

PDSAFE Stage 1 Pilot Trial

Submission date 11/12/2013	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 11/12/2013	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 12/06/2018	Condition category Nervous System Diseases	☐ Individual participant data ☐ 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
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Non-randomised interventional trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre

Southampton General Hospital
Southampton

United Kingdom
SO16 6YD

Sponsor information

Organisation

University of Southampton (UK)

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

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