**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

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| --- | --- |
| **Title** | Too tired to recover: Evaluation of a post-stroke fatigue management guideline |
| **Short Title** | Too tired to recover |
| **Protocol Number** | [45827] |
| **Project Sponsor** | Metro North Hospital and Health Service |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Hannah Gullo, UQ  Mr Anthony Walsh, MNHHS |
| **Associate Investigator(s)** | Ms Kim Doussin & Ms Sarah Davies |
| **Location** | Chermside, North Lakes, Redcliffe & Caboolture Community Health Centres |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project. This is because you are experiencing fatigue, and the research project is testing a new treatment for post-stroke fatigue. The new treatment is a fatigue management guideline and associated clinical tools for rehabilitation staff.

This Participant Information Sheet and Consent Form tells you about the research project. It explains the tests and treatments involved. 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 your doctor.

Participation in this research is voluntary. If you do not wish to take part, you don’t have to. You will receive the best possible care whether or not you take part. If you decide you want to take part in this research project, you will be asked to sign a consent form. By signing it you are telling us that you:

* Understand what you have read
* Consent to take part in the research project
* Consent to have the tests and treatments that are described
* Consent to the use of your personal and health information as described.

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

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

The presence of fatigue following stroke may be as high as 70% and the presence of fatigue has a negative impact on rehabilitation outcomes. Mental fatigue refers to the inability to sustain a mental effort over a long period of time and impacts around 62% of people with post-stroke fatigue. It is important to address post-stroke fatigue in order to improve stroke rehabilitation outcomes.

Therapists have no current reference when it comes to treatment planning for fatigue, therefore a general fatigue guideline for common modifiable causes of fatigue would be helpful in rehabilitation.

A fatigue management guideline and new mental fatigue tools for use in therapy were developed to allow clients to regain control over their energy choices. These tools aim to promote relaxation and rests but also address other strategies for mental fatigue, such as reducing multitasking, distractions, and decision making.

You are invited to participate in our project, which aims to evaluate the effectiveness of these new clinical tools at reducing post stroke mental fatigue, and to review their usefulness for participants and rehabilitation staff. The fatigue management guideline is an experimental treatment. This means that it is not an approved treatment for post-stroke fatigue in Australia, and must be tested to see if it is an effective treatment for fatigue and mental fatigue following a stroke.

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

You will be participating in a randomised controlled research trial. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance at random. There is a 50% chance that you will receive the new therapy under investigation, and a 50% chance that you will receive standard therapy. This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and this avoids study doctors or participants jumping to conclusions.

Participants are asked to commit to two assessment sessions of approximately 1 hour each, and 10 weeks of one-on-one treatment with the MNHHS Community Based Rehabilitation Team. One-on-one treatment will be carried out by a qualified occupational therapist in the MNHHS Community Based Rehabilitation Team for a 10 week intervention period.

There are no additional costs associated with participating in this research project, nor will you be paid. All tests and therapy required as part of the research project will be provided to you free of charge.

**4 What do I have to do?**

Once you have provided your consent to participate, you are required to attend two assessment sessions for approximately 1hr on each occasion, once before the therapy intervention, and again following the intervention (after 10 weeks). All assessments will be conducted in your home or local Community Health Centre. A trained researcher unaware of your intervention condition will collect demographic data and administer the assessments. Assessments will be conducted measuring fatigue, self-efficacy, cognitive function, depression and quality of life.

Following your first assessment session, you will attend one-on-one treatment carried out by a qualified occupational therapist in the MNHHS Community Based Rehabilitation Team for a 10 week intervention period. Should you feel unwell on the day of your appointment, please contact the therapist at your local community health centre to reschedule your appointment.

**5 Other relevant information about the research project**

This study will be the first to date to evaluate the effectiveness of a new fatigue management guideline for reducing mental fatigue following stroke. The research team involves a new collaboration among an Occupational Therapy researcher at The University of Queensland and a senior Occupational Therapist in the community, both with extensive experience in stroke rehabilitation and fatigue management.

**6 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.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Metro North Hospital & Health Service.

**7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this Community Health Centre. Standard Occupational Therapy stroke rehabilitation is available. This option will be discussed with you before you decide whether or not to take part in this research project. You can also discuss the options with you doctor.

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

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include a reduction in mental fatigue resulting in improved self-efficacy for daily living activities, and improved quality of life. Should this fatigue therapy and management guideline be perceived as effective and useful, it may be adopted as standard care by community based rehabilitation teams in MNHHS and other health services.

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

There are no known risks and disadvantages of taking part in this study. There may be side effects that the researchers do not expect or do not know about. Tell your study doctor immediately about any new or unusual symptoms that you get.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

**10** ​**What will happen to my test samples?**

There are no human tissue test samples required in this project. Assessments and demographic information will be de-identified and kept confidential in a locked filing cabinet, as per section 16 below.

**11 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/she will explain the reasons and arrange for your regular health care to continue.

**12 Can I have other treatments during this research project?**

Whilst you are participating in this research project, you may not be able to receive any other Occupational Therapy treatment you have been having for your condition or for other reasons. It is important to tell you study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project.

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

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow the research team to discuss any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and research staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the research team up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

**14 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include:

* Unforeseen side effects
* The treatment being shown not to be effective
* The treatment being shown to work and not need further testing

**15 What happens when the research project ends?**

Participation in this project will terminate upon completion of the follow-up assessments, following 10 weeks of intervention. Should you require ongoing rehabilitation, this will be arranged with the Community Based Rehabilitation Team.

Once the data has been analysed, the researchers will evaluate the effectiveness and usefulness of the new fatigue management guideline for rehabilitation staff. This evaluation will allow the sharing of resources to other rehabilitation services and lead to ongoing opportunities for future research.

Participants will be provided with a summary of the results by mail, within 6 months of the research project being completed. It is anticipated that the results of this evaluation will be published in an appropriate peer-reviewed journal.

**Part 2 How is the research project being conducted?**

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

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for this research project, and future related research. Any information obtained in connection with this research project and future related research that can identify you will remain confidential. Your data will be de-identified via use of a participant code, which is re-identifiable to researchers only. All data will be kept in a locked filing cabinet at the Community Health Centre with copies available for storage at The University of Queensland for a minimum of 7 years, and can be accessed only by researchers involved in the project. After this period the data will be destroyed. 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.

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

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of Metro North Hospital and Health Service, and The University of Queensland, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personal and authorities noted above.

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 permission.

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

**17 Complaints and compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication free of charge, as a public patient in any Australian public hospital.

**18 Who is organising and funding the research**

This research has been initiated by Dr Hannah Gullo, Lecturer in Occupational Therapy at The University of Queensland (UQ), and Senior Occupational Therapist Mr Anthony Walsh, Metro North Hospital & Health Service (MNHHS). This research has been jointly funded by a research collaboration grant through the Faculty of Health and Behavioural Sciences, UQ, and MNHHS. It will be conducted by the Community Based Rehabilitation Team, MNHHS.

You will not benefit financially from your involvement in this research project even if, for example, your results (or knowledge acquired from analysis of your results) prove to be of commercial value to UQ and/or MNHHS. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**19 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 The Prince Charles Hospital and ratified through the HREC of The University of Queensland.

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.

**20 Further information and who to contact**

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal investigator Dr Hannah Gullo on (07) 3365 3004 or the clinical contact person:

**Clinical contact person**

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| --- | --- |
| Name | Kim Doussin or Sarah Davies |
| Position | Occupational Therapist |
| Telephone | (07) 3365 3004 |
| Email | kim.doussin@health.qld.gov.au or sarah.davies@health.qld.gov.au |

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

**Complaints contact person**

|  |  |
| --- | --- |
| Name | Mr Anthony Walsh |
| Position | Senior Occupational Therapist |
| Telephone | (07) 3139 6053 |
| Email | Anthony.walsh@health.qld.gov.au |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

**Reviewing HREC approving this research** **and HREC Executive Officer details:**

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| --- | --- |
| Reviewing HREC name | The Prince Charles Hospital |
| HREC Executive Officer | Anne Carle |
| Telephone | (07) 3139 4500 |
| Email | ResearchTPCH@health.qld.gov.au |

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

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**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 give permission for my doctors, other health professionals, hospitals or laboratories outside this Community Health Centre to release information to The University of Queenslandconcerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential. I understand that I will be given a signed copy of this document to keep.

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 study without affecting my future health care.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purpose of research and analysis.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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**Declaration by Study Doctor/Senior 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 Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

**Form for Withdrawal of Participation -** *Adult providing own consent*

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**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Metro North Hospital & Health Service.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

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