ISRCTN14719805 https://doi.org/10.1186/ISRCTN14719805

PDSAFE Stage 1 Pilot Trial

Submission date	Recruitment status	[ ] Prospectively registered
11/12/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/12/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/06/2018	Nervous System Diseases	[ ] Record updated in last year

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, and more prone to falls. Although drugs are available to treat the symptoms of Parkinson's disease, balance control and falls do not improve. There is some evidence that physiotherapy can help but to date there is not enough evidence. This proposal is aimed at defining the benefits of physiotherapy together with the costs incurred and any health service cost savings. PDSAFE is a new personalised exercise-based treatment. The aim of this study is to find out whether people with Parkinson's disease who follow PDSAFE fall less often.

Who can participate?
People 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 follow the PDSAFE programme, which includes exercises for balance, muscle strengthening and techniques for improving walking, freezing (unable to move), steadiness and avoiding falls. Each participant’s treatment session is videoed, transferred to a DVD or tablet computer and returned to them so that they can replay it at home. This enables multiple replays of a session as required and acts as a reminder of the activity, instructions, information and feedback.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Southampton General Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2013 to March 2014

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

Who is the main contact?
Dr Barry Hounsome
b.hounsome@soton.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Barry Hounsome

Contact details
Faculty of Health Sciences
Southampton General Hospital Level E
Centre Block
Southampton
United Kingdom
SO16 6YD
-
b.hounsome@soton.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15673

Study information

Scientific Title
A randomised controlled trial of the effectiveness of PDSAFE to prevent falls among people with Parkinsons disease: Stage 1 Pilot study

Study objectives
PDSAFE is a novel, personalised, exercise-based treatment based on the latest published research evidence and our extensive experience of managing the movement and stability problems of people with Parkinsons disease. While there is some evidence that physiotherapy can help to improve movement and stability, to date there are insufficient research findings to quantify the benefits for PwPD.

The study to aims to assess the effectiveness and cost-effectiveness of PDSAFE, compared to routine care, comprises of two stages:

Stage 1: a pilot study.
Stage 2: a randomised controlled trial (RCT) (a separate ethics application will be submitted for Stage 2).

This ethics application refers to Stage 1 only. The current protocol provides details of the stage 1 pilot study; a separate protocol will be submitted for the RCT in stage 2 of the study. The Stage 1 pilot study will allow the newly developed PDSAFE intervention to be evaluated on a small sample of PwPD before being adopted in the stage 2 RCT. The stage 2 RCT will aim to define the benefits, together with the costs incurred and any health service cost savings, of the PDSAFE intervention. The stage 2 trial will seek to answer the question: do people with Parkinsons disease who follow PDSAFE fall less than those who do not during the 6 months of treatment?

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/SC/0538

Study design
Non-randomised interventional trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Dementias and Neurodegenerative Diseases Research Network; Subtopic: Parkinsons Disease; Disease: Parkinson's disease

Interventions
Therapy, For the stage 1 pilot study the intervention will take place over period of up to six weeks. A total of up to 10 sessions of therapy each lasting for one hour (30 minutes of exercises; 30 minutes of discussing/developing strategies to avoid falls) will be delivered. The programme will be videoed for the person to continue and will include advice about progression of exercise.

Sample size of up to 20 participants was deemed appropriate for the pilot trial stage of the study. The sample size for the main trial is based on a power calculation

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Review assessments before stage 2 RCT commences.; Timepoint(s): Baseline; 1 month; within 2 wks of 1mnth intervention completion; Baseline; falls diary over 3 mnths

Secondary outcome measures
Not provided at time of registration

Overall study start date
18/11/2013

Completion date
31/03/2014

Eligibility

Key inclusion criteria
1. Have a confirmed Consultant's diagnosis of Parkinson's disease
2. Live at home
3. Have experienced at least one fall in the previous 12 months
4. Able to follow commands
5. Be willing to participate
6. 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: 20; UK Sample Size: 20

Key exclusion criteria
1. People who live in nursing homes
2. 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
3. Previous entry or randomisation in the present trial
4. Participation in a clinical trial of an investigational medicinal product in the last 90 days

Date of first enrolment
18/11/2013

Date of final enrolment
31/03/2014

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
Aldermoor Health Centre
Southampton
England
United Kingdom
SO16 6YD

Sponsor type
University/education

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme (HTA) (UK) ; Grant Codes: 10/57/21

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
HRA research summary			28/06/2023	No	No