



ReHabGame: A Markerless, Game-Based Rehabilitation program

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Participant Information Sheet (PIS)

You are being invited to join a research study testing **ReHabGame**, a computer-based rehabilitation program that uses simple body movements to play games on screen.

ReHabGame is designed to make rehabilitation more enjoyable by turning exercises into interactive games. It uses a motion sensor camera (Kinect) to follow your movements, no wires, no wearable sensors.

We are running this study to find out if ReHabGame is easy to use, practical, and whether it can help recovery when compared with regular physiotherapy.

Before you decide whether to take part, please take time to read this PIS carefully. It explains why the research is being done and what it will involve for you.

Why have I been invited?

You have been invited because your therapist believes you may benefit from additional rehabilitation for your arm or shoulder, and you meet the study's eligibility criteria (such as diagnosis, age, and ability to follow instructions).

This study includes two groups of participants (called cohorts):

- **Musculoskeletal (MSK) cohort:** Participants with shoulder or arm pain, stiffness, or movement limitation due to conditions such as rotator cuff injury, frozen shoulder, or post-operative shoulder rehabilitation.
- **Neurological cohort:** Participants with movement difficulties following a stroke, traumatic brain injury (TBI), or multiple sclerosis (MS).

Each cohort will follow a similar schedule of sessions and assessments, but the type of exercises and outcome measures will be tailored to their specific rehabilitation needs.

Do I have to take part?

No. Taking part is entirely up to you. If you decide not to, or if you join and later change your mind, your usual care will not be affected.

What will the study involve for me?

- **Length of study:** About **12 weeks** in total.
- **Sessions:** Up to **16 therapy sessions** (2 per week for 8 weeks).
- **Assessments:** 3–4 assessment visits (at the start, halfway, end of treatment, and a short follow-up 4 weeks later).

What happens at each stage?

- **Baseline (Week 0):**
 - A researcher will ask you some background questions (about your health and daily activities).
 - You will do short movement and function tests (about 30–40 minutes).
 - You will then be randomly assigned to one of two groups:
 1. **Usual care only** – your standard physiotherapy.
 2. **Combined** – both ReHabGame and your usual physiotherapy.
- **Therapy sessions (Weeks 1–8):**
 - Each session lasts 30–45 minutes.
 - Sessions are supervised by trained physiotherapists or research staff.
 - If you are in the combined group, your game and physiotherapy sessions may be booked on separate days or back-to-back, depending on what works best for you.
- **Mid-point check (Week 4):**
 - Short re-test (about 20 minutes) to see how you're progressing.
 - Quick questionnaire about your experience so far.
- **End of treatment (Week 8):**
 - Repeat of your first assessment (about 40 minutes).
 - Short interview or feedback form about how you found the program.
- **Follow-up (Week 12):**
 - A final check-in (20–30 minutes) to see if improvements lasted.

Who will supervise the sessions?

All sessions will take place in a **supervised clinical setting**, at the same physiotherapy site where you normally receive care:

- **Musculoskeletal (MSK) participants:** Sessions will be held at Southend Hospital Outpatient Physiotherapy Department, supervised by a clinical physiotherapist/physiotherapy team.
- **Neurological participants:** Sessions will be held at Physio4You, a private neuro-physiotherapy clinic in Hertfordshire, supervised by a Clinical Physiotherapist.

Each site is equipped with a ReHabGame setup (computer and Kinect camera) and trained staff who will monitor all sessions to ensure safety and appropriate exercise performance.

A medical student may assist with questionnaires but will always work under the direct supervision of the physiotherapy team.

What is different from usual care?

- If you are assigned to usual care only, you will continue with your standard physiotherapy as normal.
- If you are in the combined group, you will receive both. These sessions will be scheduled to minimise overburdening (either on the same day or on different days, depending on availability and your preference).

Will it cost me anything?

We know it is not right for participants to be out of pocket. Currently, we do not have a budget to reimburse travel expenses for this study; however, we are applying for NIHR funding to cover these costs.

In the meantime, we will:

- Try to schedule research visits alongside your usual appointments to reduce extra trips.
- Provide information on any hospital transport options available locally.
- Explore site-level hardship support if travel costs are a barrier.

If we secure funding during the study, travel expenses and incentives will be reimbursed, including for participants who have already taken part.

Will the study cause me any discomfort or risk?

Participating in this study involves low to moderate risks, similar to those you might experience in regular physiotherapy. Here's what to expect and how we'll keep you safe:

- You may experience mild-to-moderate muscle tiredness or soreness, just like a typical exercise session. If you become tired, frustrated, or mentally fatigued, please let us know, and the session will pause so you can take a break. The camera is non-invasive. There is a small risk of tripping over cables; however, the room will be cleared and mats provided. Movement data are encrypted and stored using a user ID.
- **ReHabGame-Specific Risks:** Although the game dynamically adjusts difficulty, pushing yourself too hard could cause strain. We cap challenge increases and monitor your fatigue levels each session. Rare misreads could prompt you to move in ways that feel awkward. Your therapist will guide you to prevent any unsafe movements.
- **Usual-Care Physiotherapy Risks:** These follow standard clinical guidelines; risks include transient pain flare-ups or overuse strain if you push beyond recommended limits.
- If at any point you feel unsafe or in pain, let your therapist or the research staff know immediately. Your well-being is our top priority, and participation is voluntary, you may stop or withdraw at any time without affecting your usual care.
- Stringent data protection protocols will ensure confidentiality and compliance with data protection legislation (e.g., GDPR).
- Should any part of this study cause distress, remember that support services are available for you to access; whatever you're going through, please use the link: [NHS helpline](#).

What are the benefits of taking part?

You may:

- Improve your movement and independence
- Enjoy a more engaging, personalised therapy
- Help us improve rehab tools for others with similar conditions

What happens after the study?

After the study concludes, access to ReHabGame will be discontinued. Continued use would only be possible if ReHabGame receives approval as a medical device (e.g., CE mark or MHRA approval).

Will I find out the results?

- **During the study:** After each ReHabGame session (and again at your final session), you'll receive **personalised feedback** on your performance, such as your movement scores, progress over time, and any recommendations for the next session.
- **After the study:** Once all data have been analysed, you can **request a lay summary** of the overall study findings. This summary will be written in plain English and sent to you by email, so you can see how the different groups performed and what we learned.

How will my information be used?

Your data will be handled in accordance with the **Data Protection Act 2018** and the **General Data Protection Regulation (GDPR)**. It will be:

- Stored securely and anonymously using encrypted systems
- Only accessed by authorised team members
- Kept for 3 years and then deleted or anonymised
- Stored securely and anonymously using encrypted systems.
- Accessed only by authorised team members.
- Used for research purposes only, and not shared with anyone outside the research team except where required for safety or regulatory reasons.
- Relevant information from your medical notes may be reviewed by members of your clinical care team to confirm eligibility and monitor progress.
- Your GP and/or referring consultant will be notified of your participation in the study.

Please note that usual safeguarding procedures will be followed in the event of any distress or disclosure of risk of harm to yourself or others during the study.

Who can I contact?

- **To discuss the study:** Dr Shabnam Sadeghi Esfahlani – Email: ss48@aru.ac.uk
- **For general queries:** dpo@aru.ac.uk (Data Protection Officer)
- **To make a complaint:** complaints@aru.ac.uk

Future Research Opportunities

The findings from this study will lay the foundation for several future research opportunities aimed at advancing the field of neurorehabilitation and expanding the applications of gamified and AI-driven technologies.

- The study does **not** involve any medication or drug therapy.
- Participants are free to continue their usual clinical care and rehabilitation programs as recommended by their healthcare providers once the research sessions end.

Please let the research team know if you are currently taking part in any other research studies or have been involved in one recently. In particular, if you are in a trial that includes any intervention (clinical or otherwise) that could affect this study's results or place additional demands on you, please inform us. We want to ensure your safety and well-being, and that the information we

collect is accurate. The clinical and research teams will discuss your situation if needed to determine whether it is appropriate for you to join this study at this time.