Goal-oriented cognitive rehabilitation in early-stage Alzheimer’s disease: multi-centre single-blind randomised controlled trial (GREAT)

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Country

United Kingdom

Title of project or programme

Goal-oriented cognitive rehabilitation in early-stage Alzheimer's disease: multi-centre single-blind randomised controlled trial (GREAT)

Source of funding information

NIHR

Total sum awarded (Euro)

€ 2,701,180

Start date of award

01/10/2012

Total duration of award in years

4.7

The project/programme is most relevant to:

Alzheimer's disease & other dementias

Keywords
Research Abstract

Design: Multi-centre single-blind RCT comparing cognitive rehabilitation (CR) to treatment as usual (TAU). Outcomes assessed at 3 and 9 months post randomisation. Setting: The study will

take place in six centres across the UK, with a part-time therapist and a part-time research assistant appointed at each centre. Participant identification will be undertaken by local research network staff. Participants will be recruited from memory clinics, old age mental health services and GP practices. Assessments will be conducted, and interventions delivered, in participants' own homes, with a carer involved where possible. Target population: People with an ICD-10 diagnosis of Alzheimer's disease (AD), vascular or mixed dementia. For each participant, a carer (a family member or close friend who is either co-resident or in regular contact) will also be involved. Inclusion criteria: in the early-stages of dementia (MMSE score of 18 or above); if taking cholinesterase inhibitors, receiving a stable dose for 1 month prior to trial entry and with no intention to change the dose over the 9 month period of trial participation unless clinically indicated; availability of a family carer. Exclusion criteria: prior history of stroke, brain injury or other neurological condition; inability to speak English. Health technology: CR is an individualized approach for people with dementia (PwD) aimed at reducing functional disability, supporting self-management, and maximising engagement and social participation. PwD and their carers identify areas in which they would like to improve functioning and performance, and work together with a health professional (e.g. occupational therapist, psychologist) over a number of sessions to devise and implement strategies for addressing these personally-relevant goals. CR will be delivered in 10 individual sessions over 3 months, followed by 4 maintenance sessions over 6 months. There are no established alternative technologies. In the pilot (Am J Geriatr Psychiatry, 2010, DOI:10.1097/JGP.0b013e3181d579 2a) CR was compared with TAU and with an attention placebo condition (relaxation therapy). There was no evidence of a difference between the two control groups, so treatment as usual is an appropriate comparator. Sample size: Power calculations and attrition rates are based on the pilot trial. For the proposed study, intervention length has been increased in order to further strengthen effect sizes. To achieve 80% power to detect a medium effect size of 0.3, with alpha 0.05, in primary and secondary outcomes, 175 PwD need to complete the trial in each arm. Attrition was 20% at 6 months in the pilot, but is likely to be higher in a longer multi-centre trial; based on evidence from the recently-complete REMCARE trial, an attrition rate of 27% has been used. Therefore we will randomise 480 PwD, each with a family carer.

Lay Summary
Further information available at:

Types:
Investments > €500k

Member States:
United Kingdom

Diseases:
Alzheimer's disease & other dementias

Years:
2016

Database Categories:
N/A

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N/A