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Living well with memory difficulties in Parkinsonism

Submission date
31/03/2015

Recruitment status
No longer recruiting

Registration date
13/04/2015

Overall study status
Completed

Last Edited
15/03/2019

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
Parkinson's disease (PD) is a common condition that causes problems with movement. It also causes memory problems which can develop into dementia. People with a similar condition called Dementia with Lewy Bodies (DLB) also have memory and movement problems. For both conditions drugs are the main form of treatment but they can have bad side-effects and not everyone can take them. Scientists want to develop treatments that do not use drugs so that more people with memory problems can be given them. Cognitive Rehabilitation (CR) is a treatment that focuses on improving memory by helping people to make achievable goals in their daily lives. It has been shown to be useful in Alzheimer's disease but this has not been tested in PD or DLB. This study aims to find out whether CR can improve memory performance in people with PD and DLB.

Who can participate?
People diagnosed with PD and PD dementia or people diagnosed with DLB.

What does the study involve?
People are randomly divided into three groups. One group has CR, another has a form of relaxation therapy and the third group continues with their usual drug treatment. People taking part choose up to three activities or problems that trouble them and that they wish to improve. The success of the treatment is measured by how the participants feel about achieving their own goals. A number of other measures of success are also used.

What are the possible benefits and risks of participating?
The results of the study will help decide how well CR works compared with relaxation therapy and treatment as usual. The results will also help design larger studies of non-drug treatments that improve memory so that more people with PD or DLB can benefit.

Where is the study run from?
Llandudno General Hospital, BCUHB (main site) and 13 other hospitals in Wales

When is the study starting and how long is it expected to run for?
January 2015 to January 2017

Who is funding the study?
National Institute for Social Care and Health Research (NISCHR) (UK)

Who is the main contact?
1. Dr T Watermeyer (public)
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2. Dr JV Hindle (scientific)

Contact information

Type(s)
Public

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Protocol serial number
RFPPB-2012-1020

Study information

Scientific Title

COgnitive Rehabilitation for Parkinson's Disease Dementia: a pilot trial

Acronym
CORD-PD

Study objectives
This study will trial goal-oriented Cognitive Rehabilitation (CR) in Parkinson's disease (PD) dementia and Dementia with Lewy Bodies (DLB). Goal-oriented CR has been shown to be effective in Alzheimer's disease (AD) and is now subject to a major multicentre trial (the GREAT study). CR will be compared with treatment as usual for PD and DLB, and a control condition involving relaxation therapy will also be included. All participants will identify areas in which they would like to improve their current functioning or management of difficulties, and those allocated to the CR condition will be able to work with a therapist to address these goals. The hypothesis is that goal performance will improve significantly in the CR group compared with the relaxation therapy or treatment as usual groups.

Other objectives to be addressed:
1. Assess the utility of outcome measures, particularly the goal setting interview, and provide information on effect sizes to inform power calculations for a definitive multi-centre randomised controlled trial of cognitive rehabilitation in PD dementia and DLB
2. Establish whether three arms are needed in a larger trial or whether comparison with treatment as usual is sufficient
3. Explore the utility of routine involvement of therapists in the management of cognitive problems in these conditions to improve access to psychological therapies
4. Investigate the effect of CR on standard cognitive measures of memory and executive function as well as mood and behaviour
5. Investigate the potential transfer of treatment effects into daily life as demonstrated by functional outcome measures and quality of life
6. Investigate the effects of the intervention on carers' mood, quality of life, stress and health
7. Finally, a pilot assessment of cost-effectiveness will be included in the study in order to test the utility of measures and gain initial data to support the development of a larger trial which will provide definitive evidence on cost effectiveness

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Wales Research Ethics Committee - West, 24/11/2013, mREC ref: 13/WA/0340

Study design
Non-pharmacological multi-centre single-blind randomised controlled pilot trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Parkinson's disease dementia and dementia with Lewy bodies

Interventions

Goal setting:
1. All participants will collaboratively agree problem areas which are formulated in up to three personal rehabilitation goals using the Bangor Goal Setting Interview (BGSI). They will rate their own performance on these goals at initial and follow-up assessments, but only the Cognitive Rehabilitation (CR) group will work with a therapist to address these goals.

CR with the therapist:
1. Goals identified at the initial assessment will be communicated to the therapist who will use them as the starting point for therapy and further operationalise and refine them if necessary. Eight individual one hour sessions of CR will be delivered at home over 2 months. Carers will be involved in part of each session where possible. Goals will be introduced one at a time, in a flexible manner depending on rate of progress. The participant and carer will work on the selected goals between sessions following an agreed schedule of activities. The therapist will use a variety of evidence based strategies and supporting components dependent on the nature of the goals set including strategies for managing practical situations and cognitive difficulties and anxiety management. Progress with each goal will be reviewed and the strategies adopted will be adjusted as necessary on a weekly basis. In-session ratings of goal performance will be made by participants, carers and the therapist to evaluate progress.

Comparators:
1. CR will be compared with Relaxation Therapy (RT) and Treatment As Usual (TAU). RT is included as an active control condition involving equivalent therapist time and attention. RT will consist of eight individual sessions of one hour's duration in participants' own homes. After an initial 'getting to know' you session where the therapeutic model is explained, each session has a theme which includes music, pictures, radio and television, sensory stimulation and humour before a final consolidation. Each session includes consolidation of the last one, a mood checklist and some homework.
2. TAU will consist of usual medication and any other services apart from specific programmes of CR or other cognition-focused intervention. TAU may include routine monitoring by the movement disorder clinic or memory clinic, information provision, attendance at drop-in groups or support groups, or carer participation in support groups.

Intervention Type

Behavioural

Primary outcome(s)

1. Participants' performance and satisfaction on goals, identified through the Bangor Goal-Setting Interview measure are rated at baseline and at follow-up visits (a 2 month post-intervention visit and a 6 month follow-up visit)

Key secondary outcome(s))

For PD dementia patients these cover the domains of cognition, mood, behaviour, everyday functional activity, motor severity, quality of life, self-efficacy, and carer ratings (where available) of patients' performance on goals identified during the BGSI interview. Carers' outcomes will include quality of life, stress and health.

Cognition:
1. Global cognition will be measured using the Addenbrooke's Cognitive Examination-III (ACE-III) (at screening and at the 6-month follow-up visit).
2. Assessments of executive function will be the Trail Making Test (TMT), and the letter fluency

tests from the Delis-Kaplan Executive Function System (both measured at each time point).
3. Attention will be assessed using the Test of Everyday Attention (at each time point).
4. Memory will be assessed using the Rivermead Behavioural Memory Test, story recall sub-test (at each time point).

Mood and behaviour:
1. Mood will be assessed at each time point using the Hospital Anxiety and Depression Scale which contains two subscales: anxiety and depression.
2. Behavioural assessment will include delusions and hallucinations measured using the Neuropsychiatric Inventory Questionnaire (this will be measured at the baseline and 6-month follow-up visits).
3. The Unified Parkinson's Disease Rating Scale will be used to assess the motor symptoms of Parkinsonism in PD and DLB and also assess function and activities of daily living (both will be used at the baseline and 6-month follow-up visits).
4. Quality of life will be assessed in PD and DLB using the abbreviated Parkinson's disease quality of life scale (PDQ-8) and the WHO Quality of Life – BREF (WHOQOL-BREF) (both will be used at the each time point).
5. The WHOQOL-BREF will also be used for carers (at each time point).
6. In order to assess a general sense of perceived self-efficacy, the potential to influence one's situation through one's own actions, the Generalised Self Efficacy Scale will be used at each time-point for both patient and carer participants.
7. Carers' stress will be assessed using the 15-item dementia-specific Relatives' Stress Scale, at each time point.

Health economics:
1. Health care utilisation during the study period will be measured using a trial-specific Client Services Receipt Inventory.
2. Cost-effectiveness will be piloted using measures of health status, the Euroqol EQ5D. These will be administered at the baseline and 6-month follow-up visits.

Other information:
1. Gender, age, relationship between person with PD dementia and carer and whether they live together, age of onset of PD, PD dementia, or DLB, Hoehn and Yahr PD severity, medication, educational level, social class, and co-morbidities will be recorded to examine effects of demographic and social variables on treatment efficacy (recorded during screening and baseline visit).

Completion date
01/01/2017

Eligibility

Key inclusion criteria
Current inclusion criteria as of 22/06/2015:
1. Diagnosis of Parkinson's disease (PD) according to the UK PD Brain Bank Diagnostic Criteria and a diagnosis of PD dementia according to the Movement Disorder Society consensus criteria or
2. Diagnosis of Dementia with Lewy Bodies (DLB) according to the DLB Consortium consensus criteria.
3. Clinical diagnosis of mild to moderate dementia with an ACE-III score of ≤82
4. Participants will preferably have a carer or family member who is willing to participate but this

is not an absolute requirement
5. Participants should be on stable medication for their Parkinsonism and cognition (including acetylcholinesterase inhibitors) for four weeks prior to commencement with no changes planned for the duration of the intervention. Any unplanned changes in medication during the intervention will be documented

Previous inclusion criteria:
1. Diagnosis of Parkinson's disease (PD) according to the UK PD Brain Bank Diagnostic Criteria and a diagnosis of PD dementia according to the Movement Disorder Society consensus criteria or;
2. Diagnosis of Dementia with Lewy Bodies (DLB) according to the DLB Consortium consensus criteria.
3. Clinical diagnosis of mild to moderate dementia with an ACE-III score of <80
4. Participants will preferably have a carer or family member who is willing to participate but this is not an absolute requirement
5. Participants should be on stable medication for their Parkinsonism and cognition (including acetylcholinesterase inhibitors) for four weeks prior to commencement with no changes planned for the duration of the intervention. Any unplanned changes in medication during the intervention will be documented

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Lack of stability of Parkinson's disease (PD) medications, cognitive enhancers or psychotropic medication or substantial additions to medication in the four weeks before the trial or planned changes during the period of the trial
2. Other major psychiatric disorder not related to PD
3. Major depression
4. Other significant neurological disease

Date of first enrolment
01/04/2015

Date of final enrolment
01/04/2016

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Llandudno General Hospital, BCUHB
Hospital Road, Llandudno, Gwynedd
United Kingdom
LL30 1LB

Study participating centre
Dolgellau and Barmouth District Hospital
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LL40 1NT

Study participating centre
Penrhos Stanley Hospital
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Study participating centre
Eryri Hospital
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LL48 6LF

Study participating centre
Cefni Hospital
United Kingdom
LL77 7PP

Study participating centre
Gwynedd Hospital
United Kingdom
LL57 2PW

Study participating centre
Glan Clwyd Hospital
United Kingdom
LL18 5UJ

Study participating centre
Wrexham Maelor Hospital
United Kingdom
LL13 7TD

Study participating centre
Bryn Hesketh Memory Clinic
United Kingdom
LL29 8AT

Study participating centre
Bodnant Memory Clinic
United Kingdom
LL57 2PW

Study participating centre
Wepre House Hospital
United Kingdom
CH5 4HA

Study participating centre
Glan traeth Day Hospital
United Kingdom
LL18 3AS

Study participating centre
Ruthin Community Hospital
United Kingdom
LL15 1PS

Study participating centre
Holywell Community Hospital
United Kingdom
CH8 7TZ

Sponsor information

Organisation
Betsi Cadwaladr University Health Board

ROR
https://ror.org/03awsb125

Funder(s)

Funder type
Government

Funder Name
National Institute for Social Care and Health Research (NISCHR) (UK)

Results and Publications

Individual participant data (IPD) sharing plan

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	results	01/03/2016		Yes	No
Results article	results	01/05/2018	15/03/2019	Yes	No
Protocol article	protocol	22/03/2016		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes