ReHabGame: A Markerless, Game-Based Rehabilitation System for Motor-Impaired Individuals

Institution Ethics Reference Number: Ethics ETH2425-3331
Version 1.0
Date: 22.01.2025
IRAS ID:1012073

Participant Information Sheet (PIS)

Thank you for considering participating in our study titled "**ReHabGame: A Markerless, Game-Based Rehabilitation System for Motor-Impaired Individuals.**" This study explores the feasibility and effectiveness of using advanced gamified environments to enhance motor recovery and functional independence for individuals with neurological impairments such as stroke, brain injuries, or multiple sclerosis.

We invite you to participate in **ReHabGame**, an interactive system that supports neurorehabilitation through gamified experiences. The game collects data on body joint movements and orientations using motion-tracking devices like the Kinect sensor and an armband to assess motor performance and adapt to each participant's abilities in real-time. By dynamically adjusting the difficulty level, the game personalizes the rehabilitation experience, promoting consistent engagement and optimal recovery.
Your participation will help us refine this innovative approach by providing insights into its usability, effectiveness, and potential to improve rehabilitation outcomes. This study is entirely voluntary, and all data collected will be

We look forward to your involvement in shaping the future of accessible and engaging neurorehabilitation technologies. Thank you for your interest and contribution!

Purpose and Rationale of the Study:

This study aims to evaluate the feasibility, effectiveness, and user experience of **ReHabGame**, a gamified neurorehabilitation system designed to enhance motor recovery and functional independence for individuals with neurological impairments such as stroke, traumatic brain injuries, and multiple sclerosis. By combining motion tracking technology with a personalized gamified environment, ReHabGame aims to address critical challenges in traditional rehabilitation, such as limited accessibility, high costs, and low patient engagement.

Rationale:

1. **Clinical Need**: Neurological impairments often result in significant motor function deficits, requiring long-term rehabilitation. Traditional rehabilitation methods can be repetitive, costly, and inaccessible to many patients, leading to low adherence and suboptimal outcomes. There is a pressing need for innovative, scalable solutions to improve recovery and accessibility.
2. **Technological Advantage**: Gamified environments, powered by motion tracking and artificial intelligence, offer a unique opportunity to create engaging, adaptive, and cost-effective rehabilitation programs. These systems can personalize exercises in real time based on individual abilities, improving motivation and adherence.
3. **Societal and Economic Impact**: By enhancing recovery rates and reducing the need for prolonged therapy, ReHabGame has the potential to lower healthcare costs while increasing accessibility to underserved populations, making rehabilitation more inclusive.

This study seeks to validate the effectiveness of ReHabGame in improving motor function and patient engagement while exploring its scalability for both clinical and home-based care. The findings will contribute to developing innovative rehabilitation technologies, addressing a growing global need for accessible and effective neurorehabilitation solutions.

Objectives of the Study:

- **Primary Objective:**
  - To evaluate the effectiveness of **ReHabGame** in improving motor recovery and functional independence in individuals with neurological impairments, such as stroke, brain injuries, and multiple sclerosis.
- **Secondary Objectives:**
  - To assess the feasibility and usability of the gamified rehabilitation system in clinical and home-based settings.

  - To analyze the accuracy and reliability of motion tracking data collected through the Kinect sensor and an armband in supporting rehabilitation exercises.
  - To explore participants' perceptions of the gamified environment, including its impact on motivation and overall user experience.
  - To identify potential barriers and facilitators to adopting gamified neurorehabilitation technologies in routine clinical practice.
- **Exploratory Objectives:**
  - To investigate the scalability and accessibility of ReHabGame for diverse patient demographics, including those with limited access to traditional rehabilitation services.
  - To evaluate the potential for cost reduction and resource optimization in neurorehabilitation by integrating gamified systems.

What am I being asked to do?

As a participant in this study, you are being asked to engage with **ReHabgame**, a gamified rehabilitation system designed to enhance motor recovery and functional independence. Specifically, you will:

1. **Participate in Game-Based Rehabilitation Sessions:** Engage in structured movement-based rehabilitation exercises within a gamified environment. These exercises are designed to improve motor function and may lead to temporary muscle fatigue, similar to traditional physiotherapy
   - Perform a series of movements and exercises as guided by the gamified system.
   - Use motion-tracking devices like the Kinect sensor and armband to capture your joint movements and muscle activity during the sessions.
2. **Provide Feedback**
   - Share your thoughts on the usability, comfort, and overall experience of using ReHabgame.
   - Highlight any challenges or suggestions for improvement to help refine the system.
3. **Complete Surveys or Interviews**
   - Participate in a questionnaire to assess your engagement, motivation, and satisfaction with the gamified environment.
   - Provide insights on how the system impacts your rehabilitation journey and adherence to therapy.
4. **Contribute to the Study's Goals**
   - Your performance data and feedback will help us evaluate the system's effectiveness and usability, contributing to the development of accessible and innovative neurorehabilitation solutions.

Participation is voluntary, and you can withdraw at any time without any negative consequences. Your input is invaluable in shaping the future of gamified

Your decision to participate is entirely voluntary and will not impact the care you receive. You can withdraw at any time without providing a reason, and this will not affect your rehabilitation plan in any way.

How will we use information about you?

Ethical consideration: Anglia Ruskin University (ARU) manages your data as the project sponsor and Data Controllers in compliance with the Data Protection Act (2018), HRA's recommended transparency, and the use of patient information for research: Health Research Authority (HRA). If you have any concerns, don't hesitate to contact ss48@aru.ac.uk or the Data Protection Officer at dpo@aru.ac.uk for more guidance. Formal complaints can be sent to S&C's Officer at complaints@aru.ac.uk.

Data Security and Encryption: Your data's security is paramount to us. We utilize advanced encryption techniques to safeguard against unauthorized access during storage and transfer processes. All data collected during the study is securely stored on password-protected servers, ensuring compliance with data protection regulations. This data is stored securely on the Jisc Online Surveys and ARU's Multifactor Authenticated computers. It will be deleted when it is no longer needed for analysis. Rest assured, your identity will remain anonymous in our reports, maintaining your privacy and confidentiality. JISC will assign each participant a unique identification code. Access will be restricted to authorized personnel only.

What are the potential benefits of taking part?

As a participant in this study, you may experience the following benefits:

1. **Improved Motor Recovery**
   - Engaging with the **ReHabGame** system may enhance your motor function and physical abilities by providing personalized exercises designed to support your rehabilitation goals.
2. **Increased Motivation and Engagement**
   - The gamified environment offers an interactive and enjoyable approach to rehabilitation, which may improve your motivation to participate consistently in therapy.
3. **Personalized Rehabilitation Experience**
   - The system adapts to your individual abilities and progress, ensuring that the exercises remain challenging yet achievable, maximizing your potential for recovery.
4. **Accessible and Convenient Therapy**
   - The study may offer an opportunity to experience rehabilitation in a setting that reduces the need for frequent travel to clinical facilities.
5. **Contribution to Research and Innovation**
   - By participating, you will contribute valuable insights to developing innovative, technology-driven rehabilitation solutions, potentially benefiting others with similar conditions in the future.
6. **Opportunity to Shape Future Technologies**

effective and accessible therapies.

While the study's primary aim is research-focused, these benefits may provide meaningful contributions to your rehabilitation journey and offer a sense of empowerment through active involvement in cutting-edge healthcare innovation.

What are the potential disadvantages or risks of taking part?

While participating in this study is designed to be safe and beneficial, there are a few potential disadvantages or risks to consider:

1. **Physical Discomfort**
   - Some exercises or movements in the gamified environment may lead to temporary muscle fatigue, soreness, or discomfort, especially for individuals with limited mobility or pre-existing conditions.
2. **Frustration or Emotional Distress**
   - Participants may feel frustrated if they struggle with certain movements or perceive slower-than-expected progress.
   - Discussing their rehabilitation journey or limitations during feedback sessions may evoke emotional responses.
3. **Time Commitment**
   - Participation requires a regular time commitment to attending sessions **(approximately 30-45 minutes per session, 2 times per week, span 6–8 weeks)** and completing assessments, which might be inconvenient for some participants.
   - Regular sessions allow participants to engage in therapeutic exercises frequently enough to see measurable progress.
   - Multiple sessions provide a robust dataset for analyzing trends and improvements.
   - The schedule balances participant commitment with the study's research needs.
4. **Technology-Related Challenges**
   - Participants unfamiliar with motion-tracking technology or gamified systems may initially find it challenging to use the equipment, which could cause frustration.
   - Technical issues, such as calibration errors or system malfunctions, may temporarily disrupt sessions.
5. **Risk of Overexertion**
   - There is a minimal risk of overexertion during rehabilitation exercises if movements are performed too intensely or beyond the participant's physical limits.
6. **Confidentiality Risks (Low)**
   - Although all data will be anonymized and stored securely, there is always a small risk of data breach or unauthorized access. However, stringent data protection measures will be in place to minimize this risk.

To address these potential disadvantages or risks:

- The system is designed to adjust difficulty levels dynamically, reducing the risk of overexertion or frustration.
- Researchers will monitor participants during sessions and provide immediate assistance if needed.
- Clear instructions and training will be provided to familiarize participants with the technology.
- 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.

How and when can I withdraw from the study?

You can withdraw from the study anytime, and your decision will be fully respected without any consequences. If you wish to withdraw, inform the research team or email the principal investigator at ss48@aru.ac.uk.

What will happen to my data, and how will your data be processed?

Your data will be used solely for research purposes and will not be shared with any third parties without your explicit consent. After the study, your anonymized data may be used for analysis, reporting, and publication in scientific journals to disseminate the findings and support the decision-making process. If you have any further questions, don't hesitate to contact the principal investigator of the research.

What information will be collected from you, and how long it will be retained?

The following demographic data will be collected from you: age, gender, ethnicity and your experience with the ReHabgame. To protect participant privacy, anonymization measures will be implemented. We will retain the data collected from this survey for 3 years. This duration will allow sufficient time for the project to implement and adopt the proposed solutions, further analyses, publications, and/or reporting requirements associated with the study. After this period, any personal data collected will be securely disposed of or anonymized to ensure compliance with data protection regulations and to safeguard participants' confidentiality and privacy.

You may receive a copy of your responses and the signed consent form for your records if you wish. This copy will be provided immediately after you submit the survey online if you choose to receive a copy of your response and the consent form.

Access to published research findings

Participants will access the published research findings after the study's completion. The dissemination of results will ensure transparency and provide participants with an understanding of how their contributions have advanced neurorehabilitation research.

The following steps will be taken:

highlight the key outcomes and implications of the research.

- The study results will be published in reputable peer-reviewed journals in the fields of rehabilitation science, healthcare technology, and artificial intelligence. Open-access publishing will be pursued where possible, ensuring the findings are accessible to a wide audience.
- The findings will be presented at academic and industry conferences, and public talks or workshops may be held to discuss the study's impact.
- The results will be made available through the institution's official website and social media platforms, ensuring easy access for participants and the general public.
- Participants can request the study results directly via email (ss48@aru.ac.uk), where access to the published data will be provided upon request.

By providing multiple channels for accessing the research findings, we aim to ensure that participants and the broader community can benefit from the insights and advancements generated by the study.

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.

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Participant Consent Form (PCF)

2. I know what information will be collected from me for the study.
3. I am informed about how the research team will process my data in line with the Data Protection Act (2018).
4. I understand what will happen to the data I collected for the research.
5. I acknowledge the potential benefits of taking part.
6. I comprehend any potential disadvantages or risks regarding participating.
7. I know the study results will be disseminated via journal & conference proceedings and can be obtained by contacting ss48@aru.ac.uk
8. I have been briefed on the duration my data will be retained.
9. I understand that I can withdraw from the research at any point without giving any reason.

Participant's Statement: I confirm that the research project has been explained satisfactorily.
I agree to participate in the study, having read the provided Information and fully understanding what the research involves. *

- ◯ Yes
- ◯ No

- The research team will retain a copy of the signed consent form for documentation and compliance purposes.
  To receive a copy of the signed consent form for your records, please save a copy of your consent form and responses by following these steps:
  1. **Right-click anywhere on the survey page (or use the browser menu) and select 'Print'.**
  2. **Choose 'Save as PDF' as the destination in the print dialogue.**
  3. **Click 'Save' and choose a location on your device to store the PDF file.**

  This will ensure you have a copy of all the information you provided.

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