Plan Overview

A Data Management Plan created using DMPonline

Title: Home-based high-intensity interval training for people with Parkinson’s: The HIIT-Home4Parkinson’s randomised controlled feasibility study

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Project abstract:

Exercise is considered to play an integral role in the management of Parkinson’s disease (PD). However, people with Parkinson’s (PwP) struggle to sustain engagement with exercise, facing logistical and disease-specific barriers including fluctuating symptoms, lack of time, reluctance to travel and low outcome expectation. Therefore, identifying methods to make exercise accessible, achievable and sustainable is a priority. High intensity interval training (HIIT) has been evidenced to be an effective, enjoyable, and time-efficient method of improving a number of physiological and clinical outcomes in various populations. HIIT therefore, particularly based in the home, could potentially be a practical and effective exercise modality for PwP. Whilst studies confirm that PwP are able to safely and effectively perform aerobic, resistance and balance exercise training at home, it is not known whether HIIT, using minimal or no equipment, can be performed safely and effectively by PwP. Therefore, this study aims to explore the practicality and utility of home-based HIIT for PwP by undertaking a previously co-created home-based HIIT intervention. The HIIT-Home4Parkinson's (HH4P) was developed by a multidisciplinary team including people with Parkinson's, family members and clinicians, through an iterative process of focus groups and exercise testing.

The HH4P intervention is a parallel group, randomised controlled feasibility study with mechanistic, physiological and clinical components and a usual care control. The study will involve a mixed-methods approach, with qualitative and quantitative data collection and analysis relating to mechanistic, physiological and clinical outcomes, feasibility, safety and patient experience.

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Home-based high-intensity interval training for people with Parkinson’s: The HIIT-Home4Parkinson’s randomised controlled feasibility study

Data Collection

What data will you collect or create?

Data Collection

- Risk assessment data
- Initial email contact
- JISC online expressions of interest data: Name, contact telephone number, how participant found out about the study, name and address of GP, consent to undergo telephone screening
- Recruitment, screening and eligibility data

Baseline data

- Anthropometric (Height / body mass / body mass index)
- Demographic: gender, age, ethnicity, home circumstances (who they live with) and employment status (as indications of socio-economic status).
- Smoking status
- Diagnostic data: Hoehn and Yahr stage (Parkinson’s severity), time since diagnosis.
- Medication type and dose / comorbidities
- Signed consent forms
- Signed health screening questionnaires
- Maximum heart rate (HRmax)

Baseline and follow-up outcome measures:

- Blood sample (Brain-derived neurotrophic factor, BDNF)
- 30 second sit-to-stand test
- Motor Examination (MDS-UPDRS part 3)
- Oxford Participation and Activities Questionnaire acute
- Maximal oxygen uptake (VO2max)

Data collection throughout the intervention:

- Adverse events and effects
- Weekly physical activity (accelerometer data, weeks 1 and 6 of programme)
- Programme completion rates
- Exercise adherence (type, frequency, duration)
- Achieved exercise intensity (Heart rate / RPE)
- Attendance at group sessions
- Participant withdrawal
- Protocol deviations

Additional data for process evaluation: Post intervention focus group.

- Online (Zoom) focus group transcripts of exercise participant experience. (Initially Zoom audio file, transcribed into MS Word)

Given that data collection will not include audio or video files in this study stage, it is estimated that the total size of data collected will be approximately 1GB or less. All data will be stored on the secure University of Plymouth OneDrive, accessed with university owned password protected laptops.
Is is possible that data may be used from associated MSc projects evaluating barriers to exercise participation. Also, there may be data collected as part of a peripheral MSc project investigating corticomuscular coherence. However, at time of writing these aspects have yet to be finalised.

How will the data be collected or created?

- Risk assessment data

This will be completed on an official University of Plymouth electronic risk assessment form.

- Jisc online expressions of interest data

Completed with a GDPR compliant online Jisc survey form, downloaded in PDF format. The Jisc form will be deleted after data collection is complete.

- Recruitment, screening and eligibility data

Completed on the bespoke electronic "screening and expressions of interest" log.

- Baseline data

Anthropometric, demographic, smoking status, diagnostic data, medication type, comorbidities and HR max will be collected in person with validated protocols, and recorded on the bespoke "Baseline case report form". Additionally, bespoke electronic "Participant consent forms" and "Health screening questionnaires" will be completed.

- Baseline and follow-up outcome measures

BDNF; Blood samples will be collected through adherence to a strict laboratory protocol, with results recorded on the "baseline case report form" (CRF) and "Follow-up week 14 CRF"
VO2max (and HR max); Collected in a laboratory environment, recorded with Cortex Metalyzer and Bluetooth equipped Polar H-9 heart rate monitor. Recording of HRmax, RPE and VO2max will involve participants undergoing a validated incremental exercise protocol utilising a cycle ergometer. Results will be recorded on the "Baseline CRF and "Follow-up week 14 CRF"
30 second sit-to-stand test, MDS-UPDRS part 3 and Oxford Participation and Activities Questionnaire acute: These will be collected in a laboratory environment with a validated protocol, recorded on the "Baseline CRF and "Follow-up week 14 CRF".

- Data collected throughout the intervention

Adverse events and effects will be collected in bespoke participant diaries, and reported to the Chief Investigator (CI).
Program completion rates, exercise adherence, achieved heart rate and RPE per HIIT set will be recorded in participant diaries.
Heart rate will also be recorded using the Polar Beat Smart Phone application (downloaded on participant Smart phones), paired to a Bluetooth equipped Polar H9 heart rate monitor, with each session uploaded to Polar Flow online software, and exported by the PI as a Microsoft Excel spreadsheet (version 2204).
Attendance at group session will be recorded by the CI on the bespoke "Online group exercise session participation sheet".
Participant withdrawals, and reason for withdrawal will be recorded on the bespoke "Study withdrawal form"
Weekly physical activity will be objectively measured for both exercise and control groups with an activity monitor (activPAL™, Paltechnologies Ltd, Glasgow) for a seven-day period following initial baseline assessments, and during week 7 of the intervention.
Protocol deviations will be recorded on the bespoke "Protocol deviations" form.

- Additional data for post intervention process evaluation

Online focus groups will be recorded by Zoom, (internal University of Plymouth software) with consent from all participants, thoroughly checked by the Principal Investigator, transcribed verbatim and analysed with Nvivo software. Video recordings will be deleted immediately and transcription will be undertaken with only the audio recording.

Quantitative data will be extracted into an MS Excel spreadsheet, and analysed with appropriate statistical software (MS Excel, IBM SPSS). Qualitative data will be analysed with Nvivo software, using thematic analysis techniques.

Standardisation

Standardised HIIT-Home4Parkinson's CRF's will be utilised to ensure standardised data collection. Standardised operating procedures will be undertaken, regulating factors such as personnel completing the assessment and participant communication.

Folders and files

Folders will indicate whether the data refers to:

- Regulatory documents (project versions)
- Study materials (informed consents, intervention resources)
- Research participant data (case report forms, transcripts, quantitative datasets)
- Dissemination documents (trial results / conclusions / articles)

Files will be named in English and version controlled in the following format: "filename dd-mm-yyyy-v?" (e.g., "Baseline case report form 17-09-2022-v1").

Documentation and Metadata

What documentation and metadata will accompany the data?

Shared files containing participant data will include;

- Date
- Data type
- Version
- Author
- File type

- File size
- Detailed labelling of variables
- Licensing
- Citations

Ethics and Legal Compliance

How will you manage any ethical issues?

Data handling procedures will be in accordance with the General Data Protection Regulations 2018 (https://www.legislation.gov.uk/ukpga/2018/12/contents/enacted) and the University of Plymouth's Research Ethics Policy on Data Protection (https://www.plymouth.ac.uk/uploads/production/document/path/13/13024/Data_Protection_Policy.pdf)

Data handling;

All data will be encrypted and stored on on a secure University of Plymouth OneDrive, backed up on the server cloud and accessed via university owned password protected laptops set to lock automatically after a period of inactivity of 10 minutes.

Data preservation and sharing;

Research participants will be asked whether they consent to the following (on signed consent forms); personal identifiable information to be held in a secure database on University of Plymouth servers, and may be accessed by authorised members of the research team and government regulatory bodies such as the Medicines and Healthcare products Regulatory Agency (MHRA); written records of the research and its findings being held by the University of Plymouth for a period of 10 years (in which all participants will be unidentifiable); the use of research data for reports, presentations and publications.

Those who do not allow us to share their data will be removed from project datasets.

Coding and anonymisation;

Data will be coded, and handled without any information on participant names, place of birth, place of residence, date of birth or post-code. All electronic forms will be securely stored on the University of Plymouth OneDrive. Digital consent forms and case report forms will be destroyed with the assistance of University of Plymouth IT services three years after study completion. Focus groups transcripts created by Zoom will be thoroughly checked by the CI, anonymised and analysed with Nvivo software, followed by deletion of the original recording. Only the audio recording (not video) will be kept for transcription purposes.

Ethical consultation;

For issues arising throughout the study that were not anticipated at the time of writing, the University of Plymouth Faculty of Health Ethics and Research Integrity Committee or the Health Research Authority Research Ethics committee will be consulted.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

The CI will own the IP of the data collected as part of this study.

Each folder or dataset to be publicly shared will display licensing and copyright information.

Data gathered from research participants pertain primarily to these individuals. Therefore, all individual data will be available to their owners throughout the project.

Storage and Backup

How will the data be stored and backed up during the research?

Electronic data will be stored on the secure University of Plymouth OneDrive, backed up to the server cloud and accessed via university owned protected devices - password protected laptops set to lock automatically after a period of inactivity of 10 minutes. The CI will be responsible for uploading data to the secure OneDrive, and retrieving data from the server cloud in the event of data loss.

All data collection devices will be electronic with the exception of the participant consent form and health screening questionnaire, which will be immediately digitised. It is estimated that proposed devices will provide sufficient storage space.

How will you manage access and security?

Only the people directly involved in the post-intervention focus group will have access to non-anonymised data. The CI and three supervisors will have access to data. These collaborators will have knowledge of passwords with which to access study data. All researchers will have individual passwords. All field data will be entered immediately onto pass-protected laptops, with paper files (consent / health screening questionnaire) immediately digitised, then destroyed with a shredding device. If paper files require transportation for any reason, a secure, padlocked bag will be utilised.
The CI and ST will have access to the final dataset.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

Project resources and de-identified datasets will be retained and stored for a period of 10 years after study completion. It is possible that file formats will need to be adapted before data preservation. Signed and named participant health screening / consent forms will be kept for a period of three years after study completion, with paper forms digitised and stored securely on the University of Plymouth OneDrive. Paper copies will be destroyed immediately after digitisation. Digital exercise screening and consent forms will be destroyed with the assistance of University of Plymouth IT services three years after study completion.

What is the long-term preservation plan for the dataset?

All data will remain the property of the CI. Non-identifiable data will be stored free of charge for a period of 10 years in the University of Plymouth repository with requested access, in line with University of Plymouth policy (https://www.plymouth.ac.uk/uploads/production/document/path/6/6913/Research_Data_Policy.pdf.) The CI will be responsible for preparing data for preservation and sharing.

Data Sharing

How will you share the data?

De-identified data will be shared on the University of Plymouth open access repository with requested access upon study publication. Project resource data such as visual exercise instructions will be accessible for participants through an online resource (Pebblepad), created by the CI with assistance from University of Plymouth IT services.
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Are any restrictions on data sharing required?

Intervention resources (photographs / videos / exercise instructions) will be made available as soon as possible with appropriate consent.
De-identified data will be shared upon study completion with requested access from the University of Plymouth open access repository.

Responsibilities and Resources

Who will be responsible for data management?

The CI will be responsible for management of data until the completion of the PhD studentship. These responsibilities will include data capture, metadata production, data quality, storage and backup, data archiving & data sharing. The CI will also be responsible for the regular reviewing and revision of the Data Management Plan. On the completion of the studentship, the Director of Studies will be responsible for data storage.

What resources will you require to deliver your plan?

The CI, Director of Studies and two further members of the Supervisory Team will be involved in the study, along with two other members of a Trial Steering Committee. No storage charge will be applied by the University of Plymouth repository. University of Plymouth IT services will destroy identifiable digital data when required.

Delivering the plan will also require the following;

UoP Pass-protected desktop / laptops with internet access
UoP secure OneDrive for data storage
Software including Microsoft Office / Zoom / SPSS / Nvivo (available through the UoP, licenses already purchased by the institution)
Exercise equipment including; 12 polar heart rate monitors, cycle ergometer, Cortex Metalyzer, mask, stopwatch application, free-weights, resistance bands, 12 physical activity monitors, anthropometric measuring devices, water etc (all available from Peninsula Allied Health Centre, UoP)
HH4P data collection forms (consent forms, case report forms, etc)
UPDRS III / OxPAQ acute questionnaires
30s sit to stand equipment (stopwatch / chair)
Participant Smartphones equipped with free "Polar Beat" application
Participant laptop / mp3 player / CD player to run audio accompaniment
Laboratory / gym hire (Available at Peninsula Allied Health Centre with no charge)
Stationary (available from UoP)
HIIT-Home4Parkinson's created exercise resources; exercise menu, exercise sequence prompting cards, rhythmic auditory cueing mp3 accompaniment
Web storage: Online resources located at a UoP PebblePad site
Free access to "Polar Flow" online web resource
Blood serum BDNF analysis kit (enzyme-linked immunosorbent assay sandwich kit)
Blood sample collection kit (Phlebotomy tubes, 10 ml Syringe a green/blue needle or, vacutainer system with butterfly needle attachment, cotton Swab/Gauze, alcohol Swab, tourniquet, plastic gloves, available from UoP.