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**Participant Information Sheet/Consent Form**

**Interventional Study**

**Main Study**

**Royal North Shore Hospital**

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| **Title** | A Randomised Control Trial (RCT) of early Eye Movement Desensitization and Reprocessing (EMDR) intervention for post-traumatic stress symptoms following burn injury |
| **Short Title** | Early EMDR intervention |
| **Coordinating Principal Investigator/ Principal Investigator** | A/Prof Loyola McLean, Dr Rachel Kornhaber& Dr Vlasios Brakoulias |
| **Associate Investigator(s)** | Julia Kwiet, Anne Darton, Diane Elfleet,Dr Jeffrey Streimer & Dr John Vandervord |
| **Location** | Royal North Shore Hospital |

**Introduction**

You are invited to take part in this research project because you have recently experienced a severe burn injury and you are currently involved in the “Burns Screening” Study associated with this project. The research project is trialling a new treatment for Post-Traumatic Stress (PTS) symptoms. The treatment is called Eye Movement Desensitisation and Reprocessing (EMDR). The purpose of this study is to investigate whether EMDR is a more effective intervention than supportive counselling.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the 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 do not 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 treating doctor. Participation in this research is voluntary and if you choose not to participate this will not affect your current or future care.

EMDR is a psychologically based treatment that aims to help with the resolution of trauma. It involves patients talking about disturbing memories while moving their eyes back and forth. This appears to help patients process and resolve traumatic memories and reduce related disturbances.

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 have the 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 and Consent Form to keep.

**1 What does my participation involve?**

If you agree to participate in this study, you will be asked to sign the Consent Form prior to any study assessments being performed.

You will still receive the standard care provided to all burns patients. In addition, you will receive either 3 one hourly sessions of EMDR intervention, which is counselling with bilateral eye movements or 3 one hourly sessions of counselling without the eye movements (supportive counselling). The nature of your treatment will be explained to you more fully.

First, you will be interviewed to assess your psychological stress and screen for eligibility. This interview will ask you about your past and present relationships, your coping style, how you are adjusting to the injury and any other past significant events. This interview can take between 45 minutes and 1.5 hours. This interview will be audio digitally recorded and transcribed. If there are no reasons that make EMDR unsuitable for you, you will be asked to participate in this study.

You will be interviewed again at 3 months post injury to formally check your posttraumatic symptoms and then interviewed again at twelve to eighteen months after injury. If you receive the supportive counselling and your levels of PTS symptoms are still high after 3 months, you will be offered the EMDR intervention to see if that helps you recover.

You will be participating in a randomised control trial, which means you will be randomly assigned into one of two groups. One group will receive supportive counselling, which is basically a more structured version of the standard care you would be receiving if you did not participate in this study. The other group will receive EMDR intervention, which includes counselling and bilateral eye movements. Both treatments offer strategies for trauma. Sometimes we do not know if a new treatment will be as effective as a standard treatment. To find out more, we need to compare the effects of different treatments. To try to make sure the groups are the same, each participant is put into a group by chance (random).You will have a one in two chance of initially being in the EMDR group. You may receive this treatment whilst still an inpatient at the Severe Burn Injury Unit. If treatment is to occur as an outpatient, where possible this will be scheduled into your follow-up outpatient visits with the Burn Team

Before and after each treatment session you will be asked to complete a short questionnaires that rate your level of post-traumatic stress, depression and anxiety symptoms. This takes only 5 minutes each time. At the 3 month mark you will also undergo a more comprehensive assessment for PTSD, which can take up to 2 hours. At the 6 month mark you will also be asked about your experiences of recovery from burn injury. This interview can take up to an hour and will be recorded. At 12-18 months after your burn injury you will be interviewed again. At this stage you will also be asked to complete a questionnaire that measures your quality of life after burn injury. The nature of the follow up involves being asked about how you are coping, what your supports are, and how you are adjusting. The screening you consented to from the ‘Screening Study’ still applies also (see Table 1 for a full schedule of procedures)

At each visit you will continue to complete the questionnaires described in the ‘Screening Study’. In addition, some visits will involve either the counselling or EMDR sessions.

Table 1 gives an overview of what is involved and how long each study visit is likely to take.

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

The purpose of this study is to evaluate how effective early psychological care is in preventing PTSD, depression and anxiety in burn injury survivors. The results of this study will assist in the development of burn rehabilitation.

It is believed that early EMDR intervention may prevent PTSD and other chronic mental health disorders. Knowledge gained from this study may be used to develop and implement effective early trauma care.

EMDR is approved by the Australian Centre for posttraumatic Mental Health to treat PTSD, a disorder that can be diagnosed 4 weeks after experiencing or witnessing a traumatic event. However, EMDR is not

yet approved to treat patients in the early stages following trauma that is up to the first four weeks after the trauma. Our research looks at whether EMDR can be used as a preventative care measure.

Therefore, it is an experimental treatment for PTS symptoms, which occur before PTSD. This means that EMDR must be tested to see if it is safe and effective in the prevention of PTSD.

The results of this research will be used by the associate researcher Julia Kwiet to obtain a Masters of Philosophy degree. This research has been initiated by the study doctor and Chief Investigator A/Prof Loyola McLean and is funded by NSW Institute of Psychiatry.

**Table 1: Schedule of procedures for the Treatment Phase (P2)**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Visit 1:2-4 weeks | Visit2:2-4 weeks | Visit3:3-5 weeks | Visit4:4-6 weeks | Visit5:5-7 weeks | Visit 6:3 months | Visit 7:6 months | Visit 8: 9 months | Visit 9:12-18 months | Visit 10-14:Yearly f/u |
| Consent |  |  |  |  |  |  |  |  |  |  |
| Questionnaires \* |  |  |  |  |  |  |  |  |  |  |
| Interventions(Counselling or EMDR) |  |  |  |  |  |  |  |  |  |  |
| Interviews |  |  |  |  |  |  |  |  |  |  |
| Estimated time of visit: | 1 hour | 1-2 hours | 1-1.5 hours | 1-1.5 hours | 1-1.5 hour | 2-2.5 hours | 1.5-2.5 hours | 30-60minutes | 40-70minutes | 30-60minutes |

**\*Questionnaires as per the “Screening Study’**

**3 Costs and Payments**

There are no additional costs associated with participating in this research project, nor will you be paid. This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids members of the research team or participants jumping to conclusions.

This research will be monitored by the regular reporting requirements to the ethics committee and by the internal research teams monitoring of progress. Monthly reports by the team to the chief investigator will be provided in order to monitor compliance and track progress.

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

Participating in this study will not impose any lifestyle or dietary restrictions and participants can take their regular medications. If you commence any new medications during the study we would ask that you tell a member of the research team.

**5 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 without repercussions.

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 routine treatment, your relationship with those treating you or your relationship with the burn team at Royal North Shore Hospital.

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

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; supportive counselling and psychiatric review is the standard treatment available after burn injury at this hospital. Members of the research team will discuss these options with you before you decide whether or not to take part in this research project.

**7 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 post-traumatic stress symptoms and perhaps prevent other mental health symptoms. We also hope to learn about early treatment that may help future burn patients.

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

Any treatments and interventions can cause side effects. Possible side effects from EMDR are feelings of marked distress during processing of traumatic memories, dissociation (especially in those with prior risk). Dissociation is a sense of detachment from feelings, experiences and / or thoughts. Also the actual traumatic memory may or may not be altered. Please note that EMDR can alter the participants’ memory or recollection of the traumatic event. There is also a chance that EMDR may uncover memories of an event that had been forgotten. If this results in distress or disturbance you will be referred to Consultation-Liaison psychiatry for appropriate management.

If you become upset or distressed as a result of your participation in the research, the research team 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.

**9 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 or your personal risk. If this happens, members of the research team will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, members of the research team 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, members of the research team 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.

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

Yes, you can have any treatment you may usually have. As part of the study you will be asked what sort of treatment you have.

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

If you decide to withdraw from the project you can do so at any time without having to give a reason. Please notify a member of the research team before you withdraw.

If you do withdraw your consent during the research project, the relevant study 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 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.

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

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

• Unacceptable side effects

• The treatment being shown not to be effective

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

Upon completion of this project participants who remain unwell will be referred to Consultation-Liaison Psychiatry for assessment and community referral. Results will be communicated to interested participants directly by members of the research team upon completion of the project.

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

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

By signing the consent form you consent to the members of the research team collecting and using personal information about you for this research project. Any information obtained in connection with this research project that can identify you will remain confidential. Any identifiable information will be kept in a secure and locked area to which only members of the research team have access and your confidentiality will be assured. 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. All data will be stored in accordance with NSW Health Records regulations and stored accordingly. 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. Data from the questionnaires will be re-identifiable (coded). Data obtained from the recorded face to face interviews will hold identifiable personal information. These interviews will be stored electronically in password secured computers to which only members of the research team will have access to.

It is anticipated that the results of this research project will be published and/or presented in a variety of ways. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. Any identifiable information will be removed and only non- identifiable data will be published and presented. Information about your participation in this research project may be recorded in your health records. In accordance with relevant Australian and NSW Health 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. 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.

**15 Complaints and compensation**

If you suffer any distress, complications or other issues 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 or psychological 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.

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

This research project is being funded by the NSW Institute of Psychiatry via the provision of a research fellowship to Ms Julia Kwiet. Otherwise the research is funded by the research team from the Severe Burn Injury Unit.

**17 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 Northern Sydney Local Health District (NSLHD). It has also been reviewed by an expert panel of members of the NSW Institute of Psychiatry.

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.

**18 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 study doctor, Loyola McLean on 02 96657314 or 0405 539625 or Julia Kwiet on 02 9462 9477

The Northern Sydney Local Health District (NSLHD) is the Human Research Ethics Committee (HREC) approving this research. 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 them via their Ethics Manager on 02 99264590 or email: nslhd-research@health.nsw.gov.au and quoting HREC/14/HAWKE/79.

 **Thank you for your time and consideration.**

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**Consent Form**

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| --- | --- |
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| **Short Title** | Early EMDR intervention |
| **Coordinating Principal Investigator/****Principal Investigator** | A/Prof Loyola McLean, Dr Rachel Kornhaber &Dr Vlasios Brakoulias  |
| **Associate Investigator(s)** | Julia Kwiet, Anne Darton, Diane Elfleet, Dr Jeffrey Streimer &Dr John Vandervord |
| **Location** | Royal North Shore Hospital |

**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 or hospitals outside this hospital to release information to *Royal North Shore Hospital* concerning my symptoms and treatment for the purposes of this project. I understand that such information will remain confidential.

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

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|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  | Date |  |  |
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| --- |
|  |
|  | Name of Witness\* to Participant’s Signature (please print) |  |  |
|  |
|  | Signature |  | Date |  |  |
|  |

\* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

**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, the research project.

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

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**Form for Withdrawal of Participation**

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| --- | --- |
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| **Associate Investigator(s)** | Julia Kwiet, Anne Darton, Diane Elfleet, Dr Jeffrey Streimer & Dr John Vandervord |
| **Location**  | Royal North Shore Hospital |

**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 *Royal North Shore Hospital.*

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