

Item	
Name	Individual Cognitive Stimulation Therapy for people with dementia (iCST)
Why	iCST is based on theoretical principles of reality orientation, and the same structure and principles of the group CST approach. Caregiver led iCST adapts a person-centered approach, in which the person is engaging in home-based cognitive stimulation activities. iCST activities focus on opportunities to express opinions and less on discussing factual information and place an emphasis on the person with dementia and their family caregiver spending enjoyable time together, using a specific framework of discussion.
What	<p>Materials</p> <ol style="list-style-type: none"> 1) iCST Manual (guidance for caregivers) 2) iCST Activity Workbook (activities materials) 3) iCST Carer Diary (reporting and evaluating activities) 4) iCST Toolkit (boules, playing cards, dominoes, magnifying card, sound activity compact discs (CDs), colored pencils, and world and UK map) 5) iCST Training Pack (iCST role play exercises) 6) CST digital versatile disc (DVD) clips <p>Procedure</p> <p>Caregivers trained at their home, using a standardized training package aimed at demonstrating key principles of iCST. Additional support provided over the phone and additional home support visits.</p>
Who provided	iCST was provided by family caregivers. Caregiver training and support was provided by the research team of unblinded researchers who were either mental health nurses, clinical psychologists, occupational therapists or research assistants. All unblinded researchers received standardized training in supporting family caregivers in iCST.
How	iCST was delivered by caregivers. iCST Caregiver Training was delivered by unblinded researchers. Unblinded researchers received training in a

group. Support on iCST was provided as an additional home visit, and over the phone by unblinded researchers.

Where iCST was delivered at the dyad's home.

When and How Much iCST consisted of 75 sessions delivered by the family caregiver for 30 minutes, for 3 times a week over 25 weeks.

Tailoring Tailoring included additional home visits or telephone support, or provision of additional resources related to the intervention (i.e. books, DVD player)

Modifications No modifications occurred during the intervention.

How well Planned: Intervention compliance was assessed by self-reported questionnaires completed by caregivers and researchers.
Actual: Mean compliance was 31.6 (SD = 26.8) sessions, where 22% completed 0 sessions, 13% 1-10 sessions and 51% completed more than 30 sessions.

SD=Standard deviation

Text A: TIDier checklist describing the iCST intervention

iCST Session theme	Session number
My life	1, 2, 45, 46
Current affairs	3, 4, 57, 58
Food	5, 6, 55, 56
Being creative	7, 8, 63, 64
Number games	9, 10, 71, 72
Quiz games	11, 12, 75
Sounds	13, 14, 51, 52
Physical games	15, 16, 49, 50
Categorising objects	17, 18, 65, 66
Household treasures	19, 20
Useful tips	21, 22, 47, 48
Thinking cards	23, 24
Visual clips discussion	25, 26
Art discussion	27, 28, 43, 44
Faces / Scenes	29, 30, 59, 60
Word games	31, 32, 41, 42, 73, 74
Slogans	33, 34
Association words discussion	35, 36, 61, 62
Orientation	37, 38, 67, 68
Using money	39, 40, 69, 70
Childhood	53, 54

iCST= Individual Cognitive Stimulation Therapy

Table A: Themes of iCST sessions and order of appearance in the manual

Intervention and control conditions

Participants randomized to the intervention group received individual Cognitive Stimulation Therapy (iCST) at their own home. The control condition was 'treatment as usual' (TAU) with participants in this group receiving no additional intervention. The services and interventions available to people with dementia and family caregivers randomized to receive treatment as usual varied between and within the iCST centers and may have changed over time. We recorded use of drugs and services across the two groups and any changes that occurred. In general, services offered to the treatment as usual group were also available to those in the active treatment group condition.

It is very unlikely that any comparable (or even any other) individual cognitive stimulation intervention for the person with dementia would have been available, as these types of therapies are generally unavailable in the United Kingdom (UK). We followed standard best practice methods around pragmatic trials involving an intervention group as compared to usual care. Outside the iCST intervention both groups in general would have access to the same kind of mentally stimulating activities. It is possible that some participants in the treatment as usual group may have engaged in some form of mentally stimulating activities in day-centers, however this is unlikely to have been as structured as iCST. We asked sites to note instances where the person with dementia may have been engaged in cognitive stimulation groups by their local services. Those participants that have engaged in such activities during the three months prior to recruitment were considered ineligible.

Text B: Excerpt from Health Technologies Assessment (HTA) report (Orgeta et al., 2015) describing treatment as usual (TAU) in the iCST trial.

Characteristic	Total (%)	Non-completers (%)	Completers (%)
<i>Person with dementia</i>	(n=356)	(n=83)	(n=273)
Female	165 (46)	39 (24)	126 (76)
Ethnicity White	331 (93)	77 (23)	254 (77)
Marital Status: married/cohabiting/civil partnership	252 (71)	59 (23)	193 (77)
Lives with spouse/partner	251 (71)	59 (24)	193 (77)
Highest level of education school leaver (14-16 years)	213 (60)	57 (27)	156(73)
Anti-cholinesterase inhibitors	270 (76)	136 (76)	159 (73)
	Mean (SD)	Mean (SD)	Mean (SD)
Age	78.2 (7.49)	79.1 (8.52)	77.9 (7.14)
<i>Caregiver</i>			
Female	261 (73)	62 (24)	199 (76)
Ethnicity White	329 (92)	75 (23)	254 (77)
Marital Status: married/cohabiting/civil partnership	297 (83)	65 (22)	232 (78)
Lives with spouse/partner	289 (81)	62(21)	227 (79)
Highest level of education school leaver (14-16 years)	159 (45)	42(26)	117 (74)
	Mean (SD)	Mean (SD)	Mean (SD)
Age	65.7 (12.92)	65.5 (14.02)	65.8 (12.59)

Table B: Characteristics of people with dementia and caregivers who completed the trial and those who did not

Reason for drop outs* / withdrawals	Number of withdrawals Is iCST	Number of drop outs iCST	Total number of drop outs/withdrawals iCST	Number of withdrawals Is in TAU	Number of drop outs TAU	Total number of drop outs/withdrawals TAU
	13					
Dyad do not wish to continue		0	13	4	0	4
Carer unwell	8	1	8	1	0	1
Person with dementia unwell	3	2	5	1	1	2
Carer busy	4	0	4	2	0	2
Person with dementia deteriorated	3	0	3	1	0	1
Residential care	3	0	3	3	0	3
Dyad are abroad / on holiday	1	1	2	0	0	0
Family crisis	0	2	2	1	0	1
Unable to contact dyad	2	0	2	2	3	5
Cross recruitment	1	0	1	0	0	0
Moved out of area	1	0	1	0	0	0
Carer no longer caring for person with dementia	1	0	1	0	0	0
Person with dementia depressed	1	0	1	0	1	1
Carer diagnosed with dementia	1	0	1	0	0	0
Carer stress	1	0	1	0	0	0
Carer burden	1	0	1	0	0	0
Person with dementia moved (still in local area)	0	1	1	0	0	0
Person with dementia hospitalized	0	1	1	0	1	1
Person with dementia died	1	0	1	6	0	6
Person with dementia does not wish to continue	1	0	1	1	0	1
Carer died	0	0	0	1	0	1
Dyad unhappy with allocation	0	0	0	6	0	6
Person with dementia has diagnosis of a significant health condition	0	0	0	2	0	2
Carer depressed	0	0	0	1	0	1
Dyad both unwell	0	0	0	1	0	1
Dyad relationship breakdown	0	0	0	1	0	1
Person with dementia stressed	0	0	0	1	0	1
Person with dementia lacks mental capacity	0	0	0	1	0	1
Person refused assessment	0	0	0	0	1	1
Carer thinks participating in iCST trial has a negative impact on person with dementia	0	0	0	0	1	1
Total	46	8	54	36	8	44

*iCST= individual Cognitive Stimulation Therapy, TAU= Treatment as usual
Table C: Reasons for drop outs and withdrawals in the iCST and TAU groups * drop
outs defined as failure to complete an assessment at mid-point. Withdrawals defined
as ceasing to continue participating in the trial.*

Researcher rating	Actual Treatment allocation		
	iCST (%)	TAU (%)	Total (%)
Correct 'Definite' judgment	22 (19)	4 (3)	26 (10)
Correct 'More likely' judgment:	17 (15)	17 (12)	34 (13)
Equally likely to be in iCST or TAU	65 (57)	80 (57)	145 (57)
Incorrect 'More likely' judgment:	10 (9)	31 (22)	41 (16)
Incorrect 'Definite' judgment:	0	9 (6)	9 (4)
Total	114	141	255

iCST=individual Cognitive Stimulation Therapy, TAU=Treatment as usual

Table D: Researchers' perceived group allocation at 13 week mid-point assessment (n=264)

Researcher rating	Actual Treatment allocation		
	iCST (%)	TAU (%)	Total (%)
Correct 'Definite' judgment	13 (12)	6 (4)	19 (7)
Correct 'More likely' judgment:	14 (13)	28 (18)	42 (16)
Equally likely to be in iCST or TAU	68 (65)	92 (58)	160 (60)
Incorrect 'More likely' judgment:	11 (10)	20 (13)	31 (12)
Incorrect 'Definite' judgment:	0	12 (7)	12 (5)
Total	106	158	264

iCST= individual Cognitive Stimulation Therapy, TAU=Treatment as usual

Table E: Researchers' perceived group allocation at post-test assessment (n=255)

Outcome measure	Baseline				13 weeks (mid-point)				26 weeks (post-test)			
	N	iCST	N	TAU	N	iCST	N	TAU	N	iCST	N	TAU
	Mis.	N=180 Mean (SD)	Mis.	N=176 Mean (SD)	Mis.	N=142 Mean (SD)	Mis.	N=146 Mean (SD)	Mis.	N=134 Mean (SD)	Mis.	N=139 Mean (SD)
Person with dementia												
ADAS Cog	1	21.47(9.22)	1	19.79 (8.03)	4	20.86 (9.73)	6	19.50 (8.97)	6	20.69 (9.39)	5	20.39 (9.91)
QoL-AD		38.01 (5.44)		37.96 (6.04)	2	37.90 (5.52)	2	38.09 (5.63)	5	37.86 (5.13)	1	37.71 (5.91)
DemQoL	3	93.85 (11.76)	3	92.18 (13.55)	7	94.08 (10.92)	4	94.05 (11.80)	6	95.46 (11.17)	3	95.12 (11.11)
NPI total		11.21 (13.96)		10.99 (11.98)	2	10.67 (13.30)		12.07 (12.61)	1	11.57 (13.72)	1	11.59 (12.80)
GDS 15	3	3.14 (2.64)	3	3.16 (3.15)	9	2.98 (2.56)	3	3.03 (2.86)	8	2.90 (2.55)	3	2.85 (2.67)
QCPR total	6	55.17 (8.89)	2	56.72 (8.73)	4	56.30 (8.98)	3	55.82 (9.06)	3	56.88 (8.59)	1	55.55 (10.25)
QCPR Warmth	1	33.19 (5.08)	1	33.98 (5.20)	1	33.32 (5.49)		33.25 (5.38)	1	33.78 (4.97)		33.07 (5.92)
QCPR Criticism & conflict	1	22.07 (4.78)	1	22.69 (4.66)	1	22.80 (4.46)		22.54 (4.75)		22.95 (4.59)		22.46 (5.15)
MMSE		21.12 (4.48)		21.33 (4.11)	1	20.59 (5.02)	2	20.89 (4.83)	4	20.68 (4.76)	1	21.19 (5.21)
BADLS [P]		5.16 (5.45)		4.49 (4.09)		14.53 (10.34)	1	13.55 (8.20)	3	15.39 (10.78)	1	14.56 (8.86)
QoL-AD [P]	0	32.88 (6.83)		33.09 (6.22)	1	32.64 (6.25)	2	31.93 (5.84)	1	32.46 (6.20)		31.99 (6.30)
DemQoL [P]	1	97.99 (13.17)	2	98.59 (12.76)	2	99.26 (12.38)	1	98.75 (11.96)	1	99.42 (12.41)	1	98.18 (12.80)
Caregiver												
SF12 Physical component	1	51.46 (10.25)	1	50.20 (10.32)		51.13 (9.73)		49.97 (10.34)		50.06 (10.53)	1	48.63 (10.87)
SF12 Mental component	1	49.42 (8.10)	1	48.14 (9.42)		47.98 (9.90)	2	47.93 (9.96)		48.88 (9.41)		47.88 (10.13)
HADS total	3	9.63 (6.11)		10.02 (6.67)	1	10.37 (6.98)		10.41 (6.89)	1	10.06 (6.92)		11.16 (7.59)
HADS Anxiety	3	5.84 (3.58)		6.03 (3.88)	1	6.33 (4.35)		6.06 (4.00)	1	6.03 (4.32)		6.36 (4.44)
HADS Depression	3	3.79 (3.30)		3.99 (3.40)	1	4.03 (3.30)		4.36 (3.48)	1	4.03 (3.29)		4.80 (3.81)

EQ5D health state today	3	78.37 (16.63)		76.24 (19.28)	1	78.13 (16.84)		76.45 (16.93)		78.63 (17.09)		76.58 (16.90)
EQ5D calculated utility value	1	0.83 (0.20)		0.81 (0.21)	1	0.82 (0.20)		0.79 (0.22)	2	0.82 (0.21)		0.75 (0.25)
RS 14	2	83.39 (10.98)	1	83.63 (10.43)		83.27 (11.14)		83.49 (10.47)	1	83.44 (10.86)		81.83 (12.90)
NPI Carer distress		3.15 (2.67)		3.23 (2.59)	2	3.13 (2.48)		3.18 (2.39)	1	3.11 (2.65)	1	3.25 (2.41)
QCPR total	3	59.21 (6.67)	3	58.21 (6.63)	8	60.12 (6.33)	4	59.73 (6.67)	9	60.14 (6.54)	4	59.76 (6.77)
QCPR Warmth	3	34.94 (3.77)	3	34.59 (3.64)	8	35.20 (3.66)	4	35.69 (3.45)	8	35.25 (3.57)	4	34.95 (3.51)
QCPR Criticism & conflict	3	24.26 (3.63)	2	23.63 (3.81)	8	24.92 (3.57)	4	24.04 (4.41)	9	24.90 (3.66)	4	24.81 (4.01)

iCST= individual Cognitive Stimulation Therapy group, SD= Standard deviation, [P]=Proxy rated measure, Mis.= missing data, TAU=Treatment as usual group, ADAS-Cog= Alzheimer's Disease Assessment Scale-Cognitive, QoL-AD= Quality of Life Alzheimer's Disease, DEMQoL=Dementia Quality of Life, NPI= Neuropsychiatric Inventory, GDS= Geriatric Depression Scale, QCPR= Quality of the Caregiving Relationship, MMSE= Mini-Mental State Examination, BADLS= Bristol Activities of Daily Living Scale, SF12=Short Form Survey, HADS=Hospital Anxiety & Depression Scale, EQ-5D=EuroQoL, RS 14= Resilience Scale

Table F: Unadjusted means for each of the outcome measures for iCST and TAU at 13 week mid-point & 26 week post test.

	Baseline		13 week mid-point		26 week post test	
	<i>iCST</i>	<i>TAU</i>	<i>iCST</i>	<i>TAU</i>	<i>iCST</i>	<i>TAU</i>
	N=180	N=176	N=142	N=146	N=134	N=139
	<i>Mean</i>	<i>Mean</i>	<i>Mean change from baseline (SD)</i>	<i>Mean change from baseline (SD)</i>	<i>Mean change from baseline (SD)</i>	<i>Mean change from baseline (SD)</i>
Person with dementia						
ADAS Cog	21.47	19.79	-0.29 (5.87)	0.03 (6.16)	0.33 (5.65)	1.24 (5.94)
QoL-AD	38.01	37.96	-0.36 (5.01)	-0.13 (4.6)	-0.70 (4.07)	-0.43 (5.13)
DemQoL	93.85	92.18	-0.47 (7.59)	0.32 (10.85)	1.09 (7.2)	1.56 (10.39)
NPI total	11.21	10.99	0.21 (11.05)	1.96 (10.08)	1.14 (11.72)	1.40 (10.1)
GDS 15	3.14	3.16	-0.01 (1.98)	0.11 (2.24)	-0.11 (1.94)	-0.09 (2.7)
QCPR total	55.17	56.72	0.28 (5.62)	-0.94 (5.39)	0.40 (5.99)	-1.46 (6.9)
QCPR Warmth	33.19	33.98	-0.26 (3.88)	-0.75 (3.49)	-0.15 (3.6)	-1.02 (4.24)
QCPR Criticism & conflict	22.07	22.69	0.54 (3.51)	-0.18 (3.13)	0.53 (4.05)	-0.43 (3.7)
MMSE	21.12	21.33	-0.46 (3.18)	-0.87 (3.5)	-0.96 (2.99)	-0.67 (3.62)
BADLS [P]	5.16	4.49	9.51 (6.23)	9.35 (5.91)	10.52 (6.97)	10.55 (6.54)
QoL-AD [P]	32.88	33.09	-0.62 (5.49)	-1.40 (4.54)	-1.06 (5.99)	-1.49 (4.95)
DemQoL [P]	97.99	98.59	0.84 (10.77)	0.17 (11.46)	1.70 (12.06)	-0.41 (9.96)
Caregiver						
SF12 Physical component	51.46	50.20	-0.78 (5.98)	-0.45 (6.72)	-1.85 (7.18)	-2.13 (7.32)
SF12 Mental component	49.42	48.14	-1.56 (6.91)	-0.54 (7.42)	-0.92 (7.05)	-0.57 (8.43)
HADS total	9.63	10.02	0.86 (4.36)	0.62 (4.3)	0.75 (4.52)	1.37 (5.27)
HADS Anxiety	5.84	6.03	0.51 (2.75)	0.19 (2.65)	0.26 (2.95)	0.43 (3.25)
HADS Depression	3.79	3.99	0.35 (2.36)	0.44 (2.36)	0.49 (2.33)	0.94 (2.72)
EQ5D health state today	78.37	76.24	-1.36 (13.3)	-0.83 (17.23)	-0.68 (13.64)	-0.91 (18.22)
EQ5D calculated utility value	0.83	0.81	-0.01 (0.19)	-0.04 (0.15)	-0.02 (0.2)	-0.07 (0.2)
RS 14	83.39	83.63	-0.15 (7.47)	-0.14 (6.45)	-0.20 (7.2)	-1.78 (9.17)
NPI Carer distress	3.15	3.23	0.13 (2.21)	0.09 (2.19)	0.11 (2.25)	0.17 (2.08)
QCPR total	59.21	58.21	0.23 (6.71)	0.77 (7.11)	-0.15 (5.78)	1.12 (6.64)
QCPR Warmth	34.94	34.59	-0.12 (4.04)	0.87 (3.84)	-0.30 (3.4)	0.21 (3.8)
QCPR Criticism & conflict	21.47	23.63	0.36 (3.81)	-0.09 (4.43)	0.17 (3.17)	0.89 (3.88)

iCST= individual Cognitive Stimulation Therapy group, *SD*= Standard deviation, *[P]*=Proxy rated measure, *TAU*=Treatment as usual group, *ADAS-Cog*= Alzheimer's Disease Assessment Scale-Cognitive, *QoL-AD*= Quality of Life Alzheimer's Disease, *DEM*QoL=Dementia Quality of Life, *NPI*= Neuropsychiatric Inventory, *GDS*= Geriatric Depression Scale, *QCPR*= Quality of the Caregiving Relationship, *MMSE*= Mini-Mental State Examination, *BADLS*= Bristol Activities of Daily Living Scale, *SF12*=Short Form Survey, *HADS*=Hospital Anxiety & Depression Scale, *EQ-5D*=EuroQoL, *RS 14*= Resilience Scale

Table G: Change from baseline for each of the outcome measures for iCST and TAU at 13 week mid-point & 26 week post test.

Measure	Observed data				Imputed data							
	13 week mid-point				Pooled coefficient		Median F		Low F		High F	
Person with dementia	Coefficient	SE	F	p value		SE	F	p value	F	p value	F	p value
ADAS-Cog	0.006	0.030	0.042	0.838	0.002	0.030	0.038	0.846	0.005	0.946	0.071	0.790
QoL-AD	0.019	0.021	0.866	0.353	0.019	0.021	0.824	0.365	0.685	0.409	1.015	0.315
DEMqoL	-0.021	0.042	0.246	0.620	-0.020	0.042	0.190	0.663	0.122	0.727	0.408	0.524
NPI total	-0.045	0.048	0.880	0.349	-0.046	0.048	0.903	0.343	0.877	0.350	0.916	0.339
GDS-15	-0.003	0.010	0.076	0.783	-0.003	0.010	0.055	0.815	0.000	0.986	0.628	0.429
QCPR total*	0.049	0.026	3.458	0.064	0.049	0.026	3.495	0.063	3.468	0.064	3.546	0.061
QCPR warmth	0.003	0.018	0.036	0.850	0.003	0.018	0.033	0.856	0.031	0.859	0.043	0.836
QCPR criticism & conflict*+*	0.043	0.015	8.268	0.004	0.043	0.015	8.383	0.004	8.377	0.004	8.386	0.004
MMSE	0.026	0.016	2.667	0.104	0.026	0.016	2.764	0.098	2.419	0.121	2.861	0.092
BADLS (P)+	0.024	0.029	0.671	0.413								
QoL-AD (P)	0.038	0.022	3.015	0.084	0.037	0.022	2.833	0.093	2.782	0.096	3.181	0.076
DEMqoL (P)	0.019	0.048	0.155	0.694	0.019	0.048	0.160	0.689	0.137	0.711	0.195	0.659
Caregiver												
SF-12 PCS	0.015	0.030	0.270	0.604								
SF-12 MCS	0.007	0.034	0.040	0.843								
HADS total	-0.024	0.021	1.271	0.260	-0.023	0.021	1.235	0.267	1.219	0.271	1.310	0.253
HADS (anxiety)	-0.012	0.013	0.806	0.370	-0.011	0.013	0.752	0.387	0.716	0.398	0.847	0.358
HADS (depression)	-0.014	0.011	1.519	0.219	-0.014	0.011	1.496	0.222	1.450	0.230	1.667	0.198
EQ-5D health state 0.891today	0.126	0.066	3.689	0.056	0.127	0.066	3.773	0.053	3.582	0.059	3.796	0.052
EQ-5D calculated utility value	0.001	0.001	2.573	0.110	0.001	0.001	2.566	0.110	2.558	0.111	2.607	0.108
RS-14	-0.031	0.033	0.891	0.346								
NPI (carer distress)	-0.007	0.009	0.658	0.418	-0.007	0.009	0.646	0.422	0.598	0.440	0.746	0.389
QCPR total	-0.004	0.030	0.022	0.883	-0.003	0.030	0.033	0.855	0.002	0.968	0.088	0.766
QCPR (warmth)	-0.008	0.017	0.223	0.637	-0.006	0.017	0.074	0.786	0.020	0.888	0.466	0.495
QCPR (criticism & conflict)	0.005	0.019	0.061	0.806	0.004	0.019	0.070	0.792	0.001	0.980	0.206	0.650

iCST= individual Cognitive Stimulation Therapy group, SE= Standard error, [P]=Proxy rated measure, F = F statistic, TAU=Treatment as usual group, ADAS-Cog= Alzheimer's Disease Assessment Scale-Cognitive, QoL-AD= Quality of Life Alzheimer's Disease, DEMQoL=Dementia Quality of Life, NPI= Neuropsychiatric Inventory, GDS= Geriatric Depression Scale, QCPR= Quality of the Caregiving Relationship, MMSE= Mini-Mental State Examination, BADLS= Bristol Activities of Daily Living Scale, SF12=Short Form Survey, HADS=Hospital Anxiety & Depression Scale, EQ-5D=EuroQoL, RS 14= Resilience Scale

Table H: Regression coefficient (and Standard Error [SE]) of the association between each person with dementia and caregiver outcome measure and the number of sessions of iCST attended at 13 week mid-point after adjusting for the baseline outcome measures

** Significant difference*

+ No missing data so imputed data rows left blank