A feasibility randomised control trial of individual Cognitive Stimulation Therapy for dementia: impact on cognition, quality of life and positive psychology

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Disclosure statement

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Objectives: This study aimed to evaluate the feasibility of a 14-session programme of individual Cognitive Stimulation Therapy (iCST) for people with dementia (PWD). It addressed potential limitations in previous literature of iCST and evaluated possible impact on cognition, quality of life (QoL) and positive psychology.

Method: The 14-session iCST programme was developed using existing manuals for group and individual CST and consultation with experts in the field. Thirty-three PWD were recruited from care homes and randomly assigned to iCST (14, 45-min sessions) or treatment as usual (TAU) over seven weeks. Outcomes measures were assessed at baseline and follow-up after the intervention.

Results: The intervention appeared feasible with high attendance to sessions, minimal levels of attrition, and ease of recruitment. Analysis of covariance indicated significant improvements in cognition (Alzheimer's Disease Assessment Scale-Cognitive subscale) for PWD receiving iCST compared to TAU. There were no significant differences between groups on follow-up scores on the standardised Mini Mental State Examination, measures of positive psychology or self-and proxy- reported QoL.

Conclusion: A 14-session programme of iCST delivered by professionals was feasible and acceptable to PWD and may provide benefits to cognition. A larger randomised control trial would be necessary to fully evaluate intervention impact on cognition, as well as QoL and positive psychology.

Key Words: Cognitive stimulation therapy, dementia, individual therapy, quantitative methods, feasibility

Introduction

Psychosocial interventions for people with dementia (PWD), especially those offering cognitive stimulation, have been shown to provide significant benefit to cognition, social function and quality of life (QoL) (Huntley, Gould, Liu, Smith & Howard, 2014; McDermott et al., 2018). Cognitive Stimulation Therapy (CST) is a well-established group intervention focused on mental stimulation and the implementation of cognitive skills within a social setting (Spector et al. 2003). Further, CST emphasises the person-centred care approach (Kitwood, 1997) by valuing and respecting individual preferences and needs and making choice an integral part of its framework. The positive impact of CST on both cognition and QoL is strongly supported, including for those already taking dementia medications (Woods et al. 2012). It was also established to be cost-effective (Knapp et al. 2006), which led to its recommendation by the National Institute for Health and Care Excellence (NICE) for people living with mild to moderate dementia (NICE, 2018).

CST has also been shown to have a positive impact on neuropsychiatric symptoms (Niu et al., 2010) and loneliness (Capotosto et al., 2017), although evidence for its effects on depressive symptoms is more mixed (Apóstolo et al. 2014; Capotosto et al. 2017; Orrell et al. 2017) and a recent review indicated no impact on anxiety (Lobbia et al. 2018). However, measures of behavioural and psychological symptoms in dementia typically evaluate reduction in negative symptoms, which is limited when participants have minimal symptoms at baseline, suggesting the impact of CST on areas outside of QoL and cognition may warrant further exploration.

A 24-session, weekly 'maintenance CST (MCST) programme was later developed, which provided benefits in QoL and longer-term cognitive benefits for people also taking dementia medication (Orrell et al., 2014). Yet, despite its availability across the UK and increasingly

worldwide (Aguirre, Spector & Orrell, 2014), many individuals may not have access to CST. Yates, Leung, Orgeta, Spector and Orrell (2015) identified several needs for an alternative to group CST. Firstly, groups may not be accessible to individuals who require support in travelling to services. Conversely, an individual approach would provide PWD the opportunity for somebody to bring CST to them, for example those with limited mobility. Others may dislike being part of groups, or may have practical barriers, such as sensory impairments (e.g. hearing) which could make participating in groups more difficult. These individuals may also be highly isolated, which has been associated with poorer cognitive function in older adults (Boss, Kang & Branson, 2015; Shankar, Hamer, McMunn & Steptoe, 2013), and consequently be at higher risk of cognitive decline. One-to-one intervention could provide a sense of social engagement more accessible to those unsuitable to groups, which may lessen the impact of isolation.

A 75-session individual Cognitive Stimulation Therapy (iCST) was developed to be delivered by family caregivers (Yates et al. 2015), based on the original group CST and MCST programmes (Aguirre et al., 2011; Spector, Thorgrimsen, Woods & Orrell, 2006). A randomised control trial (RCT) indicated no benefits to cognition or QoL (Orrell et al. 2017), although there were improvements in caregiving relationship and carer QoL. However, there were several limitations and feasibility issues. Of note, only 40% of the sample allocated to iCST completed at least two sessions a week, with a further 22% completing no sessions. Also, qualitative interviews during development and follow-up phases highlighted difficulties including time required to deliver iCST thrice-weekly, difficulties for carers engaging PWD which related to the level of decline associated with dementia and relationship dynamics when close family members became a 'therapist', which felt discordant with their familial

relationship (Yates et al. 2015; Leung et al. 2017). Some carers also felt insufficiently skilled to deliver the sessions (Orrell et al., 2017).

In consideration of previous limitations, delivery by professionals may enable more consistent iCST delivery and involve higher motivation for both parties due to the professional, unlike family members, being less regularly exposed to the decline associated with dementia. Secondly, the adherence rates and qualitative data suggest the original frequency and number of sessions was not feasible (Orrell et al. 2017, Leung et al. 2017). Twice-weekly sessions would allow greater flexibility in the timing and delivery of sessions and past research has consistently supported the benefits of a 14-session group CST programme delivered twice weekly, suggesting this is a sufficient dose to detect benefits if they exist. Finally, CST research has historically been conducted in care homes, in which residents may be more sensitive to change. A large proportion (39%) of PWD lives in care homes (Prince et al., 2014), in which need for social contact, meaningful activity and boredom are widely unmet needs (Cohen-Mansfield et al. 2015). Thus, a further study in this setting may be suitable to re-evaluate the potential of iCST. In addition, Stoner et al. (2017) highlighted the importance of 'positive psychology' in understanding wellbeing and positive outcomes in dementia, which relates to the study of positive emotions and other factors that contribute to individual's ability to 'flourish' (Gable & Haidt, 2005; Seligman, Steen, Park & Peterson, 2005). The addition of measures based on positive psychology perspectives could offer an alternative approach focusing on the positive impact of iCST compared to the historic use of outcomes measuring reduction in negative symptoms.

The current study aims to develop and pilot a revised iCST programme that minimises the barriers identified in the previous iCST trial and subsequent qualitative feedback (Orrell et al., 2017; Leung et al., 2017). It assesses the feasibility of a programme of 14, 45-minute iCST

sessions delivered by a professional twice weekly over seven weeks and considers its impact compared to treatment as usual (TAU) on cognition, QoL and positive psychology (measured by self-rated positive psychology and engagement and independence in PWD). This study also aims to establish the feasibility of conducting a larger RCT of iCST by considering feasibility of recruitment, acceptability of randomisation, attrition and feasibility of the outcome measures used.

Method

Ethics Statement

Ethical approval was received from the University College London Research Ethics Committee (ref no. 12503/001). Participants provided informed consent in accordance with the Mental Capacity Act (2005) and they could withdraw from the study at any time. Consent to taking part in iCST activities and assessments was reviewed throughout.

Design

The study was a single blind multi-centre randomised controlled pilot study. A sample size of 32 was identified as feasible to recruit. G*Power (Faul, Erdfelder, Lang & Buchner 2007) was used to determine that based on this number, with alpha set at .05 and power at 0.80, a large effect size of 0.51 (Cohen's *f*) could be detected with an ANCOVA with one covariate.

iCST Development

Researchers reviewed the current literature on CST including the original group CST (Spector et al. 2006), MCST (Aguirre et al. 2011) and iCST (Yates et al. 2014) manuals. Key principles of iCST were retained from the original iCST manual (Yates et al. 2014), with emphasis on providing choices for each session and encouraging adjustment of session content to the individual preferences and abilities of PWD. The structure of sessions was also retained from the original iCST manual, with each session beginning with a "warm-up" consisting of

sensitive discussion of orientation information, discussion of a newspaper article or recent events, followed by a themed activity. Each session has a suggested length of 45-minutes, providing the same dose as the original CST programme in terms of frequency of sessions and weekly time (three 30-minute sessions a week). If session length was too long for individuals, allowances were made to terminate a session early.

Selection of themes for sessions was informed by qualitative feedback from the fieldtesting phase of the development of iCST (Yates, Orgeta, Leung, Spector & Orrell, 2016) which explored which of the sessions were more valued or enjoyable. For example, the original CST session on 'Current Affairs' was removed as it has been rated less interesting and enjoyable than other sessions in field-testing of iCST (Yates et al. 2016) and was still incorporated into each session during the warm-up. The revised iCST programme followed a similar order and content to group CST with adjusted guidance to reflect the one-to-one nature of the intervention. The developed manual provided sessional plans and examples of activities with additional paper resources and suggested materials for each session. Worksheets and suggested materials were developed accordingly from available manuals, alongside new suggestions where appropriate. The revised manual was finalised through iterative consultations with experts in the field, AS and LY.

Table 1 reports on the chosen themes, the content of each session and adaptations from previous manuals.

[Table 1 near here]

Participants

Participants were recruited from care homes in London. Managers were initially contacted about the study and facilitated introductions to residents meeting inclusion criteria who might be interested in taking part. Researchers discussed the study and provided full details to participants, providing the opportunity for any questions before proceeding with written informed consent. Eligible participants were required to meet the following criteria informed by previous CST research:

- meet criteria for dementia of the Diagnostic and Statistical Manual of Mental Disorders
 V (DSM-V, American Psychiatric Association, 2013)
- have the capacity to provide informed consent
- have mild to moderate dementia evidenced by scoring at least 10/30 on the standardised Mini-Mental State Examination (SMMSE) (Molloy, Alemayehu, & Roberts, 1991)
- be able to communicate, understand, see and hear well enough to participate in activities as part of iCST
- have no major health issues which might affect participation.

Procedure

After baseline assessment, participants were randomly allocated by an independent web-based randomiser to receive either iCST or TAU within the care home, with a 1:1 ratio. TAU was defined as the day-to-day care received by residents within the care home facility. All assessments and iCST sessions were delivered by members of the research team and delivered at the care homes of the participants. Researchers conducting follow-up assessments were blinded to this allocation. Follow-up assessments were completed on average within 10 weeks of baseline assessment.

Measures

The SMMSE (Molloy et al. 1991) was used as a suitability tool and measure of cognition. It is a brief test used for dementia screening, chosen for its improved reliability compared to the original Mini-Mental State Examination (Folstein, Folstein & McHugh, 1975), whilst still allowing for comparison to previous findings. It provides a total score of 0-30 which can be adjusted to account for non-cognitive impairments such as hearing, with a higher score indicating better cognitive function. However, it has modest sensitivity (Sheehan, 2012). The Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog) (Rosen, Mohs & Davis, 1984) consists of 11 tasks assessing memory, language, praxis, attention and other cognitive domains and provides a total score of 0 - 75, with a lower score indicating better cognitive function. It has good reliability and validity and is widely utilised for trials when cognition is a primary outcome (Sheehan, 2012).

QoL was measured via self and proxy-reported Quality of Life in Alzheimer's Disease scales (QoL-AD) (Logsdon et al. 1999; Logdson et al. 2002). The QoL-AD is a widely used disease-specific measure including 13 questions about different domains of QoL with a fourpoint Likert response scale, providing a total maximum score of 52. The QoL-AD has good internal consistency, reliability and validity (Thorgrimsen et al., 2003). Positive psychology was explored via the Positive Psychology Outcome Measure (PPOM) (Stoner et al. 2017) and the Engagement and Independence in Dementia Questionnaire (EID-Q) (Stoner et al., 2017). The PPOM consists of an adaptation of the Herth Hope Index (Herth, 1992) and a resilience scale developed with PWD using prominent resilience theories. It is a 16-item questionnaire utilising a five-point Likert response scale administered via interview, providing a total score of 0 - 64. The EID-Q consists of 26 questions about an individual's degree of independence and engagement with others using a five-point Likert response scale administered via interview. Both the EID-Q and the PPOM have good internal consistency and convergent validity (Stoner et al. 2017), and unlike measures of behavioural and psychological symptoms, the PPOM does not focus on difficulties and is therefore thought to have greater sensitivity to improvements regardless of baseline levels of anxiety or depression.

Data analysis

Statistical analysis was conducted using IBM SPSS Statistics 25. Data was assessed for normality and heterogeneity. Analysis of covariance (ANCOVA) was used to explore the differences between iCST and TAU groups for PWD at follow-up. The baseline score on outcome measures was used as a covariate in the analyses.

Results

Thirty-three PWD were recruited and completed baseline assessments. Their basic demographics are summarised in table 2. Following randomisation, 17 participants were allocated to iCST and 16 to TAU.

[Table 2 near here]

Feasibility and Acceptability

Recruitment and Attrition

Seven out of the 27 homes (26%) approached agreed to take part in the study. Within recruited homes, thirty-four people initially consented to the study, which was accomplished in approximately 6 months. The study had a low attrition rate overall, with four participants lost to follow-up (12%) (see Figure 1 for diagram of participant flow).

Acceptability of Randomisation

Randomisation appeared acceptable to participants as only three participants receiving TAU dropped out of the study for reasons unrelated to study participation.

Attendance and Adherence

Eighty-one percent of participants allocated to iCST completed all 14 sessions, with 97% of sessions attended overall. One participant missed one session, one missed two sessions, and one missed three sessions. Reasons for missing sessions were tiredness, not feeling in the mood, or being busy with another activity.

[Figure 1 near here]

Fidelity

No fidelity checklist was used in the current study, however neither researcher reported difficulties with manual adherence.

Adverse Events

There were no unexpected adverse events for participants.

Feasibility of Outcome Measures

Excluding the participants who were unable to complete follow-up assessments or who withdrew from the study, there was no missing data on cognition measures. The SMMSE accommodates difficulties with items relating to sensory or physical impairment by allowing an adjusted score based on total items completed. For the ADAS-Cog, items made difficult by factors other than cognitive impairment were found similarly difficult at follow-up indicating little impact on scores. It was intended for the same researchers to complete assessments at baseline and follow-up for each resident. This was not the case for 40% of cases due to researcher unavailability.

There were several discrepancies in missing items at baseline and at follow-up for measures of QoL and positive psychology related to willingness to answer more personal questions as compared to the cognitive items. There were also several items in the PPOM and EID-Q that were experienced as difficult to understand either due to unclear language or length. In addition, one participant was unwilling to complete the EID-Q at follow-up.

Missing Data Analysis

For two items on the proxy QoL-AD (items seven and twelve), there was a high percentage of missing responses. These items were therefore excluded from total scores on the QoL-AD. To allow complete analysis and maintain power, multiple imputation using a MCMC method was

used to impute other missing values. However, participants were excluded from analyses for measures in which they had large amounts of missing data across a measure. There were 63.33% of participants having at least one missing response, but only 3.57% of values missing from the data set. Eight items (5%) had 10% missing responses, and four items had between 10% and 17% missing responses. No items had more than 17% missing.

Analyses of Outcome Measures

Analyses were conducted on the 29 participants who completed both baseline and follow-up assessments. Levene's Test for Equality of Variance was not significant for all comparisons, p > .05, indicating equal variances could be assumed between groups at follow-up. Scores did not differ significantly between groups at baseline for any outcome measures (Table 2). There was a significant difference between iCST and TAU at follow-up on the ADAS-Cog, with those receiving iCST scoring significantly lower (indicating better cognitive function) than TAU with a mean difference (MD) of -5.04 (95% confidence intervals (CI) -8.57 to -1.51) whilst accounting for baseline scores. There were no significant differences between groups on the SMMSE, or on measures of QoL or positive psychology. Table 3 provides a summary of results for outcomes of cognition, QoL and positive psychology.

[Table 3 near here]

Discussion

The current study aimed to develop and evaluate a 14-session programme of iCST for PWD delivered by professionals in a feasibility randomised controlled trial. The intervention was feasible with good attendance (81% of individuals receiving a full dose of 14 sessions of iCST and 97% session attendance) and minimal attrition, with only individuals in the TAU group withdrawing from the study for reasons unrelated to study participation, and no adverse events

from taking part. In addition, there were minimal difficulties recruiting to the study, and randomisation appeared acceptable with little difference in attrition rates between iCST and TAU. Findings also suggest it may provide benefits to cognition, however there was no significant impact on measures of QoL or positive psychology. Overall, these findings suggest that a larger RCT of iCST would be both feasible and warranted, and indicated several recommendations for future research.

Interpretation of results

One of the main limitations in the previous iCST trial was poor treatment adherence (Orrell et al. 2017). There are several key differences in the current study that may underlie the improved adherence found. Firstly, the revised manual was adapted in line with both qualitative findings from iCST's development phase (Yates et al. 2015) and the original session content of CST (Spector et al. 2006). As such, each session may have been more broadly enjoyed as it incorporated sessions and activities shown to be preferred in previous research. Secondly, the use of professionals addressed difficulties experienced by family carers delivering iCST. For example, professionals were more likely to, due to the nature of their role, have more training and skills related to delivery of psychosocial interventions. Professionals were also less likely to feel burnt out, as the intervention is more likely seen as part of their role and could be less emotionally invested in the PWD's performance on tasks. Finally, carers delivering iCST had found it difficult fitting sessions into a busy schedule (Orrell et al. 2017; Yates et al. 2016) which may be addressed by the reduction to 14 sessions.

Although assessment of fidelity was beyond the resources of the current study, the intervention was manualised and there were no difficulties reported by researchers in delivering it as planned. It is also important to note that most care homes and participants were recruited for the study within approximately six months. Although 23% of people approached

did not meet inclusion criteria, this may be a result of care home manager eagerness for individuals to receive intervention, for example referring several people who were without a diagnosis of dementia.

Improved scores of five points on the ADAS-Cog for the iCST group at follow-up (compared to TAU) suggests that iCST may also provide benefits to cognition, in contrast to previous findings (Orrell et al. 2017). Of note, a change of four points or more on the ADAS-Cog has historically been considered clinically important in drug trials (Rockwood et al. 2007). In addition, the effect size of the intervention on ADAS-Cog scores was large (Cohen, 1992), but it is important to note this may be exaggerated in small sample sizes. Conversely, there was no significant differences between groups on the SMMSE. This is comparable to Hall, Orrell, Stott and Spector (2013), who found benefits to memory and orientation following group CST, but no improvement on the MMSE. However, it is possible that the MMSE, which has a relatively small range, is simply less sensitive to smaller changes in cognition. This is reflected in past findings, where change in points on the MMSE was half that found in the ADAS-Cog (Spector et al., 2010).

There may be several explanations for the difference in overall findings compared to past iCST trials. Firstly, the current study was more closely related to group CST, as the weekly dose and most content were kept the same (Spector et al. 2006) and the sample was similarly recruited from care homes. Secondly, as mentioned above, professionals may be better equipped to deliver sessions in terms of training and motivation. In combination with improved adherence, these differences may have contributed to the contrast in cognitive outcomes.

There were no significant differences between groups on measures of QoL or positive psychology, though it is possible the limited sample size did not have sufficient power to

detect small effects. Further, the lack of clarity experienced by some participants in the questionnaires could have limited understanding for those with lower functioning, which may have impacted upon responses. In addition, previous findings showing that CST benefits QoL may be explained by the general benefits of engagement in group activity for people with dementia (Cohen-Mansfield, 2018) in addition to the stimulation. It is likely that individuals also build friendships in the groups which may extend outside of the CST setting, which was not possible for the facilitators and PWD in this study, as the relationship was largely professional. Although the present study did not collect qualitative feedback, there is evidence that PWD enjoy iCST sessions (Leung et al., 2017) and may feel disappointed when the sessions end.

Strengths and Limitations

The modification of the intervention was guided by the extensive development of the original iCST program (Yates et al. 2015; Orrell et al. 2017). The advantage of this was the availability of data that could be utilised in refining the intervention, including the perspective and experience of both PWD and their carers (Yates et al. 2016). By constraining the intervention to 14 sessions, the program addressed the previous barrier of session frequency and the authors were also able to provide additional options for each session to accommodate the preferences of each participant. Secondly, although the sample size was small, there was a reasonable spread of ages included in the study and a balance of sexes within each group. However, in terms of ethnicity, participants were predominantly White British which makes it more difficult to generalise findings to other ethnic and cultural groups.

A further limitation was the difficulty in using the same researchers for assessment at baseline and follow-up, with a total of six researchers required to administer cognitive measures. Similarly, it was not always possible to administer the proxy-rated QOL-AD to the

same carer at follow-up as at baseline. Further, although this was a single blind study, which was supported by participants being reminded not to discuss their allocation with researchers, carers rating proxy measures were likely not fully blinded as their presence in the care home would have informed them who was receiving iCST. This may have led to bias when responding to questions in the proxy QoL-AD.

Implications

Should a larger RCT indicate iCST provides benefits to cognition and quality of life, it would be important to evaluate if this programme could also be delivered by family carers as was intended with the original programme. The adaptations made to the original iCST programme were accomplished through review of carer feedback, which suggests the 14-session programme could be more feasible and acceptable for carer facilitation. Orrell et al. (2017) highlighted benefits of involving family and carers in intervention for dementia and Leung et al. (2017) had identified benefits even with limited adherence. This suggest similar benefits could be found in a shorter intervention but would need to be explored in future research. In addition, if family delivery is effective, iCST could be implemented not only to reach those individuals unable to access group CST, but also to support those coming to the end of group CST in maintaining benefits at home if training were provided more routinely to carers. Past research in group CST also suggests this programme could be developed for other cultural backgrounds (Aguirre et al. 2014).

Future Research

The current findings suggest several avenues for future research and the potential worth of conducting a larger RCT. Firstly, it may be beneficial in future to measure outcomes in the interim of treatment in addition to follow-up to better establish the efficacy of iCST. Also, no longer-term follow-up data was collected so it was not possible to assess whether benefits

might be represented in longer term impact or slowing of further decline over time. It may also be helpful to consider additional or alternative outcome measures to evaluate the impact on QoL and positive psychology, given some of the difficulties experienced on these measures. In addition, future trials could utilize more sophisticated analyses exploring other factors that might predict changes in outcomes. For example, Aguirre et al. (2013) found that group CST benefitted cognition including for those on dementia medications and found associations with age and gender

Moreover, gathering qualitative data at the end of intervention has potential to enable further understanding of the acceptability of the intervention and session contents. It could also explore any additional effects of iCST that may not be picked up by the measures used within the study, for example enjoyment and interest in sessions. In addition, qualitative input is recommended for complex intervention development (Medical research Council, 2008) and would be insightful for future advances, as it would give us greater understanding of responses to the intervention (Lewin, Glenton & Oxman, 2009).

It may also benefit future research to include assessment of intervention fidelity, which could be accomplished via audio recording of sessions or creating a fidelity checklist. Lastly, different care homes likely had different standards of TAU, which would mean control groups could not be considered homogenous. It may be useful to systematically measure this in a full RCT.

Conclusions

Overall, a 14-session programme of iCST for PWD was feasible in consideration of adherence and retention. The findings suggest it may offer improvements to cognition for PWD and may offer a viable alternative to group CST. This could offer real hope to those currently unable to access treatment who are at potential risk of greater cognitive decline. Although there was no

impact on QoL or positive psychology, this requires further exploration and several recommendations are made to guide future research.

References

- Aguirre, E., Hoare, Z., Streater, A., Spector, A., Woods, B., Hoe, J., & Orrell, M. (2013).
 Cognitive stimulation therapy (CST) for people with dementia-who benefits most? *International Journal of Geriatric Psychiatry*, 28(3), 284–290.
 https://doi.org/10.1002/gps.3823
- Aguirre, E., Spector, A., & Orrell, M. (2014). Guidelines for adapting cognitive stimulation therapy to other cultures. *Clinical Interventions in Aging*, *9*, 1003–1007. https://doi.org/10.2147/CIA.S61849
- Aguirre, E., Spector, A., Streater, A., Hoe, J., Woods, B., & Orrell, M. (2011). Making aDifference 2: Volume Two: An evidence-based group programme to offer MaintenanceCognitive Stimulation Therapy (CST) to people with dementia. *London: Hawker*.
- American Psychiatric Association. (2013). Diagnostic and Statistical Manual of Mental Disorders. American Psychiatric Association. https://doi.org/10.1176/appi.books.9780890425596
- Apóstolo, J. L. A., Cardoso, D. F. B., Rosa, A. I. and Paúl, C. (2014). The effect of cognitive stimulation on nursing home elders: A randomized control trial. Journal of Nursing Scholarship, 46(3), 157-166.
- Boss, L., Kang, D. H., & Branson, S. (2015). Loneliness and cognitive function in the older adult: a systematic review. *International Psychogeriatrics*, 27(4), 541-553.
- Capotosto, E., Belacchi, C., Gardini, S., Faggian, S., Piras, F., Mantoan, V., ... & Borella, E. (2017). Cognitive stimulation therapy in the Italian context: its efficacy in cognitive and

non-cognitive measures in older adults with dementia. International journal of geriatric psychiatry, 32(3), 331-340.

Cohen, J. (1992). A power primer. Psychological bulletin, 112(1), 155.

- Cohen-Mansfield, J. (2018). The impact of group activities and their content on persons with dementia attending them. *Alzheimer's research & therapy*, *10*(1), 37.
- Cohen-Mansfield, J., Dakheel-Ali, M., Marx, M. S., Thein, K., & Regier, N. G. (2015). Which unmet needs contribute to behavior problems in persons with advanced dementia? Psychiatry research, 228(1), 59-64.
- Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2011). Developing and evaluating complex interventions. Medical Research Council, UK.

Dementia, U. K. (2014). Dementia UK: update. Alzheimer's Society, London, UK.

- Faul, F., Erdfelder, E., Lang, A.-G., & Buchner, A. (2007). G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior Research Methods*, 39, 175-191
- Folstein, M. F., Folstein, S. E., & McHugh, P. R. (1975). "Mini-mental state": a practical method for grading the cognitive state of patients for the clinician. Journal of psychiatric research, 12(3), 189-198.
- Gable, S. L., & Haidt, J. (2005). What (and why) is positive psychology? *Review of general psychology*, 9(2), 103-110.

- Hall, L., Orrell, M., Stott, J., & Spector, A. (2013). Cognitive stimulation therapy (CST):
 Neuropsychological mechanisms of change Cognitive stimulation therapy (CST):
 neuropsychological, (November). https://doi.org/10.1017/S1041610212001822
- Herth, K. (1992). Abbreviated instrument to measure hope: development and psychometric evaluation. *Journal of Advanced Nursing*, *17*(*10*), 1251-1259.
- Huntley, J. D., Gould, R. L., Liu, K., Smith, M., & Howard, R. J. (2015). Do cognitive interventions improve general cognition in dementia? A meta-analysis and metaregression. *BMJ Open*, 5(4), 1–12. https://doi.org/10.1136/bmjopen-2014-005247
- Kitwood, T. (1997). The experience of dementia. Aging & Mental Health, 1(1), 13-22.
- Knapp, M., Thorgrimsen, L., Patel, A., Spector, A., Hallam, A., Woods, B., & Orrell, M. (2006). Cognitive stimulation therapy for people with dementia: cost-effectiveness analysis. *The British Journal of Psychiatry*, 188(6), 574-580.
- Leung, P., Yates, L., Orgeta, V., Hamidi, F., & Orrell, M. (2017). The experiences of people with dementia and their carers participating in individual cognitive stimulation therapy. *International Journal of Geriatric Psychiatry*, *32*(12), e34–e42. https://doi.org/10.1002/gps.4648
- Lewin, S., Glenton, C., & Oxman, A. D. (2009). Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: Methodological study. *BMJ (Online)*, 339(7723), 732–734. https://doi.org/10.1136/bmj.b3496
- Lobbia, A., Carbone, E., Faggian, S., Gardini, S., Piras, F., Spector, A., & Borella, E. (2018). The efficacy of cognitive stimulation therapy (CST) for people with mild-to-moderate

dementia: A review. *European Psychologist*, No-Specified. https://doi.org/http://dx.doi.org/10.1027/1016-9040/a000342

- Logsdon, R. G., Gibbons, L. E., McCurry, S. M. and Teri, L. (1999). Quality of life in Alzheimer's disease: patient and caregiver reports. *Journal of Mental Health and Ageing*, *5*(*1*), 21-32.
- Logsdon, R. G., Gibbons, L. E., McCurry, S. M. andTeri, L. (2002). Assessing quality of life in older adults with cognitive impairment. *Psychosomatic Medicine*, *64*(*3*), 510-519.
- McDermott, O., Charlesworth, G., Hogervorst, E., Stoner, C., Moniz-Cook, E., Spector, A., ... Orrell, M. (2019). Psychosocial interventions for people with dementia: a synthesis of systematic reviews. *Aging & Mental Health*, 23(4), 393–403. https://doi.org/10.1080/13607863.2017.1423031
- Molloy, D. W., Alemayehu, E., & Roberts, R. (1991). Reliability of a standardized minimental state examination compared with the traditional mini-mental state examination. *Am J Psychiatry*, *148*(1), 102-105.
- NICE (2018) Dementia: assessment, management and support for people living with dementia and their carers. Retrieved from http://www.nice.org.uk/guidnace/ng97
- Niu, Y. X., Tan, J. P., Guan, J. Q., Zhang, Z. Q. and Wang, L. N. (2010). Cognitive stimulation therapy in the treatment of neuropsychiatric symptoms in Alzheimer's disease: a randomized controlled trial. Clinical Rehabilitation, 24(12), 1102-1111.
- Orrell, M., Aguirre, E., Spector, A., Hoare, Z., Woods, R. T., Streater, A., ... Russell, I. (2014). Maintenance cognitive stimulation therapy for dementia: Single-blind,

multicentre, pragmatic randomised controlled trial. *British Journal of Psychiatry*, 204(6), 454–461. https://doi.org/10.1192/bjp.bp.113.137414

- Orrell, M., Yates, L., Leung, P., Kang, S., Hoare, Z., Whitaker, C., ... Orgeta, V. (2017). The impact of individual Cognitive Stimulation Therapy (iCST) on cognition, quality of life, caregiver health, and family relationships in dementia: A randomised controlled trial. *PLoS Medicine*, 14(3), 1–22. https://doi.org/10.1371/journal.pmed.1002269
- Prince, M., Knapp, M., Guerchet, M., McCrone, P., Prina, M., Comas-Herrera, A., ... & Rehill,A. (2014). Dementia UK: Update. Alzheimer's Society.
- Rockwood, K., Fay, S., Gorman, M., Carver, D., & Graham, J. E. (2007). The clinical meaningfulness of ADAS-Cog changes in Alzheimer's disease patients treated with donepezil in an open-label trial, *8*, 1–8. https://doi.org/10.1186/1471-2377-7-26
- Rosen, W. G., Mohs, R. C., & Davis, K. L. (1984). A new rating scale for Alzheimer's disease. *The American journal of psychiatry*.
- Seligman, M. E., Steen, T. A., Park, N., & Peterson, C. (2005). Positive psychology progress: empirical validation of interventions. *American psychologist*, *60*(5), 410.
- Shankar, A., Hamer, M., McMunn, A., & Steptoe, A. (2013). Social isolation and loneliness: relationships with cognitive function during 4 years of follow-up in the English Longitudinal Study of Ageing. *Psychosomatic medicine*, 75(2), 161-170.
- Sheehan, B. (2012). Assessment scales in dementia. *Therapeutic Advances in Neurological Disorders*, 5(6), 349–358. https://doi.org/10.1177/1756285612455733

- Spector, A., Thorgrimsen, L., Woods, R. T., & Orrell, M. (2006). *Making a difference: an evidence-based group programme to offer Cognitive Stimulation therapy (CST) to people with dementia*. Hawker Publications.
- Spector, A., Orrell, M., & Woods, B. (2010). Cognitive Stimulation Therapy (CST): Effects on different areas of cognitive function for people with dementia. International Journal of Geriatric Psychiatry, 25(12), 1253–1258. https://doi.org/10.1002/gps.2464
- Spector, A., Thorgrimsen, L., Woods, B., Royan, L., Davies, S., Butterworth, M., & Orrell, M. (2003). Efficacy of a cognitive stimulation therapy programme for people with dementia. The British Journal of Psychiatry, 183, 248–254. https://doi.org/10.1192/03-23
- Stoner, C. R., Orrell, M., Long, M., Csipke, E., & Spector, A. (2017). The development and preliminary psychometric properties of two positive psychology outcome measures for people with dementia: the PPOM and the EID-Q, 1–11. https://doi.org/10.1186/s12877-017-0468-6
- Thorgrimsen, L., Selwood, A., Spector, A., Royan, L., de Madariaga Lopez, M., Woods, R. T. and Orrell, M. (2003). Whose quality of life is it anyway? The validity and reliability of the Quality of Life Alzheimer's Disease (QoL-AD) scale. *Alzheimer Disease & Associated Disorders*, 17(4), 201-208.
- Woods, B., Aguirre, E., Spector, A. E., & Orrell, M. (2012). Cognitive stimulation to improve cognitive functioning in people with dementia. *Cochrane Database of Systematic Reviews*, (2). https://doi.org/10.1002/14651858.CD005562.pub2

- Yates, L. A., Leung, P., Orgeta, V., Spector, A., & Orrell, M. (2015). The development of individual cognitive stimulation therapy (iCST) for dementia. *Clinical interventions in aging*, 10, 95–104. https://doi.org/10.2147/CIA.S73844
- Yates, L., Orrell, M., Leung, P., Spector, A. E., Woods, B., & Orgeta, V. (2014). Making a Difference 3: Individualised CST–A manual for carers.
- Yates, L. A., Orgeta, V., Leung, P., Spector, A., & Orrell, M. (2016). Field-testing phase of the development of individual cognitive stimulation therapy (iCST) for dementia. *BMC Health Services Research*, 16. https://doi.org/10.1186/s12913-016-1499-y

Tables

Session	Theme	Session content and adaptations or changes
1	Life History	Life history was retained as the first session from the iCST manual as it provided a way to get to know individuals discover preferences to tailor remaining sessions.
2	Physical Games	Physical games suitable for two individuals (e.g. catch, boules) incorporating touch and movement
3	Sounds	Activities around both music and sounds, (e.g. discussing instruments, sounds or genre of music)
4	Childhood	Discussions around childhood (e.g. demonstration of old- fashioned childhood toys)
5	Food	Discussion of food slogans and adverts was combined with other variations on food activities from the original manuals, including tasks around 'dream' menu creation and food opinions
6	Faces	Discussion of famous faces (e.g. similarities and differences, guessing their profession)
7	Word Association	Word association activities (e.g. discussing proverbs, games of free association)
8	Being Creative	Session content was created via a combination of several options including looking at famous classical and modern artwork, or alternative use of sculptures and architecture
9	Categorising Objects	Activities such as making lists of categories (e.g. fruit, boy's names, countries beginning with a vowel)
10	Orientation	Discussion of scenes, travel and culture
11	Using Money	Games or discussions about money (e.g. how prices have changed over the years, or "price is right" games)
12	Number Games	Games based on numbers (e.g. card games, dominoes)
13	Word Games	Games based on words (e.g. hangman, crossword, word search)
14	Thinking Cards	Although the individual quiz developed for iCST was popular, the 'Thinking Cards' session was chosen as a widely enjoyed activity to be used as a final session in place of the individual quiz. Provides a range of discussion topics.

Table 1. Adaptations made to the original 14-session group CST programme.

Characteristics	All participants	iCST	TAU	Mean		
	(n=33)	(n=17)	(n=16)	difference		
Age (years)						
Mean (SD)	81.85 (10.31)	86.24 (5.19)	77.19 (12.38)			
Range Ethnicity (%)	56 – 98	75 - 98	56 - 94			
White British	27 (81.8)	12 (80)	11 (78.6)			
White Other	2 (6.1)	2 (13.3)	0 (0)			
Asian	3 (9.1)	1 (6.7)	2 (14.3)			
Black British	1 (3.0)	0 (0)	1 (7.1)			
Gender (%)						
Male	17 (51.5)	8 (57.1)	5 (33.3)			
Female	16 (48.5)	6 (42.9)	10 (66.7)			
SMMSE Score						
Mean (SD)	21.70 (3.51)	20.94 (2.97)	22.50 (3.95)	<i>t</i> (31) = 1.29		
Range	14 - 27	14 - 25	14 - 27	p > .05		
Mean (SD)	24.03 (10.05)	24 24 (6 99)	23 81 (12 77)	t(31) = -0.12		
Range	8 - 45	18 - 39	8 - 45	p > .05		
QOL-AD Score						
Mean (SD)	35.07 (6.21)	33.23 (6.50)	37.02 (5.42)	t(31) = 1.81		
Range	19 - 52	19 - 45	31 - 52	<i>p</i> > .05		
EID-Q Score						
Mean (SD)	75.79 (12.33)	76.63 (9.67)	74.88 (14.92)	t(31) = -0.40		
Range	40 - 102	53 - 97	40 - 102	<i>p</i> > .05		
PPOM Score						
Mean (SD)	45.72 (9.19)	43.50 (7.96)	48.07 (10.05)	t(31) = 0.23		
Range	33 - 63	33 - 56	33 - 63	<i>p</i> > .05		
Carer QoL-AD Score						
Mean (SD)	29.16 (4.90)	29.76 (4.57)	28.53 (5.29)	t(31) = 0.35		
Range	19 - 38	19 - 35	22 - 38	<i>p</i> > .05		

Table 2. Participant Demographics at Baseline

* Denotes a significant difference at alpha = .01

iCST = individual cognitive stimulation therapy; TAU = treatment as usual; SD = standard deviation; ADAS-Cog = Alzheimer's Disease Assessment Scale-Cognitive Sub-scale; SMMSE = Standardised Mini Mental State Examination; QoL-AD = Quality of Life in Alzheimer's Disease, PPOM = Positive Psychology Outcome Measure; EID-Q = Engagement and Independence in Dementia Questionnaire, Mean Difference = mean difference at baseline

Magsura	Scores at Follow- Up		Mear	1 Difference	ANCOVA
wieasui e	iCST Mean (SD)	TAU Mean (SD)	Mean (SD)	95% CI	difference)
SMMSE	20.44 (4.05)	22.77 (4.62)	-0.49 (1.41)	-3.39 to 2.40	F(1,26) = 0.12, p = .73
ADAS- Cog	19.44 (3.50)	23.15 (11.82)	-5.04 (1.72)	-8.57 to -1.51	F (1,26) = 8.61, p = .0070* partial $\eta^2 = 0.25$
QoL-AD (Self- rated)	35.32 (5.91)	37.95 (6.02)	-0.06 (1.90)	-3.97 to 3.85	F (1,26) = 0.001, p = .98
PPOM	45.77 (8.93)	44.50 (17.91)	6.62 (4.20)	-2.02 to 15.26	F(1,26) = 2.48, p = 0.13
EID-Q	71.75 (12.11)	78.06 (17.79)	-4.47 (4.13)	-12.98 to 4.04	F(1,25) = 1.17, p = 0.29
QoL-AD (Carer)	29.84 (5.73)	28.02 (6.60)	1.67 (2.34)	-3.14 to 6.48	F(1,25) = 0.51, p = .48

Table 3. ANCOVA comparing group differences at follow-up adjusting for baseline scores

* Denotes a significant difference at alpha = .01

iCST = individual cognitive stimulation therapy; TAU = treatment as usual; SD = standard deviation; ADAS-Cog = Alzheimer's Disease Assessment Scale-Cognitive Sub-scale; SMMSE = Standardised Mini Mental State Examination; QoL-AD = Quality of Life in Alzheimer's Disease, PPOM = Positive Psychology Outcome Measure; EID-Q = Engagement and Independence in Dementia Questionnaire, Mean Difference = mean difference adjusting for baseline scores

Figure Captions

Figure 1. Flow diagram of recruitment and retention of participants