ISRCTN48152791 https://doi.org/10.1186/ISRCTN48152791

Effectiveness of PDSAFE to prevent falls among people with Parkinson’s disease

Submission date
17/04/2014

Recruitment status
No longer recruiting

Registration date
17/04/2014

Overall study status
Completed

Last Edited
09/11/2020

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Parkinson's disease is a common, progressive condition that affects the body's nervous system. Over time people with Parkinson's disease are likely to become less steady, less able to move around within their homes and outside and more prone to falls. Although drugs are available to treat the symptoms of Parkinson's disease, reduced balance control and falls do not respond to drugs as well as some other symptoms respond. There is some evidence that physiotherapy can help but to date there are insufficient research findings to quantify the benefits for people with Parkinson's disease. This study is aimed at quantifying these benefits together with the costs incurred and any health service cost savings. PDSAFE is a novel personalised treatment based on the latest published research evidence and our extensive experience of managing the movement and stability problems of people with Parkinson's disease. Our main question is, do people with Parkinson's disease who follow PDSAFE exercises and fall prevention strategies fall less often than those who do not during the 6 months of treatment?

Who can participate?
Patients with Parkinson's disease who live at home and have experienced at least one fall in the previous 12 months.

What does the study involve?
Participants will be asked to record how many times they fall using a monthly diary sheet for 3 months. Participants will then be randomly allocated to one of two groups: intervention or control. The intervention group will participate in PDSAFE, a personalised home-based programme of exercises and strategies for fall prevention to be delivered by physiotherapists. The control group will receive usual care and a DVD with a relaxation programme. Participants will be asked to record how many times they fall using a monthly diary sheet for 12 months.

What are the possible benefits and risks of participating?
There will be no direct benefit to participants that take part in the study, although they may enjoy completing the exercises and being more active. However, it is hoped that the data collected will allow us to define the benefits of PDSAFE, in terms of reducing falls and improving balance of people with Parkinson’s. The cost of PDSAFE will be assessed using information about the treatment delivery costs. This information will be used to further develop the treatment and

enhance clinical services. Answering questions from questionnaires can sometimes cause distress but we do not anticipate any disadvantage or risks. Participants do not have to answer any questions or participate in activities they don't wish to and can stop at any point. It is possible that taking part in exercises and/or assessments can cause instability and put people off balance. Participants do not have to practice any exercises or do any assessments they feel unsure about. A researcher will be present during the assessments to help ensure patient safety.

Where is the study run from?
We aim to recruit from four areas in the South of England: Southampton, Bournemouth, Portsmouth, and Exeter.

When is the study starting and how long is it expected to run for?
From May 2014 to October 2015.

Who is funding the study?
NIHR Health Technology Assessment Programme (UK).

Who is the main contact?
Dr Kim Chivers-Seymour
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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
16512; HTA 10/57/21

Study information

Scientific Title
A randomised controlled trial of the effectiveness of PDSAFE to prevent falls among people with Parkinson's disease

Acronym
PDSAFE

Study objectives
PDSAFE is a novel personalised treatment (PDSAFE) based on the latest published research evidence and our extensive experience of managing the movement and stability problems of people with Parkinson's disease. Our main question is, do people with Parkinson's disease who follow PDSAFE (exercises and fall prevention strategies) fall less than those who do not during the 6 months of treatment?

More details can be found here: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=16512 and http://www.nets.nihr.ac.uk/projects/hta/105721
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0005/97358/PRO-10-57-21.pdf

On 20/07/2015 the overall trial end date was changed from 30/04/2016 to 01/07/2017.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Hampshire B, 10/02/2014, ref: 14/SC/0039

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Dementias and neurodegeneration; Subtopic: Parkinson's Disease; Disease: Parkinson's disease

Interventions
We will recruit 600 to the pre-randomisation falls collection period, we estimate with drop outs approximately 540 will be randomly allocated to one of two groups; intervention or control. Allocation will be stratified by centre and allocated in blocks with random size of 2, 4,6 or 8. The treating therapist will access allocation on the CTU website.

All participants will have usual care. The control group will receive a standardised DVD with a relaxation programme. The experimental group will participate in PDSAFE, a personalised home-based programme of exercises and strategies for fall prevention to be delivered by physiotherapists with specific training in the intervention and use of DVD and tablet computer technology. The novelty of the treatment lies in both the content (disease-specific exercises and strategies for limiting instability, use of motor relearning and cognitive awareness) and delivery (personalised feedback using DVD for adherence and self-management). The programme comprises:
1. Exercises for balance, gait and muscle weakness
2. Strategies for reducing freezing, encouraging stability and gait efficacy
3. Feedback model to promote learning and adherence

Personal sessions with required exercises and will be recorded on DVD and returned so information and instructions can be replayed at home; DVD will be developed with the PwPD. The frequency of the intervention sessions will be faded over time, one hour twice a week for 2 month, once a week for 2 months followed by once a month for 3 months. The control group will receive usual care and a DVD with a relaxation programme.

Those who meet the inclusion criteria will be asked to prospectively record fall events using a monthly diary sheet for 3 months between recruitment and randomisation. These findings will be used for comparison with post-intervention fall rate. The assessments will take place in participants homes at baseline, 3, 6 and 12 months post-randomisation and will be completed by the assessor who will be blinded to group allocation. At baseline a medical history structured to include co-morbidities will be taken, disease severity, medication and hand grip will be recorded.

Intervention Type
Behavioural

Primary outcome measure
Risk of repeat falling between 0-6 months. Fall data will be collected through self-completed monthly diary sheets from baseline to 12 months post-randomisation.

Secondary outcome measures
Secondary outcomes will include:
1. Risk of repeat falling 6-12 months
2. Rate of falling 0-6 and 6-12 months
3. Injurious falls and near falls (from the fall diary)
4. A measure of balance, turning, mobility and quality of life
5. Individual levels of activity will be recorded using the Phone-FITT questionnaire

Overall study start date
01/05/2014

Completion date
01/07/2017

Eligibility

Key inclusion criteria
1.They have a confirmed diagnosis of Parkinson's disease
2. Live at home
3. Have experienced at least one fall in the previous 12 months
4. Able to give informed consent
5. Able to understand and follow commands
6. Able to complete a programme of exercises
7. Be willing to participate
Target Gender: Male & Female; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 600; UK Sample Size: 600;

Total final enrolment
474

Key exclusion criteria
People who live in nursing homes and those who are not independently mobile, i.e. in need of assistance to walk inside or rated the highest (worst) on the Hoehn & Yahr disease severity scale, will be excluded.

Date of first enrolment
01/07/2014

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southampton General Hospital
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

Sponsor details
Public Health & Medical Statistics
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Sponsor type
University/education

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme; Grant Codes: RHM MED 1159

Results and Publications

Publication and dissemination plan
Findings will be disseminated to academic audiences through publications in academic journals and presentations at academic conferences. Dissemination to practitioners will focus on articles in practitioner-orientated publications and presentations at practitioner-orientated conferences. Dissemination to people affected by Parkinson's disease (participants, service users and carers) and voluntary workers will be achieved using printed and web-based materials through organisations and networks such as Parkinson's UK and DeNDRoN.

Please contact the Chief Investigator to discuss data sharing opportunities.

Intention to publish date
01/11/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/05/2015		Yes	No
Results article	HTA results	01/07/2019		Yes	No
Results article	cost-effectiveness results	11/08/2020	14/08/2020	Yes	No
Other publications	analysis of therapists' delivery and experience	01/03/2021	09/11/2020	Yes	No
HRA research summary			28/06/2023	No	No