



NETSCC, HTA

13th January 2011

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

ACRONYM: PD REHAB

TRIAL PROTOCOL – VERSION 9

New REC Ref 08/H1211/168

(Old REC Ref 08/H1211/144)

HEALTH TECHNOLOGY ASSESSMENT PROGRAMME

REFERENCE 07/01/07

ISRCTN17452402

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1 Trial Outline

Design

PD REHAB is a large, pragmatic, multicentre, randomised, controlled trial of combined occupational therapy (OT) and physiotherapy (PT) versus no therapy in patients with Parkinson's disease (PD) who report limitations in activities of daily living.

Randomisation is via the internet, using a computer generated minimisation algorithm. The trial will necessarily be open label due to the nature of the intervention.

Aim of Study

The trial will evaluate the clinical- and cost-effectiveness of combined NHS OT and PT for PD versus no therapy.

Setting

Community-based therapy in approximately 40 elderly care and neurology units throughout the UK to reflect population diversity.

Target population

Patients with PD of any age who report limitations in activities of daily living.

Intervention

PT and OT will be administered in the community. The framework for the content of the therapy will be agreed in advance by expert groups based on our previous work on standard NHS OT and the PT Evaluation Project. Training will be provided for trial therapists, who will have a spectrum of experience to ensure uniformity of practice across the country. Therapists providing the intervention will complete intervention record forms, as used in previous complex intervention trials, to allow us to monitor intervention delivery.

Measurement of outcomes and costs

The primary outcome measure will be instrumental activities of daily living measured using the Nottingham Extended Activities of Daily Living scale (NEADL) as activities of daily living (ADL) is the target of the intervention. Secondary outcomes will be: health-related quality of life (Parkinson's Disease Questionnaire 39, PDQ 39; EuroQol EQ5D), cost-effectiveness (cost per quality adjusted life year), adverse events and carer quality of life (Short Form 12, SF12). Outcomes will be assessed before randomisation and by post at 3, 9 and 15 months post randomisation.

Sample size

Although definitive data are not available, it is thought that a minimally clinically relevant change in NEADL is 1 to 2 points. Such a minimal change may be of only a small benefit to patients, so a difference of around double this at 2.5 points is considered clinically meaningful. To detect a 2.5 point difference in NEADL at 3 months (SD from PD OT 10.1; $p < 0.05$ two tailed; 90% power) requires 340 patients in each arm. To allow for a 10% drop out rate, a total of 750 patients will be randomised (375 per arm).

2 Background

2.1 Objectives

Occupational therapy (OT) and physiotherapy (PT) are traditionally used when patients with Parkinson's disease (PD) develop some impairment of activities of daily living (ADL) and/or mobility. OT in PD aims to work with patients to address their goals through activity and participation, helping them to remain independent and to reduce carer strain. When delivered in a domiciliary setting, the therapist will include the provision of aids and appliances to improve person/environment fit, task-related training and educating carers. PT aims to promote and maintain mobility and activity by treating impairments (such as muscle weakness) and task related practice in the context of education and support for the whole person. The core areas of work in PD are gait, balance, posture and transfers.

Cochrane reviews of OT and PT for PD found insufficient evidence of effectiveness. A recent NIHR Service Delivery and Organisation Programme report found that to be true of all rehabilitation services for PD.¹ Although the recent NICE guidelines recognised this shortcoming and strongly recommended further trials in this area, it still stated *that all patients should have access to both therapies (OT and PT), though on the basis of poor quality evidence. However, the recommendations were very vague and provided no guidance on the timing, setting or intensity of therapy. This lack of clarity may be one of the reasons why the clinical community has struggled to implement the guidelines, in contrast to the strategy for stroke where research provided the basis for recommendations for the delivery of OT and PT. Without such details it is very difficult to plan and deliver cost-effective services. For example, the resource implications of 3 months of therapy every 2 years are very different from that of an advice session every 5 years.

The objective of this randomised controlled trial (RCT) is to evaluate the clinical and cost-effectiveness of combined domiciliary PT and OT in patients with PD. PD REHAB will be the largest ever clinical trial of any rehabilitation therapy in PD and, as such, will continue to expand the research infrastructure in PD in the UK and increase the numbers of therapists with an interest in PD. The results of the trial will inform future decisions by patients, clinicians, commissioners, NICE and the Government regarding the use of these rehabilitation therapies in PD. Patients and carers, along with the Parkinson's Disease Society (PDS), will be involved in translating the trial findings into a patient/carer leaflet to support their decision making in therapy up-take and will ensure the patient/carer voice is embedded within all recommendations for clinical practice.

2.2 Existing research

2.2.1 Physiotherapy

Efficacy and cost effectiveness

A **Cochrane review** of PT in PD published in 2001 found 11 RCTs in 280 patients.² Ten of these trials claimed a positive effect from PT, but few of the outcomes measured were statistically significant. Walking velocity was measured in four trials and increased significantly in two. Stride length was the only other outcome measured in more than one trial, and was significantly improved in two trials. Five other outcomes improved significantly in individual studies, but eight other outcomes did not improve significantly. The review concluded that: "Considering the methodological flaws in many of the studies, the small number of patients examined, and the possibility of publication bias, there is insufficient evidence to support or refute the efficacy of PT in PD." It went on to suggest: "Large well designed placebo-controlled RCTs are needed to demonstrate the efficacy and effectiveness of 'best practice' PT in PD."

The **NICE guidelines** published in June 2006³ found two subsequent studies, one with only eight participants and one concerning a form of therapy which is not mainstream in the NHS (Alexander technique). It was felt that these two studies did not change the evidence-base. NICE recommended:

"PT should be available for people with PD. Particular consideration should be given to:

- Gait re-education, improvement of balance and flexibility

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- Enhancement of aerobic capacity
- Improvement of movement initiation
- Improvement of functional independence, including mobility and ADL
- Provision of advice regarding safety in the home environment.”

However, in view of the poor evidence-base, NICE went on to recommend that a pragmatic trial of PT in PD should be performed.³

Since the **NICE guidelines** were published, the results of a further UK-based PT trial in 142 PD patients have become available.⁴ This study reported a "trend" to fewer falls 6 months after a community-based exercise programme (5% relative risk reduction; $p=0.6$). Exercise had a significant positive effect at 6 months on functional reach (95% CI 0.5, 3.5; $p=0.009$) and quality of life (EuroQol thermometer 95% CI 0.47, 11.0; $p=0.03$).

Best practice

PT Evaluation Project (PEP) used the Delphi method and case studies to document best PT practice in the NHS for PD patients.⁵ It was recommended that PT be used to help with patients' core problems of gait, balance, posture and transfers. It was perceived that PD patients were often referred for therapy too late. Service delivery was comprised of a course of 6-8 weeks with once or twice weekly contact. Therapy can be administered individually or in group sessions, but home assessment by either a physiotherapist or an occupational therapist is crucial. The details of the interventions should be recorded and the results of treatment monitored by the therapist. Carers must be involved with treatment throughout. It was acknowledged that these recommendations need to be tested in clinical trials.

2.2.2 Occupational therapy

Efficacy and cost effectiveness

The **Cochrane review** of OT for PD was updated in 2007.⁶ However, this still found only two RCTs in 84 patients. Both trials reported a positive effect from OT, but the improvements were small. The review concluded that: "Considering the significant methodological flaws in the studies, the small number of patients examined, and the possibility of publication bias, there is insufficient evidence to support or refute the efficacy of OT in PD." It went on to suggest that: "We now require large well designed placebo-controlled RCTs to demonstrate occupational therapy's effectiveness in PD. Outcome measures with particular relevance to patients, carers, occupational therapists and physicians should be chosen and the patients monitored for at least six months to determine the duration of benefit."

The **NICE guidelines** agreed that the evidence base for OT in PD was poor, but opinion leader evidence supported its use leading to the following recommendation:

"OT should be available for people with PD. Particular consideration should be given to:

- Maintenance of work and family roles, home care and leisure activities
- Improvement and maintenance of transfers and mobility
- Improvement of personal self-care activities such as eating, drinking, washing and dressing
- Environmental issues to improve safety and motor function
- Cognitive assessment and appropriate intervention."

Since the NICE guidelines were published, the results from a pilot study (PD OT) of OT versus no therapy have been reported.⁷ PD OT recruited 39 patients over 16 months. The trial found no effect of OT on NEADL, PDQ 39, or EuroQol, though it was a pilot study so was not powered to detect differences between the treatment arms..

Best practice

There have been two **surveys of current and best practice** OT in PD.^{8,9} The current practice survey questionnaire regarding demographics, service organisation and therapy content was

posted to 242 occupational therapists who treat PD.⁸ 169 therapists (70%) responded. They had worked with PD for a median of 6 years and personally treated a median of 15 patients annually. Most (86%) were senior grade or above; 85% worked in the NHS and 12% in social services. 40% worked in specialist PD clinics. Most (79%) felt they needed more specialist postgraduate training. It was concluded that occupational therapists are employed in both health and social care settings. The character of the OT is often determined by the location in which it is provided. Current OT focuses on functional activities rather than on the wider social and psychological aspects of occupation. The Delphi survey was posted to 242 occupational therapists who treated PD.⁹ It contained statements about best practice and asked therapists to indicate their level of agreement with each statement. Respondents re-rated their answers in a second mailing, and gave their opinion on the efficacy of various interventions. 150 therapists (62%) completed both rounds. 99% of the respondents agreed that PD requires lifelong provision of OT, within multidisciplinary teams, and that the social and psychological aspects of the disease are as important as the physical ones. Therapists had confidence in many techniques for achieving physical, social and psychological goals. However, 40% of respondents could not rate the efficacy of social and psychological techniques due to lack of knowledge. It was concluded that there is a high level of consensus nationally on the character of best practice OT for PD. The survey highlighted a need for more postgraduate training, especially in psychological techniques.

2.2.3 Summary of existing research

In spite of NICE recommending the availability of OT and PT for PD, the evidence for the clinical and cost-effectiveness and safety of both interventions is poor. Cochrane reviews and the NICE guidelines support the need for trials of OT and PT in PD to establish their clinical and cost-effectiveness.

3 Trial design and procedures

PD REHAB is a large, pragmatic, multicentre, randomised, controlled trial of combined OT and PT versus no therapy in patients with PD.

The trial will recruit a wide range of patients with self-reported limitations in ADL which will allow the evaluation of the effectiveness of these therapies across a range of disabilities from those with mild deficits through to those with more severe problems.

3.1 Entry criteria

3.1.1 Inclusion criteria

The inclusion criteria are deliberately broad to allow the inclusion of a wide spectrum of typical PD patients and to simplify trial procedures. If an investigator is certain that a patient is likely to benefit from OT or PT during the 15 months of the trial or is unlikely to benefit from these therapies, then the patient is not eligible for randomisation into the trial. If, however, the investigator is uncertain whether a patient would benefit or not from therapy, then they are eligible for randomisation.

Patients are eligible if they:

1. Have idiopathic PD defined by the UK PDS Brain Bank Criteria (Appendix 1).¹⁰ These criteria are in standard use throughout the NHS in the UK and supported by the NICE guidelines.
2. Report limitations in ADL.
3. The investigator is uncertain that the patient will require OT and/or PT during the 15 months of the trial.

3.1.2 Exclusion criteria

1. Dementia as usually defined clinically by the patient's physician.
2. Received OT or PT in the last one year. These figures are derived from work on the carry-over effects of these therapies in stroke^{11,12} and from the PD REHAB specialist group's expertise. There are no comparable data in PD.

3.2 Consent

Prospective patients and their carers will be given a full explanation of the trial by the neurologist, nurse or geriatrician who usually looks after their care. This will include discussion of the treatment options in the trial and the manner of treatment allocation. They will be given a patient information sheet (Appendix 2) or carer information sheet (Appendix 3) to read and sufficient time to decide whether they would like to join the trial. They will then be asked to sign consent forms (Appendix 4 & 5). The patient's general practitioner will be informed in writing of the patient's participation in the trial with the patient's consent (Appendix 6).

Although the initial trial procedures will vary from unit to unit, it is likely that research nurses from DeNDRoN or the Comprehensive Local Research Networks (CLRN) will assist in these processes as shown in Appendix 7.

3.3 Baseline assessments

Prior to randomisation, patients and the clinician will fill out a series of questionnaires (see Table 1) including:

Clinician rated:

1. **Hoehn and Yahr stage** at entry (Appendix 8). This standard staging scale for PD is required to document the severity of PD in the patient population.
2. **Current medication** (on Randomisation Notepad; Appendix 9).

Patient rated:

1. Instrumental activities of daily living measured using the **Nottingham Extended Activities of Daily Living scale** (NEADL; Appendix 11). NEADL specifically assesses aspects of patient function to which OT and PT are directed. NEADL was originally developed for stroke trials, but is now more widely used as a generic outcome measure, such as in intervention studies for older people with general frailty and in those with specific problems (e.g. visual impairment and respiratory disease).
2. Health-related quality of life using the **Parkinson's Disease Questionnaire 39** (PDQ-39; Appendix 12). PDQ-39 is now the most widely used disease-specific quality of life rating scale for PD. It has been fully validated.
3. Cost-effectiveness quality of life using the **EuroQol-5D** (EQ-5D; Appendix 13) and specifically designed resource usage form (Appendix 19; not collected at baseline). The EQ-5D is a well established measure used together with resource usage questionnaires to provide data for the cost-effectiveness analysis.
4. Carer quality of life (**Short Form 12**; SF-12; Appendix 14). There are not disease-specific measures of quality of life for carers of patients with PD, so this well established and validated measure of health status will be used.

Table 1 Assessment schedule

Measure	Completed by	Assessment time			
		Baseline	3 months	9 months	15 months
Hoehn and Yahr stage	Clinician	✓			
Medication	Clinician	✓			✓
NEADL	<i>Patient</i>	✓	✓	✓	✓
PDQ 39	<i>Patient</i>	✓	✓	✓	✓
EuroQol EQ 5D	<i>Patient</i>	✓	✓	✓	✓
Resource use questionnaire	<i>Patient</i>		✓	✓	✓
Carer SF 12	Carer	✓	✓	✓	✓

Short lay summaries of each of the patient rated assessment tools will be available for patients and carers (developed by Dr Herron-Marx of the Patient/Public Virtual Advisory group).

3.4 Randomisation

Patients will be randomised between the two groups (50:50) via the University of Birmingham Clinical Trials Unit on-line randomisation service (Appendix 9). This secure internet-based central randomisation service is available 24 hours a day and will ensure concealment of treatment allocation. Randomisation will use a computer-based algorithm with minimisation by baseline NEADL score (severe 0 to 21 / moderate 22 to 43 / mild 44 to 66 categories), Hoehn & Yahr score (≤ 2 ; 2.5; 3 and ≥ 4) and age (< 60 ; 60-69; 70-79; ≥ 80 years) to ensure balance of patients with differing levels of disability between the two arms of the trial. Informed consent must be obtained before randomisation is performed.

Clinicians should be aware of the availability of OT and PT before recruiting participants into the trial in order to minimise delay between randomisation and the start of treatment. Ideally all

participants randomised to combined OT and PT should have their initial session within 4 weeks of randomisations.

3.5 Interventions

The trial will provide community-based OT and PT in at least 40 elderly care and neurology units throughout the UK to reflect population diversity.

3.5.1 Treatment arm

PT and OT will be delivered in the community by trained therapists. The framework for the content of the therapy has been developed and has been agreed by expert groups based on previous work on standard NHS OT and PT and European guidelines. It will meet the requirements of patient-centred care as therapists will work towards the patients agreed goals within the framework. In that way therapy will be tailored to the individual patient's requirements.

Two 'expert' groups have reviewed NHS and European guidelines with the help of service users and agreed a 'menu' of activities and interventions that reflect the domiciliary setting of the trial and UK resources. The expert OT group included: Professor Walker (Professor in Stroke Rehabilitation and Associate Director UK Stroke Research Network; Nottingham), Ms Ana Aragon (Senior Occupational Therapist, Bath), Ms Angela Birleson (Senior Occupational Therapist, Teeside), Ms Vicky Kelly (Senior Occupational Therapist, St Helens). The expert PT group included: Victoria Goodwin (chair of group; Chair of the national PT special interest group, AGILE), Charlie Winwood (deputy chair; Clinical specialist in neurology, ACPIN representative), Professor Sackley (Professor in Primary Care Clinical Sciences; Birmingham). Professor Bas Bloem (Neurologist, University of Nijmegen) has agreed to the use of the European OT and PT practice guidelines developed by his group. Each expert group has consulted with patient/carer representatives through Dr Herron-Marx.

Trial therapists will have a spectrum of experience in treating PD, from those with little to those with considerable expertise. Therefore, an 'update' training day for therapists will be provided as they join the trial to ensure some uniformity of practice across the country. These will be held in Birmingham and other larger centres and will be run by a team of therapists with experience in treating PD. Four such courses will take place to account for units joining the trial over 6 to 12 months. Professional networks led by Professors Sackley and Walker are available for the less experienced therapists, so they will have ready access to advice during the course of the trial.

Treatment will be delivered to each patient through up to eight visits by both the occupational therapist and physiotherapist, in line with standard NHS practice as documented in the PT Evaluation Project and our survey of OT services in the UK. The OT and PT administered will be recorded in detail by the therapists concerned using the data acquisition forms which have been used in previous community-based trials and were piloted in the PD OT trial (Appendix 15 & 16).

3.5.2 Control arm

The control patients will consent to have OT and PT deferred until the end of their 15 months participation in the trial. Since there is insufficient evidence to prove or disprove the benefit of OT and PT in PD, equipoise still exists. Therefore, it is ethical to randomise between immediate versus no therapy.

Investigators should, however, remain vigilant throughout the 15 months of the trial for control group patients who have deteriorated to the point of needing therapy. Should this occur, OT and/or PT should be provided without delay by the usual local NHS services. This mechanism will act as a safety net for the control group patients.

Patients will be encouraged to be fully compliant with their randomised treatment allocation, however, some may have one or both therapies arranged by health or social care providers not associated with the trial (e.g. social services). Since this may lead to a dilution of the intervention effect, at each assessment, control arm patients will be asked whether they have received therapy.

At the end of their participation in the trial, patients in the control arm can be referred for therapy by their usual specialist through local NHS referral pathways.

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The Patient/Public Advisory Group will (informed by the findings of the study) develop Top Tips leaflets which will be provided to each of the participants at the end of the trial. These leaflets will also be disseminated throughout the PD community via existing dissemination channels (see section 7.1).

3.6 Outcome measures

3.6.1 Timing of assessments

Assessments will be made before randomisation, at 3 months (i.e. after treatment if in the OT/PT arm), 9 and 15 months after trial entry. Assessments at 3, 9 and 15 months will be obtained by post.

3.6.2 Primary outcome measure

NEADL has been shown to be sensitive to change in trials of OT^{12,14} and was successfully used in the recent pilot study of OT for PD.⁷ The PD OT pilot trial showed that there was a strong correlation between NEADL and the disease-specific Unified Parkinson's Disease Rating Scale (UPDRS) ADL subscale.

3.6.3 Secondary outcome measures

Patient quality of life using PDQ-39, cost effectiveness using EQ-5D and resource utilization questionnaire (Appendix 19) and carer quality of life using SF-12. The patient resource utilisation questionnaire is being used in the PD MED trial and was piloted successfully in the PD OT trial and will be used to assess cost-effectiveness together with information about current medication on the exit form (Appendix 21).

3.7 Adverse events and reactions

A risk assessment of the PD REHAB trial has been performed with the OT and PT interventions considered to be of low risk. There may be a small increased risk of falling as a result of OT and/or PT and this small risk is stated clearly in the patient information sheet. Every effort will be made to minimise the risk of falls through training the patient and the therapists. We do not expect any other risks of taking part in the study.

Therefore, it is reasonable to collect only targeted treatment-related adverse events and serious adverse events such as 'falls or equipment failure leading to injury requiring a hospital or GP visit'. Since the participants may not routinely see their local investigator, these will be initially reported by patients on the resource usage form (Appendix 19). On receipt of information that a patient has been hospitalised or seen a GP due to a fall or equipment failure, a request will be sent from BCTU for an adverse event / serious adverse event form (Appendix 20) to be completed by the relevant investigator (forms can also be downloaded from the PD REHAB website).

4 Sample size and recruitment

4.1 Sample size

Although definitive data are not available, it is thought that a minimally clinically relevant change in NEADL is 1 to 2 points.¹⁴ Such a *minimal* change may be of only a small benefit to patients, a *clinically meaningful* change in NEADL is likely to be around double this at 2.5 points. A change of 2 points on the NEADL would represent becoming independent in one item (e.g. stair climbing, crossing roads or feeding oneself) or improvement in 2 items (e.g. being dependent on another person with help to being fully independent).

To detect a 2.5 point difference in NEADL at 3 months (using the observed SD from PD OT of 10.1; $p < 0.05$ two tailed; 90% power) requires 340 patients in each arm: 750 participants (375 per arm) to allow for 10% non-compliance and drop out.

Although the primary outcome is NEADL, a sample size calculation for PDQ-39 was also performed. It has been established that a minimally clinically relevant change in PDQ-39 Summary

Score is 1.6 points.¹⁵ Again, such a *minimal* change may be of only a small benefit to patients, so a *clinically meaningful* change in PDQ-39 is considered to be around double this at 3.5 points.

To detect a 3.5 point difference in PDQ-39 Summary Score at 3 months (SD from PD OT 13.5; $p < 0.05$ two tailed; 90% power) requires about 310 patients in each arm (620 participants in total).

4.2 Recruitment

In May 2007, a **questionnaire** was sent to 176 investigators in the PD MED trial to gauge interest in PD REHAB and to identify potential sites. Of the 51 replies, 45% were 'very interested' in the proposed trial and 39% had some interest (total of 43 centres). Respondents most commonly felt that they could randomise 6-10 patients per annum. Extrapolating this to 40 sites, 750 participants will be randomised within 36 months, Responders commented that financial support will be required for additional therapy services.

To commence recruitment as soon as possible, 10 '**start-up**' sites have been identified for the trial which are anticipated will recruit large numbers of patients to PD REHAB based on their support for the PD MED trial.

Large pragmatic trials such as PD REHAB also require a large number of **smaller centres** to recruit smaller numbers of patients than the 'start-up' centres. From a questionnaire to PD MED investigators, 43 centres have indicated interest in the trial. More centres will be found by circulating information about the study to all members of the Association of British Neurologists, the British and Irish Neurologists' Movement Disorders Group, and the British Geriatrics Society Movement Disorders Section.

5 Analysis

The primary analysis will be the response in the NEADL scale in the treatment arm at the 3 month evaluation (immediately after the intervention) compared with that in the no treatment arm. An independent 2-sample t-test will be used to compare changes from baseline in the NEADL score between the two treatment groups. To examine whether there is any longer-term effect or whether any benefit of treatment persists beyond the initial intervention period, the treatments will also be compared at 9 and 15 months post-randomisation, using a repeated measures analysis across all time points. A similar analysis will be performed for the quality of life secondary outcome measure using the PDQ-39. All analyses will be intention-to-treat, whereby patients will be analysed according to the intervention to which they were randomised regardless of whether they complied with this treatment. Missing data will be imputed using established methods with appropriate sensitivity analysis.

The only planned subgroup analyses will be to compare the effect of combined PT and OT at different levels of ADL disability (analysis stratified by the patient's baseline NEADL score: severe 0 to 21; moderate 22 to 43; and mild 44 to 66 and Hoehn & Yahr score: ≤ 2 ; 2.5; 3 and ≥ 4) and age (< 60 ; 60 to 69; 70 to 79; ≥ 80 years) However, as with all subgroup analyses, these results will be interpreted cautiously.

6 Health economics analysis

The economic analysis will be conducted alongside the trial by prospectively collecting resource use data as an integral part of the study. The main resources to be monitored include: use of therapy services, primary care consultations, use of drugs, use of secondary care services, and patient costs, including time costs. Data will be collected using a patient-completed resource utilisation questionnaire which was piloted in the PD OT trial (Appendix 20).⁷ Information on unit costs or prices will then be attached to each resource item so that an overall cost per patient can be calculated. Such data will be collected from relevant routine sources,¹⁶ NHS reference costs and hospital finance departments.

The data available for this analysis will be patient-specific resource use and costs, and patient-specific outcome and quality of life data. An incremental economic analysis will be conducted. The base-case analysis will be framed in terms of cost-consequences, reporting data in a

disaggregated manner on the incremental cost, and the important consequences (including data on quality of life, etc). If this convincingly identifies a situation of dominance (i.e. one arm is associated with both better outcomes and a lower cost) then further analysis will not be required. If no dominance is found then cost-utility analysis (i.e. cost per quality-adjusted life year; QALY) will be employed over a 15 month time frame (as the follow-up interval in the trial). QALYs will be calculated using EQ-5D data. The EQ-5D is a widely-used brief generic utility-based measure of health-related quality of life which is designed to be self-completed. Missing data due to non-completion of self-report questionnaires may be a problem for the economic analysis. If this turns out to be the case, then imputation will be employed using multiple imputation methods.

The economic analysis results will be presented using cost-effectiveness acceptability curves to reflect sampling variation and uncertainties in the appropriate threshold cost-effectiveness value. Both simple and probabilistic sensitivity analyses will be used to explore the robustness of these results to plausible variations in key assumptions and variations in the analytical methods used, and to consider the broader issue of the generalisability of the results in other centres and settings.

7 Research governance

The conduct of the trial will be in accordance with the Medical Research Council (MRC) Guidelines for Good Clinical Practice 1998 and the Research Governance Framework for Health and Social Care (Second Edition; 2005). Patients/carers will be involved in the ethics process, ensuring that all participant information sheets and consent forms are fit for purpose.

7.1 Ethics

PD REHAB has NRES approval. The trial will be submitted for Site Specific Approval (SSA) and local Research and Development Department (R & D) approval at every centre.

7.2 Sponsor

The University of Birmingham has agreed to sponsor the trial.

7.3 Trial Steering Committee (TSC)

Professor David Burn (Neurologist, University of Newcastle) is the independent chair of the TSC, one geriatrician and one OT/PT with an interest in PD who are not participating in the trial have agreed to be the other two independent members (Drs Douglas MacMahon & Helen Dawes), along with two Principal Investigators (Drs Tim Malone and Diane Playford), two patient representatives and Dr Kieran Breen (Director of Research and Development, Parkinson's Disease Society). Observers from the HTA programme will be invited to TSC meetings.

7.4 Data Monitoring Committee (DMC)

Professor Gert Kwakkel (Physiotherapist, University of Amsterdam) is the independent chair of the DMEC. The committee also comprises an experienced trial statistician, a geriatrician with an interest in PD who is not participating in the trial and a neurologist with an interest in PD who is not participating in the trial (Drs Louise Hiller, Guy Sawle and Professor John Gladman).

7.5 Confidentiality of personal data

This trial will collect personal data about participants. Participants will be informed about the transfer of this information to the trial office at the University of Birmingham Clinical Trials Unit, and will be asked to consent to this. The data will be entered onto a secure computer database. Any data to be processed outside the Birmingham Clinical Trials Unit will be anonymised. All personal information obtained for the study will be held securely and treated as strictly confidential.

7.6 Long term storage of data

In line with MRC guidelines, all data will be stored for at least 20 years after the last patient has completed follow-up to allow adequate time for review, reappraisal or further research, and to allow any queries or concerns about the data, conduct or conclusions of the study to be resolved.

8 Organisation

8.1 Service users

Patient and carer involvement will be incorporated at all levels of this trial. A representative from the Parkinson Disease Society (Ms Patel) has already been involved in the design of the study and is an active member of the trial management committee. Patient and carer involvement will not be a stand-alone activity, but an integral part of all stages of the trial. Patients and carers will be directly involved as research 'partners' and not just as 'data providers' (using the INVOLVE guidance). 'Patient researchers' (as well as further patient/carers management committee members) will be identified through the PDS and appropriate training will be offered to enable patients and carers to be involved as equal partners. All support for patient and carer involvement will be provided by Sonal Shah who has experience in training and supporting patients for involvement in NHS research, service evaluation and development. A 'virtual' e-facilitated (by Sonal Shah) patient advisory group will be set up drawing nationally from the PD patient and carer population to further support the work in the trial.

Direct patient/carers involvement will support:

- Recruitment and consent - they will contribute to the development of participant information sheets and where possible will act as a patient contact for the project
- Data gathering – through developing patient information leaflets explaining the survey tools
- Interpretation of findings – through the development of recommendations for practice and patient information leaflets (top-tip leaflets) about therapy choices
- Dissemination of the findings through existing networks.

A wider patient/carers audience will also be consulted about the findings and recommendations drawn from the project. This will happen through the PDS and will be facilitated by Sonal Shah. Integrating patient/carers involvement in all stages of the trial and through further consultation with a wider audience of patients/carers will provide a partnership with patients and carers that is critical in ensuring that the evidence generated and the recommendations made for service development is underpinned by the patient/carers voice.

Service user involvement in the trial will be evaluated from a multi-stakeholder perspective. This will be done using a conversation café approach and facilitated by an 'external' service user researcher. The findings will be used to inform future involvement of service users in clinical trials and to derive further supportive mechanism for translating research knowledge into clinical practice.

8.2 Network support

This trial is supported by DeNDRoN, the PDS and the DeNDRoN PD Clinical Studies Group.

8.3 Local centre organisation

8.3.1 Training

Four **training days** will be held in Birmingham and other large centres depending on the location of investigator sites. We have assumed that one occupational therapist and one physiotherapist will require training for each of the 40 or more sites.

8.3.2 Funding

There will be **excess NHS service support costs** in identifying, informing and consenting eligible patients, gathering clinical information and organising therapy appointments. The NHS has agreed to fund these costs through its usual funding streams.

A separate budget has been provided for **aids and adaptations** to ensure that the intervention is delivered in a timely fashion. Experience in the NHS and with PD OT shows that social services departments cannot always deliver aids and adaptations as quickly as they are required.¹⁷ Under this heading we have also included provision for software to produce high quality exercise reminder printouts.

8.3.3 Meetings

Annual **collaborators' meetings** will be held to stimulate interest in the study and iron out any problems with the protocol, then to maintain recruitment and finally present the results of the trial.

8.3.4 Staffing

Each centre will nominate one clinician to act as **Principal Investigator**. He/she will be responsible for securing ethical and Research and Development Department approval for the trial and dealing with any governance issues throughout the study. They will make arrangements with their hospital and/or primary care trust managers to provide OT and PT facilities for PD REHAB.

Each centre will develop its own model for providing the two **therapists** required to deliver the trial intervention. However, these therapists are likely to be drawn from existing staff, so they will have experience in working with people with PD. This experience will be supplemented by the training day provided before the trial starts in each centre.

9 Project timetable and milestones

Six months have been set aside to recruit and train staff, to identify patients/carers for the involvement group, to gain NRES, SSA and R & D department approvals, to set up trial procedures, and for staggered entry of each investigator. With 36 months recruitment, 15 months to follow the last patient, and 3 months for data analysis, the trial will take 60 months to complete.

Table 2 PD REHAB timetable

Time	Action
September 2008	NRES application for trial submitted
December 2008	NRES approval obtained and protocol published
January 2009	Trial officially commences with HTA Trial Manager and Data Manager commence
February 2009 onwards	Applications for SSA and R & D approval submitted
May 2009	Trial launch meeting with collaborators (#1)
July 2009	Recruitment commences in 'start up' centres
January 2010	All 40+ centres recruited
May 2010	Collaborators' meeting (#2)
July 2010	All centres recruiting
May 2011	Collaborators' meeting (#3)
July 2012	Recruitment completed
October 2012	Last patient completes treatment
October 2013	Last patient completes 15 month follow up Data analysis commences
December 2013	Results available HTA report written Paper submitted for publication Final collaborators' meeting (#4)

10 References

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11 Appendices

Appendix 1 United Kingdom Parkinson's Disease Society Brain Bank Diagnostic Criteria

STEP 1 Diagnosis of Parkinsonian syndrome:

Bradykinesia (slowness of initiation of voluntary movement with progressive reduction in speed and amplitude of repetitive actions) and at least one of the following:

- a) Muscular rigidity
- b) 4-6 Hz rest tremor
- c) Postural instability not caused by primary visual, vestibular, cerebellar or proprioceptive dysfunction.

STEP 2 Exclusion criteria for Parkinson's disease:

History of repeated strokes with stepwise progression of Parkinsonian features
 History of repeated head injury
 History of definite encephalitis
 Oculogyric crises
 Neuroleptic treatment at onset of symptoms
 More than one affected relative
 Sustained remission
 Strictly unilateral features after three years
 Supranuclear gaze palsy
 Cerebellar signs
 Early severe autonomic involvement
 Early severe dementia with disturbances of memory, language and praxis
 Babinski sign (Plantar Reflex)
 Presence of a cerebral tumour or communicating hydrocephalus on CT scan
 Negative response to large doses of levodopa (if malabsorption excluded)
 MPTP exposure

STEP 3 Supportive prospective positive criteria for Parkinson's disease; three or more required for diagnosis of definite Parkinson's disease:

Unilateral onset
 Rest tremor present
 Progressive disorder
 Persistent asymmetry affecting the side of onset most
 Excellent response (70-100%) to levodopa
 Severe levodopa-induced chorea
 Levodopa response for 5 years or more
 Clinical course of 10 years or more

From: Gibb WRG, Lees AJ. The relevance of the Lewy body to the pathogenesis of idiopathic Parkinson's disease. Journal of Neurology Neurosurgery and Psychiatry 1988; 51: 745-752.

Appendix 2 Patient Information Sheet

{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

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 as to 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 June2010

11th June 2010

Appendix 3 Carer Information Sheet

{Carer 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)**

Carer 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

11th June 2010

CARER 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 as to 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 trial will include 750 patients with Parkinson's disease and their carers at over 40 centres throughout the United Kingdom.

We are asking you to take part in the study because you are the main carer for someone with Parkinson's disease who has been asked to take part in the PD REHAB trial.

Do I have to take part?

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. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care the person you care for will receive.

What will happen to me if I take part?

We want to find out whether giving the patient you care for occupational therapy and physiotherapy affects your own quality of life. We will do this by asking you to fill in a quality of life questionnaire before the trial begins, then we will post the same questionnaire to you 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 the participant.

What are the possible disadvantages and risks of taking part?

We do not anticipate any disadvantages or risks in taking part.

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 PD better.

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.

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.

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.

The study has been approved by National and Local Research Ethics Committees.

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

11th June 2010

Appendix 4 Patient Consent Form**Patient Consent Form****RANDOMISED CONTROLLED TRIAL TO ASSESS THE CLINICAL- AND
COST EFFECTIVENESS OF PHYSIOTHERAPY AND OCCUPATIONAL
THERAPY IN PARKINSON'S DISEASE (PD Rehab)**

Please initial box

1. I confirm that I have read and understand the information sheet dated 11th June2010 (Version 9) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without the quality of my medical care or legal rights being affected. ☐
3. I understand that sections of any of my medical notes may be looked at by responsible individuals running the trial or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐
4. I agree to take part in the above study. ☐
5. I give consent to my GP being informed about my participation in this study. (optional) ☐

Name of patient	Date	Signature

Name of person informing patient	Date	Signature

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

1 for patient; 1 for BCTU; 1 to be kept with hospital notes; 1 for site file

Version 9, 11th June2010

11th June 2010

Appendix 5 Carer Consent Form**Carer Consent Form****RANDOMISED CONTROLLED TRIAL TO ASSESS THE CLINICAL- AND
COST EFFECTIVENESS OF PHYSIOTHERAPY AND OCCUPATIONAL
THERAPY IN PARKINSON'S DISEASE**

Please initial box

1. I confirm that I have read and understand the information sheet dated 11th June 2010 (Version 9) for the above study and have had the opportunity to ask questions.

☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.

☐

3. I agree to take part in the above study.

☐

Name of Carer

Date

Signature

Name of person informing Carer

Date

Signature

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

1 for Carer; 1 for BCTU; 1 to be kept with hospital notes; 1 for site file

Version 9, 11th June 2010

11th June 2010

Appendix 6 General Practitioner Letter

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

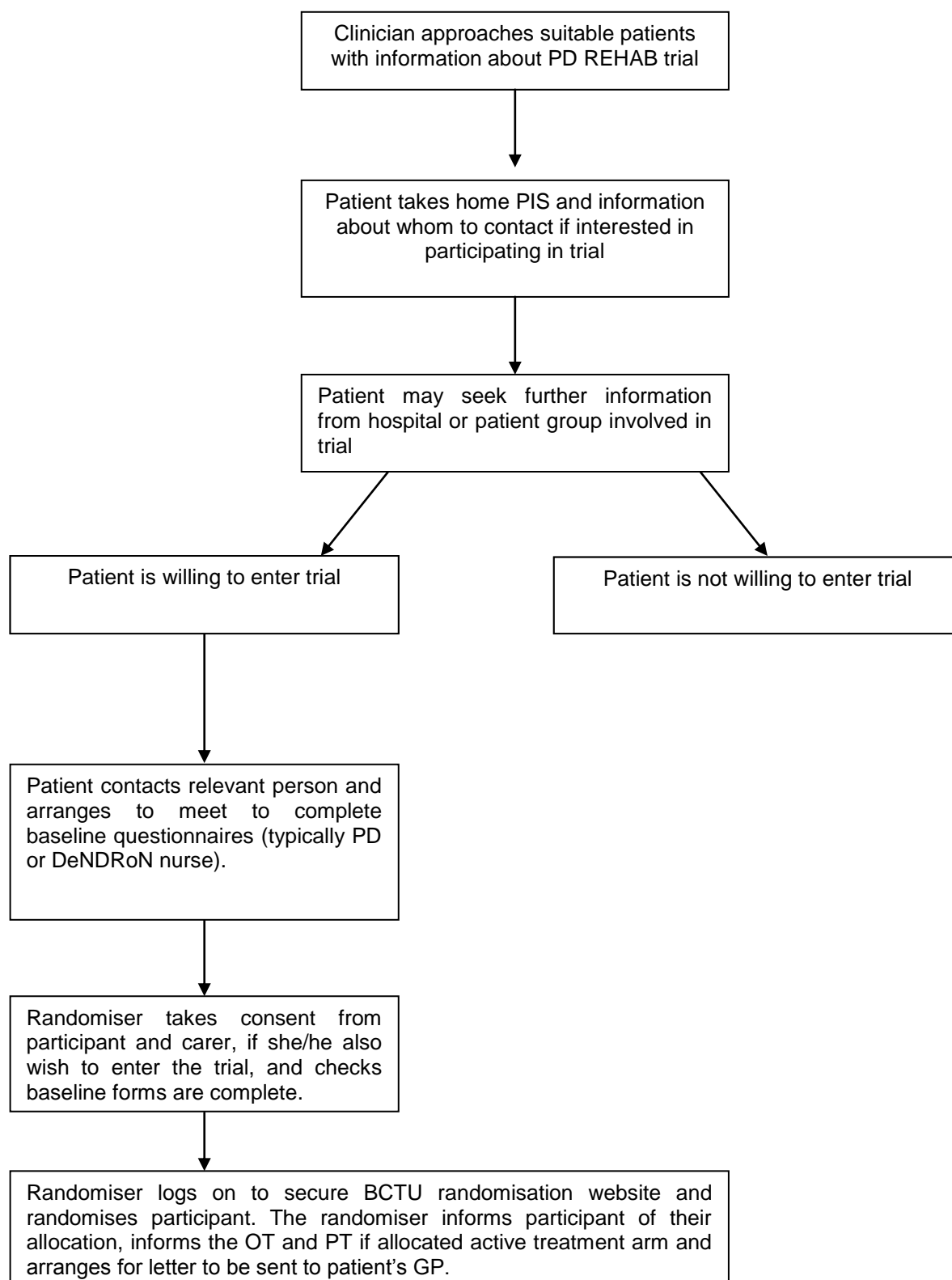
{University of Birmingham Clinical Trials Unit contact details}

Version 9, 11th June 2010

11th June 2010

Appendix 7 Flow Diagram of Randomisation Process

Clinicians should be aware of availability of OT and PT before recruiting participants into the trial to minimise delay between randomisation and start of treatment: ideally all participants randomised to OT and PT should have initial session within 4 weeks of randomisation



Appendix 8 Hoehn and Yahr Stage

Stage 1.0	Unilateral involvement only
Stage 1.5	Unilateral and axial involvement
Stage 2.0	Bilateral involvement without impairment of balance
Stage 2.5	Mild bilateral involvement with recovery on retropulsion (pull) test
Stage 3.0	Mild to moderate bilateral involvement, some postural instability but physically independent
Stage 4.0	Severe disability, still able to walk and to stand unassisted
Stage 5.0	Wheelchair bound or bedridden unless aided.

Appendix 9 Patient Baseline Data at Randomisation**PD REHAB PATIENT Randomisation FORM****Part A: Identifying Details**

Patient's full name:	Sex: Male <input type="checkbox"/> Female <input type="checkbox"/>
Date of birth: / /	Hospital number:
Responsible clinician:	Hospital:
Patient's address:	NHS number
	Patient's telephone number:

Part B: Inclusion/Exclusion Criteria

Patient has idiopathic Parkinson's disease: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Patient reports limitations in activities of daily living: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Patient has dementia: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Patient has had occupational therapy in last 1 year: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Patient has had physiotherapy in last 1 year: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Patient can be assessed and treated within 1 month: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Consent has been taken: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Baseline forms have been completed: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

If any shaded boxes are ticked, the patient is not eligible for randomisation.

Part C: Carer Information

Does the patient have a carer:

Yes ☐ No ☐

If carer has consented to join PD REHAB

Name of Carer

Date of birth: / /

Has the carer consented to join PD REHAB:

Yes ☐ No ☐

If carer has consented to join PD REHAB

Relationship to Participant

Sex: Male ☐ Female ☐

Part D: NEADL Total

Nottingham Extended ADL Index total:

Now log on to: {PD REHAB randomisation Website URL}

Part E: Trial Details

11th June 2010

Date of Randomisation: / /

PD REHAB trial number:.....

Treatment Allocation

.....

Version 9, 11th June2010

Appendix 10 Entry Form**Identifying Details**

Patient's full name:	Patient Trial Number:
Date of birth: / /	Hospital number:

Medical Details

Date of PD Diagnosis: Month: Year:	
Weight:	Unit of Measure: Kg/St (delete as appropriate)
Height:	Unit of Measure: Ft/M (delete as appropriate)
Current Medication	
Levodopa? No <input type="checkbox"/> Yes <input type="checkbox"/> If yes , which?..... Daily dose (mg)?..... Eg 1 Sinemet 125 tablet = 100mg daily dose (levodopa)	
Dopamine Agonist? No <input type="checkbox"/> Yes <input type="checkbox"/> If yes , which?..... Daily dose (mg)?.....	
MAOB inhibitor? No <input type="checkbox"/> Yes <input type="checkbox"/> If yes , which?..... Daily dose (mg)?.....	
COMT inhibitor? No <input type="checkbox"/> Yes <input type="checkbox"/> If yes , which?..... Daily dose (mg)?.....	
Amantadine? No <input type="checkbox"/> Yes <input type="checkbox"/> If yes Daily dose (mg)?.....	
Apomorphine? No <input type="checkbox"/> Yes <input type="checkbox"/> If yes Daily dose (mg)?.....	
Duodopa? No <input type="checkbox"/> Yes <input type="checkbox"/> If yes Daily dose (mg)?.....	
Other PD Medication? No <input type="checkbox"/> Yes <input type="checkbox"/> If yes What medication? Daily dose (mg)?.....	

Form completed by (print name):

Signed:

Date:

11th June 2010

Appendix 11 Nottingham Extended ADL Index

Do you?	Not at all	With help	On your own with difficulty	On your own easily
1. Walk around outside?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Climb stairs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Get in and out of a car?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Walk over uneven ground?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Cross roads?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Travel on public transport?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Manage to feed yourself?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Manage to make yourself a hot drink?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Take hot drinks from one room to another?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Do the washing up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Make yourself a hot snack?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Manage your own money when you're out?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Wash small items of clothing?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Do your own housework?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Do your own shopping?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Do a full clothes wash?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Read newspapers or books?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Use the telephone?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Write letters?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Go out socially?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Manage your own garden?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Drive a car?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Appendix 12 Parkinson's Disease Questionnaire 39

Due to having Parkinson's disease, how often, during the last month have you... Please tick one box for each question.

	Never	Occasionally	Sometimes	Often	Always or cannot do at all
1. Had difficulty doing the leisure activities which you would like to do?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Had difficulty looking after your home, e.g. DIY, housework, cooking?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Had difficulty carrying bags of shopping?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Had problems walking half a mile?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Had problems walking 100 yards?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Had problems getting around the house as easily as you would like?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Had difficulty getting around in public?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Needed someone else to accompany you when you went out?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Felt frightened or worried about falling over in public?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Been confined to the house more than you would like?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Had difficulty washing yourself?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Had difficulty dressing yourself?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Had problems doing up buttons or shoelaces?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Had problems writing clearly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Had difficulty cutting up your food?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Had difficulty holding a drink without spilling it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Felt depressed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Never	Occasionally	Sometimes	Often	Always
18. Felt isolated or lonely?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Felt weepy or tearful?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Felt angry or bitter?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Felt anxious?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Felt worried about your future?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Felt you had to conceal your Parkinson's from people?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Avoided situations which involve eating or drinking in public?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Felt embarrassed in public due to having Parkinson's disease?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Felt worried by other people's reaction to you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. Had problems with your close personal relationships?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. Lacked support in the ways you need from your spouse or partner? <i>If you do not have a spouse or partner tick here</i> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. Lacked support in the ways you need from your family or close friends?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. Unexpectedly fallen asleep during the day?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. Had problems with your concentration, e.g. when reading or watching TV?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. Felt your memory was bad?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33. Had distressing dreams or hallucinations?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. Had difficulty with your speech?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35. Felt unable to communicate with people properly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Never	Occasionally	Sometimes	Often	Always
36. Felt ignored by people?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37. Had painful muscle cramps or spasms?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
38. Had aches and pains in your joints or body?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39. Felt unpleasantly hot or cold?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Completed by

Date completed

Version 9, 11th June2010

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Appendix 13 EuroQol EQ-5D

Please indicate which statement best describes your own health today. Please answer the questions by ticking one box in each group.

1. Mobility

I have no problems walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

2. Self care

I have no problems with self-care ☐

I have some problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

3. Usual activities e.g. work, study, housework, family or leisure activities

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

4. Pain/ Discomfort

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

5. Anxiety/ Depression

I am not anxious or depressed ☐

I am moderately anxious or depressed ☐

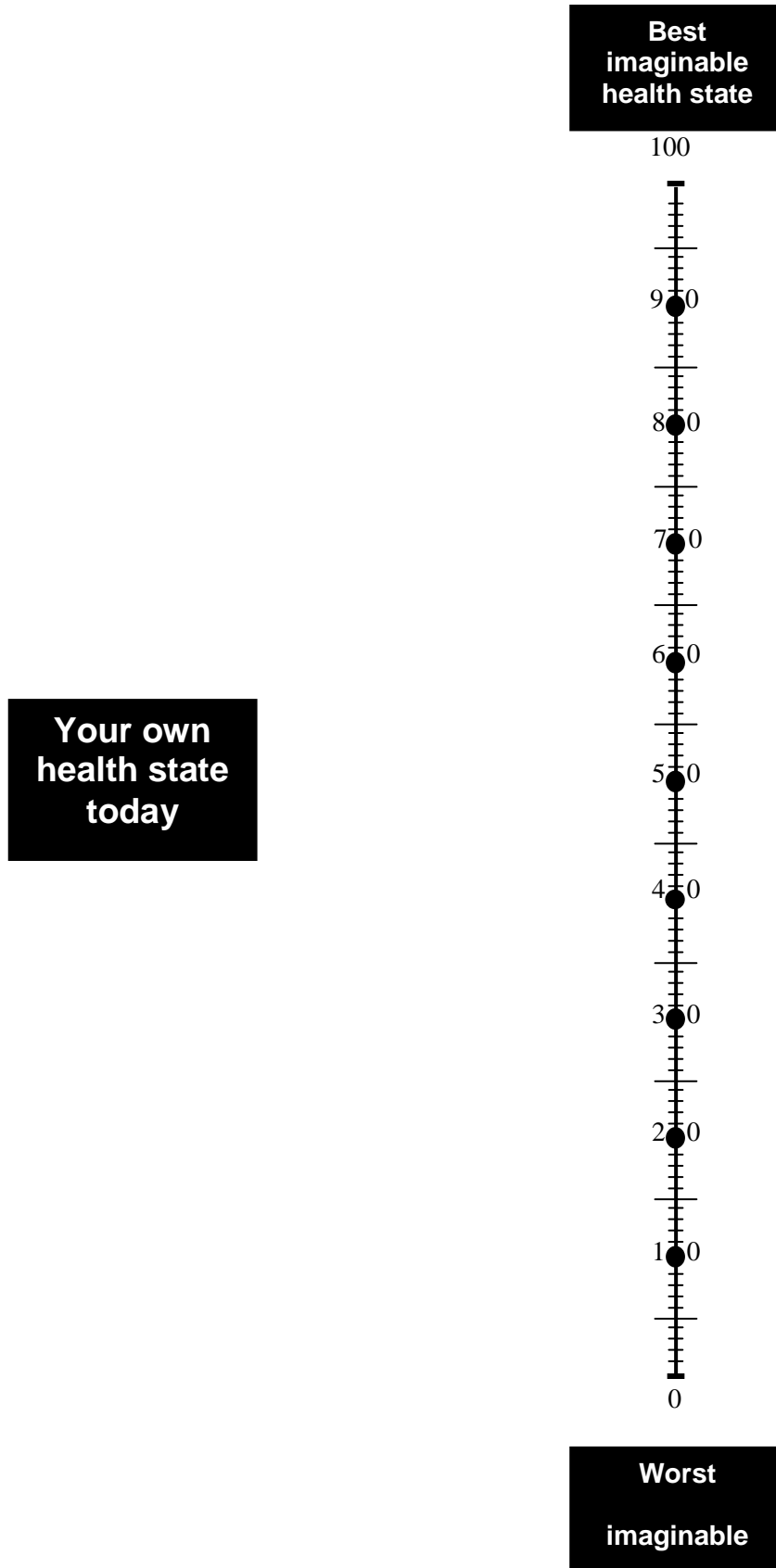
I am extremely anxious or depressed ☐

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To help people say how good or bad their health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state you could imagine is marked by 0.

We would like you to indicate on the scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box to whichever point on the scale indicates how good or bad your current health state is.



Appendix 14 Carer Short Form 12 version 2

Carer's full name:

Relationship to patient:

SF-12

Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey!

For each of the following questions, please tick the one box that best describes your answer.

1. **In general**, would you say your health is (*please tick **one** box*)

Excellent

Very good

Good

Fair

Poor

☐☐☐☐☐

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much

**Yes,
limited
a lot**

**Yes,
limited a
little**

**No, not
limited
at all**

a) Moderate activities, such as

moving a table, pushing a

☐☐☐

vacuum cleaner, bowling or playing golf

b) Climbing **several** flights of stairs

☐☐☐

3. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

**All
of the
time** **Most
of the
time** **A good
bit of
the time** **Some
of the
time** **A little
of the
time** **None
of the
time**

a) **Accomplished less** than you would like

☐☐☐☐☐

b) Were limited in the **kind** of work or other activities

☐☐☐☐☐

4. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)? (

All of the time Most of the time A good bit of the time Some of the time A little of the time None of the time

- a) **Accomplished less** than you would like

☐ ☐ ☐ ☐ ☐

- b) Didn't do work or other activities as **carefully** as usual

☐ ☐ ☐ ☐ ☐

5. During the **past 4 weeks** how much did **pain** interfere with your normal work (including work both outside the home and housework)?

Not at all **A little bit** Moderately **Quite a bit** Extremely

☐ ☐ ☐ ☐ ☐

6. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please indicate the one answer that comes closest to the way you have been feeling. *How much of the time during the last 4 weeks*

All of the time Most of the time A good bit of the time Some of the time A little of the time None of the time

- a) Have you felt calm and peaceful?

☐ ☐ ☐ ☐ ☐ ☐

- b) Did you have a lot of energy?

☐ ☐ ☐ ☐ ☐ ☐

- c) Have you felt downhearted and low?

☐ ☐ ☐ ☐ ☐ ☐

7. Has your **health limited your social activities** (like visiting friends or close relatives)?

All of the time Most of the time A good bit of the time Some of the time A little of the time None of the time

☐ ☐ ☐ ☐ ☐ ☐

Completed by

Date completed

Appendix 15 Occupational Therapy Initial Interview Log

PD REHAB Trial Participant	Name:	Trial No:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	DOB:	Date of Interview:				

1) INDOOR MOBILITY Prompts: <i>Turning</i> <i>Freezing</i> <i>Initiation</i> <i>Carrying items / Multi Tasking</i> <i>Stairs</i>	
2) OUTDOOR MOBILITY & TRAVEL Prompts: <i>Freezing</i> <i>Confidence</i> <i>Frequency & Destination</i> <i>Driving</i> <i>Car Transfers</i> <i>Public transport</i>	
3) FALLS Prompts: <i>When (Time of Day)</i> <i>What (Doing)</i> <i>Where</i> Strategies Alarm systems	

4) TRANSFERS Prompts: <i>Sit to Stand</i> <i>Bed Mobility</i> <i>Bathing/Showering</i> <i>Toilet (Day & Night)</i>	
5) DRESSING / GROOMING Prompts: <i>Timing</i> <i>Location/Position</i> <i>Buttons & fastenings</i>	
6) EATING / DRINKING Prompts: <i>Use of Cutlery</i> <i>Drinking</i> <i>Positioning</i> <i>Eating Out</i>	
7) ENVIRONMENTAL ISSUES Prompts: <i>Handrails</i> <i>Steps</i> <i>Banisters</i> <i>Organisation of furniture</i>	

8) HOUSEHOLD TASKS Prompts: <i>Shopping</i> <i>Handling Money</i> <i>Cooking</i> <i>House Work</i> <i>Paperwork & home management</i>	
9) COGNITIVE/EMOTIONAL Prompts: <i>Executive Functions</i> <i>Visuospatial</i> <i>Decision Making</i> <i>Depression</i> <i>Memory</i> <i>Anxiety</i> <i>Apathy</i> <i>Mood</i>	
10) COMMUNICATION Prompts: <i>Speech</i> <i>Handwriting</i> <i>Phone</i> Computer	
11) SOCIAL ACTIVITIES Prompts: <i>Frequency & Location</i>	

<p>12) SUPPORT</p> <p>Prompts:</p> <p><i>Carers</i></p> <p><i>Allowances / Benefits</i></p> <p><i>Contact with PDS</i></p>	
<p>13) SLEEPING & FATIGUE</p> <p>Prompts:</p> <p><i>Routine</i></p> <p><i>Daytime Sleeping</i></p> <p><i>Energy Levels</i></p>	
<p>14) EMPLOYMENT</p> <p>Prompts:</p> <p><i>Contract Hours</i></p> <p><i>Difficulties</i></p>	

Form Completed By:

Signed: _____

Date: _____

Appendix 16 Occupational Therapy Treatment Record Form

PD REHAB Trial Participant	Name:	Trial No:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	DOB:	Date of Assessment:				

Purpose of session – record time in minutes

One to one or group session.....

INITIAL INTERVIEW

Location of Intervention.....(DESCRIBE - for example - Pt's home / Out-patient Clinic / Pt's local shopping area / Pt's work place / Other)

	1. INDOOR MOBILITY	2. OUTDOOR MOBILITY	3. FALLS	4. TRANSFERS	5. DRESSING GROOMING	6. EATING DRINKING	7. ENVIRONMENTAL ISSUES	8. HOUSEHOLD TASKS	9. COGNITIVE EMOTIONAL	10. COMMUNICATION	11. SOCIAL ACTIVITIES	12. SUPPORT	13. SLEEPING & FATIGUE	14. EMPLOYMENT
ASSESSMENT														
GOAL SETTING														
EDUCATION														
REFERRAL														
LIAISON														
EQUIPMENT PRESCRIPTION														

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ADAPTATION PRESCRIPTION														
PRACTICE / TRAINING														
SPECIFIC TECHNIQUES														

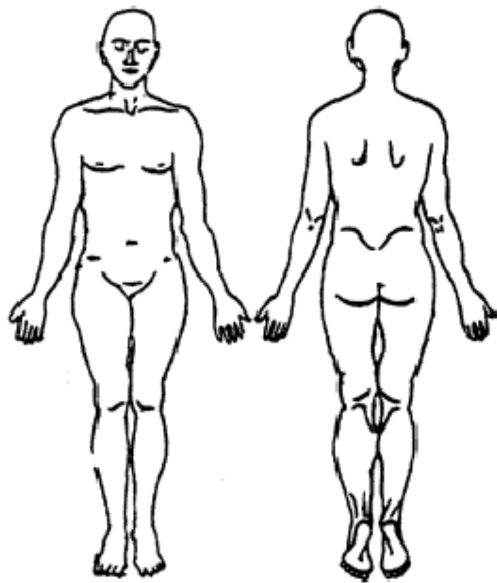
Form Completed By:

Signed:

Date:

Appendix 17 Initial Interview log

PD REHAB Trial Participant	Name:	Trial No:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	DOB:	Date of Interview:				
HISTORY	Time of Interview:	On/ Off Medication:				

**PRESENTING PROBLEM****HISTORY OF PRESENTING CONDITION**

COURSE OF DISEASE AND CURRENT STATUS

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IMPAIRMENTS IN FUNCTIONS AND ACTIVITY LIMITATIONS BODY POSTURE, TRANSFERS, BALANCE, GAIT, UPPER LIMB	
PROBLEMS WITH PARTICIPATION	
PHYSICAL ACTIVITY LEVELS	
FALLS AND RISK OF FALLS	
PD TREATMENT MEDICAL, SURGICAL, AHP	
CO-MORBIDITIES	CO-MORBIDITIES TREATMENT

SOCIAL AND FAMILY HISTORY	OTHER
EXPECTATIONS OF TREATMENT	
BODY POSTURE OBSERVATION, MEASUREMENT	
PHYSICAL CAPACITY OBSERVATION, MEASUREMENT	
TRANSFERS OBSERVATION, MEASUREMENT	

PHYSICAL EXAMINATION

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BALANCE OBSERVATION, MEASUREMENT
GAIT OBSERVATION, MEASUREMENT
UPPER LIMB OBSERVATION, MEASUREMENT

OTHER

e.g. OTHER OUTCOME MEASURES

GOAL SETTING AND TREATMENT PLANNING

Form Completed By: _____

Signed: _____

Date: _____

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Appendix 18 Physiotherapy Treatment Record Form

PD REHAB Trial Participant	Name:	Trial No: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	DOB:	Date of Assessment:

Purpose of session – record time in minutes**INITIAL INTERVIEW****One to one or group session.....****Location of Intervention.....(DESCRIBE - for example - Pt's home / Out-patient Clinic / Pt's local shopping area / Pt's work place / Other)**

	1. Gait and indoor mobility	2. Outdoor mobility	3. Balance and falls	4. Transfers	5. Posture	6. Physical Conditioning	7. Upper- Limb Function	8. Self- Care	9. Domestic ADL	10. Leisure- related activities	11. Work-related (paid and non-paid) activities	12. Other
Initial assessment												
Goal setting												
Ongoing assessment and review												
Compensatory strategies												
Cueing and cognitive strategies												
Visual, auditory (including verbal), and sensory feedback												
Strength training												
Flexibility training												
Coordination and movement control training												
Aerobic/ endurance training												
Balance training												
Functional, task-specific training												

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Education, advice and information												
Provision of aids and equipment												
Training of caregiver(s)												
Liaison												
Referral												
Other												

Assessment completed by.....
Signed.....

Date/...../.....

Appendix 19 Healthcare Usage Questionnaire

We would like to know how much use you have made of the health and social services over the last 3/6 {deleted as appropriate} months. If you are not exactly sure, we would rather have your best guess than no information at all.

Please answer every question, even if the answer is 'No'.

1 Over the last 3/ 6 {deleted as appropriate} months, if, and how many times, have you used the services of any of the following:

Type of service	No	Yes	If yes: Number of visits
a. A GP?			
At home?			
In the surgery?			
b. A practice nurse?			
At home?			
In the surgery?			
c. A Parkinson's Disease Nurse Specialist?			
d. A health visitor?			
e. A social worker?			
f. A physiotherapist?			
g. An occupational therapist?			
h. A speech or language therapist?			
i. A private practitioner such as an acupuncturist			
j. Other (please specify)			

2. Over the last 3 / 6 months, have you suffered from a fall that resulted in injury and/or medical attention?

☐ No, please go to question 3

☐ Yes, please give details:

a) Did you see your GP? No ☐ Yes ☐ How many times _____

Dates of fall (day/month/year):

1st fall _____; please give details: _____

2nd fall _____; please give details: _____

3rd fall _____; please give details: _____

b) Were you seen by Ambulance Staff? No ☐ Yes ☐ How many times _____

Dates of fall (day/month/year):

1st fall _____; please give details: _____

2nd fall _____; please give details: _____

3rd fall _____; please give details: _____

3. Over the last 3 / 6 months have you been to hospital for any reason (include falls)?

☐ No

☐ Yes, please give details:

Outpatient visit (please go to 3a) or A & E (please go to 3b); In patient (please go to 3c)

3a. Hospital outpatients

Episode*	Name of Hospital	Reason for the Appointment	Speciality of Department	Number of appointments*
1 st				
2 nd				
3 rd				

* episode means a visit or group of visits related to a particular problem. Please write down how many appointments you have had for each episode.

3b. Accident & emergency (or A&E please include visits which took place immediately before any admissions to hospital).

Episode	Name of Hospital	Reason for visits	Is this because of a fall?
1 st			
2 nd			
3 rd			

3c. Hospital Inpatient

Episode	Name of hospital	Ward Speciality	Reasons for Admission	No. of nights*
1 st				
2 nd				

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3 rd				
-----------------	--	--	--	--

**If you were treated as a day patient (day case), then please write 0 under "number of nights" Being a day patient means needing a hospital bed for tests or surgery for a half day or full day, but not needing to stay overnight.*

4a. Are you currently in paid employment?

No ☐ (please go to question 4c) Yes ☐ (please go to question 4b)

4b If yes, due to your Parkinson's disease have you had to reduce the number of hours per week you work due to your Parkinson's disease over the last 3/6 {deleted as appropriate} months? (*Please tick only one*).

☐ No, I work the same hours. Please state how many hours this is ☐

☐ Yes, I have had to reduce my working hours by ☐ working hours per- week.

4c If you are not employed:,

In the last 3/6 {deleted as appropriate} months have you had to stop work completely due to your Parkinson's disease

☐ No ☐ Yes

In the last 3/6 {deleted as appropriate} months have you had to reduce the number of hours per week you spend carrying out your normal daily activities?

☐ No

☐ Yes I have had to reduce them by ☐ hours per week. (eg gardening, housework, social activity).

5 Over the last 3/6 {deleted as appropriate} months has a relative or friend taken time off work to look after you?

☐ No

☐ Yes, how many hours ☐

☐ Yes, had to stop work completely

6 In the last 3/6 {deleted as appropriate} months did you make regular use of the following?

Name of service	No	Yes	If yes:
-----------------	----	-----	---------

			Number of times on average per week?
a. Home care/home help			How many home visits?
b. Meals on wheels			How many meals?
c. Day centre			How many days?
d. Luncheon Club			How many meals?
e. Sitting Service			How many days?
f. Other (please specify)			

7. Have you moved into institutional care (i.e. a residential or nursing home)?

☐ No

☐ Yes, date admitted (month/ year): _____

Type of home: ☐ Nursing ☐ Residential

Address of Home _____

8 In the last 3/6 {deleted as appropriate} months did you buy any aid or adaptation paid by yourself or by a friends or relative? Eg, walking frames, grab bars, stair lift, wheel chair

Type of aid or adaptations	No	Yes	Cost to you (£'s)
a			
b			
c			
d			

9. In the last 3/6 {deleted as appropriate} months, approximately how much additional money have you spent on travel (taxi car park fees and public transport because of your Parkinson's disease

☐ None

☐ Yes, I have spent £ _____

10. Do you have to pay for your Parkinson's disease medication?

☐ No

☐ Yes, I have spent £ _____ per month

11. Do you receive benefits?

☐ No

☐ Yes,

Low ☐ Medium ☐ High ☐

12. If you would like to tell us about any other costs incurred because of your Parkinson's disease over the last 3/6 {deleted as appropriate} months, please write them here.

☐ No

☐ Yes, please give details:

Thank you for your help.

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Appendix 20 Adverse Event / Serious Adverse Event Form

The only adverse events being recorded in this trial are: 'falls or equipment failure leading to injury requiring a hospital or GP visit'. If such an event should occur, please report this by fax to the trial office as soon as possible using the form below.

Patient Details:

Patient's full name: _____ Sex: Male ☐ Female ☐

Date of birth: / / Hospital number: _____

Responsible clinician: _____ Hospital: _____

PD REHAB trial number: _____

AE Description:

Date event started: / / Date event ceased: / /

Outcome: Fatal ☐ Recovered ☐ Continuing ☐

Details of adverse event:

Did the event require hospitalisation? No ☐ Yes ☐ No of days

Reason why you consider event to be intervention related:

Name of person reporting:

Telephone Number:

Date: / /

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Appendix 21 Trial Exit Form

PD REHAB Trial Participant Number	Participant name
Exited PD REHAB Trial on	{insert date}
Has the patient died? No <input type="checkbox"/> Yes <input type="checkbox"/> If Yes, When did they die, What was the cause of death	
Weight on exiting the trial	
Medication on exiting trial Levodopa? No <input type="checkbox"/> Yes <input type="checkbox"/> If yes, which? Daily dose (mg)? Eg 1 Sinemet 125 tablet = 100mg daily dose (levodopa)	
Dopamine Agonist? No <input type="checkbox"/> Yes <input type="checkbox"/> If yes, which? Daily dose (mg)?	
MAOB inhibitor? No <input type="checkbox"/> Yes <input type="checkbox"/> If yes, which? Daily dose (mg)?	
COMT inhibitor? No <input type="checkbox"/> Yes <input type="checkbox"/> If yes, which? Daily dose (mg)?	
Amantadine? No <input type="checkbox"/> Yes <input type="checkbox"/> If yes Daily dose (mg)?	
Apomorphine? No <input type="checkbox"/> Yes <input type="checkbox"/> If yes Daily dose (mg)?	
Duodopa? No <input type="checkbox"/> Yes <input type="checkbox"/> If yes Daily dose (mg)?	
Other PD Medication? No <input type="checkbox"/> Yes <input type="checkbox"/> If yes What medication?..... Daily dose (mg)?	

Your patient was randomised to the {Physiotherapy and Occupational therapy} / {Control} group.

If randomised to the control group, did you prescribe Occupational or Physiotherapy in the last 15 months?

Occupational therapy No ☐ Yes ☐ if yes, please give details

Physiotherapy No ☐ Yes ☐ if yes, please give details

Control group patients may now be referred for PT or OT through your normal mechanisms

Please return this questionnaire in the freepost envelope provided.

Version 9, 11th June 2010

11th June 2010

Appendix 22 Patient invitation letter



<<Hospital Logo>>

Local PI

Address

Address

Address

Prof. Carl Clarke

Professor of Neurology

The Medical School

Edgbaston

Birmingham

B17 2TT

INVITATION

PD REHAB - Randomised Controlled Trial to Assess the Clinical- and Cost-Effectiveness of Physiotherapy and Occupational Therapy in Parkinson's Disease

Dear Patient,

We are carrying out a clinical trial that is managed by the University of Birmingham to examine the effectiveness of Occupational therapy and Physiotherapy for people with Parkinson's disease funded by the National Institute for Health Research. We understand that you have Parkinson's disease (PD) and have {expressed an interest / joined a register indicating that you might be interested} <delete as appropriate> in taking part in Parkinson's disease research.

If you have Parkinson's disease and have difficulties with some activities of daily living and have not had Physiotherapy or Occupational therapy in the last 12 months, you could be eligible to join the trial. The trial has to compare groups of people who are receiving therapy and those who are not. So joining the trial would give you a 50:50 chance of receiving Occupational therapy and Physiotherapy.

For those joining the trial we will use questionnaires to follow the progress of your quality of life at the start, and at 3, 9 and 15 months into the trial. We would also like to ask your own doctor about your health and will need to know about any medications you are taking for your Parkinson's disease. Of course if you were deemed by your doctor to be in urgent need of either or both services you would be referred in the normal way.

We enclose a patient information sheet (version 9) for you which describes the trial.

Would you like to take part in this trial?

Would you like to learn more about this clinical trial?

Do you have any other questions?

Then please contact us at the address above or complete the attached reply slip and we will be in touch with you.

Yours sincerely,

<local PI>

11th June 2010

Reply Slip

Please complete this reply slip and send to:

<Local PI>

Address

Address

Address

I am:

☐

Interested in taking part in the study

☐

Would like to learn more about the study

☐

Do not wish to take part in the study

Name

Address
.....
.....
.....
.....

Tel:

Email:

Any other questions or comments

Thank you.