PILOT TRIAL PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Title: Music-based Upper Limb Virtual Reality Therapy Program for Chronic Stroke Rehabilitation Pilot Trial

Chief Investigator
Mr Thomas Beltrame (PhD Candidate)[1]
Email: thomas.beltrame@flinders.edu.au
Phone: (08) 8201 3167

Supervisor & Co-Investigator
Dr David Hobbs (Academic)[1,3]
Email: david.hobbs@flinders.edu.au
Phone: (08) 8201 3167

Supervisor & Co-Investigator
Associate Professor Kenneth Pope (Academic)[1]
Email: kenneth.pope@flinders.edu.au

Supervisor & Co-Investigator
Associate Professor Belinda Lange (Academic)[2]
Email: belinda.lange@flinders.edu.au

Supervisor & Co-Investigator
Professor Susan Hillier (Academic & Clinician)[3]
Email: susan.hillier@unisa.edu.au

Co-Investigator
Dr Tanya Silveira (Academic & Music Therapist)[4]
Email: tanya.silveira@unimelb.edu.au

[1]Flinders University, College of Science and Engineering, Medical Device Research Institute, Adelaide, South Australia
[2] Flinders University, College of Nursing and Health Sciences, Caring Futures Institute, Adelaide, South Australia
[3]UniSA Allied Health & Human Performance, University of South Australia, Adelaide, South Australia
[4]Faculty of Fine Arts and Music, University of Melbourne, Melbourne, Victoria

Background Information
The Chief Investigator for this project is Mr Thomas Beltrame, a Biomedical Engineer, and Flinders University PhD Candidate. The project aims to improve quality of life for stroke survivors by combining music and technology in a novel home-based upper-limb stroke rehabilitation therapy program. The custom virtual reality application represents the most significant component of Mr Beltrame's PhD project, and the outcomes from this pilot trial will contribute to the majority of his PhD findings.
As a participant or potential participant in this study, you are welcome to reach out to Mr Beltrame or his Principal Supervisor, Dr Hobbs, prior to, during, or following participation with questions, comments, concerns, or clarifications.
All investigators' information and contact details related to this project are listed above.

All members of the project team are qualified engineers, physiotherapists, and/or researchers, and each brings a unique skill set to the study. The team have been selected to ensure the objectives, methods and delivery of the proposed intervention reflect current best practice guidelines, and that the design decisions are justified by current literature recommendations.

This project is supported by the College of Science and Engineering, Flinders University, the Medical Device Research Institute, the Caring Futures Institute, the University of South Australia, the Flinders Foundation, the Arts and Health Alliance, and the Clinician Special Purposes Fund.

Description of the study

This pilot trial aims to improve post-stroke upper limb mobility and activities of daily living through a music-based mirror therapy in virtual reality. The virtual reality therapy program incorporates movements and exercises informed by stroke rehabilitation guidelines and recommendations. Additionally, feedback from co-design sessions undertaken by stroke survivors and health, research, and industry professionals has contributed to the version you will be testing in this study.

Music can improve memory, literacy and numeracy skills, mental health, health measures such as heart rate and blood pressure, and can also prolong the onset of dementia. Additionally, music has been shown to improve therapy outcomes by making therapy more enjoyable.

Mirror therapy refers to a rehabilitation technique involving placing the affected limb behind a mirror and positioning the mirror such that the reflection of the unaffected limb appears to represent the affected limb. The arrangement provides positive visual feedback of increased limb capacity to the brain and has been shown to increase control and function of the affected limb.

Virtual reality involves the experience of being immersed in a virtual environment through a headset and has also been shown to make therapy more engaging.

Continual exercise and movement are critical to maintaining and improving strength, flexibility, and balance. Therefore, music, mirror therapy and virtual reality have been combined in this project to produce a fun and motivating upper limb therapy.

This pilot trial includes three major components: four formal assessment blocks, ongoing passive activity monitoring, and the custom virtual reality therapy program.

- The assessments will occur in four separate blocks: directly before and directly after, 1 month after, and 3 months after the virtual reality therapy program.
- The wrist-worn activity monitor will continuously collect upper limb movement information for 3 months, which will be used to calculate arm usage and sleep patterns during the study.
- The virtual reality therapy program combines musical creation with functional movements that would be performed in a physical therapy session
    - The virtual reality therapy program will comprise multiple modes, each varied in difficulty, required movements, and musical involvement.
    - The system will be calibrated for each user, to ensure the arm movements and range of motion required are tailored to each individual participant

This study will formally assess the usability, acceptance, and effect of this novel virtual reality therapy program, which may lead to the development of new upper limb rehabilitation techniques.

Purpose of the study

Pilot trials are recognised as a critical step in being able to test and validate new technologies and assess the feasibility and acceptability of the approach in a small-scale study.
This pilot trial offers the ability to observe the outcomes and effects of the virtual reality therapy program in a real-life scenario (the home environment) with end-users (stroke survivors).

Benefits of the study

The results from this study will help inform the validity of this novel virtual reality combination therapy delivery technique and will be critical in shaping the future directions of this work.

This study is expected to reveal which factors, such as time post-stroke, level of impairment, dose, and musical background, are optimally supported by this therapy model. Once identified, these factors have the potential to identify which stroke survivors are likely to receive the most benefit.

Additionally, the feedback and learnings will enable improvements to be made, to increase the utility and thus maximising the potential benefit for as many stroke survivors as possible.

What are the possible benefits of taking part?

This therapy program has been developed based on research evidence that mirror therapy, music, and virtual reality can provide improvements in upper limb function; visuospatial neglect symptoms; mood; cognitive functions such as memory, literacy, and numeracy skills; and physiological measures such as heart rate and blood pressure.

As a participant trialling this virtual reality combination therapy program, you may receive or experience some, or all, of the potential benefits listed above. However, as this novel therapy program has not been tested before, and therefore lacks the validation to provide a guarantee of expected outcomes, you may not receive or experience any of the listed benefits.

Participant involvement

If you agree to participate in the research study, you will be asked to:

- Organise to have your Montreal Cognitive Assessment score sent to the research team
- Book your activity monitor fitting, which will occur in your home.
    - The activity monitor will be worn for 3 months continuously
    - The activity monitor will collect upper limb movement information, which will be used to calculate arm usage and sleep patterns
- Book and attend your initial assessment, at your nominated assessment location.
    - The initial assessment will comprise the *Fugl-Meyer Assessment of Motor Recovery for Upper Extremity*, *Stroke Impact Scale*, *Montreal Cognitive Assessment*, *Profile of Mood States*, and *Star Cancellation Test*
- Book your virtual reality headset delivery, which will occur in your home
- Attempt to complete a total of 40 hours of the virtual reality therapy program
    - 1 hour per day, 5 days per week, for 8 weeks
    - The virtual reality application will track all interactions with the device, and remotely provide usage and progress information to the research team
- Book and attend your post-trial assessment, at your nominated assessment location
    - The post-trial assessment will include all assessments performed in the initial assessment, with the addition of the *System Usability Scale* and the *Simulator Sickness Questionnaire*
- Participate in a semi-structured interview, which will be audio recorded and transcribed via Otter.ai, an artificial intelligence audio transcription service (with your consent), where you will be asked questions regarding:
    - your experiences based on your stroke
    - your experiences after completing the virtual reality therapy program
- Book your activity monitor return, which will occur in your home
- Book and attend your 1-month follow-up assessment, at your nominated assessment location
    - The 1-month follow-up assessment will repeat the initial assessments
- Book and attend your 3-month follow-up assessment, at your nominated assessment location
    - The 3-month follow-up assessment will repeat the initial assessments

Recognition of Contribution / Time / Travel costs
If you would like to participate, in recognition of your contribution and participation time, you will be provided with a $100 voucher. This voucher will be provided to you upon completion of your involvement with the study. This voucher is not dependent on completing all milestones and assessments of the pilot trial and will be awarded even in the event that you exit the study early.
The minimum requirement to receive the $100 voucher is that you have signed the consent form, completed the onboarding process, undertaken the initial assessment, and attempted to use the virtual reality therapy program independently.

Potential risks
The researchers acknowledge that discussing past or current experiences related to your stroke may be challenging and have the potential to cause feelings of discomfort. If you experience feelings of distress as a result of participation in this study, you are free to cease involvement at any time. If you feel comfortable doing so, please inform Mr Beltrame, the Chief Investigator, that you are no longer able to continue, otherwise, you may simply stop using the virtual reality system.

You can also contact the following services for support at any time:

- Stroke counselling, well-being coaching, local and national, support groups, and choir groups
    - Details are listed on the **last page** of this form
- Lifeline – 13 11 14, www.lifeline.org.au
- Beyond Blue – 1300 22 4636, www.beyondblue.org.au

The use of virtual reality has the potential to cause motion sickness, discomfort from the headset and injury due to falling or colliding with objects, and mirror therapy has the potential to cause dizziness, nausea, and confusion. The application has been designed to minimise feelings of motion sickness and will only require movements that can be performed in a seated position, to reduce the likelihood of falling. During the onboarding session, the research team will work with you to identify the most appropriate space in your home for you to use the virtual reality system independently. You are welcome to attempt to use it in different locations, however, it is advised that you first clear the area of obstacles to reduce the likelihood of a collision.
The headset will be fit specifically to each participant to maximise comfort and stability; however, the Velcro may loosen through use, resulting in discomfort. If this occurs, please adjust the Velcro straps as necessary to provide a secure but comfortable fit.
In the event that you feel unwell in any way, please gently remove, or if possible/appropriate, ask for assistance to remove, the headset immediately.

COVID-19 precautions will include the wiping down of headsets and controllers between participants.

Withdrawal Rights
You may decline to take part in this research study. If you decide to take part and later change your mind, you may withdraw at any time, including after the study has concluded, without providing an explanation. To withdraw, if you feel comfortable doing so, please inform Mr Beltrame, the Chief Investigator, that you are no longer able to continue, otherwise, you may simply stop using the virtual reality system. You will be given the opportunity to share any thoughts or reasons for withdrawing if you would like to.

Confidentiality and Privacy
Individual information you provide through this pilot trial will be stored on Flinders University servers and will be accessible only to members of the research team, including members who join the project in the future who are not listed on this form. The data may also be used in future research projects and will be accessible to members of those projects. Privacy and confidentiality will be assured at all times.

The research outcomes may be presented at conferences, written up for publication or used for other research purposes as described in this information form. However, the privacy and confidentiality of individuals will be protected at all times. You will not be named, any quotations extracted from the interview, photographs or videos published will maintain your anonymity, and your individual information will not be identifiable in any research products without your explicit consent.

Data Storage
The digital information collected will be stored securely on a password-protected computer and/or Flinders University server throughout the study. The data collected by the activity monitor will be stored locally on the device, before being uploaded directly to the dedicated Flinders University server. The audio and transcriptions will be stored on the Otter.ai secure platform, exported, and securely stored on the dedicated Flinders University server. Virtual reality usage and interaction data will be uploaded to a password-protected website, then exported, and securely stored on the dedicated Flinders University server.

Physical documents will be stored in a locked cabinet assigned to a member of the research team. Any identifiable data will be de-identified for data storage purposes unless indicated otherwise. All data will be securely transferred to and stored at Flinders University for 10 years after the publication of the results. Following the required data storage period, all data will be securely destroyed according to university protocols.

Data includes:

- your name, address, and contact information (stored digitally).
- your written responses to the questionnaires (stored in paper form, and digitally stored as a scanned copy).
- your assessment results (stored in paper form, and digitally stored as a scanned copy).
- the data logged by the virtual reality application (stored as a video enabling replay of your interactions, and a data file containing numerical information – you will not be identifiable).
- activity monitor accelerometer data (stored digitally – you will not be identifiable).
- your responses to the semi-structured interview and feedback following your virtual reality experience (stored as written or digital notes and/or an audio recording).
- photographs and/or videos of you (stored digitally).
- audio recordings and/or ai-generated transcriptions of your voice (stored digitally)

The Otter.ai Privacy Policy can be found at https://otter.ai/privacy-policy
The Otter.ai Privacy & Security Statement can be found at: https://otter.ai/privacy-security

How will I receive feedback?
On project completion, a short summary of the outcomes will be provided to all participants via email.

Ethics Committee Approval
This project has been approved by Flinders University's Human Research Ethics Committee (6151).

Queries and Concerns
Queries or concerns regarding the research can be directed to the research team. If you have any complaints or reservations about the ethical conduct of this study, you may contact the Flinders University's Research Ethics & Compliance Office team via telephone (08) 8201 2543 or email human.researchethics@flinders.edu.au.

Thank you for taking the time to read this information sheet which is yours to keep.

If you accept our invitation to be involved, please sign the enclosed Consent Form.

CONSENT FORM

Consent Statement

- ☐ I have read and understood the information about the research, and I understand I am being asked to provide informed consent to participate in this research study. I understand that I can contact the research team if I have further questions about this research study.
- ☐ I am not aware of any condition that would prevent my participation, and I agree to participate in this project.
- ☐ I understand that I am free to withdraw at any time during the study.
- ☐ I understand that I can contact Flinders University's Research Ethics & Compliance Office if I have any complaints or reservations about the ethical conduct of this study.
- ☐ I understand that my involvement is confidential, and that the information collected may be published. I understand that I will not be identified in any research products.
- ☐ I understand that if I withdraw during or after the completion of the pilot trial, the researchers will make their best efforts to withdraw my data and information from the project. However, it may not be practical for all the data and information to be withdrawn.
- ☐ I understand that my participation in the pilot trial may influence the future direction of the project, including generating Intellectual Property (IP). I am releasing any IP generated through my feedback to Flinders University and associated researchers and therefore revoking my right to claim ownership over these ideas, now and in the future.
- ☐ I understand that to participate in this pilot trial I must be willing to:
    - ☐ complete the onboarding process
    - ☐ undertake the initial assessments
    - ☐ attempt to use the virtual reality therapy program independently

I further consent to (tick all that you are willing to consent to):

- ☐ Completing multiple questionnaires
- ☐ Participating in an interview, that will be documented by the researcher(s) present
- ☐ Having my interactions within the virtual reality environment recorded
- ☐ Having my voice recorded
    - ☐ If yes, having the recording of my voice transcribed using artificial intelligence
- ☐ Having my video captured
- ☐ Having my photo taken
- ☐ My data and information being used in this project and other related projects, and accessible by researchers who join the project in the future, that are not listed on this form, for an extended period of time (no more than 10 years after the publication of the data)

Upon completion of the pilot trial, I would like to be emailed:

- ☐ A copy of the transcript (human or AI-generated) for review and confirmation of accuracy
- ☐ My results from each completed assessment
- ☐ Outputs generated as a result of this work, including but not limited to:
  - ☐ Academic Journal Articles
  - ☐ Academic Conference Proceedings
  - ☐ Newspaper, Blog, and Media Articles
  - ☐ News and Documentary Broadcasts

Signed:

Name:

Date:

STROKE SUPPORT SERVICES

National Support

- StrokeLine - Talk to a health professional for free information and advice
  - Phone: 1800 STROKE (787 653)
- The Hospital Research Foundation Group – Stroke
  - Phone: (08) 8352 4644

Local Stroke Support Groups

- Acacia Court Talkback Group
  - Email: Christina Degioia, christine.degioia@eldercare.net.au
  - Phone: (08) 8243 1844
  - When: Fridays, 9:30 am – 11:30 am.
  - Where: Day Therapy Centre, Acacia Court, 81 Tapleys Hill Road
- Central Support Group Adelaide
  - Phone: (08) 8352 4644
  - When: 4th Tuesday of the month, 10:30 am
  - Where: Parkinson's SA, 25 King William Rd, Unley
- Flinders Stroke Support Group
  - Phone: Viv Wilson, 0414 604 234
  - When: 1st Wednesday of each month, 1:00 pm – 2:30 pm
  - Where: Flinders Medical Centre, Bedford Park, Rehabilitation Building, Teal Room 1
- Hove Talkback Group
  - Email: Coralie Hayley, coraliehayley27@gmail.com OR chayley@alywndor.org.au
  - Phone: (08) 8177 3277
  - When: Tuesday, 10:00 am – 11:30 am (during school terms).
  - Where: Alwyndor Aged Care, 52 Dunrobin Rd, Hove SA
- Morphett Vale Talkback Group
  - Email: Coralie Hayley, chayley@ech.asn.au
  - Phone: (08) 8322 5700
  - When: Thursday 9:45 am – 11:00 am (during school terms).
  - Where: ECH Southern Wellness, 126 Pimpala Rd, Morphett Vale, SA 5162
- Northern Fleurieu Stroke Support Group
  - Email: Will Swart, wil.swart@outlook.com
  - Phone: (08) 8326 2668 or 0421 410 427
  - When: Meets on the second Thursday of each month
- Paradise Resthaven Communication Group
  - Phone: Jeff Smith, (08) 8337 4371
  - When: Wednesday 1:30 pm – 3:30 pm.
  - Where: Resthaven Therapy Services, 61 Silkes Road, Paradise
- South Australian Stroke Survivors (SASS)
  - Facebook: www.facebook.com/southaustralianstrokesurvivors

Choirs

- Retune Choir
  - Phone: (08) 8443 5555
  - Email: talkback@aphasia.asn.au
- With One Voice choirs
  - Website: www.creativityaustralia.org.au/choirs/join-a-choir
- Tutti Arts
  - Phone: (08) 8166 6430
  - Email: info@tutti.org.au
  - Website: https://tutti.org.au/