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Feasibility and acceptability of a specialist exercise programme for people with Parkinson's disease

Submission date
28/05/2020

Recruitment status
No longer recruiting

Registration date
04/06/2020

Overall study status
Completed

Last Edited
17/03/2023

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Current plain English summary as of 18/09/2020:
Background and study aims
Parkinson's disease is a neurodegenerative condition with no cure. Exercise has been shown to be beneficial and is associated with limiting the rate of decline in Parkinson's. Current service provision lacks specialist professionals, with services only providing short-term access to exercise classes, resulting in many people with Parkinson's (PwP) returning to sedentary habits when exercise programmes cease. Moreover, the recent COVID-19 pandemic has limited access to current exercise provision, highlighting the need to develop innovative means to promote physical activity amongst PwP. Combining the skills of NHS physiotherapists with community exercise instructors appears an ideal marriage, with the potential to encourage PwP to be more active. This study aims to explore the feasibility and acceptability of a remotely delivered programme called PDConnect, which includes online specialist NHS physiotherapy, group exercise classes and supported self-management. This study aims to explore whether this unique collaborative approach to exercise delivery is feasible to deliver, well received by PwP, and potentially an effective method of managing Parkinson's. A large-scale study will be required on conclusion of this pilot in order to establish the effectiveness of PDConnect, which is hoped to be a sustainable and effective means of supporting PwP to engage in exercise, thereby taking control of their future quality of life.

Who can participate?
Participants with a confirmed diagnosis of Parkinson's disease (PD) recruited from NHS Grampian

What does the study involve?
PwP will be recruited from NHS Grampian and will undergo testing to establish their current health, activity and exercise levels. Participants will be randomly allocated to receive standard physiotherapy care or PDConnect both delivered online via Microsoft Teams. PDConnect participants will receive six sessions with an NHS Parkinson's specialist physiotherapist, followed by 12 weeks of group-based exercise delivered by specially trained fitness instructors. On completion of the exercise, participants will have 12 weeks of independent self-management. Throughout the PDConnect programme emphasis is upon exercise prescription, education, goal

setting and strategies to support adoption of exercise into everyday life, with the aim of promoting long-term exercise involvement and self-management. Data will be collected at several timepoints: baseline, 6, 18 and 30 weeks.

What are the possible benefits and risks of participating?
The direct benefit for participants randomised to receive usual care will not be placed on a waiting list prior to receiving 1:1 Physiotherapy. For those who are randomised to PDConnect, the benefits include being seen by Professionals who have specialist training in Parkinson's and participate in a health intervention that combines exercise prescription, education and behaviour changes strategies to promote individual self-management.

Risks for all participants is the potential for injury or falls during exercising. All staff will have appropriate training and first aid in place. All falls which occur during the course of the study will be recorded within the falls diary and reported to the Principal investigator (Julie Jones), as soon as possible after the event.

Where is the study run from?
School Of Health Sciences, Robert Gordon University (UK)

When is the study starting and how long is it expected to run for?
From September 2020 to December 2021 (updated 05/01/2021, previously: September 2021)

Who is funding the study?
Parkinson's UK and Chief Scientist Office (CSO) (UK)

Who is the main contact?
Mrs Julie Jones
j.c.jones@rgu.ac.uk

Previous plain English summary:
Background and study aims
Parkinson's is a neurodegenerative condition, with no cure. Exercise has been shown to be beneficial and is associated with slowing the rate of developing difficulties with activities of daily life for people with Parkinson's (PwP). Current services available to PwP lack specialist professionals, and services only provide short-term access to exercise classes. This results in many PwP returning to sedentary habits when exercise programmes end.
The investigators of this trial have developed the programme PDConnect, which combines the skills of NHS physiotherapists with community exercise instructors to encourage PwP to be more active. This study aims to explore how feasible the PDConnect program is for physiotherapy and exercise specialists and how well received the programme is by PwP. A future large-scale study will be required to assess how effective a method the PDConnect program is for managing Parkinson's.

Who can participate?
Participants with a confirmed diagnosis of Parkinson's disease (PD) recruited from NHS Grampian

What does the study involve?
People with Parkinson's (PwP) will undergo testing to assess their current health, activity, and exercise levels. Participants will be randomly allocated to receive either standard physiotherapy care or the PDConnect programme.
Participants allocated to receive usual care will receive six, 1 hour sessions of community-based physiotherapy. PDConnect participants will receive six, 1 hour sessions by an NHS Parkinson's

specialist Physiotherapist, over 6 weeks, followed by 12 weeks of group based exercise delivered in a community gym by specially trained fitness instructors. On completion of the programme, participants will have twelve weeks of independent self-management. Throughout the PDConnect programme, participants wl be educated about the importance of exercise and emphasis will be placed upon goal setting and strategies to support adoption of exercise into everyday life, with the aim of promoting long-term exercise involvement and self-management. Participants' health and well-being will also be assessed at the start of the study and after six, eighteen, and thirty weeks.

What are the possible benefits and risks of participating?
The direct benefit for participants randomised to receive usual care will not be placed on a waiting list prior to receiving 1:1 Physiotherapy. For those who are randomised to PDConnect, the benefits include being seen by Professionals who have specialist training in Parkinson's and participate in a health intervention that combines exercise prescription, education and behaviour changes strategies to promote individual self-management.

Risks for all participants is the potential for injury or falls during exercising. All staff will have appropriate training and first aid in place. All falls which occur during the course of the study will be recorded within the falls diary and reported to the Principal investigator (Julie Jones), as soon as possible after the event.

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Who is the main contact?
Mrs Julie Jones
j.c.jones@rgu.ac.uk

Contact information

Type(s)
Public

Contact name
Mrs Julie Jones

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Type(s)
Scientific

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
280159

Protocol serial number
F-1901

Study information

Scientific Title
A collaborative approach to exercise provision for people with Parkinson's disease: a feasibility study of the PDConnect programme

Acronym
PDConnect

Study objectives
To determine the feasibility and acceptability of the PDConnect programme amongst people with Parkinson's (PwP).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 27/11/2020, North West - Liverpool Central Research Ethics Committee (Health Research Authority, 3rd Floor, Barlow House, HRA NRES Centre, Manchester, M1 3DZ UK; +44 (0) 2071048387; liverpoolcentral.rec@hra.nhs.uk), ref: 20/NW/0236

Primary study design
Interventional

Study design
Mixed methods two-arm randomized controlled feasibility study

Study type(s)
Treatment

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

Interventions
Current interventions as of 17/09/2020:

Using a stratified random sampling method by Hoehn and Yahr stage (disease severity), age and gender will be employed to balance the groups to ensure comparability at baseline. Using computer-generated random number sequencing (Excel, Microsoft Corporation) in a ratio of 1:1, a random number will be placed in a sealed, sequentially numbered, opaque envelope, and participants will be allocated randomly to PDConnect or usual care by extracting the random number from the envelope.

Both arms of the study will be delivered exclusively online using Microsoft Teams.

Intervention arm: PDConnect:
Six, one hour 1:1 Physiotherapy sessions delivered by Physiotherapists with specialist training in Parkinson's. Exercise therapy will be delivered alongside education, and behaviour change techniques. This will be followed by 12-week group-based exercise class delivered via Microsoft Teams by specially training fitness instructors. Exercise will be delivered for 1 hour with an additional 30 minutes to support self-management, behaviour change and education. This will be followed by a 12-week period of self-management when participants will be contacted every month.

Control arm: Usual care:
Participants will receive six 1-hour sessions of physiotherapy delivered online via Microsoft Teams.

Primary outcomes of feasibility and acceptability will be assessed via semi-structured interviews on completion of the study. Interviews will be conducted with participants and those delivering the PDConnect programme. Quantitative data will also be collected on recruitment processes, and adherence.

Secondary measures: a range of self-report and clinical measures encompassing physical, QoL, and health well-being measures will be undertaken at baseline, 6, 18 and 30 weeks.

Previous interventions:
Using a stratified random sampling method by Hoehn and Yahr stage (disease severity), age and gender will be employed to balance the groups to ensure comparability at baseline. Using computer-generated random number sequencing (Excel, Microsoft Corporation) in a ratio of 1:1, a random number will be placed in a sealed, sequentially numbered, opaque envelopes. Participants will be allocated randomly to either the PDConnect intervention arm or the usual care control arm by extracting the random number from the envelope.

PDConnect - Intervention arm:
Six, one-to-one, home-based, once-weekly, 1 h long physiotherapy sessions delivered by physiotherapists with specialist training in Parkinson's over 6 weeks. Exercise therapy will also be delivered alongside education, and behaviour change techniques. This will be followed by a 12 week group-based circuit exercise class delivered in a community gym setting, delivered by specially trained fitness instructors. Exercise will be delivered for 1 h with an additional 30 mins to support self-management, behavioural change and education. This will then be followed by a 12 week period of self-management when participants will be contacted every month.

Usual care - Control arm:
Participants will receive six, 1 h sessions of community-based physiotherapy.

Self-report and clinical measures encompassing physical, QoL, and health well-being measures will be undertaken at baseline, 6, 18 and 30 weeks. Participants will also be contacted on completion of study via semi-structured interviews for assessment of the feasibility and acceptability of the intervention. Interviews will be conducted with participants and those delivering the PDConnect programme. Quantitative data will also be collected on recruitment processes and adherence.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility and acceptability assessed via semi-structured interviews at 30 weeks

Key secondary outcome(s)
The course of Parkinson's disease measured using the following at 0, 6, 18, and 30 weeks:
1. Unified Parkinson’s Disease Rating Scale (UPDRS)
2. Lille Apathy Rating Scale (LARS)
3. Parkinson Fatigue Scale (PFS)
4. Timed Up and Go (TUAG)
5. 10 meter walk test (10MWT)
6. Parkinson’s Anxiety Scale (PAS)
7. Geriatric Depression Scale (GDS)
8. 6 minute walk test (6MWT)
9. Activities-Specific Balance Confidence (ABC) Scale
10. Physical Activity Scale for the Elderly (PASE)
11. Schwab and England Activities of Daily Living Scale
12. MiniBESTest
13. Physical Activity Scale for individuals with Physical Disability (PASIPD)
14. Parkinson’s Disease Questionnaire 39 (PDQ-39)
15. Self-Efficacy for Exercise Scale
16. Functional Gait Assessment- FGA

17. Nottingham Health Profile
18. Warwick Edinburgh Mental Health and Wellbeing Scale

Completion date
23/12/2021

Eligibility

Key inclusion criteria
Current exclusion criteria as of 05/01/2021:

1. Confirmed diagnosis of Parkinson's disease (PD)
2. Stage I-III Hoehn and Yahr Scale (appendix)
3. Mild to severe gait disturbance with a score of ≤2 on the Unified Parkinson’s disease Rating Scale (UPDRS) item 29
4. Able to walk independently with or without a walking aid greater than 100m
5. Stable medication for more than 3 weeks
6. Able to speak and understand English without assistance
7. Have a tablet/laptop with a webcam, that is Microsoft Teams compatible
8. Access to a stable internet connection

_____

Previous inclusion criteria:

1. Confirmed diagnosis of Parkinson's disease (PD)
2. Stage I-III Hoehn and Yahr Scale (appendix)
3. Mild to severe gait disturbance with a score of ≤2 on the Unified Parkinson’s disease Rating Scale (UPDRS) item 29
4. Able to walk independently with or without a walking aid greater than 100m
5. Stable medication for more than 3 weeks
6. Able to speak and understand English without assistance
7. Available to attend an exercise class in Aberdeen for 12 weeks

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
31

Key exclusion criteria

1. Secondary or atypical Parkinsonism
2. Severe, unpredictable episodes of motor fluctuation
3. Use of medications known to interfere with cognitive function
4. History of neurological diseases other than PD
5. Any unstable mental or physical condition that prevent consenting and participating in the exercise intervention
6. Unstable or uncontrolled medical conditions

Date of first enrolment
01/12/2020

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Robert Gordon University
School Of Health Sciences
Ishbel Gordon Building
Garthdee Road
Aberdeen
United Kingdom
AB10 7QT

Sponsor information

Organisation
Robert Gordon University

ROR
https://ror.org/04f0qj703

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Funder Name
Parkinson's UK

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
Data will only accessible by the research team based at Robert Gordon University. All data will be pseudonymised with each participant being provided with a unique identifier, so that data stored cannot be linked back to the individual. A file will be kept in a separate folder which contains a list of participant names and their unique identifier. All data collected as part of this study will be stored in accordance with professional regulations and will align with the General Data Protection Regulation Act (GDPR, 2018) requirements, and in accordance with RGU policies and procedures relating to the collection, storage and retention of research data. Information will be stored on a password-protected university server to protect confidentiality, and will be available only to the research team. All paper-based information will be stored in lockable storage cabinets within a designated research room within the school of health science, at the Robert Gordon University, which has a keypad entry system.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/04/2021	18/06/2021	Yes	No
HRA research summary			28/06/2023	No	No