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ReHabGame: a game-based rehabilitation system for motor-impaired individuals

Submission date
06/05/2025

Recruitment status
Recruiting

Registration date
19/05/2025

Overall study status
Ongoing

Last Edited
11/06/2025

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
ReHabGame is a research study exploring a fun and interactive way to support people who have difficulty moving their arm or hand due to a neurological condition like a stroke, brain injury, or multiple sclerosis. These conditions can make everyday tasks like eating, dressing, or writing more difficult, and traditional rehabilitation exercises can sometimes feel repetitive or boring. ReHabGame aims to make therapy more engaging by turning it into a game with rewards. Using a depth camera (Kinect), the system tracks the person's movements without needing any wearable sensors. The player moves their arm or hand to control a virtual avatar on the screen, completing tasks like reaching, grasping, or pressing buttons. The game provides instant feedback and adapts to the person's abilities, helping them improve.

Who can participate?
Adult patients (aged 18 years or older) diagnosed with a neurological condition, such as stroke, traumatic brain injury (TBI), or multiple sclerosis (MS), that affects upper-limb motor function.

What does the study involve?
In this study, participants will be invited to use ReHabGame for 6 to 8 weeks, attending two short sessions (each 30 min) per week. Their arm movement will be assessed before and after the program using a standard test, and again around 6 months later to see if any improvements last. The follow-up can be in-person or online over Microsoft Teams. They will also be asked how easy and enjoyable the game was and whether they would recommend it to others.
This is a feasibility study, meaning its aim is to determine whether the game works well enough for real rehabilitation settings, how easy it is to participate in the study, and whether people like using it. The information gathered will help to design a larger study in the future.

What are the possible benefits and risks of participating?
ReHabGame has the potential to offer a motivating, low-cost, and home-friendly option for people working to regain their independence after neurological injury.

Where is the study run from?
Anglia Ruskin University (UK)

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

Who is funding the study?
Anglia Ruskin University (UK)

Who is the main contact?
Dr Shabnam Sadeghi Esfahlani, shabnam.sadeghi-esfahlani@aru.ac.uk

Study website
https://www.aru.ac.uk/business-employers/develop-your-business/innovation-and-business-support/commercialisation-opportunities/rehabgame

Contact information

Type(s)
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
356908

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ETH2425-3331

Study information

Scientific Title
ReHabGame: a feasibility randomised controlled study of a markerless, Kinect-based game intervention versus standard physiotherapy to improve upper limb motor function in adults with neurological impairments

Acronym
ReHabGame

Study objectives
Primary Hypothesis (Feasibility):
ReHabGame is a feasible and acceptable rehabilitation tool, demonstrated by participant retention, adherence, usability scores, and absence of serious adverse events.

Secondary Hypothesis (Exploratory Clinical):
Participants using ReHabGame will show greater improvements in upper-limb motor function (FMA-UE score) compared to those receiving standard rehabilitation.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 11/06/2025, East of England - Essex Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8177; essex.rec@hra.nhs.uk), ref: Reference number not provided

Study design
Pilot randomized controlled feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Other therapist office

Study type(s)
Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Neurological Condition: Diagnosed with stroke, traumatic brain injury (TBI), or multiple sclerosis (MS) that impacts upper-limb motor function.

Interventions
ReHabGame is a non-invasive, game-based digital therapeutic intervention designed to support upper-limb rehabilitation in individuals with neurological impairments (e.g., stroke, TBI, MS). It combines physiotherapy principles with interactive gaming, using a markerless motion-tracking system (Microsoft Kinect) to deliver repetitive, goal-directed arm and hand exercises within a virtual environment.

The system provides:
1. Real-time visual feedback
2. Adaptive task difficulty based on performance
3. Performance logging (range of motion, task completion, frequency)

This is a two-arm, randomised, interventional feasibility study assessing the use of ReHabGame, a game-based rehabilitation system using Kinect motion tracking, for adults with upper-limb motor impairments due to neurological conditions.

Intervention Group:
Participants in the intervention arm will engage with ReHabGame for 6–8 weeks, completing 1–2 sessions per week, each lasting approximately 30 minutes. The intervention will be administered in a clinical or supervised setting. ReHabGame uses a Microsoft Kinect sensor to deliver goal-oriented upper-limb motor tasks within an interactive, adaptive virtual environment. The system captures movement metrics and provides real-time visual feedback to support rehabilitation.

Control Group:
According to their usual treatment pathway, participants in the control group will receive standard rehabilitation care (e.g., physiotherapy) or no additional intervention. Details of the control condition will be recorded for each participant.

Outcome assessments (e.g., Fugl-Meyer Assessment for upper-limb function) will be conducted at baseline, post-intervention (week 6–8), and at a follow-up appointment approximately 6 months later. Additional feasibility metrics, system usage data, and participant experience questionnaires will be collected.

Descriptive statistics for feasibility metrics:
Paired t-tests or Wilcoxon signed-rank tests for within-group changes
Independent t-tests or Mann–Whitney U tests for between-group comparisons
Cohen’s d for effect size estimation
Thematic analysis for qualitative feedback using NVivo or MAXQDA

Intervention Type
Behavioural

Primary outcome measure
Both quantitative (e.g., clinical assessments) and qualitative (e.g., questionnaire) methods will be employed to provide a comprehensive understanding of ReHabGame's effectiveness and user experience:
1. Quantitative:
1.1. Clinical assessments: Standardised measures of arm function (e.g., Fugl-Meyer Assessment) at baseline, midpoint (if applicable), and post-intervention.
1.2. System-generated metrics: The ReHabGame software will record range-of-motion data, frequency of play, and task completion rates during sessions.
1.3. Observational checklists: Researchers may observe sessions to note participant posture, any difficulties using the system, and engagement level (e.g., exercise completion, verbal feedback during sessions).
2. Qualitative data collected from the web-based questionnaire. The research team will apply a structured coding framework (e.g., Braun & Clarke's thematic analysis) to identify key themes around usability, motivation, and perceived impact. If needed, a qualitative data analysis tool (e. g., NVivo or MAXQDA) may be used to organise and manage transcripts.

Secondary outcome measures
The following secondary outcome measures will be used to evaluate the feasibility, acceptability, and preliminary clinical impact of the ReHabGame intervention via a questionnaire:
1. Feasibility is measured through recruitment rate, retention rate, session adherence, data completeness, and the occurrence of adverse events, using study screening logs, attendance records, and an adverse event log. These will be assessed continuously throughout the study and summarised at post-intervention (6–8 weeks).
2. Acceptability and user engagement are measured using automated gameplay metrics (e.g., frequency of use, task completion rates) collected at post-intervention (6–8 weeks)
The measures will be collected at baseline, post-intervention (6–8 weeks), and 6-month follow-up, where feasible.

Overall study start date
01/07/2024

Completion date
01/07/2027

Eligibility

Key inclusion criteria
1. Adults (aged 18 years or older) diagnosed with a neurological condition, such as stroke, traumatic brain injury (TBI), or multiple sclerosis (MS), that affects upper-limb motor function.
2. To ensure sufficient functional ability to engage with the ReHabGame system, participants must meet at least one of the following objective inclusion criteria:
2.1. A Fugl-Meyer Assessment – Upper Extremity (FMA-UE) score between 20 and 50 (indicating mild-to-moderate impairment and sufficient voluntary movement)
2.2. A Box and Block Test score of ≥5 blocks per minute (demonstrating basic grasp-and-release function)
2.3. Active range of motion (AROM) of at least 10° in both shoulder and elbow flexion, or a Modified Ashworth Scale score of ≤3 at the elbow or wrist (to exclude those with severe spasticity that would hinder interaction).
3. Participants must be willing and able to commit to a 6–8 week game-based rehabilitation

program (attending 1–2 sessions per week)
4. Have the capacity to provide informed consent, either independently or with support from a caregiver or legally authorised representative

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25 for each arm

Key exclusion criteria
1. Medical Instability: Unstable cardiac, respiratory, orthopedic, or neurological conditions (e.g., uncontrolled seizures, severe arrhythmias) that pose a safety risk
2. Severe Motor Deficit: Complete paralysis (e.g., plegia) or extreme spasticity preventing meaningful interaction with the system
3. Contraindications to VR/Motion Tracking: Severe motion sickness, significant visual impairments, epilepsy triggered by visual stimuli, or other conditions making Kinect/VR usage unsafe
4. Concurrent Participation in Conflicting Studies: Currently enrolled in another interventional study or rehabilitation program that could confound results

Date of first enrolment
01/07/2025

Date of final enrolment
01/06/2027

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Physio4You
Head Office:
16 Watermark Way
John Tate Road
Hertford

United Kingdom
SG13 7TZ

Study participating centre
Physio4You
Registered Office:
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Sponsor information

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Sponsor type
University/education

Website
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ROR
https://ror.org/0009t4v78

Funder(s)

Funder type
University/education

Funder Name
Anglia Ruskin University

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Anglia Ruskin University (ARU), as the Sponsor, retains ownership of all data generated by this study. The findings will be disseminated through a range of academic and public channels to maximise impact and transparency:
1. Peer-reviewed journal publications in the fields of rehabilitation science, digital health, and neurotechnology.
2. Conference presentations and abstracts at national and international events, including rehabilitation, neurophysiotherapy, and clinical innovation meetings.
3. Internal reports and briefings for institutional stakeholders and clinical collaborators.
4. Plain language summaries are shared with participants, clinical sites, and relevant charities or patient groups to ensure the accessibility of results.
5. Online publication via the university website, open-access repositories, and digital newsletters, where appropriate.

Intention to publish date
01/11/2027

Individual participant data (IPD) sharing plan
This study does not plan to share individual participant data (IPD) beyond the study team at this stage. All data will be securely stored and handled in accordance with the General Data Protection Regulation (GDPR) and Anglia Ruskin University (ARU) data governance policies on a two-factor authenticated OneDrive.

However, the following conditions apply for potential future sharing:
1. Anonymised datasets may be made available for secondary research purposes upon request, but only if such use is consistent with participant consent and ethical approvals.
2. Any data shared will be fully anonymised, meaning it will not contain any personal identifiers and will not allow individuals to be identified, directly or indirectly.
3. Requests for access to anonymised IPD must be submitted in writing to the Chief Investigator. They will be reviewed by the study's data access oversight group or ARU’s Research Governance team.
4. Any approved sharing of IPD will be governed by a data sharing agreement, which will define how the data may be used, stored, and cited, and ensure compliance with all legal and ethical standards.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			19/05/2025	No	Yes