greater risk of developing dementia themselves (Vitaliano, Murphy, Young, Echevema, & Borson, 2011). Additionally, poor psychological health is linked to poor quality of sleep, which the carer may suffer from if the care recipient experiences sleep disturbances (e.g., insomnia, sundowning) (Cupidi *et al.*, 2012). Dementia carers report poor physical health and difficulties with health maintenance (Alzheimer's Association, 2012). Being a carer has also been linked to increased levels of stress hormones, inflammatory markers (Gouin, Glaser, Malarkey, Beversdorf, & Kiecolt-Glaser, 2012), hypertension (Roepke *et al.*, 2011), and metabolic syndrome, which are all associated to cardiovascular disease (Mausbach *et al.*, 2010). Furthermore, high carer stress has been linked to increased mortality (Perkins *et al.*, 2012).

### **1.1.6 Interventions for dementia**

#### **1.1.6.1 Pharmacological treatments for dementia**

Drug treatments are available for both the cognitive and non-cognitive symptoms associated with dementia. Pharmacological treatment options vary depending on the subtype of dementia. Cholinesterase inhibitors are often prescribed for the treatment of cognitive deficits of AD of mild to moderate severity, while memantine is licensed for treatment of moderate to severe AD (Burns & O'Brien, 2006). Both treatments are also offered to those diagnosed with mixed dementia (VaD & AD). However, neither medications are suitable for the treatment of VaD alone; rather treatment is focused on the identification and treatment of vascular risk factors, such as hypertension. DLB may also be treated with cholinesterase inhibitors in conjunction with anti-parkinsonian medication (e.g., L-Dopa monotherapy) if necessary, although this may exacerbate psychosis (Burns & O'Brien, 2006).

Anti-dementia drugs act to slow the deterioration of cognitive functions, helping the person maintain their independence for a longer time (Dröes *et al.*, 2011). Prince, Bryce, & Ferri (2011) reviewed evidence for the efficacy of cholinesterase inhibitors and memantine. Five Cochrane reviews reported that patients with mild to moderate AD benefitted cognitively from the use of cholinesterase inhibitors compared to placebo groups, while memantine had a positive effect for people with moderate to severe AD. The report concluded that there is substantial evidence to suggest that drug treatments can enhance cognitive function, and recommended that they should be routinely offered to people with dementia. Despite demonstration of their efficacy, the use of anti dementia medications is not appropriate in all cases. As discussed above, medications are limited to certain types of dementia (e.g., AD, mixed), and are not tolerated by all patients (McShane, Areosa Sastre, & Minakaran, 2006) with side effects including nausea, diarrhoea, and fatigue (Dröes *et al.*, 2011). Medication is also somewhat costly, at £1000 per person per year (Kaduszkiewicz, Zimmermann, Beck-Bornholdt, & van den Bussche, 2005).

In the past BPSD (e.g., agitation, aggression) have often been treated with antipsychotics. However, the safety of antipsychotics has been called into question, with growing evidence

to suggest they increased risk of mortality (Corbett & Ballard, 2012). The Food and Drug Administration (FDA) reported a 1.5-1.7 fold increase in mortality risk for people with AD taking antipsychotics compared with a placebo over six to 12 weeks in randomised clinical trials (US FDA, 2005). In the light of these safety concerns, there is an argument for a major reduction in the use of antipsychotics as a method of managing BPSD. Corbett & Ballard (2012) recommend the use of alternative non-drug treatments where possible, effective pain management strategies, and careful consideration of the appropriateness of antipsychotic use before prescription.

#### 1.1.6.2 Psychosocial interventions for dementia

Psychosocial treatment methods can be employed either as an alternative, or in addition to pharmacological treatments. Psychosocial interventions aim to enhance QoL and maximise the person's functioning (APA, 2007). There is evidence to suggest that psychosocial interventions have a positive impact on the person with dementia's cognition, quality of life (Spector *et al.*, 2003), and may alleviate neuropsychiatric symptoms and associated distress (Teri, McKenzie, & LaFazia, 2005). Furthermore, psychosocial interventions for carers can postpone and decrease the odds of institutionalisation (Mittelman, Haley, Clay, & Roth, 2006). An added advantage of the psychosocial approach when pitted against pharmacological treatments is that adverse effects are rarely associated with participation in psychosocial interventions.

There is evidence to suggest some approaches, such as cognitive stimulation therapy (CST), are more cost effective in comparison to medication (Knapp *et al.*, 2006). The National Health Service (NHS) Institute for Innovation and Improvement investigated the cost of behavioural interventions versus use of anti-psychotics, concluding that behavioural alternatives represent a more efficient use of public money (2011). Psychosocial interventions have been in use in the UK and internationally for some time. However, in the last decade, much attention has been focused on evaluation of the effectiveness of these

treatments (Livingston, Johnston, Katona, Paton, & Lyketsos, 2005; Woods, 2003; Brodaty, Green, & Koschera, 2003; Olazaran *et al.*, 2010; Prince *et al.*, 2011), which had rarely been examined previously (Orrell & Woods, 1996).

### **1.1.7 Cognitive interventions for dementia**

Currently, reality orientation, cognitive stimulation, cognitive rehabilitation, cognitive training, and reminiscence therapy are the most widely used cognitive focused interventions for dementia. Although acknowledged as distinct, there is some overlap between elements of the interventions (World Alzheimer's Report, Prince *et al.*, 2011).

#### **1.1.7.1 Reality orientation (RO)**

People with dementia often have difficulty remaining orientated to time (e.g., date, time of day), their environment (e.g., location), and personal information (e.g., own name, family members). These difficulties tend to progressively worsen during the course of the syndrome. RO was founded in the principle that repeated exposure to, and practice of basic personal and current information can improve orientation. Further reaching impacts include greater understanding of the person's surroundings, improved self-esteem, increased social interaction, and reduction of problem behaviours (Takeda, 2012).

RO can be 'classroom' or home-based, and delivered by professionals (e.g., residential care staff) or family members. The original RO programme developed by Taulbee (1966) was classroom based, and consisted of weekly, or bi-weekly, 30 minute classes in hospital units during which residents would engage in activities such as rehearsing orientation information and completing puzzles. A RO board displaying the name and location of the unit, the date, weather, and current events was set up in each session. Home based RO often takes place in the area in which the recipient spends most of the time, so that orientation cues are readily accessible. For example, it is advantageous to have access to a window so that the person is orientated to the time of day and weather. It is also helpful to have familiar objects to hand to

stimulate the person's memory (e.g., photo albums, board games) (Takeda, 2012). RO can also be delivered in a continuous 24-hour format whereby reality based communication forms the basis of every interaction between staff and the person with dementia (Spector, Davies, Woods, & Orrell, 2000).

The effectiveness of RO was examined in a Cochrane review (Spector *et al.*, 2000). Six randomised controlled trials (RCTs), with a total sample of 125 participants were included in the review, which concluded that RO had a significant positive effect on cognition and behaviour. Spector *et al.* (2000) suggested a continued long-term programme might be necessary if benefits are to be sustained. Despite the reported benefits of RO, the intervention has been criticised for the confrontational way in which it is sometimes applied, which has been associated with adverse effects such as frustration, depression, anxiety, and lowered self-esteem (Dietsch, Hewett, & Jones, 1989). In response to concerns over adverse reactions to RO, the American Association for Geriatric Psychiatry ([AAGP] Small *et al.*, 1997) issued a consensus statement warning that the small cognitive improvements observed were outweighed by the risk of negative impacts. Subsequent incarnations of RO, such as cognitive stimulation, have been more person centred and focused on implicit information processing than rote re-learning of orientation information (Woods, 2002).

#### 1.1.7.2 Cognitive stimulation (CS)

The term 'cognitive stimulation' has been applied to approaches and interventions, which have a general cognitive focus including RO, cognitive training, and cognitive rehabilitation. Clare & Woods (2004) provided a more specific definition of CS as 'engagement in a range of activities and discussions (usually in a group) aimed at general enhancement of cognitive and social functioning', which distinguishes it from other cognitive approaches. CS is underpinned by the principle of 'use it or lose it', which is the view that being mentally active into later life has a protective effect, maintaining cognitive functioning, and perhaps even slowing or preventing decline (Salthouse, 2006). Evaluations of CS have been consistently

positive, and suggestive of statistically and clinically significant treatment effects (Prince *et al.*, 2011). Indeed, Prince *et al.* concluded that, of the psychosocial interventions currently available, the evidence of cognitive benefits yielded by CS is the ‘strongest by far’.

#### 1.1.7.3 Cognitive training

Cognitive training targets specific cognitive functions such as memory, attention, language, and executive functioning through guided practice on standard tasks (Clare & Woods, 2004). Tasks vary in difficulty according to the person’s abilities, and may be pen and paper, or computer based. Cognitive training can be administered in a group (Bernhardt, Maurer, & Froelich, 2002), or one-to-one (Farina *et al.*, 2002) environment by a therapist. Some cognitive training programmes are designed to be facilitated by family members (Quayhagen, Quayhagen, Corbeil, & Hendrix, 2000). Cognitive training is based on the notion that routine practice of a specific cognitive skill can improve functioning, or at least slow decline, in that domain, and furthermore gains made in the training context will generalise beyond into everyday life activities (Clare & Woods, 2004). However, there is little evidence to support any such significant outcomes of cognitive training (Prince *et al.*, 2011).

#### 1.1.7.4 Cognitive rehabilitation

Cognitive rehabilitation is tailored to the personal needs of the individual with cognitive impairment, who works alongside a therapist to achieve specific goals. Family members are often directly involved in cognitive rehabilitation activities, which are focused on the person’s cognitive strengths and developing strategies for coping with impairments (Clare & Woods, 2004). There is a paucity of data from randomised controlled trials (RCTs) regarding the efficacy of cognitive rehabilitation. However, a high quality trial of individual cognitive rehabilitation including collaborative goal setting within the context of meaningful activities of daily living showed promising positive results (Bahar-Fuchs, Clare, & Woods, 2013).

#### **1.1.7.5 Reminiscence**

Reminiscence looks to enhance cognition through discussion of past activities, events, and experiences. Reminiscence is typically conducted in a group setting. However, it can also be delivered on a one-to-one basis (Woods, Spector, Jones, Orrell, & Davies, 2005). Reminiscence is posited to increase autobiographical memory, and enhance communication. Often people with dementia are able to recall past experiences with great clarity, experiencing a greater degree of impairment in their short-term memory, thus reminiscence is focused on the person's strengths. There is some evidence to suggest that reminiscence can yield short-term improvements in cognition and mood. However, the significance of these findings cannot be determined due to the current lack of high quality trials examining the efficacy of the intervention (Prince *et al.*, 2011).

## **1.2 Cognitive Stimulation Therapy (CST)**

### **1.2.1 Background**

CST (Spector *et al.*, 2003) is an evidence-based intervention for people with mild to moderate dementia consisting of structured sessions of cognitive stimulation delivered in a group setting. The intervention is manualised and designed to be facilitated by healthcare professionals and/or care staff (e.g., residential care staff, occupational therapists). The development of CST adhered to the guidance outlined by the MRC framework (Craig *et al.*, 2008) for the development of complex interventions. As part of Phase I, theory and evidence was derived from a Cochrane Review of RO (Spector *et al.*, 2000). Subsequently, during phase II of the development, the intervention was piloted and revised according to the findings. A single blind, multi centre randomised controlled trial (phase III) with a sample of 201 people with dementia was carried out to evaluate the effectiveness of CST (Spector *et al.*, 2003). The intervention was run in 23 day centres and residential care homes across London. Compared to the control group, participants in the CST intervention group showed significant improvements in both cognition and QoL. Furthermore, the gains in the primary outcomes observed compared favourably with cholinesterase inhibitors for AD when

numbers needed to treat (NNT) was considered (Spector *et al.*, 2003). An economic analysis of CST concluded that CST is a cost-effective intervention (Knapp *et al.*, 2006). The CST package consisting of the ‘Making a Difference’ manual, training DVD, and training day were made available after the trial (Spector, Thorgrimsen, Woods, & Orrell, 2006).

The effectiveness and cost-effectiveness of the approach, and ease of implementation have drawn great interest in CST, and as a result, it is now widely used in the UK and internationally. CST is recommended by the National Institute of Clinical Excellence (NICE, 2006) and has been the focus of reports published by the NHS Institute for Innovation and Improvement (2011), and Alzheimer’s Disease International (Prince *et al.*, 2011). Spector and colleagues recently established an international CST centre including over 20 countries that are actively using the CST approach. The successful adaption of the programme for use in other cultures (Mahmood, Ahmed, Orrell, & Kinsler, 2012; Yamanaka *et al.*, 2013) prompted the development of a set of guidelines to inform future adaptations (Aguirre, Spector, & Orrell, 2014).

### **1.2.2 CST programme**

The CST programme comprises of 14, 45-minute sessions of structured cognitive stimulation, over seven weeks. Recent data supports the twice-weekly format of the intervention (Cove *et al.*, 2013). A main facilitator leads the sessions with the help of a co-facilitator who can offer extra support to those who need it. A group size of five to eight people is recommended. The programme is suitable for people with mild to moderate dementia. However, it is advised that the facilitators consider grouping those at similar stages of dementia so that the activities can be pitched at an appropriate level for all members. Each session follows the same basic structure, starting with a warm up activity (e.g., singing a group song, playing catch with a soft ball) to ease members into the group situation and prepare them for the activity. The next portion of the session is dedicated to orientating group members to time and place through discussion, and with the aid of the RO

board, which is displayed prominently throughout the session. The main activity is themed (Table 1.1) and involves the use of a wide range of cognitive (e.g., planning, memory, concentration) and social skills (Aguirre *et al.*, 2010). Sessions are concluded with thanks for contributions to the activities, a summary of the session events, discussion of experience of the session, and brief consideration of plans for the next session. If the group

*Table 1.1 CST session themes*

Session number	Week	Theme
1	1	Physical games
2	1	Sound
3	2	Childhood
4	2	Food
5	3	Current affairs
6	3	Faces / scenes
7	4	Word association
8	4	Being creative
9	5	Categorising objects
10	5	Orientation
11	6	Using money
12	6	Number games
13	7	Word games
14	7	Team quiz

has a chosen theme song, they will sing this before leaving. Alternatively, if group members prefer, a piece of music may be played.

### **1.2.3 Key principles of CST**

In order to guide facilitators in the delivery of CST and help them better understand the purpose and structure of the approach, a series of principles was developed (Table 1.2) (Spector *et al.*, 2006). A key aim of the programme is to engage people with dementia in stimulating exercises and thought provoking discussion, inviting new ideas and associations. Orientation is a staple of each session, but it is always used in a sensitive and implicit way. Emphasis is placed on opinion rather than facts to avoid members feeling ‘put on the spot’ to recall factual information, which may not be easily accessible due to memory impairments. Factual information may be recalled in the course of the conversation but if so, it is done freely to the extent the person is able, and without the need for explicit questions. Focusing on opinions also facilitates interesting and varied conversation in the group. The group facilitators add to the supportive learning environment by providing triggers and prompts to aid recall and concentration.

The CST exercises are varied, and often involve stimulation of a variety of senses (e.g., sight, touch). For example, in a food session, the group may be presented with an assortment of foods to touch, taste, smell and categorise. The group members work together to support each other during the sessions, strengthening their relationships and benefitting from meaningful and enriching social interactions.

Reminiscence is incorporated into sessions, as this is an enjoyable activity. However, it also serves to orientate people to the here and now through the process of linking past events to those happening in the present. Members are encouraged to compare and contrast, and note how things have changed or stayed the same over time. For example, the group may discuss how their childhood compares to that of their children or grandchildren’s.

## **1.3 Maintenance Cognitive Stimulation Therapy (maintenance CST)**

### **1.3.1 Development & trial**

Following the success of the CST trial, a pilot into the potential of a longer-term programme of CST was carried out by Orrell and colleagues (2005). The study trialled a programme of CST followed by 16 weekly 'maintenance' sessions in two care homes. Alongside the homes receiving maintenance sessions, two care homes received CST only, and two acted

*Table 1.2 Key principles of CST*

<b>Key principles</b>
1 Person centred
2 Respect
3 Involvement
4 Inclusion
5 Choice
6 Fun
7 Opinions rather than facts
8 Using reminiscence
9 Using the sense – multi-sensory stimulation
10 Always have something to look at, touch or feel
11 Maximising potential
12 Building and strengthening relationships

as controls (no CST). Those in the maintenance group showed cognitive improvements following the initial seven week programme of CST, and further improvements when assessed after the maintenance sessions (mean improvement of 1.9 points on Mini Mental State Examination [MMSE], Folstein, Robins, & Helzer, 1983), whilst those who received

CST alone deteriorated over the follow up period (mean deterioration of 0.7 points on MMSE), and the performance of those who received nothing was worse at follow up than baseline. No significant findings in the other measured domains were detected (QoL, communication, behaviour). The maintenance CST programme was subsequently developed further (Aguirre *et al.*, 2011) adhering to the MRC framework (2008).

A Cochrane Review of cognitive stimulation was conducted (Woods *et al.*, 2012) to establish an evidence base for maintenance CST. The review of RCTs found consistent evidence that cognitive stimulation programmes can yield cognitive and QoL benefits for people with mild to moderate dementia. Evidence of a positive effect of cognitive stimulation on communication and social interaction was also highlighted in the review, with reports of these improvements transferring to settings outside the group. The review concluded that further investigation of longer term programmes of cognitive stimulation as well as carer led one to one programmes would be worthwhile.

Phase I of the maintenance CST trial comprised of a consensus conference, focus groups (people with dementia, care staff, & family carers), and a Delphi survey. Four drafts of the maintenance CST manual were developed before the final version of the programme, which was evaluated in a Phase III RCT.

A multi-centre RCT with 236 participants recruited from nine care homes and nine community day centres was carried out with the aim of investigating the effectiveness and cost-effectiveness of maintenance CST (Orrell *et al.*, 2014). Participants received the seven-week programme of CST, then were randomised into the maintenance CST intervention group or treatment as usual (TAU) control. Significant QoL benefits were seen in the maintenance CST group at the six-month primary end point. At three months, improvements in proxy rated QoL and ADLs were reported in the intervention group. Furthermore, people taking cholinesterase inhibitors experienced cognitive benefits at both the three, and six

month follow up points. There is little evidence that CST indirectly benefits the general health status and QoL of the family carers of those participating in groups (Aguirre, Hoare, Spector, Woods, & Orrell, 2014).

### **1.3.2 Maintenance CST programme**

The 24-session weekly maintenance CST programme follows on from the original CST programme. Sessions are 45 minutes long and structured in the same way as the CST programme. Five new themes were introduced; ‘useful tips’, ‘thinking cards’, ‘art discussion’, ‘visual clips’, and ‘household treasures’. The key principles were also developed further (Table 1.3). The maintenance CST manual ‘Making a Difference 2’ and an accompanying DVD were made available after the trial (Aguirre *et al.*, 2011).

## **1.4 Identifying the theory: why might CST be beneficial?**

The outcomes of CST research may be understood in the context of the biopsychosocial model of dementia put forward by Spector and Orrell (2010). The model describes how psychosocial and biological factors interact to contribute to, and influence outcomes during the course of the dementia syndrome. These factors may be fixed and impervious to change, or malleable and susceptible to change and modification (tractable). Cognitive stimulation is identified in the model as a psychosocial intervention that can modify tractable factors, such as mental activity, social psychology, and personal psychology (Figure 1.4).

### **1.4.1 Mental stimulation: Why does CST benefit cognition?**

Memory impairment is typically the principle symptom of dementia. Dementia can affect both the episodic and semantic subsystems of explicit memory. In terms of episodic memory, people with dementia often have difficulty acquiring and retaining new information (Albert, 2011). However, there is evidence to suggest that capacity for cognitive information

*Table 1.3 Developed key principles of CST and maintenance CST*

<b>Key principles</b>
1 Mental stimulation in order to get people's minds active and engaged
2 Encourage the development of new ideas, thoughts and associations
3 Use orientation sensitively and implicitly
4 Focus on opinions rather than facts
5 Use reminiscence as an aid to the here and now
6 Provide triggers and prompts to aid recall e.g., objects, images
7 Establish continuity and consistency between sessions with familiar session features such as a group name, song, and structure
8 Focus on implicit rather than explicit learning
9 Stimulate language skills
10 Stimulate executive functioning
11 Person centred ethos – seeing the person first and foremost and focusing on their strengths rather than dementia and associated impairments
12 Demonstrate respect of people's background e.g., beliefs, culture and religion
13 Encourage group members to participate and contribute to the session
14 Include everyone in the group valuing the contribution of each member and welcoming diversity in views amongst group members
15 Offer choice
16 Establish a supportive learning environment where people can have fun and engage socially with other group members
17 Maximise the potential of group members
18 Strengthen relationships amongst the group

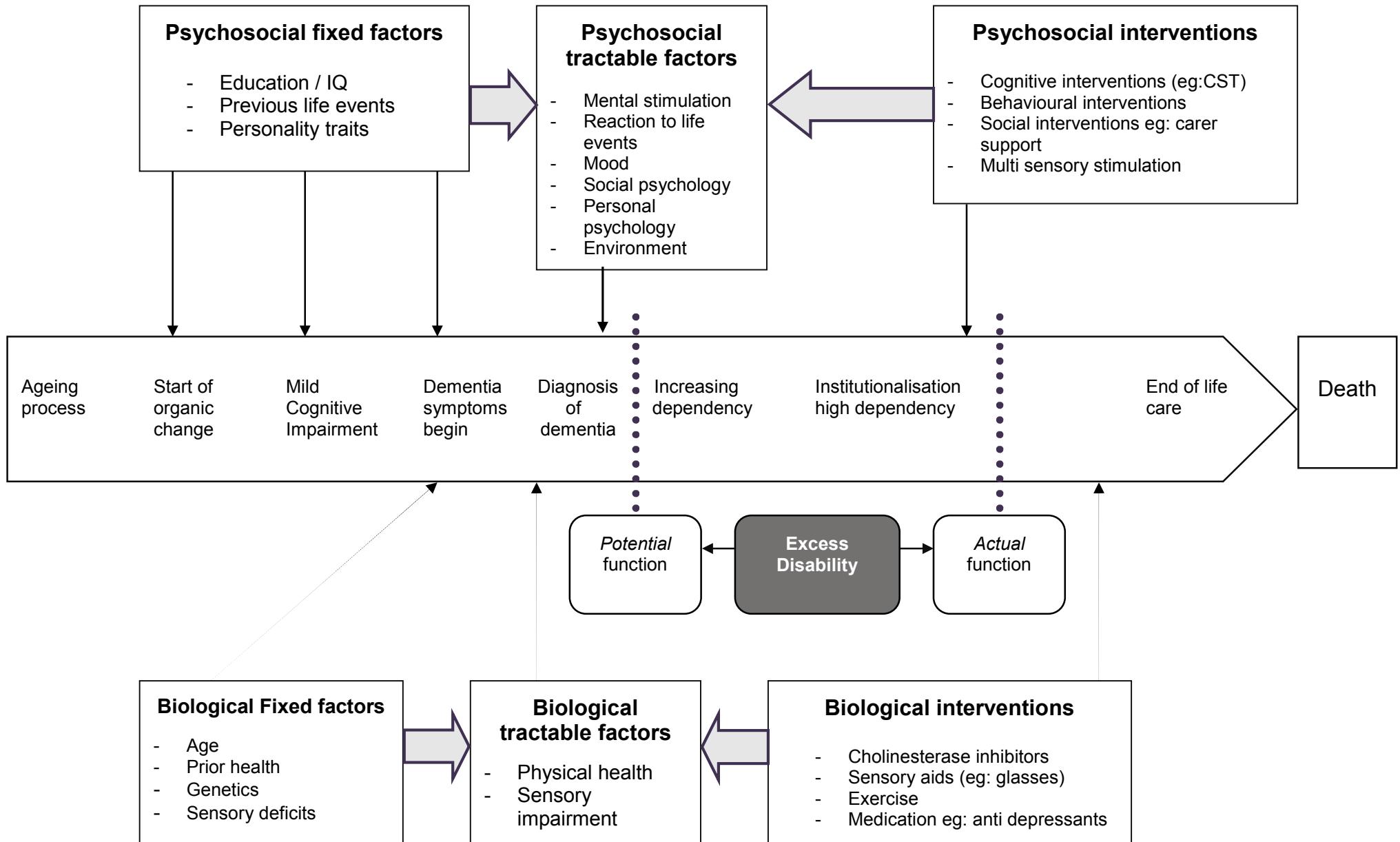


Figure 1.4 Biopsychosocial model of dementia (Spector & Orrell 2010)

processing is not entirely lost (Katzman, 1993), particularly implicit memory, which is maintained for longer than explicit memory (van Tilborg, Kessels, & Hulstijn, 2011). Moreover, implicit memory responds to stimulation, which may explain why CST with its focus on implicit rather than explicit memory, benefits cognition as is consistently reported in evaluations of the approach (Woods *et al.*, 2012). Implicit learning methods may also yield lasting improvements in everyday functioning (Harrison, Son, Kim, & Whall, 2007).

CST activities do not target a specific cognitive modality, rather they require group members to exercise a range of cognitive skills including: memory, communication, concentration, language, executive functioning, spatio-temporal orientation, and visual abilities in an environment that supports learning. Typically activities are multi-sensory and may involve classifying stimuli, discussing and exploring new ideas, planning and executing steps to create something (e.g., clay modelling, baking), and reminiscence.

Recently Hall, Orrell, Stott, & Spector (2013) explored the impact stimulating activities have on cognition from a neuropsychological perspective. In line with the theory of ‘use it or lose it’ (Swaab *et al.*, 2002), participating in cognitive stimulation may activate neurons, which can in turn improve and have a protective effect on their functioning. Cognitive activities may also directly stimulate neuronal systems, enhancing neural pathways responsible for cognitive functions such as memory. Further analysis of the CST dataset revealed significant improvements in the language subscale of the Alzheimer’s Disease Assessment Scale-Cognitive (ADAS-Cog; Rosen, Mohs, & Davis, 1984). Language may be stimulated in sessions through discussion of new ideas, thoughts and ideas, and new semantic links might be created in sessions involving categorisation (e.g., word games).

#### **1.4.2 Social and personal psychology: Why does CST improve QoL?**

Participating in CST has also been shown to yield improvements in QoL. These gains are thought to be mediated by improvements in cognitive function, with participants reporting

improvements in relation to memory, energy, relationships, and managing chores (Woods, Thorgrimsen, Spector, Royan, & Orrell, 2006). In a qualitative study of the experience of CST, people with dementia described how the groups increased their confidence, and made them feel more positive and relaxed. Alongside the perceived impact on their wellbeing, they reported improvements in cognitive skills including memory and concentration, which corroborated with proxy observations by CST group facilitators (Spector, Gardner, & Orrell, 2011).

The social nature of CST groups may enhance the benefits experienced in cognition and QoL. Indeed, there is evidence to suggest that social engagement (Beland, Zunzunegui, Alvarado, Otero, & del Ser, 2005), support (Yeh & Liu, 2003), and contact (Elwood *et al.*, 1999) can have a protective effect on cognition. CST groups provide members with a non-threatening and supportive platform for social contact in which they can engage with others, share experiences and voice their opinions. For those living alone, the groups can also offer some respite from feelings of loneliness, or social isolation (Spector, Gardner, & Orrell, 2011), which are deleterious to psychological well-being (Seeman, 1996) and may increase susceptibility to cognitive decline. Wilson *et al.* (2007) explain that decline may occur because deprivation of social stimulation may decrease neural reserve.

The person-centred values at the core of CST may be a mechanism for improvements in QoL (Woods, 2001). Kitwood (1997) developed the conceptual structure of the ‘malignant social psychology’ of dementia, noticing that reductionist biomedical views exacerbated neurological impairment and failed to acknowledge personal experiences of wellbeing, dignity, and worth. In response to this, Kitwood went on to describe the principles of ‘person centred care’ which is characterised by recognising that the person with dementia is able to experience life and relationships; offering and respecting choices; incorporating the person’s past life into their care; and focusing on the person’s strengths rather than weaknesses. CST incorporates these elements of person-centred care into sessions, guided by a set of key

principles. The design of CST activities is inherently person-centred as they can be tailored to suit the interests and abilities of the group participants. Facilitators use biographical knowledge of group members to serve as cues for their present behaviour, needs, and wishes.

### **1.5 Home-based programmes of CS/RO**

There is limited evidence to suggest that individual cognitive stimulation programmes can benefit cognitive functioning. A carer-led home based programme active training in memory management including cognitive stimulation, orientation, and counselling with psycho-educative elements piloted by Moniz-Cook, Agar, Gibson, Win, & Wang (1998) had long term benefits (at 18 months follow up) for; cognition in the person with dementia, reduced care home admissions, and improved carer wellbeing. Due to the multi-faceted nature of the intervention, it was not possible to determine which aspect of the intervention contributed to the impact on cognition, though the authors posited that this was likely to be explained by the memory management element.

Quayhagen & Quayhagen (2001) found that home-based cognitive stimulation can have a positive impact on both carers and people with dementia. In their study, people with dementia showed improvements in problem solving and memory, and carers a reduction in depressive symptoms.

Onder *et al.* (2005) trained family carers to deliver a home-based package of RO and CST. The 25-week programme was manualised, with specific schedules for each session. Carers delivered three, 30-minute sessions per week. Dyads participating in the programme improved relative to the control on both the MMSE (Folstein, Robins, & Helzer, 1983) (difference of 1.3 points) and ADAS-Cog (Rosen, Mohs, & Davis, 1984) (difference of 2.9 points). A limitation of the study is that adherence to the programme was not recorded, thus the intervention may not have been administered according to the study protocol.

## **1.6 Summary**

The body of evidence demonstrating the short and long term benefits of CST for people with dementia is substantial (Woods *et al.*, 2012). However a structured, home-based, one to one programme of CST has not yet been developed or evaluated. Research suggests that the benefits of CST do not appear to carry over to family carers (Aguirre *et al.*, 2014).

Promisingly, the findings of current studies into home based CS / RO suggest there is both the potential for carers to have an active role in an intervention (Moniz-Cook *et al.*, 1998; Quayhagen & Quayhagen, 2001; Onder *et al.*, 2005), and for them to benefit from it. The potential outcomes of participating in an individual version of CST might be improvements in cognition and quality of life for the person with dementia. A home-based version of CST would be another avenue by which people could access the intervention and its benefits. This would be particularly useful for those who cannot attend groups because of health or mobility problems, those do not wish to participate in a group environment, and those whose local services do not offer CST or have a waiting list for group attendance (Orrell, Woods, & Spector, 2012). iCST could also be offered for those who have completed group CST programmes but would like to continue participating in similar activities.

## **Chapter 2**

### **Aims and hypotheses**

#### **2.1 Aims**

##### **2.1.1 General aim**

The aim of the individual Cognitive Stimulation Therapy (iCST) research trial is to develop and evaluate iCST for people with dementia and their carers following the Medical Research Council (MRC) framework (Craig *et al.*, 2008) for the development of complex interventions.

##### **2.1.2 Specific aims**

1. To develop an individualised version of Cognitive Stimulation Therapy (CST) suitable for delivery by carers based on the group CST and maintenance Cognitive Stimulation Therapy (maintenance CST) programmes, a review of existing individual cognitive stimulation programmes, the results of a pilot study of the intervention, and a Delphi consensus process, including consultation with carers, people with dementia, healthcare professionals, and academics in a series of focus groups, interviews, and a conference. These activities represent phases I and II of the MRC framework whereby an evidence base for the intervention is identified (I), and the feasibility of the programme is tested (II) prior to a full-scale evaluation (III).
2. To develop and field-test a comprehensive iCST intervention package, including a manual, activity workbook, toolkit, and training DVD.
3. To evaluate the effectiveness of the iCST intervention compared to receiving treatment as usual (TAU) in a large scale randomised controlled trial (RCT), focusing on the primary outcomes of cognition and quality of life (QoL) for the person with dementia. The RCT constitutes phase III of the MRC framework, evaluation.

## **2.2 Hypothesis**

The null hypothesis is that there will be no difference between people with dementia receiving the iCST intervention and those in the control group receiving TAU in the primary outcomes, cognition, and QoL.

## **Chapter 3**

### **Systematic review: The impact of cognitive leisure activities on risk of cognitive impairment and dementia**

This chapter was adapted into a journal article: Yates, L., Ziser, S., Spector, A., & Orrell, M. Cognitive leisure activities and future risk of cognitive impairment and dementia: Systematic review and meta-analysis (*submitted*).

#### **3.1 Background**

Worldwide in developed and developing nations, ageing populations represent a great challenge to health and social care systems, which must address the complex physical and mental health needs of this demographic. Dementia is one of the most common age-related diseases, and a major contributor to disability, institutionalisation, and death in elderly populations (Fratiglioni, Winblad, & von Strauss, 2007). With the number of dementia cases being expected to double every 20 years (World Alzheimer's Report, Prince *et al.*, 2009), governments are being urged to make dementia a priority by allocating funding to innovative research, and structuring services so that they are better equipped to support people with dementia (World Alzheimer's Report, Prince, Prina, & Guerchet, 2013).

Investigation into modifiable risk and protective factors could lead to the identification of preventative strategies or habits that people are able to integrate into their lifestyle (Desai, Grossberg, & Chibnall, 2009). Indeed, in a recent review of population attributable risk (PAR) it was estimated that potentially modifiable risk factors may contribute to a third of cases of Alzheimer's Disease (AD) (Norton, Matthews, Barnes, Yaffe, & Brayne, 2014). The impact of these risk factors may be modified or mediated by interactions with other concurrent factors, and is likely to be related to the age at which exposures occur (Norton, Matthews, & Brayne, 2013).

Participation in mentally stimulating leisure activities has emerged as a potential contributor to sustained cognitive health, exerting a protective effect against decline and dementia (Fratiglioni, Paillard-Borg, & Winblad, 2004), as well as having social and psychological benefits (Lennartsson & Silverstein, 2001). Other valuable outcomes of maintaining cognitive health may be prolonged independence resulting in reduced institutionalisation, reduced dependence on health and social care services, and improved quality of life (Stern & Munn, 2010).

Verghese *et al.* (2006) provide a definition of leisure activities as those which ‘individuals engage in for enjoyment or well-being that are independent of work or activities of daily living’. The impact of a range of leisure pursuits, including physical (Wang, Xu, & Pei, 2012), mental (Wilson *et al.*, 2010), and social (Saczyński *et al.*, 2006) activities has been explored, generating suggestions for possible mechanisms of action. A popular theory for the observed advantages of leisure activities is that participation can improve cognitive reserve and stimulate neuronal networks in the brain (Katzman, 1993). Building cognitive reserve is thought to contribute to the capacity to retain intellectual capabilities in later life, and engage alternative neuronal networks should areas of the brain be damaged by insult or AD pathology (Fratiglioni, Paillard-Borg, & Winblad, 2004). This systematic review investigates the potential impact of cognitively stimulating leisure activities on reducing cognitive decline, and risk of dementia. Previous reviews have been presented in narrative form (e.g., Stern & Munn, 2010). However, this review seeks to pool data from recent studies in a series of exploratory meta-analyses to estimate the extent of any potential preventative impact.

### **3.2 Aim and Objectives**

#### **3.2.1 Aim**

To conduct a systematic review and meta-analyses on the impact of cognitively stimulating leisure activities on reducing risk of cognitive impairment and dementia.

### **3.2.2 Objectives of the review**

- To determine the impact of cognitively stimulating leisure activities on cognition and risk of dementia in later life.
- To assess the quality of evidence available on this topic.
- To pool data from the studies in a series of meta-analyses.

## **3.3 Methods**

### **3.3.1 Criteria for inclusion and exclusion of studies in this review**

#### **3.3.1.1 Types of participants**

Studies with adult subjects were included, although no specific age ranges were defined in the search so that longitudinal studies tracking participants from ‘mid-life’ onwards were not excluded. Participants were cognitively healthy at baseline (no diagnosis of amnestic Mild Cognitive Impairment (aMCI), Mild Cognitive Impairment (MCI), or dementia), but may have had recorded diagnosis of MCI, or dementia (any type and severity) at follow up. Case-control design studies with comparison groups of participants with aMCI, MCI, or dementia at baseline were included in a parallel set of analyses.

#### **3.3.1.2 Types of activity**

Within Verghese *et al’s* (2006) definition of leisure activities, this review specifically focused on activities with a cognitive element, in other words those which elicit a ‘mental response’ from the participant (Stern & Munn, 2010). In some cases, the category placement of activities was not clear, or classified differently between studies. For example, gardening was considered a cognitive activity by some study authors, and physical by others. However, the research team considered multi-component activities, and reached consensus on their appropriateness for inclusion. A set of criteria for inclusion of data on specific activities and composite categories is detailed in the analysis section.

#### **3.3.1.3 Types of studies**

Quantitative studies published as English-language journal articles were included in the review. Epidemiological studies and those reporting on longitudinal data, including case-control designs, were of particular interest and it was anticipated that these designs would be the most common amongst the studies identified. The review considered both randomised controlled trials (RCTs) and non-randomised studies. However, certain types of RCTs were not eligible for inclusion, as detailed in the ‘exclusion criteria’ section below.

#### 3.3.1.4 Exclusion criteria

Trials or RCTs with standardised or structured activity interventions were not included in the review (e.g., manualised approaches, professionally delivered programmes, or formal courses). The review is focused on unstructured leisure activities individuals take part in as part of their regular routine, rather than specific interventions. Studies with data on physical and social activities with no cognitive component were excluded from the review.

#### 3.3.1.5 Types of outcome

Outcomes of interest in the review were participation in leisure activities, cognitive performance, and onset of cognitive impairment or dementia measured by:

- Scores on one or more tests of cognitive functioning such as the Mini-Mental State Examination (MMSE) (Folstein, Robins, & Helzer, 1983), and the Blessed Information Memory Concentration Test (Blessed, Tomlinson, & Roth, 1968).
- Diagnosis of aMCI, MCI, or dementia using standardised criteria (e.g., Diagnostic and Statistical Manual 3<sup>rd</sup>/4<sup>th</sup> edition [DSM-III, DSM-IV]) by a clinician, or expert panel of healthcare professionals at follow up.
- Self-report or next of kin ratings of current or lifetime participation in leisure activities.

### 3.3.2 Developing and applying the search strategy

### 3.3.2.1 Development & piloting

As part of the preparation for the review, LY sought guidance about the use of healthcare databases and developing a search strategy from an experienced member of staff (Ruth Muscat, RM) at the UCL library. LY conducted pilot searches in MEDLINE to ascertain the suitability of the search terms selected. Reference lists from a small number of articles and existing literature reviews in this topic area were checked at this stage to give the research team a scope of the topic area and ensure the search and the search objectives were appropriately focused. Academic literature (Meline, 2006) was used as a reference for the principles and methodological techniques of conducting systematic reviews.

### 3.3.2.2 Search terms

As a result of the pilot searches, combinations and variations of the search terms; 'dementia', 'cognitive activity', 'leisure activity', 'cognition', 'lifestyle', and 'hobbies' were selected for use in the review.

### 3.3.2.3 Application of search strategy

Systematic searches of the following healthcare databases were carried out in March 2014:

- PsychInfo,
- MEDLINE,
- CINAHL,
- EMBASE,
- Web of Knowledge (Web of Science)

These databases were selected for the review as they cover research studies from clinical, nursing, and social sciences perspectives, which are considered pertinent to the topic selected. Studies carried out in the last 10 years (2004-2014) were considered.

In total, 3859 references were located across the five databases (see Figure 3.1). After duplicates were discarded, 3377 references were imported into an End Note library. A three stage screening process was carried out. Firstly, titles were assessed for relevance to the

search topic. The abstracts of 494 references deemed relevant were then screened. In cases where eligibility could not be confidently determined by reviewing the abstract and title, the full content of the paper was considered. Finally, the quality of the remaining 92 relevant papers was assessed (see below section for details).

Particular attention was given to the cohorts each study derived their data from. In cases where multiple papers were based on the same cohort, papers were assessed for relevance to the review question, or use of a particular subset of the cohort not included in alternative papers. Several large projects were identified: the Kungsholmen Project (Fratiglioni, Viitanen, Bäckman, Sandman, & Winblad, 1992), Mayo Clinic Study of Aging (MCSA) (Roberts *et al.*, 2008), Bronx Aging Study (Verghese *et al.*, 2003), RUSH Memory and Ageing Project (Bennett *et al.*, 2005) and the Age Gene / Environment Susceptibility-Reykjavik Study (Harris *et al.*, 2007). Seven studies were excluded as they were one of multiple papers based on the same project.

### 3.3.2.4 Assessing the quality of the studies

Slavin's (1987) 'critical evaluation approach', whereby only studies meeting a high methodological standard of quality qualify for inclusion in the review, was followed. Studies were assessed for quality using guidelines provided by the Critical Appraisal Skills Programme (CASP) Oxford UK (2014). Specifically, checklists for cohort and case-control studies were applied in the reading of papers reaching the quality assessment stage. In principle, applying quality controls will increase the likelihood that the results of the meta-analyses will be valid and generalisable. Two reviewers (LY & SZ) conducted the quality assessments independently with guidance from MO. If there were any differences in judgement of appropriateness and quality of the papers, the team reconsidered them collaboratively to reach a consensus.

### 3.3.2.5 Data extraction

Descriptive data from the final studies, including study sample, methods (including variables adjusted for in analyses), types of leisure activities, measures (e.g., leisure activity scales, cognition, diagnoses of cognitive impairment), and outcomes relevant to the review was summarised.

## 3.4 Analyses

Studies included in the meta-analyses were grouped by outcome (dementia, cognitive impairment including aMCI, MCI, and cognitive decline) and type of output (risk [RR], odds [OR], or hazard ratios [HR]). Where possible, ORs were converted to RRs so that data from several studies could be pooled for analysis. An advantage of RRs is that they allow for a more intuitive interpretation of results than ORs (Deeks, 1998). However, they are not suitable for use in case-control studies (Cummings, 2009), thus ORs were retained for the meta-analysis pooling data from studies by Fritsch, Smyth, Debanne, Petot, & Friedland (2005) and Lindstrom *et al.* (2005). Metaview and Review Manager 5.3 software packages were used to calculate the RRs and generate forest plots for the meta-analyses. A random effects model of meta-analysis was selected as the studies varied in terms of population, and measures of cognitive leisure activities therefore it was expected that effect sizes would vary between studies. This model accounts for random error within studies as well as this variation in effect sizes between studies (Borenstein, Hedges, & Rothstein, 2007).

Five meta-analyses were performed using data from 15 of the 19 studies. Three of the meta-analyses pooled data on the association between participation in leisure activities and risk of developing dementia, and two were focused on the association between leisure activities and cognitive decline and impairment. The remaining four studies provided other types of data including correlations, and output from brain imaging tests.

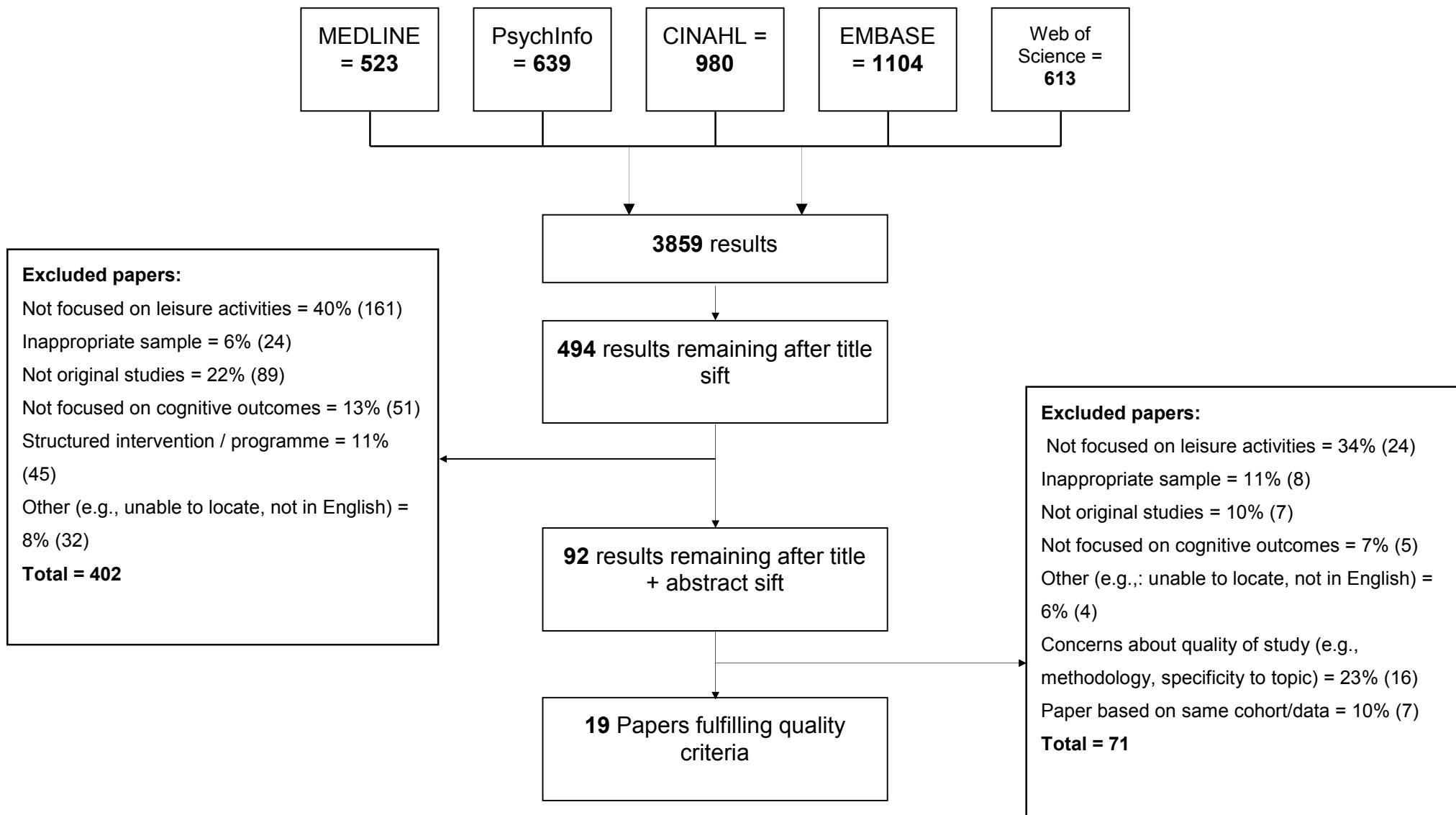


Figure 3.1 Flow chart showing the paper sifting process

*Table 3.1 Descriptive summary of studies included in the review*

<b>Study</b>	<b>Design</b>	<b>Sample size (n=)</b>	<b>Outcomes</b>	<b>Leisure activities</b>	<b>Follow up</b>
Fritsch <i>et al.</i> (2005)	Case-control	264 dementia cases, 365 matched, 181 community	Dementia	Novelty seeking activities (e.g., new skill, mentally challenging activities, solving a problem). Cases: frequency (20 years-5 years prior to AD). Controls: frequency (20-60 years).	None
Lindstrom <i>et al.</i> (2005)	Case-control	135 AD cases 331 controls	Dementia	Intellectual activities (e.g., reading, jigsaw puzzles, crosswords, playing music). Frequency: 'ever', 'never'. If 'ever', hours per month aged 20-39 & 40-59. Daily activity hours & percent intensity.	None
Akbaraly <i>et al.</i> (2009)	Longitudinal cohort	5506	Dementia	'Stimulating activities' (e.g., crosswords, playing cards). Frequency (monthly): never/rarely, 1-3x, 1x weekly, ≥2 x weekly.	4 years
Almeida <i>et al.</i> (2012)	Longitudinal cohort	5698	Dementia	Computer use. Frequency: 'never', 'every day', 'at least every week', 'less than every week'.	Mean 6 years
Paillard-Borg, Fratiglioni, Winblad, & Wang. (2009)	Longitudinal cohort	776	Dementia	Intellectual activities (e.g., reading books/newspapers, writing, studying). Frequency: 'daily', 'weekly', 'monthly', 'annually'. Lower & upper 2 tertiles.	9 years
Sattler, Toro, Schonknecht, & Schroder (2011)	Longitudinal cohort	381	Dementia	Cognitive activities (e.g., reading books, reading). Frequency: 'never', 'sometimes', 'often'. 'High', 'medium', 'low' participation.	12 years
Wilson, Scherr, Schneider, Tang, & Bennett (2007)	Longitudinal cohort	775	Dementia	Seeking/processing information activities (e.g., reading, games). Frequency: once per year or less- daily. Past & current participation.	Mean 3.5 years
Carlson <i>et al.</i> (2012)	Longitudinal cohort	436	Cognitive impairment	Highly cognitively demanding activities (e.g., crosswords, taking courses, drawing, singing). Frequency (prior year): 'not at all', '1x monthly', '2-3 x monthly', '1x weekly', '2-3' x weekly, 'every day'.	9.5 years
Verghese <i>et al.</i> (2006)	Longitudinal cohort	437	Cognitive impairment	Cognitive activities (e.g., reading, writing, crosswords, board/card games, group discussions, playing music). Frequency: 'daily', 'several days per week', 'weekly', 'occasionally/never'. Grouped by score: '<8 points, 8-14 points, >14 points)'.	Mean 5.6 years

Wang <i>et al.</i> (2006)	Longitudinal cohort	5437	Cognitive impairment	Cognitive activities (e.g., board games, reading, writing, calligraphy/painting). Frequency: 'daily', 'weekly', 'monthly', 'annually' & hours per week.	Mean 4.7 years
Geda <i>et al.</i> (2011)	Cross sectional	1321	Cognitive impairment	Cognitive activities (e.g., reading craft activities, computer activities). Frequency within 1 year of assessment.	None
Iwasa <i>et al.</i> (2012)	Longitudinal cohort	567	Cognitive impairment	Hobbies (e.g., gardening, watching TV, travelling, knitting, reading books) Frequency: 'never', 'occasionally', 'frequently'.	5 years
Li <i>et al.</i> (2013)	Longitudinal cohort	1020	Cognitive impairment	Reading, writing. Frequency: 'rare' or 'frequent'.	None
Monastero, Palmer, Qiu, Winblad, & Fratiglioni (2006) Niti, Yap, Kua, Tan, & Ng (2008)	Longitudinal cohort	718	Cognitive impairment	Mental activities (e.g., reading books / newspapers, writing, studying). Frequency: frequent (daily) or no/infrequent (no/less than daily).	Mean 3.4 years
	Longitudinal cohort	1635	Cognitive impairment	Social (e.g., church, group activities, playing games), productive (e.g., hobbies, preparing meals, shopping), physical activities (e.g., walking, keep fit). Frequency: 'never/< 1x monthly', 'sometimes / 1x monthly but < 1x weekly', 'often / at least 1x weekly'. High, medium, low participation.	1-2 years
Kareholt, Lennartsson, Gatz, & Parker (2011) Saczynski <i>et al.</i> (2008)	Longitudinal cohort	1643	Cognitive impairment	Mental activities (e.g., reading books, playing music, singing). Frequency: 'no', 'yes sometimes', 'yes often'.	Mean 22.8 years
	Longitudinal cohort	2300	Cognitive impairment	Crosswords, reading, religious services, board or card games, using computer, writing letters/poems, artwork, etc. Frequency: (past year) 'daily', 'at least weekly', 'at least monthly', 'every few months', 'never'. High quartile vs. lower quartiles.	None
Wang <i>et al.</i> (2013)	Longitudinal cohort	1463	Cognitive impairment	Mental activity (e.g., sewing, weaving, reading). Frequency: 'never', '< 1x monthly', '1-3 x monthly', '3-4x weekly', '5-6 x weekly', 'daily'. Low vs. high tertiles.	Mean 2.4 years
Wilson <i>et al.</i> (2010)	Longitudinal cohort	614 controls 395 MCI 148 AD	Cognitive impairment	Seeking/processing information activities (e.g., TV, reading newspaper / books, games, crosswords, puzzles, museum). Frequency: 'every day', 'several times per week', 'several times per month', 'several times per year', 'once per year or less'.	12 years

Where papers presented data on a range of specific leisure activities or authors created composite categories, activities or categories were selected for inclusion in the analyses on the basis that they fulfilled the following criteria:

- Activity is more common amongst the studies. To discern their frequency, the activities specified in each paper were listed and ranked according to how many studies gathered data on them. For example, reading was cited most frequently (15 studies), so data pertaining to this activity would be selected over data for playing games (11 studies).
- Activity is predominantly cognitive in nature and requires active processing of information. For example, reading requires use of memory, and also stimulates visual and abstract thinking.
- Composite categories must be specified as 'mental', 'intellectual' or 'stimulating', or describe an active cognitive skill (e.g., novelty seeking activities).

## **3.5 Results**

### **3.5.1 Included studies**

Nineteen studies passed the quality control assessment and were included in the review (Table 3.1). Of these, there were 17 longitudinal cohort studies and two case-control studies (see Table 3.1). The studies were carried out in various countries including France (1), Germany (1), Iceland (1), Australia (1), Japan (1), Singapore (1), Sweden (3), China (3) and the USA (7). The age of participants was 46 years or older. The average mean age was 77 years.

Table 3.2 Data used in meta-analyses

	Study	Type	Outcome	Original data	CI	Calculated data	CI	p value	Relative reduction
<b>Analysis set one</b>									
Cohort	Akbaraly	Cohort	Dementia	HR=0.49	0.31-0.79	N/A	N/A	N/A	51%
	Almeida	Cohort	Dementia	HR=0.62	0.47-0.81	N/A	N/A	N/A	38%
Cohort	Sattler	Cohort	Dementia	OR=0.38	0.15-0.99	RR=0.628	0.283-1.39	p=0.251	Not significant
	Paillard-Borg	Cohort	Dementia	RR=0.79	0.57-1.09	N/A	N/A	N/A	Not significant
	Wilson '07	Cohort	Dementia	RR=0.47	0.34-0.66	N/A	N/A	N/A	53%
Case control	Fritsch	Case control	Dementia	OR=0.248	0.139-0.443	N/A	N/A	N/A	75%
	Lindstrom	Case control	Dementia	OR=0.84	0.72-0.98	N/A	N/A	N/A	16%
<b>Analysis set two</b>									
Cohort	Geda	Cohort	Cog impairment	OR=0.58	0.43-0.79	N/A	N/A	N/A	42%
	Iwasa	Cohort	Cog impairment	OR=0.55	0.35-0.85	N/A	N/A	N/A	45%
	Li	Cohort	Cog impairment	OR=0.54	0.33-0.89	N/A	N/A	N/A	46%
	Monastero	Cohort	Cog impairment	OR=0.54	0.33-0.89	N/A	N/A	N/A	46%
	Niti	Cohort	Cog impairment	OR=0.87	0.67-1.13	N/A	N/A	N/A	Not significant
Cohort	Carlson	Cohort	Cog impairment	HR=0.94	0.86-1.04	N/A	N/A	N/A	Not significant
	Verghese	Cohort	Cog impairment	HR=0.39	0.250-0.609	N/A	N/A	N/A	61%
	Wang '06	Cohort	Cog impairment	HR=0.96	0.94-0.99	N/A	N/A	N/A	4%

### **3.5.2 Participation in leisure activities and risk of dementia**

#### **3.5.2.1 Cohort studies**

Data was pooled for studies by Akbaraly *et al.* (2009) and Almeida *et al.* (2012) for the first meta-analysis (Figure 3.2). Stimulating activities were found to be significantly associated with reduced risk of dementia ( $HR=0.49$ , 95% CI:0.31-0.78) (Akbaraly *et al.*, 2009). Almeida *et al.* (2012) reported that computer users were less likely to develop dementia ( $HR=0.62$ , 95% CI: 0.47-0.81) than non-users, with decreased risk associated with increased frequency of use. Pooling the results revealed an overall significant reduction in risk for those participating in stimulating activities or using computers ( $HR=0.58$ , 95% CI: 0.46-0.74, $p<0.001$ ).

Three studies (Paillard-Borg *et al.*, 2009; Sattler *et al.*, 2012; Wilson *et al.*, 2007) were collated for the second meta-analysis in this set, two of which provided RRs as original data ( $RR=0.79$ , 95% CI:0.57-1.09 [Paillard-Borg *et al.*, 2009];  $RR= 0.47$ , 95% CI:0.34-0.66 [Wilson *et al.*, 2007]). The RR was calculated for Sattler *et al.* (2012) ( $RR=0.63$ , 95% CI: 0.28-1.39). The overall result of the meta-analysis was significant ( $RR=0.61$ , 95% CI: 0.42-0.9,  $p=0.012$ ).

#### **3.5.2.2 Case-control studies**

Two case-control studies were included in the review (Fritsch *et al.*, 2005; Lindstrom *et al.*, 2005). Fritsch *et al.* (2005) found novelty seeking cognitive activities had the strongest association with this reduction in odds ( $OR=0.25$ , 95% CI: 0.15-0.41). The data from Lindstrom *et al.* (2005) was categorised as ‘intellectually stimulating’ activities ( $OR=0.84$ , 95% CI: 0.72-0.98). Both studies concluded that the odds of developing dementia were significantly lower for those who frequently participated in leisure activities. When analysed using a random effects model, the pooled results were not significant ( $OR=0.47$ , 95% CI: 0.14-1.55,  $p=0.21$ ) so a fixed effects model was applied to the data ( $OR=0.78$ , 95% CI: 0.67-0.9).

### **3.5.3 Participation in leisure activities and risk of cognitive decline and impairment**

In the first of the set of analyses of risk of cognitive decline and impairment, data was collated from five studies (Geda *et al.*, 2011; Iwasa *et al.*, 2012; Li *et al.*, 2013; Monastero *et al.*, 2006; Niti *et al.*, 2007). Geda *et al.* (2011) Li *et al.* (2013) performed an analysis of variance (ANOVA) between the participants in the study who developed MCI and those who were cognitively normal. Raw data was available for all studies so ORs for cognitive activities were calculated. Eight of the 10 leisure activities investigated in Geda *et al.*'s study (reading books, reading magazines, reading newspapers, playing music, playing games, artistic activities, craft activities, computer activities) were considered appropriate for inclusion in the analysis. Complete raw data was only available for two cognitive activities (reading, writing) from the paper by Li and colleagues. The OR for 'reading books' ( $OR=0.58$ , 95% CI: 0.43-0.79 [Geda *et al.*, 2011]) and 'reading' ( $OR= 0.54$ , 95% CI: 0.33-0.89 [Li *et al.*, 2013]) were used according to the defined criteria for selection of activity/composite score data (see section 3.4). The calculated ORs based on data from the remaining three studies were significant and in favour of a protective effect of cognitive leisure activities ( $OR=0.55$ , 95% CI: 0.35-0.85, Iwasa *et al.*, 2012;  $OR=0.54$ , 95% CI: 0.33-0.91, Monastero *et al.*, 2006;  $OR=0.87$ , 95% CI: 0.67-1.13, Niti *et al.*, 2008). Four of the five studies reported a significant association between participation in leisure activities and reduced risk of cognitive decline and impairment (Geda *et al.*, 2011; Iwasa *et al.*, 2012; Li *et al.*, 2013; Monastero *et al.*, 2006). When pooled, reduction in odds was significant ( $OR=0.63$ , 95% CI: 0.51-0.79).

Significant associations between participation in leisure activities and reduced risk of cognitive impairment were reported by Verghese *et al.* (2006;  $HR=0.39$ , 95% CI: 0.25-0.61,  $p<0.001$ ) and Wang *et al.* (2006;  $HR=0.96$ , 95% CI: 0.93-0.99,  $p=0.01$ ). The association did not reach significance in the study by Carlson *et al.* (2012;  $HR=0.94$ , 95% CI: 0.85-1.04,  $p=0.22$ ). When the studies were combined the analysis did not quite reach significance ( $HR=0.85$ , 95% CI: 0.71-1.02,  $p=0.08$ ).

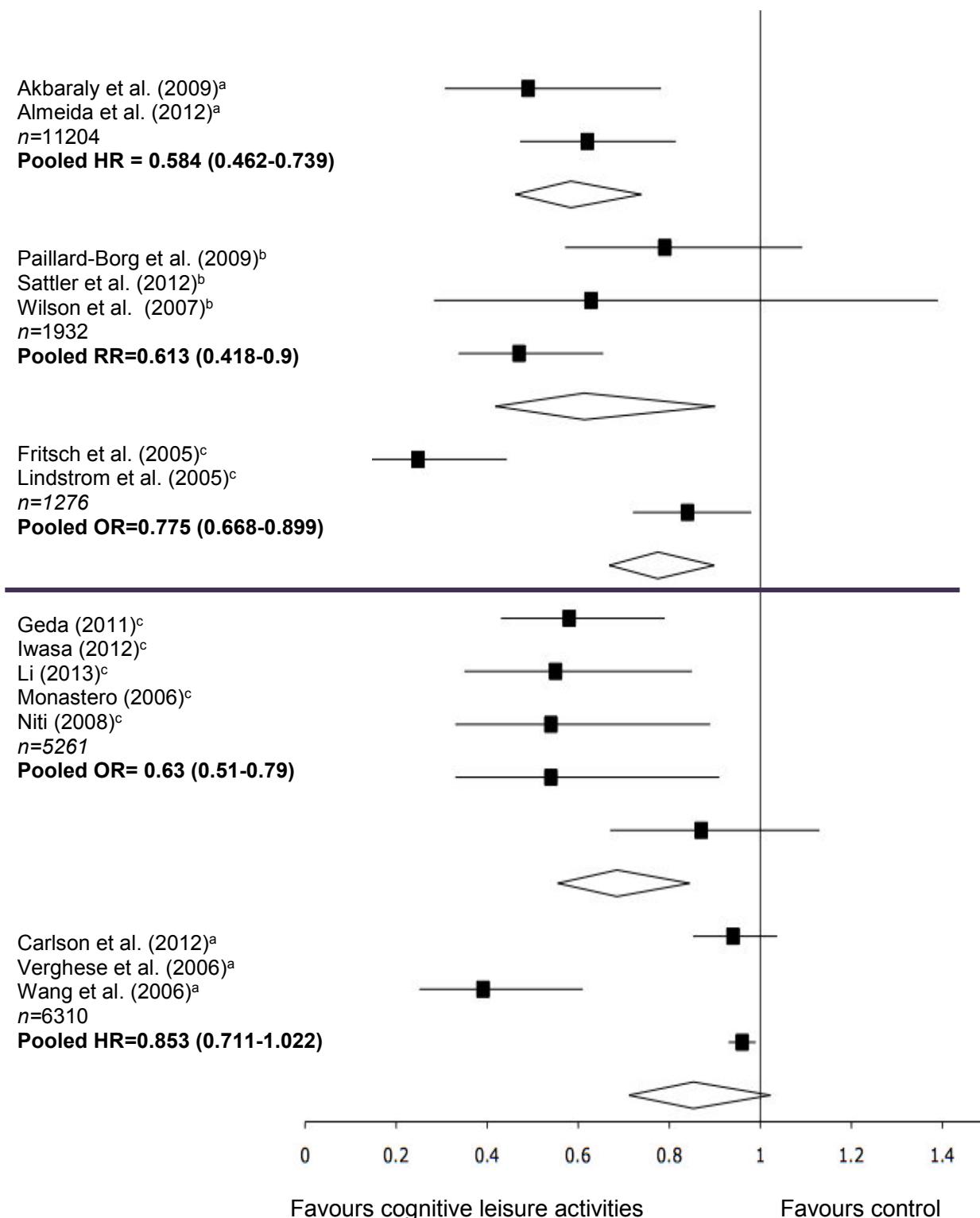
### **3.5.4 Relative Risk Reduction (RRR), Hazard Reduction & Odds Reduction**

Relative risk, hazard, and odds reduction percentages were calculated (Table 3.2) to assess the magnitude of significant protective effects. The smallest observed reduction in risk of cognitive impairment or dementia associated with participation in cognitive leisure activities was 4% (Wang *et al.*, 2006), whilst the largest reduction was 75% (Fritsch *et al.*, 2005). The mean reduction across all significant studies was 43.36%. The analysis set including data from Geda *et al.* (2011), Iwasa *et al.* (2012), Li *et al.* (2013), Monastero *et al.* (2006), and Niti *et al.* (2008) had the most consistent reduction effects (range = 42-46%). However, effect sizes were considerably different for two of the analysis sets: (1) Fritsch *et al.* (2005, 75%) and Lindstrom *et al.* (2005, 16%), and (2) Verghese *et al.* (2006, 61%) and Wang *et al.* (2006, 4%).

### **3.5.5 Tests of heterogeneity**

The  $I^2$  statistic was used as a measure of the impact of heterogeneity on the meta-analysis. Developed by Higgins & Thompson (2002), the calculation represents the proportion of total variation in estimates of treatment effects that are attributable to differences between studies rather than sampling error within studies. The  $I^2$  statistics produced for each meta-analysis set were interpreted according to the  $p$  value from the Chi-squared tests (i.e.: strength of evidence) alongside the following thresholds outlined in the Cochrane Handbook (Higgins & Green, 2008):

- (i) 0-40%: may not be important
- (ii) 30-60%: moderate heterogeneity
- (iii) 50-90%: substantial heterogeneity
- (iv) 75-100%: considerable heterogeneity



*Figure 3.2 Effect sizes for five meta-analyses (95% confidence intervals) including pooled values for each grouping. Output type: <sup>a</sup> Hazard Ratio (HR) <sup>b</sup> Relative Risk (RR) <sup>c</sup> Odds Ratio (OR).*

The level of heterogeneity for the meta-analysis set including Akbaraly *et al.* (2009) was potentially negligible and did not reach significance ( $p=0.39$ ). Heterogeneity was ‘moderate’ in two of the sets; Paillard-Borg *et al.* (2009) ( $p=0.09$ ) and Geda *et al.* (2011;  $p=0.15$ ). ‘Substantial’ heterogeneity was detected in the meta-analysis set including Carlson *et al.* (2012;  $p=0.08$ ), and highly significant ( $p=0.00$ ) and ‘considerable’ heterogeneity was found in the meta-analysis including Fritsch *et al.* (2005).

### **3.5.6 Findings of other studies included in the review**

Kareholt, Lennartsson, Gatz, & Parker (2009) conducted a longitudinal cohort study spanning over two decades to determine the association between different types of leisure activity in mid-life and cognition in later life. A total of 1643 participants were followed up at several time points during the study. Cognition was measured using the MMSE (Folstein, Robins, & Helzer, 1983). Mental activities (e.g., reading books, playing a musical instrument, hobby activities) were found to be significantly associated with later life cognition ( $\beta=0.11$ ,  $p=0.05$ ).

The data from Saczynski *et al.*’s (2008) study showed that frequent participation in leisure activities (measured in the 12 months prior to assessment) was associated with better cognition; memory ( $\beta=0.20$ , 95% CI: 0.11-0.29), speed of processing ( $\beta=0.37$ , 95% CI: 0.29-0.45), and executive functioning ( $\beta=0.23$ , 95% CI: 0.15-0.29). In addition, the study investigated the link between white matter lesions (WMLs) on risk of cognitive impairment. Participation in leisure activities was found to modify the link between WML and speed of processing ( $\beta=0.15$ , 95% CI: 0.01-0.30,  $p<0.05$ ) in that the performance of those with high WML and high participation in activities was better than those with high WML and low participation, and those with low WML regardless of their level of participation in leisure activities.

In a study of the impact of leisure activities on cognitive decline (Wang *et al.*, 2013), high engagement in mental activity was significantly associated with less decline in overall

cognition ( $\beta=-.23$ ,  $p<0.01$ ), language ( $\beta=-.11$ ,  $p<0.05$ ), and executive function ( $\beta=-.13$ ,  $p<0.05$ ).

Wilson *et al.* (2010) studied the relationship between participation in cognitive activities and rate of cognitive decline. Participation in cognitive activities did not have the same effect on those with cognitive impairment or AD at follow up as those without cognitive impairment. Rate of cognitive decline was reduced by 52% per year for each additional point on the cognitive activity scale (CAS) for those without cognitive impairment (estimate = 0.029, SE = 0.010,  $p=0.00$ ). By contrast, rate of cognitive decline was not significantly associated with participation in cognitive activity for people with MCI (estimate = -0.019, SE = 0.018,  $p=0.30$ ). For those with AD, for each point on the CAS, the mean rate of decline increased by 42% per year (estimate = 0.075, SE = 0.021,  $p<0.001$ ).

### **3.6 Discussion**

Systematic reviews of the impact of cognitive leisure activities on cognition and risk of cognitive impairment and dementia have largely been descriptive in nature due to the lack of standardisation in measures of leisure activities and diversity in measures of cognition used between studies. As part of this review, five meta-analyses were performed; three of which were focused on the impact of cognitively stimulating leisure activities on risk of dementia, and two on risk of cognitive impairment and decline. Participation in cognitive leisure activities were consistently found to be associated with reduced risk of dementia and cognitive impairment. This suggests that mental stimulation can have a protective effect on cognitive abilities. This association is not a new one; in the essay ‘De Senectute’, the Roman philosopher and statesman, Cisero (106 B.C.- 43 B.C.) wrote that ‘Old men retain their intellects well enough, if only they keep their minds active and fully employed.’ However, over the last few decades, and with the launch of several large-scale epidemiological studies, a growing body of research evidence has suggested the value of cognitive leisure activities. Neuropsychological evidence of capacity for change, new learning, and plasticity well into the so-called ‘Third Age’ (up to 80 years) (Reuter-Lorenz, 2002; Mora, Segovia & del Arco, 2007)

also suggests that cultivation of an enriched cognitive environment may contribute to successful ageing. Less encouragingly, there is some suggestion that these cognitive abilities diminish in the ‘Fourth Age’ (over 80 years) (Baltes & Smith, 2003).

Ageing can be seen as a dynamic interplay of gains and losses in function, influenced not only by cognitive mechanics (i.e.: the physiological capacity of the brain), but also by the cognitive pragmatics of intelligence or skills learned as a result of cultural environment, such as being able to read. Cognitive mechanics are largely contained within the pattern of growth in early life, stability in adulthood, and decline in later life (Baltes & Singer, 2001). By contrast, uptake, maintenance, and abandonment of cognitive pragmatics varies across lifespan and between individuals, according to levels of cultural exposure, motivation to seek out opportunities for stimulation, and perhaps innate intelligence. It is thought that cognitive reserve is developed through formation and exercise of cognitive pragmatics. Multiple or well developed cognitive resources (e.g., alternative neural pathways) are available should cognitive networks be damaged, meaning deficits in functioning associated with cognitive impairment and dementia are not expressed at all, or are not as profound as they might be in individuals with less cognitive reserve (Scarmeas & Stern, 2003).

The Fourth Age, or latter part of the Third Age may represent the point at which lifetime accumulation of cognitive pragmatics, cognitive reserve, and new cultural input are less effective in their facility to prevent or compensate for cognitive losses incurred as a result of biological capacity. This may provide a context within which to understand the observation of Wilson et al. (2010) that after onset of AD deterioration appears accelerated with increased participation in leisure activities. Indeed, with a mean age of 79.2 years, and on the threshold of the ‘Fourth Age’, participants diagnosed with AD in this study were older (approximately 3.8 years) than those who were cognitively healthy, so it is plausible that their capacity to compensate for cognitive deficits or resist deterioration at this stage was severely limited or impervious to the effect of mental stimulation provided by cognitive leisure activities. Alternatively, the accelerated deterioration of AD participants actively engaging in cognitive

leisure activities may reflect poor allocation of cognitive resources. According to the selective-optimisation with compensation model (SOC) proposed by Baltes & Baltes (1990), successful maintenance of functioning in the face of the challenge of losses is best achieved by reducing the variety of channels in which cognitive investments are made (selection). In this case, a reduction of the variety of activities the person engages in. Cognitive resources can then be channelled into a smaller pool of interests, in which performance is concentrated and, as a result optimised. Compensatory techniques (e.g., use of memory aids) may also be employed to support performance.

The key then may be quality and level of investment in, rather than quantity and variety of cognitive leisure activities in later life. Involvement in many activities in youth and adulthood when cognitive resources are readily available is not likely to be detrimental. However, taking on too many with limited cognitive resources in old age may at worst accelerate decline, or at best negate or mask any benefits. This poses the question of whether certain activities are more worthwhile investments than others, and whether this is universally applicable to all, or depends very much on the individual. If evidence emerges that certain activities are more beneficial than others, we then need to discern any specific qualities that are responsible for their effectiveness, and ideally when in lifespan participation should be advised to achieve maximum benefits.

### **3.6.1 Methodological strengths and limitations**

#### **3.6.1.1 Implications of heterogeneity of included studies**

Considerable heterogeneity was detected in two of the five meta-analyses performed. Higgins, Thompson, Deeks, & Altman (2003) reported that amongst 509 meta-analyses in the Cochrane Database of Systematic Reviews, a quarter had heterogeneity of over 50%. Of which an estimated 15% fell into the 50-80% category, and 10% greater than 80%. This suggests the levels of heterogeneity observed in analyses from this review (e.g., 41%, 58.51%, 87%, 93.71%) are not uncommon. In addition, despite the heterogeneity detected, the distribution of all of the findings was weighted towards a protective effect; the differences

between the studies being in the observed strength of this effect, or whether it reached statistical significance. A possible positive implication of heterogeneity, if diversity in sample populations was a contributor, is that the reduction in risk associated with cognitive leisure activities may be generalisable across a variety of populations. Whilst other associated risk factors for dementia (e.g., age, gender, vascular health etc.) were accounted for in the models of analysis in the majority of studies, these variables may have factored into the differences detected.

In terms of considering how best to interpret the results of this review given the observed levels of heterogeneity, it may be more valuable to consider the separate results from each study rather than the generated pooled estimate for the meta-analyses reaching a level of heterogeneity greater than 80% (Fritsch *et al.*, 2005; Carlson *et al.*, 2012). If more studies were available for pooling, the likely sources of heterogeneity and possible relationship with other risk factors for dementia could be examined further in a subgroup analysis.

### 3.6.1.2 Variation in classification of leisure activities

This field suffers from a lack of standardised classification of leisure activities, which made it difficult to compare studies. Measures of activities varied between each study, ranging from simple ‘yes’ or ‘no’ responses based on a list of pre-determined examples of leisure activities to more complex formats allowing subjects to provide information about specific activities, and the frequency and intensity of their participation.

Often, composite categories were created into which authors arbitrarily assigned individual leisure activities. The most common categories featuring in the studies included in this review were ‘mental’, ‘physical’, and ‘social’. There are advantages to collating individual activities to create composites. However, this method is not without its disadvantages. Some leisure activities have multiple components, so it is difficult to identify a primary characteristic, which determines their classification. As a result there were discrepancies between studies in category placement for certain activities. For example, Niti *et al.* (2008) categorised ‘playing

cards' as a social activity where the majority of other studies (e.g., Lindstrom *et al.*, 2005; Akbaraly *et al.*, 2009; Wang *et al.*, 2012) considered this to be a predominantly cognitive activity. Indeed, the authors of this review extracted individual activities and categories for analysis that they felt best corresponded to a definition 'cognitive leisure activities' (Stern & Munn, 2010) previously used in the literature. Furthermore, it is difficult to know how many activities within each category classification were practiced per person where overall categories were assigned. Discerning the relative impact of certain activities on cognition may be useful, as it is possible that certain leisure activities are more beneficial than others. If this is the case, the properties of these activities (e.g., neuropsychological mechanisms of change) could be examined to determine how and why they benefit cognition. In studies which considered individual activities, the strongest associations with participation and reduced risk of dementia and cognitive decline were computer activities (Geda *et al.*, 2011), and reading (Wang *et al.*, 2006; Li *et al.*, 2013). In terms of categories of cognitive activity, Fritsch *et al.* (2005) found participating in novelty seeking activities was most beneficial.

Frequency of participation was often recorded in daily, weekly, monthly, or yearly terms, then converted into an overall 'high', 'moderate' or 'low' levels. Again, the thresholds for category placement were not standardised, and so varied according to the judgement of authors. Taking these issues into account, and bearing in mind it was necessary for the authors to make subjective decisions whilst conducting this review, the reliability of the results presented must be considered carefully.

### 3.6.1.3 Design of studies and bias

Observational studies constitute the main source of evidence for the impact of lifestyle variables on cognitive function, and incidence of cognitive impairment and dementia. In the context of a lack of epidemiological intervention studies the use of this methodology is unavoidable, and represents the most practical way of investigating this area. However, causation cannot be established and studies of this nature are prone to several types of bias.

Sample bias was noted in several of the included studies (e.g., Verghese *et al.*, 2006). The types of subjects over-represented in the review studies appear to have the same characteristics of populations typically over-represented in research studies. Women are more likely to participate in research than men (Dunn *et al.*, 2004), and in the case of research in older populations women may be over-represented owing to differences in mortality rates between women and men. It is worth noting that a small selection of the studies included in this review were gender specific (men only, Almeida *et al.*, 2012; women only, Carlson *et al.*, 2012) but the authors felt this did not represent a significant bias as the majority of studies were mixed. Evidence on over and under representation of different ethnic groups is inconsistent (Galea & Tracy, 2007). The populations included in this review are relatively ethnically diverse owing to the dispersion of locations of the studies. However, there may still be some under-representation of certain ethnicities both within and between the studies. Consistent with most scientific studies, regardless of their design or methods of data collection (Partin *et al.*, 2003), there is often a distinct bias towards educated and socio-economically advantaged subjects as these individuals are more likely to volunteer for research. Due to the nature of the research question, the impact of survival bias requires consideration. A less active lifestyle is associated with higher mortality, as is lower socio-economic status (Adler & Ostrove, 1999), thus the strength of associations between participation in leisure activities and cognitive impairment may be under-estimated (Kareholt *et al.*, 2011; Niti *et al.*, 2008). Finally, the selection of English speaking studies only may also have introduced a bias towards English speaking populations.

The potential for recall and responder bias also needs to be taken into account. Participation in leisure activities may have been under or over reported by subjects themselves, or their proxy respondents. These biases can occur in both in an interview setting and when measures are self-administered. Studies gathering retrospective data tend to be particularly prone to recall bias, as subjects must rely on memory to provide the information. Responses may also be weighted towards more current behaviour if the subject is unable to accurately recall past events. The risk in these studies with such weighting is that more recent

participation in leisure activities may be prone to the influence of pre-clinical symptoms of dementia. Fritsch (2005) suggested that proxy informants in particular might weight responses to current patterns of engagement in leisure activities, depending on how long they have known the subject. Similarly proxy respondents may over or under report the cognitive or functional abilities of the subjects they are providing information for.

### 3.6.1.4 Risk of reverse causality

The studies acknowledge the risk of 'reverse causality' whereby low levels of participation in leisure activities may not be a cause of cognitive decline, rather an indication of experience of cognitive deficits in pre-clinical dementia (Verghese *et al.*, 2003). Measures to avoid this were incorporated into the design or factored into the data analysis of the majority of studies. Most screened participants for dementia and cognitive impairment at baseline using standardised diagnostic criteria such as DSM-IV and National Institute of Neurological and Communicative Disorders and Stroke/ Alzheimer's Disease and Related Disorders Association criteria (NINCDS-ADRDA).

Studies with shorter follow up periods (e.g., Akbaraly *et al.*, 2009) were more prone to detecting leisure behaviours attributable to pre-clinical dementia, as changes (e.g., apathy, reduced initiative, abandonment of hobbies) may begin to occur up to 10 years prior to the development of dementia (Elias *et al.*, 2000). However, in order to reduce this risk, a cut-off point was often defined, with those diagnosed with dementia at or before this time being excluded. For example, in the study by Akbaraly (2009) participants who were diagnosed at the two-year follow up mid-way through the study were excluded as it was assumed the data would capture the effect of pre-clinical dementia. Another method of minimising the potential effects of pre-clinical dementia employed by several of the review studies was controlling for baseline cognitive performance in multivariate analyses, excluding those who performed at levels suggestive of impairment (e.g., score  $\leq 24$  on the MMSE, Niti *et al.*, 2007).

The case-control studies included in this review (Fritsch *et al.*, 2005; Lindstrom *et al.*, 2005) dealt with the confounding effect of early or undiagnosed cognitive impairment and dementia by collecting data on activities in mid-adulthood (up to age 59) or five years prior to diagnosis or symptom onset.

### 3.6.1.5 Adjustment for confounding variables

All of the studies identified and adjusted for potential confounding variables in their analysis. This was necessary for them to qualify for inclusion in this review at the quality control stage, though some studies were more comprehensive in their management of confounders than others. Age, sex / gender, education and significant co-morbidities were universally factored into analyses. Other risk factors that have been associated with dementia and cognitive impairment were considered as confounders in some studies including; vascular health, negative health behaviours (e.g., smoking, drinking), depressive symptoms, physical functioning, social network (e.g., size of network, marital status), socio-economic status (measured by occupation or income), Apolipoprotein E (APOE) genotype, past cognitive activity, and ethnicity. As described earlier, some studies incorporated baseline cognition into their models to account for detection of pre-clinical dementia.

Disentangling the impact of engagement in cognitive activities across lifespan from the effect of participation in later life is important. It is possible that those who participate in, and pursue cognitive leisure activities in later life have always done so, and the significance of a possible cumulative effect of lifetime enrichment may be greater than stimulation in the shorter term. Controlling for lifetime leisure habits and baseline cognition function, which is likely to reflect lifelong level of cognitive function (Wilson *et al.*, 2007), at the point of analysis can increase certainty that the influence of activity in old age is being measured. In studies which applied these controls, it appeared cognitive enrichment in late life was still associated with a protective effect (Almeida *et al.*, 2012; Iwasa *et al.*, 2012; Wang *et al.*, 2006; Wilson *et al.*, 2007; Wilson *et al.*, 2010).

Adjustment for confounders can increase confidence in study results and any associations identified. However, it is not possible to anticipate or account for all factors that influence the development of dementia or experience of cognitive impairment in the short or long term, thus results must still be interpreted with caution.

### **3.6.2 Implications of findings and future research**

Interventions at a population level with a focus on reducing incidence may be the most effective way to reduce future prevalence of dementia (Ritchie *et al.*, 2010; Norton, Matthews, & Brayne, 2013). Indeed, public health strategies aiming to remove risk have been successful historically, even in cases where the cause of the disease had not been established (e.g., condoms to prevent propagation of AIDS). Delaying the onset or progression of cognitive decline could impact incidence. Desai, Grossberg, & Chibnall (2009) estimate that even a relatively moderate delay could significantly impact incidence, as deaths are attributable to others causes before any experience of impairment. Projections of global dementia cases suggest that of the 106 million cases expected by 2050, 23 million could be averted if onset were delayed by just two years (Brookmeyer, Gray, & Kawas, 1998). These delays could also translate to economic savings, an estimated \$10 billion over 10 years for an average one-year delay (Brookmeyer, Johnson, Ziegler-Graham, & Arrighi, 2007). Given the growing body of evidence that participating in cognitively stimulating leisure activities may contribute to reducing the risk of cognitive impairment in later life, promoting participation in such activities across lifespan, or at least from middle adulthood onwards, would be a worthwhile focus of primary prevention strategies. In an analysis of the relative impact of different risk factors for dementia, Ritchie *et al.* (2010) suggested increasing crystallised intelligence, a proxy indication of participation in intellectual activities, may be an impactful method of prevention, with the potential to decrease incidence of cognitive impairment and dementia by 18.1%. However, the authors highlight the caveat that discerning the optimum level of exposure to achieve protective benefits, and distinguishing the benefits alongside those attributable to other lifestyle factors would make this a difficult target to implement.

Increasing awareness of the advantages of an engaged and cognitively enriching lifestyle may be achieved through public awareness campaigns, which may be led by the government, health service, voluntary organisations, or academic institutions. Although the success of these campaigns also depends on access to a supportive environment, which will facilitate the recommended lifestyle changes or behaviours (Randolph & Viswanath, 2004) thus investment in public or community facilities providing opportunities for participation in mentally stimulating activities may be required. An additional benefit of such investment is that these kinds of facilities will also be a means to access social stimulation, which has also been linked to reduced risk of cognitive impairment (Fratiglioni, Paillard-Borg, & Winblad, 2004). Desai (2011) suggests that the healthy cognitive aging message should be communicated by healthcare professionals in discussion with patients, or through mediums such as patient information leaflets. Furthermore, Desai emphasises the need for individualised cognitive fitness plans tailored to the strengths, limitations, and preferences of the individual, and that these should be integrated into daily routine as soon as possible for maximum effect. There may be an argument for encouraging cognitive leisure activities from an early age in education (Gold *et al.*, 1995).

In terms of future studies, the development of a standardised measure of leisure activities with clearly defined categories and details of where individual activities should be placed would be a useful contribution to this area of research. Placement of activities should be corroborated by experts in the field, and target populations who will be administered the questionnaires in studies to ensure the measure has validity and reliability. Further examination of specific leisure activities and differential impacts would also be valuable once a standardised scale is available. Although heterogeneity was an issue in this review, the results of the included studies are consistently in favour of a protective effect of leisure activities, suggesting further investigation employing more rigorous statistical methods of pooling data such as a Cochrane Review would be worthwhile. The benefits of using technology such as computers is an area of research warranting attention since current data suggests an association with reduced risk of dementia. Given general computer use is

helpful, cognitive leisure activities delivered via a computer platform may have enhanced benefits, as the content and platform are cognitively stimulating in their own right.

### **3.7 Review in the context of PhD work**

This review was a retrospective piece of work based on a broader topic area than Cognitive Stimulation Therapy (CST) and home based carer delivered programmes of cognitive stimulation, given that mechanisms of action for CST have been explored previously, and studies of home based cognitive stimulation had already been examined as part of the grant proposal for the individual Cognitive Stimulation Therapy (iCST) trial. The review contributes to the evidence supporting the use of cognitive leisure activities as a means of reducing risk of cognitive impairment or dementia by collating findings from recent high quality studies. Through this work I hoped to build my understanding of the conditions in which cognitive activities are beneficial after onset of dementia, examining how these benefits might be maximised in the context of the SOC model (Baltes & Baltes, 1990). Interestingly, many of the activities (e.g., reading, puzzles, arts and crafts) reported to be associated with reduced risk feature in the CST programme. It may well be that the impact of CST on cognition is related to the nature of the activities as well as the way in which they are delivered in the sessions (e.g., adhering to the key principles, in a consistent structure). The findings of the review may also assist in my interpretation of the results of the iCST trial.

## **Chapter 4**

# **Development of individual Cognitive Stimulation Therapy (iCST) for people with dementia**

This chapter was adapted into a journal article: Yates, L., Leung, P., Orgeta, V., Spector, A., & Orrell, M. (2015). The development of individual cognitive stimulation therapy (iCST) for dementia. *Clinical Interv Aging*, 10, 95-104.

### **4.1 Background**

In line with the previous body of Cognitive Stimulation Therapy (CST) research (Spector *et al.*, 2003; Orrell *et al.*, 2014), the trial followed the Medical Research Council (MRC) guidelines, which describe a systematic step-by-step framework for the development and evaluation of complex interventions (Craig *et al.*, 2008). Figure 4.1 shows the research activities conducted within each phase of the iCST trial in the context of this framework.

This chapter describes the process by which the iCST materials (iCST manual, activity workbook, & toolkit) were initially adapted then progressively refined according to feedback from service users (carers and people with dementia) and experts in the field. The first step in the development process was the ‘pre-clinical phase’ in which the evidence for CST and home based programmes of cognitive stimulation (CS) / reality orientation (RO) was reviewed to identify theories that may explain why these interventions yield benefits. This was followed by a ‘phase I’ qualitative modelling process (focus groups, interviews, consensus methods). Finally, a phase II field-testing stage was conducted before the launch of the main randomised controlled trial (RCT).

## **4.2 Aims and objectives**

### **4.2.1 Preliminary development phase**

The aims of the preliminary development phase were: to identify the strengths and limitations of existing research into individual programmes, to develop a theoretical understanding of the mechanisms of action behind the reported benefits of cognitive stimulation and whether these could be applied to iCST (see Chapter 1 for description and discussion of findings), to assess the acceptability of an individualised version of CST suitable for delivery by carers, and to develop the first draft of the programme materials, including a manual (see Figure 4.1).

### **4.2.2 Modelling phase (focus groups & interviews, Chapter 5)**

The objectives of the modelling process were: to ensure the therapeutic materials were easy to use, clear, and appropriately tailored to the needs of people with dementia and their carers, and to assess the feasibility of the programme in theory.

### **4.2.3 Field-testing phase (Chapter 6)**

The aims of the field-testing phase were: to evaluate each of the 75 sessions of the programme, to determine whether the feasibility concerns highlighted in the focus groups and interviews were speculative, or whether they would occur and act as barriers in practice, and to produce a second draft of the materials.

### **4.2.4 Consensus process**

The aims of the online survey and consensus conference were: to consolidate the information gathered from the focus groups, interviews, and field-testing, to reach consensus on key themes identified in the analysis of these activities, and to produce the final version of the materials.

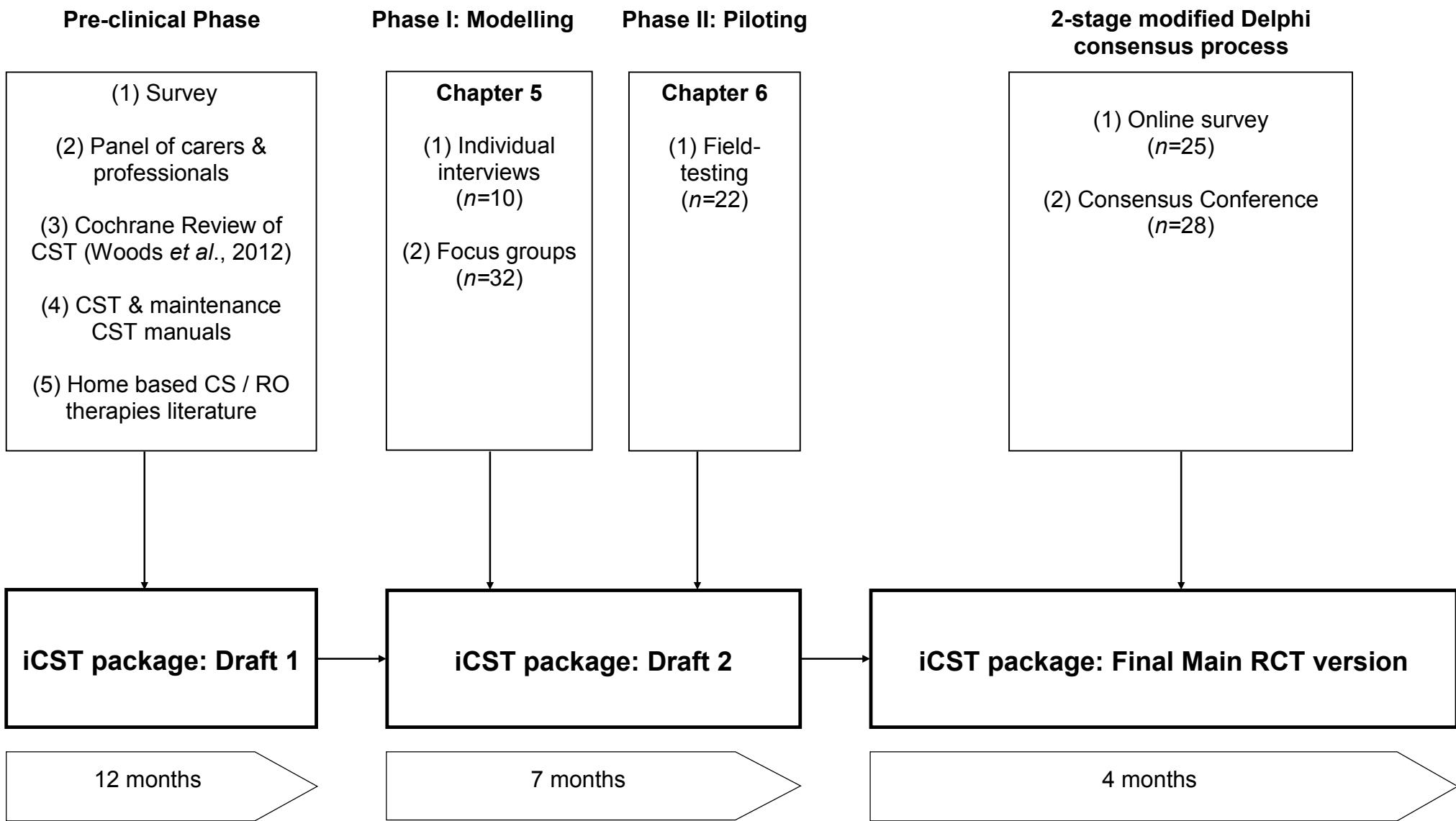


Figure 4.1 Development of the iCST programme within the MRC framework

#### **4.2.5 DVD development**

A DVD was integrated into the published iCST package as a training aid for carers. The aims of the DVD were: to demonstrate examples of sessions, and provide problem-solving vignettes as learning points to compliment the information provided in the iCST manual.

### **4.3 Preliminary consultations with service users and healthcare professionals (pre-clinical phase)**

#### **4.3.1 Design**

Prior to designing the iCST programme and drafting the materials, preliminary consultations with service users and healthcare professionals took place and a panel of experts was invited to advise the research team. Service user involvement can help develop theoretically coherent and evidence-based interventions, which are more likely to be meaningful and address the needs of the target population (Burnell *et al.*, 2012). In preparation for the development of the programme, a literature scoping exercise was also performed to determine the current understanding of the field and identify any potential for innovation (Erich, Freeman, Richards, Robinson, & Shepperd, 2002).

##### **4.3.1.1 Sample**

Twenty-seven care staff and 20 carers and people with dementia participated in the consultations. Care staff were approached for their views at CST training days, and carers and people with dementia were contacted through the charity, 'Dementia UK'. The advice panel was made up of two carers, and two professionals.

##### **4.3.1.2 Methods**

The consultations focused on the acceptability of an individualised version of CST. Participants were invited to discuss their ideas, needs for the programme and the feasibility of developing the programme. Alongside these discussions, the research team examined the current literature on group CST, including the CST (Spector, Thorgrimsen, Woods, & Orrell, 2006) and maintenance CST manuals, (Aguirre *et al.*, 2011) and one to one programmes of

CS and RO. This evidence was also reviewed by the panel, who advised the research team about the adaption of the group CST and individual approaches identified.

### **4.3.2 Results**

#### **4.3.2.1 First draft of iCST materials (Draft 1)**

The first drafts of the iCST manual and activity workbook were developed by the research team at the London site (LY, FH, PL, VO, MO) (Table 4.1).

#### **4.3.2.2 Acceptability of iCST programme**

Carers and people with dementia felt that an individualised version of CST would be very useful and priority should be placed on its development. Participants anticipated that the programme would be beneficial in a variety of ways including, bringing the carer and person closer together, providing those who are unable to get out of the house an opportunity to take part in CST, and possible use of the programme as an alternative if medication is unsuitable for the person.

#### **4.3.2.3 Structure and duration of iCST sessions**

A key feature of the group CST sessions is their consistent structure comprising of; introductions and warm up activity (e.g., group song, softball game, discussion of orientation information), a themed mentally stimulating activity, and session closing / summary. As the iCST sessions are intended to be delivered by a family member or friend, the formal ‘introduction’ element of the session was deemed unnecessary and omitted, as was the ‘closing of the session’. However, iCST sessions include the discussion of orientation information (e.g., date, time, weather), current affairs and a themed activity. Thus the iCST session structure represents a simplified version of the original CST model.

iCST sessions last 20-30 minutes, making them shorter than the 45 minute session duration recommended in the group CST programmes. Participants of the discussion forum felt that sessions should not be too long. Onder *et al's* (2005) study suggested this duration was

feasible. It is unclear whether there is an optimum ‘dose’ of CST. However, it was reasoned that group participants receive 90 minutes of CST per week and experience benefits in cognition and quality of life, thus iCST participants may experience similar benefits if given the opportunity to spend an equal amount of time taking part in activities. As a result of the reduction in session duration, the 21 group CST themes were each split into two iCST sessions, with the exception of the final session, resulting in a 75-session programme.

#### 4.3.2.4. Content of the iCST programme

The panel of professionals and carers advised that the iCST manual should be more concise than the group manuals and the instructions provided should be simple and free from ‘academic terminology’. It was also suggested that the dyadic nature of the programme should be emphasised throughout. The iCST session themes (e.g., my life, food, current affairs) and many of the ideas for activities were taken directly from the group CST manuals. The team also had access to a bank of resources that had been created by researchers for use in groups in the maintenance CST trial (LY, ASt, EA). Activities were reviewed according to their scope for adaption for a one to one session, and how well they had been received by group members in the trial. Those that had received positive responses and appeared relevant for delivery in a one to one setting were incorporated into the first draft of the iCST manual. The consultees felt that the activities should be varied so that there would be flexibility to cater for the abilities of the person with dementia.

Neither of the group CST manuals (Spector, Thorgrimsen, Woods, & Orrell, 2006; Aguirre *et al.*, 2011), supplied paper based resources for the suggested activities outlined. The group CST programmes are designed to be delivered by staff members in day centres or residential care facilities, thus it is expected resources may be available to them, or can be sourced with support from their workplace. However, the decision was made to provide pre-prepared materials for iCST because it was acknowledged that family carers may have difficulty in acquiring materials themselves, or may be unable to take the time to do so.

#### **4.3.2.5 Principles of the iCST programme**

The guiding principles of the group CST programmes (see Chapter 1) were adapted to create the nine key principles of iCST. Many of the principles developed as part of the original programme are applicable in a one-to-one setting, and all are founded in the person-centred approach to care. However, those specific to a group environment were omitted (e.g., ‘inclusion’ and ‘involvement’). The advice panel recommended that the principles should be concise for ease of understanding.

#### **4.3.2.6 Design and format of iCST manual Draft 1**

A graphic designer from the University College London (UCL) design services department developed the layout of the first draft of the manual. Key requirements expressed by the expert panel were that the manual should be visually appealing with a simple and clear layout, taking a similar approach to the group CST manuals. The design features of the manual were applied in the first drafts of the activity workbook ‘in house’ by the research team (LY & PL).

At this stage the programme was split across six manuals and accompanying workbooks. Each manual contained 12 sessions, except for manual six, which contained the final 15 sessions.

### **4.4 Evaluation of Draft 1 (Phase I: modelling process)**

#### **4.4.1 Design**

As recommended in the MRC guidelines (Craig *et al.*, 2008), the modelling phase of the development of the iCST intervention included focus groups and interviews (see Chapter 5). The first drafts of the iCST manuals and activity workbooks, and prototype toolkit items were presented to carers and people with dementia for appraisal.

##### **4.4.1.1 Sample**

Twenty-four carers, and 28 people with dementia participated in the focus groups and interviews. Participants were recruited from the voluntary sector, memory services, and a local authority organisation.

#### **4.4.1.2 Method**

Ten individual interviews and six focus groups (three people with dementia groups, two carer groups, and one collaborative group of carers and their relative with dementia) were carried out. The purpose of combining these qualitative methods was to obtain data with both depth and breadth (Lambert & Loiselle, 2008). The groups and interviews involved discussion of mental stimulation and mentally stimulating activities, consideration of the feasibility of the iCST intervention and exploration of potential barriers that might be encountered during the programme, and appraisal of the iCST materials. In addition, people with dementia were invited to try a selection of the iCST activities and provide feedback about their enjoyment and the level of difficulty of the activities. Materials for the first 12 sessions of the programme were presented in the groups and interviews.

#### **4.4.1.3 Analysis**

Audio recordings of the groups and interviews were transcribed by a medical transcription service, and inductive thematic analysis techniques applied to the data (Boyatzis, 1998). The results from the groups and interviews were considered at first separately, then compared and grouped by source (carer and person with dementia).

### **4.4.2 Results**

The feedback gathered from the groups and interviews was used alongside the findings from the field-testing phase to create the second drafts of the iCST manuals, activity workbooks, and toolkit (see results of phase II, and Table 4.1).

## **4.5 Field-testing Draft 1 (Phase II piloting)**

### **4.5.1 Design**

The data from the focus groups and interviews was restricted in that participants could only discuss the programme ‘in theory’, and only materials for the first 12 sessions were available at this stage. Owing to time constraints, the programme was not tested in full (75 sessions over 25 weeks) by any one dyad, rather it was split into six sections, and each dyad was allocated 12-15 sessions to complete. Field-testing (see Chapter 6) is worthwhile prior to a main RCT as issues with the research design or intervention can be identified and resolved before investing time, resources and funding in a full study (Mason & Zuercher, 1995).

#### 4.5.1.1 Sample

Twenty-two carers and people with dementia participated in the field-testing. The sample of carers was consisted of both family members ( $n=16$ ) and paid carers ( $n=6$ ). The research team liaised with key contacts from the voluntary sector, National Health Service (NHS), and local authority organisation established during recruitment for the focus groups and interviews to recruit family carers. Five paid carers were recruited from a private home care agency in North London, and a live-in carer approached the team about participating after seeing an article about the study in an Age Concern newsletter.

#### 4.5.1.2 Method

Dyads completed a portion of the programme with training and support from a researcher. ‘Monitoring progress’ forms were used to gather data about each activity, including quantitative ratings of enjoyment, interest, communication, and level of difficulty. Detailed qualitative feedback was gathered during the set up visit, telephone support calls with researchers, and debrief visits.

### 4.5.2 Results

Consistent with the feedback from the focus groups and interviews, carers felt the manual and activity workbook were clearly laid out and written in a way that was easy to understand. Both carers and people with dementia commented on how visually appealing they found the

materials, notably the quality of the images used in the activity workbooks, and the clear layout and professional look of the materials.

#### 4.5.2.1 Modifications incorporated into draft 2

The feedback from the modelling activities and field-testing was consolidated to create second drafts of the iCST materials, which were professionally printed prior to the launch of the online survey (see section 4.6). Minor changes to the manuals included the correction of some mistakes in spelling and grammar, editorial changes to improve the clarity of some of the instructions provided, and alterations to the size of some text and images (Table 4.1).

The monitoring progress forms underwent significant adjustments in response to feedback from carers who felt the approach to appraising sessions should be more informal to avoid the person feeling as though their performance was being scrutinised. ‘Monitoring progress’ was replaced with ‘How was your session today?’, which invites a more collaborative approach to session appraisal. In addition, carers felt that it would be too time consuming to assess every session so feedback was sought every two sessions, and grouped by theme instead. The rating scale was also amended to discourage bias towards rating at the mid-point of the scale.

#### 4.5.2.2 Practical issues with intervention delivery

Few difficulties were experienced with the programme itself. However, challenges related to the programme structure and technique were reported in a small number of cases. Some carers struggled with the orientation discussion at the beginning of each session, others found delivering the programme ‘hard’, struggling to apply the key principles, and having difficulty maintaining conversation. In terms of delivery, the main barriers to completing sessions were lack of time, or illness of the carer or person with dementia. The materials were not changed in response to these issues at draft two stage, but were considered as part of the consensus process (see consensus process results), and the findings provided justification for amendment of guidance included the final draft.

*Table 4.1 Summary of key features of the manual drafts and final version*

<b>Phase</b>	<b>Research activities</b>	<b>Key features</b>
Pre-clinical phase	Survey, panel consultation, establish theoretical understanding of CST, identify current studies of individual CS/RO	<b>Draft 1:</b> <ul style="list-style-type: none"> <li>- Three, 30 minute sessions, 75 sessions</li> <li>- Themes from CST/maintenance CST</li> <li>- CST key principles adapted</li> <li>- Activity workbook developed</li> </ul>
Phase I: Modelling	Focus groups, interviews, online survey, consensus conference	<b>Draft 2:</b> <ul style="list-style-type: none"> <li>- Correction of spelling and grammar mistakes, editorial changes to improve the clarity of instructions, size text / images alterations.</li> <li>- Monitoring progress replaced with 'How was your session today?'</li> <li>- Changes to Likert rating scale</li> </ul>
Phase II: Piloting & consensus process	Field-testing, online survey, consensus conference	<b>Final main RCT version:</b> <ul style="list-style-type: none"> <li>- Editorial changes to manual &amp; key principles, more person-centred, focus on the positive outcomes, 'academic' terminology altered, concise introduction, distinction between level A and level B activities.</li> <li>- UK county map instead of towns &amp; cities, marbles excluded as health and safety risk</li> <li>- 'Getting started' section included</li> <li>- Alternative images and suggestions for activities 'too difficult' e.g., food,</li> <li>- Programme collated into 1 manual and 1 activity workbook rather than serialised across six.</li> </ul>

## **4.6 Online survey and consensus conference**

### **4.6.1 Design**

A two-round modified Delphi process was conducted; the first of which was an online survey and the second, a conference. The Delphi technique was selected as a means of achieving consensus on themes that participants had been unable to reach agreement on in the focus groups, interviews, and field-testing. Delphi participants can be valuable contributors to decision making processes, informed by their direct knowledge and experience (Murphy *et al.*, 1998).

#### **4.6.1.1 Sample**

Twenty-five people completed the online survey, and 28 attended the conference. Sixteen participants completed the Delphi process by taking part in both rounds (57%). The sample consisted of a variety of professionals and service users including academics, health care professionals, and carers.

#### **4.6.1.2 Method**

##### ***4.6.1.2.1 Design and content of online survey***

Participants were sent a copy of one of the six serialised manuals and activity workbooks in the post along with instructions for the online survey. Consent was obtained as part of the survey.

The online questionnaire was created using KwikSurvey, a free online questionnaire and survey tool. The questionnaire included a cover letter containing instructions for completing the survey, information about the purpose of the survey, and thanking participants for taking the time to complete the survey. Evaluation focused on the following aspects of the iCST materials:

- overall impression;
- format (e.g., size of font);

- perceived engagement with carers;
- amount of information presented;
- language;
- clarity of presentation;
- layout;
- variety in activities;
- perceived enjoyment of activities;
- suggestions for improvements.

The overall impressions of the manual and workbook were rated on a four-point scale ('poor', 'fair', 'good' or 'excellent'). All other dimensions required the respondent to indicate the strength of their agreement or disagreement (5-point scale ranging from 'strongly agree' to 'strongly disagree' with a 'neutral' mid-point) to statements such as 'The language used in the iCST manual is easy to understand'. Respondents could also add further comments to elaborate on their ratings.

#### *4.6.1.2.2 Consensus conference procedure*

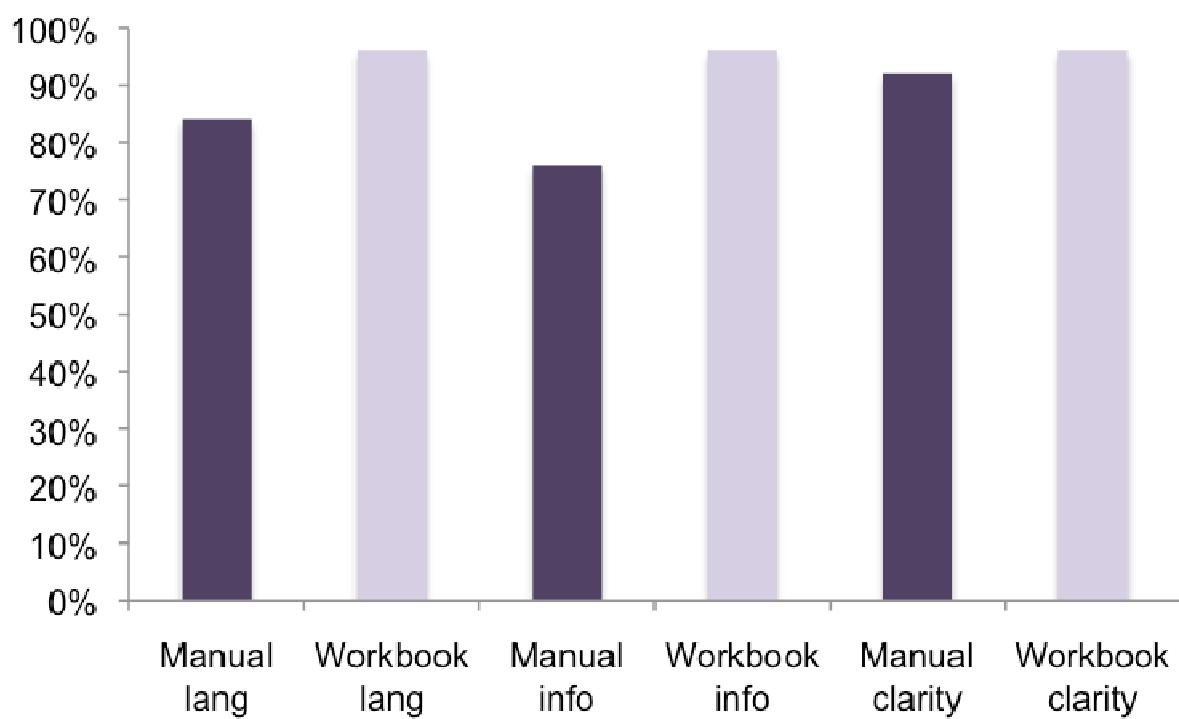
A conference was subsequently held at UCL. Attendees were presented with the findings of the focus groups, individual interviews, and field-testing, then asked to work in small multi disciplinary groups on six key themes; iCST Toolkit, getting started with iCST, home-based training for carers, sessions associated with difficulties in field-testing, presentation of iCST, and support for carers delivering iCST. Question prompts were provided with each theme to stimulate the discussion. The groups presented their feedback and invited additional comments from other group members.

## **4.6.2 Results**

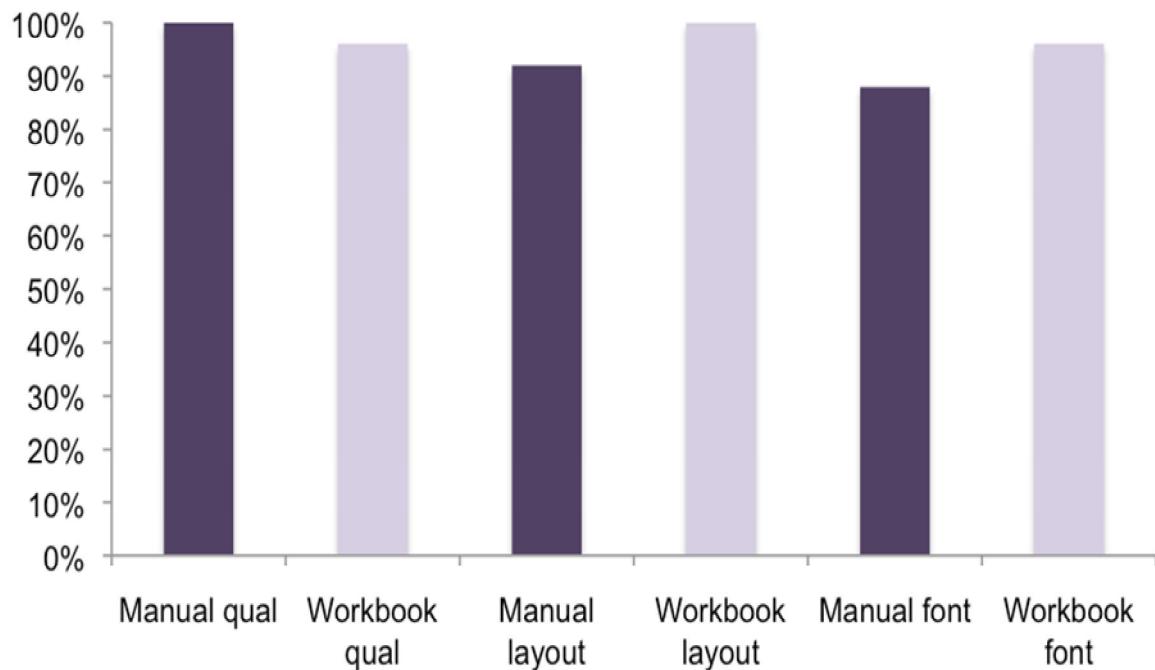
### **4.6.2.1 Online survey results**

Twenty-five responses were received (see Kwiksurvey results, Appendix 2.1). Of the respondents, 11 (44%) were NHS professionals, seven (28%) academics, two (12%) private sector professionals, two (8%) family carers, and two (8%) voluntary sector professionals.

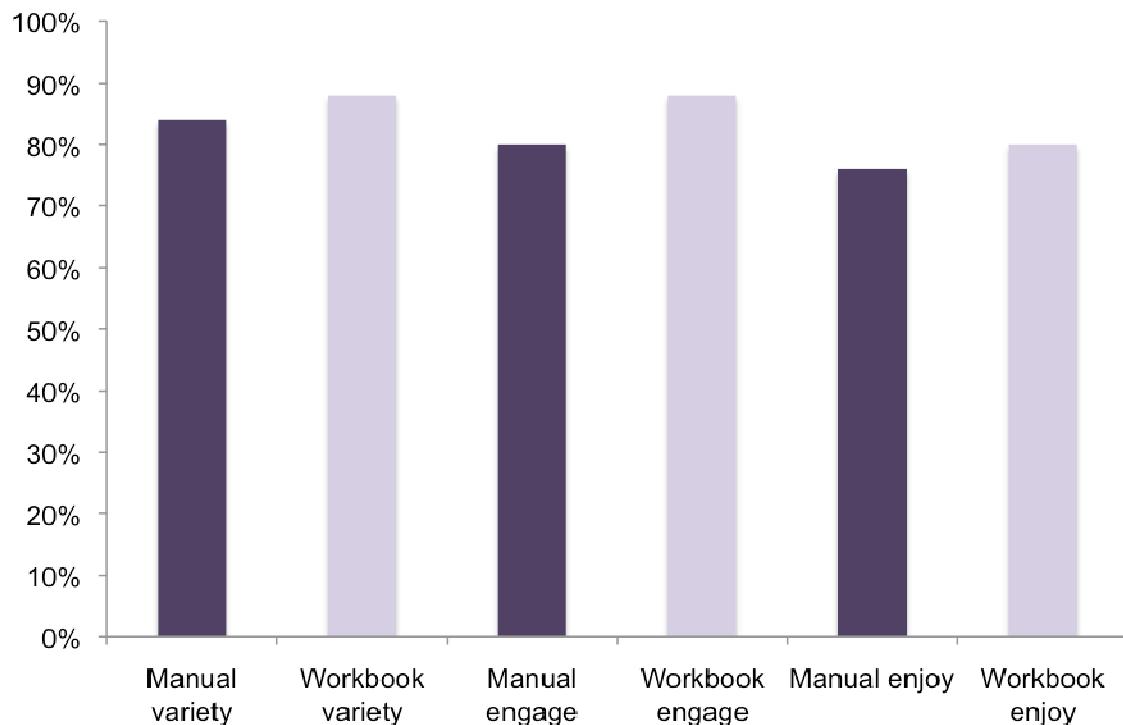
Over 80% consensus (ratings of 'Good' or 'Excellent') was reached on the majority of features of the materials the respondents were asked to rate (Figures 4.2, 4.3, & 4.4). For both the manual and activity workbook, these included overall impression of quality (manual 100%, workbook 96%), appropriate use of language (manual 84%, workbook 96%), layout (manual 92%, workbook 100%), clarity of presentation (manual 92%, workbook 96%), variety of activities provided (manual 84%, workbook 88%), and font size (manual 88%, workbook 96%). There was a disparity in the consensus about the amount of material presented in the manual and the activity workbook, with the manual achieving less than 80% consensus (76%) on this aspect compared to 96% for the activity workbook.



*Figure 4.2 Ratings of appropriate use of language, amount of information presented, and clarity of content for iCST manual and activity workbook.*



*Figure 4.3 Ratings of quality, layout, and font for iCST manual and activity workbook*



*Figure 4.4 Ratings of variety of activities presented, perceived engagement with materials, and enjoyment of activities for iCST manual and activity workbook*

The workbook (88%) was perceived as more engaging than the manual (80%). Less than 80% consensus was also recorded for the rating of perceived enjoyment of the activities for the manual (76%), but reached 80% for the activity workbook. The ratings and additional comments provided by the respondents were used to generate emergent themes, which served as ‘action points’ for the third draft of the manual and workbook.

#### 4.6.2.2 Final version of the iCST materials (main RCT)

The final version of the iCST materials was produced based on the findings of the Delphi process (Table 4.1). This draft was printed and bound professionally for use in the main RCT.

#### 4.6.2.3 Modifications incorporated into final version

The online survey respondents felt that the manual and key principles should be more person-centred and focused on the positive outcomes of taking part in the sessions together. Terminology in the manual considered to be ‘too academic’ was rephrased in accordance with feedback that the manual should be easy to understand. Additionally, the introduction was made more concise in an effort to add clarity to the information presented. Another suggested adjustment was that there needed to be a clearer distinction between level A and level B activities.

The contents of the iCST toolkit were reviewed at the conference. The consensus group concluded that the physical games materials provided should be adequate for use indoors as well as outdoors, to cater for those with limited mobility, or lack of outdoor access. The UK map included in the second version of the toolkit was replaced with a map including counties, which was thought to be more useful than just towns and cities. A set of marbles was considered a potential health and safety risk, and was not included in the final toolkit.

Field-testing participants felt that more guidance about the warm up elements of the session (e.g., discussion of date, time, weather) would be helpful. Additional information on this was

not incorporated into the second draft of the manual. However, the need to include extra information was also highlighted by the online survey and conference participants, so a 'Getting started' section was developed and included in the final version of the manual.

Sessions that had been poorly rated in the field-testing and were thought to be too challenging by the consensus groups and online survey respondents were simplified. These included 'food' and 'orientation' activities. Additionally, it was suggested that some of the stimuli (e.g., images, topics) were not relevant to the age group of the people likely to participate in the programme. Alternative images and suggestions for activities were sourced in response.

At the final consensus meeting there was still some debate around the format in which the manual and workbook should be presented (e.g., in one document or serialised). Professionals and academics felt that serialised presentation would ensure the dyad was not overwhelmed by the amount of materials they were receiving and may incentivise them to progress through the different manuals. However, carers felt that the whole programme should appear in one manual with one accompanying activity workbook, and as a result this format was adopted for the final version.

In the first and second drafts of the materials, the activity workbooks were referred to as 'resource manuals'. In the third draft the collection of resources was renamed as the 'iCST activity workbook'. This amendment was made because in some cases, carers felt there needed to be a greater distinction between the 'instructional' element of the materials, and the session resources.

#### 4.6.2.4 Training and support

Methods of supporting carers to deliver the programme were discussed. Ideas generated including peer support from nominated carers with experience of iCST, online forums, diaries, involvement of other family members, and newsletters containing additional

materials. It was suggested that carers would be motivated to adhere to the programme if they felt well supported and had access to help whenever necessary. Many of the ideas including the peer support from a fellow carer and online forum are likely to developed as part of the dissemination of the iCST package after the trial. The suggestion of having a carer diary for the purpose of rating the sessions and monitoring adherence separate from the manual was taken forward into the third version of the materials. In addition, editorial changes were made to the introduction of the manual to emphasise the scope for participation of other family members in the programme.

Key action points for the home based training package included; incorporating guidance for carers about identifying and making use of everyday home resources in the sessions, using the maintenance CST training DVD to demonstrate CST techniques, and offering the dyad the opportunity to complete their first iCST session with the researcher at the training visit.

## **4.7 Development of the DVD**

### **4.7.1 Rationale for the development of the iCST DVD**

Production of an iCST DVD was incorporated into the iCST trial protocol. This is consistent with the group CST and maintenance CST trials, which also included the development of training DVDs. Feedback gathered during the iCST study confirmed that the DVD would be a particularly valuable element of the iCST package. Clips from the most recently produced maintenance CST DVD ('Making a Difference 2') were shown to dyads participating in the iCST study during the set up visit. The response of carers and people with dementia to seeing these clips suggested that seeing Making a Difference 2 had limited utility due to its focus on the group setting, which was perceived as very different from the one-to-one format of iCST. Carers generally agreed that seeing footage would give them a better understanding of iCST sessions, and wanted to see examples of a variety of approaches. This need was addressed by the inclusion of different techniques for the orientation and current affairs discussions. Both people with dementia and carers suggested it would be helpful to see a few different sessions, rather than just one, thus a selection of activities was filmed with

several different dyads. Footage of carers and people with dementia speaking about the programme, any problems they faced, and tips they could share also features on the DVD as carers commented they would like to hear about the experiences of others. Carers said that they would prefer to be trained to deliver the programme by a person, rather than relying on just the content of the manual and a DVD. However, they acknowledged that this was not likely to be possible outside the research setting, so having the DVD would be a good substitute

#### **4.7.2 Pre-production phase**

The pre-production phase of the DVD began upon completion of trial recruitment. Piers Video, a filming company previously used in the production of the Making a Difference 2 DVD, were selected to work on the iCST DVD given their familiarity with CST and experience of working with people with dementia. Data gathered from the set up visit forms and the transcript from a focus group held with unblind researchers at a training day were reviewed for comments about the use of clips of Making a Difference 2 in the set up visit, and requirements for the iCST DVD. These comments informed the selection of techniques shown in the problem solving clips.

#### **4.7.3 Participants**

Four dyads agreed to participate in filming for the DVD. Recruitment was restricted to dyads from the London site, as this was the most easily accessible area for both the filming company, and the researcher (LY) overseeing the production of the DVD. Intervention dyads who had completed their participation in the research were approached to participate in the filming. Those who completed when the pre-production phase had begun were invited to participate at the final monitoring visit with the unblind researcher (LY). Dyads who had expressed interest in further research opportunities, but had completed some time before pre-production, were sent a letter to inform them of the DVD development, which was then followed up with a call from the researcher (LY) to determine interest. Staff from a professional home care agency who trialled the programme informally after the main study

were also approached to appear in the DVD. Of the three staff, one agreed to participate with a client she had been delivering the programme to. The main reason dyads declined to participate was feeling uncomfortable with the idea of being filmed. One dyad refused as the person did not want to be identified as having a memory problem.

Dyads met the inclusion criteria of the trial (Spector et al., 2003), and thus were deemed eligible to participate in the filming.

#### **4.7.4 Ethical considerations**

Verbal consent from both the carer and person with dementia. In the case of the person with dementia participating with a paid carer, a member of the person's family was contacted prior to scheduling a filming appointment to give them information about the DVD. The researcher made it clear that participation was voluntary, and should the dyad change their mind about being filmed they could withdraw at any time. Permission to film in the home of the carer or person with dementia was also sought at this stage. Written consent was taken from both the carer and person with dementia (see iCST DVD Consent Form, Appendix 2.2) on the day of filming. People with dementia were in the mild to moderate stages of dementia and so were considered competent to provide consent.

#### **4.7.5 Procedure**

Dyads were offered a pre-filming meeting with the researcher to discuss the plan for the filming day. Two dyads met with the researcher, whilst the other two dyads said they were happy to participate in the filming with no such preparation. Upon arrival at the filming appointment, the researcher (LY) reiterated the purpose of the filming, discussed the plan for the session, and provided the opportunity for the dyad to ask any questions, to ensure the dyad understood their roles and could provide fully informed consent to participate. The attending cameraman then showed the dyad the cameras and equipment (e.g., lighting, microphones) that would be used, and sought permission to make any adjustments to the room (e.g., placement of furniture) necessary to accommodate this equipment. Filming

began when the dyad indicated they were ready. The researcher intervened in the filming where appropriate to give feedback, and set up materials for the different activities being shown. During the process of filming the researcher was alert to the needs of the dyad to ensure they were comfortable. Breaks in filming were taken as and when necessary. A filming schedule was planned to give the session structure. Footage of the orientation and current affairs warm up discussions was taken first, then the dyad engaged in a series of different activities in short segments. The dyad was then asked to demonstrate some commonly encountered problems identified in the reviews of the qualitative data gathered. Lastly, the carer and person with dementia were asked to talk about their experience of the programme in an interview style led by the researcher off camera. Adjustments to the schedule were made if necessary according to the needs of the dyad, however, the majority of filming sessions ran in this planned order. Sessions lasted for 2-2.5 hours on average. All participants were provided with Marks & Spencer vouchers as a gesture of thanks for their time and willingness to participate.

#### **4.7.6 Content of filming sessions**

The content of each filming session was tailored to the participating dyad. All dyads demonstrated the warm up exercises (orientation and current affairs discussion) as feedback suggested that it would be beneficial to see a variety of different approaches to these parts of the session. The activities shown varied between dyads. In terms of selection of activities, the researcher reviewed carer diaries (completed as a measure of adherence during the research trial) to identify those that had positive feedback, and asked dyads if there were any themes they particularly wanted to demonstrate. All dyads had copies of the iCST manual and activity workbook from their participation in the study. However, if any additional resources were required that the dyad no longer had, or had returned to the research team, the researcher provided them for the filming day (e.g., maps, cards).

A list of commonly encountered problems reported by carers was compiled based on the qualitative data gathered throughout the trial. Some of these were 're-enacted' by dyads as

problem solving vignettes. In some cases, examples of relevant ‘good’ and ‘bad’ practice and helpful techniques emerged naturally during filming. These were identified in the editing process and highlighted with text subtitles. The aim of the subtitles was to draw the viewer’s attention to both positive and negative learning points in the clip and suggest useful tips.

Interview questions for the carer and person with dementia were drafted based on those featuring in the discussion guide for the focus groups. These included ‘What was your experience of the iCST programme?’, ‘Do you think you benefitted from the programme?’, ‘Do you think mentally stimulating activities are important?’, ‘Did you encounter any barriers to completing sessions?’, and ‘Do you have any tips for other people doing the programme?’.

LY returned to one of the dyads for an additional filming day, as during the process of producing the DVD, the team (MO, ASp, LY) it became clear that a section for healthcare professionals and care staff demonstrating a training visit with a carer and person with dementia would be a useful addition to the DVD. Footage of a mock visit was paired with a voice over. LY wrote a script for this, which was reviewed and approved by MO and ASp before recording.

#### **4.7.7 Post-production and editing phase**

A large volume of footage (approximately 2-2.5 hours per session) was gathered from each filming visit. This had to be edited down to concise clips. The filming company sent the raw footage to the researcher (LY) who made notes and suggestions for rough cuts for each section of the DVD, which were then carried out by the cameraman. MO and ASp were then sent the rough cuts and invited to make comments and suggestions for amendments as experts in the CST approach. LY identified clips that showed examples of carers applying the iCST key principles during the review process. These clips were then approved by ASp, who devised the original CST key principles. Further edits were produced based on feedback from LY, MO and ASp.

*Table 4.2 Description of DVD content*

<b>Section</b>	<b>Menu</b>	<b>Description of content</b>
Key principles	Main menu 1	Short focused clips of all four dyads demonstrating the application of key principles with text subtitles to highlight learning points.
Orientation discussion	Main menu 1	Three dyads demonstrating use of newspapers, diaries and free discussion as part of the orientation discussion with text subtitles to highlight learning points.
Current affairs discussion	Main menu 1	Three dyads demonstrating use of newspapers and free discussion of current affairs with text subtitles to highlight learning points.
Main activity	Main menu 1	All four dyads completing a main activity: art discussion, categorising objects, household treasures and sound.
Sound activity clips	Main menu 1, plus a further four sub menus (sub menu 1: select which session, sub menu 2: session 13 sound	Sound effects, music, and musical instruments tracks for 'sound' sessions (13, 14 & 51.)

	effects tracks, sub menu 3: session 14 music tracks & sub menu 4: session 51 musical instruments tracks.	
Tips for orientation discussion	Main menu 2	One dyad demonstrating a clear example of ineffective technique in the orientation discussion.
Tips	Main menu 2	Three carers sharing tips for the delivery of sessions.
Experience	Main menu 2	Three carers and three people with dementia discussing their experience of participating in the iCST programme.
Train the trainer	Main menu 2	'Mock' training visit with a researcher (LY) and one dyad suggesting how to arrange the visit, explain the content of the programme and materials, and support dyads in their first session. Voiceover throughout providing guidance for the viewer.

The final edits of each clip were approved by LY, MO ASp, and ASt who was invited to view the footage having produced the maintenance CST DVD. The editing process was concurrent with the filming. An advantage of editing as footage became available, rather than waiting until all filming days were complete was that, if an example from existing footage were deemed unclear, another of the dyads could be asked to demonstrate this as part of their filming session.

Piers Video designed the two DVD menus (see Table 4.2) and navigation based on notes and storyboards provided by LY. The aim was to make the DVD as easy to navigate as possible, and to give the viewer the option of seeing complete sessions, or watching selected clips in isolation. The final step in the process of creating the DVD was to record the voice-over for the ‘Train the trainer’ section, and add text subtitles to all of the clips. This was done at the film company’s editing suite at the British Library.

#### **4.8 Discussion**

The three stages specified in the MRC guidelines were implemented in the development of the iCST intervention (Craig *et al.* 2008). The first step was to identify and review the evidence base for group CST (Spector *et al.*, 2003), and one to one cognitive stimulation programmes (Moniz-Cook *et al.*, 1998; Quayhagen & Quayhagen. 2001; Onder *et al.*, 2005). Subsequently, a theoretical understanding of the likely process of change in the outcomes observed in previous research (e.g., cognition and quality of life for the person with dementia, and wellbeing of the carer) .The development of the first version of the iCST materials was guided by the evidence gathered and reviewed in these preliminary stages. The intervention was progressively refined in a series of qualitative evaluations, including focus groups, interviews, a consensus survey and conference, and a field-testing phase.

An advantage of such a rigorous development process is that the intervention and programme materials have been developed to the point at which they can be reasonably

expected to have a worthwhile effect when examined in a full-scale trial. This is recommended by the MRC as a means of safeguarding against problems of acceptability, compliance, delivery of the intervention, recruitment and retention, and smaller than expected effect sizes, which can undermine the evaluation of the intervention (Craig *et al.*, 2008). Thorough development, including a field-testing or piloting phase, can also prevent unwarranted full-scale evaluation, which can be costly and time consuming. Service user involvement in clinical research trials is recommended by the Department of Health (2000). The focus groups, interviews and field-testing provided a platform by which people with dementia and carers could indicate their views about, needs for, and expectations of iCST. Drawing on the experiences of individuals who are 'experts' in their knowledge of dementia and mental health services can be a useful way of improving care packages and services, ensuring they are appropriately tailored and fit for purpose (Tait & Lester, 2007).

A feature of the Delphi consensus process is the collection of feedback in multiple stages from the panel of experts taking part, which carries the risk of a low response rate, and can compromise the quality of information obtained (Hsu & Sandford, 2007). However, the risk was reduced in this study as the Delphi process comprised of only two stages. Participant retention rate was relatively high across the two stages (57%). Consensus was achieved on all presented themes with the exception of how the manual should be presented (e.g., serialised vs. complete manual).

Whilst the implementation of the MRC framework and the careful development of an intervention represent best practice, this process does not guarantee either the efficacy of the intervention or that the full-scale evaluation will be unaffected by any challenges in the design, methods, and implementation. No formal measures of our outcomes of interest (e.g., cognition and quality of life for the person with dementia) were taken during the field-testing phase, providing no indication of the likely efficacy of the intervention. However, some carers reported improvements in the communication skills and alertness of the person as well as enjoyment. In addition, some dyads felt that participating in iCST had improved their

understanding of the person and, as a result, their relationship with them. A large-scale Phase III RCT is required to provide more definitive evidence of the effectiveness of the intervention. If the findings of the main RCT are clinically significant, the data obtained from each phase in the process of developing the intervention may add to the understanding of the mechanisms underpinning the effects of the intervention. However, if the intervention does not succeed, the thorough nature of the development phase may yield some insight into the possible reasons for this.

The development phase of the iCST programme was extensive, resulting in the production of the two drafts and a final version of the iCST manual, activity workbook, and toolkit.

Feedback and advice was gathered from experts in the field, and service users throughout the process to ensure the programme was tailored to the needs of people with dementia and carers. The next step in the process of the development of this complex intervention (Phase III) was the evaluation of the final version of the programme in a large-scale multi-centre RCT (see Chapters 7, 8, & 9).

## **Chapter 5**

# **Qualitative methodology: service users' involvement in the development phase of individual Cognitive Stimulation Therapy (iCST)**

This chapter was adapted into a journal article: Yates, L., Orrell, M., Spector, A., & Orgeta, V. (2015). Service users' involvement in the development phase of iCST: a qualitative study. *BMC Geriatrics*, 15(4).

The principles of the Medical Research Council (MRC) framework were applied in the development of the individual Cognitive Stimulation Therapy (iCST) programme (Craig *et al.*, 2008). In accordance with Phase I (modelling) of the guidelines, people with dementia and carers were consulted in a series of focus groups and interviews. The key objectives of the modelling phase were to ensure the therapeutic materials were easy to use, clear, and appropriately tailored to the needs of people with dementia and their carers, and to assess the feasibility of the programme. The data gathered from the groups and interviews was used to refine and improve the iCST manual and resource manual. The data concerning feasibility shaped the development of the training package and yielded insight into the kind of support dyads require to complete the programme.

### **5.1 Methods**

#### **5.1.1 Design**

Semi-structured interviews and focus groups were selected as complimentary qualitative methods to assess the feasibility of the iCST programme, and the quality of the first draft of the materials produced. An advantage of implementing this combination of qualitative methods, as identified by Morgan (1996), is that we were able to gather data from carers and people with dementia with a range of experiences efficiently, and supplement the emergent opinions and comments with in depth data gathered from the interviews.

Using a combination of qualitative methods can give more accurate and reliable response to research questions (Hall & Rist, 1999). In an interview setting, moderators have more control over interview timing and agenda, and thus can pursue points of interest in more detail (Britten, 1995) and probe for further elaboration of incomplete or vague responses (Hall & Rist, 1999). Agar & MacDonald (1995) suggest that the interview setting places more burden on the participant to explain their responses to the moderator. By contrast, in the focus group context, it is often the participants themselves who both query the responses of fellow members, and clarify their own contributions to the discussion. According to Morgan & Kreuger (1993) these interactions are valuable because they reveal the extent of consensus and diversity amongst the views of participants. However, there is evidence to suggest that focus group participants do not generate as many ideas as they would in an individual interview setting (Fern, 1982). The risk of lower productivity in this sense, and relative lack of depth in the data gathered was balanced by conducting the interviews.

People with dementia and carers were consulted separately, as well as collaboratively, to ensure both parties could express their opinions and outline their preferences for the programme, which may be disparate according to their role and needs.

#### 5.1.1.1 Discussion guide

A discussion guide was developed prior to the focus groups and interviews (see ‘Discussion Guide’, Appendix 3.1 and Table 5.1). The guide included open questions designed to promote discussion around mentally stimulating activities in general terms, and more focused questions that invited specific responses to the iCST materials provided at the session. Discussion of practical issues (e.g., ‘How long should sessions last?’) constituted a key part of the guide produced. The guide was altered slightly for the groups and interviews with people with dementia, as these sessions were intended to be more focused on trying the activities than the practicalities of delivering the programme (see Table 5.1).

## **5.1.2 Sample**

### **5.1.2.1 Sources of recruitment**

Participants were recruited from the voluntary sector, memory services part of North East London Foundation Trust (NELFT), and a local authority organisation. The research team (LY and FH) identified voluntary organisations across London using internet resources, and contacted them via email and telephone to determine interest in the study. Carers of Lewisham, For Dementia, and Staywell (formerly Age UK Kingston) agreed to assist with recruitment and provide venues for the focus groups. Existing links with a Jewish Care (voluntary) day centre, which had recently completed participation in the maintenance Cognitive Stimulation Therapy (maintenance CST) trial, were utilised to organise one of the groups for people with dementia. Two of the groups for people with dementia were held at a day hospital part of NELFT, which also had previous involvement in similar research activities as part of the SHIELD (Support at Home: Interventions to Enhance Life in Dementia) programme.

The research team approached Crossroads Care Redbridge (voluntary sector) and the Living Well Resource Centre (National Health Service [NHS] & local authority partnership), to recruit for the interviews. Both organisations provide support and services, such as peer groups for carers and day services for people with dementia, in the Redbridge area. A consultant psychiatrist based at Petersfield Centre in Havering (NELFT memory services) also supplied the research team with referrals for interview participants.

### **5.1.2.2 Eligibility and referral pathways**

People with dementia were screened for eligibility according to the Spector *et al.* (2003) criteria, which were also applied in the main RCT (described in Chapter 7). The organisations made initial contact with carers and people with dementia who were suitable and interested in the research activities, typically approaching them during support groups, or during memory clinic appointments. Copies of the information sheets for the interviews and groups were given to professionals to distribute.

As described above, in the majority of cases, the first contact with participants concerning the research was made by the referring organisations. However, with guidance from staff, LY approached people with dementia from Broad Street Day Hospital and the Dennis Centre about the groups, and those who expressed interest in taking part were invited to attend.

Where possible, the research team accessed the person with dementia's medical notes to confirm their eligibility. The eligibility of the people with dementia recruited from the Dennis Centre (Jewish Care) to participate in the focus groups was determined by a researcher (LY), who facilitated maintenance CST groups and conducted assessments at the centre as part of the maintenance CST trial.

The details of dyads consenting to be contacted about the groups and interviews were passed on by the recruiting organisations to the research team via telephone, or email to a researcher's (LY) secure NHS email account. Where referrals were made via email, contact details were saved into a password-protected document and sent as an attachment. The email and attachment were deleted once the information had been transferred to a password-protected database containing the details of all referrals for the study.

The research team contacted consenting dyads via telephone. In all cases of referrals received from professionals, the carer was the point of contact. The researcher performed a brief eligibility check during the call to confirm each referral met the inclusion criteria. If referred to take part in a focus group, the researcher also determined the availability of the carer or dyad for the date set for the group. If referred to take part in interviews, the researcher negotiated a convenient time to visit with the carer.

### **5.1.3 Procedure**

#### **5.1.3.1 Focus groups**

Of the nine groups planned, six were conducted; two with carers, three with people with dementia, and one with both carers and people with dementia (collaborative group). Each

*Table 5.1 Discussion guide themes*

Themes	Focus points	Group			Interview		
		Carer	PwD	Combined	Carer	PwD	
<b>Mental</b>							
<b>Stimulation</b>							
	Importance of mental stimulation	X	X	X	X	X	
	Mentally stimulating activities	X	X	X	X	X	
<b>iCST</b>							
<b>Manual</b>							
<i>Content</i>	Spelling / grammar	X		X	X		
	Appropriate language	X		X	X		
	Adequate explanations of terminology & concepts	X		X	X		
	Ideas for additional information	X		X	X		
<i>Layout</i>	Size of text & images	X		X	X		
	Clarity of layout	X		X	X		
	Images	X		X	X		
	Format (e.g., ring bound)	X		X	X		
<i>General</i>	Positive comments	X		X	X		
	Negative comments	X		X	X		
	Ease of use	X		X	X		
<b>iCST</b>							
<b>Activity</b>							
<b>Workbook</b>							
<i>Content</i>	Clarity of instructions	X		X	X		
	Activities	X		X	X		
<i>Layout</i>	Format (e.g., ring bound)	X		X	X		
	Clarity of layout	X		X	X		

Images	X	X	X
<b>Activity</b>			
Difficulty of activity completed in session	X	X	X
Level of stimulation / engagement	X	X	X
Level of enjoyment	X	X	X
Ideas to improve activity	X	X	X
<b>Feasibility</b>			
Acceptability of delivering / receiving a home based programme	X	X	X
Acceptability of programme schedule (e.g., 3, 30 min sessions per week)	X	X	X
Acceptability of providing own materials	X	X	X
Anticipated practical difficulties	X	X	X
Support needed	X	X	X
Acceptability of telephone support and visits	X	X	X
Group training vs. one to one home based training	X	X	X

group was attended by two members of the research team, one of whom took on the role as facilitator and led the group discussion, and the other of whom observed the group and made notes to supplement the audio data collected by the dictaphone. The field notes produced by the researcher were intended to provide additional depth and richness to the interpretation of the discussions following their transcription. This practice is advocated by Burgess (1984). The group discussions were conducted in a semi-structured style guided by a series of pre determined focus points and questions (Table 5.1). Each session lasted approximately 90 minutes in total. All of the groups concluded with a question and answer session, and presentation of small token gifts (gift vouchers) to show gratitude for assistance with the research.

#### *5.1.3.1.1 Carer groups*

The carers were allocated time at the beginning of the session to critically appraise sample copies of the first drafts of manual one (containing the first 12 sessions of the programme) and resource manual one. This time was not formally recorded, but participants were provided with materials to take notes in preparation for the recorded discussion. The facilitator gave a brief presentation about the background of the iCST programme, including a clip of the 'Making a Difference 2' training DVD. The clip showed a group CST session and was selected to give the participants a salient example of the type of activities that would be included in the iCST programme. The presentation was followed by the main discussion, which focused on perceptions of the feasibility and appeal of a structured programme of mental stimulation. The carers were then invited to give feedback about the quality of the sample materials presented.

#### *5.1.3.1.2 Groups for people with dementia*

The main goal for the person with dementia groups was to try a selection of the activities in practice and reflect on this experience. The introductory presentation used in the carer groups was made more informal and shorter for use in the people with dementia groups. It was agreed that it was important for the members of these groups to have an understanding

of the purpose of the focus groups and the iCST programme, but that this knowledge need not be as in depth or theoretical as for the carers. An advantage of a shorter introduction in the people with dementia groups was that more time could be spent doing the activities and providing feedback. The introductory presentation was followed by a brief discussion, beginning with the theme of mental stimulation. The discussion then led to the first of the two sample activities planned for the session. Each member of the group was provided with resources from manual one and resource manual one (see Table 5.2). After each of the activities, group members were asked to comment on their enjoyment, the level of difficulty of the activity, the quality and format of the materials, and suggest ways in which the activity could be improved.

*Table 5.2 Activities tested in focus groups*

Group	Sample size	Theme	Activity 1	Activity 2
1	5	Physical Games	Skittles	Beanbag and target game
2	6	Quiz	True or False Quiz	Music Quiz
3	5	My Life Current Affairs	My Life game board	1950s Newspaper discussion / reminiscence

#### *5.1.3.1.3 Collaborative group*

The collaborative group followed the procedure outlined in the carer groups section above (see section 5.1.3.1.1), however the dyads were additionally invited to try selected activities together and provide feedback.

#### *5.1.3.2 Individual Interviews*

Ten interviews were conducted. Two members of the research team (LY & FH) conducted the first two interviews, with each researcher interviewing either the person with dementia or the carer. Subsequent interviews were attended by one member of the research team, who interviewed both the person with dementia and the carer. Interviews were conducted separately. There is evidence to suggest this can be advantageous in that participants feel

they are more able to express their own opinions than when interviewed jointly (Taylor & de Vocht, 2011). The researcher made field notes during and after the interview to supplement the audio data gathered.

#### *5.1.3.2.1 Interviews with people with dementia*

The interview with the person with dementia was conducted first to allow the carer time to appraise a set of sample materials. The session involved completing two iCST activities, and then an interview inviting the person to give feedback about their enjoyment and comprehension of the activities, and a general discussion about perceptions of and needs for a home based programme of mentally stimulating activities. The discussion guide was used to generate questions in the interview.

#### *5.1.3.2.2 Carer interviews*

The researcher conducted a semi-structured interview following the topics in the discussion guide. Topics included the value of mentally stimulating activities and feasibility of delivering a home-based activity programme. Carers were then asked to give feedback about the materials presented. The main aims of the carer interviews were to identify any practical issues that might affect the delivery of the programme, and to gather data about the quality and appropriateness of the activities and manuals, which would inform the development of further drafts of the materials.

### **5.1.4 Ethical considerations**

#### *5.1.4.1 Provision of study information*

Information sheets were developed for carers (see Information Sheet for Caregivers: Focus Groups, Appendix 3.2 and Information Sheet for Caregivers: Individual Interviews, Appendix 3.3) and adapted for people with dementia (see Information Sheet for Participants: Focus Groups, Appendix 3.4, and Information Sheet for Participants: Individual Interviews, Appendix 3.5). All information sheets were approved by the Multi-centre Research Ethics Committee (ref no.10/H0701/71). As discussed above, professionals distributed information

sheets to potential participants prior to their involvement in the focus groups or interviews. In the majority of cases, information sheets were provided to referrals prior to the research team initiating contact. If referrals had not received the information sheets before the contact call, the research team sent copies in the post. All participants received the information sheets a minimum of 24 hours before the scheduled research activity in accordance with Good Clinical Practice (GCP) guidelines.

During the contact call with the referral, the researcher explained the procedure and aims of the research activity they would be participating in, and provided further clarification of any information if requested. The researcher also sought permission to record the interview or group with a dictaphone at this stage.

Information about the procedure and aims of the research activity was also reiterated verbally at the beginning of each focus group or interview. The research team offered the opportunity for participants to raise any queries prior to participation. These measures were in place to ensure that participants fully understood the procedure of the interviews and focus groups, and the way in which data would be collected from them.

### **5.1.5 Consent**

All people with dementia recruited for focus groups and interviews were in the mild to moderate stages of dementia, and were able to provide informed consent for participation.

#### **5.1.5.1 Obtaining consent in the focus group setting**

Consent from carers and people with dementia was obtained on the day of the groups at the beginning of each session (see Caregiver Consent Form - Focus Groups, Appendix 3.6 and Participant Consent Form - Focus Groups, Appendix 3.7). The research staff explained the terms of the consent form and took written consent from each member of the group. Continuing assent was established by informing the group members that they were free to leave the group at any time if they wished. All participants were also specifically asked for

permission to record the session using a dictaphone. One carer at the declined to consent to being recorded and left the group before the discussion began.

#### **5.1.5.2 Obtaining consent in the interview setting**

Written consent (see Caregiver Consent Form - Individual Interviews, Appendix 3.8 and Participant Consent Form - Individual Interviews, Appendix 3.9) was provided by the dyad on the day of the interviews at the beginning of the visit. The researcher explained each term on the consent forms. A statement indicating participants had read and understood the information sheets was included as further assurance that participants were fully informed prior to providing consent. The researcher offered both the carer and the person with dementia the opportunity to ask any questions before commencing the interviews, and again requested permission to use a dictaphone. The researcher explained that participation in the research was voluntary so the dyad could terminate the interview at any stage and withdraw from the study if they wished. Confidentiality of information given during the interviews was also discussed with the dyad at the beginning of the visit.

#### **5.1.6 Analyses**

In order to understand the process of transcription, the research team (LY and FH) transcribed the first two individual interviews. The team followed the techniques and principled outlined by Bailey (2008). The remaining eight interviews and focus groups were transcribed by DICT8 medical transcription service. This was efficient in terms of time, and meant that we could ensure the transcribed scripts were of professional quality.

Inductive thematic analysis techniques were employed in the coding and analysis of the data gathered. Data driven analysis strategies involve detailed readings of the raw data, from which concepts, themes or models are derived based on the interpretation of those analysing the data (Thomas, 2006). This approach was best suited to the aim of the groups and interviews, which was to gather descriptive exploratory data concerning perceptions of the first drafts of the iCST materials. The research team (LY and FH) independently examined

the focus group and interview transcripts in conjunction with the field notes, which were used to clarify any points recorded as ‘inaudible’ in the transcripts, and any comments, which required further contextual information in order to be fully understood. Excerpts of text were extracted from the transcripts and used as labels for categories emerging from the data (e.g., ‘potential difficulties’). Researchers highlighted the text within the original transcripts in Microsoft Word then entered the categories and relevant excerpts into a Microsoft Excel spreadsheet. The research team reviewed any selected excerpts that could be coded to more than one category and reached consensus over their category placement. Throughout the analysis, the categories were continually refined to identify the themes most relevant to our evaluation objective, which was to gather feedback about the first draft of the iCST materials. Data from all groups was collated (person with dementia, carer and collaborative), then examined it further by source (carers and people with dementia) to identify any variations in views. The interview data was also grouped by source (carers and people with dementia) and compared to the data gathered from the focus groups. No specialist software was used to perform the data analyses.

## **5.2 Results**

### **5.2.1 Focus group demographics**

Thirty-two people participated in the groups; 14 carers and 18 people with dementia (see Table 5.3). Across the three people with dementia groups, six participants were male (37.5%), and 10 female (62.5%) with a mean age of 82 years.

The carer groups consisted of five males (42%) and seven females (58%) with a mean age of 59 years. All of the participants were family carers (7 children of the person with dementia; 58%, 5 spouses / partners; 42%), and reported having occupied their caring role for an average of six years (range 1-16 years). The majority of the sample was of a white ethnic background (8; 67%) with 25% (3) of black ethnic origin. Across the three groups, six participants were male (37.5%), and 10 female (62.5%) with a mean age of 82 years.

Four people attended the collaborative carer and person with dementia focus group, of which two were female (50%) and two were male (50%). The mean age of the carers was 75 years old, 77 for the people with dementia. The group consisted of two spousal carers and their partners with dementia. Both carers had been caring for their partners for three to four years. All members of the group were also of a white ethnic background.

### **5.2.2 Interview demographics**

Ten carers and 10 people with dementia participated in the interviews (see Table 5.3). Participants were recruited as familial dyads (8 children of the person with dementia; 40%, 12 spouses; 60%). The sample was made up of 12 females (5 people with dementia; 42%, 7 carers; 58%), and eight males (5 people with dementia; 63%, 3 carers; 37%). A larger proportion of female carers was recruited (70%). The majority of carers lived with their relative with dementia (90%) and had been caring for an average of three years (range 1.5-7 years). The mean age of carers was 68 years, and 84 years for people with dementia. Full demographic data (age, duration of caring role) was not collected from one participating dyad.

The following themes emerged from the thematic analysis of the focus groups and interviews: ‘effects of mentally stimulating activities’; ‘range of mentally stimulating activities’; ‘feasibility of a home based programme of mental stimulation’; ‘quality of the materials’ and ‘feasibility of individual versus group training’.

### **5.2.3 Theme 1: Effects of mentally stimulating activities**

People with dementia emphasised the importance of mental stimulation citing benefits such as keeping up to date with everyday events, increasing sense of wellbeing, learning, improving the mind, and preventing cognitive deterioration.

*‘...save us going backwards this is an advance on anything that will help us talk and improve our thoughts....’* (Person with dementia [PwD]: Focus group [FG] 1)

*Table 5.3 Demographics of carers and people with dementia participating in the focus groups and interviews*

<b>Characteristics</b>		<b>Focus groups (%)</b>	<b>Individual interviews (%)</b>
<b>People with dementia</b>		<i>n</i> =18	<i>n</i> =10
Gender	Female	11 (61)	5 (50)
Mean age (years)		80.50 ( <i>SD</i> =5.80)	84.44 ( <i>SD</i> =4.10)
Ethnicity	White	18 (100)	10 (100)
<b>Carer</b>		<i>n</i> =14	<i>n</i> =10
Gender	Female	8 (57)	7 (70)
Mean age (years)		65.23 ( <i>SD</i> =9.65)	67.67 ( <i>SD</i> =14.35)
Ethnicity	White	11 (79)	10 (100)
Relationship	Spouse	7 (50)	6 (60)
	Child (son/daughter)	7 (50)	4 (40)
Living status	Spouse living with person	6 (43)	6 (60)
	Adult child living with person	2 (14)	3 (30)
	Person lives alone	4 (29)	1 (10)
	Person lives in care home	2 (14)	0
Mean years caring		5.61 (range 1-16, <i>SD</i> =4.03)	2.89 (range 1.5-7, <i>SD</i> = 1.78)

In the interviews, people with dementia spoke about mentally stimulating activities as a way of occupying their time in a meaningful way, linking being active to the ability to retain a sense of self.

*'Can't give you a proper reason but it gives you an activity, doesn't it? There's activity there, and without it you're nothing.'* (PwD: Interview [IV] 10)

*'Well otherwise I would probably be sitting round just doing nothing, you know. And I have never been like that before.'* (PwD: IV5)

Some people with dementia said it was important to keep the mind and the body active, as both affect each other.

*'...benefits the brain, brain effects the body and the body improves...'* (PwD FG1)

Carers noted several benefits of mentally stimulating activities including; better quality of life for the person, improvements in mood, helping the person to think back, and increasing their alertness. There was consensus that it didn't matter whether the person could remember the activity they had done (and indeed, often they would forget soon afterwards) as long as they had enjoyed it and been stimulated for a little while.

*'I mean, we go to the theatre, we come home, not even two minutes after we've left there, she doesn't remember we've ever been, but that buoyant feeling is good.'* (Family carer [FC]:

FG1)

*'She can't speak but you know, the carers will tell you, she comes back and if we've visited, she's a different person just in her mood.'* (FC:FG1)

Although people with dementia seemed to value mental stimulation, several carers said that the person they were caring for did not seek out mentally stimulating activities independently,

and those that had attempted to engage their relative in activities reported difficulty motivating them.

*'I might get it out and sort of see if he can get into it, but he wasn't interested at all when I bought all the stuff (drawing materials).' (FC:IV8)*

Interestingly, dependence on the carer for stimulation was acknowledged in one of the groups for people with dementia.

*'May I just say I believe that we are all crying out for help and stimulation but we can't, haven't so much got ideas in our own head as we hope other people can encourage us.'*

(PwD:FG1)

Few carers spoke negatively about the concept of mental stimulation. However, one carer commented that doing mentally stimulating activities could "*stretch the person's mind too much*". He added that this could de-motivate the person and serve to discourage them from engaging in activities.

#### **5.2.4 Theme 2: The range of mentally stimulating activities**

Both carers and people with dementia suggested that quizzes stimulate the mind and can be educational.

*... 'that's stimulation really, I mean, you're trying to answer the questions and on Sky (TV quiz show) particularly, they go over the old things that they used to do and we're very familiar with them and we quite enjoy them...' (FC:FG3)*

Puzzles (e.g., crosswords, jigsaws, number games) were also a popular suggested activity, along with games such as cards and dominoes. People with dementia felt that reading the newspaper keeps the mind stimulated. However, a carer in the collaborative group commented that activities with a visual or auditory element were more worthwhile than just sitting and reading. Both carers and people with dementia advocated social activities, such as attending clubs or being part of a choir. Carers felt that meeting people and feeling involved was important, stimulating, and enjoyable.

*'You know, everybody gets involved with it, and you just don't feel out on a limb really, you know, you're with other people and everybody's the same and you just feel great about it.'*

(FC:FG3)

In contrast to the findings from the focus groups, social activities were not discussed in the context of mental stimulation in the interviews. Most of the examples of activities offered by the carers and people with dementia who took part in the interviews were those that are usually done alone. Watching TV was mentioned by people with dementia as a way of keeping up to date. The notion of 'keeping up to date' was repeatedly discussed, which indicates it is perceived as a key function of mentally stimulating activities.

*'I mean, watching the box...you...'Cor! No, I didn't know that!' That goes round the world and keeps you more up to date with everyday happenings.' (PwD: IV4)*

People with dementia highlighted the need to keep both the brain and the body active, citing activities such as dancing, keep fit classes, sports and yoga as valuable sources of mental and physical stimulation. Some carers also identified physical activities such as gardening and bowling as forms of stimulation, but they focused largely on activities requiring no physical exertion. In an interview, one carer commented that although her relative found gardening stimulating, it was now too tiring for him. Concern about the person's physical capabilities may explain why carers tended to offer non- physical examples of mental

stimulation and appeared to place less emphasis than people with dementia on physical activities as a valuable source of stimulation.

The types of activities suggested by the group members and interviewees suggest a low reliance on modern technologies for stimulation, however one person with dementia said they enjoyed playing solitaire on the computer.

### **5.2.5 Theme 3: Feasibility of a home based programme of mental stimulation**

#### **5.2.5.1 Delivering the programme at home**

The idea of a programme of mentally stimulating activities was generally well received by the focus group participants. Some carers said it would be particularly useful to have activities to do together in the winter when they might be isolated by bad weather. People with dementia said that they would like to do activities at home, but again emphasised that they would need someone to help them.

*'The idea of activities (in the home) is good, people with dementia just need assistance with it.'* (PwD:FG1)

Some people with dementia said they lived alone and could not think of anyone who might help them. Those who were co-habiting or regularly visited by relatives expressed uncertainty about whether their relatives would have time to do activities with them. This was particularly a worry if their carer had a job. This concern was also expressed by carers in the groups.

The idea of doing mentally stimulating activities at home with a carer was met with mixed response from the people with dementia who took part in the interviews. The majority of interviewees found the idea appealing, and felt their carer would enjoy the experience. However, some expressed concern about how receptive their carer would be to the idea of doing activities, and consistent with the focus group comments, whether they would have the time. Some people with dementia felt that they were able to keep themselves busy at home

without doing activities, and prioritised tasks that felt had to be done (e.g., housework, cooking).

Much of the data gathered from carers about the feasibility of the programme was focused on practical issues that might arise whilst delivering the activities. Largely, their receptiveness to delivering the programme appeared to be determined by whether these practical issues were viewed as insurmountable barriers, or difficulties that could be overcome.

*'If they're difficult as soon as somebody is not there then you can't do anything about it, if you know what I mean. Anything in a book is not going to explain it.'* (FC:IV3)

*'If Dad's got 20 minutes, and I'll find 20 minutes.'* (FC:IV6)

#### 5.2.5.2 Potential difficulties in delivering the programme

Carers volunteered an array of anticipated difficulties with the programme. In the interviews the difficulties were contextualised within the carer's own personal circumstances, but some carers indicated they believed others would also encounter the same kinds of barriers. Feeling burdened by caring responsibilities might reduce willingness to deliver the programme:

*'This kind of programme that requires all that amount of patience on top of the patience that you have to exercise for the everyday care is a lot to ask of a carer.'* (FC:FG2)

Perceiving the programme to be too demanding for both themselves and the person they are caring for might compromise capacity to complete the programme:

*'You know, there's a physical side of it and a mental side of it, I don't know how many carers would be able to follow this programme consistently for 25 weeks.'* (FC:FG2)

Carers anticipated difficulty engaging their relative in activities without encountering resistance from them:

*'You know, he would expect me to do it, but at the same time when I'm doing it, he would ask me 'why all these?' you know, so I'd just have to say 'well, it's to help you, you know, to remember things, he would say "enough is enough".'* (FC:FG2)

The length of the programme and adhering to a 'formal' structure might impact the success of the sessions:

*'I find it difficult to identify who actually would give the programme because I think anyone from the family, it probably wouldn't work because it's too formal...'* (FC: FG2)

Further difficulties included lack of time due to work or other commitments, the person's level of cognitive functioning, and maintaining motivation to deliver the programme:

*'That is my only issue, working full time [...] but it's 20 minutes so there's no reason with Dad.'* (FC:IV6)

*'He'd lose interest after 5 minutes.'* (FC:IV8)

*'Keeping the person delivering it is just as important as the person receiving it, in fact, more so.'* (FC:IV7)

*'We should have done this a long while ago, when he wasn't quite as, erm, bad.'* (FC:IV8)

Carers were invited to discuss who might deliver the programme if they encountered the preconceived difficulties detailed above. Some carers (3, 30%; 2 spousal, 1 child of the person) suggested that the programme would be more successful if delivered by a professional (e.g., therapist, nurse, day centre staff), or a paid carer.

*'We really don't have the time to give her the type of stimulation that is mentioned in this programme, so an Alzheimer's carer would certainly be helpful for us if there is such a thing.'*

(FC:FG2)

*'My reaction was that I could see more benefits in this approach, but I find it difficult to identify who actually would give the programme because I think anyone from the family, it probably wouldn't work because it's too formal and you'd need a lot of co-operation from the person who you have given it to.'* (FC:FG2)

It was thought that a 'stranger' or 'outsider' might elicit more of a response from a person with dementia than a family member. Carers were concerned that their relative would be less co-operative with themselves and this would be distressing for them and the person.

*'I could probably do the job better with someone else but my own wife! I think you can be too close. I feel you should, you need to be detached a little bit, and I couldn't be detached, bearing in mind, you know, the situation.'* (FC:IV5)

*'I thought all the way through that it's not entirely suitable for a family carer [...] After all, a wife or daughter is in a very special position, not always taken entirely seriously.'* (FC:IV9)

*"The problem is when a family member does it, it's not the same as an outsider because there is more attention given to an outsider than there is the family.'* (FC:IV3)

The view that the programme would be more suitable for delivery by a professional was not shared by all carers; many either did not comment on the involvement of a professional, or felt that they would be capable of delivering the programme themselves with training and support. Of these carers, 57% were spousal. Some carers saw scope for the involvement of other family members or friends, whilst others considered it a task they would undertake by themselves.

*'I'm not saying it's wrong to have a member of staff, but I think the person, like me and Eric, would do it quite nicely together.'* (FC:IV10)

*[...] it's something, mum, you could join in with dad as well. Once you get the idea of what's going on, I think it would be good for you.'* (FC:IV6)

The level of support available to carers appeared to influence how feasible they considered the programme to be. Those with little support from family members tended to speak about barriers such as lack of time or feeling burdened.

*'It is difficult when it's your mum. See I have got another five brothers and a sister, but nobody really helps.'* (FC:IV3)

#### 5.2.5.3 Appropriateness of home based activities

A carer commented that their relative with dementia expects to take part in stimulating activities in settings like the day centre or clubs, but would not be interested in doing activities at home.

*'This would probably be very appropriate in a more formal setting like at a day centre, the carers at a day centre, because speaking from my experience with my mother, she recognises that she is going to a day centre for activities and this could form part of that activity and she would accept that. In her home, she wants to be more laid back. She doesn't want to be stimulated she doesn't want all these questions..'* (FC:FG2)

Carers were aware that their relative might experience some trepidation about taking part in the activities at home, which might influence how receptive the person was to the programme. However, it was suggested that any concerns could be overcome if the programme was presented in an appealing and relaxed way.

*'Sessions should be) more subtle, so no one feels testy. It's more of a conversation and discussion rather than "it's therapy time now".' (FC:IV7)*

The tone of the activities was considered to be important as, if not pitched correctly, there might be a risk of the person viewing the activities as 'childish' or 'boring'.

*'Dad felt at first that it was going to be treating him like a child [...] but I think once it comes to doing the manual, he'll realise it can be quite fun [...] It mustn't become a bore, a chore.'*

*'It's got to be fun. Dad's got to enjoy it.'* (FC:IV6)

The design of the materials was also commented on in the context of its contribution to the appeal of the programme.

*'It's got to sort of look appealing for the person who is doing it, you know.'* (FC:IV9)

#### 5.2.5.4 Duration and frequency of the sessions

The necessity of flexibility was discussed in relation to how many sessions could be completed per week, the duration of each session and when sessions would take place. Most carers agreed that completing three sessions a week would be feasible, but perhaps not always possible depending on factors such as motivation (both the carer and person with dementia), mood or needing to prioritise other tasks.

*'I can imagine saying to him 'come on we'll have a game of skittles' and he'd say 'oh I don't feel up to it at the moment'. There's all those factors to consider really so then, by the time you come to do it on that day, something else has gone on and it hasn't happened. So I think the flexibility here is important.'* (FC:FG3)

In an interview one carer commented that they should not feel under pressure to complete three sessions per week as failing to reach this target might de-motivate them.

*'If someone thinks, "oh god, I haven't done three!", it's like when you start off on evening classes. You're really enthusiastic in the beginning and then, "I'm not really enjoying this". [...] I think you need to get something across, "well if you don't do 3, it's not the end of the world.'* (FC:IV7)

There was general agreement that spending 20-30 minutes on an activity would be possible, however many carers expressed a preference for short, informal sessions, and suggested breaking down sessions across the day.

*'Well if you could do snippets, you know, five or ten minutes. You could do it.'* (FC:FG1)

Some carers pointed out that if the sessions were any longer, they would be too tiring for the person with dementia. Incorporating rest breaks was suggested if the carer felt the person was bored or tired. By contrast, some carers were concerned that 20-30 minutes would not be a sufficient amount of time in which to complete the activities.

*'We wouldn't even have got started in the 30 minutes, actually I think it said 20 minutes for the actual activity. We wouldn't have even got started.'* (FC:FG1)

Carers expressed a preference for a more pragmatic approach to scheduling activities. They placed emphasis on having the freedom to do sessions when they felt like it, rather than setting specific times during which they must be completed. Carers' perceptions of the session structure varied. Whilst some carers acknowledged the advantage of sessions being delivered in a consistent and structured way, others indicated they may not adhere to the structure outlined in the programme.

*'I read it through and as I said, even if I didn't do the programme as you probably would like me to do it, I have taken bits of it which I feel would be helpful.'* (FC:FG2)

## **5.2.6 Theme 4: Quality of the materials**

In terms of perceived quality, the response to the first draft of the iCST manual and resource manual was overwhelmingly positive. Carers felt that both manuals were clearly laid out and written in a way that was easy for them to understand. Many of the participants commented on how visually appealing they found the materials, notably the quality of the images used in the resource manual, and the clear layout and professional look of the manual.

*'I like the attractive cover. It gives one the impression it's going to be interesting.'* (FC:IV2)

People with dementia indicated a preference for images rather than lengthy blocks of text. The size of images and text was considered to be suitable, although some carers suggested that the sizing of both could be increased in the resource manual to accommodate those with impaired vision. The clarity of the content of the manual was consistently highly rated, as was the selection of activities provided.

Carers indicated that the tone of the language and terminology used were appropriate. All of the carers felt that the manual was easy to understand, and the instructions clear enough to enable them to deliver the activities.

*'Well it was plain speaking, it wasn't fancy words [...] It was straightforward so you couldn't mess about you know, you wouldn't make a mistake reading it would you? I found it good.'*

(FC:IV4)

When asked about how the materials should be presented, most carers said they would prefer a ring bound manual with the facility to pull out the pages they were working on. The need for durable, re-useable materials was also emphasised. Laminating or printing the resources on thick card were offered as possible improvements on the sample manuals shown during the interviews.

### **5.2.7 Theme 5: Feasibility of individual versus group training**

Carers were asked to consider whether training for the package should take place in a group setting or on a one to one basis. Advantages of training in a group setting suggested were, that it would be more economical to train several people at the same time, and group members would be able to share ideas and interact with each other making for a more successful training experience. Key considerations carers highlighted included, the location of the training, arranging care for their relative whilst they attended, and finding the time to attend alongside other commitments including work. A consensus emerged that one to one training would be preferable as carers indicated they would feel more comfortable if they needed to ask questions to clarify points. In turn, this would facilitate a greater understanding of the materials.

*'You can say, "Well I'm not quite sure about that", you know. And it can be explained to you. I think that might be a good idea.'* (FC:IV4)

## **5.3 Discussion**

This study yielded valuable insight into the needs of service users for the iCST programme, and the importance of mental stimulation, both from the point of view of carers and people with dementia. Carers and people with dementia responded positively to the first drafts of the iCST manual and resource manual, particularly the clarity of the language, range of ideas, and professional look of the materials. Feasibility issues, such as finding time to do the sessions, were identified and possible solutions offered by participants. This gave the research team an idea of the support carers will need in delivering the programme, as well as an understanding of likely reasons for non-adherence. The first draft of the training package was also devised based on the comments of interviewees and focus group members.

### **5.3.1 Mentally stimulating activities**

Carers and people with dementia emphasised the importance of being mentally active, attributing a wide range of cognitive, emotional, and functional benefits to taking part in mentally stimulating activities. In terms of cognitive outcomes, both carers and people with dementia believed that mental stimulation could improve memory, foster learning, and prevent deterioration in functioning. These ideas reflect the notion of 'use it, or lose it' proposed by Swaab (1991) who asserted that activation of neurons may influence the effect of the aging process on the brain by preventing cell death, or prolonging their life span, thus preserving cognitive function for longer.

Katzman (1993) identified a link between the loss of cerebral connectivity, and the cognitive changes observed in Alzheimer's Disease (AD). Mental stimulation and use of cognitive skills may help to maintain a level of neocortical synapse density above the estimated threshold for clinical manifestation of dementia symptoms. Terry *et al.* (1991) estimated that this threshold is reached when there is a loss of around 40% of neocortical synapses. However, the amount of damage that can be tolerated before clinical symptoms are expressed, known as 'brain reserve', seems to vary between individuals (Stern, 2006). An individual's brain reserve and brain plasticity may be influenced by environmental factors such as education and continued mental activity.

In terms of neuropsychology, education is postulated to increase neocortical density and enhance brain plasticity (Katzman *et al.*, 1989), thus we might expect those with a high level of education to have substantial brain reserve and be less susceptible to cognitive decline. Indeed, some observational studies indicate a link between a high level of education and reduced risk of dementia (Gatz, Prescott, & Pedersen, 2006).

Further to Swaab's assertion that mental activity strengthens and prolongs the life span of neurons, there is some evidence to suggest that it also stimulates the formation of synapses in the brain (Fratiglioni & Wang, 2007).

Carers also noted from their own experience that taking part in activities seems to have a positive effect on alertness on their relative with dementia. This is supported by Kovach & Henschel (1996) who found that taking part in recreational activities could increase alertness in dementia patients.

The idea that mentally stimulating activities serve the purpose of 'keeping you up to date' was expressed frequently by people with dementia. Capacity to keep track of orientation information such as date, time, and whereabouts, and to retain new information is often impaired in people with dementia. Indeed, these dimensions are measured in clinical assessment and diagnostic tools such as the Mini-Mental State Examination (MMSE) (Folstein, Robins, & Helzer, 1975) and Clinical Dementia Rating (CDR) (Morris, 1993). Perhaps it is the experience of diminishing ability to remain orientated that renders 'keeping up to date' important to people with dementia. This suggests that activities with an orientation component, such as discussion of the day, date, month, current affairs, or creating a family tree might be well rated and considered to be helpful by people with dementia.

The emotional impact of mentally stimulating activities was discussed in the focus groups and interviews. Carers felt that being mentally stimulated could improve quality of life and have a positive impact on mood. Anecdotally, some carers who took part in the groups or interviews reported observing improvements in the mood of their relative following participation in activities such as going to the theatre. In terms of supporting research, a key finding of the Cognitive Stimulation Therapy (CST) research trial (Spector *et al.*, 2003) was that people attending CST groups showed improvements in quality of life. Csikszentmihalyi & LeFevre (1989) add that engaging in activities can create positive affect, however notably, this effect is observed when the activity is matched to the abilities of the person.

People with dementia placed emphasis on the need for meaningful activity in order to retain their sense of self, and provide continuity between 'now' and other stages in their life. These findings are consistent with those of Phinney, Chaudhury, & O'Connor (2007) who suggested

that people garner meaning from involvement in activities in three ways: the pleasure and enjoyment of their experience, the feeling of belonging, and the ability to retain a sense of autonomy and identity. The significance of meaningful activity is also stressed by older adults without dementia (Bryant, Corbett, & Kutner, 2001). However, the experience of dementia may mean that involvement in activity becomes more challenging. In particular 'independent' involvement, which was acknowledged by people with dementia and carers in this study, who noticed an increased reliance on others to provide opportunities and support in engaging in meaningful activities.

People with dementia expressed the need to be physically, as well as mentally active. They suggested activities such as dancing, keep fit classes and sports could be beneficial. Consistent with the beliefs of our participants with dementia, exercise and fitness have been linked to positive cognitive outcomes (Andel, Hughes, & Crowe, 2005). This is thought to be because engaging in exercise and keeping fit promotes vascular health. Colcombe & Kramer (2003) propose that increased blood flow to essential brain structures via proliferation of blood vessels may foster patterns of neuronal activity akin to that observed in young adults. If this is the case we might expect that cardiovascular fitness may reduce the risk of, or slow age related cognitive decline. Indeed, there is evidence to suggest that regular physical activity may reduce the risk of developing AD (Lindsay *et al.*, 2002) and help to protect against age related loss of brain tissue density (Colcombe *et al.*, 2003).

### **5.3.2 Feasibility of delivering a programme of mental stimulation at home**

Much of the data gathered from carers about the feasibility of the programme was focused on practical issues that might arise whilst delivering the activities. Largely, their receptiveness to delivering the programme appeared to be determined by whether practical issues were viewed as insurmountable barriers or difficulties that could be overcome.

#### **5.3.2.1 Time**

Lack of time available to deliver the programme was a key concern for carers. Certainly, providing care often reduces the time available for other activities (Montgomery & Williams, 2001). It is therefore reasonable to expect that time would be a concern, particularly for children of people with dementia, who often have to juggle family and work commitments alongside their caring responsibilities. Spousal carers also reported being busy, particularly with appointments and dealing with finances and managing their household. The impingement on time caused by occupying a caring role, and how well it is managed may lead to perceptions of role conflict and overload (Yates, Tennstedt, & Chang, 1999b). Some of the carers who felt unable to dedicate the time to delivering the programme may well have been experiencing overload.

### 5.3.2.2 Impact of Carer Burden

Several carers said that the programme was 'too demanding', explaining that delivering an intervention in addition to having to provide everyday care was too much to ask of them. Others viewed the provision of mentally stimulating activities for their relative as part of their caring role. The perception of the feasibility of delivering the programme may be determined by the experience of carer burden. The demands of caring for an elderly relative with dementia can result in negative outcomes such as psychological distress and negative feelings about care-giving (McKinlay, Crawford, & Tennstedt, 1995), yet these outcomes are not experienced by all carers. Some carers cope well, and their role has little impact on their wellbeing (Merrill, 1997). The functional level of the person with dementia, the extent of care provided, and the care-giving context have been identified as potential predictors of carer burden (Montgomery & Williams, 2001). Consideration of the care-giving context and its impact on carer burden may reveal why some carers felt the iCST programme was not feasible, and additionally, why several carers suggested it would be more suitable if delivered by a professional.

### 5.3.2.3 Impact of context of care

According to Montgomery & Williams (2001) the context of care can be defined as 'a set of pragmatic circumstances and a set of social norms that influence both the behaviours and attitudes of carers within that context'. The context of care will define *what* and *how* care is provided, and how occupying the role of carer will impact on an individual (i.e.: the presence or absence of carer burden). The familial relationship between the carer and person contributes to the context of care. It is thought that becoming a carer places greater strain on spouses than children, as spouses tend to provide more intense care (Smerglia & Deimling, 1997). This may explain why some spouses saw the programme as an additional 'care task' they anticipated difficulty with, whereas adult children appeared to be more receptive to the idea of trying the programme with their relative.

#### 5.3.2.4 Impact of family dynamics

Some carers were doubtful they would be able to engage their relative in a programme of activities at home. An understanding of the role relationship between the caregiver and the care recipient may provide insight into this belief. Pruchno, Burant, & Peters (1997) suggest that family histories influence the interactions between the carer and care recipient. The personalities of the carer and cared for can also define these interactions (Zarit, Stephens, Townsend, & Greene, 1998). The dyad develops expectations for the care-giving role, which define the basic parameters for the appropriateness of certain care tasks (Montgomery & Williams, 2001). Delivery of a therapeutic intervention by a family member may not be deemed appropriate by the family member themselves, or their relative with dementia, or both based on their expectations. In this study the 'appropriateness' of a family member delivering the programme was questioned by carers, but by contrast, people with dementia welcomed the idea. It remains to be seen how the programme will be received by the dyad in practice and this is likely to depend largely on the context of the relationship, and perhaps the person with dementia's understanding of the purpose of the programme.

#### 5.3.2.5 Skill base of the carer

Some carers felt that they lacked the skill base to deliver an intervention, indicating they believed a professional would deliver the programme more effectively and be able to engage with their relative more successfully than they could themselves. Several studies have demonstrated that family carer led interventions are feasible and can yield positive outcomes for the carer including improvements in well being (Moniz-Cook *et al.*, 1998), and reduction in depressive symptoms (Quayhagen & Quayhagen, 2001), as well as improved cognition (Onder *et al.*, 2005; Moniz-Cook *et al.*, 1998; Quayhagen & Quayhagen, 2001) for the person with dementia. Carers in these studies were provided with training and support from research staff and clinicians, and in the case of Onder *et al.* (2005), a manual. These findings suggest that, contrary to the opinions expressed by some carers in the focus groups and interviews, the delivery of interventions need not be solely the domain of paid carers or healthcare professionals. With adequate training, accessible materials and a support system in place, it will be possible to equip carers with the skills they require to deliver the iCST intervention.

#### 5.3.2.6 Formal structure of sessions

Carers discussed the idea of adapting the session structure so that it would feel more 'natural', anticipating a formal session would not be appealing to their relative. Prospectively, this data indicates we may expect issues around intervention fidelity in the field-testing phase of the trial. Intervention fidelity can be defined as 'the adherent and competent delivery of an intervention by the interventionist as set forth in the research plan' (Santacroce, Maccarelli, & Grey, 2004). Adopting the 'Technology Model of Intervention Fidelity' whereby the intervention package includes a manual, training, and incorporates regular monitoring of the interventionist (Carroll *et al.*, 2000) may increase the likelihood of carers implementing iCST as specified in the treatment protocol.

#### 5.3.2.7 Duration and frequency of sessions

The proposed schedule of three, 20-30 minute sessions of iCST per week was largely considered acceptable by carers. However, it was acknowledged that certain factors, such as mood or being busy, would influence the dyad's ability to adhere to this recommendation

from week to week. Carers stressed the need for the programme to be flexible around their lifestyle and commitments. The recommended duration and frequency of iCST sessions was based on the intervention schedule of a home-based carer led programme of reality orientation evaluated by Onder *et al.* (2005). However, adherence to this intervention was not measured, thus it is difficult to use the study as a model to assess the feasibility of the proposed iCST intervention schedule. Further information about the feasibility of the proposed duration and frequency of sessions will be obtained from a period of field-testing.

### **5.3.3 iCST programme materials**

The sample materials presented were highly rated by both carers and people with dementia. They felt the manual and resource manual were clearly laid out and easy to understand. Suggestions for improvements included presenting the manual in a ring bound format for ease of handling, and increasing the size of the images in the resource manual. As a result, the iCST manual and activity workbook were produced in a ring bound format for the main randomised controlled trial (RCT).

### **5.3.4 Methodology strengths**

Service user involvement in clinical research trials is recommended by the Department of Health (1999). The focus groups and interviews provided a platform by which people with dementia and carers could indicate their views about, needs for, and expectations of this home based cognitive intervention.

Data gathered from focus groups can provide valuable insight into complex behaviours and motivations (Morgan & Krueger, 1993). The advantage of their use in this trial, and in the maintenance CST trial (Aguirre *et al.*, 2011), was that they could provide information about the implementation of the intervention at an early stage even before field-testing or piloting. Particularly useful was the data gathered concerning potential barriers to the implementation of the iCST programme. The anticipated difficulties were proposed by a sample of carers quite diverse in their circumstances (i.e.: spousal carers, carers still in full time employment,

co-habiting carers). A strength of having such a diverse sample in this sense is that we were able to see which difficulties appeared to be most common, and which were characteristic of certain circumstances. For example, spousal carers were more likely than children to anticipate problems with engaging their relative in the activities. Being alerted to these barriers, and the types of carers they apply to early on prompted us to think about measures we could put in place to minimise their occurrence in the main RCT. The data we gathered concerning practical difficulties also highlighted the importance of providing a comprehensive training package and support structure for carers participating in the main RCT.

We felt it would be important to consult with people with dementia in the development phase of iCST in order to ensure the programme is person centred and fully reflects their needs. The involvement of people with dementia in the development of therapeutic services is advocated by Goldsmith (1996). Goldsmith argues that giving people with dementia the opportunity to voice their opinions, and provide feedback is the key to improving services so that they address individual needs more effectively.

A rationale for the development of the iCST programme was that it would facilitate access to CST for those unable to attend the group programme for reasons such as poor mobility. Conducting interviews in people's homes allowed us to include a sample of participants whose needs were likely to be reflective of the target audience for the intervention.

### **5.3.5 Limitations**

A limitation of the focus group data gathered about iCST activities from people with dementia is that the activities were carried out in a setting bearing no resemblance to the intended intervention. However, an advantage of carrying out interviews is that the activities could be tested in a one-to-one capacity, which gave us a more representative insight into the quality and the appropriateness of the activities.

As described earlier (see methods section 5.1), three of each type of focus group (person with dementia, carer, and collaborative) were planned, however only six were carried out due to time constraints. At times the general outlook and perceptions of the carers participating in each of the focus groups were notably different. A further carer group may have been useful to moderate some of the more conflicting opinions expressed. However, when the data gathered from the 10 individual interviews was considered alongside the data from the focus groups, it appeared that many points were reiterated by multiple participants, indicating adequate data saturation.

Across all of the focus groups, at times it was difficult for the moderators to keep the carers and people with dementia ‘on topic’. Often their discussion would stray to unrelated issues. In the people with dementia groups this may have occurred because focus group discussions rely on short-term memory and verbal communication, which are typically impaired (Murphy, Killick, & Allan, 2001). Some carers saw the groups as an opportunity to share experiences or ‘complaints’ about their caring role in general. Moderators dealt with diversions from the intended topic by attempting to re-focus participants in a tactful manner as promptly as possible. Experience of this issue was also reported by Qazi, Spector, & Orrell (2010), and appears to be a common limitation in qualitative methods involving service users. The problem of deviation from the questions in the topic guide also occurred in the interviews. Despite this, a substantial amount of informative data was gathered overall by means of both qualitative methods, so the impact of instances of lack of meaningful data is likely to be minimal. According to Morgan & Kreuger (1993) and Morgan (1995), the quality of data gathered can be attributed to factors such as choice of relevant questions, and appointment of qualified moderators in the data collection. Certainly in this case, the topic guide should have been more closely followed, and perhaps more experienced moderators selected to perform the interviews, as these errors may have compromised the data quality in some cases.

The groups could have been more ethnically diverse, comprising of 91% attendees of a white ethnic background. The data was used to inform the development of the second draft of the manual, thus the activities included in the programme and materials included in the resource manual may not have cross-cultural appeal. However, in line with work on group CST, it is likely that cultural adaptation would be needed for different groups.

Two researchers (LY and FH) alternated in the role of facilitator, and four researchers (LY, FH, ASt, PC) took on the responsibility of note taking across the six groups held. Ideally, the researchers should occupy the same role in all of the groups in order to achieve consistency in data collection and reporting. However, this was not possible in this instance due to availability of staff at the time the focus groups were held. In addition, the researchers acting as facilitators had limited experience of conducting focus groups, which may have affected the quality and amount of relevant data gathered. In order to minimise any impact this may have had on the data collection, research staff with extensive experience in qualitative methodology were consulted throughout the process of running the groups, and played a key role in the development of the discussion guide.

#### **5.4 Conclusions**

The proposed idea of an individualised, home based programme of CST and the sample materials presented were well received by both carers and people with dementia. The focus groups and interviews yielded valuable insight into the feasibility of the programme. Carers' estimations of feasibility appeared to be shaped by their preconceptions about iCST and the anticipated experience of delivering an intervention. These preconceptions, especially those focusing on difficulties or negative outcomes, could create barriers in the delivery and effective implementation of the programme. The findings of the groups and interviews were valuable in that they identified these potential barriers at an early stage. The next phase in the trial was to field test the programme in accordance with the guidelines outlined in the MRC Framework.

## **Chapter 6**

### **Field-Testing phase**

This chapter was adapted into a journal article: Yates, L., Orgeta, V., Leung, P., Spector, A., & Orrell, M. (*in press*) Field-testing phase of the development of individual cognitive stimulation therapy (iCST) for dementia, *BMC Health Services Research*.

In interviews and focus groups carried out as part of the development phase (Yates, Orrell, Spector, & Orgeta, 2015), carers indicated the value of field-testing, commenting that they would have a clearer idea of the practical issues and the success of the activities if they were able to try the programme. A sample of professional paid carers was included in response to suggestion from a number of family carers that the programme would be best delivered by a professional. Feedback from the Phase I activities indicated that some carers harboured preconceptions about delivering the programme. These were often focused on difficulties they might encounter, so a key aim of the field-testing phase was to determine whether these difficulties were speculative, or whether they would occur and act as barriers in practice. In addition, the aims of the field-testing phase were: to identify facilitators to delivering iCST, to determine the feasibility of the programme in practice, including adherence, and to assess the appropriateness of the iCST materials (e.g., manual, activity workbook, iCST toolkit).

### **6.1 Methods**

#### **6.1.1 Design**

It is considered best practice to carry out a feasibility study or period of field-testing before investing time, resources and funding in a full study (Craig *et al.*, 2008) thus a field-testing phase was factored in to the development phase of the trial to determine the feasibility of the programme in practice and assess the appropriateness of the iCST materials (i.e.: manual, activity workbook, iCST toolkit). The data gathered was used to inform the second draft of the iCST materials.

## **6.1.2 Sample**

### **6.1.2.1 Sources of recruitment**

Participants were recruited as familial dyads, or pairs of paid carer / client with dementia (see Table 6.2 for full demographic information). Channels of recruitment established earlier in the trial during modelling phase were used to recruit family carers in this phase. Forty-four percent (7) were recruited from carer support groups in Barking & Dagenham and Ilford, 38% (6) from memory clinics in Havering, 13% (2) from the Living Well Resource Centre, and one carer approached the team about participation after attending a group CST training day. Five of the six paid carers were recruited from Sweet Tree, a private home care organisation in North London. Sweet Tree was known to the research team as their organisation was involved in research into the implementation of maintenance CST. One of the paid carers contacted the team after seeing an article about the iCST trial in an Age Concern newsletter (see Figure 6.1). Participants were screened for eligibility using the Spector *et al.* (2003) standardised criteria for psychological treatment of people with dementia (see Chapter 7).

## **6.1.3 Procedure**

### **6.1.3.1 Field-testing intervention**

The 75-session iCST programme was split between six draft manuals and accompanying resource manuals. Each manual served as a ‘how to’ guide for delivering the sessions, and included outlines of the structure and content of each session. The corresponding ‘resource manuals’ contained paper based resources (e.g., puzzles, images) for the suggested activities. Manuals one to five contained 12 sessions, and manual six contained the remaining 15 sessions. Table 6.1 shows manual allocations. Participants were allocated a manual and advised to complete three, 20-30 minute sessions per week (see Figure 6.1). Dyads were offered the opportunity to complete an additional selection of sessions once they had completed their original allocation.

*Table 6.1. Manual allocations*

Manual	Number of sessions	Number of times allocated as first manual	Number of times allocated as an additional manual	Total number of allocations
1	12	5	1	6
2	12	5	0	5
3	12	2	2	4
4	12	4	0	4
5	12	3	1	4
6	15	3	1	4
<b>Total</b>	<b>75</b>	<b>22</b>	<b>5</b>	

In order to measure the quality of the materials and adherence to the programme feedback about each activity was captured on a ‘Monitoring progress’ form (see Appendix 4.1. Monitoring Progress form), which was adapted from the adherence form featured in the original group Cognitive Stimulation Therapy (CST) manual (Spector *et al.*, 2006). The forms required carers to record which sessions they completed and rate aspects of each session including; the person with dementia’s interest, communication, enjoyment, how difficult they found the session (5-point Likert scale: not at all, a little, moderately, quite a lot, extremely), and their mood (poor, fair, good, very good, excellent).

#### 6.1.3.2 Set up visit

A standardised training package was created for the purpose of field-testing (see Figure 6.1). Familial dyads were trained in their homes. Although the training was primarily targeted at the carer, in many cases the person with dementia also took an active role in the set up visit, and joined their carer and the researcher for a guided iCST activity. For convenience, a group training session was organised for the Sweet Tree carers at the main office of the agency. However, their clients with dementia did not attend. A senior member of Sweet Tree attended the session, but did not have an eligible client so another carer from the organisation was given the iCST materials. The substitute carer did not receive formal training to deliver the intervention. The live-in carer recruited as a result of the Age Concern newsletter received one to one training at the person’s home. Training sessions lasted approximately one to one and a half hours and were led by a member of the research team (LY, FH). The training session was intended to be informal and interactive.

#### 6.1.3.3 Materials

Visual and multimedia aids were incorporated into the training package. The use of multimedia aids is advocated by Mayer (2003), who suggests that multimedia learning fosters deeper learning of a process, and capacity for application of problem solving techniques. A handout summarising the key points of the training was produced for carers to refer to (see Appendix 4.2). Clips of the group CST training DVD ('Making a Difference 2) were shown on a laptop, to demonstrate the application of the key principles.

#### 6.1.3.4 Content

The training session was split into two parts. The first part of the session was focused on describing the programme, familiarising participants with the iCST materials, and explaining the key principles of the intervention. The carer was then invited to deliver the first activity with support from the researcher. The guided activity served to confirm the carer understood the information they had been given, and allowed them to try an activity in a supportive environment. At the group training session, carers paired up and tried an activity between themselves.

#### 6.1.3.5 Measures

At the end of the training session, carers completed a short questionnaire (see Carer Feedback Form Set-up visit, Appendix 4.3) rating their knowledge of iCST (5 point Likert scale: excellent, very good, good, fair, poor), confidence in delivering the programme (5-point Likert scale: very little, some, fair, good, very confident), perceived level of support required (4-point Likert scale: not at all, a little, quite a lot, a lot), and training preference (one to one in own home, or group). The data on training preferences was taken to discern which method would be most suitable in the main trial. The researcher also completed a questionnaire (see Researcher Feedback Form Set-up visit, Appendix 4.4) rating the success of the visit (5 point Likert scale: excellent, very good, good, fair, poor), likelihood of the carer engaging with the person with dementia and amount of support anticipated (4 point Likert scale: not at all, a

little, quite a bit, a lot). In addition, the researcher noted comments in relation to perceived carer ability, confidence, positive or negative issues raised during the visit, carer's perception of the materials, any anticipated problems highlighted by the carer, and general observations.

#### 6.1.3.6 Support and adherence

Researchers aimed to contact each dyad weekly to obtain qualitative feedback about their experiences and provide advice and support about delivering the programme. A telephone support questionnaire was completed for every contact (see Telephone support questionnaire, Appendix 4.5), which gathered data on; sessions completed, difficulties, comments about the resources (manual, activity workbook and toolkit items), whether the dyad provided their own resources, enjoyment of the person with dementia, whether any advice was needed about specific issues, and whether the carer had received support with the programme from family or friends. Consent to continue with field-testing was sought at the end of each contact. Dyads were provided with contact details so that they could approach the research team with any queries outside of scheduled telephone support.

#### 6.1.3.7 Final visit

A debrief visit was arranged with dyads who completed their allocated sessions ( $n=9$ ). The researcher interviewed the carer and person about their experience using a questionnaire as a guide (see Researcher Feedback Form Final Visit, Appendix 4.6). The carer also completed a short questionnaire (see Carer Feedback Form Final Visit, Appendix 4.7) rating their knowledge, confidence, quality of support received, and perceived level of success in engaging in iCST. The researcher collected the dyad's manual containing the adherence data (monitoring progress forms). However, the dyad could keep their workbook and toolkit items if they wished.

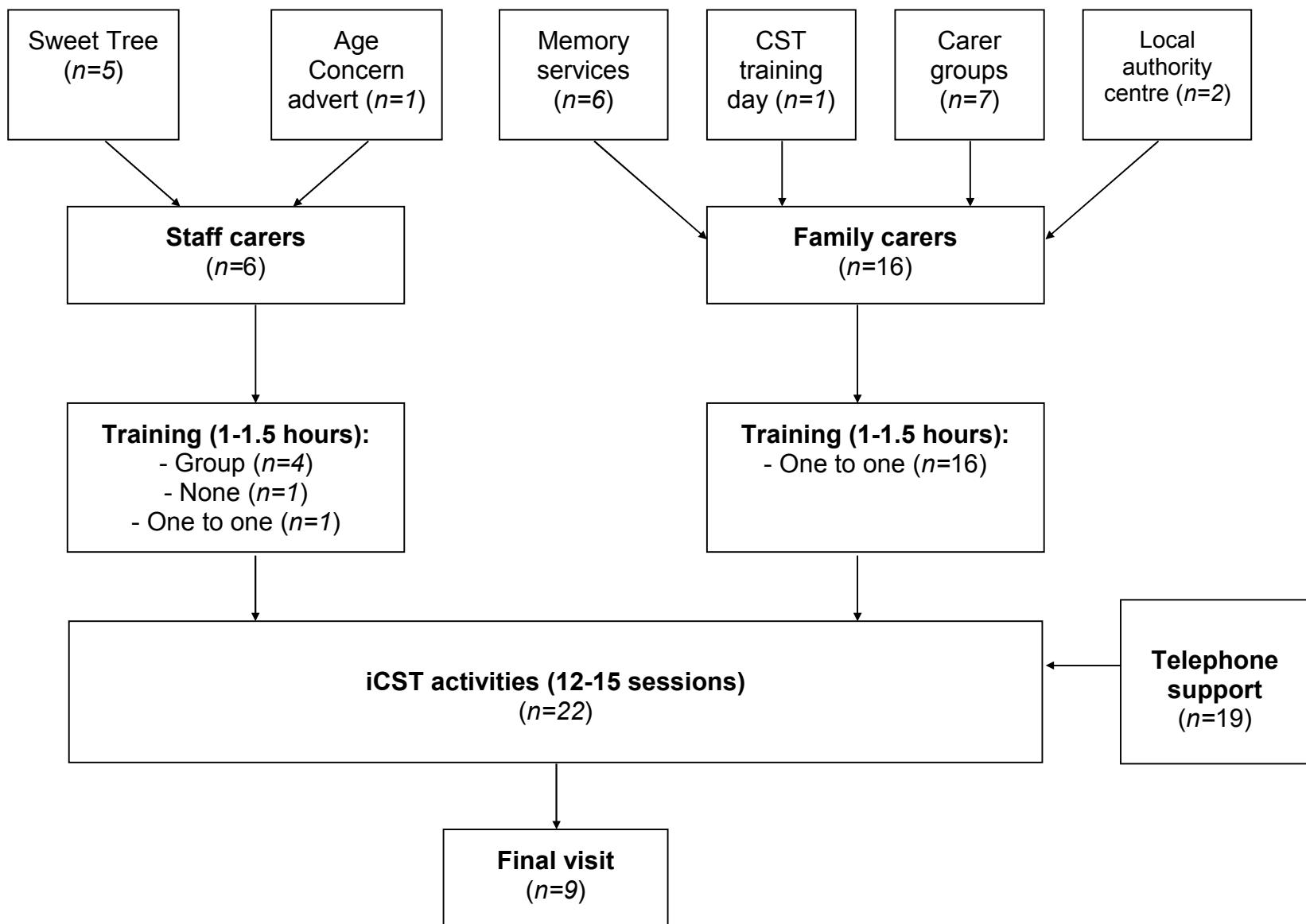


Figure 6.1 Design of the field-testing phase

#### **6.1.4 Ethical Considerations**

Standard procedures were applied in the process of obtaining informed consent from the carers and people with dementia. These included; (a) ensuring dyads were provided with information sheets (see Information Sheet for Caregivers: Field Testing, Appendix 4.8 and Information Sheet for Participants: Field Testing, Appendix 4.9) a minimum of 24 hours before providing written consent at the researcher set up visit to allow enough time to consider their participation; (b) offering participants the opportunity to ask questions; and (c) incorporating a clause confirming understanding of information sheets on the consent forms (see Caregiver Consent Form – Field Testing, Appendix 4.10 and Participant Consent Form – Field Testing, Appendix 4.11). The paid carers, their clients with dementia, and a family member of each nominated client gave written consent prior to the group training session. Consistent with the research from the development phase of the trial (i.e.: focus groups, interviews, see Chapter 5), the people with dementia were in the mild to moderate stages, and were able to provide consent to participate. The right to withdraw participation (and any data provided) was also emphasised by the researcher in the process of obtaining consent.

#### **6.1.5 Analyses**

Inductive thematic analysis techniques (Thomas, 2006) were applied to the written qualitative data obtained from the carer and researcher set up, final visit, and telephone support questionnaires. The research team (LY & FH) followed the same steps as they had previously with the interview and focus group data (see Chapter 5).

## **6.2 Results**

### **6.2.1 Demographics of sample**

Twenty-two dyads took part; sixteen of which were family carers (50% spouse, 50% children of the person), and six of which were paid carers (see Table 6.2 for full demographic information). The mean age of participating family carers was 65 years. The sample of paid carers had a mean age of 42.6 years. The mean age of people with dementia was 81 years. Half of the sample (11) were female.

Table 6.2. Demographic information

<b>Characteristics</b>			<b>Field-testing (%)</b>
<b>People with dementia (n=22)</b>	<b>Gender</b>	Female	11 (50)
	<b>Mean age (years)</b>		81.15 ( <i>SD</i> =5.76)
	<b>Ethnicity</b>	White	20 (90)
		Black	1 (5)
		Unknown	1 (5)
<b>Family carers (n=16)</b>	<b>Gender</b>	Female	14 (88)
	<b>Mean age (years)</b>		65 ( <i>SD</i> =10.52)
	<b>Ethnicity</b>	White	15 (94)
		Mixed	1 (6)
	<b>Relationship</b>	Spouse	8 (50)
		Child (son/daughter)	8 (50)
	<b>Living status</b>	Spouse living with person	8 (50)
		Adult child living with person	3 (19)
		Person lives alone	5 (31)
	<b>Mean years caring</b>		4.32 ( <i>SD</i> =1.87)
<b>Paid carers (n=6)</b>	<b>Gender</b>	Female	5 (83)
	<b>Mean age (years)</b>		42.60 ( <i>SD</i> =16.13)
	<b>Living status</b>	Person lives at own home	5 (83)
		Carer lives with person	1 (17)
	<b>Mean years caring</b>		1.75 ( <i>SD</i> =1.50)

## 6.2.2 Types of data gathered

Both qualitative and quantitative data was gathered from dyads and researchers. Table 6.3 shows the data available for analysis from each of the measures, and table 6.4 shows a breakdown of the number of times each manual was allocated alongside the type of data collected. A data set was considered complete if data was gathered for all of the measures relevant to the research activity (e.g., per set up, a carer and a researcher measure should have been completed).

*Table 6.3. Data available for analysis.*

Questionnaire	Type of data	Dyad (%) n=22	Researcher (%)	Total complete data sets* (%)	Total incomplete data sets (%)
Set up	Quantitative & qualitative	21 (95)	17 (77)	17 (77)	5 (23)
Telephone support	Qualitative	N/A	19 (86)	19 (86)	3 (14)
Final visit	Quantitative & qualitative	9 (41)	9 (41)	9 (41)	13 (59)
Manuals with monitoring progress	Quantitative & qualitative	N/A	N/A	10**	N/A
All measures	Quantitative & qualitative	N/A	N/A	6 (27)	16 (73)

\*\*One carer returned monitoring progress forms for 2 manuals

*Table 6.4 Manual allocations and manuals returned*

Manual	Total number of allocations	Telephone support data collected	Monitoring progress data collected
1	6	5	1
2	5	4	1
3	4	4	2
4	4	4	2
5	4	3	2
6	4	4	2
<b>Total</b>	<b>27</b>	<b>24</b>	<b>10</b>

### **6.2.3 Quantitative data from carers**

Twenty-two participating carers completed a set up visit questionnaire. The set up data from the senior member of staff from Sweet Tree with no suitable client was excluded (see ‘set up visit’ section) from the final data set ( $n=21$ ). In total, 17 corresponding researcher questionnaires were completed as the researcher (FH) leading the training at Sweet Tree did not provide set up data. Of the nine dyads followed up, set up ratings were not available for two dyads. Ratings are shown in Table 6.5.

Post-field-testing ratings showed that 57% (4) carers felt their knowledge of iCST improved. The perceived knowledge of iCST of 43% (3) carers remained the same from set up to the final visit. Seventy-one percent (5) of carers felt just as confident about delivering the intervention at their set up as they did at their final visit, with 43% (3) noting improvement. In terms of anticipated level of support required from the research team, 86% (18) carers felt their needs would be minimal. The quality of support was rated highly by 89% (8) of carers. Seventy-eight percent of carers (7) felt that they had been able to engage in the activities successfully with their relative. Fifty-seven percent (12) of carers preferred a one to one setting for training.

### **6.2.4 Quantitative data from researchers**

Pre and post field-testing researcher ratings were available for seven dyads. Researchers’ final visit ratings of successful engagement were based on the feedback throughout the dyad’s participation, and comments at the visit (Table 6.5). Sixty-seven percent (6) of dyads were thought to have engaged successfully ‘a lot’ of the time, 22% (2) ‘quite a bit’ of the time, and one ‘a little’ of the time. The carers (78%, 7) who felt they had successfully engaged in the programme (‘totally agree’ or ‘agree’) were also considered to have been successful by researchers (‘a lot’ or ‘quite a bit’). Low levels of support were anticipated, and needed in all cases.

### **6.2.5 Monitoring progress data**

Complete monitoring progress data was collected for nine dyads. A total of 10 manuals were returned, as one dyad returned two manuals. Within each of the 21 themes, between two and eight sessions were completed. An average of five sessions were completed per theme. On average, three dyads provided feedback about each theme (range=1-4). The mean number of sessions completed was 12.

Scores for the aspects rated on the monitoring progress forms (interest, communication, enjoyment, difficulty, and mood) were converted into ‘low’, ‘moderate’ and ‘high’ categories (see Table 6.6 for details). An overall rating was then generated for each theme. This was either a single rating (e.g., ‘high’) if there was a majority of one category, or a combined rating (e.g., ‘low-moderate’) if a majority could not be established. Thirteen of the 21 themes received an overall ‘high’ rating (3 or more ‘high’ categories excluding ‘difficulty’). Amongst the remaining themes, four received a ‘Moderate-High’ rating, one a ‘Moderate’ rating, one a ‘Low-Moderate’ rating, and two were categorised as ‘mixed’ because the ratings were split equally between ‘high’ and ‘low’. Qualitative comments about each of the themes are shown in Table 6.6. Seventy-one percent (15) of the themes were placed in the ‘low’ category for difficulty, compared to only 14% (3) in the ‘high’ category. The remaining three themes were in the ‘low-moderate’ (10%, 2) or ‘moderate’ categories (5%, 1).

### **6.2.6 Data from telephone support questionnaires**

The data gathered ( $n=19$ ) was split into the following categories; barriers affecting progress with sessions, difficulties experienced with the programme, feasibility of session structure and duration, iCST manual, iCST resources, perception of sessions, and positive outcomes, and support.

#### **6.2.6.1 Barriers affecting progress with sessions**

Sixty-three percent (12) of carers reported that being busy with ‘life commitments’ affected their progress with the programme. These included job responsibilities for the carer, day

centre attendance for the person, appointments (e.g., hospital visits), holidays, household responsibilities (e.g., moving house, repairs), and social events (e.g., visiting relatives, celebrations). Attending to these 'life commitments' compromised the amount of time the dyad had available to do sessions together. Forty-two percent (8) of carers found that finding the time to complete sessions was a problem for them. The experience of health problems was also a common reason for lack of progress with the programme. Issues with the person's health (32%, 6) were reported equally as often as issues with the carer's health (32%, 6). Another commonly cited barrier to completing sessions was the person's motivation and willingness to participate (32%, 6).

The barriers described thus far were experienced by both family carers, and paid carers. However, paid carers also reported some events that delayed progress related to their job role, such as taking annual leave, and formally ceasing visits with their client.

#### 6.2.6.2 Difficulties experienced with the programme

Relatively few difficulties were experienced with the programme itself. However, four carers reported struggling with the orientation discussion at the beginning of each session. Other difficulties mentioned in a small number of cases were; finding delivering the programme 'hard', struggling with applying the key principles, and difficulty maintaining conversation. Four carers experienced difficulty engaging the person in the activities.

#### 6.2.6.3 Feasibility of session structure and duration

A key concern for carers was ensuring that sessions felt 'informal'. Some carers adjusted the structure or order of the sessions in an effort to create a more informal atmosphere. Adjustments included breaking up the session into smaller 'chunks', completing the orientation and current affairs sections of the session independently from the main activity, or even skipping these completely in some cases. Some carers completed more than one session in a day, or repeated sessions the person had enjoyed. Two carers routinely

*Table 6.5. Set up and final visit ratings derived from carer and researcher measures*

Ratings of ‘poor’, ‘not at all’ and ‘a little’ classified as ‘low’, ratings of ‘fair’ and ‘quite a bit’ as ‘moderate’, and ‘good’, ‘very good’, ‘excellent’ and ‘a lot’ as ‘high’

Set up (%)					Final (%)			
Carer	<i>n=21</i>				<i>n=9</i>			
	Low	Moderate	High	Missing	Low	Moderate	High	Missing
Knowledge	0	7 (33)	14 (67)	0	Knowledge	1 (11)	0	8 (89)
Confidence	0	7 (33)	14 (67)	0	Confidence	0	2 (22)	7 (78)
Support needed	18 (86)	1 (5)	1 (5)	1 (5)	Quality of support received	0	0	8 (89)
Researcher					Researcher			
Success of first session	0	0	17 (100)	0	Success of sessions	1 (11)	1 (11)	7 (78)
Ability to engage PwD in sessions	0	5 (29)	12 (71)	0	Ability to engage pwd in sessions	1 (11)	2 (22)	6 (67)
Anticipated support needed	17 (100)	0	0	0	Amount of support received	9 (100)	0	0

**Table 6.6 Quantitative ratings from monitoring progress forms alongside qualitative comments from telephone support questionnaires. Ratings of 'not at all' and 'a little' classified as 'low' and shown abbreviated as 'L', ratings of 'moderately' as 'moderate', shown abbreviated as 'M', and 'quite a bit' or 'extremely' as 'high', abbreviated as 'H'.**

\*For 'difficulty', 'high' indicates most difficult

Themes	Interest (%)	Communication (%)	Enjoyment (%)	Mood (%)	Overall rating	Positive comments	Negative comments	Difficult* (%)
<b>Physical Games</b>	H (67)	H (67)	H (67)	H (67)	H	Good, successful session	Too heavy, cannot be used indoors, person does not like skittles	M/L (67)
<b>Word Association</b>	H (100)	H (67)	H (67)	H (100)	H	Best session, fun, easy but gave the person confidence, did well in the session		L (67)
<b>Word Games</b>	H (100)	H (100)	H (100)	H (100)	H	Good, fun, gave the person confidence, word grid not easy but enjoyable	Word search provided looks too difficult, jumbled letter grid looks too difficult	L (75)
<b>Thinking Cards</b>	H (100)	H (100)	H (100)	H (100)	H	Good fun, amusing	Too easy	L (100)
<b>Childhood</b>	H (100)	H (100)	H (100)	H (100)	H	Interesting images of childhood toys	Games shown in images obscure, difficult to locate photographs	M/L (100)
<b>Quiz</b>	H (100)	H (100)	H (100)	H (100)	H	Fun, enjoyed the exercise but didn't do very well, did well at music quiz		L (100)

<b>Faces &amp; Scenes</b>	H (100)	H (100)	H/M (67)	H (83)	H	<i>Enjoyed looking at images, images brought back happy memories, stimulated discussion</i>	<i>Not as interested in faces as scenes, questions for scenes activity difficult</i>	L (67)
<b>Sound</b>	H (100)	H (100)	M/L (100)	H (100)	H	<i>Had fun listening to the music, lot of discussion generated, types of music activity better, session went well</i>	<i>Difficult due to problems with hearing, clips too short, too easy, too difficult to identify instruments</i>	H (67)
<b>Number Games</b>	H (50)	H/M(100)	M/L (100)	H (100)	H	<i>Person did well with dominoes</i>	<i>Not interested in dominoes or cards, person found the sessions hard</i>	L (75)
<b>Useful Tips</b>	M (60)	H (80)	H/M (80)	H (83)	H	<i>Created a lot of discussion, session went very well</i>	<i>Activity is 'silly'</i>	L (80)
<b>Art Discussion</b>	H/M (100)	H (100)	H (100)	H (100)	H	<i>Good, lots of discussion</i>		L (100)
<b>Visual Clips</b>	H (100)	H (100)	M-H (100)	H (100)	H	<i>Interesting</i>	<i>Controversial adverts too difficult</i>	L (100)
<b>Current Affairs</b>	H (50)	H (50)	M (50)	H (75)	H		<i>Person had no idea of world events</i>	M (50)
<b>My Life</b>	M (100)	H (83)	M (67)	H (100)	H/M	<i>Family tree challenging but enjoyable, good questions on game board, loved old photos,</i>	<i>Not interested in family tree, images of occupations need to be clearer</i>	L (67)

<b>Categorising Objects</b>	M (67)	M (67)	H (67)	H (100)	H/M	<i>Enjoyed activity and gave lots of reasons and ideas, discussion beneficial, odd one out cards easy and swift, positive session</i>	L (100)	
<b>Household Treasures</b>	M (67)	H (67)	M (100)	H (100)	H/M	<i>Good, happy to identify pairs and discuss images, easy but created a lot of discussion</i>	<i>Difficult to identify old and new objects, topics did not interest the person</i>	L (100)
<b>Slogans</b>	M (100)	M (100)	L (100)	H (100)	H/M	<i>Logos enjoyable</i>	<i>Logos look too difficult, slogans too difficult and too old</i>	H (100)
<b>Using Money</b>	M/L (67)	M (67)	M (67)	H (67)	M	<i>Enjoyed talking about currency, very good</i>	<i>Not interesting, no idea of value of money</i>	L (67)
<b>Orientation</b>	M (71)	M (57)	L (57)	L (57)	M/L	<i>World map interesting</i>	<i>Did not like looking at maps, too difficult, not interesting or engaging, images of landmarks difficult to recognise</i>	L (57)
<b>Food</b>	L (67)	H (67)	L (67)	H (67)	Mixed	<i>Images very clear</i>	<i>Difficult to recognise some types of food</i>	H (50)
<b>Being Creative</b>	H (40)	L (60)	H (40)	L (60)	Mixed		<i>Not interesting, person has never done anything creative</i>	L (100)

included some form of physical exercise or movement into sessions (e.g., dancing, stretching). Sixteen percent (3) said they were able to complete three sessions per week, whilst the majority of carers were only able to complete one or two. The shortest session duration reported was 20 minutes, and the longest about an hour.

#### 6.2.6.4 iCST Manual

Feedback about the manual was predominantly positive. Carers found the manual easy to use (68%, 13), describing it as ‘very good’ (58%,11) and commenting positively on several aspects of the manual including the layout, size of text, key principles, and ideas provided.

Some carers made suggestions for improvements. It was thought that having a selection of ideas for the session warm up would be useful, especially for those who struggled with the orientation discussion. One carer noticed that in some of the text, the person was referred to as a ‘patient with dementia’, which they felt should be re-phrased as it might be distressing for the person to read.

#### 6.2.6.5 iCST resources

The majority of carers said that they used the resources provided in the activity workbook and toolkit and thought they were ‘good’ (63%, 12). However, five carers (26%) supplemented those provided with their own resources. Additional resources included; newspapers, photographs, creative materials (e.g., calligraphy kit), puzzle books, board games, and physical games equipment (e.g., sponge ball).

#### 6.2.6.6 Perception of sessions and positive outcomes

Enjoyment was reported by all field-testing dyads, with the exception of one who refused to engage in the activities. Carers noted that some activities were more enjoyable than others according to the person’s interests (see Table 6.6). People with dementia were enthusiastic about the activities, showed willingness to participate, and appeared engaged and interested

in the activities. Carers described positive outcomes of participation for the person such as feeling a sense of achievement, being more affectionate, and improvements in the person's mood, conversation skills and memory. Delivering the programme was also beneficial for carers in many cases. One carer said the activities gave them purpose when spending time with the person and the programme gave them a lot of help, whilst another felt they were more tolerant of the person because the programme gave them a greater understanding of how memory works. Some carers reported they were surprised that the person was willing and able to do the activities. Benefits to the relationship between the carer and person were also reported by a carer, who said that the activities brought the pair closer together as it gave them something in common, encouraged them to communicate, which was normally absent, and gave them an opportunity to enjoy themselves and 'have a laugh'.

#### 6.2.6.7 Support

The majority of carers did not seek support from the research team about any issues related to the delivery of the programme. The only support issue raised was by a staff carer, who requested advice about their client's refusal to engage in the sessions. Eight carers received help in the delivery of the programme from friends, family members (e.g., spouses, grandchildren, siblings) and, in some cases sitters or paid carers.

### 6.3 Discussion

The purpose of the period of field-testing undertaken during the development phase of the trial was to explore the feasibility of the iCST programme in practice, and gather data about the quality of the materials and training package. The results indicate that with training and support from the research team (LY & FH) carers were able to deliver iCST with few difficulties. The main difficulties experienced were not associated with the programme itself, rather finding time and being motivated to do sessions. This was impacted by both expected (e.g., moving house) and unexpected events (e.g., illness), or commitments (e.g., medical

appointments). Carers noted benefits of taking part in the programme for both the person and themselves.

### **6.3.1 Evaluation of the training and support package**

The knowledge and confidence ratings of carers who participated in a debrief visit remained stable or improved in the majority of cases. For those who reported improvement, application of the intervention ‘in practice’ may have served to enhance the ‘theoretical’ information about the programme provided in the training session (van de Ven & Johnson, 2006). Carers felt the support they had received was of high quality, but rarely requested help beyond the training and researcher initiated calls, which may be indicative that the intervention is easy to deliver, and the training and support package was fit for purpose.

### **6.3.2 Appraisal of materials, activities, and themes**

The majority of the programme themes were highly rated. The least successful themes were ‘orientation’, ‘food’, and ‘being creative’, which received mixed or negative feedback. As a result these themes were subject to review and modification for the second draft of the materials (see Chapter 4).

The relationship between engagement in an activity and assessment of its difficulty was not straightforward. Some participants found it difficult to engage in activities they perceived as ‘easy’. Problems associated with inadequately pitched activities are reported in other studies of activity-based interventions (Teri & Logsdon, 1991; Gigliotti & Jarrott, 2005). Adverse effects of activities deemed ‘too easy’, can include boredom, or adoption of repetitive self-stimulating behaviours. At the other end of the scale, if activities are too challenging, the person may be left feeling frustrated, confused or agitated. However, Gigliotti & Jarrot (2005) comment that pitching activities at an average level may not be the solution, as they may not provide enough stimulation. This makes sense alongside the findings that ‘moderate’ or ‘high’ difficulty ratings did not necessarily predict negative ratings in other dimensions measured

(e.g., interest, communication, enjoyment). In order to feel stimulated by activities, some individuals may require them to be progressively more challenging, whereas other people take more pleasure in being able to complete tasks with ease.

An alternative explanation for the findings may be that people begin to find activities easier if their cognition improves along with participation. Furthermore, the implications of a ‘ceiling effect’ on the potential cognitive benefits of participating in cognitively stimulating activities may need to be considered. If a person is functioning at a high level, the intervention may be of limited use until they reach a certain threshold of impairment in cognitive performance. It is likely that the most effective activities are those which are appropriate for the person’s level of functioning, and this may be subject to change over time (Teri & Logsdon, 1991). Teri and Logsdon (1991) highlight the need for activities to be appropriate for the person’s level of functioning, and acknowledge that although identification of pleasant and appropriately pitched activities can be challenging for carers, and may be dependent on the their creativity, there are benefits to doing so for both the care giver and recipient. For the carer, the benefits of providing appropriate and enjoyable activities for the person include; improved sense of self-efficacy (Gitlin *et al.*, 2008), reduction in feelings of burden, enhanced relationship with the person (Hellstrom, Nolan, & Lundh, 2005; Hellstrom, Nolan, & Lundh, 2007), and improved well being (Teri, Logsdon, Uomoto, & McCurry, 1997). For people with dementia, participating in pleasant activities can alleviate depression (Marshall & Hutchinson, 2001) as well as enhancing the relationship with the carer (Hellstrom, Nolan, & Lundh, 2007).

In the first draft of the iCST programme materials, two levels of difficulty (level A and level B) were provided for most of the activities, but not all. Since some dyads sometimes struggled to find a balance in the difficulty of the activities, and evidence in the literature emphasises the importance of appropriately tailored activities, activities with one level of difficulty were reviewed, and where appropriate split into two defined levels in the second draft so that carers have more choices available. This finding also indicated that in the main randomised

controlled trial (RCT), a researcher may need to support carers in tailoring the programme and choosing activities.

### **6.3.3 Outcomes observed by carers**

Although the questionnaires were driven towards obtaining data about dyads' perceptions of the materials and activities, and experience of the programme, many of the carers commented on the impact taking part in the research had on both themselves, and the person. Carers felt that that participating in the activities was beneficial for the person, and noted improvements in their mood, alertness, and communication during and following the sessions. These outcomes are consistently associated with group CST (Woods, Aguirre, Spector, & Orrell, 2012), perhaps indicating that the properties of CST that impact cognition, communication skills, and quality of life (QoL) may be retained in this individualised format. No formal measures of outcomes (e.g., cognition, QoL) were conducted, so the positive impacts of participating in the field-testing described by carers can only be treated as anecdotal at this stage. The effectiveness of the intervention was not the main focus of the field-testing phase. However, it was investigated fully in the main RCT (see Chapters 7 & 8).

### **6.3.4 Impact on communication**

The programme was seen as a catalyst for communication and a source of mutual enjoyment, which encouraged carers to spend time with the person. Communication between the carer and person can become increasingly challenging through the course of dementia. Gillies (2011) asserts that this is not simply due to any difficulties with expression and understanding of language the person may develop, but can occur when the nature or boundaries of the relationship between the carer and person change. Both the quantity and quality of conversation can be marred by maladaptive patterns of communication including; the person withdrawing and initiating conversation less, cycles of repetitive questions from the person met with repetitive reminders or frustration from the carer, and getting information wrong or being unable to recall things leading to the carer correcting or 'testing' the person.

iCST's focus on opinions rather than facts, emphasis on errorless learning principles, and introduction of new ideas and topics to engage with may serve to alleviate the cycle of these dysfunctional communications, which may account for improvements in communication reported by carers in the field-testing study.

Enhancing the quality of dyadic communication can have a profound impact on the person, beyond the pleasure of engaging with and relating to their carer. According to Kitwood (1997) social interactions affect the maintenance of identity. Kitwood's definition of identity stipulates 'knowing who one is' and 'maintaining a sense of continuity with the past, and some kind of consistency across the course of present life'. Although a person's sense of identity persists in dementia, cognitive impairment and social-psychological factors (e.g., experience of social exclusion, depression) can make maintenance increasingly difficult. As a result, the input of others becomes very important, particularly the way in which they reinforce the person's 'life story narrative' in their behaviour and responses towards them. The person's carer, as the principal or exclusive source of interaction, will inevitably play a vital role in affirming their 'narrative', so poor quality interactions have the potential to exert a deleterious effect on the preservation of self identity. The positive impact of iCST on quality of dyadic communication reported by carers suggests that the programme may have compelling potential wider-reaching benefits for the person related to maintaining identity.

### **6.3.5 Benefits of mutual engagement in an activity**

The loss of mutual hobbies, leisure activities, and social events which sometimes occurs after the onset of dementia can be difficult for carers to come to terms with, and can be a source of stress (Pinquart & Sorensen, 2003). The determinants of carer experience of gratification or frustration and burden are complex (see discussion in Chapter 5) but, by providing carers and people with a mutual interest, iCST may be used as a simple aid to reduce this stress.

### **6.3.6 Benefits of observing the person's skills**

Several carers expressed surprise at the performance of the person in the activities. Family carers tend to underestimate the person's ability to perform activities of daily living (ADL) (Zank & Frank, 2002), and their perception of the person's level of impairment often differs to those of independent observers, or professional carers (Moye, Robiner, & Mackenzie, 1993). The closeness of the relationship (Moye *et al.*, 1993) and carers' subjective burden (Mangone *et al.*, 1993) are thought to have an influence on these estimations. Observing the person's success in iCST sessions appeared to develop carers' understanding of the person's abilities and interests, and how to cope with the experience of their cognitive impairments.

### **6.3.7 Impact of findings on drafting of iCST programme**

Feedback from this study, along with data obtained from the interviews and focus groups carried out as part of the development process contributed to the second draft of the intervention materials (see Chapter 4). Alterations to the first draft of the materials were largely editorial including; correction of spelling and grammar mistakes, improvements to enhance the clarity of instructions, adjustments to the size of some text and images, and changes to the 'monitoring progress' forms. No changes were made to the programme in response to feasibility issues identified (e.g., finding time for sessions, difficulties with iCST technique) at draft two-stage. However, these issues were reviewed as part of the consensus process, resulting in amendments to the guidance provided in the final version of the manual.

### **6.3.8 Methodological limitations**

A significant limitation of the field-testing study was the small sample size ( $n=22$ ) and the gaps in both qualitative and quantitative data collected from researchers and dyads (see Table 6.3). The rate of dyads who did not complete a final visit with a researcher was particularly high (59%, 13). With only a small number of complete set up and final visit data sets it was difficult to analyse and meaningfully interpret the quantitative ratings provided by

carers and researchers. This was also a problem with the data from the monitoring progress forms concerning evaluation of each session theme. Qualitative data was obtained from a bigger proportion of the sample ( $n=19$ ) (e.g., feedback from the telephone support calls, returned monitoring progress forms, final visit questionnaires) and was used to derive meaning from the ratings.

The iCST themes were rated a varying number of times by a varying number of dyads, therefore less in depth data was obtained for certain themes. The research team aimed to distribute the six manuals as equally as possible, given the numbers recruited, but the type of data gathered was impacted by dropouts and those who did not participate in a final visit (see table 6.3). Lack of breadth of data was problematic when identifying activities that needed reworking for draft two of the materials. In some cases, for example, when only two dyads had rated a theme and their feedback was opposing, it was difficult to justify any modifications to the activities.

Similarly to the sample of focus group and interview participants, the sample of field testers was not ethnically diverse, thus the findings reported may not be representative of the experience or needs of carers and people with dementia of other cultures. As a result, the content of the resources provided for the activities may not fully reflect the interests of a diverse population of participants. However, this may be the case within as well as between cultures. Indeed, as described above, many of the session themes received both positive and negative ratings and some comments were very specific (e.g., 'decided to leave session as mother has never done anything creative') which suggests that personal preference and interests may ultimately be the most influential factor in the level of enjoyment and engagement in each session theme, as well as how challenging the activities are. A larger and more diverse sample would have been more likely to reveal any stronger trends in appraisals of the themes. However even with a larger sample, the notion of creating an individualised programme of activities 'suitable for all' is somewhat paradoxical, so to

address this, it is important the intervention is as flexible as possible with the potential to adapt activities to best suit the dyad. Encouragingly, the most successful psychosocial interventions for carers seem to have similar qualities to iCST in that they are tailored to the needs of individuals and involve both the carer and person (Brodaty, Green, & Koschera, 2003).

## **6.4 Conclusion**

The field-testing phase was informative as it demonstrated implementation of the iCST intervention is feasible, and relatively simple. The training and support package appeared to be suitable and effective as carers were able to deliver the intervention without intensive support from the research team. Barriers to implementation occurred largely as a result of life commitments and responsibilities, rather than problems with the intervention itself. Based on the data from this phase, the amendments required to produce the second draft of the materials were minimal. The development phase culminated in a two-step consensus process resulting in the final version of the programme materials (see Chapter 4). Once this was complete, the effectiveness of the intervention compared to treatment as usual was investigated in a large scale RCT (see Chapters 7 & 8).

## **Chapter 7**

### **Methodology for the main randomised controlled trial (RCT)**

The aim of the trial was to evaluate the effectiveness of the individual Cognitive Stimulation Therapy (iCST) programme. The programme evaluation methodology described in this chapter has also been reported in the trial protocol, Health Technologies Assessment (HTA) report, and a submitted journal article:

Orrell, M., Yates, L., Burns, A. *et al.* (2012). Individual Cognitive Stimulation Therapy for dementia (iCST): study protocol for a randomised controlled trial. *Trials*, 13(1), 172-172.

Orgeta, V., Leung, P., Yates, L. *et al.* (2015). Individual cognitive stimulation therapy for dementia: a clinical effectiveness and cost-effectiveness pragmatic, multicentre, randomised controlled trial. *Health Technol Assess*, 19(64).

Orrell, M., Yates, L., Leung, P. *et al.* Individual cognitive stimulation therapy for dementia (iCST): a single-blind, multi-centre pragmatic randomised controlled trial. (submitted)

#### **7.1 Design**

The design was a multi-centre, single blind, clinical randomised controlled trial (RCT) of iCST over 25 weeks vs. treatment as usual (TAU). All pairs of people with dementia and their carer (dyads) recruited began by completing a baseline assessment. Subsequently, they were randomly allocated into either the treatment group (completing three, 30 minute sessions of iCST per week for 25 weeks) or control group (receiving TAU for 25 weeks). Primary and secondary outcome measures were completed at three time points; baseline (BL) prior to randomisation; first follow up 13 weeks after baseline (FU1); and second follow up 26 weeks after baseline (FU2) (Figure 7.1).

### **7.1.1 Sample**

#### **7.1.1.1 Study sites**

London, Bangor, Hull, and Manchester were the four original planned study sites for the main RCT. The Principal Investigators (PI) for each site have previously collaborated on a number of dementia research trials, including the SHIELD (Support at Home: Interventions to Enhance Life in Dementia) project. Several NHS trusts across the country expressed interest in acting as trial sites. Each trust was assessed for eligibility by the iCST Trials Co-ordinator (VO). Of the six trusts that applied, four were accepted as additional sites: Norfolk and Suffolk National Health Service (NHS) Foundation Trust, Northern Devon Health Care Trust and Devon Partnership Trust, Lincolnshire Partnership Foundation Trust, and Dorset Health Care University Foundation Trust (Table 7.1).

Site Specific Identification (SSI) forms were completed for each site and submitted to local Research and Development (R&D) Departments in each trust (see approval letters, Appendix 5.1). Once approval was confirmed, the sites were able to commence their involvement in the trial.

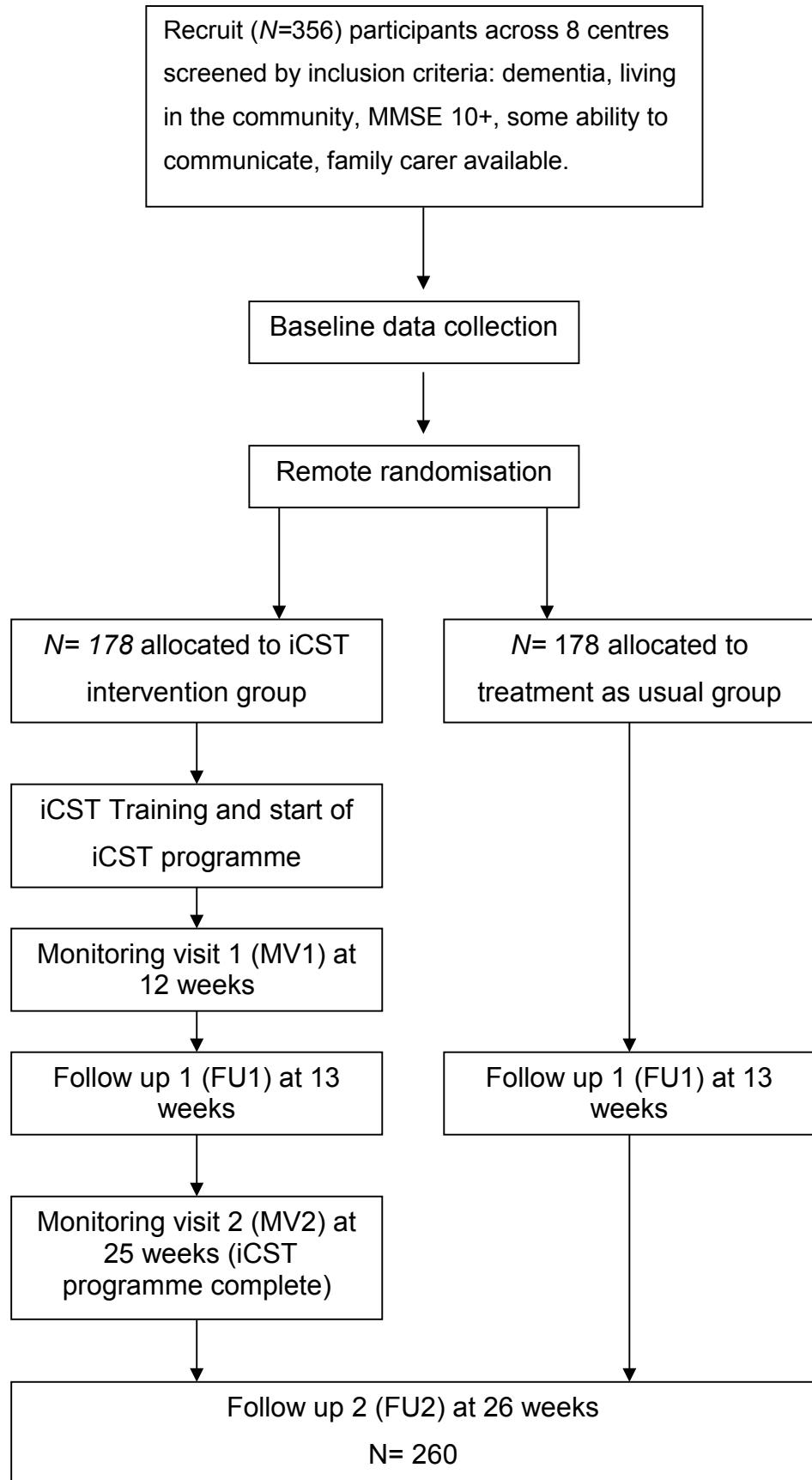
The London site acted as a co-ordinating centre for all other sites involved in the trial. The London team, including the Trials Co-ordinator (VO), and research assistants (PL, FH, JS, & LY) provided training and continuous support to each site. Prior to commencement of recruitment, two of the London team carried out set up visits at each site. Several training and ‘refresher training’ events were held throughout the course of the trial to accommodate new members of staff, as a method of quality control and to enhance treatment fidelity. Additional site visits were carried out as and when necessary. Materials, such as assessment packs and iCST treatment kits, were ordered and distributed by the London site.

#### **7.1.1.2 Participant Identification Centres (PICs)**

Barnet, Enfield, and Haringey Mental Health Trust (BEHMHT) was taken on as a PIC to supplement recruitment from North East London Foundation Trust (NELFT) at the London site. The PIC application was approved by the R&D Departments in NELFT and BEHMHT (see PIC Approval Letter, Appendix 5.2). With PIC approval, clinicians and professionals from BEHMHT organisations (e.g., memory clinics, outpatient services) were able to refer potential participants to the study. The research team (LY & FH) also worked closely with the Dementias and Neurodegenerative Diseases Network (DeNDRoN) in Barnet, Enfield and Haringey (BEH), who assisted them to establish links with health care professionals in the three boroughs.

*Table 7.1 Participating organisations within each study site*

Centre	Participating organisations
London	University College London North East London NHS Foundation Trust Barnet Enfield and Haringey Mental Health NHS Trust
Bangor	Bangor University Betsi Cadwaladr University Health Board
Hull	Humber NHS Foundation Trust
Manchester	The University of Manchester Manchester Mental Health and Social Care Trust Lancashire Care NHS Foundation Trust
Dorset	Dorset HealthCare University NHS Foundation Trust
Lincolnshire	Lincolnshire Partnership NHS Foundation Trust
Norfolk and Suffolk	Norfolk and Suffolk NHS Foundation Trust
Devon	Devon Partnership NHS Trust Northern Devon Healthcare NHS Trust



*Figure 7.1 iCST trial design showing outcome assessments and intervention visits (e.g., training and monitoring)*

## **7.1.2 Participants**

Recruitment to the trial took place in a variety of community settings, including community mental health teams for older people (OPCMHTs), memory clinics, outpatient clinics, day centres, and voluntary sector organisations such as Age Concern and the Alzheimer's Society (see research partnership application, Appendix 5.3).

### **7.1.2.1 Recruitment strategy**

Experience from previous dementia care trials, such as Reminiscence groups for people with dementia and their family caregivers (REMCARE), and the development phase of this trial shaped the team's recruitment strategy. It was observed that working closely with professionals and visiting clinical settings such as OPCMHTs and memory clinics regularly seemed a fruitful way of obtaining referrals. Links with professionals in NELFT established through the SHIELD programme and during the trial development phase were utilised where possible. London site received support from clinical studies officers from the National Institute for Social Care and Health Research Centre (NISCHR-CRC), and DeNDRoN.

### **7.1.2.2 Referral pathways at the London site**

The majority of referrals were supplied by staff and clinicians via telephone or email. Consent to pass on contact details to the research team (LY & FH) was sought. A secure, password-protected Microsoft Excel spreadsheet was created to hold the information of referrals to the trial. All referrals received were recorded regardless of whether they resulted in enrolment to the trial (categorised as a completed baseline assessment and randomisation) so that reasons for non-enrolment and exclusions could be monitored and reported to the Data Monitoring and Reporting Ethics Committee (DMEC). Knowledge of this information also enabled us to assess generalisability of the programme.

If the referral was made via email, contact details were saved into a password protected Microsoft Word document or Excel spread sheet and sent as an attachment to a researcher's

(LY) NHS email account. Document passwords were never disclosed in the same email as the protected attached document as a further measure of security. When the referral had been received and the information transferred into the secure database, the attachment was deleted.

The research team (LY & FH) regularly had direct contact with carers and people with dementia at peer support groups and events run by NHS and voluntary organisations in NELFT and BEH. Remote recruitment methods were also employed, including provision of iCST information leaflets and posters to the organisations and professionals assisting with identification of potential participants. The leaflets were either distributed to carers and people with dementia by professionals or displayed in waiting rooms and meeting rooms (see recruitment leaflet, Appendix 5.4).

#### **7.1.2.3 Referral pathways at other sites**

Bangor and Manchester were supported by clinical studies officers from the NISCHR-CRC, and the DeNDRoN. In Hull and the East Riding of Yorkshire area an ‘opt in information’ system was in place, whereby all people with dementia and carers referred were provided with details of all current recruiting NHS portfolio studies by the Hull Memory Clinical Resource Centre. General Practitioners (GPs) in this area also had DeNDRoN support enabling them to assist with recruitment for dementia trials.

#### **7.1.3 Sample size**

The effect size (standardised mean difference, or SMD) for this trial was estimated based on research into group Cognitive Stimulation Therapy (CST), maintenance Cognitive Stimulation Therapy (maintenance CST), Cochrane reviews of reality orientation (RO) and cognitive stimulation (CS), and Onder and colleagues’ (2005) individual RO/CST study. The group CST study by Spector *et al.* (2003), and maintenance CST pilot by Orrell *et al.* (2008) found effect sizes of 0.32 and 0.68 compared to TAU, respectively. The Spector *et al.* (1998)

Cochrane review of RO found a SMD of 0.58. The latest Cochrane review of cognitive stimulation found an SMD of 0.37 (Woods *et al.*, 2012). Onder (2005) found an SMD of 0.41. SMD relative to TAU for iCST was estimated to be at least 0.35, taking into account the aforementioned findings of similar research.

A sample size of 260 at follow up 2 (FU2) was required to demonstrate an SMD of 0.35 on the Alzheimer's Disease Assessment Scale-Cognitive (ADAS-Cog, Rosen, Mohs, & Davis, 1984) with 80% power at a 0.05 (two sided) significance level. Taking into account an expected attrition rate of 15%, a recruitment target of 306 dyads was set. Experience in previous trials including the CST trial, the needs in care homes trial (Orrell *et al.*, 2008), and the activities in care homes trial (Wenborn, Challis, & Orrell, 2010) indicated that a loss to follow up rate of 12-15% (7-10% excluding deaths) should be expected.

To safeguard loss to follow up, standard procedures to maximise the retention rate of the sample were applied. These included regular contact with carers via telephone, reminder letters (see appointment reminder letter, Appendix 5.5) and email, if requested by the carer.

In order to meet the target of 306 dyads, recruitment goals were set for each research site taking into account the capacity of the researchers and resources available. The London site was required to enrol a minimum of nine dyads per month. Four dyads per month were expected from each of the Manchester, Hull and Bangor sites, and two dyads per month from each of the additional sites of Dorset, Devon, Lincolnshire, Norfolk and Suffolk.

Withdrawals and dropouts were monitored, and retention rates calculated regularly throughout the trial. A withdrawal was defined as a complete departure from participation in the trial. A drop out was categorised as a failure to complete follow up 1 (FU1). It became apparent during the course of the trial that the rate of attrition was higher than expected, particularly amongst those recruited at the London site (NELFT and BEH). The trial

statistician (ZH) was consulted to assess whether this would impact the detection of the estimated SMD of 0.35. A new target of 351 dyads was established in the latter stages of recruitment (April-May 2013) to take into account the unexpected level of attrition. A total of 356 dyads were enrolled by the close of recruitment.

#### **7.1.4 Inclusion criteria**

Participants referred to the trial were screened for eligibility using the Spector *et al.* (2003) standardised criteria for psychological treatment of people with dementia. Referrals were deemed eligible for enrolment if they:

- a) met Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV criteria for dementia (American Psychiatric Association [APA], 2000) (see Appendix 5.6.1),
- b) scored 10 or above on the Mini-Mental State Examination (MMSE, Folstein, Robins, & Helzer, 1983) (see Appendix 5.6.2),
- c) had some ability to communicate and understand communication, scoring '0' or '1' on communication items on the Clifton Assessment Procedures for the Elderly-Behaviour Rating Scale (CAPE-BRS, Pattie & Gillear, 1979) (see Appendix 5.6.1),
- d) could see / hear well enough to participate in the programme activities,
- e) had no major physical illness or disability affecting their participation.

Additional criteria included, living in the community and having regular contact with an informal carer. An 'informal carer' was defined as an unpaid carer in regular contact with the person with dementia who could deliver the programme and act as an informant for the assessments at baseline (BL), FU1, and FU2. Many of the carers were relatives (e.g., spouses, children) or close friends of the person. It was acceptable for the delivery of the programme to be split between several carers. In the majority of cases the programme was split between family members (e.g., amongst the children of the person), but in some cases a paid carer or sitter assisted with sessions. The same informant was required to participate in

the assessments at all time points (BL, FU1 & FU2), and the paid carer could not act as an informant.

#### 7.1.4.1 Screening for eligibility

Participants were initially screened for eligibility by referring professionals and organisations, who were provided with the inclusion criteria for the trial. The research team (LY, FH & JS) performed additional informal checks of suitability when contacting referred dyads over the phone, or in person if at a carer group or event. In NELFT LY was able to access RiO, an NHS electronic patient record system, if confirmation of diagnosis of dementia was required for any referrals. Where this type of system was not available, patient records and case notes were reviewed at clinics with guidance from relevant staff. Participants who fulfilled the inclusion criteria specified above, and were able to give informed consent in accordance with the provisions of the Mental Capacity Act (Department of Health, 2005) were recruited into the trial.

#### 7.1.4.2 Screening tools

Formal screening tools were built into the baseline assessment visit (see Questionnaire Booklet [QB]0, Appendix 5.6.1). The researcher spent some time in conversation with the dyad prior to the commencement of the questionnaires to gauge suitability. The researcher was guided by the DSM-IV criteria and the CAPE-BRS. The DSM-IV criteria specifies that the person must have multiple cognitive deficits including memory impairment and at least one of the following; aphasia (disturbance in language), apraxia (impairment of motor function), agnosia (impairment of object recognition or identification of objects), or disturbance in executive functioning (impairment in planning, organising, sequencing, abstracting). Experience of cognitive deficits must have a significant impact on the social or occupational functioning of the person for at least six months and represent a significant decline compared to the person's previous level of functioning. The type of dementia diagnosed was not specified in the inclusion criteria, however, it was recorded where possible for analysis

purposes. The DSM-IV criteria are often used in clinical and research, and is considered to have strong face validity (Prince *et al.*, 2008).

The CAPE-BRS was used to assess the person with dementia's production and comprehension of communication. 'Communication' may constitute speaking, writing, or gesturing. Participants had to score '1' or '0' on questions 12 (He/she understands what you communicate to him / her) and 13 (He/ she communicates in any manner) on the scale. A score of '0' on question 12 indicates the person understands almost everything communicated to them, and a score of '1' indicates the person understands some of what is communicated to them. A score of '0' on question 13 indicates the person communicates well enough to be easily understood at all times, where a score of '1' indicates the person can be understood sometimes, or with some difficulty. The CAPE-BRS is widely used as a measure of behavioural problems in dementia (Jerrom, Mian, Rukanyake, & Prothero, 1993) and includes four subscales; physical disability; communication difficulties; apathy and social disturbance. Only the communication subscale was used in this trial.

### **7.1.5 Randomisation**

Randomisation was performed after screening and baseline assessment. The allocation ratio for randomisation was 1:1, into either the iCST intervention group or TAU. Participants were stratified by centre (London, Bangor, Hull, Manchester, Dorset, Norfolk & Suffolk, Lincolnshire or Devon) and whether they were taking anticholinesterase inhibitors, to ensure even distribution of the sample between treatment and TAU. A web-based randomisation service was used. The service was managed by North Wales Organisation for Randomised Trials in Health (NWORTH), an accredited UK Clinical Trials Unit funded by the Welsh Assembly Government. The randomisation algorithm selected is a dynamic adaptive method that ensures balance overall, within each stratification variable and within each stratum. This allows sequential randomisation of participants, minimising selection bias while maintaining an acceptable level of balance (Russell, Hoare, Whitaker, Whitaker, & Russell, 2011).

Unblind researchers performed randomisations using the online system. Participants' ID, date of birth, and anticholinesterase inhibitor status were submitted, then the allocation was returned instantly. Nominated unblind researchers at each site received confirmation of each randomisation via email. Dyads were contacted via telephone to inform them of their allocation (see iCST letter, Appendix 5.7 and TAU letter, Appendix 5.8), and in the case of iCST dyads, arrange a training visit. Letters confirming allocation were also sent in the post as soon as possible after randomisation.

### **7.1.6 Blinding**

It was not possible to blind the participant to their allocated treatment because the intervention is non-pharmacological. However, the result of the dyads' randomisation was not disclosed to the researchers conducting the assessments at FU1 and FU2. Researchers at the London site (LY & FH) occupied a dual role. LY was a blind assessor in the NELFT boroughs (Barking & Dagenham, Havering, Redbridge, Waltham Forest), and provided carer training and support in the BEH boroughs (Barnet, Enfield, Haringey). FH took on the alternate role of blind assessor in BEH and unblind support in NELFT. In terms of support, JS was a blind assessor in all boroughs, and PL was aware of treatment allocations in all boroughs, thus could provide carer training, and support where necessary. All members of the research team were able to conduct baseline assessments. At the other study sites, data was collected by one team of researchers, and training and support was delivered by a second team. From experience with similar projects we were aware that occasionally participants would reveal their treatment allocation to blind assessors. In order to reduce this effect, participants were given explicit reminders before the assessment visit (see reminder letter, Appendix 5.5). Blinded assessors recorded their impression of the allocation of each dyad and their confidence in that prediction at FU1 and FU2 (see Interviewer Perception Sheet, Appendix 5.9). Based on this data, we were able to examine the integrity of blinding retrospectively to test whether inadvertent loss of blinding leads to bias, and to adjust for any

bias detected. The trial statisticians remained blind to allocation whilst performing the main analyses. Unblind adherence data was analysed after the main analyses were complete.

### **7.1.7 Intervention**

The iCST programme is based on a modified Cognitive Stimulation Therapy (CST) programme (Spector *et al.*, 2003) incorporating themes from the maintenance CST (Orrell *et al.*, 2014) programme (both of which are described in Chapter 1), the recent Cochrane Review of CS (Woods *et al.*, 2012), Onder and colleagues' programme (2005), and consultation with carers, people with dementia, healthcare professionals, and academics (see Chapters 4, 5 & 6). iCST is a one to one, carer-led, home-based programme of structured CS for people with dementia. Dyads completed up to three, 30-minute sessions per week together over 25 weeks. The programme consists of 75 activity sessions in total.

#### **7.1.7.1 Structure of iCST sessions**

Each iCST session follows a consistent structure, which is designed to support memory and learning. The dyad begins by spending a few minutes discussing orientation information (e.g., day, date, weather, time, location). The purpose of this discussion is to orientate the person with dementia to the here and now. The ability to remain orientated is often impaired in people with dementia, however there is evidence to suggest that RO techniques can yield benefits in both cognition and behaviour (Spector *et al.*, 2000). The approach to orientation characteristic of cognitive stimulation differs to traditional methods of RO. Where RO tends to be more focused on re-learning orientation information, and may involve asking direct questions (e.g., What is the date today?), cognitive stimulation encourages a more sensitive, implicit approach. For example, in CST groups information such as the day, date, and location is displayed prominently on a RO board for all group members to refer to. The facilitator may also ask questions like 'Do you think the weather is normal for April?' to subtly orientate the group to the month. As part of the iCST training package, carers were given

specific guidance about how to adopt this implicit approach in the orientation discussion at the beginning of each session.

After the orientation discussion, the dyads discuss a current event, such as a news story, or special family occasion. Again, the purpose of this is to orientate the person with dementia to the here and now. Feedback from the development phase of this programme (see Chapters 4, 5 & 6), and the maintenance CST programme (Aguirre

*Table 7.2 iCST session themes*

<b>iCST Session theme</b>	<b>Session number</b>
My life	1, 2, 45, 46
Current affairs	3, 4, 57, 58
Food	5, 6, 55, 56
Being creative	7, 8, 63, 64
Number games	9, 10, 71, 72
Quiz games	11, 12, 75
Sounds	13, 14, 51, 52
Physical games	15, 16, 49, 50
Categorising objects	17, 18, 65, 66
Household treasures	19, 20
Useful tips	21, 22, 47, 48
Thinking cards	23, 24
Visual clips discussion	25, 26
Art discussion	27, 28, 43, 44
Faces / Scenes	29, 30, 59, 60

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Word games	31, 32, 41, 42, 73, 74
Slogans	33, 34
Association words discussion	35, 36, 61, 62
Orientation	37, 38, 67, 68
Using money	39, 40, 69, 70
Childhood	53, 54

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*et al.*, 2011) suggests that people with dementia are interested in current affairs, and find activities like reading about and discussing the news mentally stimulating. The main activity follows the current affairs discussion. The dyad spends 20 minutes engaging in a themed stimulation exercise. The programme encompasses a variety of different themes and topics (Table 7.2) to cater to the interests, and needs of the person with dementia. As in the CST and maintenance CST programmes, a choice of activities is suggested for each session. These suggestions are graded by difficulty so the programme can be tailored to the person's abilities. Level A activities tend to be less challenging, and more discussion based than level B activities, which tend to be more cognitively demanding. The activities suggested in the manual are designed to provide global stimulation of cognitive abilities, including memory, concentration, language, and executive functioning.

#### 7.1.7.2 iCST package

Carers received the iCST manual and activity workbook. The iCST manual provides guidance on how to run the sessions, the key principles of iCST, and ideas for activities for all 75 sessions. The activity workbook contains paper-based resources for activities suggested in the manual. Carers were also provided with the iCST toolkit which contained additional resources including a set of boules, playing cards, dominoes, magnifying card, sound activity CDs, coloured pencils, and world and UK maps. The materials used in the main RCT were assessed for suitability during the development phase of the trial (see

Chapters 4, 5 & 6). Although the group CST and maintenance CST programmes are manualised, activity resources are not provided for either as they are delivered by healthcare staff who are often allocated time and a budget to source materials. It was considered that informal carers may not be able to provide their own resources, or may be inconvenienced in doing so therefore the activity workbook and iCST toolkit were developed. However, dyads were not restricted to using only the materials provided during the trial. The supporting

*Table 7.3 iCST Key Principles*

<b>iCST Key Principles</b>	
1	Mental stimulation
2	Develop new ideas, thoughts and associations
3	Use orientation in a sensitive manner
4	Focus on opinions, rather than facts
5	Use reminiscence
6	Provide triggers to help memory
7	Stimulate learning and communication
8	Stimulate language and discussion
9	Stimulate every day planning ability
10	Use a person-centred approach
11	Offer choice of activities
12	Enjoyment and fun

- 
- 13 Maximise potential
  - 14 Spend quality time together
  - 15 Strengthen the care giving relationship
- 

researcher discussed ways in which the activities could be adapted if the dyad preferred to use their own resources, or found any of the resources unsuitable at the set-up visit.

#### 7.1.7.3 iCST principles

The guiding principles of CST and maintenance CST were adapted to create the 15 key principles of iCST (see Table 7.3). Many of the principles developed as part of the original programme are applicable in a one-to-one setting, and all are founded in the person-centred approach to care. However, those specific to a group environment were omitted, and some academic terminology was rephrased in the manual development in accordance with feedback from consultation with carers who felt that the manual should be easy to understand (see Chapters 4 & 5).

Of the 15 ‘aims of iCST’, nine have been highlighted in the manual, and were each described to the carer as part of their training. The first of these is that the programme is designed to be person-centred. That is, emphasis should be placed on the person as an individual, determined by their unique life experiences, personality, and preferences. The sessions should focus on the person’s strengths, rather than any impairment they may experience. Carers are encouraged to offer the person a choice of activities. The programme comprises of a variety of different themes, and several suggestions for activities for each session are provided in the manual so that there are alternatives if the person does not wish to do a particular activity. Furthermore, two levels of difficulty (level A and level B which is designed

to be more challenging) are provided so that the activities can be tailored to the person's abilities.

A key element of the activities is the focus on opinions rather than facts. This is to ensure the person does not feel pressured, or 'put on the spot' having to provide specific information they may be unable to recall. Often, people will recall factual information or memories spontaneously without the need for specific questions. This principle creates a relaxed and positive environment in the session, which promotes the person's strengths. Reminiscence is used as a means of orientation in the programme. Rather than simply discussing past events, the activities encourage the person to link the past with the here and now. For example, in a current affairs discussion, the person with dementia might be invited to discuss their childhood, and how it compares to that of their grandchildren today.

The activities can be adapted to be multi-sensory which is very stimulating and creates a focus for the person. The person with dementia and carer are encouraged to interact and take part in the activities together, which allows the person to practice their cognitive skills and maximise their potential. Along with the feeling of 'togetherness' the programme encourages the carer and person with dementia to have fun and see the time spent doing the activities as quality time together. A key goal of the sessions is to stimulate discussion, which can improve the language skills of the person with dementia.

### **7.1.8 Treatment adherence, carer training, and support**

#### **7.1.8.1 Adherence and treatment integrity**

The 'treatment implementation' model developed by Lichstein, Riedel, and Grieve (1994) was applied to ensure 'treatment integrity' (TI). In other words, that the intervention delivered was indeed the intended intervention. According to the model, in clinical trials of psychosocial interventions TI must be established in order to make valid conclusions. Examination and control of the treatment processes of 'delivery', 'receipt', and 'enactment' is crucial in order to

achieve TI. Treatment ‘delivery’ refers to the interventionist’s ability to deliver the intervention as specified without adapting it, or incorporating elements of other treatments. ‘Receipt’ is the extent to which the participant has received the intervention, and ‘enactment’ whether, and how far the participant’s behaviour has changed (expected behavioural outcomes) after receiving the intervention. Providing detailed descriptions of treatment components and applying standardised procedures are ways of increasing the likelihood of faithful adherence to treatment.

In order to maximise TI, thorough training of the unblind researchers was crucial. The role of the unblind researchers was to train carers to deliver the intervention, provide support, and monitor them throughout their participation in the trial. A treatment protocol containing descriptions of the treatment, training, and adherence monitoring procedures was drafted and distributed to all unblind researchers working on the trial. In addition, the researchers were trained to deliver the iCST carer training package, and supported by researchers at the London site throughout the trial.

Treatment manuals are considered to be the standard for ensuring accurate delivery of an intervention, thus providing carers with the iCST manual as a formal induction method contributed to the TI of the iCST programme.

#### 7.1.8.2 iCST training package

Carers were trained in their homes by an unblind researcher (see training handout, Appendix 5.10). In most cases both the carer and the person with dementia were present during the session. Training was standardised and designed to be interactive, including a role-play exercise and the opportunity to see a clips of the maintenance CST training DVD, ‘Making a Difference 2’. The researcher spent the first part of the training session introducing the dyad to the iCST materials (manual, activity workbook, and toolkit), and explaining the session structure and key principles of the programme. Following this, the dyad was shown the DVD

clip of a group CST ‘Art Discussion’ session, and asked to identify examples of the key principles in practice. The carer was then invited to take part in a role-play exercise demonstrating ‘good’ and ‘bad’ practice with the researcher. If they were uncomfortable doing this, the researcher talked through the role-play examples with them instead. Finally, the carer was invited to deliver the first iCST session with support from the researcher, who provided feedback afterwards. Some carers indicated they would prefer to complete the first session at a later time by themselves to give them the opportunity to prepare and familiarise themselves with the materials. In cases in which multiple family carers or friends would be involved in delivering the programme, the researcher invited them to be trained with the main carer. If they could not attend, the researcher scheduled training at a time convenient for them. Set-up visit questionnaires were completed by both the researcher and carer (see carer set up questionnaire, Appendix 5.11 and researcher set up questionnaire, Appendix 5.12).

#### 7.1.8.3 Support and measures of adherence

##### 7.1.8.3.1 *Carer diaries*

Assessments measuring adherence to the iCST programme were carried out with treatment dyads throughout their participation in the trial. A carer’s diary was provided in which carers were required to record which sessions had been completed, dates of completion, assessments of the person’s response to each session, and comments about their experience of each session (see sample page, Appendix 5.13). The diary was split into two parts. ‘Carer’s Diary 1’ (containing sessions 1-32) was given to the dyad at the set up visit, and collected by the unblind researcher at the first monitoring visit (12 weeks after BL). At this monitoring visit the dyad was given an additional copy of ‘Carer’s Diary 1’ if their first copy was not complete, and a copy of ‘Carer’s Diary 2’ (containing sessions 33-75). The purpose of splitting the diaries and collecting Diary 1 at the first monitoring visit was to safeguard against loss of data should the dyad withdraw from the study or be uncontactable after the monitoring visit. The remaining diaries were then collected at the second monitoring

visit (25 weeks after BL). If the dyad wished to continue with sessions they were given another copy of ‘Carer’s Diary 2’ and a freepost envelope to post it back to the team upon completion.

#### *7.1.8.3.2 Telephone support*

Unblind researchers provided dyads with regular support via telephone (or email in some cases, at the carer’s request) throughout their participation in the trial. Intensive support was provided in the two weeks after the set up visit. Subsequently, the carer expressed a preference for the frequency of support calls. This could be weekly, fortnightly, or monthly, and could be changed at any time according to the needs of the dyad. During the call the researcher took information, such as how many sessions were completed on average, how long sessions lasted on average, and how much time carers spent preparing for the sessions. A telephone support questionnaire was developed to record this data (Appendix 5.14). Data regarding time spent delivering and preparing for sessions, and if any support was sought from friends or other family members was collected for the purposes of costing carer time in the economic evaluation of the intervention (not part of this PhD project). The calls were semi-structured according to the questionnaire, however, the carer was also invited to discuss their experience of the programme, or request advice from the researcher.

#### *7.1.8.3.3 Monitoring visits*

Monitoring visits by the unblind researcher were scheduled for 12 and 25 weeks, prior to the FU1 and FU2 assessments. In some cases, it was not possible for the unblind researcher to visit the dyad before the blind assessment due to the dyad’s schedule. The purpose of the visits was to collect the Carer Diaries (as discussed above), complete a brief questionnaire with the carer requiring them to reflect on their success with the programme (see carer monitoring questionnaire, Appendix 5.15), and discuss the dyad’s experience of the programme, problem solving any issues if necessary. The researcher recorded their impressions of the visit using the researcher monitoring questionnaire (see Appendix 5.16).

The unblind researcher used these visits as an opportunity to remind the dyad that they should not reveal their randomisation allocation to the blind researcher conducting their FU1 or FU2 assessment.

#### *7.1.8.3.4 Out of protocol contacts*

During the trial, dyads were expected to receive up to ten hours of support including a set up visit, telephone support calls, and two monitoring visits. Any additional visits (e.g., additional training) or carer-initiated contacts were classified as ‘out of protocol’. Forms were developed to record the occurrence of any ‘out of protocol’ contact (see additional support questionnaire, Appendix 5.17).

#### **7.1.9 Treatment as usual (TAU)**

Dyads randomised into the TAU arm did not receive any additional intervention for the duration of their participation. The services and treatments accessed by control group dyads varied between and within centres, and changed over time. In terms of services, many of the people with dementia attended lunch clubs, support groups, or day centres, the availability of which varied from area to area. As expected, a large proportion of the people with dementia involved in the trial were on cholinesterase inhibitor medication. It was acknowledged that the services and treatments available to the control were also likely to be available to those in the intervention group, thus the trial evaluated the additional effects of iCST. The Client Service Receipt Inventory (CSRI) (Beecham & Knapp, 1992) recorded the use of services and medications across the two groups, and enabled us to monitor whether the control and intervention group had been receiving similar therapeutic interventions during the trial (see QB4, Appendix 5.6.5 & QB6 Appendix 5.6.7).

Dyads receiving TAU may have participated in other cognitive stimulation interventions, such as group CST, during the 26 weeks of the trial. Group CST sessions are run in many day centres and day hospitals across the study sites, and CST materials are widely available. It

was considered very unlikely that any structured home-based interventions were available to participants. Indeed, there were no reported cases of any of the dyads being involved in comparable individual cognitive interventions, or home based versions of CST during the trial. Should this have been the case, the data would have been recorded in the CSRI and accounted for in the final analysis of the data set. Dyads were not involved in any other dementia intervention research alongside their participation in the iCST trial.

#### **7.1.10 Assessment procedure**

Staff conducting the assessments at BL, FU1, and FU2 had clinical and/or research experience. The London team (LY, FH, JS) had previous experience of conducting assessments in the community on the Maintenance CST, Carer Support Programme (CSP), and REMCARE trials. All researchers working on the trial received extensive training in the study outcome measures. This training was co-ordinated by the London site. The London site also produced user guides for the measures, and acted in a supportive capacity to address any queries researchers had regarding either the measures themselves, or the assessment procedure.

Assessments took place at dyads' homes. In most cases one researcher conducted the visit, interviewing both the carer and the person with dementia. However, if deemed necessary on occasions where the dyad had limited time, or when appointments were scheduled outside of office hours, two researchers attended the visits. The person with dementia and the carer were interviewed separately whenever possible. In some cases, the carer was present for the interview with the person with dementia. Most commonly this was at their or the person's request, or due to space constraints in the interview setting. Carers were asked not to intervene during the interview to prevent them from assisting the person to answer the researcher's questions, and to avoid bias in responses, as in the presence of their carer there is a risk the person might not feel free to answer honestly (Taylor & de Vocht, 2001).

Assessment visits usually lasted around one and a half to two hours in total. Baseline visits were often longer due to the process of obtaining fully informed consent. Cognition, QoL, mood, and quality of the care giving relationship were assessed in the person with dementia's interview. Carers were interviewed about their health and wellbeing, as well as behavioural and psychological symptoms, functional status, and quality of life of the person with dementia. Socio-demographic data for the dyad and service use were also collected from the carer.

Typically the researcher interviewed the person with dementia first (QB1, see Appendix 5.6.2), giving the carer questionnaire booklets QB2 (see Appendix 5.6.3), and QB3 (see Appendix 5.6.4) to complete independently in the meantime. The researcher then obtained the information required for QB4 (at BL only, see Appendix 5.6.5) or QB6 (at FU1 and FU2, see Appendix 5.6.7), and QB5 (see Appendix 5.6.6) from the carer upon completion of the interview with the person with dementia. The measures were generally administered in the order they appeared in the questionnaire booklets. However, the order was occasionally adapted to suit the needs of the carer or person with dementia.

At the beginning of the interview the researcher explained the content of the measures, answered any questions the dyad had, and explained that any questions the dyad felt uncomfortable with could be omitted. The vast majority of participants were able to complete the interviews. However, in some cases the assessment was terminated as the person with dementia was too tired or showed signs of distress. The researcher returned to complete the assessment at a later date if the dyad consented.

Contact details for the person with dementia's GP were recorded (Appendix 5.18), so that they could be notified of the person's involvement in the study (GP letter, Appendix 5.19).

### **7.1.11 Ethical arrangements**

The trial ethics application was submitted to East London 3 Research Ethics Committee (REC) (ref no. 10/H0701/71) in January 2010, registered as a clinical trial (ISRCTN 65945963) in May 2010, and provisionally granted approval in July 2010. The committee requested further information and modifications regarding the following points:

- Information sheets for participants (see information sheet for carer, Appendix 5.20 and information sheet for people with dementia, Appendix 5.21) were altered to include permission for video recordings, information about the nature of the TAU allocation group, and minor changes to some of the language and terminology used.
- Consideration of the potential for TAU participants to receive iCST materials after their participation in the trial.
- Confirmation of whether leaflets and posters would be used as recruitment tools.
- Include more information about interviews on the consent forms for participants.

Further to these amendments full ethical approval was issued in September 2010 (see approval letter, Appendix 1). All other sites received approval for participation according to local research governance procedures involving local REC and NHS R&D departments. All researchers working on the trial had Good Clinical Practice (GCP) training.

#### 7.1.11.1 Risks and anticipated benefits

There appear to be no documented harmful side effects from participating in CST groups, nor were any serious adverse reactions apparent in the CST (Spector *et al.*, 2003), or maintenance CST (Orrell *et al.*, 2014) studies. Benefits such as enjoyment, feelings of validation, enhanced self-worth and improvements in verbal fluency have been consistently reported by those who have participated in CST groups (Spector *et al.*, 2011). It was expected that taking part in the iCST programme would yield similar benefits, and

furthermore positive outcomes, such as feeling empowered, for the carers delivering the sessions. Dyads were fully informed of the potential risks and benefits of participating in the study prior to providing written consent.

A standard procedure was in place to ensure that any serious adverse events (SAE) involving a carer or person with dementia were reported to the Chief Investigator (MO). Researchers were usually made aware of SAEs during follow up assessment visits, or during treatment support contacts. Upon being informed of the occurrence of a SAE, researchers notified the Trials Co-Ordinator (VO) and Chief Investigator (MO) who then assessed its severity, and whether it could be attributed to participation in the trial. A reporting form was developed (see Appendix 5.22) to document each SAE. This could be submitted electronically or as a hard paper copy. Hard copies of the documents were stored in the trial master file at each site. An SAE was defined as; 'an untoward occurrence experienced by either a participant or carer which:

- resulted in death,
- was life threatening,
- required hospitalisation or prolongation of existing hospitalisation,
- resulted in persistent or significant disability or incapacity,
- was otherwise considered medically significant by the investigator,
- fell within the scope of the Protection of Vulnerable Adults protocol, which is in place to ensure that suspected cases of abuse or neglect are followed up in an appropriate manner.

SAEs deemed related to trial participation and unexpected had to be reported to REC and the trial DMEC within 15 days of being made aware of the event.

#### **7.1.11.2 Consent**

People with dementia recruited into the trial were in the mild to moderate stages of dementia, and would therefore generally be expected to be able to give informed consent for participation, provided that the nature and purpose of the research is explained fully, and ample time is allowed for them to consider their decision. Written consent from both the carer and person with dementia was taken at the baseline assessment (see carer consent, Appendix 5.23 and person with dementia, Appendix 5.24). The researcher allowed as much time as was necessary for the dyad to discuss the study, and ask any questions about their participation. It was made clear that deciding not to participate, or choosing to withdraw from the study would not disadvantage them in terms of services available or future research opportunities.

Current guidance from the British Psychological Society (BPS) on evaluation of capacity was followed. The guidelines state that consent must be regarded as a continuing process rather than a one-off decision, thus willingness to participate was checked during the assessments. In cases where the person with dementia's level of impairment increased, so they were deemed no longer to provide informed consent, the provisions of the Mental Capacity Act (Department of Health, 2005) were followed. Providing informed consent at the beginning of the study was viewed as an indication of the person's likely opinion on continuing participation in the research should they reach this point, and the carer was consulted.

#### **7.1.12 Outcome measures**

Cognition and quality of life are the key outcomes of interest for the trial. Dyads were assessed at baseline (pre-iCST, BL), 13 weeks after BL (FU1), and 26 weeks after BL (FU2). The purpose of FU1 was to safeguard data against loss to follow up. The chosen duration of 26 weeks was long enough to allow for measurable deterioration in dementia and assess the impact on overall costs of care.

#### 7.1.12.1 Primary outcome measures

- a) Cognition was measured using the ADAS-Cog (Rosen *et al.*, 1984)(Appendix 5.6.2). The ADAS-Cog consists of 11 tasks assessing disturbances of memory, language, praxis, attention, and other cognitive abilities, referred to as the core symptoms of Alzheimer's Disease (AD). The higher the score (0-70), the more cognitively impaired the individual. The measure is widely used, has good reliability and validity (Weyer *et al.*, 1997). The ADAS-Cog is often used in clinical trials of drug treatments for dementia, thus it was selected as a primary outcome measure to allow for comparison of the effects of iCST to anti-dementia medication.
- b) Quality of life (QoL) was measured using the Quality of Life Alzheimer's disease Scale (QoL-AD) (Logsdon, Gibbons, & McCurry, 1999)(Appendix 5.6.2), which consists of 13 domains of QoL including; physical health, energy, mood, living situation, memory, family, marriage, friends, chores, fun, money, self, and life as a whole. The person with dementia is asked to rate each domain as 'Poor' (1 point), 'Fair' (2 points), 'Good' (3 points) or 'Excellent' (4 points). Scores can range from 13-52, with a higher score indicating higher perceived QoL. The person with dementia was given a laminated card showing the possible responses to prompt them during the assessment. The measure was selected as an appropriate primary outcome measure because it has good internal consistency, validity, and reliability, (Logsdon *et al.*, 1999; Thorgrimsen *et al.*, 2003) and is recommended by the European consensus on outcome measures for psychosocial interventions in dementia (Moniz-Cook *et al.*, 2008).

#### 7.1.12.2 Secondary outcome measures

- a) Cognition was also measured using the MMSE (Folstein, Robins, & Helzer, 1983)(Appendix 5.6.2). The MMSE is widely used in both clinical practice and research (Burns, Lawlor, & Craig, 2004). The MMSE is a brief measure of cognition comprising of tests of; orientation (place, time, location), registration, attention and calculation, recall, language (naming, repetition), three-stage command, reading, writing, and copying.

Scores range from 0-30 points, with a higher score indicating less impairment. Criterion and concurrent validity, inter-rater and test-retest reliability were established in Folstein's study. Tombaugh & McIntyre (1992) also credit the measure with good reliability and validity.

- b) The Dementia Quality of Life (DEMQOL)(Smith *et al.*, 2005) (Appendices 5.6.2 and 5.6.4) scale was selected as a secondary quality of life measure. The scale uses self-rated reports of QoL administered to the person with dementia by a trained interviewer. The DEMQOL measures five domains; health and wellbeing, cognitive functioning, social relationships, and self-concept on a four point scale ('Not at all', 'A little', 'Quite a bit', 'A lot'). It has high internal consistency (0.87), acceptable inter-rater reliability (ICC 0.84), and good concurrent validity with moderate associations with the QoL-AD. It has been included as a QoL scale and a utility measure as an algorithm is now available to convert the DEMQOL and DEMQOL-Proxy into utility scores.
- c) Behavioural and psychological symptoms were assessed using the Neuropsychiatric Inventory (NPI) (Cummings *et al.*, 1994) (Appendix 5.6.6). Ten behavioural disturbances commonly occurring in people with dementia are measured, including delusions; hallucinations; dysphoria; anxiety; agitation / aggression; euphoria; disinhibition; irritability / lability; apathy; and aberrant motor behaviour. The measure is administered in a structured interview format with a caregiver familiar with the person's behaviour. The carer is first asked about the presence of each symptom. If the person does not show this symptom, the researcher moves on to the next question. If the behaviour is present, the informant is asked to select from a list of specific examples of the disturbance. Multiple examples can be selected. The frequency (range 1-4) and severity (range 1-3) of the disturbance in the last month, and how much distress the carer experiences (range 0-5) as a result, are also rated. These dimensions are scored as '0' if the behaviour is not present. If the behaviour is present the scores for frequency and severity are multiplied (possible scores range from 1 to 12) to indicate whether the behaviour is a significant

problem. Generally a score of nine or above indicates a significant problem. The measure is reported to have content and concurrent validity and between rater, test-retest, and internal consistency reliability (Cummings *et al.*, 1994). Furthermore it has shown to be sensitive to behavioural changes, and has been recommended by the INTERDEM group (Moniz-Cook *et al.*, 2008).

- d) Functional ability of the person with dementia was measured using the Bristol Activities of Daily Living Scale (BADLS) (Bucks, Ashworth, Wilcock, & Siegfried, 1996) (Appendix 5.6.4), a carer-rated instrument assessing 20 daily living abilities. The items were rated as important by carers, who also generated the levels of ability, giving the measure good face validity. The measure has also been demonstrated to have construct and concurrent validity, and good test-retest reliability as measured by Cohen's Kappa. The BADLS shows sensitivity to change in people with AD taking anticholinesterase medication, and is associated with changes in the ADAS-Cog and MMSE (Byrne, Wilson, Bucks, Hughes, & Wilcock, 2000).
- e) Depressive symptoms were measured by the Geriatric Depression Scale (GDS-15) (Sheikh & Yesavage, 1986) (Appendix 5.6.2). The shorter version of the scale was selected, which comprises of 15 easy-to-use items requiring yes/no answers. The scale excludes somatic symptoms of depression that may also be observed in non-depressed elderly people. Although principally a self-rating scale, the GDS-15 was administered by the researcher. The scale has acceptable sensitivity and specificity in people with mild to moderate dementia (Lach, Chang, & Edwards, 2010).
- f) Relationship quality was measured by the quality of the care giving Relationship (QCPR) (Spruytte, van Audenhove, Lammertyn, & Storms, 2002). Both the person with dementia (Appendix 5.6.2) and the carer (Appendix 5.6.3) completed this measure. The scale is comprised of 14 items designed to assess warmth and levels of conflict and criticism in the care giving relationship. Respondents indicate the strength of their agreement or

disagreement with each item on a five-point scale. The QCPR has good internal consistency for carers, and people with dementia (Woods *et al.*, 2009) and concurrent validity with other measures of relationship quality (Spruytte *et al.*, 2002).

### **7.1.13 Analyses**

#### **7.1.13.1 Primary effectiveness analyses**

An intention-to-treat (ITT) analysis was carried out, in that all available data was included. Sample size calculations were based on the numbers estimated to be available at the study primary end-point (FU2) 26 weeks after randomisation into the iCST intervention group, or TAU control.

An analysis of covariance (ANCOVA) was conducted to evaluate any differences between the iCST and TAU group in the primary outcome measures for people with dementia (cognition, ADAS-Cog; QoL, QoL-AD). The dependent variable was the outcome at FU2. Baseline measurement, age of people with dementia, and their relationship with their carer were fitted as covariates as it was thought that they may influence outcome variables. Using an analysis model which accounts and controls for the effect of covariates allows for better investigation of the effects of the independent variable. The odds of a Type II error occurring are reduced using this method because the amount of variance in the dependent variable attributable to known variables other than the experimental treatment (iCST) is minimised. The overall error variance is reduced as more of the variance can be explained by the covariates. In order to control for covariates, the analysis model adjusts each group mean on the dependent variable so that the model estimates how the experimental and intervention groups would have performed if their group means on the covariate were identical (Vogt, 1999). Fitted fixed factors included gender, marital status, and anticholinesterase inhibitor status. Centre was fitted as a random factor. Centre and anticholinesterase inhibitors were also used as stratification variables.

#### 7.1.13.2 Secondary effectiveness analyses

In addition to the primary outcomes, effectiveness analyses were performed on all secondary outcomes. The ANCOVA models for the data from people with dementia and carers were similar to those fitted for the primary outcomes.

#### 7.1.13.3 Adherence analyses

The number of iCST sessions was factored into the model of the main analysis as a continuous variable to determine whether number of sessions completed was associated with the outcomes.

#### 7.1.13.4 Data entry

Data from assessments was entered into MACRO, a web-based data capture system, by blind researchers at each of the sites. Treatment adherence data was entered into the system by unblind researchers. Blind researchers were unable to access the treatment adherence data held on MACRO to maintain blindness to participant treatment allocation. Throughout the trial, data entry was closely monitored, and regular audits were conducted by the team at the London site (JS, LY, FH). The purpose of these audits was to minimise the occurrence of missing data points where possible. All researchers were trained to use MACRO, and were given user guides for the system. They were also able to contact the London researchers (JS, LY, FH, PL) and designated members of staff from NWORTH (DH, AB) to discuss any queries if necessary. This system meant that data entry was generally accurate and missing data minimal. The data was directly extracted from MACRO into SPSS (SPSS PASW version 20, IBM Corporation, New York) for analysis.

Adherence data was also entered onto MACRO by unblind researchers. Blind researchers were not authorised to access the unblind data entry database. Adherence data was factored into the main and economic analyses. Upon completion of the data entry, a trial statistician

(SK) conducted ‘data cleaning’ whereby any inconsistencies were identified and resolved where possible by checking the hard copies of the assessment packs. LY was the main contact and co-ordinated data queries across sites. CSRI data was cleaned and analysed using Stata 13 software.

#### 7.1.13.5 Treatment of missing data

Missing data constituted both missing items within outcome measures, and missing measures at any of the assessment time-points (BL, FU1, FU2). The LOCF (last observation carried forward) method of imputation was considered inadequate for use in this trial as in dementia, it is expected that those receiving TAU will decline cognitively, and participants will be lost through death and illness. Missing data rules specific to each measure were followed in the case of missing items. Pro-rating was employed within measures in cases where 20% of items were missing. For example, if one item was missing on a five-item scale, the mean of the other items was assigned to the missing item.

In order to account for missing measures at time points, regression within the group (iCST or TAU) was applied to impute summary scores in accordance with the trend observed in the group. Multiple imputations were made to enable assessment of the sensitivity of the data. The multiple imputation model incorporated demographic variables (e.g., gender, age, ethnicity, type of relationship, centre) and completed scores for other outcome measures at each time point. BL scores were used to predict FU1 scores, and in turn scores at BL and FU1 were used to predict FU2 scores.

## **Chapter 8**

### **Results of the main randomised controlled trial (RCT)**

This chapter describes the results of the evaluation of the effectiveness of the individual Cognitive Stimulation Therapy (iCST) intervention, which were also reported in the Health Technologies Assessment (HTA) report and a submitted journal article:

Orgeta, V., Leung, P., Yates, L. et al. (2015). Individual cognitive stimulation therapy for dementia: a clinical effectiveness and cost-effectiveness pragmatic, multicentre, randomised controlled trial. *Health Technol Assess*, 19(64).

Orrell, M., Yates, L., Leung, P. et al. Individual cognitive stimulation therapy for dementia (iCST): a single-blind, multi-centre, pragmatic randomised controlled trial. (submitted)

#### **8.1 Participant flow and response rate**

##### **8.1.1 Recruitment of participants**

Recruitment into the trial took place between April 2012 and July 2013. The response rate and reasons for losses between referral and randomisation are shown in Table 8.1. Across the eight study sites, 1340 participants were approached and screened. Of these, 356 provided consent, completed baseline assessments and were randomised (iCST vs. treatment as usual [TAU]) giving a conversion rate of 27%. The main reason for failure of referrals to become active participants in the trial was the dyad not wishing to be involved (24%). The sample was randomised on a roughly 1:1 basis, with 180 dyads in the iCST group, and 176 in the control group. Table 8.2 provides a breakdown of referrals to randomisations per site. The four original sites (London, Bangor, Hull, Manchester) recruited 73% of the total number of participants, with the four additional sites (Dorset, Devon, Lincolnshire, Norfolk & Suffolk) contributing the remaining. Dorset had the highest conversion rate from referral to active participant.

*Table 8.1 Response rate and losses between referrals and randomisation*

<b>Reason</b>	<b>Total (%)</b>
Total referred or screened	1340
Does not wish to take part	320 (24)
iCST exclusion criteria apply	295 (22)
Dyad approached has not responded	215 (16)
Could not make contact / reason not known or disclosed	53 (4)
Not available due to holiday, family or work commitments	33 (2)
Health problems for dyad	21 (2)
Prefers group activities or does activities at home or considers treatment not suitable	18 (1)
Already participating in similar study	16 (1)
Distressed during interview	4 (< 1)
Family not discussing diagnosis	3 (< 1)
Moved out of the area	3 (< 1)
Person with dementia has died	3 (< 1)
<b>Total lost between referral/screening and randomisation</b>	<b>984 (73)</b>
<b>Total number randomised</b>	<b>356</b>
<b>Conversion rate</b>	<b>27%</b>

### **8.1.2 Sources of referrals**

The main sources of referrals were memory clinics (45%), consultant psychiatrists

(23%), and Community Mental Health Teams (CMHT) (9%). Table 8.3 shows a detailed breakdown of referral sources.

*Table 8.2 Referrals and randomisations per centre*

Centre	Total referrals	Total randomisations (%)
London	255	127 (50)
Bangor	296	35 (12)
Hull	111	45 (40)
Manchester	482	53 (11)
Dorset	29	20 (69)
Lincolnshire	36	20 (55)
Norfolk & Suffolk	83	28 (34)
Devon	48	28 (58)
<b>Total</b>	<b>1340</b>	<b>356</b>

### 8.1.3 Participant flow

The flow of participants through the trial is shown in Figure 8.1. A small number of dyads (16) dyads were lost to follow up 1 (FU1). The majority of withdrawals from the trial occurred after randomisation, with the main reason being dissatisfaction with the intervention or difficulty engaging in the activities. Treatment allocation is shown in relation to participant flow in Figure 8.2. Rates of withdrawal and drop out at FU1 and follow up 2 (FU2) were similar in both the intervention and control groups.

### 8.1.4 Follow-up retention rates at FU1 and FU2

A total of 83 dyads withdrew over the course of the trial. Of the 68 dyads lost between randomisation and FU1, 52 withdrew completely (Table 8.4). Sixteen dyads did not

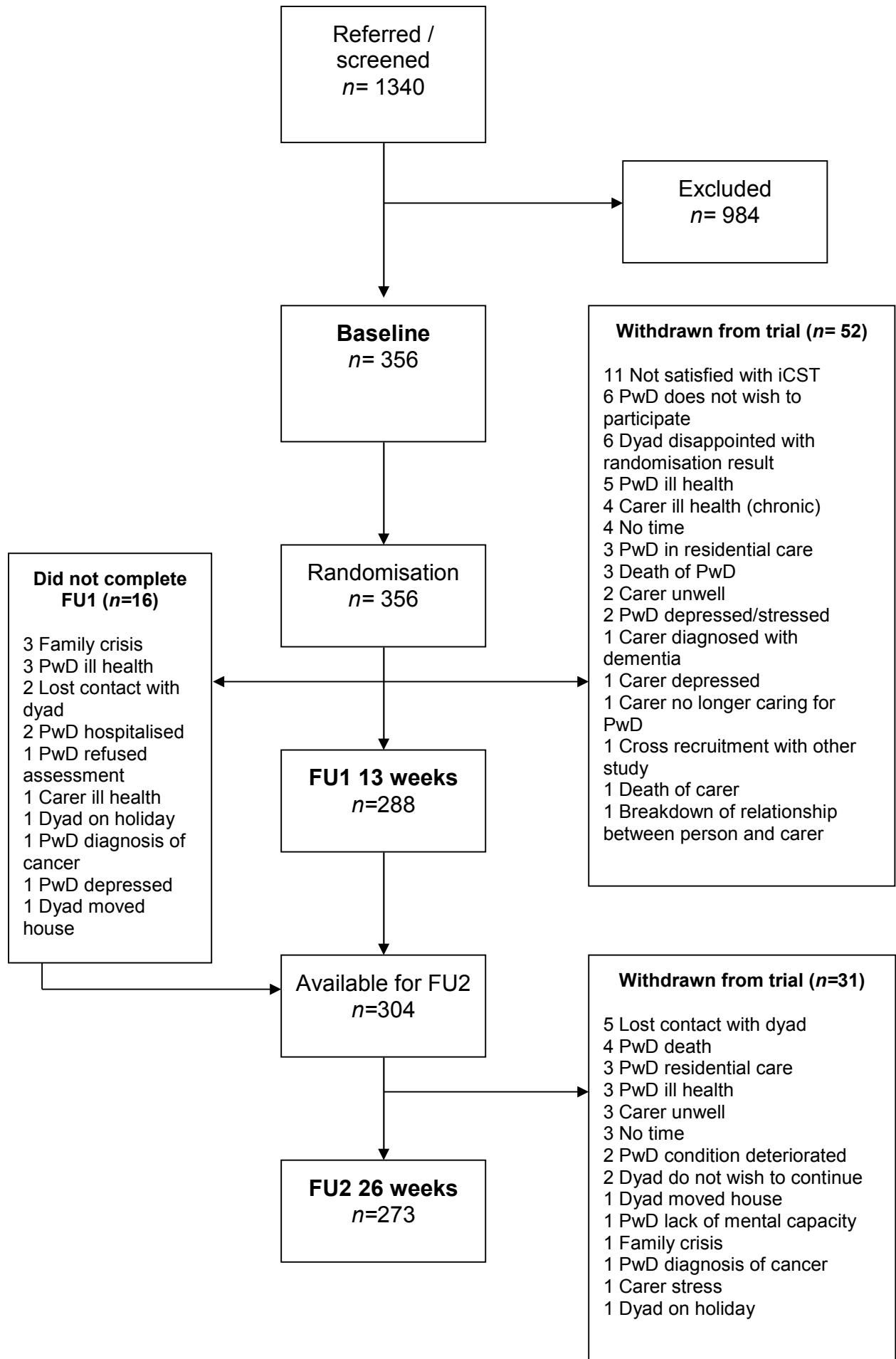
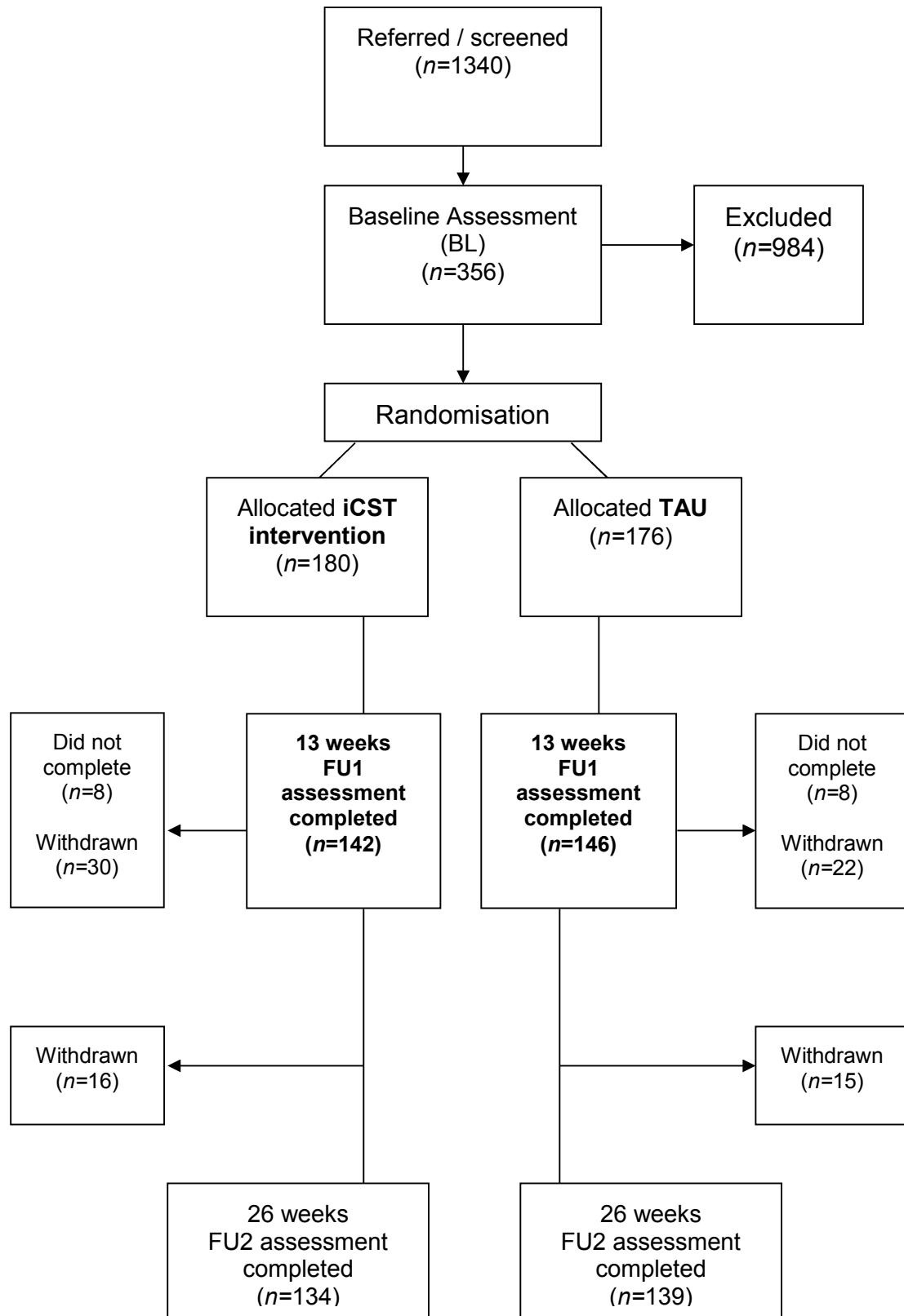


Figure 8.1 Participant flow through the trial.



*Figure 8.2 Participant flow through the trial with treatment allocation.*

*'Withdrawn'* indicates participants withdrawal from trial and all associated research activities.  
*'Did not complete'* indicates participants who missed FU1 assessment but returned for FU2

complete FU1 but returned to complete FU2. At FU2 an additional 31 dyads withdrew, of which four were deaths.

*Table 8.3 Sources of referrals*

Source	Total (%)
Memory Clinic	602 (45)
Consultant Psychiatrist referral	315 (23)
CMHT	119 (9)
Clinical Studies Officer DeNDRoN (Dementias and Neurodegenerative Diseases Network)	67 (5)
Consultant Psychologist referral	57 (4)
Alzheimer's Society	52 (4)
Primary care Dementia Practitioner	41 (3)
Previous studies	25 (2)
Local Voluntary Organisation	20 (1)
Carers Support Services/Association	19 (1)
Age Concern	10 (< 1)
Newspaper article/media release	7 (< 1)
Local day centre	4 (< 1)
Admiral Nurse	2 (< 1)
<b>Total</b>	<b>1340</b>

Analysis revealed no significant differences in retention rate between centres at either FU1 ( $\chi^2=11.9$ ;  $df = 11$ ;  $p=0.37$ ) or FU2 ( $\chi^2=12.5$ ;  $df = 11$ ;  $p=0.33$ ). Retention rates were higher than 70% across all sites with an overall retention rate for the trial of 77%.

Fewer dyads withdrew in the control (37, 21%) than in the intervention group (46, 25%). Analyses to determine whether there were significant differences in baseline characteristics

were performed including: gender, ethnicity, marital status, relationship with the person with dementia, living status (e.g., ‘with the person’, ‘other’, ‘alone’), and highest level of education. Again, no significant differences were found in the characteristics of the groups.

*Table 8.4 Follow up retention rates per centre*

Centre	Baseline	Completed 13 weeks FU1 (retention rate) (%)	Completed 26 weeks FU2 (retention rate) (%)
London	127	101 (79)	96 (76)
Bangor	35	30 (86)	31 (89)
Hull	45	34 (75)	32 (71)
Manchester	53	39 (74)	37 (70)
Dorset	20	18 (90)	18 (90)
Lincolnshire	20	16 (80)	14 (70)
Norfolk & Suffolk	28	26 (93)	23 (82)
Devon	28	24 (86)	22 (79)
<b>Total</b>	<b>356</b>	<b>288 (81)</b>	<b>273 (77)</b>

## 8.2 Description of the sample

Demographic information for people with dementia and carers is shown in Tables 8.5, 8.6, and 8.7. Overall, the mean age of people with dementia was 78.20 years (Table 8.5), 165 (46%) were female, and the majority were either married, cohabiting or in civil partnerships (252, 71%). The sample of people with dementia and carers was predominantly white ( $n=331$ , 93%;  $n=329$ , 92% respectively). More spousal carers participated than non-spousal carers (e.g., friends, children). Of the 130 non-spousal carers, 113 (31.7%) were the children of, or the person’s son/daughter-in-law, or their sibling (brother/sister). The remaining carers were described as ‘other relationship’ ( $n=9$ , 2.5%), or ‘other relative’ ( $n=8$ , 2.2%). Two hundred and seventy people were taking anti-dementia medication at baseline with roughly

equal numbers in iCST ( $n=136$ ) and TAU ( $n=134$ ) demonstrating stratification in the randomisation model effectively distributed.

*Table 8.5 Age of people with dementia and carers. \* Data missing for these groups*

	Total			iCST			TAU		
	n	Mean	SD	n	Mean	SD	n	Mean	SD
Person with dementia	356	78.20	7.49	180	78.40	7.30	176	78.00	7.70
Carer	353*	65.73	12.92	179	66.01	12.76	176	65.49	13.11
Spousal carer	223*	72.80	7.89	112	73.11	7.57	111	72.50	8.22
Non-spousal carer	130	53.66	10.80	67	54.13	10.67	63	53.16	11.00

*Table 8.6 Person with dementia demographics*

Characteristic	Total	iCST (%)	TAU (%)
Female person with dementia	165/356 (46)	83/180 (50)	82/176 (50)
Ethnicity White	331/356 (93)	164/180 (50)	167/176 (50)
Marital Status:	252/356 (71)	125/180 (50)	127/176 (50)
married/cohabiting/civil partnership			
Lives with spouse/partner	225/356 (63)	113/180 (50)	112/176 (50)
Highest level of education school leaver (14-16 years)	213/356 (60)	113/180 (53)	100/179 (47)
Taking anti dementia medication	270/356 (76)	136/180 (76)	134/176 (76)

*Table 8.7 Carer demographics*

<b>Characteristic</b>	<b>Total</b>	<b>iCST (%)</b>	<b>TAU (%)</b>
Female carer	261/356 (73)	135/180 (52)	126/176 (48)
Ethnicity White	329/356 (92)	164/180 (50)	166/176 (50)
Marital Status: married/cohabiting/civil partnership	297/356 (84)	149/180 (50)	148/176 (50)
Lives with spouse/partner	236/356 (66)	119/180 (50)	117/176 (50)
Highest level of education school leaver (14-16 years)	156/356 (45)	79/180 (50)	80/179 (50)

Table 8.8 shows the gender mix of dyads. The most common gender profile of dyads was a female carer participating alongside a male person with dementia ( $n=179$ , 50%). Dementia diagnoses are described in Table 8.9. The most common diagnosis amongst the sample was Alzheimer's Disease (AD) (64%), followed by vascular dementia (VaD) (11%). Details of diagnosis were not obtained for 41 people (12%).

*Table 8.8 Gender mix of dyads*

<b>Gender of person with dementia</b>		
<b>Gender of carer</b>	<b>Female (%)</b>	<b>Male (%)</b>
Female	82 (23)	179 (50)
Male	83 (23)	12 (3)
<b>Total</b>	<b>165</b>	<b>191</b>

*Table 8.9 Dementia diagnoses*

Diagnosis	Total (%)	iCST (%)	TAU (%)
AD	227/355 (64)	108/179 (60)	119/176 (68)
VaD	40/355 (11)	18/179 (10)	22/176 (13)
Lewy body	11/355 (3)	5/179 (3)	6/176 (3)
Mixed AD and VaD	36/355 (10)	22/179 (12)	14/176 (8)
Not known	41 (12)	26/179 (15)	15/176 (8)

Seventy percent of the sample had a Clinical Dementia Rating (CDR) score of '1', indicating 'mild dementia' (Morris, 1993). Twelve percent were assessed as having 'moderate dementia' (CDR=2), and 18% as very mild dementia (CDR=0.5). Mini Mental State Examination (MMSE) scores were also used as a measurement of severity of dementia (Folstein, Robins, & Helzer, 1975). The mean MMSE score was 21.23 ( $SD=4.30$ ) for the overall sample, 21.12 ( $SD=4.48$ ) for the iCST group, and 21.33 ( $SD=4.11$ ) for the TAU group.

### **8.3 Perception of allocation of dyads by unblind researchers**

Researchers conducting the follow up assessments were asked to record whether they thought dyads had been assigned to the iCST or TAU groups on a Likert-type scale ('definitely in iCST group', 'more likely to be in the iCST group', 'equally likely to be in iCST or TAU', 'more likely to be in TAU group', 'definitely in TAU group'). Table 8.10 shows ratings collected at FU1 ( $n=264$ ). Sixty percent were neutral (equally likely to be in iCST or TAU) suggesting in the majority of cases no evidence of allocation was disclosed to researchers. Twenty-three percent of ratings were correct judgements of allocation (7% 'definite') compared to 17% incorrect judgements (5% 'definite').

*Table 8.10 Blind researcher perception ratings at FU1 (n=264)*

<b>Researcher Judgement</b>	<b>iCST (%)</b>	<b>TAU (%)</b>	<b>Total (%)</b>
Correct 'definite'	13 (12)	6 (4)	19 (7)
Correct 'more likely'	14 (13)	28 (18)	42 (16)
Equally likely to be in iCST or TAU	68 (65)	92 (58)	160 (60)
Incorrect 'more likely'	11 (10)	20 (13)	31 (12)
Incorrect 'definite'	0	12 (7)	12 (5)
<b>Total</b>	<b>106</b>	<b>158</b>	<b>264</b>

Slightly fewer ratings ( $n=255$ ) were collected at FU2 (Table 8.11), but they remained consistent with the patterns observed at FU1. Fifty-seven percent of the ratings were neutral. Again 23% judgements were correct, of which 10% were 'definite'. Twenty percent of judgements were incorrect.

*Table 8.11 Blind researcher perception ratings at FU2 (n=255)*

<b>Researcher Judgement</b>	<b>iCST (%)</b>	<b>TAU (%)</b>	<b>Total (%)</b>
Correct 'definite'	22 (19)	4 (3)	26 (10)
Correct 'more likely'	17 (15)	17 (12)	34 (13)
Equally likely to be in iCST or TAU	65 (57)	80 (57)	145 (57)
Incorrect 'more likely'	10 (9)	31 (22)	41 (16)
Incorrect 'definite'	0	9 (6)	9 (4)
<b>Total</b>	<b>114</b>	<b>141</b>	<b>255</b>

#### **8.4 Analysis of primary outcomes**

Analysis of covariance (ANCOVA) was performed for each of the measures. The 26-week primary end point of the study (FU2) was the dependent variable, and the centre was used as the random factor in the model. Marital status, living status, the gender of the participant,

use of anti dementia medication, and treatment allocation were the fixed factors. Age, baseline outcome score, and dyad relationship were fitted covariates in the model. The same model was applied to outcomes at the shorter-term 13-week follow up (FU1). Table 8.12 shows the mean values for the iCST and TAU groups at baseline (BL), 13, and 26 weeks.

Data from the outcome measures for the iCST and TAU groups at FU1 and FU2, including ANCOVA group means, mean differences, number of cases with missing data, 95% confidence intervals (CIs) of mean differences, and *p*-values after adjusting for baseline outcome measures and covariates are shown in Tables 8.13 and 8.14. Complete case data is presented, as there was little difference between imputed value data and complete data.

A regression model analysis was performed in which the entire data set ( $n=356$ ) at each point was imputed. Different methodology can be applied to different types of missing data (e.g., death, illness). However, all missing data was treated with the same imputation method. There was no significant difference between the results of the original data and imputed model.

#### **8.4.1 Primary outcomes**

Analysis demonstrated no significant difference between the iCST and TAU groups at either FU1 (MD=0.29, 95% CI -1.10-1.68,  $p=0.68$ ) (Table 8.13) or FU2 (MD=-0.55, 95% CI -2.00-0.90,  $p=0.45$ ) (Table 8.14) for cognition measured by the ADAS-Cog. The estimated adjusted marginal means decreased more in the iCST group (-1.97) than the TAU (-1.13) group between FU1 and FU2, which is indicative of improvement on this measure. There was no significant difference in QoL (QoL-AD) between iCST and TAU groups at FU1 (MD=-0.14, 95% CI -1.12-0.84,  $p=0.78$ ) or FU2 (MD=-0.02, 95% CI -1.04-1.00,  $p=0.97$ ).

Table 8.12 Unadjusted means for each of the outcome measures for iCST and TAU at FU1 & FU2. Mis.=missing data, SD= standard deviation

Outcome measure	Baseline				13 weeks				26 weeks			
	N	iCST	N	TAU	N	iCST	N	TAU	N	iCST	N	TAU
	Mis.	N=180	Mis.	N=176	Mis.	N=142	Mis.	N=146	Mis.	N=134	Mis.	N=139
<i>Person with dementia</i>												
ADAS Cog	1	21.47(9.22)	1	19.79 (8.03)	4	20.86 (9.73)	6	19.50 (8.97)	6	20.69 (9.39)	5	20.39 (9.91)
QoL-AD		38.01 (5.44)		37.96 (6.04)	2	37.90 (5.52)	2	38.09 (5.63)	5	37.86 (5.13)	1	37.71 (5.91)
DemQoL	3	93.85	3	92.18	7	94.08	4	94.05	6	95.46	3	95.12 (11.11)
		(11.76)		(13.55)		(10.92)		(11.80)		(11.17)		
NPI total		11.21		10.99	2	10.67		12.07	1	11.57	1	11.59 (12.80)
		(13.96)		(11.98)		(13.30)		(12.61)		(13.72)		
GDS 15	3	3.14 (2.64)	3	3.16 (3.15)	9	2.98 (2.56)	3	3.03 (2.86)	8	2.90 (2.55)	3	2.85 (2.67)
QCPR total	6	55.17 (8.89)	2	56.72 (8.73)	4	56.30 (8.98)	3	55.82 (9.06)	3	56.88 (8.59)	1	55.55 (10.25)
QCPR Warmth	1	33.19 (5.08)	1	33.98 (5.20)	1	33.32 (5.49)		33.25 (5.38)	1	33.78 (4.97)		33.07 (5.92)
QCPR Criticism & conflict	1	22.07 (4.78)	1	22.69 (4.66)	1	22.80 (4.46)		22.54 (4.75)		22.95 (4.59)		22.46 (5.15)
MMSE		21.12 (4.48)		21.33 (4.11)	1	20.59 (5.02)	2	20.89 (4.83)	4	20.68 (4.76)	1	21.19 (5.21)
BADLS [P]		5.16 (5.45)		4.49 (4.09)		14.53	1	13.55 (8.20)	3	15.39	1	14.56 (8.86)
						(10.34)				(10.78)		
QoL-AD [P]	0	32.88 (6.83)		33.09 (6.22)	1	32.64 (6.25)	2	31.93 (5.84)	1	32.46 (6.20)		31.99 (6.30)
DemQoL [P]	1	97.99	2	98.59	2	99.26	1	98.75	1	99.42	1	98.18 (12.80)

(13.17)

(12.76)

(12.38)

(11.96)

(12.41)

*Table 8.13* The means (& 95% CI) comparing the iCST and TAU for person with dementia outcome measures at FU1 after adjusting for the baseline outcome measures. (Complete case data is presented due to little difference between this and imputed data results)

*MD=Mean difference, Missing= Number of cases with missing data,[P]=Proxy rated measure \* Significant difference at 5% level, CI=confidence interval*

<b>FU1</b>	<b>Missing</b>	<b>iCST (N=142)</b>	<b>TAU (N=146)</b>	<b>MD</b>	<b>95% CI of MD</b>	<b>p value</b>
ADAS-Cog	10	22.00	21.71	0.29	(-1.10, 1.68)	0.68
QoL-AD	4	38.40	38.54	-0.14	(-1.12, 0.84)	0.78
DEMQoL	11	91.72	92.05	-0.33	(-2.31, 1.65)	0.74
NPI [P]	2	12.27	13.72	-1.45	(-3.68, 0.76)	0.20
GDS-15	12	3.27	3.36	-0.09	(-0.56, 0.38)	0.71
QCPR total	7	56.62	55.52	1.10	(-0.15, 2.35)	0.09
QCPR warmth	1	34.04	33.65	0.39	(-0.43, 1.21)	0.36
QCPR criticism & conflict	1	22.49	21.85	0.64	(-0.10, 1.36)	0.09
MMSE	3	20.32	20.16	0.16	(-0.60, 0.92)	0.69
BADLS [P]	1	12.73	12.93	-0.20	(-1.44, 1.04)	0.75
QoL-AD [P]	3	32.66	31.91	0.75	(-0.27, 1.77)	0.15

DemQoL [P]	3	99.28	98.73	0.55	(-1.70, 2.80)	0.64
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*Table 8.14* The means (95% CI) comparing the iCST and TAU for person with dementia outcome measures at FU2 after adjusting for the baseline outcome measures (Complete case data is presented due to little difference between this and imputed data results), *MD=Mean difference, Missing= Number of cases with missing data,[P]=Proxy rated measure.\* Significant difference at 5% level*

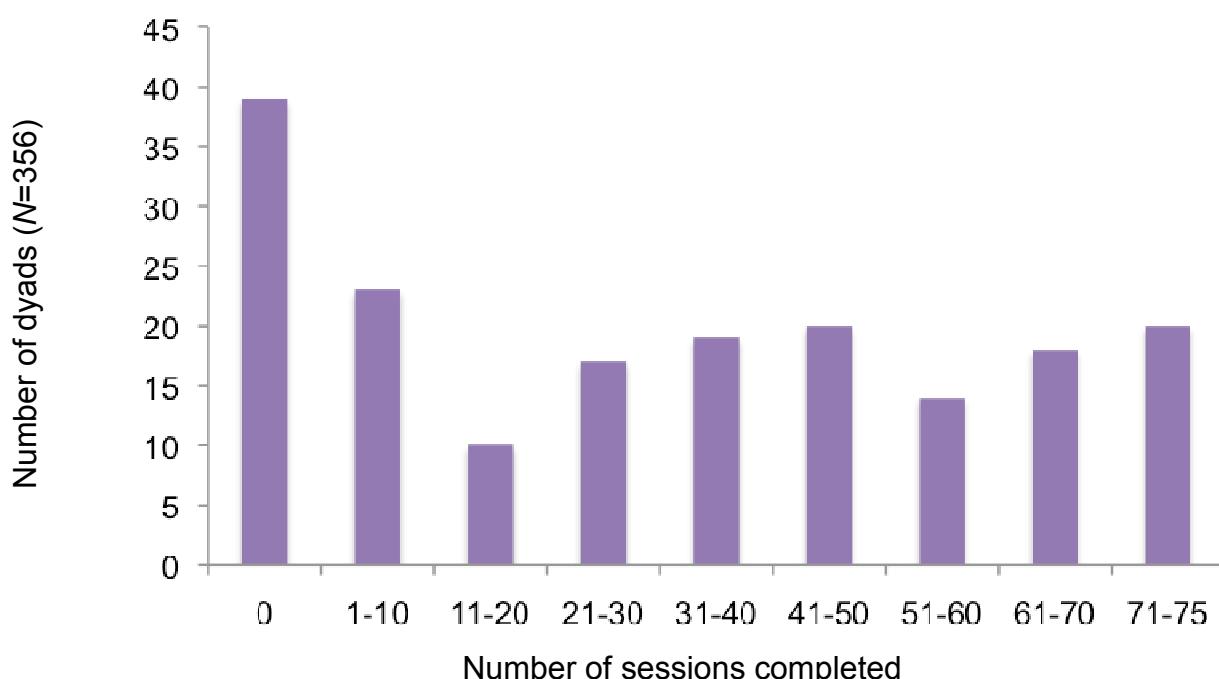
FU2	Missing	iCST (N=134)	TAU (N=139)	MD	95% CI of MD	p value
ADAS-Cog	11	20.03	20.58	-0.55	(-2.00, 0.90)	0.45
QoL-AD	6	37.90	37.92	-0.02	(-1.04 ,1.00)	0.97
DEMQoL	9	94.45	94.14	0.31	(-1.62, 2.22)	0.79
NPI [P]	2	8.10	8.42	-0.32	(-2.78, 2.12)	0.79
GDS-15	11	3.29	3.31	-0.02	(-0.51, 0.47)	0.94
<b>QCPR Total *</b>	<b>4</b>	<b>57.42</b>	<b>55.65</b>	<b>1.77</b>	<b>(0.26, 3.28)</b>	<b>0.02</b>
QCPR warmth	1	33.74	32.93	0.81	(-0.11, 1.73)	0.09
QCPR criticism & conflict		23.51	22.65	0.86	(-1.74, 0.02)	0.06
MMSE	5	19.63	20.10	-0.47	(-1.26, 0.30)	0.23
BADLS [P]	4	11.91	12.57	-0.66	(-2.07, 0.75)	0.36
QoL-AD [P]	1	32.45	32.00	0.45	(-0.71, 1.60)	0.448
DemQoL [P]	2	99.67	97.94	1.73	(-0.61, 4.07)	0.149

#### **8.4.2 Secondary outcomes**

Amongst the secondary outcomes, significant improvements were detected in the Quality of the Carer Patient Relationship (QCPR) (Spruytte *et al.*, 2002), total score in the iCST group ( $SMD=1.77$ ; 95% CI 0.26 to 3.28,  $p=0.02$ ) at FU2 (Table 8.14). However, there were no significant differences between the groups for all other secondary outcomes including cognition (MMSE; Folstein, Robins, & Helzer, 1983), quality of life (QoL) (Dementia Quality of Life Scale [DEMQoL]; Smith *et al.*, 2005), behavioural and psychological symptoms (Neuropsychiatric Inventory [NPI]; Cummings *et al.*, 1994), functional ability (Bristol Activities of Daily Living [BADLS]; Bucks *et al.*, 1996), and depressive symptoms (Geriatric Depression Scale [GDS]; Sheikh & Yesavage, 1986).

#### **8.5 Adherence analysis**

Dyads completed up to 75 iCST sessions over 26 weeks. Figure 8.3 shows the number of sessions completed by each intervention dyad. Sixty percent completed less than half of the programme (37.5 sessions). Of these 22% did not complete any sessions.



*Figure 8.3 Number of iCST sessions completed by each intervention dyad*

Exploratory analyses of the relationship between adherence and outcomes were performed. A linear regression model incorporating the total number of sessions completed at each time point was selected to assess this relationship, adjusting for baseline outcome measures. The regression coefficients, pooled coefficients, standard errors, *F*-values (median, low, high), and *p*-values for observed and imputed data are shown in Tables 8.15 and 8.16.

The relationship between number of sessions completed and cognition (ADAS-Cog) was not significant at either time-point. However, number of sessions completed at FU2 was significantly associated with improvement in QCPR total score (*p*<0.01) and QCPR criticism subscale (*p*<0.01). This finding remained significant for the QCPR total score after regression analysis was performed with imputed data. At FU1 only the QCPR criticism subscale was significantly associated with number of sessions completed (*p*<0.01). The QCPR total (*p*=0.06; imputed value *p* range=0.06-0.06), MMSE (*p*=0.10; imputed value *p* range=0.09-0.12) and QoL-AD (*p*=0.08; imputed *p* range=0.08-0.10) did not quite reach significance, but appeared to show a pattern of improvement.

## **8.6 Serious Adverse Events (SAEs)**

Fifty-one serious adverse events (SAEs) were reported to the chief investigator (CI), of which 25 occurred in the iCST group, compared to 26 in the TAU group. Of the total of ten deaths, one was a carer. Forty-four SAEs were related to the person with dementia. None of the reported SAEs were deemed to be associated with the trial.

Table 8.15 Regression coefficient (and Standard Error [SE]) of the association between each person with dementia outcome measure and the number of sessions of iCST attended at FU1 after adjusting for the baseline outcome measures

(P) = Proxy measure

\* Significant difference

+ No missing data so imputed data columns left blank

Measure	Observed data					Imputed data					Median F		Low F		High F	
	FU1	Coefficient	SE	F	p value	Pooled coefficient	SE	F	p value	F	p value	F	p value	F	p value	
Person with dementia																
ADAS-Cog	0.006	0.030	0.042	0.838	0.002	0.030	0.038	0.846	0.005	0.946	0.071	0.790				
QoL-AD	0.019	0.021	0.866	0.353	0.019	0.021	0.824	0.365	0.685	0.409	1.015	0.315				
DEMQoL	-0.021	0.042	0.246	0.620	-0.020	0.042	0.190	0.663	0.122	0.727	0.408	0.524				
NPI total	-0.045	0.048	0.880	0.349	-0.046	0.048	0.903	0.343	0.877	0.350	0.916	0.339				
GDS-15	-0.003	0.010	0.076	0.783	-0.003	0.010	0.055	0.815	0.000	0.986	0.628	0.429				
QCPR total*	0.049	0.026	3.458	0.064	0.049	0.026	3.495	0.063	3.468	0.064	3.546	0.061				
QCPR warmth	0.003	0.018	0.036	0.850	0.003	0.018	0.033	0.856	0.031	0.859	0.043	0.836				
QCPR criticism & conflict*,+	<b>0.043</b>	<b>0.015</b>	<b>8.268</b>	<b>0.004</b>	<b>0.043</b>	<b>0.015</b>	<b>8.383</b>	<b>0.004</b>	<b>8.377</b>	<b>0.004</b>	<b>8.386</b>	<b>0.004</b>				
MMSE	0.026	0.016	2.667	0.104	0.026	0.016	2.764	0.098	2.419	0.121	2.861	0.092				
BADLS (P)+	0.024	0.029	0.671	0.413												
QoL-AD (P)	0.038	0.022	3.015	0.084	0.037	0.022	2.833	0.093	2.782	0.096	3.181	0.076				
DEMQoL (P)	0.019	0.048	0.155	0.694	0.019	0.048	0.160	0.689	0.137	0.711	0.195	0.659				

Table 8.16 Regression coefficient (and SE) of the association between each person with dementia outcome measure and the number of sessions of iCST attended at FU2 after adjusting for the baseline outcome measures

(P) = Proxy measure

\* Significant difference

+ No missing data so imputed data columns left blank

Measure	Observed data					Imputed data								
	FU2					Median F					Low F		High F	
	Person with dementia	Coefficient	SE	F	p value	Pooled coefficient	SE	F	p value	F	p value	F	p value	
ADAS-Cog	-0.013	0.014	0.837	0.361		-0.015	0.015	1.156	0.283	0.633	0.427	1.488	0.224	
QoL-AD	0.008	0.010	0.703	0.402		0.009	0.010	0.659	0.418	0.601	0.439	1.260	0.263	
DEMQoL	0.007	0.019	0.158	0.691		0.008	0.019	0.210	0.647	0.068	0.794	0.352	0.553	
NPI total	-0.002	0.023	0.008	0.927		-0.003	0.023	0.018	0.892	0.004	0.952	0.029	0.865	
GDS-15	0.001	0.005	0.055	0.815		0.002	0.005	0.091	0.763	0.019	0.889	0.270	0.604	
<b>QCPR total*</b>	<b>0.043</b>	<b>0.014</b>	<b>9.184</b>	<b>0.003</b>		<b>0.042</b>	<b>0.014</b>	<b>9.256</b>	<b>0.003</b>	<b>9.016</b>	<b>0.003</b>	<b>9.659</b>	<b>0.002</b>	
QCPR warmth	0.012	0.009	1.973	0.161		0.011	0.009	1.661	0.199	1.557	0.213	1.839	0.176	
<b>QCPR criticism &amp; conflict*<sup>+</sup></b>	<b>0.029</b>	<b>0.008</b>	<b>12.633</b>	<b>0.001</b>										
MMSE	0.006	0.008	0.559	0.455		0.006	0.008	0.447	0.504	0.383	0.536	0.846	0.359	
BADLS (P)	-0.015	0.013	1.254	0.264		-0.015	0.013	1.272	0.260	1.230	0.268	1.413	0.236	
QoL-AD (P)	0.012	0.011	1.225	0.269		0.012	0.011	1.225	0.269	1.225	0.269	1.225	0.269	
DEMQoL (P)	0.013	0.023	0.344	0.558		0.013	0.023	0.326	0.569	0.312	0.577	0.421	0.517	

## **Chapter 9**

### **Discussion**

#### **9.1 Study findings**

This work was based on the data collected as part of a large scale, pragmatic, multi-centre, single-blind, clinical, randomised controlled trial (RCT) evaluating the effectiveness of individual Cognitive Stimulation Therapy (iCST) for people with dementia and their carers. Previously, Cognitive Stimulation Therapy (CST) (Spector *et al.*, 2003) had only been delivered in a group setting by a member of staff or healthcare professional, thus the home-based, family carer-led format of iCST represents an innovation in CST-based approaches. Furthermore, with 356 participating dyads, this is the largest known piece of CST research to date.

iCST did not yield significant cognitive or quality of life (QoL) benefits for people with dementia as hypothesised. In terms of secondary outcomes, there was no evidence that people with dementia allocated iCST experienced improvements in activities of daily living (ADLs), or behavioural, psychological, or depressive symptoms. However, iCST appeared to enhance the quality of relationship between the person with dementia and their carer, from the person with dementia's perspective. When level of adherence to the programme (number of sessions completed) was factored into analyses, it emerged that people with dementia who participated in more sessions were much more likely to experience gains in the quality of the relationship with their carer at 26 weeks.

#### **9.2 Findings in the context of current research**

##### **9.2.1 Relationship quality and communication**

The measure of relationship quality (Quality of the Carer Patient Relationship [QCPR]; Spruytte *et al.*, 2002) was not specified in the original protocol (Orrell *et al.*, 2012). However, it was added as a secondary outcome in response to feedback from carers and people with dementia participating in the field-testing phase, which indicated this was likely to be an area

of benefit. Quayhagen & Quayhagen (2001) reported maintenance of marital interaction in their study of a carer-led cognitive stimulation intervention, as measured by the Marital Needs Satisfaction Scale (Stinnett, Collins, & Montgomery, 1970). This scale was not selected for use in the iCST trial, as our sample was not restricted to spousal carers. Furthermore, Quayhagen & Quayhagen (2001) indicated possible issues with the sensitivity of the measure, given they expected to observe improvements rather than stability in marital interaction following their programme.

The significant improvements observed on the warmth and criticism subscale of the QCPR (Spruytte *et al.*, 2002) may be related to the effective application of the iCST key principle of 'focusing on opinions, rather than facts'. People with dementia can feel 'put on the spot' or criticised if attention is drawn to their inability to recall information, or provision of an incorrect answer to a question. Thus the principle is intended to help carers avoid this by taking a more opinion-based approach in discussions and activities. It may well be that the information provided in the iCST manual including the principles, as well as the training and support provided by the unblind researcher may contribute to carers having a greater understanding of the person's difficulties, encouraging 'warm' interactions and reducing criticism.

The trial provides further evidence that participation in enjoyable activities with a family carer can have a positive effect on the care giving relationship. Hellstrom, Nolan, & Lundh (2005;2007) emphasise the value of taking a 'relationship-centred' approach to care, whereby couples actively manage how they live with dementia together. Carers and people with dementia identified four activities they felt 'sustained couplehood': 'talking things through', 'being appreciative and affectionate', 'making the best of things', and 'keeping the peace'. The iCST programme and key principles correspond elegantly to each of these needs, which may explain why improvements in the quality of the care giving relationship were observed from the perspective of people with dementia. In terms of 'talking things through' iCST activities facilitate discussion and may reinforce positive patterns of

communication, which may transfer to interactions outside the sessions. Affection and appreciation may be demonstrated in the supportive and fun atmosphere that sessions are intended to create. Dyads may view participating in activities together as a source of enjoyment related to ‘making the best of things’. Finally, applying the iCST key principle of ‘focusing on opinions rather than facts’ may contribute to ‘keeping the peace’ by reducing criticism and celebrating success rather than concentrating on failure.

### **9.2.2 Conflicting findings**

In contrast with previous studies of group short-term CST (Spector *et al.*, 2003), longer-term maintenance CST pilot (Orrell *et al.* 2005), and one-to-one, home-based programme of reality orientation (RO) / cognitive stimulation (CS) (Moniz-Cook *et al.*, 1998; Quayhagen & Quayhagen, 2001; Onder *et al.*, 2005), iCST did not lead to improvements in cognition.

The intervention investigated in the study by Moniz-Cook and colleagues (1998) consisted of several components. The authors were unable to specify which were associated with the observed improvements in cognition. However, they suggested the individually tailored, goal-focused memory rehabilitation work dyads participated in was likely to be responsible for this outcome. The difference in outcomes between this intervention and iCST may be attributable to the different features of the interventions. iCST offers sessions, which were designed to stimulate a range of cognitive skills, rather than focus on specific domains. Sessions also place emphasis on maximising the person’s current strengths rather than identifying strategies to compensate for, or improve impairments in everyday functioning. RO serves the purpose of general reference to the ‘here and now’ in the context of iCST, whereas in Moniz-Cook and colleagues intervention, RO is applied to tackle specific issues. For example, teaching the person to use a notice board of familiar faces with the aim of improving face recognition and reducing risk of allowing strangers into the home. A more rehabilitative approach to improving cognition, working on areas the person is experiencing difficulty in may be more useful and effective for people with early stage and mild dementia than the type of general CS and RO provided by CST-based interventions, which may be better suited to

people with moderate dementia (Clare & Woods, 2003). The extent to which iCST can be fully individualised compared to the intervention described in Moniz-Cook and colleagues study may also explain the difference in outcomes. Dyads were encouraged to take a flexible approach to choosing and adapting iCST activities, but it appears many adhered to the content provided in the manual and activity workbook regardless of whether it was suitable for them or not. In qualitative interviews conducted after the trial, some carers and people commented that they didn't gain much from certain sessions, but acknowledged the intervention was designed to meet the needs of a wide range of people (Orgeta *et al.*, 2015). Moniz-Cook and colleagues' intervention targeted specific goals according to the needs of dyads, and was therefore completely individualised. Quayhagen & Quayhagen (2001) suggest meaning and motivation are important in intervention research, and that they can be enhanced when participants self-select specific activities or tasks. Perhaps more positive outcomes were attributable to the fact there was more facility to do this in the intervention described by Moniz-Cook and colleagues than in the iCST intervention.

The difference in outcomes between the iCST intervention and the home-based, family carer-led programme of CS tested by Quayhagen & Quayhagen (2001) may be related to the intensity and content of the interventions. Dyads participated in hour-long CS sessions five days a week as part of Quayhagen & Quayhagen's (2001) programme, which is much more intensive than the recommended three, 30-minute iCST sessions per week. In terms of content, Quayhagen & Quayhagen's intervention sessions had a different cognitive focus each week compared to iCST, which provides general stimulation within different topic themes. The programme was also shorter in overall length (8 or 12 weeks) than iCST (25 weeks). It is possible that shorter-term, more intense programmes of CS are more effective. Indeed, short-term CST (14 sessions over 7 weeks) consistently yields cognitive benefits (Woods *et al.*, 2012), whereas longer-term maintenance CST (7 weeks of CST followed by 24 weekly sessions) does not appear to (Orrell *et al.*, 2014). However, the findings of Onder and colleagues (2005) do not fit with this rationale, as their home based, 25-week programme of CS/RO improved cognition.

In terms of dose (3, 30 minute sessions per week), and manualised approach iCST was most alike the intervention evaluated by Onder *et al.* (2005). The content of the programme was more RO-based than iCST and included some work throughout the day outside the formal sessions, which may have had more of an impact on cognition. In addition, all participants were on anti-dementia medication in conjunction with the programme of RO, therefore synergy between the two may facilitate cognitive improvements (Orrell *et al.*, 2014). Seventy-six percent of the iCST sample were taking anti-dementia medication, with an even distribution between the iCST and TAU groups as a result of the randomisation model. The results of the main ITT analysis did not suggest a synergistic relationship between iCST and medication, but a sub group analysis of the data could be performed to investigate this.

Lack of cognitive benefits may reflect a ‘ceiling effect’ whereby participants were already functioning at their maximum level of cognitive performance at baseline, thus were not able to glean any benefits or additional improvement from the intervention. Indeed 70% of the sample had mild dementia (Clinical Dementia Rating Scale [CDR] score = 1; Morris, 1993), and a relatively large proportion (18%) were placed in the very mild category on the CDR (0.5). If this is the case, individuals may benefit if they were to participate in the intervention at a later stage in the progression of dementia. However, the evidence for group cognitive stimulation suggests that the effects of the intervention are similar regardless of the severity of dementia (Woods *et al.*, 2012).

In addition, in contrast to our current findings, QoL benefits have been consistently associated with both short and longer term programmes of CST (Spector *et al.*, 2003; Orrell *et al.*, 2014; Woods *et al.*, 2012). Woods and colleagues (2012) suggest that the reported QoL benefits associated with CST are likely to be mediated by improvements in cognition. Thus the lack of significant cognitive change experienced by iCST participants may account for our findings on QoL outcomes.

### **9.3 Treatment fidelity**

### **9.3.1 Implementation Error (Type III error)**

It is possible that the failure of the iCST trial to demonstrate effectiveness in the primary outcomes may reflect an implementation error (e.g., failure to implement an intervention as planned). Considered an equivalent of type I and II errors (Hulscher, Laurant, & Grol, 2005), implementation error (Type III) can compromise the internal validity and credibility of an intervention (Moniz-Cook *et al.*, 2008), masking any positive impact on those receiving it. In order to address this, the extent to which treatment fidelity was achieved in the iCST will be considered within the framework for evaluation of implementation fidelity described by Carroll and colleagues (2007) which specifies intervention complexity, facilitation strategies, quality of delivery, and participant responsiveness as moderating factors.

#### **9.3.1.1 Intervention complexity and facilitation strategies**

The more complex an intervention, the more difficult it is to ensure high fidelity (Greenhalgh, Robert, MacFarlane, Bate, & Kyriakidou, 2004). The nature of the intervention and its components and how clearly it is defined determine complexity (Hasson, 2010). iCST was designed to be easy to use, with feedback from consultees (e.g., carers, people with dementia, experts in the field) in the development phase activities (Chapters 4, 5 & 6) suggesting this goal had been achieved. The intervention was not feasible for all dyads, and in some cases lack of adherence may have been related to difficulty in implementing the intervention. In terms of being clearly defined, iCST followed the example of CST, which is described in detail in the programme manuals (Making a Difference, Spector *et al.*, 2006; Making a Difference 2, Aguirre *et al.*, 2011) and in numerous research reports, and is implemented in services in the UK (Memory Services National Accreditation Programme [MSNAP]; Hodge, Hailey, & Orrell, 2014) and internationally (see International CST Centre, <https://www.ucl.ac.uk/international-cognitive-stimulation-therapy>). Consequently it is unlikely that any fidelity issues were as a result of a lack of detail provided in the iCST manual and treatment protocol.

Facilitation strategies may be employed to enhance and standardise fidelity. In the trial, a combination of facilitation strategies aimed at both the unblind researchers and dyads were implemented. For unblind researchers, strategies included: (1) training on the rationale for iCST, previous CST research, the intervention components, materials, how to train and support dyads, (2) a detailed treatment protocol to use as a reference, and (3) access to support from staff at the London site throughout the trial including telephone contact, email and an Frequently Asked Questions (FAQ) document which was regularly updated and circulated to staff. Dyads received: (1) training, (2) support, (3) the iCST manual including guidelines for sessions, and (4) the carer diaries to record progress. Carroll *et al.* (2007) point out that the use of many strategies does not necessarily result in better implementation. In light of this, the content, frequency, and mode of delivery, and quality of delivery of training and support by unblind researchers warrant examination.

### 9.3.1.2 Quality of delivery

The quality of delivery must be examined from the perspective of the researchers responsible for training and supporting dyads, and from the perspective of carers who delivered the intervention to people with dementia. Firstly, a consideration of factors influencing the quality of delivery by the research teams. Despite the use of the facilitation strategies described above, the quality of the training and support unblind researchers provided to dyads may have varied between the eight research sites. This issue has been highlighted in other studies of implementation of psychosocial programmes across several geographical locations (Dröes *et al.*, 2004). Furthermore, the teams of unblind researchers were multi-disciplinary, including nurses (62%), clinical psychologists (14%), clinical studies officers (10%), research assistants (10%), and occupational therapists (5%), and although all had worked in the field of dementia care previously, levels of experience, skills, and qualifications varied within and between sites. Variations in the delivery of support and transmission of information about the intervention between researchers or across participating dyads was not monitored closely, thus it is difficult to quantify its impact on treatment integrity or fidelity.

Secondly, for carers quality of delivery might be defined as how faithfully they adhered to the content, principles, and structure of the iCST intervention rather than uptake or frequency of participation. The measures of adherence used (e.g., carer's diary, telephone support questionnaires) provided information about frequency of sessions and qualitative feedback on perceived quality of sessions. However, without observing or recording dyads completing every session, it is difficult to discern whether they truly enacted 'iCST' as intended.

The definition of iCST 'as intended' also poses some problems, as the trial was pragmatic, aiming to investigate the effectiveness of iCST in contexts and settings akin to real world practice, thus few restrictions were placed on intervention delivery. Dyads were actively encouraged and supported to tailor activities, with the guidance administered in the content of the manual and by the researcher promoting a flexible, person-centred approach to sessions. Recommendations on the structure and frequency of sessions and the rationale for these recommendations were also given to dyads, but these were not strictly enforced. Sessions were likely an interpretation of the information dyads were provided with, and this interpretation may have varied amongst sessions for each dyad, as well as between dyads.

If we consider flexibility and person-centredness to be the most instrumental components of the intervention, it appears dyads did follow the guidance they received, so perhaps treatment fidelity was not breached in this sense. There is evidence to suggest that psychosocial interventions are most effective when tailored to the individual needs of those involved (Olazeran *et al.*, 2010), therefore adapting the programme should not necessarily compromise effectiveness. However, it is difficult to know how far the specific features of CST-based interventions (e.g., session structure, key principles) can be altered or omitted before the intervention is rendered ineffective, or indeed cannot be considered 'CST' at all.

### 9.3.1.3 Person responsiveness

Again, this must be considered at the level of research team delivery of training and support to dyads, as well as carer delivery of iCST to the person with dementia. Responsiveness is

defined as the extent to which interventionists and participants respond to, or are engaged by an intervention (Carroll *et al.*, 2007), which will be affected by perceptions of the results, how relevant the intervention is to them, and whether they like it. Put simply, if interventionists and participants are not enthusiastic about the intervention, or if the intervention does not appear to be a good ‘fit’ for them, they are less likely to adhere to it faithfully. For unblind researchers, previous exposure to or experience of group CST may also have affected how well they understood the components of the intervention, how enthusiastic they were about iCST, or how confident they were in their provision of training and support to the intervention dyads.

No researchers highlighted any issues around negative perceptions of the intervention, or lack of motivation to train and support dyads. Perhaps some researchers felt this way whilst working on the trial, but felt uncomfortable disclosing their views to the London team during support contacts. Conversely, dyads having issues with the programme did tend to relay these back to the unblind researcher supporting them. For carers, factors such as lack of engagement by the person with dementia, uncertainty about the suitability of the content of the activities (e.g., topics not of interest to person, difficulty etc.), experiencing barriers to participation (e.g., lack of time, illness), perceiving the programme as burdensome, and whether they enjoyed the sessions may have influenced their responsiveness and thus fidelity to the intervention. For people with dementia, responsiveness and fidelity may have been related to perceived appropriateness of the activities for their needs (e.g., difficulty) or interests (e.g., themes), their enjoyment of the sessions, and their carer’s response to the intervention.

#### 9.3.1.4 Frequency of support

An association between frequency of contact with an interventionist and likelihood of implementation of a strategy-based intervention for carers was observed in a study by Chee, Gitlin, Dennis, & Hauck (2007). The authors reasoned that having more practice opportunities with an interventionist (researcher) who provided training positively influenced

adherence. For the majority of iCST dyads, the only opportunity to participate in a guided session with a researcher was during the set up visit, unless the dyad required additional out of protocol support visits to consolidate their training, which sometimes involved joint delivery of sessions. The focus of the scheduled monitoring visits (12 & 25 weeks) was collection of adherence data and provision of advice if necessary, rather than repeated modelling of the intervention. Therefore, although the supporting researcher was not the main iCST 'interventionist' per say, a more intensive and structured support programme incorporating more opportunities to participate in sessions with the researcher at face-to-face visits, or more frequent telephone contacts may have augmented adherence.

### **9.3.2 Measurement of treatment fidelity: adherence to the intervention**

#### **9.3.2.1 Dose of iCST received**

Lack of significant cognitive and QoL benefits may be attributable to adherence, which was lower than expected. On average, dyads completed just less than half (31.68) of the recommended number of sessions (75) over 25 weeks. However, 22% were not able to complete any sessions. Intention to treat (ITT) analyses are not sensitive to variations in receipt of an intervention, thus using all available data including that of dyads who received less or none of the planned intervention, may have underpowered the study against a potential significant result.

The patterns of adherence, and large variation in number of sessions completed between dyads ( $SD=26.81$ ) suggest that very few dyads participated in sessions consistently week to week. There may be a relationship between regular engagement and capacity to benefit from cognitive stimulation based interventions. For example, delivering the intervention intermittently, with long periods of 'rest' in between, or bouts of intense participation in sessions followed by inactivity may not be effective approaches. There is evidence to suggest that participating in group CST once, as opposed to twice weekly as recommended does not yield the cognitive or QoL benefits typically associated with the intervention (Cove *et al.*, 2014). Thus it is conceivable that 'dose' is similarly important with iCST. Indeed, the

recommended schedule of three, 30-minute sessions per week equates to what appears to be the optimum effective dose of group CST.

Dyads were given flexibility to fit in sessions when possible, in response to feedback from carers who emphasised the need for this approach when consulted in the development phase activities (see Chapters 4, 5, & 6). However, based on the adherence data, this pragmatic approach did not appear to be effective in ensuring dyads completed the recommended number of sessions. This issue was not unique to our study, in a recent study of home-based cognitive stimulation, carers tended to complete fewer sessions than instructed in training (Milders, Bell, Lorimer, MacEwan, & McBain, 2013). In terms of strategies to improve adherence, it seems unlikely that provision of more detailed and fixed schedules of delivery for iCST would have made an impact, particularly if the reasons for non-adherence in the main trial were related to practical issues such as lack of time or illness as described in the field-testing phase (Chapter 6).

#### **9.4 Response rate and attrition**

Conversion from referral to enrolment in the trial varied between the sites, with an overall recruitment rate of 27%. Referrals were most likely to become trial participants in Dorset, Devon, Lincolnshire, and London (rate exceeding 50%). However, different recruitment targets were set for each site according to their available resources, thus for some sites the recruitment rate appears less successful than it was. The main reason for loss of referrals (24%) was the dyad expressing a wish not to participate. It is unclear whether this was related to the intervention itself, or general participation in a research trial. However, it is possible that factors such as taking on an intervention involving active delivery rather than simple receipt, investing six months in the project, or anticipating the programme would not meet their needs may have dissuaded some dyads. Trial exclusion criteria applied in 22% of

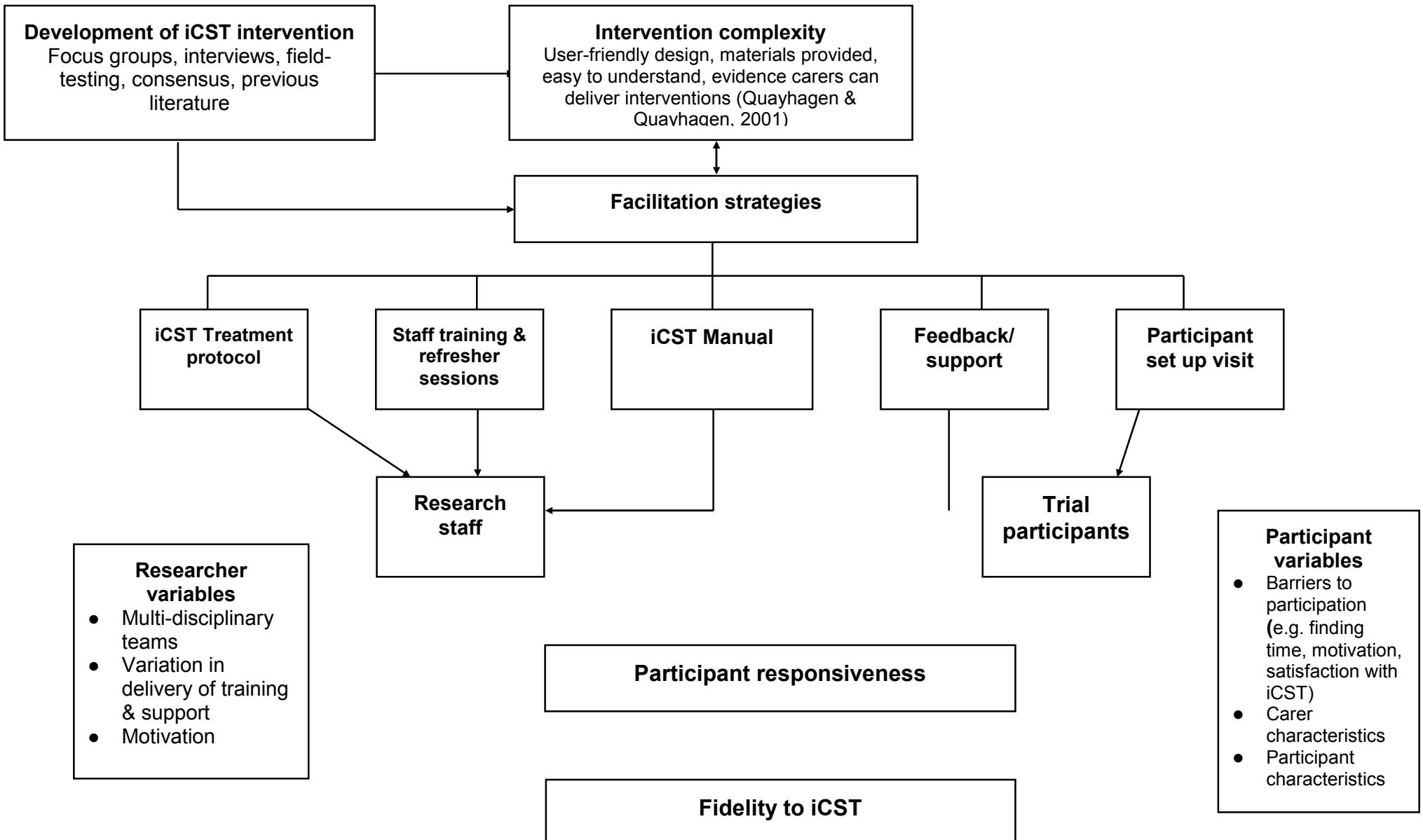


Figure 9.1 Factors influencing fidelity to iCST intervention  
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cases, making it the second most common reason for non-enrolment. It is unlikely that the criteria used were too restrictive in nature as they were used successfully in previous CST research (Spector *et al.*, 2003; Orrell *et al.*, 2014). However, it may well be that despite meetings with researchers and distribution of information sheets specifying criteria, the organisations or individuals identifying potential participants needed to be better informed as to who to pass study information on to.

The overall rate of attrition (excluding deaths) was higher than projected (20% at follow up 1 [FU1], 24% at follow up 2 [FU2]) with no significant differences between sites. Generally, an attrition rate of up to 20% is considered acceptable (Sackett, Richardson, Rosenberg, & Haynes, 1997), any higher than this may compromise the validity of the trial, particularly if one trial arm has significantly higher attrition. Retention was similar in both arms of this trial at 74%, and 79% for iCST and treatment as usual (TAU) respectively. Dropouts and withdrawals were monitored closely throughout the trial, with regular reports sent to the clinical trials unit (NWORTH), thus when it became clear attrition was higher than expected, the trial statistician was consulted to recalculate the sample size (260 dyads at FU2). All sites contributed to recruitment to achieve the readjusted goal. Two hundred and seventy three dyads completed FU2, surpassing the required target and ensuring the trial had enough power to detect an effect (80% power,  $p=0.05$ ). Typically participants who drop out or withdraw from trials after being allocated an intervention are not representative of those who remain in the trial (Jüni & Altman, 2001), even if they were well matched at baseline (Gustavson, von Soest, Karevold, & Røysamb, 2012), which may introduce attrition bias. This form of bias may undermine the generalisability of findings if incorrect conclusions are made about the effect of the intervention on the trial sample as a result. By including all available data from all dyads in an ITT analysis model, this risk was balanced despite the relatively high levels of attrition.

## **9.5 Study design**

### **9.5.1 Randomisation**

In order to reduce sample bias, dyads were randomly allocated on a 1:1 basis between the iCST and TAU groups. The randomisation model stratified the sample by centre and use of anticholinesterase inhibitors to control and balance for their influence as covariates (Suresh, 2011). The baseline demographic and clinical characteristics of the iCST and TAU groups were well matched, indicating the randomisation was effective. Using a web-based randomisation service managed by an accredited clinical trials unit (NWORTH) ensured that allocation sequences were concealed from all staff on the trial thus preventing them from deciphering the sequence of assignment into iCST or TAU.

Researchers conducting follow-up assessments and the trial statistician performing analyses on the data set were blind to group allocation to ensure they were objective and not prone to the influence of preconceived ‘expected’ outcomes, which can introduce bias (Viera & Bangdiwala, 2007). In this trial this would mean a bias towards better cognitive performance and higher QoL for those known to be in the iCST group. However, outcomes were not significant, suggesting assessments were not influenced in this way. Data on assessor perceptions also indicated blinding was successful as the majority of ratings (60%) were neutral ('equally likely to be in the iCST or TAU group') (see Chapter 8, Tables 8.10 & 8.11).

Across all sites there were incidences of carers and people with dementia disclosing their allocation. This was sometimes directly in conversation (e.g., indicating disappointment about being in TAU, discussing contact with the unblind researcher with the blind assessor), or happened because intervention materials (e.g., manual, toolkit items) were left in view of the researcher during assessment visits. In an effort to avoid unblinding of assessors, the initial randomisation letter to all dyads requested that they avoid discussing their allocation at follow up visits and explained why this was important. iCST dyads were also reminded by the unblind researcher supporting them at monitoring visits prior to assessments. Even with these measures in place, it appeared that some iCST dyads found it difficult to distinguish between the roles of the blind assessors and unblind researcher they were in contact with, which led to unblinding. In an effort to minimise unblinding due to role confusion, where

possible dyads in the iCST group worked with the same unblind researcher throughout their participation and completed follow-ups with the same assessor.

Since researchers did everything possible to provide sufficient information and reminders, preventing unblinding completely could only be achieved if dyads were blind to their own allocation. As well as the risk of unblinding, participant awareness of allocation can influence their behaviour or self reported responses to outcome measures, so the data gathered may have been prone to response bias (Viera & Bangdiwala, 2007). Given the nature of the intervention, it was not possible to blind dyads to which trial arm they were in, therefore it was not possible to completely eliminate either sources of bias.

## **9.6 Recruitment**

### **9.6.1 Engagement of participants and sources of referrals**

Participants were recruited from a variety of National Health Service (NHS), local authority, and voluntary sector settings across the UK. The sites were geographically varied, including urban, suburban, and rural areas with populations with diverse socioeconomic and ethnic backgrounds, which should have resulted in a diverse sample of participants. Despite the variation in settings, the sample lacked diversity as over 90% of the trial participants were of a white ethnic background, indicating failure to engage ethnic minority populations. Engagement of ethnic minority populations has been raised as an issue in recruitment for health related research studies with documented low levels of participation (Moreno-John *et al.*, 2004). A more purposive method of recruitment could have been implemented to generate an adequately diverse sample. For example, Jewish Care was the only culture-specific organisation involved in the trial, so it would have been useful to establish connections with other culture specific support groups or organisations. The implication of this is that the findings of the trial may not hold across different cultural groups and the intervention materials may require some adaption. Guidelines for cultural adaption of group CST (Aguirre, Spector, & Orrell, 2014) were published recently, thus they could be applied, or similar guidelines could be developed for iCST.

The demographic data on gender and level of education in this sample reflects the documented trends in research participant characteristics. In terms of gender, women are more likely to participate in research (Dunn *et al.*, 2004), and in this study the majority of carers (73%) were female. The gender split of people with dementia was roughly equal. The overrepresentation of female carers also reflects the high proportion of women (60-70%) providing care for people with dementia in the UK (Alzheimer's Research UK, 2015). Level of education is associated with recruitment in that highly educated people are more likely to volunteer to participate in research (Cooper, Ketley & Livingston, 2013). The minimum level of education amongst the sample was school leaver (14-16 years). However, 40% of people with dementia and 55% of carers had college or higher qualification, indicating the sample was predominantly highly educated.

In the experience of the London site, of the four North East London Foundation Trust (NELFT) boroughs, Havering and Redbridge generated the most referrals. In Barnet, Enfield & Haringey Mental Health Trust (BEHMHT) boroughs, Barnet was the most prolific provider of referrals. However, conversion from referral to enrolment was generally high in BEHMHT. Staff were easy to engage and these boroughs have excellent NHS, local authority and voluntary organisations servicing a large population of older people. Our recruitment efforts were boosted further in BEHMHT by the involvement of a CSO and use of a dementia research register. The register is a record of carers and people with dementia who have expressed interest in research and consented to receiving information about studies seeking participants. The professionals in the memory clinic and community mental health team (CMHT) in Barking and Dagenham were easy to engage with and happy for researchers to be present at clinic sessions and meetings. However, there were fewer dementia services available, and it was difficult to engage carers and people with dementia. The team had similar experiences in Waltham Forest where at the time of recruitment, services were undergoing a lot of changes and there was a shortage of staff. For these reasons, and again, difficulties engaging carers and people with dementia, few participants were recruited in this borough.

As well as the various recruitment strategies themselves (e.g., face to face, mail shots, consultant referrals), the demographic profile of the boroughs we recruited in may explain some of the variation in engagement of volunteers. As discussed above, there is evidence to suggest that volunteers for research tend to be more highly educated, therefore we might have expected that carers and people with dementia approached in boroughs with a relatively high proportion of residents achieving degree equivalents or above, such as Haringey (46%) and Redbridge (45%) (Greater London Authority, 2014), would be more likely to agree to participate in the study.

Haringey and Waltham Forest boroughs presented a paradox because although they have the largest proportions of residents with higher education qualifications amongst the recruiting boroughs in London (46% and 43.9% respectively), they also have amongst the highest percentage of residents with no qualifications (11.9% and 10.5%). However, the referral to enrolment conversion was much higher in Haringey (14/24, 58%) compared to Waltham Forest (8/42, 19%). In Haringey, although information about the study was not distributed to a great deal of people, it seemed to reach suitable and receptive participants, most likely due to the expertise of the CSO and the availability of the dementia research register. By contrast, our experience of fewer enrolments in Waltham Forest may have been attributable to a combination of the demographic profile of the area, plus the paucity and reorganisation of services, which meant that researchers had to employ more remote methods of recruitment (e.g., mail shots).

The level of current or recent research activity in areas also affected how well we were able to engage potential participants. For example, in NELFT over the last few years several large-scale dementia research projects had been recruiting (e.g., the Support at Home Interventions to Enhance Life in Dementia [SHIELD] project), so the research team had to ensure referrals were not already participating in other trials. Researchers checked referrals from these boroughs against a database of people who were either active or had recently

completed participation in studies held at the Research & Development (R&D) Department. As an extra precaution, as part of the consent process, researchers asked all dyads if they were involved in any other studies. If they were, the visit was terminated and if given consent, the research team contacted them at a later date to see if they were still interested in participating in iCST. Generally, individuals who moved on to participate in iCST after completing other trials had enjoyed the process of being involved in research. Care was taken when approaching people for recruitment to ensure they did not feel overwhelmed or hassled by repeated requests to participate in different projects. Indeed, this has been identified in the literature as a key reason for refusals (Galea & Tracy, 2007).

### **9.6.2 Engagement of recruitment sources**

Some recruitment sources referred participants consistently throughout the trial, whilst others only referred on an ad hoc or one off basis. This seemed to be related to client turnover, time, and resources available, and how closely researchers worked alongside them.

Organisations with a large client base, or frequent stream of new clients accessing their service had the capacity to provide a constant stream of participants. However, this did not always guarantee referrals, which suggests that other factors such as time, availability of resources, and contact with the research team may have been important determinants of the rate of referrals. In short-staffed organisations, assisting with recruitment was seen as low priority therefore very few, if any, referrals were made. If researchers were aware of any time or resource constraints, they offered to assist with, or co-ordinate tasks such as mail outs to their client base. Staff and clinician interest in the study may also have impacted referrals in that staff who were more enthusiastic about the trial, participating in research in general, or felt the intervention would be useful to their clients were more likely to refer at least once, if not repeatedly even if they did not have a great deal of time to focus on recruitment. For instance, staff who had previous experience of CST groups generally seemed keen to meet with researchers to discuss the trial and subsequently help with recruitment.

Presenting at, or attending support groups were successful methods of recruitment, but only as one-off opportunities to enrol into the trial. Sessions were often regularly attended by the same people with little turnover, so repeated visits by the researcher would not yield new referrals. If researchers did return to groups, enough time was left in between visits to allow for new members to join.

Recruitment at some centres (e.g., BEHMHT) was supported by CSOs from research networks such as the Dementias and Neurodegenerative Diseases Research Network (DeNDRoN). Their role was to assist the research teams to establish links with services and organisations. At some centres dementia research registers or 'opt in' schemes whereby service users are provided with information on current NHS portfolio studies in dementia care were also used. These were efficient methods of recruitment, as individuals were open to participation in research so it was just a case of determining whether iCST was the right study for them. The other methods of recruitment we employed were more 'catch all' so the teams would encounter people who weren't necessarily interested in participation in research.

The recruitment partnerships established with CMHTs and memory clinics gave access to multi-disciplinary staff including consultants, clinical psychologists, admiral nurses, and occupational therapists (OTs), each with a varied client base, which yielded the greatest proportion of referrals. Researchers visited these settings in person regularly, which was advantageous as their presence reminded staff about the trial, and any questions about referrals or suitability of clients staff had in mind could be answered. Researchers could also monitor availability of recruitment brochures, replenishing displays in waiting rooms or the supply of practitioners. The added advantage of visiting memory clinics was being able to discuss the trial with carers and people with dementia directly as they could be introduced by the consultant straight after their appointment. The only disadvantage the team experienced when investing time to attend memory clinics and allocation meetings in person was that sometimes they resulted in no referrals.

At the London site under recruitment was an issue for several months during the trial, notably over the summer and Christmas periods. During these times, it was difficult to arrange recruitment opportunities as staff were on annual leave and attendance of carers and people with dementia to support groups was lower due to holidays or being busy during festive periods. To compensate for unmet targets, the team recruited additional dyads at times when the referral rate was high.

## **9.7 Instruments**

### **9.7.1 Rationale for selection**

All of the measures had robust psychometric properties and their suitability for use with people with dementia and carers has been demonstrated previously. In line with previous research into group CST (Spector *et al.*, 2004; Orrell *et al.*, 2014), cognition and QoL were chosen as primary outcomes for the person with dementia in this trial. The same scales were also used to measure these outcomes: the Alzheimer's Disease Assessment Scale (ADAS-Cog) (Rosen *et al.*, 1984), and Quality of Life-Alzheimer's Disease (QoL-AD) scale (Logsdon, Gibbons, McCurry, & Teri, 1999). The advantage of this is that direct comparisons can be made between the iCST trial findings and those from other CST studies. Furthermore, drug trials frequently use the ADAS-Cog to measure effectiveness, so the findings on cognition can be compared with those from trials of medication. Many of the secondary outcomes had also been measured in previous studies of CST, including dementia specific QoL, neuropsychiatric symptoms, functional ability, and depressive symptoms.

As described earlier, a measure of the quality of the carer-patient relationship was added for based on findings from the development phase of the trial, which suggested this outcome warranted investigation. The Quality of the Carer-Patient Relationship Scale (QCPR; Spruytte *et al.*, 2002) was chosen as it could be used to examine the quality of the relationship both from the perspective of the person with dementia and the carer, and the scale is not spousal carer specific.

### **9.7.2 Limitations of measures**

Although the rationale for the selection of ADAS-Cog as a primary measure of cognition was adequate, it may not have been suitable for the sample recruited. It was anticipated that within the specified inclusion criteria (Mini Mental State Examination [MMSE] score 10+; Folstein, Robins, & Helzer, 1983) there would be fairly even proportions of people with mild or more moderate dementia. However the sample was comprised primarily of people with very mild or mild dementia. Some studies of the psychometric properties of this scale have highlighted that it is not sensitive to change at milder degrees of impairment (Llano, Laforet, & Devanavayan, 2011), and may not be as useful for monitoring higher functioning individuals, particularly in the short term (Doraiswamy, Kaiser, Bieber, & Garman, 2001). As a result, failure to detect a significant impact of iCST on cognition may be related to the measure rather than the intervention itself.

### **9.7.3 Dyads' experience of assessments**

The duration of assessments was variable between dyads and the type of visit. For instance, baseline visits typically took the longest because they involved the process of giving informed consent, and researchers were encouraged to spend time in conversation around completion of the measures to build rapport with the dyad and also to allow them to perform checks such as whether the dyad fulfilled the inclusion criteria. Subsequent visits tended to be shorter as participants were familiar with the questionnaires. Other factors contributing to the length of visit included: how skilled individual researchers were at administering the measures, in part related to their familiarity with the items, and confidence in delivery; people's level of impairment and whether they needed additional time for particular aspects of the questionnaires; how focused the carer or person was on the assessment; and whether any issues arose during the visit and interrupted the assessment process. For example, an unexpected visitor or telephone call.

Assessments were conducted in the person or carer's home or their shared home, which were comfortable environments for the dyad. Researchers aimed to interview participants

and carers separately. This increased the likelihood of honest and open responses to the questions, which may otherwise have been influenced by the presence of the other person. If present, sometimes carers attempted to intervene in the person's assessment so separate interviews discouraged this. There were instances in which it wasn't possible to see the person and carer separately, for instance due to the layout of the home, or if the dyad wanted to remain together during the visit. Although this has the potential to affect responses, it is unlikely these instances will have had a major impact on the validity of the data.

Where possible, the same assessor returned to conduct follow up visits. This was advantageous from a methodological perspective in terms of consistency in delivery and ratings of measures resulting in better quality data, but often also for the researcher and the dyad. For researchers, knowing what to expect from the dyad's home environment (e.g., any hazards, practical knowledge such as where to park) and any issues to be mindful of in the process of conducting the assessment (e.g., adverse reactions to questions, how long the assessment might take). For dyads, being interviewed by a familiar person may have helped them feel more comfortable with the assessment procedure through development of rapport. The value of building rapport with the person and carer throughout their participation was profound and could transform an assessment or support visit from an administrative task into an engaging and enjoyable experience. The importance of the behaviour of the researcher conducting assessments is well documented. It can affect accuracy of responses, whether participants acquiesce to complete measures, whether there are negative consequences of participating in research (Bell, Fahmy, & Gordon, 2014), or whether participants make the decision to continue their participation in the study. Some researchers argue rapport increases the risk of response bias because it encourages people to alter their responses (Weiss, 1968), others argue it reduces bias by motivating people to give more honest, in depth and engaged answers, and still others have found no significant systematic impact on data quality (Hensen, Cannell, & Lawson, 1977).

The issue of the extent to which interactions between the researcher and participants should be standardised or flexible is also contentious. Standardisation may restrict ability to develop rapport, and in people's home environments it is difficult to eliminate conversational interactions (Fowler & Mangione, 1990). Moreover, in assessments rephrasing may be required to elicit genuine understanding of a question in order to give an accurate response (Conrad & Schober, 1997). All researchers participating in the study were trained to deliver the measures according to the guidance or accompanying manuals devised by the authors in an effort to ensure they were administered correctly and data gathered was of high quality.

#### **9.7.4 Problems with specific measures**

Dyads communicated some dissatisfaction with the QCPR scale (Spruytte *et al.*, 2002) around the phrasing of the items, which some found frustrating or 'stupid'. If these issues arose, researchers asked the carer or person completing the measure whether they wanted to continue and emphasised that they did not have to provide answers to specific items if they preferred not to.

Sometimes the cognitive tests included in the assessment (MMSE; Folstein, Robins, & Helzer, 1983; ADAS-Cog; Rosen *et al.*, 1984) elicited negative responses from participants. Many people were familiar with the MMSE from visits to the memory clinic. This either instilled confidence in them, as they knew what to expect, or a source of frustration that they had to repeatedly complete the measure. There were some instances where very mildly impaired participants commented that they felt some of the items on the MMSE and ADAS-Cog were 'stupid', particularly less complex items such as the naming task (MMSE). Some also reflected on whether others found these items difficult, and whether perhaps one day they would too. In these cases, researchers explained the purpose of the measure and made sure the participant was not distressed before continuing with the assessment. Given that the ADAS-Cog is a longer measure, it was not uncommon for participants to find the process of completion tiring, particularly those who were more impaired. The word recognition item was

particularly challenging, as it required three trials of identifying words seen before amongst new words. Some participants refused to complete all three trials.

Only one dyad was lost to follow up specifically because of the assessment procedure, indicating that overall the process and measures selected were acceptable to most people, and researchers could successfully negotiate full, or at least partial completion of measures even if there were issues. Generally dyads seemed to enjoy the assessment visits, although some complained about the amount of time it took to complete the measures. The measures were ordered in the assessment booklets so that cognitive tests were intermingled with QoL measures to ensure that participants had enough of a break between cognitive tasks. At times, researchers had to be flexible in their administration of measures according to the needs of the participant. For example, if beginning with a cognitive measure caused or was likely to cause distress, or the person became defensive, the researcher would introduce a QoL measure and return to the cognitive measure when the person was comfortable.

### **9.7.5 Proxy measures**

Generally the carers participating in the trial were suitable proxy respondents for the outcome measures because they were the person's primary care provider, therefore would be expected to have enough information and insight to provide accurate responses to the questions. The same respondent was asked to complete measures at baseline, FU1 and FU2 for continuity of the data. Use of proxy measures completed by informants is not without its drawbacks. Informants are more likely to underestimate the person's abilities if they are depressed or feel burdened (Loewenstein & Rubert, 1992), and in some cases, carers do not fully acknowledge the person's impairment in ADLs or cognition, even if they are objectively apparent to others, such as healthcare professionals. It is possible that the Bristol Activities of Daily Living Scale (BADLS; Bucks *et al.*, 1996) was prone to this issue.

There is some debate over whether proxy reports are more useful than those provided by people themselves (Loewenstein *et al.*, 2001). In terms of QoL, cognitive impairment may

affect the person's ability to understand and answer questions. Depression and lack of insight can also impact judgment of QoL. Proxy measures of QoL can vary significantly with the reports of people with dementia, with informants tending to provide lower ratings than the person themselves (Trigg, Jones, & Skevington, 2007). However, if measures appropriate for completion by people with mild to moderate dementia are used (e.g., QoL-AD) as in this trial, the ratings provided can give valuable and accurate insights into their lived experience. When considered alongside one another, participant and informant responses provide a more rounded picture of the situation.

Some carers found rating certain QoL proxy items (e.g., handling finances, household chores) from the perspective of how the person would answer challenging, as they felt the person was unaware of certain issues. On occasions, when completing the Dementia Quality of Life Scale Proxy (DEMQoL Proxy; Smith *et al.*, 2005), carers would make comments like 'They don't worry about anything!', 'They wouldn't know to worry about that', or 'They can't do that anymore'. Carers may not have recognised expressions of worry that weren't explicit or direct. For instance, worries about money may have manifested in the person always looking for their wallet. It is possible that this may have resulted in underestimation of things like distress and worries, and provision of answers influenced by their own value judgments of the situation.

## **9.8 Limitations**

### **9.8.1 Programme content**

All of the development phase activities and consultations took place at the London site. Members of staff from all sites were invited to participate in the online survey and consensus conference, therefore it would be expected that their feedback would provide insight into the different needs of dyads in a range of areas other than London. It was also considered more practical to conduct the development activities at the London site as the research team based there designed, edited, and produced the manual, so it was helpful to have direct access to the data gathered during the drafting process.

For some dyads, the activities may not have been mentally stimulating enough. This may account for cases in which the person did not engage in the sessions and subsequently failed to adhere to the programme, or dropped out of the trial completely. Moreover, the activities may have failed to provide enough stimulation to have an impact on cognition. Given the majority of the sample had mild dementia, this experience may have been common enough to contribute to the lack of significant result for this outcome. In discussions at the consensus conference, there was concern that some of the activities were too challenging so they were simplified to avoid demotivating people. In retrospect, rather than simplifying activities, a 'level C' option could have been introduced for each activity to cater for those who were looking for more of a challenge.

The suggested activities and resources provided in the iCST manual and activity workbook were based on material published in the group CST manuals, *Making a Difference* (Spector *et al.*, 2006) and *Making a Difference 2* (Aguirre *et al.*, 2011). However they were not exactly the same and, in adaption, may have lost the components that stimulate cognitive skills and activate neuropsychological mechanisms responsible for improvements in cognition.

### **9.8.2 Programme format**

The social setting and additional stimulation from participating in a group context may account for the difference in outcomes between iCST and group CST. Non-specific components of CST, such as the social environment or receiving social attention do not entirely account for the observed benefits of the intervention. When these factors are controlled for, the intervention still has a significant impact on cognition and some neuropsychological symptoms including apathy and depression (Niu, Tan, Guan, Zhang, & Wang, 2010). However, they appear to contribute to cognitive change (Woods, Thorgrimsen, Spector, Royan, & Orrell, 2006). Being involved in a social setting may generate more stimulation through development and expression of new ideas, thoughts, and associations and use of language skills, owing not only to the input of the facilitator, but the group members who prompt responses from one another. In a one-to-one setting fewer, and

crucially less diverse, ideas may be exchanged between two people, and the onus is on the carer to constantly encourage the person to discuss their opinions and respond to the stimuli presented as part of the activity. If the carer is not adept at this, is not a particularly verbally expressive person, or if there are challenges in communication between the dyad, the sessions may be missing a crucial component, which may elicit benefits.

### **9.8.3 Multiple outcome measures**

Information on a large number of outcomes was collected, which carries the risk of detecting statistically significant false positives due to random variability. It is worth acknowledging that the improvements detected in the quality of the patient-carer relationship could be attributable to multiple testing. However, given that the positive impact of the intervention on the quality of the care-giving relationship was a theme within the qualitative data collected from the field-testing phase (Chapter 6) and post-trial interviews (Orgeta *et al.*, 2015) in addition to the quantitative data from the QCPR scale, it is likely the data demonstrates a real effect.

## **9.9 Further research**

Given that a major limitation of this study is the low level of adherence to the intervention, which potentially diminished power to detect differences in outcomes between the iCST and TAU groups, more work is needed to explore whether fidelity to the intervention can be improved. This may be achieved by enhancing methods of support or training, changing the format of delivery as described above (e.g., via a paid carer / healthcare professional, on a computer platform), or identifying characteristics of dyads which might predict suitability and likelihood of benefit (e.g., carer and participant characteristics). At this stage, research should focus on further evaluating the effectiveness of carer-led, home-based programmes of cognitive stimulation, rather than mechanisms of change, or comparisons with group CST in view of the fact that the findings of this trial contrast previous studies showing promising benefits in the areas of cognition and QoL (Moniz-Cook *et al.*, 1998; Quayhagen & Quayhagen, 2001; Onder *et al.*, 2005).

Although there is evidence to suggest that family carers can be active participants in therapeutic interventions (Quayhagen & Quayhagen, 2001), the low rates of adherence to iCST suggest that taking on the role of interventionist did not suit all carers. In certain circumstances it might be preferable for the intervention to be delivered by healthcare professionals, befrienders, or paid carers. Certainly it seems this would be feasible given iCST was successfully field-tested by a small sample of paid carers in the development phase, and group CST is typically facilitated by healthcare professionals and/or care staff. However, a full investigation would be worthwhile to identify any differences in outcomes when delivered by a family carer compared to a paid carer or professional.

Prospectively, using a paid carer, befriendeer, or healthcare professional as an interventionist would offer several advantages in research and real world settings. Firstly, paid carers or healthcare professionals may have dementia care skills and previous experience of interventions, which may enhance the quality of delivery, or fidelity to the principles and techniques of iCST. Secondly, professionals may be more likely to be able to deliver the intervention consistently as visits are often scheduled regularly. In a research trial, this could facilitate a more systematic evaluation of the intervention. Thirdly, as carers highlighted in consultations during the development phase of the trial, interactions with a professional are more likely to be free from any relationship dynamics that may compromise successful engagement in sessions. For instance, carers were concerned they would not be taken seriously or the person would refuse to engage if they were the ones to deliver the sessions and felt that an 'outsider' might elicit a more positive response. Indeed some of the activities featured in the programme, such as constructing a family tree, lend themselves to discussion with people who are not as close to the person as they cover information the person might expect their carer to know. Fourthly, in circumstances in which iCST would not be feasible for a family carer (e.g., lack of time, carer ill health or frailty, feeling burdened) it would be useful to have a professional available to deliver the sessions. Delivery by a professional would also suit people who do not have a family carer, or have family who live a long distance away, as is now common. This was not an area we could investigate in the current trial. Lastly, in

terms of practical implications, offering a structured intervention with demonstrated benefits is advantageous for healthcare services and care agencies. For healthcare services using iCST could demonstrate compliance with guidelines and recommendations on early, home based interventions issued by the government and bodies such as the National Institute for Clinical Excellence (NICE). Use of interventions by paid staff from care agencies is not compulsory, but may set their services apart from others.

The intervention materials were presented in a paper-based format in this trial. However, there may be benefit in adapting them for a computer-based platform (e.g., computer tablet, laptop, smart phone). This would be convenient for people who might have difficulty handling a manual, means that the materials can be re-used, and if on a computer tablet, the sessions could be done while out and about (e.g., in a café, at another person's home). A computer-based programme would also have the capacity to track or monitor progress, record adherence to sessions, and help users decide which level of activity (A or B) is most appropriate for them, perhaps creating reports for the dyad themselves or for a supporting healthcare professional or researcher. A prompt system could be built in to generate reminders to complete sessions to encourage adherence, or suggest sessions for the dyad to do based on their interests and monitoring progress feedback. On a computer-based platform there is more scope for sessions to include media (e.g., images, video clips, audio tracks) which could be easily accessed using the internet, and unlike the manual which is restricted in terms of content, a large bank of activity materials could be made available and regularly updated. A computer platform would also have the facility for social interaction tools such as forums and online help, which could be useful for users to discuss their experiences of the programme, share materials and tips, as well as seek support. There is evidence to suggest that using computers can enhance participation in mentally stimulating activities and may be associated with maintenance of cognition (Almeida *et al.*, 2012), thus delivering cognitive stimulation via computer could maximise or enhance the effects of the intervention.

## **9.10 Implications for practice**

This trial contributes further to the body of knowledge of psychosocial interventions and supports relationship-centred care, placing emphasis on the benefits of working with the person with dementia and family carer together. Although the main areas of benefit were not cognition or QoL for people with dementia, iCST could be used as a tool to help family carers and people with dementia actively improve the quality of their relationship and communication. The programme could also be recommended to carers of people attending CST groups who wish to participate in similar CST-based activities with them between sessions, or after they have completed the group programme. The intervention might also be useful in care homes for residents who would prefer one to one interactions. If iCST has a similar effect on the quality of the relationship between care staff and residents and QoL of care staff, using the intervention could have a positive impact within the care home environment.

## **9.11 Conclusions**

This is both the largest trial of a CST-based approach, and as far as we are aware, the largest trial of a home-based carer-led intervention. iCST does not appear to yield cognitive or QoL benefits for people with dementia. Nor does it significantly impact activities of daily life, mood, or behavioural and psychological symptoms. The main area of benefit arose from the secondary outcomes of quality of the care giving relationship for people with dementia. The trial findings on cognition and QoL are discrepant with existing studies of similar programmes of individual and group cognitive stimulation, highlighting issues around adherence, intervention fidelity, and raising the question of whether in some circumstances the intervention may be more suitable for delivery by a paid carer, healthcare professional, or befriender, which should be addressed in future work. The methodology and results of the development phase and main RCT have been published so that they may be used by other research groups as a basis for further research.

iCST may be useful to help carers and people with dementia actively improve the quality of their relationship. Improvements in the care-giving relationship may contribute to the QoL of the person with dementia and potentially result in reduced institutionalisation. These outcomes are valuable, thus the intervention manual and DVD have now been published (Yates, Orrell, Leung, Spector, Woods, & Orgeta, 2014) so that they are widely available for carers and people with dementia.

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## **Appendices**



**National Research Ethics Service  
East London 3 Research Ethics Committee**  
2<sup>nd</sup> Floor, Becketts House  
2/14 Ilford Hill  
Ilford IG1 2QX  
Telephone: 020 8926 5025  
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24 September 2010

**Professor Martin Orrell**  
**Professor of Ageing and Mental Health**  
**University College London**  
**2nd Floor, Charles Bell House**  
**67-73 Riding House Street**  
**London**  
**W1W 7EJ**

Dear Professor Orrell

**Study Title:** Individual Cognitive Stimulation Therapy for dementia (ICST Trial)  
**REC reference number:** 10/H0701/71  
**Protocol number:** 8

Thank you for your letter of 20 September 2010, responding to the Committee's request for further information on the above research [and submitting revised documentation].

The further information was considered by a sub-committee of the REC at a meeting held on 23<sup>RD</sup> September 2010. A list of the sub-committee members is attached.

#### **Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation [as revised], subject to the conditions specified below.

#### **Ethical review of research sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

### **Conditions of the favourable opinion**

The favourable opinion is subject to the following conditions being met prior to the start of the study.

**Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.**

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rforum.nhs.uk>.

*Where the only involvement of the NHS organisation is as a Participant Identification Centre (PIC), management permission for research is not required but the R&D office should be notified of the study and agree to the organisation's involvement. Guidance on procedures for PICs is available in IRAS. Further advice should be sought from the R&D office where necessary.*

*Sponsors are not required to notify the Committee of approvals from host organisations.*

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

### **Approved documents**

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Covering Letter		20 September 2010
Participant Information Sheet	9	14 September 2010
Participant Consent Form: caregiver	9	20 September 2010
Response to Request for Further Information	1	20 September 2010
Participant Information Sheet: Home caregivers	9	14 September 2010
Participant Consent Form	9	20 September 2010

### **Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### **After ethical review**

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email [referencegroup@nres.npsa.nhs.uk](mailto:referencegroup@nres.npsa.nhs.uk).

10/H0701/71

Please quote this number on all correspondence

Yours sincerely

Revd Dr Joyce Smith  
Chair

PP

Email: [janet.carter@redbridge-pct.nhs.uk](mailto:janet.carter@redbridge-pct.nhs.uk)

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments [if final opinion was confirmed was given at a meeting]*

"After ethical review – guidance for researchers"  
SL- AR2 for other studies]

Copy to:

Dr Aimee Spector  
[R&D office for NHS care organisation at lead site]

**East London REC 3****Attendance at Sub-Committee of the REC meeting on 23 September 2010****Committee Members:**

Name	Profession	Present	Notes
Miss Elaine Mason	Retired Pharmacist	Yes	
Revd Dr Joyce Smith	Chair - Clergy/Consultant Dentist	Yes	
Dr Elizabeth Webster	General Practitioner	Yes	

## Results for survey: Untitled Survey

Page: 1/1

iCST Consensus Conference



Dear iCST Consensus Conference Member

Thank you for joining us in our Consensus Conference scheduled for Wednesday, the 14th of December, 2011. During this Conference we will present an overview of our work developing an Individual Cognitive Stimulation Therapy for People with Dementia and their Family Carers.

The Individual Cognitive Stimulation therapy is composed of separate cognitive stimulation sessions (75 in total), completed together by the person with dementia and their family carer. It provides an opportunity for mental stimulation, as well as enjoyment. In order to assist family carers in delivering the therapy to their relative, we have designed a Manual to guide the family carer through the process. The individual cognitive stimulation sessions, are described and presented in the [Activities Workbook](#). In this part of the Conference we would like you to help us evaluate the quality of the [iCST Manual](#) and [iCST Activities Workbook](#), in order for us to improve the final version prior to the main study evaluating the therapy in a randomized controlled trial.

Thank you very much for your feedback. Your time in completing this questionnaire is greatly appreciated.

Note that you are completing this questionnaire anonymously. You should have received a copy of the [iCST Manual](#) and the [iCST Activities Workbook](#) prior to completing this questionnaire. Note that the [iCST Manual](#) and the [iCST Activities Workbook](#) are protected under UCL Copyright law, and should not be distributed to a third party.

## Question 1\*

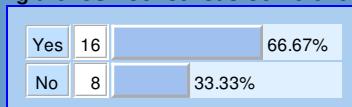
Are you:

1. a family carer
2. working in the NHS/social services
3. working in the Private Sector
4. working in an Academic Institution
5. working in the Voluntary Sector

1	2	3	4	5	Responses	Total
8%	46%	8%	29%	8%	24	100%

## Question 2\*

Are you attending the iCST Consensus Conference on 14/12/2011?

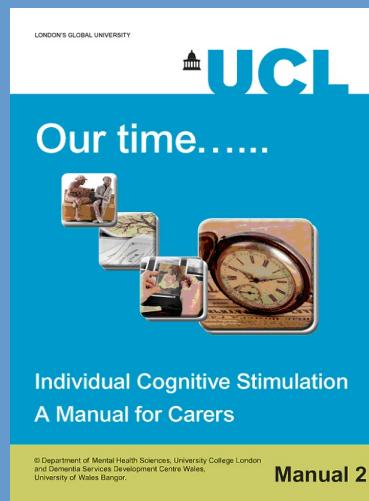


## Question 3\*

1. Do you agree to complete this short questionnaire?

Yes	No	Responses	Total
100%	0%	24	100%

## Question 4\*



The following questions evaluate the Individual Cognitive Stimulation Manual ([iCST Manual](#))

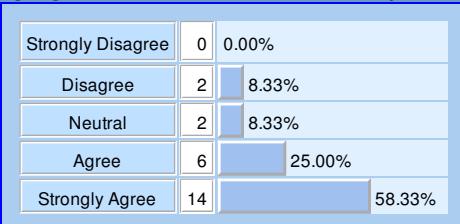
Please tick the most appropriate answer to each of the following statements.

2. How would you rate the overall quality of the iCST Manual?

Poor	Fair	Good	Excellent	Responses	Total
0%	0%	63%	38%	24	100%

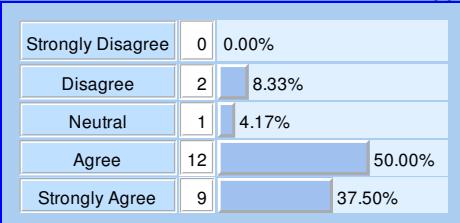
## Question 5\*

3. The language used in the iCST Manual is easy to understand.



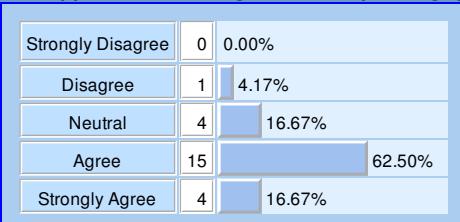
## Question 6\*

4. The size of the font used in the iCST Manual is appropriate.



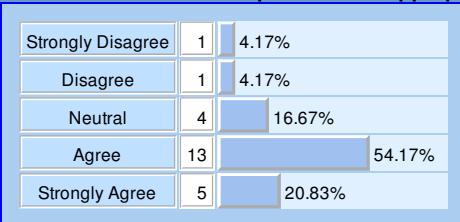
## Question 7\*

5. The iCST Manual appears stimulating and is likely to engage family carers.



## Question 8\*

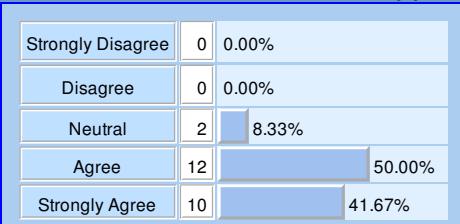
6. The amount of information presented is appropriate.



ID	View Survey	
9400501	<a href="#">View</a>	It manages to give the right amount of information and is not patronising in any way
9488494	<a href="#">View</a>	There needs to be more explanation on each activity / session, and also to clearly separate Level A & Level B.
9549837	<a href="#">View</a>	I think it is better to add a chapter about how carers could feel administering the exercises.
9623355	<a href="#">View</a>	the introduction seems a bit long, and there are a couple of sentences where the meaning could be slightly clearer.

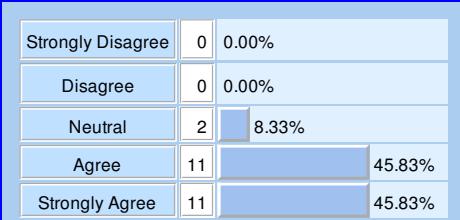
## Question 9\*

7. The activities in the iCST Manual are clearly presented.



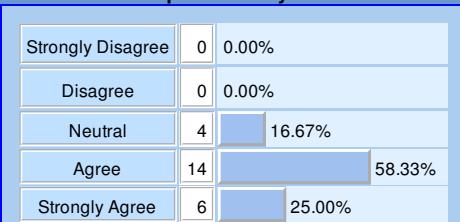
## Question 10\*

8. The layout of the iCST Manual is appropriate and easy to follow.



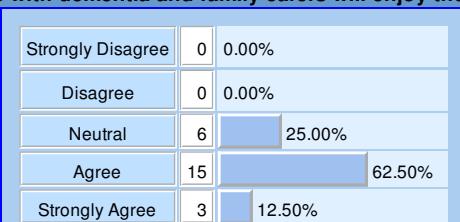
## Question 11\*

9. There is adequate variety in the activities.



## Question 12\*

10. People with dementia and family carers will enjoy the activities.



## Question 13

**We would greatly value your comments in the sections below.**

### 11. Do you have any suggestions to improve the iCST Manual?

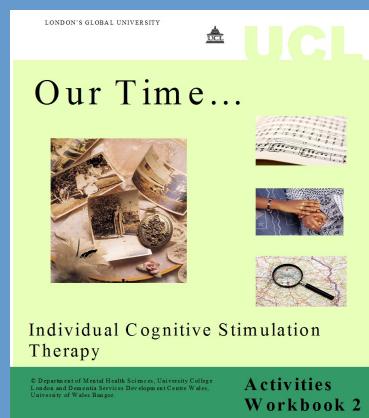
ID	<a href="#">View</a>	Survey
9477810	<a href="#">View</a>	Update references, further reading including Maintenance CST literature and Making a difference 2 manual. Update key principles as developed by Spector et al and listed in making a difference 2.
9488494	<a href="#">View</a>	There needs to be Level A & Level B split so that a carer can clearly see the differences in the activity.
9494666	<a href="#">View</a>	Could provide an example of how to start the discussions on 'day, month, year, season, weather and time', and for the discussion of 'a recent event or something currently in the news'.
9549837	<a href="#">View</a>	see point 6
9586417	<a href="#">View</a>	Perhaps just to make it clear how you go about getting the resource pack and manuals, are they provide? who pays for them ? etc.
9590516	<a href="#">View</a>	In an abridged form with key points could be useful for those time is precious and physically exhausting in caring. Both manuals should made availalble online with materials to supply to those who accessed the internet; OR develope interactive online training.
9591000	<a href="#">View</a>	The topics in the warming up part are similar for every session. I think carers would welcome a bit of variation in this. Not for everybody all sessions can be performed, like Sounds or Physical games. I think it would be helpful for carers to provide some suggestions what to do in these instances. The distinction between the level A and B activities is not always clear or present.
9601576	<a href="#">View</a>	It may be useful to include a section on what to do if people are illiterate. It may be useful to include a section on what to do if people do not read in English. It may be useful to include some additional ideas about physical games for people with dementia who have poor mobility or who are bedbound.
9642889	<a href="#">View</a>	I have been a family carer. Yes I understand all that is in the manual. I also have strong agreement with almost all. However I have mixed with many other family carers during my years caring. I am not special but I am aware that I am unusual in that group in my understanding of the thinking on which this manual is based. To most the word devastating is frequently in their vocabulary in reference to their own life now and that of the person they are caring for. A switch in thinking to believe that there may be a positive way in their new life experience is 180 degrees away. I think Key Principles pages 4 to 7 need to be rewritten from this starting point whilst still arriving at the end point that you have. Dementia changes the thinking ability of the person with dementia - iCST to work needs to change the thinking of the family carer. Getting those two changes to develop in complimentary rather than contradictory fashion seems to me to be necessary to success in managing the condition for both. Somehow that needs to be accomplished in those four pages often starting from a less than conducive family carer starting perception.
9662264	<a href="#">View</a>	There is some confusion over the target audience for this manual. It is trying to be all things to all people I think.

## Question 14

### 12. Would you like to comment on a specific section of the iCST Manual?

ID		View Survey
9400501	<a href="#">View</a>	Really like the useful tips section, not only is it useful, but it is great for self esteem to be able to share knowledge.
9471654	<a href="#">View</a>	The frequently asked questions should provide helpful support. The initial guidance on pages 3 - 6 is very interesting and useful. However, it may be rather a lot for carers to take in and digest.
9488494	<a href="#">View</a>	In key principles, the wording of the introduction is quite aggressive and may put carers off such as 'not optional' 'real risk' & 'negative impact'. Manual is with a capital m when it does not need to be. Monitoring progress form has capital letters in the question when it is unnecessary. 'was the session too easy & was the session too hard are the same question. In the F&Qs section Q2 'warn the person in advance' sounds aggressive. For Q5 of F&Qs 'sessions you left off and don't worry about the sessions that you have not been able to complete' contradicts itself. Q7 Does materials need to be with a capital m?
9494666	<a href="#">View</a>	The 'Things to discuss...' section begins with some direct questions (such as 'What are the objects?') which if asked in this way could make a person feel uncomfortable if they are unsure of the answer. Perhaps these questions could be phrased differently or it could be made clearer that these questions should be conversational not an attempt to challenge or put the person under pressure to answer correctly.
9544784	<a href="#">View</a>	Bob Woods' intro should be updated. It has been taken from the CST manual and some of it is incorrect, e.g. the section named 'It's effective'. We don't yet know whether it is effective or not. Also, the 'guiding principles' text does not match the key principles in the table.
9551053	<a href="#">View</a>	I am not sure the instructions are clear in Session 17 Categorizing Objects. Presumably the person with dementia and carer are jointly to choose a category and then each suggest items that might be in this category. The instructions do not really make clear who is thinking of the items, and at first reading it seems as though the carer has to write the list.
9590516	<a href="#">View</a>	YES, after reading the printed version.
9601576	<a href="#">View</a>	I like the way that 'Welcome to Our time...' section is written and talks about carers wanting to make a difference. I think this will have the effect of making other carers want to do this.
9642889	<a href="#">View</a>	Bob Woods opening page. It is a necessary and authoritative opening statement of belief and as such is very good. I would prefer for this manual and its intended readers also to have running through this opening statement a simpler and clearer message of intent. We trying to do? To enhance the quality of life of both the person with dementia and their family carer through stimulating activity that is enjoyable to both. The equally important subplot here is the parallel enhancement to the quality of life of the carer through understanding and involvement. After all it is the (family) carer who will be reading this manual, the opening statement is addressed to them.
9662264	<a href="#">View</a>	I feel the tone of the manual being very basic, the additional reading should not be a lot of academic papers! These will not be helpful, or accessible, by the majority of manual users!

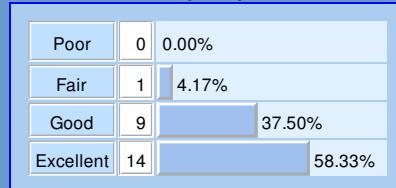
### Question 15\*



The following questions evaluate the Individual Cognitive Stimulation Activities Workbook (iCST Activities Workbook)

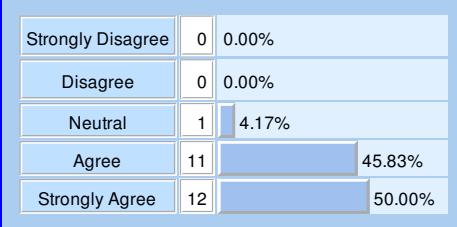
Please tick the most appropriate answer to each of the following statements.

13. How would you rate the overall quality of the iCST Activities Workbook?



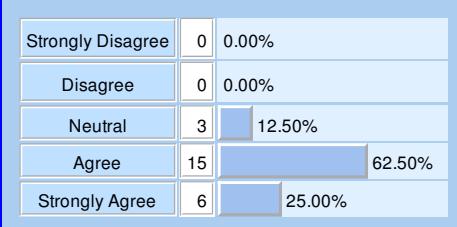
### Question 16\*

14. The language used in the iCST Activities Workbook is easy to understand.



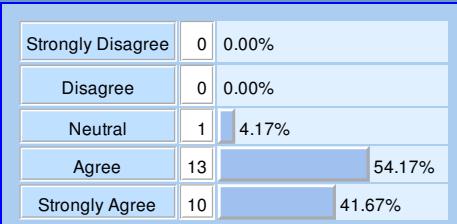
### Question 17\*

15. The iCST Activities Workbook appears stimulating and is likely to engage people with dementia.



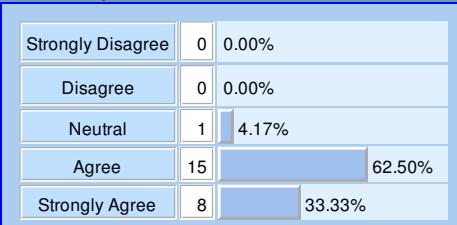
## Question 18\*

16. The size of the font used in the iCST Activities Workbook is appropriate.



## Question 19\*

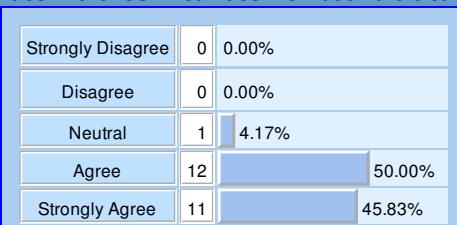
17. The amount of information presented in the iCST Activities Workbook is appropriate.



ID	<a href="#">View Survey</a>	
9488494	<a href="#">View</a>	It is necessary to give a variety of activities as the carer is likely to need as many prompts as possible.
9544784	<a href="#">View</a>	See comments below

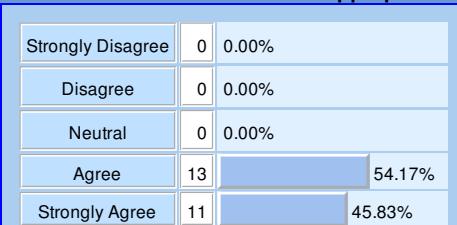
## Question 20\*

18. The activities in the iCST Activities Workbook are clearly presented.



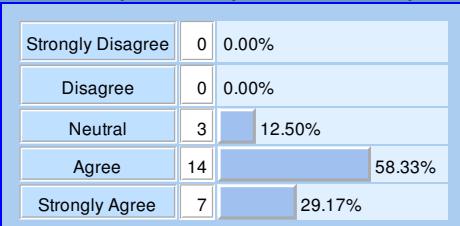
## Question 21\*

19. The layout of the iCST Activities Workbook is appropriate and easy to follow.



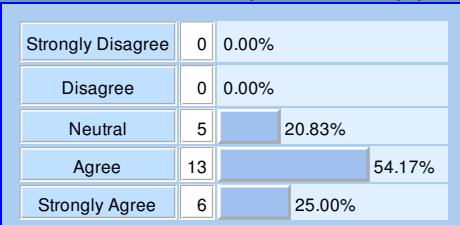
## Question 22\*

20. There is adequate variety in the activities presented.



## Question 23\*

21. People with dementia and family carers will enjoy the activities.



## Question 24

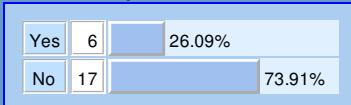
We would greatly value your comments in the sections below.

22. Do you have any suggestions to improve the iCST Activities Workbook?

ID	View Survey	
9311117	<a href="#">View</a>	Page 2 and 4 'Listen to....' the word 'to' is missing from line 4 of text.
9400501	<a href="#">View</a>	no
9488494	<a href="#">View</a>	N/A
9544784	<a href="#">View</a>	I think that some of the activities might be too hard, e.g. the music categories and some of the odd ones out are very tricky! In household tips, I think that it would be better for people to come up with their own ideas, rather than matching. This would be (i) more empowering and (ii) easier (I think that there is potentially too much information to take in in one go). Some of the thinking cards questions are slightly dull e.g. about it raining for 2 years> But apart from that it is really good indeed.
9590516	<a href="#">View</a>	Could also consider provision of ethnically/culturally appropriate activites/items.
9591000	<a href="#">View</a>	Using blue colours instead of green in the workbook, might be less 'flashy'.
9601576	<a href="#">View</a>	Some of the photos could be printed a bit bigger for people who have visual difficulties.
9662264	<a href="#">View</a>	I am unsure if the activitiesw will be accessale to all demographics. They appear a little ethnocentric and require a certain level of cognitive ability that may be beyond many clients with dementia. There is also a fell of "middle classness" to much of this manual - not many of my clients have laptops, flat screen TVs or digital cameras!

## Question 25\*

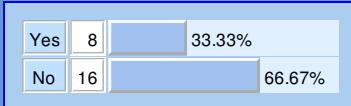
23. Would you like to comment on a specific section of the iCST Activities Workbook?



ID	<a href="#">View Survey</a>	
9400308	<a href="#">View</a>	The only activity I was unsure of was number 21 - as they were old fashioned tips - some even I was unsure of!
9400501	<a href="#">View</a>	Particularly liked the thinking cards section, really good idea. Household tips matching activity really good fun and great starting point for people to discuss other tips for the same problem
9549837	<a href="#">View</a>	In the "Sound effects activity" table (page 3), some images are not so clear for people with dementia. For example train whistling, birdsong, horse neighing and squeaky kiss. Also about "styles of music activity": I think that not all aged people could identify "funk" and "reggae" music.
9551053	<a href="#">View</a>	I think some of the odd one out pictures are quite difficult. For example page 8 - it was obvious the coins were the odd one out but as they had no relation to water it seemed strange to say the reason was because they did not float. Perhaps a picture of a rock on the seabed would be clearer.
9586417	<a href="#">View</a>	really liked the household tips section, I imagine this would provoke a lot of good conversation, with people providing their own family tips etc.
9591000	<a href="#">View</a>	I can imagine that the pictures in the Sounds effects activity are not always clear to people with dementia, especially when they have visual impairments.

## Question 26\*

24. Do you have any further comments?



ID	<a href="#">View Survey</a>	
9400501	<a href="#">View</a>	Really liked workbook very well suited for ICST, could be used just as it stands but feel it would stimulate people to come up with more of their own ideas. It was also well laid out, easy to read and understand.
9477810	<a href="#">View</a>	Very good and easy to follow manual.
9488494	<a href="#">View</a>	I think that the manual with a bit more explanation alongside the resource manual will be a great package for carers to try with their relative.
9549837	<a href="#">View</a>	I think it is a good job.
9586417	<a href="#">View</a>	I understand this is one manual and workbook and that there are others in the ICST programme, are they all given out together or in stages? perhaps this could be clarified
9587997	<a href="#">View</a>	In terms of the comment 'people with dementia and their carers will enjoy the activities' - I am not too sure? I have sat in on a CST group where the participants appeared to enjoy the activities which were similar to those in the manual, however we often asked participants to evaluate involvement and we observed their engagement etc. Have the activities been discussed with a focus or discussion group made up of those people who the manual is aimed at?
9601576	<a href="#">View</a>	As mentioned above, it may be useful to include a section on what to do if people are illiterate and it may be useful to include a section on what to do if people do not read in English.
9642889	<a href="#">View</a>	Need to move strongly away from the concept of question and answer to avoid getting stuck in right and wrong which is the last place I found that I needed to be with someone with a degenerative condition such as dementia - things are not going to get better in that direction. The positive direction has to be towards co-operation and involvement through the enjoyment of conversation (whether particularly logical or not) and activity together, for me the sessions are all new and different ways into that zone. It is in any case what we all do in our own lives in perhaps frequently more complex ways. We all enjoy and seek cognitive stimulation - the session activities should be trying to replicate that with complexity constantly moderated to match the current level of cognitive impairment in the person with dementia.

## Consent form for use of film footage

Some sessions of Individualised Cognitive Stimulation Therapy (iCST) may be video taped. The purpose of video taping is to help train future volunteers and group facilitators. You may at any point request that video taping is stopped, withdraw your consent for the taping and any further use of the taped footage, at this stage the tape will be edited and destroyed.

We consent to video taping our Individualised CST sessions for treatment use and training purposes only. The research project “Individualised CST for people with dementia” is funded by the Health Technology Assessment (HTA).

**Name of participant** \_\_\_\_\_ Date \_\_\_\_\_ Signature \_\_\_\_\_

**Name of Carer** \_\_\_\_\_ Date \_\_\_\_\_ Signature \_\_\_\_\_

Name of person taking consent  
(if different from the researcher) \_\_\_\_\_ Date \_\_\_\_\_ Signature \_\_\_\_\_

**Researcher** \_\_\_\_\_ Date \_\_\_\_\_ Signature \_\_\_\_\_

# **Focus Group Discussion Guide**

1. Introduce ourselves, hand out information sheets and do consent forms
2. Ask participants to look at manuals (give out 'Things to think about..' and explain no discussion should take place at this point) whilst having refreshments (make sure everyone feels they have enough time to look at the manual)
3. Present the research and show the video clip (10 mins)
4. Explain ground rules and that we would like feedback about this programme, it is not a forum for discussion of personal experiences
5. Ask if anyone has questions before the session begins

## **Start the tape:**

### **1. Introductions**

- X Ask people to introduce themselves and tell the group how they feel today

### **2. Mentally stimulating activities**

- X Do you think taking part in mentally stimulating activities is important? Why / why not?
- X What sort of activities are mentally stimulating? Why?
- X Would you consider doing a programme of activities at home with one of your relatives or a close friend?
- X How often do you think you would be able to do activities at home?
- X Do you think you could do the activities 3 times a week?
- X Do you think 30 minutes per session is enough time to allow to do activities?

(10 minutes)

### **3. Manuals** (Explain you will be going through the 'Things to think about' document point by point)

#### **Manual content:**

- X Any mistakes in spelling / grammar?
- X Is the language used appropriate and easy to understand?

- X Are concepts and terms explained well?
- X Is there any information not currently in the manual that you think would be helpful?

**Manual layout:**

- X Size of the text and images
- X Is the layout clear?
- X What do you think about the images?
- X Which version of the manual do you prefer? (i.e. Stapled, ring bound)

**General points about the manual:**

- X Overall, what do you like / dislike about the manual?
- X Do you think it would be easy to use?
- X Are there any other comments you would like to make?

(10 minutes)

**4. Practical issues related to running the programme**

- X In some of the sessions such as those involving cooking or being creative, you will have to provide your own resources, do you think this might be a problem?
- X Can you foresee any practical difficulties carers might face if they were to take part in this programme?
- X What kind of support do you think you might need if you were to take part in this programme?
- X Would you be happy to receive regular phone calls from a researcher to address any problems or issues with the programme?
- X How often do you think telephone support would be required? What about home visits?
- X Do you think attending a group training day would be feasible for carers?
- X How easy do you think it would be to arrange care for the person with dementia if you were to attend a group training day?

(20 minutes)

**5. Activities**

**Resource manuals**

- X What do you think about the layout of the resources?
- X What do you think about the images?

- X What do you think about the activities in the manual?
- X Would you prefer to have the resources bound as a book or as loose sheets of paper in a box folder?
- X Are the instructions clear and easy to follow?

(20 minutes)

**STOP TAPE**

**6. Finish with thanks, raffle and token gifts**

## INFORMATION SHEET FOR CAREGIVERS: FOCUS GROUPS

### Individualised (one-to-one) Cognitive Stimulation Therapy (iCST) for People with Dementia

#### **Invitation to participate in a focus group**

You are being invited to take part in a focus group about a form of one-to-one Cognitive Stimulation Therapy administered by caregivers to people with dementia. The following information is for you to understand why the research is being done and what it will involve. Please take time to read it carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

#### **What is the purpose of the study?**

In recent years, cognitive stimulation therapy (CST) groups have shown to be an enjoyable and beneficial therapy for people with dementia and are now a recommended treatment. However, many people cannot or do not want to attend group sessions. This project will show whether individualised (one-to-one) cognitive stimulation is effective in improving cognition and quality of life for the person with dementia. The activities will include, for example, multi-sensory stimulation, word categorisation and discussion of current affairs. The idea is to keep the mind active through enjoyable activities catered to the interest and ability of the individual.

#### **What happens in a focus group?**

You will be part of a small group of between 6 to 8 people, and will be given a presentation about the study by a researcher, who will show you a video clip of a CST session, and some examples of activities and games to be administered during the sessions. You will then have an opportunity to convey and discuss your ideas and opinions on what you have seen with the group. Your feedback and views are very important in helping us to create the most suitable and relevant therapy package of cognitive stimulation for people with memory problems.

#### **Why have I been chosen?**

You have been invited to take part because of your support for a person who at some point had a memory assessment.

#### **Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care your relative/friend receives.

## **What will happen to me if I take part?**

If you decide to take part, you will be asked to attend a venue that is local to you. Your participation in the focus group will last for approximately one hour. You will have a chance to express your views and this will be immensely helpful to us.

## **Expenses**

Any travel expenses incurred by yourself or your relative/friend will be reimbursed.

## **What do I have to do?**

The focus group is aimed at eliciting information and feedback from people like you who are caring for someone with memory problems, and also from those who are experiencing memory problems. Expressing your opinions and views on the activities are crucial in order for us to create an effective and comprehensive therapy package. Therefore you are encouraged to participate and share your ideas with the researchers and the rest of the group.

## **What are the possible disadvantages and risks of taking part?**

iCST aims to be stimulating and enjoyable. Sessions involve discussing themes such as food, childhood and current affairs and the level of risk in taking part is therefore minimal.

## **What are the possible benefits of taking part?**

Taking part in a focus group will be an enjoyable experience. You will be meeting people like yourself, and will be making a worthwhile contribution to an important research study. Previously, people participating in focus groups have reported that they have enjoyed the experience greatly. The advice and feedback we get from all participants in the focus group may help us to treat people with memory problems better in the future.

## **Will my taking part in the study be kept confidential?**

Any information which you provide during the course of the session will be kept strictly confidential. All data is stored without any identifying details under secure conditions.

## **What will happen if I don't want to carry on with the study?**

You and your relative/friend will be free to withdraw from the study at any time, without giving a reason. Withdrawing from the study will not affect the standard of care your relative/friend receives. We will need to use any data collected in the study up to the point of withdrawal.

## **What if something goes wrong?**

If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for your legal costs. Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedures should be available to you. If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution.

## **Who is organising and funding the research?**

The research is funded by Health Technology Assessment (HTA). This funding covers the running costs of the research project and is led by Professor Martin Orrell, who is an Old Age Consultant at North East London Foundation NHS Trust and a Professor of Mental Health and Ageing at University College London.

**What will happen to the results of the research?**

The results will be published by the Department of Health, and in relevant journals. No participants will be identified in any publication arising from the study, without their written consent. We will make arrangements for participants to be informed of the progress of the research and the results through newsletters and local meetings.

**Who has reviewed the study?**

All NHS research is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by the East London 3 Ethics Committee.

**Who can I contact for further information?**

For more information about this research, please contact:

Fara Hamidi  
University College London  
Charles Bell House  
67-73 Riding House Street, London, W1W 7EJ,  
Phone: 02076799461, 07910998915  
Email: [f.hamidi@ucl.ac.uk](mailto:f.hamidi@ucl.ac.uk)

**Or if you have any complaints about this study please contact:**

Fiona Horton R&D Administrator  
R& D Department, NELFT  
Goodmayes Hospital, Maggie Lilley Suite  
Barley Lane  
Ilford Essex, IG3 8YB  
Phone 0844 600 1200 Ext 4485  
Fax 0844 493 0289

Email: [Fiona.Horton@nelft.nhs.uk](mailto:Fiona.Horton@nelft.nhs.uk)

**Thank you for considering taking part in the focus group!**

## INFORMATION SHEET FOR CAREGIVERS: INDIVIDUAL INTERVIEWS

### **Individualised (one-to-one) Cognitive Stimulation Therapy (iCST) for People with Dementia**

#### **Invitation to participate in an Individual Interview**

You are being invited to take part in a one-to-one interview about a form of individual Cognitive Stimulation Therapy administered by caregivers to people with dementia. The following information is for you to understand why the research is being done and what it will involve. Please take time to read it carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

#### **What is the purpose of the study?**

In recent years, cognitive stimulation therapy (CST) groups have shown to be an enjoyable and beneficial therapy for people with dementia and are now a recommended treatment. However, many people cannot or do not want to attend group sessions. This project will show whether individualised (one-to-one) cognitive stimulation is effective in improving cognition and quality of life for the person with dementia. The activities will include, for example, multi-sensory stimulation, word categorisation and discussion of current affairs. The idea is to keep the mind active through enjoyable activities catered to the interest and ability of the individual.

#### **What happens in the individual interview?**

A researcher from UCL will visit you in your home to explain the therapy in more detail and to show you a video clip of a CST session, and some examples of activities and games to be administered during the sessions. You will then have an opportunity to convey and discuss your ideas and opinions on what you have seen with the researcher. Your feedback and views are very important in helping us to create the most suitable and relevant therapy package of cognitive stimulation for people with memory problems.

#### **Why have I been chosen?**

You have been invited to take part because of your support for a person who at some point had a memory assessment.

#### **Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care your relative/friend receives.

## **What will happen to me if I take part?**

If you decide to take part, a researcher from UCL will contact you to arrange a time to visit you that is most suitable for you. The interview will last for approximately one hour. You will have a chance to express your views and this will be immensely helpful to us.

## **Expenses**

No travel expenses will be incurred by yourself or your relative/friend, but in the event that they are, you or your relative/friend will be reimbursed.

## **What do I have to do?**

The interview is aimed at eliciting information and feedback from people like you who are caring for someone with memory problems, and also from those who are experiencing memory problems. Expressing your opinions and views on the activities are crucial in order for us to create an effective and comprehensive therapy package. Therefore you are encouraged to share your ideas with the researcher.

## **What are the possible disadvantages and risks of taking part?**

iCST aims to be stimulating and enjoyable. Sessions involve discussing themes such as food, childhood and current affairs and the level of risk in taking part is therefore minimal.

## **What are the possible benefits of taking part?**

Taking part in an individual interview will be a worthwhile experience. You will be making an important contribution to the research study. The advice and feedback we get from all participants in the interview may help us to treat people with memory problems better in the future.

## **Will my taking part in the study be kept confidential?**

Any information which you provide during the course of the interview will be kept strictly confidential. All data is stored without any identifying details under secure conditions.

## **What will happen if I don't want to carry on with the study?**

You will be free to withdraw from the study at any time without giving a reason. Withdrawing from the study will not affect the standard of care your relative/friend receives. We will need to use any data collected in the study up to the point of withdrawal.

## **What if something goes wrong?**

If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for your legal costs. Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedures should be available to you. If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution.

## **Who is organising and funding the research?**

The research is funded by Health Technology Assessment (HTA). This funding covers the running costs of the research project and is led by Professor Martin Orrell, who is an Old Age Consultant at North East London Foundation NHS Trust and a Professor of Mental Health and Ageing at University College London.

**What will happen to the results of the research?**

The results will be published by the Department of Health, and in relevant journals. No participants will be identified in any publication arising from the study, without their written consent. We will make arrangements for participants to be informed of the progress of the research and the results through newsletters and local meetings.

**Who has reviewed the study?**

All NHS research is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by the East London 3 Ethics Committee.

**Who can I contact for further information?**

For more information about this research, please contact:

Fara Hamidi  
University College London  
Charles Bell House  
67-73 Riding House Street, London, W1W 7EJ,  
Phone:

**Or if you have any complaints about this study please contact:**

Fiona Horton R&D Administrator  
R& D Department, NELFT  
Goodmayes Hospital, Maggie Lilley Suite  
Barley Lane  
Ilford Essex, IG3 8YB  
Phone

**Thank you for considering taking part in the individual interview!**

## INFORMATION SHEET FOR PARTICIPANTS: FOCUS GROUPS

### Individualised (one-to-one) Cognitive Stimulation Therapy (iCST) for People with Dementia

#### **Invitation to participate in a focus group**

You are being invited to take part in a focus group about a form of one-to-one Cognitive Stimulation Therapy administered by caregivers to people with dementia. The following information is for you to understand why the research is being done and what it will involve. Please take time to read it carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

#### **What is the purpose of the study?**

In recent years, cognitive stimulation therapy (CST) groups have shown to be an enjoyable and beneficial therapy for people with dementia and are now a recommended treatment. However, many people cannot or do not want to attend group sessions. This project will show whether individualised (one-to-one) cognitive stimulation is effective in improving cognition and quality of life for the person with dementia. The activities will include, for example, multi-sensory stimulation, word categorisation and discussion of current affairs. The idea is to keep the mind active through enjoyable activities catered to the interest and ability of the individual.

#### **What happens in a focus group?**

You will be part of a small group of between 6 to 8 people, and will be given a presentation about the study by a researcher, who will show you a video clip of a CST session, and some examples of activities and games to be administered during the sessions. You will then have an opportunity to convey and discuss your ideas and opinions on what you have seen with the group. Your feedback and views are very important in helping us to create the most suitable and relevant therapy package of cognitive stimulation for people with memory problems.

#### **Why have I been chosen?**

You have been invited to take part because you have at some point had a memory assessment.

#### **Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

## **What will happen to me if I take part?**

If you decide to take part, you will be asked to attend a venue that is local to you. Your participation in the focus group will last for approximately one hour. You will have a chance to express your views and this will be immensely helpful to us.

## **Expenses**

Any travel expenses incurred by yourself or your relative/friend will be reimbursed.

## **What do I have to do?**

The focus group is aimed at eliciting information and feedback from people like you who are experiencing memory problems, and also from those who are caring for people with memory problems. Expressing your opinions and views on the activities are crucial in order for us to create an effective and comprehensive therapy package. Therefore you are encouraged to participate and share your ideas with the researchers and the rest of the group.

## **What are the possible disadvantages and risks of taking part?**

iCST aims to be stimulating and enjoyable. Sessions involve discussing themes such as food, childhood and current affairs and the level of risk in taking part is therefore minimal.

## **What are the possible benefits of taking part?**

Taking part in a focus group will be an enjoyable experience. You will be meeting people like yourself, and will be making a worthwhile contribution to an important research study. Previously, people participating in focus groups have reported that they have enjoyed the experience greatly. The advice and feedback we get from all participants in the focus group may help us to treat people with memory problems better in the future.

## **Will my taking part in the study be kept confidential?**

Any information which you provide during the course of the session will be kept strictly confidential. All data is stored without any identifying details under secure conditions.

## **What will happen if I don't want to carry on with the study?**

You and your relative/friend will be free to withdraw from the study at any time, without giving a reason. Withdrawing from the study will not affect the standard of care you receive. We will need to use any data collected in the study up to the point of withdrawal.

## **What if something goes wrong?**

If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for your legal costs. Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedures should be available to you. If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution.

## **Who is organising and funding the research?**

The research is funded by Health Technology Assessment (HTA). This funding covers the running costs of the research project and is led by Professor Martin Orrell, who is an Old Age Consultant at North East London Foundation NHS Trust and a Professor of Mental Health and Ageing at University College London.

**What will happen to the results of the research?**

The results will be published by the Department of Health, and in relevant journals. No participants will be identified in any publication arising from the study, without their written consent. We will make arrangements for participants to be informed of the progress of the research and the results through newsletters and local meetings.

**Who has reviewed the study?**

All NHS research is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by the East London 3 Ethics Committee.

**Who can I contact for further information?**

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**Thank you for considering taking part in the focus group!**

## INFORMATION SHEET FOR PARTICIPANTS: INDIVIDUAL INTERVIEWS

### **Individualised (one-to-one) Cognitive Stimulation Therapy (iCST) for People with Dementia**

#### **Invitation to participate in an Individual Interview**

You are being invited to take part in a one-to-one interview about a form of individual Cognitive Stimulation Therapy administered by caregivers to people with dementia. The following information is for you to understand why the research is being done and what it will involve. Please take time to read it carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

#### **What is the purpose of the study?**

In recent years, cognitive stimulation therapy (CST) groups have shown to be an enjoyable and beneficial therapy for people with dementia and are now a recommended treatment. However, many people cannot or do not want to attend group sessions. This project will show whether individualised (one-to-one) cognitive stimulation is effective in improving cognition and quality of life for the person with dementia. The activities will include, for example, multi-sensory stimulation, word categorisation and discussion of current affairs. The idea is to keep the mind active through enjoyable activities catered to the interest and ability of the individual.

#### **What happens in the individual interview?**

A researcher from UCL will visit you in your home to explain the therapy in more detail and to show you a video clip of a CST session, and some examples of activities and games to be administered during the sessions. You will then have an opportunity to convey and discuss your ideas and opinions on what you have seen with the researcher. Your feedback and views are very important in helping us to create the most suitable and relevant therapy package of cognitive stimulation for people with memory problems.

#### **Why have I been chosen?**

You have been invited to take part because you have at some point had a memory assessment.

#### **Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

## **What will happen to me if I take part?**

If you decide to take part, a researcher from UCL will contact you to arrange a time to visit you that is most suitable for you. The interview will last for approximately one hour. You will have a chance to express your views and this will be immensely helpful to us.

## **Expenses**

No travel expenses will be incurred by yourself or your relative/friend, but in the event that they are, you or your relative/friend will be reimbursed.

## **What do I have to do?**

The interview is aimed at eliciting information and feedback from people like you who are experiencing memory problems, and also from those who are caring for people with memory problems. Expressing your opinions and views on the activities are crucial in order for us to create an effective and comprehensive therapy package. Therefore you are encouraged to share your ideas with the researcher.

## **What are the possible disadvantages and risks of taking part?**

iCST aims to be stimulating and enjoyable. Sessions involve discussing themes such as food, childhood and current affairs and the level of risk in taking part is therefore minimal.

## **What are the possible benefits of taking part?**

Taking part in an individual interview will be a worthwhile experience. You will be making an important contribution to the research study. The advice and feedback we get from all participants in the interview may help us to treat people with memory problems better in the future.

## **Will my taking part in the study be kept confidential?**

Any information which you provide during the course of the interview will be kept strictly confidential. All data is stored without any identifying details under secure conditions.

## **What will happen if I don't want to carry on with the study?**

You will be free to withdraw from the study at any time without giving a reason. Withdrawing from the study will not affect the standard of care you receive. We will need to use any data collected in the study up to the point of withdrawal.

## **What if something goes wrong?**

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**Who has reviewed the study?**

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R& D Department, NELFT  
Goodmayes Hospital, Maggie Lilley Suite  
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Phone

**Thank you for considering taking part in the individual interview!**

**Caregiver Consent Form (MCA) – Focus Groups  
Individualised Cognitive Stimulation Therapy (iCST) for People with Dementia**

Name of Researcher:.....

**Please Initial Boxes**

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without the medical care or legal rights of myself or my relative being affected.
3. I understand that all information given by me or about me will be treated as confidential by the research team.
4. I agree to take part in the above focus group.

**Name of Caregiver**

Date

Signature

**Name of relative**

Name of Person taking consent  
(if different from the researcher)

Date

Signature

**Researcher**

Date

Signature

**Participant Consent Form (MCA) – Focus Groups  
Individualised Cognitive Stimulation Therapy (iCST) for People with Dementia**

Name of Researcher:.....

**Please Initial Boxes**

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected.
3. I understand that all information given by me or about me will be treated as confidential by the research team.
4. I agree to take part in the above focus group.

**Name of Participant**

Date

Signature

Name of Person taking consent  
(if different from the researcher)

Date

Signature

**Researcher**

Date

Signature

**Name of carer**

Date

Signature

**Caregiver Consent Form (MCA) – Individual Interviews**

**Individualised Cognitive Stimulation Therapy (iCST) for People with Dementia**

Name of Researcher:.....

**Please Initial Boxes**

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without the medical care or legal rights of myself or my relative being affected.
3. I understand that all information given by me about me will be treated as confidential by the research team.
4. I agree to take part in the above interview.

**Name of Caregiver**

Date

Signature

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**Name of relative**

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Name of Person taking consent  
(if different from the researcher)

Date

Signature

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**Researcher**

Date

Signature

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**Participant Consent Form (MCA) – Individual Interviews  
Individualised Cognitive Stimulation Therapy (iCST) for People with Dementia**

Name of Researcher:.....

**Please Initial Boxes**

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.
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3. I understand that all information given by me or about me will be treated as confidential by the research team.
4. I agree to take part in the above interview.

**Name of Participant**

Date

Signature

Name of Person taking consent  
(if different from the researcher)

Date

Signature

**Researcher**

Date

Signature

**Name of carer**

Date

Signature

# Monitoring Progress

## My Life

Part 1 completed? Yes  No

Part 2 completed? Yes  No

Please circle the appropriate response

Statement	Not at All	A little	Moderately	Quite a Lot	Extremely
Did the person show <b>interest</b> ?	1	2	3	4	5
Did the person <b>communicate</b> ?	1	2	3	4	5
Did the person show <b>enjoyment</b> ?	1	2	3	4	5
Were the sessions too <b>easy</b> ?	1	2	3	4	5
Were the sessions too <b>difficult</b> ?	1	2	3	4	5
How would you rate the person's <b>mood</b> ?	Poor	Fair	Good	Very Good	Excellent

How long did you spend on each session?

Part 1 \_\_\_\_\_ minutes

Part 2 \_\_\_\_\_ minutes

Comments about part 1:

Comments about part 2:

# iCST

**Individual Cognitive Stimulation Therapy for people with dementia**

**iCST Skills Training for Carers**

**Information Leaflet**



## **Individual Cognitive Stimulation**

### ***Information for Carers***

This information leaflet has been designed to help and support carers:

- to familiarize themselves with Individual Cognitive Stimulation Therapy
- to increase their knowledge of the main purpose of Individual Cognitive Stimulation
- to provide a brief guide in assisting them in delivering the sessions
- to provide carers with information about support available by the research team

### **What is Individual Cognitive Stimulation Therapy?**

Individual Cognitive Stimulation is a form of therapy that aims to provide people with dementia the opportunity to engage in enjoyable activities catered to their interests. This leaflet provides information on how this form of therapy can be used by family carers to encourage the person with dementia to successfully engage in the activities described in the Manual. The purpose of this leaflet is also to provide you with a brief guide in delivering the sessions, enabling you to build on your own expertise.

We recommend that each carer spends a few minutes reading through this leaflet and we hope that you find the information provided useful. If you have any questions about the therapy or the programme please feel free to ask the researcher at any time for assistance.

## **How can I provide opportunities for mental stimulation for the person I am caring for?**

The aim of iCST is to mentally stimulate, that is to get peoples' minds active and engaged. By engaging in the activities with the person you are caring for you give them the opportunity to exercise skills that they may not use very often or have not used for a while. By observing together pictures and photographs you give them a chance to think of new ideas, and thoughts. One of the purposes of the programme is to stimulate discussion between you and the person you are caring for. All of the sessions provide an opportunity to stimulate language, for example by engaging in activities involving naming people and objects.

## **Is the way I ask questions during iCST sessions important?**

You may have often observed that asking people with dementia 'questions that put them on the spot' is very challenging for the person. We need to ask questions in a way that is more subtle. For example, when speaking about the weather we can say "Do you think this weather is normal for October?, Is it hotter/colder than usual?". We need to focus on the person's strengths and opinions, and not on facts. We should not be asking direct questions about names and facts about individuals, but questions about what the person prefers as opposed to what they know or remember. We also encourage the use of reminiscence during the sessions, which a lot of people seem to enjoy and can help compare how things have changed over time. It is important however to avoid situations where the person we are caring for is exposed to remembering painful memories, or things they prefer not to talk about in relation to the past.

## **Is it important to use visual aids and materials during the sessions?**

Using a lot of materials and senses in the sessions is very important because memory works much better if we do not rely on just one sense. So using a mix of activities involving vision, touch, hearing, taste and smell, and combining all senses if possible can work really well. For example, identifying sounds is helped by looking at pictures, and in food sessions people can taste, smell and feel food with interesting textures. Looking and touching an object, photograph or picture helps support the person's attention and focus during the activities.

## **Is offering choices and different activities helpful?**

It is important to offer choices of activities that will interest and engage the person you are caring for. Offering choices and alternative activities will ensure the person enjoys the programme and is suited to their preferences, and allows them to become involved and make the programme their own. For each session, we have suggested a choice of activities, often geared to people at different levels of ability or different interests. The activities have been organised according to how demanding they are on the person's memory and other cognitive skills. All of these activities could be changed in order to make the programme personally relevant and enjoyable to the person you are caring for.

## **How can I make sure the person makes the most of the programme sessions?**

Ensuring that the person has their glasses or hearing aid while engaging in the activities will help them make most of the sessions. It is helpful to remember that people who experience memory loss often function at less than their full potential, due to lack of stimulation or opportunity to engage in activities. Providing encouragement will allow the person to feel more confident, therefore correcting the person or giving them instructions should be avoided. Making sure that we give the person enough time to respond while engaging in the activities, being careful not to overload or overwhelm them with information, will enable the person to enjoy each activity. This way we can increase exposure to success.

## **Where can I get support and advice in delivering the sessions?**

A member of the research team will always be available to provide you with information, answer any questions you may have, help you with resources or any other aspects of the programme. We welcome all carers to get in touch with us and let us know how we can best support them in delivering the sessions, or ways to improve the programme.

ID Number: \_\_\_\_\_

Caregiver Feedback Form

(to be completed at the end of the set-up visit)

- 1. In general, how would you rate your knowledge of individual cognitive stimulation therapy? (please tick one box):**

**My knowledge of Individual Cognitive Stimulation is:**

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>				

- 2. How would you rate your confidence in delivering the individual cognitive stimulation sessions? (please tick one box):**

Very little	Some	Fair	Good	Very confident
<input type="checkbox"/>				

- 3. How much support will you need by the research team in delivering the individual cognitive stimulation sessions? (please tick one box):**

Not at all	A little	Quite a lot	A lot
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**If you were offered the choice of being trained in using iCST at home or in a venue near where you leave, what would be your preference?**

	Yes	No
I would prefer to be offered the training at my own home	<input type="checkbox"/>	<input type="checkbox"/>
I would prefer to attend group training somewhere outside my own home	<input type="checkbox"/>	<input type="checkbox"/>

ID Number: \_\_\_\_\_

**Researcher's Feedback Form**  
**(to be completed during the set-up visit of field testing)**

The question below refers to the first session delivered by the family carer (that the researcher observed during the set-up visit)

1. In general, how would you rate the success of the first session of the set-up visit? (please tick one box):

Excellent

Very good

Good

Fair

Poor

2. Please complete the items below in terms of carer's ability/confidence and amount of support they will need during the intervention:

STATEMENT	Not at all	A little	Quite a bit	A lot
1. The carer will be able to engage successfully with the person with dementia in the sessions	1	2	3	4
2. Please rate the amount of support you think the carer will need in delivering the sessions	1	2	3	4

Any comments in relation to carer ability & confidence, problems they may encounter, or areas of support can be described below

In this section you can report questions or issues raised during the training session by highlighting both positive & negative comments

**Family carer's comments about the paper based activities, and iCST toolkit. Please provide details below**

**Comments of the family carer about the iCST Manual. Please provide details below**

**Did the family carer communicate any problems he/she may experience while delivering the intervention? Please provide details below**

**Please provide any general further comments or observations below (both positive and negative)**

**PARTICIPANT ID:** \_\_\_\_\_

**Date of call:** \_\_\_\_\_

**Follow-up (eg: 1<sup>st</sup> call, 2<sup>nd</sup> call) :** \_\_\_\_\_

**Duration of call:** \_\_\_\_\_

### **Questions to ask caregivers in follow-up phone calls**

**1)** How are things going in general with the programme?

**2)** How many sessions have you completed so far? (If less than expected  
ie: 3x a week, why?)

**3) Have you encountered any difficulties with the programme? (eg: unable to get hold of resources, difficulty applying the key principles, resistance from your relative / friend etc.)**

**4) Do you have any comments to make about the manual?**

**5) Do you have any comments to make about the resources?**

**6) Have you used the resources provided or your own? (if provided own, why?)**

**7) Do you think your relative / friend is enjoying the programme so far?**

**8) Do you need any help with a particular issue? (record details of issue and advice given)**

9) Have you received any support with the programme from family or friends? (eg: relatives helping to buy resources, relatives running the sessions)

10) Are you happy to continue with field testing? (if not, why not)

ID Number: \_\_\_\_\_

**Researcher's Feedback Form**  
**(to be completed at the end of the field testing phase- final visit)**

1. In general, how would you rate the success of the sessions after feedback you received by the family carer? (please tick one box):

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>				

2. Please complete the items below in terms of carer's ability/confidence and amount of support required/received during the intervention:

<b>STATEMENT</b>				
	<b>Not at all</b>	<b>A little</b>	<b>Quite a bit</b>	<b>A lot</b>
1. The carer was able to engage successfully with the person with dementia in the sessions	1	2	3	4
2. Please rate the amount of support the carer required/received during the intervention	1	2	3	4

Any comments in relation to carer ability & confidence, problems they encountered, or areas of support can be described below

In this section you can report questions or issues related to the training session by highlighting both positive & negative comments

**Family carer's comments about Manual 1 paper based activities, and iCST toolkit.  
Please provide details below**

**iCST kit items:**

**Magnifying Card:**

**Cards:**

**Dominoes:**

**Session activities:**

**My Life:**

**Current Affairs:**

**Food:**

**Being Creative:**

**Number Games:**

**Quiz Games:**

**Comments of the family carer about iCST Manual 1. Please provide details below**

**Did the family carer communicate any problems he/she experienced while delivering the intervention? Please provide details below**

**Please report below details of contact with participant /carer, describing the type of contact (visit, telephone), the amount for each type of contact (i.e. how long the visit/phone call lasted) and at which time point the contact took place (i.e. after completion of 3 sessions – Week 1)**

Week 1

Week 2

Week 3

Week 4

**Report carer's comments on the feasibility of 3 visits during treatment (separate From assessments)**

**Report carer's preference for 6 separate manuals and 6 separate resource manuals, or combined manuals and resources.**

**Please provide any general further comments or observations below (both positive and negative)**

ID Number: \_\_\_\_\_

Caregiver Feedback Form  
(to be completed at the final visit)

- 1. In general, how would you rate your knowledge of individual cognitive stimulation therapy? (please tick one box):**

**My knowledge of Individual Cognitive Stimulation is:**

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>				

- 2. How would you rate your confidence in delivering the individual cognitive stimulation sessions? (please tick one box):**

Very little	Some	Fair	Good	Very confident
<input type="checkbox"/>				

- 3. How would you rate the support you have received so far in delivering the individual cognitive stimulation sessions? (please tick one box):**

**I would rate the support I have received as:**

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>				

- 4. Please indicate your response to the following statement:**

**“My relative and I have been able to engage successfully in the individual cognitive stimulation sessions”.**

Totally agree	Agree	Not sure	Disagree	Totally disagree
<input type="checkbox"/>				

**It will be really helpful for us to know if you experienced any difficulties during the sessions. This will enable us to improve the support that carers receive during the intervention. If you could provide any details below that would be greatly appreciated.**

## INFORMATION SHEET FOR CAREGIVERS: FIELD TESTING

### Individualised (one-to-one) Cognitive Stimulation Therapy (iCST) for People with Dementia

#### **Invitation to participate in field testing**

You are being invited to take part in the field testing of individual Cognitive Stimulation Therapy (individual CST) administered by caregivers to people with dementia. The following information is for you to understand why the research is being done and what it will involve. Please take time to read it carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

#### **What is the purpose of the study?**

In recent years, cognitive stimulation therapy (CST) groups have shown to be an enjoyable and beneficial therapy for people with dementia and are now a recommended treatment. However, many people cannot or do not want to attend group sessions. This project will show whether individualised (one-to-one) cognitive stimulation is effective in improving cognition and quality of life for the person with dementia. The activities will include, for example, multi-sensory stimulation, word categorisation and discussion of current affairs. The idea is to keep the mind active through enjoyable activities catered to the interest and ability of the individual.

#### **What happens in the field testing?**

You will be given a portion of the individual CST programme to complete with the person with dementia at their home. We will then ask you for feedback about your experience trying the programme. Your feedback and views are very important in helping us to create the most suitable and relevant therapy package of cognitive stimulation for people with memory problems.

#### **Why have I been chosen?**

You have been invited to take part because of your support for a person who at some point had a memory assessment.

#### **Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care your relative/friend receives.

## **What will happen to me if I take part?**

If you decide to take part, you will be provided with training about how to deliver individual CST by a researcher from UCL. Once you have been trained, you will be given the materials and resources you need to complete a portion of the individual CST programme with the person with dementia. You will be supported by a member of the research team during the field testing and will be asked to give feedback about the programme. Expressing your opinions and views on the activities are crucial in order for us to create an effective and comprehensive therapy package. Therefore you are encouraged to share your ideas with the researcher.

## **Expenses**

No travel expenses will be incurred by yourself or your relative/friend, but in the event that they are, you or your relative/friend will be reimbursed.

## **What are the possible disadvantages and risks of taking part?**

Individual CST aims to be stimulating and enjoyable. Sessions involve discussing themes such as food, childhood and current affairs and the level of risk in taking part is therefore minimal.

## **What are the possible benefits of taking part?**

Taking part in the field testing will be a worthwhile experience. You will be making an important contribution to the research study. The advice and feedback we get from all participants in the interview may help us to treat people with memory problems better in the future.

## **Will my taking part in the study be kept confidential?**

Any information which you provide during the course of the interview will be kept strictly confidential. All data is stored without any identifying details under secure conditions.

## **What will happen if I don't want to carry on with the study?**

You will be free to withdraw from the study at any time without giving a reason. Withdrawing from the study will not affect the standard of care your relative/friend receives. We will need to use any data collected in the study up to the point of withdrawal.

## **What if something goes wrong?**

If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for your legal costs. Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedures should be available to you. If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution.

## **Who is organising and funding the research?**

The research is funded by Health Technology Assessment (HTA). This funding covers the running costs of the research project and is led by Professor Martin Orrell, who is an Old Age Consultant at North East London Foundation NHS Trust and a Professor of Mental Health and Ageing at University College London.

## **What will happen to the results of the research?**

The results will be published by the Department of Health, and in relevant journals. No participants will be identified in any publication arising from the study, without their written consent. We will make arrangements for participants to be informed of the progress of the research and the results through newsletters and local meetings.

**Who has reviewed the study?**

All NHS research is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by the East London 3 Ethics Committee.

**Who can I contact for further information?**

For more information about this research, please contact:

Fara Hamidi  
University College London  
Charles Bell House  
67-73 Riding House Street, London, W1W 7EJ.  
Phone: 0

Lauren Yates  
University College London  
Charles Bell House  
67-73 Riding House Street, London, W1W 7EJ.  
Phone:

**Or if you have any complaints about this study please contact:**

Fiona Horton R&D Administrator  
R& D Department, NELFT  
Goodmayes Hospital, Maggie Lilley Suite  
Barley Lane  
Ilford Essex, IG3 8YB  
Phone 0

**Thank you for considering taking part in the field testing!**

## INFORMATION SHEET FOR PARTICIPANTS: FIELD TESTING

### **Individualised (one-to-one) Cognitive Stimulation Therapy (iCST) for People with Memory Problems**

#### **Invitation to participate in field testing**

You are being invited to take part in the field testing of the individual Cognitive Stimulation Therapy (individual CST) programme. Individual CST is a programme of enjoyable and mentally stimulating activities you can do at home with a friend or carer. The following information is for you to understand why the research is being done and what it will involve. Please take time to read it carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

#### **What is the purpose of the study?**

In recent years, cognitive stimulation therapy (CST) groups have shown to be an enjoyable and beneficial therapy for people with memory problems and are now a recommended treatment. However, many people cannot or do not want to attend group sessions. This project will show whether individual CST is effective in improving cognition and quality of life for people with memory problems. The activities will include, for example, multi-sensory stimulation, word categorisation and discussion of current affairs. The idea is to keep the mind active through enjoyable activities catered to the interest and ability of the individual.

#### **What happens in the field testing?**

Your carer or friend will be given a portion of the individual CST programme to complete with you at home. We will then ask you for feedback about your experience trying the programme. Your feedback and views are very important in helping us to create the most suitable and relevant therapy package of cognitive stimulation for people with memory problems.

#### **Why have I been chosen?**

You have been invited to take part because you have at some point had a memory assessment.

#### **Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

## **Expenses**

No travel expenses will be incurred by yourself or your relative/friend, but in the event that they are, you or your relative/friend will be reimbursed.

## **What are the possible disadvantages and risks of taking part?**

Individual CST aims to be stimulating and enjoyable. Sessions involve discussing themes such as food, childhood and current affairs and the level of risk in taking part is therefore minimal.

## **What are the possible benefits of taking part?**

Taking part in field testing will be a worthwhile experience. You will be making an important contribution to the research study. The advice and feedback we get from all participants in the interview may help us to treat people with memory problems better in the future.

## **Will my taking part in the study be kept confidential?**

Any information which you provide during the course of the interview will be kept strictly confidential. All data is stored without any identifying details under secure conditions.

## **What will happen if I don't want to carry on with the study?**

You will be free to withdraw from the study at any time without giving a reason. Withdrawing from the study will not affect the standard of care you receive. We will need to use any data collected in the study up to the point of withdrawal.

## **What if something goes wrong?**

If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for your legal costs. Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedures should be available to you. If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution.

## **Who is organising and funding the research?**

The research is funded by Health Technology Assessment (HTA). This funding covers the running costs of the research project and is led by Professor Martin Orrell, who is an Old Age Consultant at North East London Foundation NHS Trust and a Professor of Mental Health and Ageing at University College London.

## **What will happen to the results of the research?**

The results will be published by the Department of Health, and in relevant journals. No participants will be identified in any publication arising from the study, without their written consent. We will make arrangements for participants to be informed of the progress of the research and the results through newsletters and local meetings.

## **Who has reviewed the study?**

All NHS research is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by the East London 3 Ethics Committee.

## **Who can I contact for further information?**

For more information about this research, please contact:

Fara Hamidi  
University College London  
Charles Bell House  
67-73 Riding House Street, London, W1W 7EJ,  
Phone:

Lauren Yates  
University College London  
Charles Bell House  
67-73 Riding House Street, London, W1W 7EJ,  
Phone: 0

**Or if you have any complaints about this study please contact:**

Fiona Horton R&D Administrator  
R& D Department, NELFT  
Goodmayes Hospital, Maggie Lilley Suite  
Barley Lane  
Ilford Essex, IG3 8YB  
Phone

**Thank you for considering taking part in field testing!**

### Caregiver Consent Form (MCA) – Field Testing

### Individualised Cognitive Stimulation Therapy (iCST) for People with Dementia

Name of Researcher:.....

**Please Initial Boxes**

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without the medical care or legal rights of myself or my relative being affected.
3. I understand that all information given by me about me will be treated as confidential by the research team.
4. I agree to take part in the above interview.

**Name of Caregiver**

Date

Signature

---

**Name of relative / friend**

---

Name of Person taking consent  
(if different from the researcher)

Date

Signature

**Researcher**

Date

Signature

**Participant Consent Form (MCA) –Field Testing  
Individualised Cognitive Stimulation Therapy (iCST) for People with Memory  
Problems**

Name of Researcher:.....

**Please Initial Boxes**

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected.
3. I understand that all information given by me or about me will be treated as confidential by the research team.
4. I agree to take part in the above interview.

**Name of Participant**

Date

Signature

\_\_\_\_\_  
Name of Person taking consent  
(if different from the researcher)

Date

Signature

**Researcher**

Date

Signature

**Name of carer**

Date

Signature

## North Central London Research Consortium

### North Central London Research Consortium

3rd Floor, West Wing  
Camden PCT, St Pancras Hospital  
4 St Pancras Way, London, NW1 0PE

Telephone: 020 7530 5375

Facsimile: 020 7530 3235

[www.camdenproviderservices.nhs.uk](http://www.camdenproviderservices.nhs.uk)

11<sup>th</sup> November 2010

Professor Martin Orrell  
Honorary Consultant Old Age Psychiatrist  
North East London NHS Foundation Trust  
Admin Block, Mascalls Park Hospital  
Mascalls Lane, Brentwood,  
Essex.  
CM14 5HQ

Dear Professor Orrell,

**Title:** Individual Cognitive Stimulation Therapy for dementia (iCST Trial)

**REC Ref:** 10/H0701/71

**R&D Ref:** CSP 51246

I am pleased to confirm that the above study has now received R&D approval, and you may now start your research in **North East London NHS Foundation Trust**. May I take this opportunity to remind you that during the course of your research you will be expected to ensure the following:

- **Patient contact:** only trained or supervised researchers who hold the appropriate Trust/NHS contract (honorary or full) with each Trust are allowed contact with that Trust's patients. If any researcher on the study does not hold a contract please contact the R&D office as soon as possible.
- **Informed consent:** original signed consent forms must be kept on file. A copy of the consent form must also be placed in the patient's notes. Research projects are subject to random audit by a member of the R&D office who will ask to see all original signed consent forms.
- **Data protection:** measures must be taken to ensure that patient data is kept confidential in accordance with the Data Protection Act 1998.
- **Health & safety:** all local health & safety regulations where the research is being conducted must be adhered to.
- **Adverse events:** adverse events or suspected misconduct should be reported to the R&D office and the Ethics Committee.
- **Project update:** you will be sent a project update form at regular intervals. Please complete the form and return it to the R&D office.
- **Publications:** it is essential that you inform the R&D office about any publications which result from your research.
- **Ethics:** R&D approval is based on the conditions set out in the favourable opinion letter from the Ethics Committee. If during the lifetime of your research project, you wish to make a revision or amendment to your original submission, please contact both the Ethics Committee and R&D Office as soon as possible.

Please ensure that all members of the research team are aware of their responsibilities as researchers. For more details on these responsibilities, please check the R&D handbook or NoCLOR website:  
<http://www.noclor.nhs.uk>

We would like to wish you every success with your project

Yours sincerely,

Angela Williams  
R&D Manager

Professor Robert Woods  
 Professor of Clinical Psychology  
 Institute of Medical & Social Care Research  
 Bangor University  
 Bangor  
 LL57 2DG

Chairman/Cadeirydd – Dr. Richard Tranter, MBChB, MRCPsych, PhD  
 Email:

Betsi Cadwaladr University Health Board  
 Ysbyty Gwynedd  
 Clinical Academic Office  
 Bangor, Gwynedd  
 LL57 2PW

10 October 2011

Dear Professor Woods

**Re: Research Project Review**

**Woods 10/H0701/71 iCST Trial : Individual Cognitive Stimulation Therapy for dementia**

The above research project was reviewed at the meeting of the R&D Internal Review Panel held on 06 October 2011.

Documents reviewed:	Version	Date
NHS R&D Form - 51246/131592/14/726	-	29/06/2010
NHS SSI Form - 51246/238443/6/729/109628/220149	-	04/08/2011
Protocol	8	28/06/2010
Participant Information Sheet	1	05/08/2011
Participant Information Sheet – Carers	1	05/08/2011
Consent Form - Consent to Video	1	05/08/2011
Consent Form – Participant	1	05/08/2011
Consent Form – Carers	1	05/08/2011
Participant Information Sheet (Welsh)	1	05/08/2011
Participant Information Sheet – Carers (Welsh)	1	05/08/2011
Consent Form - Consent to Video (Welsh)	1	05/08/2011
Consent Form – Participant (Welsh)	1	05/08/2011
Consent Form – Carers (Welsh)	1	05/08/2011
NHS R&D Form – Signature Page	-	28/06/2010
Funding Approval	-	16/02/2010
Sponsorship Letter	-	29/06/2011
Funding Commencement Letter	-	05/10/2010
Funding Payment Schedule	-	03/06/2010
Insurance Confirmation Letter	-	03/06/2010
Ethics Cover Letter	-	14/07/2010
Ethics Approval Letter	-	24/09/2010
Checklist – SSI	-	-
CV of CI (M Orrell)	-	04/05/2009
CV of PI (B Woods)	-	04/08/2011
CV of Correspondence Contact (A Spector)	-	-

The Committee is satisfied with the scientific validity of the project, the risk assessment, the review of the cost and resource implications and all other research management issues pertaining to the application.

**Please note that it's the PI's responsibility to ensure that all research officers will have to comply with HR policies for the Health Board and apply for honorary contracts/letters of access where appropriate.**

**I have pleasure in confirming that the Internal Review Panel is pleased to grant approval to proceed at BCUHB sites as described in the application.**

Attached you will find a set of approval conditions outlining your responsibilities during the course of this research. Failure to comply with the approval conditions will result in the withdrawal of the approval to conduct this research at this site.

All research conducted at the Betsi Cadwaladr University Health Board sites must comply with the Research Governance Framework for Health and Social Care in Wales (August 2009). An electronic link to this document is provided on the R&D WebPages. Alternatively, you may obtain a paper copy of this document via the R&D Office.

If you would like further information on any other points covered by this letter please do not hesitate to contact me. On behalf of the Committee, may I take this opportunity to wish you every success with your research.

Yours sincerely

Dr Richard Tranter MBChB, MRCPsych, PhD  
Consultant Psychiatrist  
Chairman Internal Review Panel  
Assistant Director of R&D



**RESEARCH IN HUMAN SUBJECTS  
OTHER THAN CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS**

**Standard conditions of approval by the R&D Internal Review Panel**

**Further communications with the Internal Review Panel (IRP)**

Further communications during the research with the IRP that gave R&D Approval (hereafter referred to in this document as "the Committee") are the personal responsibility of the Chief Investigator.

**Commencement of the research**

The study should not commence until the Ethics Committee reviewing the research has confirmed final ethical approval (favourable opinion).

It is assumed that the research will commence within 12 months of the date of the approval. Should the research not commence within 12 months, the Chief Investigator should give a written explanation for the delay. It is open to the Committee to allow a further period of 12 months within which the research must commence. Should the research not commence within 24 months, the approval will be suspended and the application would need to be re-submitted.

**Duration of approval**

The approval for the research generally applies for the duration of the research. If it is proposed to extend the duration of the study as specified in the application form, the Committee should be notified.

**Progress reports**

The Committee is required to keep the approval under review in the light of progress reports and any developments in the study. The Chief Investigator should submit a progress report to the Committee 12 months after the date on which the approval was given. Annual progress reports should be submitted thereafter.

Progress reports should be in the format prescribed by the Committee. An electronic version is available from the R&D office. The R&D Office will send a reminder to the Chief Investigator when the progress report is due. If the progress report is not received within one month the Committee will notify the Sponsor. A failure to submit the report following these steps will result in suspension of the R&D approval for this project.

The Chief Investigator may be requested to attend a meeting of the Committee or Sub-Committee to discuss the progress of the research.

**Amendments**

If it is proposed to make a substantial amendment to the research, the Chief Investigator should submit a notice of amendment to the Committee.

A substantial amendment is any amendment to the terms of the application for review, or to the protocol or other supporting documentation approved by the Committee, that is likely to affect to a significant degree the safety or physical or mental integrity of the research participants, the scientific value of the research or the conduct or management of the research.

Notices of amendment should be in the format prescribed by NRES and published on the website, and should be signed by the Chief Investigator or Sponsor.

A substantial amendment should not be implemented until approval has been given by the IRP and a favourable ethical opinion has been issued by the Ethics Committee, unless the changes to the research are urgent safety measures.

#### Urgent safety measures

The sponsor or the Chief Investigator, or the local Principal Investigator at a research site, may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety.

The Committee must be notified within three days that such measures have been taken, the reasons why and the plan for further action.

#### Adverse Events

The Chief Investigator (or PI as applicable) is responsible for the recording of adverse events and adequate reporting in accordance to the regulatory requirements and BCUHB policies.

#### Conclusion or early termination of the research

The Chief Investigator should notify the Committee in writing that the research has ended within 90 days of its conclusion. The conclusion of the research is defined as the final date or event specified in the protocol, not the completion of data analysis or publication of the results.

If the research is terminated early, the Chief Investigator should notify the Committee within 15 days of the date of termination. An explanation of the reasons for early termination should be given.

Reports of conclusion or early termination should be submitted in the form prescribed by the Committee.

#### Final report

A summary of the final report on the research should be provided to the Committee within 12 months of the conclusion of the study. This should include information on whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research including any feedback to participants.

#### Review of approval

The Committee may review its opinion at any time in the light of any relevant information it receives.

The Chief Investigator may at any time request that the Committee reviews its opinion, or seek advice from the Committee on any issue relating to the research.

#### Breach of approval conditions

Failure to comply with these conditions may lead to suspension or termination of the approval by the Committee.

Wednesday, 15 February 2012

Professor Esme Moniz Cook  
Professor of Clinical  
Psychology/Consultant Clinical  
Psychologist  
Room F31, Health House,  
Grange Park Lane  
Willerby  
HU10 6DT

Dear Prof Esme Moniz Cook

**Re: R&D N°: 11/10/481                    REC N°: 10/H0701/71                    CSP/UKCRN N°: 51246**

**Individual Cognitive Stimulation Therapy for dementia (iCST Trial)**

I am please to notify you formally that NHS permission for research has been granted for this study by Humber NHS Foundation Trust.

**Date of approval of NHS permission for research: 15/02/2012**

NHS permission for the above research has been granted on the basis described in the application form, protocol and supporting documentation. The documents reviewed were:

- Protocol – v8 – 28/06/10
- Participant Information sheet:
  - Participant – v9 – 14/09/2010
  - Home caregivers – v9 – 14/09/2010
- Participant Consent form
  - Caregiver – v9 – 20/09/2010
  - Participant – v9 – 20/09/2010
- CV's

Indemnity for this study is provided by the University College London Hospitals NHS Foundation Trust.

Humber NHS Foundation Trust conducts all research in accordance with the requirements of the Research Governance Framework, and the NHS Intellectual Property Guidance. In undertaking this study you agree to comply with all reporting requirements, systems and duties of action put in place by the trust to deliver research governance, and you must comply with the Trust information management and data protection policies. In addition, you agree to accept the responsibilities associated with your role that are outlined within the Research Governance Framework as follows:

- That satisfactory honorary contracts/letters of access are obtained and copied to Humber NHS Foundation Trust Research Governance team prior to the commencement of any research activity (including those required by new researchers joining the study post-approval).
- The study follows the agreed protocol
- All amendments (including changes to the local research team) need to be submitted in accordance with guidance in IRAS.
- All changes in the status of the project should be reported to the Humber NHS Foundation Trust Research Governance team.
- That the PI co-operates with appropriate monitoring activity carried out by the Humber NHS Foundation Trust Research Governance team.

- Participants should receive appropriate care while involved in the study
- The integrity and confidentiality of clinical, other records and data generated by the study will be maintained.
- All adverse events must be reported using the Trust's Adverse Incidents Policy.
- The research sponsor or the Chief Investigator, or the local Principal Investigator at a research site, may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety.
  - The R&D office should be notified that such measures have been taken. The notification should also include the reasons why the measures were taken and the plan for further action.
  - The R&D Office should be notified within the same time frame of notifying the REC and any other regulatory bodies.
- Any suspected misconduct by anyone involved in the study must be reported
- Permission is only granted for the activities for which a favourable opinion has been given by the REC [and which have been authorised by the MHRA if applicable]

Please note - you must ensure that the protocol is followed at all times. Should you need to amend the protocol, please follow the national research ethics service procedures. You should forward a copy of all amended versions of the protocol and/or documentation together with written confirmation that a favourable opinion has been given by the REC, to the R&D office at the trust, and confirmation that there has been no change in the NHS permission status should be obtained prior to further research activity commencing.

You will be required to complete electronic progress reports and a final monitoring form on completion . As part of this requirement, please ensure that you are able to supply an accurate breakdown of research participant numbers for this trust (recruitment target, actual numbers recruited). To reduce bureaucracy, progress reporting is kept to a minimum, however, if you fail to supply the information requested, the trust may withdraw approval.

Please note that the NHS organisation is required to monitor research to ensure compliance with the Research Governance Framework and other legal and regulatory requirements. This is achieved by random audit of research.

I would like to wish you every success with this project

Yours sincerely

  
Duncan Courtney  
Clinical and Research Governance Manager

CC: Mrs Cathryn Hart

Tel: 01772 773498 (R&amp;D Secretary)

[beverley.lowe@lancashirecare.nhs.uk](mailto:beverley.lowe@lancashirecare.nhs.uk)6<sup>th</sup> July 2012

Professor Martin Orrell  
Professor of Ageing and Mental Health  
University College London  
UCL, Charley Bell House  
67-73 Riding House Street  
London, W1W 7EJ

Dear Prof Orrell,

**Re: NHS Trust Permission to Proceed**

**Project Reference:** 51246

**Project Title:** *Individual Cognitive Stimulation Therapy for dementia (iCST Trial)*

I am pleased to inform you that the above project has received research governance permission.

Please take the time to read through this letter carefully and contact me if you would like any further information. You will need this letter as proof of your permission.

Trust R&D permission covers all locations within the Trust; however, you must ensure you have liaised with and obtained the agreement of individual service/ward managers. You must also contact the relevant service/ward managers prior to accessing the service to make an appointment to visit before you can commence your study in the trust.

**Honorary Research contracts (HRC)**

All researchers with no contractual relationship with any NHS body, who are to interact with individuals in a way that **directly affects the quality of their care**, should hold Honorary Research NHS contracts. Researchers have a contractual relationship with an NHS body either when they are employees or when they are contracted to provide NHS services, for example as independent practitioners or when they are employed by an independent practitioner (*Research Governance Framework for Health and Social Care*, 2005). If a researcher does not require an HRC, they would require a Letter of Access (LoA). For more information on whether you or any of your research team will require an HRC or LoA please liaise with this office. It is your



**Supporting Health and Wellbeing**

Nursing & Governance Directorate



responsibility to inform us if any of your team do not hold Honorary Research NHS contracts/Letters of Access.

### **Research Governance**

The Research Governance Sponsor for this study is The University College London. Whilst conducting this study you must fully comply with the Research Governance Framework. This can be accessed at:

[http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT\\_ID=4108962&chk=Wde1Tv](http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4108962&chk=Wde1Tv)

For further information or guidance concerning your responsibilities, please contact your research governance sponsor or your local R&D office.

### **Risk and Incident Reporting**

Much effort goes into designing and planning high quality research which reduces risk; however untoward incidents or unexpected events (i.e. not noted in the protocol) may occur in any research project. Where these events take place on trust premises, or involve trust service users, carers or staff, you must report the incident within 48 hours via the Trust incident reporting system. If you are in any doubt whatsoever whether an incident should be reported, please contact us for support and guidance.

Regardless of who your employer is when undertaking the research within Lancashire Care NHS Foundation Trust you must adhere to trust policies and procedures at all times.

### **Confidentiality and Information Governance**

All personnel working on this project are bound by a duty of confidentiality. All material accessed in the trust must be treated in accordance with the Data Protection Act (1998) For good practice guidance on information governance contact us.

### **Protocol / Substantial Amendments**

You must ensure that the approved protocol is followed at all times. Should you need to amend the protocol, please follow the Research Ethics Committee procedures and inform all NHS organisations participating in your research.

### **Monitoring / Participant Recruitment Details**

If your study duration is less than one year, you will be required to complete an end of study feedback report on completion. However if your study duration is more than one year, you will be required to complete a short electronic progress report annually and an end of study report on completion. As part of this requirement, please ensure that you are able to supply an accurate breakdown of research participant numbers for this trust (recruitment target, actual numbers recruited). To reduce bureaucracy, progress reporting is kept to a minimum; however, if you fail to supply the information requested, the trust may withdraw permission.

### **Recruitment**

As your study has been included on the UKCRN Clinical Research Portfolio it is important that you ensure your monthly recruitment figures are uploaded onto the UKCRN Portfolio and recorded as Lancashire Care participants, where applicable.

National guidelines expect trusts to report the date when the first participant is recruited to the study, therefore please can you provide this information at that point to the R&D Facilitator, Katie Helm ([Katie.helm@lancashirecare.nhs.uk](mailto:Katie.helm@lancashirecare.nhs.uk)).

Katie will then contact you on a monthly basis with regards to monitoring your recruitment and at this time if you have any concerns please discuss this with her.

### **Final Reports**

At the end of your research study, we will request a final summary report so that your findings are made available to local NHS staff. The details from this report may be published on the NHS Trust internet site to ensure findings are disseminated as widely as possible to stakeholders.

On behalf of this Trust, may I wish you every success with your research. Please do not hesitate to contact us for further information or guidance.

Yours sincerely,

*Louise Worrell*  
**Quality & Research Lead**  
**On Behalf of the Research Governance Sub-Committee**

Cc: [john.mulinga@lancashirecare.nhs.uk](mailto:john.mulinga@lancashirecare.nhs.uk)  
[Salman.karim@lancashirecare.nhs.uk](mailto:Salman.karim@lancashirecare.nhs.uk)  
[David.wilson@ucl.ac.uk](mailto:David.wilson@ucl.ac.uk)  
[a.spector@ucl.ac.uk](mailto:a.spector@ucl.ac.uk)  
[adam.kennedy@dendron.org.uk](mailto:adam.kennedy@dendron.org.uk)  
[angela.aldrige@dendron.org.uk](mailto:angela.aldrige@dendron.org.uk)  
[nichola.verstraelen@dendron.org.uk](mailto:nichola.verstraelen@dendron.org.uk)

Research and Development Directorate  
Wonford House Hospital  
Dryden Road  
Exeter  
EX2 5AF

Tel: 01392 675689/208765  
Fax: 01392 403445

Email: stevencard@nhs.net

21/06/2012

Dr Michael Van Buren Schele  
Abbotsvale Bideford Community Hospital  
Abbotsham Road  
Bideford  
EX39 3AG

Dear Dr Michael Van Buren Schele,

RE: iCST

DPT 0228

REC: 10/H0701/71

NHS permission for the above research has been granted on the basis described in the application form, protocol and supporting documentation. The documents reviewed were:

Protocol V 8 28/04/2010  
Patient Information Sheet V 9 14/09/2010  
Information Sheet for Caregiver V 9 14/09/2010  
Patient Consent Form V 9 20/09/2010  
Consent form for Caregiver V 9 20/09/2010  
Consent form for use of film footage V 8 28/06/2010

Permission is granted on the understanding that the study is conducted in accordance with the Research Governance Framework, ICH GCP (if applicable), and NHS Trust policies and procedures available at <http://rdeweb.exe.nhs.uk/default.asp?a=2&m=0>

Permission is only granted for the activities for which a favourable opinion has been given by the REC (and which have been authorised by the MHRA).

You are reminded that you must report to the R&D office any **adverse event or serious incident**, whether or not you feel it is serious. This requirement is in addition to informing the Chairman of the Research Ethics Committee which approved the study. The research sponsor or the Chief Investigator, or the local Principal Investigator at a research site, may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety. The R&D Department should be notified that such measures have been taken. The notification should also include the reasons why the measures were taken and the plan for further action. The R&D Department should be notified within the same time frame of notifying the REC and any other regulatory bodies.

All amendments (including changes to the local research team) need to be submitted in accordance with guidance in IRAS. These changes must also be reported to the R&D Department. Likewise any change to the status of a project must also be reported to the R&D Department.

Please note that the NHS organisation is required to monitor research to ensure compliance with the Research Governance Framework and other legal and regulatory requirements. This is achieved by random audit of research and requests for study related data. You are also required to submit to the R&D office a **final outcome report** on completion of your study, and to provide interim reports on progress as requested. Should **publications** arise, please send copies to the R&D office, Wonford House for inclusion in the study's R&D file and the Trust's research publications library.

I would also like to remind you of the responsibilities of anyone who conducts research within the NHS, which are:

1. The Data Protection Act requires that you follow the eight principles of 'good information handling' as summarised in the guide for staff.
2. You must be aware of, and comply with Health and Safety standards in relation to your research
3. You must also be aware of NHS Indemnity Arrangements; summary details can be found in Appendix 1.

With best wishes for a successful study.

Yours sincerely,

Dr. Peter Aitken  
Directorate of Research and Development.

## Appendix 1

### RESEARCH IN THE NHS: INDEMNITY ARRANGEMENTS

- NHS indemnity covers clinical negligence. It does not cover indemnity for any other liability such as product liability or employers' liability.
- NHS indemnity is Government policy: it is not a statutory obligation.
- NHS indemnity covers negligent harm to patients and volunteers.
- NHS indemnity means that NHS organisations forgo the right to recover costs and damages from their staff in respect of liabilities arising out of clinical negligence (except where that involves criminal or wilfully negligent behaviour).
- Research is a core NHS activity. It is therefore treated in the same way as any other NHS activity in relation to potential liabilities for clinical negligence.
- For all NHS research activity, whether commercial or non-commercial, liability for clinical negligence on the part of NHS staff lies with the health-care professional's NHS or honorary NHS employer.
- Being a research sponsor does not increase potential liability. However, the sponsorship agreement should clarify where liability lies.
- *Where appropriate*, honorary contracts may be used for those involved in research. They provide the opportunity under the NHS organisation's vicarious liability to define the legal arrangements for non-NHS personnel undertaking research.
- An honorary contract extends an NHS employer's responsibilities, but not beyond its existing legal duty of quality and its common-law duty of care.

**Dorset Community Health Services**

**Forston Clinic**  
**Charminster**  
**Dorchester**  
**Dorset**  
**DT2 9TB**

**Telephone:**  
[www.dorset-pct.nhs.uk](http://www.dorset-pct.nhs.uk)  
[paul.dillon@dhuft.nhs.uk](mailto:paul.dillon@dhuft.nhs.uk)

Dr Steve Simpson  
Consultant Psychiatrist  
Dorset Healthcare University NHS  
Foundation Trust  
Stewart Lodge  
Yeatman Hospital  
Sherborne  
Dorset  
DT9 3JU

28 May 2012

Dear Dr Simpson

**Title:** *Individual Cognitive Stimulation Therapy for dementia (ICST) Trial*

Thank you for submitting the above project to the Dorset Healthcare University NHS Foundation Trust (DHUFT) for NHS permission for research at this Trust.

I am pleased to inform you that Research Governance approval was granted NHS permission to proceed within DHUFT on the basis described in the application form, protocol and supporting documentation. The documentation received and the governance reviews are detailed in the attached Research Governance Report. NHS permission for the above research is subject to the following conditions:

- DHUFT will act as a research site, conducting the research activities described in the DHUFT Site Specific Information (SSI) form.

The study should be conducted in accordance with the Research Governance Framework for Health and Social Care (2<sup>nd</sup> edition 2005), and Trust policies and procedures. Additionally, it is a legal requirement that Clinical Trials of Investigational Medicinal Products (CTIMPs) are conducted in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004 and Amendment Regulations 2006 incorporating Good Clinical Practice as well as any other relevant regulations.

You should notify the R&D office, within the same timeframe of notifying the REC and any other regulatory bodies, of the following:

- any urgent safety measures implemented by the research sponsor/the chief investigator in order to protect research participants against any immediate hazard to their health or safety

Ref:10/H0701/71 – CSP51245

Date: 13<sup>th</sup> June 2012

Research and Effectiveness Team

Trust Headquarters

Unit 9, The Point

Lions Way

SLEAFORD

Lincolnshire

NG34 8GG

Professor Martin Orrell

Professor of Ageing Mental Health

University College London

UCL, Charles Bell House

67 – 73 Riding House Street

London

W1W 7EJ

Tel: 01529 222206

Fax: 01529 222226

Dear Professor Martin Orrell

**Study title: Individual Cognitive Stimulation Therapy for Dementia (iCST Trial)**

**Chief investigator name: Professor Martin Orrell**

**Sponsor name: University College London**

**REC number: 10/H0701/71**

**Date of permission: 13<sup>th</sup> June 2012**

List of all site(s) for which NHS permission for research is given: Lincolnshire Partnership NHS Foundation Trust

NHS permission for the above research has been granted by Lincolnshire Partnership NHS Foundation Trust on the basis described in the application form, protocol and supporting documentation.

Permission is granted on the understanding that the study is conducted in accordance with the Research Governance Framework, ICH GCP and NHS Trust policies and procedures (available at <http://www.lpt.nhs.uk/>).

Permission is only granted for the activities for which a favourable opinion has been given by the REC [and which have been authorised by the MHRA]

The research sponsor or the Chief Investigator, or the local Principal Investigator at a research site, may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety.

The Research and Effectiveness office should be notified, at the address above, that such measures have been taken. The notification should also include the reasons why the measures were taken and the plan for further action. The Research and Effectiveness Office should be notified within the same time frame of notifying the REC and any other regulatory bodies.

Any research carried out by a Trust employee with the knowledge and permission of the employing organisation will be subject to NHS indemnity. NHS indemnity provides indemnity against clinical risk arising from negligence through the Clinical Negligence Scheme for Trusts

(CNST). Further details can be found at Research in the NHS: Indemnity arrangements (Department of Health 2005).

All amendments (including changes to the local research team) need to be submitted in accordance with guidance in IRAS.

Please inform the Research and Effectiveness department of any changes to study status.

Please note that the NHS organisation is required to monitor research to ensure compliance with the Research Governance Framework and other legal and regulatory requirements. This is achieved by random audit of research.

We are pleased to inform you that you may now commence your research. Please retain this letter to verify that you have Trust permission to proceed. We wish you every success with your work.

Yours sincerely

**Dianne Tetley  
Assistant Director Research and Effectiveness  
Lincolnshire Partnership NHS Foundation Trust**

Cc Sponsor Dr Aimee Spector, Department of Clinical Psychology, 1 – 19 Torrington Place, London, WC1E 6BT

Enc: Data Protection Guidance on the transportation of personal identifiable data

Research and Development  
The Knowledge Centre  
Hellesdon Hospital  
Drayton High Road,  
Norwich, NR65BE  
Telephone 01603 421255  
E mail: [RDofficemailbox@nsft.nhs.uk](mailto:RDofficemailbox@nsft.nhs.uk)

Professor Martin Orrell  
Professor of Ageing and Mental Health  
University College London  
2<sup>nd</sup> Floor, Charles Bell House  
67-73 Riding House Street  
London  
W1W 7EJ

29<sup>th</sup> May 2012

Dear Professor Orrell,

**Re: Individual Cognitive Stimulation Therapy for dementia (iCST Trial) (CSP #51246)**

Thank you for submitting the above project for local research governance approval. I am pleased to inform you that your project has been given full approval and you may begin your research at the following site:

- Norfolk & Suffolk NHS Foundation Trust

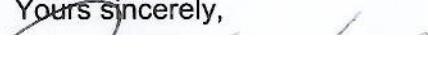
I have enclosed two copies of the Standard Terms and Conditions of Approval. Please sign both copies returning one copy to the Research and Development office, at the above address, and keeping the other in your study file. Failure to return the standard terms and conditions may affect the conditions of approval. **Under the agreed Standard Terms and Conditions of Approval you must inform the R&D department of any proposed changes to this study and submit annual progress reports to the R&D department.**

Any researcher(s) whose substantive employer is not the Norfolk & Suffolk NHS Foundation Trust must have a Letter of Access or Honorary Research contract and evidence of Good Clinical Practice (GCP) training before coming on site to conduct their research in this project. Please note that you cannot take part in this study until you have this documentation. If a Letter of Access / Honorary Research Contract has not been issued – please contact us immediately.

If you have any queries regarding this or any other project, please contact, Tom Rhodes, Research Governance Administrator, at the above address.

The reference number for this study is: 2012MH10, and this should be quoted on all correspondence.

Yours sincerely,

  
**Dr Jon Wilson**  
Deputy Medical Director (Research)



Chair: Maggie Wheeler  
Chief Executive: Aidan Thomas  
Trust Headquarters: Hellesdon Hospital, Drayton High Road, Norwich, NR6 5BE  
Tel: 01603 421421 Fax: 01603 421440 [www.nwmhft.nhs.uk](http://www.nwmhft.nhs.uk)



Your research governance approval is valid providing you comply with the conditions set out below:

1. You commence your research within one year of the date of this letter. If you do not begin your work within this time, you will be required to resubmit your application.
2. You notify the Research and Development Office should you deviate or make changes to the approved documents.
3. You alert the Research and Development Office by contacting the address above, if significant developments occur as the study progresses, whether in relations to the safety of individuals or to scientific direction.
4. You complete and return the standard annual self-report study monitoring form when requested to do so at the end of each financial year. Failure to do this will result in the suspension of research governance approval.
5. You comply fully with the Department of Health Research Governance Framework and Trust Research Policies, and in particular that you ensure that you are aware of and fully discharge your responsibilities in respect to Data Protection, Health and Safety, financial probity, ethics and scientific quality. You should refer in particular to Sections 3.5 and 3.6 of the Research Governance Framework.
6. You ensure that all information regarding patients or staff remains secure and strictly confidential at all times. You ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice, Data Protection Act and Human Rights Act. Unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.
7. **UKCRN Portfolio Studies only:** You will make local Trust research team members aware that it is expected that the "first participant, first visit" date should be within 70 days of the full submission for Trust Research Governance Approval, and this date must be reported to the Research and Development office using the email address above. Delay to recruitment due to study-wide developments must be reported to the Trust as soon as possible.
8. **UKCRN Portfolio Studies only:** You will report and upload Trust recruitment to the UKCRN portfolio accurately and in a timely manner, and will provide recruitment figures to the Trust upon request.

#### List of Approved Documents:

<b>Documents Received</b>	<b>Version</b>	<b>Date</b>
Protocol	8a	07.09.11
<b>Patient Information Sheets and Consent</b>		
Caregiver consent form	9	20.09.10
Participant consent form	9	20.09.10
Caregiver Information Sheet	9	14.09.10
Participant Information Sheet	9	14.09.10
<b>Other Patient Related Documentation</b>		
Consent form for use of film footage	8	28.06.10
GP Info Sheet	8	28.06.10



North Central London  
Research Consortium

North Central London Research Consortium

3rd Floor, Bedford House  
125 - 133 Camden High Street  
London, NW1 7JR

24/05/2012

Professor Martin Orrell  
UCL, Charles Bell House  
67-73 Riding House Street  
London  
W1W 7EJ

Dear Professor Orrell,

I am pleased to confirm that any site within **the trust(s) identified above** can act as a PIC for the above study subject to the following conditions:

- Any site within **the trust(s) identified above** that is acting as a PIC **MUST** indicate their willingness to participate by completing the second page of this letter and returning it to our office.
  - The role of the relevant sites will be restricted to identifying potential patients. No research procedures will be conducted in these PICs and these sites **will not** take on the duty of care for patients in relation to the research study; this responsibility will be retained by the external research site.
  - The ethically approved details and relevant guidelines, including data protection, are adhered to.
  - The Trust accepts no responsibility, and provides no indemnity, for any patient-related research procedures, including recruitment and informed consent. Please ensure that all members of the research team are aware of their responsibilities as researchers. For more details on these responsibilities, please check the NoCLOr website: <http://www.noclor.nhs.uk>.

We would like to wish you every success with your project.

Yours sincerely,

## **Emmanuel Rollings-Kamara Senior Research Governance Officer**



North Central London  
Research Consortium

North Central London Research Consortium

3rd Floor, Bedford House

125 - 133 Camden High Street

London, NW1 7JR

**Study Title:** Individual Cognitive Stimulation Therapy for dementia (iCST Trial)  
**Study CI:** Professor Martin Orrell  
**R&D reference:** CSP 51246  
**REC reference:** 10/H0701/71

I agree that this study will involve the PIC site named below. I am happy for this site to be considered as a PIC, and that the facilities available at this site are appropriate, and I am aware of the potential risks and implications of the study. I am satisfied with the method of referring potential participants, and any associated data, to the research team.

Yours sincerely

Please sign here:

---

Name of site coordinator: Dr Liz Sampson

---

Address of site:

---

Name of the trust:

---

Date:

---

# Application for research partnership



## All applicants please note:

- The principal investigator must be sponsored by a recognised higher education learning institute (eg. a University)
- The principal investigator must be studying at PhD level OR has already achieved a PhD
- The project must have received ethics consent from the National Research Ethics Service
- The project must be of local interest and show benefit or value to the Society
- The applicant must prove sufficient experience of working with vulnerable adults, knowledge of the intricacies of working with people with dementia and/or their carers and empathy towards the challenges associated with living with dementia.

## Please attach with your application form:

- Proof of CRB clearance for working with vulnerable adults
- Any additional information which will enhance your application.
- A full scanned copy of the IRAS application form including ALL attachments and supporting documentation and the final letter of consent from NRES.

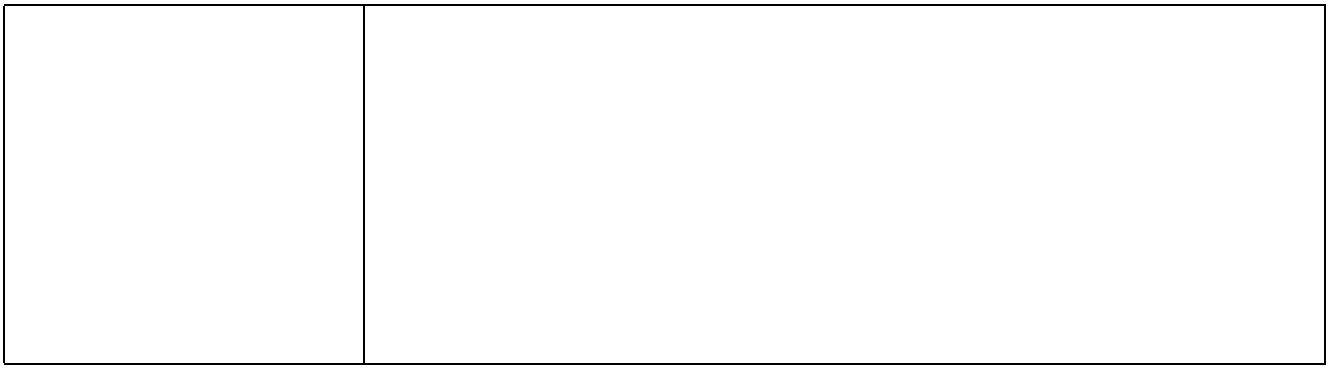
Date submitted: 14/03/2012

Principal Applicant		
Title and full name	Professor Martin Orrell BmedSci, BM BS, FRCPsych, PhD	
Institution	University College London (UCL) and North East London Foundation Trust (NELFT)	
Post held	Prinicpal Investigator for iCST Trial	
Department and address	UCL: Department of Mental Health Science, Charles Bell House, 67-73 Riding House Street, London, W1W 7EJ  NELFT: Research & Development Department, 1 <sup>st</sup> Floor Maggie Lilley Suite, Goodmayes Hospital, Barley Lane, Ilford, IG3 8XJ.	
Contact details	Telephone 07535658341	Email m.orrell@ucl.ac.uk
If you are a student please state the degree you will attain on completion of this research project	N/A	
Please list other applicants and institutes involved in the application	Applicant	Institute

	Miss Fara Hamidi <a href="mailto:f.hamidi@ucl.ac.uk">f.hamidi@ucl.ac.uk</a> 0207 679 9329	UCL : Department of Mental Health Science, Charles Bell House, 67-73 Riding House Street, London, W1W 7EJ
	Miss Lauren Amy Yates <a href="mailto:lauren.yates@ucl.ac.uk">lauren.yates@ucl.ac.uk</a> 0207 679 9329	UCL : Department of Mental Health Science, Charles Bell House, 67-73 Riding House Street, London, W1W 7EJ  NELFT: Research & Development Department, 1 <sup>st</sup> Floor Maggie Lilley Suite, Goodmayes Hospital, Barley Lane, Ilford, IG3 8XJ.

Research title	Individual Cognitive Stimulation Therapy for Dementia (iCST Trial)					
<b>Does this research have ethics approval from NRES?</b>	<p>Yes</p> <p><b>If yes, please include a full scanned copy of the IRAS application including ALL attachments and supporting documentation and the final letter of consent.</b></p>					
Research dates	Start date: March 2012			Finish date: January 2014		
Participants (please circle all that apply)	Staff	Volunteers	<b>Persons with dementia</b>	Carers	<b>Family members</b>	None
Is funding allocated to supporting any costs incurred by the Society in the application	Yes					
Have you contacted anyone within Alzheimer's Society about the proposal?	<p>Yes</p> <p>Coral Kathro / James Pickett / Matt Murray  <a href="mailto:coral.kathro@alzheimers.org.uk">coral.kathro@alzheimers.org.uk</a> / <a href="mailto:james.pickett@alzheimers.org.uk">james.pickett@alzheimers.org.uk</a> /  matt.murray@alzheimers.org.uk</p> <p>Date: 10<sup>th</sup> Feb 2012 / 8<sup>th</sup> March 2012 / 14<sup>th</sup> March 2012</p>					
Are there any conflicts of interest? (eg. do you work or volunteer at the Society)	No					
How specifically do you hope the Alzheimer's Society will be involved and when do you expect involvement to start and finish?	<p>We would like to regularly attend carer groups and Alzheimer's Society events to present the research, and publicise the research in newsletters in order to recruit carers and people with dementia interested in taking part in the project.</p> <p>We would like to begin recruiting from 1<sup>st</sup> March 2012, and we expect to finish recruitment in July 2013.</p>					
Why do you consider the Alzheimer's Society to be an appropriate partner for your research proposal?	<p>The Alzheimer's Society branches in the NELFT boroughs have been instrumental in recruitment of people with dementia and carers in previous projects such as the Support at Home: Interventions to Enhance Life in Dementia project, which is led by Professor Martin Orrell, principal investigator of the iCST trial. Since this partnership has been so successful, we are confident that the Alzheimer's Society will be an appropriate partner in recruitment for iCST.</p> <p>We feel that taking part in iCST will be enriching and beneficial for carers and people with dementia. If, as expected, iCST leads to improvements in quality of life and cognition, this may lead to improved wellbeing for people with dementia, and economic and social benefits such as reduced costs of care and delayed institutionalisation. iCST could be used long term and could rapidly become widely used as a manualised, clinically and cost-effective, standardised, and feasible intervention.</p>					

<p><b>Please detail your experience working with people with dementia or other vulnerable groups?</b></p>	<p><b>Previous experience for Prof Martin Orrell:</b>      Martin was Director/Chair of London Centre for Dementia Care (2001-2009) and Clinical Director/Associate Medical Director, Mental Health Services for Older People, NELMHT (2003-2009). Since 2004 Martin has been Professor of Ageing and Mental Health at the Department of Mental Health Sciences, University College London and Consultant Old Age Psychiatrist and Associate Medical Director for Research and Development, NELFT (North East London Foundation NHS Trust).</p> <p>Martin is Principal Investigator for Support at Home - Interventions to Enhance Life in Dementia (SHIELD). The SHIELD comprises a group of psychological and social interventions designed to reduce disability, improve outcomes, and enhance the quality of life for people with dementia and their carers.</p> <p><b>Previous experience for Fara Hamidi:</b>      Fara spent four years (2006-2010) as a research assistant working on two different projects trialling treatment programmes for prisoners. For the last two years (2010-2012), Fara has been working in the field of dementia care research, trialling Reminiscence Therapy, and more recently the individual Cognitive Stimulation Therapy study. Fara's main responsibilities in her research posts have included:</p> <ul style="list-style-type: none"> <li>• Recruitment in NELFT and the voluntary sector for focus groups, interviews, field testing and the main trial</li> <li>• Facilitating focus groups with people with dementia and carers.</li> <li>• Conducting psychometric testing and interviews with vulnerable people (prisoners and people with dementia)</li> <li>• Training carers to deliver the iCST programme to their loved one with dementia</li> <li>• Presenting at carer groups, staff meetings at voluntary sector organisations for recruitment purposes.</li> </ul> <p><b>Previous experience for Lauren Amy Yates:</b>      Lauren spent a year (2008-09) volunteering for Riding for the Disabled (RDA) in Wales, working with both children and adults, supporting them during their riding lessons. She has been working in the field of dementia care research since September 2009. Lauren's main responsibilities as a research assistant on the Maintenance Cognitive Stimulation Therapy (MCST) project (UCL / NELFT) were:</p> <ul style="list-style-type: none"> <li>• Running Cognitive Stimulation Therapy groups for people with dementia in day centres and care homes across London.</li> <li>• Conducting clinical assessments with people with dementia, staff and family carers.</li> </ul> <p>Lauren has been working on the development of iCST since April 2011. During this time she has been involved in:</p> <ul style="list-style-type: none"> <li>• Recruitment in NELFT and the voluntary sector for focus groups, interviews and field testing.</li> <li>• Facilitating focus groups with people with dementia and carers.</li> <li>• Interviewing people with dementia and carers in their homes.</li> <li>• Training and supporting carers to deliver iCST to their friend or relative with dementia.</li> </ul>
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<p><b>Summary of project</b></p> <p>Please include project aim and objectives, a detailed methodology (including recruitment, anticipated number and location of participants) and details of dissemination plans to a maximum of <b>1000 words</b></p> <p>Please attach all appropriate documents with your submission Including;</p> <ul style="list-style-type: none"> <li>- consent forms</li> <li>- information forms</li> <li>- questionnaires</li> <li>- interview templates</li> </ul>	<p><b>Research aim:</b></p> <ul style="list-style-type: none"> <li>- To develop and evaluate a one to one home based version of Cognitive Stimulation Therapy designed to be delivered by carers.</li> </ul> <p><b>Research objectives</b></p> <ol style="list-style-type: none"> <li>1) To investigate whether individual home-based CST benefits cognition and quality of life in people with dementia over six months relative to a control (treatment as usual group).</li> <li>2) To assess the cost effectiveness of iCST relative to treatment as usual.</li> </ol> <p><b>Research methods</b></p> <p><b>Study design</b></p> <p>Multicentre, pragmatic, single blind, randomised 2 treatment arm (iCST vs treatment as usual) controlled clinical trial over 26 weeks.</p> <p><b>Sample</b></p> <p>Participants will be from a range of community settings in the four study sites including London/Essex, Manchester, Hull, and Bangor. People with dementia living in the community and their carers will be recruited from a variety of settings including CMHTs, memory clinics, outpatient clinics, day centres and via existing networks including the voluntary sector e.g. Age Concern, the Alzheimer's Society and the Admiral Nursing services. We intend to recruit 306 dyads (carers and people with dementia) across the 4 study sites.</p> <p><b>Allocation to treatment groups</b></p> <p>The North Wales Clinical Trials Unit (NWORTH) will provide trial management, data management, quality assurance and statistical assistance. Registration of patients and remote randomisation to treatment will be by an adaptive web based randomisation service managed by the North Wales Organisation for Randomised Trials in Health (NWORTH).</p> <p><b>Inclusion criteria</b></p> <p>We will use the Spector, Woods Orrell et al. (2003) standardised criteria for the psychological treatment of people with dementia:</p> <ul style="list-style-type: none"> <li>• Meet DSM IV criteria for dementia</li> <li>• Score 10 or above on the MMSE</li> <li>• Some ability to communicate and understand</li> <li>• See/hear well enough to participate</li> <li>• No major physical illness or disability affecting their participation</li> </ul> <p>Additional criteria will include living in the community and regular availability of a carer (or friend or befriender) to participate in the sessions.</p> <p><b>Intervention</b></p> <p>The iCST programme is based on a modified CST manual, the updated Cochrane Review of CST and Onder et al.'s (2005) programme, and focus group consultation with people with dementia and their carers via Age Concern, the Alzheimer's Society and For Dementia, using the MRC guidance for the development and evaluation of complex interventions (MRC, 2008). Cognitive Stimulation Therapy (CST) as</p>
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	<p>developed by this research group (Spector et al., 2003) is an effective 14 session group programme for people with dementia recommended by the NICE dementia guidelines (NICE, 2006). Maintenance CST (24 weeks) is an extended version of group CST. iCST would be delivered by a carer in regular contact with the person with dementia, either a family carer, a close friend, or a volunteer befriender for 30 minutes, 3 times a week over 25 weeks. Each session will consist of structured cognitive stimulation, of themed activities (such as categorizing objects and word association) tailored to the ability, interests and needs of the individual. All sessions will be described in the manual, and carers will be provided with an Activity Workbook containing paper based resources, and the iCST Toolkit which is comprised of resources such as a deck of cards and maps.</p> <p><i>Training and support</i></p> <p>Carers will receive standardised training to deliver iCST. The carers will be trained using a standardised manual, a DVD, and a standardised protocol. We will ensure that the carer training involves principles of good practice in CST as set out in the CST manual (Spector et al., 2001; Spector et al., 2006). Carers will receive a set up visit at home before the CST programme starts, which will include an appraisal of the interests of the person with dementia and their carer and the resources available at home. Carers will also receive up to ten hours support over six months including telephone support and 3 visits.</p> <p><i>Treatment as usual</i></p> <p>The treatment as usual control group (TAU), comprising of half of the study sample, will not receive any additional intervention. The control group (TAU) would be needed for a comparison with the natural progression of people with dementia.</p> <p><b>Proposed outcome measures</b></p> <p>Assessments will be conducted by a researcher with carer and person with dementia at baseline (pre-iCST); 13 weeks, and 26 weeks (post iCST). The primary outcomes of interest in this trial are cognition, quality of life and cost-effectiveness of iCST. We have selected the ADAS-Cog as the standard measure of cognition in the person with dementia. Quality of life will be measured by the QoL-AD, which is the European standard measure of quality of life in dementia (Moniz-Cook et al., 2008). The Client Service Receipt Inventory (CSRI) is a standardised measure of health/social and formal/informal costs and will be used to measure the cost-effectiveness of iCST.</p> <p><b>References</b></p> <p>Beecham J, Knapp M: Costing psychiatric interventions. In <i>Measuring mental health needs</i>. Edited by Thornicroft G, Brewin C, Wing J. London: Gaskell; 1992:163-183.</p> <p>Logsdon RG, Gibbons LE, McCurry SM et al (1999) Quality of life in Alzheimer's disease: patient and caregiver reports. <i>Journal of Mental Health and Aging</i>, 5, 21– 32.</p> <p>Medical Research Council (2008) Developing and evaluating complex interventions - new guidance. <a href="http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC00487">http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC00487</a></p>
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	<p>1.</p> <p>Moniz-Cook E, Vernooij-Dassen M, Woods R, A et al. (2008) European consensus on outcome measures for psychosocial intervention research in dementia care. <i>Aging and Mental Health</i>, 12, 14-29</p> <p>National Institute for Health and Clinical Excellence and the Social Care Institute for Excellence (NICE-SCIE): <i>Dementia: supporting people with dementia and their carers in health and social care. Clinical Guideline 42</i>. London: NICE-SCIE; 2006.</p> <p>Onder G, Zanetti O, Giacobini E, et al (2005) Reality orientation therapy combined with cholinesterase inhibitors in Alzheimer's disease: randomised controlled trial. <i>British Journal of Psychiatry</i>, 187, 450-455.</p> <p>Rosen WG, Mohs RC, Davis KL (1984) A new rating scale for Alzheimer's disease. <i>American Journal of Psychiatry</i>, 141, 1356-64.</p> <p>Spector A, Orrell M, Davies S, Woods B (2001) The development of an evidence based package of psychological therapies for dementia groups. <i>Neuropsychological Rehabilitation</i> 11, 3\4, 377-397.</p> <p>Spector A, Thorgrimsen L, Woods B, Orrell M (2006) Making a difference - an evidence based group program to offer cognitive stimulation to people with dementia – manual for group leaders. Hawker Publications. London.</p> <p>Spector A, Thorgrimsen L, Woods B, Royan L, Davies S, Butterworth M, Orrell M (2003) A randomised controlled trial investigating the effectiveness of an evidence-based cognitive stimulation therapy programme for people with dementia. <i>British Journal of Psychiatry</i>, 183, 248-254.</p>
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## What is the iCST Programme?



The iCST study is a Health and Technology Assessment funded programme (HTA), sponsored by University College London (UCL). It aims to increase quality of life and cognition for people with dementia.



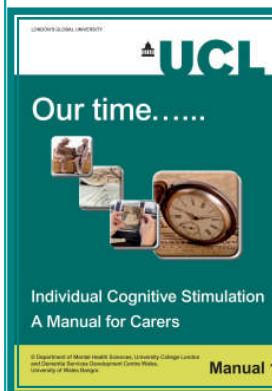
In response to the government's emphasis on improving early interventions and home care for people with dementia, we have developed a home based individual Cognition Stimulation Therapy (CST) package delivered by family carers.

## What is Individual Cognitive Stimulation Therapy?

Individual Cognitive Stimulation Therapy (iCST) is based on the evidence based group CST therapy for people with mild to moderate dementia, which has been found to be beneficial for cognition and quality of life.



The individual CST programme, is delivered by a relative or close friend of the person with dementia for 30 minutes, 3 times a week, over 25 weeks.



Each individual CST session consists of a themed activity (i.e. life story, discussion of current affairs, being creative) and is designed to be mentally stimulating.



## Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given an information sheet to keep and be asked to sign a consent form.

A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you or your relative/friend receives.

## What are the possible benefits of taking part?

If you decide to take part, and your relative/friend is involved in iCST, we hope that this may be of some help to them. Previously, people participating in group CST have reported that they have enjoyed the experience greatly.



## What will participation involve?

If you decide to take part in iCST, you and your relative will be asked to meet with a researcher for an interview, which will involve completing several questionnaires.

If you are allocated in the treatment group, you will be additionally asked to receive training, which will teach you how to deliver iCST. If you are randomized to the treatment as usual (control) group you and your relative will not receive any additional intervention.



Taking part in the study does not involve any lifestyle restrictions or changes. You can carry on your everyday activities as normal while participating in the study. All we ask is that you keep your appointments with us during the time that you are taking part.

## If you are interested in taking part in the iCST programme

Please contact

**Lauren Yates**

**Tel: 0207 679 9329**

**Mobile:**

**Email: lauren.yates@ucl.ac.uk**

## For more information about the study

**Dr Vasiliki Orgeta**

iCST Trial Coordinator

University College London  
Mental Health Science Unit  
67-73 Riding House Street  
2nd Floor, Charles Bell House  
London W1W 7EJ



**Tel: 0207 679 9294**

**Mobile:**

**Fax: 0207 679 9426**

**Email: v.orgeta@ucl.ac.uk**

The iCST study is funded by the National Institute for Health Research's Health Technology Assessment Programme.

**UCL**

**iCST**

**Individual Cognitive Stimulation Therapy**



**A programme of research to improve quality of life and cognition for people with dementia**



**NHS**

**National Institute for Health Research**



Date:

Name and Address of Blind Researcher  
University College London  
Charles Bell House  
67-73 Riding House Street  
W1W 7EJ

Phone:

Mobile:

Email:

Dear Mr and Mrs ,

I hope my letter finds you well and may I take this opportunity to thank you for your time and interest in our study. I am writing to you to inform you that we will be contacting you by phone within the next two weeks. The purpose of my phone call will be to arrange a time to visit you (at a time that is most suitable for you). During the visit you will be asked to complete several questionnaires. The interview process is identical to the previous one and will take approximately two hours.

All information that is collected about you during the course of the research will be kept strictly confidential. Access to this information will be limited to the research team.

May I also remind you that because of the nature of the project **it is significant that you do not communicate to me whether you have been delivering the cognitive stimulation sessions or not.**

If you would like any further information please feel free to contact me at any time. If you would not like to be further contacted about this research please phone mobile or my office number at office number.

Thank you very much for your time in reading this letter and your commitment to our project.

I am looking forward to seeing you soon.

Yours sincerely,

Name of Blind Researcher

QB0

1

**iCST: Individual Cognitive Stimulation Therapy for People with Dementia**

## **Participant Eligibility Sheet**

This sheet should be completed by project researchers conducting baseline interviews with participants and carers.

### **General Instructions to Interviewer**

Before commencing the interview, please insert the **Participant Identity Number** on the questionnaire booklet (using the boxes below).

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

At the end of the interview please complete the boxes below.

Thank you for your cooperation.

**To be completed by the interviewer**

Participant Identity Number:

Centre Name: \_\_\_\_\_

Which assessment is this? *Please tick one box only.*

Baseline Assessment

1<sup>st</sup> Follow-up

2<sup>nd</sup> Follow-up

(13 weeks after baseline)

(26 weeks after baseline)

Completed by (please print name): \_\_\_\_\_

Signed: \_\_\_\_\_

Interview date:  /  /

/   /

QB0

2

## Eligibility Criteria

Please check these criteria for the participant and tick the appropriate box for each row:

- |   |                 |                              |                             |
|---|-----------------|------------------------------|-----------------------------|
| 1. DSM-IV criteria met:   | See Sheet 2 & 3 | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 2. MMSE Score 10 or above   | See QB1         | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 3. CAPE – BRS Score 0 or 1 for both items:  | See Sheet 3     | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 4a. Participant living in community at baseline:  |                 | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| 4b. Care-giver who maintains regular contact, would be <b>willing</b> and <b>able</b> to participate regularly in the intervention and can act as an informant: |                 | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

## Exclusion Criteria

Please check this exclusion criteria for the participant and tick the appropriate box:

1. Does the participant have a major physical illness or sensory impairment Yes  No

Participants should only be entered into the iCST trial if the 'Yes' box for each row under Eligibility Criteria has been ticked and the 'No' box has been ticked under Exclusion Criteria.

## DSM IV Criteria for dementia

- A. The development of multiple cognitive deficits manifested by both
  - 1. memory impairment (impaired ability to learn new information or to recall previously learned information).
  - 2. one (or more) of the following cognitive disturbances:
    - a) aphasia (language disturbance)
    - b) apraxia (impaired ability to carry out motor activities despite intact motor function)
    - c) agnosia (failure to recognize or identify objects despite intact sensory function)
    - d) disturbance in executive functioning (i.e., planning, organizing, sequencing, abstracting)
- B. The cognitive deficits in Criteria A1 and A2 each cause significant impairment in social or occupational functioning and represent a significant decline from a previous level of functioning.
- AND C.** **Alzheimer's Dementia 290.1.** The course is characterised by gradual onset and continuing cognitive decline (the cognitive deficits are not due to vascular dementia or general medical conditions)
- OR C.** **Vascular Dementia (formerly Multi-Infarct Dementia) 290.4.** Focal neurological signs and symptoms (e.g., exaggeration of deep tendon reflexes, extensor plantar response, pseudobulbar palsy, gait abnormalities, weakness of an extremity) or laboratory evidence indicative of cerebrovascular

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Eligibility Criteria version 1.doc

Page 2 of 4

**QB0****3**

disease (e.g. multiple infarctions involving cortex and underlying white matter) that are judged to be etiologically related to the disturbance (not due to general medical conditions)

**OR C.** **Dementia due to other general medical conditions.** There is evidence from the history, physical examination, or laboratory findings that the disturbance is the direct physiological consequence of one of the general medical conditions listed below. (plus all of D above) Code Based on etiological general medical condition: 294.9 Dementia due to HIV Disease; 294.1 Dementia due to Head Trauma; 294.1 Dementia due to Parkinson's Disease; 294.1 Dementia due to Huntington's Disease; 290.10 Dementia due to Pick's Disease; 290.10 Dementia due to Creutzfeldt-Jakob Disease; 294.1 Dementia due to other medical condition [indicate the general medical condition not listed above] (e.g., normal-pressure hydrocephalus, hypothyroidism, brain tumour, vitamin B12 deficiency, intracranial radiation).

**OR C. Dementia not otherwise specified 294.8**

**PLUS D and E**

- D The deficits do not occur exclusively during the course of a delirium.
- E The disturbance is not better accounted for by another Axis I disorder (e.g., Major Depressive Disorder, Schizophrenia).

## **Clifton Assessment Procedures for the Elderly (CAPE) Behaviour Rating Scale (BRS)**

Please consider the following statements for the participant, indicating the appropriate response for each.

1. He / she understands what you communicate to him / her (you may use speaking, writing, or gesturing):  
*Please indicate which of the following is correct. Please tick one box only.*

- understands almost everything you communicate      0
- understands some of what you communicate      1
- understands almost nothing of what you communicate      2

2. He / she communicates in any manner (by speaking, writing, or gesturing):  
*Please indicate which of the following is correct. Please tick one box only.*

- well enough to make him / herself easily understood at all times      0
- can be understood sometimes or with some difficulty      1
- can rarely or never be understood for whatever reason      2

**QB0****4**

## Diagnosis

The type of dementia is not an eligibility criterion, but would be helpful for analysis purposes (if known).

Please indicate which diagnosis of dementia has been given (if known)?

*Please tick one box only.*

Alzheimer's Type

Vascular

Lewy Body

Mixed

Not known

**iCST: Individual Cognitive Stimulation Therapy for People with Dementia**

## Participant Questionnaire

This booklet of questionnaires should be completed by a project researcher in an interview with the participant.

### General Instructions to Interviewer

Before commencing with the interview, please insert the **Participant Identity Number** on the questionnaire booklet (using the boxes below).

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

At the end of the interview please complete the boxes below.

Thank you for your cooperation.

**To be completed by the interviewer**

Participant Identity Number:

--	--	--	--	--	--	--	--	--	--	--	--

Centre Name:

Which assessment is this? *Please tick one box only.*

Baseline Assessment

1<sup>st</sup> Follow-up

(13 weeks after baseline)

2<sup>nd</sup> Follow-up

(26 weeks after baseline)

Completed by (please print name):

Signed:

Interview date:

		/			/				
d	d		m	m		y	y	y	y

**QB1****2****Mini Mental State Examination (MMSE)****Questionnaire 1**

**Instructions:** The following questionnaire is divided into two sections. The first section requires vocal responses, (i.e. orientation, memory, and attention) whereas the second part tests ability to name, follow verbal/written commands, write a sentence and copy a complex polygon. Ask the patient each of the following questions.

**1. ORIENTATION**

Ask for the date. Then ask specifically for parts omitted, e.g. "Can you also tell me what season it is?". Ask in turn "Can you tell me the name of this place?" (town, county, etc.). One point for each correct answer.

	<b>Correct</b>	<b>Incorrect</b>
1. What year are we in?	<input type="checkbox"/>	<input type="checkbox"/>
2. What season is it?	<input type="checkbox"/>	<input type="checkbox"/>
3. What is today's date?	<input type="checkbox"/>	<input type="checkbox"/>
4. What day of the week is it today?	<input type="checkbox"/>	<input type="checkbox"/>
5. What month are we in?	<input type="checkbox"/>	<input type="checkbox"/>
6. What country are we in?	<input type="checkbox"/>	<input type="checkbox"/>
7. What county are we in?	<input type="checkbox"/>	<input type="checkbox"/>
8. What town are we in?	<input type="checkbox"/>	<input type="checkbox"/>
9. Can you tell me the name of this place?	<input type="checkbox"/>	<input type="checkbox"/>
10. What floor of the building are we on?	<input type="checkbox"/>	<input type="checkbox"/>

**Score 0-10**

QB1

## 2. REGISTRATION

Ask the patient if you may test his memory. Then say the names of 3 unrelated objects, clearly and slowly, about one second for each, "**Apple, Table, Penny**". After you have said all 3, ask the patient to repeat them. This first repetition determines his score (0-3) but keep saying them until he can repeat all 3, up to 6 trials. If he does not eventually learn all 3, recall cannot be meaningfully tested.

Score 0-3

## 3. ATTENTION AND CALCULATION

Ask the patient to begin with 100 and count backwards by 7. Stop after 5 subtractions (93, 86, 79, 72, 65). Score the total number of correct answers.

If the patient cannot or will not perform this task, ask him to spell the word "world" backwards. The score is the number of letters in correct order. (E.g. dlrow = 5, dlorw = 3).

Score 0-5

## 4. RECALL

Ask the patient if he can recall the 3 words you previously asked him to remember. Score 0-3.

Score 0-3

## LANGUAGE

### 5. NAMING

Show the patient a wrist watch and ask him what it is. Repeat for pencil. Score 0-2.

Score 0-2

## 6. REPETITION

Ask the patient to repeat the sentence "**No ifs, ands or buts**" after you. Allow only one trial. Score 0 or 1.

Score 0-1

## 7. 3-STAGE COMMAND

Give the patient a piece of plain blank paper and ask him to follow the following 3-stage command: "**Take a paper in your right hand, fold it in half, and put it on the floor**". Score 1 point for each part correctly executed.

Score 0-3

**QB1****4****8. READING**

On a blank piece of paper print the sentence “**Close your eyes**” in letters large enough for the patient to see clearly. Ask him to read it and do what it says. Score 1 point only if he actually closes his eyes.

Score 0-1

**9. WRITING**

Give the patient a blank piece of paper and ask him to write a sentence for you. Do not dictate a sentence, it is to be written spontaneously. It must contain a subject and verb and be sensible. Correct grammar and punctuation are not necessary.

Score 0-1

**10. COPYING**

On a clean piece of paper, draw intersecting pentagons, each side about 1 in. (see response sheet provided), and ask the patient to copy it exactly as it is. All 10 angles must be present and 2 must intersect to score 1 point. Tremor and rotation are ignored.

Score 0-1

**TOTAL SCORE**  
(out of 30) **Alzheimer's Disease Assessment Scale (ADAS-COG)****Questionnaire 2.**

**Instructions:** Please use the Administration Manual for this measure. The test items should be given in the order indicated. Note that the **Word Recall test is given first** and the **Word Recognition task is given last** with the other cognitive tests given in-between.

**1. WORD RECALL**

The subject is given 3 trials to learn a list of 10 high-frequency words, printed in block letters on white cards. The patient reads the 10 words exposed for 2 seconds each. The patient then recalls the words aloud. A total of **3 trials** of reading and recall are given. The score equals the mean number of words not recalled on 3 trials (maximum = 10).

QB1



At the start of the first trial, give the following instructions: "**I am going to show you some words, printed on these white cards one at a time. Please read each word out loud and try to remember it, because later I will ask you to try to remember all of the words I have shown you . Ready, read the word and try to remember it**". After the presentation, ask the subject to try to recall as many of the words as possible by saying: "**Good, now tell me all the words you remember that were on the list**". **Two more** learning and recall trials follow. For trials 2 and 3, say to the subject: "**Now I'm going to show you that same list again. Read each word out loud and try to remember it**".

Trial 1		Trial 2		Trial 3	
Recalled	Not Recalled	Recalled	Not Recalled	Recalled	Not Recalled
Home	<input type="checkbox"/>	<input type="checkbox"/>	Skin	<input type="checkbox"/>	<input type="checkbox"/>
Coin	<input type="checkbox"/>	<input type="checkbox"/>	Child	<input type="checkbox"/>	<input type="checkbox"/>
Railroad	<input type="checkbox"/>	<input type="checkbox"/>	Wheat	<input type="checkbox"/>	<input type="checkbox"/>
Child	<input type="checkbox"/>	<input type="checkbox"/>	Library	<input type="checkbox"/>	<input type="checkbox"/>
Army	<input type="checkbox"/>	<input type="checkbox"/>	Home	<input type="checkbox"/>	<input type="checkbox"/>
Flag	<input type="checkbox"/>	<input type="checkbox"/>	Ocean	<input type="checkbox"/>	<input type="checkbox"/>
Skin	<input type="checkbox"/>	<input type="checkbox"/>	Railroad	<input type="checkbox"/>	<input type="checkbox"/>
Library	<input type="checkbox"/>	<input type="checkbox"/>	Flag	<input type="checkbox"/>	<input type="checkbox"/>
Wheat	<input type="checkbox"/>	<input type="checkbox"/>	Coin	<input type="checkbox"/>	<input type="checkbox"/>
Ocean	<input type="checkbox"/>	<input type="checkbox"/>	Army	<input type="checkbox"/>	<input type="checkbox"/>

TOTAL NOT  
RECALLED
 
TOTAL NOT  
RECALLED
 
TOTAL NOT  
RECALLED
 

**Score = mean number of words not recalled on three trials  
(maximum score = 10)**

SCORE

**QB1****6****2. NAMING OBJECTS AND FINGERS**

The subject is asked to names 12 randomly presented real objects. Give the subject the following instructions: "**Now I am going to show you some objects. I want you to tell me what their names are. What is this called? or What is the name of this thing?**". If the subject does not respond, the examiner should give the clue for that item provided below. If the subject still does not respond or makes an error, go on to the next object.

ITEM	CLUES	Correct	Incorrect (or not named)
Flower – (grows in a garden)		<input type="checkbox"/>	<input type="checkbox"/>
Bed – (used for sleeping in)		<input type="checkbox"/>	<input type="checkbox"/>
Whistle – (makes a sound when you blow on it)		<input type="checkbox"/>	<input type="checkbox"/>
Pencil – (used for writing)		<input type="checkbox"/>	<input type="checkbox"/>
Rattle – (a baby's toy)		<input type="checkbox"/>	<input type="checkbox"/>
Mask – (hides your face)		<input type="checkbox"/>	<input type="checkbox"/>
Scissors – (cuts paper)		<input type="checkbox"/>	<input type="checkbox"/>
Comb – (used on hair)		<input type="checkbox"/>	<input type="checkbox"/>
Wallet – (holds your money)		<input type="checkbox"/>	<input type="checkbox"/>
Harmonica – (a musical instrument)		<input type="checkbox"/>	<input type="checkbox"/>
Stethoscope – (doctor uses it to listen to your heart)		<input type="checkbox"/>	<input type="checkbox"/>
Tweezers – (used to pick up things)		<input type="checkbox"/>	<input type="checkbox"/>

**Total Incorrect  
(maximum 12)**

**QB1****7**

The subject is also asked to name the fingers of his/her dominant hand (e.g. thumb, index [pointer/forefinger], middle, ring finger, and little finger/pinky). Give the subject the following instructions: **“Now I am going to point to a part of your hand and I want you to tell me what it’s called. What is this? or What is another name for this finger?”**.

Item	Correct	Incorrect (or not named)
Thumb	<input type="checkbox"/>	<input type="checkbox"/>
Index/forefinger/pointer	<input type="checkbox"/>	<input type="checkbox"/>
Middle	<input type="checkbox"/>	<input type="checkbox"/>
Ring	<input type="checkbox"/>	<input type="checkbox"/>
Little finger/Pinky	<input type="checkbox"/>	<input type="checkbox"/>

Total Incorrect  
(maximum 5)

 / 

**Score**

- 0 0-2 items (objects and fingers) named incorrectly
- 1 3-5 items (objects and fingers) named incorrectly
- 2 6-8 items (objects and fingers) named incorrectly
- 3 9-11 items (objects and fingers) named incorrectly
- 4 12-14 items (objects and fingers) named incorrectly
- 5 15-17 items (objects and fingers) named incorrectly

Score  
(maximum 5)

QB1

**3. COMMANDS:**

The subject is asked to carry out 5 separate commands with 1 to 5 steps per command. Each command should be read once. If the subject does not respond or makes an error, give the ENTIRE command one more time. Give the following instructions: “**Now I am going to ask you do a few things. First, ... “Make a FIST”, “Point to the CEILING and then to the FLOOR”.** Line up a Pencil, Watch, and Card on the table. Say: “**Put the PENCIL ON TOP OF THE CARD and then PUT IT BACK**”. “**Put the WATCH on the OTHER SIDE OF THE PENCIL and then TURN OVER THE CARD**”. Remove items and say: “**TAP EACH SHOULDER TWICE with TWO FINGERS keeping your EYES SHUT**”. All components must be correct for the response to be scored as correct.

	Correct	Incorrect (or not performed)
Make a <u>fist</u>	<input type="checkbox"/>	<input type="checkbox"/>
Point to the <u>ceiling</u> and then to the <u>floor</u>	<input type="checkbox"/>	<input type="checkbox"/>
Line up a pencil, watch, and card, on the table		
Put the <u>pencil</u> on top of the <u>card</u> and then <u>put it back</u>	<input type="checkbox"/>	<input type="checkbox"/>
Put the <u>watch</u> on the <u>other side of the pencil</u> and then <u>turn over the card</u>	<input type="checkbox"/>	<input type="checkbox"/>
Tap <u>each shoulder twice</u> , with <u>two fingers</u> , keeping your <u>eyes shut</u>	<input type="checkbox"/>	<input type="checkbox"/>

**Score**

- 0 All commands correct
- 1 1 command incorrect, 4 commands correct
- 2 2 commands incorrect, 3 commands correct
- 3 3 commands incorrect, 2 commands correct
- 4 4 commands incorrect, 1 command correct
- 5 All 5 commands incorrect

SCORE  
(maximum 5)

**4. CONSTRUCTIONAL PRAXIS**

Give the subject the following instructions: “**On this piece of paper is a shape. Try to draw another one that looks just like this, somewhere on the page**” and (if required) “**Take your time and try to draw it just like this one**””. The subject should be allowed two attempts for each shape.

QB1

	Correct	Incorrect
Circle	<input type="checkbox"/>	<input type="checkbox"/>
Two Overlapping Rectangles	<input type="checkbox"/>	<input type="checkbox"/>
Diamond (Rhombus)	<input type="checkbox"/>	<input type="checkbox"/>
Cube	<input type="checkbox"/>	<input type="checkbox"/>

**Score**

- |   |   |
|---|---|
| 0 | All 4 drawings correct  |
| 1 | 1 form drawn incorrectly  |
| 2 | 2 forms drawn incorrectly   |
| 3 | 3 forms drawn incorrectly   |
| 4 | 4 forms drawn incorrectly   |
| 5 | No figures drawn, scribbles; parts of forms; words instead of forms |

**SCORE**  
(maximum 5)

**5. IDEATIONAL PRAXIS**

Give the subject the following instructions: "**I want you to pretend you have written yourself a letter. Take this piece of paper, fold it so that it will fit into the envelope, and then put it into the envelope. Then, seal the envelope, address the envelope to yourself, and show me where the stamp goes**". There are 5 components to this task and each one is underlined in the instructions.

After the first complete instruction only one additional reminder should be given for each component, if the subject forgets or is having difficulty.

	Correct	Incorrect (or not done)
Fold the letter	<input type="checkbox"/>	<input type="checkbox"/>
Put the letter in envelope	<input type="checkbox"/>	<input type="checkbox"/>
Seal the envelope	<input type="checkbox"/>	<input type="checkbox"/>
Address the envelope	<input type="checkbox"/>	<input type="checkbox"/>
Indicate where the stamp goes (put stamp on envelope)	<input type="checkbox"/>	<input type="checkbox"/>

QB1

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**Score**

- 0 All components performed correctly
- 1 Failure to perform 1 component
- 2 Failure to perform 2 components
- 3 Failure to perform 3 components
- 4 Failure to perform 4 components
- 5 Failure to perform 5 components

SCORE  
(maximum 5)

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**6. ORIENTATION**

The components of orientation are **person, day of the week, date, month, year, season, time of the day, place**. Make sure no watches, clocks, calendars, etc. are visible to the subject. One restatement of question is allowed (e.g. if subject confuses day and date).

Item	Correct	Incorrect (or not given)
Full name	<input type="checkbox"/>	<input type="checkbox"/>
Day of the Week	<input type="checkbox"/>	<input type="checkbox"/>
Date	<input type="checkbox"/>	<input type="checkbox"/>
Month	<input type="checkbox"/>	<input type="checkbox"/>
Year	<input type="checkbox"/>	<input type="checkbox"/>
Season	<input type="checkbox"/>	<input type="checkbox"/>
Time of Day	<input type="checkbox"/>	<input type="checkbox"/>
Place	<input type="checkbox"/>	<input type="checkbox"/>

**Score = 1 point  
is given for each incorrect response**

SCORE  
(maximum 8)

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Acceptable answers include: Date: +/- one day, Time: +/- one hour, Place: Partial name acceptable (e.g., name of hospital, clinic, or professional building), Season: Within one week prior to onset or within two weeks of termination. Month, Year, Day of the Week, and the subject's first and last name must be exact.

QB1

11

## 7. WORD RECOGNITION

Give the subject the following instructions: “I am going to show you some words printed on these white cards. I want you to read each word out loud and try to remember it”. Continue with the following instructions: “Now I’m going to show you another set of words. Some of the words were on the list I just showed you, and others are new. For each word, I want you to tell me whether it is one of the words I just showed you”.

Then say: “Is this one of the words I showed you before, yes or no?” or “Did I show you this word before?” or “How about this one?”

If the subject does not remember the task (e.g., reads the word rather than responding “Yes” or “No”), then repeat or rephrase the entire question and make a note that the subject had to be reminded of the task instructions. The score equals the mean number of incorrect responses for the **3 trials** (maximum = 12).

Trial 1: score	<input type="text"/>	Reminders	<input type="text"/>
Trial 2: score	<input type="text"/>	Reminders	<input type="text"/>
Trial 3: score	<input type="text"/>	Reminders	<input type="text"/>
<b>Score (mean number of incorrect responses for three trials) (maximum = 12)</b>	<input type="text"/>	<b>Total Reminders (for scoring item 8)</b>	<input type="text"/>

QB1

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**WORD RECOGNITION**

Bold words are the words shown before. Italicized words are the words that the subject has not seen. Tick the subject's responses; circles = incorrect responses.

TRIAL 1			TRIAL 2			TRIAL 3		
Yes/ Shown before	No/ New	Rem	Yes/ Shown before	No/ New	Rem	Yes/ Shown before	No/ New	Rem
Corn	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>River</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<b>Plant</b>
<i>Effort</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Officer</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>River</b>
<i>Party</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Thought</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Amount</i>
<b>River</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<b>Event</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<b>Event</b>
<i>Folly</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>Queen</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<b>Queen</b>
<i>Locker</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>Position</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Industry</i>
<b>Event</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Camp</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>Position</b>
<b>Queen</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Fate</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Occasion</i>
<b>Position</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Golf</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>Dove</b>
<i>Quality</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>Dove</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Cradle</i>
<i>Sunset</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>Belief</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Banality</i>
<b>Dove</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Permission</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Singer</i>
<b>Belief</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<b>Umbrella</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<b>Belief</b>
<b>Umbrella</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<b>Hint</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<b>Umbrella</b>
<i>Allegory</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>Missile</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Hypothesis</i>
<i>Hound</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Blister</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>Hint</b>
<i>Idiom</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Concept</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>Missile</b>
<b>Hint</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<b>Proxy</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<b>Proxy</b>
<b>Missile</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Pianist</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Noose</i>
<i>Gem</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>Lobster</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Distinction</i>
<b>Proxy</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Gender</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>Lobster</b>
<b>Lobster</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<b>Criterion</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Tank</i>
<b>Criterion</b>	<input type="checkbox"/>	<input type="radio"/>	<input type="checkbox"/>	<i>Bullet</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<b>Criterion</b>
<i>Deceit</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Intellect</i>	<input type="radio"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Decree</i>
Total circles ticked (incorrect responses)			Total circles ticked (incorrect responses)			Total circles ticked (incorrect responses)		

Rem = reminded of instructions

**QB1****13****8. REMEMBERING TEST INSTRUCTIONS**

On each recognition trial, the subject is asked prior to presentation of the first two words: "**Did I show you this word before, or is this a new word?**". For the third word, the subject is asked: "**How about this one?**". The procedure used for the third word is repeated for words 4-24. Each instance of memory failure for the test instructions is noted.

Score: 0 = Subject never needs extra reminders of instructions

1 = Very mild – forgets once

2 = Mild – must be reminded 2 times

3 = Moderate – must be reminded 3 or 4 times

4 = Moderately severe – must be reminded 5 or 6 times

5 = Severe – must be reminded 7 or more times

SCORE  
(maximum 5)

**9. SPOKEN LANGUAGE ABILITY**

This item is a global rating of the quality of speech, *i.e.*, clarity, difficulty in making oneself understood. In rating this item the tester should consider all of the speech produced by the subject during the test session. Quantity of speech and word finding difficulty are not rated on this item.

Score: 0 = No instances when it is difficult to understand the subject

1 = Very mild – one instance of lack of understandability

2 = Mild – subject has difficulty less than 25% of the time

3 = Moderate – subject has difficulty 25-50% of the time

4 = Moderately severe – subject has difficulty more than 50% of the time

5 = Severe – one or two word utterance; fluent, but empty speech; mute

SCORE  
(maximum 5)

**10. WORD-FINDING DIFFICULTY IN SPONTAENEOUS SPEECH**

Along with Spoken Language Ability, this item rates impairment in expressive speech, but it rates **only word finding difficulty**. To rate this item, the tester must determine whether the subject has difficulty in finding the desired word in spontaneous speech. The problem may be overcome by circumlocution, *i.e.* giving explanatory phrases or nearly satisfactory synonyms. Do not include finger and object naming in this rating.

**QB1****14**

Score: 0 = No evidence of word finding difficulty in spontaneous speech

1 = Very mild – 1 or 2 instances, not clinically significant

2 = Mild – noticeable circumlocution or synonym substitution

3 = Moderate – loss of words without compensation on occasion

4 = Moderately severe – frequent loss of words without comprehension

5 = Severe – near total loss of content of words; speech sounds empty;  
1 -2 word utterances

**SCORE**  
(maximum 5)

## **11. COMPREHENSION**

This item rates the subject's ability to understand speech. To rate this item, the tester considers how well the subject was able to understand the tester's speech during the opening discussion and during the test session. Do not include responses to commands.

Score: 0 = No evidence of poor comprehension

1 = Very mild – 1 or 2 instances of misunderstanding

2 = Mild – 3-5 instances of misunderstanding

3 = Moderate – requires several repetitions and rephrasing

4 = Moderately severe – subject only occasionally responds correctly, *i.e.*, yes/no questions

5 = Severe – subject rarely responds to questions appropriately, not due to poverty of speech

**SCORE**  
(maximum 5)

**QB1**

Sheet  
No.

**15**

## **12. CONCENTRATION/DISTRACTABILITY**

This item rates the frequency with which the patient is distracted by irrelevant stimuli and/or must be reoriented to the ongoing task because of loss of train of thought or the frequency with which the patient appears to be caught up in his or her own thoughts.

Score: 0 = No evidence of poor concentration or distractibility

1 = Very mild; one instance of poor concentration

2 = Mild; 2-3 instances of poor concentration/distractability; signs of restlessness and inattentiveness

3 = Moderate; 4-5 instances during interview

4 = Moderately severe; poor concentration/distractability throughout much of interview

5 = Severe; extreme difficulty in concentration and extremely distractible, unable to complete tasks

**SCORE  
(maximum 5)**

## ADAS-COG SCORE SUMMARY SHEET

1. WORD RECALL (maximum 10)	<input type="text"/> <input type="text"/>
2. NAMING OBJECTS AND FINGERS (maximum 5)	<input type="text"/> <input type="text"/>
3. COMMANDS (maximum 5)	<input type="text"/> <input type="text"/>
4. CONSTRUCTIONAL PRAXIS (maximum 5)	<input type="text"/> <input type="text"/>
5. IDEATIONAL PRAXIS (maximum 5)	<input type="text"/> <input type="text"/>
6. ORIENTATION (maximum 8)	<input type="text"/> <input type="text"/>
7. WORD RECOGNITION TASK (maximum 12)	<input type="text"/> <input type="text"/>
8. REMEMBERING TEST INSTRUCTIONS (maximum 5)	<input type="text"/> <input type="text"/>
9. SPOKEN LANGUAGE ABILITY (maximum 5)	<input type="text"/> <input type="text"/>
10. WORD FINDING DIFFICULTY IN SPONTANEOUS SPEECH (maximum 5)	<input type="text"/> <input type="text"/>
11. COMPREHENSION (maximum 5)	<input type="text"/> <input type="text"/>
12. CONCENTRATION/DISTRACTABILITY (maximum 5)	<input type="text"/> <input type="text"/>
TOTAL SCORE (maximum 75)	<input type="text"/> <input type="text"/>

**Questionnaire 3. Instructions:** Please administer according to **QOL-AD** standard instructions, using the response sheet. Please indicate the response given by ticking the appropriate box for **each** row.

	Poor	Fair	Good	Excellent	Unable to Choose / Missing
1. Physical health	<input type="checkbox"/>				
2. Energy	<input type="checkbox"/>				
3. Mood	<input type="checkbox"/>				
4. Living situation	<input type="checkbox"/>				
5. Memory	<input type="checkbox"/>				
6. Family	<input type="checkbox"/>				
7. Marriage (or close kin)	<input type="checkbox"/>				
8. Friends	<input type="checkbox"/>				
9. Self as a whole	<input type="checkbox"/>				
10. Ability to do chores around the house	<input type="checkbox"/>				
11. Ability to do things for fun	<input type="checkbox"/>				
12. Money (financial situation)	<input type="checkbox"/>				
13. Life as a whole	<input type="checkbox"/>				

## DEMQOL

**Questionnaire 4. Instructions:** Please administer according to **DEMQOL** standard instructions, using the response sheet.

**For all of the questions I'm going to ask you, I want you to think about the last week.**

**First I'm going to ask about your feelings. In the last week, have you felt .....**

	A lot	Quite a bit	A little	Not at all
1. Cheerful?**	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Worried or anxious?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. That you are enjoying life?**	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Frustrated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Confident?**	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Full of energy?**	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Sad?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Lonely?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Distressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Lively?**	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Irritable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Fed up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. That there are things that you wanted to do but couldn't?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Next, I'm going to ask you about your memory. In the last week, how worried have you been about.....**

	A lot	Quite a bit	A little	Not at all
14. Forgetting things that happened recently?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Forgetting who people are?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Forgetting what day it is?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Your thoughts being muddled?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Difficulty making decisions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Poor concentration?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**QB1****19**

**Now, I'm going to ask you about your everyday life. In the last week, how worried have you been about .....**

	A lot	Quite a bit	A little	Not at all
20. Not having enough company?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. How you get on with people close to you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Getting the affection that you want?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. People not listening to you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Making yourself understood?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Getting help when you need it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Getting to the toilet in time?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. How you feel in yourself?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. Your health overall?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Total	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**We've already talked about lots of things: your feelings, memory and everyday life. Thinking about all of these things in the last week, how would you rate ...**

	Very good	Good	Fair	Poor
29. Your quality of life overall?**	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\*\* items that need to be reversed before scoring

Other total

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------	--------------------------

QB1

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**Questionnaire 5. Instructions:** The carer referred to here is the person who is completing the questionnaire booklets. Response sheets are provided for this questionnaire. Please indicate the response given by ticking the appropriate box for **each** row. Ask the participant to think of their relationship with the person who is caring for them, when answering the questions.

1. My carer [or use name of carer] and I often spend time together in an enjoyable way.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

2. My carer [or use name of carer] and I often disagree.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

3. There is a big distance in the relationship between my carer [or use name of carer] and myself.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

4. My carer [or use name of carer] and I accept each other as we are.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

5. If there are problems my carer [or use name of carer] and I can usually resolve these easily.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

6. I get on well with my carer [or use name of carer].

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

**QB1**


7. My carer [or use name of carer] and I are tender towards each other.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

8. My carer [or use name of carer] often annoys me.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

9. I feel very good if I am with my carer [or use name of carer].

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

10. My carer [or use name of carer] and I often try to impose our opinions on each other.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

11. I blame my carer [or use name of carer] for the cause of my problems.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

12. My carer [or use name of carer] and I appreciate each other as people.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

13. My carer [or use name of carer] does not appreciate enough what I do for him/her.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

**QB1**

14. I am always glad to see him/her if I have not seen him/her for some time.

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

**Geriatric Depression Scale: Short Form**

**Questionnaire 6. Instructions:** Ask the participant to choose the best answer for how they have felt over the past week. Response sheets are provided for this questionnaire.

	<b>Yes</b>	<b>No</b>
1. Are you basically satisfied with your life?	<input type="checkbox"/>	<input type="checkbox"/>
2. Have you dropped many of your activities and interests?	<input type="checkbox"/>	<input type="checkbox"/>
3. Do you feel that your life is empty?	<input type="checkbox"/>	<input type="checkbox"/>
4. Do you often get bored?	<input type="checkbox"/>	<input type="checkbox"/>
5. Are you in good spirits most of the time?	<input type="checkbox"/>	<input type="checkbox"/>
6. Are you afraid that something bad is going to happen to you?	<input type="checkbox"/>	<input type="checkbox"/>
7. Do you feel happy most of the time?	<input type="checkbox"/>	<input type="checkbox"/>
8. Do you often feel helpless?	<input type="checkbox"/>	<input type="checkbox"/>
9. Do you prefer to stay at home, rather than going out and doing new things?	<input type="checkbox"/>	<input type="checkbox"/>
10. Do you feel you have more problems with memory than most?	<input type="checkbox"/>	<input type="checkbox"/>
11. Do you think it is wonderful to be alive?	<input type="checkbox"/>	<input type="checkbox"/>
12. Do you feel pretty worthless the way you are now?	<input type="checkbox"/>	<input type="checkbox"/>
13. Do you feel full of energy?	<input type="checkbox"/>	<input type="checkbox"/>
14. Do you feel that your situation is hopeless?	<input type="checkbox"/>	<input type="checkbox"/>
15. Do you think that most people are better off than you are?	<input type="checkbox"/>	<input type="checkbox"/>

**QB 2****1****iCST: Individual Cognitive Stimulation Therapy for People with Dementia****Carer Questionnaire – Own Health**

Thank you for agreeing to participate in this study. In this booklet you will find 5 short questionnaires about your own health. Please read the general instructions below before completing the questionnaires. Should you have any difficulties, please ask the visiting researcher for assistance.

**General Instructions**

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

Your cooperation is very much appreciated.

**To be completed by the interviewer**

Participant Identity Number:

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Centre Name:

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Which assessment is this? *Please tick one box only.*

Baseline Assessment

1<sup>st</sup> Follow-up

(13 weeks after baseline)

2<sup>nd</sup> Follow-up

(26 weeks after baseline)

Completed by (please print name):

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Signed:

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Interview date:

		/			/				
--	--	---	--	--	---	--	--	--	--

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y

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y

y

**Questionnaire 1**

This survey asks for your views about your health, how you feel and how well you are able to do your usual activities. Thank you for completing this survey. For each of the following questions, please place a tick in the box that best describes your answer.  
*Please tick one box for each item.*

**1. In general, would you say your health is:**

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>				

**2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?**

a) Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf      Yes, limited a lot      Yes, limited a little      No, not limited at all  
           

a) Climbing several flights of stairs      Yes, limited a lot      Yes, limited a little      No, not limited at all  
           

**3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?**

a) Accomplished less than you would like      All of the time      Most of the time      Some of the time      A little of the time      None of the time  
                       

b) Were limited in the kind of work or other activities      All of the time      Most of the time      Some of the time      A little of the time      None of the time

QB 2


4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

a) Accomplished less than you would like      All of the time      Most of the time      Some of the time      A little of the time      None of the time

<input type="checkbox"/>				
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

b) Did work or other activities less carefully than usual      All of the time      Most of the time      Some of the time      A little of the time      None of the time

<input type="checkbox"/>				
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all      A little bit      Moderately      Quite a bit      Extremely

<input type="checkbox"/>				
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

a) Have you felt calm and peaceful?      All of the time      Most of the time      Some of the time      A little of the time      None of the time

<input type="checkbox"/>				
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

b) Did you have a lot of energy?      All of the time      Most of the time      Some of the time      A little of the time      None of the time

<input type="checkbox"/>				
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

c) Have you felt downhearted and low?      All of the time      Most of the time      Some of the time      A little of the time      None of the time

<input type="checkbox"/>				
--------------------------	--------------------------	--------------------------	--------------------------	--------------------------

QB 2

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends and relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/>				

**QB 2****5****Questionnaire 2**

The questionnaire below asks about feelings. Please read each item and tick the box for the reply which comes closest to how you have been feeling in the past week. Don't take too long over your replies; Your immediate reaction to each item will probably be more accurate than a long thought out response. *Please tick one box for each item.*

**I feel tense or 'wound up':**

- |                                 |                          |
|---------------------------------|--------------------------|
| Most of the time                | <input type="checkbox"/> |
| A lot of the time               | <input type="checkbox"/> |
| From time to time, occasionally | <input type="checkbox"/> |
| Not at all                      | <input type="checkbox"/> |

**I still enjoy the things I used to enjoy:**

- |                    |                          |
|--------------------|--------------------------|
| Definitely as much | <input type="checkbox"/> |
| Not quite so much  | <input type="checkbox"/> |
| Only a little      | <input type="checkbox"/> |
| Hardly at all      | <input type="checkbox"/> |

**I get a sort of frightened feeling as if something awful is about to happen:**

- |                                   |                          |
|-----------------------------------|--------------------------|
| Very definitely and quite badly   | <input type="checkbox"/> |
| Yes, but not too badly            | <input type="checkbox"/> |
| A little, but it doesn't worry me | <input type="checkbox"/> |
| Not at all                        | <input type="checkbox"/> |

**I can laugh and see the funny side of things:**

- |                            |                          |
|----------------------------|--------------------------|
| As much as I always could  | <input type="checkbox"/> |
| Not quite so much now      | <input type="checkbox"/> |
| Definitely not so much now | <input type="checkbox"/> |
| Not at all                 | <input type="checkbox"/> |

**QB 2****6****Worrying thoughts go through my mind:**

- A great deal of the time
- A lot of the time
- From time to time but not too often
- Only occasionally

**I feel cheerful:**

- Not at all
- Not often
- Sometimes
- Most of the time

**I can sit at ease and feel relaxed:**

- Definitely
- Usually
- Not often
- Not at all

**I feel as if I am slowed down:**

- Nearly all the time
- Very often
- Sometimes
- Not at all

**I get a sort of frightened feeling like 'butterflies' in the stomach:**

- Not at all
- Occasionally
- Quite often
- Very often

**QB 2****I have lost interest in my appearance:**

- Definitely
- I don't take so much care as I should
- I may not take quite as much care
- I take just as much care as ever

**I feel restless as if I have to be on the move:**

- Very much indeed
- Quite a lot
- Not very much
- Not at all

**I look forward with enjoyment to things:**

- As much as I ever did
- Rather less than I used to
- Definitely less than I used to
- Hardly at all

**I get sudden feelings of panic:**

- Very often indeed
- Quite often
- Not very often
- Not at all

**I can enjoy a good book or radio or TV programme:**

- Often
- Sometimes
- Not often
- Very seldom

**QB 2****Questionnaire 3**

By placing a tick in **one** box in **each** group below, please indicate which statements best describe your own health state today.

**Mobility**

- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

**Self-Care**

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

**Usual Activities (e.g. work, study, housework, family or leisure activities)**

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

**Pain/Discomfort**

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

**Anxiety/Depression:**

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

**QB 2**

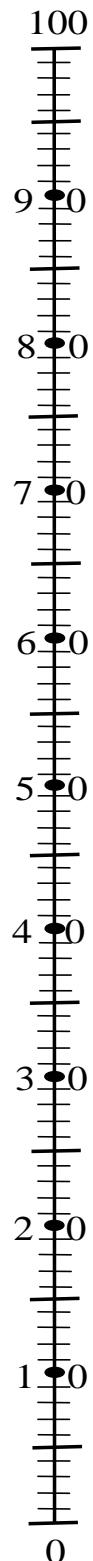
To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**Your own  
health state  
today**

<b>For office use only</b>	<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------------	----------------------	----------------------	----------------------

Best  
imaginable  
health state



Worst  
imaginable  
health state

**Questionnaire 4**

Please think about your relationship with the person you are caring for and answer the following questions by ticking the appropriate box. *Please tick one box in each row.*

**1. My relative and I often spend time together in an enjoyable way.**

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

**2. My relative and I often disagree.**

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

**3. There is a big distance in the relationship between my relative and myself.**

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

**4. My relative and I accept each other as we are.**

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

**5. If there are problems my relative and I can usually resolve these easily.**

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

**6. I get on well with my relative.**

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

**7. My relative and I are tender towards each other.**

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

**8. My relative often annoys me.**

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

**9. I feel very good if I am with my relative.**

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

**10. My relative and I often try to impose our opinions on each other.**

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

**11. I blame my relative for the cause of my problems.**

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

**12. My relative and I appreciate each other as people.**

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

**13. My relative does not appreciate enough what I do for him/her.**

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

**14. I am always glad to see him/her if I have not seen him/her for some time.**

Totally disagree	Disagree	Not sure	Agree	Totally agree
<input type="checkbox"/>				

**QB 2**

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**Questionnaire 5**

Please read the following statements. To the right of each you will find seven numbers, ranging from "1" (Strongly Disagree) on the left to "7" (Strongly Agree) on the right. Tick the box underneath the number that best indicates your feelings about that statement. *Please tick one box in each row.*

**1. I usually manage one way or another.**

Strongly Disagree	Neutral					Strongly Agree
1	2	3	4	5	6	7
<input type="checkbox"/>						

**2. I feel proud that I have accomplished things in life.**

Strongly Disagree	Neutral					Strongly Agree
1	2	3	4	5	6	7
<input type="checkbox"/>						

**3. I usually take things in stride.**

Strongly Disagree	Neutral					Strongly Agree
1	2	3	4	5	6	7
<input type="checkbox"/>						

**4. I am friends with myself.**

Strongly Disagree	Neutral					Strongly Agree
1	2	3	4	5	6	7
<input type="checkbox"/>						

QB 2


**5. I feel that I can handle many things at a time.**

Strongly Disagree		Neutral			Strongly Agree	
1	2	3	4	5	6	7
<input type="checkbox"/>						

**6. I am determined.**

Strongly Disagree		Neutral			Strongly Agree	
1	2	3	4	5	6	7
<input type="checkbox"/>						

**7. I can get through difficult times because I've experienced difficulty before.**

Strongly Disagree		Neutral			Strongly Agree	
1	2	3	4	5	6	7
<input type="checkbox"/>						

**8. I have self-discipline.**

Strongly Disagree		Neutral			Strongly Agree	
1	2	3	4	5	6	7
<input type="checkbox"/>						

**9. I keep interested in things.**

Strongly Disagree		Neutral			Strongly Agree	
1	2	3	4	5	6	7
<input type="checkbox"/>						

QB 2

--

**10. I can usually find something to laugh about.**

Strongly Disagree	Neutral					Strongly Agree
1	2	3	4	5	6	7
<input type="checkbox"/>						

**11. My belief in myself gets me through hard times.**

Strongly Disagree	Neutral					Strongly Agree
1	2	3	4	5	6	7
<input type="checkbox"/>						

**12. In an emergency, I'm someone people can generally rely on.**

Strongly Disagree	Neutral					Strongly Agree
1	2	3	4	5	6	7
<input type="checkbox"/>						

**13. My life has meaning.**

Strongly Disagree	Neutral					Strongly Agree
1	2	3	4	5	6	7
<input type="checkbox"/>						

**14. When I'm in a difficult situation, I can usually find my way out of it.**

Strongly Disagree	Neutral					Strongly Agree
1	2	3	4	5	6	7
<input type="checkbox"/>						

**QB 2**

**15**

**Thank you for completing these questionnaires.  
Your help is very appreciated.**

QB 3

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**iCST: Individualised Cognitive Stimulation Therapy for People with Dementia****Carer Questionnaire – Relative's Health**

Thank you for agreeing to participate in this study. In this booklet you will find 2 short questionnaires about the health of the person that you are caring for. Please read the general instructions below before completing the questionnaires. Should you have any difficulties, please ask the visiting researcher for assistance.

**General Instructions**

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

Your cooperation is very much appreciated.

**To be completed by the interviewer**

Participant Identity Number:

--	--	--	--	--	--	--	--	--	--	--	--

Centre Name:

---

Which assessment is this? *Please tick one box only.*

Baseline Assessment

1<sup>st</sup> Follow-up

(13 weeks after baseline)

2<sup>nd</sup> Follow-up

(26 weeks after baseline)

Completed by (please print name):

---

Signed:

---

Interview date:

		/			/				
d	d		m	m		y	y	y	y

Questionnaire 1

**Instructions:** When you think about your relative's life, there are different aspects, some of which are listed below. Please rate these items based on your relative's life **at the present time** (e.g. within the past few weeks). Please indicate your response by ticking the appropriate box for **each** row.

	Poor	Fair	Good	Excellent
1. Physical health	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Mood	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Living situation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Memory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Family	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Marriage (or close kin)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Self as a whole	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Ability to do chores around the house	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Ability to do things for fun	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Money (financial situation)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Life as a whole	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Questionnaire 2**

**Instructions:** For each activity described below, statements a-e refer to a different level of every-day ability for your relative. Thinking about the last 2 weeks, tick the box that represents your relative's ability. *Please tick one box for each activity.*

**1. Food Please tick one box.**

- a Selects and prepares food as required
- b Able to prepare food if ingredients set out
- c Can prepare food if prompted step by step
- d Unable to prepare food even with prompting and supervision
- e Not applicable

**2. Eating Please tick one box.**

- a Eats appropriately using correct cutlery
- b Eats appropriately if food made manageable and/or uses spoon
- c Uses fingers to eat food
- d Needs to be fed
- e Not applicable

**3. Drink Please tick one box.**

- a Selects and prepares drinks as required
- b Can prepare drinks if ingredients left available
- c Can prepare drinks if prompted step by step
- d Unable to make a drink even with prompting and supervision
- e Not applicable

**4. Drinking Please tick one box.**

- a Drinks appropriately
- b Drinks appropriately with aids, beaker/straw etc.
- c Does not drink appropriately even with aids but attempts to
- d Has to have drinks administered (fed)
- e Not applicable

QB 3

**5. Dressing Please tick one box.**

- a Selects appropriate clothing and dresses self
- b Puts clothes on in wrong order and/or back to front and/or dirty clothing
- c Unable to dress self but moves limbs to assist
- d Unable to assist and requires total dressing
- e Not applicable

**6. Hygiene Please tick one box.**

- a Washes regularly and independently
- b Can wash self if given soap, flannel, towel, etc.
- c Can wash self if prompted and supervised
- d Unable to wash self and needs full assistance
- e Not applicable

**7. Teeth Please tick one box.**

- a Cleans own teeth/dentures regularly and independently
- b Cleans teeth/dentures if given appropriate items
- c Requires some assistance, toothpaste on brush, brush to mouth etc.
- d Full assistance given
- e Not applicable

**8. Bath/Shower Please tick one box.**

- a Bathes regularly and independently
- b Needs bath to be drawn/shower turned on but washes independently
- c Needs supervision and prompting to wash
- d Totally dependent, needs full assistance
- e Not applicable

**9. Toilet/Commode Please tick **one** box.**

- a Uses toilet appropriately when required
- b Needs to be taken to the toilet and given assistance
- c Incontinent of urine or faeces
- d Incontinent of urine and faeces
- e Not applicable

**10. Transfers Please tick **one** box.**

- a Can get in/out of a chair unaided
- b Can get into a chair but needs help to get out
- c Needs help getting in and out of a chair
- d Totally dependent on being put into and lifted from chair
- e Not applicable

**11. Mobility Please tick **one** box.**

- a Walks independently
- b Walks with assistance, i.e. furniture, arm for support
- c Uses aids to mobilize, i.e. frame, sticks etc.
- d Unable to walk
- e Not applicable

**12. Orientation - Time Please tick **one** box.**

- a Fully orientated to time/day/date etc.
- b Unaware of time/day etc. but seems unconcerned
- c Repeatedly asks the time/day/date
- d Mixes up night and day
- e Not applicable

**13. Orientation - Space** Please tick **one** box.

- a Fully orientated to surroundings
- b Orientated to familiar surroundings only
- c Gets lost in home, needs reminding where bathroom is, etc.
- d Does not recognise home as own and attempts to leave
- e Not applicable

**14. Communication** Please tick **one** box.

- a Able to hold appropriate conversation
- b Shows understanding and attempts to respond verbally with gestures
- c Can make self understood but difficulty understanding others
- d Does not respond to or communicate with others
- e Not applicable

**15. Telephone** Please tick **one** box.

- a Uses telephone appropriately, including obtaining correct number
- b Uses telephone if number given verbally/visually, or predialled
- c Answers telephone but does not make calls
- d Unable/unwilling to use telephone at all
- e Not applicable

**16. Housework/Gardening** Please tick **one** box.

- a Able to do housework/gardening to previous standard
- b Able to do housework/gardening but not to previous standard
- c Limited participation even with a lot of supervision
- d Unwilling/unable to participate in previous activities
- e Not applicable

**QB 3****17. Shopping Please tick **one** box.**

- a Shops to previous standard
- b Only able to shop for 1 or 2 items with or without a list
- c Unable to shop alone, but participates when accompanied
- d Unable to participate in shopping even when accompanied
- e Not applicable

**18. Finances Please tick **one** box.**

- a Responsible for own finances at previous level
- b Unable to write cheque but can sign name and recognises money values
- c Can sign name but unable to recognise money values
- d Unable to sign name or recognise money values
- e Not applicable

**19. Games/Hobbies Please tick **one** box.**

- a Participates in pastimes/activities to previous standard
- b Participates but needs instruction/supervision
- c Reluctant to join in, very slow, needs coaxing
- d No longer able or willing to join in
- e Not applicable

**20. Transport Please tick **one** box.**

- a Able to drive, cycle or use public transport independently
- b Unable to drive but uses public transport or bike etc.
- c Unable to use public transport alone
- d Unable/unwilling to use transport even when accompanied
- e Not applicable

**QB 3**

Sheet No.

**8**

**Thank you for completing these questionnaires  
Your help is very appreciated**

# CSRI: Service Use Questionnaire

## iCST: Individual Cognitive Stimulation Therapy for People with Dementia

This booklet of questionnaires should be completed by the researcher in an interview with the carer.

### **General Instructions to Interviewer**

Before commencing the interview, please ensure that the **Participant Identity Number** has been entered in the boxes below.

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment.

To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

At the end of the interview please complete the remaining boxes below.

Your cooperation is very much appreciated.

#### **To be completed by the interviewer**

Participant Identity  
Number:

--	--	--	--	--	--	--	--	--	--

Centre Name:

\_\_\_\_\_

Which assessment is this? *Please tick one box only.*

Baseline Assessment

1<sup>st</sup> Follow-up

(13 weeks after baseline)

2<sup>nd</sup> Follow-up

(26 weeks after baseline)

Completed by (please print  
name):

\_\_\_\_\_

Signed:

\_\_\_\_\_

Interview date:

		/			/			
--	--	---	--	--	---	--	--	--

d d m m y y y y

## Section 1: Participant

**1. How many people are there in your relative's (participant's) household?**

Number

Number of adults including service user

<input type="text"/>	<input type="text"/>
----------------------	----------------------

Number of children under the age of 16

<input type="text"/>	<input type="text"/>
----------------------	----------------------

**2. What kind of accommodation does your relative (participant) live in at the moment? (tick one box)**

Council-rented housing

Housing-association rented housing

Private rented housing

Owner-occupied housing

Other housing

Please describe

**3. Is your relative's (participant's) accommodation "sheltered" housing (has a warden or scheme manager on-site)?**

Yes

No

**4. Has your relative (participant) lived anywhere else during the last 3 months? (excluding hospital stays)**

Yes

Go to Q5

No

Go to Q6

**5. What type of accommodation did your relative (participant) stay in at that time?**

If participant reports a stay in a care/nursing home or other location, complete the questions in that row.

For 'Participant or family contribution', ask: 'Did you or a family member pay for this accommodation?' and tick yes if the person reports having paid all or part of the costs

Service	No	Yes	Reason for using service (e.g. respite)	Name of home (not to be entered into database)	Number of days	Participant or family contribution		Provider (see note*)		
						No	Yes			
Care home	<input type="checkbox"/>	<input type="checkbox"/>				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nursing home	<input type="checkbox"/>	<input type="checkbox"/>				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other - please describe using 'Name of home' box	<input type="checkbox"/>	<input type="checkbox"/>				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

[\*Note: Use the "Name of home" information to complete the Provider box, using WHO codes, after the interview]

**WHO codes**

1	Local Authority/Social Services/Council
2	NHS
3	Voluntary/charitable organisation
4	Private company or insurance company
5	Self or family members
6	Other
7	Researcher unable to classify response
8	Not completed

**Community health and social services**

**6. In the last 3 months, has your relative (participant) used any of the services below? [SHOW CARD 1]**

*Note: please tick the 'no' box if participant has not used the service*

Service	No	Yes	Number of home visits	Number of clinic or office visits	Average duration of contact (minutes)			
GP	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Practice nurse (at GP surgery)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Community/District Nurse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Community psychiatric/Community Mental Health Nurse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Psychiatrist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Social worker or care manager	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Psychologist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Physiotherapist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Occupational therapist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dietician	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Counsellor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mental health team worker	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Specialist nurse (e.g. Admiral Nurse, palliative care nurse, respiratory nurse)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>please describe:</i>								

**7. In the last 3 months, has your relative (participant) used any of the services below? [SHOW CARD 2]**

Note: please tick the 'no' box if participant has not used the service

For 'Participant or family contribution', ask: 'Did you or a family member pay for this service?' and tick yes if the person reports having paid all or part of the costs

Service	No	Yes	Number of home visits	Number of clinic or office visits	Average duration of contact (minutes)	Participant or family contribution	
	No	Yes				No	Yes
Home care/home help	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Home care/home help - Additional organisation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Home care/home help - Additional organisation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cleaner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Meals on wheels	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Laundry service	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sitting service (e.g. Crossroads)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Carer's support worker	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Optician	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Chiropodist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dentist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other health or social care service							
1. .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Day services**

**8. In the last 3 months, has your relative (**participant**) used any of the day services below?**  
 [SHOW CARD 3]

*Note: please tick the 'no' box if participant has not used the service*

*For 'Participant or family contribution', ask: 'Did you or a family member pay for this service?' and tick yes if the person reports having paid all or part of the costs*

Service	No	Yes	Number of times per week	Number of times in last 3 months	Name of service (not to be entered into database)	Participant or family paid or contributed		Provider (see note*)
	No	Yes				No	Yes	
Day centre	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lunch club	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient education group (e.g. reminiscence) <i>please describe:</i> .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other health or social care day services: 1. ....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. ....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

[\*Note: Use the "Name of service" information to complete the Provider box, using WHO codes, after the interview]

**Direct Payments**

**9. Has your relative (**participant**) been in receipt of direct payments, individual budget or personal budget\* **in the last 3 months?****

Direct payments/Personal Budgets	No	Yes	Total weekly value in £
Direct payments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>
Individual budget / Personal budget	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>

\*see Q9 definitions card

**Use of Hospital services**

**10. In the last 3 months, has your relative (participant) used any of the following hospital services?**

*Note: please tick the 'no' box if participant has not used the service*

Service	No	Yes	Name of ward, clinic hospital or centre	Reason for using service (condition, specialty)	Unit of measure	Number of days/ attendances	NHS Trust code*
Accident & Emergency Department (A&E)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Attendance	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
Inpatient ward admission 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Inpatient day	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
Inpatient ward admission 2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Inpatient day	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
Inpatient ward admission 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Inpatient day	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
Inpatient ward admission 4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Inpatient day	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
Inpatient ward admissions 5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Inpatient day	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
Outpatient Department (OPD) Attendance 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Appointment	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
OPD Attendance 2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Appointment	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
OPD Attendance 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Appointment	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
OPD Attendance 4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Appointment	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
OPD Attendance 5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Appointment	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
Day hospital Attendance 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Day attendance	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
Day hospital Attendance 2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Day attendance	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>

[\*Note: Use 'name of hospital' information to assign NHS Trust code after the interview]

### Equipment and adaptations

**11. In the last 3 months, has your relative (participant) had any adaptations or equipment to meet their needs? [SHOW CARD 4]**

Yes

No

If yes, tick the box for each type of change or equipment that the participant has had and ask 'who or which organisation paid for these'.

Type of adaptation or equipment	Tick if yes	Who/Which organisation paid for this?				
		Council	NHS	Self	Voluntary /charity	Other
Outdoor railing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Outdoor ramp	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Grab rail/Stair rail	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walk-in shower/shower cubicle replacing bath	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Over-bath shower	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking stick	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking frame	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Wheelchair	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hoist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Kitchen trolley	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Kitchen stool	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Toilet frame/raised seat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Commode	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bed lever/rail	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bath seat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Continence pads	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**12. Any other changes or equipment in the last 3 months: please describe.**

*If yes, tick the box for each type of change or equipment that the participant has had and ask 'who or which organisation paid for these'.*

Type of adaptation or equipment	Tick if yes	Who/which organisation paid for this?				
		Council	NHS	Self	Voluntary	Other
1. _____		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. _____		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. _____		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. _____		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Medications**

**13. Has your relative (participant) taken any medications for his/her condition over the last 3 months?**

Tradename	First day	Last day (if applicable)	Ongoing (if applicable)	Dose	Medication unit code	Frequency code	Medication code*
DEMENTIA DRUGS	dd/mm/yy yy	dd/mm/yy yy			<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	-/-/-	-/-/-			<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	-/-/-	-/-/-			<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	-/-/-	-/-/-			<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	-/-/-	-/-/-			<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	-/-/-	-/-/-			<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	-/-/-	-/-/-			<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
OTHER MENTAL HEALTH DRUGS					<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	-/-/-	-/-/-			<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	-/-/-	-/-/-			<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	-/-/-	-/-/-			<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	-/-/-	-/-/-			<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	-/-/-	-/-/-			<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

[\*Note: Use 'Tradename' information to assign medication code after the interview]

Tick if participant does not take any medications for his/her condition

**Medication unit codes**

1	mg	7	Drops
2	microgram	8	Sprays (spray)
3	gram	9	Bottles
4	ml	10	Packs
5	Tubs/tubes	11	IU (injections)
6	Puffs (inhalers)	99	Other - give details

**Medication frequency codes**

1	Once daily	7	Once a week
2	Twice daily	8	Once every two weeks
3	Three times daily	9	Once every three weeks
4	Four times daily	10	Once every four weeks
5	Three times a week	11	Once every five weeks
6	Twice a week	88	As required / "PRN"

**Benefits**

**14. Over the past 3 months has your relative (participant) received any of the following state benefits? (include payments made jointly to others in household) [SHOW CARD 5]**

	Service User (participant) (tick as many as apply)	Other member of household 1. Spouse/partner 2. Child 3. Other	How long has service user (participant) received this benefit (in weeks, over the last 3 months)
State Retirement (old age) Pension	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Widow's or War Widow's Pension	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Pension Credit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
War Disablement Pension	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Winter fuel payment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Income Support/Minimum Income Guarantee (MIG)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Severe Disablement Allowance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Disability Living Allowance Care Component	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Disability Living Allowance Care Component rate: 1. high 2. medium 3. low	<input type="checkbox"/>		
Disability Living Allowance, Mobility Component	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Disability Living Allowance Mobility Component rate: 1. high 2. low	<input type="checkbox"/>		
Attendance Allowance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Housing Benefit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Council Tax Benefit (discount)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Incapacity Benefit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Any other state benefit not listed (please state) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Any other state benefit not listed (please state) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Any other state benefit not listed (please state) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
<b>Tick if participant does not receive any state benefits</b>	<input type="checkbox"/>		

**Section 2: Carer****1. Do you live with your relative (the service user/participant)?**

- Yes   *Go to Q5*
- No   *Go to Q2*

**2. How many people are there in your household?**

	Number
Number of adults (including responder)	<input type="checkbox"/> <input type="checkbox"/>
Number of children under the age of 16	<input type="checkbox"/> <input type="checkbox"/>

**3. What kind of accommodation do you live in at the moment? (tick one box)**

- Council-rented housing
- Housing-association rented housing
- Private rented housing
- Owner-occupied housing
- Other housing

Please describe

**4. Is your accommodation “sheltered” housing (has a warden or scheme manager on-site)?**

- Yes
- No

**Employment**

5. Which of the following best describes your current employment situation?

(Tick the one box that applies best to carer's situation)

In paid employment

**GO TO Q6**

Retired

Unable to work

Unemployed and looking for work

At home and not looking for work (e.g.  
housewife/husband)

Doing voluntary work

Student (full or part-time)

Other (Please describe)

**Go to Q8**

**If carer is employed:**

6. What is your current job(s)/occupation(s)?

7. Number of hours you work per week in all the jobs you do

 
**If carer is unemployed/unable to work/at home/retired:**

8. When were you last employed? (Month/Year)

   
mm

   
yy

9. What was/were your most recent job(s)/occupation(s)?

10. Have you given up or cut down on work in order to provide care for your relative?

Yes, given up work

**Go to Q11**

Yes, cut down

No

**Go to Q13**

**If carer gave up or cut down work:**

11. When did this happen? (Month/Year)

   
mm

   
yy
**12. If carer cut down on work:**

By how much did you cut down on work each week?

Hours per week

**If the carer lives with the service user/participant, ask Q13**

**If the carer does not live with the service user/participant, ask Q14**

**13.** On a typical day, how much time do you spend looking after/providing help for your relative? (Tick if yes)

Provides no help in a typical day

Less than 1 hour

More than 1 hour and up to 2 hours

More than 2 hours and up to 3 hours

More than 3 hours and up to 5 hours

More than 5 hours and up to 10 hours

More than 10 hours, but not overnight

More than 10 hours *and/including* overnight

Other, describe:

**14.** How many hours do you spend each week looking after/providing help to your relative?  
(*If the carer does not live with the service user*)

Hours per week

**15.** On a typical day, what tasks do you usually help your relative with? (Tick as many as apply)

Personal care

Helping with finances

Practical help

Taking the person to appointments

Medications

Keeping the person company

Making sure the person is safe (supervision)

Other, describe:

Other carers

**16.** Other than yourself, do other friends or relatives regularly help/provide care for your relative?

Yes

No

**17.** If yes, thinking about an average week, and about all such carers, for how many hours do they help/provide care for your relative? (If no, write 0 in boxes and go to next question)

Hours per week

**18.** Have any **friends and relatives** taken time off paid work over the last 3 months to help/provide care for your relative?

Yes

No

**19.** If yes, can you estimate the total number of days relatives/friends have taken off work over the last 3 months to help/provide care for your relative? (If no, write 0 in boxes and go to next question)

Total days

**TRAVEL COSTS**

**20.** In the last 3 months, have you accompanied your relative to any clinic, hospital, or day services for his/her condition?

Yes  → **Go to Q21**

No  → **Go to Q28**

**21.** If yes, over the last 3 months, how many times did you accompany your relative?

Accompanied respondent	Number of times per week	Number of times in last 3 months
	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

**22.** How did you normally travel to get to the services your relative used (e.g. to go to your GP surgery or hospital)? If you used more than one form of transport please say how you travelled for the main/longest part of your journey.



[use TRANSPORT code]

**TRANSPORT codes**

1	Walked	7	Took hospital transport
2	Cycled	8	Went by ambulance
3	Took the bus	9	Other
4	Took the train		
5	Took a taxi		
6	Drove the car		

23. How long did it normally take to travel there from home?

Number of                          Hours                          Minutes  
      

24. If you normally travelled by public transport, what was the cost of the fare in one direction (cost of a one-way ticket)?

Cost of one-way fare                          £                          pence  
      

25. If you normally travelled by taxi, what was the cost of the fare in one direction (cost of a one-way journey)?

Cost of one-way fare                          £                          pence  
      

26. If you normally travelled by car, how many miles/kilometres did you travel to get there (one-way journey)? (*write in underlined space whether using miles or kilometres*)

Number of    one-way     

27. If you normally travelled by car, if you had to pay for parking, how much did you pay?

Expenditure on parking                          £                          pence

**Benefits**

**28. Over the past 3 months have you received any of the following state benefits? (include payments made jointly to others in household) [SHOW CARD 6]**

	Carer (tick as many as apply)	Other member of carer's household (1.Spouse/partner 2. Child 3. Other)	How long has carer received this benefit (in weeks, over last 3 months)
State Retirement (old age) Pension	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Widow's or War Widow's Pension	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Pension Credit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
War Disablement Pension	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Winter fuel payment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Income Support/Minimum Income Guarantee (MIG)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Severe Disablement Allowance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Direct Payments from Social Services	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Disability Living Allowance Care Component	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Disability Living Allowance Care Component rate: 1. high 2. medium 3. low	<input type="checkbox"/>		
Disability Living Allowance Mobility Component	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Disability Living Allowance Mobility Component rate: 1. high 2. low	<input type="checkbox"/>		
Attendance Allowance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Carer's Allowance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Housing Benefit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Council Tax Benefit (discount)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Inc incapacity Benefit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Job Seeker's Allowance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Child Benefit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Working Tax Credit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Any other state benefit not listed (please state)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Any other state benefit not listed (please state)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
<b>Tick if carer does not receive any state benefits</b>	<input type="checkbox"/>		

iCST: Individual Cognitive Stimulation Therapy for People with Dementia

## **General Questionnaire**

This booklet of questionnaires should be completed by the researcher in an interview with the carer.

## **General Instructions to Interviewer**

Before commencing the interview, please ensure that the Participant Identity Number has been entered in the boxes below.

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
  - Please do not fold or crease the form.
  - Please complete all the questions.
  - Please enter your responses in the boxes/spaces provided, as instructed.
  - Please use only a single line to delete mistakes and initial each such correction.

At the end of the interview please complete the remaining boxes below.

Your cooperation is very much appreciated.

**To be completed by the interviewer**

**Participant Identity Number:**

\_\_\_\_\_

Centre Name:

Which assessment is this? *Please tick one box only.*

## Baseline Assessment

1

## 1<sup>st</sup> Follow-up

1

(13 weeks after baseline)

## 2<sup>nd</sup> Follow-up

1

*(26 weeks after baseline)*

Completed by (please print name):

Signed:

Interview date:

The diagram consists of a row of eight empty rectangular boxes. Vertical lines divide the row into three segments: a pair of boxes on the left, another pair in the middle, and a group of four boxes on the right. Below the first pair of boxes is the lowercase letter 'd'. Below the second pair is the lowercase letter 'm'. Below the final group of four boxes is the lowercase letter 'y'.

**Questionnaire 1**

**Note to Interviewer:** Please interview the carer about each of the following 32 items, using the standard instructions provided. Please indicate each response provided by the carer by ticking the appropriate box for **each** row.

**For all of the questions I'm going to ask you, I want you to think about the last week.**

**First I'm going to ask about ----- (your relative's) feelings. In the last week, would you say that ----- (your relative) has felt.....**

	A lot	Quite a bit	A little	Not at all
1. cheerful?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. worried or anxious?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. frustrated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. full of energy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. sad?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. content?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. distressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. lively?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. irritable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. fed up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. that he/she has things to look forward to?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Next, I'm going to ask you about ----- (your relative's) memory. In the last week, how worried would you say ----- (your relative) has been about ...**

	A lot	Quite a bit	A little	Not at all
12. his/her memory in general?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. forgetting things that happened a long time ago?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. forgetting things that happened recently?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. forgetting people's names?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. forgetting where he/she is?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. forgetting what day it is?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. his/her thoughts being muddled?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. difficulty making decisions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. making him/herself understood?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Now, I'm going to ask about ----- (your relative's) everyday life. In the last week, how worried would you say ----- (your relative) **has been about ...**

	A lot	Quite a bit	A little	Not at all
21. keeping him/herself clean (e.g. washing and bathing)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. keeping him/herself looking nice?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. getting what he/she wants from the shops?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. using money to pay for things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. looking after his/her finances?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. things taking longer than they used to?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. getting in touch with people?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. not having enough company?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. not being able to help other people?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. not playing a useful part in things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. his/her physical health?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

We've already talked about lots of things: ----- (your relative's) **feelings, memory and everyday life**. Thinking about all of these things in the last week, how would you say ----- (your relative) **would rate ...**

	Very good	Good	Fair	Poor
32. his/her quality of life overall?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**QB 5**

--

**Questionnaire 2. Instructions:** Please interview the carer using standard instructions.

**A. Delusions - Does the patient have beliefs that you know are not true?**

N/A  
NO  
YES  
**If yes proceed to subsections**

- A1 **Does the patient believe that he/she is in danger – that others are planning to hurt him/her?**
- A2 **Does the patient believe that others are stealing from him/her?**
- A3 **Does the patient believe that his/her spouse is having an affair?**
- A4 **Does the patient believe that unwelcome guests are living in his/ her house?**
- A5 **Does the patient believe that his/her spouse or others are not who they claim to be?**
- A6 **Does the patient believe that his/her house is not his/her home?**
- A7 **Does the patient believe that family members plan to abandon him/her?**
- A8 **Does the patient believe that television or magazine figures are actually present in the home? (does he/she try to talk or interact with them?)**
- A9 **Does the patient believe any other unusual things that I haven't asked about?**

**FREQUENCY**

- Occasionally – less than once per week
- Often – about once per week
- Frequently – several times per week but less than every day
- Very frequently – once or more per day

**SEVERITY**

- Mild – delusions present but seem harmless and produce little distress in the patient
- Moderate – delusions are distressing and disruptive
- Marked – delusions are very disruptive and are a major source of behavioural disruption (if PRN medications are prescribed, their use signals that the delusions are of marked severity)

**CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?**

- Not at all
- Minimally
- Mildly
- Moderately
- Severely
- Very severely or extremely

**TOTAL DELUSIONS  
(FREQUENCY X SEVERITY)**

--

**TOTAL CAREGIVER  
DISTRESS**

--

**B. Hallucinations – Does the patient have hallucinations such as false visions or voices?**N/A  
NO  
YES  
**If yes proceed to subsections**

- B1 **Does the patient describe hearing voices or act as if he/she hears voices?**
- B2 **Does the patient talk to people who are not there?**
- B3 **Does the patient describe seeing things not seen by others or behave as if he/she is seeing things not seen by others (people/animals/lights etc.)?**
- B4 **Does the patient report smelling odours not smelled by others?**
- B5 **Does the patient describe feeling things on his/her skin or otherwise appear to be feeling things crawling or touching him/her?**
- B6 **Does the patient describe tastes that are without any known cause?**
- B7 **Does the patient describe any other unusual sensory experience?**

**FREQUENCY**

- Occasionally – less than once per week
- Often – about once per week
- Frequently – several times per week but less than every day
- Very frequently – once or more per day

**SEVERITY**

- Mild – hallucinations present but seem harmless and cause little distress for the patient
- Moderate – hallucinations are distressing and are disruptive to the patient
- Marked – hallucinations are very disruptive and are a major source of behavioural disturbance. PRN medications may be required to control them.

**CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?**

- Not at all
- Minimally
- Mildly
- Moderately
- Severely
- Very severely or extremely

TOTAL HALLUCINATIONS  
(FREQUENCY X SEVERITY)TOTAL CAREGIVER  
DISTRESS

QB 5

--

**C. Agitation/Aggression – Does the patient have periods where he/she refuses to cooperate or won't let people help him/her?**

N/A

NO

YES

**If yes proceed to subsections**

- C1 **Does the patient get upset with those trying to care for him/her or resist activities such as bathing or changing clothes?**
- C2 **Is the patient stubborn, having to have things his/her way?**
- C3 **Is the patient uncooperative, resistive to help from others?**
- C4 **Does the patient have any other behaviours that make him/her hard to handle?**
- C5 **Does the patient shout or curse angrily?**
- C6 **Does the patient slam doors, kick furniture, throw things?**
- C7 **Does the patient attempt to hurt or hit others?**
- C8 **Does the patient have any other aggressive or agitated behaviour?**

**FREQUENCY**

- Occasionally – less than once per week
- Often – about once per week
- Frequently – several times per week but less than every day
- Very frequently – once or more per day

**SEVERITY**

- Mild – behaviour is disruptive but can be managed with redirection or reassurance
- Moderate – behaviour is disruptive and difficult to redirect or control
- Marked – agitation is very disruptive and difficult to redirect or control; there may be a threat of personal harm. Medications are often required.

**CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?**

- Not at all
- Minimally
- Mildly
- Moderately
- Severely
- Very severely or extremely

**TOTAL AGITATIONS/AGGRESSION  
(FREQUENCY X SEVERITY)**

--

**TOTAL CAREGIVER  
DISTRESS**

--

**D. Depression/Dysphoria – Does the patient seem sad or depressed?**N/A  
NO  
YES  
**If yes proceed to subsections**

- D1 Does the patient have periods of tearfulness or sobbing that seem to indicate sadness?
- D2 Does the patient say or act as if he/she is sad or in low spirits?
- D3 Does the patient put him/herself down or say that he/she feels like a failure?
- D4 Does the patient say that he/she is a bad person or deserves to be punished?
- D5 Does the patient seem very discouraged or say that he/she has no future?
- D6 Does the patient say he/she is a burden to the family or that the family would be better off without him/her?
- D7 Does the patient express a wish for death or talk about killing him/herself?
- D8 Does the patient show any other signs of depression or sadness?

**FREQUENCY**

- Occasionally – less than once per week
- Often – about once per week
- Frequently – several times per week but less than every day
- Very frequently – essentially continuously present

**SEVERITY**

- Mild – depression is present but usually responds to redirection or reassurance
- Moderate – depression is distressing, depressive symptoms are spontaneously voiced by the patient and difficult to alleviate
- Marked – depression is very distressing and a major source of suffering for the patient

**CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?**

- Not at all
- Minimally
- Mildly
- Moderately
- Severely
- Very severely or extremely

TOTAL DEPRESSION/DYSPHORIA  
(FREQUENCY X SEVERITY)TOTAL CAREGIVER  
DISTRESS

QB 5

--

**E. Anxiety – Is the patient very nervous, worried or frightened for no apparent reason?**

N/A

NO

YES

**If yes proceed to subsections**

- E1 Does the patient say that he/she is worried about planned events?
- E2 Does the patient have periods of feeling shaky, unable to relax, or feeling excessively tense?
- E3 Does the patient have periods of (or complain of) shortness of breath, gasping or sighing for no other reason other than nervousness?
- E4 Does the patient complain of butterflies in his/her stomach, or of racing or pounding of the heart in association with nervousness? (Symptoms not explained by ill health)
- E5 Does the patient avoid certain places or situations that make him/her more nervous such as riding in the car, meeting with friends, or being in crowds?
- E6 Does the patient become nervous and upset when separated from you (or his/her caregiver)? (does he/she cling to you to keep from being separated?)
- E7 Does the patient show any other signs of anxiety?

**FREQUENCY**

- Occasionally – less than once per week  
 Often – about once per week  
 Frequently – several times per week but less than every day  
 Very frequently – once or more per day

**SEVERITY**

- Mild – anxiety is distressing but usually responds to redirection or reassurance  
 Moderate – anxiety is distressing, anxiety symptoms are spontaneously voiced by the patient and difficult to alleviate  
 Marked – anxiety is very distressing and a major source of suffering for the patient

**CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?**

- Not at all  
 Minimally  
 Mildly  
 Moderately  
 Severely  
 Very severely or extremely

**TOTAL ANXIETY  
(FREQUENCY X SEVERITY)**

--

**TOTAL CAREGIVER  
DISTRESS**

--

QB 5

--

**F. Elation/Euphoria – Does the patient seem to be too cheerful or too happy for no reason?**

N/A

NO

YES

**If yes proceed to subsections**

- F1 Does the patient appear to feel too good or to be too happy, different from his/her usual self?
- F2 Does the patient find humour and laugh at things that others do not find funny?
- F3 Does the patient seem to have a childish sense of humour with a tendency to giggle or laugh inappropriately (such as when unfortunate things happen to others)?
- F4 Does the patient tell jokes or make remarks that have little humour for others but seem funny to him/her?
- F5 Does he/she play childish pranks such as pinching or playing 'keep away' for the fun of it?
- F6 Does the patient 'talk big' or claim to have more abilities or wealth than is true?
- F7 Does the patient show any other signs of feeling too good or being too happy?

**FREQUENCY**

- Occasionally – less than once per week
- Often – about once per week
- Frequently – several times per week but less than every day
- Very frequently – essentially continuously present

**SEVERITY**

- Mild – elation is notable to friends and family but is not disruptive
- Moderate – elation is notably abnormal
- Marked – elation is very pronounced, patient is euphoric and finds nearly everything to be humorous

**CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?**

- Not at all
- Minimally
- Mildly
- Moderately
- Severely
- Very severely or extremely

TOTAL ELATION/EUPHORIA  
(FREQUENCY X SEVERITY)

--

TOTAL CAREGIVER  
DISTRESS

--

**G. Apathy/Indifference – Has the patient lost interest in the world around him/her?**

N/A                  NO                  YES  
           

**If yes proceed to subsections**

- G1 Does the patient seem less spontaneous and less active than usual?
- G2 Is the patient less likely to initiate a conversation?
- G3 Is the patient less affectionate or lacking in emotions when compared to his/her usual self?
- G4 Does the patient contribute less to household chores?
- G5 Does the patient seem less interested in the activities and plans of others?
- G6 Has the patient lost interest in friends and family members?
- G7 Is the patient less enthusiastic about his/her usual interests?
- G8 Does the patient show any other signs that she doesn't care about doing new things?

**FREQUENCY**

- Occasionally – less than once per week
- Often – about once per week
- Frequently – several times per week but less than every day
- Very frequently – nearly always present

**SEVERITY**

- Mild – apathy is notable but produces little interference with daily routines; only mildly different from patient's usual behaviour; patient responds to suggestion to engage in activities
- Moderate – apathy is very evident; may be overcome by the caregiver with coaxing and encouragement; responds spontaneously only to powerful events such as visits from close relatives or family members
- Marked – apathy is very evident and usually fails to respond to any encouragement or external events

**CAREGIVER DISTRESS- How emotionally distressing do you find this behaviour?**

- Not at all
- Minimally
- Mildly
- Moderately
- Severely
- Very severely or extremely

**TOTAL APATHY/INDIFFERENCE  
(FREQUENCY X SEVERITY)**

**TOTAL CAREGIVER  
DISTRESS**

**H. Disinhibition – Does the patient seem to act impulsively without thinking?**

N/A

NO

YES

**If yes proceed to subsections**

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------	--------------------------

- H1 Does the patient act impulsively without appearing to consider the consequences?
- H2 Does the patient talk to total strangers as if he/she knew them?
- H3 Does the patient say things to people that are insensitive or hurt their feelings?
- H4 Does the patient say crude things or make sexual remarks that they would not usually have said?
- H5 Does the patient talk openly about very personal or private matters not usually discussed in public?
- H6 Does the patient take liberties or touch or hug others in a way that is out of character for him/her?
- H7 Does the patient show any other signs of loss of control of his/her impulses?

**FREQUENCY**

- Occasionally – less than once per week
- Often – about once per week
- Frequently – several times per week but less than every day
- Very frequently – essentially continuously present

**SEVERITY**

- Mild – disinhibition is notable but usually responds to redirection and guidance
- Moderate – disinhibition is very evident and difficult to overcome by the caregiver
- Marked – disinhibition usually fails to respond to any intervention by the caregiver, and is a source of embarrassment or social distress

**CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?**

- Not at all
- Minimally
- Mildly
- Moderately
- Severely
- Very severely or extremely

**TOTAL DISINHIBITION  
(FREQUENCY X SEVERITY)**

**TOTAL CAREGIVER  
DISTRESS**

QB 5

--

**I. Irritability/Lability – Does the patient get irritated and easily disturbed?**

N/A

NO

YES

**If yes proceed to subsections**

- I1 Does the patient have a bad temper, flying ‘off the handle’ easily over little things?
- I2 Does the patient rapidly change moods from one to another, being fine one minute and angry the next?
- I3 Does the patient have sudden flashes of anger?
- I4 Is the patient impatient, having trouble coping with delays or waiting for planned activities?
- I5 Is the patient cranky and irritable?
- I6 Is the patient argumentative and difficult to get along with?
- I7 Does the patient show any other signs of irritability?

**FREQUENCY**

- Occasionally – less than once per week
- Often – about once per week
- Frequently – several times per week but less than every day
- Very frequently – essentially continuously present

**SEVERITY**

- Mild – irritability or lability is notable but usually responds to redirection and reassurance
- Moderate – irritability and lability are very evident and difficult to overcome by the caregiver
- Marked – irritability and lability are very evident, they usually fail to respond to any intervention by the caregiver, and they are a major source of distress

**CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?**

- Not at all
- Minimally
- Mildly
- Moderately
- Severely
- Very severely or extremely

**TOTAL IRRITABILITY/LABILITY  
(FREQUENCY X SEVERITY)**

--

**TOTAL CAREGIVER  
DISTRESS**

--

**QB 5**

--

**J. Aberrant motor behaviour – Does the patient pace, do things over and over such as opening closets or drawers, or repeatedly pick at things or wind string or threads?**

N/A  
NO  
YES  
**If yes proceed to subsections**

J1 **Does the patient pace around the house without any apparent purpose?**

J2 **Does the patient rummage around opening and unpacking drawers or closets?**

J3 **Does the patient repeatedly put on and take off clothing?**

J4 **Does the patient have repetitive activities or ‘habits’ that he/she performs over and over?**

J5 **Does the patient engage in repetitive activities such as handling buttons, picking, wrapping string etc.?**

J6 **Does the patient fidget excessively, seem unable to sit still, or bounce his/her feet or tap his/her fingers a lot?**

J7 **Does the patient do any other activities over and over?**

**FREQUENCY**

- Occasionally – less than once per week
- Often – about once per week
- Frequently – several times per week but less than every day
- Very frequently – essentially continuously present

**SEVERITY**

- Mild – abnormal motor activity is notable but produces little interference with daily routines
- Moderate – abnormal motor activity is very evident; can be overcome by the caregiver
- Marked – abnormal motor activity is very evident, it usually fails to respond to any intervention by the caregiver and is a major source of distress

**CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?**

- Not at all
- Minimally
- Mildly
- Moderately
- Severely
- Very severely or extremely

**TOTAL ABERRANT MOTOR BEHAVIOUR  
(FREQUENCY X SEVERITY)**

--

**TOTAL CAREGIVER  
DISTRESS**

--

## QB 5

K. Sleep – Does the patient have difficulty sleeping (do not count as present if the patient simply gets up once or twice per night only to go to the bathroom and falls back asleep immediately)?

N/A

NO

YES

**If yes proceed to subsections**

- |    |  |                          |
|----|--|--------------------------|
| K1 | <b>Does the patient have difficulty falling asleep?</b>  | <input type="checkbox"/> |
| K2 | <b>Does the patient get up during the night (do not count if the patient simply gets up once or twice per night only to go to the bathroom and falls back asleep immediately)?</b> | <input type="checkbox"/> |
| K3 | <b>Does the patient wander, pace or get involved in inappropriate activities at night?</b>   | <input type="checkbox"/> |
| K4 | <b>Does the patient awaken you during the night?</b>   | <input type="checkbox"/> |
| K5 | <b>Does the patient awaken during the night, dress and plan to go out, thinking that it is morning and time to start the day?</b>  | <input type="checkbox"/> |
| K6 | <b>Does the patient awaken too early in the morning (earlier than was his/her habit)?</b>  | <input type="checkbox"/> |
| K7 | <b>Does the patient sleep excessively during the day?</b>  | <input type="checkbox"/> |
| K8 | <b>Does the patient have any other night-time behaviours that bother you that we haven't talked about?</b>   | <input type="checkbox"/> |

## FREQUENCY

- Occasionally – less than once per week
  - Often – about once per week
  - Frequently – several times per week but less than every day
  - Very frequently – once or more per day

#### **SEVERITY**

- Mild – night-time behaviours occur but they are not particularly disruptive
  - Moderate – night-time behaviours occur and disturb the patient and the sleep of the caregiver; more than one type of night-time behaviour may be present
  - Marked – night-time behaviours occur; several types of night-time behaviour may be present; the patient is very distressed during the night and the caregiver's sleep is markedly disturbed

## **CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?**

- Not at all
  - Minimally
  - Mildly
  - Moderately
  - Severely
  - Very severely or extremely

### **TOTAL SLEEP (FREQUENCY X SEVERITY)**

## **TOTAL CAREGIVER DISTRESS**

A blank square box with a black border, intended for a student to draw a picture.

**L. Appetite and eating disorders – Has he/she had any change in appetite, weight, or eating habits?**

N/A

NO

YES

**If yes proceed to subsections**

- |    |  |                          |
|----|--|--------------------------|
| L1 | <b>Has he/she had a loss of appetite?</b>  | <input type="checkbox"/> |
| L2 | <b>Has he/she had an increase in appetite?</b>   | <input type="checkbox"/> |
| L3 | <b>Has he/she had a loss of weight?</b>  | <input type="checkbox"/> |
| L4 | <b>Has he/she gained weight?</b>   | <input type="checkbox"/> |
| L5 | <b>Has he/she had a change in eating behaviour such as putting too much food in his/her mouth at once?</b>   | <input type="checkbox"/> |
| L6 | <b>Has he/she had a change in the kind of food he/she likes such as eating too many sweets or other specific types of food?</b>                    | <input type="checkbox"/> |
| L7 | <b>Has he/she developed eating behaviours such as eating exactly the same types of food each day or eating the food in exactly the same order?</b> | <input type="checkbox"/> |
| L8 | <b>Have there been any other changes in appetite or eating that I haven't asked about?</b>   | <input type="checkbox"/> |

## FREQUENCY

- Occasionally – less than once per week
  - Often – about once per week
  - Frequently – several times per week but less than every day
  - Very frequently – once or more per day

## **SEVERITY**

- Mild – changes in appetite or eating are present but have not led to changes in weight and are not disturbing
  - Moderate – changes in appetite or eating are present and cause minor fluctuations in weight
  - Marked – obvious changes in appetite or eating are present and cause fluctuations in weight, are embarrassing, or otherwise disturb the patient

**CAREGIVER DISTRESS - How emotionally distressing do you find this behaviour?**

- Not at all
  - Minimally
  - Mildly
  - Moderately
  - Severely
  - Very severely or extremely

## **TOTAL APPETITE AND EATING DISORDERS (FREQUENCY X SEVERITY)**

# TOTAL CAREGIVER DISTRESS

**Neuropsychiatric Inventory (NPI)****SUMMARY SCORE SHEET**

	<b>TOTAL SCORE</b>	<b>CAREGIVER DISTRESS</b>
<b>A. Delusions</b>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<b>B. Hallucinations</b>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<b>C. Agitation/Aggression</b>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<b>D. Depression/Dysphoria</b>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<b>E. Anxiety</b>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<b>F. Elation/Euphoria</b>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<b>G. Apathy/Indifference</b>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<b>H. Disinhibition</b>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<b>I. Irritability/Lability</b>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<b>J. Aberrant motor behaviour</b>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<b>K. Sleep</b>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
<b>L. Appetite and eating disorders</b>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

**TOTAL SCORES**

<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>

QB 5

**Questionnaire 3****Instructions:** Please administer this instrument using the instructions provided.**Clinical Dementia Rating Scale****CDR**

Category	Healthy CDR 0	Questionable dementia CDR 0.5	Mild dementia CDR 1	Moderate dementia CDR 2	Severe dementia CDR 3
Memory	No memory loss or slight inconstant forgetfulness	Mild consistent forgetfulness; partial recollection of events; 'benign' forgetfulness	Moderate memory loss, more marked for recent events; deficit interferes with everyday activities	Severe memory loss; only highly learned material retained; new material rapidly lost	Severe memory loss; only fragments remain
Orientation	Fully orientated		Some difficulty with time relationships; orientated for place and person at examination but may have geographic disorientation	Usually disoriented in time, often to place	Orientation to person only
Judgement + problem solving	Solves every day problems well; judgement good in relation to past performance	Only doubtful impairment in solving problems, similarities, differences	Moderate difficulty in handling complex problems; social judgement usually maintained	Severely impaired in handling problems, similarities, differences; social judgement usually impaired	Unable to make judgements or solve problems
Community affairs	Independent function at usual level in job, shopping, business and financial affairs, volunteer and social groups	Only doubtful or mild impairment, if any, in these activities	Unable to function independently at these activities though may still be engaged in some; may still appear normal to casual inspection	No pretence of independent function outside home	
Home + hobbies	Life at home, hobbies, intellectual interests well maintained	Life at home, hobbies, intellectual interests well maintained or only slightly impaired	Mild but definite impairment of function at home; more difficult chores abandoned; more complicated hobbies and interests abandoned	Only simple chores preserved; very restricted interests, poorly sustained	No significant function in home outside of own room
Personal care	Fully capable of self care		Needs occasional prompting	Requires assistance in dressing, hygiene, keeping of personal effects	Requires much help with personal care; often incontinent
Score using box overleaf. Score as 0.5, 1, 2, 3 only if impairment is due to cognitive loss.					

**QB 5**

--

**Assigning the Clinical Dementia Rating**

An algorithm can be used to give the overall CDR score, as follows:

The global CDR score is derived from the scores in each of the six categories. Memory (M) is considered the primary category and all others are secondary. CDR = M if at least three secondary categories are given the same score as memory. Whenever three or more secondary categories are given a score greater or less than the memory score, CDR equals the score of the majority of secondary categories that are on whichever side of M has the greatest number of secondary categories. If there are ties in the secondary categories on one side of M, the CDR score closest to M is chosen.

When M = 0.5, CDR = 1 if at least three of the other categories are scored one or greater.

If M = 0.5, CDR cannot be 0; it can only be 0.5 or 1. If M = 0, CDR = 0 unless there is questionable impairment in two or more secondary categories, in which case CDR = 0.5

Score	0	0.5	1	2	3
M					
O					
JPS					
C					
HH					
PC					

CDR 0 –No Dementia					
Score	0	0.5	1	2	3
M					
O					
JPS					
C					
HH					
PC					

CDR 2 – Moderate Dementia					
Score	0	0.5	1	2	3
M					
O					
JPS					
C					
HH					
PC					

CDR 0.5 – Questionable Dementia					
Score	0	0.5	1	2	3
M					
O					
JPS					
C					
HH					
PC					

CDR 3 – Severe Dementia					
Score	0	0.5	1	2	3
M					
O					
JPS					
C					
HH					
PC					

Mark in only one box for each category. To assign the CDR, see grids on the right. Shaded areas indicate defined range within which the scores of individual subjects must fall to be assigned a given CDR.

**Clinical Dementia Rating:**

Please tick **one** box only.

0	<input type="checkbox"/>
0.5	<input type="checkbox"/>
1	<input type="checkbox"/>
2	<input type="checkbox"/>
3	<input type="checkbox"/>

CDR 1 – Mild Dementia					
Score	0	0.5	1	2	3
M					
O					
JPS					
C					
HH					
PC					

**Questionnaire 4 – Background Details****This section is completed by interviewing the family carer.**

**Provide the carer the following information: To help with our study it will be helpful to have some background details about you and your relative. These will allow us to compare groups in the study with the general population. All data is confidential and stored in an anonymised form.**

**4. 1 What is your relationship to the participant?***Please tick one box only*

- a. Wife/Husband (Spouse) \_\_\_\_\_
- b. Partner \_\_\_\_\_
- c. Son/daughter \_\_\_\_\_
- d. Son/daughter-in-law \_\_\_\_\_
- e. Brother/sister \_\_\_\_\_
- f. Other relative \_\_\_\_\_
- g. Friend \_\_\_\_\_
- h. Neighbour \_\_\_\_\_
- i. Other (please specify) \_\_\_\_\_

**4. 2 Please indicate the gender of the participant and carer  
(tick as appropriate)****Participant**Male  Female **Carer**Male  Female **4. 3 Age of participant and carer**
**Participant**    
**Carer**  
**4.4 Date of birth (dd/mm/yyyy) of participant and carer**
**Participant**   /   /      
**Carer**   /   /

QB 5

**4.5 Ethnicity of participant and carer****Participant** **WHITE or**

- White British
- White Irish
- Other White Background

 **BLACK or BLACK BRITISH or**

- Caribbean
- African
- Other Black Background

 **MIXED or**

- White & Black Caribbean
- White & Black African
- White and Asian
- Other Mixed Background

 **ASIAN or ASIAN BRITISH or**

- Indian
- Pakistani
- Bangladeshi
- Other Asian Background

 **CHINESE or OTHER ETHNIC GROUP**

- Chinese
- Other ethnic group

 **NOT STATED / DO NOT WISH TO SPECIFY**

QB 5

**Carer** **WHITE or**

- White British
- White Irish
- Other White Background

 **BLACK or BLACK BRITISH or**

- Caribbean
- African
- Other Black Background

 **MIXED or**

- White & Black Caribbean
- White & Black African
- White and Asian
- Other Mixed Background

 **ASIAN or ASIAN BRITISH or**

- Indian
- Pakistani
- Bangladeshi
- Other Asian Background

 **CHINESE or OTHER ETHNIC GROUP**

- Chinese
- Other ethnic group

 **NOT STATED / DO NOT WISH TO SPECIFY**

QB 5

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**4.6 Please indicate participant's and carer's marital status  
(please tick **one** box)**

**Participant**

- Single (never married)
- Married
- Co-habiting
- Civil partnership
- Separated
- Divorced
- Widowed

**Carer**

- Single (never married)
- Married
- Co-habiting
- Civil partnership
- Separated
- Divorced
- Widowed

**4.7 Please indicate participant's and carer's living status.**

**Participant lives with**  
(please tick **all** that apply)

- Spouse/Partner
- Other family
- Other
- No-one

**Carer lives with**  
(please tick **all** that apply)

- Spouse/Partner
- Other family
- Other
- No-one

**4.8 At what age did the participant and carer leave full-time education?**

**Participant**       
**Carer**

QB 5

--

**4.9** Please indicate participant's level of education  
*(please tick one box)*

- School Leaver (14-16 years of age)
- School Leaver (18 years of age)
- Further Education (Vocational Qualifications: i.e. GNVQ/NVQ/HND)
- Higher Education (BSc/BA or equivalent)
- Postgraduate Education (MSc/MA/PhD or equivalent)

**4.10** Please indicate carer's level of education  
*(please tick one box)*

- School Leaver (14-16 years of age)
- School Leaver (18 years of age)
- Further Education (Vocational Qualifications: i.e. GNVQ/NVQ/HND)
- Higher Education (BSc/BA or equivalent)
- Postgraduate Education (MSc/MA/PhD or equivalent)

**4.11** What was your relative's previous occupation?

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**4.12** Is your relative on AChEIs?

- YES       NO

**Check list for interviewer at close of interview**

On behalf of the iCST team, please thank the participant and carer for their participation in the study.

- Please check that all 5 Questionnaire packs have been completed
- Please check Carer Questionnaire Packs for missing and/or incorrectly completed items
- Please ensure the participant identity number is written on the front of each Questionnaire Pack in the boxes provided

# CSRI: Service Use Questionnaire

## iCST: Individual Cognitive Stimulation Therapy for People with Dementia

This booklet of questionnaires should be completed by the researcher in an interview with the carer.

### **General Instructions to Interviewer**

Before commencing the interview, please ensure that the **Participant Identity Number** has been entered in the boxes below.

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment.

To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

At the end of the interview please complete the remaining boxes below.

Your cooperation is very much appreciated.

#### **To be completed by the interviewer**

Participant Identity  
Number:

--	--	--	--	--	--	--	--	--	--

Centre Name:

---

Which assessment is this? *Please tick one box only.*

Baseline Assessment

1<sup>st</sup> Follow-up

(13 weeks after baseline)

2<sup>nd</sup> Follow-up

(26 weeks after baseline)

Completed by (please print  
name):

---

Signed:

---

Interview date:

		/			/			
--	--	---	--	--	---	--	--	--

d      d      m      m      y      y      y      y

## Section 1: Participant

1. How many people are there in your relative's (participant's) household?

Number

Number of adults including service user

<input type="text"/>	<input type="text"/>
----------------------	----------------------

Number of children under the age of 16

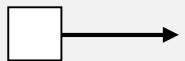
<input type="text"/>	<input type="text"/>
----------------------	----------------------

2. What kind of accommodation does your relative (participant) live in at the moment? (tick one box)

Council-rented housing



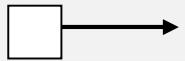
Housing-association rented housing



Private rented housing



Owner-occupied housing



Permanently resident in long-term care accommodation



Other housing



Please describe

<input type="text"/>
----------------------

3. Is your relative's (participant's) accommodation "sheltered" housing (has a warden or scheme manager on-site)?

Yes

<input type="checkbox"/>
--------------------------

No

<input type="checkbox"/>
--------------------------

4. Has your relative (participant) lived anywhere else during the last 3 months? (excluding hospital stays)

Yes



No



**5. What type of accommodation did your relative (participant) stay in at that time?**

If participant reports a stay in a care/nursing home or other location, complete the questions in that row.

For 'Participant or family contribution', ask: 'Did you or a family member pay for this accommodation?' and tick yes if the person reports having paid all or part of the costs

Service	No	Yes	Reason for using service (e.g. respite)	Name of home (not to be entered into database)	Date entered this home as permanent resident <u>(if applicable)</u> dd/mm/yyyy	Number of days	Participant or family contribution	Provider (see note*)	
								No	Yes
Care home	<input type="checkbox"/>	<input type="checkbox"/>			__/__/__	<input type="checkbox"/> <input type="checkbox"/>			
Nursing home	<input type="checkbox"/>	<input type="checkbox"/>			__/__/__	<input type="checkbox"/> <input type="checkbox"/>			
Other - please describe using 'Name of home' box	<input type="checkbox"/> <input type="checkbox"/>				__/__/__	<input type="checkbox"/> <input type="checkbox"/>			

[\*Note: Use the "Name of home" information to complete the Provider box, using WHO codes, after the interview]

**WHO codes**

1	Local Authority/Social Services/Council
2	NHS
3	Voluntary/charitable organisation
4	Private company or insurance company
5	Self or family members
6	Other
7	Researcher unable to classify response
8	Not completed

**Community health and social services**

**6. In the last 3 months, has your relative (participant) used any of the services below? [SHOW CARD 1]**

*Note: please tick the 'no' box if participant has not used the service*

Service	No	Yes	Number of home visits	Number of clinic or office visits	Average duration of contact (minutes)
GP	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Practice nurse (at GP surgery)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Community/District Nurse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Community psychiatric/Community Mental Health Nurse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Psychiatrist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Social worker or care manager	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Psychologist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Physiotherapist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Occupational therapist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Dietician	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Counsellor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Mental health team worker	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Specialist nurse (e.g. Admiral Nurse, palliative care nurse, respiratory nurse)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<i>please describe:</i>					

**7. In the last 3 months, has your relative (participant) used any of the services below? [SHOW CARD 2]**

*Note: please tick the 'no' box if participant has not used the service*

*For 'Participant or family contribution', ask: 'Did you or a family member pay for this service?' and tick yes if the person reports having paid all or part of the costs*

Service	No	Yes	Number of home visits		Number of clinic or office visits		Average duration of contact (minutes)			Participant or family contribution		
	No	Yes										
Home care/home help	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
Home care/home help - Additional organisation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
Home care/home help – Additional organisation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
Cleaner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
Meals on wheels	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
Laundry service	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
Sitting service (e.g. Crossroads)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
Carer's support worker	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
Optician	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
Chiropodist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
Dentist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
Other health or social care services:												
1. .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
2. .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					

**Day services**

**8. In the last 3 months, has your relative (**participant**) used any of the day services below?**  
 [SHOW CARD 3]

*Note: please tick the 'no' box if participant has not used the service*

*For 'Participant or family contribution', ask: 'Did you or a family member pay for this service?' and tick yes if the person reports having paid all or part of the costs*

*If the participant is now permanently resident in a care home, do not include any day services provided within that care home*

Service	No	Yes	Number of times per week	Number of times in last 3 months	Name of service (not to be entered into database)	Participant or family paid or contributed		Provider (see note*)
	No	Yes				No	Yes	
Day centre	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lunch club	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Patient education group (e.g. reminiscence) please describe: .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other health or social care day services:								
1. ....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. ....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

[\*Note: Use the "Name of service" information to complete the Provider box, using WHO codes, after the interview]

**Direct Payments**

**9. Has your relative (**participant**) been in receipt of direct payments, individual budget or personal budget\* **in the last 3 months?****

Direct payments/Personal Budgets	No	Yes	Total weekly value in £
Direct payments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Individual budget / Personal budget	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\*see Q9 definitions card

## Use of Hospital services

**10. In the last 3 months, has your relative (participant) used any of the following hospital services?**

*Note: please tick the 'no' box if participant has not used the service*

Service	No	Yes	Name of ward, clinic hospital or centre	Reason for using service (condition, specialty)	Unit of measure	Number of days/ attendances	NHS Trust code*
Accident & Emergency Department (A&E)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Attendance	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
Inpatient ward admission 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Inpatient day	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
Inpatient ward admission 2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Inpatient day	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
Inpatient ward admission 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Inpatient day	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
Inpatient ward admission 4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Inpatient day	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
Inpatient ward admissions 5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Inpatient day	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
Outpatient Department (OPD) Attendance 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Appointment	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
OPD Attendance 2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Appointment	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
OPD Attendance 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Appointment	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
OPD Attendance 4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Appointment	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
OPD Attendance 5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Appointment	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
Day hospital Attendance 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Day attendance	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>
Day hospital Attendance 2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	Day attendance	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>

[\*Note: Use 'name of hospital' information to assign NHS Trust code after the interview]

### Equipment and adaptations

**11. In the last 3 months, has your relative (participant) had any adaptations or equipment to meet their needs? [SHOW CARD 4] (*If the participant is now permanently resident in a care home, do not include adaptations/equipment provided in the care home*)**

Yes

No

If yes, tick the box for each type of change or equipment that the participant has had and ask 'who or which organisation paid for these'.

Type of adaptation or equipment	Tick if yes	Who/Which organisation paid for this?				
		Council	NHS	Self	Voluntary /charity	Other
Outdoor railing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Outdoor ramp	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Grab rail/Stair rail	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walk-in shower/shower cubicle replacing bath	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Over-bath shower	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking stick	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking frame	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Wheelchair	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hoist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Kitchen trolley	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Kitchen stool	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Toilet frame/raised seat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Commode	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bed lever/rail	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bath seat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Continence pads	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**12. Any other new changes or equipment in the last 3 months: please describe.**

If yes, tick the box for each type of change or equipment that the participant has had and ask 'who or which organisation paid for these'. (If the participant is now permanently resident in a care home, do not include adaptations/equipment provided in the care home)

Type of adaptation or equipment	Tick if yes	Who/which organisation paid for this?				
		Council	NHS	Self	Voluntary	Other
1. _____		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. _____		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. _____		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. _____		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Medications**

**13. Has your relative (participant) taken any medications for his/her condition over the last 3 months?**

Tradename	First day	Last day (if applicable)	Ongoing (if applicable)	Dose	Medication unit code	Frequency code	Medication code*
DEMENTIA DRUGS	dd/mm/yyyy	dd/mm/yyyy					
	-/-/-	-/-/-		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	-/-/-	-/-/-		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	-/-/-	-/-/-		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	-/-/-	-/-/-		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	-/-/-	-/-/-		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	-/-/-	-/-/-		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
OTHER MENTAL HEALTH DRUGS							
	-/-/-	-/-/-		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	-/-/-	-/-/-		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	-/-/-	-/-/-		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	-/-/-	-/-/-		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	-/-/-	-/-/-		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

[\*Note: Use 'Tradename' information to assign medication code after the interview]

**Tick if participant does not take any medications for his/her condition**

**Medication unit codes**

1	mg	7	Drops
2	microgram	8	Sprays (spray)
3	gram	9	Bottles
4	ml	10	Packs
5	Tubs/tubes	11	IU (injections)
6	Puffs (inhalers)	99	Other - give details

**Medication frequency codes**

1	Once daily	7	Once a week
2	Twice daily	8	Once every two weeks
3	Three times daily	9	Once every three weeks
4	Four times daily	10	Once every four weeks
5	Three times a week	11	Once every five weeks
6	Twice a week	88	As required / "PRN"

**Benefits**

**14. Over the past 3 months has your relative (participant) received any of the following state benefits? (include payments made jointly to others in household) [SHOW CARD 5]**

	Service User (participant) (tick as many as apply)	Other member of household 1. Spouse/partner 2. Child 3. Other	How long has service user (participant) received this benefit (in weeks, over the last 3 months)
State Retirement (old age) Pension	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Widow's or War Widow's Pension	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Pension Credit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
War Disablement Pension	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Winter fuel payment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Income Support/Minimum Income Guarantee (MIG)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Severe Disablement Allowance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Disability Living Allowance Care Component	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Disability Living Allowance Care Component rate: 1. high 2. medium 3. low	<input type="checkbox"/>		
Disability Living Allowance, Mobility Component	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Disability Living Allowance Mobility Component rate: 1. high 2. low	<input type="checkbox"/>		
Attendance Allowance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Housing Benefit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Council Tax Benefit (discount)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Incapacity Benefit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Any other state benefit not listed (please state)_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Any other state benefit not listed (please state)_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Any other state benefit not listed (please state)_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
<b>Tick if participant does not receive any state benefits</b>		<input type="checkbox"/>	

**Section 2: Carer****1. Do you live with your relative (the service user/participant)?**

- Yes  → *Go to Q5*
- No  → *Go to Q2*

**2. How many people are there in your household?**

	Number
Number of adults (including responder)	<input type="checkbox"/> <input type="checkbox"/>
Number of children under the age of 16	<input type="checkbox"/> <input type="checkbox"/>

**3. What kind of accommodation do you live in at the moment? (tick one box)**

- Council-rented housing
- Housing-association rented housing
- Private rented housing
- Owner-occupied housing
- Other housing

Please describe

**4. Is your accommodation “sheltered” housing (has a warden or scheme manager on-site)?**

- Yes
- No

**Employment**

5. Which of the following best describes your current employment situation?

(Tick the one box that applies best to carer's situation)

In paid employment

**GO TO Q6**

Retired

Unable to work

Unemployed and looking for work

At home and not looking for work (e.g.  
housewife/husband)

Doing voluntary work

Student (full or part-time)

Other (Please describe)

**Go to Q8**

**If carer is employed:**

6. What is your current job(s)/occupation(s)?

7. Number of hours you work per week in all the jobs you do

 
**If carer is unemployed/unable to work/at home/retired:**

8. When were you last employed? (Month/Year)

   
mm

   
yy

9. What was/were your most recent job(s)/occupation(s)?

10. Have you given up or cut down on work in order to provide care for your relative?

Yes, given up work

**Go to Q11**

Yes, cut down

No

**Go to Q13**

**If carer gave up or cut down work:**

11. When did this happen? (Month/Year)

   
mm

   
yy

12. If carer cut down on work:

By how much did you cut down on work each week?

Hours per week

**If the carer lives with the service user/participant, ask Q13**

**If the carer does not live with the service user/participant, ask Q14**

**If the service user has entered a care home permanently within the past 3 months, the following questions apply to the period prior to entry**

**13.** On a typical day, how much time do you spend looking after/providing help for your relative? (Tick if yes)

Provides no help in a typical day

Less than 1 hour

More than 1 hour and up to 2 hours

More than 2 hours and up to 3 hours

More than 3 hours and up to 5 hours

More than 5 hours and up to 10 hours

More than 10 hours, but not overnight

More than 10 hours *and/including* overnight

Other, describe:

**14.** How many hours do you spend each week looking after/providing help to your relative? (If the carer does not live with the service user)

Hours per week

**15.** On a typical day, what tasks do you usually help your relative with? (Tick as many as apply)

Personal care

Helping with finances

Practical help

Taking the person to appointments

Medications

Keeping the person company

Making sure the person is safe (supervision)

Other, describe:

Other carers

**16.** Other than yourself, do other friends or relatives regularly help/provide care for your relative?

Yes

No

**17.** If yes, thinking about an average week, and about all such carers, for how many hours do they help/provide care for your relative? (If no, write 0 in boxes and go to next question)

Hours per week

**18.** Have any **friends and relatives** taken time off paid work over the last 3 months to help/provide care for your relative?

Yes

No

**19.** If yes, can you estimate the total number of days relatives/friends have taken off work over the last 3 months to help/provide care for your relative? (If no, write 0 in boxes and go to next question)

Total days

**TRAVEL COSTS**

**20.** In the last 3 months, have you accompanied your relative to any clinic, hospital, or day services for his/her condition?

Yes  → **Go to Q21**  
 No  → **Go to Q28**

**21.** If yes, over the last 3 months, how many times did you accompany your relative?

Number of times per week	Number of times in last 3 months
Accompanied respondent <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

**22.** How did you normally travel to get to the services your relative used (e.g. to go to your GP surgery or hospital)? If you used more than one form of transport please say how you travelled for the main/longest part of your journey.

[use TRANSPORT code]

**TRANSPORT codes**

1	Walked	7	Took hospital transport
2	Cycled	8	Went by ambulance
3	Took the bus	9	Other
4	Took the train		
5	Took a taxi		
6	Drove the car		

**23. How long did it normally take to travel there from home?**

Number of                          Hours                          Minutes  
      

**24. If you normally travelled by public transport, what was the cost of the fare in one direction (cost of a one-way ticket)?**

Cost of one-way fare                          £                          pence  
      

**25. If you normally travelled by taxi, what was the cost of the fare in one direction (cost of a one-way journey)?**

Cost of one-way fare                          £                          pence  
      

**26. If you normally travelled by car, how many miles/kilometres did you travel to get there (one-way journey)? (*write in underlined space whether using miles or kilometres*)**

Number of    one-way     

**27. If you normally travelled by car, if you had to pay for parking, how much did you pay?**

Expenditure on                          £                          pence  
parking

**Benefits**

**28. Over the past 3 months have you received any of the following state benefits? (include payments made jointly to others in household) [SHOW CARD 6]**

	Carer (tick as many as apply)	Other member of carer's household (1. Spouse/partner 2. Child 3. Other)	How long has carer received this benefit (in weeks, over last 3 months)
State Retirement (old age) Pension	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Widow's or War Widow's Pension	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Pension Credit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
War Disablement Pension	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Winter fuel payment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Income Support/Minimum Income Guarantee (MIG)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Severe Disablement Allowance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Direct Payments from Social Services	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Disability Living Allowance Care Component	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Disability Living Allowance Care Component rate: 1. high 2. medium 3. low	<input type="checkbox"/>		
Disability Living Allowance Mobility Component	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Disability Living Allowance Mobility Component rate: 1. high 2. low	<input type="checkbox"/>		
Attendance Allowance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Carer's Allowance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Housing Benefit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Council Tax Benefit (discount)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Incapacity Benefit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Job Seeker's Allowance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Child Benefit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Working Tax Credit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Any other state benefit not listed (please state) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Any other state benefit not listed (please state) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
<b>Tick if carer does not receive any state benefits</b>	<input type="checkbox"/>		

Date

(Name and address of local unblind researcher)

Mental Health Sciences Unit (Bloomsbury Campus)  
University College London  
Room 114, Charles Bell House  
67-73 Riding House Street  
London W1W 7EJ

Tel  
Mobile  
Fax

Dear Mr & Mrs,

**Individual Cognitive Stimulation Therapy (iCST) study,**

Thank you for agreeing to take part in the iCST study, and for completing the questionnaires when my colleague (Local iCST blind researcher) visited you at home recently. I can now tell you that you have been allocated to the iCST group. This means that both you and the person you are caring for will be participating in the Individual Cognitive Stimulation Therapy (iCST) sessions.

(I / Local iCST unblind researcher) will be contacting you very shortly to arrange a time that is most convenient to you for a visit in order to receive one-to-one Individual Cognitive Stimulation Therapy (iCST) training in your home. This training session will prepare you to effectively and confidently deliver iCST prior to commencing the iCST sessions.

iCST will involve engaging in activities such as word games and number games with the person you are caring for. All the resources you require for the sessions will be provided in the training visit and you will receive continuous support throughout the programme (regular phone calls and visits) should you require them.

My colleague, (Local iCST blind researcher) will arrange to visit you again in 13 weeks and 26 weeks, to repeat the questionnaire process. Please remember that **it is important that you do not tell him/her that you are delivering iCST sessions**. If you need to discuss any aspect of the study, please contact me on (office number and mobile of Local iCST unblind researcher) or (email of Local unblind researcher surname@ucl.ac.uk).

Thank you again for taking part in this research study, your help is greatly appreciated.

Yours sincerely,

Name of Local iCST Unblind researcher

Date

(Name and address of local unblind researcher)

Mental Health Sciences Unit (Bloomsbury Campus)  
University College London  
Room 114, Charles Bell House  
67-73 Riding House Street  
London W1W 7EJ

Tel:  
Mobile:  
Fax:

Dear Mr & Mrs,

**Individual Cognitive Stimulation Therapy (iCST) study,**

Thank you for agreeing to take part in the iCST study, and for completing the questionnaires when my colleague (Local iCST blind researcher) visited you at home recently. I am writing to inform you that you have been allocated to the control group. This means that both you and the person you are caring for will be continuing with your usual activities and not participating in the Individual Cognitive Stimulation Therapy (iCST) sessions.

However, you are an important part of the research process, so we still require you to fill out the questionnaires in 13 weeks and again in 26 weeks time. The reason we ask the same questions again is to compare the results with the group that is receiving Individual Cognitive Stimulation Therapy (iCST). When my colleague (Local iCST blind researcher) arranges to visit you again to complete the questionnaires, please remember that **it is important that you do not tell him/her that you are not participating in iCST.**

If you need to discuss any aspect of the study, please contact me on (office number and mobile of Local iCST unblind researcher) or (email of Local unblind researcher surname@ucl.ac.uk)

Thank you again for taking part in this research study, your help is greatly appreciated.

Yours sincerely,

Name of Local iCST unblind researcher

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PS

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**iCST: Individual Cognitive Stimulation Therapy for people with dementia****Interviewer Perception Sheet (Interviewer 1)**

This sheet should be completed by project researchers conducting the first and second follow-up interviews of participants and carers. There are separate sheets for each interviewer. If only one interviewer is involved, this sheet should be left blank.

**To be completed by the interviewer 2**

Participant identity Number:


Centre Name:

--

1<sup>st</sup> Follow-up
2<sup>nd</sup> Follow-up

Completed by (please print name):

--

Signed:

--

Interview date:

d	d

/

m	m

/

y	y	y	y

Who did you interview today? Please tick one box only.

Participant only

Carer Only

Participant and carer

Following your interview with the participant and/or carer today, to which group in the trial do you think they have been allocated? Please tick one box only.

The participant and carer are ...

Definitely in the CONTROL Group	More likely to be in the CONTROL Group	Equally likely to be CONTROL Group or INTERVENTION Group	More likely to be in the INTERVENTION Group	Definitely in the INTERVENTION Group
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



# iCST

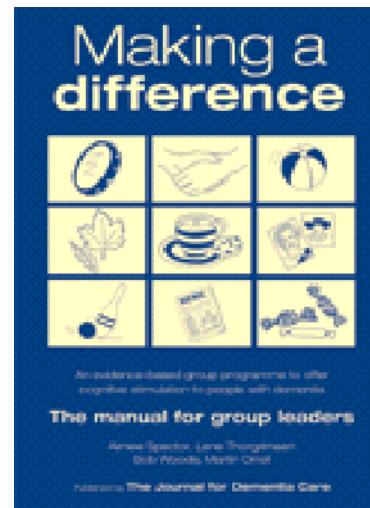
Individual Cognitive Stimulation Therapy

## Background information leaflet for carers

# What is CST?



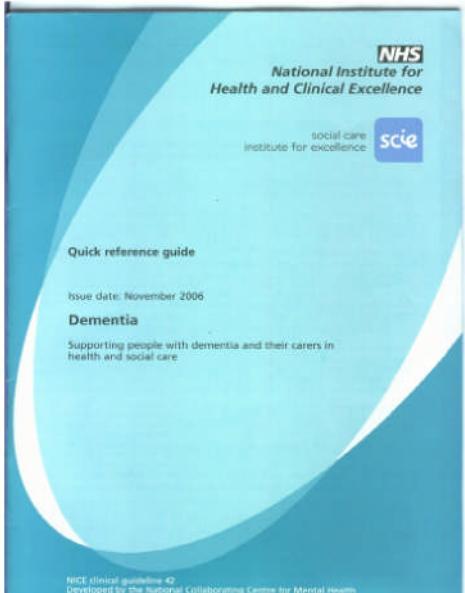
- Group activity sessions for people with mild to moderate dementia
- Activities designed to be mentally stimulating and fun
- A study found that attending CST groups was beneficial for cognitive skills such as communication. Group members also reported improvements in quality of life
- Extended programme of CST developed – Maintenance CST



## Notes:

# NICE-SCIE guidelines (2006)

The National Institute of Clinical Excellence is a health authority that recommends which treatments people should receive.



*'People with mild/moderate dementia of all types should be given the opportunity to participate in a structured group cognitive stimulation programme ... provided by workers with training and supervision ... irrespective of any anti-dementia drug received ...'*

## Notes:

# What is the iCST programme?



- Home based activity programme for carers and people with dementia
- Activities mentally stimulating and enjoyable
- 3 sessions per week
- Each session should last 20-30 minutes
- Research programme is 25 weeks long
- Themed activities eg: word games, art discussion, current affairs discussion



## Notes:

# Session structure

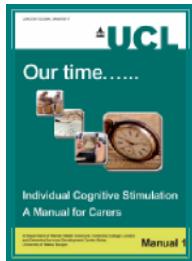


1. Discussion of the day, date, weather, location (5 mins)
2. Discussion of events in the news or current issues (5 mins)
3. Main activity (20 mins)



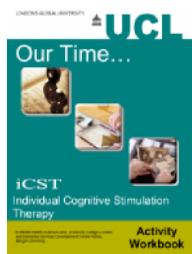
## Notes:

# What resources will I receive?



## iCST Manual:

- First point of call when preparing for a session
- How-to guide to iCST
- Outlines theme and structure for each session



## Activity Workbook:

- All paper based resources for activities suggested in the Manual
- Page numbers for paper based resources can be found in the iCST Manual

## iCST Toolkit:

- Extra resources eg: boules, cards

## Notes:

# What is the Carer's Diary?



- Use the diary to tell us how your sessions went
- Page for each theme (2 sessions)
- Rate session for person's enjoyment, interest, communication and mood
- Box to write any extra comments about the sessions
- Carer's Diary 1 will be collected half way through the programme by your supporting researcher. During this support visit you will receive Carer's Diary 2. If you have not completed Diary 1, you will be given another copy to use.
- Carer's Diary 2 will be collected at the end of the programme

## Notes:

# Key principles of iCST



1	<b>Person centred approach</b>
2	<b>Offering choice</b>
3	<b>Focusing on opinions rather than facts</b>
4	<b>Using reminiscence</b>
5	<b>Always have a tangible focus – something to look at, touch, or feel</b>
6	<b>Maximising potential</b>
7	<b>Enjoyment and fun</b>
8	<b>Stimulating language</b>
9	<b>Strengthening the caregiving relationship</b>

**Notes:**

# Role playing exercise



Imagine you are a person with Dementia, and the researcher is your carer. You will now spend some time going through a session together in 2 role playing exercises.

**Keep the following points in mind during exercise 1:**

- Did you notice any '**bad**' practice from your carer?
- Could your carer have done anything differently during the session?

**Keep the following points in mind during exercise 2:**

- Did you notice any '**good**' practice from your carer?
- How did your carer use the materials she / he had?



**Notes:**

## Your supporting researcher is:

---

will provide advice and support for you  
and your friend / relative during the study.

**You can contact them on:**

**Telephone:** \_\_\_\_\_

**Mobile:** \_\_\_\_\_

**Email:** \_\_\_\_\_

# Putting the key principles into practice

## How will the key principles help me with iCST sessions?

The key principles are here to help you and your relative/friend get the most out of this programme, so it is important that you feel ready to put them into practice. Take some time to read the following pages before you begin, and feel free to revisit them during the programme. The principles are grouped according to when and how you can use them in the session.

### Choosing activities:

#### Choice

This programme is **not prescriptive**. In the Manual there are a range of different themes but you can tailor the programme to your friend / relative's interests by coming up with your own ideas for activities or using your own resources.

### How do I make sure activities are stimulating?

A stimulating activity will get your relative/friend thinking and encourage them to explore ideas.

Activities are categorised into **Level A** and **Level B**. Level B activities tend to be more challenging than Level A activities. Choose the one you think will be engaging but take care to ensure the activity is not so difficult the person feels deskilled.

You do not need to stick to the same 'level' for the duration of the programme, mix and match according the person's skills and interests.

## ?

### Problem Solving

#### What if the person seems to be struggling with the activity I have chosen?

- Some sessions will be more challenging than others, especially since people have different interests and skills.
- If the person asks why things are difficult or seems to be anxious, let them know that you are trying to get them to exercise skills that have not been used for a while, and stimulate different parts of the brain.
- Try a different activity if you have time.
- If the person is distressed, do not continue with the activity. Try to end on a good note by doing something you know they enjoy instead.

## Maximising Potential

Be careful not to assume the person is unable to contribute or carry out an activity simply because they were not able to yesterday or last week. People with dementia often function at less than their full potential, perhaps due to lack of stimulation or opportunity.

### Tips:



- Keep an **open mind** when choosing activities
- Give the person **time** to gather their thoughts or carry out an activity
- **Do not overload or overwhelm** them with information
- Provide just enough **prompting** to enable the person to do the activity themselves

## Prompting discussion: Stimulating language and discussion

Often with people with dementia, we tend to talk about things from the past. Whilst this is enjoyable for people, it often involves recalling information, which has been over-rehearsed. The aim of CST is to continually encourage new ideas, thoughts and associations, rather than just recall previously learned information.

### How do I encourage discussion?

- 1) **By asking questions:** The way you phrase questions is important in encouraging the person to explore ideas. Here are some examples:

What do these have in common?

What do you think about....?

How are these different?

- 2) **By introducing a variety of topics:** Rather than introducing topics likely to have been discussed before, e.g.: "What do you think of the Royal family?", encourage discussions about new topics such as "Is modern art really art?" or "What do you think of same sex weddings?" In discussion based activities, you will be provided with examples of discussion topics to give you ideas.

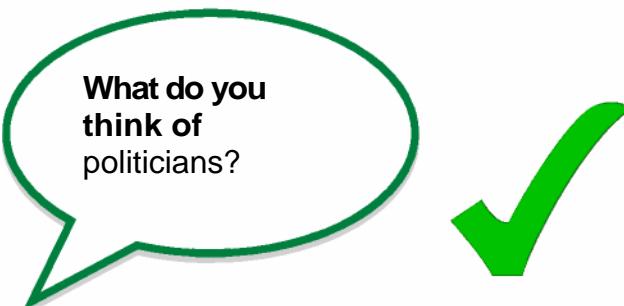
## Using reminiscence

Using past memories is an excellent way of tapping into a strength that many people with dementia have, in terms of recalling experiences from much earlier in their lives. Remember though that some people may have unhappy (even traumatic) memories of their earlier life, and some sensitivity is needed. Reminiscence can also be a useful tool towards orientation, which is a key goal of iCST. Many iCST sessions allow you to compare old and new, thinking about how things have changed over time.

## Asking questions: Opinions rather than facts

In iCST sessions, we need to focus on the person's strengths. **If we focus on 'facts' too much, there is the risk that the person will often be wrong.** If we ask the person for their opinions they cannot be wrong. **The way you ask questions is key to ensuring you do not put the person on the spot** by focusing on facts. Here are some examples:

### Opinion based questions



### Fact based questions



At first making sure you ask questions in this way might feel challenging, but with practice it will become second nature.

#### Tips:

- Jot down some opinion based questions and have them to hand during the session.
- If the person offers fact based information of their own accord during discussions (e.g.: "I remember when I learnt to ride a bike when I was 5", "That's the Eiffel Tower in the picture" etc.) this is great. The main thing is not to ask your friend / relative direct questions with the intention of getting this information.
- If there is a fact based element to any of the activities, give the person a selection of options to choose from or cues such as images to help them find the answer.



## ?

## Problem Solving:

### The person said something I know is not right, what do I do?

It doesn't matter whether the person offers comments that you know are not right or 'not true'. There is no need to correct them, just move on to the next question or topic. Answers have been provided for activities in the resource workbook, but there is no need to 'mark' responses. They are simply there for you to look at if you wish, or if the person requests the answer to a question. Most of the activities are designed to be 'open' with several possible answers.

## Supporting the person during the session:

### Person centered

We need to **see the person first and foremost**, rather than focusing on the dementia and the associated impairments. Ask yourself about the person's **strengths**, and think about how you can incorporate their interests into the sessions, rather than concentrating on their areas of difficulty.

### Always have a tangible focus – something to look at, touch or feel

Multi-sensory cues are really important, as memory works much better if you do not rely on just one sense. Try to have a mix of activities involving vision, touch, hearing, taste and smell. Often it is a combination of senses that is most effective.



**Tip:** Having something to look at or touch really helps aid concentration. Words in a discussion may soon be lost when memory is limited; having the object, a photograph or picture keeps the person's attention on the activity.

### Strengthening the caregiving relationship

The activities present a great opportunity for you and your relative / friend to enjoy some quality time together.

# Carer Questionnaire Set up

iCST: Individual Cognitive Stimulation Therapy for People with Dementia

## Carer Questionnaire

This booklet of questionnaires should be completed via self-report by the carer delivering the iCST Treatment.

### General Instructions to Interviewer

Before completing this questionnaire, please ensure that the **Participant Identity Number** has been entered in the boxes below.

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

Your cooperation is very much appreciated.

### To be completed by the interviewer

Participant Identity Number:

--	--	--	--	--	--	--	--	--	--	--	--

Centre Name:

---

Which time point is this? *Please tick one box only.*

Set-up visit

1<sup>st</sup> Monitoring Visit

(Week 12 of iCST Treatment)

2<sup>nd</sup> Monitoring Visit

(Week 25 of iCST Treatment)

Completed by (please print name):

---

Signed:

---

Interview date:

		/			/				
--	--	---	--	--	---	--	--	--	--

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# Carer Questionnaire Set up

This questionnaire asks about your views in delivering Individual Cognitive Stimulation Therapy. For each of the following questions, please place a tick in the box that best describes your answer. *Please tick one box for each item.*

## Set-up Visit

- 1. In general, how would you rate your knowledge of Individual Cognitive Stimulation Therapy? (please tick one box):**

**My knowledge of Individual Cognitive Stimulation Therapy is:**

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>				

- 2. How would you rate your confidence in delivering the individual cognitive stimulation sessions? (please tick one box):**

Very little	Fair	Good	Very confident
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- 3. How much support will you need by the research team in delivering the individual cognitive stimulation sessions? (please tick one box):**

Not at all	A little	Quite a lot	A lot
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- 4. Will you require weekly telephone support in delivering the iCST sessions? (please tick one box):**

I would prefer weekly telephone support   
I would prefer to receive telephone support once or twice per month

**Please indicate your response to the following statement:**

- 5. "My relative and I will be able to engage successfully in the individual cognitive stimulation sessions"? (please tick one box):**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/>				

## **Carer Questionnaire Set up**

We would greatly appreciate comments that carers may have about Individual Cognitive Stimulation Therapy, which will help us improve the intervention in the future. You can use the section below to provide your feedback. Thank you for your time in completing this questionnaire.

# Adherence Questionnaire

## Researcher Setup

iCST: Individual Cognitive Stimulation Therapy for People with Dementia

This booklet of questionnaires should be completed by the unblind researcher providing support to the family carer delivering the iCST Treatment.

### General Instructions to Interviewer

Before completing this questionnaire, please ensure that the **Participant Identity Number** has been entered in the boxes below.

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

Your cooperation is very much appreciated.

#### To be completed by the interviewer

Participant Identity Number:

--	--	--	--	--	--	--	--	--	--	--	--

Centre Name:

\_\_\_\_\_

Which time point is this? *Please tick one box only.*

Set-up visit

Telephone Contact

(Number: \_\_\_\_\_, Week \_\_\_\_\_ of iCST Treatment)

Monitoring Visit

(Number: \_\_\_\_\_, Week \_\_\_\_\_ of iCST Treatment)

Completed by (please print name):

\_\_\_\_\_

Signed:

\_\_\_\_\_

Interview date:

		/			/				
d	d		m	m		y	y	y	y

# Adherence Questionnaire

## Researcher Setup

**Note to Interviewer:** The following questions should be completed by the unblind researcher during and after the iCST Set-up Visit.

### A. Section 1 Set-up Visit (Visit 1)

1. Has the family carer been trained to use iCST?

YES                    NO  
           

If no please state the reason

---

2. Please report the date of iCST training for the family carer

/  /

3. Please report the date of the set-up visit

/  /

4. Please report the start date of the iCST treatment (the date when the first iCST session was completed)

/  /

5. Please indicate the duration of the set-up visit (in minutes and hours)

----- (hours)  
----- (minutes)

**It is recommended that the unblind researcher observes the first iCST session run by the family carer (and provides additional help if required).**

6. In general, how would you rate the success of the first session of the set-up visit? (please tick one box):

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>				

**Please complete the items below in terms of carer's ability/confidence and amount of support they will need during the intervention:**

7. The carer will be able to engage successfully with the person with dementia in the iCST sessions (please tick one box):

A lot	Quite a bit	A little	Not at all
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

# **Adherence Questionnaire Researcher Setup**

8. Please rate the amount of support the carer will need in delivering the iCST sessions (please tick one box):

<b>A lot</b>	<b>Quite a bit</b>	<b>A little</b>	<b>Not at all</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. Will the intervention be delivered (mostly) by the (primary) family carer?

YES       NO      *if no go to question 10*

10. If no please indicate below who will deliver most of the iCST sessions:

Other family member

Please specify \_\_\_\_\_

Other (i.e. f

Please specify \_\_\_\_\_

Paid carer

Please specify \_\_\_\_\_  
 Member of staff (Voluntary Sector)

Member of staff (Volunteer)  
Please specify

Please specify  
 Member of

Member of staff (NHS, Local Services)  
Please specify

Please specify  
 Member of

Member of staff (private)

Please specify \_\_\_\_\_

1

Please report a

---

# How was your session today?

## MY LIFE: Sessions 1 & 2

Part 1 completed

Yes

No

Part 2 completed

Yes

No



Date: .....

Date: .....

Please circle the appropriate response

	Not at all	A little	Quite a lot	Very much	Extremely
Did the person show interest?	1	2	3	4	5
Did the person communicate?	1	2	3	4	5
Did the person show enjoyment?	1	2	3	4	5
How would you rate the person's mood today?	Poor	Fair	Good	Very good	Excellent

### Comments .....

.....

.....

.....

.....

# Telephone contact Adherence Questionnaire

iCST: Individual Cognitive Stimulation Therapy for People with Dementia

This booklet of questionnaires should be completed by the unblind researcher providing support to the family carer delivering the iCST Treatment.

## General Instructions to Interviewer

Before completing this questionnaire, please ensure that the **Participant Identity Number** has been entered in the boxes below.

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

Your cooperation is very much appreciated.

### To be completed by the interviewer

Participant Identity Number:

--	--	--	--	--	--	--	--	--	--	--	--

Centre Name:

\_\_\_\_\_

Which time point is this? *Please tick one box only.*

Set-up visit

Telephone Contact

(Number: \_\_\_\_\_, Week \_\_\_\_\_ of iCST Treatment)

Monitoring Visit

(Number: \_\_\_\_\_, Week \_\_\_\_\_ of iCST Treatment)

Completed by (please print name):

\_\_\_\_\_

Signed:

\_\_\_\_\_

Interview date:

		/			/				
--	--	---	--	--	---	--	--	--	--

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# Telephone contact Adherence Questionnaire

**Note to Interviewer:** The following questions should be completed by the unblind researcher during Telephone Contacts with the family carer.

## Telephone Contact \_\_\_\_\_ ( which scheduled call)

1. Was Telephone Contact made?

YES       NO

If no please indicate why the telephone contact did not take place

---

---

2. Please report the date of Telephone Contact

\_\_\_\_ / \_\_\_\_ / \_\_\_\_ \_\_\_\_

3. How many minutes/hours did the telephone contact last?

----- (hours)

----- (minutes)

4. On average how many sessions per week did the carer and participant report completing?

- 0 sessions
- 1 session
- 2 sessions
- 3 sessions
- Other please specify -----

5. How long does one iCST session last on average (one session only) according to the family carer?

----- (minutes)

6. How long does the carer spend on average in preparing for the iCST sessions (one session only)?

----- (minutes)

7. Is the intervention delivered (mostly) by the (primary) family carer?

YES       NO      *if no go to question 8*

8. If no please indicate below who delivers most of the iCST sessions:

- Other family member  
Please specify \_\_\_\_\_
- Other (i.e. friend, neighbour)  
Please specify \_\_\_\_\_
- Paid carer visiting participant  
Please specify \_\_\_\_\_

# Telephone contact Adherence Questionnaire

Member of staff (Voluntary Sector)

Please specify \_\_\_\_\_

Member of staff (NHS, Local Services)

Please specify \_\_\_\_\_

Member of staff (Private sector)

Please specify \_\_\_\_\_

No-one (participant and carer dropped out)

Unknown

9. Has the family carer stopped providing the iCST sessions?

YES                   NO

10. Has the carer reported any difficulties running the iCST sessions or reasons why (some/all) sessions were not completed?

YES                   NO

11. Please indicate below any areas of difficulties reported by the carer that has resulted in not providing (all or some) of the iCST sessions (*tick all that apply*)

- Patient ill health
- Carer ill health
- Patient is not enjoying the sessions
- Carer is not enjoying the sessions
- Patient not able to participate due to stress, anxiety, mood etc.
- Carer not able to participate due to stress, anxiety, burden etc.
- Holidays/Family commitments
- Work commitments for carer
- The carer is experiencing difficulties in running the sessions
- Patient does not want to take part in the sessions
- Carer can not find free time to deliver the sessions
- Difficulties with the Manual and Activities
- Other please specify \_\_\_\_\_
- Unknown

1. Has there been any 'out of protocol' telephone contact with the family carer?

YES                   NO

Number of telephone calls

1. Telephone Call 1 Lasting \_\_\_\_\_ minutes

2. Telephone Call 2 Lasting \_\_\_\_\_ minutes

3. Telephone Call 3 Lasting \_\_\_\_\_ minutes

4. Telephone Call 4 Lasting \_\_\_\_\_ minutes

5. Telephone Call 5 Lasting \_\_\_\_\_ minutes

# **Telephone contact Adherence Questionnaire**

Please report details of any 'out of protocol' contact

Handwriting practice lines consisting of three horizontal lines: a solid top line, a dashed midline, and a solid bottom line.

Please report any additional comments/observations

# Carer Monitoring Questionnaire

iCST: Individual Cognitive Stimulation Therapy for People with Dementia

This booklet of questionnaires should be completed via self-report by the carer delivering the iCST Treatment.

## General Instructions

Before completing this questionnaire, please ensure that the **Participant Identity Number** has been entered in the boxes below.

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

Your cooperation is very much appreciated.

### To be completed by the interviewer

Participant Identity Number:

--	--	--	--	--	--	--	--	--	--	--	--

Centre Name:

\_\_\_\_\_

Which time point is this? *Please tick one box only.*

Set-up visit

1<sup>st</sup> Monitoring Visit

(Week 12 of iCST Treatment)

2<sup>nd</sup> Monitoring Visit

(Week 25 of iCST Treatment)

Completed by (please print name):

\_\_\_\_\_

Signed:

\_\_\_\_\_

Interview date:

		/			/				
--	--	---	--	--	---	--	--	--	--

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# Carer Monitoring Questionnaire

The questionnaire below asks about your views in delivering Individual Cognitive Stimulation Therapy. For each of the following questions, please place a tick in the box that best describes your answer. *Please tick one box for each item.*

## Monitoring Visit \_\_\_\_\_

### 1. I have been able to focus on opinions rather than facts during the individual cognitive stimulation sessions (please tick one box):

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/>				

### 2. I have been able to develop ideas in a sensitive manner during the individual cognitive stimulation sessions (please tick one box):

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/>				

### 3. I have incorporated my relative's personal interests in the activities (please tick one box):

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/>				

### 4. I have been able to adapt the sessions to accommodate my relative's abilities (please tick one box):

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/>				

Please indicate your response to the following statement:

### 5. "My relative and I have been able to engage successfully in the individual cognitive stimulation sessions"? (please tick one box):

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/>				

# **Carer Monitoring Questionnaire**

**6. In general, how would you rate your knowledge of Individual Cognitive Stimulation Therapy? (please tick one box):**

**My knowledge of Individual Cognitive Stimulation Therapy is:**

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>				

**7. How would you rate your confidence in delivering the individual cognitive stimulation sessions? (please tick one box):**

Very little	Fair	Good	Very confident
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**8. How would you rate the support you have received so far in delivering the individual cognitive stimulation sessions? (please tick one box):**

**I would rate the support I have received as:**

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>				

# **Carer Monitoring Questionnaire**

We would greatly appreciate comments that carers may have about Individual Cognitive Stimulation Therapy, which will help us improve the intervention in the future. You can use the section below to provide your feedback. Thank you for your time in completing this questionnaire.

# Adherence Questionnaire

## Monitoring researcher

iCST: Individual Cognitive Stimulation Therapy for People with Dementia

This booklet of questionnaires should be completed by the unblind researcher providing support to the family carer delivering the iCST Treatment.

### General Instructions to Interviewer

Before completing this questionnaire, please ensure that the **Participant Identity Number** has been entered in the boxes below.

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

Your cooperation is very much appreciated.

#### To be completed by the interviewer

Participant Identity Number:

--	--	--	--	--	--	--	--	--	--	--	--

Centre Name:

\_\_\_\_\_

Which time point is this? *Please tick one box only.*

Set-up visit

Telephone Contact

(Number: \_\_\_\_\_, Week \_\_\_\_\_ of iCST Treatment)

Monitoring Visit

(Number: \_\_\_\_\_, Week \_\_\_\_\_ of iCST Treatment)

Completed by (please print name):

\_\_\_\_\_

Signed:

\_\_\_\_\_

Interview date:

		/			/				
d	d		m	m		y	y	y	y

# Adherence Questionnaire

## Monitoring researcher

**Note to Interviewer:** The following questions should be completed by the unblind researcher during and after the iCST Monitoring Visit.

### Monitoring Visit \_\_\_\_\_

1. Did the Monitoring Visit take place?

YES

NO

If no please state the reason

---

2. Please report the date of the Monitoring Visit

\_\_\_\_ / \_\_\_\_ / \_\_\_\_

3. Please indicate the duration of the Monitoring Visit

----- (hours)

----- (minutes)

**Please complete the items below in terms of carer's ability/confidence and amount of support received during the intervention:**

4. Has the carer been able to engage successfully with the person with dementia in the iCST sessions? (please tick one box):

A lot

Quite a bit

A little

Not at all

5. Please rate the amount of support the carer has received in delivering the iCST sessions? (please tick one box):

A lot

Quite a bit

A little

Not at all

6. Is the intervention delivered (mostly) by the (primary) family carer?

YES       NO      *if no go to question 7*

7. If no please indicate below who is delivering most of the iCST sessions:

Other family member

Please specify \_\_\_\_\_

Other (i.e. friend, neighbour)

Please specify \_\_\_\_\_

Paid carer visiting participant

Please specify \_\_\_\_\_

Member of staff (Voluntary Sector)

Please specify \_\_\_\_\_

# Adherence Questionnaire

## Monitoring researcher

Member of staff (NHS, Local Services)

Please specify \_\_\_\_\_

Member of staff (Private sector)

Please specify \_\_\_\_\_

No-one (participant and carer dropped out)

Unknown

**Please note that during this visit the unblind researcher should collect the Diary Sheets that have been completed by the family carer.**

8. How many iCST sessions has the carer and person with dementia completed (indicate full amount of sessions as reported in Carer's Diary)

Treatment Adherence Point \_\_\_\_\_

----- (sessions)

9. Has the family carer stopped delivering the iCST sessions?

YES                     NO

10. Has the carer reported any difficulties running the iCST sessions or reasons why (some/all) sessions were not completed?

YES                     NO

11. Please indicate below any areas of difficulties reported by the carer that has resulted in not providing all or some of the sessions (*tick all that apply*)

Patient ill health  
 Carer ill health  
 Patient is not enjoying the sessions  
 Carer is not enjoying the sessions  
 Patient not able to participate due to stress, anxiety, mood etc.  
 Carer not able to participate due to stress, anxiety, burden etc.  
 Holidays/Family commitments  
 Work commitments for carer  
 The carer is experiencing difficulties in running the sessions  
 Patient does not want to take part in the sessions  
 Carer cannot find free time to deliver the sessions  
 Difficulties with the Manual and Activities  
 Other please specify \_\_\_\_\_  
 Unknown

12. Has there been any 'out of protocol' telephone contact with the family carer?

YES                     NO

Number of telephone calls

1. Telephone Call 1 Lasting \_\_\_\_\_ minutes/hours

2. Telephone Call 2 Lasting \_\_\_\_\_ minutes/hours

# **Adherence Questionnaire Monitoring researcher**

3. Telephone Call 3 Lasting \_\_\_\_\_ minutes/hours  
4. Telephone Call 4 Lasting \_\_\_\_\_ minutes/hours  
5. Telephone Call 5 Lasting \_\_\_\_\_ minutes/hours

Please report details of any 'out of protocol' contact

Please report any additional comments/observations

# Carer Additional Support Visit

iCST: Individual Cognitive Stimulation Therapy for People with Dementia

This booklet of questionnaires should be completed by the unblind researcher providing support to the family carer delivering the iCST Treatment when visiting the family carer on out of protocol visit(s). Please use a photocopy of this form.

## General Instructions

Before completing this questionnaire, please ensure that the **Participant Identity Number** has been entered in the boxes below.

Subsequent processing of these questionnaires involves photocopying and the use of data scanning equipment. To ensure the smooth operation of the equipment, it would be appreciated if the following could be observed:

- Please complete the form using a **black** ballpoint pen.
- Please do not fold or crease the form.
- Please complete all the questions.
- Please enter your responses in the boxes/spaces provided, as instructed.
- Please use only a single line to delete mistakes and initial each such correction.

Your cooperation is very much appreciated.

### To be completed by the interviewer

Participant Identity Number:

--	--	--	--	--	--	--	--	--	--

Centre Name:

Which Additional Support Visit is this?

Completed by (please print name):

Signed:

Interview date:

		/			/				
d	d		m	m		y	y	y	y

# Carer Additional Support Visit

**Note to Interviewer:** The following questions should be completed by the unblind researcher during and after the iCST Monitoring Visit.

1. Please indicate the duration of the Additional Support Visit

----- (hours)  
----- (minutes)

2. What is the purpose of this visit?

- Additional Carer Support
- Training for setup if skipped during setup visit. Please complete the setup questionnaire in addition
- Other \_\_\_\_\_

3. Has the family carer stopped delivering the iCST sessions?

YES       NO

4. Please indicate below the reason that the carer has requested an additional support visit (*tick all that apply*)

- Patient ill health
- Carer ill health
- Patient is not enjoying the sessions
- Carer is not enjoying the sessions
- Patient not able to participate due to stress, anxiety, mood etc.
- Carer not able to participate due to stress, anxiety, burden etc.
- Holidays/Family commitments
- Work commitments for carer
- The carer is experiencing difficulties in running the sessions
- Difficulties with the Manual and Activities
- The carer is not confident delivering the sessions
- Other please specify \_\_\_\_\_
- Unknown

5. Has the carer been able to engage successfully with the person with dementia in the iCST sessions? (please tick one box):

A lot

Quite a bit

A little

Not at all

6. Please rate the amount of support the carer has received in delivering the iCST sessions? (please tick one box):

A lot

Quite a bit

A little

Not at all

## **Carer Additional Support Visit**

Please report any additional comments/observations

**GP****1****iCST: Individual Cognitive Stimulation Therapy for People with Dementia****Participant's GP Details**

This sheet should be completed by project researchers conducting the baseline interviews of participants. This form should be retained by the centre and not forwarded to the trial co-ordinating centre.

**To be completed by the interviewer**Participant Identity Number:     

Centre Name: \_\_\_\_\_

Completed by (please print name): \_\_\_\_\_

Interview date:   /   /      
d d m m y y y yName of Doctor: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_Practice Name: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Notes:

UCL, Mental Health Sciences Unit  
(Bloomsbury Campus)  
67-73 Riding House Street  
2nd Floor, Charles Bell House  
London W1W 7EJ  
Phone@ +44 (0)20 7679 9452  
Fax: +44 (0)20 7679 9426

## GENERAL PRACTITIONER INFORMATION SHEET

**Title:** Individualised Cognitive Stimulation Therapy (iCST) for people with dementia

..... (Dob)..... has been invited and consented to take part in a research study. Please let us know if there is anything that is not clear, or if you would like more information.

Professor Martin Orrell runs this project from North East London NHS Foundation Trust (NELFT).

Cognitive Stimulation Therapy (CST) groups are an enjoyable and beneficial therapy for people with dementia, recommended by the NICE (2007) guidelines. They aim to keep the mind active through enjoyable activities, which are undertaken as a structured programme facilitated by experienced and trained staff. However, many people do not have access to, or are not suited to group treatment. Therefore, this study will evaluate the impact of carer-led, individualized CST (iCST) on cognition and quality of life for people with dementia. It will involve three weekly sessions for 25 weeks, covering similar themes to group CST (for example physical games, discussion of current affairs, sounds, food, word and number games). Carers will receive training and ongoing support in order to deliver the intervention effectively. It is a randomized controlled trial, therefore half the people participating will be allocated to a 'no treatment' control group, and will just be required to complete the assessment interview.

These assessments will be conducted prior to the intervention and then after 13 and then 26 weeks. They will include outcome measures looking at:

- Personal details (age, relationship, medication, educational level, etc.)
- Quality-of-life (for both the person and their carer)
- Cognition
- Depression
- Activities of daily living and behaviour
- Carer mental health

The study will **not** affect your patient's current or future treatment.

The results of this study are expected to be published in relevant journals and at conferences. All interviews are confidential and will not be disclosed to anyone else. The information collected in the study will be anonymous and patients will not be identified in any report/publication.

All proposals for research using human subjects are reviewed by the local Ethics Committee before they can proceed and the appropriate permission.

Thank you for reading this information sheet. Please do not hesitate to contact Prof Orrell if you need any further information.

Kind regards,

---

\_\_\_\_\_  
Research Assistant

## INFORMATION SHEET FOR CAREGIVERS

### Individualised (one-to-one) Cognitive Stimulation Therapy (iCST) for People with Dementia

#### **Invitation to participate in a research study**

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

#### **What is the purpose of the study?**

In recent years, cognitive stimulation therapy (CST) groups have shown to be an enjoyable and beneficial therapy for people with dementia and are now a recommended treatment. However, many people cannot or do not want to attend group sessions. This project will show whether individualised (one-to-one) cognitive stimulation is effective in improving cognition and quality of life for the person with dementia.

#### **What happens in individualised cognitive stimulation?**

iCST sessions, lasting 30 minutes, will take place three times a week for 25 weeks. They will be delivered by yourself, and you will receive training and ongoing support to help you with this. The activities will include, for example, multi-sensory stimulation, word categorisation and discussion of current affairs. The idea is to keep the mind active through enjoyable activities catered to the interest and ability of the individual.

#### **Why have I been chosen?**

You have been invited to take part because of your support for a person who at some point had a memory assessment. We need a large number of people with memory problems to help us evaluate iCST – 260 in total.

#### **Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care your relative / friend receives.

## **What will happen to me if I take part?**

This study is a randomised trial. We need to establish the additional benefits of iCST, so we need to compare any changes experienced by people receiving treatment to other people receiving no treatment. The fairest way of doing this is to select people for the group by chance; everyone agreeing to take part will have a 50:50 chance of receiving iCST. The decision is made by an independent computer, which will not have any identifying information about you or your relative/friend.

If you decide to take part, your participation in the study will last for a time period of six months. Following discussion of any questions you may have with a researcher, and signing the consent form, **all participants** will be asked to:

1. Meet with a researcher for between one / one-and-a-half hours for an interview and to complete some questionnaires. These will concern both the person you are caring for (asking questions about their quality of life, use of services, medication, accommodation, behaviour and activities of daily living) and yourself (asking questions about your general health, mood and quality of life). The time stated to complete the interviews and questionnaires is an estimate; you and your friend/relative may take as many breaks as you want or feel necessary, and even complete the process over two sessions if preferred.
2. Repeat these questionnaires with the researcher after 13 weeks and then after another 13 weeks. This is to see whether any of these factors change as a result of the iCST intervention.

Usually, the researcher will come to your home or the home of your relative/friend if you live separately, but will be happy to meet you elsewhere if you would prefer. The researcher will meet with and interview your relative/friend at the same time as you are completing the questionnaires.

If you are allocated to deliver the iCST intervention, you will be additionally asked to:

1. Attend a training over two half-days, which will teach you how to deliver iCST. You will also be given a manual and DVD to assist you through the iCST sessions. A researcher will visit you at home before the iCST programme starts, and go through the sessions with you, helping to plan what you will be doing. This will include an appraisal of the interests and abilities of the person you are caring for, adapting the programme to suit their needs. They will also discuss the resources available at home. You will receive up to ten hours support over the six months, including telephone support (initially weekly) and three home visits. You will be asked to keep a diary, so that we have a record of what you are doing including how much you think the person is interested in and enjoying the sessions.
2. Some people will additionally be asked to be interviewed (alongside the person with dementia), to investigate the impact of iCST on the person with dementia's experience, both during the sessions and any generalised effects into everyday life, the carer role and carer relationship. Participation in this part of the study is entirely voluntary and whether or not you take part will have no impact on the rest of the study.

## **Expenses**

Any travel expenses incurred by yourself or your relative/friend will be reimbursed.

## **What do I have to do?**

Taking part in the study does not involve any lifestyle restrictions or changes either for you or your friend, relative. You can carry on your everyday activities as normal while participating in the study. All we ask is that you help your relative /friend to keep their appointments with us during the time that they are taking part.

## **What if my relative/friend is unable to consent to take part, or loses the ability to consent?**

All participants in research are invited to complete a consent form before the research commences. Sometimes people with dementia are unable to make a decision to consent to a research project because they have difficulty in understanding or retaining the information provided about the project. Sometimes people with dementia are able to do this at the beginning of the project, but later may not be able to provide their consent. In either of these circumstances, the research team is required to consult with someone who is involved in the person's care, such as a family member, regarding whether the person should participate, or continue to participate, in the project. If concerns do arise regarding the your relatives'/friends' ability to consent, we would seek your advice regarding whether the person should participate and what you think the person's feelings and wishes would be regarding taking part. If the person has previously made an advance statement or advanced decision that is relevant, we would not do anything to go against this.

## **What are the possible disadvantages and risks of taking part?**

iCST aims to be stimulating and enjoyable. Sessions involve discussing themes such as food, childhood and current affairs and the level of risk in taking part is therefore minimal. During the training and support, you will be given guidance on what to do if the person with dementia becomes distressed in sessions. If the intervention really does not suit you or the person you are caring for, you are free to finish at any point.

## **What are the possible benefits of taking part?**

If you decide to take part, and your relative/friend is involved in iCST, we hope that this may be of some help to them. Previously, people participating in group CST have reported that they have enjoyed the experience greatly. For all participants, the information we get from this study may help us to treat people with memory problems better in the future.

## **Will my taking part in the study be kept confidential?**

We will ask for your permission to send your relative/friend's GP a letter explaining that you have both agreed to take part in the study. All information which is collected about you during the course of the study will be kept strictly confidential. All data is stored without any identifying details under secure conditions.

## **What will happen if I don't want to carry on with the study?**

You and your relative/friend will be free to withdraw from the study at any time, without

giving a reason. Withdrawing from the study will not affect the standard of care your relative/friend receives. We will need to use any data collected in the study up to the point of withdrawal.

### **Consent form for use of film footage**

Some sessions of Individualised Cognitive Stimulation Therapy (iCST) may be video taped. The purpose of video taping is to help train future volunteers and group facilitators. You may at any point request that video taping is stopped, withdraw your consent for the taping and any further use of the taped footage, at this stage the tape will be destroyed.

### **What if something goes wrong?**

If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for your legal costs. Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedures should be available to you. If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution.

### **Who is organising and funding the research?**

The research is funded by Health Technology Assessment (HTA). This funding covers the running costs of the research project and is led by Professor Martin Orrell, who is an Old Age Consultant at North East London Foundation NHS Trust and a Professor of Mental Health and Ageing at University College London.

### **What will happen to the results of the research?**

The results will be published by the Department of Health, and in relevant journals. No participants will be identified in any publication arising from the study, without their written consent. We will make arrangements for participants to be informed of the progress of the research and the results through newsletters and local meetings.

### **Who has reviewed the study?**

All NHS research is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by the X Ethics Committee.

### **Who can I contact for further information?**

For more information about this research, please contact:

Martin Orrell,  
Professor of Ageing and Mental Health,  
Charles Bell House, UCL  
67-73 Riding House Street, London, W1W 7EJ,  
Phone: 020-7679-9452  
Email: [m.orrell@ucl.ac.uk](mailto:m.orrell@ucl.ac.uk)

**Or if you have any complaints about this study please contact:**

Fiona Horton R&D Administrator  
R& D Department, NELFT  
Goodmayes Hospital, Maggie Lilley Suite  
Barley Lane  
Ilford Essex, IG3 8YB

Phone 0844 600 1200 Ext 4485  
Fax 0844 493 0289

Email: [Fiona.Horton@nelft.nhs.uk](mailto:Fiona.Horton@nelft.nhs.uk)

**Thank you for considering taking part in this research study!**

## PARTICIPANT INFORMATION SHEET

### Individualised (one-to-one) Cognitive Stimulation Therapy (iCST) for People with Dementia

#### **Invitation to participate in a research study**

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

#### **What is the purpose of the study?**

In recent years, Cognitive Stimulation Therapy (CST) groups have shown to be an enjoyable and beneficial therapy for people with memory problems. This project will show whether individualised (one-to-one) CST is effective in improving things like memory and quality of life for people with memory problems.

#### **What happens in individualised cognitive stimulation therapy (iCST)?**

iCST sessions will last for 30 minutes and will be led by your relative/friend. They will take place three times a week for 25 weeks. The activities will include, for example, discussion of food and current affairs. The idea is to keep the mind active through enjoyable activities.

#### **Why have I been chosen?**

You have been invited to take part because you have at some point had a memory assessment. We need a large number of people with memory problems to help us evaluate iCST – 260 in total.

#### **Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

## **What will happen to me if I take part?**

This study is a randomised trial. We need to see whether iCST is better than no treatment, so we need to compare any changes experienced by people receiving iCST to those receiving nothing. The fairest way of doing this is to select people for the group by chance; everyone agreeing to take part will have a 50:50 chance of receiving iCST. The decision is made by an independent computer, which will not have any identifying information about you or your relative/friend.

If you decide to take part, your participation in the study will last for a time period of about six months. Following discussion of any questions you may have with a researcher, and signing the consent form, **all participants** will be asked to:

1. Meet with a researcher for between one / one-and-a-half hours for an interview and to complete some questionnaires covering your quality of life, cognition (e.g. memory) and mood. The time stated to complete the interviews and questionnaires is an estimate; you and your friend/relative may take as many breaks as you want or feel necessary, and even complete the process over two sessions if preferred.
2. Repeat these questionnaires with the researcher after 13 weeks and then after another 13 weeks. This is to see whether any of these factors change as a result of the iCST intervention.

Usually, the researcher will come to your home or the home of your relative/friend, but will be happy to meet you elsewhere if you would prefer. The researcher will meet with and interview your relative/friend at the same time as you are completing the questionnaires.

## **Expenses**

Any travel expenses incurred by yourself or your care-giver will be reimbursed.

## **What do I have to do?**

Taking part in the study does not involve any lifestyle restrictions or changes. You can carry on your everyday activities as normal while participating in the study. All we ask is that you keep your appointments with us during the time that you are taking part.

## **What are the possible disadvantages and risks of taking part?**

iCST aims to be stimulating and enjoyable. Sessions involve discussing themes such as food, childhood and current affairs and the level of risk in taking part is therefore minimal. Your caregiver will be given guidance on what to do if you become anxious or distressed during sessions. If the intervention really does not suit you, you are free to finish at any point.

## **What are the possible benefits of taking part?**

If you decide to take part and receive iCST, we hope that it might be enjoyable for you. We also anticipate that the stimulating activities might improve some of your skills, including memory and language, and improve your quality of life. Such changes have been demonstrated through group CST. The information that we get from this study may help us to treat people with memory problems better in the future, so you will be making a valuable contribution.

### **Will my taking part in the study be kept confidential?**

We will ask for your permission to send your GP a letter explaining that you have agreed to take part in the study. All information which is collected about you during the course of the study will be kept strictly confidential. All data is stored without any identifying details under secure conditions.

### **What will happen if I don't want to carry on with the study?**

You will be free to withdraw from the study at any time, without giving a reason. Withdrawing from the study will not affect the standard of care you receive. We will need to use any data collected in the study, up to the point of withdrawal.

### **What if something goes wrong?**

If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for your legal costs.

Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedures should be available to you. If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution.

### **Who is organising and funding the research?**

The research is funded by the Health technology Assessment (HTA). This funding covers the running costs of the research project and is led by Professor Martin Orrell, who is an Old Age Consultant at North East London Foundation NHS Trust and a Professor of Mental Health and Ageing at University College London.

### **Consent form for use of film footage**

Some sessions of Individualised Cognitive Stimulation Therapy (iCST) may be video taped. The purpose of video taping is to help train future volunteers and group facilitators. You may at any point request that video taping is stopped, withdraw your consent for the taping and any further use of the taped footage, at this stage the tape will be destroyed.

### **What will happen to the results of the research?**

The results will be published by the Department of Health, and in relevant health journals. No participants will be identified in any publication arising from the study, without their written consent. We will make arrangements for participants to be informed of the progress of the research and the results through newsletters and local meetings.

**Who has reviewed the study?**

All NHS research is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by the X Ethics Committee.

**Who can I contact for further information?**

For more information about this research, please contact:

Martin Orrell,  
Professor of Ageing and Mental Health,  
Charles Bell House, UCL  
67-73 Riding House Street, London, W1W 7EJ,

Phone: 020-7679-9452

Email: [m.orrell@ucl.ac.uk](mailto:m.orrell@ucl.ac.uk)

**Or if you have any complaints about this study please contact:**

Fiona Horton R&D Administrator  
R& D Department, NELFT  
Goodmayes Hospital, Maggie Lilley Suite  
Barley Lane  
Ilford Essex, IG3 8YB

Phone 0844 600 1200 Ext 4485

Fax 0844 493 0289

Email: [Fiona.Horton@nelft.nhs.uk](mailto:Fiona.Horton@nelft.nhs.uk)

**Thank you for considering taking part in this research study!**

# **Reporting Serious Adverse Events in iCST**

## **Instructions**

1. Upon becoming aware of an adverse event involving a participant or carer, determine whether it is "serious" by examining the criteria below.

A Serious Adverse Event (SAE) is an untoward occurrence experienced by either a participant or carer which:

- a) results in death;
- b) is life-threatening;
- c) requires hospitalisation or prolongation of existing hospitalisation;
- d) results in persistent or significant disability or incapacity;
- e) is otherwise considered medically significant by the investigator.

In addition, any cases where action has been taken under the iCST protocol for the protection of vulnerable adults (dealing with suspected abuse or neglect of participants) should be reported to the London centre using this procedure.

2. If a Serious Adverse Event is deemed to have taken place, please complete the attached form and forward it to the London centre as instructed therein.

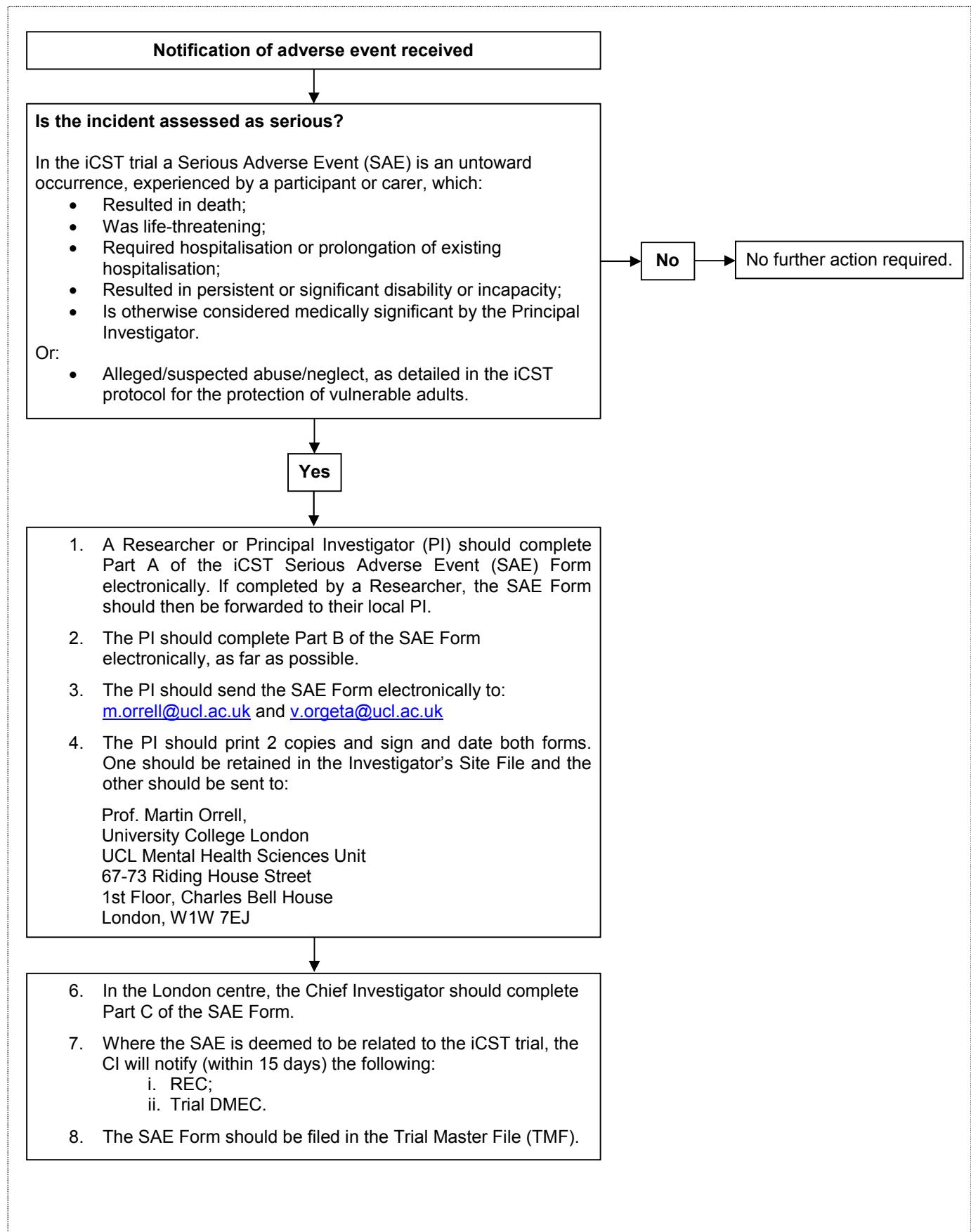
It should be noted that all Serious Adverse Events should be reported to the London centre, even if initially there may be no obvious connection to the trial. In particular:

All deaths of participants and carers should be reported to the London Centre.

All incidents of hospitalisation (and prolongation of hospitalisation) for participants and carers should be reported to the London centre (even when the illness or condition being treated has no connection to the trial).

3. The iCST Data Ethics and Monitoring Committee (DMEC) has specifically requested that, as far as possible, all hospitalisations are recorded. Researchers undertaking follow-up assessments (this does not apply to baseline assessments) should, therefore, consider this when completing questionnaire booklet QB6 (Service Use). A SAE form should be completed where the participant or carer has indicated that they have stayed in hospital and this has not already been reported to the research team.

**Figure 1. – Flow chart of iCST Serious Adverse Event Reporting Procedure**



# iCST Serious Adverse Event Reporting Form

## PART A (to be completed by Researcher or Principal Investigator)

A1. Centre Name: \_\_\_\_\_

Completed by: \_\_\_\_\_

A2. Date form completed: 

d	d

m	m

y	y	y	y	y

A3. Participant Identity (Trial) Number 

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A4. How did the centre become aware of this incident?  
\_\_\_\_\_  
\_\_\_\_\_

A5. Was this SAE suffered by the participant or carer? *Please place an "x" in one box only.*

Participant   
Carer

A6. Are you reporting a death? *Please place an "x" in one box only.*

Yes  Please proceed to **Question A8**  
No  Please proceed to **Question A7**

A7. Please categorise this event, by placing an "x" in all appropriate options.

- Life threatening
- Hospitalisation or prolongation of existing hospitalisation
- Persistent or significant disability or incapacity
- Otherwise considered medically significant by the investigator
- Alleged/suspected abuse/neglect, as detailed in protection of vulnerable adults protocol

A8. Date of SAE: 

d	d

m	m

y	y	y	y	y

A9. Location of SAE: \_\_\_\_\_

Describe the  
circumstances of the  
event. Is there any  
evidence that participation  
in the trial may have been  
a contributing factor?

(Attach further sheets if  
necessary)

**PART B (to be completed by Principal Investigator)**

- B1.** In your opinion, did this SAE arise as a result of the participant's or carer's involvement in the iCST trial? *Please place an "x" in one box only.*

Yes

No

- B2.** Please add any comments regarding the SAE.

Please complete the details below:

- B3.** Name of PI: \_\_\_\_\_

Please send an electronic version to [m.orrell@ucl.ac.uk](mailto:m.orrell@ucl.ac.uk) and [v.orgeta@ucl.ac.uk](mailto:v.orgeta@ucl.ac.uk)

- B4.** Signature of PI: \_\_\_\_\_

- B5.** Date of signature: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

<input type="text"/>	<input type="text"/> d	/	<input type="text"/> m	<input type="text"/> m	/	<input type="text"/> y	<input type="text"/> y	<input type="text"/> y	<input type="text"/> y
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Please print two copies. After signature, please send by post to the address below and retain a copy for the Investigator's Site File.

Prof. Martin Orrell,  
University College London  
UCL Mental Health Sciences Unit  
67-73 Riding House Street  
1st Floor, Charles Bell House  
London, W1W 7EJ

**PART C (to be completed by Chief Investigator)**

- C1.** Action taken: \_\_\_\_\_

- C2.** Name of CI: Prof. Martin Orrell \_\_\_\_\_

- C3.** Signature of CI: \_\_\_\_\_

- C4.** Date of signature: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

<input type="text"/>	<input type="text"/> d	/	<input type="text"/> m	<input type="text"/> m	/	<input type="text"/> y	<input type="text"/> y	<input type="text"/> y	<input type="text"/> y
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## Caregiver Consent Form (MCA)

Participant Identification Number for this trial \_\_\_\_\_

### Individualised Cognitive Stimulation Therapy (iCST) Groups for People with Dementia

Name of Researcher:.....

**Please Initial Boxes**

1. I confirm that I have read and understand the information sheet (Version X) for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care or legal rights of myself or my relative being affected.
3. I understand that sections of any of my relative's medical notes may be looked at by individuals involved in the trial or from regulatory authorities where it is relevant to taking part in this research.
4. I give permission for my relative's GP to be informed of our participation in the study.
5. I have been consulted regarding the participation of my relative, as required by the Mental Capacity Act, and I believe they would wish to take part / continue to take part in the study.

6. I understand that my relative and I will each participate in interviews with a member of the research team as part of this study.

**Name of Caregiver**

Date

Signature

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**Name of relative**

---

---

---

Name of Person taking consent  
(if different from the researcher)

Date

Signature

---

---

---

**Researcher**

Date

Signature

---

---

---

## Participant Consent Form

Participant Identification Number for this trial \_\_\_\_\_

### Individualised Cognitive Stimulation Therapy (iCST) for People with Dementia

Name of Researcher:.....

**Please Initial Boxes**

1. I confirm that I have read and understand the information sheet (Version X) for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand that sections of any of my medical notes may be looked at by individuals involved in the trial or from regulatory authorities where it is relevant to my taking part in this research. I give my permission for these individuals to have access to my Records.
4. I give permission for my GP to be informed of my participation in the study.
5. I understand that all information given by me or about me will be treated as confidential by the research team.

6. I understand that my carer and I will each participate in interviews with a member of the research team as part of this study.

7. I agree to take part in the above study.

**Name of Participant**

Date

Signature

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Name of Person taking consent  
(if different from the researcher)

Date

Signature

---

---

---

**Researcher**

Date

Signature

---

---

---

**Name of Carer**

Date

Signature

---

---

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