Group cognitive stimulation therapy versus usual care for people with intellectual disabilities and dementia (CST-IDD) in the UK: protocol for a mixed-methods feasibility randomised controlled trial

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STRENGTHS AND LIMITATIONS OF THIS STUDY
⇒ A strength is the use of both qualitative and quantitative data and analysis, enabling triangulation of information to fully answer our feasibility questions.
⇒ A further strength is that recruitment is taking place in culturally diverse populations, which will improve the generalisability of the findings.
⇒ A potential limitation is that dementia is underdiagnosed or diagnosed late in this group, which could challenge recruitment.

INTRODUCTION
The prevalence of dementia is almost five times higher in people with intellectual disabilities compared with the general population.1 However, evidence-based treatments for this population are lacking, as most randomised controlled trials for dementia interventions have not included people with intellectual disabilities. Cognitive stimulation therapy (CST) has a robust evidence base in the general dementia population, consistently showing benefits to cognition, quality of life and being cost-effective.2 We are conducting a mixed-methods feasibility trial of group CST for people with intellectual disabilities and dementia, to determine if a future definitive randomised controlled trial is feasible.

Methods and analysis
Fifty individuals with intellectual disabilities and dementia will be randomised to either the intervention arm (14 sessions of group CST plus treatment as usual) or the control arm (treatment as usual). Randomisation will occur after informed consent has been obtained and baseline assessments completed. Each arm will have 25 participants, with the intervention arm divided into five or more CST groups with three to five participants in each. The outcomes will be feasibility of recruitment, acceptability and adherence of the intervention, suitability of study outcome measures and feasibility of collecting resource use data. Quantitative and qualitative approaches, including semistructured interviews with group participants, carers and group facilitators, will be employed to assess these outcomes.

Ethics and dissemination
This study has been approved by Essex REC (Ref: 21/EE/027) and the HRA ethical approval process through the Integrated Research Application System (IRAS ID: 306756). We plan to publish the results in peer-reviewed journals and conferences as well as provide feedback to funders, sponsors and study participants.

Trial registration number ISRCTN88614460.

INTRODUCTION
The prevalence of dementia is almost five times higher in people with intellectual disabilities than the general population,1 and people with Down Syndrome have over 90% risk of developing dementia in their later years.2 Cognitive stimulation therapy (CST) has a robust, global evidence base in terms of benefits for people with dementia in cognitive function, as well as quality of life and mood.3 In the UK National Institute for Health and Care Excellence guidelines,4 group CST is the only non-pharmacological post-diagnostic intervention specifically recommended to support cognition, independence and well-being in individuals with dementia. CST has been shown to be cost-effective5 and has comparable cognitive benefits to anti-dementia medication6 in the general dementia population. CST is delivered in a group, typically as two 45-min sessions a week, for 7 weeks.6 The intervention involves activities such as word association, number and word games and discussion of current affairs. It uses a range of methods to stimulate cognition including executive functioning tasks, reminiscence as an aid to orientation and implicit learning through focusing on opinions rather than facts.7 The proposed mechanism of action of CST is through the
activation of neuronal networks associated with cognition such as memory and language, and the social interaction within groups supporting group learning and well-being.8

Currently, there is limited published research on CST in people with intellectual disabilities. A pilot study investigating the effectiveness of group CST in 25 participants with Down Syndrome without dementia found improvement in cognitive functioning at 3 months in the treatment group in comparison to treatment as usual (TAU), but no change to adaptive functioning and quality of life.9 The study demonstrated that CST can be adapted for people with intellectual disabilities, indicating that it would be valuable to explore this further in a population with comorbid intellectual disability and dementia.

We previously conducted a feasibility study on individual CST (iCST) in people with intellectual disabilities and dementia,10 delivered by a family member or paid caregiver. The study found that iCST was feasible and acceptable in this population, leading to improvements in the individual’s quality of life (as reported by carers). However, a key limitation of this study was poor intervention adherence. Moreover, the evidence base in the general population is stronger for group as opposed to iCST,11 and therefore group CST delivered by professionals working with people with intellectual disabilities could be considered a more optimal mode of delivering CST.

The lack of evidence-based treatments for dementia in the intellectual disability population is particularly concerning given dementia’s high incidence, prevalence, early onset and mortality in this group.12 In most clinical services, only anti-dementia medication is currently offered as a potential treatment. However, the evidence for its effectiveness in the intellectual disability population is scarce and people with intellectual disabilities may be more prone to side effects.12 Given the limited access to CST and other psychosocial interventions for dementia in people with intellectual disabilities, it is paramount that this health inequity is prioritised by exploring how CST might benefit people with intellectual disabilities and comorbid dementia.

This study aims to assess the feasibility and acceptability of group CST as a treatment for people with intellectual disabilities and dementia. The objective is to determine whether a future, larger randomised controlled trial (RCT) of group CST is feasible by assessing the feasibility of recruitment in this study, the suitability of study outcome measures, the acceptability and adherence of CST and the collection of resource use data.

METHODS AND ANALYSIS

Trial design

This will be a single-blind, feasibility RCT of group CST plus TAU versus TAU only, for people with intellectual disabilities and dementia. There will be assessments at baseline (prior to randomisation) and 8–9 weeks later at the end of the intervention. A process evaluation will be conducted to examine the acceptability, adherence and fidelity of the intervention and study methods and as part of this, interviews will be held with group participants, group facilitators and carers.

Trial setting

The trial will take place in community intellectual disability services across several National Health Service sites in England.

Study timeline

The study duration is 30 months and began on 1 October 2021. Recruitment started on 22 March 2022 and will continue until July 2023. Follow-up assessments, data cleaning and analysis will take place between July 2023 and January 2024.

Sample size

This is a feasibility study with no formal power calculation. Instead, a sufficient number of participants need to be recruited in order to determine the attrition and recruitment rates and how these are related to the feasibility of a full-scale RCT. By setting our target sample size at 50, we will achieve adequate precision around our expected retention rate of 75% (95% CI 62% to 86%) to determine the feasibility going forward. Based on our previous study,10 it is anticipated that screening approximately 70 people will be required to reach the sample size. There are no available data on the use of group CST to treat dementia in people with intellectual disabilities. This sample should also provide adequate precision using a CI approach which considers the likelihood of a future definitive study finding a relevant effect size.

Recruitment of participants

Participants will be recruited from community intellectual (or learning) disability teams and memory services from participating National Health Service Trusts in England, and General Practice surgeries in the participating areas. Professionals at those services will be asked to screen case-loads for possible participants and will discuss the study with potential participants and their carers. If they are interested in taking part, they will be provided with an information sheet and their details will be passed on to the research team. Posters will be displayed at the above services, local charities and social care organisations in the participating areas allowing potential participants to contact the research team directly. A researcher will then make contact with the potential participant and their carers to arrange a meeting to discuss the study and assess the capacity to consent. If the individual agrees to take part, written consent will be obtained from them. If they lack capacity, a relative or a friend will be approached and provided with information about the study and asked to sign a declaration form. If the individual does not have a family member or friend who can act as a consultee, a nominated consultee (eg, a clinician not involved in the study) will be approached and asked to sign a declaration form. We will ask carers who will be completing proxy/
informant measures to also provide consent to taking part in the study.
Inclusion criteria:
1. Premorbid mild or moderate intellectual disabilities (based on clinical notes).
2. Aged 18 and over.
3. Clinical diagnosis of mild or moderate dementia based on service records.
4. Ability to provide informed consent or (if the participant lacks capacity) availability of a personal consultee who has agreed to participate in the study.
5. Ability to communicate in English.
Exclusion criteria:
1. Significant visual or hearing impairment that may interfere with participation.
2. Significant physical illness or disability, affecting the ability to attend groups.
3. Significant behavioural problems that could affect participation (e.g., aggressive behaviour).
Other concomitant care and interventions are permitted during the trial.

Randomisation procedures and blinding
Randomisation will be undertaken by the coordinating trials unit (North Wales Organisation for Randomised Trials in Health; NWORTH) using a dynamic adaptive randomisation algorithm via a secure online interface. A researcher will enter the necessary details into the web-based randomisation system which will randomly allocate participants to the intervention or control arm after baseline assessments. Randomisation will be stratified by site/centre on a 1:1 allocation ratio. Participants will be informed of group allocation by an unblinded researcher. Although participants cannot be blinded to their allocated group, researchers collecting follow-up data will be blinded to group allocation and participants and carers will be reminded before the follow-up assessments not to divulge this information. At the end of the study, researcher blindness will be assessed by asking them to guess group allocation.

Intervention
The CST intervention will comprise 14 face-to-face group sessions delivered over 7 weeks, in groups of three to five participants, with two facilitators. Sessions will follow the CST treatment manual with a supplement outlining adaptations for clients with intellectual disabilities. Further details of the CST intervention and manual can be found in other publications. The supplement to the manual has been created as part of this study through focus groups and interviews with 14 people (5 occupational therapists, 5 psychologists, 1 speech and language therapist, 1 nurse, 1 psychiatrist and 1 person with intellectual disability) along with feedback from carers and from the iCST study for people with intellectual disabilities. In addition, we have incorporated activities and suggestions from a co-produced manual developed by clinicians and carers of people with dementia and intellectual disabilities from the Wirral Community Learning Disability team. Example adaptations include removing pricing and adding up food items and instead focusing more on the multisensory aspects of the food items used; using visual cues and replacing words with pictures where possible.

Facilitators will be clinicians from community intellectual disability services from any profession. They will attend the standard 1-day CST training course and will be provided with the standard CST manual and supplement. They will additionally receive training from the research team on the supplement, which will involve discussion on how to adapt sessions for people with intellectual disabilities. The intervention group will continue to have access to TAU (see below).

Treatment as usual
Participants in both arms of the trial will have access to their usual care for the duration of the trial, hence will continue to have access to support and care from their community intellectual disability service, including support from psychiatrists, nurses and psychologists. They will continue to access any day time activities such as day centres. Participants will continue with ‘medication as usual’, including cognitive enhancing medication (e.g., acetylcholinesterase inhibitors). These will be recorded carefully at baseline and followed up in the case report form.

Quantitative measures
Demographic information on the participants will be collected, which will include age, gender, ethnicity, severity of intellectual disability and dementia diagnosis. Demographic information about participants’ carers (including age, gender, ethnicity and whether they are a family or paid carer) and group facilitators (including profession and number of years they have worked) will also be collected.

Researchers will meet face to face with participants and their carers present to collect demographic information and outcome measures. The researcher will initially complete hard copies of the assessments and enter data in the online database (REDCap) ideally within 2 weeks. The outcome measures will be completed before randomisation and at post-intervention follow-up (during week 8 or 9 from the start of the intervention). The following outcomes will be measured:
1. Cognition
   - The Severe Impairment Battery is a 40-item measure including six main subscales (language, praxis, construction, memory, orientation and attention) designed for people with severe cognitive impairment. Scores range from 0 to 100 with lower scores indicating more severe cognitive impairment. This measure has good reliability and validity with people with intellectual disabilities. This measure will be conducted with the participant.
- The Dementia Questionnaire for People with Learning Disabilities\textsuperscript{16} is a 50-item measure which assesses the participant’s social and cognitive functioning as perceived by their carers. It includes eight subscales split into two categories: Cognitive Scores (short-term memory, long-term memory and orientation) and Social Scores (speech, practical skills, mood, activity and interest and behavioural disturbance). Scores range from 0 to 100, with higher scores indicating more severe cognitive impairment. This measure has good reliability and validity with people with intellectual disabilities.\textsuperscript{15, 17} This measure will be completed by the participant’s carer.

2. Quality of life
- The Quality of Life in Dementia proxy questionnaire\textsuperscript{18} is a 13-item measure which considers different domains of quality of life with a four-point Likert response scale. Scores range from 13 to 52 with higher scores indicating better quality of life. This measure has good reliability and validity\textsuperscript{19} and was found to be sensitive to change in people with intellectual disabilities and dementia in the iCST feasibility study.\textsuperscript{10} This measure will be completed by the participant’s carer.
- Health-related quality of life will be measured by the EuroQol-5 Dimensions-3 Levels (EQ-5D-3L) version.\textsuperscript{20}\textsuperscript{2} This measure has five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), each with three response levels, and a measure of health on the day using a 0–100 visual analogue scale with 100 being the best health one can imagine and 0 the worst. It has been used in a number of trials with participants with a learning disability\textsuperscript{21, 22} and is preferable to other measures of health status in a cognitively impaired population.\textsuperscript{23} This measure will be completed by the participant, and the EQ-5D-5L proxy version 1 will be completed by their carers.

3. Depression
- The Carer Supplement to the Glasgow Depression Scale for people with a Learning Disability\textsuperscript{24} is a 16-item questionnaire on mood. Scores range from 0 to 32 with higher scores indicating higher levels of depression. It is reliable and validated for the intellectual disabilities population.\textsuperscript{24} This questionnaire will be completed by the participant’s carer.

4. Health and social care resource use
- The Client Service Receipt Inventory (CSRI)\textsuperscript{25} is a questionnaire that records information on health and social care utilisation patterns in order to estimate cost. Studies have shown that it is a reliable and valid tool for collecting and estimating economic data.\textsuperscript{26, 27} A modified version of the CSRI tailored to this specific context will be completed with carers.

**Process evaluation**

Group facilitators will be asked to complete attendance registers after each CST session to record how many sessions participants attend. They will also be asked to complete a fidelity checklist after each session to rate the extent to which the training manual was followed and the quality of the session according to the CST principles. Four intervention sessions will be audio recorded and two will be selected at random and assessed by a member of the research team using the fidelity measure. After each CST session, participants will be asked to provide feedback about the activity and whether they found it enjoyable or not.

Semistructured interviews will be conducted with 15–30 participants, carers and group facilitators, including the carers of participants who do not attend all sessions or are in the control arm. Group participants will be invited to take part in brief interviews following CST sessions and carers and group facilitators will be invited to take part in interviews after the intervention and assessments have been completed. Topic guides will explore experiences of the intervention and the study procedures. Carers of participants in the control arm of the study will be invited to comment on study procedures only. Thematic analysis will be applied to identify aspects of the intervention and the research methods that work well or require modification.

**Feasibility outcomes**

In order to assess the success of the feasibility study, we will be using the ‘traffic light’ approach and have set targets that will determine whether a future study would be feasible. Achieving the ‘Go’ criteria will indicate that a future definitive trial is likely to be feasible; achieving the ‘review’ target indicates that a future trial might be feasible if there are changes to the study procedures or protocol and only achieving the ‘stop’ criteria would indicate that a future study is unlikely to be feasible.

1. Feasibility of recruitment will be ascertained from:
   - Adequate recruitment, defined as the total number recruited (consented and randomised) to the trial. Go: At least 38 participants recruited to the trial; Review: 25–37 participants recruited to the trial; Stop: Fewer than 25 participants recruited to the trial. The average recruitment rate per site will be calculated (total number of participants divided by the number of sites).
   - Eligibility rate, defined as number of people referred to the study and screened, who meet the eligibility criteria. Go: At least 75% of screened participants are eligible; Review: 50%–74% of screened participants are eligible; Stop: <50% of screened participants are eligible. Both the numerator and denominator are important here—if the denominator is too large it may be that the recruitment strategies need to be refined to streamline recruitment; the numerator being too small may indicate that the eligibility criteria need to be reviewed.
   - Consent rate, defined as the proportion of eligible participants who agree to participate in the study. Go: At least 75% of eligible participants give consent; Review: 50%–74% of eligible participants consent; Stop: <50% of eligible participants give consent.
Retention, defined as the number of participants completing the follow-up measures from those recruited. Go: At least 75% of recruited participants complete the trial; Review: 50%–74% of recruited participants complete the trial; Stop: <50% of recruited participants complete the trial. The proportion of participants in the treatment and control groups who return for follow-up assessments will be compared. Reasons for discontinuation in the study will be recorded (e.g., physical illness).

Acceptability of study methods, demonstrated through qualitative interviews with participants, carers and group facilitators.

2. To assess the suitability of study outcome measures and determine the primary outcome measure for a future larger RCT:

- Analysis of completion/response rates of outcome measures with confirmation that these can be collected from the participants. Go (for each measure): At least 85% of participants complete the measure at an acceptable level each time point; Review: 70%–84% of participants complete the measure at an acceptable level each time point; Stop: <70% of participants complete the measure at an acceptable level each time point.

- Examining whether the measures are sensitive to change as a result of the intervention will be established by the preliminary statistical analysis.

- Acceptability of outcome measures demonstrated through qualitative interviews with participants, carers and group facilitators.

3. Acceptability and feasibility of CST will be ascertained from:

- Overall attendance among the CST group participants based on the group attendance register. Go: 75% of participants attend at least 10 delivered intervention sessions; Review: 50%–74% attend at least 10 delivered sessions; Stop: <50% attend at least 10 delivered sessions.

- Confirmation of fidelity: Go: 75% of recorded intervention sessions contain all the components according to the checklist; Review: 50%–74% of recorded sessions contain all components; Stop: <50% of recorded sessions delivered contain all components.

- Acceptability of CST demonstrated through qualitative interviews with participants, carers and group facilitators.

- Any unintended consequences of adverse events—this will be recorded using a serious adverse events form.

The flow of participants in the study will be summarised using a Consolidated Standards of Reporting Trials (CONSORT) flow diagram. Baseline characteristics will be summarised for all participants and for intervention and control arms separately. Participants’ uptake of and adherence to the intervention, as well as follow-up rates, will be summarised and presented as percentages.

Statistical analysis

Although determining differences in clinical outcomes between the arms is not the primary purpose of this trial, comparisons will be undertaken to investigate the feasibility of studying these outcomes and to calculate estimates for the likely effect sizes and 95% CIs. We will obtain estimates of the treatment effects. Differences between the two comparison groups will be presented as unadjusted mean differences for continuous outcomes, and an OR for binary outcomes, with their associated 95% CIs. Despite the individual randomisation, this is a group-based treatment and therefore consideration will also be made in regard to the estimation of the potential intra-cluster correlation (ICC) coefficient. The estimation of the likely ICC together with external information from the literature will guide the sample size calculation for a future trial. No methods of imputation will be used for missing data due to the feasibility nature of the study but levels of missingness will be considered as part of the feasibility criteria.

Health economic analysis

The feasibility of collecting health-related quality of life and resource-use data will be assessed by rates of completion of the EQ-5D-3L and CSRI. This will inform whether changes need to be made to enable the reporting of cost-effectiveness of using group CST plus TAU compared with TAU alone in a future larger RCT.

Patient and public involvement

We have a service user co-applicant in the study who is the patient and public involvement (PPI) lead and attends some trial management group meetings. Two carers are members of the trial steering committee (TSC). Service users with intellectual disabilities and their carers have been involved in adapting the intervention manual and modifying the CSRI questionnaire for use in this study, and PPI members will be consulted throughout for the development of the analysis and dissemination of study findings.

ETHICS AND GOVERNANCE

The study received Research Ethics Committee (REC) and Health Research Authority (HRA) ethical approval (21/EE/0247) in February 2022. Any amendments to the protocol or planned procedures will need further ethical approval from the HRA before proceeding with these changes and any amendments will be communicated to the trial sites and principal investigators. A TSC has been appointed to provide independent study oversight and will be meeting every 6 months.

Dissemination

Feedback of the research findings will be provided to participants and carers in a newsletter at the end of the study. The research will be presented at local and national conferences and published in peer-reviewed journals. Data from the trial will be shared on reasonable request.
Contributors AS and AA are the joint chief investigators for the study and are responsible for the management of the study. EA, AA, AS, ZH, CSC and GC were involved in the conceptualisation of the study and are the study co-applicants. SH and JC are involved in data collection. NG and ZH are members of the clinical trials unit overseeing the governance of the trial. NG, ZH and CSC have provided statistical and health economic input. DA has provided clinical input as a key site trials manager. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. AS, AA and NG will have access to the final trial dataset.

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design, conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not applicable.

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