CO-DESIGN PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Title: Co-designing a virtual reality intervention for upper limb chronic stroke rehabilitation

Chief Investigator
Mr Thomas Beltrame (PhD Candidate)[1]
Email: thomas.beltrame@flinders.edu.au
Phone: (08) 8432 4043

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. This co-design session will form a critical user experience validation component of Mr Beltrame's PhD project, and the outcomes will inform the pilot study that will follow this session.
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.
The information and contact details for all investigators 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 co-design session aims to gather user feedback on a music-based mirror therapy in virtual reality, for post-stroke upper limb rehabilitation. The application incorporates movements and exercises informed by stroke rehabilitation guidelines and recommendations, with the aim of improving upper limb mobility and activities of daily living.

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 co-design session involves three components, a semi-structured interview, questionnaires, and virtual reality prototype testing.

- The interview will provide an understanding of the personal rehabilitation journeys of stroke survivors, rehabilitation experiences, current levels of impairment and the factors that would make the biggest impact in improving their quality of life. Additionally, questions themed around technology and internet access, and musical proficiency and preferences will be asked.
- The questionnaires will include the Motion Sickness Susceptibility Questionnaire (MSSQ), Simulator Sickness Questionnaire (SSQ), and System Usability Scale (SUS). The MSSQ and SSQ focus on the likelihood of experiencing motion sickness and the actual sensations experienced, while the SUS indicates how intuitive and usable to product is.
- The virtual reality testing will enable potential end users the opportunity to provide feedback while the application is still in development. Multiple applications will be trialled, each varied in difficulty, required movements, and musical involvement.

This co-design session forms the first phase of a larger study, that will involve an 8-week intervention pilot study to formally assess the usability, acceptance, and effect of the final version of the virtual reality application that will be trialled. 10 stroke survivors and 10 professionals are hoped to participate in the co-design sessions, totalling 20 participants. You are invited to provide feedback as a stroke survivor with lived experience that will help to shape this future work.

During this co-design session, you will be exposed to the concept that will reflect the final system, in addition to discussing potential feature modifications and improvements. This study can be viewed as a “first look” at the released version, which does not preclude you from participating in the pilot study.

Purpose of the study
Co-design is recognised as a critical step in the creation of valued and desired products and services that meet the original objectives of the creators. This study aims to understand how stroke survivors experience, evaluate, and interact with a prototype virtual reality upper limb intervention. The feedback and learnings obtained from these co-design sessions will enable the overall result to be improved.

Benefits of the study
The sharing of your experiences will help to improve the relevance, utility, and overall quality of the final solution. The feedback will contribute to a novel stroke rehabilitation intervention, that has the potential to improve the quality of all life for all stroke survivors affected by upper limb impairments.

What are the possible benefits of taking part?
As a participant trialling the technology prior to its completed version, and for only a single session, it is not expected that any lasting rehabilitative benefits will be observed.
However, if the concept of mirror therapy or virtual reality therapy is appealing to you and something you wish to explore further, please inform Chief Investigator Mr Beltrame of your interest and he will provide you with information regarding the upcoming pilot trial based on this work.

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

- Book a date and time for your co-design session.
- Organise transportation to Flinders University at Tonsley, 1284 South Rd, Tonsley, SA, 5042 OR University of South Australia (City East/West Campus), North Terrace, Adelaide, SA, 5000.
- Complete a questionnaire that will determine your likelihood of experiencing motion sickness.
- Experience virtual reality, including the fitting of the headset, and an introduction to the system.
- Trial the novel virtual reality applications, designed for upper limb rehabilitation, each with increasing levels of difficulty, themed around movements to control the playback of a song, movements in time with a song, and movements to actively create music.
- Evaluation of each of the virtual reality applications on multiple VR headsets, which will include testing the application itself, including the taking/recording of photos/videos (with your consent), a short feedback session, and then a break.
- If appropriate, perform and/or demonstrate additional upper limb movements during feedback sessions, that may be recorded in videographic and/or photographic form (with your consent).
- Complete two questionnaires, one about how easy or difficult the system was to use, and another about how comfortable you felt while experiencing virtual reality.
- 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
    - access to a smartphone and the internet
    - your musical preferences
    - your impressions of different activity monitors

The entire co-design session will take about 3 hours and participation is entirely voluntary.

As a participant, you are welcome to bring a support person, such as a family member, significant partner, and/or carer, to be present during the co-design session to assist you if required and/or preferred. If they provide their consent, the nominated support person will also have the opportunity to participate in the semi-structured interview component. Following your virtual reality experience, the support person will also be able to share their opinions as an observer/assistant of the process. Participation from a support person will not include any virtual reality experiences or the completion of any questionaries.

Selection Criteria

You **are** eligible to participate if you:

- are an adult (18+)
- experienced a stroke more than six months ago
- are currently experiencing a loss in function in one arm and/or hand due to a stroke

You **are not** eligible to participate if you:

- have no function in both arms or hands
- are unable to read/write in English or follow instructions
- experience virtual reality or music due to visual or hearing impairments, respectively
- have a history of seizures, loss of awareness, or other symptoms linked to an epileptic condition

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 the co-design session.

If a nominated support person consents to participate in the study, their contributions will be highly valued and appreciated, however, they will not receive remuneration in any form.

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 leave at any time. If you feel comfortable doing so, please inform a member of the research team that you require a break or would prefer to conclude the co-design session early, otherwise, you may simply leave at your discretion.

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. The laboratory for the trial was selected due to its large, open space, preventing collision with walls or objects. Finally, the headset will be fit specifically to each participant to maximise comfort, and the researcher(s) will check if any adjustments are necessary after every 15 minutes of use.

In the event that you feel unwell in any way please gently remove, or ask for assistance to remove, the headset immediately

COVID-19 precautions will include the supplying of masks for all participants, and the wiping down of headsets, controllers, tables, and chairs before and after use.

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, and if you feel comfortable doing so, please inform a member of the research team that you are no longer able to continue or you may simply refuse to answer any questions, abstain from the exercises at any time, or leave the co-design session prior to formal completion. 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 co-design session 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 audio and transcriptions will be stored on the Otter.ai secure platform, 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 and contact information.
- 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).
- your written responses to the questionnaires (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).
- 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 (5738).

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 *Stroke Survivor* Consent Form.
If your support person wishes to also be involved, they must sign the *Support Person* Consent Form.

CONSENT FORM – STROKE SURVIVOR

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 co-design session, 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 to participate in this co-design session, I must attempt to trial at least one (1) virtual reality music-based mirror therapy mode.
- ☐ I understand that my participation in the co-design session may influence the future direction of the project, including generating Intellectual Property (IP). I am releasing any IP generated through my co-design participation to Flinders University and associated researchers and therefore revoking my right to claim ownership over these ideas, now and in the future.

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 this session, I would like to be emailed:

- ☐ A copy of the transcript (human or AI-generated) for review and confirmation of accuracy
- ☐ Information and an invitation to participate in the pilot study, the next phase of this project
- ☐ 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:

CONSENT FORM – SUPPORT PERSON

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 co-design session, 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 co-design session may influence the future direction of the project, including generating Intellectual Property (IP). I am releasing any IP generated through my co-design participation to Flinders University and associated researchers and therefore revoking my right to claim ownership over these ideas, now and in the future.

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

- ☐ Participating in an interview, that will be documented by the researcher(s) present
- ☐ 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)

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/