Patient Information Sheet – Front Sheet

Insert Local NHS Trust Logo

RANDOMISED CONTROLLED TRIAL TO ASSESS THE CLINICAL- AND COST-EFFECTIVENESS OF PHYSIOTHERAPY AND OCCUPATIONAL THERAPY IN PARKINSON'S DISEASE (PD REHAB)

Patient Information Sheet

PD REHAB logo – To be inserted

Local PI Contact details here

Local Nurse Contact details here

Local PALS Group Contact detail here

BCTU Contact details

Version 9, 11th June 2010

PATIENT INFORMATION SHEET

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?

We want to know whether occupational therapy and physiotherapy help people with Parkinson's disease. Occupational therapy mainly aims to improve physical function and independence. It involves a qualified therapist assessing a patient's problems with their disease, often at home, then devising practical ways to help them such as providing aids and adaptations (e.g. walking aids, hand rails, raised seating etc). Physiotherapy focuses on working with the patient, carer and family to improve their understanding of the condition, maintain general fitness and independence in mobility, both inside and outside the home.

Currently there is no good evidence whether occupational therapy and physiotherapy benefit patients with Parkinson's disease. This study aims to answer the question: do patients benefit from therapy and does any benefit persist after they have finished their occupational therapy and physiotherapy? This information will be used to help optimise treatment for future Parkinson's disease patients.

Why have I been asked?

The study will include 750 patients with Parkinson's disease at about 40 centres throughout the United Kingdom. We are asking you to take part in the study because you have Parkinson's disease and you may potentially benefit from occupational therapy and/or physiotherapy.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason though it would be very helpful if you would agree to continue to provide information. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

This is a randomised study. Sometimes, because we do not know which way of treating patients is best, we need to make comparisons. People will be put into two groups. The groups are selected by a computer at random, like flipping a coin. Patients in each group then have a different treatment and these are compared. If you decide to take part, you will be allocated at random to receive occupational therapy and physiotherapy immediately or to

have the therapies deferred until the end of the study after 15 months. You will have a 50:50 chance of getting therapy immediately.

If you decide to take part, the research staff at your site will answer any questions you have then ask you to sign a consent form. They will then ask you to complete the study questionnaires. There are 4 brief questionnaires for you (and one for your carer if they chose to join the trial) at baseline, 3 9 and 15 months. These are easy to do and have been used in Parkinson's disease studies and other conditions for many years. It will take around 20 minutes for you to complete all of these questionnaires.

If you are allocated to immediate therapy, then the trial occupational therapist and physiotherapist at your site will visit you at home to assess what help can be offered. They will then arrange this help and, if necessary, visit you again.

If you are allocated to delayed therapy, we will ask your general practitioner or hospital specialist to defer arranging any occupational therapy or physiotherapy until the study finishes 15 months after you join the trial. You will also get some 'Top-tip' leaflets which will have been developed by the patient/carer group who are part of the study team.

We will send you the same questionnaires to fill in at home 3, 9 and 15 months after you enter the study. You will be asked to complete these, then post them back to us in the freepost envelope we will send you.

What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages or risks in taking part. There may be a small increased risk of falls during therapy as participants may become more mobile, but your therapists will minimise this risk by carefully training you. The risk of falls will further be minimised by the specific training of therapists in handling patients with Parkinson's disease.

What are the possible benefits of taking part?

Although you may not benefit directly from taking part, the information we get from this study may help us to look after future patients with Parkinson's Disease better. The top-tip leaflets developed at the end of the study will also be shared with the wider Parkinson's disease community.

What if something goes wrong?

If you are harmed by taking part in this research, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you: ask to speak to the complaints manager of the hospital.

If you have a concern about any aspect of this study you should ask to speak to the researcher who will do their best to answer your questions (Local PI contact details here). If you remain unhappy and wish to complain formally you can contact your local PALS group (contact details here)

Will my taking part in this study be kept confidential?

All information collected in the study will remain strictly confidential in the same way as your other medical records. The information will be put into a computer and analysed, but you will not be identified when the results are reported.

We would also like your permission to tell your GP that you are taking part in the study. You may still take part in the study, if you do not wish us to contact your GP

What will happen to the results of the research study?

The results of the study will be published in a medical journal after the study has been completed but you will not be identified in any report or publication. Carers and patients with Parkinson's disease are part of the study team. They will lead on using the findings from the study to develop 'Top-Tip' leaflets and other lay summaries and share this information with the wider Parkinson's disease community.

What happens if I become incapacitated during the trial?

If you become incapacitated during the trial, you will be withdrawn from the study and we will not send you any further questionnaires. We will keep the information you gave us before you became incapacitated and it will be used in the results of the study.

Who is organising and funding the research?

The study is being funded by the Health Technology Assessment Programme which is part of the UK National Institute for Health Research. No payments will be made to the patients, therapists, nurses, or doctors taking part in the study.

Who has looked at the research?

All research in the NHS is looked at by a independent group of people called a Research Ethics Committee to protect your safety, rights, well being and dignity. This study has been reviewed and approved by *Warwick* Research Ethics Committee *insert date*

Contact for Further Information

Should you want further information about the study please contact: *<Insert details of local PI>*

If you decide to take part in this study, you will be given a copy of this information sheet and a signed consent form to keep.

Thank you for taking the time to read this information sheet.

Version 9, 11th June 2010