**Rehabilitation in the Home**

**Modified Constraint-Induced Movement Therapy Study**

**Participant Information Sheet/Consent Form**

**Patient Interview**

|  |  |
| --- | --- |
| **Title** | Modified constraint-induced movement therapy: a process evaluation of implementation within an early-supported discharge rehabilitation service |
| **Short Title** | RITH mCIMT Implementation Process Evaluation |
| **Protocol Number** |  |
| **Project Sponsor** |  |
| **Coordinating Principal Investigator/ Principal Investigator** | Ashan Weerakkody |
| **Associate Investigator(s)** | Prof Barby Singer  A/Prof Erin Godecke |
| **Location** | Rehabilitation in the Home |

**1 Introduction**

Rehabilitation in the Home (RITH) has recently started providing a therapy called modified constraint-induced movement therapy (mCIMT) for patients who come to RITH with difficulty using their arm after stroke. We want to learn more about what patients think about this therapy.

You have been invited to participate in this study because you are:

* a patient who received mCIMT as part of your rehabilitation with RITH
* a patient who was eligible to receive mCIMT but chose not to

This study includes patients of all RITH bases: Armadale, Fremantle, Joondalup, Rockingham, Royal Perth Hospital, Sir Charles Gairdner Hospital and South Guildford.

Your contact details were obtainedduring your admission to RITH and from your RITH therapist.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or RITH therapist.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to be involved in the research described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

There has been a lot of research behind mCIMT for patients after stroke. However, there has been little research into the opinions and experiences of patients who participate in mCIMT as part of their rehabilitation after stroke. This study will give us more information about the experiences of patients who received mCIMT during their rehabilitation with RITH.

The results of this research will be used by the researcher Ashan Weerakkody as part of a Master of Medical and Health Science by Research degree.

**3 What does participation in this research involve?**

This study involves participating in an interview with the research team to understand your views and experiences of mCIMT. This will occur after you have been discharged from RITH.

Participation in this study will not affect your rehabilitation with RITH.

If you consent to participate, a time and location will be discussed with you to organise an interview. This can be at your home or another location that is preferable to you. We will not conduct the interview until you have signed the attached consent form.

The interview will take place with yourself and a member of the research team. The interview may take up to 1 hour. The interview will be audio-recorded and the interviewer from the research team may also take notes. We will be transcribing the recorded interview at a later date. You are welcome to look through the transcribed interview notes to check accuracy of your responses, although this is not a requirement.

We will also collect basic information about such as your age, gender and type of stroke you had.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids researchers or participants jumping to conclusions about the meaning of the information gathered.

There are no costs associated with participating in this research project, nor will you be paid.

**4 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your rehabilitation with RITH.

**5 What are the possible benefits of taking part?**

There will be no clear benefit to you from your participation in this research. Your participation in this study may help future patients of RITH from the knowledge gained in this study.

**6 What are the possible risks and disadvantages of taking part?**

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. The researchers are experienced clinicians who are sensitive to your concerns.

**7 What if I withdraw from this research project?**

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. If you do withdraw, you will be asked to complete and sign a ‘Withdrawal of Consent’ form; this will be provided to you by the research team.

**8 What will happen to information about me?**

By signing the consent form you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. All information from the recorded interviews and transcripts will be assigned a unique identification number as soon as possible to protect your identity. All interview transcripts will be uploaded onto a password-protected WA Health computer drive, which will only be accessible by the research team. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Transcription may be performed by a professional transcriptionist who is not an employee of WA Health; however your full name will not be used during the interview to protect your identity.

The personal information that the research team collect and use is basic demographic information about you such as your age, gender, information about your stroke and your interview responses. This information will be kept confidential and only accessible by the research team.

Information about you may be obtained from your health records held at this and other health organisations for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission. Any quotations or responses you provide will be allocated a unique identifier code to protect your identify.

In accordance with relevant Australian and/or Western Australia privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

When the study ends:

The study data will be stored securely for seven years on a secure WA Health server, after which time it will be destroyed.

The study results can be obtained by emailing Ashan Weerakkody at [ashan.weerakkody@health.wa.gov.au](mailto:ashan.weerakkody@health.wa.gov.au) or [aweerakk@our.ecu.edu.au](mailto:aweerakk@our.ecu.edu.au).

**9 Who is organising and funding the research?**

This research project is being conducted by SMHS Rehabilitation in the Home. It is being supported by in-kind support through SMHS Rehabilitation in the Home.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**10 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC).

The ethical aspects of this research project have been approved by the HREC of WA Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**11 Further information and who to contact**

If you want any further information concerning this study, please contact Ashan Weerakkody at [ashan.weerakkody@health.wa.gov.au](mailto:ashan.weerakkody@health.wa.gov.au) or [aweerakk@our.ecu.edu.au](mailto:aweerakk@our.ecu.edu.au) or 0451 305 593.

If you have any concerns or complaints about the research project and wish to talk to an independent person, you may contact:

**Complaints Contact person**

For matters relating to research at the site at which you are participating, please contact:

Manager, South Metropolitan Health Service Research Support and Development Unit

Phone: 08 6152 3214. Email: [smhs.rgo@health.wa.gov.au](mailto:smhs.rgo@health.wa.gov.au)

**Reviewing HREC approving this research**

South Metropolitan Health Service Human Research Ethics Committee

Contact person: Ethics Coordinator Phone: 08 6152 2064.

Email: [smhs.hrec@health.wa.gov.au](mailto:smhs.hrec@health.wa.gov.au)

**Consent Form -** *Adult providing own consent*

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| **Location** | Rehabilitation in the Home |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.

I understand that I will be given a signed copy of this document to keep.

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|  | | | | | | | |
|  | Name of Participant (please print) | |  | |  |  |  |
|  | | | | | | | |
|  | Signature |  | | Date | |  |  |
|  | | | | | | | |

**Declaration by Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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|  | | | | | | |
|  | Name of Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.