Individual Cognitive Stimulation Therapy (iCST) for people with Intellectual Disability and Dementia: a feasibility randomised controlled trial

Abstract

Objectives

To examine the feasibility, acceptability and fidelity of individual Cognitive Stimulation Therapy (iCST) in people with intellectual disability (ID) and dementia.

Method

We aimed to recruit forty dyads (carer and individual with dementia and ID) who were randomised to iCST or a waiting list control group. Both groups received treatment as usual. Family and paid carers delivered the manualised intervention (40 sessions over 20 weeks). Recruitment and retention of participants, intervention adherence, fidelity and acceptability were assessed. Outcome measures of cognition, adaptive functioning, quality of life (QoL) and carer outcomes were collected at baseline, midpoint (11 weeks) and at 21 weeks. Qualitative interviews were conducted with six carers about their experience of iCST.

Results

Forty dyads were recruited over 10 months from 12 National Health Service trusts. One dyad dropped out and 87.5% and 97.5% completed the midpoint and end-point assessments respectively. Assessment of fidelity indicated that the correct session structure was not followed; 70% completed at least 20 sessions and there was a high level of satisfaction with iCST. QoL was significantly higher in the iCST arm at 21 weeks (adjusted mean difference: 3.11; 95% CI: 0.64 to 5.58). There were no differences in the other outcome measures.

Conclusion

The intervention was feasible and acceptable. A full-scale trial is warranted but some modifications are needed, including improved training and supervision for carers to improve fidelity.

Trial registration number: ISRCTN18312288

Key words

Dementia, Cognitive Stimulation Therapy, , intellectual disabilities, Down Syndrome, feasibility study.

Introduction

Intellectual disability (ID) is defined as impaired intellectual and adaptive functioning, arising before the age of 18 (American Psychiatric Association, 2013) and affects approximately 1% of the population (Emerson et al., 2010). The prevalence of dementia in people with ID is 7.5 times that of people without ID (Carey et al., 2017) and is likely to increase due to increasing life expectancy (Patja, Iivanainen, Vesala, Oksanen & Ruoppila, 2000). The risk of dementia is highest amongst people with Down Syndrome over the age of 40, with one longitudinal study indicating that over 97% will go on to develop dementia over a 20-year period (McCarron et al., 2017). Dementia is also the leading cause of mortality in people with Down Syndrome (Hithersay et al., 2019). Reduced cognitive reserve resulting from pre-existing brain damage may contribute to the higher risk and early onset dementia observed in people with ID (Strydom , Chan , King , Hassiotis & Livingston, 2013).

Current National Institute for Health and Clinical Excellence (NICE) guidelines recommend that people with mild to moderate dementia should be offered group Cognitive Stimulation therapy (CST) (National Institute for Health and Clinical Excellence, 2018a). CST incorporates a variety of activities such as reminiscence, puzzles, discussion of topics of interest, word and number games, which aim to provide mental stimulation in areas of thinking, concentration and memory (Stewart et al, 2017). CST has been consistently associated with improvements in cognitive functioning, self-reported wellbeing, quality of life, communication and social interaction in people with dementia from the general population (Aguirre, Woods, Spector & Orrell 2013; Woods, Aguirre, Spector & Orell, 2012).

Dementia care-giving is associated with negative outcomes in carers including mental ill-health, physical illness, reduced quality of life, family dysfunction and diminished social support (Etters, Goodall & Harrison, 2008). This in turn can lead to reduced quality of life in individuals with dementia and early nursing home placement (Etters, Goodall & Harrison, 2008). Individual CST (iCST), delivered by carers, has been shown to enhance the quality of the care-giving relationship and caregivers' quality of life (Orrell et al., 2017) and to improve cognition in dementia participants (Gibbor et al., 2020; Onder, Zanetti, Giacobini, et al., 2005).

Paid carers often have limited knowledge of dementia in people with ID and caring for such individuals is often stressful and time consuming (Cleary & Doody, 2017). The NICE guidelines on the "care and support of people growing older with learning disabilities" (National Institute for Health and Care Excellence, 2018b) recommends the need to evaluate dementia training programmes for this population. This could include iCST as it aims to improve carers' knowledge of delivering appropriate stimulating activities that could enhance cognition in the individual with dementia. The principles of iCST include: mental stimulation; developing new ideas, thoughts and associations; maximising potential; offering a choice of activities; using reminiscence; providing triggers to support memory; using a 'person-centred' approach; focusing on opinions rather than facts; enjoyment and fun; and building relationships by spending quality time together (Yates et al., 2014).

To date, there have been no randomised controlled trials (RCTs) of any psychosocial cognitive interventions, including CST, in people with ID who also have dementia. Given the high prevalence of dementia in this population, there is a critical need to evaluate psychosocial interventions for dementia. This study therefore aims to make a valuable contribution to the

evidence-base. In this study we assessed the feasibility and acceptability of an adapted version of iCST that could be delivered by carers to people with ID and dementia

We chose to assess iCST rather than group CST due to the heterogeneity in cognitive profiles and the presence of sensory impairment that could present challenges for individuals participating in a group setting.

As part of the study, we adapt iCST in order to make it more suitable for use with adults with ID. The original themes were retained where possible, but the activities were simplified or substituted with alternative ones. This involved input from a speech and language therapist who advised the research team on how the activities could be simplified, followed by focus group consultations with health and social care professionals, carers and individuals with ID who reviewed the activities and made suggestions for improvements. A revised manual was then piloted with five individuals with ID and dementia and their carers, and they were asked to provide feedback on selected activities(Ali , Brown , Spector , Aguirre & Hassiotis , 2018). The number of sessions of iCST was reduced from 75 to 40 sessions, in order to reduce burden on family and paid carers, as one previous RCT in the general population indicated that only 50% of carers completed half the number of sessions (Orrell et al, 2017).

A feasibility trial was conducted rather than a full scale RCT due to the novel nature of the intervention and that it has not been tested in this population group. Feasibility studies can be used to assess important parameters that are uncertain and need to be estimated before designing the main study (National Institute of Health Reseach, 2017). We assessed the recruitment and retention of dyads (participants with ID and dementia and their carer) as there was uncertainty about the number of participants who would be eligible or willing to take part and whether they would remain in the study. As the intervention was delivered by carers, it was also important to determine whether the intervention (and trial processes) were considered appropriate and acceptable to the participants as this could impact on retention of participants in the study. Our third outcome of interest was whether the intervention was delivered as intended (intervention fidelity) as failure to deliver the intervention to an appropriate standard would lead to subtherapeutic delivery of the intervention and reduced effects on the outcome measures. This was crucial due to the low levels of adherence demonstrated by Orrell et al (2017). We also conducted exploratory analysis of the effectiveness of the intervention on a range of outcome measures in order to ascertain the most appropriate primary outcome and to calculate the sample size of a future RCT. We assessed

cognition, adaptive functioning and quality of life in individuals with dementia, and burden, competence in managing dementia and anxiety and depression in carers.

Methods and Materials

Trial Design

A single blind, feasibility RCT of iCST, using a parallel design with 1:1 allocation, delivered by carers to people with ID and dementia, was compared to a waiting list control group. Both groups had access to their usual care.. We aimed to randomise 40 dyads to either the intervention or control arm, with 20 dyads in each study arm. A sample size of 40 was selected for pragmatic reasons and considered to be sufficient in order to allow estimation of the

recruitment and retention rates (Ali et al., 2018). The randomisation process was performed centrally using a web-based system (Sealed Envelope), by an administrator external to the study, and was based on randomly varying block sizes. An un-blind member of the team informed participants of their allocated group. Outcomes were collected at baseline, midpoint (week 11) and at the end of the intervention (21 weeks post randomisation by a research assistant who was blind to the allocation group. Further details about the study procedures can be found in the study protocol paper (Ali et al., 2018).

Participants

Inclusion Criteria

- Aged 40 or over (dementia is uncommon before this age and clinical guidelines suggest prospective screening in adults with Down Syndrome from 40 onwards (British Psychological Society & Royal College of Psychiatrists, 2015).
- Pre-morbid mild or moderate ID
- Confirmed clinical diagnosis of mild or moderate dementia
- Ability to communicate verbally in English
- Ability to participate in simple games/activities.
- Had to have a carer (paid carer, family member or friend) who knew the individual well and was willing to deliver the activities.
- Carers had to be over the age of 18 and able to speak English.

Exclusion Criteria

- Severe dementia (significant deterioration in cognition and adaptive functioning leading to complete dependence on carers)
- Significant physical illness or disability, visual or hearing impairments or behavioural problems that could prevent participation in activities from the iCST manual

Ethical approval and recruitment

The study received ethical approval from the Harrow NHS Research Ethics Committee on the 20/03/2017 (reference no:17 LO/0030).

Recruitment took place from April 2018 to the end of January 2019 (10 months). Recruitment from Community ID teams within five National Health Service (NHS) trusts in North London was slower than expected, resulting in an extension of recruitment to other trusts in and outside of London. Participants were eventually recruited from 12 NHS trusts (six in London and six were outside of London). The Local Clinical Research Networks within the study NHS trusts assisted with identifying potential eligible participants for recruitment, but were not involved in carrying out the baseline or follow-up assessments. Participants with a confirmed diagnosis of dementia and their carer were approached about the study by a clinician working within the community ID team. If they were interested in taking part, a referral form was completed and their details were passed onto the trial research team.

The study research assistant conducted an eligibility assessment, obtained written informed consent from all participants (carers and individuals with ID and dementia), in accordance with the Mental Capacity Act (2005). If the participant lacked the capacity to consent, a personal consultee (relative or friend of the participant) was sought for their views about whether the participant would wish to take part and a declaration form was signed by the consultee before

the participant was included in the study. If participant lacked a personal consultee, a nominated consultee (member of a clinical team independent from the study) discussed whether the participant should take part and signed a declaration form.

The intervention

The intervention consisted of 40 sessions of iCST, delivered by carers using an adapted manual for people with ID and dementia. Information on how the manual was adapted is described elsewhere (Ali et al., 2018) . Each carer was asked to administer an activity from the manual twice a week for 30 minutes, over a period of 20 weeks. Each session followed the same structure: i. warm up (activity such as reminding the participant about what they were doing and why, singing a song or engaging in gentle movement and stretches); ii. Orientation (brief discussion about the day, date, weather and location, or of recent or upcoming events from the news or in the person's life); and iii. the main activity, which was expected to last 20 minutes. Each activity was based on a theme (e.g. food, current affairs, number games) and there were two levels of difficulty per activity to ensure that tasks were sufficiently challenging for individuals with varying abilities. Carers were encouraged to follow the principles of iCST (e.g. making the activity person centred by using pictures and objects that were meaningful and recognisable to the person). While it was encouraged that one carer deliver the activities throughout, for some participants more than one carer delivered the sessions in order to reduce disruption resulting from carer illness, leave or other absence.

Carer training and support

Prior to starting the intervention, one to one training was delivered to carers by a member of the research team or by a trained Clinical Studies Officer from the LCRN. We aimed to deliver the training within 1-2 weeks of randomisation but this was not always possible due to lack of carer availability, and in a few cases, it was delayed up to 6 weeks. This impacted on the number of total sessions of iCST that could be delivered by carers at 21 weeks. Carers received the adapted iCST manual and additional materials for specific activities (e.g. activity Compact Disc, dice, counters and easy read newsletter). They were provided with a diary to keep track of activities that had been completed and leave feedback. Carers were contacted by the research team monthly by phone or email in order to support with any issues that may have arisen directly related to delivering the activities.

The intervention arm also had access to their usual care, which included dementia medication and access to day services and health and social care professionals.

Waiting List Control arm

The control arm continued to have access to their usual care, as described above. Participants in the control arm were offered a copy of the manual and training was provided in administering iCST after completion of the 21-week end-point assessment.

Outcomes

Feasibility Outcomes

i. Recruitment of participants

We assessed the proportion of people who were eligible from the total number of referrals as this provided data on the number of referrals we would require in a future study. The recruitment rate was assessed as the proportion of people who were willing to take part in the trial from those who were eligible. The reasons for refusing to take part in the study were recorded. We aimed to recruit 40 dyads within the 10 month recruitment period and set a pre-defined criteria of recruiting at least 70% of this target (28 dyads). This number was selected on the basis that it would be possible to make changes to the trial protocol to improve recruitment if needed. If recruitment was lower than 70%, then recruitment into a future trial is likely to be unfeasible.

ii. Retention and dropout rate

This was assessed by examining the proportion of participants who completed assessments at each of the time points. Reasons for withdrawal from the study or non-completion of assessments were recorded. We aimed to have a retention rate of over 70% as a lower retention rate would make a future trial unfeasible

iv. Adherence, fidelity and acceptability of the Intervention

A process evaluation, using a mixed methods approach, was utilised based on the Medical Research Council guidance (Moore et al., 2015).[19] In order to assess acceptability of iCST, carers were asked to complete a Likert scale questionnaire about their experience and satisfaction with the study, regarding the information provided about the study, delivery of the training, ease of carrying out iCST, and the support received (1= strongly disagree; 5= strongly agree). Where possible, participants with ID were also asked to complete an accessible Likert scale questionnaire about the study and their experience of the intervention (1= not at all; 3= a lot).

Carers were invited to a semi structured interview to gain more detailed feedback. The transcripts were analysed independently by two members of the research team, using thematic analysis. Themes were identified in relation to barriers and facilitators of completing the intervention. The intervention was considered to be acceptable if feedback was positive on both the questionnaires and qualitative interviews.

Adherence to the intervention was assessed by examining carer diaries to identify the number of sessions completed by each dyad. We aimed to achieve a target of at least 75% of carers completing more than 20 sessions. As the total number of sessions had already been reduced in this adapted version of iCST, a high threshold was set to ensure delivery of an adequate "dose" of iCST.

Fidelity (the extent to which carers delivered the iCST sessions in accordance with the manual and principles of iCST) was assessed by audio-recording two sessions (at week 5 and 15 of the intervention). A rating form was developed for the purpose of the study in order to assess the quality of the delivery of iCST and comprised three questions about the structure of the session and six questions relating to adherence to the principles of iCST. Each item was rated 0-2 (0= did not complete; 1= partially completed; 2= fully completed). The sessions were rated by a member of the research team but a subset of eight audio-recordings were also independently assessed by a researcher, not involved in the study.

Outcome measures

Outcome assessments were completed face to face at 11 weeks (midpoint) and 21 weeks (end of intervention) with the individual with ID and their carer. If there was more than one carer administering iCST, the person's main carer completed the outcome assessments. The Cognitive outcomes have been previously validated in people with ID and have good psychometric properties. Other outcomes (e.g. quality of life) were selected as they had been used in prior CST research.

Measures of cognition completed with participant with ID:

i. The Cambridge Cognitive Examination for Older Adults with Down Syndrome (CAM-COG-DS) was used to assesses orientation, language, attention, praxis and abstract thinking. Higher scores indicate better ability (Ball, Holland & Huppert, 2006).

ii. The Modified Memory for Objects tests from the Neuropsychological assessment of Dementia in Intellectual Disabilities Battery was used to measure recall of seven every-day items (Oliver, Crayton, Holland, Hall & Bradbury, 1998). Higher scores indicate better ability.

Proxy measures completed with carers:

iii. The Cognitive Scale for Down Syndrome (CSDS) was used to assess executive functioning, memory and language (Startin, Rodger, Fodor-Wynne, Hsmburg & Strydom, 2016). Higher scores indicate better cognitive functioning.

iv. The Alzheimer's Dementia Cooperative Study-Activities of Daily Living Inventory (ADCS-ADL) was used to assess ability of the individual to carry out a range of daily activities (Galasko et al., 1997). Higher scores indicate better functioning.

v. The Quality of Life-Alzheimer's Disease (QOL-AD) was used to assess physical health, mood, family life and functioning (Thorgrimsen, Royan , de Madariaga Lopez, Woods & Orrell , 2003). Higher scores indicate better quality of life.

Carer Outcome measures

i. Care Giving Burden Scale was used to assess the burden of care giving (Macera, Eaker, Jannarone, Davis & Stoskopf, 1993). Higher scores suggest more burden.

ii. The Sense of Competence in Dementia Care Staff Scale (SCIDS) was used to measure perceived competence of both care home staff and informal carers in managing dementia (Schepers, Orrell, Shanahan & Spector, 2012). Minor modifications to the wording of the questions were made when administering the measure to family carers. Higher scores indicate more competence.

iii. The Hospital Anxiety and Depression Scale (HADS) was used to measure symptoms of depression and anxiety (Zigmond & Snaith, 1983). Higher scores indicate more symptoms.

Statistical Methods

The feasibility outcomes were the main focus of analysis. The baseline clinical and demographic characteristics of the Intervention and control arms were compared using descriptive statistics. The proportion of participants who completed assessments or dropped out were compared between the two arms at 11 and 21 weeks. Analysis of Covariance

(ANCOVA) was used to calculate the mean difference in the outcomes measures between the two arms at both time points, adjusting for baseline scores. The results are presented as unadjusted and adjusted means with 95% Confidence Intervals and are based on intention to treat. Effect sizes (Cohen's d) were computed by dividing the difference in the means between the two groups with the pooled standard deviation. These were used to identify the most suitable primary outcome for estimating the sample size that would be required for a future trial. The inter-rater reliability (intraclass Correlation Coefficient (ICC)) was calculated to assess agreement between the two researchers rating the audiotapes for intervention fidelity.

Results

Sample characteristics

Individuals with ID and dementia had a mean age of 60; 65% were male (n=27); 95% were White British (n=38); 60% had Down Syndrome (n=23); 65% had Alzheimer's disease (n= 27), 55% had mild dementia (n=22); 42.5% lived in residential care (n=17) and 30% in supported housing (n=12). The socio-demographic characteristics and baseline outcome assessments of participants in the intervention arm and control arm are presented in Table 1. The groups are similar with the exception of gender. The control group had more females (n=15, 75%) and the intervention group had more males (n=12, 60%; *p*=0.03)

The carers were mainly female (n = 32; 80%); with an average age of 50.5 years and 67.5% (n=13) were White. The majority were paid carers (n=33; 82.5%). The baseline characteristics and outcomes of carers are presented in Table 2 for both arms. There were no differences between the two groups.

[Table 1 and 2 near here]

Feasibility outcomes

1. Recruitment rate

Figure 1 is a Consolidated Standards of Reporting Trials (CONSORT) diagram, which shows the flow of participants in the study. A total of 70 dyads were screened for eligibility and 52 (74%) were eligible to take part. Thirty dyads were excluded due to not meeting the inclusion criteria, or where unwilling or unable to take part. The proportion of dyads who were eligible and willing to take part (recruitment rate) was 40 out of 48 (83%).

2. *Retention and dropout rate*

At 11 weeks, 35 dyads completed the midpoint assessments (87.5%). Three dyads from the control arm and 2 dyads from the iCST arm did not complete the assessments at 11 weeks. The reasons were: the carer or participant was on leave (n=3); family bereavement (n=1) and illness (n=1).

At 21 weeks, overall 39 dyads completed the endpoint assessments (97.5%). One dyad from the intervention arm dropped out from the study completely after the midpoint assessment due to a deterioration in health and withdrawal of assent from the personal consultee. Another

dyad in the intervention arm did not complete any sessions but completed the end point follow up assessments. No adverse events were found to be attributable to iCST.

4. Adherence and fidelity to the Intervention

The average number of sessions completed by the 20 dyads was 28/40 sessions (70%). Only two (10%) completed all 40 activities; 12 (60%) completed more than half the activities (range 23-39); and six (30%) completed less than half the activities (range 1-16). The average duration of each session was 22 minutes. Three dyads (15%) had more than one carer administering the activities.

A total of 24 (out of 40) audio-recordings of sessions were completed. The range of scores obtained on the adherence rating checklist was from 4 to 12 (maximum score possible was 18). The mean score was 7.46 (standard deviation 2.65) and the inter-quartile range was 5-10. Almost all the participants did not complete "warm up" (87.5%) or orientation (91.7%) and less than half used reminiscence during the sessions (41.1%; see supplementary table 1). Carers performed better on following instructions in the manual (37.5% did this partially; 45.8% did this fully) and adapting the sessions to the person's needs (66.7% partially; 33.3 fully). Inter-rater reliability suggested moderate agreement between the two raters (ICC: 0.71; 95% CI 0.077, 0.93).

5. Acceptability of the intervention

Quantitative approach:

Seventeen out of 20 carers from the iCST arm completed the end of study questionnaire. Almost all the items received a score between 4 and 5, indicating high levels of satisfaction with the study processes and procedures (see supplementary data, table 2). Twelve participants with ID and dementia completed the end of study questionnaire. Most participants were satisfied with the study information, enjoyed the sessions, and thought that the duration and number of sessions were appropriate. However, some of the activities were considered to be too difficult (see supplementary data, table 3)

Qualitative approach:

Eleven carers from both arms were approached to take part in semi-structured interviews but only six carers from the iCST arm agreed to take part. Four were paid carers and two were family carers. Seven themes were identified and are summarised in table 4. In general, carers were satisfied with the explanation of study processes, assessment measures, the training and support that they received and the layout of the manual. Taking part in the study was considered a positive experience for most carers as it helped them to gain a better understanding of the person. However, some indicated that finding time to carry out the sessions was problematic, and other factors such as the mood and motivation of the individual and the suitability of some of the activities, affected the delivery of the sessions.

[Table 3 near here]

Outcome assessments

1. Outcomes in individuals with dementia:

The changes in the outcome measures are presented in table 4. There were no significant differences between the iCST arm and the control group in the outcome measures for cognition and adaptive functioning at 11 weeks or 21 weeks, after adjusting for baseline scores. All these effect sizes were small. The biggest effect size in favour of iCST was for the CSDS (effect size of 0.24 at 21 weeks). There were no differences in quality of life at 11 weeks, but at 21 weeks, it was higher in the iCST arm compared to the control arm (adjusted mean difference: 3.11; CI: 0.64 to 5.58; *p*=0.015) and had a large effect size (Cohen's d = 0.89).

2. Outcomes in carers

There were no differences between the two groups in relation to care-giving burden, carer sense of competence or symptoms of anxiety and depression at 11 weeks and 21 weeks (see table 5)

[table 4 and 5 near here]

Blinding of group allocation

The research assistant undertaking the outcome assessments correctly guessed 29 (75%) of the group allocations (16 in control group and 13 in the intervention group). There was a weak but significant level of agreement in the number of guesses that were correct (Kappa 0.45; p=0.04), suggesting that blinding was only partially successful. This was because some of the carers inadvertently revealed which group they were in despite being asked not to.

Sample size calculation for a future trial

Previous studies of CST in the general population have used cognitive functioning and quality of life as primary outcomes, although sample size calculations have usually been based on changes in cognition (Onder et al., 2005; Orrell et al., 2017) . Based on the effect sizes, the CSDS and the QOL-AD could be appropriate primary outcome measures. Using the CSDS as the primary outcome measure, the small effect size of 0.24 would require 381 people in each group in order to detect a difference of 3.61 units with 90% power and a significance level of 5%. Using the QOL-AD as the primary outcome measure, with an effect size of 0.89, 27 people would be required in each group in order to detect a difference of 3.40 units at 90% power and 5% significance level.

Discussion

Summary of findings

This is a novel study that tested an adapted manualised version of iCST delivered by both paid and family carers and is the first randomised controlled trial of CST in adults with ID and dementia. Forty dyads were successfully recruited from multiple sites in England over ten months and the retention rates were good with 87.5% and 97.5% completing the midpoint and end point assessment respectively. There were high levels of satisfaction from carers and individuals, indicating that the intervention was acceptable. Although the study was not powered to detect differences between arms in relation to clinical outcomes, exploratory analyses indicated that the proxy measure of quality of life (QOL-AD) was most amenable to change at 21 weeks follow up, with significantly higher scores in the iCST arm compared with the control arm and the effect size was large.

In terms of adherence to the intervention, 70% percent of dyads in the iCST arm completed half the number of sessions. This was slightly below our target of 75%, mainly due to issues with the timing of the training, which was delayed in some cases due to lack of carer availability. Assessment of fidelity indicated that carers were generally good at completing the manualised activities but the majority of carers failed to incorporate "orientation" and "warm-up" in their session. A few carers commented that it was a challenge to fit the sessions into their busy schedule and that some activities in the manual could be simplified further if included in a future trial.

Results in the context of the literature

Previous studies have examined psychosocial interventions in people with Down Syndrome or ID without dementia, which were mainly aimed at improving cognition with a view to potentially preventing dementia. They have shown promising results in improving cognition, and include a pilot study of group CST in people with Down Syndrome (Shanahan, 2014), which also found improvements in quality of life in the group receiving CST three months post intervention. Two studies involving computerised cognitive training (one in people with Down Syndrome and another in people with ID have also reported improvements in cognition (McGlinchey , McCarron, Holland & McCallion, 2019; Siberski et al., 2015). To our knowledge, our study is the first RCT of a psychosocial intervention in people with ID who also have dementia. Although cognition did not improve in our sample, the findings related to an improvement in quality of life were surprising, as previous RCTs of iCST in the general population have not shown these benefits (Onder et al., 2005; Orrell et al., 2017), although improvements in quality of life have been found with group CST (Woods et al., 2012) The apparent benefit may arise from iCST providing opportunities for individuals with ID and dementia to engage in stimulating and enjoyable activities, and to have positive interactions with carers, which may have previously been lacking.

Unlike Orrell at al's (2017) trial, there were no improvements in outcomes for carers. Possible reasons include differences in the type of carers who participated in this study. The majority of carers in this study were paid carers rather than family carers and therefore the nature of their relationship is likely to be different compared to family carers. Outcome measures were selected on the basis that they could be used in both groups and therefore we were not able to assess certain outcome measures that were included in Orrell et al's (2017) paper such as the care giving relationship. However, the qualitative interviews found that carers appreciated

and enjoyed the opportunities for positive interactions with the person with dementia and therefore the intervention may have benefitted the care-giving relationship.

Strengths and Limitations of the study

There are several strengths of the study: the intervention was adapted for people with ID and manualised; it was a multicentre study employing mixed methods to assess the feasibility and acceptability of the trial; and we submitted a protocol prior to data collection to ensure greater transparency in the research process. To our knowledge, this is the first study examining a psychosocial intervention for people with ID and dementia and provides data that will help to inform a future a full-scale RCT.

There are also limitations: not all of the proxy measures have been validated in this population with some of the measures designed for use in dementia without ID (e.g. QOL-AD and the ADCS-ADL); These measures were selected as they were used in previous trials of CST. While the QOL-AD was responsive to change, other measures (e.g. ADCS-ADL) showed less variability and may not be appropriate for use in a future trial. Participants were only followed up until the end of the intervention and we also did not carry out a health economic evaluation of the intervention.

Implications for future research

Our study suggests that it would be feasible to carry out a future large scale randomised controlled trial. We met most of the progression criteria that we described in our protocol paper (Ali et al., 2018), although adherence (number of dyads completing 20 sessions) was a little lower than our target (target 75%, achieved 70%). Delays in carers being available to attend iCST training was a factor and would need to be considered in a future trial.

We encountered some challenges in recruitment that would need to be addressed in a future study. This was partly due to an over-estimation of the number of eligible people with dementia who were known to community ID services, and some carers being unavailable or unwilling to deliver the intervention. We tried to mitigate challenges in recruitment by increasing the number of recruitment sites from five to 12. This suggests that a future study will need to have a greater number of study sites (possibly across the whole of England) and a longer duration of recruitment in order to recruit a larger sample.

Participation of the Local Clinical Research Networks was crucial: as well as assisting with recruitment, they facilitated training of carers, kept in contact with participants and obtained audio-recordings. However, in order to maintain blinding, they were not involved in the assessments, which were carried out by the study research assistant. We did not assess the quality of the delivery of the training to carers, which could explain why fidelity was not as good. Almost all the carers failed to follow the correct session structure indicating that more training and supervision would need to be provided for carers in a future trial. One recent feasibility randomised controlled trial of iCST in people with dementia in the general population, found an improvement in cognition in the intervention group, and was the first study to have used trained professionals to deliver therapy (Gibbor et al, 2020). It found good adherence and retention rates. The sessions closely resembled those offered in group CST, including the same number of sessions, suggesting that the availability, motivation and

expertise of the therapist is important in achieving positive outcomes in cognition (Gibbor et al, 2020). However, this does have implications for services in terms of availability and costs attributed to the therapists' time.

The smaller than expected number of eligible participants on the case loads of clinicians, at the participating sites, suggests that there may be an under-recognition of cases of dementia in people with ID (Strydom, Livingston, King & Hassiotis, 2007) indicating the need for improved detection by both primary care and community ID services. The NICE guidelines NG 54 highlight the lack of reliable and valid tools for identifying common mental health problems including dementia in this population (National Institute for Health and Care Excellence, 2016). The dementia screening process in people with ID can be a long process as it usually entails repeated longitudinal assessments over time (The British Psychological Society and the Royal College of Psychiatrists, 2015). By the time a diagnosis is given, the person's cognition may have deteriorated to the extent that they are no longer able to participate in psychosocial interventions. Better screening and earlier diagnoses could lead to more individuals benefiting from targeted interventions at an earlier stage of dementia. Current guidelines recommend premorbid baseline assessments in adults with Down Syndrome at age 30 and prospective screening (The British Psychological Society and the Royal College of Psychiatrists, 2015), which should improve the diagnosis of dementia, at least in people with Down Syndrome. Many NHS trusts have a dementia pathway or are in the process of developing pathways for people with ID, and a future trial could target these sites in order to maximise recruitment.

Implications for clinical practice

The advantages of iCST is that it can be delivered by both paid and informal carers, requires only a few hours of training, is acceptable to carers and individuals with ID and dementia and is less demanding of clinicians' time compared to group CST. These factors suggest that iCST could be implemented successfully in clinical practice. This is particularly pertinent as access to psychosocial interventions such as group CST, is currently limited for this group.

Conclusion

This feasibility randomised controlled trial of iCST delivered by carers, was feasible and acceptable to participants. In order to conduct a future large scale RCT, some modifications to the recruitment strategy are required to ensure adequate recruitment (e.g. longer recruitment period, inclusion of a larger number of sites and those with established dementia pathways). Some modifications are also required in order to improve intervention fidelity such as improved training and supervision of carers and assessment of the quality of the training provided to carers. Possible primary outcome measures include cognition, measured using the CSDS, or quality of life (rated by carers) using the QOL-AD.

Disclosure of Interest:

The authors report no conflicts of interest.

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Table 1. Baseline comparisons of the socio-demographic, clinical characteristics and outcomes measures in individuals with ID and dementia in the intervention and control arm

	iCST (N=20) **Numbers (%)***	**Control (N=20)** **Numbers (%)***	**Chi Square/ t test and *p* value**
Age: mean (SD)	59.5 (7.6)	61.2 (8.7)	t=0.68; *p*=0.50
Sex: Male Female	 12 (60) 8 (40)	 5 (25) 15 (75)	 Chi Square=5.01; *p*=0.03
Severity of ID: Mild Moderate	 5 (25) 15 (75)	 8 (40) 12 (60)	 Chi Square 1.03 *p*=0.31
Down Syndrome present	14 (70)	10 (50)	Chi Square =1.67 *p*=0.20
Ethnicity: White British Other	 18 (90) 2 (10)	 20 (100) 0	 Chi Square = 2.11 *p*=0.15
Living arrangements: Lives on their own/ family Lives in supported housing/ residential care/ other	 5 (25) 15 (75)	 1 (5) 19 (95)	 Chi Square= 3.14; *p*=0.08
Type of Dementia: Alzheimer's Other	 12 (60) 8 (40))	 14 (70) 6 (30)	 Chi Square = 0.44 *p*=0.51
Severity of Dementia Mild Moderate	 11 (55) 9 (45)	 11 (55) 9 (45)	 Chi Square = 0.00 *p*=1.0
Hearing problems	3 (15)	6 (30)	Chi Square = 1.29 *p*=0.26
Visual problems	4 (20)	2 (10)	Chi square = 0.78; *p*=0.38
Epilepsy	5 (25)	3 (15)	Chi Square =1.67; P=0.20
Taking anti-dementia Medication	10 (50)	8 (40)	Chi Square =0.40 *p*=0.53
Cambridge Cognitive Examination for older Adults with Down Syndrome – mean (SD) (range)	 39.5 (23.6) (13 to 91)	 43.5 (21.9) (13 to 90)	 t=0.56; *p*=0.58
Modified Memory for Objects Test – mean (SD) (range)	 29.1 (10.5) (3 to 43)	 30.6 (12.7) (1 to 46)	 t=-0.42 *p*=0.68
Cognitive Scale for Down Syndrome – mean (SD)	 53.7 (13.7)	 52.0 (14.6)	 t=-0.16;

(range)	(34 to 91)	(25 to 80)	*p*=0.88
Alzheimer's Dementia Cooperative Study Activities of Daily Living Inventory - mean (SD)	33.7 (15.3)	36.0 (17.9)	t=0.45;
(range)	(7 to 60)	(11 to 72)	*p*=0.66
Quality of Life-Alzheimer's Disease Scale – mean (SD)	31.4 (4.4)	29.8 (4.8)	t=-1.06
(range)	(25 to 44)	(21 to 39)	*p*=0.30

* the figures are numbers and percentages unless stated

Table 2. Baseline socio-demographic characteristics and outcome measures in carers in the intervention and control groups

	iCST Numbers (%)*	**Control Numbers (%)***	**Chi Square test/ t test and p value**
Age of carer (SD)	49.5 (14.7)	48.7 (10.1)	t=-0.21; p=0.83
Gender of carer:			Chi Square=
Female	15 (75)	17 (85)	0.63;
Male	5 (25)	3 (15)	*p*=0.43
Ethnicity of carer:			Chi Square =
White British	11 (55)	16 (80)	2.85;
Other	9 (45)	4 (20)	*p*=0.09
Relationship to participant:			Chi Square=
Relative/ friend	5 (25)	2 (10)	1.56;
Paid Carer	15 (75)	18 (90)	*p*=0.21
Years of experience as a carer (SD)	14.2 (21.4)	10.8 (16.3)	t=-0.56; *p*=0.58
Care Giving Burden Scale: – mean (SD) (range)			
Patient needs	8.2 (1.6) (4 to 11)	8.7 (1.5) (6 to 11)	t=1.11; *p*=0.27
Caregiver tasks	6.8 (2.02) (3 to 10)	7.60 (2.3) (2 to 11)	t=1.23; *p*=0.23
Caregiver burden	1.5 (1.9) (0 to 6)	2 (2.2) (0 to 7)	t=0.78; *p*=0.44
Sense of Competence in Dementia Care Staff Scale: – mean (SD) (range)	52.1 (6.80) (36 to 61)	54.5 (7.1) (41 to 66)	t=1.12; *p*=0.27
Hospital Anxiety and Depression Scale – mean (SD) (range)	5.9 (4.95) (0 to 18)	8.35 (7.44) (0 to 31)	t=1.23; *p*=0.23

* The figures are numbers and percentages unless stated otherwise

Table 3: Findings from the qualitative interviews of carers.

Theme	Comments	Quotes
i. Explanation of study processes	Carers thought that the study processes were explained well. One participant felt that filling in the carer diary was quite "time-intensive" and this should be mentioned to carers in a future trial:	*"It sounded pretty straightforward, and it was easy enough to follow. I didn't feel like I didn't know what I was doing…" – family carer (carer no.3)* *"I think the only thing I think I'll say is let them know the amount of paper work involved…" – paid carer (carer no.4)*
ii. Follow up assessments	All carers thought the outcome measures and the number of assessment times were appropriate and they had received adequate support for completing them. Some felt the time it took to complete the assessments was adequate, whilst others felt it took a while. One carer indicated that they would prefer to have more "open" questions.	*"I think they were good follow up questions really. And I think whoever thought that you should do it three times…That was a good thought." – paid carer (carer no.2)* *"…I felt like I needed to explain stuff, but there isn't that kind of option" – paid carer (no.5)*
iii. iCST training	All carers felt that the training was adequate and explained very thoroughly. One carer valued the suggestions to help tailor the activities to the individual participant.	*"..So I was given a few suggestions as to how I could tailor it or change it slightly to meet his needs, which was helpful…" family carer (carer no. 3)*
iv. Layout of the manual	All the carers were satisfied with the layout of the manual overall. One suggested that it would be useful to have different fonts and colours in text:	*"I felt some of the writing in the book was…Standard…Black and White…If it's in different colours…It might stand out to them more" – paid carer (carer no. 5)*
v. Support throughout the trial	All the carers valued and were satisfied with the support received throughout the trial.	*"I didn't sort of feel like I was just left to get on with it, and I didn't feel like I was being badgered or anything…" – family carer (no.3).*
vi. Barriers to completing iCST	Carers stated that some of the activities were not suitable for the individual because of their cognitive abilities or were not relevant to the person and needed to be tailored to the individual's interest. The participant's mood was also found to be a significant factor in whether the	*"…Some of them just weren't suitable for [participant's name], mainly because of his understanding of it really…" – family carer (no. 3)* *"the only thing I was concerned was when some of them she didn't really show interest…" – paid carer (carer no. 5)* *"…I had to print out more images from the internet…Of things that I thought maybe might be more relevant to the participant" – paid carer (carer no. 5)* *"…Some days when he just wasn't in the mood it would be hard work getting him, so*

	participant was motivated to complete the activities The two paid carers indicated that there were issues in finding time to complete the activities within their work schedule	*we just sort of gave it a rest…" – participant 3* *"…I have to look for times that I'm less busy to slot it in and do it." – paid carer (carer no. 4)*
vii. Taking part was a positive experience	They felt that taking part in the study was a positive experience, with some stating interest in gaining knowledge in ID and dementia Carers also thought that iCST helped them gain a better understanding of the individual participant. Two carers stated that the iCST activities have helped them to develop ideas in their line of work, and thought that the intervention would be useful for the ID population as a whole, rather than just individuals with dementia:	*"I would like to be the one who knows about it and have the information…" – paid carer (carer no. 2)* *"They brought another side that I didn't know about the participant, which is quite good" – paid carer (carer no. 6)* *"I felt like later I could use it for my sessions as well here (day care centre)" – paid carer (carer no. 5)*

Table 4: Comparison of the iCST and control groups for outcomes in individuals with dementia and carers at 11 weeks

Measures at 11 Weeks	Mean (SD) - iCST	Mean (SD) – Control	Unadjusted mean difference (reference group = TAU)	Adjusted mean difference (reference group = TAU) [a]	95% CI for adjusted mean difference	p-value	Effect size (Cohen's d)
CAMCOG-DS	39.94 (23.56)	45.94 (26.07)	-6.00	-0.62	-7.11 to 5.87	0.85	0.24
Modified Memory for Objects Test	27.67 (13.01)	31.47 (11.86)	-3.80	-0.71	-5.58 to 4.16	0.77	0.31
CSDS	51.44 (12.44)	48.50 (15.22)	2.94	2.79	-5.77 to 11.35	0.51	0.21
ADCS-ADL	34.72 (14.72)	32.69 (16.70)	2.03	3.36	-2.11 to 8.83	0.22	0.13
QOL-AD	29.94 (4.57)	28.94 (5.12)	1.01	0.82	-2.41 to 4.05	0.61	0.21
Care Giving Burdens Scale							
Patient Needs	8.41 (2.03)	8.69 (0.95)	-0.28	0.26	-0.92 to 1.44	0.66	0.18
Caregiver Task	7.24 (2.61)	8 (1.21)	-0.76	0.28	-1.07 to 1.63	0.68	0.37
Caregiver-Burden	1.59 (2.06)	2.25 (2.18)	-0.66	0.28	-0.77 to 1.34	0.59	0.31
SCIDS	52.06 (8.19)	54.75 (6.94)	-2.69	-0.93	-4.65 to 2.79	0.61	0.35
HADS	6.33 (6.26)	7.13 (5.30)	-0.80	0.50	-3.20 to 4.20	0.78	0.14

Note. [a]*After adjusting the measure's corresponding baseline score*

CAMCOG-DS= The Cambridge Cognitive Examination for Older Adults with Down Syndrome; CSDS= Cognitive Scale for Down Syndrome; ADCS-ADL= Alzheimer's Dementia Cooperative study – Activities of Daily Living Inventory; QOL-AD = Quality of life-Alzheimer's Disease Scale; SCIDS = Sense of Competence in Dementia Care Staff; HADS= Hospital Anxiety and Depression Scale

Table 5: Comparison of the iCST and control groups for outcomes in individuals with dementia and carers at 21 weeks

Outcome measure	Mean (SD) - iCST arm	Mean (SD) – Control arm	Unadjusted mean difference (TAU as reference category)	Adjusted mean difference (TAU as reference category) [a]	95% CI for adjusted mean difference	p-value	Effect size (Cohen's d)
CAMCOG-DS	39.47 (22.61)	42.79 (28.10)	-3.32	-1.58	-8.44 to 5.28	0.64	0.13
Modified Memory for Objects Test	30.21 (11.55)	29.32 (12.47)	0.89	1.44	-2.93 to 5.80	0.51	0.07
CSDS	46.5 (13.70)	42.89 (16.88)	3.61	2.47	-5.99 to 10.94	0.56	0.24
ADCS-ADL	31.15 (14.82)	30.05 (18.43)	1.10	2.23	-2.57 to 7.03	0.35	0.07
QOL-AD	30.35 (3.73)	26.95 (3.91)	3.40	3.11	0.64 to 5.58	0.02	0.89
Care Giving Burdens Scale:							
Patient Needs	8.1 (1.59)	8.53 (1.93)	-0.43	-0.13	-1.14 to 0.89	0.80	0.24
Caregiver Task	7 (2.25)	7.53 (2.74)	-0.53	0.10	-1.14 to 1.34	0.87	0.21
Caregiver Burden	1.85 (2.01)	2.53 (2.50)	-0.68	-0.43	-1.60 to 0.73	0.46	0.30
SCIDS	52.4 (7.76)	55.53 (7.53)	-3.13	-0.81	-3.97 to 2.35	0.61	0.41
HADS	6.63 (6.20)	7 (6.04)	-0.37	0.59	-2.35 to 3.54	0.69	0.06

Note. [a]*After adjusting the measure's corresponding baseline score*

CAMCOG-DS= The Cambridge Cognitive Examination for Older Adults with Down Syndrome; CSDS= Cognitive Scale for Down Syndrome; ADCS-ADL= Alzheimer's Dementia Cooperative study – Activities of Daily Living Inventory; QOL-AD = Quality of life-Alzheimer's Disease Scale; SCIDS = Sense of Competence in Dementia Care Staff; HADS= Hospital Anxiety and Depression Scale

Figure 1. Participant flow diagram