UNIVERSITY OF CANBERRA

Human Research Ethics Application

Notes for applicants

1. Information about the research project

1.1. Short Project Title

Virtual Reality-Based Upper Limb Interventions for People Recovering from Stroke

1.2. Full Project Title

Identifying Factors that Enhance Therapeutic Power in Virtual Reality-Based Upper Limb Occupational Therapy Interventions for People Recovering from Stroke

1.3. Type of Project

- (•) Research involving Human Participants
- ( ) Coursework projects involving Human Participants
- ( ) Teaching & Learning Program involving Human Participants
- ( ) Clinical Trial involving Human Participants
- ( ) Research not involving Human Participants

1.4. Is this research project related to a previous application?

- ( ) Yes
- (•) No

1.5. Will this research project repeat a previous study?

- ( ) Yes
- (•) No

1.6. Has this research project already been approved by another NHMRC registered Human Research Ethics Committee?

- ○ Yes
- ◉ No

1.7. Anticipated Start Date

01/08/2019

1.8. Anticipated Completion Date

30/06/2020

1.9. Would you like to add your project to the Research Ethics & Integrity team's research study register?

- ○ Yes
- ◉ No

2. Information about the research sites

2.1. Will this research study be conducted in Australia and/or overseas?

- ☑ Australia
- ☐ Overseas

2.1.1.a Please provide the sites where the research will be conducted.

Recovery VR (10 Stumm Pl Latham ACT) and University of Canberra

2.2. Will the research be undertaken in schools and/or child care centres?

- ○ Yes
- ◉ No

3. About the Chief Investigator

3.1. Are you a student or a staff member?

- ○ Student
- ◉ Staff

3.2. Chief Investigator (Staff)

Title	First Name	Surname
Dr	Craig	Greber

Staff ID	s438986
Phone	62068585
Email	craig.greber@canberra.edu.au

3.2.1. Please provide your qualifications and detailed information about your research experience.

My qualifications include a Doctor of Philosophy (2011), Bachelor of Occupational therapy (1993) and Bachelor of Human Movement Studies - Education (1988)

I am an occupational therapist with broad research interests. I am currently Assistant Professor in Occupational Therapy and teach into Bachelor and Masters Occupational Therapy courses at University of Canberra. My publication record includes 10 peer reviewed publications and three book chapters (with another in press). I received the 2012 Dean' award for Postgraduate Research from the University of Queensland for my PhD Research, as well as the Best paper award at the 2011 Queensland Health Research Conference. My grant record includes the 2006 Occupational Therapy Board of Queensland Research Grant ($5000), 2006 Education Queensland New Professionalism Scholarship ($3000) and 2011 Queensland Health Post Graduate Scholarship (backfill relief to a total of $20000). Most recently, I was Project Lead for a Queensland Health project funded by the Integrated Care Innovation Grant ($1.2 Million)

3.3. Please select your Faculty or Research Centre.

Faculty of Health

3.4. Have you undertaken the University's integrity training?

- ○ Yes
- ◉ No

4. About the Co-Investigators

4.1. Are there any co-investigators?

- ◉ Yes
- ○ No

4.1.1. Please provide the details of your co-investigators.

Title	First Name	Surname
Associate Professor	Stephen	Isbel

Qualifications

HScD, MOT, MHA, B.AppSc(OT), GCHE

Phone 62015246

Email stephen.isbel@canberra.edu.au

Please select the Faculty or Research Centre.

Faculty of Health

If "External Organisation" or "Other Research Centre", please provide details.

4.1.1. Please provide the details of your co-investigators.

Title	First Name	Surname
Associate Professor	Jane	Frost

Qualifications

RN,NP, BSC(Hons), MSc NP, DNP, GCTE, SFHEA

Phone 62068692

Email jane.frost@canberra.edu.au

Please select the Faculty or Research Centre.

Faculty of Health

If "External Organisation" or "Other Research Centre", please provide details.

4.1.1. Please provide the details of your co-investigators.

Title	First Name	Surname
Mr	Nathan	D'Cunha

Qualifications: Bachelor of Human Nutrition (Honours), Bachelor of Human Nutrition, Bachelor of General Studies (Communication Studies)

Phone: 0437709355

Email: nathan.dcunha@canberra.edu.au

Please select the Faculty or Research Centre.

Faculty of Health

If "External Organisation" or "Other Research Centre", please provide details.

5. Details of any others involved in the research.

5.1. Are there other persons involved in the research project?

- ○ Yes
- ◉ No

6. Funding

6.1. How will your research project be funded?

- ○ Internal Funding
- ◉ External Funding
- ○ Other

6.1.1. Please provide the Pure Award ID.

27595845

6.1.2. Please provide the Pure Ethics Review ID.

2096

6.1.3. Please advise the source of funds and the amount of funding received.

Grant monies to support the project have been obtained through Canberra Innovation Networks' ICON Grant by an external party (Christian Doran). A total of $6000 has been made available to University of Canberra to enable collaboration.

6.2. Will the funding and/or commercial and intellectual property arrangements place you in a conflict of interest as a researcher?

- ○ Yes
- ◉ No

7. Review

7.1. Has your research project been reviewed?

- ☐ Supervisor/s
- ☐ Colleague/s
- ☐ Confirmation Seminar
- ☐ Funding Body
- ☑ Research Team
- ☐ Other
- ☐ No review

7.2. Will there be any constraints on publication?

- ○ Yes
- ◉ No

8. Rationale and Literature Review

8.1. Please provide a short summary of the project in plain English.

This project will identify important characteristics in designing virtual reality-based interventions for people undergoing upper limb rehabilitation following stroke.

8.2. Please provide a justification for your research based on a literature review (including references for citations).

Conventional occupational therapy provides a means for people with upper limb dysfunction following stroke to re-establish motor proficiency for the performance of everyday occupations. Such therapy embeds repetitive, active use of the affected arm in line with evidence-based protocols at high levels of volume and intensity of practice (1). Effective occupational therapy also acknowledges the importance of motivation and personally relevant contexts in determining occupational goal attainment (2).

In recent years, therapists and product developers have explored the viability of virtual reality as a modality for upper limb rehabilitation. Virtual reality can be been defined as an ‘‘interactive, immersive experience generated by a computer’’ (p.11) (3).

Many platforms have been developed based on simulated interactive experiences, and these have been used in both home and clinical contexts (4). The virtual reality experience in this study will use a head mounted device that immerses the participant in a computer generated environment. While evidence of the effectiveness of these forms of therapy is still emerging (5), there are indications that well designed virtual reality platforms could complement conventional therapy in attainment of client goals. Presently, there is nothing to guide product developers in building platforms that embrace broad principles of therapeutic power.

The proposed study focuses on identifying characteristics of virtual reality therapeutic environments that contribute to the efficacy of treatment. Pierce’s “Occupation by Design” model (6) will be used to structure investigations. This model considers three elements that together influence the power of therapeutic interventions: Appeal, Intactness and Accuracy. In broad terms, these relate respectively to motivational, contextual and evidence-based features of an intervention. Using this model enables each of those elements to be understood as they relate to the development of virtual reality experiences.

Other theoretical lenses will be used to operationalise the subjective, contextual and design dimensions. Self Determination Theory (SDT) (7) is a well-established theory of human motivation and will serve as the basis of questions regarding the appeal of virtual reality experiences. Occupational therapy has a rich theory base concerned with the interaction of context and performance, and Occupational Therapy theory will be used to design investigations into contextual factors. The design dimension will be informed by evidence in the management of upper limb movement dysfunction following a stroke, including the Australian Stroke Guidelines (8).

Much of the existing work into engagement with virtual reality comes from the gaming industry and therefore, is published in the grey literature (9). Since the contexts of gaming and virtual therapy differ in their role, scope and purpose, caution must be exercised in generalising between the two. A thorough exploration of the experiences of stroke survivors in using virtual reality approaches to therapy is required to understand the factors most likely to lead to sustained engagement and optimal therapeutic outcomes.

This research will help to identify aspects of the virtual reality experience that will sufficiently engage patients over the duration of their therapy. It will also investigate factors that determine how well evidence relating to upper limb rehabilitation is embedded in the virtual therapy experience. Both of these outcomes will lead to the identification of factors that should guide virtual therapy product developers in their product design.

References

1. Doman, C. A., Waddell, K. J., Bailey, R. R., Moore, J. L., & Lang, C. E. (2016). Changes in upper-extremity functional capacity and daily performance during outpatient occupational therapy for people with stroke. The American Journal of Occupational Therapy, 70(3), 7003290040p1–7003290040p11. doi:10.5014/ajot.2016.020891
2. Kielhofner, G. (2009). Conceptual foundations of occupational therapy practice (4th ed.). Philadelphia: FA Davis.
3. Pimentel, K., & Teixeira, K. (1993). Virtual reality through the new looking glass. New York: McGraw-Hill.
4. Aminov, A., Rogers, J. M., Middleton, S., Caeyenberghs, K., & Wilson, P. H. (2018). What do randomized controlled trials say about virtual rehabilitation in stroke? A systematic literature review and meta-analysis of upper-limb and cognitive outcomes. Journal of Neuroengineering and Rehabilitation, 15(1), 29.
5. Laver, K., George, S., Thomas, S., Deutsch, J. E., & Crotty, M. (2012). Cochrane review: virtual reality for stroke rehabilitation. European journal of physical and rehabilitation medicine, 48(3), 523-530.
6. Pierce, D. (2003). Occupation by design: Building therapeutic power. Philadelphia: FA Davis.
7. Siegert, R. J., & Taylor, W. J. (2004). Theoretical aspects of goal-setting and motivation in rehabilitation. Disability and Rehabilitation, 26(1), 1-8.
8. National Stroke Foundation (Australia). (2005). Clinical guidelines for stroke rehabilitation and recovery. National Stroke Foundation.
9. Lindgaard, G. (2018). Games and exergames in rehabilitation. Interactions, 25(4), 24-25. doi:10.1145/3229364

9. Research Approach, Methods and Instruments

9.1. Which of the following instruments will be used in your research project?

- [x] Hard copy questionnaire
- [ ] Electronic questionnaire
- [ ] Focus Groups
- [x] Interviews
- [ ] Observations
- [ ] Ethnography
- [ ] Photographs
- [ ] Video recordings
- [ ] Audio recordings
- [ ] Creative, artistic or design process
- [ ] Performance tests
- [ ] Other

9.2. Will your research project include the following types of research?

- [ ] Collection of human samples
- [ ] Genetic testing
- [ ] Cellular therapy
- [ ] Ionising and non-ionising radiation
- [x] None of the above

9.3. Please describe the research approach and methods in more detail.

Theoretical Background

The overall structure of investigations is duly informed by two theoretical frameworks. Pierce's (2004) Occupation by Design framework presents the power of therapeutic interventions as reliant upon three factors - appeal, context and accuracy. This broad framework shapes the areas of investigation in this study.

Because motivation to engage in therapy is a significant contributor to therapeutic outcomes, the factors of appeal and context are best investigated with regard to theories of motivation. Self Determination Theory (Deci & Ryan, 2000) focuses on the self-motivated nature of human behaviour. It forms an appropriate theoretical background from which to engage in investigations of engagement and motivation in virtual approaches to upper limb therapy.

Methods

This research uses a mixed methods approach to understand the experiences of stroke survivors participating in virtual reality-based approaches to upper limb rehabilitation.

Participants

Two participant groups will be recruited:

1. Stroke Survivors - 6-8 people with upper limb dysfunction following stroke will be recruited. Because the nature of investigations demands high levels of insight, judgment and reasoning, people with significant higher cognitive deficits following stroke will be excluded from the study.

2. Expert Clinicians - Two experienced occupational therapists and/or physiotherapists who are experts in upper limb rehabilitation will be recruited. These clinicians must have a strong working knowledge of the Australian Stroke Guidelines and associated evidence regarding upper limb rehabilitation.

Intervention

Participants recovering from stroke will:
1. Become orientated to the use of the virtual reality system through a 3-minute adjustment phase during which they will have the appropriate technology fitted and tested. Adverse reactions will be checked for during this period.
2. Engage in five 5-10 minute virtual reality-based therapy sessions, with a 3-5 minute interval between each. During the interval, the technology will be removed, and participants will complete the Intrinsic Motivation Inventory (IMI) questionnaire (see Appendix 1). Longer intervals can be used if the participant becomes unduly fatigued or disorientated.
3. Complete the User Satisfaction Evaluation Questionnaire (USEQ) (see Appendix 2) once all scenarios have been experienced and all IMI questionnaires have been completed.

4. Engage in a 45-minute semi-structured interview 1-2 weeks following participation in the virtual reality-based therapy sessions. A general questioning route is provided in Appendix 3, however specific probing questions will be generated based on responses to the questionnaires.

Expert Clinician participants will:

1. Become orientated to the use of the virtual reality system through a 3-minute adjustment phase during which they will have the appropriate technology fitted and tested. Adverse reactions will be checked for during this period.
2. Engage in five 5-10 minute virtual reality-based therapy sessions, with a 3-5 minute interval between each. During the interval, the technology will be removed. Longer intervals can be used if the participant becomes unduly fatigued or disorientated.
3. Engage in a 45-minute semi-structured interview immediately following participation in the virtual reality-based therapy sessions. The questioning route for these interviews is provided in Appendix 4.

Data Gathering

Participants recovering from stroke:
We will use questionnaires as a preliminary quantitative data gathering tool. Qualitative semi-structured interviews will supplement these data. The combined data will enable us to extract factors that participants describe as affecting their engagement in virtual reality-based upper limb therapy.

Expert Clinician participants:
Semi-structured interviews will be used to gather data from expert clinicians regarding factors determining how well the virtual therapy scenarios embed principles of best practice.

Questionnaires

Participants recovering from stroke will complete two questionnaires. Following the completion of each scenario, participants recovering from stroke will complete the IMI. The IMI is a validated tool for assessing subjective experiences of target activities in line with components of Self Determination Theory. It can validly be customised by inserting the name of the evaluated activity in the question stems. The full inventory contains 45 items across seven scales; however, because of in-built redundancy, only a selection of the complete question scales are required. A minimum of four items per scale is recommended to maximise reliability of the measure. The questionnaire can thus be customised to suit the activity under investigation. The same customised version of the IMI will be administered following each virtual scenario.

The User Satisfaction Evaluation Questionnaire is a validated tool designed to evaluate the satisfaction of users of virtual rehabilitation systems. This six-item questionnaire will be administered immediately following the completion of all five virtual reality scenarios. This will provide information about the participant's overall satisfaction with the virtual reality experience.

Semi-Structured Interviews

Semi-Structured Interviews will be used with both participant groups to gather qualitative data about perceptions of the virtual scenarios. The broad questioning routes for consumer and expert clinician participant groups are included in Appendix 3 and Appendix 4 respectively. For participants recovering from stroke, the specific questions will be developed in response to their questionnaire responses. This will enable more detail to be drawn about those things that enhanced or detracted from their satisfaction and engagement with the scenarios. For the expert clinician group, questions will relate both to the way best practice evidence is embedded in the scenarios, and also the appropriateness of the context of each scenario.

References
Pierce, D. (2003). Occupation by design: Building therapeutic power. Philadelphia: FA Davis.
Ryan, R. M. & Deci, E. L. (2000). Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. American Psychologist, 55, 68-78. https://dx.doi.org/10.1037/0003-066X.55.1.68

9.3.1. Please upload the questionnaire, interview and/or Focus Group questions.

Type	Document Name	File Name	Version Date	Version	Size
Default	Appendix 1 Intrinsic Motivation Inventory	Appendix 1 Intrinsic Motivation Inventory.docx	08/07/2019	1.0	138.5 KB
Default	Appendix 2 User Satisfaction Evaluation Questionnaire	Appendix 2 User Satisfaction Evaluation Questionnaire.docx	08/07/2019	1.0	134.0 KB
Default	Appendix 3 Questioning Route - consumers	Appendix 3 Questioning Route - consumers.docx	09/07/2019	1.0	13.7 KB
Default	Appendix 4 Questioning Route - Clinicians	Appendix 4 Questioning Route - Clinicians.docx	09/07/2019	1.0	13.6 KB

9.4. Please outline how the data will be collected, processed and analysed.

Collection:
Questionnaires - A research assistant will administer questionnaire 1 (Intrinsic Motivation Inventory) after each virtual reality experience. A research assistant will also administer questionnaire 2 (User Satisfaction Evaluation Questionnaire) following completion of all virtual reality experiences. The research assistant will process the questionnaires.

Semi-structured interviews: Interviews will be conducted by the research assistant 1 week following the virtual reality experiences. These will be audio-recorded.

Analysis:
Questionnaires - SPSS will be used for descriptive statistics and univariate analysis (e.g. frequency and percentage response distributions, measures of central tendency). As the sample size is expected to be small we will use descriptive statistics to comment on the data.

Semi-structured Interviews - Interviews will be professionally transcribed. Thematic analysis methodology 12 will be used for analysis. Three stages will occur: coding of text line by line; development of descriptive themes; and generation of analytical themes.

10. Aims and Benefits of the Research

10.1. What are the aims of the research project?

The overall aim of this pilot study is to identify those factors that should be considered by virtual reality product developers in designing powerful therapeutic upper-limb experiences for people recovering from stroke.

10.2. What are the benefits and other impacts of the research project?

Many virtual reality platforms and experiences are currently being developed as therapeutic modalities for people recovering from stroke seeking to improve upper limb function. This research will provide a guide for virtual reality developers to increase the potential effectiveness of those products based on occupational therapy principles. This could have the effect of improving outcomes for people recovering from stroke who participate in these modalities as part of their recovery.

10.3. What research products will be created by this research project?

- ☐ Book(s)
- ☐ Commercial Product(s)
- ☑ Conference Paper(s)
- ☐ Exhibition(s)
- ☑ Journal Article(s)
- ☐ Performance(s)
- ☐ Report(s)
- ☐ Therapeutic Product(s)
- ☐ Thesis
- ☐ Other

11. Participants

11.1. Will you target participants for whom there are specific ethical considerations?

- ☐ Children and young people
- ☐ People in dependent and unequal relationships
- ☐ People unable to give consent for health or other reasons
- ☐ People with a cognitive impairment, intellectual disability or mental illness
- ☐ Women who are pregnant and the human foetus
- ☐ Aboriginal and Torres Strait Islanders
- ☐ People who are homeless
- ☐ People who are incarcerated
- ☐ People who may be involved in illegal activities
- ☐ Victims of crime
- ☐ People in other countries
- ☐ People for whom English is a second language
- ☐ Migrants, refugees and asylum seekers
- ☑ None of the above

11.2. Will you exclude any participant categories?

- ◉ Yes
- ○ No

11.2.1. Please provide a rationale for the exclusion.

Because the area of interest relates to upper limb rehabilitation, people recovering from stroke without upper limb impairment will be excluded.
Participant opinion and feedback regarding virtual reality experiences will be sought, therefore people with significant cognitive impairment will be excluded from participating in the study. Because of the potential for adverse vestibular responses arising from Virtual Reality, people with vestibular dysfunction will be excluded from participating.

11.3. Please indicate how participants will be recruited.

- [x] Advertisements
- [ ] Covert Observations
- [x] Email
- [ ] External Research Panel
- [x] In Person
- [ ] Participants from previous study
- [ ] Phone
- [ ] Postal Service
- [ ] Snowballing Technique
- [ ] Social Media
- [ ] Other

11.3.1.a. Please upload all recruitment materials, including flyers, introductory emails, letters etc.

Type	Document Name	File Name	Version Date	Version	Size
Default	Appendix 5 Consumer Advertisement	Appendix 5 Consumer Advertisement.docx	09/07/2019	1.0	14.0 KB
Default	Appendix 6 consumer email	Appendix 6 consumer email.docx	09/07/2019	1.0	13.0 KB
Default	Appendix 8 - Initial email to prospective clinician participants	Appendix 8 - Initial email to prospective clinician participants.docx	09/07/2019	1.0	14.1 KB
Default	Appendix 9 OTA & APA Advertisement	Appendix 9 OTA & APA Advertisement.docx	09/07/2019	1.0	13.9 KB
Default	Appendix 10 clinical expert email	Appendix 10 clinical expert email.docx	09/07/2019	1.0	12.9 KB

11.4. Please describe who the participants are and outline in more detail how they will be recruited.

Two participants groups will be recruited.

The first group will comprise people recovering from stroke who experienced upper limb dysfunction, but not significant cognitive impairment, as a consequence of their stroke. Potential participants within the Australian Capital Territory will be contacted by distribution of a recruitment notice (see Appendix 5) advertised:
1. In the Canberra Stroke Foundation newsletter .
2. Through relevant Facebook groups.
3. Through Council on the Ageing (COTA) newsletters.

Contact with potential participants who respond to the advertisement will be made by email (see Appendix 6) which will also contain the Participant Information Sheet and Consent Form (See Appendix 7).

The second group will be occupational therapists/physiotherapists with more than ten years of experience in stroke rehabilitation. Participants will have a strong working knowledge of the Clinical Guidelines for Stroke Management 2017 . Potential participants will be identified from membership details of Occupational Therapy Australia (OT Australia) - ACT and the Australian Physiotherapy Association (APA) - NSW/ACT. Invitation to participate will be made by:
1. Email using the details available from OT Australia and APA registers (See Appendix 8).
2. University of Canberra Occupational Therapy newsletter (distributed to industry partners) (See Appendix 9).
3. A direct approach to known local experts.
Participation by expert clinicians will be undertaken outside of normal work hours and duties, eliminating the need for ethical clearance through ACT Health or other employers.

Contact with potential participants who respond to the advertisement will be made by email (see Appendix 10) which will also contain the Participant Information Sheet and Consent Form (See Appendix 11).

11.5. How many participants will you recruit and what is the rationale for this number?

Group 1 (people recovering from stroke) will comprise 6-8 participants. It is important that individual experiences of the virtual reality-based therapy scenarios are gathered. Large amounts of qualitative and quantitative information will be obtained from each participant, hence this number will provide clear indications of the range of factors to be considered virtual reality scenario design.

Group 2 (experienced occupational therapists) will bring knowledge of the Clinical Guidelines for Stroke Management 2017 as well as minimum 10 years experience in engaging clients in conventional upper limb therapy. These participants will scrutinise the virtual reality scenarios to ensure they embed best practice in stroke rehabilitation. Because of their high level of expertise, and the objective measures of therapy quality parameters arising from the Clinical Guidelines for Stroke Management 2017, only two expert clinicians are required to review the scenarios to make this evaluation.

11.6. Will you need to obtain approval to access participants?

- ○ Yes
- ◉ No

11.7. Do you and/or your co-investigators have any pre-existing relationship with participants?

- ○ Yes
- ◉ No

11.8. Will you provide any payment or compensation to participants?

- ○ Yes
- ◉ No

11.9. How will you provide feedback to participants?

Reports and publications will be provided to participants who request them.

12. Risks

12.1. What will participants be required to do or agree to have done to them?

1. People recovering from stroke who agree to participate in the study will attend University of Canberra Hospital to engage in five virtual reality therapy scenarios. Each scenario will require them to participate in upper limb rehabilitation activities that reflect the sorts of things they would typically be asked to do in a conventional therapy session. The entire virtual reality experience, including questionnaire completion, will take approximately one hour.

Following each scenario, each participant will complete an Intrinsic Motivation Inventory regarding their experience of the scenario.

At the completion of all five scenarios, each participant will complete a six-question User Satisfaction Evaluation Questionnaire regarding their overall virtual reality experience across all five scenarios.

Approximately one week following the virtual reality experience, participants will take part in an individual semi-structured interview reflecting on their virtual reality experience. This interview will take approximately 30-45 minutes.

2. Expert clinicians who participate in the study will attend University of Canberra Hospital to engage in five virtual reality therapy scenarios. Each scenario will require them to participate in the same activities as the stroke survivor group. Breaks will be taken as necessary between the scenarios. At the conclusion of all scenarios, clinician participants will participate in a semi-structured interview reflecting on the clinical integrity of the scenarios as a therapeutic experience. Their comments will be drawn from their knowledge of the Clinical Guidelines for Stroke Management 2017, and their clinical experience. The combined participation in the scenarios and the interview will take approximately 90 minutes.

12.2. What are the risks for participants and your strategies for minimising this risk?

There is a slight risk of disorientation, vertigo and nausea for participants who are unused to virtual reality experiences. This risk will be minimised by:
1. Excluding people with known vestibular dysfunction form participating in the study.
2. Informing participants of the signs and symptoms they might encounter and instructing them of their right to cease or take a break from participation as required.
3. Having participants wear the virtual reality equipment for a five minute attenuation period prior to the commencement of therapy scenarios.
4. Ensuring all scenarios are completed in a sitting position.
5. Providing supportive seating that eliminates the possibility of falling during the virtual reality experience.
6. Providing rest periods after each scenario, and more frequently if required.

There is also a possibility of fatigue resulting from the level of upper limb movement practice in each scenario. Fatigue is a natural consequence of high-intensity practice and is an important stimulus for adaption of muscular capacity, however, it can also be distressing for participants. This will be addressed by providing rest breaks at the conclusion of each scenario and allowing the participant to decide when they are ready to commence the next scenario. Participants will also be reminded of their right to cease participation should fatigue become excessive.

Because the therapeutic process addresses compromises to a person's capacity that are imposed by their condition, there is a slight possibility that some participants might become emotional during the session as they are confronted with the limits in their capacity. This could manifest as expressions of frustration, low self-confidence or depression. If these signs are identified by either the research team or participant, the participant will be offered the opportunity to discuss their concerns with a trained occupational therapist, not connected with the study who has expertise in counselling, who can review the participant's concerns and refer them for ongoing support services as required.

12.3. Is there any possible risk to you as the researcher and if so, what are your strategies for minimising this risk?

There are no risks to the researchers.

12.4. Is there any possible risk to others arising from this research project?

No

13. Consent

13.1. Will participants be able to provide informed consent?

- (•) Yes
- ( ) No

13.1.1 How will participants consent to the research and how will you ensure that participation is voluntary?

Participants will read a participant information sheet and sign a consent form. The participant information sheet will explain the nature of the research, identify potential risks and risk minimisation strategies and note the voluntary nature of participation.

13.1.2. Please upload a copy of the Participant Information and Consent Form.

Type	Document Name	File Name	Version Date	Version	Size
Default	Appendix 7 HREC Participant Information and Consent Form - consumers	Appendix 7 HREC Participant Information and Consent Form - consumers.docx	09/07/2019	1.0	90.1 KB
Default	Appendix 11 HREC Participant Information and Consent Form - clinicians	Appendix 11 HREC Participant Information and Consent Form - clinicians.docx	09/07/2019	1.0	89.5 KB

13.2. How will participants be able to withdraw from the research project without penalty and without feeling discomfort?

In the participant information sheet and at the commencement of participation, participants will be advised of their right to withdraw at any time without adverse consequences. Should fatigue or emotional response to the tasks become obvious, participants will be reminded of their right to withdraw without consequence. Withdrawal will be facilitated following any form of request - verbal or in writing.

13.3. Do you intend to withhold or disguise the purpose of the research in any way?

- ( ) Yes
- (•) No

14. Data, Access and Storage

14.1. What type of data will be collected?

- [x] Non-personal information
- [x] Personal information
- [ ] Sensitive Information
- [x] Health Information
- [ ] Information about the health of Aboriginal people

14.1.1. Please outline in more detail what type of sensitive and/or health information will be collected.

The nature of the participant's symptoms and therapy goals following their stroke will be gathered. This will be valuable in understanding any relationship between symptomatology and experiences of Virtual Reality-based therapy.

14.2. Will the data be individually identifiable, re-identifiable or non-identifiable?

- ☐ Individually identifiable
- ☑ Re-identifiable
- ☐ Non-identifiable

14.2.1. Please outline in detail how re-identifiable data will be coded.

Each participant will be allocated an alpha-numeric code when data is collected. This code will be used to identify both questionnaires and qualitative transcripts.

14.3. Will other persons be able to identify research participants from published data or other sources?

- ○ Yes, but only with the participants' consent
- ◉ No

14.4. Who will have access to the data?

- ☑ Only personnel listed in this application
- ☐ Researchers other than those listed in this application
- ☐ Transcription and/or translation services

14.5. What source(s) of information will be used in this research project?

- ☑ Individual participants
- ☐ Relatives or associates of participants
- ☐ Medical/health/mental health records
- ☐ Electoral roll
- ☐ Law enforcement agency
- ☐ Publicly available database
- ☐ Privately available database
- ☐ Internet

14.6. Where will the data be stored?

- ☑ Electronic data will be stored for at least five years after publication at UC
- ☐ Clinical Trial data will be stored for at least 15 years after publication at UC
- ☑ Data in paper format will be stored for at least five years in a secure cabinet and office at UC
- ☐ Clinical Trial data in paper format will be stored for at least 15 years in a secure cabinet and office at UC
- ☐ The data will be archived at UC (longer than the required period)
- ☑ A copy of the dataset will be stored on my password protected private computer/laptop
- ☐ Data will be stored in the cloud or other devises throughout the project but transferred to UC at the conclusion of the project
- ☐ Data will be stored at another organisation

14.7. Do you intend to use the data in future research projects?

- ○ Yes
- ◉ No

Upload relevant attachments

Please upload any other documents supporting your application.

Declarations and Signatures

Declaration

I certify that:

1. All information is truthful and as complete as possible.
2. I have had access to and read the National Statement on Ethical Conduct in Human Research, and that the research will be conducted in accordance with the National Statement and in accordance with the ethical arrangements of the organisations involved.
3. I have consulted any relevant legislation and regulations, and the research will be conducted in accordance with these.
4. I have, if applicable, discussed this application with any collaborators and other persons involved in this research project, they are aware of the requirements and conditions and will conduct the research in accordance with these.
5. I will immediately report to Research Ethics & Integrity anything which might warrant review of the ethical approval of the proposal.
6. I will inform Research Ethics & Integrity, giving reasons, if the research project is discontinued before the expected date of completion.
7. I will adhere to the conditions of approval stipulated by the Committee and will cooperate with the Committee's monitoring requirements, including the provision of annual progress reports and final reports as required.

Signature of Chief Investigator