

Study contacts

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Research Information Sheet for Practices

PD-Exercise



REC: 11/SC/0267
 CSP: 79836



The Study

Study Title: Longer-term exercise interventions in people with Parkinson's disease

Aims: Using a randomised controlled trial with one intervention arm and an active comparator control group with blinded assessments and semi-structured interview techniques we will determine in people with PD:

1. The effect of longer-term exercise participation on motor symptoms
2. The effect of longer-term exercise participation on non motor symptoms, fitness, health and wellbeing.
3. Participants views of the process and sustainability of community provision of exercise over a longer period of time.

Principal Investigator: Prof Helen Dawes

Host Institution: Oxford Brookes University

Total Number and Type of Patients Invited: 100, Idiopathic Parkinson's Disease

Number of practices to be approached: GP practices in the Thames Valley Primary Care research partnership (Oxon, Bucks, Berks east and Berks west). While we shall initially focus on GP practices in Oxon, going for a single widespread approval will mean we can pursue recruitment via the other PCTs in due course as necessary.

Number of patients per practice to be recruited: Once PCT approval is in place, selected GP practices (those who wish to support study in this way) will screen their patient lists for eligible people. **Difficult to tell dependent who many take part, how many recruited OUH/RBH)**

Funded By: NIHR RfPB

Practice Involvement in the Study - Summary

Eligible practices: GP practices in the Thames Valley Primary Care research partnership (Oxon, Bucks, Berks east and Berks west)

Patient recruitment period: Jan 2012- June 2013

Data collection:

By clinicians:

By participants:

By researchers: At Oxford Brookes University

Inclusion Criteria: Idiopathic Parkinson's disease diagnosed by neurological examination (idiopathic PD defined by the UK Parkinson's Disease Society Brain Bank Criteria), who are able to walk $\geq 100\text{m}$, and maintained a stable medical regime for 12 weeks prior to initiation of the study, and anticipated to maintain a stable regime for the course of study (as determined by the referring clinician)

Exclusion Criteria: 1) Dementia. 2) History of additional prior neurological condition; 3) Severe depression or psychosis or a mental state that would preclude consistent active involvement with the study over its duration. 4) Cardiac precautions* that would prevent the subject from completing the exercise program or the full battery of outcome measures. 5) Any known contraindication to exercise (30) 6) Reduced cognition of any cause [Minimal state examination [(MMSE) < 23] 31. 7) an orthopaedic condition that independently limits walking;

*Participants will be asked to complete a screening questionnaire for coronary artery disease risk factors and any signs or symptoms: outlined in American College of Sports Medicine guidelines for exercise testing and prescription.

Potential Benefits for the Practice:

Not sure what to put here. Possible Benefits to patients taking part?

Practice Involvement: Details of Process

Study activity:

GP practices (those who wish to support study in this way) will screen their patient lists for eligible people. Eligible people will be given information about the study and an invitation letter describing the study. They will be asked for their consent for their details to be passed to the research team. **(ask the GP to give the info sheet?)-then we contact?**

Research Team Involvement: Details of Process

Study activity: The research team will then contact that person directly to discuss their potential involvement in the study. potential participants will be contacted by the research team to arrange an appointment for the consent and baseline assessment. Members of the research team taking consent will be trained in taking consent and good clinical practice. Assessments will take place at Oxford Brookes University, the intervention will take place either in a community leisure facility or at the patients home

If you wish to take part in the study, what happens next?

Please complete the sign-up sheet attached to this RISP and either send or fax to Vicki Clatworthy.

Reimbursement

Not sure to put here

Patient Confidentiality

All work undertaken as part of this study will comply with the Research Governance Framework for Health and Social Care in the UK and Oxford Brookes University Research Governance Framework. All participant identification and referral procedures as well as procedures for data storage, processing and management will comply with the Data Protection Act 1998. Data will be stored confidentially on password protected computers maintained on the Oxford Brookes University Network. A laptop computer may be used for the assessment procedures. However, data will not be permanently stored on this computer. Any data that is collected via the laptop computer will be transferred to the main hard drive via an encrypted USB data transfer device on completion of each specific assessment procedure. Files will only be accessible to researchers responsible for the running of the study and the Chief Investigator (CI). All paper records will be stored in a locked filing cabinet, with keys available only to researchers and the Chief Investigator. All essential documents generated by the study will be kept in the Study Master File. All conversations that take place during the process interviews will be audio recorded for the purposes of analysis. Consent for audio recording will be obtained beforehand. All audio records obtained will be stored in locked cabinets in the Movement Science Group Oxford Brookes University. Audio information and data will not be used for commercial purposes and will be retained for a period of 20 years. This retention period complies with Guidelines set out by University Research Governance Framework.

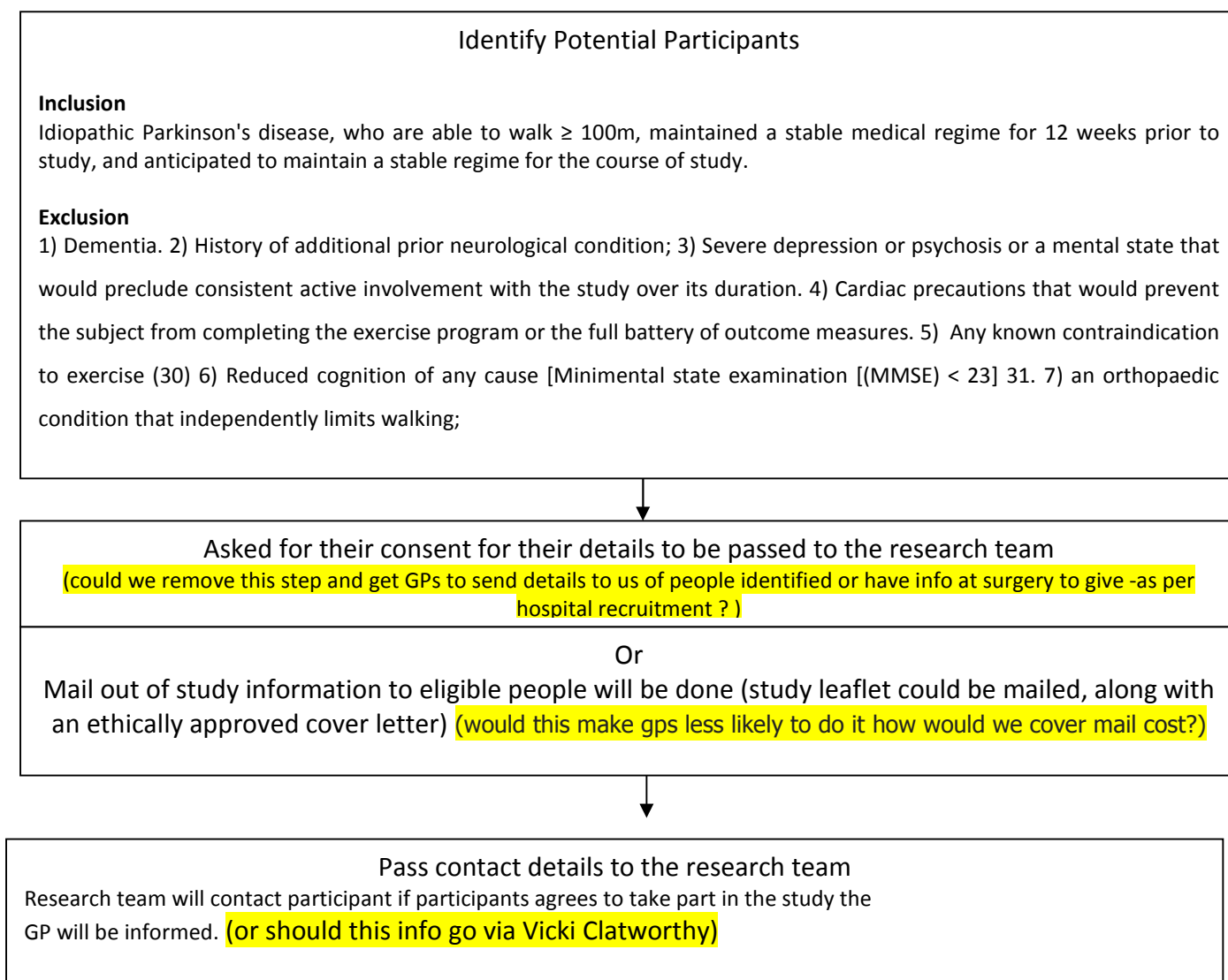
Thank-you for your interest in this study.

Please call the Principal Investigator or Researcher if you would like to discuss this study further.



PD-Exercise

Summary of steps to follow / Flow Chart





PD-Exercise

If you are willing to take part in this study, please complete the form below and either fax or send it to Vicki Clatworthy.

My practice will take part in the study

Name: _____ Signature: _____

Practice Address:

Telephone Number: _____

Fax Number: _____

Email address: _____

Please return to:

Vicki Clatworthy
Thames Valley Primary Care Research Partnership
The Farm House
Warneford Hospital
Roosevelt Drive
Headington
Oxford OX3 7JX

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