ISRCTN10738201 https://doi.org/10.1186/ISRCTN10738201

Virtual reality for rehabilitation in stroke and musculoskeletal disorders.

Submission date
30/06/2021

Recruitment status
No longer recruiting

Registration date
03/08/2021

Overall study status
Completed

Last Edited
04/08/2021

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Virtual reality has been successfully used in rehabilitation in a wide range of areas and in various contexts. The aim of this study is to assess the feasibility of using virtual reality games as part of the rehabilitation programmes of adults with musculoskeletal problems (i.e. injuries or conditions that affect the bones, muscles and tendons of the body), or people who have a stroke, in addition to their usual therapy sessions.

Who can participate?
Patients aged 18 years and over with musculoskeletal injuries or conditions, or who have had a stroke

What does the study involve?
All participants will take part in the following activities:
1. A guided interview that will help the researchers to understand the participants' disability, and activities to guide the design of the VR games and controllers.
2. Measurement of the shape of the participants' arms and hands to guide the shape and design of the controller, including how the participant will interact with the controller. The researchers will also measure the forces that the participant is able to apply with their hands, for example, their strength to pinch or grasp objects.
3. The participants' movements are captured during simple tasks and gameplay using small lightweight wearable motion sensors and video and audio recordings
4. Observation of how people interact with commercial virtual reality controllers.
5. The researchers will explore how the participants feel when they use a controller to play virtual reality games, for example, whether they feel sick, and how they experience their real body in the virtual world. These aspects will be assessed using standard questionnaires that have been used in other studies about virtual reality.

What are the possible benefits and risks of participating?
The study aims to inform the design and production of both physical controllers and virtual reality environments. Within the virtual reality environments, tasks will be designed for specific patients to address their individual needs. The researchers think that virtual reality may improve the success of rehabilitation programmes. This is because the therapy sessions could become

more fun and motivating than standard repetitive exercises/therapy. The researchers think that virtual reality can provide an environment that is safe and interesting, and which can be designed to motivate and enable people to practice movements that help them to improve their ability to do useful activities. Making rehabilitation sessions more effective might in turn increase the patient's participation and hours of practice, therefore achieving the recommended amount of therapy. The most frequent side-effects that have been reported in other virtual reality studies are motion sickness, flashbacks, short-term disturbances in vision, and photosensitive epilepsy.

Where is the study run from?
1. St James Hospital (Malta)
2. Nicomed Rehabilitation Centre (Cyprus)

When is the study starting and how long is it expected to run for?
October 2019 to September 2022

Who is funding the study?
European Commission Horizon 2020 programme

Who is the main contact?
1. Milos Stanisavljevic, milos.stanisavljevic@stjameshospital.com
2. Hadjionisiforou Onisiforos, onisiforos@kinisiforoltd.com

Study website
https://prime-vr2.eu/

Contact information

Type(s)
Scientific

Contact name
Mr Milos Stanisavljevic

Contact details
Marble Arch Blk A1, Flat 3, Lapsi Street
St Julians
Malta
STJ1261
+356 (0)99876689 / +356 (0)27210671
milos.stanisavljevic@stjameshospital.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
v1

Study information

Scientific Title
Feasibility of Personalised Recovery In a Multi-user Environment: Virtual Reality for Rehabilitation (PRIME VR2) to explore, develop and regain functional movement in people with musculoskeletal disorders and stroke

Acronym
PRIME-VR2

Study objectives
The proposed study will evaluate the feasibility and potential usability of virtual reality as an intervention in addition to usual care in groups of adults with musculoskeletal injuries /conditions or stroke.

This study aims to explore:
1. The safety, feasibility and acceptability of virtual reality as a rehabilitation intervention for people with musculoskeletal injury and stroke
2. Whether the use of co-piloting by an assistant enhances the experience and performance while using commercial virtual reality by people with musculoskeletal injury and stroke

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 03/01/2020, Saint James Ethical Committee (George Borg Olivier Street, Sliema, Malta; +356 (0)23292003; charlotte.santportanier@stjames hospital.com), ref: EC001
2. Approved 28/05/2020, Cyprus National Bioethics Committee (Laertou No 22, 2365, Nicosia City, Cyprus; +357 (0)22-809038 / +357 (0)22-809039; cnbc@bioethics.gov.cy), ref: ΕΕΒΚ/ΕΠ/2020 /09

Study design
Multi-centre feasibility study using quantitative and qualitative methods and purposive sampling

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Musculoskeletal disorders and injuries, stroke

Interventions
This is a project to explore how people with musculoskeletal injuries and stroke might use commercial virtual reality games to explore developing and assessing skills; and also how a controller for these virtual reality games should be designed so that people with musculoskeletal disorders and stroke can use them to control their movements and interactions within the game.

Screening for eligibility will take place at the physiotherapy department, Saint James Hospital in Malta or at Nicomed Rehabilitation Centre (NRC) in Cyprus. This will consist of MSD/MSI or Stroke examination (testing and taking measurement), brief neurological examination, which is similar to current clinical practice. The researchers will confirm whether there is any history of epilepsy, psychiatric or cardiomyopathic issues before a patient is enrolled in the study for the reasons given in the exclusion criteria. All patients that undergo screening are logged into a screening log associated with the study and it is the Principal Investigator who is authorized to complete this task.

Interview:
A guided interview which will help us understand the participants' disability, and activities to guide the design of the VR games and controllers:
1. What movements are involved in these activities
2. How their condition affects their ability to perform activities
3. What abilities they have that could be employed in operating a controller
4. Their experience of using the virtual reality games, including the co-pilot accessibility tool

Measurement:
Measurement of the participants' arms and hands to guide the shape and design of the controller, including how the participant will interact with the controller. The following data will be collected:
1. Key dimensions of the participants' arms and hands, captured using calibrated photographs and video;
2. The shape of participants' hands and arms captured with a hand-held 3D scanner that creates a file describing the scanned shape containing thousands of points defined in three dimensions. This is to provide information to the designers about the shape of the participants' hands and arms. The researchers are also exploring the use and accuracy of the scanning system in this context. Scanning a hand and arm is expected to take up to about 10 minutes.

Observation:
Participants' movements are captured during simple tasks and gameplay using small lightweight wearable motion sensors and video and audio recordings.

Measurement:
Measurement of forces that the participant is able to apply with their hands will be done using standard analogue manual dynamometers to measure handgrip strength and pinch strength

between thumbs and fingers. Forces while interacting with controllers will be measured using thin force sensors. The researchers will measure the player's hand movement during gameplay using data from the virtual reality system.

Observation:
Observation of how people interact with simple representative three-dimensional forms and commercial virtual reality controllers. The purpose of this observation is to explore how people with musculoskeletal disorders and injuries, and people with stroke, intuitively interact with three-dimensional shapes. It will be explored how people with musculoskeletal disorders and injuries, and people with stroke choose to interact with these forms when imagining and experiencing interactions within commercial virtual reality games.

Questionnaires:
The researchers will explore simulator sickness, presence, social presence and user experience using streamlined standard questionnaires.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Measured at baseline:
1. Whether participants with MSI and stroke can access off-the-shelf VR systems and games: assessment of comfort, accessibility and usability of the off the shelf controllers and games, enjoyment of the gameplay, captured through observation during the session and the responses to the semi-structured interview
2. Embodiment: the degree to which a person feels “ownership” of the virtual representation of their body in VR. From the first-person perspective, this is mostly restricted to the representation of their arms and hands. This is measured by using a variation of a standard embodiment questionnaire
3. Presence: the degree to which a person feels, acts and behaves as if the simulated environment is real. This is measured by using a variation of a standard presence questionnaire
4. Feasibility and acceptability of co-piloting and preliminary quantitative and qualitative data on efficacy and enjoyment of co-piloting with patients with MSI and stroke. This is measured through game metrics derived from the screen recording, analysis of tracking data from the VR system, and patient responses to adapted versions of standardised questionnaires (User Experience Questionnaire -Short (UEQ-S), Networked Minds Measure of Social Presence)
5. Participants' arms and hands measured using photos and video
6. Handgrip strength and pinch strength measured using standard analogue manual dynamometers
7. Forces while interacting with controllers measured using thin force sensors
8. The shape of participants' arms and hands measured with a hand-held 3D scanner

Secondary outcome measures
Measured at baseline:
1. Suitable values for VR session length and the number of sessions assessed through observation during the session and through the responses to the semi-structured interview
2. Incidence of adverse events including Incidence and avoidance of simulator sickness, assessed through observation during the session and through the responses to the semi-structured

interview
3. Therapist time and session frequency required to assist a user with real-time VR therapy sessions, assessed through observation during the session and through the responses to the semi-structured interview
4. Technical problems might arise when VR technology is used in a clinical setting, assessed through observation during the session and through the responses to the semi-structured interview

Overall study start date
01/10/2019

Completion date
30/09/2022

Eligibility

Key inclusion criteria
1. Adults with musculoskeletal disorders or injuries, and adults with stroke
2. Self-identified through communications from the project, or contacted because they have been involved in previous work with the research team
3. Suffering from pain and inhibited function of the upper limbs: fingers and/or hand and/or wrist and/or arm
4. Aged 18 years and over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20 (10 from each site)

Key exclusion criteria
All participants that do not fall within all eligibility criteria as mentioned above, such as people with any history of epilepsy (especially the photosensitive type), psychiatric or cardiomyopathic issues will be automatically excluded from participating in the study. This is because they might suffer from fits, fatigue, disorientation, agitation with the use of VR set/environment.

Date of first enrolment
01/02/2020

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
Cyprus

Malta

Study participating centre
Saint James Hospital, Malta (STJH)
George Borg Olivier Street
Sliema
Malta
SLM 1807

Study participating centre
Nicomed Rehabilitation Centre
No.8, Lambrou Charalambous
Akrounta
Limassol
Cyprus
4552

Sponsor information

Organisation
Saint James Hospital Malta

Sponsor details
George Borg Olivier Street
Sliema
Malta
SLM 1807
+356 (0)23291000
info@stjameshospital.com

Sponsor type
Hospital/treatment centre

Website
http://www.stjameshospital.com/

Funder(s)

Funder type
Government

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
The team of PRIME-VR2 is coordinating an open access dissemination plan for research findings from the project. The outcomes of the project will also be communicated to participants through a newsletter about the project and its research.

Intention to publish date
01/01/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Sandro Barone (s.barone@ing.unipi.it).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Consent form in English		04/08/2021	No	Yes
Participant information sheet	Consent form in Greek		04/08/2021	No	Yes
Participant information sheet	PIS in English		04/08/2021	No	Yes