ISRCTN18312288 https://doi.org/10.1186/ISRCTN18312288

Cognitive stimulation therapy in people with intellectual disability and dementia

Submission date
04/09/2017

Recruitment status
No longer recruiting

Registration date
12/09/2017

Overall study status
Completed

Last Edited
20/12/2021

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Individual Cognitive Stimulation Therapy (CST) is a treatment for dementia that involves the individual with dementia taking part in activities such as a life story, discussion of current affairs, puzzles and being creative, which is designed to be mentally stimulating. There is evidence that group CST is effective in improving cognition in people with dementia in the general population. CST is now widely available for people with dementia in the general population but it is not routinely used in people with dementia who have learning disabilities. Sometimes it may be less appropriate to provide group based CST, for example in individuals who have mobility or behavioural problems. For these individuals, individual CST may be an alternative option. Individual CST involves a carer carrying out activities with the individual with dementia using a manual. However, there have been few studies of individual CST in the general population and they have shown mixed results in improving cognition. People with intellectual disabilities may find it more difficult to take part in group CST because the needs and abilities differ greatly between individuals and they are more likely to have visual and hearing problems that could make participating in a group more challenging. At the moment there is very little evidence for the use of CST in people with dementia and intellectual disabilities. The aim of this study is to find out whether the treatment is feasible and acceptable to individuals with dementia and their carers to see if it is carry out a larger study in the future to find out if the treatment is effective in improving cognition and quality of life.

Who can participate?
Adults aged 40 and older who have a diagnosis of intellectual disabilities and dementia.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive their usual care. Those in the second group receive the iCST programme as well as the usual care. All the participants have access to the care that they normally receive, which may include anti-dementia medication and visits to see their psychiatrist or nurse. In the intervention group, the carers of the participants will deliver a programme of activities designed to keep the brain active. The programme runs for 20 weeks, with the carer delivering two 30 minute sessions a

week. Participants are assessed on their cognition, quality of life and functional ability. Carers are assessed on their competence to look after someone with dementia, the burden of looking after someone with dementia and their levels of anxiety and depression.

What are the possible benefits and risks of participating?
By participating, it may slow the rate at which memory or other cognitive functions decline in dementia. There are no direct risks from taking part in the study.

Where is the study run from?
This study is being run by the University of London (UK) and takes place in 6 trusts in the UK.

When is the study starting and how long is it expected to run for?
January 2014 to June 2019

Who is funding the study?
Baily Thomas Charitable Fund (UK)

Who is the main contact?
Dr Afia Ali
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
33410

Study information

Scientific Title
Feasibility randomised controlled trial of individual Cognitive Stimulation Therapy (iCST) for dementia in people with intellectual disability

Study objectives
The aim of this study is to carry out a feasibility randomised controlled trial to determine the tolerability and acceptability of the intervention, individual Cognitive Stimulation Therapy (iCST), delivered to people with intellectual disability and dementia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Harrow Research Ethics Committee, 20/03/2017, ref: 17/LO/0030

Study design
Randomised; Both; Design type: Treatment, Screening, Diagnosis, Complex Intervention, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Participants are randomly assigned to the intervention or control arm using a web based system called Sealed Envelope. Those in the control arm with receive treatment as usual. Those in the intervention arm receive a manualised programme of cognitive activities delivered by their carer twice a week for 20 weeks. Carers are trained in the delivery of the manual. Once the intervention and outcome measures have been completed, those in the control arm are offered the manual and training on how to use it if they wish.

Participants are assessed on their cognition, quality of life and functional ability. Carers are assessed on the amount of time spent caregiving, the burden they feel and their levels of anxiety and depression. These assessments are completed before the intervention, halfway through and when it has finished. The control group are offered access to the iCST manual and training at the end of the study.

Intervention Type
Other

Primary outcome(s)
Participant’s cognitive functioning will be measured using the CAMCOG-DS at baseline, 11 weeks and 21 weeks.

Key secondary outcome(s))
Current secondary outcome measures as of 03/08/2018:
1. Participants cognitive functioning is measured using the Modified Memory for Objects test from the Neuropsychological Assessment of Dementia in Intellectual Disabilities Battery at baseline, 11 weeks and 21 weeks, and the Cognitive Scale for Down Syndrome (CS-DS) at

baseline, 11 weeks and 21 weeks.
2. Functional ability is measured using ADCS- Activities of Daily Living Inventory (ADCS-ADL) at baseline, 11 weeks and 21 weeks
3. Participant's health related quality of life is measured using the QOL-AD proxy at baseline, 11 weeks and 21 weeks
4. Caregiver burden is measured using the Care Giving Burden Scale at baseline, 11 weeks and 21 weeks
5. Competence to look after someone with dementia will be assessed using the Sense of Competence in Dementia Care Staff (SCIDS) scale at baseline, 11 weeks and 21 weeks
6. Carer anxiety and depression is measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, 11 weeks and 21 weeks

Previous secondary outcome measures:
1. Participants cognitive functioning is measured using the Modified Memory for Objects test from the Neuropsychological Assessment of Dementia in Intellectual Disabilities Battery at baseline, 11 weeks and 21 weeks, and the Cognitive Scale for Down Syndrome (CS-DS) at baseline, 11 weeks and 21 weeks.
2. Functional ability is measured using ADCS- Activities of Daily Living Inventory (ADCS-ADL) at baseline, 11 weeks and 21 weeks
3. Participant's health related quality of life is measured using the DEMQOL-proxy at baseline, 11 weeks and 21 weeks
4. Caregiver burden is measured using the Care Giving Burden Scale at baseline, 11 weeks and 21 weeks
5. Time spent caring for the participant with dementia will be measured using the Care Giver Activity Survey-Intellectual Disability (CAS-ID) at baseline, 11 weeks and 21 weeks
6. Carer anxiety and depression is measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, 11 weeks and 21 weeks

Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. Diagnosis of mild- moderate intellectual disability
2. Diagnosis of mild- moderate dementia
3. Aged 40 years old or above
4. Suitable verbal communication in English
5. No significant visual or hearing impairment
6. No significant physical illness, physical disability or behavioural problems that would affect participation
7. A willing carer available to deliver the intervention

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
80

Key exclusion criteria
1. Severe intellectual disability
2. Late stage dementia
3. Significant hearing or visual impairment
4. Unable to speak English
5. No carer willing to participate in the study

Date of first enrolment
01/12/2017

Date of final enrolment
31/03/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Waltham Forest Learning Disability Service (Lead centre)
30 Coleridge Road
Walthamstow
London
United Kingdom
E17 6QU

Study participating centre
Barking and Dagenham Learning Disability Service
Civic Centre
Rainham Road North
Dagenham
London
United Kingdom
RM10 7BN

Study participating centre

Community Learning Disability Team - Havering
The Hermitage
Billet Lane
Hornchurch
United Kingdom
RM11 1XL

Study participating centre
Community Learning Disability Team - Redbridge
852 Cranbrook Road
Illford
London
United Kingdom
IG6 1HZ

Study participating centre
Camden Learning Disability Service
Camden Town Hall
Judd Street
London
United Kingdom
WC1H 9JE

Study participating centre
Islington Learning Disability Service
52D Drayton Park
Islington
London
United Kingdom
N5 1NS

Study participating centre
Tower Hamlets Learning Disability Service
Beaumont House
Mile End Hospital Bancroft Road
London
United Kingdom
E1 4DG

Study participating centre

Newham Learning Disability Service
29 Romford Road
Stratford
London
United Kingdom
E15 4LY

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

Study participating centre
Haringey Learning Disabilities Partnership
River Park House
225 High Road
Wood Green
London
United Kingdom
N22 8HQ

Study participating centre
Barnet Learning Disability Service
Building 4
North London business Park
Oakleigh Road South
London
United Kingdom
N11 1NP

Study participating centre
Enfield Learning Disability Service
St Andrew's Court
1-4 River Front
Enfield
London
United Kingdom
EN1 3SY

Study participating centre
Westminster Learning Disability Partnership
215 Lisson Grove
London
United Kingdom
NW8 8LF

Study participating centre
Kensington and Chelsea Learning Disability Service
1-9 St Mark's Road
London
United Kingdom
W11 1RG

Study participating centre
Forston Clinic
Dorset Healthcare University NHS Foundation Trust#
Herrison Road
Dorchester
United Kingdom
DT2 9TB

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Baily Thomas Charitable Fund

Alternative Name(s)

The Baily Thomas Charitable Fund

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/01/2021	20/12/2021	Yes	No
Protocol article	protocol	09/12/2018	18/12/2019	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version V3	10/03/2017	12/09/2017	No	No
Protocol file	version V5	14/02/2018	06/08/2018	No	No