ISRCTN14760402 https://doi.org/10.1186/ISRCTN14760402

The First Steps pathway for taking control after a diagnosis of Parkinson's

Submission date
19/03/2018

Recruitment status
No longer recruiting

Registration date
29/03/2018

Overall study status
Completed

Last Edited
07/04/2025

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Background and study aims
Parkinson's disease is a condition in which parts of the brain become progressively damaged over many years. People with Parkinson's (PwP) report being diagnosed as devastating and could be better handled with a subsequent reduction in stress and anxiety for those affected and their families. Stress and anxiety have been highlighted as one of the top 10 research priorities for PwP with the need for improvement in the information those newly diagnosed receive. The aim of this study is to assess the First Step program for taking control after diagnosis, which has been developed by PwP for PwP.

Who can participate?
Patients aged over 18 with a diagnosis of Parkinson's within the previous 12 months

What does the study involve?
The First Step program consists of two workshops over a 6-week period. The workshops are delivered by PwP who provide information on how to face the future positively, address fears and misconceptions and how they can help manage the condition themselves. Participants are asked to complete assessments delivered over the phone, through the post or online before starting the program and after 3 and 6 months. Questions are asked about health, wellbeing and activity. People's experiences of the program and the study are also collected.

What are the possible benefits and risks of participating?
There is minimal risk associated with assessment and the study has been designed to minimise burden on the participants. Assessment takes place over the phone at a time convenient to the participant, thus avoiding the need to travel. Follow-up assessment should take no longer than 40 minutes, with assessments at the start of the study taking longer due to the consenting procedure and obtaining demographic information. Whilst unlikely, the questionnaires used in the study may cause mild distress to participants. However, they are all commonly used in both research and clinical practice and the researcher will have adequate experience of their use.

Where is the study run from?
The program takes place in suitable community venues in Oxfordshire, Hampshire or Surrey (when the program becomes available). Currently the Oxfordshire program runs out of Witney Lakes Resort.

When is the study starting and how long is it expected to run for?
June 2017 to November 2018

Who is funding the study?
Parkinson's UK

Who is the main contact?
Sophie Lawrie

Contact information

Type(s)
Scientific

Contact name
Miss Sophie Lawrie

Contact details
Oxford Brookes University
Headington Campus
Oxford
United Kingdom
OX3 0BP

Additional identifiers

Central Portfolio Management System (CPMS)
35346

Study information

Scientific Title
The First Steps pathway for taking control after a diagnosis of Parkinson’s: a feasibility study

Study objectives
People with Parkinson's (PwP) report being diagnosed as devastating and could be better handled with a subsequent reduction in stress and anxiety for those affected and their families. Stress and anxiety have been highlighted as one of the top 10 research priorities for PwP (James Lind Alliance) with the need for improvement in the Information those newly diagnosed receive. This research is to evaluate the ‘First Step program' for taking control after diagnosis, which has been developed by PwP for PwP.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Hampshire A Research Ethics Committee, 23/08/2017, ref: 17/SC/0346

Study design
Non-randomized; Interventional; Design type: Treatment, Complex Intervention

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
Adults with diagnoses of Parkinson's within the previous 12 months, will be invited to attend the program and be offered the opportunity to take part in the research. It will be made clear to individuals that taking part in the program is not dependent on them taking part in the research.

The program will take place in suitable community venues in Oxfordshire, Hampshire or Surrey (when the program becomes available). Currently the Oxfordshire program runs out of Witney Lakes Resort.

The First Step program consists of two workshops over a 6-week period. The workshops are delivered by pwp who provide information on how to face the future positively, address fears and misconceptions and how they can help manage the condition themselves. Those taking part in the research will be asked to take part in assessments delivered over the phone. The EPIC Questionnaire will be completed at their convenience either through post or by completing online. Assessment will take place before starting the program (baseline) and at 3 months and 6 months. At assessment we will asks questions about health, wellbeing and activity, using standard questionnaires. People’s experiences of the program and the research will also be asked. All people taking part in the research will have the opportunity to receive the program, however, delivery of the program will begin when available in that area.

Intervention Type
Other

Primary outcome(s)
1. Acceptability, assessed using Process Evaluation Questionnaire (view of venue, staff /facilitator, course content, ease of attendance, impact)
2. Demographics (age, gender, ethnicity, socioeconomic status and rural or urban home, employment)
3. Adherence: % of attendance for Day 1 and Day 2 of First Steps Program
4. Eligibility: number of people screened and that match the eligibility criteria
5. Recruitment: rate of eligible participants enrolled onto the study (%), rate of eligible patients that attended First Steps (%)
6. Retention: no. of enrolled patients that completed the 6 month telephone assessment, number of patients that completed the process evaluation questionnaire, number of patients that completed each outcome measure at baseline, 3 months and 6 months
7. Step-wedge trial: differences in onset of programme provision, number of patients who have

attended and not attended First Steps per site
8. Fidelity of delivery, assessed using fidelity checklist at delivery of program

Key secondary outcome(s))
1. Generic health status is measured by the Euro-QOL (EQ5D-5L) questionnaire at baseline (0 weeks), three months (12 weeks) and six months (24 weeks)
2. Anxiety and depression is measured by the Hospital, Anxiety and Depression Scale (HaDs) at baseline (0 weeks), three months (12 weeks) and six months (24 weeks)
3. Social participation is measured by the World Health Organisation Disability Assessment Schedule (WHODAS) at baseline (0 weeks), three months (12 weeks) and six months (24 weeks)
4. Service use is measured by the modified Client Service Receipt Inventor (modified CSRI) at baseline (0 weeks), three months (12 weeks) and six months (24 weeks)
5. Activities of daily living is measured by the Schwab and England (S&E) questionnaire at baseline (0 weeks), three months (12 weeks) and six months (24 weeks)
6. Physical activity is measured by the International physical activity questionnaire-short version (IPAQs) at baseline (0 weeks), three months (12 weeks) and six months (24 weeks)
7. Diet over the past year is measured by the EPIC-Norfolk Food Frequency Questionnaire. At baseline (0 weeks) a link to an online version of the EPIC questionnaire OR a paper copy is sent by post to the participant to be completed at the participants convenience
8. Diet over the previous day is measured using the 24-hour Food Recall at baseline (0 weeks), three months (12 weeks) and six months (24 weeks)
9. Carer strain is measured by the Caregiver Strain Index at baseline (0 weeks), three months (12 weeks) and six months (24 weeks)

Completion date
30/11/2018

Eligibility

Key inclusion criteria
1. A recent (within 12 months) diagnosis of Parkinson’s disease
2. Above the age of 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
57

Key exclusion criteria
1. Severe depression or psychosis
2. Reduced cognition that would preclude active involvement and capacity to consent to participate
3. Unable to understand English

Date of first enrolment
01/02/2018

Date of final enrolment
30/05/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Ashford Hospital
London Road
Ashford
United Kingdom
TW15 3AA

Study participating centre

St Peter’s Hospital
Guildford Road
Chertsey
United Kingdom
KT16 0PZ

Sponsor information

Organisation
Oxford Brookes University

ROR
https://ror.org/04v2twj65

Funder(s)

Funder type
Charity

Funder Name
Parkinson's UK; Grant Codes: M6002

Alternative Name(s)
Parkinson's Disease Society

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/11/2023	07/04/2025	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Qualitative data	10/10/2019	19/05/2023	Yes	No