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Promoting Activity, Independence and Stability in Early Dementia and Mild Cognitive Impairment 2

Submission date
23/07/2018

Recruitment status
No longer recruiting

Registration date
04/09/2018

Overall study status
Completed

Last Edited
24/04/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
People with memory problems can struggle with everyday activities and may stop doing things they want to do. They are more prone to accidents and have a higher risk of falling. Occupational therapists can advise how to do daily activities more easily and safely. Physiotherapists can teach exercises which increase activity and improve balance, and may help maintain memory. There is little research on how to make these interventions work for with people with memory problems. The aim of this study is to compare an activity and exercise programme developed for people with memory problems to standard falls prevention assessment and advice.

Who can participate?
Patients aged 65 or over with early dementia or memory problems, recruited from memory clinics or the 'Join Dementia Research' register

What does the study involve?
Participants are randomly allocated to either the control group or the intervention group. The control group receive standard brief falls assessment and advice, and up to two further visits if required. The intervention group receive an assessment, tailored strength and balance exercise programme, activity analysis and risk enablement advice, and assessment for environmental hazards. The intervention is delivered over 1 year in participants' own homes, and is tailored to individual interests, abilities and need for supervision. Participants are encouraged to exercise by themselves or with family members between visits, and once the programme ends. Researchers visit at the start of the study and after 12 months to measure ability in activities of daily living, activity, quality of life, memory and health service use. Participants complete monthly falls diaries over 15 months. The researchers conduct interviews and video record some therapy sessions to help understand how the programme works in practice.

What are the possible benefits and risks of participating?
Some participants may benefit from taking part in the intervention, as exercise is generally known to be beneficial to health and well-being, including benefits to heart, blood pressure, diabetes, joints, mood and daily life. These participants may find that they are better able to do

their daily activities. All participants and their relatives may enjoy having the researchers coming to visit them in their house. Some people appreciate having the opportunity to contribute to the well-being of others through research.

Where is the study run from?
1. Nottinghamshire Healthcare NHS Foundation Trust (UK)
2. Derbyshire Healthcare NHS Foundation Trust (UK)
3. Lincolnshire Partnership NHS Foundation Trust (UK)
4. RICE - Research Institute for the Care of Older People (Bath, UK)
5. CRN East Midlands (UK)
6. Oxford Health NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2017 to January 2023 (updated 17/02/2021, previously: May 2022; updated 10/07/2020, previously: March 2022)

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

Who is the main contact?
Dr Sarah Goldberg

Study website
http://nottingham.ac.uk/praised/index.aspx

Contact information

Type(s)
Scientific

Contact name
Dr Sarah Goldberg

ORCID ID
http://orcid.org/0000-0001-5109-798X

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
36405

Study information

Scientific Title
Promoting Activity, Independence and Stability in Early Dementia and Mild Cognitive Impairment 2

Acronym
PrAISED 2

Study objectives
People with memory problems can struggle with everyday activities and may stop doing things they want to do. They are more prone to accidents and have a higher risk of falling. Occupational therapists can advise how to do daily activities more easily and safely. Physiotherapists can teach exercises which increase activity and improve balance, and may help maintain memory. There is little research on how to make these interventions work for with people with memory problems. This study compares an activity and exercise programme developed for people with memory problems to standard falls prevention assessment and advice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber – Bradford Leeds Research Ethics Committee, 15/03/2018, ref: 17HC006

Study design
Randomized; Both; Design type: Education or Self-Management, Psychological & Behavioural, Complex Intervention, Physical, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet
Not available in web format. Contact: MS-PrAISED@nottingham.ac.uk

Health condition(s) or problem(s) studied
Dementia, mild cognitive impairment

Interventions
The study will use a randomized controlled trial design to test the clinical and cost-effectiveness of a package of interventions designed to promote activity and independence and reduce falls, amongst people with early dementia and mild cognitive impairment. Randomised controlled trials are the best way to determine the effectiveness of an intervention. Participants will be people with a diagnosis of dementia or mild cognitive impairment, and a relative or friend who is able to answer questions about them (hereafter referred to as the informant). Participants will be randomly allocated to either the control group or the intervention. Randomisation will be 'stratified' so that numbers of participants in the intervention and control group will be equal at each site and with the same number of participants with previous experience of falls across the two groups at each site. It will be made clear in the information sheets for participants and informants that they do not get to choose which group they are allocated to.

The trialists' experience during the feasibility trial was that it is not possible to blind researchers to treatment allocation (participants always say something that makes it possible for the researcher to guess the allocation). To prevent researcher bias, all researchers collecting follow up visits will receive anti-bias training. An additional benefit of the researchers not being blind to allocation is they will be able to provide continuity to participants promoting retention in the study.

Participants will be identified by clinicians in NHS Memory Assessment Services and invited to take part in the research by members of the research team, or NIHR Clinical Research Network Clinical Studies Officers (CSOs). Participants registered on the 'Join Dementia Research' (JDR) register will have agreed for researchers or CSOs to contact them directly about new research.

Participants and informants will receive an information sheet about the study prior to the first researcher visit. Researchers will visit the participants and informants in their homes or at a similar location (such as a relative's home). Researchers will discuss the study further and answer any questions. The researcher will assess the participant's capacity to give informed consent and complete an initial screening checklist with the participant. This screening procedure will involve completing a short cognitive assessment (MoCA) with the researcher to ensure they meet the eligibility criteria. If the participant has capacity and meets the inclusion criteria, and if the participant and informant still wish to take part in the study, informed consent will be obtained from the participant and the informant. The participant will be allocated a study ID number and the baseline assessments will be completed with the informant and participant. The participant will be randomly allocated to the treatment or control group, once the baseline assessment is completed. If the participant is not eligible, they will be thanked for their interest but told they are not able to take part in the study this time, and their MoCA assessment and contact information will be destroyed.

The intervention group will receive an assessment, tailored strength and balance exercise programme, activity analysis and risk enablement advice, and assessment for environmental hazards. Tailored adherence support and supervision for 12 months. The control group will receive standard brief falls assessment and advice, and up to two further visits if required.

Participants will be visited 12 months after recruitment to collect follow-up data, similar to that collected at baseline. Where possible, researchers will conduct baseline and follow-up visits in pairs so that one researcher conducts assessments with the participant whilst the other

conducts assessments with the informant. This helps maintain privacy whilst also reducing the time of the visit, minimizing responder burden. Some participants and informants may wish to be visited separately, in which case the researchers will schedule a visit to their preference and may visit alone. Researchers will ask participants and informants a battery of questionnaires and the participant will be asked to complete cognitive and physical assessments. The consent process and assessments will last up to 2 and a half hours, but this can be completed over more than one visit if the participant wishes, and there will be plenty of opportunity for 'breaks'.

Participants will be asked to complete a service use, exercise and falls calendar, which will be returned once a month in a pre-paid envelope, for 15 months from recruitment. Where necessary, monthly phone calls will be conducted to remind participants to return the calendar. Participants and informants may be invited to take part in an interview to share their experiences of taking part in the study and the intervention. Interviews are likely to last around 30-60 minutes, and will take place in the participant's home, or a similar location such as a relative's home, or at the University. They may also be asked if therapy sessions can be video-recorded for training and monitoring purposes.

Intervention Type
Other

Primary outcome measure
Disability in activities of daily living, assessed using Disability Assessment in Dementia (DAD) at 12 months after randomisation

Secondary outcome measures
1. Self-reported Activities of Daily Living (ADL) measured using the Nottingham Extended ADL Scale at baseline and 12 month follow up
2. Falls rate measured by monthly diary up to 15 months
3. Quality of life measured by questionnaires DEMQOL-self, DEMQOL proxy and EQ5D3L (self) at baseline and 12 months; EQ5D5L (proxy) at baseline, 6 and 12 months; Demqol-u weights at 6 months
4. Cognition measured by three scales from CANTAB [Cambridge Cognition, 2015]; Montreal Cognitive Assessment, verbal fluency (from MoCA) at baseline and follow up
5. Time to first fall, rate of fractures and injurious falls measured by monthly diary and adverse events reporting (fractures). Data on falls, injurious falls and fractures are also collected at baseline
6. Rate of hospital and care home admissions, and days spent in hospital are measured by questionnaire at baseline, 6 and 12 months and by monthly diary and hospital administrative records at 12 months. Care home admissions also can be reported at any time in the study by staff
7. Rate of hospital and care home admissions, and days spent in hospital measured by monthly diary and hospital administrative records
8. Carer strain measured by Caregiver Strain Index at baseline and 12 month follow up
9. Carer health-related quality of life measured by questionnaire EQ5D-5L at baseline and 12 month follow up
10. Personality measured by Big Five Personality Inventory– short questionnaire at baseline and 12 month follow up

Overall study start date
01/10/2017

Completion date
12/01/2023

Eligibility

Key inclusion criteria
1. Age 65 years or over (no maximum)
2. Diagnosis of MCI or dementia (of any subtype, except Dementia with Lewy Bodies i.e. Parkinson's Disease Dementia)
3. Have a carer or friend who knows the participant well (at least one hour a week contact over the phone, internet, or in person), and is willing and able to act as an informant
4. Able to walk without human help
5. Able to communicate in English
6. Able to see, hear and have dexterity sufficiently to perform neuropsychological tests
7. Have capacity to give consent to participate, and consenting to do so

Participant type(s)
Patient

Age group
Senior

Lower age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 736; UK Sample Size: 736

Total final enrolment
730

Key exclusion criteria
1. Co-morbidity preventing participation (e.g. severe breathlessness, pain, psychosis, Parkinson’s or other severe neurological disease)
2. Life expectancy of less than one year
3. Likely to be unable to undertake the intervention regularly (e.g. planned elective surgery, planning to move away or commitments elsewhere).

Date of first enrolment
10/09/2018

Date of final enrolment
23/06/2021

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Nottinghamshire Healthcare NHS Foundation Trust
Nottingham
United Kingdom
NG3 6AA

Study participating centre
Lincolnshire Partnership NHS Foundation Trust
Lincoln
United Kingdom
NG34 8GG

Study participating centre
Derbyshire Healthcare NHS Foundation Trust
Centre for Research and Development
Kingsway Hospital
Derby
United Kingdom
DE22 3LZ

Study participating centre
RICE - Research Institute for the Care of Older People
The RICE Centre
Royal United Hospital
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
CRN East Midlands
Knighton Street Outpatients
1st Floor, Leicester Royal Infirmary
Leicester
United Kingdom
LE1 5WW

Study participating centre
Oxford Health NHS Foundation Trust
Research and Development Department
Warneford Hospital
Warneford Lane
Oxford
United Kingdom
OX3 7JX

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

Sponsor details
Research & Innovation
Nottingham Integrated Clinical Research Centre,
C floor, South Block,
Queens Medical Centre Campus
Nottingham
England
United Kingdom
NG7 2UH

Sponsor type
Hospital/treatment centre

Website
https://nuhrise.org/

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0614-20007

Results and Publications

Publication and dissemination plan

Publications on:
1. Falls prevention intervention development, and manual
2. Clinical and cost-effectiveness
3. Practical and contextual factors that should be addressed for delivery, maintenance and implementation of the programme, including motivation and behaviour change.
Outputs will include materials to support future implementation including educational materials for the public, for mental health and falls prevention staff, and an instruction video. We will produce knowledge summaries for health, social and third sector organisations, made available via multiple approaches to maximise reach, including university and dementia education portals, East Midlands CLAHRC and AHSN, and PPI contacts. We will engage with traditional national media (broadcast, newspapers), and social media (Twitter, blogs) to enhance dissemination, and speed and extent of impact.

Intention to publish date

12/01/2023

Individual participant data (IPD) sharing plan

Participant level data will be available by contacting Prof. Rowan Harwood (rowan.harwood@nottingham.ac.uk). Data will be available from April 2023, and will be available for 5 years following this date. The data will be the full anonymised trial dataset (quantitative data) and anonymised interview and focus group transcripts. The trialists have included within the participant information sheet a GDPR statement which includes that the anonymised data will be shared. Professor Harwood will work in collaboration with anyone who requests to use the data.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V2	16/07/2018	04/09/2018	No	No
Protocol file	version v2.3	04/04/2019	13/09/2019	No	No
Protocol article	protocol	30/12/2019	02/01/2020	Yes	No
Protocol article	protocol	27/08/2020	02/09/2020	Yes	No
Other publications	results of the sub-set of the PrAISED study participants receiving the intervention during during a lockdown in response to the COVID-19 pandemic	21/07/2022	21/07/2022	Yes	No
Preprint results	Primary and secondary results	20/12/2022	03/01/2023	No	No
Preprint results	Commissioner and stakeholder perspectives	29/03/2023	31/03/2023	No	No
Statistical Analysis Plan	version 6	01/11/2022	31/03/2023	No	No

Results article	29/08/2023	30/08/2023	Yes	No
Results article	01/08/2023	06/12/2023	Yes	No
Results article	23/04/2024	24/04/2024	Yes	No