

**The development and evaluation of a
Maintenance Cognitive Stimulation
Therapy (CST) programme for
people with dementia**

Elisa Aguirre

University College London (UCL)

Mental Health Sciences Unit

Faculty of Brain Sciences

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Declaration

I, Elisa Aguirre, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Date

Elisa Aguirre

Abstract

Background: Cognitive Stimulation Therapy (CST) is a cognitive-based approach for dementia that has been shown to be cost effective and beneficial for cognition and quality of life. However future evidence is needed in relation to the length of the programme required and the effects of CST over an extended period.

Aim: To develop and evaluate a 24-week programme of MCST, following the Medical Research Council (MRC) framework for the development and evaluation of complex interventions.

Methods: A Cochrane Review was conducted in order to consolidate the evidence of cognitive stimulation for dementia and the results were used in the development of the programme, including a Delphi process with a consensus conference and focus groups with service users. A multicentre randomised controlled trial followed, including 18 centres and recruiting 272 people with mild to moderate dementia who received CST initially and were randomised afterwards to receive 24 weeks of either MCST or treatment as usual.

Results: The intention to treat analysis showed that the MCST programme significantly improved quality of life of people with dementia at three and six months follow up, and activities of daily living at three month follow up. A sub analysis of people on acetyl cholinesterase inhibitors, showed that the effects of the long-term intervention were additive to the medication effect.

Conclusion: This study provides good evidence for the long-term quality of life benefits of the CST maintenance programme for people with dementia.

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I am grateful to all the participants, staff, managers and family caregivers from all the residential and community centres from Essex, London and Bedfordshire who took part in this study and without whom, this project wouldn't have been possible. I would also like to thank the National Institute for Health Research for funding the SHIELD programme and awarding the grant to Prof. Martin Orrell.

Finally, I would like to thank my beloved family and friends, specially my husband who has been invaluable in his encouragement, love and belief in me and my mum, although distant, has always encouraged me to follow my dreams and without whom I wouldn't be who I am.

Statement of contribution

The research study presented in this thesis as specified in acknowledgements, has been undertaken as part of a large research study called “Support at Home, Interventions to Enhance Life in Dementia (SHIELD) programme” awarded to Prof. Martin Orrell and funded by the NIHR Programme Grants for Applied Research funding scheme. This research programme aimed to reduce disability, improve health outcomes and enhance quality of life for people with dementia and their carers and comprised a group of three psychosocial interventions, including MCST, for which I was the research lead, implemented the design and overall organisation of the trial under close supervision from Prof. Martin Orrell and Dr. Juanita Hoe.

In relation to my contribution to Chapter 3, I was the second main reviewer for the Cochrane review of cognitive stimulation that was lead by Prof. Bob Woods. I searched for the trials - obtaining copies of the reports and contacting authors when needed, entered the data in REVMAN, did data analysis and contributed to the interpretation of findings. I drafted the first version of the co-published version of the review paper for Ageing Research Reviews being first author.

I developed the survey that was used for the pilot CST implementation into practice study (Chapter 4), collected the data, entered the data in SPSS, analysed it and contributed to the write-up of the paper making a significant contribution to the background and theory.

In relation to my contribution to chapters 5 and 6 that describe the development of the MCST programme, I wrote the first draft of the full research protocol for the first phase development of the intervention and trial (predictors of successfulness of CST) including the hypotheses, design and analysis of the data from the different phases: Delphi Consensus Conference, focus groups and predictors of success and drafted and lead the research papers and MCST programme manual that were developed from it. I drafted the research papers published from it, which led to my position as first author.

I also wrote the first full draft of the methodology for the evaluation of the programme (Chapter 7), following on from the grant application specifications, and drafted the research paper which led to my position as first author on the methodological paper published on Trials.

I was employed as a member of the SHIELD research team, coordinating and leading the MCST programme, for which I recruited all the 18 centres, ran half of the CST and MCST groups and recruited and assessed approximately over a third of the study participants. In addition, I provided the overall management of the recruitment timetable, provided advice to the other Researchers in the team on administrating the instruments and delivery of the intervention and coordinated the centres, providing them with advice and support when needed under close supervision by the PI (Prof. Martin Orrell) and SHIELD programme coordinator (Dr. Juanita Hoe).

I contributed and collaborated to the analysis of the RCT main analysis that was led by NWOORTH statisticians in particular Dr. Zoe Hoare.

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Glossary and abbreviations

AChEI	Acetyl cholinesterase inhibitor
AD	Alzheimer disease
ADAS-Cog	Alzheimer's disease Assessment Scale – cognitive subscale
ADCS-ADL	Alzheimer's Disease Co-operative Study – Activities of Daily Living Inventory
ADI	Alzheimer's disease International
ADL	Activities of daily living
ADQ	Approaches to dementia questionnaire
ANCOVA	Analysis of covariance
APA	American Psychiatric Association
AS	Aimee Spector
ASt	Amy Streater
BPSD	Behavioural and psychological symptoms of dementia
Blo	Baseline zero
BL1	Baseline 1
BLTSI	Brief Learning Transfer System Inventory
BPS	Biopsychosocial
BW	Bob Woods
CDR	Clinical Dementia Rating
CI	Confidence interval
CR	Cognitive Rehabilitation
CMHT	Community Mental Health Team
CONSORT	Consolidated Standards of reporting Trials
CST	Cognitive Stimulation Therapy
DEMQOL	Measure of health related quality of life for people with dementia

DSM-IV	Diagnosis and Statistical Manual of Mental disorders
DOH	Department of Health
EA	Elisa Aguirre
FC	Family caregiver
FG	Focus Group
FU1	Follow up 1
FU2	Follow up 2
GP	General Practitioner
HD	Helen Donovan
HTA	Health Technology Assessment
IADL	Instrumental activities of daily living
ICC	Intraclass correlation
ISRCTN	International Standard Randomised Controlled Trial Number
LTSI	Learning Transfer System Inventory
JH	Juanita Hoe
JS	Job Satisfaction
MCST	Maintenance Cognitive Stimulation Therapy
MMSE	Mini Mental State Examination
MO	Martin Orrell
MRC	Medical Research Council
NELFT	North East London NHS Foundation Trust
NHS	National Health Service
NICE	National Institute of Clinical Excellence
NISW	National Institute of Social Workers Noticeable Problems checklist
NSF	National Service Framework
n	Number

NPI	Neuropsychiatric Inventory
NWORTH	North Wales Organisation for Randomised Trials in Health
p	Level of significance
PWD	People with dementia
QoL	Quality of life
QoL-AD	Quality of Life - Alzheimer Disease
RAID	Rating of Anxiety in Dementia
RCT	Randomised controlled trial
REC	Research Ethics Committee
RO	Reality Orientation
RT	Reminiscence Therapy
R&D	Research and Development
SAE	Serious Adverse event
SC	Staff caregiver
S.D.	Standard deviation
SHIELD	Support at Home- Interventions to Enhance Life in Dementia
SMD	Standardised mean difference
SPSS	Statistical Package for the Social Sciences
TAU	Treatment as usual
UCL	University College London
UK	United Kingdom
UKCRN	United Kingdom Clinical Trials Collaboration
WHO	World Health Organisation

Ethical approval

The study was approved by the Barking & Havering Local Research Ethics Committee, ethical approval reference number: 08/H0702/68 in October 2008 (Appendix 2.1).

Trial registration

The study was registered with the North East London Foundation Trust (NELFT) Research & Development Department (Appendix 2.2), Hertfordshire NHS Mental Health Foundation Trust REC (Appendix 2.3) East London Mental Health NHS Foundation Trust Research & Development Department (Appendix 2.4), and Camden and Islington NHS Foundation Trust as a Participant Identification Centre site (Appendix 2.5).

The randomised controlled trial was registered with the International Standard Randomised Controlled Trial Number (ISRCTN) register and assigned the following unique trial identification number: ISRCTN 26286067.

CHAPTER 1

Introduction

1.1 Dementia

1.1.1 Ageing and the epidemiology of dementia

Alzheimer's disease International (ADI) estimated in the World Alzheimer's Report 2009 that around the world, 36 million people live with dementia. They further predicted a doubling of this number every 20 years. That is, by 2030 it will reach 66 million, and by 2050, 115 million. In 2007 Knapp et al.'s Dementia UK Report estimated that around 1.1% of the entire UK population (almost 700,000 people) were living with dementia. The methodology used to calculate this estimate was an Expert Delphi Consensus – a team of experts that reviewing the evidence base systematically and reaching a consensus. The team included ten leading European and UK experts. They forecast that by 2021 this number would increase to over 940,000 and by 2051 to 1.7 million, increasing by 38% in the coming fifteen years (Figure 1-1).

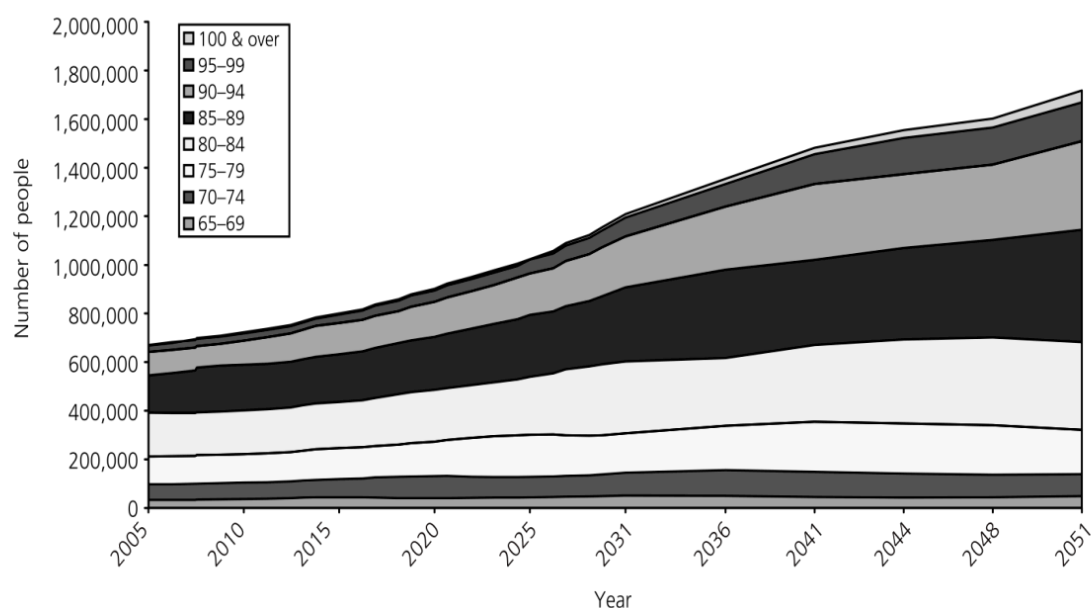


Figure 1-1. Projected number of people with late onset dementia by age group (UK)
Source: Dementia UK report (Knapp et al., 2007)

Dementia has long been linked with ageing (Yip et al., 2006) and the population prevalence of dementia (Knapp et al., 2007) (Figure 1-2) rises with age, such that almost a quarter of people aged 85 or over suffer from dementia. Due to demographic changes and the increased prevalence of dementia with age, it will become one of the primary health and social problems in the future.

Age (years)	F (%)	M (%)	Total (%)
65–69	1.0	1.5	1.3
70–74	2.4	3.1	2.9
75–79	6.5	5.1	5.9
80–84	13.3	10.2	12.2
85–89	22.2	16.7	20.3
90–94	29.6	27.5	28.6
95+	34.4	30.0	32.5

Figure 1-2. Estimation of the population prevalence of late onset dementia
Source: Dementia UK report (Knapp et al., 2007) - F: (females) M: (males)

1.1.2 Definition and types of dementia

DSM-IV (American Psychiatric Association, 1994), defines the state of dementia as “the development of multiple cognitive deficits manifested by both memory impairment and one (or more) of the following cognitive disturbances: aphasia, apraxia, agnosia, and disturbance in executive functioning”. These deficiencies in cognition result in substantial impairment in occupational or social functioning, representing a major decline from a preceding level (pp.275). A good definition that fits well with this thesis is that of Alexander Kurz in the Alzheimer’s Europe Report 2002, where we are reminded by the author that dementia is a syndrome instead of a disease – a syndrome that can be the result of various diseases.

Alzheimer’s disease (AD) is dementia’s most common form, comprising around 62% of UK’s total population having dementia (Knapp et al., 2007). AD presents a cortical type of brain damage with a gradual onset, characterized by a progressive cognitive decline (American Psychiatric Association, 2000). Vascular dementia is the second most common type, accounting for 17% of UK’s population with dementia (Knapp et al., 2007). It is caused by the occurrence of cerebrovascular disease and its clinical presentation is often very similar to AD. A common presentation is vascular dementia and AD together, often known as Mixed Type Dementia, 10% of the cases in the UK (Knapp et al., 2007). Another type of dementia is Lewy Body dementia, associated with the presence of cortical Lewy Bodies and characterized by fluctuating cognitive symptoms, recurring visual hallucinations, and Parkinsonism, which represents 4% of the cases presented in the UK (Knapp et al., 2007). Less common types of

degenerative dementia include Frontotemporal dementia accounting for 7% of the cases of dementia in the UK (Knapp et al., 2007).

1.1.3 Symptoms of dementia

Cognitive symptoms

The most common symptom that characterise dementia is memory impairment. It is common that the person living with dementia presents losses in episodic memory (autobiographical), visuospatial memory (pictures or faces) and semantic memory (knowledge about the world, meanings and facts)(Thomas and O'Brien, 2002). Alongside memory impairment the following cognitive symptoms might also present in parallel:

- Aphasia, defined as language impairment. In the early stages this presents as difficulties in naming objects (nominal aphasia) and as dementia develops to middle stages, problems in understanding and expression of language can occur.
- Apraxia, defined as the inability to execute learned or known actions. A variety of dyspraxias might lead to functional difficulties, for example dressing dyspraxia (difficulty to dress correctly) and constructional dyspraxia (problems to reproduce a two or three dimensional drawing) (Burns, Downs and Kammers, 2003).
- Agnosia defined as inability to recognise or associate meaning to a sensory perception in the absence of problems in the sensory system. In the early stages of dementia visual agnosia (inability to recognize objects) is common whereas prosopagnosia (inability to recognize familiar faces, sometimes

even including their own) may occur during the later stages (Burns, Downs and Kammers, 2003; Langlois and Borson, 2008). Disturbances in problem-solving, judgment, planning and abstraction can also be present (executive dysfunction).

Other symptoms include dysgraphia (difficulty to write), dyslexia (difficulty to read) and acalculia (inability to do arithmetical calculations) (Burns, Downs and Kammers, 2003).

Non-cognitive symptoms

These symptoms are common in people with dementia (Burns et al. 1990; Holroyd 2000) and these include problems in “Activities of Daily Living” (ADL) and “Behavioural and Psychological Symptoms of Dementia” (BPSD). BPSD encompasses a group of non-cognitive behaviours and symptoms that people with dementia display (Lawlor 2002). BPSD occurs at some point in up to 90% of people with AD, although there is a marked inter-individual variability (Frisoni et al., 1999; Levy et al., 1996). BPSD are now proposed as a major component of the dementia syndrome and as clinically important as disorders of cognition (Finkel et al., 1996). BPSD has sometimes been described as challenging behaviours (eg wandering, sexually inappropriate behaviours, agitation) and psychological symptoms (depression, delusions, anxiety) (Finkel et al, 1996).

Changes in functional abilities include a progressive loss of abilities in activities of daily living. All patients suffering from AD display functional impairment, initially appearing as difficulties in “Instrumental Activities of Daily Living”

(IADL) activities such as taking medications and using the telephone. With a progression in the disease, changes in basic “Activities of Daily Living” (ADLs), such as dressing and feeding become evident (Gauthier et al., 1990). Physical symptoms such as epileptic seizures, difficulties swallowing, and gait disorder can also present as the dementia progresses to later stages. Dementia care management must therefore aim at maintaining cognition but also maintaining the management of ADLs and physical health for as long as possible (Woods et al., 2006).

1.1.4 Impact of dementia

Dementia, as described above, is one of the most prevalent geriatric diseases and a major public health problem, which not only affects the person with dementia, but also has an impact on relatives and society. According to the latest UK Dementia Report (2007), one of the biggest causes for disability in later life is dementia, contributing to 11.2% of 60+ people’s total years lived with disability, more than cardiovascular disease (5%), stroke (9.5%), and all forms of cancer (2.4%). Dementia-induced disability was accorded a more weight than that for nearly any other condition in a wide consensus held for the “World Health Organization’s Global Burden of Disease” report (2003). It also impacts the capacity for independent living disproportionately with data suggesting that loss of independence in two thirds of all elderly people is caused by dementia (Qiu et al., 2007). As a consequence, a key policy issue across the world including Europe and the UK is to meet the multiple needs of those who have dementia as well as their loved ones so the health and social care systems’ role is essential.

For each of the different groups of symptoms described above, the person with dementia needs support. Advice and orientation; care, supervision and support in daily life is needed. The care of people with dementia is a big challenge requiring the total physical and psychological energy of the formal and or informal caregiver. Dementia UK Report (Knapp et al., 2007) cites the services' range supplied for dementia-inflicted people is restricted and requires significant work.

The cost of Alzheimer's disease has been calculated as approximately between £7 and £15 billion every year (Comas-Herrera, 2007) greater than cancer, stroke and heart disease put together. The net cost of dementia in the UK was estimated to be £17 billion, or £25,472 on average for every person having late-onset dementia (Knapp et al., 2007).

Figure 1-3. *Sources of costs. Source: Dementia UK report (Knapp et al., 2007)*

The financial cost and facts and figures regarding dementia can be worked out, but the psychological and emotional effect on dementia-infected people and their loved ones, is much harder to measure. The results from a systematic review evaluating the caregiver burden (Etters et al., 2008) showed that caregivers to dementia patients gain negative impacts on their health and they are placed into nursing homes earlier. The review also indicated that the factors influencing the caregiving experience's impact were relationship to the patient, gender, personal characteristics and culture. 80% or more of AD caregivers have to bear with high stress levels and nearly 40% report depression (Alzheimer's Association, 2006).

Caregiver burden includes suffering ailments such as illness, depression and decreased quality of life (Schulz, Shear, Boerner, Gitlin & Zhang, 2006) and resultant outcomes for patients like being placed into nursing homes earlier (Gaugler, Kane, Kane, & Newcomer, 2005; Yaffe et al., 2002).

1.2 Psychosocial interventions for dementia

1.2.1 Interventions for dementia and the role of psychosocial approaches

In the last 40 years a variety of interventions for dementia have emerged, and research has been focusing on development and evaluation of these interventions ranging from pharmacological interventions such as acetylcholinesterase inhibitors (AChEIs) to psychosocial intervention such as cognitive based interventions. Pharmacological interventions for cognitive decline in dementia comprise AChEI medication and memantine (ADI report 2011). A recent review of the efficacy of these interventions (Prince et al., 2011) found that a positive effect of using AChEIs was reported by five Cochrane reviews for patients having a mild to moderate intensity Alzheimer's disease in comparison with placebo groups, and formemantine for the moderate to severe group. The report revealed possessing significant evidence supporting the AChEI's efficacy in dementia's early stage (Prince et al., 2011). Moreover, the 2011 World Alzheimer's Report (Prince 2011) concluded that "Acetylcholinesterase inhibitors may enhance cognitive function in people with mild Alzheimer's disease, and this intervention should therefore be routinely offered." However, although the important role that drug treatments for dementia have received in the UK, current NICE guidelines only recommends

their use for managing cognitive symptoms in mild to moderate AD (NICE, 2006). They also impact the illness in a limited manner, and lack suitability for patients universally, costing around £1000 per year (Kaduszkiewicz et al., 2005).

Although pharmacological interventions have been granted most attention, it is increasingly recognized that psychosocial interventions' value may be comparable (Knapp et al. 2006), and may be preferable, for example, where medication may have intolerable side-effects (McShane et al. 1997), as they are as non-toxic, safe and unlikely to require medical supervision (Orrell and Woods 1996). In the UK there is recognition that psychosocial interventions for older people should be more widely available, and the Older People's (Department of Health, 2001) "National Service Framework" (NSF) states that 'treatment for dementia always involves using non-pharmacological management strategies such as mental stimulation'. Although these treatments have been used for close on fifty years now, and are used widely internationally as well as in the UK, Orrell and Woods (1996), noted they had rarely been adequately evaluated, standardised, or systematically implemented. In the last decade, a few systematic reviews were conducted in order to evaluate its effectiveness (Livingston, 2005, Woods, 2003, Brodaty, 2003, Olazaran, 2010, Prince, 2011).

1.2.2 Cognitive focused interventions for dementia

Reality Orientation

Taulbee developed the Reality Orientation (RO) in the '60s in response to disorientated older hospitalized patients in the USA, and was recognized as the

typical approach to cognitive stimulation (Taulbee 1966). Sessions (once or twice a week for 30 mins) included basic personal and current information and various materials, like word-letter games, individual calendars, large-piece puzzles and building blocks. One characteristic of this programme was the RO board which each session made use of. It enlisted the unit's name, location, the date and day, weather and current events.

Brook et al. (1975) reported the first controlled RO evaluation in the UK by and found positive changes in the cognitive and social functioning of patients who attended the programme for 30 minutes every day, 5 days a week for 4 months. A number of controlled studies followed on from this one, with outcomes measured typically by assessing orientation and other cognitive functioning's aspects and independent functioning's level. One Cochrane review set to examine specifically the effectiveness of Reality Orientation (Spector et al. 2000a, 2000b) included six randomised controlled trials (RCTs) with a total of 125 participants and concluded that some evidence was suggestive of RO's benefits for dementia patients on both behaviour and cognition. The idea of "24 hour RO", other than that of "classroom RO" has also been introduced. It involved the staff providing the person with current information, outside of the RO group's formal setting, while employing environmental features as an orientation assistance. The 24 hour RO's evaluation (Williams et al., 1987) revealed improvements in independent functioning, cognition, and orientation compared to the imposition of a control group on another ward. Element of sign posting's evidence on orientation around a care unit (e.g. McGilton et al., 2003, Hanley et al., 1981,) showed to be positive. However, other than a few countries

(notably Italy), RO's practice or research has been very limited since the 1990s, even attracting some criticism when it was being applied in an inflexible, mechanical, confrontational, or insensitive manner (Burton 1982; Dietch 1989; Powell-Proctor 1982). Concerns regarding the clinical significance of any improvements in cognition were raised with it being suggested that the negative impacts on the patients' personal well-being outweighed any small improvements in cognition (APA 1997).

The literature regarding cognitive stimulation and what is described as RO often overlaps distinctively, since similar features are often described in both programmes. The difference is that while RO lays greater emphasis on information on re-learning orientation, cognitive stimulation focuses on the processing of implicit information. Apart from cognitive stimulation, in recent years, growing interest has been expressed in the application of cognitive training's various forms, and in teaching dementia patients to employ memory aids and strategies to their assistance. Two other important types of cognition-based dementia approaches are cognitive rehabilitation and cognitive training.

Cognitive stimulation

Because of the overlap in the use of the terms 'training', 'stimulation' and 'rehabilitation' when referring to different cognitive based interventions, cognitive stimulation has been defined as involvement in a variety of discussions and activities (usually in a group) which aims at general enhancement in social and cognitive functioning (Woods and Claire 2004). 'Cognitive stimulation' is a general view that believes that a engaging in less cognitive activity makes cognitive decline faster, in both dementia as well as

normal ageing (Small et al., 2002; Breuil et al., 1994) and appeared partly in order to make use of RO's positive aspects, while making sure of its respectful and sensitive implementation (Spector et al., 2001; Woods et al., 2002).

The 2011 World Alzheimer Report in a systematic review of psychosocial approaches for dementia care, concluded that cognitive benefits' "strongest evidence by far" was cognitive stimulation for of psychosocial interventions for dementia (Prince et al., 2011). Around one-third of UK's older people's community mental health services employ cognitive stimulation therapy in groups and the NICE UK dementia guidelines (2006) suggested that all mild/moderate category dementia patients should be "given the opportunity to participate in a structured group cognitive stimulation programme".

Cognitive training

Cognitive training has been defined as a practice guided on a collection of standard tasks whose purpose is to show certain cognitive functions within a spectrum of difficulty levels belonging to the set of tasks, in accordance with the level of ability of the individual. This practice may be conducted in group or individual sessions, with either computerised or pencil/paper exercises (Clare and Woods 2004). Evidence for the effectiveness of this intervention to improve cognition in dementia is weak. A Cochrane review (Clare and Woods 2004) concluded there is a limited availability of substantial evidence and cognitive training's benefits were indicated minimally. Moreover the World Alzheimer's Report (Prince et al., 2011) concluded that structured cognitive training was ineffective.

Cognitive rehabilitation

Cognitive rehabilitation (CR) has been defined as an approach where an individual's personal goals are recognized, and the therapist devises techniques to work with the patient and their family in order to achieve these. This approach emphasizes on the improvement of everyday life performance, instead of testing cognition, thereby focusing and utilizing the patient's personal strengths while developing ways of impairment compensation (Clare and Woods 2004).

In relation to the effectiveness for early-stage dementia patients of such interventions for cognitive rehabilitation, the Cochrane Review in an attempt to evaluate its effectiveness (Clare and Woods 2004) couldn't draw any conclusions, due to the lack of the area's available RCTs. Following the review, a single blind RCT of CR in AD's initial stages (Clare, 2010) found that significant improvements were produced by CR in satisfaction and goal performance ratings. Based on study results, the authors concluded that CR assists early-stage AD patients as well as their loved ones in handling the consequences of the condition.

Reminiscence therapy

A final and more generic approach, aimed at increasing cognition in people with dementia includes (RT) or Reminiscence Therapy. The practice discusses past activities, experiences and events, involving another individual or group of people (Woods et al., 2005). It is intended that RT can increase level of communication and autobiographical memory in people with dementia by developing links with the person's cognitive strengths as they recall events from

the past that are accessible to them (Woods et al., 2005). Evidence from a Cochrane review examining the effectiveness of RT for dementia (Woods et al., 20005), found inconclusive evidence of its efficacy. However, viewing the included four studies' limitations, (very small samples, different types of reminiscence work, relatively low quality examined) it was concluded by the review that the field was in desperate need for more quality research. Presently a pragmatic, randomised, eight-centre trial of usual treatment versus joint maintenance and reminiscence is being undertaken (Woods et al., 2009).

1.3 Cognitive Stimulation Therapy (CST)

1.3.1 Definition

Cognitive Stimulation Therapy (CST) (Spector, 2003) is the version of cognitive stimulation with the best-evidenced and best-defined intervention. This brief, evidence-based group intervention was developed using a systematic approach based on theory and evidence from a Cochrane review of Reality Orientation (RO) (Spector et al., 2000). The development of the therapy followed the "Medical Research Council" (MRC) 2008 framework for complex interventions' development and, as phase II, the programme was piloted (Spector et al., 2001) and further modified before the extensive evaluation through a large randomised controlled trial (RCT) (Spector et al., 2003). For the evaluation, 201 dementia patients were gathered in a single multi-centre blind RCT. Recruitment took place in residential homes in 23-day centres in greater London. The CST group was shown in the results to have significantly improved on the major outcome measures (cognition and quality of life) (Figure 1-4). CST

had a favourable comparison in NNT (Numbers Needed to Treat) terms with cholinesterase inhibitors for Alzheimer's disease (Spector et al., 2003). The economic analysis also showed that CST was likely to be cost- effective (Knapp et al., 2006). Following its evaluation, a manual and a training DVD have been developed (Spector et al., 2006) and it is now widely used across the UK as well as a number of other countries.

Efficacy measure ¹	Change from baseline		Group difference		ANCOVA: between-group difference	ANCOVA: other significant differences ¹
	Treatment Mean (s.d.)	Control Mean (s.d.)	Mean (s.e.)	95% CI		
MMSE	+0.9 (3.5)	−0.4 (3.5)	+1.14 (0.09)	0.57 to 2.27	$F=4.14, P=0.044$	None
ADAS–Cog	+1.9 (6.2) ³	−0.3 (5.5) ⁴	+2.37 (0.87)	0.64 to 4.09	$F=6.18, P=0.014$	C: $P=0.006$
QoL–AD	+1.3 (5.1)	−0.8 (5.6)	+1.64 (0.78)	0.09 to 3.18	$F=4.95, P=0.028$	G: $P=0.010$
Holden	+0.2 (6.1)	−3.2 (6.3)	+2.3 (0.93)	−0.45 to 4.15	$F=2.92, P=0.090$	C: $P=0.009$
CAPE–BRS	−0.2 (6.1)	−0.7 (5.5)	+0.40 (0.65)	−0.9 to 1.69	$F=0.58, P=0.449$	G: $P=0.001$
RAID	−0.5 (10.2)	−0.7 (10.3)	−1.30 (1.10)	−3.48 to 0.87	$P=0.200$	C: $P<0.001$
Cornell	0 (6.2)	−0.5 (7.0)	+0.12 (0.72)	−1.56 to 1.31	$P=0.648$	C: $P<0.001$

ADAS–Cog, Alzheimer's Disease Assessment Scale – Cognition; ANCOVA, analysis of covariance; CAPE–BRS, Clifton Assessment Procedures for the Elderly – Behaviour Rating Scale; Cornell, Cornell Scale for Depression in Dementia; Holden, Holden Communication Scale; QoL–AD, Quality of Life – Alzheimer's Disease; RAID, Rating Anxiety in Dementia.

1. Primary outcome measure: MMSE; secondary outcome measures: ADAS–Cog and QoL–AD.
2. C, difference between centres; G, difference between genders.
3. Zero or more points improvement: $n=58$ (50%); 4 or more points improvement: $n=34$ (30%).
4. Zero or more points improvement: $n=32$ (37%); 4 or more points improvement: $n=11$ (13%).

Figure 1-4. CST trial results;(Reported from Spector et al., 2003)

1.3.2 CST programme

The CST programme includes 14 sessions, each lasting for 45 minutes, which usually run twice a week for seven weeks. Each session has two facilitators, and the same group of five to eight participants, who ideally should be at the same level of dementia so their activities can be designed accordingly. Each CST session initiates with a light activity to warm up, designed with the purpose of increasing alertness and encouraging group interaction. Then the participants complete a 'reality orientation board' (listing the place name and location, the name of the group, the day, date, weather and current events), whose aim is the orientation of all group members with the place and time. This is followed by a main theme activity – consisting of stimulation exercises, grouped by theme (e.g. food, sounds, childhood, famous faces, physical exercises, number games and word game).

The main theme of every CST session contains different types of exercises, focused on concentration, memory, executive and linguistic abilities. Therefore CST's approach seeks to incorporate all the various aspects of cognitive activity in a framework centred on individuals (Aguirre et al., 2010). At the close of a session, participants are thanked for their contributions and participation; ideas of a session are summed up, and the encouragement is given to feedback. A theme song is also given to the group, which is chosen when giving the group its name at the course's outset. This song is sung at each session's opening and closing. The start time of the next session is reminded to the group and provided with its outline before they depart.

1.3.3 CST Principles

Eighteen guiding principles of CST (Table 1.1) have been developed by the CST pioneers. People are always encouraged to develop new associations, thoughts and ideas. The patients should be orientated implicitly and sensitively. The aim of the programme is the creation of an environment in which people learn, have fun and they increase their relationships' and abilities' strength among the group members, hence maintaining their cognitive and social skills optimally. CST was constructed in order to stimulate people implicitly rather than explicitly, thereby reducing the feeling of anxiety that may be caused by being put under the limelight.

The approach rests on asking people their opinions rather than searching for facts. This process often enables participants to recall names later without the need for explicit questions. CST focuses on a variety of individually tailored, multisensory stimulation exercises, e.g. matching common sounds to pictures in the 'Sounds' session. People are involved in decision- making and encouraged to interact together, rather than just with the group facilitator. The purpose of reminiscence is orientation in the programme, e.g. by comparing old and new coins, objects and prices, and the discussion of current affairs (e.g. the war in Afghanistan in comparison with memories of the Second World War).

Table 1-1. CST Guiding principles

Key principles	
1	To mentally stimulate, in order to get people's minds active and engaged
2	To continually encourage new ideas, thoughts and associations, rather than just recall previously learned information
3	To use orientation, but sensitively and implicitly
4	To based discussions in opinions, rather than facts
5	To use reminiscence, and as an aid to the here and now
6	To provide triggers and prompts to aid recall and concentration
7	To provide continuity and consistency between sessions, with a group name, song and same structure in every session
8	To use implicit rather than explicit learning
9	To stimulate language skills
10	To stimulate executive functioning
11	To be person-centred, to see the person first and foremost, rather than focusing on the dementia and the associated impairments
12	To show respect for each participant in the group acknowledging personal, cultural and religious background
13	To encourage participant to contribute to the group and get involve.
14	To include everyone in the group: encourage an atmosphere where everyone's contribution is valued and respected, and diversity of views is welcomed.
15	To offer choices, alternative activities and approaches to group members
16	To provide a learning atmosphere which is fun and enjoyable, with a group of friends
17	To maximise participants potential and not to assume participants cannot do things
18	To assist members to get to know each other better, and can strengthen relationships

1.3.4 CST theory -how it might work for people with dementia?

The biopsychosocial model of dementia proposed by Spector and Orrell (2010) provides a framework for understanding how CST might work. In the model, the trajectory of dementia is presented as a process in where psychosocial and biological factors interact. For each of these two domains, the model includes a combination of fixed factors (not amenable to change) and tractable factors (amenable to change) (Figure 1-5). This section focuses on three psychosocial tractable factors that according to the model, can be influenced and potentially

improved with CST: mental stimulation, social and personal psychology and environment.

Mental stimulation

Mental stimulation

Dementia is characterised by declining cognition but nevertheless, people with dementia often have reserve capacity for cognitive information processing (Katzman et al., 1988, 1993). Implicit memory in people with Alzheimer's is kept intact longer than memory of episodes, and makes response to regular stimulation also (Fleischman et al., 2005). Beneficial effects on cognition may not only be based on implicit memory, but may enhance facilitation of residual explicit memory (Hunkin et al., 1998; Tailby and Haslam, 2003). Offering people with dementia a collection of mental activities that takes into account the remainder of reserving capacity might make allowance for their maintenance for a specific time-period, an enhancement in cognitive performance. CST therefore, provides global stimulation of cognitive abilities: memory, concentration, language, executive functioning, spatio-temporal orientation and visuo-constructive abilities and apparently has certain effects in language function promotion, probably leading to general benefits, by opinion generation and creation of new semantically oriented links via categorisation (Spector, Orrell and Woods, 2010). Strategies such as including multi-sensory stimulation, semantic association, categorical classification and mental imagery aim at maximising semantic and episodic memory functions as well as a consolidation of implicit memory.

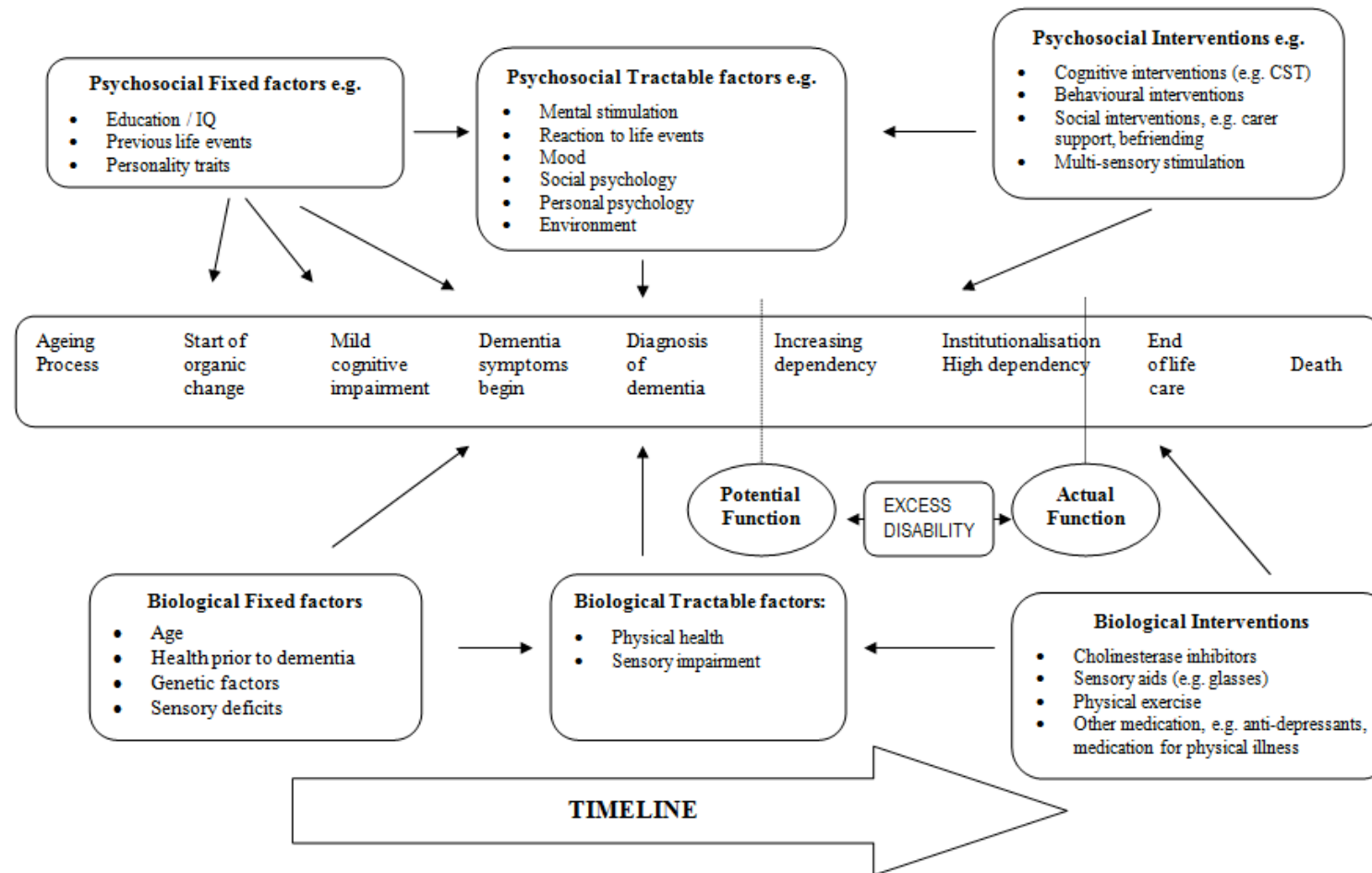


Figure 1-5. Biopsychosocial model of dementia (Spector and Orrell 2010).

An important element in CST is stimulation of orientation and each session includes an orientation board with information about the day, time, place and current news, so participants can discuss current information and news. Another element of the programme is the use of physical activity in the sessions, including 10 minutes of warm up activity at the beginning of each session, and a session theme called 'physical games'. This constitutes an important element of the intervention as some studies have shown that the onset of dementia can be delayed and cognitive decline slowed down by engaging in physical exercise in healthy older adults to end in the prevention of declining cognitive ability (Forbes et al., 2008).

Social psychology

Cognitive and affective functions influence the social roles of people with dementia, such as, maintenance of social relationships, family activities and participation in social activities. CST also seeks to target the intervention on the patient's personal wellbeing and QoL or "Quality of Life". Cognitive based approaches in dementia care have been criticised suggesting that cognitive gains from the intervention may be attained at the cost of adverse effects and an overall reduction in wellbeing and (American Psychiatric Association, 1997). Viewing these concerns, person centred care has been included as the basis of the development of the CST programme (Spector et al., 2001). The improvements in QoL have not risen merely from general factors, such as the social interaction and group activities' enjoyment, except as far as these determinants had an impact upon change in cognition (Woods et al., 2006) and

in the Cochrane Review control groups, which offered social activities found no benefit in comparison to CST.

CST groups' participants suggested improvements in their quality of life especially regarding memory, relationships, energy, and chore management (Woods et al., 2006).

The structure of the CST activities (where 5 to 8 people are grouped together) allows participants to come across people dealing with similar circumstances. This resultantly reduces anxiety with respect to people's personal situations. Feedback from groups indicates that people with dementia prefer the CST group size compared to other activities, which involve too many people, which acts as an inhibiting factor. The basis for delivering CST as a psycho-social intervention in group form is the notion that when peoples are gathered to voice their worries, they are better able to deal with their problems than when they are on their own. The group supplies: (a) a reduction in feelings of isolation via emotional bonding; (b) a boost in self-esteem by possessing sharable information about prevailing coping strategies; and (c) an exchange of information that results in a sense of efficacy and hope (Toseland, 1997). Offering CST in a group might increase the performance of the cognitive tasks presented in sessions (such as problem-solving, decision-making, inference and idea generation), as it has been argued that groups can be conceptualized as information processors (Hinsz, Tindale, & Vollrath, 1997). Information processing in group form activities occurring at group as well as individual level which involves the sharing of solutions, preferences and ideas during discussion (Tindale & Kameda, 2003).

Personal psychology

The CST activities are adapted to the interests and abilities of the participants. Each theme contains exercises of different types including categorical classifications, old /new comparisons of objects, musical and numerical exercises created to provide richness to general cognitive stock and using implicit strategies in order to recall concepts or words. The latter is particularly important for increasing confidence due to cognitive problems and the resultant anxiousness caused by the mid-conversation forgetting of words is a risk factor for withdrawal from society (Rubin, 1982; Rubin, LeMare, & Lollis, 1990). CST uses reminiscence as an aid to orientation; this may contribute to the psychological health of people with dementia since the disease's continuous deterioration kills the ability to succeed at a range of previous activities, making past accomplishments sources of dependence for individuals to maintain a sense of competency (Kiernat, 1979). People with dementia may keep their ability of recalling and integrating the past since the disease process spares most of the remote memory (Woods, 1992).

A possible mechanism for QoL change, is that the CST approach is rooted in a base of strong values such as respecting personhood and individuality (Woods, 2001). Kitwood (1997) conceptualised, individualized dementia care as an answer to the biomedically reductionist view of dementia that reduced the identity of a person to that of an incurable disease's carrier, overlooking all individual experiences of dignity, well-being and worth (Kitwood, 1997). Kitwood described the defining characteristics of person-centred care in his influential work: acknowledging the individual as a human being capable of

experiencing relationships and life, in spite of the progressive disease; respecting and offering choices; including the person's history and past life in providing them with care; focusing on that person's abilities, rather than his capabilities that the disease had devoured (Kitwood 1997). This type of care is believed to be supportive of the individual's rights, beliefs and values; providing them with positive regard unconditionally; going into their world and finding all behaviour meaningful, despite the difficulty in its interpretation; taking each person's potential to the maximum and having shares in decision making (Kitwood 1997).

The different CST principles serve as strategies to meet and fulfill the psychological needs expressed by Kitwood (1997): Identity, attachment, comfort, inclusion, occupation and love. The approach of the CST in delivering person-centred care includes:

- 1) The person's biographical knowledge that helps facilitators to adapt the different sessions according to the individual's needs and interest. Their previous life's accounts, occupation and routines, provide cues to interpret their existing behaviour, wishes and needs.
- 2) The use of reminiscence to promote person-centredness as an aid to the here and now. It is believed to reinstate the views and experiences of patients of dementia about the world and nurture social communication by sharing memories from their life employing multiple senses' stimuli like music, scrapbooks and pictures.
- 3) A focus on opinion rather than facts. This promotes the use of validation as a means of acknowledging the individual's views about reality by validating

their personal experiences. Positive regard of such an unconditional nature must result in a boost in well being and confidence (Overshott & Burns 2006; Neal & Wright 2003). CST sessions render people free to express and get rid of any previously existing concerns and constraints to offer new sources of satisfaction and pleasure for the patient of dementia.

- 4) Person-centeredness is also about giving value to all group members and aiding them in feeling content; presenting dignity and fighting to conserve their sense of self; acknowledging everyone's way and opinions; providing a sense of togetherness in everyday life (ten minutes included before the session with refreshments for extra social interaction); supporting the group with a sense of belonging (selecting their group name and song in the first session of the programme); offering a secure environment (consistency of environment through out the programme); providing opportunities for occupation through the different proposed activities; and encouraging them to feel control and power (encouraging participant different roles within the group).

Environment

The setting for the CST groups and the consistency of environment between sessions, e.g. using the same place and session structure, provides home-like surroundings to the participants. This is believed to have positive effects on the mood and behaviour of dementia patients (Cohen-Mansfield & Werner 1998), and smaller-sized groups has shown to increase social interaction and community formation (McAllister & Silverman 1999; Moore, 1999).

1.4 Long term effects of cognitive stimulation and related interventions

1.4.1 Evidence from long-term programmes

A key area of difference between studies of cognitive stimulation, relates to the duration and frequency of the programme offered. There does not appear to be a clear relationship between dosage (length of the sessions x frequency x duration in weeks) and the effect size on cognitive function in the available studies in the literature. It is difficult to ascertain whether the frequency of sessions per week makes a difference (Woods et al., 2012). Evidence from one study that continued cognitive stimulation for two years (Requena et al., 2006) suggest that the effects on cognition and self-reported mood appeared to be sustained over this long term period of time. Other studies of longer programmes of cognitive stimulation and related interventions are in line with this finding. Zanetti et al. (1995) developed and evaluated an RO intervention that ran in 4 rounds of twenty sessions each lasting for over 8 months. Their study indicated that the long-term intervention led to increased cognition of 0.7 points in the MMSE score compared to a decline of 2.6 points in the control group. This suggests that it counteracted the inevitable decline in cognitive performance. A novel aspect of this study was the authors' expectation of an annual decline in Mini-Mental-State-Examination score of 1.8 to 4.2 points in dementia patients. Likewise, Metitieri et al. (2001) discovered that in patients who were getting long-term treatment (8 to 40 weeks) cognitive function significantly declined later. Furthermore, such patients stayed at home for a longer period than the patients at the receiving end of a shorter RO programme

(4 weeks). The conclusion from both studies was that it might be that longer RO terms' intervention successfully slowed down, at least on a temporary basis, the process of dementia. Based on the given result, a long-term CST's pilot study (maintenance CST) (Orrell et al., 2005), sessions of maintenance CST sixteen times every week after the first CST programme's initiation, discovered a notable enhancement in cognitive function of 1.9 points on MMSE for those getting on-going Maintenance CST ($p = 0.012$). The said programme made it through six months, compared to a CST only group and controls. There is a clear need for further research on maintenance cognitive stimulation, looking at its effectiveness in comparison to shorter cognitive stimulation programmes in order to examine whether lower intensity input maintains gains from an initial period of cognitive stimulation.

1.4.2 Evidence from studies with follow up data

Most studies on cognitive stimulation and related interventions (e.g. RO) have looked at the evaluation of the intervention immediately after the treatment period has been completed, regardless the length of the programme (shorter or longer) and only a few studies, have reported data in relation to whether changes were maintained after a period of follow up after the intervention had finished. Data from Gerber et al., (1991) found that participants performance at 10 week follow up was worse than prior to treatment, however, evidence from Wallis et al., (1983) and Baines et al., (1987) that had a one month follow-up, and Baldelli et al., (1993) that had a three month follow-up, showed that the significant advantage for cognitive stimulation on cognitive measures seen immediately post-treatment remained at this point. In relation to longer follow

up data, there is evidence from only one study (Chapman et al., 2004) that showed that the effects of cognitive stimulation in cognition were lost at a 10 month follow up after completing the groups.

Data from Orrell et al., (2005) suggested that at follow up, cognitive scores on the MMSE fell down to far lower than baseline-level (before CST groups), suggestive of the notion that cognitive functional benefits gained after attending the initial seven week programme, were gone sixteen weeks after CST's end. Orrell et al., (2005) also indicated that the cognitive deterioration observed in their pilot study reflects that discovered ten and four weeks after intervention in other research work (Wallis et al., 1983; Gerber et al., 1991), and suggested that a large, multicentre, randomised control trial with a larger sample size should explore these results further.

1.5 Best practice for development and the evaluation of complex interventions

In recent years, the 'evidence-based' approach has become an integral part of research and practice. This approach implies that clinical practice decisions must be based on research that clearly demonstrates the evidence of treatment effectiveness. A framework has been developed by the Medical Research Council (MRC) (Figure 1.6) for the development and evaluation of complex interventions (MRC, 2000; 2008), in order to establish clear evidence of the effectiveness of interventions that can help decision makers and budget holders to consider using those treatments. The phases that the MRC framework distinguish are (1) Phase I or development of an intervention, (2) Phase II or piloting, (3) Phase III or evaluation, (4) Phase IV or implementation (Previous

CST work (Spector et al., 1998, 2000, 2001, 2003; Orrell et al., 2005) has followed the Medical Research Council guidelines for the development and evaluation of complex interventions (MRC, 2000) including a systematic review of the literature to develop CST (Spector et al., 2000), a pilot study of the intervention (Spector et al., 2001), a randomised controlled trial (Spector et al., 2003), and a pilot evaluating the effectiveness of a maintenance CST study (Orrell et al., 2005). Although the effectiveness of cognitive stimulation is well established, little research has been done in relation to the implementation into practice of the CST programme and further research is needed both on the long term effects of a lower intensity but longer maintenance programme (MCST) but also with respect to the consequences of stopping CST after the initial seven week programme has been completed. There is also a clear need for further research on maintenance cognitive stimulation, looking at its effectiveness in comparison to shorter cognitive stimulation programmes with or without ACHEI medication.

Following from previous CST work of Spector et al., (2000; 2001; 2003), and under the MRC framework (2000, 2008), this thesis begins with an updated systematic review of the evidence in relation to cognitive stimulation for dementia (Chapter 3) and an exploratory study evaluating the effectiveness of disseminating CST in practice (Chapter 4), results of which fed into the development (Chapter 5 and 6) and evaluation (Chapter 7 to 9) of the MCST programme, the main focus of this PhD work (Figure 1-7). The evaluation of the MCST programme included a two stage process: Stage one: before and after CST programme (Chapter 8) and stage two: MCST RCT trial (Chapter 8). The stage

one included the comparison of the data before and after attending the CST programme, a comparison of the data with Spector et al., 2003 control group and a sub analysis of the data looking at predictors of success of CST, in order to consolidate the evidence in relation to CST and inform the development of MCST. The stage two includes the comparison of the TAU and treatment group (MCST) and a sub analysis of the data taking into account ACHEI use in order to understand the effectiveness of the developed MCST programme. Secondary analyses in Chapter 9 include the analysis of the data taking into account the variable “quality of the centres”. The PhD thesis finishes with Chapter 10 discussion of the findings and results.

This presented work will be followed by a phase IV study (outside the scope of this PD thesis), evaluating its implementation in practice (Streater et al., 2012) as outlined in figure 1-7.

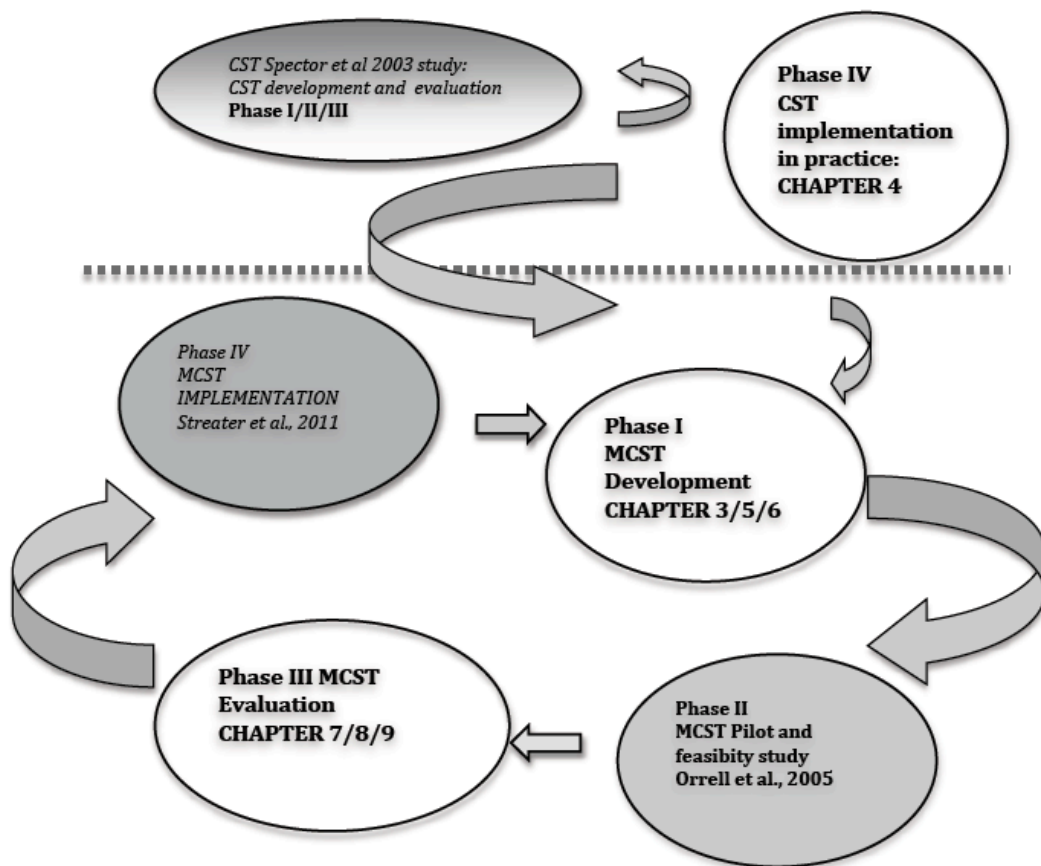


Figure 1-7. PhD thesis overview

). The purpose of each phase is briefly described below.

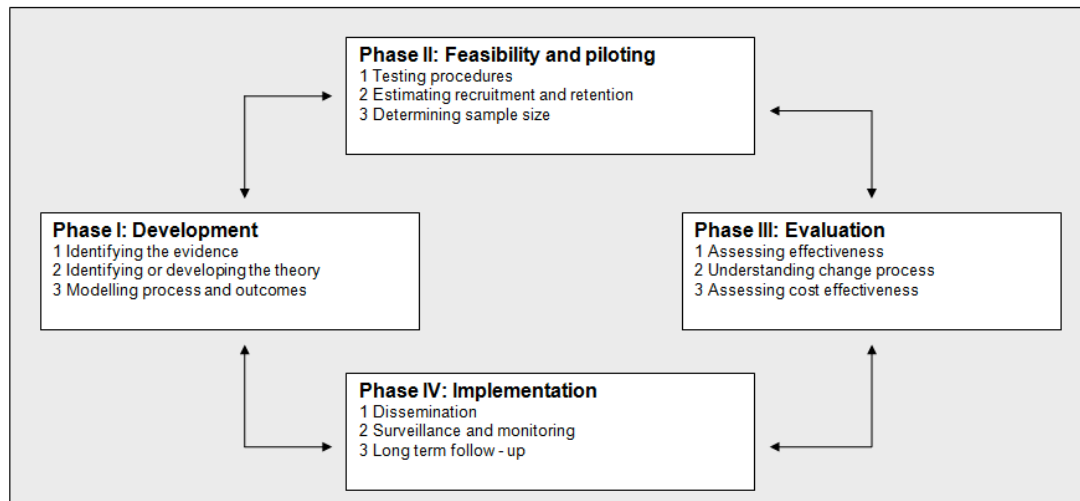


Figure 1-6. Framework for the development of complex interventions (MRC 2008)

1.5.1 Phase 1 or development of the intervention

The MRC framework recommends before undertaking a substantial evaluation of any intervention to first take the development of the intervention to the place whereby it would be reasonable to expect a worthy impact. They divided this phase into three different steps in order to help researchers when developing any intervention (MRC 2008).

- 1) Identifying the evidence base
- 2) Identifying/developing appropriate theory
- 3) Modelling process and outcomes.

1.5.2 Phase II or piloting

The framework states that the piloting stage must include procedures to test their acceptability. This step needs to include an estimate of the probable recruitment and subject retention rates, and the approximation of reasonable sizes of samples. This step will facilitate the evaluation process as problems of

acceptability, delivery of the intervention, compliance, recruitment, smaller-than-expected effect sizes and retention, often undermined trials. Piloting could be used to anticipate all of these factors (Craig et al., 2008).

1.5.3 Phase III or evaluation

The phase III of the MRC describes the variety of study designs to choose from. The recommendation is that the specific study design needs to be based on the study's certain characteristics, such as estimated size of effect and probability of selection and other prejudices. The standard recommendation for evaluation of clinical interventions is a randomised controlled trial, as it is the most effective method of bias prevention and has become the gold standard for assessing the effectiveness of these interventions (Byar et al., 1976). However, recent criticism suggests that most RCTs focus on outcomes, rather than the processes involved in implementing an intervention (Oakley et al., 2006) and recommends the use of process evaluation within trials in order to explore the implementation, receipt, and setting of an intervention and to help in the interpretation of the results.

1.5.4 Phase IV or long implementation and beyond

The framework defines this stage as “getting the findings of the study translated into routine practice or policy”. This stage includes the publication of the research results on the literature as an essential and effective part of the implementation strategy. It also includes the translation of the research results into practice, however, it has been long acknowledged that effective interventions in research studies are not equivalent to effective interventions in

practice, so this phase represents a key element of the framework, as evidence base for effective implementation remains limited (Grimshaw et al., 2004).

1.6 Summary and overview of the thesis

Previous CST work (Spector et al., 1998, 2000, 2001, 2003; Orrell et al., 2005) has followed the Medical Research Council guidelines for the development and evaluation of complex interventions (MRC, 2000) including a systematic review of the literature to develop CST (Spector et al., 2000), a pilot study of the intervention (Spector et al., 2001), a randomised controlled trial (Spector et al., 2003), and a pilot evaluating the effectiveness of a maintenance CST study (Orrell et al., 2005). Although the effectiveness of cognitive stimulation is well established, little research has been done in relation to the implementation into practice of the CST programme and further research is needed both on the long term effects of a lower intensity but longer maintenance programme (MCST) but also with respect to the consequences of stopping CST after the initial seven week programme has been completed. There is also a clear need for further research on maintenance cognitive stimulation, looking at its effectiveness in comparison to shorter cognitive stimulation programmes with or without ACHEI medication.

Following from previous CST work of Spector et al., (2000; 2001; 2003), and under the MRC framework (2000, 2008), this thesis begins with an updated systematic review of the evidence in relation to cognitive stimulation for dementia (Chapter 3) and an exploratory study evaluating the effectiveness of disseminating CST in practice (Chapter 4), results of which fed into the

development (Chapter 5 and 6) and evaluation (Chapter 7 to 9) of the MCST programme, the main focus of this PhD work (Figure 1-7). The evaluation of the MCST programme included a two stage process: Stage one: before and after CST programme (Chapter 8) and stage two: MCST RCT trial (Chapter 8). The stage one included the comparison of the data before and after attending the CST programme, a comparison of the data with Spector et al., 2003 control group and a sub analysis of the data looking at predictors of success of CST, in order to consolidate the evidence in relation to CST and inform the development of MCST. The stage two includes the comparison of the TAU and treatment group (MCST) and a sub analysis of the data taking into account ACHEI use in order to understand the effectiveness of the developed MCST programme. Secondary analyses in Chapter 9 include the analysis of the data taking into account the variable “quality of the centres”. The PhD thesis finishes with Chapter 10 discussion of the findings and results.

This presented work will be followed by a phase IV study (outside the scope of this PD thesis), evaluating its implementation in practice (Streater et al., 2012) as outlined in figure 1-7.

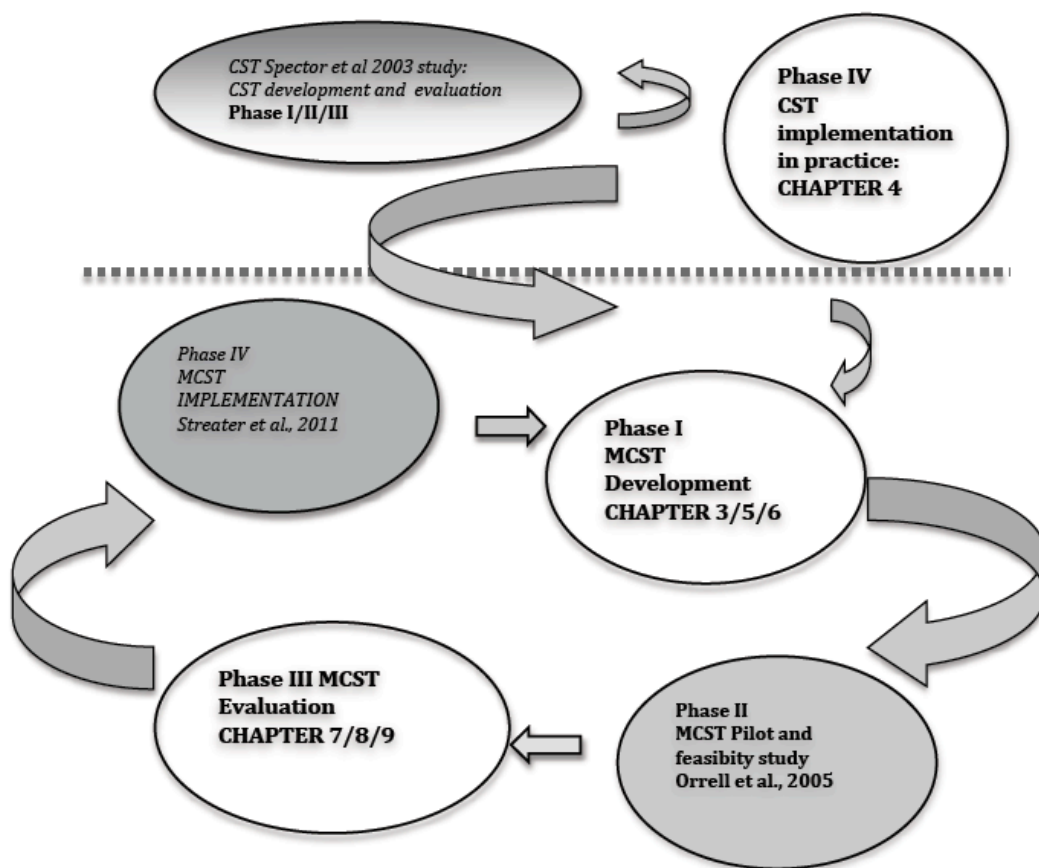


Figure 1-7. PhD thesis overview

CHAPTER 2

Aims and Hypotheses

2.1 Aims

2.1.1 General Aim

To develop and evaluate, a maintenance Cognitive Stimulation Therapy (CST) programme for dementia following the MRC framework (2008) for the development of complex interventions.

2.1.2 Specific Aims

- 1) To conduct an updated Cochrane Systematic review on the effectiveness of cognitive stimulation for dementia as part of the Phase I or development phase of the MRC framework. This should identify the best evidence in relation to cognitive stimulation programmes for dementia.
- 2) To conduct a pilot study investigating the feasibility of running CST groups after a one-day training course, as part of the Phase IV, implementation into practice study. This should help better understand the effectiveness in practice of CST.
- 3) To develop a MCST programme as part of the Phase I of the MRC framework, using the results of the systematic review, implementation into practice pilot study and a Delphi consensus process, including focus groups with service users. This will test feasibility of the MCST programme.

- 4) To conduct an RCT to determine the effectiveness and long-term effects (cognition and quality of life) of the MCST intervention versus CST alone in people with dementia as part of the phase II and phase III of the MRC framework.
- 5) To investigate based on the before and after CST data from the RCT (phase1), factors that may predict response to CST.
- 6) To evaluate the effectiveness of the maintenance programme in relation to ACHEI therapy.

2.2 Hypothesis

The null hypothesis is that the MCST programme will show no differences compared to the control group (CST only) between the two primary outcomes for people with dementia, cognition and quality of life.

CHAPTER 3

The systematic review

This chapter describes the development and results of a Cochrane review of the effectiveness of cognitive stimulation programmes for dementia. The results from this review fed the development of the MCST programme as described in point 1.6 and Chapter 5 (Figure 5.1).

This chapter is based on the published systematic review (Appendix 6.1) published as a Cochrane Review in the Cochrane Database of Systematic Reviews 2012, Issue 2. Cochrane Reviews are regularly updated as new evidence emerges and in response to comments and criticisms, and the Cochrane Database of Systematic Reviews should be consulted for the most recent version of the Review.’ Woods B, Aguirre E, Spector A, Orrell M. Cognitive stimulation to improve cognitive functioning in people with dementia. Cochrane Database of Systematic Reviews 2012, Issue 2. Art. No.: CD005562. DOI: 10.1002/14651858.CD005562.pub2.

The chapter has been accepted for co publication “Aguirre E, Woods B, Spector AE, Orrell M. “Cognitive Stimulation for dementia: a systematic review of the evidence of effectiveness of randomised controlled trials by Aging Research Reviews” (Appendix 6.2).

3.1 Aim and objectives

3.1.1 Aim

To conduct a systematic review on cognitive stimulation following the framework of the Cochrane Collaboration.

3.1.2 Objectives

- To evaluate the effectiveness and impact of cognitive stimulation interventions aimed at improving cognition for people with dementia, including any negative effects.
- To indicate the nature and quality of the evidence available on this topic.
- To assist in establishing the appropriateness of offering cognitive stimulation interventions to people with dementia and identifying the factors associated with efficacy.

3.2 Methods

3.2.1 Search Strategy

A systematic search for randomised controlled trials (RCTs) evaluating the effectiveness of cognitive stimulation programmes for dementia was conducted.

A combination of the search terms cognitive stimulation, reality orientation, memory therapy, memory groups, memory support, memory stimulation, global stimulation and cognitive psychostimulation were used to search ALOIS on 6 December 2011. The studies were identified from the following databases:

- 1) Healthcare databases: Medline, Embase, Cinahl, Psycinfo and Lilacs

- 2) Trial registers: meta Register of Controlled Trials; Umin Japan Trial Register; WHO portal (which covers ClinicalTrials.gov; ISRCTN; Chinese Clinical Trials Register; German Clinical Trials Register; Iranian Registry of Clinical Trials and the Netherlands National Trials Register, plus others)
- 3) *The Cochrane Library's* Central Register of Controlled Trials (CENTRAL)
- 4) Number of grey literature sources: ISI Web of Knowledge Conference Proceedings; Index to Theses; Australasian Digital Theses.

Additional searches in each of the sources listed above to cover the timeframe from the last searches performed for the Specialized Register to December 2011 were run to ensure that the search for the review was as up-to-date as possible. A total of 670 references were retrieved from the December 2011 update search. After de-duplication and a first-assessment, authors were left with 94 references to further assess for inclusion, exclusion or discarding.

3.2.2 Inclusion criteria for considering studies for this review

Studies: All RCTs examining the effect of cognitive stimulation for dementia were initially included if they have been published and written in English and presented in a journal article. Authors were contacted for missing data, such as details of randomisation, means, and standard deviations.

Participants: Participants that had a diagnoses of dementia (Alzheimer's disease, vascular dementia or mixed Alzheimer's and vascular dementia, other types of dementia), including all levels of dementia, indicated through group mean scores, range of scores, or individual scores on a standardized scale such as the Mini-Mental State Examination (MMSE) (Folstein 1975) or Clinical

Dementia Rating (CDR) (Hughes 1982). The participants could receive the intervention in a variety of settings (own home, out-patient, day care, residential setting).

Interventions: Participants attended regular therapy groups (involving a group or family caregiver) for a minimum period of 4 weeks. The intervention needed to described a cognitive stimulation intervention targeting cognitive and social functioning, offering generalised cognitive practice. These may also be described as RO groups, sessions or classes. The intervention needed to be compared to 'no treatment', 'standard treatment', or placebo.

The following variables were considered as outcome measures for the person with dementia:

- Performance on at least one test of cognitive functioning (including tests of memory and orientation).
- Self-reported, clinically rated or carer-reported measures for mood.
- Self-reported or carer-reported quality of life or well-being measures.
- Observer or carer ratings of everyday functioning (activities of daily living).
- Carer ratings of behaviour.
- Clinician or carer ratings of neuropsychiatric symptoms.
- Clinician or carer ratings of communication, social interaction/ engagement.

3.2.3 Data collection

Descriptive characteristics (such as quality of randomisation and blinding) and study results were extracted, recorded and entered into RevMan 5. Additionally,

letters and e-mails were sent to some authors of controlled trials asking for essential and additional information (statistics and/or details of randomisation). The summary statistics required for each trial and each outcome for continuous data were the mean change from baseline, the standard error of the mean change, and the number of patients for each treatment group at each assessment. Where changes from baseline were not reported, the reviewers extracted the mean, standard deviation and the number of patients for each treatment group at each time point if available. The reviewers calculated the required summary statistics from the baseline and assessment time treatment group means and standard deviations, assuming in this case a zero correlation between the measurements at baseline and assessment time. This conservative approach was chosen, as it is preferable in a meta-analysis. For binary data we seek the numbers in each treatment group and the numbers experiencing the outcome of interest. The baseline assessment was defined as the latest available assessment prior to randomisation, but no longer than two months prior.

For each outcome measure, data were sought on every patient randomised. To allow an intention-to-treat analysis, the data were sought irrespective of compliance, whether or not the patient was subsequently deemed ineligible, or otherwise excluded from treatment or follow-up. Discussion between the two main reviewers (BW, EA) and the other authors were used to resolve any queries.

3.2.4 Analyses

RevMan 5.1 (Update Software, 2011) was used. The meta-analyses presented overall estimates of the treatment difference from a fixed-effect model and a test for heterogeneity was performed using a standard Chi square statistic. Where there was evidence of heterogeneity of the treatment effect between trials then a random-effects model was utilised (which results in broader confidence intervals than for those of a fixed-effect model). Because trials used different tests to measure the same outcomes, the measure of the treatment difference for any outcome that we used was the weighted mean difference, when the pooled trials used the same rating scale or test, and the standardised mean difference (the absolute mean difference divided by the standard deviation) when different rating scales or tests were used. A weighted estimate of the typical treatment effect across trials was calculated. The reviewers achieved consensus on the interpretation of the statistical analyses, seeking specialist statistical advice from CDCIG as required.

Table 3-1. Description of included studies and bias

Study ID	Intervention	Content of therapy	Alternative activity	Randomisation	Attrition bias (dropouts)	Blindness
Baines 1987	30 min 5 times a week 4 weeks	RO board, multisensory stimulation	Reminiscence therapy/ no treatment	No details	0/15 dropouts	Assessment by independent psychologist and staff not involved in therapy. No details of assessors
Baldelli 1993	60 min 3 times a week 3 months	Formal RO	No treatment (TAU)	No details	0/23	No details of assessors
Baldelli 2002	60 min 5 times a week 1 month	Physical therapy augmented by RO sessions	Physical therapy programme	No details	0/87	No details of assessors
Bottino 2005	90 min 1 time a week 5 months	Temporal and spatial orientation, discussion of interesting themes, reminiscence activities, naming people, daily activities, planning use of calendars and clocks	AChEIs only	Randomised blocks design	0/13	Assessment by a blind and independent assessor
Breuil 1994	60 min 2 times a week 5 weeks	Drawing, associated words, object naming, categorizing objects	No treatment	No details	5/61 dropouts	Assessment by a psychologist unaware of group allocation

Study ID	Intervention	Content of therapy	Alternative activity	Randomisation	Attrition bias (dropouts)	Blindness
Buschert 2011	120 min 1 time a week 6 months	Multi-component cognitive group intervention - for AD group emphasis on cognitive stimulation (for MCI group more emphasis on cognitive training);	Pencil and paper exercises for self-study and monthly meetings	Blocked randomisation procedure.	No attrition N=35	Cognitive assessments made by an assessor blind to group allocation
Chapman 2004	90 min 1 time a week 8 weeks	Current events; discussion of hobbies and activities; education regarding Alzheimer's disease; life story work; links with daily life encouraged.	AChEIs only	SAS procedure	6/54	Assessment by a psychologist unaware of group allocation
Coen 2011	45 min 2 times a week for 7 weeks	Cognitive Stimulation	No treatment	Computerised randomisation and random number tables were used	No attrition N=27	Tests administered by staff blind to group membership. Not clear if staff ratings were made by staff who were blinded.
Ferrario 1991	60 min 5 times a week 21 weeks	Classroom RO	No treatment	No details	2/21 dropouts	No details of assessors
Onder 2005	30 min 3 times a week 25 weeks	Current information, topics of general interest, historical events and famous people, attention, memory and visuo-spatial	AChEIs only	Computerised block randomisation procedure	19/156	Assessment by a psychologist unaware of group allocation

Study ID	Intervention	Content of therapy	Alternative activity	Randomisation	Attrition bias (dropouts)	Blindness
Requena 2006	45 min 5 times a week 24 months	Orientation, Body awareness, family and society, caring for oneself, reminiscing, household tips, animals, people and objects	ACHIES only No treatment	Registration order procedure	10/50	Assessment by a psychologist unaware of group allocation
Spector 2001	45 min 2 /3 times a week 7 weeks	Orientation, categorizing objects, sounds, number, physical and word games, current events.	No treatment	Drawing names from a sealed container	8/35	Assessment by a researcher blind to group allocation
Spector 2003	45 min 2 times a week 7 weeks (14 sessions)	Orientation, categorizing objects, sounds, number , physical and word games , current events.	No treatment	Drawing names from a sealed container	34/201	Assessment by a researcher blind to group allocation
Wallis 1983	30 min 5 times a week 3 months	Repetition of orientation information (e.g., time, place, weather), charts, pictures, touching objects and material.	Diversional occupational therapy (group and individual activities.	Drawing from a hat, consecutive allocation	22/60 dropouts	Assessment by a senior nurse or occupational therapist unaware of group allocation
Woods 1975	30 mins 5 times a week 20 weeks	Daily personal diary, group activities (dominoes, spelling, bingo) naming objects, reading RO board.	"Social therapy" (various group activities	Drawing from a hat	4/18 dropouts	Mixture: some assessments blind, some others not.

3.3 Results

3.3.1 Selection of Trials

Ninety-four studies from the initial set of references were identified since the RO review through the literature search (Spector et al., 2000). Out of the 94 references, 9 studies met the inclusion criteria (Baldelli et al., 2002; Bottino et al., 2005; Buschert et al., 2011; Chapman et al., 2004; Coen et al., 2011; Onder et al., 2005; Requena et al., 2006; Spector et al., 2001 and Spector et al., 2003) and were included in the analysis. Three recent studies were left awaiting classification, with further details being required (Buettner et al., 2011; Fernandez Calvo et al., 2010 and Niu et al., 2010). The previous review (Spector et al., 2000) included 8 studies in the meta-analysis and six of these met the criteria for inclusion in this new review (Baines et al., 1987; Baldelli et al., 1993a; Breuil et al., 1994; Ferrario et al., 1991; Wallis et al., 1983 and Woods et al., 1979). Two studies from the previous RO review (Spector et al., 2000) were excluded this time, as the data needed for the meta analysis were not available (Gerber et al., 1991 and Hanley et al., 1981) Therefore, a total of fifteen studies were included in the analysis (Table 3.1). All the studies included in this review included participants with a diagnosis of dementia and in general, targeted participants in the mild to moderate range of cognitive impairment. In all studies, the average age of participants was over 70 years (except Wallis et al., 1983 where it was 69.8 years) and the average mean age across the 15 studies was 78.8 years (from 38 to 97 years). Over half the studies reported inclusion of participant(s) aged 90 years and above. Apart from six studies (Bottino et al., 2005; Breuil et al., 1994; Buschert et al., 2011; Chapman et al., 2004; Onder et

al., 2005 and Requena et al., 2006) where all the participants were outpatients living in the community, the rest of the studies included participants that were residents in care homes, nursing homes or hospitals. Spector et al. studies (2001 and 2003) included participants from both residential and community settings.

3.3.2 Quality of Included Studies

The quality of each study was assessed and details for each study are shown in Table 3-1.

Randomisation

All studies included randomly allocated participants to either treatment or control groups. Earlier studies described the randomisation process to be 'as drawing names from a hat' or 'using a sealed container process of randomisation' whereas later studies described a remote or computerised randomisation procedure (Table 3-1).

Blindness

Performance bias was difficult to evaluate. With psychological interventions, unlike drug trials, it is impossible to totally blind patients and staff to treatment. Patients are often aware that they are being treated preferentially, staff involved may have different expectations of treatment groups, and independent assessors may be given clues from patients during the assessments. Ratings of day-to-day behaviour and function are typically carried out by care staff who may be more difficult to keep blind to group allocation, unless the group sessions are carried out in a separate location, to which all participants are taken. There may also be 'contamination' between groups, in terms of groups

not being held in separate rooms and staff bringing ideas from one group to another. In relation to contamination, Baines et al., (1987) and Wallis et al., (1983) said that staff were removed from the ward setting for treatment and other studies said that groups were held in separate areas, reducing the chance of contamination (Ferrario et al., 1991; Spector et al., 2001; Spector et al., 2003 and Woods et al., 1979). Information regarding where groups were held was not provided in the other studies (Bottino et al., 2005; Chapman et al., 2004; Onder et al., 2005). In relation to detection bias, most studies took steps to ensure that at least part of the assessment of outcomes was carried out by assessors blind to treatment allocation. Baldelli et al., (1993a); Baldelli et al., (2002); Ferrario et al., (1991) did not report blinding of assessors.

Attrition

Given the nature of the condition, and the age of the participants, attrition in several studies was remarkably small, with zero attrition recorded in six studies (Baines et al., 1987; Baldelli et al., 1993a; Baldelli et al., 2002; Bottino et al., 2005; Buschert et al., 2011 and Coen et al., 2011), out of 180 participants. The largest attrition rate was reported by Wallis et al., (1983), where there was 39% attrition in the group of participants with dementia. In this study, patients who attended less than 20% of the group sessions were eliminated from the study. Requena et al., (2006) reported 32% attrition over a two-year period. The two largest studies had rates of 19% (Onder et al. 2005) and 17% (Spector et al., 2003), over periods of 6 months and 2 months respectively.

Other sources of bias

There was an absence of detailed treatment protocols, so the extent to which the intervention was delivered as intended in each study, could be questioned. Some recent studies described that staff received training and/or supervision in running the groups. Chapman et al., (2004) described weekly meetings to ensure their treatment programme was implemented as designed and Onder et al., (2005) also described how family caregivers were trained by a multi-disciplinary team and given a manual and specific schedules for each session. No records were made, however, of how often caregivers did deliver the sessions, or how closely the manual was followed. The only available data on treatment adherence came from Woods et al., (1979), who stated in a personal communication, "A sample of sessions were tape-recorded and rated to ensure compliance with the therapeutic protocol".

3.3.3 Meta-Analysis

Data from the included studies was entered into "Metaview" (the Cochrane term for meta-analysis). Data were identified, included and pooled from the 15 included RCTs, including a total of 718 participants (407 in experimental groups, 311 in control groups). In order to evaluate the effect of cognitive stimulation on cognitive function, data from 14 RCTs were included in the analysis as one study (Chapman et al., 2004) did not include the data needed at post treatment, leaving a total of 657 participants for analysis (377 received treatment and 281 received no treatment or placebo). Where more than one cognitive measure had been used, the more detailed test was used (e.g. ADAS-

Cog was selected for inclusion in this analysis over the MMSE where both were available from a study).

In comparison with the control groups at the post-treatment assessment, cognitive stimulation was associated with significant improvements across the range of cognitive measures used. The overall results in the cognitive section were significantly in favour of treatment (Figure 3-1). The overall effect size (SMD) was 0.41 (95% CI:0. 25, 0.57). The results were strongly weighted by Onder et al., (2005) (n= 137) and Spector et al., (2003) (N= 201) the largest studies. Largest effect sizes can be seen at the 12-month point in the Requena et al., (2006) study (SMD 0.70 on ADAS-Cog) and the Baldelli et al., (1993a) study (SMD 0.99 on MMSE), both of which offered above average duration of exposure to cognitive stimulation.

Four studies included staff ratings of the person's communication and social interaction (n=223). The overall effect size (SMD) was 0.44 (95% CI 0.17 to 0.71) with participants in the cognitive stimulation groups showing a significant improvement in this area (Figure 3-2).

Four studies included self-reported well being and quality of life measures (N=219) (Figure 3-3). Analysis showed a significant improvement on this outcome following treatment compared to control groups. The SMD was 0.38 (95% CI:0. 11,0.65); $Z=2.76$, $P=0.006$.

Five studies, involving 201 participants, used a self-report measure of mood (the Geriatric Depression Scale or the MADRS) (Figure 3-4) but cognitive stimulation was not associated with a significant improvement in mood (SMD

0.22 (95% CI: - 0.09,0.53), $Z=1.42$, $P=0.16$. and for proxy reports of mood and anxiety the SMD is close to zero ;0.05 (95% CI:-0. 21,0.31)(Figure 3-5). No differences were apparent in relation to either activities of daily living (ADL) or challenging behaviour (Figure 3-6 and Figure 3-7).

Follow-up

Short-term follow up analysis after finishing the therapy included 52 participants (Baines et al., (1987) and Wallis et al., (1983) studies with a one month follow-up, and from Baldelli et al., (1993a) with a three month follow-up. These studies found significant benefits for cognitive stimulation on cognitive measures at follow up (SMD 0.57 (95% CI: 0.01, 1.14), $Z = 2.00$, $P = 0.05$). Long-term follow up data included 54 participants from the Chapman et al., (2004) study that reported on a ten month follow-up but found no significant effects on either the MMSE (SMD 0.18) or the ADAS-Cog (SMD 0.12). No other significant results were found in the other outcome measures at either short term or long term follow up analysis (Figure 3-8).

Medication effect in comparison to cognitive stimulation effect

In five of the included studies (Chapman et al., 2004, Bottino et al., 2005, Onder et al., 2005, Requena et al., 2006 and Buschert et al., 2011) all of the participants were prescribed ACHEI medication. For the four of these RCTs providing post-treatment data, the additional effect of cognitive stimulation over and above the medication was 3.18 points on the ADAS-Cog, compared with the overall finding (from seven RCTs) of 2.27 points. This supports the proposition that cognitive

stimulation is effective irrespective of whether or not ACHEIs are prescribed, and any effects are in addition to those associated with the medication.

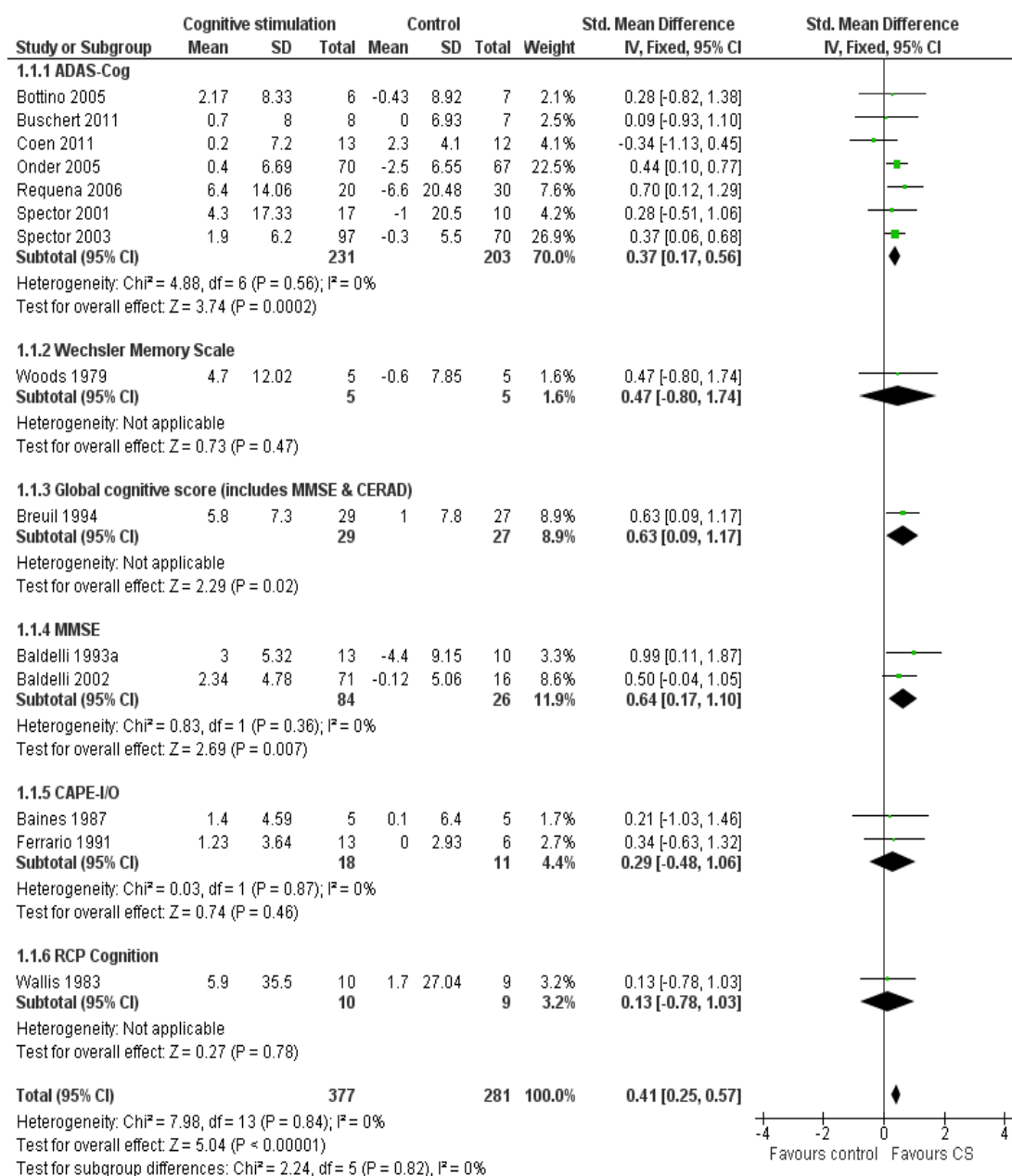


Figure 3-1. Meta analysis of the cognitive measures

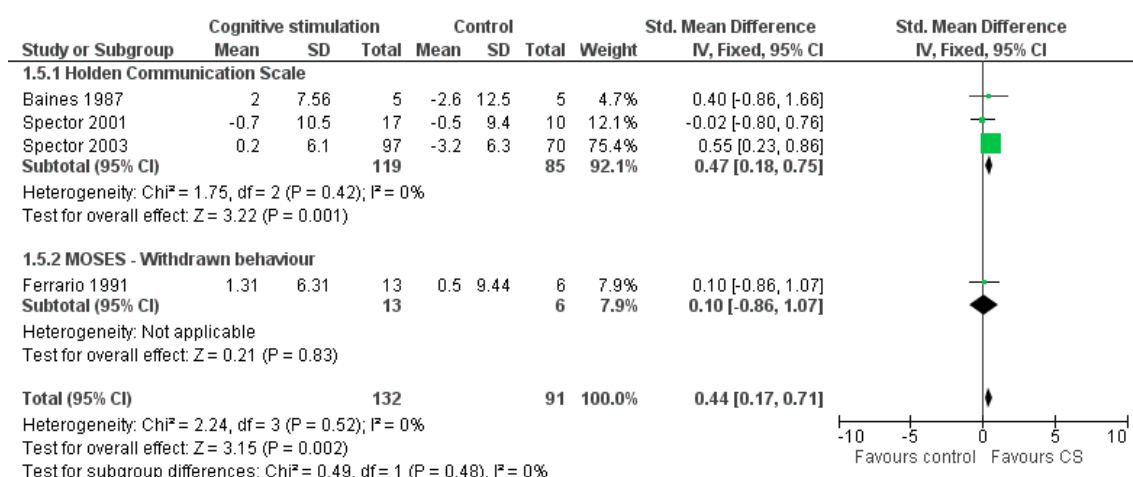


Figure 3-2. Meta analysis of communication and social interaction scales

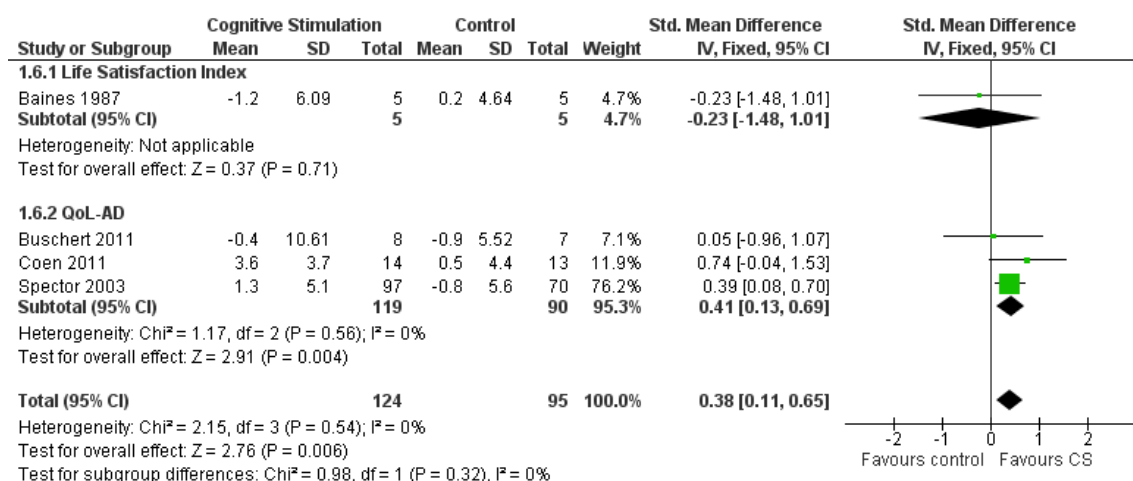


Figure 3-3. Meta analysis of quality of life and well being measures

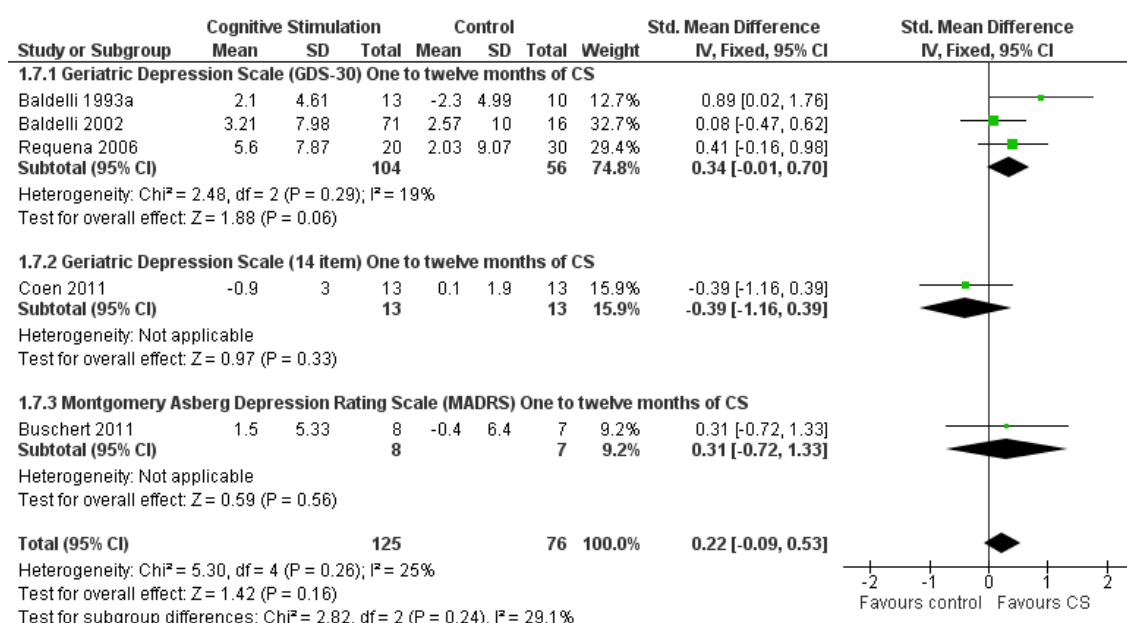


Figure 3-4. Meta analysis of self reported mood measures

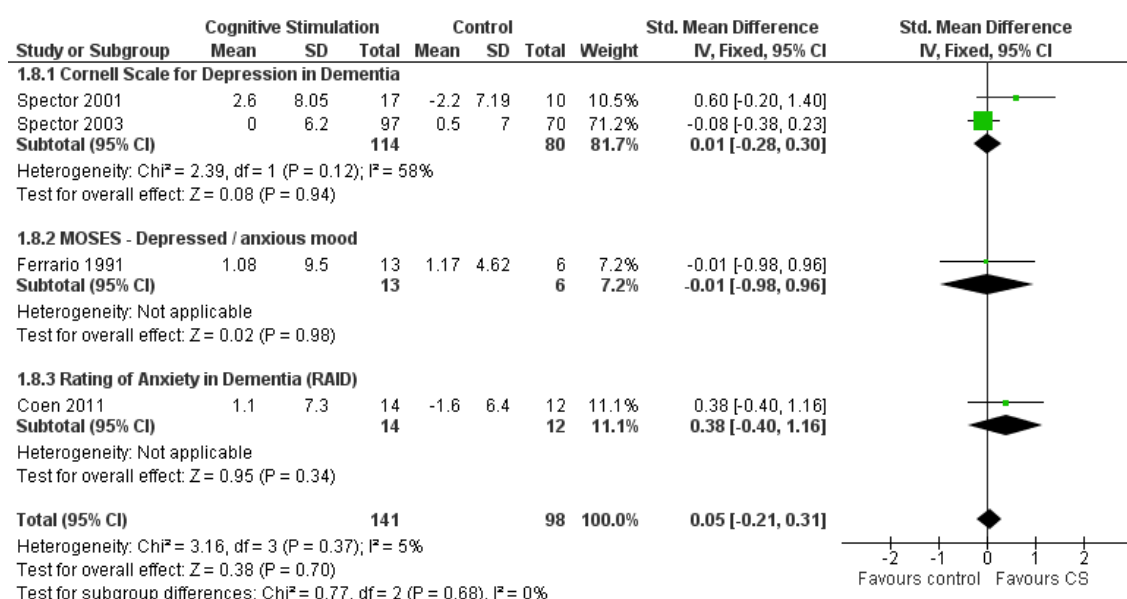


Figure 3-5. Meta analysis of proxy reported mood measures

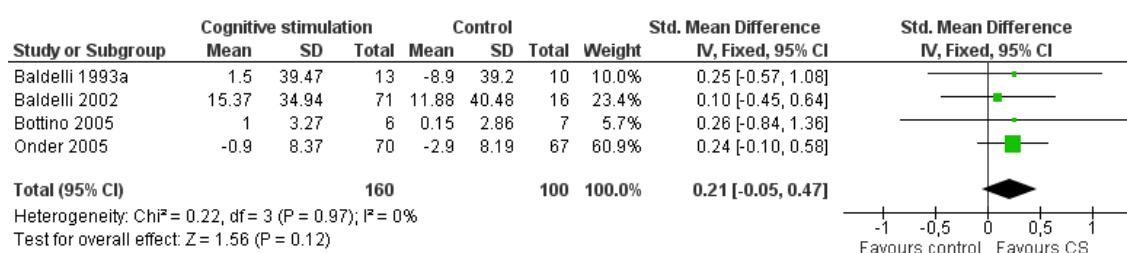


Figure 3-6. Meta analysis of activities of daily living measures

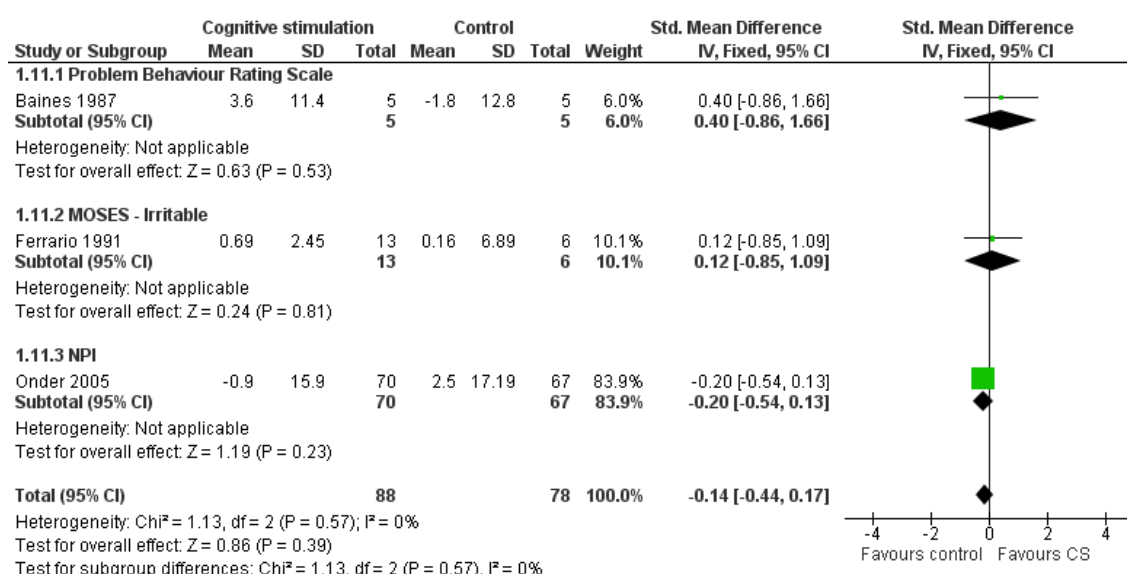


Figure 3-7. Meta analysis of challenging behaviour measures

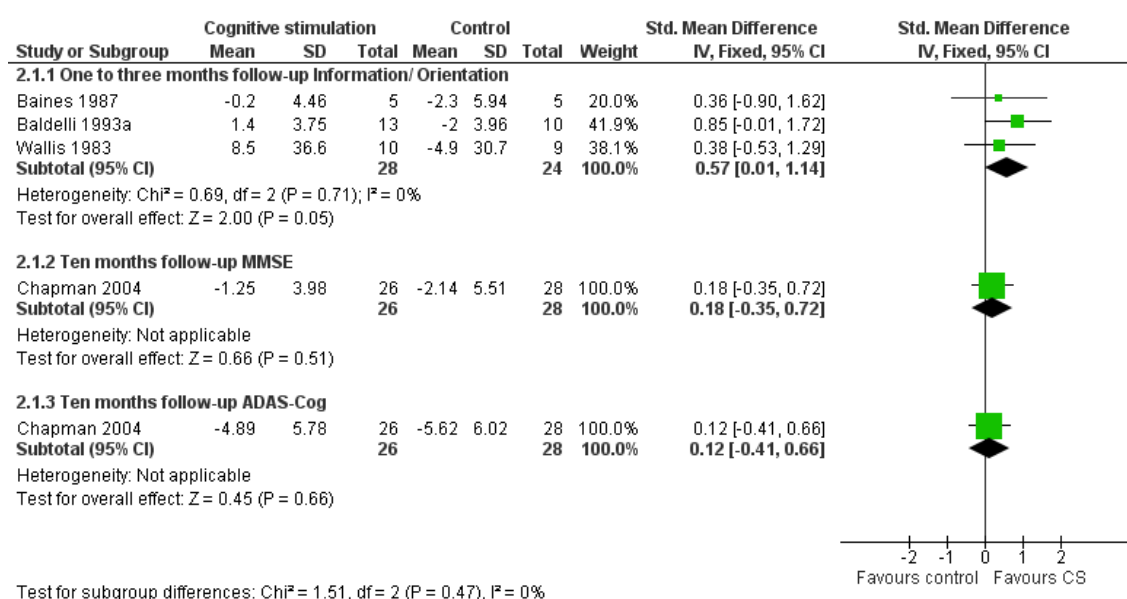


Figure 3-8. Meta analysis of follow up cognitive measures

3.4 Discussion

These results including 15 studies have shown consistently that cognitive stimulation benefits cognition for people with dementia but that it also benefits self rated well being and quality of life which is arguably of greater importance than any change in cognition (Woods et al., 2006). Included studies came from a variety of settings and countries and trials varied greatly in factors such as length of intervention, methodological quality and outcome measures. There was some variation in the alternative activities offered to control groups, with some trials giving them no treatment, others providing some alternative 'social' therapy, and others providing a control group with identical dementia drug treatment to those in the cognitive stimulation group. The results showed no effect in relation to the type of control group on outcome, indicating that the actual qualities of cognitive stimulation programmes are the ones that matter, rather than merely social contact and attention. Staff may however have had more positive attitudes to, and greater expectations for the cognitive stimulation therapy group, which may have affected participants' performance.

All included trials were randomised studies and had assessors blind to treatment group but RCTs may be especially valuable if used in conjunction with qualitative studies (e.g. Spector et al., 2011) or quasi-experimental studies in which different treatments are carried out in different centres. These may offer a greater insight into the most effective features of cognitive stimulation, the most effective ways in which it may be applied, and the types of people most suited to this type of intervention. As with all psychological interventions, the success of cognitive stimulation programmes may be dependent on it being

used at the appropriate time, by sensitive and experienced facilitators or therapists with interested participants. Apart from Onder et al. study (2005) where the therapy was run at home by a trained family caregiver, all the other interventions were run in a group setting by therapist, with a variety of backgrounds, experience and training. However, this review found no indications in relation to the required amount of training or type of training necessary to run cognitive stimulation in an effective way and Onder et al., (2005) provide a novel approach for individual cognitive stimulation which appears to be a promising area for further research (Orrell et al., 2012).

This review reports findings immediately after treatment and only four small studies, reported on follow up data. The results did not show a clear relationship between either amount/frequency or length of intervention. Largest size effects were seen in both long and short trials (Requena et al., 2006 and Breuil et al., 1994) and long exposure trials (Ferrario et al., 1991) showed below average effects sizes. It remains unclear if the frequency of sessions per week makes a difference as the study with the largest effect sizes (Requena et al., 2006) had five 45-minute sessions per week and also had the longest duration. As the duration increases, the anticipated decline associated with dementia should tend to reduce the effects of cognitive stimulation, and so a simple linear relationship is not likely to last. Long-term benefit of the intervention remained unclear primarily because of the lack of follow up data and definitive evidence for the long-term effects is needed. Short-term follow up data from three studies suggested that a benefit from cognitive stimulation might be maintained for at least three months but for cognitive stimulation to

have more lasting effects, there should be a detailed schedule of reinforcement and follow-up, with an ongoing program.

Recent reviews of psychosocial interventions for dementia are in line with the findings of this review and give strong recommendations for the use of cognitive stimulation for dementia (Livingston et al., 2005, Olazaran et al., 2010). Moreover, the 2011 World Alzheimer's Report (Prince et al., 2011) concludes that "acetylcholinesterase inhibitors (ACHEI) and cognitive stimulation may enhance cognitive function in people with mild Alzheimer's disease, and these interventions should therefore be routinely offered." In relation to ACHEI medication and in line with Prince et al (2011) recommendations, this review results indicates that cognitive stimulation is effective irrespective of whether ACHEIs are prescribed, and any effects are in addition to those associated with the medication.

3.5 Conclusions

This review indicates that cognitive stimulation, defined according to agreed criteria, consistently improves cognitive function in people with dementia. It also indicates that it not only benefits cognition but also self reported well-being and quality of life as well as proxy ratings of communication and social interaction. Qualitative research is consistent with these findings (Spector et al., 2011). These findings are consistent with the recent 2011 World Alzheimer's Report (Prince et al., 2011) and the NICE-SCIE 2006 guidelines recommendations that people with mild to moderate dementia should be given the opportunity to participate in cognitive stimulation therapy

groups, irrespective of whether or not they are receiving ACHEI medication. Future research should investigate the longer term benefits of this intervention, and individual cognitive stimulation delivered by the caregiver also needs to be more systematically evaluated.

The results from this review were used to support the development of the MCST intervention as described in more detail in Chapter 5.

CHAPTER 4

A survey exploring CST implementation in practice

This chapter describes the evaluation of the implementation in practice of CST after a one day CST training course. The results from this survey helped to better understand the implementation in practice of CST and fed the development of the MCST programme (Chapter 5; Figure 5.1) and the methodology used in order to evaluate the programme (Chapter 7).

Following from the results of Spector et al., (2003) trial, this chapter describes a Phase IV or implementation into practice field study. The study results were used to develop the MCST programme, increasing its usability. The chapter is based on the published paper (Appendix 6.3) entitled “Translating research into practice: A pilot study examining the use of Cognitive Stimulation Therapy (CST) after a one day training course” (Spector, Orrell and Aguirre 2010).

4.1 Method

4.1.1 The training intervention

The evaluated intervention was a one day CST training course designed by AS. The training involved a theoretical and research background to CST with a focus on the 14 sessions of the intervention. Methods included a PowerPoint presentation, small group exercises, role-play and DVD observation followed by a discussion. Eight courses were run by AS, the lead researcher on the CST trial.

Two courses were run by HD, a Consultant Clinical Psychologist who was trained by AS. There was no contact with trainees following the training day.

4.1.2 Sample and Data Collection

The sample were 168 staff working with people with dementia, trained across ten courses in the UK from January 2007 to June 2008. All trainees were contacted by e-mail and/or post (depending on contact information available) and asked to complete a questionnaire. Sixteen had moved jobs or were no longer contactable; therefore 152 people were approached of whom 76 responded. Data were collected over a three-month period, which meant that data from the first trainees was collected approximately 18 months after the training, with a minimum period of three months for the final trainees.

4.1.3 Measures and other information

Information was gathered from feedback forms immediately following training, and people were asked to rate different aspects of the training, such as the methods used and trainer's knowledge, on a likert scale where 1 = poor and 5 = excellent. Because feedback forms were anonymous, it was not possible to match them with the participants in this study. However, across all the training courses, scores of 4 (good) and 5 (excellent) were given for most items by most trainees. The only item which was predominantly scored as average (3) concerned the audiovisual equipment used.

The post-training questionnaire included the outcome measures described below. The factors investigated and sources of information are summarized in

Table 4-1. The questionnaire included general information such as job title, place of work, (e.g. specialist dementia setting), gender, ethnic group, age, years working in dementia care. Information relating to CST included whether or not the trainee had run CST groups, problems/barriers that they had encounter setting up groups, and any further support they perceived might have been helpful in the process of running CST groups.

*The Learning Transfer System Inventory
(LTSI: Holton et al, 2000)*

The LTSI comprises sixty-eight items grouped into sixteen constructs, which were categorized into four major groups: trainee characteristics, motivation, work environment, and ability (Noe & Schmitt, 1986). It was selected because this measure considers both personal and environmental factors, which might impact on the delivery of CST. Reliability and validity (including cross-cultural validity) is high (e.g. Holton et al, 2000; Khasawneh et al, 2006). The LTSI can be used as a diagnostic tool (to assess training needs) as well as an evaluation tool of training policies. For this survey we used a brief version of the LTSI comprising sixteen items, which represented each construct (Holton et al, 2000) (Table 4-2). All of the items use five-point Likert-type scales from 1 (strongly disagree) to 5 (strongly agree).

Table 4-1. *Transfer system inventory and sources of information*

Domains assessed	Source of information / outcome measures
Design and Quality of Training	Feedback forms Items on questionnaire, e.g. about whether training provided necessary skills

Personal factors	Hope (ADQ) Person-centredness (ADQ) Job satisfaction (JS) Motivation (brief LTSI) Learner characteristics (brief LTSI)
Organisational factors	Environment (brief LTSI) Ability / enabling (brief LTSI) Obstacles, as reported in questionnaire

Table 4-2. The brief learning transfer system Inventory (BLTSI)

<i>Learner characteristics</i>	<i>Question used</i>
Learner Readiness	Before the training I had a good understanding of how it would fit my job-related development.
Performance Self-Efficacy	I am confident in my ability to use newly learned skills on the job.
<i>Motivation</i>	<i>Question used</i>
Motivation to Transfer	I get excited when I think about trying to use my new learning on my job.
Transfer Effort–Performance Expectations	My job performance improves when I use new things that I have learned.
Performance-Outcomes Expectations	When I do things to improve my performance, good things happen to me.
<i>Work environment</i>	<i>Question used</i>
Positive Personal Outcomes	Employees in this organization receive various ‘perks’ when they utilize newly learned skills on the job.
Negative Personal Outcomes	If I do not utilize my training I will be cautioned about it.
Motivation to Transfer	I get excited when I think about trying to use my new learning on my job.
Transfer Effort Performance Expectations	My job performance improves when I use new things that I have learned.
Performance-Outcomes Expectations	When I do things to improve my performance, good things happen to me.
Resistance/ Openness to Change	People in my group are open to changing the way they do things.
Performance Coaching	After training, I get feedback from people about how well I am applying what I learned.
<i>Ability / enabling</i>	<i>Question used</i>
Personal Capacity for Transfer	My workload allows me time to try the new things I have learned.
Perceived Content Validity	What is taught in training closely matches my job requirements.
Transfer Design	The activities and exercises the trainers used helped me know how to apply my learning on the job.
Opportunity to Use	The resources I need to use what I learned will be available to me after training.

Approaches to Dementia Questionnaire
(ADQ: Lintern and Woods, 2001)

This is a 19-item Likert scale in which staff rate their extent of agreement with different statements about dementia (e.g. “people with dementia are very much like children”) from (5) ‘strongly agree’ to (1) ‘strongly disagree’. A total score and two sub-scores, ‘hope’ and ‘person-centredness’ can be calculated. It was selected because these seem to be important characteristics in care staff as, for example, staff hope and person centredness has been associated with quality of life in people with dementia (Spector and Orrell, 2006). Test-retest reliability is good (total = 0.76, hope = 0.70, person-centredness = 0.69) and predictive validity is good for the hope subscale.

Job Satisfaction Index (Aspects of work inventory (AWI)
Barkham et al, 1989).

This is an 18-item likert scale in which respondents rate their satisfaction with different aspects of their job on a scale from extremely dissatisfied (1) to extremely satisfied (7). Inter-rater reliability and validity are good.

4.1.4 Analyses

Data were entered into SPSS version 10. Independent samples t-tests were used to compare the trainees who had run CST and those who had not after the training intervention on the outcome measures used.

4.2 Results

4.2.1 Demographics

The questionnaire was sent to 152 people of whom 76 responded (50%). People were contacted by post and e-mail including up to three reminders, but the biggest problem was where all contact/correspondence with a group who had been trained needed to go via a single person. Of the respondents, the mean age was 43.6 years (s.d. = 10.9, range 20 – 72 years). Sixty (79%) were female and 16 (21%) were male. Forty-three (56%) worked in a specialist dementia setting. The majority of the trainees (60 / 79%) were professional staff including 26 (34%) occupational therapists, 24 (32%) nurses, 8 (11%) psychologists, and 2 (2%) physiotherapists. Of the remainder there were 5 (7%) care staff, 3 (4%) who worked for a charity, and 8 (10%) others. 33 (43%) worked in CMHTs for older people, 10 (13%) in day hospital, 7 (9%) in care homes, 3 (4%) in day centres and 3 (4%) in the voluntary sector. 20 (27%) fell into the 'other' category which included a civic centre, ward for elderly, acute inpatient unit, university, EMI unit and in a self-employed capacity. Most respondents (91%) were white. Of the 76 respondents, 27 (35%) had run CST groups following training and 49 (65%) had not. There was no relationship between having started a CST group and job title, place of work, gender, age or ethnicity.

Quality of training

The post-training questionnaire asked whether people felt that the training equipped them with the necessary skills for the delivery of CST. Of the 75 respondents, 65 (86%) responded 'yes' and 10 (14%) responded 'no'. People were asked to comment on what further support might be necessary to run CST

effectively and 100 responses were received (some people marked more than one option). 24 (24%) wanted more support from staff, 23 (23%) regular supervision from a specialist, 17 (17%) an online forum, 16 (16%) training in other areas, 15 (15%), regular supervision, and 7 (7%) made other comments. Including the other comments, six key themes were identified to improve the set up and running of groups: support from colleagues, learning from colleagues, training in group facilitation, facilitators experience running activities/groups, understanding of the groups, and work flexibility.

4.2.2 Characteristics of staff running CST groups

For the purpose of this analysis, the sample was divided into two groups: people who had run CST groups after training and people who had not (see Table 4-3). Staff who had run CST groups did significantly better in terms of total BLTSI score and three of the subscales: learner characteristics, work environment and ability/enabling. There were no differences between the groups on scores on the ADQ and Job Satisfaction measures (Table 4-3).

Table 4-3. *Group differences using independent sample t-test*

Measure	'Did CST' group	'Did not do CST' group	t-test: Difference
Brief LTSI total	2.5 (0.4)	2.8 (0.3)	P = 0.002*
Brief LTSI motivation	2.3 (0.7)	2.4 (0.6)	P = 0.27
Brief LTSI learner characteristics	2.0 (0.6)	2.3 (0.6)	P = 0.05*
Brief LTSI work environment	2.8 (0.5)	3.0 (0.4)	P = 0.04*
Brief LTSI ability / enabling	2.4 (0.6)	2.9 (0.7)	P = 0.01*
ADQ total	4.2 (0.3)	4.2 (0.4)	P = 0.85
ADQ hope	3.9 (0.6)	3.9 (0.6)	P = 0.87
ADQ person-centredness	4.6 (0.3)	4.5 (0.5)	P = 0.54
Job satisfaction	5.1 (1.0)	5.1 (0.7)	P = 0.88

4.2.3 Barriers to running CST groups

Amongst the 27 people that reported they had run CST groups, all of them expressed that they had encountered some difficulties. 11 (41%) highlighted a lack of staff time, 6 (23%) a lack of resources, 4 (15%) not enough suitable participants, 2 (7%) no suitable room, 2 (7%) transport problems, and 2 (7%) lack of support from management. Everybody stated that they felt skilled enough to run CST.

The 49 people who did not do CST were asked to give one or more reasons as to why groups did not run. Of the 62 responses 27 (44%) mentioned lack of staff time, 9 (14%) lack of resources, 7 (11%) no suitable room, 7 (11%) not enough suitable participants, 6 (10%) transport problems, 4 (7%) not feeling skilled enough, and 2 (3%) lack of support from management.

4.3 Discussion

This study is one of the few studies in the dementia literature that has looked at the dissemination in practice of a psychosocial intervention after a training course in normal practice, with most having evaluated training as part of an experimental design. As such, it offers a useful insight into how effective this training was in achieving a clearly defined goal i.e. running CST groups following the training course. This study may also be the first that has used transfer of learning theory measures in dementia care. The key finding was that people running CST groups scored significantly better on the brief LTSI than those who did not, suggesting that they had effective learner characteristics,

work environment and ability/enabling factors. The study to some degree addressed the three areas which Holton & Baldwin (2000) suggested may affect success in putting training into practice: training factors, personal factors and environmental factors. The results suggested that the training itself was adequate enough to equip people with the skills necessary for running CST groups, with 86% of the sample stating that this was the case. However, whereas support from staff and regular supervision were highlighted as the main areas in which further support would have been useful, the key barrier to running groups appears to have simply been staff time, although lack of resources was also important. This fits in with informal feedback given during training, addressing concerns about having sufficient staff to prioritise CST above essentials such as personal care.

These results were essential in the development of the MCST programme (Aguirre et al., 2010) (Chapter 5) and the development of the methodology of the evaluation of the developed programme (Aguirre et al., 2010) (Chapter 7). As staff time and lack of resources was defined as being one of the key barriers for staff to run CST groups, it was decided that all the CST groups were going to be facilitated and run by a member of the research team responsible for the provision of all resources for the CST groups (setting up room in the recruited centre, bringing CST session materials, record sheets, adherence forms) and co facilitated by a member of the recruited site (Chapter 7).

In terms of personal factors, no link was found between the groups in job satisfaction or attitudes to dementia (hope and person-centredness). Trainee characteristics on the BLTSI, which include learner readiness and performance

self-efficacy, however, were greater in the group, which took up CST. One must interpret these results with caution, as these patterns do not necessarily imply causation. In other words, people who are more likely to run CST groups may by nature have enhanced readiness and self-efficacy, as opposed to these characteristics enabling them to 'learn' something, which they then applied in practice. Research has examined the influence of work environment factors such as interpersonal support (Bates et al 2000), opportunity to transfer (Ford et al, 1992) and culture (Tracey et al, 1995) and in this study environmental factors also appeared to play some part, with the group offering CST scoring better in 'work environment' and 'ability/enabling'. The work environment scale includes performance coaching, supervisor support, supervisor sanctions, peer support, resistance-openness to change, positive personal outcomes, and negative personal outcomes.

4.4 Limitations

Due to the pilot nature of the project, this study begins to address some areas of investigation in implementation into practice of a psychosocial intervention for dementia, but none are examined in depth. As such, the sample size limited the scope of the statistical comparison. The design and quality of the training was not addressed in any detail, although participants indicated that they viewed it as high quality and adequate to prepare them for running CST groups. The personal characteristics such as attitude to dementia and job satisfaction, that we hypothesised might link to uptake of CST were not found to predict CST use. The elements were selected due to parallel drawn from other research, for example hope in care staff has shown to be associated with quality of life for the

person with dementia (Spector & Orrell, 2005). However, it is possible that other factors (such as sense of competence) may be more relevant when evaluating staff training. Learning was not specifically evaluated since to do this, an individual's competence in and adherence to CST would need to be assessed (in addition to CST uptake). The population recruited was only 50% of the sample contacted, and may not be fully representative of the trainees. This could have been increased if full contact details for each trainee had been recorded on the day of training rather than relying on a single contact person. The responders may have been a more motivated group, possibly with a higher percentage of qualified staff and CST use than the full sample. Time between training and assessment of participants was variable and it may be that some of the trainees who were followed up after shorter periods would have taken up CST groups if the follow-up had been longer. The degree to which these results may generalise to trainings in other psychosocial interventions is unknown and future research may help to determine this.

4.5 Conclusion

This implementation study has been useful in considering the practicalities of putting CST into practice, following a one-day training course. Individuals with better learning characteristics may also be more likely to take up CST following training, and simple factors such as a lack of staff time and resources may prevent people from doing CST. Changing practice in dementia care will optimize the existing resources to improve the quality of life of people living with dementia. Future research could focus on comparing the effectiveness of different training methods, for example comparing a one day training course

with and without ongoing support and supervision. In addition, studies need to examine whether the training method might influence how effectively CST is carried out by measuring competence, adherence and using simple cognitive and quality of life outcome measures such as the MMSE (Folstein et al, 1975) and the QoL-AD (Logsdon et al, 1999). It would also be interesting to examine the relationship between personal characteristics and skills in group facilitation.

CHAPTER 5

Development of an evidence-based programme of MCST for people with dementia

This chapter describes the development of the MCST programme for dementia using the evidence found in the Cochrane review (Chapter 3) and the survey exploring the implementation into practice of CST (Chapter 4) followed by a Delphi Consensus Conference approach complemented with focus groups with service users (Chapter 6).

This chapter is based on the published paper entitled “Development of a maintenance Cognitive Stimulation Therapy (CST) programme for people with dementia” (Aguirre et al., 2011) (Appendix 6.4).

5.1 Methods

The development of the MCST intervention represents the Phase 1 of the MRC framework (Figure 1.5) and follows the 3 steps set up by the framework: (1) identifying the evidence, (2) identifying the theory and (3) modeling the process.

In order to identify the evidence, results from the Cochrane review described in chapter 1 were used. This resulted in the first draft of the MCST programme (Figure 5.1) In order to identify the theory and the elements of successfulness of this type of programme plus developing a further version of the MCST

programme, a consensus conference followed with a Delphi method including two surveys was convened. The Delphi method is based on structural surveys and makes use of the intuitive available information of the participants, who are mainly experts. Thus, the Delphi method is a 'relatively strongly structured group communication process, in which matters, on which naturally unsure and incomplete knowledge is available, are judged upon by experts' (Häder and Häder 1995, p. 12). Therefore the consensus conference included international experts in the field of cognitive stimulation programs and some expert family caregivers. As we also wanted to involve people with dementia in the process of developing the programme, but it was felt that the consensus conference and Delphi method was not going to be the most appropriate way of doing this, focus groups were used in between the Delphi process survey 1 and 2 (Chapter 5). After the consensus conference and first Delphi survey, a draft two of the MCST manual was developed, presented and used in the focus groups. After the focus groups a draft version three was developed and presented in the final second survey that was sent out to consensus conference attendees. The analysis of this final survey was used in order to develop final MCST programme.

5.2 Identifying the evidence base

As described in Chapter 3, an updated Cochrane Systematic Review on the effectiveness of cognitive stimulation programmes for people with dementia was conducted. The therapeutic content of each study and subsequent outcomes were tabulated (Table 3.1 and 5.1). Priority to study interventions was given to

studies with stronger methodology, such as RCTs. Studies, which did not match the inclusion criteria for the Cochrane Review, but were classified, as high quality studies were also included in the process of developing the maintenance intervention. The criteria for classification as high quality studies were: 1) extensive description of the intervention classified as being cognitive stimulation, 2) positive outcome and 3) strong methodological design (although not a RCT). Studies with positive outcomes were drawn out from the tables, and the contents of the intervention examined. Through this process, potentially beneficial elements of each type of therapy were identified, and were incorporated into the design of the new MCST programme on the basis of consensus agreement amongst the expert group (EA, BW, AS, MO).

5.2.1 Identifying and developing appropriate theory: the theoretical basis for CST in dementia

A theoretical understanding of the likely process of change in the primary outcomes (cognition and quality of life) was developed by drawing on existing evidence and theory. This basis have been described in Chapter 1, point 1.3.4 Theory behind CST- how it might work for people with dementia.

Using consensus methods drawing on evidence and theory to develop the programme

The next step in the development of the programme was to convene an international consensus conference. This conference brought together the knowledge and expertise of local and external professionals from the UK, Japan and Spain, researchers and family caregivers involved in cognitive programmes in the dementia care field. The MCST programme Version 1 that was developed

from the included review studies evidence, was presented at the conference in London to the attendees. A consensus method was chosen as it provides a means of synthesising the available information (Jones and Hunter, 1995). The aim of the consensus conference was to develop indicators for the successfulness of CST activities by considering the research evidence for the effectiveness of this therapy, and to use the feedback from participants to validate and review the draft Version 1. Participants reviewed the different presented themes in the programme and considered which activities they felt would be successful or unsuccessful for a long term cognitive based intervention for dementia. The conference began with a presentation of the evidence from an early version of the Cochrane review (Woods et al., 2012), a presentation about the evidence from the CST trial (Spector et al., 2003) and a presentation about the development of the MCST programme Version 1. The participants worked in small multidisciplinary groups that facilitated the discussion about the presented themes (old and new themes) in the maintenance programme. Each group included clinical and research professionals plus family caregivers. Each group was asked to appoint a chairman whose role was to ensure that the group worked to the brief and to report back to the other groups. The groups worked on their brief for one and a half hours and drew up a list of the themes that they were reviewing. The groups were asked to split the themes into pros and cons for each of the activities. Subsequently, the groups came together and presented their opinions about the themes to the whole group. After the consensus conference, the different discussed points were typed and circulated to the MCST panel and

consensus attendees, in the first phase Delphi survey, to encourage comments on the points. The changes from the consensus conference were included and integrated into the programme, leading to the MCST programme draft Version 2. A list of the key principles of CST underlying the relevant theory behind the success of this therapy was also established among the CST panel (AS, BW, MO, JH, EA).

Table 5-1. *Description of interventions from the included studies*

**C: Cognition; B: Behaviour*

+: Intervention brought benefits to cognition or behaviour

-: Intervention did not bring benefits to cognition and/or behaviour

Authors	Description	Outcome
Studies in the Cochrane Review Woods et al., 2010 (Also included in Spector et al., 2000)		
C / B*		
Baines 1987	RO Board, old and current newspapers, personal and local photos, materials to stimulate all senses (e.g. cinnamon, silk, honey)	+ B*
Baldelli, 1993	No info given	
Breuil 1994	Copying pictures, associated words, naming and categorising objects.	+C
Ferrario, 1991	No info given	
Gerber 1991	Simple exercises, self-care, food preparation, orientation room with RO board, large clock, coloured illustrations.	+C
Hanley 1981	RO Board, clocks, calendars, maps, posters, and room overlooked garden area to enable discussion.	+C
Wallis 1983	Repetition of orientation information (e.g., time, place, weather), charts, pictures, touching objects and material.	-C
Woods 1979	Daily personal diary, group activities (dominoes, spelling, bingo) naming objects, reading RO board.	+C
New studies included in the Cochrane Review Woods et al., 2010		
Baldelli 2002	No info given	+C
Bottino 2005	Temporal and spatial orientation, discussion of interesting themes, reminiscence activities, naming people, daily activities, <i>planning use of calendars and clocks</i>	+C
Chapman, 2004	Current events; discussion of hobbies and activities; <i>education regarding Alzheimer's disease</i> ; life story work; links with daily life encouraged.	+C

Authors	Description	Outcome
Onder 2005	Current information, topics of general interest, historical events and famous people, attention, memory and visuo-spatial exercises; <i>use of clocks, calendars and notes</i>	+C
Requena 2007	Orientation, Body awareness, family and society, <i>caring for oneself</i> , reminiscing, <i>household tips</i> , animals, people and objects	+C

Authors	Description	Outcome
High quality studies used in the development of the manual but not included in the Cochrane Review		
Olazaran 2004	Reminiscing parents home, significant event, sounds, favourite sports, word game, visual clues to make a trajectory, similarities, <i>what to do in case of ... fire</i> , verbal calculations, serial additions, current affairs, write a letter, orientation, make a cake, make budget from shopping.	+C
Farina, 2002	Searching for words in a text, naming pictures, ranging words in alphabetical order, identifying specific visuospatial stimuli, matching figures, drawing figures, puzzles.	+C
Farina, 2004	Conversation, singing, comments on pictures, collage, and poster creation.	+C
Zanetti 2001	Procedural memory training stimulation. Basic and instrumental activities of daily living train, washing face, closing door, writing a letter, locking door.	+C

5.2.2 Modelling process

To improve the therapy programme in terms of clarity, appropriateness and effectiveness as outlined in Phase I (modelling) of the MRC guidelines (2008), we included qualitative testing of the intervention through focus groups. This step is fully described in chapter 6.

Establishing consensus

In order to establish the extent of agreement and consensus among the consensus conference participants with regard to the therapy programme Version 3, a final step was taken. A Delphi survey was sent to the consensus conference attendees that consisted of a covering letter introducing and explaining the steps followed for the development of the manual Version 3, plus

a survey questionnaire that aimed to clarify points of the development of the programme and reach consensus about its development and key features

5.3 Results

The different stages that were undertaken for the development of the intervention resulted in different therapy programme manual versions (Figure 5-1). These are detailed below:

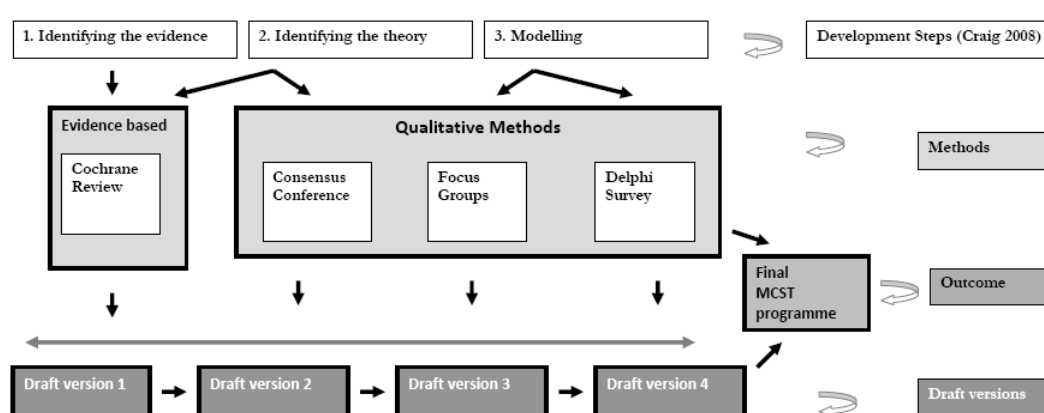


Figure 5-1. Development of the MCST programme

Table 5-2. CST and MCST programme themes development

N	Pilot MCST	Version 1	Version 2	Version 3	Final Version
1	Childhood	Childhood	My life / Childhood	My life / Childhood	My life / Childhood #
2	Current affairs	Current affairs	Current affairs	Current affairs	Current affairs #
3	Current affairs	Food	Food	Food	Food #
4	Using objects	Being creative	Being creative	Being creative	Being creative #
5	Number Games	Number Games	Number Games	Number Games	Number Games #
6	Team Games, Quiz	Team Games, Quiz	Team Games, Quiz	Team Games, Quiz	Team Games, Quiz# #
7	Sound	Sound	Sound	Sound	Sound #
8	Physical Games	Physical Games	Physical Games	Physical Games	Physical Games #

N	Pilot MCST	Version 1	Version 2	Version 3	Final Version
9	Categorising objects	Categorising Objects	Categorising Objects	Categorising Objects	Categorising Objects #
10	Using objects	Using objects	Household treasures	Household treasures	Household treasures *P
11	Useful tips	Useful tips (Household)	Useful tips (Household)	Useful tips (Household)	Useful tips (Household) *C
12	Golden Expression cards	Golden Expression cards	Thinking cards	Thinking cards	Thinking cards *P
13	Golden Expression cards	Visual Clips	Visual Clips	Visual Clips	Visual Clips *C
14	Art Discussion	Art Discussion	Art Discussion	Art Discussion	Art Discussion *P
15	Famous faces/Scenes	Famous faces/Scenes	Famous faces/Scenes	Famous faces/Scenes	Famous faces/Scenes #
16	Word Games	Word Games	Word Games	Word Games	Word Games #
17		Food	Food	Food	Food #
18		Associated words	Associated words	Associated words	Associated words #
19		Orientation	Orientation	Orientation	Orientation #
20		Using money	Using money	Using money	Using money #
21		Current affairs	Current affairs	Word Games	Word Games #
22		Golden Expression cards	Thinking cards	Household treasures	Household treasures *P
23		Childhood	My life / Occupations	My life / Occupations	My life / Occupations #
24		Useful tips (Health/Memory)	Useful tips (Health/Memory)	Useful tips (Health/Memory)	Useful tips (Health/Memory) *C

**C: Themes developed from the systematic review*

**P: Themes from the pilot MCST*

Themes included from the original CST program

5.3.1 Draft Manual Version 1

The MCST programme was based on the structural model of CST (Spector et al., 2003) and had similar criteria set out for it before development was started, as its aim was to complement it. This criterion was that the programme sessions had to be flexible, with stimulating exercises grouped by theme (e.g. food,

childhood, sounds, physical exercises, famous faces, word game, and number games). Each theme had to contain exercises of different types, focusing on memory, concentration, linguistic, and executive abilities and each session had to follow the following structure: beginning with introductions and a warm-up activity (such as ball game), followed by a main activity and finishing with a closing to the session.

In addition to Spector et al., 2003 two other studies from the included studies in the Cochrane review were the most influential in the design of this maintenance programme: Requena et al., (2006) and Onder et al., (2005). Requena et al., (2006) was a single blind RCT demonstrating improvements in cognition and memory over a two-year period. Their programme included a new technique using 'visual clips' that was included in the draft Version 1 of our programme. Onder et al, (2005) was a single blind RCT that demonstrated improvements in cognition over 25 weeks of therapy, delivered individually by family care-givers for 30 minutes three times a week. They included a session about the use of calendars, notes and clocks that was adapted and included in the draft Version 1 of the manual as a new theme called "useful tips - caring for oneself".

As a result of the process of identifying and developing appropriate theory for the programme, a table identifying themes and properties of the manuals was developed. A database was also created including the different elements, guiding principles and session themes that were found in the Cochrane review included studies. The 14 themes developed for the original CST study (Spector et al., 2006) were organised in a table that also included the three extra themes developed for the MCST pilot project (Orrell et al., 2005) (golden expression

cards, art discussion and using objects). From the analysed interventions of the Cochrane review studies, two extra themes were added to the table (useful tips and visual clips) and a first draft of the 24 weekly session programme of the MCST programme developed (Table 5-2).

5.3.2 Draft Manual Version 2

The consensus conference took place at University College London (UCL) over one afternoon and was attended by 34 participants in total. As a result, the activities included in the different presented themes were extended and adapted to be more suitable for the target population. Some theme titles were also modified, 'using objects' was replaced by 'household treasures', 'golden expression cards' was replaced by 'thinking cards' and 'childhood' by 'my life'. 'My life' theme was incorporated twice in the programme, the first one focusing on childhood and the second one focusing on occupations. The overall format of the programme Version 1 was preserved, although it was suggested that the programme should incorporate activities that could be drawn on by different cultural communities. At the consensus conference, it was fed back that the way that CST was defined and how this differed to other cognitive therapies or other occupational activities normally run in day centres and care homes was not entirely clear. In response to this, '18 key principles' explaining the uniqueness of CST were developed by AS. These were subsequently included in the manual and used as an additional measure of adherence and continuous training for group facilitators and co-facilitators.

5.3.3 Draft Manual Version 3

The programme Version 2 was presented in nine focus groups. Full details in relation to methodology and results of this process are presented in chapter 6. The results presented in detail in the next chapter, were used to produce the manual for the MCST programme Version 3 of the programme. It involved the re-organisation of the different session themes in a different order according to service users opinions, and reclassification of the session themes that were planned to run twice during the 24 weeks of intervention. Two session themes (current affairs and thinking cards) that were originally planned to run twice on the Version 2 of the programme were reduced to once, and replaced by two session themes that were rated very highly in the focus groups with people with dementia: word games and household treasures.

5.3.4 Final MCST programme

As the final step of the Delphi process, 23 questionnaires were sent to the consensus conference participants. Six were returned and considering the multiple feedback processes inherent in the Delphi process, the potential exists for low response rates. Striving to maintain robust feedback can be a challenge as poor response rate is magnified fourfold as a maximum of four surveys may be sent to the same panellists (Witkin & Altschuld, 1995). All participants who replied to the survey felt that the draft Version 3 included all the elements discussed at the consensus conference and felt that would be a beneficial programme for people with dementia, as well as a useful tool for professionals working in the field. Although a low response rate was achieved in this survey, a

consensus about the long-term maintenance programme being appropriate was expressed by the number of professionals that replied.

The feedback from the surveys resulted in some minor editorial changes and survey participants expressed their concerns about preparation time in order to run the sessions. They suggested that in order to make the manual more user friendly for staff, the appendices of the manual could be extended. Appendices were added with: resources for each session, and guidance for co-facilitators of CST, recommending steps to help prepare for the sessions, and procedures to follow when co facilitating a group. Following the feedback from these questionnaires the final Version of the Maintenance programme was prepared. Table 5-2 shows how each theme within the programme has evolved through the different developmental stages from Version 1 to final version.

5.4 Discussion

This phase 1 study shows that it is feasible to develop a psychosocial therapy as a complex intervention following the MRC (2008) guidelines using the three stages: identifying the evidence, developing the theory and modelling. The original framework of the MRC (2000) identified describing, designing and applying an intervention with proper definition as: “the most challenging part of evaluating a complex intervention and the most frequent weakness in such trials.” By developing a programme following the framework, we have ensured that the intervention’s development has been taken to the where there would be reason to believe that it would have a worthy effect. Although several studies have described using the MRC framework for the development of their

intervention, the interpretation of the content and purpose of phases seems to differ between the studies (Rowlands, 2005; Robinson, 2005; Haw, 2007). It appears that carefully developing complex interventions is regarded as best practice, but details of how to achieve phase 1 (review of theory and evidence) and modelling of the framework are lacking.

The specific model (Figure 5-1) shows the use of mixed methods along phase I: the use of a systematic review; qualitative methods including the involvement of service users through the consensus conference and focus groups; and a final Delphi survey. The involvement of service users being has practical advantages intervention's evaluation's future and is also ethically preferable. Selection and retention would probably be better if the intervention is considered valuable by candidates of participation, apprehensions about judiciousness are addressed and knowing that the evaluation is supported by community leaders in the case of community-based interventions (MRC framework 2008). The use of focus groups as a modelling exercise to prepare for the trial, also allowed us to think about implementation at an early stage (before the expensive and cumbersome evaluation process is embarked upon) as recommended by some studies (Glasgow et al., 2003; Tunis et al., 2002). Although awareness about the role of qualitative research in evaluation and design of interventions is growing, nevertheless in light of a recent methodological research of the employment of randomly controlled trials of complex interventions along with qualitative methods (Lewin et al., 2009) less than a third of shortly ended complex intervention trials in the register of Cochrane Effective Practice and Organisation of Care had some elements of qualitative research. Nearly two

thirds of these were published studies. The research may contribute to the notion that the research's earlier phases, like trials measuring effectiveness, do not require the incorporation of studies of quality, as an exploration of the contextual's effects and other factors inflicting moderation.

5.5 Limitations

The number of questions we sought to answer in relation to developing the theory from our literature review and the limited resources we found from the included studies meant relying predominantly on expert knowledge. The generalisability of the qualitative results may also have been limited as our consensus conference steering group relied on individuals participating, and the small number of participants in the focus groups. Definitive evidence of effectiveness of the intervention requires an evaluation in an RCT. We now have an intervention worthy of further evaluation although comprehensive development of intervention is not synonymous with efficacy. Harderman et al., (2005) developed an intervention for encouraging possible diabetes patients to take more physical activity and followed the MRC framework but the intervention was subsequently shown to be ineffective in an RCT. Therefore, the results of the maintenance CST RCT (Phase III) are needed before drawing conclusions about its effectiveness.

5.6 Conclusion

This phase I study demonstrates that an evidence-based approach, tempered with the input of experienced professionals and input from service users, is feasible and productive. The involvement of people with dementia ensured that the maintenance CST sessions included in the programme were appropriate to

their preferences and abilities. The detailed manual to accompany the Maintenance programme has been prepared (Aguirre et al., 2011). A multi-centre RCT is the next step of this thesis, representing phase III of the development of a complex intervention (Aguirre et al., 2010), which evaluates the final version of the Maintenance CST programme.

CHAPTER 6

Service users' involvement in the development of the programme

This chapter describes the development of nine focus groups with people with dementia, family caregivers and staff working in dementia care settings. The results from the focus groups help to inform and develop the draft manual 3 of the MCST programme as described in Chapter 5 (Figure 5.1).

The chapter is based on the published article entitled: "Service user's involvement in the development of a MCST programme for dementia" (Aguirre et al., 2011) (Appendix 6.5).

6.1 Methods

6.1.1 Sample

Separate focus groups were made separately with the three main groups of users who constituted key stakeholders in the project. Three of these groups held the staff, three had dementia patients, and three held family carers of the dementia patients. 13 staff members, 17 dementia patients, and 18 family members took part in separate focus groups, constituting a total of 48 people. There were three males (23%) and 10 females (77%) in the staff groups, whose mean age was 36 years. They were all a residential home's permanent staff, day centre or day hospital specialised in dementia and they were all employed for at

least a month. One of their main duties involved caring for people with dementia as the main task. The dementia patients groups held eight males (47%) and 9 females (53%), with a mean age of 78; they all scored mild to moderate on the CDR (Clinical Dementia Rating) Scale (Hughes, 1982) and had the ability and were willing to take part in the focus groups. The last set of groups, that of the family carers, consisted of six males (33%) and 12 females (67%), with a mean age of 53 years. They were all former or current carers of a person with dementia and had contact at least once monthly during time as a carer. Sampling was done with the purpose of ensuring a wide range of participants. E.g., family carers composed of both females (N= 12) and males (N= 6); and carers having at least ten years of experience as well as novices; those who tended to patients having Alzheimer's type dementia and those caring for someone with other types of dementia. The selected centres were of typical organisational structure, size and management. Here recruitments were done through local organizations dealing in carers (Uniting Carers for dementia and Alzheimer's Society), from these groups' managerial committees oral permission was also sought. Three organisations' managers accepted the invitation to participate in the study.

6.1.2 Procedure

The Noticeable Problems Checklist (Levin, 1989) was used to screen the dementia patients. The consent of potential participants was sought and they were screened further with the use of CDR. All those participants with a CDR score of mild to

moderate were accepted to take part, provided they were not characterized to be disqualified from the study (having a severe learning disorder, anxiety, depression or other physical or mental illness), and had indicated their willingness to participate in discussion groups. Seventeen participants fulfilled the criteria for inclusion and were willing to participate. All staff members from the different approached centres were invited to take part in the groups when they were working directly with dementia patients. 18 caregivers of families were recruited through Uniting Carers for Dementia and the Alzheimer's Society. Continued assent was obtained in that participants were reminded that that they could leave the group whenever they wished.

Two members of the research team conducted self-contained, hourly focus groups. Brief presentations elaborating the characteristics of the project were given as the sessions commenced. The interview was led by one member while the other's task was to listen actively and seek clarification, ensure accuracy and adequacy of the interview's content (Morgan 1997). It was also the second person's responsibility to take methodological and substantive field-notes in the process of the focus groups as well as after them, as Burgess recommended (1984). The CST's empirical literature formed the base of the interview's structure, which was used as cues for open questions. The groups focused on the 24 themes developed for the maintenance CST programme and the cognitive stimulation definition by Clare et al (2004).

Design

A focus group interview schedule was made and designed as the discussions' framework, after being piloted and adapted. A design of focus groups was made preferably over individual interviews, because they are useful tools as discussion stimulants (Bowling, 1997). Participants were asked various questions, covering a variety of aspects of mental stimulation activities. The focus group began with a presentation of the programme on a DVD followed by a series of open questions like "what do you think about use it or lose it / mental stimulation?", "What kind of things do you find mentally stimulating and you enjoy doing?" Pictures and materials used in the different themes and activities were used as discussion stimulants. The family carers and staff members groups made use of the same schedule, but questioned the participants on the kind of activities / themes they felt would be successful among people with dementia.

6.1.3 Analyses

The interviews were recorded on tape and later written down. The facilitator then reviewed the transcripts. The notes taken by the second facilitator were consulted when appropriate during the process, in order to clarify the context of a particular discussion (e.g. benefits of being part of a group that were expressed by people with dementia focus groups). The authors used an data driven inductive analysis (Boyatzis, 1998) in this study to code and analyze the data. Inductive analysis or "looser" analysis allows the data to yield themes and is of use when the intention is descriptive and exploratory as in this case. The qualitative focus group's research is flexible, inductive and open-ended by

nature, responsive to each unique session's flow. The focus group's inquiry system, like many quality research methods, leaves participants free to provide information that is not relevant to the research. This openness is what leads researchers to new and unexpected information (Sofaer, 1999).

To develop a thematic codebook, researchers immersed themselves in the transcripts and re-reading to gain deeper understanding and familiarity with the content. One transcript was revisited and analysed into exclusive *in vivo* categories; that is, one theme was applied to one unit of meaning and the words used by the participant were adopted as the label of the theme. These themes were then applied to the remaining transcripts using a method of constant comparison to refine themes within the coding manual. During this process, more conceptual themes were split into subthemes whilst others were linked under one category depending on the emphasis placed on each theme within the transcripts. The resulting coding manual provided a meaningful way of understanding the views of the participants and assessing similarities and differences across the different groups (people with dementia, staff and family caregivers). All transcripts were encoded separately by both readers using the final codebook (EA and ASt) and then 100% consensus was reached upon by comparing the two.

6.2 Results

Thematic analysis revealed themes relating to perceptions and opinions of 'mental stimulation/ use it or lose it'; 'examples of mental stimulating activities of daily life'; 'factors influencing successfulness and unsuccessfulness of a mental stimulation

activity’ and ‘opinions and perceptions of specific themes of the presented MCST programme’. Patterns of themes were found among the different groups (people with dementia, family caregivers and members of staff).

6.2.1 Mental Stimulation; “Use it or lose it”

This included talking about their opinions with regards to mental stimulating activities and “use it or lose it” quote, in terms of their views and beliefs about the effects of keeping the brain active. There was general agreement among the different focus groups on the usefulness of keeping the brain active.

People with dementia expressed the view that keeping the brain active was very important and a way of relieving frustration. They also felt that it was essential for a healthy life, preserving their mental abilities and engaging with something that would keep the brain going. Some family carers expressed the view that the need for mental stimulation was universal and could bring neurological (building connections in the brain) and mental benefits (helping with mood, anxiety, depression) to everyone, it could be crucial to promote a healthy lifestyle and well being. Staff and family carers also felt that it could bring added benefits to people with dementia such as increasing confidence, giving a sense of achievement, satisfaction, retaining skills and enjoyment.

Nobody with dementia expressed any negative views about the value of the approach ‘use it or lose it’, however, there were some concerns expressed in relation to the importance of keeping the brain active from the members of staff and family carers groups, who gave examples of individuals where the idea of “use it or lose it” did not apply. Famous writers and politicians were used as

examples of people who maintained a mentally stimulating active life style, but developed dementia anyway. Some family caregivers expressed concerns about mental stimulation programs as they felt that people with dementia could lose confidence, experience anxiety or a sense of inferiority if confronted with their own cognitive deficits and problems through a challenging mental activity.

6.2.2 Perceived stimulation in everyday life

Listening to music, singing and dancing, reading, painting, drawing, cooking and knitting were highlighted as being important activities for PWD. Some factors that made them important included being interesting, enjoyable, relaxing effect and passing the time. Reading appeared to be a popular activity for most people with dementia as it raised their confidence and helped interaction and participation when being in a group. Talking and listening to others in particular appeared to be enjoyable and highly valued among people with dementia. They felt that talking either to someone, an animal or the TV helped them remained linked with important past and present relationships and helped them not to feel alone.

“Being part of a group helps considerably. I think being left on your own is not as effective as being part of a group. I belong to an African-Caribbean group and I find that very stimulating. We talk on a number of things what we have done and why we did it. I think talking is very important “

For family caregivers activities involving music, (e.g. listening to music, singing, tapping and clapping) was one of the activities that they perceived people with dementia enjoyed the most.

“Sounds and music are very important to stimulate something that’s there already so they recognise...”

(²FC: FG2; 183 -184)

Other interesting activities mentioned by the family caregivers group were the opportunity to enjoy dinner together and to have the opportunity to reminisce together looking at pictures or sharing memories.

“They learned a lot about others, everyone was telling their old past stories of how they went to school in shared shoes and things like this as a family. And we got so much information and it really stimulated them”

(FC: FG2; 232 – 238).

Staff caregivers felt that the planned activities they offered were the most valuable stimulating activities of daily living for people with dementia. Some staff members also named reminiscence as an the activity enjoyed by dementia

¹ PWD refers to the group “people with dementia”, FG1 refers to focus group number, and digits refer to line number within transcript.

² FC refers to the group “caregivers”, FG2 refers to focus group number, and digits refer to line number within transcript.

patients and something that they often busied themselves in. However, few understood its complete value since it was not linked to the present.

“I think we have to be careful with reminiscence, for me one of the best bits of this therapy is the variety of activities that you are going to do, otherwise it can get very repetitive as you tend to do things that you know work well, like reminiscence. You have to set goals within every session...”

(SC: FG1; 60 – 66).

6.2.3 Factors influencing successfulness of a cognitive stimulation programme

Perceptions about the main factors that made a CST programme successful were apparently based on beliefs and values related to their selves, routines and interests rekindling a sense of belonging and identity. The family caregivers and staff appreciated this where they stated that the philosophy of the programme should be person centred and enjoyment also seemed to be a measure of what made activities in the programme successful.

People with dementia gave importance to basic human courtesies; such as trying to make others happy and being kind, not underestimating participants abilities and kindness were valued.

“Nothing that involves cruelty. As long as there’s kindness you can’t fault it”

(PWD: FG1; 366).

Being able to discuss, learn and make contributions was also mentioned.

"I think it is very important to learn new things, you do not stop learning till you die"

(PWD; FG1; 669 – 672).

Other factors that were highly valued among the different groups were that activities in the programme included reminiscence as an aid to orientation and the activities being provided in a multisensory way using as many senses as possible. Activities that included discussion and sharing opinions among the group were highly valued as well as challenging activities, and quiz activities with a goal and based on right or wrong answers as a final goal.

*"Some people will remember more things than others, you know.
But it's good for the brain ..."*

(PWD; FG1; 576- 579).

In contrast family caregivers and staff participants groups stated that the activities in the programme shouldn't be based on right or wrong so people with dementia did not feel under pressure and "playing it safe" was perceived as being very important to help them feel more secure.

"You have to adapt to the person and never ask them to do anything they can't do because they have a sense of self and it will give them a sense of inferiority or inadequacy"

(FC; FG2; 90 – 94).

The staff mostly granted the importance of identifying each the individual likes and dislikes, abilities and skills of the participant, since this affected their activity level. Some on the other hand felt the need to employ adaptive activities suited to a participant's personal abilities in order to provide choice and contribute to their wellness. A few family caregivers insisted upon the importance of the provision of this programme to people only in the mild to moderate levels of dementia as they felt it shouldn't be appropriate for people in the more advance stages.

"The group participants should be of similar level of dementia"

(SC; FG2; 176).

They also felt that people of the group should be chosen with similar abilities and interests in order for the group to run successfully and to be stimulating and enjoyable for the participants. Staff and family carer groups noted that attention needed to be paid to the level of hearing and vision impairment for each participant as they felt people with high levels of impairment wouldn't be able to participate.

"You have to think about the personality dynamics within each group"

(SC: FG2; 109).

Staff and family caregivers also indicated that the group facilitator's skills, knowledge; understanding of dementia and attitudes towards participants was also a key to run groups effectively. The need for a number of facilitators was mentioned as well as the importance of having a small group of participants.

Appropriate equipment was also identified as a key factor for the successfulness of this programme.

“I think the size of the group has to be pretty small as an important factor”

(FC: FG2; 388 – 391)

6.2.4 Presented themes

A total of 19 themes were presented to the different focus groups of people with dementia, family caregivers and staff. Fourteen themes were from the existing CST programme. Five new themes were developed from the literature review and the pilot MCST study (Table 6-1).

The five new maintenance themes.

Useful tips, thinking cards and using objects were rated as very positive themes among people with dementia. People with dementia stated that they were good for learning, hearing other people's opinions and giving their own opinions in the group. They felt that it would help the group cohesiveness and it will trigger conversation. Family caregivers and staff groups also felt that useful tips and using objects would be a good theme for the session and they highly valued the involvement of reminiscence in the activities as an aid to orientation. Some staff felt that the thinking cards theme would not work but others said that it would be because they do not give enough credit to people with dementia. Some family caregivers felt that the proposed activities for this theme wouldn't be appropriate as some people did not like 'closing your eyes and imagining' and they felt people might feel uncomfortable with that. Other carers liked it and felt

that the questions were a good way of stimulating conversation and that it might help the group cohesiveness.

Visual clips discussion and art discussion were rated as neutral themes for the people with dementia. Although they liked the idea of group discussion, they did not feel enthusiastic about the topics presented. Staff and family caregivers groups rated these themes very positively as visual prompts were highly valued and they liked the idea of promoting discussion. Some staff said that they had previously run this kind of activities and it worked very well with a dementia patients' group if the materials were chosen appropriately.

Existing 14 CST themes

Eleven themes were rated well by all groups as they all promoted reminiscence. Participants were asked to rate and organise the presented themes as very positive, neutral or negative and rank them in order where at the top of the list they include the perceived most successful themes and at the bottom the least. My life (childhood and occupations), food and orientation were perceived as positive themes as they were applicable to everyone, helped people to keep in touch with themselves and were multisensorial. Quizzes and word games were rated very highly among people with dementia as they felt that were very stimulating and helped the brain working and "ticking together".

Table 6-1. Presented themes and comments from service users

Maintenance session	V2	V3	PWD	Staff	Family carers
New sessions themes					
Useful tips	11 & 24	11 & 24	*Excellent: discussion (learn and teach) & reminiscence	*Excellent: discussion (learn and teach) & reminiscence	Good: some concerns about healthy tips
Visual clips	13	13	Not interested	Good theme	*Very good, discussion, reminiscence and multisensorial
Thinking cards	12 & 22	12	Very good	Mixed opinions, down on list	Mixed opinions
Art discussion	14	14	Mixed emotions	Mixed emotions: will generate discussion	*very good, discussion
Using objects	10	10 & 22	Very good	*Excellent theme: discussion & reminiscence	*Excellent theme: discussion & reminiscence
CST sessions themes					
Physical games	8	8	Very good	Very good	Very good
Sounds	7	7	Very good	Very good, music & multisensorial	Very good, music & multisensorial
Childhood	1 & 23	1 & 23	Good, enjoyable	*Very good: multisensorial & reminiscence	*Very good: multisensorial & reminiscence
Food	3 & 17	3 & 17	Very good	*Very good: multisensorial	*Very good: multisensorial
Current affairs	2 & 21	2	Very interesting	Mixed emotions: needs to include reminiscence	Mixed emotions, not for everyone. Needs to include reminiscence
Faces/scenes	15	15	Very successful (discussion & reminisce)	Very good theme: discussion	Very good theme: discussion, recognition
Associated words	18	18	Very good	Very good at the right level	Very good
Being creative	4	4	Fun	Good theme, some dangers (not for everyone)	*Very good Multisensorial
Categorizing objects	9	9	Mixed emotions	Very successful (discussion & reminisce)	Very successful (discussion & reminisce) group cohesiveness
Orientation	19	19	Very good	*Very good: discussion & reminiscence	*Very good: discussion & reminiscence
Using money	20	20	Very good	Mixed emotions, sensitive topic	No good topic
Number games	5	5	No popular	Mixed opinions, some dangers (not for everyone)	Mixed emotions
Word games	16	16 & 21	* Excellent activities	Very popular, good	Good activity, pay attention to presentation
Quiz	6	6	* Excellent theme	Very popular, good	Good

Physical games, sounds, faces and scenes, categorizing objects, associated words and being creative were also rated positively by all groups as they were good for stimulating recognition, reminiscence and discussion, were a useful tool as multisensorial stimulation and would be good to keep healthy and active.

Number games was the only theme rated very low by people with dementia who said numbers were not something they related to very well, were a bit meaningless to them and it would not be something of their choice for activity. Family caregivers and staff felt the same way and sometimes in their experience it required one to one work and something that could frustrate people with dementia, and unless there were prizes people with dementia wouldn't see the point.

Using money and current affairs were rated very low by the family caregivers and staff groups but were rated highly by people with dementia. Some family caregivers and staff participants said that often people with dementia do not relate to current affairs (due to the disease), that it would be meaningless to them to be presented topics about current news and they said it would only work if using reminiscence was used as an aid to current information. People with dementia on the other hand expressed a great interest in current affairs and stated that they loved reading the newspaper. People with dementia also stated that they would enjoy talking about the value of money, and there were spontaneous comments about the value of money and the cost of bus journeys years ago and today. Family caregivers and staff in contrast felt that money was too complicated and wouldn't be a good theme as it could be a very sensitive topic for some people with dementia.

6.3 Discussion

This study uses a novel approach to refine an existing psychological intervention programme to investigate opinions, qualities and types of activities which to make a cognitive stimulation programme more effective and appropriate for people with dementia. Using focus groups may be advantageous since sharing experiences may lead them into recalling their past; while the downside is possible that short-term memory and verbal communication is employed, which dementia patients are impaired of (Murphy, Killick, & Allan, 2001).

Opinions about mental stimulation programme and key factors for success

People with dementia felt that keeping the brain active was essential to them as they acknowledged that it helped with their losses and memory difficulties. This finding is supportive of Barnett's (2000) belief that memory loss leaves dementia patients bereaved which makes them cherish the chance of being listened to. It expresses the importance of being in a group for them. In this line some other researches indicate that older people in care give a lot of importance to socializing (Atwal et al., 2003; Cummings, 2002; Jonas-Simpson et al., 2006). People with dementia gave quality communication a lot of value, particularly while being part of a group and feeling a sense of belonging, echoing Kitwood's (1997) theories, that claimed positive interactions to rekindle dementia patients' personhood.

Family carers and staff members on the other hand expressed mixed opinions about the effectiveness of keeping the brain active giving examples of public

figures where it had not prevented dementia and felt that attention to detail should be given to the factors that would make a programme successful or unsuccessful for people with dementia. Participant characteristics (level of dementia, sensory impairments, personality, interests, life history); facilitator characteristics (knowledge about dementia, group skills, and personality); group size and materials (multisensorial prompts, age appropriate) were listed as the main factors to be taken into account when planning a CST group.

Opinions about specific themes in the programme

General agreement was found among the groups with regards 14 themes rated high in the different focus groups. Several common elements were identified in some of those themes: use of reminiscence, good use of multisensorial stimulation, promotion of discussion and sharing opinions and good to keep active and stimulation the brain.

Themes that included reminiscence (e.g. orientation, childhood, useful tips, using objects) were a popular and important element of the programme for people with dementia, family caregivers and staff and it's use is widely supported throughout intervention of psychosocial nature in caring for dementia patients (Woods, Spector, Jones, Orrell, & Davies, 2006). However, its benefits are not supported by quality research (Livingston, Katona, Johnston, Lyketsos & Paton 2005; Woods, 2006) leading to it being seen "easy option", which can aid in the distraction of old people from their worries (Coleman, 2005). Special attention must be given when running a CST programme in order to use reminiscence always as an aid to current orientation. The focus groups made it evident that another element that was valued among the different focus

groups was the use of multisensorial prompts (e.g. sounds, physical games, food, faces / scenes, being creative). This is supported by a multisensorial stimulation randomised control trial, which was found to be an effective and appropriate therapy for people with dementia (Wareing et al., 2001).

Another element of importance was opportunity for discussion, talking and sharing opinions about presented materials (e.g. art discussion, visual clips, orientation, being creative, faces/ scenes). A condition of 'flow' was described by Csikszentmihalyi (1993), which is characterized by deep involvement and pure engagement and in achieving a challenge that is manageable. He discovered that singing and conversing with friends and family are some of the commonest experiences that are characterized by this state. They also state that having discussion and having someone to talk to generated a sense of belonging to the group and would help for group cohesiveness working against the association of older people with stereotypes of the negative kind (Higgs & Gilleard, 2000), dementia patients particularly are victims of the "malignant social psychology" of dehumanization and exclusion (Kitwood, 1997).

Among the themes perceived and described as being especially stimulating in getting the brain working were associated words, word games and quizzes, themes that people with dementia rated the highest. It seemed that for people with dementia it was very important to experience the feeling of getting the brain working and they valued the activities that stimulate their minds. This finding suggests that people with dementia support and believe the Cicero's suggestion in his essay "De Senectute" that old men preserve their intellects if they preserve their interests. Dementia is characterised by declining cognition

but nevertheless people with dementia often reserved cognitive function capacity, and even though this capacity is definitely not unlimited, it can nevertheless be generated (Katzman et al., 1988; 1993). The person should be led to benefiting from mnemonic and cueing strategies through this reserve strategy.

Using money and current affairs were two themes rated very low by family caregivers and staff and judged not appropriate for people with dementia, who felt that using money could be a sensitive topic for dementia patients. In contrast, dementia patients expressed a strong interest in the using money theme. Similarly, staff and carers felt that current affairs was a theme that people with dementia wouldn't relate to, whereas people with dementia expressed a great interest in the news.

This difference in opinion about what people with dementia wanted to do and what staff and carers felt they ought to do, has implications for empowerment in people with dementia. In recent years there has been a lot of work demanding the rights to 'personhood' and autonomy for dementia patients (Kitwood 1995, Marshall 1997, Kitwood 1997, Rafferty 1997). A few scholars have also studied dementia and empowerment (Chapman 1993, Goldsmith 1996). Their studies' objective was to seek service user's opinions to improve the maintenance CST programme providing more patient involvement, choice and control. Number games were rated low by all groups including people with dementia but some suggestions from staff and family carers included in the modification of the programme was to introduce prizes to make the game more fun orientated and

dynamic, and to draw the exercises and activities for the programme from TV and radio number games programmes.

6.4 Limitations

Staff groups included managers or senior carers with the other members of staff. This might have had an impact on opinions, expressed by the staff in the focus groups. Participants sometimes appeared reluctant to give personal examples, perhaps afraid to let other group members in on their personal matters – a disadvantage of employing focus groups. The data were analysed by two people, allowing consistency but failing to provide a multitude of opinions. While employing this procedure in another study, the data's encoding could involve more people. We analysed thematically because this method identified, analysed and reported patterns in the given data. Although thematic analysis is widely used, there lacks consensus regarding its precise methodology (Tuckett, 2005).

6.5 Conclusion

The user focus groups' main findings relative to a maintenance CST programme is clearly supportive of guidelines that NICE recently announced on dementia (NICE-SCIE, 2006). They express that all dementia patients belonging to the moderate or mild level should be "given the opportunity to participate in a structured group cognitive stimulation programme". Dementia patients found this chance to be a part of this programme of mental stimulating highly valuable, considering it vital to their good health and activity level. However, our findings suggested that for family carers and staff, there were some concerns with

regards the effectiveness of this type of programme. Staff and family caregivers felt that a person centred approach, multisensory stimulation, and reminiscence were all important aspects of this type of programme. They felt that the group should be kept to a minimum of participants therefore maximizing the opportunity for all participants to feel comfortable with the activities proposed. Positive agreement was found among 14 themes and suggestions were made for the 5 remaining new themes. These results were used to revise the manual for the maintenance CST programme as described in Chapter 5.

CHAPTER 7

Programme evaluation; methods

This chapter describes the methodology used for the evaluation of the MCST programme described in Chapter 5 (Figure 5.1) and it is based on the published paper (Appendix 6.6) entitled “Maintenance Cognitive Stimulation Therapy (CST) for dementia: A single-blind, multi-centre, randomised controlled trial of MCST vs. CST for dementia” (Aguirre et al., 2010).

7.1 Procedure

7.1.1 Design

The design was a single-blind, multi-centre, randomised controlled trial of Cognitive Stimulation Therapy (CST) groups for dementia vs. MCST groups (Figure 7-1). After completion of the initial CST programme (twice weekly, 45-minute sessions for 7 weeks) representing the Phase 1 trial, participants were randomly allocated into the treatment group (maintenance sessions once a week for 24 weeks) or control group (treatment as usual for 24 weeks), Phase 2 trial.

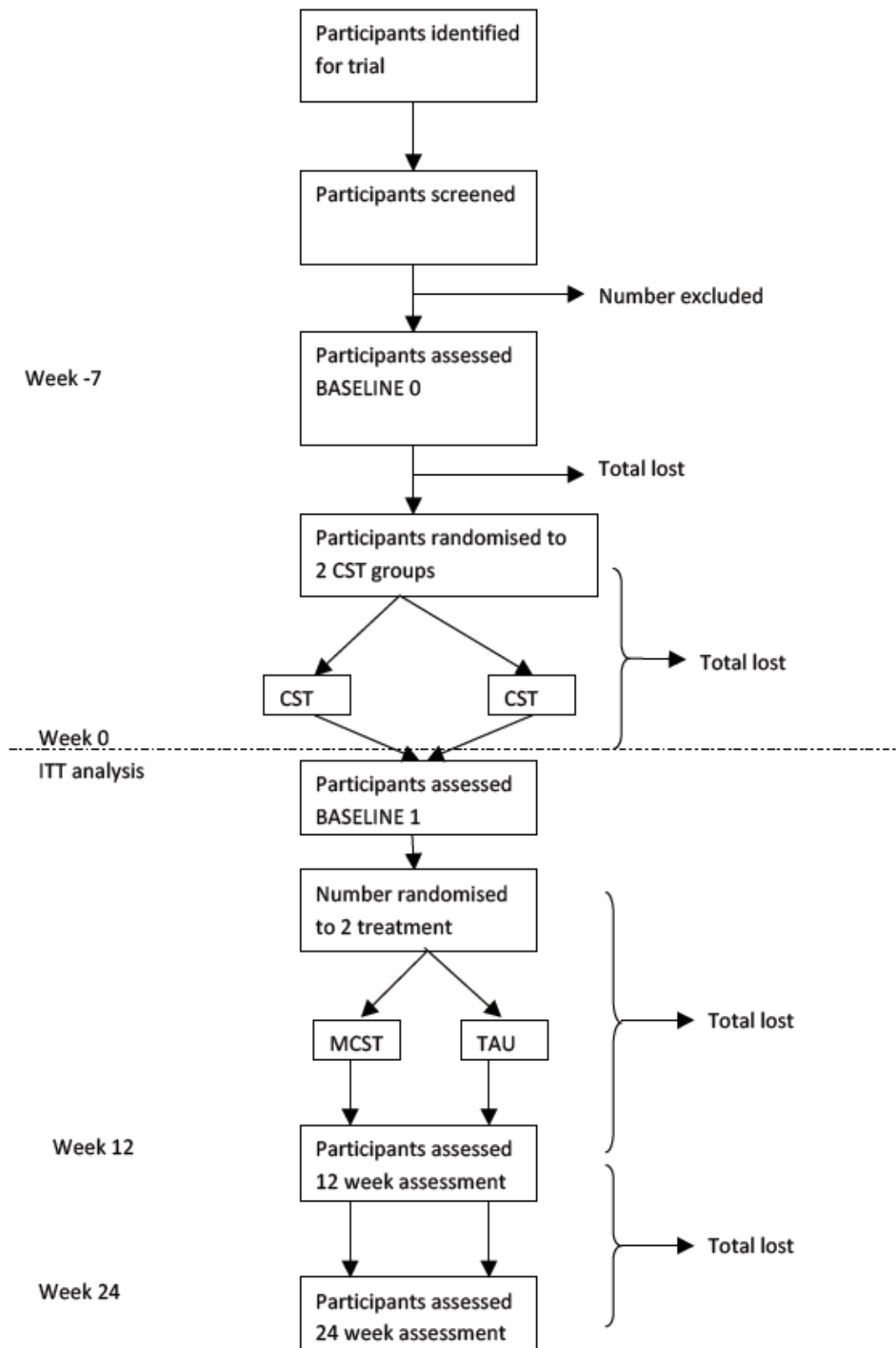


Figure 7-1. MCST trial flow chart

7.1.2 Centre recruitment

Recruitment to this trial took place through day centres, residential homes and Community Mental Health Teams (CMHTs) in the participating study centres, with at least a minimum of 14 potential participants per site. Half of the sample (50%) were recruited from the community, including day centres, Community Mental Health Team (CMHTs) and voluntary sector and the other half of the sample (50%) from care and residential homes settings.

7.1.3 Inclusion criteria

Within each centre, all participants referred by managers were screened in discussion with the manager or a nominated member of staff who knew the participants well. It was anticipated that a large proportion of participants would meet the DSM-IV criteria for dementia (APA, 1994), despite the absence of a formal, recorded diagnosis of dementia. An inclusion criteria flow chart was used to identify all eligible residents (Appendix 5.1) that included the following tools.

The National Institute for Social Work (NISW) Noticeable Problems Checklist (Levin et al., 1989) was used as an initial screening tool (In appendix 5.1). This Checklist consists of six items related to the person's ability to: remember recent events; work out how to do basic everyday tasks; know the time; know where s/he is; correctly name people s/he regularly sees; and to keep in touch with a conversation. It is scored from 0- 6, with a score of 0 to 1 indicating no dementia, 2 to 4 indicating possible dementia and a score of 5 or 6 indicating probable dementia. Residents who scored 0 or 1 on the NISW were excluded

from the study. The patients with probable and possible dementia were then further evaluated by a researcher through discussion with relevant staff and review of the case notes, to establish if they fulfilled the DSM-IV criteria for dementia (APA, 1994) (In appendix 5.1). To meet the DSM-IV criteria an individual had to experience memory impairment, plus at least one of the following cognitive problems: aphasia, apraxia, agnosia, or disturbance in executive functioning. These cognitive deficits needed to have caused a significant decline and impairment of social or occupational functioning for the individual over at least six months. Those who met the DSM-IV criteria were screened further using the Clinical Dementia Rating scale (CDR) (Hughes et al., 1982). The CDR (In Appendix 5.1) is a global rating of the severity of dementia. Six domains: memory; orientation; judgement and problem solving; community affairs; home, hobbies and interests; and personal care, are each rated as: 0 = no impairment; 0.5 = questionable impairment; 1 = mild impairment; 2 = moderate impairment; 3 = severe impairment. A score of between 0.5 and 2 was established in order for participants to be included in the study. It only takes five minutes to complete and its correlation with other cognitive assessments is highly significant (0.57 to 0.84, $p < 0.0001$) (Hughes et al., 1982). Hughes et al. (1982) also demonstrated good inter-rater reliability ($r = 0.89$), and this screening measure is accepted as the gold standard for use in research involving people with dementia (Burns et al., 2004).

Those participants who scored between 0.5 and 2 were screened further using the inclusion criteria flow chart (In Appendix 5.1). Participants meeting all the

inclusion criteria were approach and if consent given they were recruited into the study.

Participants were considered suitable for full assessment and participation if they:

- 1) meet the DSM-IV criteria for dementia (American Psychiatric Association 1994)
- 2) score between 0.5 and 2 on the Clinical Dementia Rating (CDR) (Hughes et al., 1982)
- 3) have some ability to communicate and understand communication
- 4) were able to see and hear well enough to participate in the group and make use of most of the material in the programme, as determined by the researcher
- 5) did not have any major physical illness or disability which could affect participation
- 6) did not have a diagnosis of a learning disability.
- 7) were able to communicate in English

People with dementia meeting the inclusion criteria and who consented to take part in the study, giving signed informed consent in accordance with the provisions of the Mental Capacity Act 2005, were recruited into the trial and randomised to take part in any of the two CST groups that were running per centre (7 to 10 per group) representing phase 1 of the trial.

People with Alzheimers disease were offered cholinesterase inhibitors by their local clinical team provided that they were willing and eligible (according to

NICE guidelines 2006), for the medication. People currently on cholinesterase inhibitors continued taking them.

7.1.4 Randomisation

The randomisation process in this trial was undertaken in two stages, randomisation 1 and randomisation 2. These led to each trial stage; trial stage 1 (before and after CST) and trial stage 2 (after randomisation into treatment group – MCST and control group). Figure 7-1 sets out the two-stage randomisation process. The allocation ratio at randomisation 1 stage was 1:1; into either group A or group B, with both groups receiving 7 weeks of CST. The aim of randomisation 1 stage was to reduce the intra-class correlation coefficient, therefore increasing the variability within the two CST groups and ensuring that any change between baseline 1 and baseline 2 was due to the intervention, therefore reducing any bias. The allocation ratio at randomisation 2 stage was 1:1; into either the control group or treatment group. The sample was stratified to ensure that equal numbers of participants taking cholinesterase inhibitors were randomised into either the MCST or the control group. The second randomisation was also stratified by the first randomisation result to ensure that the group cohesion (or dislike) was not carried over in the next stage of the trial (stage 2).

The North Wales Organisation for Randomised Trials in Health (NORTH) was responsible for undertaking the remote randomisation. NORTH is accredited as a Clinical Trials Unit by the UK Clinical Research Collaboration (UKCRC) and

funded as part of the Clinical Research Collaboration Cymru, notably for HTA trials.

7.1.5 Blinding

Participants couldn't be blinded to their allocated treatment but all follow-up data since the beginning of the maintenance groups, was gathered by interviewers blind to groups. However as previous experience has shown, participants may occasionally and inadvertently inform researchers of the intervention they are receiving. Explicit reminders to participants before the assessment visit and by the use of self-report measures wherever feasible was used.

7.1.6 Intervention

The CST intervention was designed following extensive evaluation of the available research literature and clinical evidence and described in Chapter 1. The Maintenance Cognitive Stimulation Therapy (CST) programme is an evidence-based maintenance group therapy programme for people with dementia and its development and structure has been defined in Chapter 5.

Each CST and MCST group was run by two facilitators, one from the SHIELD research team (main facilitator) and a co-facilitator who was a member of staff from the recruited centre (e.g. care home, day centre). The main facilitators had at least one year of experience in dementia care and often had a mental health nursing, occupational therapy or clinical psychology background, experience in dementia care and group facilitation skills. The use of two facilitators for each group enabled effective de-briefing and reflection to occur at the end of each

session. All facilitators attended a one-day CST training developed by one of the CST pioneers (AS) as part of the dissemination strategy. The training provided a detailed background and description of CST, and used learning methods including group observation, role-playing and small group exercise. Further details of the training day can be found in Chapter 4.

7.1.7 Usual Care

The participants allocated to the control group received intervention as usual in the stage 2 of the study. This varied between and within centres and change occurred over time, but in principle, the interventions offered to this group were also available to those in the active intervention groups. Therefore, the trial examined the additional effects of MCST. Our approach to costing the services and interventions received was used as a way of monitoring whether the treatment-as-usual group had been receiving similar therapeutic interventions. Use of antimentia medication was recorded as part of the costing information collected. It is possible that participants in the treatment-as-usual group were involved in some form of cognitive stimulation work during the 24 weeks of the study stage 2 period. However, it is very unlikely that such a structured approach to CST was offered in any of the centres. It is this systematic group-based approach that was the focus of this evaluation.

7.2 Ethical arrangements

Risks and anticipated benefits for trial participants

There appear to be no documented harmful side-effects from participating in CST groups, and no serious adverse reactions were apparent in the CST study.

Benefits were consistently reported by participants in the groups, including enjoyment, feelings of validation and self-worth (Spector et al., 2011). The inclination of participants to continue meeting following the sessions provided an indication of the value placed on the benefits. Prospective participants were fully informed of the potential risks and benefits of the project.

As the project was part of the SHIELD research programme, the SHIELD reporting procedure was in place to ensure that serious adverse events were reported to the Chief Investigator (MO). Upon becoming aware of an adverse event involving a participant or carer, a senior clinical member of the research team assesses its seriousness (JH). A Serious Adverse Event (SAE) was defined in the trial as an untoward occurrence experienced by either a participant or carer which:

- results in death;
- is life threatening;
- requires hospitalisation or prolongation of existing hospitalisation;
- results in persistent or significant disability or incapacity;
- is otherwise considered medically significant by the investigator;
- falls within the scope of the Protection of Vulnerable Adults (POVA) protocol which is in place to ensure that suspected cases of abuse or neglect are followed-up in an appropriate manner.

A reporting form (Appendix 4.3) was submitted to the CI who assesses whether the SAE is related to the conduct of the trial and is unexpected. SAEs that were judged to be related and unexpected had to be reported to MREC and the trial DMEC.

7.3 Consent

Inclusion criteria for recruited participants stated that participants needed to be in the mild to moderate stages of dementia according to the CDR scale (Hughes et al., 1982), and would therefore generally be expected to be competent to give informed consent for participation, provided that appropriate care is taken in explaining the research and sufficient time allowed for them to reach a decision. Wherever possible a family member or other supporter such as a member of staff from the day centre or care home was included. It was made clear to participants and family caregivers that no disadvantage could occur if they chose not to participate. In seeking consent, current guidance from the British Psychological Society (BPS) on evaluation of capacity were followed. In this context, consent had to be regarded as a continuing process rather than a one-off decision, and willingness to continue participating was continually checked through discussion with participants during the assessments. Where the participant's level of impairment increased, so that they were no longer able to provide informed consent, the provisions of the Mental Capacity Act 2005 was followed. The initial giving of informed consent provided an indication of the person's preference for participation in the research, and the family caregiver's viewpoint was also sought. If the person with dementia showed discomfort at any point with the assessments they were discontinued.

7.4 Assessment procedure

Interviews were carried out by a researcher employed to work on the SHIELD programme who was trained to undertake the assessment. Assessments took

place at participants home when people were living in the community or at the day centre or care home. All staff assessments were undertaken at the care home. Whenever possible, the person with dementia and the family caregiver or member of staff were interviewed separately. However, some family caregivers wanted to be present during the person with dementia's interview.

Using standardised instruments (section 7.5.), people with dementia were interviewed about their cognitive status and quality of life. This interview lasting for an average of 45- 60 minutes depending on the participant. Family caregivers and/or staff were interviewed about the person with dementia's sociodemographic details, behavioural and psychological symptoms, functional status, quality of life, mood, communication levels and services received. In addition, family caregivers were assessed about their own general health and quality of life. This interview took about one hour. At the beginning of each assessment the researcher started the interview reminding participants what the interview was about and answering any questions they might have. After that, at baseline assessment, informed consent was sought (see section 7.1.8). There was no particular order to administer the instruments, but usually the interview with the person with dementia started with the MMSE or the QoL-AD. In very few occasions, the assessment was stopped because the participant was feeling stressed or tired and a new date or time for continuing the assessment was arranged if the participant consented.

7.5 Outcome measures

Primary and secondary measures were completed at stage 1; baseline 1 (B1) and after the seven weeks of the CST programme (baseline 2, B2) and at stage 2; three months after beginning of the maintenance groups (first follow-up FU1) and six months after the beginning of the maintenance groups (second follow up FU2 and primary end-point T3).

7.5.1 Primary outcome measures

Cognition was measured using the Alzheimer's Disease Assessment Scale DAS-Cog (Rosen et al., 1984)(Appendix 5.2).

ADAS-Cog was designed to measure the severity of the most important symptoms of Alzheimer's disease (AD). It consists of 11 tasks measuring the disturbances of memory, language, praxis, attention and other cognitive abilities, which are often referred to as the core symptoms of AD. This is a brief, widely used test of cognitive function, with good reliability and validity (Rosen et al., 1984). As this measure is often used in the evaluation of the effectiveness of drug trials, it was chosen as a primary outcome measure in able to allow to compare the results to anti-dementia drugs. The standardized scoring method (used in trials) from 0-70, with 70 indicating the most impairment.

Quality of life was measured using the Quality of Life—Alzheimer's Disease Scale; Participant and proxy report (QoL-AD) (Logsdon et al., 1999).

The QOL-AD (Appendix 5.4) is a self and proxy report of quality of life in people with dementia. The scale contains 13 items: physical health, energy, mood, living situation, memory, family, marriage, friends, self as a whole, ability to do chores around the house, ability to do things for fun, money and life as a whole.

Each item is rated on a four point scale; where poor = 1, fair = 2, good = 3 and excellent = 4, generating a total score from 13 to 52, with higher scores reflecting higher quality of life. The Participant QOL-AD scale is completed individually by the person with dementia using an interview format whilst following their own copy of the measure. The proxy QOL-AD is completed independently by the proxy as a written questionnaire. Originally developed in the USA, Logsdon et al. (1999) assessed its psychometric properties when used with 77 community dwelling, ambulatory patient-caregiver pairs showing good reliability and validity (Logsdon et al., 1999; Thorgrimsen et al., 2003).

The QOL-AD was therefore selected as a relevant and appropriate primary outcome measure to use in this study as it has good validity and reliability; has previously been used with care home residents who have dementia; and can be completed by people with MMSE scores as low as 3 (Thorgrimsen et al., 2003) and the INTERDEM collaboration recommended the QOL-AD in preference to other scales for use in clinical practice and as a research tool to evaluate psychosocial interventions in dementia care (Moniz-Cook et al., 2008).

7.5.2 Secondary Outcomes

Cognition using the Mini-Mental State Examination (MMSE), (Folstein et al., 1975).

The MMSE (Folstein et al., 1975) (Appendix 5.3) is a well-known rating scale of cognition, frequently used in clinical practice and in research studies (Burns et al., 2004). It screens orientation to time and place, registration of three words, attention and calculation, recall of three words, language, and visual construction and takes five to ten minutes to administer. Folstein et al. (1975)

established criterion and concurrent validity, inter-rater and test-retest reliability in a sample of 269 patients with mixed pathology. The MMSE's psychometric properties have been assessed, and the results reviewed by Tombaugh & McIntyre (1992). It has shown to have good reliability and validity (Tombaugh & McIntyre 1992). Scores range from 0 to 30, with 0 indicating the most impairment. Fillenbaum et al., 1998 suggest that refusal to answer questions probably indicates an inability to answer correctly; so unanswered questions were scored as zero.

Quality of life using the DemQoL (Smith et al., 2005)(Appendix 5.5).

This scale was developed in the UK, through a review of the literature, qualitative interviews and consultations, which included people with dementia, family caregivers, and experts in dementia. The aim of the measure was to provide a psychometrically rigorous measure of health-related quality of life in people with dementia. The scale measures five domains; health and well-being, cognitive functioning, social relationships and self-concept along a 4 point scale ranging from 1 (a lot) to 4 (not at all) and summed to produce a total score. The scale uses self-rated reports of quality of life administered to the person with dementia by a trained interviewer. This measure can also be administered to the family caregiver to provide the DEMQOL-proxy. It has high internal consistency (0.87) and acceptable inter-rater reliability (ICC 0.84) and indicates concurrent validity through moderate associations with the QoL-AD and DQoL.

Behaviour is assessed using the Neuropsychiatric Inventory (NPI) (Cummings et al., 1994).

The NPI (Appendix 5.6) is a structured interview designed to assess a broad range of behavioural and psychological symptoms commonly encountered in dementia patients such as delusions; hallucinations; dysphoria; anxiety; agitation/aggression, euphoria; disinhibition; irritability/lability; apathy; and aberrant motor behaviour (Cummings et al., 1994). The measure was rated by the researcher in an interview with the member of staff or family caregiver.

Its format includes screening questions that evaluate the presence or absence of a symptom. If the behaviour is absent, the clinician continues with the next question. If the behaviour is present, detailed information is asked. The frequency (range 1 to 4) and severity (range 1 to 3) of the symptoms in the last month are separately scored. Scores for each item can range from 0 to 12, with scores of 9 and above usually estimated as a significant problem. The NPI also assesses the impact of the participant behaviour on family caregiver distress. This tool has shown high internal consistency and reliability (Cummings et al., 1994; Cummings, 1997). The NPI has been indicated by the INTERDEM group as the measure of choice for assessing behavioural and psychological symptoms in dementia because it assess a wide range of behaviours and it has shown sensitivity to behavioural changes (Moniz-Cook et al., 2008).

Activities of daily living assessed using the Alzheimer's Disease Co-operative Study – Activities of Daily Living Inventory (ADCS-ADL) (Galasko et al., 1997)(Appendix 5.7).

The ADCS-ADL provides an evaluation of individual performance and autonomy in activities of daily living, either basic or instrumental (Galasko et al., 1997).

There are 23 items measured through informant-based observation of each action or behaviour. This instrument was completed with the family caregiver or staff and the items covered are related to activities of daily living such as eating, walking, toileting, bathing, grooming, dressing, telephone use, watching television, etc. The ADCS-ADL can be used to determine levels of functional ability across the range of dementia severity, which is scored between 0 and 78. Higher scores imply fuller functioning with a score of 78 indicating full function. The ADCS-ADL was included as a measure of ADL and can be used to demonstrate change in levels of dependency in all stages of the dementia process (Galasko et al., 1997).

7.6 Sample Size

In the CST trial (Spector et al., 2003) which recruited people with mild/moderate dementia (MMSE 10-24), community and institutional participants had a similar level of cognitive impairment (mean MMSE 14.5 and 14.1 respectively). The RO review (Spector et al., 1998) found a moderate effect size of 0.58 between the RO and control groups though the studies had some differences in methodology, outcome measures, and length of treatment/follow up. The MCST pilot study found a large effect size of 1.0 compared with CST alone. To detect an effect size for MCST of 0.39 on the ADASCog with power of 80% using a 5% significance level and an estimated attrition of 15% needed, a sample size of 230 after stage 1 trial at baseline 2 (BL2) was required. If an estimated 60 participants had Alzheimer's disease and were suitable/willing to take cholinesterase inhibitors (ACHEIs), this provided sufficient numbers for

the MCST/ACHEIs trial platform to estimate effect size and the feasibility of the trial.

7.7 Analyses

Assessments were scored and data entered into MACRO, an electronic data capture system that produces a fully auditable trail for the data from input to extraction for analysis. For cleaning and analysis purposes SPSS syntax was written to extract the relevant data from MACRO. No changes were made to the SPSS files. Analysis for this trial followed the intention to treat principles and all guidelines set out and required by the 2010 CONSORT statement (Schulz et al. 2010). Whether or not the participant received their randomised treatment the data were analysed within the group they were allocated to. Complete case analysis was used initially to establish the results and was followed by the work with imputations. Methods of imputation such as LOCF (last observation carried forward) are of limited utility in dementia, where the expectation is cognitive decline for the usual treatment group, and participants will be lost through death and illness. Hence our sample size calculations were based on the numbers estimated to be available at the study primary end-point (FU2), 6 months after second randomisation to either the CST only group or the MCST group.

In order to impute values for missing data the following methods were followed:

- 1) For items missing within measure the rules for completing missing data for the relevant measure were applied. The missing data rules implemented for

each measure were considered part of the validated tool and therefore were used as designed in line with the original validation.

- 2) Once the measure rules were applied there was only a missing time point data left. In this instance, a linear regression within treatment group was applied in order to impute the summary scores in line with the trend seen within the group. That is, the group line of regression was applied to the existing values for the participant. A sensitivity analysis was conducted on all data with values imputed. Multi-level modelling was used to address the issue of clustering within randomised groups. An analysis of covariance to adjust for baseline differences in outcome variables (Vickers et al., 2001) was also used. Secondary analyses considered the effects at 3 months (BL1) follow up.

For the purpose of the stage 1 trial a paired T-Test analysis was used in order to compare the before and after of CST for the whole group. Repeated measures was used afterwards, in order to assess whether any other variables were contributory factors to any detectable change between the before and after attending CST groups results. The Kappa statistic (chi square) was used in order to search for predictors of successfulness for CST (e.g. gender, living condition, etc).

For the purpose of the MCST effectiveness a mixed model ANCOVA analysis was used (Stage 2 trial). Age, gender, cholinesterase inhibitor and baseline scores on the scales being examined will be entered as covariates, together with 'centre' entered as a random factor, because treatment was defined as participation in the group programme within the confines of the centres. Within each centre

there was an experimental and a control group. This method was chosen because it controls for variability in pre-test scores (the covariate), meaning that undesirable variance in the dependent variable such as individual differences were estimated by scores on covariates. By providing these adjustments, the relationship between the dependent variable and covariates were removed from the error term.

Finally, in order to analyse if there was an effect between factors in the MCST-ACHEIS trial platform, the same model as for the complete analysis was used, including an interaction term between ACHEIS and the treatment group.

CHAPTER 8

Study stage 1 (before and after CST) results

This chapter describes the before and after CST programme results (first stage trial). The chapter is based on the published paper (Appendix 6.7) entitled “Cognitive Stimulation Therapy (CST) for dementia: who benefits most?” (Aguirre et al., 2012).

8.1 Participant flow and response rate

Figure 8-1 illustrates the flow chart of the participants and the response rate through the first stage trial. The results in this chapter are reported using the format outlined in the 2010 Consolidated Standards of Reporting Trials (CONSORT) statement (Schulz et al., 2010).

8.2 Centre enrolment

A total of 21 centres were initially contacted by post and follow-up phone-calls. Of these 21 centres, one refused to take part in the study and two were excluded as the centres did not have enough participants to take part in the study (minimum of 14 participants were needed at first stage randomisation). None of the centres expressed disapproval of the research project and all of the centres after first contact with EA expressed their intention to take part in the trial. A total of 18 centres were recruited by EA, enrolled and took part in the study trial (nine care homes and nine community centres).

From the recruited community centres, 4 of them were specialist dementia day centres from the voluntary sector: Jewish Care (3 centres) and Alzheimer's Society (1 centre). The other 5 community centres were part of the CMHT services of different areas East London NHS Foundation Trust (ELFT) (1 centre), Bedfordshire NHS Foundation Trust (3 centres) and Camden and Islington NHS Foundation Trust (1 centre). From the recruited care homes, 1 of them was a private care home (Care UK), 5 of them part of Social Services (Camden and Westminster boroughs) and 3 of them from a voluntary organization (Jewish Care). Full details of recruited centres can be found in tables 8.1, and 8.2.

Table 8-1. *Centre subtypes details*

Centre subtype	Number of centres	Number of participants (%)
Voluntary	7	122(45%)
NHS	5	70 (26%)
Social Services	5	66 (24%)
Private	1	14 (5%)
Total	18	272 (100%)

Table 8-2. *Centre details*

Centre type	Setting type	Frequency (%)
Jewish Care	Both	79 (29%)
Camden Social Services	Care Home	55 (20%)
Bedfordshire and Luton Partnership NHS Trust	Community	46 (17%)
East London NHS Foundation Trust	Community	18 (7%)
Camden and Islington NHS Foundation Trust	Community	16 (6%)
Alzheimer's Society	Community	15 (5.5%)
Westminster	Care Home	15 (5.5%)
Care UK	Care Home	14 (5%)
Redbridge Respite Care	Community	14 (5%)

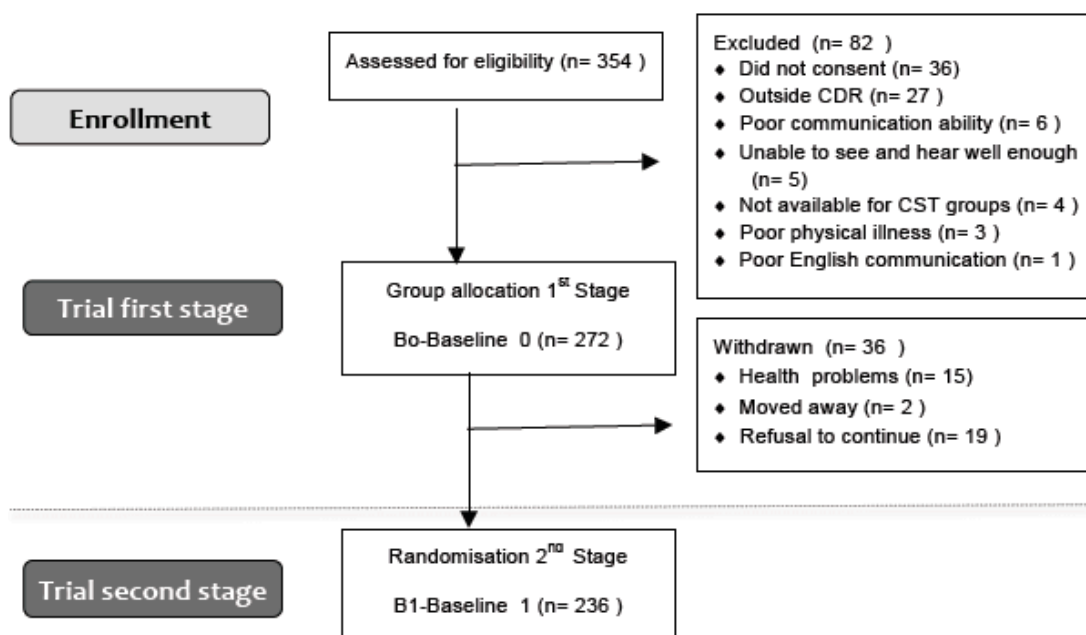


Figure 8-1. Consort diagram at Stage 1 study

8.2.1 Participant recruitment

Within the recruited 18 centres (9 community and 9 care homes), 354 participants were screened (Table 8.3) and 81 (23%) were excluded because: (1) had CDR outside 0.5-2 range (mild to moderate dementia); (2) were too hearing-impaired or visually impaired; (3) did not consent to take part; (4) had communication problems; (5) had major physical illness; (6) poor english communication and (7) other reasons. Table 8.3 summarises the outcome of the screening process, which identified a total of 272 suitable participants.

The above are the primary reasons for exclusion, although some people fell within more than one category. Approximately two to four people in each centre did not consent to take part in the study.

Table 8-3. Summary of the screening process outcome (n = 354)

Screening process		Frequency (%)
Eligible		272 (77 %)

Participants at BL0 (Before CST groups)		272
Not eligible	Reasons	81 (23 %)
	Did not consent	36 (45 %)
	Outside CDR 0.5-2 range	27 (33 %)
	Poor communication ability	6 (7%)
	Unable to see and or hear well enough	5 (6 %)
	Poor physical illness	3 (4 %)
	Other	3 (4 %)
	Poor english communication	1 (1 %)

8.2.2 Attrition trial stage 1

There were a total of 272 participants recruited at study stage 1 and randomised into either CST group A or CST group B. During the CST group 7-week period, a total of 36 participants were lost (Table 8.4), giving a retention rate of 85%. No participants over the 7-week period of the CST intervention were lost due to death, 15 participants were lost due to health issues and 2 due to moving to a different care home.

The remaining 19 drop outs, were lost due to group related issues, that is, not “liking the group setting”, not liking “other members in the group”, or not “liking the activities in the group” and consequently not attending CST groups at Stage 1 and wanted to withdraw (41%) and two participants (6%) not being able to attend the CST sessions as group time was conflicting with other activities the participant wanted to attend.

Table 8-4. *Summary of participants lost between study stages 1 and 2*

Participants at BL1 (After CST groups)		236
Total lost		36
Reason for withdrawal	Did not like CST groups and did not attend sessions and wanted to withdraw	17 (49%)
	Health issues	15 (40%)
	Inconvenience of group time or other participants	2 (6%)
	Moved to a different care home and wanted to withdraw	2 (6%)

The remaining participants, 236, entered the study stage 2 and were randomised to either receiving the intervention of MCST or control group (TAU).

8.3 Description of the sample

The mean age was 82.6 (SD 8.1, range 52 to 100), 177 (61%) were females; 113 (42%) lived in care homes and 159 (58%) in the community. Participants were mainly white (n=245, 90 %). Nearly half of the sample were widowed (n=127, 46.7%). All the participants met the diagnostic criteria for dementia (DSM-IV). There were 93 (34.5%) with Alzheimer's, 68 (26%) with vascular dementia, and 23 (8.5%) with other dementias (Lewy Body dementia, mixed type dementia, Korsakov's disease). A total of 88 participants (31%) had an unspecified type of dementia.

A total of 82 (30.1%) participants were receiving AChEIs with only 16 (20%) of these participants residing in care homes. Table 8.5 compares community and care home participant characteristics in terms of age, sex and gender and provides information about the total participant group. Most of the sample had moderate dementia with a mean MMSE score of 16.8, (SD 5.5), and a mean ADAS-Cog score of 34.3 (SD 12.9). The community group were less cognitively

impaired at baseline (MMSE 18.9, SD 5.7) and had a higher mean ADAS-cog of 30.5 (SD 13.1), compared with a mean MMSE of 16.2 (SD 5.1) and ADAS-Cog of 40.6 (SD 11.4) for the care home sample (Figure 8-2). The total sample scored in the mid-range on the QOL-AD (mean 36.3, SD 12.9) and DEMQOL (mean 93.4, SD 11.4). Mean scores were in the mid-range on the measures of dependency (ADCL 42.3, SD 17.7) and behavioural symptoms (NPI 16.0, SD 12.9).

Table 8-5. *Summary of participant's characteristics*

Characteristics	Community	Residential	All
Number of participants	159	113	272
Number prescribed AChEI	67 (42%)	16 (14%)	82 (31%)
Mean age (sd) [range]	81.6 (7.6)	84.7 (8.5)	82.6 (8.1)
Gender ratio F [%]	96 [60%]	81 [72%]	177 [61%]

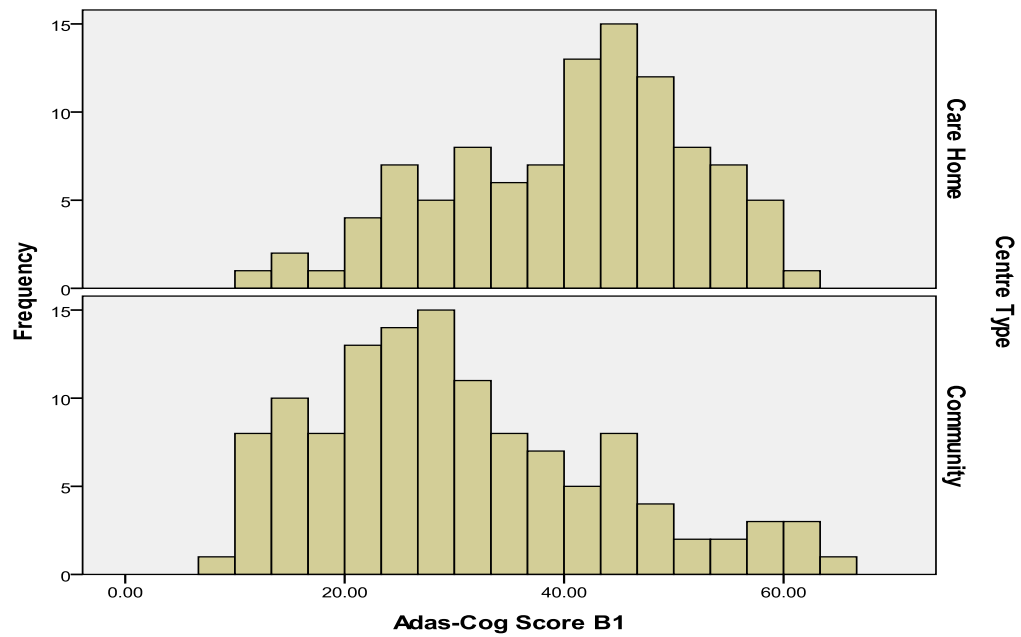


Figure 8-2. *Adas-Cog score at baseline according to centre type*

Table 8-6. *Differences before and after CST; values are given for the initial paired t-test*

Measure	n for IC	Before CST/Mean (SD)	After CST/ Mean (SD)	Mean difference (SD _{DIFF})	t value	P value
MMSE	270	16.73 (5.53)	17.83 (5.55)	1.09 (3.51)	5.12	<.001
ADAS-Cog	270	34.46 (13.39)	36.25 (5.51)	-2.339 (8.79)	-4.37	<.001
QoL-AD	270	36.33 (5.03)	36.25 (5.51)	-0.08 (5.24)	-0.26	.79
DEMQOL	270	92.89 (11.14)	94.75 (11.22)	1.85 (10.26)	2.30	.003
Proxy QOL-AD	272	32.85 (5.21)	33.45 (5.60)	0.60 (5.21)	1.91	.057
Proxy DEMQoL	272	97.98 (13.82)	102.23 (12.44)	4.25 (13.42)	4.84	<.001
ADCL-ADL	272	42.10 (17.37)	41.63 (18.15)	0.48 (9.45)	0.83	.40
NPI	272	15.17 (12.36)	13.05 (11.41)	-2.13 (13.82)	2.54	.012

8.4 Results

8.4.1 Differences between before and after the CST programme

Paired t-test imputed case analyses showed a significant difference between before and after scores for both cognitive measures (MMSE and ADAS-COG) ($p < .001$); and quality of life scores as measured by the DEMQoL participant completed versions ($p = 0.003$) (Table 8.6) but not on the self completed QOL-AD ($p = 0.79$).

Paired t-test analyses showed a significant difference before and after CST in behaviour (NPI) ($p = 0.012$) and quality of life (DEMQoL proxy versions) ($p < .001$) but not for the QOL-AD proxy ($p = 0.057$) (Table 8.6). There were no differences between the pre-post scores in terms of activities of daily living (ADCS-ADL). Living situation (care home/community) emerged as a significant covariate in relation to a number of staff rated scales and was taken into consideration for the analysis.

8.4.2 Predictors of change in cognition and quality of life between baseline and follow-up

A repeated measure linear model explored the impact of other variables. The model was fitted using post score as the dependent variable and age, living situation (community/care home), gender, marital status, and taking AChEIs as factors or covariates. In fitting the models in this way the results showed that age and gender variables were important factors for the effectiveness of CST (Table 8.7). For MMSE, age was a significant predictor of effectiveness of CST with older participants appearing to benefit more. At the mean age of 82 there is

little difference between the pre and post score but participants older than this appear to benefit more with a possible increase in MMSE score. For ADAS-Cog, age again is a significant predictor of the effectiveness of CST with older participants benefiting more on the MMSE (Table 8.7).

Table 8-7. *Differences before and after CST . Statistics are given for the repeated measures models*

Measure	Estimated marginal mean Before CST (SE)	Estimated marginal mean after CST (SE)	F value	p value	Other variable significant in the model
MMSE	15.8 (0.99)	18.5 (0.89)	20.7	<.001	Age F=5.5, p=.019
ADAS-Cog	35.0 (2.0)	30.6 (2.3)	16.8	<.001	Age F=12.5, p<.001
QoL-AD	35.7 (0.9)	36.3 (0.9)	0.001	.97	None
DEMQoL	93.4 (2.0)	92.4 (1.9)	8.38	.004	None
ADCS-DL	44.0 (2.8)	44.6 (2.8)	0.24	.32	Age F=8.64, p=.004
NPI	14.7 (2.2)	13.6 (2.2)	4.11	.044	Type F=6.25, p=.013
Proxy QoL-AD	33.3 (1.0)	32.8 (1.0)	2.91	.089	None
Proxy DEMQOL	96.7 (3.4)	100.6 (3.2)	27.24	<.001	Type F=8.39, p=.004

Gender showed to be a significant variable in the complete case study analysis, and showed a strong correlation with cognitive improvement, with female ADAS-Cog scores improving more than male scores (F=5.1, p=.025) (Figure 8-3).

Living situation was also shown to be an important variable for some of the staff-completed outcome measures (Table 8.7). For the NPI a decrease in score was seen for the community sample from 18.1 (se 2.2) to 13.9 (se 2.2) while there was a small increase in NPI score for the care home based participants from 11.3 (se 2.4) to 13.4 (se 2.4). This indicates a potential benefit for the community sample. For the DEMQOL (proxy) both community and care home

based participants saw a mean increase. However the care home group increased from 94.2 (se 3.6) to 100.9 (se 3.3) which was larger than the community change from 99.3 (se 3.4) to 100.2 (se 3.2)). In fact this can be seen as the community sample remaining steady while the care home sample have been brought into alignment with what was observed in the community. In summary we have identified benefits for the community sample on NPI scores while there is a benefit for care home sample for the proxy DEMQoL.

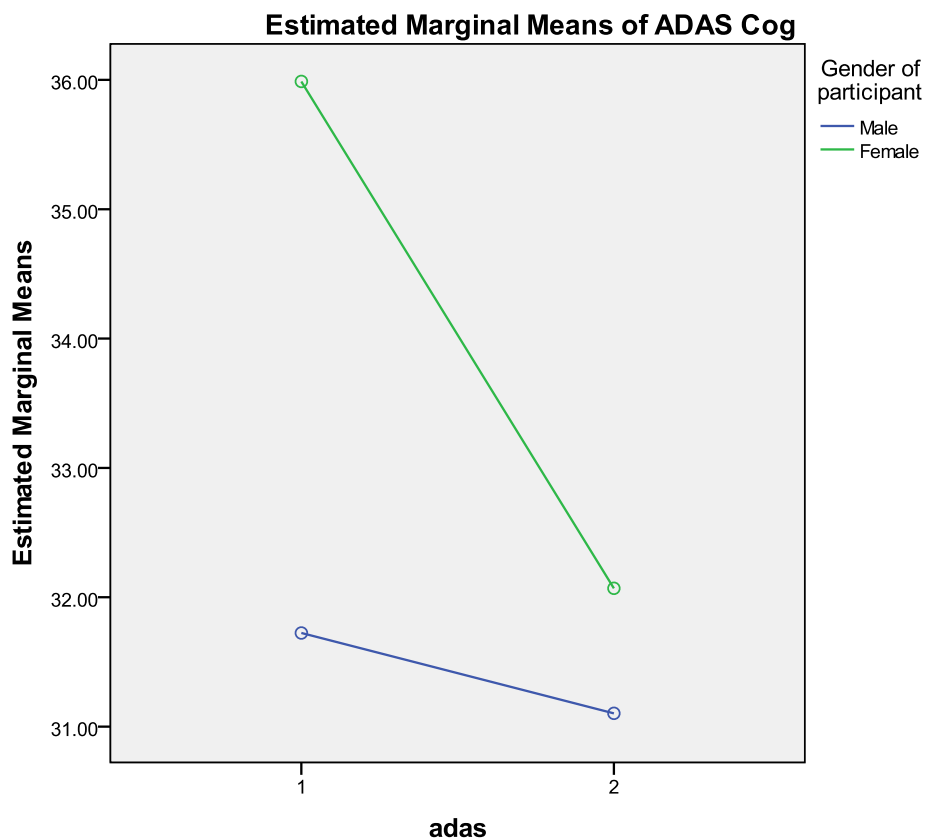


Figure 8-3. *Change in cognitive scores (ADAS-Cog) according to gender*

8.4.3 Change when comparing to a similar control group

Independent sample t-tests were used to compare the complete case dataset results with the Spector study control group (Spector et al., 2003) which had

used the same inclusion criteria and so formed a comparable sample. The Spector study sample had a mean age of 84.7 and a 3:1 female: male ratio. For the ADAS-Cog the Spector control group showed a mean reduction of 0.3 while the CST group showed a mean reduction of 2.7 a mean difference of 2.4 ($t=2.27$, $df=240$, $p=.024$) with confidence intervals of 0.33 to 4.51). For the MMSE the Spector control group reduced by an average of 0.4 points, while the CST group saw a mean increase of 0.9 points so there was a mean difference of 1.3 points ($t=2.76$, $df=293$, $p=.006$) with a confidence interval of 0.38 to 2.22 (Table 8.8). At follow up the CST group had demonstrated significantly better results on both MMSE and ADAS-Cog than the Spector (2003) control group. There was no significant difference between the CST group and the Spector 2003 control group on the QoL-AD.

Table 8-8. *Comparison of mean change in CST groups versus control group of Spector et al., (2003) study*

MEASURE	Spector 2003 control Mean change (SD) [N]	Current study Mean change (SD) [N]	Values
MMSE	-0.4 (3.5) [70]	0.93 (3.3)[225]	$t= 2.76$; $p= .006$
ADAS-Cog	-0.3 (5.5) [70]	-2.72 (8.3) [172]	$t= 2.26$; $p= .02$
QOL-AD	-0.8 (5.6) [70]	-0.08 (4.9) [225]	$t= 0.92$; $p= .35$

CHAPTER 9

Study Stage 2 trial results; MCST RCT

This chapter describes the RCT MCST programme results (second stage trial). The chapter is based on the paper (Appendix 6.8) entitled “Maintenance cognitive stimulation therapy (CST) for dementia: a single-blind, randomised controlled trial of MCST vs. CST for dementia ” (Aguirre et al., 2012 submitted).

9.1 Participant flow and response rate between stage 1 trial and stage 2

Figure 9.1 illustrates the consort diagram of the participants and the response rate through the trial. Out of 236 participants that were randomised in to the trial at Stage 2, 123 were allocated to the intervention MCST group and 113 to the TAU control group.

9.2 Participant characteristics

Table 9.1 presents baseline data on demographic variables. In the intervention group the mean age was 82.7 with a SD of 8.0 min=54, max=100. In the control group the mean age (years) was 83.5 with a SD of 7.2, min=63 max =97. Most participants were white and female and half of the sample were living in the community and the other half in residential care homes. Over one third of the total sample was taking ACHEI medication (32.2%). As can be seen from Table 9.1, baseline comparability between the groups was well matched.

There were two missing instances of ethnicity - these were imputed as white as this was by far the most common response. The ethnicity values were combined into two groups, White and Asian/Black/Other (Table 9.1) In relation to marital status, there were 22 missing marital statuses and were imputed as divorced /widowed as this again was the most common response. The marital statuses have been combined into Single, Married/Civil Partner and Widowed/Divorced.

Table 9-1. *Baseline characteristics of 236 participants randomised to intervention and control. Values are numbers (percentages) unless stated otherwise.*

Variable	Level	Control	Intervention
Age	Mean (SD) age (years)	82.7(7.9)	83.5 (7.2)
Gender	Male	43	43
	Female	70	80
Marital status	Single	14	13
	Married	29	38
	Divorced	4	4
	Widow	57	54
	Civil partner	0	1
Ethnicity	White	104	111
	Asian	1	3
	Black	5	7
	Other	2	1
Dementia diagnosis	Alzheimer's	35	38
	Vascular	34	31
	Lewy Body	0	1
	Other	8	10
	Not known	35	39
Taking Acheis	Yes	34	42
	No	79	81
Accommodation	Care home	50	51
	Community	63	72

Table 9.2 presents the clinical characteristics of the randomised participants. Most of the sample had moderate dementia with a mean MMSE score of 17.79,

(SD 5.6) and 17.79 (5.4) for the intervention and control group respectively. The mean ADAS-Cog score was also similar in both groups and in the moderate range of severity of dementia. Both groups were in the mid-range on the QoL-AD (mean 36.12, SD 4.9 and 36.51, SD 5.7) and DEMQOL (mean 94.81, SD 10.9 and 95.08, SD 11.7). Mean scores were well matched at baseline in both groups and in the mid-range on the measures of dependency (ADCL and behavioural symptoms (Table 9.2).

Table 9-2. *Clinical characteristics of randomised participants*

Characteristics	Intervention (n=123)	Control (n=113)
Mean (SD) ADAS-Cog score	31.12 (14.6)	33.21 (13)
Mean (SD) QoL-AD score	36.12 (4.9)	36.51 (5.7)
Mean (SD)MMSE score	17.79 (5.6)	17.79 (5.4)
Mean (SD) DEMQOL score	94.81 (10.9)	95.08 (11.7)
Mean (SD) NPI score	13.84 (12.9)	11.34 (9.1)
Mean (SD) ADCS score	42.67 (17.2)	41.51 (18.1)
Mean (SD) Proxy QoL-AD score	33.69 (5.8)	33.33 (4.9)
Mean (SD) Proxy DEMQoL score	102.19 (13.5)	102.25 (11.2)

9.3 Retention rate

Overall retention at this stage was very good. At 6-month follow up (primary end point) FU2, 199 (84%) of the participants were still participating in the study and 218 (92%) were involved at 3 month follow up (FU1). The response rate excluding death was 88.9% at FU2 and 96.4% at FU1. The withdrawal rate was similar in both arms of the trial and the main reasons for loss were participants' poor physical health and death (Figure 9-1).

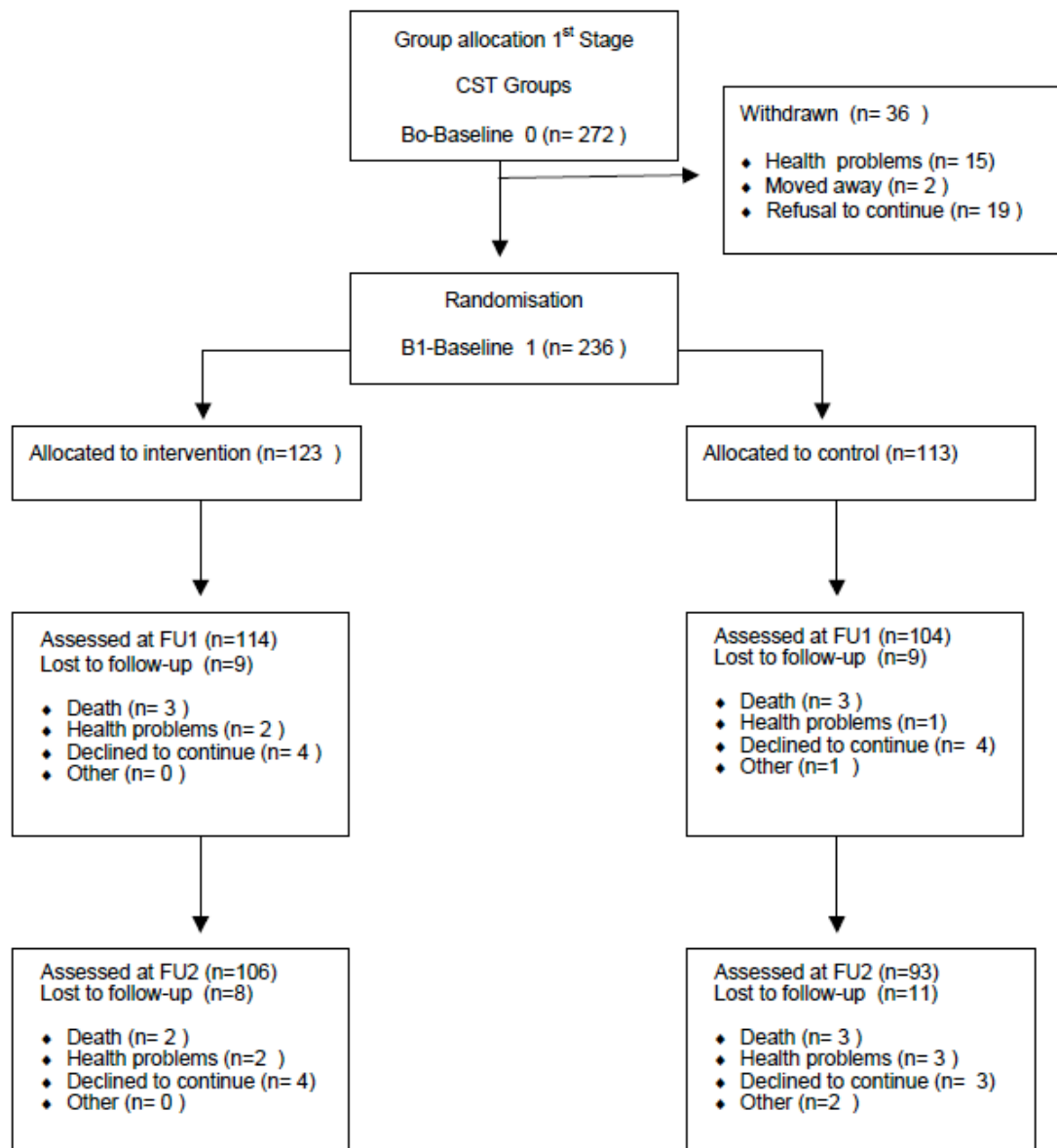


Figure 9-1. Consort diagram of participants through trial second stage RCT

9.4 Results

The results are reported using adjusted ANCOVA comparing groups (intervention and controls) for the primary end point (FU2) and secondary end point (FU1). Completed case (CC) and mean Imputed case (IC) results for each of the outcome measures are described in detail in the text and tables bellow:

9.4.1 ADAS-Cog results

At follow up 2 the complete case data indicated no significant difference between the two groups, $F_{1,104}=0.01$, $p=.91$. None of the 5 multiple imputations indicated a significant difference between the two intervention groups either, $F_{1,163}=0.02, 0.69, 0.94, .01, .18$ $p=.90, .42, .34, .95, .67$ respectively. At follow up 1 the complete case data indicated no significant difference between the two intervention groups, $F_{1,119}=1.99$, $p=.16$. None of the 5 multiple imputations indicated a significant difference between the two intervention groups, $F_{1,181}=2.09, 1.53, 1.20, 0.07$, $p=.15, .22, .27, .80, 1$ respectively (Table 9-3).

Table 9-3. ADAS-Cog scores at FU2 and FU1

		Group	Mean	SE	Mean difference	SE
Follow up 2	CC	Control	31.39	2.71	0.19	1.61
		Intervention	31.20	2.62		
	IC	Control	35.29	2.85	-0.65	1.55
		Intervention	35.94	2.79		
Follow up 1	CC	Control	31.84	2.50	-1.71	1.22
		Intervention	33.55	2.54		
	IC	Control	34.47	2.59	-0.85	1.29
		Intervention	35.32	2.56		

9.4.2 MMSE results

At follow up 2 the complete case data indicated no significant difference between the two intervention groups, $F_{1, 147} = 1.91$, $p = .17$. None of the 5 multiple imputations indicated a significant difference between the two intervention groups either, $F_{1, 163} = 2.03, 2.05, 1.31, 3.72, 3.56$ $p = .16, .15, .25, .06, .06$ respectively. At follow up 1 the complete case data indicated no significant difference between the two intervention groups, $F_{1, 170} = 0.41$, $p = .52$. None of the 5 multiple imputations indicated a significant difference between the two intervention groups, $F_{1, 181} = 0.16, 0.09, 0.35, 0.45, 1.32$ $p = .69, .77, .56, .51, .25$ respectively.

The table below (Table 9-4) indicates the complete case (CC) and imputed case (IC) group means from the model and the mean differences with the associated standard errors.

Table 9-4. MMSE scores at FU2 and FU1

		Group	Mean	SE	Mean difference	SE
Follow up 2	CC	Control	15.71	1.23	-0.79	0.57
		Intervention	16.50	1.27		
	IC	Control	15.49	1.25	-0.85	0.58
		Intervention	16.34	1.21		
Follow up 1	CC	Control	15.90	0.89	-0.32	0.50
		Intervention	16.22	0.87		
	IC	Control	15.79	0.91	-0.30	0.52
		Intervention	16.09	0.88		

9.4.3 QoL-AD results

At follow up 2 the complete case data indicated a significant difference between the two intervention groups, $F_{1,141}=4.35$, $p=.04$ Four of the 5 multiple imputations indicated a significant difference between the two intervention groups $F_{1, 163}=11.17, 5.12, 6.91, 2.48, 4.82$ $p=.001, .03, .01, .11, .03$ respectively. At follow up 1 the complete case data indicated no significant difference between the two intervention groups, $F_{1, 168}=0.15$, $p=.70$ None of the 5 multiple imputations indicated a significant difference between the two intervention groups, $F_{1, 181}=0.0, 0.86, 0.38, 0.53, 0.29$, $p=.99, .36, .54, .47, .59$ respectively (Table 9-5).

Table 9-5. QoL-AD scores at FU2 and FU1

		Group	Mean	SE	Mean difference	SE
Follow up 2	CC	Control	33.22	1.70	-1.64	0.79
		Intervention	34.85	1.64		
	IC	Control	33.84	1.53	-1.78	0.91
		Intervention	35.62	1.43		
Follow up 1	CC	Control	33.99	1.04	-0.22	0.58
		Intervention	34.21	1.02		
	IC	Control	33.97	1.04	-0.32	0.61
		Intervention	34.29	1.03		

9.4.4 DEMQoL results

At follow up 2 the complete case data indicated no significant difference between the two intervention groups, $F_{1, 140}=0.03$, $p=.8$. None of the 5 multiple imputations indicated a significant difference between the two intervention groups either $F_{1, 163}=0.003, 0.03, 0.004, 0.32, 0.30$ $p= .96, .87, .95, .57, .59$ respectively. At follow up 1 the complete case data indicated no significant difference between the two intervention groups, $F_{1, 169}=0.35$, $p=.55$ None of the 5 multiple imputations indicated a significant difference between the two intervention groups $F_{1, 181}= 0.58, 0.37, 0.36, 0.31, 0.61$ $p=.45, .54, .55, .58, .44$ respectively (Table 9-6)

Table 9-6. DEMQOL scores at FU2 and FU1

		Group	Mean	SE	Mean difference	SE
Follow up 2	CC	Control	88.42	2.41	-0.27	1.55
		Intervention	88.69	2.47		
	IC	Control	88.83	3.56	-0.30	1.52
		Intervention	89.13	3.55		
Follow up 1	CC	Control	90.74	2.40	0.79	1.34
		Intervention	89.94	2.35		
	IC	Control	90.71	2.38	0.86	1.31
		Intervention	89.85	2.34		

9.4.5 NPI results

At follow up 2 the complete case data indicated no significant difference between the two intervention groups, $F_{1, 129}=0.61$, $p=.44$ None of the 5 multiple imputations indicated a significant difference between the two intervention groups either, $F_{1, 163}=0.39, 0.34, 0.22, 0.80, 2.10$ $p=.53, .56, .64, .37, .15$ respectively. At follow up 1 the complete case data indicated no significant difference between the two intervention groups, $F_{1, 147}=1.32$, $p=.25$ None of the 5 multiple imputations indicated a significant difference between the two intervention groups, $F_{1, 181}=2.85, 0.96, 0.33, 0.90, 0.92$ $p=.09, .33, .57, .34, .34$ respectively (Table 9-7).

Table 9-7. NPI scores at FU2 and FU1

	Group	Mean	SE	Mean difference	SE
Follow up 2	CC	Control	20.69	4.01	1.79
		Intervention	18.89	4.02	
	IC	Control	20.35	3.94	1.58
		Intervention	18.76	3.78	
Follow up 1	CC	Control	18.34	3.12	1.89
		Intervention	16.45	3.08	
	IC	Control	16.18	2.76	1.47
		Intervention	14.71	2.84	

9.4.6 ADCS-ADL results

At follow up 2 the complete case data indicated no significant difference between the two intervention groups, $F_{1, 160}=0.51$, $p=.48$ None of the 5 multiple imputations indicated a significant difference between the two intervention groups either $F_{1, 163}= .31, .46, 0.50, 0.39, 0.33$ $p= .58, .50, .48, .54, .57$ respectively. At follow up 1 the complete case data indicated a significant difference between the two intervention groups, $F_{1, 180}= 3.95$, $p=.05$ All of the 5 multiple imputations indicated a significant difference between the two intervention groups, $F_{1, 181}=4.55, 4.13, 4.34, 3.88, 4.02$ $p= .03, .04, .04, .05, .05$ respectively (Table 9-8)

Table 9-8. ADCS-ADL scores at FU2 and FU1

		Group	Mean	SE	Mean difference	SE
Follow up 2	CC	Control	42.21	2.87	-1.09	1.53
		Intervention	43.30	2.89		
	IC	Control	42.35	2.87	-0.94	1.51
		Intervention	43.29	2.88		
Follow up 1	CC	Control	40.95	2.35	-2.56	1.29
		Intervention	43.52	2.32		
	IC	Control	40.94	2.32	-2.64	1.30
		Intervention	43.58	2.32		

9.4.7 PROXY QOL-AD results

At follow up 2 the complete case data indicated no significant difference between the two intervention groups, $F_{1, 157} = 0.01$, $p = .93$. None of the 5 multiple imputations indicated a significant difference between the two intervention groups either, $F_{1, 163} = 0.001, 0.01, 0.001, 0.14, 0.003$ $p = .97, .91, .98, .71, .95$ respectively. At follow up 1 the complete case data indicated a significant difference between the two intervention groups, $F_{1, 179} = 7.22$, $p = .008$. All of the 5 multiple imputations indicated a significant difference between the two intervention groups, $F_{1, 181} = 6.89, 7.50, 6.58, 6.26, 7.23$ $p = .009, .007, .011, .013, .008$ respectively (Table 9-9).

Table 9-9. Proxy QoL-AD scores at FU2 and FU1

		Group	Mean	SE	Mean difference	SE
Follow up 2	CC	Control	34.15	1.41	0.07	0.75
		Intervention	34.08	1.41		
	IC	Control	34.05	1.41	-0.07	0.74
		Intervention	34.12	1.41		
Follow up 1	CC	Control	32.33	1.06	-1.57	0.58
		Intervention	33.90	1.05		
	IC	Control	32.40	1.07	-1.53	0.59
		Intervention	33.93	1.05		

9.4.8 PROXY DEMQOL results

At follow up 2 the complete case data indicated no significant difference between the two intervention groups, $F_{1, 160} = 0.53$, $p = .47$. None of the 5 multiple imputations indicated a significant difference between the two intervention groups either, $F_{1, 163} = 0.58, 0.22, 0.46, 0.58, 0.47$, $p = .44, .64, .50, .45, .50$ respectively. At follow up 1 the complete case data indicated a significant difference between the two intervention groups, $F_{1, 179} = 4.40$, $p = .04$. All of the 5 multiple imputations indicated a significant difference between the two intervention groups $F_{1, 181} = 4.35, 4.85, 4.80, 4.89, 4.66$ $p = .04, .03, .03, .03, .03$ respectively (Table 9-10)

Table 9-10. Proxy DEMQOL scores at FU2 and FU1

		Group	Mean	SE	Mean difference	SE
Follow up 2	CC	Control	96.64	3.21	-1.25	1.71
		Intervention	97.88	3.23		
	IC	Control	96.61	3.21	-1.13	1.71
		Intervention	97.75	3.23		
Follow up 1	CC	Control	98.16	2.70	-3.14	1.49
		Intervention	101.29	2.66		
	IC	Control	98.12	2.71	-3.24	1.50
		Intervention	101.36	2.67		

Table 9-11. Primary and secondary end point results for all outcome measures; adjusted analysis model

	Primary end point FU2 (6 month follow up)				Secondary end point FU1 (3 month follow up)			
	Intervention	Control	Group diff.	Between group diff.	Intervention	Control	Group diff.	Between group diff.
	Mean (SE)	Mean (SE)	Mean (SE)		Mean (SE)	Mean (SE)	Mean (SE)	
ADAS-Cog score	35.94 (2.79)	35.29 (2.85)	-0.65 (1.55)	$F_{1,104}=0.01$, $p=.91$	35.32 (2.56)	34.47 (2.59)	-0.85 (1.29)	$F_{1,119}=1.99$, $p=.16$
QoL-AD score	35.62 (1.43)	33.84 (1.53)	-1.78 (0.91)	$F_{1,141}=4.35$, $p=.04$	34.29 (1.03)	33.97 (1.04)	-0.32 (0.61)	$F_{1,168}=0.15$, $p=.70$
MMSE score	16.34 (1.21)	15.49 (1.25)	-0.85 (0.58)	$F_{1,147}=1.91$, $p=.17$	16.09 (0.88)	15.79 (0.91)	-0.30 (0.52)	$F_{1,170}=0.41$, $p=.52$
DEMQUOL score	89.13 (3.55)	88.83 (3.56)	-0.30 (1.52)	$F_{1,140}=0.03$, $p=.86$	89.85 (2.34)	90.71 (2.38)	0.86 (1.31)	$F_{1,169}=0.35$, $p=.55$
NPI score	18.76 (3.78)	20.35 (3.94)	1.58 (2.16)	$F_{1,129}=0.61$, $p=.44$	14.71 (2.84)	16.18 (2.76)	1.47 (1.55)	$F_{1,147}=1.32$, $p=.25$
ADCS-ADL score	43.29 (2.88)	42.35 (2.87)	-0.94 (1.51)	$F_{1,160}=0.51$, $p=.48$	43.58 (2.32)	40.94 (2.32)	-2.64 (1.30)	$F_{1,180}=3.95$, $p=.05$
Proxy QoL-AD	34.12 (1.41)	34.05 (1.41)	-0.07 (0.74)	$F_{1,157}=0.01$, $p=.93$	33.93 (1.05)	32.40 (1.07)	-1.53 (0.59)	$F_{1,179}=7.22$, $p=.008$
Proxy DemQUOL	97.75 (3.23)	96.61 (3.21)	-1.13 (1.71)	$F_{1,160}=0.53$, $p=.47$	101.36 (2.67)	98.12 (2.67)	-3.24 (1.50)	$F_{1,179}=4.40$, $p=.04$

9.5 MCST-ACHEI platform results

9.5.1 ADAS-Cog results

The MCST-ACHEIs platform results at 6 month and 3 month follow up on the ADAS-Cog outcome measure showed that there was a no significant interaction between these two factors at 6 month follow up ($p=0.71$) nor at three month follow up ($p=0.13$).

Table 9-12. MCST ACHEI platform adjusted results ADAS-Cog (estimated marginal means)

Intervention	Taking AChEIs?	6 month FU2 Mean (SE) N	3 month FU1 Mean (SE) N
Control	Yes (n=34)	36.23 (3.53)	36.86 (2.84)
	No (n=79)	34.41 (2.97)	32.15 (2.68)
MCST	Yes (N=42)	35.51 (3.28)	36.36 (3.15)
	No (N=81)	35.73 (2.98)	33.66 (2.56)

9.5.2 MMSE results

The MCST-ACHEIs platform results at 6 month and 3 month follow up on the MMSE outcome measure showed that there was a significant difference between the MCST and on AChEIs group and the control and on AChEIs only group both at six and three month follow up ($p=0.025$), with the group on MCST plus AChEIs scoring the highest on the MMSE (Table 9-13).

Table 9-13. MCST ACHEI platform adjusted results MMSE

Intervention	Taking AChEIs?	6 month FU2 Mean (SE) N	3 month FU1 Mean (SE) N
Control	Yes (n=34)	14.62 (1.37)	15.26 (1.08)
	No (n=79)	16.26 (1.28)	16.25 (0.92)
MCST	Yes (N=42)	17.25 (1.33)	17.17 (1.06)
	No (N=81)	16.26 (1.26)	15.77 (0.88)

9.5.3 QoL-AD results

The MCST-ACHEIs platform results at 6 month and 3 month follow up on the self reported QoL-AD outcome measure showed that there was a no significant interaction between these two factors at six month follow up ($p=0.48$) nor at three month follow up ($p=0.97$).

Table 9-14. MCST ACHEI platform adjusted results self reported QoL-AD (estimated marginal means)

Intervention	Taking AChEIs?	6 month FU2 Mean (SE)	3 month FU1 Mean (SE)
Control	Yes (n=34)	33.94 (1.87)	32.82 (1.23)
	No (n=79)	33.81 (1.52)	35.13 (1.10)
MCST	Yes (N=42)	34.72 (1.70)	33.15 (1.27)
	No (N=81)	36.07 (1.44)	35.45 (1.05)

9.6 Intervention provision and quality of the intervention analysis

In order to analyse the quality of the intervention provision, the researchers who run the different groups in the centres, wrote brief notes following the sessions. These included information scoring manager's attitude, centre atmosphere, co facilitators input, CST and MCST group atmosphere and attendance to sessions as criteria specified in Table 9-15. This information was used in order to rank the

different centres and the results were divided in a binary variable of low quality (score <15) and good quality (score ≥15) (Table 9-15). Full details in relation to how the ratings were made and each of the centre rates can be seen in Table 9-15. Overall, community centres scored better than care homes with only one out of nine, scoring low quality in comparison to five out of nine care homes.

In order to analyse the influence of ‘quality’ in the primary outcome results, this new variable was incorporated in the model of analysis with baseline score, centre type, age and allocation as a fixed effect and within a random effect of centre nested within the interaction of quality and type.

Table 9-15. *Quality of centres scores*

Keys to Table 9-15

CH: Care home; DC: Day care

I: Institutionalised:*

So used to living in or being part of an institution, that one becomes alike to it or unable to live independently.

*L**: Learned helplessness:*

Developed passivity as a response to institutionalisation, e.g. using a wheelchair when able to walk slowly.

Manager's attitude: 0 = hostile 1 = average; 2 = favourable

Atmosphere: 0 = institutionalized; 1 = average; 2 = friendly / happy

Co-facilitator Input: 0 = avoidant / no co-facilitator; 1 = average; 2 = actively involved

Group atmosphere: 0 = poor interaction / dynamics; 1 = average ; 2=good interaction

Mean participation Ph1: 0 = less than 7 sessions ; 1 = 8– 12 sessions; 2 = 13 – 14 sessions

Mean participation Ph2: 0 = less than 12 sessions; 1 = 13 – 20 sessions; 2= 21-24 session

Centre ID	QUALITATIVE ANALYSIS	CST A (Ph1)	CST B (Ph1)	M CST (Ph2)	TOTAL
MR– DC	Co-facilitator input	2	2	1	5
	Group atmosphere	2	2	1	5
	Group participation	1	1	1	3
	Managers attitude				2
	Home atmosphere				2
	Total				17
FR – CH	Co-facilitator input	0	1	0	1
	Group atmosphere	1	2	2	5
	Group participation	1	1	1	3
	Managers attitude				0
	Home atmosphere				2
	Total				11
IG – CH	Co-facilitator input	1	1	1	3
	Group atmosphere	1	2	2	5
	Group participation	1	2	1	4
	Managers attitude				1
	Home atmosphere				0
	Total				13
BH1 – DC	Co-facilitator input	1	1	2	4
	Group atmosphere	1	1	1	3
	Group participation	2	2	2	6
	Managers attitude				2
	Home atmosphere				2
	Total				17
BH2 – DC	Co-facilitator input	2	2	2	6
	Group atmosphere	2	2	2	6
	Group participation	2	2	2	6
	Managers attitude				2
	Home atmosphere				2
	Total				22
CD – CH	Co-facilitator input	2	2	2	6
	Group atmosphere	2	1	2	5
	Group participation	2	1	2	5
	Managers attitude				2
	Home atmosphere				1
	Total				19

Centre ID	QUALITATIVE ANALYSIS	CST A (Ph1)	CST B (Ph1)	M CST (Ph2)	TOTAL
BH- CH	Co-facilitator input	1	1	0	2
	Group atmosphere	2	2	2	6
	Group participation	1	1	1	3
	Managers attitude				1
	Home atmosphere				1
	Total				13
SM- CH	Co-facilitator input	1	1	0	2
	Group atmosphere	1	1	1	3
	Group participation	1	1	0	2
	Managers attitude				1
	Home atmosphere				1
	Total				9
WR- CH	Co-facilitator input	0	1	1	2
	Group atmosphere	1	0	0	1
	Group participation	1	1	0	2
	Managers attitude				0
	Home atmosphere				0
	Total				5
SB – DC	Co-facilitator input	2	2	2	6
	Group atmosphere	2	2	2	6
	Group participation	2	2	2	6
	Managers attitude				2
	Home atmosphere				2
	Total				22
EL –DC	Co-facilitator input	2	2	2	6
	Group atmosphere	2	2	2	6
	Group participation	1	1	1	3
	Managers attitude				2
	Home atmosphere				2
	Total				19
RR- DC	Co-facilitator input	1	1	1	3
	Group atmosphere	2	0	1	3
	Group participation	1	1	1	3
	Managers attitude				1
	Home atmosphere				1
	Total				11
DC- DC	Co-facilitator input	2	2	2	6

Centre ID	QUALITATIVE ANALYSIS	CST A (Ph1)	CST B (Ph1)	M CST (Ph2)	TOTAL
	Group atmosphere	2	1	2	5
	Group participation	1	1	2	4
	Managers attitude				2
	Home atmosphere				2
	Total				19
ER – CH	Co-facilitator input	1	1	1	3
	Group atmosphere	2	2	2	6
	Group participation	2	2	2	6
	Managers attitude				1
	Home atmosphere				1
	Total				17
CM –CH	Co-facilitator input	2	2	2	6
	Group atmosphere	2	1	2	5
	Group participation	2	2	2	6
	Managers attitude				2
	Home atmosphere				2
	Total				21
VJ– CH	Co-facilitator input	2	2	2	6
	Group atmosphere	2	1	1	4
	Group participation	2	2	1	5
	Managers attitude				2
	Home atmosphere				1
	Total				18
BH– DC	Co-facilitator input	2	2	2	6
	Group atmosphere	2	2	2	6
	Group participation	2	2	2	6
	Managers attitude				2
	Home atmosphere				2
	Total				22
RH– DC	Co-facilitator input	2	2	2	6
	Group atmosphere	2	2	2	6
	Group participation	2	2	2	6
	Managers attitude				2
	Home atmosphere				2
	Total				22

9.6.1 Quality of the intervention analysis results at primary end point (FU2)

The analysis results showed that quality of CST provision was not significant in the model in its own right. Overall MCST resulted in an increase Adas-cog score of 0.08 compared to Control at FU2.

Table 9-16. *Change in cognition according to quality scores of centres*

Centre type	Quality of CST provision	Centre Name	n	Control		n	MCST	
				Adas Mean change	Adas FU2 score		Adas Mean change	Adas FU2 Score
Care Home	Low	BH	5	-6.42	46.22	5	-7.33	39.97
		FR	6	5.93	37.12	5	5.35	24.05
		IG	5	4.71	36.23	5	4.15	32.18
		SM	5	-4.36	52.45	6	-7.2	35.53
		WR	4	-1.88	37.63	1	-4.1	21.77
	Good	CD	5	3.13	30.40	7	4.48	39.23
		CM	5	1.03	35.09	6	0.73	34.67
		ER	7	-0.73	28.81	5	-0.31	34.11
Community	Low	RR	5	-1.3	44.53	7	-3.25	35.25
	Good	BH2	7	2.32	14.22	6	2.48	14.60
		BH1	5	-1.47	26.09	6	-2.07	26.61
		DC	4	-2.8	26.30	6	-2.85	30.24
		EL	7	-4.28	28.52	8	-4.75	27.96
		MR	3	-1.81	33.52	6	-2.79	27.96
		RH	6	-7.84	50.80	7	-9.7	42.87
		SB	5	3.12	25.35	8	2.82	26.58
		SH	3	0.93	15.55	4	1.94	21.05
		VJ	6	-2.95	35.75	8	-1.38	45.75

Table 9-16 shows the differences amongst the centres that cannot be explained by quality, type or the provision of intervention. A negative change indicates that the follow up score was higher than the baseline i.e. a decrease in cognitive function. From the scores seen at follow up and the amount of change seen in each centre,

the results showed differences between the centres that couldn't be explained by type or quality of centre. For both the intervention and control groups the direction of change was the same in each centre. There was no clear pattern showing either intervention or control to be more beneficial than the other.

In relation to quality of life and quality of intervention provision at FU2, the QoL-AD score showed to be significantly different between the two intervention groups as indicated by earlier analysis (Table 9-17). The qualitative analysis of the results showed that there were differences between the centres but with such small numbers seen in each centre it was impossible to assess reliability. However, quality and centre type did not appear to explain these differences.

Table 9-17. *Change in quality of life according to quality scores of centres*

Centre type	Quality of CST provision	Control MCST						
		Centre Name	n	Mean change QoL-AD	QoL-AD FU2	n	Mean change QoL-AD	QoL-AD FU2
Care Home	Low	BH	5	-0.21	35.31	5	-2.73	35.28
		FR	6	1.01	34.03	5	0.3	35.77
		IG	5	4.15	35.56	5	1.07	36.65
		SM	5	0.76	34.44	6	-1.31	35.82
		WR	4	2.76	37.54	1	-4.03	31.03
	Good	CD	5	0.78	34.84	7	-0.65	36.36
		CM	5	0.58	35.42	6	-3.02	36.11
		ER	7	2.7	36.25	5	1.16	38.70
Community	Low	RR	5	0.78	34.22	7	-1.66	35.94
	Good	BH2	7	2.13	36.58	6	-0.06	37.23
		BH1	5	-0.46	32.88	6	0.04	38.64
		DC	4	1.61	35.39	6	-0.2	38.37
		EL	7	1.7	37.40	8	-2.08	37.33
		MR	3	1.7	35.85	6	0.03	36.63
		RH	6	-2.23	35.41	7	-2.88	37.12
		SB	5	1.97	38.03	8	-0.59	38.59
		SH	3	2.98	38.11	4	3.42	39.58
		VJ	6	-0.65	36.54	8	-2.88	37.05

9.6.2 Quality of the intervention analysis results at secondary end point (FU1)

For ADAS-Cog, the findings at follow up 1 are consistent with follow up 2 but for QoL-AD there was no evidence that quality of CST provision had an effect on the scores seen in the data. In summary, the differences that were found between the centres, were not fully explained by either type of quality of CST provision (low or high). However, given the small number of participants in each centre, finding a factor or covariate that would satisfactorily explain the differences found would have been difficult to achieve.

9.7 Numbers needed to treat

The number needed to treat (NNT) is a calculation of the number of people who needed to be treated in a particular intervention in order to achieve one favourable outcome (Spector et al., 2003). The NNT calculation uses the proportion of participants who benefit in each treatment group. A NNT analysis using QoL-AD change was used between BL1 and FU2 as this was the primary end point. An improvement of one standard deviation on the QoL-AD (large effect size) was taken to indicate major clinical benefit, and 0.5 of a standard deviation change (moderate effect size) was taken to indicate moderate clinical benefit. When calculating a large size effect (1SD), the proportion benefiting was 17/96 (0.18) for the treatment group compared to 6/81 (0.07) of the control group and therefore 9.7 people needed to be treated in order for 1 to benefit (95% CI 5.0 to 129.9). When calculating a moderate size effect (0.5 SD), the proportion benefiting was 42/96 (0.44) for the treatment group compared to

16/81 (0.20) of the control group and therefore 4.2 people needed to be treated in order for 1 to benefit (95% CI = 2.7 to 9.2).

CHAPTER 10

Discussion

This study provides further evidence for the benefits of CST and MCST. The results from the RCT showed that the MCST programme improved the quality of life of people with dementia at three ($p = 0.008$) and six months ($p = 0.04$), and activities of daily living at three months follow up ($p = 0.05$). The results from the trial in relation to cognitive outcome measures showed that the mean cognitive scores before the first CST programme remained unchanged at final follow up 8 months later suggesting that CST may help to reduce the expected decline in cognition for people with dementia over time. In summary, the cognitive benefits in ADAS-Cog and MMSE outcome measures after attending the intensive 7 week CST programme can be seen immediately after it, whilst not so much changes in quality of life as measured by the QoL-AD. This information combined with the results of the full MCST RCT data, could be interpreted as the cognitive stimulation programme benefiting cognition immediately after the intensive period of the intervention while quality of life improving in the longer-term section of the programme.

10.1 Response rate and attrition

The response rate from first approach to centres of 95.2% and subsequent recruitment rate of 90% reflects the high level interest that has arisen in recent years in cognitive stimulation approaches for dementia. Certainly, approached centre managers appeared to welcomed the opportunity to take part in this trial, which offered a psychosocial intervention recommended by NICE guidelines, and all of them, welcome the opportunity to receive 'free' training on CST by one of the CST pioneers (AS). They were also very attracted by the opportunity that this study provided a highly experienced facilitator to run the CST sessions and support the centre staff at the same time. Moreover, the fact that even the participants randomised to the TAU group of this trial received at least the 7 weeks of CST was an extra benefit when recruiting centres. No centres were lost to the study and although response rate excluding death was very high (88.9% at FU2 and 96.4% at FU1), some participants refused to participate at different stages, with the loss between first and second phases being the highest loss (15%).

10.2 Methodological considerations

10.2.1 Study design

A two-stage randomisation process with allocation ratio of 1:1 was selected in order to increase variability within the CST groups at first trial stage and therefore, reduce the intra-class correlation and any other bias. The sample was stratified according to whether participants were receiving ACHEI medication and living condition. The similarity of the two CST groups at first baseline, and

the intervention and control groups and second baseline, suggests that this was an effective way of randomising the participants and managing the two trial stages of the study.

10.2.2 Sample size

Sample size was calculated using an effect size for MCST of 0.39 on the ADASCog with power of 80% using a 5% significance level and an estimated attrition of 15%, based on other studies, using the same outcome measure conducted within similar settings. As this was the first study to run a longer version of the intervention (24 weeks in comparison to seven weeks that lasted the Spector et al., 2003 study and therefore, three times large than the original CST study), the estimated power calculation concluding that 230 participants were needed at second stage randomisation, might have been underpowered for the primary outcome measure cognition, and the finding of no significant difference between groups over time but a positive trend could have been due to a Type II error.

10.2.3 Recruitment

Centres included at the developmental stage and evaluation of the trial for the first round, were initially identified through personal networks such as the Alzheimer's Society, Care UK and Dementia UK organisations. This potentially introduced bias to the recruited sample at this stage, as some participating centres volunteered, having attended the consensus conference in a proactive attempt to improve their services to people with dementia. Other recruited centres were referred by a research colleague who had run a similar study about occupational therapy for dementia and suggested to approach and recruit

their study TAU randomised centres, so they could have an opportunity of receiving seven weeks of CST and free training.

Centre managers, participants and family caregivers differed in their level of understanding of the research process, despite provision of written information and face-to-face meetings when required, as per protocol. Therefore depending especially on the manager level of commitment to the research programme, the compliance varied between centres, with differences found amongst community versus care home settings, the latter being more challenging to engage. An additional challenge that was found in the care home sample was the change of managers and staff during the course of the study (three managers out of the nine recruited homes). Perhaps a signed and agreed 'contract' should have been established before recruitment, to pass from manager to manager. These high rates of turn over represent the reality of the settings and have persisted over decades since the 1970s (Halbur et al., 1986), despite efforts to change it and the large number of studies documenting an association of turn over rates with poor quality care (Bostick et al 2006, Castle et al., 2005). A recent study that evaluated national estimates of turnover and retention for staff in nursing homes, calculated that the annualised turnover rate amongst this staff was found to be the highest among certified nursing assistants (Donoghue 2010). The screening flowchart (Appendix 5.1) and the study flow chart (Figure 7-1) was useful when clarifying to managers and staff the trial summary and participants' recruitment inclusion criteria and therefore, receiving appropriate list of referred participants and saving time when having to update new staff and managers.

However, the efforts of the research team, managers sometimes, struggled to assign two nominated members of staff to take part in the training and to co-facilitate sessions as part of the CST programme. There were times when managers expected the member of the research team to be the only facilitator of the group, and in some care environments it was seen as staff taking time 'off' to complete the assessment measures. This will be described in more detail in section 10.2.5.

10.2.4 Instruments

Rationale for selection

Cognition and quality of life were selected as primary outcome measures. The ADAS-Cog was selected as it is a well-established instrument for measuring cognition for people with dementia and it is the standard measure of choice in the evaluation of effectiveness of drug trials, where a four point change over six months is held to be clinically important by many regulatory authorities (Rockwood et al., 2007). The QOL-AD was selected on the basis that it is easy to use, enables a self rating score of quality of life and it is recommended for use within clinical and research practice (Moniz-Cook et al., 2008). Secondary outcome measures included activities of daily living, behaviour and secondary outcome measures of cognition (MMSE) and quality of life (DEMQoL). As this thesis was part of a larger study funded by the National Institute for Health Research (NIHR) further outcome measures were included in the pack, aimed to measure cost and family caregivers general health within the community sample.

All the instruments were assessed as having adequate reliability and validity to support their use for this population in the particular setting of the research study.

Limitations and issues in use

Overall, the main issue after the completion of the baseline assessments by the participant, staff member and family caregiver was the length of the full assessment pack. In addition, some participants complained that two different measures appeared to be measuring the same thing and felt it was not necessary to answer a similar question twice in one interview. However, only one participant dropped out because of this, and assessments tended to get quicker at follow ups. This depended to a great extent on the interviewers familiarity with the measures and the level of experience they had assessing people with dementia. So if a person was assessed by an experienced interviewer, the assessment would generally need less time to be applied and also less time was needed to establish a good rapport between the interviewer and interviewee.

In most cases, depending on the level of cognitive impairment and or general physical health of the interviewee, it was useful to have a break in between the assessment. However, as people needed to be assessed in a two-week gap at a time (e.g. between the end of CST groups and beginning of the maintenance programme) it was not possible at all times to have the interviews spitted in two. It might be worth considering for future research how to minimize the instruments used in order for participants not to feel too overwhelmed by an excessive number of questions and commands.

Whenever possible participants were interviewed at the centre or care home they were attending, however this was not always possible, especially when assessing participants living in the community and, for example, the family caregiver was not able to get to the centre easily. In these cases, the assessment was done at home. In practice, this proved very useful, in order to assess the person in their own environment, where they felt more comfortable and resulted in being highly beneficial especially when visiting participants and family caregivers as a couple. As one researcher was able to meet with the participant and the other researcher with the family caregiver concurrently, although a point was made of conducting the interviews separately e.g. in separate rooms.

Practicalities of the outcome measures

In relation to how the participants completed and responded to the ADAS-Cog outcome measure, there was a clear difference between care home and community sample completion and the response to it. The distribution of the sample in baseline ADAS-cog score appeared to be normal. However, after observing how people in the community and in the care homes responded to some items in the scale, a detailed examination of the scores by living condition revealed that scores on the ADAS-COG for people living in the community were generally lower than the scores for people living in the care homes, indicating less cognitive impairment (Figure 8.2). The response to some items from this measure, specifically the naming of objects from participants in the community became defensive on occasion. Feelings expressed were that it was a childish task; others mentioned the thought of one day forgetting how to name those

objects or losing the ability to draw a circle. In comparison care home participants tended to become defensive when they were asked to complete the more complex items in the ADAS-Cog scale such as, remembering words and word recognition. This may have been due to the care home participants generally having a higher level of cognitive impairment and hence they might have felt as 'being put on the spot', as well as the length of the item that had three items each.

In relation to the other selected primary outcome measure, QOL-AD, level of cognitive impairment was likely to have influenced the response to the measure. When completed by participants with a higher level of cognitive impairment, the answers were in most cases, answered in their reality as it was years ago, although attempts were made to bring them in to the present and answer accordingly. The accuracy of the data collection here might have reflected differing levels of expertise and person centre approaches that had been used by the different assessors.

Measures relying on proxy reports

Staff frequently had difficulty in rating the 'money' item as they felt they were unaware of their financial situation and 'ability to do chores' as they felt that in most cases, they were not allowed to do the chores due to health and safety issues but participants might have been able to do so if allowed to. The same was reflected on some items on the ADCL-ADL scale (e.g. being able to use a kettle, etc) and reflects findings from other studies (e.g. National Care Homes Research and Development Forum, 2007). Although the QoL-AD has been used in care home studies and has demonstrated to be valid for people with cognitive

impairment, in some cases the use of the DEMQOL that has a straight forward questionnaire, allowed participants to focus quickly on the question, and was perceived to be more appropriate, useful and more accurate, when assessing quality of life, minimizing bias and effects depending on assessors' expertise.

The NPI was a useful measure when used with family caregivers for the community sample, as it included caregiver levels of distress in relation to each of the behaviours that were discussed in the interview. However, amongst staff, it was perceived as a very repetitive and time consuming measure, as collected information in relation to variables already collected in other scales such as sleeping and eating items (already collected in the ADCS-ADL scale), and the attitude when describing the behaviours varied amongst staff members, as seen in other studies (Moniz-Cook et al., 1998).

Completion of two quality of life measures were done with by the participant, staff and or family caregiver. The measures seemed to work very well when discussed with the participants and most welcomed the opportunity to talk about items in the scales. Further studies should look into analysing the differences between self reported and proxy reported ratings, as some staff did not have much insight into the participants experiences of the symptoms, or there were discrepancies between ratings as have been noted by some other authors (Hancock et al., 2006).

10.2.5 Data collection

Data were collected either at the centre (community or residential) or participant private home. Despite agreeing a time to visit for data collection

with the manager or directly with a family caregiver, some participants and staff were often unaware or forgot about it. This sometimes caused delays whilst the study and purpose of the visit was explained and staff were freed up to be assessed. The level of commitment between members of staff and or family caregivers varied, with some being very happy to be interviewed whilst others felt disinterested, feeling that 'this was the 'price' to pay in order to get the intervention'. Some staff members complained about being taken away from their 'proper' work, and were sceptical about the usefulness of the study.

Unfortunately, due to shifts, staff and manager turn over rates and other practical issues, it was not always possible to interview the same member of staff at the different time points. In relation to family caregivers, whilst some were very grateful to the researchers and enjoyed the assessment time, others complained about the time required for completion and felt that there were far too many assessment measures to complete. The time per interview for each participant ranged from 45 to 120 minutes and the proxy pack from 40 to 120 minutes. Participant pack completion time depended on the level of cognitive impairment, needs and mood of the participant.

In relation to the proxy measures, the completion time varied depending on the time needed to explain the questions, mood and or time that staff and family caregivers needed to explain themselves.

10.3 Internal validity

10.3.1 Selection bias

Selection bias was reduced by using an independent randomisation unit, NWORTH to carry out the randomisation process. Allocation of the participants was conducted remotely and the method used to generate the sequence was not disclosed to the research team until the study was completed. The different groups at baseline were well matched suggesting effectiveness of the method of randomisation used in reducing selection bias.

10.3.2 Performance bias

Performance bias was difficult to reduce as the interventions were run by a number of different facilitators. In order to reduce this type of bias, the same trainer (who pioneered of CST with extensive experience of the programme), delivered the same one day training course to all the facilitators and co facilitators that run the programme. The same person also ran clinical supervision sessions on a group and one to one basis for the group facilitators.

Participants and staff and or family caregivers who completed the assessments, could not be blinded to the allocation, in turn this could have led to "resentful demoralisation" (Medical Research Council, 2000) within the control participants. This suggests that the control group participants, staff and family caregivers, in the belief that they were not receiving the long term intervention, might have affected their attitude and behaviour in a negative way, and as a consequence, the outcomes. In order to assess compliance with the intervention, an adherence to intervention form was developed specifically for the trial

programme (Appendix 4.8), and completed after each session. This ensured that the programme was delivered as intended per protocol and that it followed the key principles of the programme.

10.3.3 Attrition bias

There was no evidence of attrition bias as the overall rate of attrition was identical in both groups as shown in Figure 9-1.

10.3.4 Detection bias

As outlined above, care home managers, staff and family caregivers were not blind to allocation and this knowledge could have influenced their responses when interviewed. As already discussed, some of the data collection was based on information provided by staff and or family caregivers and as such varied in its quality. Furthermore, as previously noted, it was not possible to interview the same member of staff about each resident at all points, which potentially could have had introduced further bias into the assessment process. Whilst these issues could potentially bias the data collected, they applied equally to all centres, participants, family caregivers and staff.

The assessors at follow up were blind to intervention allocation, however, sometimes clues from participants, staffs and or family caregivers during assessments were noted and unblinded the assessors. In order to reduce this bias, a blind record form was completed by assessors after each follow up assessment (Appendix 4.9). Although unblinding of the researcher did occur on occasion, due to assessors having no knowledge of the baseline data, this was

considered unlikely to have influenced the manner in which they completed the assessment.

10.3.5 Reporting bias

The analysis was completed as outlined in a previously defined data analysis plan, , thus preventing data dredging. That is to say that although large amounts of data were analysed, by following the data analysis plan, we avoided seeking more information from a data set that it actually contained and avoided preventing unnecessary multiple analysis with the intention of finding a significant result.

All reported data within this thesis, and subsequent dissemination of the SHIELD – MCST study, adopted or will adopt this approach.

10.4 Effects of the intervention

By following the MRC framework (2000, 2008), the intervention at stage I was taken to the level at which it was reasonable to expect to have a worthy impact. The intention to treat analysis showed that the MCST was of effect in enhancing the QoL of dementia. Cognition was higher in the groups receiving MCST compared to CST only, but the difference was not significant. The ACHEI-MCST platform showed that long term CST appeared to be effective irrespective of whether or not ACHEIs were prescribed, with greater improvements showed in the ACHEI-MCST arm. Overall this study provides good evidence for the benefits of continuing CST beyond the initial programme and suggests that whilst people

are still able and willing, there is a benefit of continuing CST as run in the MCST programme.

10.4.1 Effectiveness of the first stage, CST programme

The benefits that cognitive function gains from cognitive stimulation are recorded well now (Woods et al., 2012, Orrell et al., 2012) and the results of this study provide additional evidence for the effectiveness of the programme developed by Spector (2003). This study showed that CST has cognitive benefits for people with dementia, evident in comparisons of change scores, and in comparisons with the changes shown by the control group from the previous trial. Unlike the Spector (2003) study and the recent Review of Cochrane (Woods et al. 2012) this study found a positive change in behaviour following the CST intervention as did the first Cochrane review on Reality Orientation (Spector et al., 2000). There was also a significant improvement in quality of life as measured by the DEMQOL but not on the QOL-AD.

Previous studies have identified the need for quality of life measures in dementia that can identify alterations in quality of life as a response to progression and interventions of the disease, both (Hoe et al. 2009), in order to use them in the establishment of the advantages of intervention for dementia patients. This analysis suggests the two measures may be measuring different aspects of quality of life. These findings need to be explored further in future trials.

Who benefits most from CST?

The benefits of CST were found to be independent of the use of ACHEIs and this is in line with the Cochrane Review findings and other studies (Woods et al. 2012; Chapman 2004; Onder 2005; Bottino 2005) which show that cognitive stimulation is effective irrespective of whether or not ACHEIs are prescribed, and any effects of the intervention are in addition to those associated with the medication (Woods et al., 2012).

The greater effect for the very old people in this study (over 80s) is an unexpected finding. It may suggest that these older participants are experiencing more excess disability, showing impairment beyond that resulting directly from the dementia. It may be that they receive less stimulation in general than the less old participants, and so benefit more from the intervention. When designing cognitive based interventions for dementia its important to be aware of the cognitive changes that occur with age even without a dementia diagnosis. It might be that the designing of cognitive based interventions for dementia, needs to take this variable into account, so that the activities match the cognitive requirements of the participants and one aspect might be the differences found between “fluid’ abilities (novel problem solving), and ‘crystallised’ abilities (existing ‘world knowledge’). Research evidence suggests that ‘crystallised’ abilities follow a markedly slower trajectory of decline in very old adults (specially over 80s) (Bäckman, Small, Wahlin & Larsson, 2000). It might be that CST programmes for very old adults might benefit more from the use of reminiscence strategies as an aid to orientation to the here and now (using crystallized abilities) and less of activities designed to

use their fluid intelligence focusing on stimulation of the senses and cognitive exercises.

In the complete case analysis, greater improvements in cognition were associated with female gender ($F=5.1$, $p=.025$). The ratio female: male for this study was 4 to 1. Resultantly the average group was constituted by two males out of 7 participants. Males might be more reluctant to communicate as they are usually in the minority in most groups with females generally outnumbering men in the groups (Spector 2003; Woods 2006). It may be that the gender majority dictates the style in which the groups are run, for example more 'talking' in female dominated groups and more 'doing' in male dominated groups. However experience from one all male group from this study, suggested that the dynamics of the group were completely different, the group appeared to be less conversational, not as free flowing and there was less interaction between group members. The exploration of these differences in gender in response to CST and to develop interventions more geared towards the preferences of men requires further research.

Finally, in relation to the differences we found between those living in the community and those living in care homes, it needs to be mentioned that these differences could be related to the measures completed by different proxies such as a family member in the community or a member of staff in the care home. For example the community sample was associated with an improvement in behavioural outcomes that might be affected by the fact that family carers ratings are influenced by their level of strain, whereas residential participants had greater enhancements in QoL which might be attributed to how increased

hope in staff is linked with improved QoL (Spector, 2006). These differences in perspectives also warrant further research.

10.4.2 Effectiveness of the second stage, MCST programme

This is the first major study to compare the short term versus long term impact of CST for people with dementia. The study indicates that after seven weeks of twice-weekly CST, 24 weeks of MCST sessions improves quality of life for people with dementia at six month follow up, and benefits quality of life and activities of daily living at three month follow up in comparison to the usual care (CST only) control group. The results indicate that a lower intensity input of once a week CST sessions, can continue to be beneficial after the initial twice-weekly CST programme has been completed. In addition, the Cochrane review showed that type of control condition (e.g. usual care or social activities) makes no difference to outcome, demonstrating that cognitive stimulation was responsible for the improvements in outcome rather than some kind of social activities.

It is well established that cognitive stimulation programmes for dementia have a significant positive effect on cognition (Woods et al., 2012) and in the earlier stage of this study the analysis of key outcomes before and after CST showed both cognition and quality of life improved for people with dementia, including those people on ACHEIs. Although there were no significant differences the results for cognition at follow up showed a mixed picture with little or no difference between the groups on the ADAS-Cog but a 0.85 points benefit to the MCST group for the MMSE. This suggests that MCST has no substantial effect on

cognition over and above the original benefits of the initial CST programme and the cognitive benefits may only persist for a limited period of time (Woods et al., 2012). However, since MMSE scores in mild to moderate dementia are expected to decrease by 2 to 4 points per year (Clarck et al., 1999) it is possible that relative to no treatment the MCST programme may continue to have some degree of protective effect on cognition. Other studies using no treatment control groups have also found that a longer term cognitive stimulation intervention can be effective in reducing cognitive decline in dementia (Zanetti et al., 1995, Metetieri et al., 2001).

It has been argued that benefits to cognition alone may not be sufficient to justify an extensive programme of intervention unless they are accompanied by other benefits such as quality of life (Woods et al., 2006). In chronic conditions quality of life may be more important for older adults than disease-specific outcomes and it is a key important outcome that interventions for dementia need to target. In line with previous studies (e.g. Selwood et al., 2005, Lykestsos et al., 2003, Missotten et al., 2007) individual changes in quality of life were apparent for nearly three-quarters of our sample. However, two recent systematic reviews have highlighted that there are few well designed studies on the effectiveness of either pharmacological (Cooper et al., 2012a) or psychosocial interventions (Cooper et al., 2012b) on quality of life. These reviews, found a lack of definitive evidence for either psychosocial or pharmacological interventions improving quality of life for people with dementia but the NNT for quality of life in our study suggests that MCST is an effective intervention.

In contrast to the Cochrane review of cognitive stimulation this study found that activities of daily living improved at 3 month follow up. However, previous research (Hoe et al., 2007) suggests that there is a correlation between proxy rated quality of life and activities of daily living, so it might be that the effects of the intervention on proxy rated quality of life was linked with effects on activities of daily living. Nevertheless, at 6 month follow up these proxy rated domains showed no difference.

The MCST-ACHEIs sub analysis results, were in line with other studies that have assessed the effectiveness of cognitive stimulation programmes in combination with ACHEIs (Woods et al., 2012) and suggest that the additional effect of cognitive stimulation on cognition are over and above the effects of medication alone. The benefits of ACHEIs on cognition have been demonstrated for mild to moderate Alzheimer's disease (Birks et al., 2006), but the impact of ACHEIs on quality of life has been difficult to assess because of the lack of appropriate quality of life measures within the clinical trials (Birks et al., 2006; Kaduszkiewicz et al., 2005). Future trials should include quality of life measures when evaluating the effectiveness of drugs for dementia.

10.5 Intervention compliance

In the stage 1 trial, CST session mean attendance was 10.4. Overall, there were 19 people who attended seven or less sessions out of the 14 session programme. Out of those 19 participants, four of them said that they did not want to come, without providing an explanation; five did not attend regularly giving reasons such as they were busy doing other things; another person said

that although they enjoyed the activities in the programme, they did not feel comfortable with the other group members and wanted to withdraw. Seven other participants withdrew and said that the group wasn't for them, as they did not feel comfortable in the group setting. The remaining two, verbally expressed their dislike for the group, the first due to "not liking" other participants and the second one due to 'time inconvenience' as the time of the group was the same as his attendance to an exercise class. When discussing attendance of these participants with staff co-facilitating the groups at this stage, staff often claimed that the participants mentioned above, were not 'much' of a group person and did not join any other activities run in the facility. All of the 19 participants who dropped out did so at stage 1 trial and did not want to take part in the second stage, reducing the number of people who refused to join the programme at the stage 2 stage of the trial.

With regard to the maintenance programme, mean attendance was 18 sessions; and 90% attended 14 sessions or more. There were no participants dropping out of the trial at this stage due to group issues, and only 6 participants overall, decided to drop out at this stage, when being approached for the follow up assessment. Amongst all the groups, attendance varied more between centres than between groups within a centre. Quality and type of centre were also amongst the most influential factors influencing the attendance and successfulness of the groups. The centre that was assessed as having the lowest quality (see point 9.6) was the one with lowest attendance amongst the three CST groups that were run in the facility (Group A, B and Maintenance).

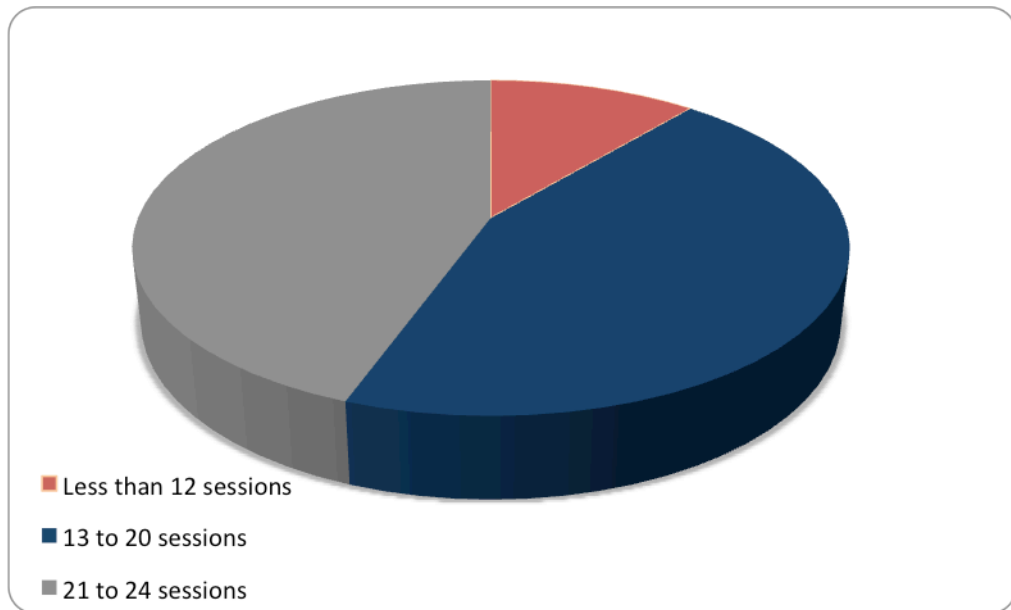


Figure 10-1. Graph showing the percentage of participants attending MCST

However, in order to explore whether compliance to the MCST programme affected or not the outcome measure results, a compliance analysis was run. With the aim of running this secondary analysis, compliance was defined as attendance at two thirds of the sessions. The analysis indicated that there was no evidence or relationship between level of MCST attendance and the outcomes measured. The directions of the relationships were inconsistent, with sometimes each of the three groups (control, MCST no compliance, MCST compliance) performing the best.

10.6 Comparison with past research

The results of this study, can be compared to the results from other cognitive stimulation RCTs results in a meta analysis, by taking into account the estimated means and standard deviations associated with this. In order to do this comparison, the effect seen on the primary outcome measures cognition and quality of life during the initial CST sessions with the 272 participants have been

taken into account and named as MCST 2011 (effectively this being the difference between baseline 1 and baseline 2 over the course of receiving CST) and compared to the effects seen in the studies that were included in the Cochrane review (Figure 10.2, 10.3 and 10.4). For ADAS-Cog and MMSE, the MCST 2011 study results are in line with other studies, giving a 1.86 change in ADAS-Cog and 0.98 change in MMSE in favour of CST (Figure 10.4 and 10.5).

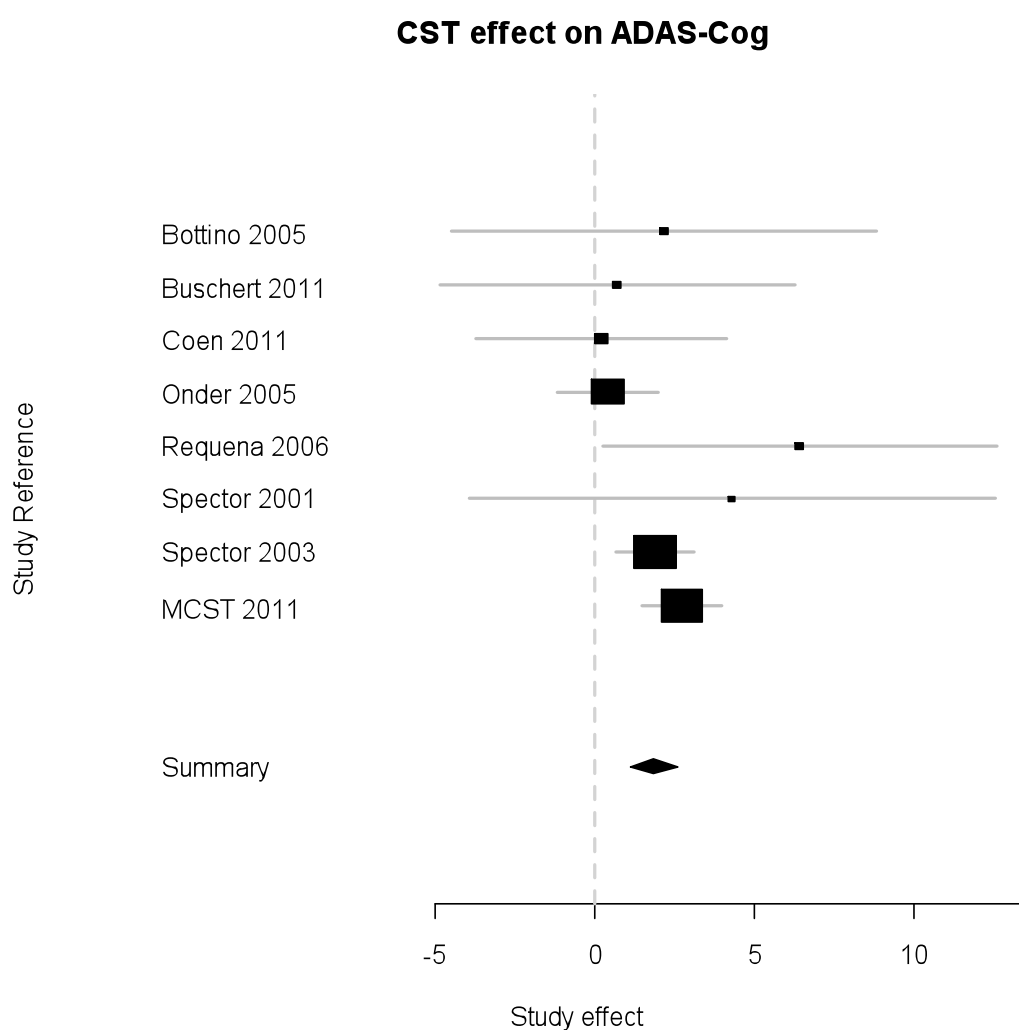


Figure 10-2. CST effect on ADAS-Cog

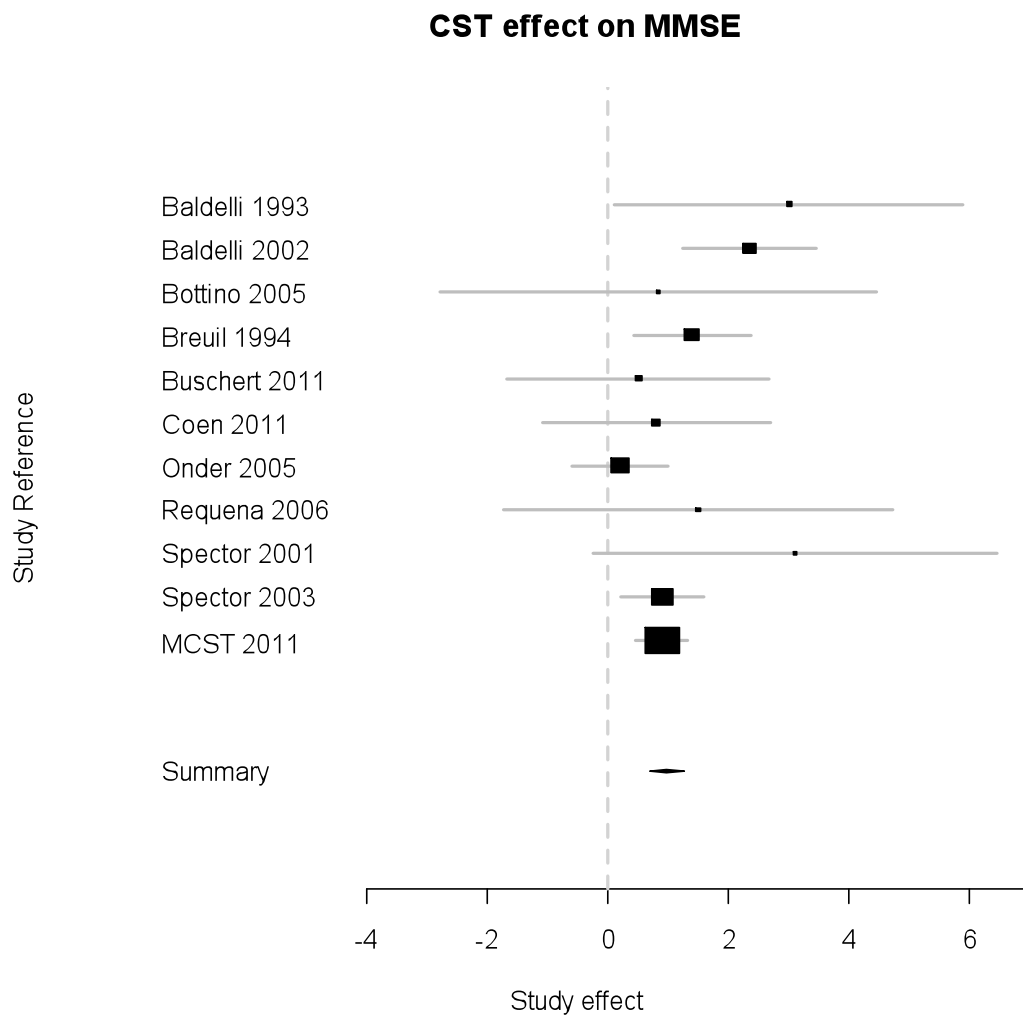


Figure 10-3. CST effect on MMSE

For QoL-AD the results showed that the effect for the CST group was around 0, adding information to the evidence from previous studies and giving a summary estimate of 0.55 in favour of CST (Figure 10.4).

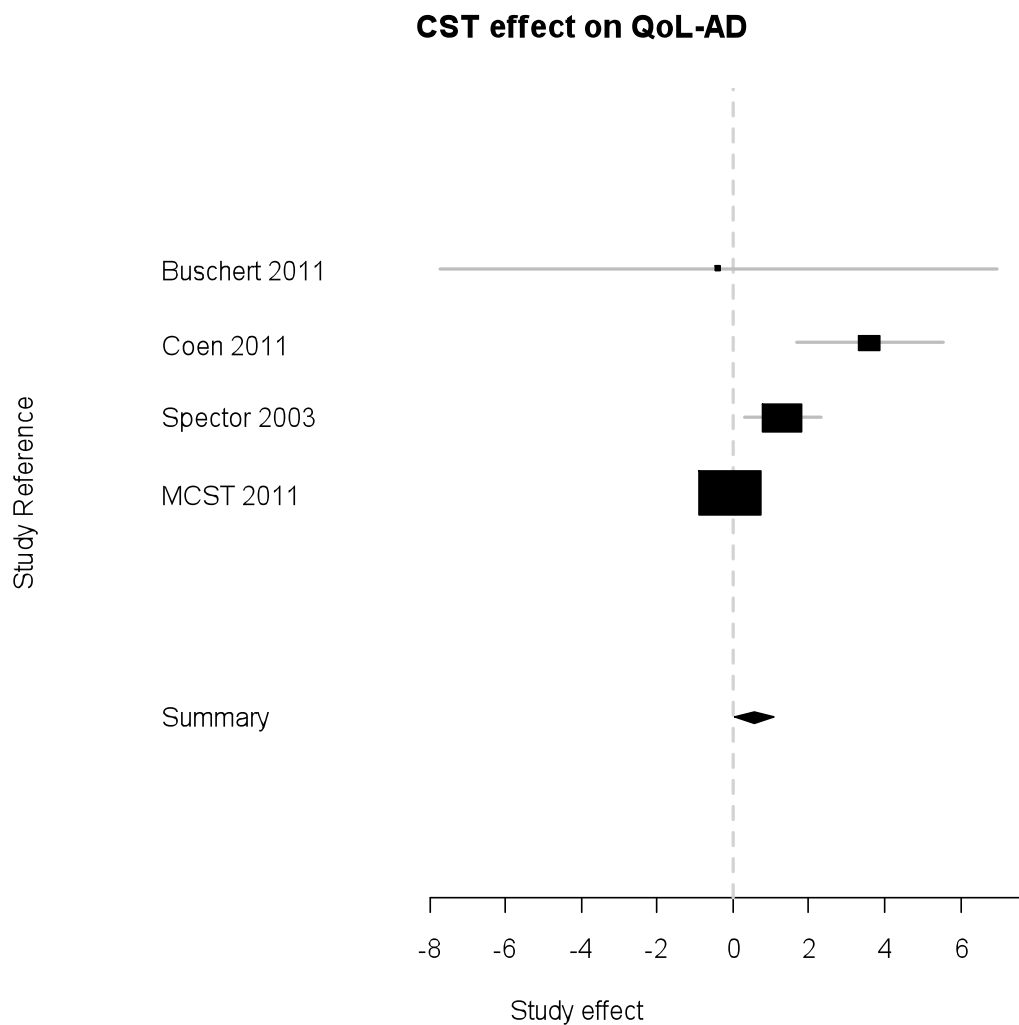


Figure 10-4. CST effect on QoL-AD

In summary, the cognitive benefits in ADAS-Cog and MMSE outcome measures after attending the intensive 7 week CST programme, can be seen immediately after it, whilst not so much changes in quality of life as measured by the QoL-AD. This information combined with the results of the full MCST RCT data, could be interpreted as the cognitive stimulation programme benefiting cognition immediately after the intensive period of the intervention while quality of life improving in the longer term section of the programme.

10.7 Limitations of the study

This trial aimed to meet the 'gold' standards of clinical trials. However as in many trials, a variety of biases were experienced (section 10.2), and these need to be taken into account when discussing the results. The reported study followed a well established framework for the development and evaluation of a complex clinical intervention, and the use of qualitative methods alongside the quantitative ones in the evaluation phase, might have benefited the study. This could have helped to better understand mechanisms of change.

The study might have benefited from a control group that does not received the initial 7 weeks of CST but treatment as usual from stage 1. This might have helped to better understand the effectiveness of the intervention in comparison with a comparable control group over the 8-month period time that lasted the trial. However, including this group in the trial could have been viewed as unethical since cognitive stimulation is well established as a standard treatment for dementia and recommended by NICE guidelines (2006).

An intention to treat analysis was chosen in order to evaluate effectiveness of the intervention, as it is the method that provides fewer biases. However, the amount of treatment each participant received couldn't be taken into account by using this method of analysis and therefore, the study could not assess the influence of other confounding variables (e.g. life events) that might have influenced outcome.

The biases raised from the selected outcome measures were discussed in detail in point 10.2 and the number of specific limitations at each of the trial stages discussed at the end of each of the previous chapters.

10.8 Future research

As described in chapter one, the number of people living with dementia is rising, with increased numbers of people living with dementia needing effective long term interventions, as the estimated median survival time from onset of dementia to death has been estimated to be between 6.6 years (Wolfson et al., 2001) and 4.1 years (Xie et al., 2008). However, as we know, there are many variables that influence life expectancy in people with dementia that make it difficult to define a prognosis (Zanetti et al., 1995), so further studies need to better define prognostic models and define, develop and evaluate long term interventions accordingly. Furthermore, although the results of these studies are promising in relation to a future where a combination of interventions might be of greater success than one intervention alone, future research is needed in order to explore the combination of different pharmacological and psychosocial interventions aimed at increasing not only cognition but also quality of life for people living with dementia in the long term.

This trial evaluating the development and efficacy of an overall 8 month intervention for dementia and its results offer promising results for the future of dementia care. Future studies therefore, need to consider the study results and the use of qualitative methods in order to better understand the processes and mechanisms of change. These trials should also aim to better understand

the neuropsychological basis of the intervention, using a larger sample size. Furthermore, alternative outcome measures could include the use of neuroimaging techniques that might help to explore the associations between regions of the brain and specific standardized psychometric tests to guide systematic observations of brain behavior relationships and high cognitive benefit to functional imaging. Other outcome measures could also be included, aimed to evaluate the effectiveness of such interventions focusing on staff and family caregiver effects to enable implementation and integration of these in practice.

Future studies needs to further evaluate the effectiveness of this intervention in quality of life as it is being considered one of the main outcomes that interventions for dementia need to target. As the trial showed to bring benefits in different quality of life outcome measures, (e.g. significant results on the DEMQOL after the CST first stage and QoL-AD significant differences after the MCST second stage) and as previous studies have shown that QoL-AD and DEMQOL might be measuring different constructs (Smith et al., 2005), the correlations between quality of life measures needs to be further explored in future trials. This will help to improve the development and evaluation of future psychosocial and pharmacological interventions, aimed at increasing quality of life in dementia care. Furthermore, as the results seemed to indicate that it might be that different elements of the CST/MCST intervention affect outcome measures at different period times (cognition immediately after the intensive CST programme and quality of life after the lower intensity but longer properties of the MCST programme) in order to better understand how CST and

MCST affect people with dementia quality of life, additional outcome measures such as Dementia Care Mapping, (Innes et al., 2003) and QUIS (Dean and Proudfoot 1993) should be included. These observational tools have shown to have potential qualities to measure quality of life (QOL) and well-being of people with dementia, and they include measuring some elements of person centred care. This will help to better understand how the different elements of CST specified in chapter 1 (mental stimulation, personal and social psychology and environment) might influence outcome measures differently (e.g. mental stimulation element in the programme might influence cognition whereas personal psychology and the person centred elements of the programme might influence quality of life). Therefore this future studies will help to better understand whether the person centred care elements of the intervention are the ones affecting quality of life outcome measures in the long term or whether CST acts as a unit and quality of life changes are mediated by cognitive changes seen after the first CST intensive phase as suggested by previous research (Woods et al., 2006). Qualitative analysis such as detailed field notes describing interactions in each session to developed ground theory (Glaser and Strauss) might also be helpful in order to understand the mechanisms for change. Involving service users, especially staff, care managers and family caregivers at the planning stages of these future studies as well as alongside the evaluation of the studies in an RCT, should potentially increase commitment to its implementation as it was shown to be very effective in the developmental stages of this study. These future studies would help to better understand if the proposed intervention is feasible in its implementation in practice.

Although this study evaluated the long term effectiveness of a cognitive based intervention, it might be of benefit that future research completes follow up assessments, for example after 3 and 6 months of completion of the MCST programme. in order to explore whether an intervention could be discontinued at the end of the 24 week session programme or be offered indefinitely.

The majority of participants in this study were white British, and although the successfulness of the psychosocial interventions for dementia might be the same, participants from other cultures may value different activities, which future studies could develop and explore. A good example of this is the translation of the programme into Hindi by a local team and adaptation of the sessions to their culture.

An economic analysis of the intervention is required, and is being carried out as an extension to this project by using the Client Services Receipt Inventories (CSRI), that was completed at all 3 time points and estimates the total cost of services used by each individual. This analysis is necessary in order to understand whether the effects seen by the intervention are value for money. These results are expected to influence future recommendations of the availability of the intervention in Governmental guidelines.

Finally, after the promising results from the long-term intervention, the 19 people who dropped out at the first stage of the trial, for whom a “group setting wasn’t ideal”, need to be taken into account. Future research should explore the development and evaluation of one to one cognitive stimulation programmes, either with a family caregiver or with a professional member of staff.

Furthermore, future studies will need to explore the effectiveness of these interventions in terms of family caregiver and staff outcomes as changes in quality of life in the person with dementia are likely to influence the quality of life of the family caregivers, the same way as levels of staff hope have been associated with residents perceived quality of life (Spector et al., 2005).

10.9 Implications for practice

The study results show that following the MRC framework for the development and evaluation of complex interventions, is a worthwhile way of setting up a pragmatic clinical research study and that the developed long term intervention of CST, when evaluated, showed to bring clear benefits over the eight month period that the intervention lasted. A MCST programme manual and DVD have been developed from the study and is now available (Aguirre et al., 2011). This manual should be used by staff in order to run the programme effectively and make it widely available.

As the study results showed to benefit not only cognitive abilities in people with dementia over the intervention period but significant changes in quality of life and activities of daily living. Therefore these results showed that the intervention should be disseminated and made routinely available in a variety of community and care home settings so that it can make a difference in dementia care.

Additionally the trial results showed that a long-term programme of CST in combination with antidementia drugs is extremely useful in potentially slowing down the process of dementia, so policy makers should promote the use of this

long term intervention and make it available alone or in combination with antimentia drugs.

10.10 Conclusions

This study is the first one comparing a long term versus a short term psychosocial intervention for dementia and brings not only empirical evidence to the field in relation to the effectiveness of long term programmes for dementia but also a powerful insight into the use of psychosocial interventions for dementia. The study shows how psychosocial interventions bring an added benefit to medication in dementia and can not only improve cognition but quality of life of people with dementia, making a 'real' difference to their lives. Its design from developmental stages to evaluation, based on the MRC framework for the development and evaluation of complex interventions, demonstrates the usefulness of the framework in the design and evaluation of good clinical interventions, and its results confirmed the latter.

Although the long term benefits of cognitive stimulation seem evident from the Cochrane Review available data, this study also confirms the short term follow up results from Baines (1987), Wallis (1983) and Baldelli (1993) showing that the effects of cognitive stimulation can be extended and prolonged for a longer period of time, independently of the dementia process, and moreover, showing that this type of programme may slow down the dementia process. The results from the ACHEI-MCST platform confirmed the same and suggest a promising future for the use of antimentia drugs and psychosocial therapies in combination over an extended period of time.

Dissemination of these findings should be made widely available, as a way of demonstrating that there is hope in dementia care and that there is something that can be done in order to help people with dementia to bring improvements to their lives. Future research needs to focus on the development and evaluation of one to one cognitive stimulation approaches, either with family caregivers, or professional facilitators as well as evaluate the long term implementation of programmes.

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Appendix 1

Study protocol:

Maintenance CST programme for dementia

MAINTENANCE COGNITIVE STIMULATION THERAPY GROUPS FOR DEMENTIA

1 Project title

Development and evaluation of a Maintenance CST programme for dementia

2. Background information

2.1 General information

Dementia is very common in old age and the frequency of dementia increases with age from around 5% in the over 65's to around 20% of those over 85. Approximately 700,000 people in the UK have dementia and of these 154,000 live alone. It has been estimated that by 2026 there will be 840,000 people with dementia in the UK rising to 1.2 million by 2050 (Department of Health, 2001). Around a third of people with dementia are severely affected and need help with activities of daily living, and of these 50% live at home with a carer, 13% live alone and 37% live in care homes. Older people with dementia frequently have complex needs because cognitive impairment often coexists with additional mental health problems, disabilities, physical illness and social problems. Dementia is a national priority and it has a vast impact on Health and Social Care Services. A recent review estimated the direct cost of Alzheimer's disease to be between £7 and £15 billion per year (Comas-Herrera et al., 2001) greater than stroke, heart disease and cancer combined.

Dementia has an enormous social and economic impact on health and social care services, and on family carers. This means that there is an urgent need to find more useful and effective interventions to help reduce the impact of dementia on people with dementia, carers and society. Drug treatments for dementia have an important role in dementia care but in the UK they are limited to people with Alzheimer's disease with moderately severe dementia. They have a limited impact on the illness, are not suitable for all patients, and cost around £1000 per year (Kaduszkiewicz et al., 2005). Although most attention has been given to pharmacological interventions, there is increasing recognition that psychosocial interventions may have comparable value (Spector et al. 2003), and may be preferable, for example, where medication may have intolerable side-effects (McShane et al. 1997).

Psychological treatments for dementia such as reality orientation and reminiscence sessions have been in use for nearly half a century, and are widely used in the UK and internationally. In the UK there is recognition that psychological therapies for older people should be more widely available, and the NSF for Older People (Department of Health, 2001) states that 'treatment for dementia always involves using non-pharmacological management strategies such as mental stimulation'.

2.2 Maintenance CST background information

There are many psychosocial interventions for dementia but often these have not been standardised, adequately evaluated or systematically implemented. A number of systematic reviews of psychosocial interventions are now available (Livingston et al., 2005; Woods, 2002; Brodaty et al., 2003), as well as a number of Cochrane reviews of specific approaches (e.g. Clare et al., 2004; Spector et al., 1998).

Our Cochrane review of RO was used to develop a seven week evidence-based Cognitive Stimulation Therapy (CST) programme for people with dementia (Spector et al., 2003). In our Department of Health (Responsive Funding) funded project, 201 people were recruited for this single-blind, multi-centre RCT from 23 day centres and residential homes in greater London. The CST group improved significantly on the main outcome measures (cognition and quality of life). Indeed, in the recent draft NICE guidelines on dementia (NICE-SCIE, 2006) recommend that all people with mild/moderate dementia should be ‘given the opportunity to participate in a structured group cognitive stimulation programme’.

A number of studies have suggested that cognitive stimulation approaches may have longer term effects (Zanetti et al., 1995; Metitieri et al., 2001). However, the long-term effects of CST were not evaluated by Spector et al. (2003) and the Cochrane review found no clear evidence of any long-term effects of RO. Gerber et al. (1991) found that benefits for cognition and behaviour gained from RO were lost ten weeks after stopping the programme. Wallis et al. (1983) found that one month after RO terminated, benefits in cognition were lost yet behavioural functioning continued to improve. It therefore appears uncertain as to how long any benefits of RO, or similar interventions, may remain after the programme finishes. Further, it is uncertain how far maintenance programmes of RO might continue to benefit the participants.

The studies included in the RO Cochrane review ranged from using programmes of four to 21 weeks. However, there did not appear to be a relationship between the duration of the intervention and the outcome, and the trial with the best results (Breuil et al., 1994) only had a five-week intervention. Zanetti et al. (1995) cited an expected yearly decrease in Mini- Mental-State-Examination score (MMSE, Folstein et al., 1975) of 1.8–4.2 points in people with dementia. Therefore, it might be that pre-post comparisons in the studies which had used longer interventions (20 and 21 weeks) would have shown weaker results (Ferrario et al., 1991; Woods, 1979).

A number of studies have looked at the effects of an extended RO programme. Zanetti et al. (1995), in a controlled trial, evaluated the effects of more long term RO. Their intervention ran in four cycles of 20 session blocks with rest periods in between, lasting 8.2 months in total. They found that the effect of RO on cognitive performance (a small increase in MMSE score of 0.68 points) appeared to counteract the decline, observed in the control group, of 2.58 points. Metitieri et al. (2001) studied

the more long term effects of RO by assessing 74 people with dementia over a 30-month period, who completed at least one 'cycle' of RO groups (20 sessions). They compared 46 people who completed from 2–10 cycles (8–40 weeks of training) with the 28 who only completed one cycle. They found that people receiving long-term treatment declined in cognitive function significantly later, and remained at home longer than those receiving only one cycle of RO. Both studies concluded that more long-term RO was effective in slowing, at least temporarily, the dementia process. A recent pilot study of maintenance CST (Orrell, 2005), running once a week for an additional 16 weeks, found a significant improvement in cognitive function (MMSE) for those receiving MCST. The study identified the need for a large-scale, multi-centre RCT to define the potential longer-term benefits of MCST for dementia.

The results of the RCT CST compared favourably with trials of cholinesterase inhibitors for Alzheimer's disease (Spector et al, 2003) and the economic analysis showed that CST was likely to be cost-effective (Knapp et al, 2006). Two recent RCTs found that over 6 months cognitive stimulation and cholinesterase inhibitors in combination were more effective than cholinesterase inhibitors alone (Olazaran 2004, Onder 2005). On a recent RCT of Reality Orientation therapy (3 days a week, 30min/day, for 25 consecutive weeks) combined with cholinesterase inhibitors vs. cholinesterase inhibitors alone found that Reality Orientation enhances the effects of donepezil on cognition in Alzheimer's disease. They randomly assigned 79 of 156 patients treated with donepezil to receive a reality orientation programme. The treatment group showed a slight improvement in Mini-Mental State Examination (MMSE) scores (mean change +0.2, s.e. 0.4) compared with a decline in the control group (mean change -1.1, s.e. 0.4; $P=0.02$). (Onder et al., 2005). According to this results Olazaran et al. 2004 in a RCT evaluating the efficacy of a cognitive-motor program in patients with early Alzheimer disease (AD) who were treated with a cholinesterase inhibitor (ChEI). They found that patients in the CMI group maintained cognitive status at month 6, whereas patients in the control group (without psychosocial intervention) had significantly declined at that time. In addition, they found that more patients in the experimental group maintained or improved their affective status at month 12 (experimental group, 75%; control group, 47%). (Olazaran 2004). However better evidence for their effectiveness is required before wider implementation is considered. It is also necessary to examine whether the combination of Maintenance CST with cholinesterase inhibitors for Alzheimer's disease is cost effective and brings extra long term benefits to cognition and quality of life of people with dementia. This research programme will provide essential evidence to clarify the role of each of these interventions alone and in combination in improving the quality of life and cognition for people with dementia and its long term effects.

3. Research objectives

3.1 Aim

To develop, evaluate, and implement a Maintenance CST programme and carry out a multicentre RCT for its evaluation.

3.2 Objectives

1. To conduct a Cochrane Systematic review on the effectiveness of cognitive stimulation for dementia.
2. To conduct a Systematic review on the effectiveness of maintenance cognitive stimulation
3. To develop a systematic revision of maintenance CST and training materials using the results of the systematic review.
4. To conduct a feasibility study maintenance CST to field test training package and outcomes adherence measures
5. To conduct a randomised control trial to determinate the effectiveness and long term effects (cognition and quality of life) of maintenance CST vs. CST alone in people with dementia.

4 Trial Methods

4.1 Work Package 1

Cochrane Review Protocol on Cognitive Stimulation to improve cognitive functioning in people with dementia (Woods et al., 2005)

Objectives

- To evaluate the effectiveness and impact of cognitive stimulation interventions aimed at improving cognition for people with dementia, including any negative effects.
- To indicate the nature and quality of the evidence available on this topic.
- To assist in establishing the appropriateness of offering cognitive stimulation interventions to people with dementia and identifying the factors associated with efficacy.

Criteria for considering studies for the review

Types of studies

Randomized controlled trials, for which adequate information is provided or can be obtained from the researchers, will be considered for inclusion.

Types of participants

- Participants with a diagnosis of dementia will be included. The main diagnostic categories involved are likely to be Alzheimer's disease, vascular dementia or mixed Alzheimer's and vascular dementia. These diagnostic categories will be considered together. If the data permit, the specific diagnostic categories will also be considered separately, but it is recognised that this may not be possible.
- Severity of dementia must be indicated through group mean scores, range of scores, or individual scores on a standardized scale such as the Mini-Mental State Examination (MMSE) or Clinical Dementia Rating (CDR). All levels of severity may be included.
- Qualifying participants may receive the intervention in a range of settings, including their home, out-patient, day-care and residential settings.
- No specific restrictions regarding age will be applied.
- Data from family caregivers will be included where this is available, and where the relationship between the caregiver and the person with dementia is specified, including whether they are co-resident.
- Numbers of participants receiving concurrent treatment with acetyl cholinesterase inhibitors will be documented where possible.

Types of intervention

- Cognitive stimulation interventions targeting cognitive and social functioning will be included. These may also be described as RO groups, sessions or classes.
- Interventions must offer generalised cognitive practice, rather than training in a specific modality.
- Interventions will typically be conducted in a group to enhance social functioning, and may involve family caregivers.
- Studies may compare the intervention to 'no treatment', 'standard treatment', or placebo. 'Standard treatment' is that normally provided in the study setting to patients with dementia, and may include provision of medication, clinic consultations, contact with a community mental health team, day care, or support from voluntary organizations. Placebo conditions may consist, for example, of an equivalent number of sessions in which general support, but no structured intervention, is offered.
- The minimum duration of intervention will be one month, but there will be no restriction on the number of treatment sessions, although this will be noted.

Types of outcome measures

- Outcomes will be considered in relation to the impact of intervention on the person with dementia and on the primary family caregiver. Studies may present data in both these categories.
- Short-term (up to 1 month) and medium-term (1 month to 1 year) outcomes will be considered.
- Outcomes for the person with dementia and caregiver will be considered where these are assessed using scores on standardized tests, rating scales and questionnaires.
- Rates of attrition and reasons for this will be noted.

Outcomes for the person with dementia

Outcome measures for the person with dementia seek to identify whether changes are observed following the intervention. Outcomes for the person with dementia must include:

- Performance on at least one test of cognitive functioning (may include tests of memory and orientation).

In addition, the following range of outcomes will be considered:

- Self-reported, clinically-rated or carer-reported mood.
- Self-reported or carer-reported quality of life or well-being.
- Observer or carer ratings of everyday functioning (activities of daily living).
- Carer ratings of behaviour.
- Clinician or carer ratings of neuropsychiatric symptoms.
- Clinician or carer ratings of social engagement.

Outcomes for the family caregiver

Outcomes for the family caregiver that will be considered include any of the following:

- Self-reported well-being, depression and anxiety.
- Self-reported burden, strain and coping.
- Satisfaction with the intervention.

Search methods for identification of studies

Searches will be based on the Cochrane Dementia and Cognitive Improvement Group methods used in their reviews. Searches will involve consulting the following sources to identify relevant studies and other papers that have cited these studies:

- CDCIG specialized trials register
- DARE
- Electronic databases: Science Citation Index, Social Science Citation Index.
- Reference lists of published articles and books.
- Hand search of relevant conference proceedings.
- First authors of any identified RCTs that are potentially suitable for inclusion.
- Dementia researchers in European countries for information about studies published in languages other than English.
- Key dementia researchers and research centres internationally for information on unpublished or in press studies.

Search terms used will involve all possible combinations of terms from the following two categories (apart from searches of the CDCIG specialised trials register which require only the latter category):

- Alzheimer's disease, Alzheimer disease, Alzheimer-type dementia, Alzheimer's, Alzheimer, vascular dementia, multi- infarct dementia, mixed dementia, dementia.
- Cognitive stimulation, Reality Orientation, memory therapy, memory groups, memory support, memory stimulation, global stimulation, cognitive psychostimulation, psychomotor performance.

Methods of the review

1. Searches will be conducted as detailed above to identify all relevant published studies. The date and time of each search, together with details of the version of the database used, will be recorded.
2. Additional information will be sought as outlined above.
3. Hard copies of articles will be obtained.
4. RCTs will be identified and the reviewers will work independently to determine which studies meet the criteria for inclusion. Trials that do not meet the criteria will be excluded. Reviewers' selection of trials will be compared and the final list of studies will be reached by consensus.

5. The selected RCTs will be described in tabular form, permitting an evaluation of their methodological quality. Studies will be assessed against a checklist of quality requirements using the Cochrane approach:

- Grade A: Adequate concealment (randomization; concealed allocation).
- Grade B: “Randomized” but methods uncertain.
- Grade C: Inadequate concealment of allocation and/or no randomization.

Only trials with a grade A or B ranking will be included in the review. Again, the reviewers will work independently to ascertain which studies meet quality criteria, and consensus will then be reached through discussion. If necessary, attempts will be made to obtain additional information from the study authors.

6. Data from the RCTs selected for inclusion will be extracted, recorded and entered into RevMan. The summary statistics required for each trial and each outcome for continuous data are the mean change from baseline, the standard error of the mean the reviewers will extract the mean, standard deviation and the number of patients for each treatment group at each time point if available. The reviewers will calculate required summary statistics from the baseline and assessment time treatment group means and standard deviations, assuming in this case a zero correlation between the measurements at baseline and assessment time. This method overestimates the standard deviation of the change from baseline, but this conservative approach is preferable in a meta-analysis. For binary data they will seek the numbers in each treatment group and the numbers experiencing the outcome of interest. The baseline assessment is defined as the latest available assessment prior to randomization, but no longer than two months prior.

For each outcome measure, they will seek data on every patient randomized. To allow an intention-to-treat analysis, the data will be sought irrespective of compliance, whether or not the patient was subsequently deemed ineligible, or otherwise excluded from treatment or follow-up. If intention-to-treat data are not available in the publications, “on-treatment” or the data of those who complete the trial will be sought and indicated as such. In studies where a cross-over design was used, only data from the first treatment phase after randomization will be eligible for inclusion.

The outcomes measured in clinical trials of dementia and cognitive impairment often arise from ordinal rating scales. Where the rating scales used in the trials have a reasonably large number of categories (more than 10) the data will be treated as continuous outcomes arising from a normal distribution.

The meta-analysis requires the combination of data from trials that may not use the same rating scale to assess an outcome. The measure of the treatment difference for any outcome will be the weighted mean difference when the pooled trials use the same rating scale or test, and the standardised mean

difference (the absolute mean difference divided by the standard deviation) when they use different rating scales or tests. The duration of the trials may vary considerably. If the reviewers consider the range too great to combine all trials into one meta-analysis, they will divide it into smaller time periods and conduct a separate meta-analysis for each period. Some trials may contribute data to more than one time period if multiple assessments are made. For binary outcomes, such as clinical improvement or no clinical improvement, the reviewers will use the odds ratio to measure treatment effect. They will then calculate a weighted estimate of the typical treatment effect across trials.

The reviewers will present overall estimates of the treatment difference. In all cases they aim to present the overall estimate from a fixed effects model and perform a test for heterogeneity using a standard chi-square statistic. If, however, there is evidence of heterogeneity of the treatment effect between trials then they will either pool only homogeneous results, or use a random-effects model (in which case the confidence intervals would be broader than those of a fixed-effects model).

7. The reviewers will discuss and reach consensus on the interpretation of the statistical analyses, seeking specialist statistical advice from CDCIG as required. Non-randomized studies will be described in tabular form and the reviewers will similarly discuss and reach consensus on the presentation of the findings in the background to the review.

8. The review will then be drafted and circulated for comment to the reviewers and lay commentators, leading to production of the final version for submission to CDCIG.

Implications

This protocol and the subsequent review will replace the review of Reality Orientation for dementia (Spector A, Orrell M, Davies S, Woods B. Reality orientation for dementia. The Cochrane Database of Systematic Reviews 2000, Issue 3. Art.No.: CD001119).

Updates the Cochrane review on Reality Orientation/Cognitive Stimulation by repeating the systematic literature search and meta-analysis in collaboration with the Cochrane Dementia & Cognitive Impairment Group (CDCIG).

4.2 Work Package 2

Development of a maintenance CST training package based on the Cochrane Review on Cognitive Stimulation to improve cognitive functioning in people with dementia and the existing CST manual (Spector et al., 2006).

Objectives

- To identify from the Cochrane Review studies the interventions that have shown to be effective and have had an impact at improving cognition and quality for people with dementia including any negative effects.
- To indicate the nature and quality of the interventions and identify key themes and elements.
- To develop from the analysed interventions and current CST training manual a 24 weekly sessions of Maintenance CST.
- To develop a Maintenance CST training package for care staff based on the existing CST manual. This comprising a manual workbook, DVD and training seminars.

Development of a Maintenance CST sessions and workbook.

1. To select all relevant and effective interventions from the CST Cochrane review
2. The selected interventions from the Cochrane Review (WP1) will be described in tabular form, permitting an evaluation of the authors and contact details. Authors will be contacted with the aim of getting additional information and hard copies of the intervention programs manuals will be obtained and translated into English.
3. The research team will develop a list identifying themes and properties of the manuals and will create a database with the different elements of each intervention including guiding principles and sessions found.
4. Key themes from the initial CST manual (Spector, 2006) guiding principles and sessions will then organised in a database including the 16 sessions developed for the Maintenance CST pilot project.
5. Based on the results of step 4 a draft manual (Version I) will be produced by the CST team (AS, MO, BW, EA).
6. The results from the analysis of the cognitive stimulation manuals including the original papers, manuals and table database will be presented in a consensus workshop (comprising key academics, research staff and clinical staff involved in CST practice) and used to validate and review the draft version of the CST manual draft (Step 5).
7. A draft of CST manual (Version II) including 24 maintenance sessions will be revised using the results of the consensus workshop.
8. The CST manual draft will be discussed in focus groups with care staff (3), carers (3) and people with dementia (3) to review key themes, feasibility and potential modifications.

9. The revised CST manual will be further modified in a final Delphi process including the attendees of the consensus workshop and key contributors to other aspects of process (e.g. a sample of care staff, carers, clinical staff and leading experts on CST; (EMC, BW, AS, Spanish and Italian experts).

10. The revised CST manual (version III) will be produced to publication quality.

11. The revised CST manual will be used in the development of a revised version of the CST training package (AS) comprising the revised manual, a CST/DVD including extra maintenance sessions, PowerPoint presentation, methods of evaluation and adherence. The team developing the training package will comprise AS, EA, MO, BW and trainers from for dementia.

Implications

Complete development of a maintenance CST training package that will comprise a workbook, DVD and training seminars. A training package will then be tested for adherence and competence on the WP2.

4.3 Work Package 3

A multicentre RCT of Maintenance CST vs. CST for dementia .

4.3.1 Methods

Participants

Day centres, residential homes and CMHTs with a minimum of 14 residents each (to maximise numbers of suitable participants) will be contacted in the participating areas (NELFT). 50% of the sample will be recruited from the community and 50% from care homes. The researchers will investigate all interested centres (day centres, CMHTs and residential homes) to determine whether there are adequate numbers of potential participants with dementia, by using an inclusion criteria flow chart. A minimum of eight or more eligible people will be required in each centre, because five are the minimum needed number for the group, leaving three or more control participants.

Inclusion criteria

People will be considered suitable for full assessment and participation if they:

- a. meet the DSM–IV criteria for dementia (American Psychiatric Association 1994)
- b. score between 0.5 and 2 on the Clinical Dementia Rating (CDR) (Hughes et al., 1982)
- c. have some ability to communicate and understand communication—a score of 1 or 0 in questions 12 and 13 of the Clifton Assessment Procedures for the Elderly – Behaviour Rating Scale (CAPE–BRS; Pattie & Gilleard, 1979)
- d. are able to see and hear well enough to participate in the group and make use of most of the material in the programme, as determined by the researcher
- e. do not have major physical illness or disability which could affect participation
- f. do not have a diagnosis of a learning disability.
- g. able to communicate in English

Procedure and process of randomization

In residential homes, community and day centres with at least eight suitable participants, full assessments are going to be conducted in the week prior to, and the week following, the intervention by a researcher blind to group membership. It is expected that it will be more people in the intervention group because frequently centres as in the RCT of CST will have only eight or nine suitable participants, and five of these had to be randomised to the intervention group (CST only). Control group participants from each centre will continue with usual activities while the group therapy is in progress. As previous research experiences it is predicted that for most residential homes ‘usual activities’ will be doing nothing. For other centres, usual activities will include games such as bingo, music and singing, arts and crafts, and activity groups. Within each centre, one researcher (the therapist) will run the group (CST plus 24 Week maintenance) and the other (the assessor) will

conduct initial and follow-up assessments. People with dementia recruited into the trial and meeting the inclusion criteria will be recruited into the CST groups (5 to 8 per group).

After completion of the initial CST programme (twice weekly 45 min sessions for 7 weeks) they will be randomised into either the CST only control group (treatment as usual for 24 weeks) or MCST group (maintenance CST weekly for 24 weeks). We will stratify the sample according to whether or not they are receiving cholinesterase inhibitors; stratification will be used to ensure balance between the randomised groups in respect of use of cholinesterase inhibitors. This will ensure that the randomisation of participants with Alzheimer's taking cholinesterase inhibitors, leads to approximately equal numbers being allocated to either the Maintenance CST or the control group.

During the Maintenance CST phase any changes to cholinesterase inhibitor medication will be recorded. As part of the trial information regarding cholinesterase inhibitors will be recorded and randomization will be stratified depending on the type of dementia and living situation. The clinical team will be encouraged to consider using cholinesterase inhibitors if appropriate and to follow good clinical practice and standards. This study is not a drug trial and the responsibilities for prescribing and monitoring the medication remain within the clinical team and not the research team

The primary outcome measures would be cognition (ADAS-Cog) and quality of life (QoL-AD) at 24 weeks follow up. In the CST trial (2001), which recruited people with mild/moderate dementia (MMSE 10-24), community and institutional participants had the same mean level of cognitive impairment (MMSE 14.5 and 14.1). The RO review (Spector et al., 1998) found a moderate effect size of 0.58 between the RO and control groups though the studies had some differences in methodology, outcome measures, and length of treatment/follow up. The MCST pilot study found a large effect size of 1.0 compared with CST alone. To detect an effect size for MCST of 0.39 on the ADAS-Cog with power of 80% using a 5% significance level and an estimated attrition of 15% needs a sample size of 230

Measures

• *Primary Outcomes:*

Cognition. ADAS- Cog, (Rosen et al., 1984)

ADAS was designed to measure the severity of the most important symptoms of Alzheimer's disease (AD). Its subscale ADAS-cog is the most popular cognitive testing instrument used in clinical trials of no tropics. It consists of 11 tasks measuring the disturbances of memory, language, praxis, attention and other cognitive abilities which are often referred to as the core symptoms of AD. This is a brief, widely used test of cognitive function, with good reliability and validity.

Quality of life.

Quality of Life—Alzheimer's disease Scale (QoL-AD; Logsdon et al., 1999)

This brief, self-report questionnaire has 13 items covering the domains of physical health, energy, mood, living situation, memory, family, marriage, friends, chores, fun, money, self and life as a whole. It has good internal consistency, validity and reliability (Logsdon et al., 1999; Thorgrimsen et al., 2003).

• *Secondary Outcomes:*

Cognition. Mini-Mental State Examination (MMSE) (Folstein et al.1975)

The MMSE is a brief, widely used test of cognitive function, with good reliability and validity.

Quality of life. Dem QoL (Smith et al., 2005b)

The DEMQOL was developed to provide a psychometrically rigorous measure of health related QoL in people with dementia and the scale measures 5 domains: health and well-being, cognitive functioning, social relationships and self-concept. The domain items are rated as a lot, quite a bit, a little and not at all with scores calculated from 1 (a lot) – 4 (not at all) and summed to produce a total score. The scale uses self rated reports of QoL administered by a trained interviewer; there is also a separate scale for family caregiver reports, the DEMQOL-proxy. The DEMQOL was developed in the UK through a review of the literature, qualitative interviews and consultation which included people with dementia, family caregivers and experts in dementia. The DEMQOL had high internal consistency (0.87) and acceptable inter-rater reliability (ICC 0.84) and indicates concurrent validity through moderate associations with the QOL-AD and DQOL.

Depression. The Cornell Scale for Depression in Dementia (Alexopoulos et al, 1988)

This scale rates depression in five broad categories (mood-related signs, behavioural disturbance, physical signs, biological functions and ideational disturbance) using information from interviews with staff and participants. Good reliability and validity have been demonstrated.

Anxiety. Rating Anxiety in Dementia (RAID; Shankar et al, 1999)

This rates anxiety in four main categories (worry, apprehension and vigilance, motor tension, and automatic hypersensitivity) using interviews with staff and participants. It has good validity and reliability.

Behaviour. Neuropsychiatric Inventory (NPI) (Cummings et al. 1994)

The NPI assess 10 behavioural disturbances occurring in dementia patients: delusions, hallucinations, dysphoria, anxiety, agitation/aggression, euphoria, disinhibition, irritability/lability, apathy, and aberrant motor activity. The NPI uses a screening strategy to minimize administration time, examining and scoring only those behavioural domains with positive responses to screening questions. Both the frequency and the severity of each behaviour are determined. Information for the NPI is obtained from a caregiver familiar with the patient's behaviour. Studies reported here demonstrate the content and concurrent validity as well as between-rater, test-retest, and internal consistency reliability; the instrument is both valid and reliable.

Activities of daily living. Alzheimer's Disease Co-operative Study – Activities of Daily Living Inventory (ADCS-ADL) (Galasko, et al., 1997)

The ADCS-ADL is a structured questionnaire originally created to assess functional capacity over a broad range of severity of dementia. Each item consists of a series of hierarchical questions designed to determine a patient's ability to perform one of the activities of daily living, ranging from total independence to total inability.

Planned interventions

The plan interventions that constitute this trial are Cognitive Stimulation Therapy and Maintenance Cognitive Stimulation Therapy.

Although the first phase of the trial consist of identifying the people with dementia that are taking Cholinesterase inhibitors and the potential candidates suitable for taking Cholinesterase inhibitor the only part of the trial consist of referring people to the appropriate health care teams in order to prescribe and monitor the medication. This randomised control trial is not a drug trial therefore all clinical responsibilities remain within the clinical team on charge of prescribing and monitoring medication.

The interventions include on this RCT are Cognitive Stimulation Therapy for all the sample, brief treatment for people with mild to moderate dementia, designed following extensive evaluation of research evidence, hence is an evidence-based treatment (Spector et al, 2003) and is been recommended on the recent NICE guidance for people with mild to moderate dementia, irrespective of drug treatments received. CST treatment can be administered by anyone working with people with dementia, such as care workers, Occupational Therapists or nurses. CST groups can take place in settings including residential homes, hospitals or day centres. Practitioners can learn to provide CST treatment for people with dementia by following the CST manual or attending CST training. The programme consisted of 14, 45-minute sessions which ran twice weekly for groups of approximately

five people. Topics included; using money, word games, the present day and famous faces, and multisensory stimulation was used when possible. The programme included an 'RO board', displaying both personal and orientation information, including the group name (chosen by participants). The guiding principles of CST are the principles of Person-Centred Care - treating people as unique individuals with their own personality and preferences. This is an essential aspect when delivering CST therapy for people with dementia. For this reason, group members are often assigned a role within the group, according to their interests and abilities. People must be respected and involved throughout. The CST programme aims to create an environment where people learn and strengthen their existing resources, hence functioning at their maximum capacity. This is achieved through implicit learning rather than explicit teaching. For example, people are asked of their opinions rather than to provide factual answers; and multi-sensory stimulation is used to stimulate all the senses.

Reminiscence is integrated into the programme, partly used as a means to orientate to the here and now. There is always a tangible focus - something for each person to look at, feel, hear or smell - aiding concentration. Creating consistency and continuity between sessions minimises confusion and can help to aid retrieval.

Sessions are as follows:

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

After completion of the initial CST programme participants will be randomised into either the CST only control group (treatment as usual for 24 weeks) or Maintenance CST group (Maintenance CST weekly for 24 weeks). The original maintenance CST of 16 sessions follows the same themes and principles that will be revised and further developed for this trial on the trial phase I. The current 16 sessions (16 Weeks) from the pilot Maintenance CST (Orrell et al., 2005) were as follows:

- | | |
|---------------------------|--------------------------------|
| 1. <i>Childhood</i> | 9. <i>Categorizing objects</i> |
| 2. <i>Current affairs</i> | 10. <i>Using objects</i> |
| 3. <i>Current affairs</i> | 11. <i>Useful tips</i> |
| 4. <i>Using objects</i> | 12. <i>Discussion topics</i> |
| 5. <i>Number Games</i> | 13. <i>Discussion topics</i> |
| 6. <i>Quiz</i> | 14. <i>Discussion topics</i> |
| 7. <i>Music session</i> | 15. <i>Famous faces</i> |
| 8. <i>Physical games</i> | 16. <i>Word completion</i> |

The participants randomly allocated to the control group will receive treatment as usual and will naturally vary between and within centres and may change over time. In general, the interventions that could possibly been offered to this group will also be available to those in the active treatment groups, so that we will be examining the additional effects of maintenance CST. The only exception to this would be where the active treatment is scheduled at the same time as an alternative intervention. Our approach to costing the services and interventions received should allow us to monitor whether the usual treatment group is receiving alternative interventions in this way.

Changes and developments in the availability of medications for Alzheimer's and other dementias will affect both groups equally, and will be recorded as part of the costing information collected. It is entirely feasible that participants in the usual treatment group may be involved in some form of cognitive stimulation work during the 24 weeks of the study period. It is a popular approach in day-care centres. However, it is very unlikely that, in our experience, such a structured approach to CST will be offered in any of the centres. It is this systematic group-based approach, rather than a general exhortation to cognitive stimulation activity to improve cognition and quality of life, that is the concern of this evaluation.

is reproducible and ready for wide dissemination.

4.3.2 Recruitment and training of facilitators

CST treatment can be administered by anyone working with people with dementia, such as care workers, Occupational Therapists or nurses. CST groups can take place in settings including residential homes, hospitals or day centres. Practitioners can learn to provide CST treatment for people with dementia by following the CST manual or attending CST training. In the proposed trial, training will be delivered by Dr. Aimee Spector (clinical psychologist and research pioneer on the CST RCT) and researchers (EA) will be trained on CST providing the training and supervision to staff running the groups as well as running CST sessions for the main RCT. We anticipate that main

facilitators will have a mental health nursing or occupational therapy or clinical psychology background but experience in dementia care, group facilitation skills, warmth, energy and enthusiasm are as important as any particular professional qualification. The use of two facilitators for each group enables effective de-briefing and learning to occur at the end of each session.

4.3.3 Trial Analyses

RCT Data Analyses

We shall analyse by intention to treat, in that all available data will be included, however methods of imputation such as LOCF are of limited utility in dementia, where the expectation is decline for the usual treatment group, and participants will be lost through death and illness. Hence our sample size calculations are based on the numbers estimated to be available at the study end-point, 6 months after randomisation to either CST only group or maintenance CST group. Multi-level modelling will be used to address the issue of clustering within randomised groups. We shall also use analysis of covariance to adjust for baseline differences in outcome variables. Analyses will consider the evaluation 6 months after randomisation as the primary end-point in evaluating whether the intervention has had a substantive effect on the person with dementia. Secondary analyses will consider the effects immediately following the CST, 3 and 6 months. Statistical Package for the Social Sciences, SPSS will be used to analyze the data. An intention-to-treat analysis will be conducted and analysis of covariance (ANCOVA) has been chosen as the method of analysis because it controls for variability in pre-test scores (the 'covariate'; Vickers & Altman, 2001). Age, gender, cholinesterase inhibitor and baseline score on the scale being examined will be enter as covariates, together with 'centre' enter as a random factor, because treatment has been defined as participation in the group programme within the confines of the centres.

Power calculation

The RO review found a moderate effect size of 0.58 between the RO and control groups though the studies had some differences in methodology, outcome measures, and length of treatment/follow up. The MCST pilot study found a large effect size of 1.0 compared with CST alone. To detect an effect size for MCST of 0.39 on the ADASCog with power of 80% using a 5% significance level and an estimated attrition of 15% needs a sample size of 230. If an estimated 60 have Alzheimers and are suitable/willing to take Donepezil, this will provide sufficient numbers for the MCST/Donepezil trial platform to estimate effect size and the feasibility of the trial.

4.3.4 Ethical arrangements

Risks and anticipated benefits for trial participants

There appear to be no documented harmful side-effects from participating in CST or Maintenance CST groups, and no adverse reactions were apparent in the CST study. Benefits are consistently reported by participants in the groups, including enjoyment, feelings of validation and self-worth. The desire of participants to continue meeting following the sessions provides an indication of the value placed on the benefits. Prospective participants will be fully informed of the potential risks and benefits of the project.

Consent

Participants will be in the mild to moderate stages of dementia, and therefore would generally be expected to be competent to give informed consent for participation, provided that appropriate care is taken in explaining the research and sufficient time is allowed for them to reach a decision. It is helpful for a family member or other supporter to be involved, and we would aim to ensure that this is done wherever possible. It will be made clear to both participants and family care-givers that no disadvantage will accrue if they choose not to participate.

In seeking consent, we will follow current guidance from the British Psychological Society on evaluation of capacity. In this context, consent has to be regarded as a continuing process rather than a one-off decision, and willingness to continue participating will be continually checked through discussion with participants during the assessments.

Where the participant's level of impairment increases, so that they are no longer able to provide informed consent, the provisions of the Mental Capacity Act will be followed. The initial giving of informed consent provides a clear indication of the person's likely perspective on continuing at this point, and the family care-giver will be consulted in this regard. At any point where a participant with dementia becomes uncomfortable with the assessments they will be discontinued.

Retention of trial documentation

It is planned that anonymous data will be kept securely for a period of seven years following the completion of the trial, subject to discussion with relevant Ethics Committees.

Confidentiality

The research will follow the Data of protection Act 1998 guidance. Only members of the research team will have access to the original data. Participants' personal details will be stored separately from the data, and will be kept in a separate file on a password protected computer at the University College London. Each participant will be assigned an identification code, which will be used in all data storage files; these will not contain names or any other means of personal identification. All personal details will be deleted on completion of the study.

4.4 Research Governance

The trial will be sponsored by University College London and NELMHT.

A Trial Steering Committee will be established with an independent chair and at least three other independent members, recruited from the UKCRC Dementias & Neurodegenerative Research Network (DeNDRoN) and the corresponding network in Wales, NEURODEM Cymru. By analogy with two trials currently funded by the NHS HTA Programme – COGNATE and FolATED – we shall create the Data Monitoring & Ethics Committee (DMEC) as a sub-committee of the TSC, so as to enhance continuity and make efficient use of expert scientific resources. The TSC will include user/carer representatives from the NEURODEM Cymru panel. The first TSC/DMEC meeting will be held in January 2008, followed by meetings in December 2008 and December 2009.

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Appendix 2

Ethics letters:

Maintenance CST programme for dementia

Barking and Havering Local Research Ethics Committee

Room 7, 2nd Floor
Becketts House
2/14 Ilford Hill
Ilford
Essex
IG1 2QX

Telephone: 0208 9265025
Facsimile: 0208 926 5009

14 October 2008

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

Full title of study:

A multicentre randomised control trial of maintenance CST vs CST only for dementia.

REC reference number:

08/H0702/68

Thank you for your letter of 26 September 2008, responding to the Committee's request for further information on the above research [\[and submitting revised documentation\]](#).

The further information has been considered on behalf of the Committee by the [Chair](#) on the 14th October 2008.

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.

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.

Management permission at NHS sites ("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 is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document

Version

Date

Gantt Chart

1

Participant Consent Form

1

20 August 2008

Participant Information Sheet

1

20 August 2008

GP/Consultant Information Sheets

1

20 August 2008

Letter of invitation to participant

1

20 August 2008

Questionnaire

1

Interview Schedules/Topic Guides

1

20 August 2008

Peer Review

1

11 December 2007

Letter from Sponsor

1

21 August 2008

Summary/Synopsis

1

20 August 2008

Covering Letter

1

20 August 2008

Protocol

1

20 August 2008

Investigator CV

1

Application

1

20 August 2008

Response to Request for Further Information

1

26 September 2008

Participant Information Sheet

2

26 September 2008

Covering Letter

1

26 September 2008

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 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
- 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.

08/H0702/68

Please quote this number on all correspondence

With the Committee’s best wishes for the success of this project

Yours sincerely

Mrs JR IrwinHunt
Chair

Email: janet.carter@redbridge-pct.nhs.uk

Enclosures:

“After ethical review – guidance for researchers”

[SL- AR2 for other studies\]](#)

Site approval form

Copy to:

North East London Foundation Trust (NELFT)

[\[R&D office for NHS care organisation at lead site\]](#)

Barking and Havering Local Research Ethics Committee

LIST OF SITES WITH A FAVOURABLE ETHICAL OPINION

For all studies requiring site-specific assessment, this form is issued by the main REC to the Chief Investigator and sponsor with the favourable opinion letter and following subsequent notifications from site assessors. For issue 2 onwards, all sites with a favourable opinion are listed, adding the new sites approved.

REC reference number:

08/H0702/68

Issue number:

0

Date of issue:

14 October 2008

Chief Investigator:

Professor Martin Orrell

Full title of study:

A multicentre randomised control trial of maintenance CST vs CST only for dementia.

This study was given a favourable ethical opinion by Barking and Havering Local Research Ethics Committee on 14 October 2008. The favourable opinion is extended to each of the sites listed below. The research may commence at each NHS site when management approval from the relevant NHS care organisation has been confirmed.

*Principal Investigator
Professor Martin Orrell*

*Post
Professor (Ageing & Mental Health*

*Research site
North East London Foundation Trust*

*Site assessor
Barking & Havering REC*

*Date of favourable opinion for this site
14 October 2008*

Notes ⁽¹⁾

Approved by the Chair on behalf of the REC:

..... (Signature of Chair/Co-ordinator)
(delete as applicable)

..... (Name)

(1) The notes column may be used by the main REC to record the early closure or withdrawal of a site (where notified by the Chief Investigator or sponsor), the suspension or termination of the favourable opinion for an individual site, or any other relevant development. The date should be recorded.

RESEARCH AND DEVELOPMENT DEPARTMENT
1ST FLOOR
MAGGIE LILLEY SUITE
GOODMAYES HOSPITAL
BARLEY LANE
GOODMAYES
ESSEX

TEL: 0844 600 1200 EXT. 4453
FAX: 0844 493 0289

THURSDAY 5TH JUNE 2008

PROFESSOR MARTIN ORRELL
ADMIN BLOCK
MASCALLS PARK
MASCALLS LANE
BRENTWOOD
ESSEX.

**RE: SHIELD- SUPPORT AT HOME- INTERVENTIONS TO ENHANCE LIFE IN DEMENTIA
MCST**

I AM PLEASED TO CONFIRM THAT THE ABOVE NAMED PROJECT HAS BEEN GRANTED R&D
APPROVAL AND INDEMNITY BY PROFESSOR ORRELL, DIRECTOR OF NELMHT RESEARCH
AND DEVELOPMENT DEPARTMENT. GOOD LUCK WITH THE PROJECT.

YOURS SINCERELY,



SANDEEP SANDHU
R&D ACADEMIC ADMINISTRATOR

Barking and Havering Local Research Ethics Committee

Room 7, 2nd Floor
Becketts House
2/14 Ilford Hill
Ilford
Essex
IG1 2QX

Telephone: 0208 9265025
Facsimile:

21 April 2009

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

Full title of study: A multicentre randomised control trial of maintenance
CST vs CST only for dementia.
REC reference number: 08/H0702/68

The REC gave a favourable ethical opinion to this study on 14 October 2008.

Further notification(s) have been received from local site assessor(s) following site-specific assessment. On behalf of the Committee, I am pleased to confirm the extension of the favourable opinion to the new site(s). I attach an updated version of the site approval form, listing all sites with a favourable ethical opinion to conduct the research.

R&D approval

The Chief Investigator or sponsor should inform the local Principal Investigator at each site of the favourable opinion by sending a copy of this letter and the attached form. The research should not commence at any NHS site until approval from the R&D office for the relevant NHS care organisation has been confirmed.

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.

08/H0702/68

Please quote this number on all correspondence

Yours sincerely

Janett Carter

Committee Co-ordinator

Email: janet.carter@redbridge-pct.nhs.uk

Enclosure: *Site approval form*

Copy to: *North East London Foundation Trust (NELFT)*

Barking and Havering Local Research Ethics Committee

LIST OF SITES WITH A FAVOURABLE ETHICAL OPINION

For all studies requiring site-specific assessment, this form is issued by the main REC to the Chief Investigator and sponsor with the favourable opinion letter and following subsequent notifications from site assessors. For issue 2 onwards, all sites with a favourable opinion are listed, adding the new sites approved.

REC reference number:	08/H0702/68	Issue number:	1	Date of issue:	21 April 2009
Chief Investigator:	Professor Martin Orrell				
Full title of study:	A multicentre randomised control trial of maintenance CST vs CST only for dementia.				
<p><i>This study was given a favourable ethical opinion by Barking and Havering Local Research Ethics Committee on [##SF1ClockStopDate##]. The favourable opinion is extended to each of the sites listed below. The research may commence at each NHS site when management approval from the relevant NHS care organisation has been confirmed.</i></p>					
<i>Principal Investigator</i>	<i>Post</i>	<i>Research site</i>	<i>Site assessor</i>	<i>Date of favourable opinion for this site</i>	<i>Notes ⁽¹⁾</i>
Dr Helen Donovan	Consultant Clinical Psychologist	Bedfordshire & Luton Mental Health & Social Care Partnership NHS Trust	Hertfordshire REC	21/04/2009	
<p>Approved by the Chair on behalf of the REC:</p> <p>..... (Signature of Chair/Co-ordinator) (delete as applicable)</p> <p>..... (Name)</p>					

⁽¹⁾ *The notes column may be used by the main REC to record the early closure or withdrawal of a site (where notified by the Chief Investigator or sponsor), the suspension or termination of the favourable opinion for an individual site, or any other relevant development. The date should be recorded.*

Professor Martin Orrell

North East London Mental Health Trust
Admin Block, NELMHT
Mascalls Park, Mascalls Lane
Brentwood, Essex
CM20 1QX

Research Office

Academic Unit
Newham Centre for Mental Health
London E13 8SP

Telephone: 020 7540 4380

Fax: 020 7540 2976

Email: ResearchOffice@eastlondon.nhs.uk

Website: <http://www.eastlondon.nhs.uk/rande>

19 November 2009

Dear Professor Orrell,

Re: Support at Home - Interventions to Enhance Life in Dementia (SHIELD) –
Maintenance CST (MCST) groups for dementia: A single-blind, multi-centre,
randomized controlled trial of Maintenance CST vs. CST for dementia.

R&D ref no. S0910/4

Thank you for sending confirmation of your approval from the ethics committee and submitting your proposed research project, which has now been assessed by the Trust Research Management Group.

I am now happy to inform you that the East London NHS Foundation Trust has approved this study, therefore NHS Indemnity will extend to any negligence that might occur as a result of or during the course of this project. Should any untoward events occur, it is **essential** that the team member involved contact his/her Trust supervisor and the Research Office immediately. If patients or staff are involved in an incident, you should also contact the Assurance department via Incident.Reporting@eastlondon.nhs.uk

Please note that all NHS and social care research is now subject to the DoH Framework for Research Governance. If you are unfamiliar with the standards contained in this document, or the Trust policies that reinforce them, you can obtain details from the Trust (www.eastlondon.nhs.uk) or Department of Health (www.doh.gov.uk) websites.

You must inform the Research Office if your project is amended and you need to re-submit it to the ethics committee or if your project terminates. This is necessary to ensure that your indemnity cover is valid and also helps the office to maintain up to date records. For studies where the Trust is acting as sponsor you must send a copy of any monitoring/audit reports to the Research Office.

You are also required to inform the Research Office of any changes to the research team membership, or any changes in the circumstances of researchers that may have an impact on their suitability to conduct research.

Yours sincerely,



Prof. Stefan Priebe
Research Director

Chair: Baroness Molly Meacher

Chief Executive: Dr Robert Dolan

If you would like to become a member of East London NHS Foundation Trust, you can call our freephone number: 0800 032 7297, visit the Trust website at www.eastlondon.nhs.uk or email: foundation@eastlondon.nhs.uk

**North Central London
Research Consortium**

Research Operations Unit
3rd Floor West Wing
St Pancras Hospital
4 St Pancras Way
London
NW1 0PE

General Enquiries: 020 7445 8506
Office Fax: 020 7530 3235

25th March 2010

Professor Martin Orrell
North East London Mental Health Trust
Admin Block, NELMHT
Mascalls Park, Mascalls Lane
Brentwood, Essex
CM20 1QX

Dear Professor Orrell,

Re: A multicentre randomised control trial of maintenance CST vs CST only for dementia

REC Reference Number: 08/H0702/68

PIC Site: Camden & Islington NHS Mental Health Foundation Trust

Thank you very much for contacting us about the above study.

As the role of **Camden & Islington NHS Mental Health Foundation Trust** will be restricted to identifying patients and providing basic anonymous information to a research team based in another organisation (following ethics approval), then in this instance the Trusts are considered as 'patient identification centres' (PIC) and not 'research sites'. No research procedures will be conducted at **Camden & Islington NHS Mental Health Foundation Trust** and this site **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.

We have reviewed this request and are happy to provide approval as a PIC on the understanding that the ethically approved details and all 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 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
Research & Development Manager

Appendix 3

Information letters:

Maintenance CST programme for dementia



SHIELD

Support at Home:

Interventions to Enhance
Life in Dementia

North East London 
NHS Foundation Trust



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PARTICIPANT INFORMATION SHEET

Maintenance Cognitive Stimulation Therapy (CST) groups 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 maintenance cognitive stimulation therapy groups (a further 24 maintenance CST sessions) are effective in improving cognition and quality of life for the person with memory problems.

What happens in a cognitive stimulation therapy (CST) group?

CST groups are held as a 14 session programme, twice a week for seven weeks,. The activities include for example multi-sensory stimulation, word categorisation and discussion of current affairs. The idea is to keep the mind active through enjoyable activities, undertaken as a structured programme facilitated by experienced and trained staff that will look after the group. Sessions include discussion of current affairs, food, sounds, physical games, number games and word games among others.

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 maintenance CST groups – 230 in total. Each CST group may include up to 8 people.

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 establish the additional benefits of maintenance CST groups, and so we need to compare any changes experienced by people in these groups with changes in people who have only been attending CST groups for 7 weeks. 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 being offered a place in a maintenance CST group. 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 10 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 an hour and an hour and a half to complete some questionnaires covering quality of life, cognition and mood. The time stated to complete the interviews and questionnaires is an estimate; you may take as many breaks as you want or feel necessary, and even complete the process over two sessions if preferred.
2. To repeat these questionnaires with the researcher, after attending the first 7 weeks of CST.
3. Three months later, to repeat these questionnaires with the researcher.
4. Six months later, to repeat these questionnaires with the researcher.

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. Usually, the researcher will meet with and interview your relative/friend at the same time as you are completing the questionnaires.

All participants entering the trial will be asked to attend twice a week for seven weeks a CST groups. They will include up to eight people and each session will last for about an hour.

Those **participants invited to attend maintenance cognitive stimulation therapy groups** will be asked to attend an additional 24 weekly CST group sessions, each lasting for about 1 hour.

The CST group sessions will be held in a suitable venue within your area and refreshments and transport will be arranged if needed.

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?

CST involves participating in a group programme that 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. If the participant feels uncomfortable or distressed while taking part in a group, facilitators will be able to give additional one to one support if this is needed.

What are the possible benefits of taking part?

If you decide to take part, and are involved in the CST Groups we hope that this may be of some help to you, and previous group members have indeed 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 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 Department of Health, National Institute for Health Research Programme. 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 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 Barking and Havering Research Ethics Committee.

Who can I contact for further information?

For more information about this research, please contact:

Elisa Aguirre,
Charles Bell House, UCL
67-73 Riding House Street, London, W1W 7EJ,

Phone: 0207679 9590, Mobile: [REDACTED]

Email: e.aguirre@ucl.ac.uk

Or if you have any complaints about this study please contact:

Sandeep Sandhu, R&D Administrator
R& D Department NELFT
Goodmayes Hospital, Maggie Lilley Suite
Barley Lane
Ilford Essex, IG3 8YB

Phone: 0844 600 1200 4453

Email: Sandeep.sandhu@nelmht.nhs.uk

Thank you for considering taking part in this research study!



SHIELD

Support at Home:
Interventions to Enhance
Life in Dementia

North East London 
NHS Foundation Trust



UCL

Participant Consent Form

Participant Identification Number for this trial _____

Maintenance Cognitive Stimulation Therapy (CST) Groups for People with Dementia

Name of Researcher:.....

Please Initial Boxes

1. I confirm that I have read and understand the information sheet (Version P1 20/08/08) 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 agree to take part in the above study.



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



SHIELD
Support at Home:
Interventions to Enhance
Life in Dementia

North East London **NHS**
NHS Foundation Trust



UCL

INFORMATION SHEET FOR CAREGIVERS

Maintenance Cognitive Stimulation Therapy (CST) Groups 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 maintenance cognitive stimulation groups (a further 24 maintenance CST sessions) are effective in improving cognition and quality of life for the person with memory problems.

What happens in a cognitive stimulation group?

CST groups are held as a 14 session programme, twice a week for seven weeks. The activities include for example multi-sensory stimulation, word categorisation and discussion of current affairs. The idea is to keep the mind active through enjoyable activities, undertaken as a structured programme facilitated by experienced and trained staff that will look after the group. The sessions include physical games, current affairs discussions, sounds, food, word games, and numbers games.

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 maintenance CST groups – 230 in total. Each CST group may include up to 10 people.

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 maintenance CST groups, and so we need to compare any changes experienced by people in these groups with changes in people who have only been attending CST groups for 7 weeks. 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 being offered a place in a maintenance CST group. 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 10 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 an hour and an hour and a half to complete some questionnaires covering your perception about the quality of life, cognition and mood of your relative/friend and about your general health 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. To repeat these questionnaires with the researcher, after the first 7 weeks of CST have been held.
3. Three months later, to repeat these questionnaires with the researcher.
4. Six months later, to repeat these questionnaires with the researcher.

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. Usually, the researcher will meet with and interview your relative/friend at the same time as you are completing the questionnaires.

The CST group sessions will be held in a suitable venue within your area and refreshments and transport will be arranged if needed.

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 memory problems 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 memory problems 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 with memory problems 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?

CST involves participating in a group programme that aims to be stimulating and enjoyable. Sessions involve discussing themes such as food, childhood and current affairs and it the level of risk in taking part is therefore minimal. If while taking part the participant feels uncomfortable or distressed while taking part in a group, facilitators will be able to give additional one to one support if this is needed

What are the possible benefits of taking part?

If you decide to take part, and your relative/friend is involved in the CST groups we hope that this may be of some help to them, and previous group members have indeed 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 request permission to send the person with memory problem's GP a letter explaining that you have both agreed to take part in the study. Otherwise, all information 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.

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 Department of Health, National Institute for Health Research Programme. 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 Barking and Havering Research Ethics Committee.

Who can I contact for further information?

For more information about this research, please contact:

Elisa Aguirre,
Charles Bell House, UCL
67-73 Riding House Street, London, W1W 7EJ,

Phone: 0207679 9590, Mobile: [REDACTED]

Email: e.aguirre@ucl.ac.uk

Or if you have any complaints about this study please contact:

Sandeep Sandhu, R&D Administrator
R& D Department, NELFT
Goodmayes Hospital, Maggie Lilley Suite
Barley Lane
Ilford Essex, IG3 8YB

Phone: 0844 600 1200 4453

Email: Sandeep.sandhu@nelmht.nhs.uk

Thank you for considering taking part in this research study!



Caregiver Consent Form (MCA)

Participant Identification Number for this trial _____

Maintenance Cognitive Stimulation Therapy (CST) Groups for People with Dementia

Name of Researcher:

Please Initial Boxes

1. I confirm that I have read and understand the information sheet (Version C1.0 14th August 2008) 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 all information given by me or about me or my relative will be treated as confidential by the research team.

☐

7. I agree to take part in the above study with my relative.

☐

Name of Caregiver

Date

Signature

Name of relative

**Name of Person taking consent
(if different from the researcher)**

Date

Signature

Researcher

Date

Signature



SHIELD

Support at Home:
Interventions to Enhance
Life in Dementia

North East London 
NHS Foundation Trust



UCL

UCL, Department of Mental Health Sciences
(Bloomsbury Campus)
67-73 Riding House Street
2nd Floor, Charles Bell House
London W1W 7EJ
Phone@ +44 (0)20 7679 9418
Fax: +44 (0)20 7679 9426

20 August 2010

GENERAL PRACTITIONER INFORMATION SHEET

Title: Maintenance Cognitive Stimulation Therapy (CST) groups 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.

Prof 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 memory problems. The idea is to keep the mind active through enjoyable activities, which are undertaken as a structured programme facilitated by experienced and trained staff. The activities include multi-sensory stimulation, for example: physical games, discussion of current affairs, sounds, food, word and number games. CST groups are held as a 14 session programme, twice a week for seven weeks.

This study aims to show whether maintenance CST groups (a further 24 CST sessions) are effective at improving cognition and quality of life for people with dementia, in comparison to CST groups for 7 weeks only.

We are interested in including people with any type of dementia and we will follow them up for 10 months, with repeat interviews at pre and post the 7 week CST group, then 3 and 6 months later.

The interviews will be about:

- Personal details (age, relationship, educational level, etc.)
- Quality-of-life
- Cognition
- Depression
- Activities of daily Living
- Communication

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,

Elisa Aguirre,
Research Assistant

Appendix 4

Additional data

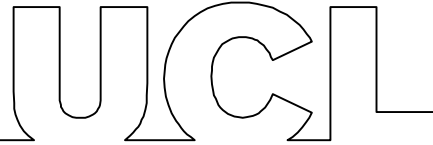
Maintenance CST programme for dementia



SHIELD

Support at Home:
Interventions to Enhance
Life in Dementia

North East London 
NHS Foundation Trust



UCL, Department of Mental Health Sciences
(Bloomsbury Campus)
67-73 Riding House Street
2nd Floor, Charles Bell House
London W1W 7EJ
Phone@ +44 (0)20 7679 9418
Fax: +44 (0)20 7679 9426

29 January 2009

Dear Doctor

Re: Mr First Name/Last Name/Address/Date of birth/

Your patient has agreed to participate, in a multi-centre randomised controlled trial, funded by the Department of Health, National Institute for Health Research. Prof Martin Orrell runs this project from North East London NHS Foundation Trust (NELFT).

This study aims to show whether maintenance CST groups (a further 24 CST sessions) are effective at improving cognition and quality of life for people with dementia, in comparison to CST groups for 7 weeks only. Assessments of cognition and the quality of life and mood of the person with dementia will be made initially, after 7 weeks of CST, at 3 months and at 6 months.

The study includes a cost-effectiveness analysis and so details of the services received by the participants will also be collated. As part of the research programme we are contacting doctors of participants who are suitable for Acetylcholinesterase inhibitors according to the NICE guidelines. *Mr/Mrs Surname* scored $x/30$ on a recent MMSE and we would like you to refer *him/her* to a consultant in order to assess their suitability to be prescribed acetylcholinesterase inhibitors.

If you wish further details of the trial, please do not hesitate to contact me on : Elisa Aguirre, Charles Bell House, 67-73 Riding House Street, W1W 7EJ, Phone: 0207679 9590, Mobile: [REDACTED], Email: e.aguirre@ucl.ac.uk.

Yours sincerely,

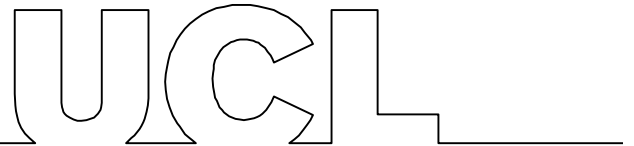
Elisa Aguirre



SHIELD

Support at Home:
Interventions to Enhance
Life in Dementia

North East London 
NHS Foundation Trust



SHIELD - Maintenance Cognitive Stimulation Trial

Questions re prescription of ACHEIs

To be answered following the baseline assessment.

Participant CRF number:

Researcher:

1. Does this participant have a diagnosis of Alzheimer's Disease? Yes/No

2. Is this participant currently prescribed ACHEIs? Yes/No

IF NO -> move to next question

IF YES -> when started?

- more than 3 months ago
- 1 to 3 months ago
- less than 1 month ago

3. Is this participant under the care of the OPMHS? Yes/No

IF YES -> Has a Standardised letter re prescribing of ACHEI's been sent to the responsible Consultant Old Age Psychiatrist or Keyworker. Yes/No

Keyworker/Consultant contacted

Date sent

Researcher's Signature:



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Support at Home:
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Life in Dementia



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Support at Home:
Interventions to Enhance
Life in Dementia

Cognitive Stimulation Therapy (CST) Survey

1. Date

2. Date you attended CST training

3. Job title

4. **Place of Work** Choose one section from A-G, and then tick the appropriate box to indicate your place of work

- A ☐ Care Home
- B ☐ CMHT for OP
- C ☐ Day Centre
- D ☐ Day Hospital
- E ☐ Voluntary Sector, please specify
- F ☐ Any other, please specify

5. **Do you work in a specialist dementia care setting?** (E.g. dementia day centre, dementia care home)

- ☐ No ☐ Yes → if yes please specify

6. **Sex**

- ☐ Male ☐ Female

7. Age

7. **Years of working in dementia care**

8. **Ethnic Group** Choose one section from A-G, and then tick the appropriate box to indicate your cultural background.

- A ☐ White; (British, Irish, Other White Background)
- B ☐ Asian; (British, Indian, Pakistani, Bangladeshi)
- C ☐ Black; (British, Caribbean, African, Other Black Background)
- D ☐ Chinese
- E ☐ Mixed Race
- F ☐ Any other background, please specify
- G ☐ Do not wish to specify

9. 'Have you run CST groups after attending the CST training course?

Please tick the correct answer: ✓

Answer: YES ☐NO ☐ → if no please go to question 10

A) How many groups have you run?

- ☐ About to start running the first one 14 session programme
- ☐ One 14 session programme (In progress)
- ☐ One 14 session programme
- ☐ More than one 14 session programme
- ☐ One 14 session programme plus Maintenance Sessions
- ☐ More than one 14 session programme plus Maintenance Sessions
- ☐ Individual sessions
- ☐ Run CST in a different form (e.g. different stimulation activities, themes...)
- ☐ More than one 14 session programme plus Maintenance Sessions
- ☐ Other, please specify

B) How long after the training did the first group started?

- | | | |
|--|--|--|
| <input type="checkbox"/> Within 1 month | <input type="checkbox"/> Within 3 months | <input type="checkbox"/> Within 6 months |
| <input type="checkbox"/> Within 9 months | <input type="checkbox"/> Within a year | <input type="checkbox"/> Over a year |

C) Did you encounter any difficulties in getting CST going?

NO ☐YES ☐ → if yes please go to question 10

10. Please tick the box that applies to the reasons why you haven't run CST groups or difficulties you encounter getting CST running.

- ☐ Lack of staff time
- ☐ Lack of resources / equipment
- ☐ No suitable room
- ☐ Transport problems
- ☐ Lack of support from senior staff / management
- ☐ Not enough suitable participants for the group
- ☐ Not feeling skilled enough to offer CST
- ☐ Not believing that CST would help or make a difference
- ☐ Other, please specify ...

1= strongly agree; 2= Agree; 3= Neither agree o disagree; 4= Disagree; 5= strongly disagree

The activities and exercises the training used helped me know how to apply my learning on the job.	1	2	3	4	5
The resources I need to use what I learned will be available to me after training.	1	2	3	4	5
My job performance improves when I use new things that I have learned.	1	2	3	4	5
When I do things to improve my performance, good things happen to me.	1	2	3	4	5
People in my group are open to changing the way they do things.	1	2	3	4	5
I am confident in my ability to use newly learned skills on the job.	1	2	3	4	5
After training, I get feedback from people about how well I am applying what I learned.	1	2	3	4	5
It is important to have a very strict routine when working with dementia sufferers.	1	2	3	4	5
People with dementia are very much like children	1	2	3	4	5
There is no hope for people with dementia	1	2	3	4	5
People with dementia are unable to make decisions for themselves	1	2	3	4	5
It is important for people with dementia to have stimulating and enjoyable activities to occupy their time	1	2	3	4	5
Dementia sufferers are sick and need to be look after	1	2	3	4	5
It is important for people with dementia to be given as much choice as possible in their daily lives	1	2	3	4	5
Nothing can be done for people with dementia, except for keeping them clean and comfortable	1	2	3	4	5
People with dementia are more likely to be contented when treated with understanding and reassurance	1	2	3	4	5
People with dementia should be treated just like any other person	1	2	3	4	5

1= strongly agree; 2= Agree; 3= Neither agree o disagree; 4= Disagree; 5= strongly disagree

Once dementia develops in a person, it is inevitable that they will go down hill	1	2	3	4	5
People with dementia need to feel respected, just like anybody else	1	2	3	4	5
Good dementia care involves caring for a person's psychological needs as well as their physical needs.	1	2	3	4	5
It is important not to become too attached to residents	1	2	3	4	5
It doesn't matter what you say to people with dementia because they forget it anyway	1	2	3	4	5
People with dementia often have good reasons for behaving as they do	1	2	3	4	5
Spending time with people with dementia can be very enjoyable	1	2	3	4	5
It is important to respond to people with dementia with empathy and understanding	1	2	3	4	5
There are lot of things that people with dementia can do	1	2	3	4	5
People with dementia are just like ordinary people who need special understanding to fulfill their needs	1	2	3	4	5

14. Please tick the appropriate box: How satisfied are you with...?

1= extremely dissatisfied; 2= Very Dissatisfied; 3= Quite Dissatisfied; 4= Not sure;
5= Quite Satisfied; 6= Very Satisfied; 7= Extremely Satisfied.

The physical work conditions?	1	2	3	4	5	6	7
The freedom to choose your own method of working?	1	2	3	4	5	6	7
Your fellow workers?	1	2	3	4	5	6	7
The recognition for good work?	1	2	3	4	5	6	7
The supervision you receive?	1	2	3	4	5	6	7
The amount of responsibility you are given?	1	2	3	4	5	6	7
Your rate of pay?	1	2	3	4	5	6	7
The opportunities to use your abilities?	1	2	3	4	5	6	7
Your chance of promotion?	1	2	3	4	5	6	7

1= extremely dissatisfied; 2= Very Dissatisfied; 3= Quite Dissatisfied; 4= Not sure;
5= Quite Satisfied; 6= Very Satisfied; 7= Extremely Satisfied.

The way your organization is managed?	1	2	3	4	5	6	7
The attention paid to suggestions you make?	1	2	3	4	5	6	7
Your hours of work?	1	2	3	4	5	6	7
The amount of variety in your work?	1	2	3	4	5	6	7
Your job security?	1	2	3	4	5	6	7
The training you receive?	1	2	3	4	5	6	7
Relationships in your workplace?	1	2	3	4	5	6	7
The quality of relationships between your workplace and other departments?	1	2	3	4	5	6	7
Now taking everything into consideration how do you feel about your job as a whole?	1	2	3	4	5	6	7

Thank you very much for your collaboration. I would really appreciate if you could please return it to me by e mail or by post using the stamped enveloped enclosed.

FAO:

Elisa Aguirre
67-73 Riding House Street
2nd Floor, Charles Bell House
London W1W 7EJ
e.aguirre@ucl.ac.uk



SHIELD

Support at Home:
Interventions to Enhance
Life in Dementia

North East London
NHS Foundation Trust



Department of Mental Health Sciences

06 October 2008

Dear All,

Consensus conference - Maintenance Cognitive Stimulation Therapy for Dementia

We are pleased to invite you to participate in the development workshop for the Maintenance CST draft manual on the 10th of November 2008. The workshop will be used to review and revise the draft manual and will include experts in dementia care and CST. CST, or 'Cognitive Stimulation Therapy', is a brief treatment for people with dementia which CST was designed following an extensive evaluation of the research evidence by Dr Spector, Prof Orrell, Prof Woods and colleagues. The recent NICE guidance on the management of dementia recommends the use of group Cognitive Stimulation for people with mild to moderate dementia, irrespective of drug treatments received. The evaluation of CST showed benefits to cognition and quality of life of people for people with dementia. Now we aim to evaluate the maintenance programme (24 weeks/once a week) through a randomised control trial. We would appreciate your contribution as a dementia specialist on the development of the programme that will help to increase the quality of life and care of people with dementia. The workshop includes a working lunch involving opportunity to share ideas amongst other professionals and experts in the field. If you can confirm your participation we will send you an agenda and the draft manual. The workshop will be held from **12,00pm till 4,00pm at Board Room 544, University College London, Sub-Department of Clinical Health Psychology, 5th Floor, 1-19 Torrington Place, London WC1E 6BT.**

CONTACT: Sandeep Sandhu, SHIELD Administrator

Phone: +44 (0) 844 600 1200 4453

SHIELD- NIHR Project

RP-PG-0606-1083

Email: Sandeep.sandhu@nelmht.nhs.uk

Travel and accommodation expenses can be reimbursed.

Do not hesitate to contact us if you need any further information.

Yours sincerely,

Prof Martin Orrell, Dr Aimee Spector, Prof Bob Woods, Elisa Aguirre



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Support at Home:
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MAINTENANCE CST DEVELOPMENT

Focus groups for people with dementia, carers and staff

AGENDA

00.00 Welcome, Thanks and Presentation of the focus group

00.05 Consent forms reiterate issues of confidentiality and set ground rules. Questions

00.10 Icebreaker, introductions. Famous pictures exercise, readapt

00.15 General questions about mental stimulation programmes “Use it or Lose it”.

1. Is it important to keep brain active?

2. What aspects of you or your life (your family’s/friend’s/ cared for) do you consider as being mental stimulating?

3. Is there anything you (your friend/cared for) do that exercises the brain?

4. In your opinion, does it make any difference?

00.25 Play DVD with examples of programme

5. What do you think about this type of mental stimulation programmes?

6. In your opinion, is there anything particularly helpful about exercising your brain? Is there anything particularly unhelpful about exercising your brain? Do you find it boring, fun, and childish, like being back at school...?

00.35 Presentation of the new manual.

Pass around copies and present a big sheet with six themes to each group:

Physical games	Faces/ Scenes.	Number game
Sound.	Associated Words, discussion	Word game
Childhood	Being creative.	Quiz
Food.	Categorising objects	Useful tips.
Current affairs.	Orientation.	Thinking Cards
Faces/ Scenes.	Using Money.	Art Discussion
Visual clips	Using Objects	Faces/ Scenes.

Food

- Taste foods which act as memory triggers or have personal meaning e.g. cream soda, ginger beer, bread pudding, Bovril
- Brainstorm food categories on the whiteboard, listing as many as possible in each category (e.g. soups; meats; puddings; fish; vegetables).
- Complete names of food items e.g. Yorkshire X; Bakewell X; self-raising X; name a food beginning with a particular letter.
- Using real groceries or miniature grocery replicas which have been priced, give people a budget and a scenario to plan, e.g. dinner for four.
- Using real groceries or miniature grocery replicas which have been priced, categorise the foods, e.g. for different mealtimes, special occasions, savoury / sweet.

Present six cards to the group with one theme each and activities propose for the theme at the back of the card. Ask participants to discuss with the group the different activities and to agree an order for the different themes. At the top they will include those items they think they, the person they care for might enjoy doing greatly and at the bottom the ones they think they might not enjoy at all. The middle can be for those who they feel uncertain about and they haven't come to an agreement among the group.

Questions to facilitate discussion if needed:

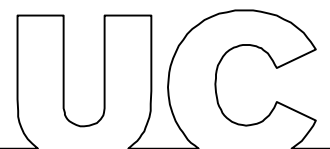
7. What do you think about the different suggested task in this theme?
8. Is there anything particularly good-bad about them?
9. Is there anything you would like to suggest with regards this theme tasks?
10. In relation to (Theme, e.g. sound, word games, number games...)
 - a. How confident you feel (your family/friend/ cared for would be participating in a session like that one?
 - i. In what way?
 - b. What sorts of things you (your family/friend/ cared for) enjoy doing? e.g. talking more/less about current affairs, daily life, personal memories,
 - i. In what way

- c. How frequently would you (your family/friend/ cared for) initiate activities like that one?
- d. How much would you (your family/friend/ cared for) enjoy doing this activities?
- e. How easy is it for you (your family/friend/ cared for) to do this activities?

00.55 Concluding question

11. Is there anything else that you would like me to know about your opinions on what it has been commented on this focus group?

00.60 Thank everyone for participation, reiterate confidentiality, give further opportunity to ask questions, provide further possible sources for CST information, website offer farewells.



Adherence to project checklist (Ideally this should be filled in by an observer on a weekly session and the results relayed to the group leaders)

Communication

	Item	Y/N	Comments
1	Was appropriate encouragement given to people with dementia to participate?		
2	Was extra time allowed to enable people with dementia to gather their thoughts and speak?		
3	Were team members indicating by their body language etc that they were really listening?		
4	Were team members responding appropriately to non-verbal communication, indicating how participants were feeling?		
5	Were facilitators/team members showing they understood what people were saying by reflecting it back to them?		
6	Did facilitators amplify and share individual contributions with whole group?		
7	Did facilitators emphasise connections between participants to the whole group?		
8	Was there space for both positive and negative feelings to be expressed?		
9	Were ways found to involve everyone in the session?		



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Communication (continued)

	Item	Y/N	Comments
10	Was the knowledge of the participants in the groups used to help to involve the people with dementia?		
11	Were situations where facilitators dominated the conversation managed in a tactful manner?		
12	Were situations where some members of the group talked negatively about other members of the groups in front of them well handled?		
13	Did the participants have the opportunity to talk about problems in private?		
14	Did participants work with other participants, and not exclusively with facilitator of the group?		
15	Were participants greeted individually?		
16	Were name labels used in the session?		



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Session structure and management

	Feature	Y/N	Comments
1	Was there an opening (where participants are warmly welcomed, oriented to what is happening?)		
2	Was there a warm-up activity including movement and optional physical contact?		
3	Did the session have a chosen theme?		
4	Was the session plan adapted in response to what was happening?		
5	Was there a range of carefully chosen multi-sensory triggers appropriate to the theme (objects, images, music both live and recorded)?		
6	Were one or more creative methods (other than just talking) used to explore memories e.g. movement, song, improvisation, drawing		
7	Was the team working well to ensure that participants were all getting the support they needed throughout the session?		
8	Was there a mixture of small group and large group work?		
9	Was there feedback from the small groups to the main group?		
10	Was the pacing of the different activities within the session appropriate?		



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Session structure and management (continued)

	Feature	Y/N	Comments
11	Was there a closing where the work of the session was summed up and appreciated?		
12	Did the closing involve participants thinking about the next session, including items they can bring in from home to help?		
13	Were participants reminded of any missing participant in the group?		
14	Were good-byes personal and appreciative?		
15	Were personal farewells given to everyone?		
16	Was time allowed for the project team to reflect together, evaluating each session, noting individual responses?		
17	Were these managed over all the sessions, if not in individual ones?		



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MCST trial; CST KEY PRINCIPLES CHEKLIST

This list should be used with the CST key principle document.

	Key principle	Y\N	Comments
1	Mental stimulation		
2	New ideas, thoughts and associations		
3	Using orientation, but sensitively and implicitly		
4	Opinions, rather than facts		
5	Using reminiscence, and as an aid to the here-and-now		
6	Providing triggers to aid recall		
7	Continuity and consistency between sessions		
8	Implicit (rather than explicit) learning		
9	Stimulating language		
10	Stimulating executive functioning		
11	Person-centred		
12	Respect		
13	Involvement		
14	Inclusion		
15	Choice		
16	Fun		
17	Maximising potential		
18	Building / strengthening relationships		

Appendix 5

Assessment scales

Maintenance CST programme for dementia

Appendix 4A

Final field test item-reduced DEMQOL (v4)

Study ID

DEMQOL (version 4)

To be used with interviewer manual

Instructions: Read each of the following questions (in bold) verbatim and show the respondent the response card.

I would like to ask you about your life. There are no right or wrong answers. Just give the answer that best describes how you have felt in the last week. Don't worry if some questions appear not to apply to you. We have to ask the same questions of everybody.

Before we start we'll do a practice question; that's one that doesn't count. (*Show the response card and ask respondent to say or point to the answer.*) In the last week, how much have you enjoyed watching television?

a lot quite a bit a little not at all

*Follow up with a prompt question: **Why is that? or Tell me a bit more about that.***

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 ...

- | | | | | |
|---|--------------------------------|--------------------------------------|-----------------------------------|-------------------------------------|
| 1. cheerful? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 2. worried or anxious? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 3. that you are enjoying life? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 4. frustrated? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 5. confident? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 6. full of energy? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 7. sad? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 8. lonely? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 9. distressed? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 10. lively? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 11. irritable? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 12. fed-up? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 13. that there are things that you wanted to do but couldn't? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |

Next, I'm going to ask you about your memory. In the last week, how worried have you been about ...

- | | | | | |
|---|--------------------------------|--------------------------------------|-----------------------------------|-------------------------------------|
| 14. forgetting things that happened recently? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 15. forgetting who people are? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 16. forgetting what day it is? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 17. your thoughts being muddled? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 18. difficulty making decisions? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 19. poor concentration? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |

Now, I'm going to ask you about your everyday life. In the last week, how worried have you been about ...

- | | | | | |
|--|--------------------------------|--------------------------------------|-----------------------------------|-------------------------------------|
| 20. not having enough company? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 21. how you get on with people close to you? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 22. getting the affection that you want? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 23. people not listening to you? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 24. making yourself understood? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 25. getting help when you need it? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 26. getting to the toilet in time? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 27. how you feel in yourself? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 28. your health overall? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |

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 ...

- | | | | | |
|--------------------------------------|------------------------------------|-------------------------------|-------------------------------|-------------------------------|
| 29. your quality of life overall? ** | <input type="checkbox"/> very good | <input type="checkbox"/> good | <input type="checkbox"/> fair | <input type="checkbox"/> poor |
|--------------------------------------|------------------------------------|-------------------------------|-------------------------------|-------------------------------|

** items that need to be reversed before scoring

Appendix 4B

Final field test item-reduced DEMQOL-Proxy (v4)

Study ID

DEMQOL-Proxy (version 4)

To be used with interviewer manual

Instructions: Read each of the following questions (in bold) verbatim and show the respondent the response card.

I would like to ask you about _____ (your relative's) life, as you are the person who knows him/her best. There are no right or wrong answers. Just give the answer that best describes how _____ (your relative) has felt in the last week. If possible try and give the answer that you think _____ (your relative) would give. Don't worry if some questions appear not to apply to _____ (your relative). We have to ask the same questions of everybody.

Before we start we'll do a practice question; that's one that doesn't count. (Show the response card and ask respondent to say or point to the answer.) In the last week how much has _____ (your relative) enjoyed watching television?

a lot quite a bit a little not at all

*Follow up with a prompt question: **Why is that? or Tell me a bit more about that.***

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 you about _____ (your relative's) **feelings**. In the last week, would you say that _____ (your relative) has felt ...

- | | | | | |
|---|--------------------------------|--------------------------------------|-----------------------------------|-------------------------------------|
| 1. cheerful? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 2. worried or anxious? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 3. frustrated? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 4. full of energy? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 5. sad? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 6. content? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 7. distressed? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 8. lively? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 9. irritable? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 10. fed-up | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 11. that he/she has things to look forward to? ** | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |

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 ...

- | | | | | |
|--|--------------------------------|--------------------------------------|-----------------------------------|-------------------------------------|
| 12. his/her memory in general? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 13. forgetting things that happened a long time ago? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 14. forgetting things that happened recently? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 15. forgetting people's names? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 16. forgetting where he/she is? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 17. forgetting what day it is? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 18. his/her thoughts being muddled? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 19. difficulty making decisions? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 20. making him/herself understood? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |

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 ...

- | | | | | |
|---|--------------------------------|--------------------------------------|-----------------------------------|-------------------------------------|
| 21. keeping him/herself clean (e.g. washing and bathing)? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 22. keeping him/herself looking nice? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 23. getting what he/she wants from the shops? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 24. using money to pay for things? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 25. looking after his/her finances? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 26. things taking longer than they used to? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 27. getting in touch with people? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 28. not having enough company? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 29. not being able to help other people? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 30. not playing a useful part in things? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |
| 31. his/her physical health? | <input type="checkbox"/> a lot | <input type="checkbox"/> quite a bit | <input type="checkbox"/> a little | <input type="checkbox"/> not at all |

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 ...

- | | | | | |
|---|------------------------------------|-------------------------------|-------------------------------|-------------------------------|
| 32. his/her quality of life overall? ** | <input type="checkbox"/> very good | <input type="checkbox"/> good | <input type="checkbox"/> fair | <input type="checkbox"/> poor |
|---|------------------------------------|-------------------------------|-------------------------------|-------------------------------|

** items that need to be reversed before scoring

Appendix 5

Rules for scoring and imputing missing data

Direction of coding

DEMQOL PWD self-report	higher = better HRQoL
DQOL self-esteem PWD self-report	higher = better HRQoL
DQOL positive affect PWD self-report	higher = better HRQoL
DQOL absence of negative affect PWD self-report	higher = better HRQoL
DQOL sense of belonging PWD self-report	higher = better HRQoL
DQOL sense of aesthetics PWD self-report	higher = better HRQoL
QOLAD PWD self-report	higher = better HRQoL
MMSE	higher = less severe
SF-12 PCS	higher = better HRQoL
SF-12 MCS	higher = better HRQoL
DEMQOL carer proxy report	higher = better HRQoL
GDS-30 carer proxy report	higher = worse depression
BARTHEL carer proxy report	higher = less dependent
CDR interviewer report	higher = worse dementia
GHQ carer self-report	higher = more distressed

Use of imputation

DEMQOL PWD self-report	If at least 50% of items are complete, impute with person-specific mean of completed items
DQOL self-esteem PWD self-report	If <2 items missing, impute with person-specific mean of completed items
DQOL positive affect PWD self-report	If <3 items missing, impute with person-specific mean of completed items
DQOL absence of negative affect PWD self-report	If <3 items missing, impute with person-specific mean of completed items
DQOL sense of belonging PWD self-report	If <2 items missing, impute with person-specific mean of completed items
DQOL sense of aesthetics PWD self-report	If <2 items missing, impute with person-specific mean of completed items
QOLAD PWD self report	If at least 50% of the data are complete, impute with person-specific mean of completed items
SF-12 PCS	For scales with 2 items and only one item complete, impute missing item with the complete item
SF-12 MCS	For scales with 2 items and only one item complete, impute missing item with the complete item
MMSE	None
DEMQOL carer proxy report	If at least 50% of items are complete, impute with person-specific mean of completed items
GDS-30 carer proxy report	If at least 50% of items are complete, impute with person-specific mean of completed items
BARTHEL carer proxy report	None
CDR interviewer report	None
GHQ carer self-report	If <3 items missing impute with 0, otherwise exclude the case

