

PARTICIPANT INFORMATION SHEET

A randomised controlled trial of the effectiveness of PDSAFE to prevent falls among people with Parkinson's: Main Trial

We would like to invite you to take part in our research trial. Before you decide whether or not to take part, we would like you to understand why the research is being carried out and what it would involve for you. Please take time to read the following information carefully and discuss it with friends, relatives, and your GP if you wish. A member of our research team will go through this Information Sheet with you and answer any questions you may have. If you would like further information, please do not hesitate to telephone the number above.

What is the purpose of this trial?

Parkinson's is a common, progressive condition that affects the body's nervous system. Over time people with Parkinson's 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, reduced balance control and falls do not respond to drugs. There is some evidence that physiotherapy can help, though to date there are insufficient research findings to quantify the benefits for people with Parkinson's. A new exercise and strategy-based intervention for people with Parkinson's, called PDSAFE, has been developed by a research team led by Professor Ann Ashburn in Southampton. PDSAFE is a personalised physiotherapy programme that is aimed to help with balance and movement. The purpose of this trial is to see if the PDSAFE intervention helps people with Parkinson's to fall less often and to assess whether it is cost-effective. More specifically, our main question is: do people with Parkinson's who follow PDSAFE fall less than those who do not follow it?

Why have I been invited?

We are planning to recruit 600 people with Parkinson's to this trial. You have been identified as someone who has been diagnosed with Parkinson's and might be interested in taking part in this research trial. You have been told about this trial either a) by a health professional who is known to you, b) by your Parkinson's support group, or c) because you have previously agreed that we could inform you of further research taking place at the University of Southampton or with the local research network.

Do I have to take part?

It is up to you to decide if you wish to join the trial. By returning the reply slip accompanying this Information Sheet you are only agreeing to be contacted by a researcher at this point. He/she will describe the trial and go through this Information Sheet with you. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time without giving a reason. Deciding not to take part or withdrawing from the trial at any point will not affect the standard of care you receive.

What will happen to me if I take part?

How long will I be involved with the research?

You will be involved in the research over a period of approximately 15 months.

How many times will I meet the researcher for assessments?

You will meet the researcher on five separate occasions for assessments. The first assessments will take place in the three months before the trial formally starts (a screening visit to obtain your written consent). At the baseline assessment visit (three months later) you will be randomly allocated either to the exercise group, who will receive the PDSAFE intervention, or the control group. The researcher will see you again for assessments at 3, 6 and 12 months after your random group allocation.

Where will I meet the researcher?

The assessments will take place in your own home.

How long will these visits for assessments be?

The assessments will take up to 90 minutes.

What happens during these assessment visits?

During the screening visit, the researcher will talk to you about the research trial and ask you to sign a consent form. The researcher will then ask you to complete two assessments to confirm your eligibility to join the trial. Should you be unable to complete these, the researcher will advise you that, unfortunately, you are not suitable to be included in the trial. If you complete the assessments the researcher will proceed to ask you questions about your balance, ability to move about, stamina, vision, any falls you have had, ability to remember instructions and any medical and/or surgical condition you feel may affect the way you move. They will also ask you whether you have a carer whom we could approach to take part in the trial. Having a carer is not a requirement for you to take part in the trial.

During the assessment visits (at baseline, 3, 6 and 12 months), you will be asked to complete a questionnaire on your quality of life, mood, fear of falling and an ability to complete everyday tasks. You only have to answer the questions you feel comfortable with and if you are unhappy with any of the questions you may stop at any time. The researcher will also ask you questions about your usual leisure activities and ask you to complete tests of your balance, posture, turning and walking. The assessment of turning involves you turning round and may require video recording. The balance tests involve you completing a series of exercises like standing up, reaching forward and attempting to stand on one leg. You may also be asked to complete a hand grip test. You will not be asked to complete any tests you feel you cannot manage. You will be allowed to rest during and between tests. The tests can be stopped at any time if you become tired.

Throughout the duration of the trial, you will be asked to record any falls you may have in a diary, which we will provide. We will explain the falls diary to you during the screening visit and give you a contact number to call if you have any queries about completing the falls diary.

Which group will I be put into?

To date there are insufficient research findings to quantify the benefits of exercise on fall risk for people with Parkinson's. We do not know if taking part in these exercises will reduce your fall risk and how big the benefits of exercising are on other aspects of your wellbeing e.g. your balance. To find out, we need to compare different treatments. We will allocate people to two groups; one group will have the PDSAFE exercises and their usual care, while the other group will only have their usual care. The results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly).

If you are allocated to the PDSAFE exercise group: you will be asked to continue with your usual care and normal day to day life and you will be asked to follow the PDSAFE programme which will be personalised to your needs and ability by a physiotherapist. If you are happy to do so the physiotherapist will ask you to comply with an exercise agreement, but only if you feel that this will encourage you to practice the agreed exercises. The programme includes exercises for *balance* (such as standing still and reaching forwards and back and standing on foam and stepping sideways) *muscle strengthening* (such as standing up from sitting, stepping up and down from a step, these may be progressed by wearing a weighted vest adjusted to your ability) and strategies for improving walking, freezing (unable to move), steadiness and avoiding falls, as well as identifying fall hazards in and around your home. The physiotherapist will discuss the exercise treatment with you, teach you the exercises and together you will identify how often you would practice the exercises during the week. The physiotherapist will come to your house to practice the exercises with you. The frequency of his/her visits will be reduced over a six month period; starting with one hour twice a week for two or three weeks, then once a week for four to six weeks, followed by a visit at three months and a final visit at five months.

In each treatment session, the physiotherapist will illustrate ways of improving means of moving around by showing videos of demonstrations and s/he may video the treatment session, then transfer the film onto DVD and return it to you, so that you can replay it at home. You will be provided with all of the necessary equipment (including lending you a DVD player if you do not have one at home) to allow you to take part in the intervention. The DVD will enable multiple replays of a session as required and act as a reminder of the activity, instructions, information and feedback. PDSAFE will be delivered by physiotherapists in your own home over a period of up to five months. As part of the intervention, the physiotherapist will identify fall hazards in and around your home. If the physiotherapist identifies any fall hazards, we will discuss these issues with you and try to find possible solutions. However, if the hazards cannot be easily rectified by the research team, the physiotherapist will ask you for your permission to contact relevant authorities to address these hazards. You will be asked not to share the

treatment with other Parkinson's friends as it is important that the exercises and videos are only available to those under supervision in the treatment group of this trial.

If you are in the control group: you will be asked to continue with your usual care and normal day to day life. A physiotherapist will visit you to give you a DVD with information about Parkinson's and visit again at the end of the trial to advise about safe mobility and leave a booklet containing general tips on fall prevention and general advice about physical activities and strategies for balance and safety. Participants in the control group play an important role in the success of the trial.

Quality assurance

In order to check the quality of assessments being performed on all participants and the delivery of physiotherapy, advice and information, an additional member of the PDSAFE team may join the assessor and/or physiotherapist on an occasional visit. This will only apply to a very small number of participants.

Personal views interviews:

A small group of trial participants (40 in total) will be invited to take part in interviews to talk about your personal views of the treatment. If you agree to take part in this aspect of the trial, the first interview will be conducted soon after the baseline assessments are completed and prior to the start of the intervention. The second interview will be six months later. The researcher will visit you at home to discuss your experience. Interview visits will last approximately 60 minutes.

What are the possible benefits of taking part?

There will be no direct benefit to you from taking part in the trial although you might 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.

Are there any risks involved?

Answering questions from questionnaires can sometimes cause distress but we do not anticipate any disadvantage or risks. You do not have to answer any questions or participate in activities you 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 you off balance. You do not have to practice any exercises or do any assessments you feel unsure about. A researcher will be present during the assessments to help ensure your safety.

Can you practice the exercises on your own?

Only after you have practiced with the physiotherapist and you both agree that you are happy and safe to do so with the help of your strategy DVD.

What if there is a problem or I have a complaint?

If you feel you have any concerns or complaints about this trial you should contact Professor Ann Ashburn ([REDACTED]). If you remain unhappy and wish to complain, Ann will provide you with details of the University of Southampton and University Hospital Southampton NHS Foundation Trust Complaints Procedure. Alternatively, you may wish to speak to the local Patient Support Services, PALS on < *contact details for local Patient Support Services*>.

Who is organizing the research & reviewing the trial?

The research is being led by Professor Ann Ashburn, Professor of Rehabilitation at the University of Southampton. It has been reviewed by the National Ethics Research Service Committee South Central – Hampshire B Research Ethics Committee and University Hospital Southampton are the sponsors.

Will my participation be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Each person will be allocated an ID number by which any documentation will be identifiable to the researchers only. All information will be kept in a locked filing cabinet in accordance with storage of medical records. The results from the trial will be entered into a University computer, accessible only to the researchers. Any information about you which is used in research reports or publications will have your name and address removed so that you cannot be identified. Nevertheless, the research team is required by law to break confidentiality where cases of malpractice, abuse, or risk to self or others are disclosed. Such cases will be referred to the appropriate authority.

What happens when the research trial stops?

When the research trial stops, the PDSAFE exercises as delivered by a physiotherapist will come to an end and participants will continue to receive their usual care. The group who took part in the PDSAFE exercises can choose to continue the exercises and will be able to keep their personalised PDSAFE exercise DVD. The group who did not take part in the exercises will be able to keep the Parkinson's information DVD and falls prevention booklet. We will disseminate our findings after the completion of the study.

What will happen to the results of the research?

At the end of the research, the data collected will be securely stored at the University of Southampton for 10 years. The results will be presented at conferences and may be published in research papers for scientific journals. If you would like a copy of the published results at the end of the trial please let us know.

Contact for further information:

If you would like any further information please contact:

< LOCAL CONTACT DETAILS >

Or

Dr Kim Chivers Seymour (Trial Manager)



Thank you for taking the time to read this information.