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Augmented reality (Reality DTx®) compared to routine physiotherapy for patients with Parkinson's

Submission date
10/04/2025

Recruitment status
Recruiting

Registration date
15/04/2025

Overall study status
Ongoing

Last Edited
19/08/2025

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Around 145,000 people in the UK are affected by Parkinson’s disease, and that number is expected to double in the next 16 years. As Parkinson’s gets worse, it’s harder to move around and stay balanced. This means people with Parkinson’s are more likely to fall, which makes life more difficult for them and their families. Physiotherapy rehabilitation can be helpful in managing Parkinson’s. It works best when it's tailored to your needs, is challenging enough, and you do it in a comfortable setting, like your home. However, getting to a clinic can be difficult, appointments may not fit with your medication schedule, it can be challenging to stay motivated at home without a physiotherapist, and waiting lists for physiotherapy can be long. This study aims to find out if a new technology called Reality DTx® is better than the physiotherapy which is currently offered.

Who can participate?
Patients aged 18 years old and over with Parkinson’s disease who are having difficulty with balance or walking.

What does the study involve?
Patients who are eligible and agree to join RESTART-PD will be randomly allocated to receive either the physiotherapy using augmented reality glasses or the usual physiotherapy offered at their hospital. Participants will either use their provided glasses for a six-week period, as instructed by their physiotherapist or receive their usual care for a period of six weeks.

The two groups will be followed up 8 weeks and 20 weeks after their first appointment. During this appointment, a physiotherapist will complete some assessments, and the participants will have to complete a short questionnaire about their health and quality of life.

What are the possible benefits and risks of participating?
The information obtained from this study may help to improve future support for people with Parkinson’s disease. Physiotherapy can benefit physical health and improve patients' quality of life, and physiotherapy will be offered whether patients choose to take part in the study or not.

Being in this study should not harm or limit care in any way. Some people may experience motion sickness while wearing the augmented reality glasses. The device may also increase the chance of hallucinations or seizures; however, this is not common. Being more mobile when using the glasses at home could also mean participants are more likely to fall.

Where is the study run from?
The University of Leeds is the sponsor of this research. York Trials Unit at the University of York are undertaking the day-to-day running of the study.

When is the study starting and how long is it expected to run for?
June 2024 to January 2027

Who is funding the study?
National Institute for Health and Care Research Invention for Innovation (i4i) Programme

Who is the main contact?
Ms Catherine Arundel, catherine.arundel@york.ac.uk

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
329864

Protocol serial number
CPMS 67200, NIHR206530

Study information

Scientific Title
RESTART-PD: rehabilitation exercise study with therapeutic augmented reality treatment for patients with Parkinson's disease: a randomised controlled trial comparing Reality DTx® plus usual care with usual care

Acronym
RESTART-PD

Study objectives
Reality DTx® software used at home can provide an effective, safe and cost-effective treatment for motor impairments associated with Parkinson's Disease.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/05/2025, East of England – Cambridgeshire and Hertfordshire (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 1048096; cambsandherts.rec@hra.nhs.uk), ref: 25/EE/0084

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Design
Two-arm, multi-centre, superiority RCT with two parallel groups (and a 6-month internal pilot).

Setting
Participants will be identified and rehabilitation will be provided in a minimum of 4 NHS hospital sites representing diverse populations across the UK.

Target population
We will include all adult patients (18 years or older) who have Parkinson's disease and who report having a bothersome gait or balance and who meet the eligibility criteria.

Sample size
A total of 216 (108 in the intervention group and 108 in the control group) patients will be recruited for the study

Recruitment
Consent
Prior to study involvement: Patients will be given a participant information sheet to read and be given sufficient time to consider this information.

Eligible and consenting patients will be randomly allocated to either Reality DTx® or usual care. Participants will be informed of their treatment allocation.

Baseline data collection
After being invited to join the study, patients will be invited to attend a face-to-face baseline visit in an outpatient department setting.

During the baseline visit participants will be given the opportunity to talk through the study with a member of the site research team and ask any questions they may have. If the patient wishes to join the study, they will be asked to provide written consent.

After consent has been granted, the participant will be asked to complete the following assessments:

Further Demographic information (Sex, ethnicity)
Relevant medical history.
Risk assessments.
Quality of Life assessments (EQ-5D-SL, PDQ-39) (to be used for data analysis).
Physical assessments (Lindop Parkinson's Assessment Scale, Timed up andGo (TUG), Berg Balance Scale).
Health service resource use questionnaire.

Randomisation
Following the baseline data being collected and baseline assessments having been completed, a member of the research team will randomise the participant using the REDCap and inform them of their allocation (usual care or Reality DTx®).

Follow up data collection
Patients will receive all other medical care as per standard of care
Follow up assessments will take place at 8 weeks and 20 weeks from the date of randomisation. The assessments at these time points will include:

Participant completed data
Quality of Life questionnaires (EQ-5D-SL, PDQ-39)
Health service use questionnaire
Investigator completed data
Physical assessments (Lindop Parkinson's Assessment Scale, Timed Up and Go, Berg Balance Scale).

Qualitative interviews
'Go along' interviews will be carried out with up to 20 physiotherapists responsible for introducing patients to Reality DTx® and supporting them in using it. 'Go along' interviews involve a researcher shadowing an individual to observe how they interact with others, interspersed with brief interviews between observations to gather the participant's views on the interaction (Carpiano, 2009). In this study, the purpose of the 'go along' interview is to understand how patients are introduced to Reality DTx® and supported to use it, including: the standard guidance and support provided; how guidance and support is adapted according to individual needs and preferences; what is going well and what is proving problematic; and whether there is a need to offer any additional support to patients beyond what was originally planned.

Interviews with 32 participants will be conducted either by telephone or face-to-face in the patient's own home, depending on what is most suitable for the patient. Interviews will cover: past experiences of exercise rehabilitation and/or physiotherapy: initial impressions of Reality DTx®: views on initial training and support provided in setting up and using Reality DTx® experiences in using Reality DTx® at home, including the barriers and facilitators to use: recommendations on the future use of Reality DTx®, including support needed by patients.

Patient & public involvement and engagement (PPIE)
Patient and public co-applicants have been involved in the project from the start of the funding application process. A group of patients from across the UK with a range of ages and disease severity and with lived experience of PD have provided their views on the trial design, outcome measurements, the interventions and use of the Reality DTx® equipment and the follow-ups. This group will remain involved in all aspects of the trial. A RESTART-PD PPI plan has been developed in line with NIHR recommendations, with costs included for all PPI activity in our PPI group and input to other trial meetings. The designated PPI lead will ensure that all trial processes are designed with our PPI team and that the study is inclusive for all potential participants.

Intervention Type
Behavioural

Primary outcome(s)
Mobility, balance, walking ability, and fall risk measured using the Timed Up and Go (TUG) test at 8 weeks post-randomisation

Key secondary outcome(s))
Current secondary outcome measures as of 19/08/2025:
1. Quality of life measured using the EQ-5D-5L at 8 and 20 weeks post-randomisation
2. Difficulties in daily living measured using the Parkinson's Disease Questionnaire (PDQ-39) at 8 and 20 weeks post-randomisation
3. Balance performance measured using the Mini-BESTest at 8 and 20 weeks post-randomisation
4. Falls measured using the DRESDEN Falls Questionnaire at 8 and 20 weeks post-randomisation
5. Freezing of gait measured using the Freeze of Gait Questionnaire (FOG) at 8 and 20 weeks post-randomisation
6. Fall risk measured using the 10-meter walk test and the sit-to-stand test at 8 and 20 weeks post-randomisation
7. Participant engagement with the intervention measured using concordance data at 8 and 20 weeks post-randomisation
8. Health resource use measured with health resource use information at 8 and 20 weeks post-

randomisation
9. Mobility, balance, walking ability, and fall risk measured using the TUG test at 20 weeks post-randomisation

Previous secondary outcome measures:
1. Quality of life measured using the EQ-5D-5L at 8 and 20weeks post-randomisation
2. Difficulties in daily living measured using the Parkinson's Disease Questionnaire (PDQ-39) at 8 and 20weeks post-randomisation
3. Function measured using the Lindop Parkinson's Mobility Assessment Scale at 8 and 20weeks post-randomisation
4. Balance measured using the Berg Balance Scale at 8 and 20weeks post-randomisation
5. Mobility, balance, walking ability, and fall risk measured using the TUG test at 20 weeks post-randomisation

Completion date
30/01/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 19/08/2025:
1. Aged 18 years or older
2. Diagnosed with Parkinson's disease according to the UK PD Brain Bank criteria (stages 1-4 on the Hoehn and Yahr scale). Stages 1 to 4 reflect varying levels of functional disability as a result of Parkinson's, ranging from minimal/no disability (level 1) to severe disability but still able to walk/stand unassisted (level 4). This will be assessed by the trained physiotherapist.
3. Bothersome gait or balance as self-reported by the individual, while on optimal medication
4. Using a stable dose of medication (i.e., no change within the last 28 days)
5. Ability to walk independently, with or without a walking aid, but not with the assistance of another person.
6. Ability to provide informed consent and comply with the protocol (for example, no additional neurological diseases and/or orthopaedic problems seriously interfering with gait function, insufficient general fitness, or cognitive/communicative inability (as observed by the researcher or clinician) to understand device instructions and participate in the tests

Previous inclusion criteria:
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4. Using a stable dose of medication (i.e., no change within the last 28 days)
5. Ability to walk independently, with or without a walking aid, but not with the assistance of another person.
6. Ability to provide informed consent and comply with the protocol (for example, no additional neurological diseases and/or orthopaedic problems seriously interfering with gait function, insufficient general fitness, or
7. Cognitive/communicative inability (as observed by the researcher or clinician) to understand device instructions and participate in the tests

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. (Severe) visual or hearing impairments (after corrective aids) that would prevent participants from seeing the visual display or hearing the audio cues provided
2. (Severe) visual hallucinations or illusions
3. Physically unable to wear the augmented reality glasses (e.g., presence of a head injury).
4. Unable to use the augmented reality glasses due to health condition (e.g., which would make wearing the glasses uncomfortable)
5. Patient is currently taking part in another study using augmented reality software
6. Patient has used augmented reality software in the last 6 weeks.

Date of first enrolment
30/09/2025

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St James's University Hospital
St James's University Hospital NHS Trust
Gledow Wing
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Midlands Partnership University NHS Foundation Trust
Trust Headquarters
St Georges Hospital
Corporation Street
Stafford
United Kingdom
ST16 3SR

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes