ISRCTN11288961 https://doi.org/10.1186/ISRCTN11288961

Promoting independence in dementia (PRIDE): a feasibility randomised controlled trial of the PRIDE intervention for people with mild dementia

Submission date
22/10/2018

Recruitment status
No longer recruiting

Registration date
23/10/2018

Overall study status
Completed

Last Edited
08/03/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The researchers are looking at ways to better support people with early stage dementia in their home and in the community. The research is for people who have been diagnosed with early stage dementia who would like to maintain or increase their independence and participation in activities. The researchers would like to find out what help people with dementia currently get to support independence and participation, and develop a programme that could be effective in addressing these issues. The programme called Promoting Independence in Dementia (PRIDE) will provide information, advice and support on the maintenance of pleasure, independence, and relationships. It is not known whether a programme of this kind could work and a large study is needed to test it. Before doing a large study, the aim of this study is to find out the best way to carry out the research, see what people with dementia think about the programme, and check that there would be enough people interested in taking part.

Who can participate?
People aged 18 or over with mild dementia recruited from NHS sites providing dementia services

What does the study involve?
Participants are allocated at random to one of two groups; one group is offered the PRIDE programme in addition to usual care and one group carries on with usual care as provided by their NHS Trust. Participants complete assessments and questionnaires at the start of the study and again after 3 and 6 months. Some people are also invited to take part in focus group interviews about their experiences of the programme and the research.

What are the possible benefits and risks of participating?
If the study is successful the researchers would then apply for funding to do a much larger study in the future. The information from this research will help them to plan and carry out the larger study to evaluate how best to support people with early stage dementia and improve care in the future.

Where is the study run from?
1. Central and North West London NHS Foundation Trust (UK)
2. Derbyshire Healthcare NHS Foundation Trust (UK)
3. Humber Teaching NHS Foundation Trust (UK)
4. Leicestershire Partnership NHS Trust (UK)
5. North West Boroughs Healthcare NHS Foundation Trust (UK)
6. Oxford Health NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2018 to June 2020 (updated 11/03/2020, previously: February 2020)

Who is funding the study?
Economic and Social Research Council (UK)

Who is the main contact?
Mrs Aisha Shafayat
pride@nottingham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Aisha Shafayat

Contact details
Nottingham Clinical Trials Unit
School of Medicine, University of Nottingham
C Floor, South Block, Queen's Medical Centre
Nottingham
United Kingdom
NG7 2UH
+44 (0)115 8231578
pride@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
39076

Study information

Scientific Title

Promoting independence in dementia (PRIDE): a feasibility randomised controlled trial of the PRIDE intervention for people with mild dementia

Acronym
PRIDE

Study objectives
To investigate the feasibility and acceptability of conducting a randomised controlled trial (RCT) to compare the clinical and cost effectiveness of the PRIDE intervention delivered in addition to usual care with usual care only for people with mild dementia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Solihull Research Ethics Committee, 18/10/2018, ref: 18/WM/0281

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

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
Dementia

Interventions
Identification of potential participants
Potential participants will be invited to take part by their usual care team, or may become aware of the study through Join Dementia Research or publicity through other relevant groups and organisations. All potential participants will be provided with a copy of the written participant information sheet and the researcher will arrange to visit the potential participant at home if they remain interested in taking part.

Visit 1
At the first visit, the researcher will explain the study and obtain written consent from the participant. Basic demographic information will be collected and an initial assessment will be

done to confirm if the participant is eligible to be randomised. If the participant is found not to be eligible to take part after this assessment, the researcher will explain this and will provide a brief report of the results, if this is requested. If the participant is eligible to take part, the researcher will continue with the visit and complete the baseline assessments and questionnaires. This visit should take no more than 90 minutes in total.
The participant can also choose a supporter to take part in the study with them. The supporter will fill out questionnaires and will support the participant during the PRIDE programme. If a supporter would like to take part, they will be asked to be present and provide consent at the first visit.

Randomisation
When the first visit has been completed, and the participant is confirmed as suitable, they will be randomly allocated to receive the PRIDE programme and usual care or their usual care only. Participants will be individually allocated on a 1:1 ratio using minimisation with a probabilistic element. The minimisation variables will be study site, sex, age (< 80 or ≥ 80) and medication for dementia (any versus none).

Intervention phase
If the participant is allocated to receive the PRIDE programme, they will be offered 3 sessions, supported by a trained facilitator who works for the NHS. Each session will be carried out in the participants' home on a monthly basis. Each session will last approximately 60-90 minutes, and will follow a manual which contains chapters on how to promote independence and facilitates living well with dementia.
If the participant is allocated to receive usual care then they will not be offered these additional sessions, but their usual care will continue.

Follow-up
All participants will be invited to attend follow-up visits 3 months and 6 months after randomisation. A researcher will carry out the follow-up visits in the participant's home. The researcher will complete assessments and questionnaires with the participant which should take no more than 60-90 minutes.

Participants may also be invited to take part in qualitative focus group interviews, which will ask more about their experiences of taking part in the trial, the PRIDE intervention and usual care.

Intervention Type
Behavioural

Primary outcome measure
The feasibility of conducting a full RCT related to participant recruitment and follow-up, intervention delivery including the recruitment, training and retention of PRIDE trained facilitators, clinical outcomes, intervention and resource use costs and the acceptability of the intervention and study related procedures.

Secondary outcome measures
The following clinical outcomes will be measured to assess the relevance and acceptability of these outcomes for use in a future definitive RCT and to obtain information to inform selection of the primary outcome measure for a future trial. All outcomes are assessed at baseline, 3 and 6 month follow-up.
1. Activities of daily living measured using the Lawton Instrumental Activities of Daily Living (IADL) Scale

2. Health-related quality of life measured using the EuroQoL Quality of Life Questionnaire – 5 Domains, 5 Levels (EQ-5D-5L)
3. Quality of life measured using the DEMQOL
4. Mood measured using the Geriatric Depression Scale (GDS)
5. Cognition measured using the Standardised Mini Mental State Exam (S-MMSE)
6. Wellbeing measured using the Control, Autonomy, Self-realisation and Pleasure (CASP)
7. Quality of relationships measured using the Social Relationships sub-scale of the Impact on Participation and Autonomy Questionnaire for older people (IPAQ-O)
8. Positive emotions measured using the Positive Psychology Outcome Measure (PPOM)
9. Social engagement measured using the number of social contacts and leisure activities per week
10. Global rating of change assessed by the person with dementia and the supporter
11. Resource use measured using a modified version of the Client Service Receipt Inventory (CSRI)

Overall study start date
01/09/2018

Completion date
30/06/2020

Eligibility

Key inclusion criteria
Inclusion criteria for the person with dementia:
To be eligible for the trial participants must meet all of the following inclusion criteria:
1. -Resident within the catchment area of one of the participating NHS sites
2. -Aged 18 or over; there is no upper age limit
3. -Meet the Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition (DSM-IV) criteria for dementia of any type, including Alzheimer's, vascular, Lewy body type and mixed
4. -Able to engage with and participate in the intervention in the judgement of the investigator or designee
5. -Able to provide informed consent in the judgement of the investigator or designee
6. Able to read and communicate verbally in English
In addition, to be eligible for randomisation, the following inclusion criteria must be met. This is ascertained by a formal screening assessment completed after consent:
7. -Mild dementia, defined as a score of 0.5 or 1 on the Clinical Dementia Rating Scale. The CDR will be completed during a face-to-face visit, as a post-consent screening assessment to determine eligibility for randomisation.

Inclusion criteria for the supportive other:
Note that participation of a supportive other is not mandatory and will be at the discretion of the participant. If the participant chooses to identify a supportive other they wish to participate with, the following inclusion criteria will apply:
1. Aged 18 or over; there is no upper age limit
2. -Able to engage with and participate in the intervention
3. -Able to provide informed consent
4. Able to read and communicate verbally in English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 80; UK Sample Size: 80

Total final enrolment
92

Key exclusion criteria
Exclusion criteria for the person with dementia:
-Living in institutional care

Date of first enrolment
15/11/2018

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Central and North West London NHS Foundation Trust
London
United Kingdom
NW1 3AX

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

Study participating centre
Humber Teaching NHS Foundation Trust
Hull
United Kingdom
HU10 6ED

Study participating centre
Leicestershire Partnership NHS Trust
Leicester
United Kingdom
LE4 8PQ

Study participating centre
North West Boroughs Healthcare NHS Foundation Trust
Warrington
United Kingdom
WA2 8WA

Study participating centre
Oxford Health NHS Foundation Trust
Oxford
United Kingdom
OX3 7JX

Sponsor information

Organisation
University of Nottingham

Sponsor details
c/o Ms Angela Shone, Head of Research Governance
Research and Innovation
University of Nottingham
East Atrium, Jubilee Conference Centre
Triumph Road
Nottingham
England
United Kingdom
NG8 1DH
+44 (0)115 8467906
sponsor@nottingham.ac.uk

Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Research council

Funder Name
Economic and Social Research Council; Grant Codes: ES/L001802/2

Alternative Name(s)
ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
28/02/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the trial coordinating centre (Nottingham Clinical Trials Unit, pride@nottingham.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/12/2019	13/12/2019	Yes	No

Results article	results	25/02/2021	08/03/2021	Yes	No
HRA research summary			28/06/2023	No	No