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Living well with memory difficulties

Submission date
11/10/2012

Recruitment status
No longer recruiting

Registration date
16/10/2012

Overall study status
Completed

Last Edited
25/10/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims:
Early treatment offers the possibility of helping people with early-stage dementia (PwD) and their family members (carers) to manage the impact of the disease on everyday life, and reduce or delay the progression of disability. A new treatment called cognitive rehabilitation (CR), has been developed to meet this need. CR involves identifying realistic and achievable goals in the areas of everyday activity affected by changes in memory and other cognitive abilities, where the PwD wishes to see improvements. A therapist works with the PwD and carer on the priorities they have identified and helps to tackle the things that are most important to them and most likely to make a difference. This study aims to provide evidence about whether CR is a beneficial and cost-effective treatment for PwD and carers.

Who can participate?
Participants will be PwD diagnosed with early-stage Alzheimers disease (AD), vascular dementia, or mixed AD and vascular dementia. They will be recruited from memory clinics, old age mental health services and GP practices. For each participant, a carer will also be involved.

What does the study involve?
After initial assessment, PwD will be randomly assigned to receive either treatment as usual or to receive CR. The therapist will want to find out how memory difficulties are affecting the everyday life of the PwD and where they would like to see improvements, and will work with the patients to address these goals. CR will be conducted in participants homes. All participants will be re-assessed after 3 months and again 6 months later.

What are the possible benefits and risks of participating?
Participants may find it interesting and enjoyable to talk with the researcher and complete the questionnaires and tasks included in the study. The findings will be used to train staff working in Memory Clinics to improve the services they for people with early-stage dementia. We do not anticipate any risks associated with taking part in the study.

Where is the study run from?
Bangor University

When is study starting and how long is it expected to run for?
The study will start in October 2012 and run for 51 months.

Who is funding the study?
NIHR Health Technology Assessment Programme

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
11/15/04

Study information

Scientific Title
Goal-oriented cognitive Rehabilitation in Early-stage Alzheimer's disease: multi-centre single-blind randomised controlled Trial (GREAT)

Acronym
GREAT

Study objectives
To provide definitive evidence about whether goal-oriented cognitive rehabilitation (CR) is a clinically-effective and cost-effective intervention for people with early stage dementia and their family carers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Wales Research Ethics Committee, 25/06/2012, ref: 12/WA/0185

Study design

Multi-centre single blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dementia

Interventions
Participants will be randomised to either cognitive rehabilitation or treatment as usual. The cognitive rehabilitation intervention protocol will consist of 10 weekly sessions followed by 4 maintenance sessions spread over a 6 month period. Outcomes will be assessed at 3 and 9 months post randomisation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Bangor Goal-Setting Interview

Key secondary outcome(s))
For participants with dementia (PwPD)
1. DEMQOL
2. Generalized Self-Efficacy Scale (GSES)
3. Hospital Anxiety and Depression Scale (HADS)
4. Rivermead Behavioural Memory Test (RBMT) story recall sub-test
5. Test of Everyday Attention (TEA) elevator counting and elevator counting with distraction sub-tests
6. Delis-Kaplan Executive Function System (D-KEFS) letter fluency sub-test
7. Client Services Receipt Inventory (CSRI)

For carers:
1. Relatives' Stress Scale (RSS)
2. EuroQOL (EQ5D)
3. WHO Quality of Life BREF (WHOQOL-BREF)

Completion date
31/01/2017

Eligibility

Key inclusion criteria
1. The participant must have an ICD-10 diagnosis of Alzheimers disease (AD), vascular dementia, or mixed AD and vascular dementia

2. The participant must be in the early stages of dementia, as indicated by an MMSE score of 18 or above
3. If taking acetylcholinesterase inhibitors, the participant must have been receiving a stable dose for one month prior to trial entry, and there should be no intention to change the dose over the period of participation in the study unless clinically indicated
4. The participant must have a carer who is willing to participate
5. The participant must be able to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
475

Key exclusion criteria
1. Participants will be excluded if they have a prior history of stroke, brain injury or other significant neurological condition
2. Participants will be excluded if they are unable to speak English

Date of first enrolment
01/10/2012

Date of final enrolment
31/01/2017

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Bangor University
Bangor
United Kingdom
LL57 2AS

Sponsor information

Organisation
Bangor University (UK)

ROR
https://ror.org/006jb1a24

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK) ref:11/15/04

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2019		Yes	No
Results article		01/03/2019	30/07/2021	Yes	No
Results article		26/10/2021	28/10/2021	Yes	No
Protocol article	protocol	27/05/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes