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A psychosocial therapy to benefit people with Parkinson's-related dementia (INVEST)

Submission date
17/03/2016

Recruitment status
No longer recruiting

Registration date
18/03/2016

Overall study status
Completed

Last Edited
26/04/2023

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Parkinson's disease (PD) is a long-term medical condition which is caused by the gradual loss of nerve cells (neurons) in a part of the brain called the substantia nigra. These neurons are normally responsible for producing dopamine, a chemical messenger (neurotransmitter) which carries signals around the brain that help to coordinate movement. In people suffering from PD, these neurons gradually die over time, causing the level of dopamine in the brain to gradually fall. As the levels of dopamine become lower, the brain is unable to coordinate movement as effectively, causing abnormal movements such as stiffness, tremor (uncontrollable shaking) and slowness of movement (bradykinesia). Parkinson's related dementia is a gradual decline of cognitive function (thinking and reasoning) that develops in someone with Parkinson's disease. There are two forms of dementia associated with PD: Parkinson's disease dementia, PDD (which is diagnosed when someone has had PD for some time) and dementia with Lewy bodies, DLB (which is diagnosed earlier or at the same time as someone is diagnosed with dementia). Increasing availability of psychosocial treatments (psychological therapy which help people develop the social, emotional and intellectual skills they need in order to get by) for people with dementia on the NHS is a key objective of the National Dementia Strategy (2009) and other national dementia policy drivers, however there is almost no evidence to support their use in people with more complex forms of dementia such as a PDD and DLB. For these patients, who make up around 7-10% of dementia cases, there is only very limited drug-bassed treatments available. Without adequate disease management, the risk of these patients being admitted to care is high and providing psychosocial therapies could help to reduce this risk. The aim of this study is to find out whether a new psychosocial therapy called cognitive stimulation therapy (CST) could help to improve cognitive function and quality of life in patients with Parkinson's-related dementia.

Who can participate?
Adults with dementia who are well enough to take part in the therapy and their carer

What does the study involve?
Patients and their carers are randomly allocated to one of two groups. Couples in the first group

receive a 10 week course of cognitive stimulation therapy (CST). This involves taking part in two-three 30 minute sessions every week in the patient's home. Those in the second group continue to receive treatment as usual and do not take part in any additional treatment during the study.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
February 2016 to October 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Sheree McCormick
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20631

Study information

Scientific Title
A psychosocial therapy to benefit people with Parkinson’s-related dementia: a feasibility and exploratory pilot study of individual cognitive stimulation therapy (INVEST)

Acronym
INVEST

Study objectives
The aim of this study is to investigate whether it is feasible to implement individual Cognitive Stimulation Therapy for people with Parkinson's disease with mild cognitive impairment (PD-MCI), dementia in Parkinson's disease (PDD) and dementia with lewy bodies (DLB).

Ethics approval required
Old ethics approval format

Ethics approval(s)
15/YH/0531

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Dementia; Subtopic: Parkinson's Disease; Disease: Parkinson's Disease

Interventions
Participants are randomly allocated to one of two groups:

Active iCST group
Each caregiver-participant dyad will receive a 10-week course of Cognitive Stimulation Therapy. This involves completing two-three activity sessions per week, each session lasting approximately 30 minutes. The therapy is delivered to the participant by the caregiver at home.

Treatment as usual
In the 'Treatment as usual’ (TAU) arm, the comparator, dyads will not receive any additional

intervention. TAU is defined as standard NHS treatment for the individual's condition and symptomology. In general, the services offered to this group will also be available to those in the active treatment group, the study will, therefore, be examining the additional effects of individual Cognitive Stimulation Therapy.

Total duration of treatment, including a two-week lead-in period is 12 weeks. The two-week lead-in period is provided to ensure the caregiver is confident in delivering the therapy in an effective and efficient manner.

Intervention Type
Behavioural

Primary outcome measure
1. Quality of life is measured using the Parkinson's Disease Questionnaire-39
2. Cognitive functioning is measured using the Addenbrook's Cognitive Examination - Revised Version

Secondary outcome measures
1. Apathy is measured using the Lille Apathy Rating Scale
2. Caregiver burden is measured using the Zarit Burden Interview

Overall study start date
15/02/2016

Completion date
31/10/2017

Eligibility

Key inclusion criteria
Caregiver inclusion criteria:
1. Caregiver of a person with PD-MCI, PDD or DLB: Must live with or be carer for someone who has a diagnosis of PDMCI, PDD or DLB
2. Must be well enough to deliver 20 – 30 minute sessions of iCST, two or three times per week

Patient inclusion criteria:
1. Must have received a diagnosis of probable PD-MCI, PDD or DLB. Diagnosis will be based on standard clinical diagnostic criteria (Emre et al, 2007; McKeith et al., 2005) determined by the referring clinician and verified by the lead applicant (IL).
2. Must be willing to participate in 20 – 30 minute sessions of iCST, two or three times per week
3. Must be well enough to participate in 20 – 30 minute sessions of iCST, two or three times per week
4. Must be stable on medication regime four weeks prior study entry

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
Planned Sample Size: 186; UK Sample Size 186

Total final enrolment
76

Key exclusion criteria
Caregiver exclusion criteria:
1. Not a caregiver for someone with PD-MCI, PDD or DLB
2. Cannot understand English or are non-literate
3. Severe physical illness
4. Diagnosis of dementia
5. The person being cared for meets the patient exclusion criteria

Patient exclusion criteria:
1. Unwilling to participate in 20 – 30 minute sessions of iCST, two or three times per week
2. Not well enough to participate in 20 – 30 minute sessions of iCST, two or three times per week
3. Caregiver contact less than 3 time per week
4. No caregiver (or caregiver not willing) to deliver therapy and complete study assessments
5. Lives in residential care
6. Cannot understand English or are non-literate
7. Severe physical illness

Date of first enrolment
15/02/2016

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Manchester
Jean MacFarlane Building
Oxford Road
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
Manchester Mental Health & Social Care Trust

Sponsor details
Rawnsley Building
Manchester Royal Informary
Oxford Road
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England
United Kingdom
M13 9WL

Sponsor type
Hospital/treatment centre

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
Not provided at time of registration

Intention to publish date
31/10/2018

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?
Protocol article	protocol	19/06/2017		Yes	No
Results article	results	01/07/2019	05/06/2019	Yes	No
Results article		04/07/2019	26/04/2023	Yes	No
HRA research summary			28/06/2023	No	No