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Promoting activity, independence and stability in early dementia

Submission date
22/08/2016

Recruitment status
No longer recruiting

Registration date
31/08/2016

Overall study status
Completed

Last Edited
10/06/2022

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] 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. They may stop doing things they want to do. They are more prone to accidents and are more likely to fall. Occupational therapists can advise on how to do daily activities at the right level for a individual and how to do these activities safely. Physiotherapists can teach exercises, which improve balance, and help people to be more physically active, feel more confident, have more energy. The best results come from doing exercises several times a week for at least 6 months. They may also help people to maintain their memory but there is little research on how to make these therapies work for people with memory problems. In this study, researchers want to investigate this by testing out three different programmes. All three combine advice on physical activity and exercise, but offer different amounts of support from therapists. One programme involves a lot of support (50 visits from a therapist over one year). Another offers a moderate amount of support (11 visits over three months). And the third programme is that of 'usual care'; which involves both a standard falls prevention assessment and advice that is normally available from the NHS, and follow-up visits to check progress if thought necessary. At this stage, the researchers are just testing to see if the programmes can work and that they can collect all the information they need to do any further study. This includes seeing if enough people want to join the study and how best to deliver the programmes to people. The researchers want to know what works best, how useful the support is, and how else participants can be encouraged to keep up with the programme. If all goes well, a larger study will be run.

Who can participate?
Participants aged 65 or over who have been diagnosed with dementia and able to walk without assistance from other people.

What does the study involve?
Participants are randomly allocated to one of three groups. All are encouraged to exercise regularly at home and at least three times a week. Members of the participants family, or carers may like to help participants to complete the exercises or to join in if they wish. Those in group 1 are supported by way of "high intensity" supervision, that is they are visited 50 times by physiotherapists, occupational therapists and research support workers over the course of a year. Participants in group 2 are supported via "moderate-intensity" supervision, which involves

11 visits by physiotherapists, occupational therapists and research support workers over a three month period. Those in group 3 are allocated to the “treatment as usual” group, which involves having a standard falls prevention assessment and advice as routinely provided by the NHS.

What are the possible benefits and risks of participating?
There are likely to be benefits to participants health and well-being, including for their heart, blood pressure, diabetes, joints, mood and daily life. In addition, they might be better able to do daily activities and enjoy having researchers and therapists coming to visit.

Where is the study run from?
Hospitals run by the Nottinghamshire Healthcare NHS Trust and Derbyshire Healthcare Foundation NHS Trust (UK)

When is the study starting and how long is it expected to run for?
September 2016 to February 2018

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

Who is the main contact?
1. Dr Veronika van der Wardt (scientific)
2. Dr Melanie Heeley
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02874300

Protocol serial number
30654

Study information

Scientific Title
A programme of work to develop and evaluate an intervention to promote activity and independence for people with early dementia and mild cognitive impairment

Acronym
PrAISED

Study objectives
The aim of this study is to test the feasibility of running a randomised controlled trial evaluating different programmes developed to promote activity and independence, and to prevent falls, for people with early dementia and mild cognitive impairment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Bradford Leeds Research Ethics Committee, 16/03/2016, ref: 16/YH/0040

Study design
Randomised; Interventional; Design type: Treatment, Screening, Prevention, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Physical

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied

Specialty: Ageing, Primary sub-specialty: Ageing; UKCRC code/ Disease: Neurological/ Other degenerative diseases of the nervous system

Interventions
Participants will be individually randomised using an allocation algorithm accessed by a secure web portal to the system held at the clinical trials unit NWORTH, in Bangor University.

Two activity and exercise programmes suitable for people with memory problems are being tested in this study.

One programme involves high-intensity supervision (50 visits by physiotherapists, occupational therapists and research support workers over one year), the other moderate-intensity supervision (11 visits by physiotherapists and occupational therapists over three months).

These programmes are tested against standard falls prevention assessment and advice (1-3 therapist visits). Participants are encouraged to exercise by themselves or with family members over the period of the study (12 months), and to continue afterwards.

Intervention Type
Other

Primary outcome(s)
Following the protocol, these feasibility questions will be asked:
1. Can a successful and safe Rehabilitation Support Worker (RSW) training programme be developed and implemented?
2. Can participants be recruited at a sufficient rate across multiple sites? Will potential participants consent? Do randomisation systems work?
3. Can the intervention be delivered across sites? Can the intervention be tailored? Do the components work together?
4. Can the intervention be undertaken at home?
5. Is the intervention acceptable, tolerated and adhered to? How many withdraw?
6. What level of supervision intensity is required for the main trial, that will enable engagement at a level to likely
to be effective at preventing falls? Or whether, in practice, level of supervision can be matched to individual
participant characteristics?
7. What proportion continue to adhere during 24 months follow-up?
8. Are there unexpected or adverse consequences?
9. Can trial health status and falls data be collected at baseline and follow up? Does blinding work? Is the
assessment schedule too burdensome?
10. Are the sample size assumptions correct?

The answer to these questions will be collected via a combination of interviews. focus group sessions, questionnaires and participant self-report. The interviews take place throughout the study, the questionnaires are completed at baseline, once a month throughout the study and again at follow-up. Participants are asked to self report falls, physical activity and exercise throughout their involvement in the study.

Key secondary outcome(s))

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Completion date
01/03/2019

Eligibility

Key inclusion criteria
1. WP1:
1.1. Health care staff with professional knowledge and expertise on falls, dementia, or related health conditions
1.2. The PPI focus group will be recruited from members of a established dementia-specialist PPI group
1.3. Patient and carer focus group, will be a group of people with mild dementia, meeting the inclusion criteria for the feasibility trial (recruited via Alzheimer Society)
2. WP2: Uptake and adherence focus group. A group of people with mild dementia, meeting the inclusion criteria for the feasibility trial, and their family carers (recruited via Alzheimer Society)
3. WP3 feasibility trial:
3.1 Age 65 or over (no maximum)
3.2. A diagnosis of dementia or MCI (of any subtype)
3.3. Able to walk without human help
3.4. Able to communicate in English, with a translator if necessary
3.5. Able to see, hear and have dexterity sufficiently to perform neuropsychological tests
3.6. Capacity to give consent to participate, and agreeing to do so
3.7. Montreal Cognitive Assessment (MoCA) 15-25 or Mini-mental state examination (MMSE) 18-26 or Addenbrooke's Cognitive Examination (ACE-III) 50-83
4. Carer participants will be spouses, family members or others in a caring relationship who see the patient participant for at least an hour most weeks, are willing to take part and can communicate in English, with a translator if necessary
5. WP4: Patient participants will be drawn from those taking part in WP3 (supplemented by those in the main trial, WP5 if needed). Semi-structured interviews will be conducted with about 10 participants in each active-treatment arm in the feasibility study (moderate- and high-intensity supervision). Carers will be interviewed separately, if they are willing

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment

Key exclusion criteria
1. WP 1-2: There will be no specific exclusion criteria, but people recruited are likely to be those who would otherwise have been appropriate for the feasibility trial
2. WP3:
2.1. Co-morbidity preventing participation (e.g. severe breathlessness, pain, psychosis, Parkinson's or other severe neurological disease)
2.2. Life expectancy of less than 1 year
2.3. Likely to be unable to undertake the intervention regularly (e.g. planned elective surgery, planning to move away or commitments elsewhere)
3. WP4 participants will be drawn from those taking part in WP3, exclusion criteria will be the same

Date of first enrolment
01/09/2016

Date of final enrolment
28/02/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottinghamshire Healthcare NHS Trust
Duncan Macmillan House
Porchester Road
Nottingham
United Kingdom
NG3 6AA

Study participating centre
Derbyshire Healthcare Foundation NHS Trust
Kingsway site
Derby
United Kingdom
DE22 3LZ

Sponsor information

Organisation
Nottingham University Hospitals Trust

ROR
https://ror.org/05y3qh794

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

Individual participant data (IPD) sharing plan
Not added at time of reception

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/12/2019	18/12/2019	Yes	No
Results article	Social return on investment results	03/06/2022	10/06/2022	Yes	No
Protocol article	protocol	17/02/2018	28/06	Yes	No

HRA research summary			/2023	No	No
Other publications	development of the intervention	01/07/2018		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11 /2025	No	Yes
Study website	Study website	11/11/2025	11/11 /2025	No	Yes