

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

Submission date 10/04/2025	Recruitment status Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/04/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/04/2025	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English Summary

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

Study website

<https://www.york.ac.uk/healthsciences/research/trials/ytutrialstandstudies/trials/restartpd/>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

329864

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 hypothesis

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)

Submitted, 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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Condition

Specialty: Dementia and Neurodegeneration, Primary sub-specialty: Parkinson's Disease; Health Category: Neurological

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 measure

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

Secondary outcome measures

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. Function measured using the Lindop Parkinson's Mobility Assessment Scale at 8- and 20-weeks post-randomisation
4. Balance measured using the Berg Balance Scale at 8- and 20-weeks post-randomisation
5. Mobility, balance, walking ability, and fall risk measured using the TUG test at 20 weeks post-randomisation

Overall study start date

01/06/2024

Overall study end date

30/01/2027

Eligibility

Participant inclusion criteria

1. 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
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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 216; UK Sample Size: 216

Participant 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.

Recruitment start date

01/06/2025

Recruitment end date

31/07/2026

Locations**Countries of recruitment**

England

United Kingdom

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

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NW1 2PG

Sponsor information

Organisation

University of Leeds

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<https://www.leeds.ac.uk>

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

Publication and dissemination plan

1. Planned publication in a peer reviewed journal
2. Published evidence on the effectiveness and cost-effectiveness of Reality DTx® in real-world healthcare settings.
3. Post-implementation multi-media toolkit to enable wider uptake in the NHS (E.g., training guides, template, business case, process flow/blue-print, instruction manuals, guides, videos, and patient material)
4. Conference presentations for wider dissemination at professional events.

Intention to publish date

30/06/2027

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