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Mirror therapy stroke rehabilitation using an immersive virtual reality headset with people who have a weakness or impairment in one of their hands

Submission date
02/12/2021

Recruitment status
No longer recruiting

Registration date
03/12/2021

Overall study status
Completed

Last Edited
10/10/2022

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Mirror Therapy has been used to treat one-sided arm and hand impairments following stroke for the last 20 years. Virtual Reality (VR) has been used as a technological medium to deliver mirror therapy interventions with people with stroke in numerous applications with promising results. However, these virtual reality rehabilitation systems have mainly been non-immersive (computer screen) rather than immersive (head-mounted displays). The recent emergence of affordable, off-the-shelf head-mounted displays (like the Oculus Rift or HTC Vive) has opened the possibility for novel and cost-effective approaches for immersive mirror therapy interventions. We have developed one such system, Augmented Reflection Technology VR (ART VR), which allows persons with stroke to carry out a clinically-validated mirror therapy protocol in an immersive virtual environment (in a clinical setting).
This system allows people with stroke to carry out virtual mirror therapy while experiencing the virtual environment with a head-mounted display (HMD). Our VR system allows people with stroke to carry out the BeST (Berliner Spiegeltherapieprotokoll) rehabilitation protocol while using our system. A trained clinician will be present to control the system, carry out the intervention protocol, and collect data after each intervention.
The aim of our study is to find out if our developed mirror therapy system (in conjunction with the BeST protocol) could be used in a clinical setting by people with stroke. We will measure clinical outcomes, VR safety, motivation, acceptance, and user experience.

Who can participate?
Patients aged 18 years or older who have suffered a first-time stroke and have a severe, one-sided paresis (weakness and/or impaired movement) of the hand.

What does the study involve?
All participants will undergo the following procedure:
1. Assessment of affected hand function and pain before mirror therapy
2. Three 30-minute interventions using the developed immersive VR system under the guidance

of a trained clinician. The intervention consists of carrying out the BeST (Berliner Berliner Spiegeltherapieprotokoll) mirror therapy protocol with our VR system. A trained clinician will instruct participants on different hand exercises to carry out and they will record the participant's progress as they move through the protocol across the interventions.
3. After each intervention, participants will be asked to complete different questionnaire(s) regarding their experience using VR, safety, and user experience.
4. After the final intervention, the participant will undergo a post-therapy assessment to identify any changes.

What are the possible benefits and risks of participating?
Participants will have the opportunity to receive one on one mirror therapy interventions with a trained clinician. Research has shown that progress can be made at any point in the recovery of a person who has had a stroke. This study will provide opportunities for that to occur with a novel approach to mirror therapy. The researchers associated with this study believe that immersive VR offers participants potential benefits to people with stroke compared to traditional approaches by providing a more 'real' experience that directs their gaze/attention to the mirrored hand with no distractions to take them out of the mirror therapy illusion. A potential risk of using VR is that some people report feeling motion sickness when using the head-mounted device (this effect goes away within a few minutes once the device is taken off). Steps have been taken to reduce this risk by having a task that does not require the participant to move their head and gaze while in VR. During the study, the clinician is instructed to check for this during the intervention and a simulator sickness and other adverse events questionnaire is completed by the participant after each intervention to check as well. Participants will be instructed that they are allowed to stop and withdraw from the study at any point.

Where is the study run from?
MEDIAN Klinik Berlin-Kladow (Germany)

When is the study starting and how long is it expected to run for?
June 2019 to January 2020

Who is funding the study?
Brain Research New Zealand, University of Otago (New Zealand), MEDIAN Klinik-Kladow (Germany)

Who is the main contact?
1. Chris Heinrich, chris.heinrich@postgrad.otago.ac.nz
2. Holger Regenbrecht, holger.regenbrecht@otago.ac.nz

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ART-VR-BERLIN

Study information

Scientific Title
Clinical feasibility of an immersive virtual reality mirror therapy system using an established clinical protocol to explore clinical outcomes, usability and acceptability with inpatient people with stroke

Study objectives

This feasibility study will look to determine if our developed virtual reality (with head-mounted display) mirror therapy system could be used in a clinical setting with an adapted clinical rehabilitation protocol for stroke rehabilitation.

We aim to explore:
1. For the person with stroke, we want to investigate clinical outcomes, rehabilitation dose, adherence, VR acceptance, motivation, adverse event monitoring and user experience
2. For the therapist, we want to investigate the applicability of the protocol (BeST) with our immersive VR system. Can the therapist carry out the BeST protocol with their patient while the patient is immersed in the virtual rehabilitation environment?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/09/2021, Ethikausschuss [Ethics Committee] am Campus Charité - Mitte (Charitéplatz 1, 10117 Berlin, Germany; +49 030/450-517222; ethikkommission@charite.de), ref: EA1/195/19

Study design
Single-centre interventional non-blinded non-randomized single group feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Rehabilitation following stroke (ischaemic and haemorrhagic)

Interventions
Participants will be people with stroke who are at an in-patient rehabilitation facility in Berlin. If they wish to participate in the study, they will given the virtual mirror therapy intervention using the developed system along with the BeST (Berliner Spiegeltherapieprotokoll) mirror therapy rehabilitation protocol. After being screened for the inclusion criteria and agreeing to participate in the study, they undergo baseline (pre-assessment) clinical assessment for upper limb function/ability and stroke. This includes: Modified Rankin Scale (MRS), Modified Ashworth Scale (MAS), National Institutes of Health - Stroke Scale (NIH-SS), Numeric Rating Scale, Verbal Rating Scale, Rivermead assessment of somatosensor performance (subset 05), and the Fugl-Meyer Assessment Upper Extremity subset (Part B - Wrist and Part C - Hand).

ART VR + BeST Protocol: Participants will use the Augmented Reflection Technology VR (ART VR) mirror therapy rehabilitation system to carry out the BeST protocol hand exercises (as dictated by the attending clinician). The ART VR system is an immersive rehabilitation system that uses the Leap Motion hand tracking camera to capture the participant's hand movements. The participant experiences the virtual environment while wearing an Oculus Rift CV1 head-mounted display (HMD). The system mirrors the unaffected hand movement and presents it to the participant in the virtual environment such that it looks like their affected hand is carrying out the mirrored movements. Only the affected hand is shown in the virtual environment as per BeST protocol requirements to focus purely on the mirrored (virtual) hand illusion. The clinician controls the system using a tablet computer where they can control the system and personalise the system to their patient (affected side, different mirroring conditions).

At the start of the intervention, the participant is seated comfortably at a height adjustable table where the system is placed. The clinician helps the participant put on the head-mounted display and has the participants mirroring conditions set with the system (which side is affected). The participant is then instructed to carry out a subset of the BeST protocol which has been adapted for our system, BeST-ART VR. This consists of the attending clinician asking the participant to carry out different hand exercises such as making the number 3 with their virtual mirrored hand. They continue through the protocol with different hand exercises and modifications to those hand exercises can be added for more challenge and variety. When the clinician or participant determines they need a rest, they are allowed a break. At the conclusion of the intervention, the clinician writes down the participant progress (rehabilitation time, BeST-ART VR protocol progress, break times, session numbers, whether they felt any tingling /paraesthesia during the exercises). They will then answer questionnaires relating to simulator sickness, VR tolerence, acceptance and motivation.

After the final (3rd) intervention, they are also given a post-assessment which consists of the same clinical assessments as was done during the pre-assessment detailed earlier. They are also asked to complete a user experience questionnaire.

Clinical Assessments: Modified Rankin Scale (MRS), Modified Ashworth Scale (MAS), National Institutes of Health - Stroke Scale (NIH-SS), Numeric Rating Scale, Verbal Rating Scale, Rivermead assessment of somatosensor performance (subset 05), and the Fugl-Meyer Assessment Upper Extremity subset (Part B - Wrist and Part C - Hand) at pre-assessment (before first intervention) and post-assessment (after final intervention).

Mirror Therapy Documentation: BeST documentation form (time carrying out mirror therapy, rest time, modifications performed, attention/engagement in rehabilitation, whether they report feeling any tingling or paraesthesia)

Questionnaires: Simulator Sickness , VR Tolerance and Adverse Event Monitoring , VR Acceptance, Motivation and Self-Evaluation , meCUE 2.0 User Experience

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Augmented Reflection Technology VR (ART VR)

Primary outcome measure
1. Adherence assessed using the BeST documentation after first, second and third intervention
2. Rehabilitation dose assessed using the BeST documentation after first, second and third intervention
3. Protocol progress assessed using the BeST documentation after first, second and third intervention
4. Safety assessed using the Simulator Sickness questionnaire and VR Adverse Event Monitoring questionnaire after first, second and third intervention
5. Affected Hand Function assessed using the Fugl-Meyer UE subset (Part B + C) during the pre- and post-assessments

Secondary outcome measures
1. Perceptions regarding immersive VR intervention by person with stroke measured using the VR Acceptance, Motivation, and Self-Evaluation questionnaire after the first and third intervention
2. Tingling/paraesthesia occurrences determined by BeST documentation during the first, second and third interventions
3. User experience measured using the meCUE 2.0 questionnaire after the third intervention

Overall study start date
01/06/2019

Completion date
17/01/2020

Eligibility

Key inclusion criteria
1. Aged at least 18 years
2. Suffered a first-time stroke
3. Has a severe, one-sided paresis of the hand

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12

Total final enrolment
11

Key exclusion criteria
1. Severe cognitive or emotional limitations
2. Insufficient seat-sitting stability
3. Severe speech comprehension or speech production deficit
4. Simultaneous participation in another study

Date of first enrolment
20/09/2019

Date of final enrolment
10/01/2020

Locations

Countries of recruitment
Germany

Study participating centre
MEDIAN Klinik Berlin-Kladow
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ROR

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Sponsor type
Hospital/treatment centre

Website
https://www.median-kliniken.de/de/median-klinik-berlin-kladow/

Funder(s)

Funder type
University/education

Funder Name
University of Otago

Alternative Name(s)
Te Whare Wānanga o Otāgo, Te Whare Wānanga o Ōtākou

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
New Zealand

Funder Name
Brain Research New Zealand

Alternative Name(s)

Rangahau Roro Aotearoa, BRNZ

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
New Zealand

Funder Name
MEDIAN Klinik Berlin-Kladow

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal (Journal of NeuroEngineering and Rehabilitation)

Intention to publish date
15/12/2021

Individual participant data (IPD) sharing plan
The data generated and analysed during the current study will be available upon reasonable request from Chris Heinrich (heinrich.chris@gmail.com).
Type of data: summary data located in Excel files
When the data will become available and for how long? The data will be available 01/01/2022 and available for 7 years
By what access criteria data will be shared including with whom: researchers in the field
For what type of analysis: survey/overview level analysis
By what mechanism: contacting the investigator above
Whether consent was obtained: yes, informed consent was obtained from all participants
Comments on data anonymisation: participant data was anonymised using an assigned pseudonym

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/10/2022	10/10/2022	Yes	No