ISRCTN88614460 https://doi.org/10.1186/ISRCTN88614460

Cognitive Stimulation Therapy (CST) for people with intellectual disabilities and dementia

Submission date
07/03/2022

Recruitment status
No longer recruiting

Registration date
15/03/2022

Overall study status
Completed

Last Edited
31/03/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People with learning disabilities make up one percent of the population. Learning disabilities are often described as problems and difficulties with memory and attention that affect day-to-day life, normally appearing before the age of 18 years. Nowadays, people with these difficulties are living longer and therefore are at higher risk of developing dementia.

Cognitive Stimulation Therapy (CST) is the only recommended non-drug treatment by the NHS for people living with dementia. It is proven to improve quality of life as well as slowing down the loss of memory and attention problems. Sadly, people with an Intellectual Disability and dementia have been excluded from studies evaluating how effective it is. As the number of people with these difficulties is increasing it is important to evaluate whether it is also beneficial for this population.

Evidence from an exploratory study of an individually delivered programme by a family caregiver (as opposed to group) delivered CST indicated that people with an Intellectual Disability and dementia can engage with the proposed programme; however treatment delivery was challenging for carers. This suggested that group CST, which is delivered by a trained professional may be a more practical way of delivery.

This research seeks to find out if it will be possible to carry out an evaluation of group CST for this population using full randomised controlled trial.

Who can participate?
People who have been diagnosed with an Intellectual Disability and dementia.

What does the study involve?
We plan to carry out a study of 50 people across five NHS trusts in Greater London. We will allocate people to either group CST or treatment as usual. This will be done randomly by a computer, so everyone will have an equal chance of receiving CST or treatment as usual. Group CST will involve 14 CST sessions over 7 weeks delivered by trained staff, using a modified

manual. Researchers will test participants before and after the group CST period, to see whether CST led to any changes compared to treatment as usual. We will also interview participants, their relatives and the staff running the groups, asking them about their experience of the groups.

What are the possible benefits and risks of participating?
The benefit in partaking is if people are in the treatment they could possibly gain benefit from the groups. IT may help in slowing down the progression of dementia. The social aspect of the groups may also be enjoyable and present an opportunity to meet others with the same diagnosis. The risk may be they may not enjoy the groups. People may also not enjoy the questionnaires before and after the groups.

Where is the study run from?
The main site of the study is North East London Foundation Trust (UK) and will be lead by our Research and Development department. However, the trial treatments and all involvement of the participants will be from within their local community learning disabilities teams.

When is the study starting and how long is it expected to run for?
March 2021 to February 2024

Who is funding the study?
The study is funded by the National Institute for Health Research (NIHR) and is under research for Patient Benefit (RfPB) (UK)

Who is the main contact?
Professor Aimee Spector, a.spector@ucl.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Aimee Spector

Contact details
1-19 Torrington place
London
United Kingdom
WC1E 7HB
+44 7958 993973
a.spector@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil Known

IRAS number
306756

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 306756, CPMS 52053

Study information

Scientific Title
Cognitive Stimulation Therapy (CST) for people with intellectual disabilities and dementia, a feasibility, randomised controlled trial

Acronym
CST IDD

Study objectives
To assess the feasibility and acceptability of a randomised controlled trial of group CST for people with ID and dementia compared to treatment as usual. The results of this study will inform the design of a future definitive RCT

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/02/2022, Essex Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 2071048227; essex.rec@hra.nhs.uk), ref: 21/EE/0247

Study design
Multi centre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Dementia in people with intellectual disabilities

Interventions

Current intervention as of 17/03/2022:
Fifty individuals with intellectual disabilities and dementia will be randomised to either the intervention group or control group (treatment as usual). Randomisation will occur after informed consent has been given and baseline assessments completed. Each arm will have 25 participants and be divided into 5 or more CST groups with up to 5 participants in each.

All participants will be randomised using the computer program NWORTH. Half will be randomised into the Intervention arm and half into the Control/Treatment as usual arm. All participants will have a baseline assessment of cognitive ability, mood, quality of life and health questionnaires as well as a costs and receipt inventory to measure use of health services.

The intervention arm will receive Cognitive Stimulation Therapy that has been adapted for people with Intellectual Disability. This is a psychosocial therapy group for people with dementia. It consists of activities aimed at exercising different types of cognitive abilities, as well as orientating group participants to place and time. The groups are run for 45 minutes twice a week for 7 weeks therefore group members receive 14 sessions in total. This group will also continue to receive any treatments from their health teams that they already receive including any anti-dementia medication. Following this intervention the assessments from baseline will be repeated within 2 weeks of completion of the groups.

The control groups will have the treatment as usual from their health teams, they will receive the same baselines and will not attend the intervention. They will receive the follow-up assessments at the same time as the intervention groups, between 8-9 weeks later.

Previous intervention:
50 individuals with intellectual disabilities and dementia will be randomised to either the intervention group or control group (treatment as usual). Randomisation will occur after informed consent has been given and baseline assessments completed. Each arm will have 25 participants and be divided into 5 or more CST groups with up to 5 participants in each.

All participants will be randomised using the computer program NWORTH 50% into the Intervention arm and 50% into the Control/Treatment as usual arm. All participants will have a baseline assessment of cognitive ability, mood, quality of life and health questionnaires as well as a costs and receipt inventory to measure use of health services.

The intervention arm will receive Cognitive Stimulation Therapy that has been adapted for people with learning disabilities. This is a psychosocial therapy group for people with dementia. It consists of activities aimed at exercising different types of cognitive abilities as well as orientating group participants to place and time. The groups are run for 45 minutes twice a week for 7 weeks therefore group members receive 14 sessions in total. This group will also continue to receive any treatments from their health teams that they already receive including any anti-dementia medication. Following this intervention the assessments from baseline will be repeated within 2 weeks of completion of the groups.

The control groups will have the treatment as usual will receive the same baselines and will not attend the intervention, they will go on to receive all treatment they receive from their health teams. They will receive the follow-up assessments at the same time as the intervention groups, between 8-9 weeks later.

Intervention Type
Behavioural

Primary outcome measure

Current primary outcome measures as of 14/03/2023:
1. Cognitive functioning measured using the Severe Impairment Battery (SIB) and Dementia in Learning Disabilities Questionnaire (DLD) at 2 weeks prior to the intervention and then followed up 2 weeks following the intervention
2. Adaptive functioning measured using The Dementia in Learning Disabilities Questionnaire (DLD) at 2 weeks prior to the intervention and 2 weeks following the intervention
3. Quality of life measured using the Quality of life in Alzheimer's Dementia (QoL-AD) proxy questionnaire and the EQ-5L-5D quality of health questionnaires at 2 weeks prior to the intervention and two weeks following the intervention
4. Feasibility of collecting the cost-effectiveness measures measured using Clinical Service Receipt Inventory (CSRI) at 2 weeks prior to the intervention and two weeks following the intervention
5. A process evaluation will include qualitative interviews with participants, staff and carers to identify aspects of the intervention and study methods including adherence at the end of the intervention
6. Overall attendance amongst the CST group participants by recording the attendance of each participant in each group session. This will be given to the researchers following the intervention
7. Feasibility of recruitment measured using recruitment, eligibility rate, consent rate and retention data in study records at the end of the intervention
8. To assess the suitability of study outcome measures and determine the primary outcome measure for a future larger RCT measured using the data outcomes of the tools used at pre- and post-intervention
9. Acceptability and feasibility of CST measured using overall attendance data for the CST groups in study records, and fidelity measured using recordings of the groups at the end of the intervention

Previous primary outcome measures:
1. Cognitive functioning measured using the Severe Impairment Battery (SIB) and Dementia in Learning Disabilities Questionnaire (DLD) at 2 weeks prior to the intervention and then followed up 2 weeks following the intervention.
2. Adaptive functioning measured using The Dementia in Learning Disabilities Questionnaire (DLD) at 2 weeks prior to the intervention and 2 weeks following the intervention.
3. Quality of life measured using the Quality of life in Alzheimer's Dementia (QoL-AD) proxy questionnaire and the EQ-5L-5D quality of health questionnaires at 2 weeks prior to the intervention and two weeks following the intervention.
4. Feasibility of collecting the cost-effectiveness measures measured using Clinical Service Receipt Inventory (CSRI) at 2 weeks prior to the intervention and two weeks following the intervention.
5. A process evaluation will include qualitative interviews with participants, staff and carers to identify aspects of the intervention and study methods including adherence at the end of the intervention.
6. Overall attendance amongst the CST group participants by recording the attendance of each participant in each group session. This will be given to the researchers following the intervention.

Secondary outcome measures

The fidelity of delivery of the groups measured using:
1. Number of group CST sessions completed by each participant measured using the group attendance register at the end of the data collection.

2. Level of engagement in the sessions measured using CST participation forms developed alongside the CST manual recorded during the sessions collected after the interventions by the researchers.

Overall study start date
24/03/2021

Completion date
29/02/2024

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 14/03/2023:
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

Previous participant inclusion criteria:
1. Mild or moderate Learning disabilities
2. ICD-10 diagnosis of mild or moderate dementia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
Current participant exclusion criteria as of 14/03/2023:
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)

Previous participant exclusion criteria:
1. Severe learning disabilities
2. Severe dementia
3. Visual or hearing impairment that prevents participation

Date of first enrolment
15/03/2022

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Goodmayes Hospital - Block 8 and Maggie Lilley
Goodmayes Hospital
157 Barley Lane
Ilford
United Kingdom
IG3 8XJ

Study participating centre
The Hermitage Centre
Billet Lane
Hornchurch
United Kingdom
RM11 1XL

Study participating centre
Coleridge Road
30 Coleridge Road
London
United Kingdom
E17 6QU

Study participating centre
Beacontree Avenue
508 Becontree Avenue
Dagenham
United Kingdom
RM8 3HR

Study participating centre
Redbridge Learning Disabilities Clinic (cranbrook Road)
852 Cranbrook Road
Ilford
United Kingdom
IG6 1HZ

Study participating centre
London Borough of Barnet - Colindale
2 Bristol Avenue
Colindale
London
United Kingdom
NW9 4EW

Study participating centre
Haringey Learning Partnership, Commerce Road, London, N22 8DZ
2nd floor River park house, 225 High road
London
United Kingdom
N22 8HQ

Study participating centre
Enfield Integrated Learning disabilities Service
St Andrews Court, 1-4 Riverfront
London
United Kingdom
EN1 3SY

Study participating centre
The Learning Disability Service
Kensington and Chelsea
St. Marks Road
London
United Kingdom
W11 1RG

Study participating centre
hammersmith and fulham learning Disabilities Team
Parkview centre for health, Cranston Court, 56 Bloemfontain Road,

London
United Kingdom
W12 7FG

Study participating centre
Westminter Learning Disabilities Partnership
215 Lisson Grove
London
United Kingdom
NW8 8LW

Study participating centre
Camden Learning Disabilities Service
Camden Town hall, Judd Street
London
United Kingdom
WC1H 9JE

Study participating centre
Islington Learning Disabilities Partnership
52 Dreyton Park
London
United Kingdom
N5 1NS

Study participating centre
Newham Health team for adults with learning disabilities
29 Romford Road
London
United Kingdom
E15 4LY

Study participating centre
Tower Hamlets Community Learning Disabilities Service
Beaumont House Mile end hospital, Bancroft Road
London
United Kingdom
E1 4DG

Study participating centre
City and Hackney Integrated Learning Disability Service
Hackney Service Centre, 1 Hillman Street
London
United Kingdom
E8 1DY

Study participating centre
Centre for Autism, Neurodevelopmental Disorders, and Intellectual Disability (CANDDID)
Cheshire and Wirral Partnership NHS Foundation Trust
Eastway
Countess of Chester Health Park
Chester
United Kingdom
CH2 1BQ

Sponsor information

Organisation
North East London NHS Foundation Trust

Sponsor details
1st Floor Maggie Lilley Suite
Goodmayes Hospital
157 Barley lane
Goodmayes
Ilford
London
England
United Kingdom
IG3 8XJ
+44 300 555 1200 Ext: 64485
fiona.horton@nelft.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nelft.nhs.uk/

ROR
https://ror.org/023e5m798

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Peer reviewed papers: We will follow the approach from other research studies sponsored at NELFT and follow the publication policy agreed with the Study Steering Group and a systematic plan, including authorship. Methodology papers including those describing the development of methodology and the protocol are likely to be targeted at major online free to access publications (e.g. Trials, BMC Geriatrics, BMC Health Services Research).
Major papers including the results of qualitative and quantitative results from the feasibility study and cost effectiveness will be targeted high impact journals.
2. Other and PPI publications: Articles will be produced for relevant professional and educational journals (e.g. Health Services Journal, Generations, Signpost) and newsletters for lay readers including those for carers and the voluntary sector (e.g. Age UK newsletter) and websites.
3. Conference presentations: We will submit abstracts for major conferences and present locally (e.g. NELFT R&D conference). We will specifically target conferences relevant to policy and commissioning services for dementia and ID services. This approach has been very successful in other research studies delivered at the involved Trust where a number of researchers have received acclaim for the quality of their presentations.
4. Dissemination of study progress through the current NELFT R&D social media channels of Facebook and twitter accounts.

We will aim to translate the research findings into the NHS and wider healthcare community in order to provide improvements in service delivery, patient health and/or wellbeing by:
a) Raised awareness of the co-morbidity of dementia amongst people with Intellectual Disabilities.
There is currently a referrals pathway that has been created at NELFT in order to develop and

improve services for people with ID who develop dementia. We will link at all times with these pathways leads. We hope this trial will raise awareness of the importance of screening for dementia amongst people with ID and offer hope to those who live with these two comorbidities.
b) Dissemination and policy change. NELFT and part of the applicant team has been involved in the past in a successful trial influencing NICE guidelines and we have been extremely effective in disseminating the tested intervention Cognitive Stimulation Therapy (CST) for dementia. If the study results are positive, we would follow asimilar dissemination route with the aim of influencing public health guidance for people with ID policy and practice, e.g. NICE, and commissioning guidance. We expect that in just over three years, this proposed trial could lead to changes in the way ID services offers support for people with ID and dementia is organised with opportunities for national implementation. The applicants' networks and the key drivers to influence policy means there could be extensive implementation of the intervention by ID services across the UK and influence guidelines for the treatment of dementia in people with ID.

Intention to publish date
28/02/2025

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 14/03/2023:
The datasets generated during and/or analysed during the current study are/will be available upon request from Aimee Spector Professor of Clinical Psychology of Aging, a.spector@ucl.ac.uk and Dr Afia Ali, Consultant Psychiatrist East London Foundation NHS Trust, afia.ali4@nhs.net. All IPD collected during the trial, can be shared after de-identification. All data in the study is anonymised and no personally identifiable data is used in the publication or analysis of the data in this trial. Data will be available beginning 3 months and ending 5 years following article publication. This information will be available to Investigators whose proposed use of the data has been approved by an independent review committee (“learned intermediary”) identified for this purpose. The availability is limited to this because we do not have ethical approval and consent from participants to use the data for secondary analysis.

Previous IPD sharing statement:
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Carer version version 1	02/12/2021	08/03/2022	No	Yes
Participant information sheet	Nominated consultee version version 2	21/01/2022	08/03/2022	No	Yes
Participant information sheet	Personal consultee version version 3	21/01/2022	08/03/2022	No	Yes
Participant information sheet	Service user version version 3	21/01/2022	08/03/2022	No	Yes
Protocol file	version 8	15/12/2021	08/03/2022	No	No

Protocol article	28/04/2023	02/05/2023	Yes	No
HRA research summary		28/06/2023	No	No