

Doctor
Practice
Street
City
Postcode

PATIENT NAME DATE RANDOMISED
DATE OF BIRTH TRIAL NUMBER
HOSPITAL NUMBER ALLOCATED TREATMENT

Dear Dr GP

Re: Randomised controlled trial to assess the clinical and cost-effectiveness of physiotherapy and occupational therapy in Parkinson's disease (PD REHAB trial)

Your patient, named above, has agreed to take part in the PD REHAB trial. This is a large nationwide pragmatic randomised controlled trial to assess whether occupational therapy and physiotherapy are effective and safe in Parkinson's disease.

In this study, we will examine the effects of occupational therapy and physiotherapy provided in the patient's home compared with no therapy in 750 patients with PD who have significant problems with activities of daily living. Patients who are allocated at random to receive therapy immediately will be visited at home by qualified occupational therapists and physiotherapists who will assess their needs and arrange for treatments, aids and adaptations, etc as necessary. Patients allocated to no therapy will receive standard NHS care.

We would be grateful if you would defer the arrangement of occupational therapy and physiotherapy until after the end of the trial (15 months from randomisation) for this patient. At the end of this period, if this patient was allocated to no therapy, we will contact you in order that the patient can receive physiotherapy and occupational therapy per your usual practice.

We will monitor all patients' mobility, disability (activities of daily living), health-related quality of life and health care costs. These will be assessed by questionnaires before entry to the trial and, by post, at 3, 9 and 15 months after entry to the study. With the data from this trial, we will have sufficient statistical power to show whether combined occupational therapy and physiotherapy are effective and safe in Parkinson's disease and whether they are cost-effective.

The trial is designed to fit in with routine practice as far as possible and to impose minimal additional workload, especially on general practitioners.

PD REHAB is being run by the University of Birmingham Clinical Trials Unit and is co-ordinated by Professor Clarke (neurologist), Professor Sackley (physiotherapist), and Ms Natalie Ives (statistician).

The local co-ordinator for the trial is [*insert name and hospital*]. The trial has been reviewed by the National Research Ethics Committee.

If you require any further information about the study, it can be obtained from: *<Insert details of local PI>*

Please file this letter in the patient's notes. I would appreciate being notified if he/she is no longer one of your patients.

Yours sincerely

Local co-ordinator

University of Birmingham Clinical Trials Unit contact details

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