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Home-based trunk intervention training to improve rigidity and functionality in people with Parkinson's disease

Submission date
02/07/2025

Recruitment status
No longer recruiting

Registration date
08/07/2025

Overall study status
Completed

Last Edited
03/07/2025

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Parkinson's disease is a progressive neurodegenerative disorder that causes a wide range of debilitating motor and non-motor symptoms. Dopaminergic medication is the first management tool used to control and alleviate symptoms. However, medication only leads to partial improvements in symptoms, and its effectiveness decreases throughout the disease cycle. As a result, people with Parkinson's disease suffer from worsening functionality, subsequently affecting independence and quality of life. Previous research into exercise referral and physiotherapy showed that exercise can improve Parkinsonian symptoms and functionality. The trunk is responsible for about 50% of body mass and is essential to balance and gait performance, allowing individuals to perform activities of daily living in a safe manner. However, when the trunk is impaired by Parkinsonian symptoms, such as axial rigidity, an increased fall risk occurs, and the quality of life of those involved is hampered. As such, targeted, accessible exercise programmes need to be investigated to see their impact on axial rigidity and its subsequent impact on functionality. The aim of this study is to investigate the effects of a trunk-targeted home-based exercise programme on axial rigidity and functionality in people with Parkinson's disease.

Who can participate?
People with Parkinson's disease aged 40-80 years who fit all the inclusion/exclusion criteria stated

What does the study involve?
Participants will be initially screened online for eligibility. They will then visit the lab on five occasions over a 24-week period. They will be allocated into one of two groups, one where they will follow a 12-week trunk-specific home-based exercise programme, or one where they will follow a 12-week general exercise programme. Throughout the 12-week period, participants will be called weekly to track adherence to the programme and answer any questions they have.

Week 0: Initial Screening
Week 1: Questionnaires, functional assessments, 3D motion capture (baseline)

Week 4: Questionnaires, functional assessments, 3D motion capture
Week 8: Questionnaires, functional assessments, 3D motion capture
Week 12: Questionnaires, functional assessments, 3D motion capture
Week 24: Questionnaires, functional assessments, 3D motion capture (retention visit)

What are the possible benefits and risks of participating?
There are no direct benefits of participating. Participants will be provided with reasonable expenses for their time.
There is a mild risk of muscle soreness due to the exercise involved in the study. However, this will likely be as a result of delayed-onset muscle soreness (DOMS) and should 'wear off' within 48 hours. Participants are promoted to take breaks at any point they wish throughout the exercise. Warm-ups and cool-downs are utilised in the programme to minimise the small risk of muscle/joint injuries. Participants are screened for readiness to exercise and thus the risk of cardiac emergencies are minimised. Participants are encouraged to always exercise in a wide, open, well-ventilated and clean environment to reduce the risk of trips/slips/falls, and always with a member of the house present. During on-site testing, a first-aid trained individual will be on hand if necessary.

Where is the study run from?
University of Kent (UK)

When is the study starting and how long is it expected to run for?
April 2025 to June 2026

Who is funding the study?
University of Kent (UK)

Who is the main contact?
Lewis Ball, lrb33@kent.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number

UoK SERS REAG Ref No. 20_2025

Study information

Scientific Title
Home-based trunk intervention training to improve axial rigidity and functionality during activities of daily living in people with Parkinson's disease: a randomised clinical trial

Acronym
HBPD

Study objectives
To investigate the effect of a 12-week home-based trunk-specific exercise programme on axial rigidity and functionality

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/06/2025, Sport, Exercise and Rehabilitation Sciences Research Ethics and Advisory Group (REAG) (University of Kent, Chipperfield Building, Canterbury, CT2 7PE, United Kingdom; + 44 (0)1227 816943; k.taylor-399@kent.ac.uk), ref: 20_2025

Primary study design
Interventional

Study design
Single-centre interventional single-blinded randomized controlled trial

Study type(s)
Quality of life

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

Interventions
1. Trunk-targeted exercise programme
2. General exercise programme

Treatments will be administered using a single-blind matched-pairs design. Participants will undergo either trunk-targeted exercise training 3x a week over a 12-week period.

Intervention Type
Other

Primary outcome(s)
Axial rigidity measured using 3D motion capture at baseline, 4, 8, 12 and 24 weeks

Key secondary outcome(s)

1. Gait kinematics measured using 3D motion capture at baseline, 4, 8, 12 and 24 weeks
2. Functionality measured using Timed-Up and Go (TUG), Functional Reach Test (FRT), Berg Balance Scale (BBS) and Five-Times Sit to Stand Test (FTSST) at baseline, 4, 8, 12 and 24 weeks
3. Postural balance during 30-second quiet stand using 3D motion capture at baseline, 4, 8, 12 and 24 weeks

Completion date
01/06/2026

Eligibility

Key inclusion criteria
1. Clinically diagnosed with idiopathic Parkinson's disease
2. Classified between stage I-IV on Hoehn and Yahr (H&Y) classification scale during the clinical 'ON' state
3. Able to understand simple motor commands and of adequate cognition (screened using the Montreal Cognitive Assessment [MoCA])
4. Able to walk 10 m without assistance
5. Regular use of and no change in antiparkinsonian medication in the last month
6. Aged 40-80 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
40 Years

Upper age limit
80 Years

Sex
All

Key exclusion criteria
1. Previously had deep-brain stimulation (DBS) surgery.
2. Presented with comorbidities that may affect movement patterns.
3. Presented with comorbidities that may affect their capacity to exercise.
4. Changed their medication type and/or dosage throughout the duration of the study.
5. Score poorly on the Falls Risk Assessment Tool (FRAT) and Falls Efficacy Scale - International (FES-I) assessment for fall risk.
6. Score poorly on the MoCA.
7. Investigator's determination of unsuitability for trial participation.

Date of first enrolment
01/09/2025

Date of final enrolment
01/01/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Kent
Chipperfield Building
Park Wood Road
Canterbury
United Kingdom
CT2 7PE

Sponsor information

Organisation
University of Kent

ROR
https://ror.org/00xkeyj56

Funder(s)

Funder type
University/education

Funder Name
University of Kent

Alternative Name(s)
The University of Kent

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Lewis Ball (lrb33@kent.ac.uk) or Dr Jake Bowd (J.Bowd@kent.ac.uk) following completion and publication of study results, using de-identification of participant data. Data may be used for secondary analysis or meta-analyses and/or part of other relevant and legitimate scientific sources. All data will be fully anonymised so that participant information will be impossible to identify.

Researchers will ask for information regarding the use of any data and a clear proposal outlined to ensure data sharing is correct. This will form a data-sharing agreement where necessary which clearly details the criteria for data access and conditions for research use.

IPD sharing plan summary
Available on request