**A Quality Improvement Study on Psychosocial Screening and Outcome Tracking and a Randomised Control Trial of Eye Movement Desensitization and Reprocessing (EMDR) for Post-Traumatic Stress Following Burn Injury.**

**Psychosocial Screening & Early EMDR Intervention**

**VERSION 5, DATE: 30/06/2014**

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# STATEMENT OF COMPLIANCE

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

Table of Contents

[**STATEMENT OF COMPLIANCE 1**](#_Toc383685846)

[**TABLE OF CONTENTS 1**](#_Toc383685847)

[**PROTOCOL SYNOPSIS 3**](#_Toc383685848)

[**GLOSSARY OF ABBREVIATIONS 4**](#_Toc383685849)

[**1. INVESTIGATORS AND FACILITIES 5**](#_Toc383685850)

[**2. INTRODUCTION AND BACKGROUND 7**](#_Toc383685851)

[**2.2 Research Question 9**](#_Toc383685852)

[**2.3 Rationale for Current Study 10**](#_Toc383685853)

[**3. STUDY OBJECTIVES 10**](#_Toc383685855)

[**4. STUDY DESIGN 11**](#_Toc383685856)

[**5. STUDY TREATMENTS 19**](#_Toc383685857)

[**5.1 Treatment Arms 19**](#_Toc383685858)

[**5.2 Description of the Intervention/Treatment 19**](#_Toc383685860)

[**6. PARTICIPANT ENROLMENT AND RANDOMISATION 22**](#_Toc383685862)

[**6.3 Informed Consent Process 24**](#_Toc383685863)

[**7. STUDY VISITS AND PROCEDURES SCHEDULE 25**](#_Toc383685864)

[**Study Flow Chart 25**](#_Toc383685865)

[**8. ADVERSE EVENT REPORTING 26**](#_Toc383685866)

[**8.1 Definitions 26**](#_Toc383685867)

[**9. STATISTICAL METHODS 27**](#_Toc383685868)

[**9.1 Sample Size Estimation 27**](#_Toc383685869)

[**9.2 Population to be analysed 27**](#_Toc383685871)

[**9.3 Statistical Analysis Plan 27**](#_Toc383685873)

[**10. DATA MANAGEMENT 28**](#_Toc383685874)

[**11 ADMINISTRATIVE ASPECTS 29**](#_Toc383685875)

[**12 USE OF DATA AND PUBLICATIONS POLICY 30**](#_Toc383685876)

[**13 REFERENCES 30**](#_Toc383685877)

# PROTOCOL SYNOPSIS

|  |  |
| --- | --- |
| Title | A Quality Improvement Study on Psychosocial Screening and Outcome Tracking and a Randomised Control Trial of Eye Movement Desensitisation and Reprocessing (EMDR) for Post-Traumatic Stress Following Burns Injury. |
| ObjectivesPrimary:Secondary: | 1. Psychosocial screening and outcome tracking
2. Evaluation of the efficacy of early trauma interventions to improve outcome (EMDR vs standard care)
 |
| Study Design | A descriptive questionnaire longitudinal survey followed by a 2-arm randomised controlled clinical trial.  |
| Planned Sample Size | 1. Phase 1: Screening - all burns patients admitted to the Severe Burn Injury Unit (SBIU) at Royal North Shore Hospital (RNSH) (ca 200/year)
2. Phase 2: Main Study – 80 patients (40 in each group)
 |
| Selection Criteria | 1. Admission to SBIU with burn injury
2. Uncomplicated PTS symptoms
 |
| Study Procedures | 1. Screening of patients on SBIU2. Offering participation in intervention study for patients with uncomplicated PTS symptoms3. Randomization to EMDR or treatment as usual (TAU)4. Administration of Treatment5. Offer of EMDR to those in TAU arm who remain significantly symptomatic (after 3 months)6. Immediate post treatment comparison and formal PTSD diagnosis at 3 months post burn.6. Follow-up of both screening and intervention participants |
| Statistical ProceduresSample Size Calculation:Analysis Plan: | For the screening study:Sample size and analysis planWe will aim to analyse the data set and data cohorts over time looking at predictors of post-traumatic symptoms, depression, anxiety and quality of life parameters, using regression and logistic regression models. We aim to recruit the majority of SBIU patients and follow them longitudinally, accruing approximately 200 patients per year. Our small prior study with a sample size of around 50 was able to show strong correlations between personality, coping style, mental health diagnoses and early high PTS and depression scores. We anticipate the larger numbers and longitudinal follow-up will strengthen the data for planning and policy and act as a basis on which to build intervention studiesFor the interventional study:Effect size, measured as Cohen’s d from similar published studies of early intervention is very strong (d≥≥1.0). Allowing for a possible lower effect size in this medically unwell group of 1.0 >d >0.9 with power of 0.8 and significance set at an alpha of 0.05 (two-tailed) with a minimum sample size of 17-20 in each group for an independent samples t-test. Dependent testing usually yields a higher power, because the interconnection between data points of different measurements are kept and is relevant here in the repeated measures design This suggests that even smaller samples with a lower effect size may be able to be analysed. (http://www.psychometrica.de/effect\_size.html#transform) Given however the unwell nature of our sample group, high attrition rate of patients with PTSD and need for covariate analysis, we plan to over recruit, aiming for 40 subjects in each arm of the intervention study.Statistical analysis will require comparison of pre- and post-measures within subjects and between groups. It is planned to analyse the data using M/ANCOVA techniques with the independent variables as the treatment type (EMDR vs optimised standard care and the dependent variable of post-traumatic stress (PTS). Important covariates that may be analysed will include total body surface area (TBSA), burn site, gender and age. Analyse at the 3 month mark will examine the effect of the interventions on the prevalence of post-traumatic stress disorder (PTSD), depressive and anxiety symptoms and quality of life. Logistic regression models will be used to establish models of factors predicting risk and outcome over time.Qualitative analysis on the interviews on the experience of recovery and rehabilitation and treatment will proceed via thematic analysis. |
| Duration of the study | 5 years |

# GLOSSARY OF ABBREVIATIONS

|  |  |
| --- | --- |
| **ABBREVIATION** | **TERM** |
| EMDR | Eye Movement Desensitization and Reprocessing |
| PTS | Post-Traumatic Symptoms |
| PTSD | Post-Traumatic Stress Disorder |
| SBIU | Severe Burn Injury Unit |
| CBT | Cognitive-Behavioural Therapy  |
| CL | Consultation-Liaison Psychiatry |
| RNSH | Royal North Shore Hospital |
| IES | Impact of Event Scale |
| DES | Dissociative experience Scale |
| CAPS | Clinician-Administered PTSD Scale |
| COPE | COPE Inventory\Questionnaire |
| PCL-C | Posttraumatic Stress Disorder Checklist -Civilian |
| DASS | Depression Anxiety Stress Scale |
| A-TIP | Acute –Traumatic Incident Procedure  |
| TAU | Treatment as usual |
| SUDs | Subjective units of disturbance |
| VoC | Validity of Cognition |
| PICF | Patient Information Consent Form |

# INVESTIGATORS AND FACILITIES

* 1. **Study Location/s**

This research will be conducted with patients of the Severe Burn Injury Unit at Royal North Shore hospital.

* 1. **Study Management**
		1. **Principal Investigator**

Associate Professor Loyola McLean is the main principal researcher and supervisor of this project and will be responsible for overseeing all aspects of this project. Dr Vlasios Brakoulias and Dr Rachel Kornhaber are involved as principal researchers. Dr Vlasios Brakoulias will provide associate supervision to Julia Kwiet as part of her enrolment in a research degree and Dr Rachel Kornhaber will be involved with the qualitative component and subsequent thematic data analysis.

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* + 1. **Associate Investigators**

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* + 1. **Statistician**

A/Prof Loyola McLean will undertake oversight of the statistical analysis. (Contacts as above). As this is also a postgraduate research project for Ms Kwiet, she will be supported to learn and apply statistical analysis methods to the data.

* + 1. **Independent Safety and Data Monitoring Committee**

As this is a small local trial, data and safety monitoring will be undertaken by the research team and

a local person as the external person responsible. The team will examine recruitment and data in regular two-monthly meetings as well as follow protocol for notification of incidents. Anne Darton, Manager of the Statewide Burn Injury Service has suitable expertise in this area and

will be the designated person responsible for advising the HREC of any reports of serious events.

Dr Vanessa Rogers, Psychiatric Staff Specialist at Academic and Liaison Psychiatry, RNSH will be the nominated external person responsible for our Safety and Data Monitoring Board. Any adverse reactions occurring as a result of this research will be reported to her directly by members of the research team. She will review all cases where patients have experienced an adverse reaction and inform the NSLHD HREC of any concerns regarding this research.

* + 1. **Funding and resources**

The NSW Institute of Psychiatry awarded Julia Kwiet with a training Fellowship in psychiatric research for 2014. This will provide Julia Kwiet with salary support for a period of 11 months to the value of $50.000, this being a part-time fellowship.

The Social Work Department, RNSH supports this project and any necessary administrative support will be provided such as costs for phone calls and stationary involved in the patient follow-up.

Research time for A/Prof McLean and Dr Brakoulias and Dr Kornhaber is provided as part of academic affiliations.

# INTRODUCTION AND BACKGROUND

* 1. **Background Information**

Severe burn injuries are associated with considerable psychological trauma and psychosocial sequelae ([1-7](#_ENREF_1)). Burns patients are at increased risk of developing Post-Traumatic Stress Disorder (PTSD), depression and other mental health disorders ([4-8](#_ENREF_4)). Early intervention is potentially important for this vulnerable and marginalized client group, before new trauma becomes chronic and disabling and interferes with recovery. Improving detection of posttraumatic symptoms, mental health symptoms and adverse coping styles is a necessary first step to addressing the health and mental health burden experienced by these patients.

Screening all severe burns injury patients admitted to the Severe Burns Injury Unit has aimed to identify at risk patients. However the experience of the Burn team and the Burns Psychosocial Research Group over the life of the Adjustment to Burns project has been that the long-standing bedside screening undertaken by Consultation-Liaison Psychiatry can be optimized by the addition of initial questionnaires, and the need for follow-up monitoring extends well beyond the initial SBIU admission. To address this issue and to collect as complete as possible a dataset on the Severe Burn Injury Unit cohort on which to base future treatment, policy and advocacy, this first study within the project will establish routine optimized psychosocial screening and then track outcomes of patents over time, using their return visits for Burns follow-up and, where necessary, phone and GP contact to gather data. It will also form the cases for targeted studies on intervention for PTSD and other mental health sequelae, such as the early intervention study that follows. The screening program is the foundation upon which future research will be built. The second study is a treatment study focussing on early intervention for posttraumatic symptoms, evaluating the efficacy of early post-trauma interventions by comparing the more novel treatment EMDR vs the standard treatment of supportive counselling.

EMDR is an effective evidence based treatment for psychological trauma ([9-13](#_ENREF_9)) as it is a psychotherapy that facilitates resolution of traumatic memories. It has been well researched. To date there are 21 randomized clinical trials demonstrating its efficacy in reducing and eliminating PTSD symptoms ([14](#_ENREF_14), [15](#_ENREF_15))and is recommended as an effective treatment for trauma ([16](#_ENREF_16), [17](#_ENREF_17)). The World Health Organization (WHO) new guidelines for mental health care after trauma (18) recommend EDMR as an effective treatment method along with trauma-focused CBT. These guidelines specifically call for more research with acute trauma([18](#_ENREF_18)).

To date, there are few studies on early EMDR intervention following trauma and many researchers and clinicians have identified this as an important area requiring further investigation ([11](#_ENREF_11)). It is believed that early EMDR intervention may help patients integrate traumatic memories preventing the development of chronic pathology ([10-13](#_ENREF_10), [15](#_ENREF_15))and may influence adaptive integration, promote positive coping and contribute to the development of resilience ([11](#_ENREF_11), [19](#_ENREF_19), [20](#_ENREF_20)). Recent research on early EMDR intervention in acute care settings has shown very promising results in reducing post-traumatic symptoms and subsequent PTSD ([10](#_ENREF_10), [12](#_ENREF_12), [20](#_ENREF_20)). There are however, surprisingly few publications addressing early EMDR intervention ([15](#_ENREF_15)) although these are starting to emerge ([10](#_ENREF_10), [12](#_ENREF_12), [21](#_ENREF_21)). There are several case studies reporting positive outcomes after acute stress with early EMDR intervention ([10](#_ENREF_10), [20](#_ENREF_20), [22](#_ENREF_22)).Recent studies from Mexico and Israel have supported other anecdotal reports on the rapid effects of brief EMDR interventions on intrusive symptoms in early posttraumatic cases ([10](#_ENREF_10), [23](#_ENREF_23)) and claim “that treatment may have helped prevent the development of chronic PTSD and facilitated greater resilience and coping”([12](#_ENREF_12)). Jarero et al. ‘s ([12](#_ENREF_12)) randomized control study with a waitlist/delayed treatment control group of earthquake survivors found that one session of early EMDR produced significant improvement on symptoms of posttraumatic stress, with results maintained at 12 week follow up([12](#_ENREF_12))). They also demonstrated symptom improvement within the delayed treatment group post intervention. These researchers suggest that EMDR may be the key brief early intervention modality after traumatic events([12](#_ENREF_12)) .

The question of the timing of early EMDR and whether it can thereby reduce the incidence of PTSD and other disorders that can follow trauma are among the general challenges that need to be studied empirically ([11](#_ENREF_11), [19](#_ENREF_19)). However within the complexity of burns trauma, the basis safety and efficacy, over and above normal psychological “first aid” needs demonstrating. Furthermore, in all psychological treatments there is a non-specific effect of the therapeutic alliance which needs to be differentiated from the specific effect/s of the offered treatment.

This research then aims to explore the effects of early EMDR interventions on burn patients’ mental health outcomes with a primary focus on posttraumatic symptoms and secondarily tracking mood and coping, which are often poorly addressed during rehabilitation. This project has the support of the Burns Psychosocial Research Group, which has been researching burn patients mental health recovery and rehabilitation for several years ([24](#_ENREF_24)). This project would represent the next collaborative project for the Group who has been struck by the severe psychopathology that is present in burn survivors. The opportunity to promptly intervene with simple and effective psychological treatment to avoid sequelae in those who were previously well warrants investigation and sits with clinical observation that even good psychological “first aid” with counselling and Consultation-Liaison Psychiatry support appears to be insufficient to support best recovery.

The hypothesis that early EMDR intervention/treatment has a positive effect on burns patients’ mental health outcomes, in terms of reduction in PTS, PTSD and depression will be tested. After screening for chronic complex trauma and other exclusion factors, patients will be randomly assigned to ensure groups are similar and therefore help control for extraneous variables. The proposed project will utilize a quantitative approach that will examine the pre- and post-measures on PTSD scales and coping measures both in those patients who receive a specific EMDR intervention and those who receive optimized standard care (including stabilization, stress management strategies and supportive counselling). Data will then be compared and it is hypothesized that outcomes may match other research findings ([10](#_ENREF_10), [12](#_ENREF_12), [21-23](#_ENREF_21)) that show significantly reduced prevalence of PTSD and lower PTS scores in patients that have received early EMDR treatment. As depression is a longer term outcome of traumatic symptoms, it is hypothesized that this will also be less in the EMDR treated group at 3 month follow-up (CAPS interview). Patients will also be invited to participate in qualitative interviews on recovery from Burns and the rehabilitation experience undertaken by the affiliated post-doctoral researcher Dr Rachel Kornhaber. Participants will be interviewed about their experience of Burns recovery and rehabilitation including their experience of EMDR treatment 6 months after injury. A semi structured interview will be conducted and digitally audio recorded and verbatim transcripts generated. Data will be analysed using thematic analysis to explore emerging themes. As qualitative data generates a large amount of data, a small sample size of approximately 10-15 participants would be expected to reach data saturation, a key concept in qualitative research.

* 1. **Research Question**
1. What is the prevalence of PTSD, depression and anxiety symptoms, and adjustment disorder in survivors of severe burns injury?
2. Is early EMDR intervention a safe and more effective treatment for post-traumatic symptoms than standard treatment and does it reduce the rate of PTSD and other mental health disorders in burn injury patients
	1. **Rationale for Current Study**

As detailed above Burns patients are at increased risk of developing PTSD, depression and other mental health disorders ([1](#_ENREF_1), [3](#_ENREF_3), [5-8](#_ENREF_5), [25](#_ENREF_25)). Early intervention is potentially important for this vulnerable and marginalized client group, before new trauma becomes chronic and disabling and interferes with recovery.

PTSD has largely been unrecognized in primary care ([26](#_ENREF_26)). Burn patients are at risk of developing this disorder, which is associated with increased rates of medical morbidity, poor health-related quality of life, and functional impairment. PTSD is prevalent in primary care settings, however only few patients with PTSD receive mental health services as detection in acute care setting has been difficult. It is now believed that PTSD is one of the most unrecognized and untreated anxiety disorders in primary care settings. The Burns Psychosocial Research Group at RNSH, who has been grappling with this problem over the last years, believes that routine optimized screening for PTSD is key to providing more targeted and effective mental health treatment to burns patients. Recent work over the last years from our group has established that our local patients, like international cohorts, have a high level of psychological symptomatology and mental health diagnoses, early in post-burn recovery (McLean et al, unpublished data, currently in preparation for publication and abstract for ISBI Conference, 2014). From our work we are clear that there is as much psychopathology in the group that tend to refuse questionnaires as those that will voluntarily participate in early follow-up (unpublished data as above) and that the level of symptomatology that is picked up by questionnaires tends to be higher than clinical screening, possibly due to the strong social avoiding and denying responses in this group. It is important to note that primary care, rather than specialty mental health services, has been the point of contact with the health care system for the majority of individuals with PTSD([26](#_ENREF_26)). Improving detection in early recovery, when the burns patient has access to specialty services for diagnosis, management planning and referral, may improve outcome.

Improving detection of PTSD, adverse coping styles and depression are important steps in addressing the health and mental health burden experienced by these patients. Screening all severe burns injury patients admitted to the Severe Burns Injury Unit will offer all patients the opportunity for outcome tracking and collect the necessary extensive cohort data on which to base future treatment, policy and advocacy as well as a targeted study on early intervention for PTSD. This screening will constitute the first phase of this study; the second part will evaluate the efficacy of EMDR vs standard treatment for early trauma interventions. As detailed in the previous section, EMDR is a potential early intervention that warrants assessment in this patient group at risk of post-traumatic and psychosocial disorders.

1. **STUDY OBJECTIVES**

The first phase of this study proposes to improve the quality and extent of psychosocial screening in burns patients with a view to early recognition of psychological symptoms and referral to appropriate care. Hence our plan is to incorporate questionnaires into routine screening, that has included a clinical assessment by Consultation-Liaison psychiatry, tapping into both at risk styles of coping and symptoms and to follow patients longitudinally to aim for early referral and to track the outcomes so that we can offer data to support health care and policy for this unwell and disadvantaged group.

* 1. **Primary Objective**

The primary objective of this study is to measure and track the psychosocial consequences of a severe burn injury in terms of its impact of patients’ mental health. Referral for assessment and treatment will be offered where symptom levels suggest clinical impairment.

* 1. **Secondary Objectives**

The secondary but important objective of this study is to evaluate the efficacy of early trauma interventions (EMDR vs (optimised) standard treatment). Interventions that reduce post-traumatic symptoms early in the recovery and rehabilitation are likely to enhance patients’ outcomes, resilience and coping. Effective early intervention may prevent development of chronic pathology, potentially reduce length of hospital admission, and positively influence rehabilitation and psychosocial reintegration. This would not only have a positive impact on patient’s health outcome but would be resource and cost effective for the health system in the long run.

Knowledge gained from the proposed research can be utilized to inform and further develop more effective early trauma interventions. Early EMDR interventions may facilitate improved psychosocial recovery of burns patients and this first step towards full evaluation is necessary to establish basic proof of concept that early EMDR intervention is safe, useful and valuable in this acute and medically complex setting. There is consensus in the literature that more controlled research to evaluate further the efficacy of early EMDR intervention is warranted ([10](#_ENREF_10), [15](#_ENREF_15), [19](#_ENREF_19), [21](#_ENREF_21), [22](#_ENREF_22), [27-30](#_ENREF_27)). The objectives are to examine and improve psychosocial outcomes of severe burn injury patients.

# STUDY DESIGN

* 1. **Type of Study**

This proposal details a two-pronged prospective study. Phase one will screen and track psychosocial outcomes of severe burns injury patients (See Table 1) and phase two will evaluate how effective early trauma interventions are in improving patients’ overall outcome (See Table 2). The efficacy of EMDR will be compared to standard treatment albeit an optimised version of this.

**Table 1: Schedule of questionnaires and study visits for the Screening Phase (P1)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Visit 1:2-4 weeks | Visit 2:3 months | Visit 3:6months | Visit 4: 9 months | Visit 5:12-18 months | Visit 6-10:Yearly f/u |
| **Consent** |  |  |  |  |  |  |
| **Questionnaires:**1.Impact of Event Scale-Revised (IES-R) |  |  |  |  |  |  |
| 2. COPE |  |  |  |  |  |  |
| 3. DS-16 |  |  |  |  |  |  |
| 4. Relationship Questionnaire (RQ) |  |  |  |  |  |  |
| 5. ABCD-Self Report, revised (ABSD-SRR) |  |  |  |  |  |  |
| 6. The Depression Anxiety and Stress Schedule (DASS) |  |  |  |  |  |  |
| 7. Measure of Alcohol use |  |  |  |  |  |  |
| Burns Specific Health Scale( BSHS-B) |  |  |  |  |  |  |
| **Estimated time of visit:** | 30 – 60minutes  | 30 – 60minutes | 30 – 60minutes | 30-60minutes | 40-70minutes | 30-60minutes |

**Table 2: Schedule of procedure for the Treatment Phase (P2)**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Visit 1:2-4 weeks | Visit 2:2-4 weeks | Visit3:3-5 weeks | Visit 4:4-6 weeks | Visit 5:5-7 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:**1.Impact of Event Scale-Revised (IES-R) |  |  |  |  |  |  |  |  |  |  |
| 2. COPE |  |  |  |  |  |  |  |  |  |  |
| 3. DS-16 |  |  |  |  |  |  |  |  |  |  |
| 4. Relationship Questionnaire (RQ) |  |  |  |  |  |  |  |  |  |  |
| 5. ABCD-Self Report, revised (ABSD-SRR) |  |  |  |  |  |  |  |  |  |  |
| 6. The Depression Anxiety and Stress Schedule (DASS) |  |  |  |  |  |  |  |  |  |  |
| 7. Measure of Alcohol use |  |  |  |  |  |  |  |  |  |  |
| Dissociative experience Scale (DES ) |  |  |  |  |  |  |  |  |  |  |
| Burns Specific Health Scale( BSHS-B) |  |  |  |  |  |  |  |  |  |  |
| **Interventions:**Counselling or EMDR |  |  |  |  |  |  |  |  |  |  |
| **Interviews:** |  |  |  |  |  |  |  |  |  |  |
| Burns Modified AAI |  |  |  |  |  |  |  |  |  |  |
| CAPS Interview |  |  |  |  |  |  |  |  |  |  |
| Semi Structured Interview |  |  |  |  |  |  |  |  |  |  |
| **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 |

* 1. **Study Design**

There are two arms of this study. The first part involves screening all patients admitted to the Severe Burns Injury Unit for PTSD, depression, anxiety and coping. The second part involves measuring how effective early interventions are in reducing these in severe injury burns patients.

Table 3 outlines the different interventions for participants (either cases or controls) and compares this to non-participants’ experience. Protocol Stages:

*Stage 1- Screening for posttraumatic symptoms*.

All patients admitted to the SBIU, RNSH will be screened within the first two-four weeks following injury (or the first 2 weeks following discharge from Intensive Care), by the usual Consultation-Liaison bedside screening and with a set of questionnaires (see page 15) including the Impact of Event Scale –Revised (IES-R)([31](#_ENREF_31)). Patients whose baseline scores on this scale indicate moderate-to-severe posttraumatic stress symptoms will be considered for recruitment into the intervention study (IES score ≥26).The remainder of the questionnaires are used to track depression, anxiety and coping style, pain and alcohol use. Information re burn depth, size and location will also be obtained (collected routinely in all burns patients).These measures will be repeated at Burns outpatient follow-up visits at 3 monthly intervals over the first year and then annually for five years. Patients who have not returned for follow-up will be contacted by phone to arrange follow-up questionnaire completion. From the end of the first year a questionnaire on quality of life will be added. For an account of the measures see the section below.

All patients with elevated risk factors will be referred for reassessment if an inpatient and to GP care and follow-up if close to discharge or discharged.

*Stage 2\_- Clinical assessment to identify exclusions and pre-treatment variables.*

The subgroup of patients with elevated IES-R scores from the screening study will be evaluated further via a full psychiatric assessment by the Consultation-Liaison Psychiatry team to determine clinical exclusions and Ms Kwiet will also perform a fuller psychosocial research assessment, including evaluation of dissociative symptoms via interview and the Dissociative Experiences Scale (DES)([32](#_ENREF_32)).Past trauma history as well as other risk and resilience factors, such as past psychiatric illnesses, family history, medications, premorbid personality and functioning and levels of social support will also be assessed. This will be obtained via a semi-structured interview incorporating these clinical domains, the Adult Attachment Interview (Burns Modified with Social Support probes) ([33](#_ENREF_33)) and the Clinician-Administered PTSD Scale (CAPS), the gold standard interview measure of PTSD ([34](#_ENREF_34)). Patients identified as having unresolved chronic complex trauma (including prior PTSD) and high levels of dissociation as well as patients with self-inflicted burns injuries will not be considered for inclusion in the randomized-control trial (RCT), as they are likely to require a prolonged period of stabilization and treatment within a longer term therapeutic relationship. They will be referred to the Consultation-Liaison (C-L) Psychiatry Team for advice re management and follow-up. While on the ward these patients will receive the appropriate support and follow-up from Consultation-Liaison Psychiatry and Social Work.

Other potentially relevant biopsychosocial variables were obtained by the screening study to which will be added the PTSD Checklist-Civilian(PCL-C)([35](#_ENREF_35)), or the PTSD Checklist-Military (PCL-M) (if relevant due to Military service as the cause of the burn) and current medications and pain relief. As time since injury is central to the process of development of traumatic symptoms and their consolidation, this will be tracked. This data will be available for consideration in analyses of covariance. *See 4.7 for a full list of measures.*

The intervention design is 2 stepped:

1) A RCT of early EMDR, using the Acute –Traumatic Incident Procedure (A-TIP)([36](#_ENREF_36)), where this novel treatment will be compared with an early intervention of supportive counselling that includes basic stabilization and stress management strategies and a supportive psychotherapeutic relationship, constituting optimized standard care. The rationale for this control treatment is that some early positive effects of treatment might occur through psychophysiological stabilization and de-arousal, brought about by the powerful effects of social soothing in a therapeutic relationship and/or via simple instruction and/or encouragement to engage in stress management strategies. Comparison of the proposed “active” component of EMDR with an “active”, albeit supportive psychotherapy, with provision of basic stress and affect management skills delivered within a supportive therapy frame diminishes the risk of overlooking the therapeutic effect of good psychosocial care.

2) Participants from the control group who remain symptomatic (IES ≥26) will be offered the EMDR intervention after 3 months. This additional treatment after the standard care is offered out of ethical concerns that the literature to date suggests that EMDR may be a more effective intervention than supportive counselling ([12](#_ENREF_12), [23](#_ENREF_23)). Analysis will be from the immediate post treatment PTS levels and formal PTSD assessment at 3 months post injury.

*Stage 3: Randomized treatment*

Patients with (uncomplicated) moderate to severe posttraumatic stress symptoms will be recruited and randomly allocated into two groups. One group will receive three hours of EMDR as per the Acute – Traumatic Incident Procedure (A-TIP) (see table 4) and the other group will receive three hours of supportive psychotherapy, which will include basic psychological stabilization and stress management, considered as psychological “first aid”, provided within a supportive psychotherapeutic relationship (see table 5). All interventions will be provided by Ms Kwiet, who will establish rapport and a therapeutic alliance with each of the patients of both groups and has worked with burn patients in this acute care setting for 10 years. All treatment sessions will be taped to foster close supervision and to allow a review of adherence to protocol by other members of the research team. At commencement and completion of each session of treatment the IES will be repeated to track any change in the interval between screening and treatment and any interval changes between sessions.

*Stage 4: Outcome and Follow-up assessments*

The IES-R (24) will be administered to all patients following each treatment intervention and again at 3 monthly intervals in the first year and once per year for the next five years so that levels of symptoms can be measured and tracked.

At 3 months follow-up the Clinician-Administered PTSD Scale (CAPS) (28) the gold standard for PTSD symptoms will be administered to all participants from both groups. At 6 months post injury participants from P2 will be interviewed to obtain qualitative data about their recovery and ‘lived experiences’ of EMDR. At the 12-18 month follow up Ms Kwiet will perform another Burns Modified Adult Attachment Interview (26) to all participants from both groups. The COPE (29), DASS (31) and DES (27) will also be re-administered to each patient at each follow up.

**Sample**

Phase 1: All patients admitted to the SBIU will be offered optimized screening and participation in the psychosocial tracking.

Phase 2: Willing participants admitted to the SBIU, (RNSH), a subgroup of participants from phase 1, with moderate-severe posttraumatic symptoms established at baseline screening who do not have exclusion criteria.

* 1. **Number of Participants**

For Phase 1 of this study, we aim to recruit all burn patients admitted to the SBIU, which historically has been an average of 200 per year.

For Phase 2, we aim to recruit 80 participants (40 in each group). For meaningful data analysis (to show meaningful difference in outcome between groups) we need a sample size of 20 for each group. Recruiting more takes the high dropout/withdrawal rate expected and seen in previous studies, into account.

* 1. **Number of centres**

This is a single site study and all research and recruitment will take place Royal North Shore Hospital.

* 1. **Expected Duration of Study**

This study will commence as soon as ethics approval has been established and is expected to run for a duration of 5 years. This first treatment study will launch Ms Kwiet’s formal research training with an MPhil that will be a qualifying year for a PhD. Ms Kwiet’s first fellowship year will allow time to set up and substantially execute this first study. The latter years of the PhD would allow these results to be completed and reviewed, analyse cohorts from the Psychosocial Database and then to develop further research focused in this area of psychosocial recovery from Burns.

* 1. **Primary and Secondary Outcome Measures**

Screening for symptoms and coping still will identify at risk patients and interventions can then be targeted at those most in need ([26](#_ENREF_26)). This could allow for more effective and targeted mental health interventions in an acute care clinical setting ([37](#_ENREF_37)). Interventions that reduce post traumatic symptoms early in the recovery are likely to enhance patients' outcomes, resilience and coping. Effective early intervention may prevent the development of chronic pathology, potentially reduce length of hospital admission and re admission and positively influence rehabilitation in terms of return to work and social reintegration and adjustment. This would not only have a positive impact on patients' health outcomes but likely to be resource and cost effective for the health system and wider community in the long run.

* 1. **Research Tools and Measures**

The screening study will administer questionnaires that have been trialled in the Adjustment to Burns Pilot study (2009-2014). These will included measures of depression, anxiety and stress (DASS)([38](#_ENREF_38)) and measures of coping strategies (COPE)([39](#_ENREF_39)) and the ways people use social relationships to manage stress and trauma (DS-16, Relationships Questionnaire [RQ] and the ABCD-SRR). This set of coping and relationships measures are those that have yielded high correlations with the DASS and with posttraumatic symptoms measures ([8](#_ENREF_8)). To these we will add the Impact of Events Scale- Revised (IES-R)([31](#_ENREF_31)) to measure post-traumatic symptoms as this will give international comparisons for the symptoms and for treatment studies such as the Randomized Control Trial we describe below. We will also add a measure of Alcohol use (AUDIT)([40](#_ENREF_40))as many patients use alcohol to manage stress. We will also ask all participants about levels of pain. We will repeat the questionnaires at 3-monthly intervals in the first year and then yearly until 5 years post injury. This data will be combined with the clinical screening data as to current mental health diagnoses and psychosocial risk from the Consultation-Liaison Psychiatry Teams screening. We also will add a quality of life measure, The Burn Specific Health Scale-Brief (BSHS-B)([41](#_ENREF_41)) to measure quality of life post burn at one year and check it yearly to tap overall functioning and recovery.

**The routine psychosocial screening study:**

1. *Demographic and medical details:* A questionnaire that updates demographic details, records pain levels, drug and alcohol use and current health care utilisation.
2. *Mental health disorders screening form:* The Consultation –Liaison psychiatry team screens burns patients and this information on current absence/presence and type of mental health disorder is recorded
3. *COPE (*[*39*](#_ENREF_39)*):*a valid and reliable self-report questionnaire measure of coping style. As coping style impacts on recovery from burns([42](#_ENREF_42)) and avoidant strategies markedly impact on recovery([5](#_ENREF_5)),we wish to track this and other coping strategies that may impact on the recovery of our cohort.
4. *DS-16:* A self-report questionnaire that identifies a type of personality style with high negative affect and reduced use of social coping. This is included for the recognition of an at risk group, suggested in our recent work.
5. *Relationships Questionnaire (RQ):* This questionnaire describes how patients feel in close relationships and predicts aspects of psychosocial symptoms as confirmed in our recent work.
6. *ABCDSelf Report, revised (ABCD-SRR):* A short self-report scale that identifies an adult’s attachment style hat predicts aspects of outcome and can help formulate treatment. It was revised to be shortened on the basis of results from the group’s Adjustment to Burns study.
7. *The Depression Anxiety and Stress Schedule (DASS) (31):* a valid and reliable self-report measure for symptoms of depression, anxiety and stress. As depression is often a sequel of trauma and post-traumatic symptoms, we wish to track these symptoms in our cohort as well as anxiety and a measure of subjective stress.
8. *Impact of Event Scale (IES):* This 15-item widely used self-report questionnaire is a reliable measure of subjective posttraumatic stress to a traumatic or stressful life event ([31](#_ENREF_31)).
9. *Measure of Alcohol use (AUDIT) (*[*40*](#_ENREF_40)*)*

**The intervention study:**

To the above measures the intervention study will add:

1. *PTSD Checklist-Civilian (PCL-C):* This is a validated and reliable screen for post-traumatic symptoms ([35](#_ENREF_35)). It is included here to gauge its correlation with the IES and CAPS as a future screening tool in this population. For military personnel injured as a result of their position, the related *PTSD Checklist-Military (PCL-M)* will be used.

*2. The DES: Used to identify levels of dissociation(*[*32*](#_ENREF_32)*).*

3. *Burns Modified Adult Attachment Interview (BM-AAI)(*[*33*](#_ENREF_33)*):* is modified from the Adult Attachment Interview ([42](#_ENREF_42)) which is a gold standard for assessing unresolved loss and trauma and attachment state of mind. This modification has been trialled in the recent work of the Burns Psychosocial Research Group and has been found by the group to be an empathic and effective way of gathering sensitive data on chronic and complex trauma, necessary to establish the relevant exclusion of chronic complex trauma patients who require more long-term trauma treatments.

4. *CAPS (Clinician-Administered PTSD Scale):* a semi-structured interview that is the gold standard for assessing PTSD symptoms and the presence of PTSD([34](#_ENREF_34)).

5. The Burn Specific Health Scale-Brief (BSHS-B): measures quality of life post burns (41).

6. A semi structured interview on burns recovery and rehabilitation that will be analysed using thematic analysis.

* 1. **Qualitative component**

The qualitative component of this study will utilise a qualitative research method, utilising an interpretive paradigm to facilitate critical reflection within a phenomenological methodological framework. A phenomenological methodology appreciates a holistic view of the experience and for the individual to intuit and reflect on these experiences ([43](#_ENREF_43)). The goal of phenomenology is to gain a deep understanding of the participants’ experiences, with its central focus being the ‘lived experience’ of the world within everyday life ([44](#_ENREF_44), [45](#_ENREF_45)). Phenomenology is the investigation of meanings rather than an empirical investigation of occurrences or events; therefore a phenomenological methodology is recommended to capture and reveal how people experience the world in which they live ([46](#_ENREF_46)). Phenomenological research has the ability to clarify and enlighten phenomena that provide descriptions that are rich in detail and reveal meanings entrenched in the circumstances, as opposed to making inferences or identifying causality ([43](#_ENREF_43)).

As a methodological framework, phenomenology allows the researcher to investigate the ‘lived experience’ that are present in the everyday world. Phenomenology addresses the questions - what is it like, how does it feel and what was the experience, enabling a rich description and understanding of the participants’ experiences. Unlike positivism in which the intention is to hypothesise and find causality, a phenomenological methodology utilises language to reflect the meaning implanted in the ‘lived experience’([47](#_ENREF_47)).Walton and Madjar ([48](#_ENREF_48)) stated that phenomenological research challenges nurses to question further and provides the framework to do so.

A descriptive (Husserlian) research methodological approach will be adopted involving “direct exploration, analysis and description of particular phenomena, as free as possible from unexamined presuppositions, aiming at maximum intuitive presentation” ([49](#_ENREF_49)). An essential component of Husserlian phenomenology, is for the researcher to discard all prior personal knowledge, biases and beliefs in order to grasp the essence of the ‘lived experience’ being studied([50](#_ENREF_50)).Husserl’s phenomenology is of an epistemological nature, which “is concerned with asking questions of knowledge about objects gained through conscious awareness” ([43](#_ENREF_43)). Husserl’s philosophical ideals gave rise to descriptive phenomenology as a research approach and played a part in the departure from a positivistic approach bringing inspiration to the methodology of social science ([51](#_ENREF_51)). Husserl was concerned with the essence of consciousness emphasising the description of a person’s ‘lived experience’ that is free of interpretation, believing that consciousness was the path to the material world in which all knowledge was a result of experience ([44](#_ENREF_44)). Husserl’s approach aims to bring understanding to phenomena in everyday life, with the investigation of people’s experiences ([52](#_ENREF_52)) utilising a rigorous scientific methodology in order to answer questions related to “how do we know it?” ([53](#_ENREF_53)). Husserl proposed that the truth can be found in the study of human experience that attributed to the meanings which humans assign to their existence, and this is the essence of living ([54](#_ENREF_54)).

*Data collection:* Interview is the core method of data collection within phenomenology ([45](#_ENREF_45)). A semi structured face-to-face interview method utilizing open-ended questions has been selected for this study allowing for a greater scope in the response provided by participants. The benefits of a semi-structured interview are that the researcher can prompt and investigate at a deeper level the participant’s ‘lived experience’. Open-ended questions are one of the most frequently used tools for data collection in qualitative research ([45](#_ENREF_45)) as this allows participants freedom to control the interview in relation to issues discussed and completely describe their experience. Therefore, the interviewer does not have to adhere to a ridged in interview guide.Moyle ([55](#_ENREF_55)) suggests that by not restricting the participant’s response, rich data are gained.

Interviews will be undertaken face to face, will be digitally recorded and last approximately 45 minutes. The interview will be conducted in a place and time suitable to both the participant and the researcher. The interview will begin by obtaining a detailed description of the participants’ ‘lived experience’ of rehabilitation following a severe burn injury. During the interview process the researcher will prompt the participant to facilitate a richer, fuller account and to explore a particular point in more detail (see Appendix 6). The interview will draw to a close when information becomes repetitive and no new information is forthcoming ([56](#_ENREF_56)). The recorded interviews will be transcribed with the services of a professional research transcription service. The participants’ names and any other potentially identifiable information will not be contained in the digital audio files in order to maintain anonymity and privacy. It may be necessary to clarify or verify information gained during the initial interview. If so, the participants will be contacted again by either phone or email to clarify or validate any information contained within the transcripts. Permission will be sought from participants to contact them again if clarification is required.

*Rigor:* The need for rigor in qualitative research is critical for the credibility, trustworthiness and validity of the information ([45](#_ENREF_45), [53](#_ENREF_53)). Prior to the commencement of this study, the researcher’s beliefs relating to severe burn injury patientsexperiences of rehabilitationwill be listed and reflected upon. This is known as phenomenological reduction or bracketing. The Husserlian technique of bracketing to ensure rigor, identifies and articulates assumptions prior to the data collection and analysis process ([57](#_ENREF_57)). Phenomenological reduction is a key epistemological approach of phenomenology ([58](#_ENREF_58)). It is the suspension of beliefs, assumptions, preconceptions and biases related to the phenomenon that is under investigation, in which the phenomenon can be seen with a fresh approach ([45](#_ENREF_45)). The aim of phenomenological reduction (bracketing) is to isolate the pure phenomenon from what the researcher already knows about the phenomenon. Phenomenological reduction is achieved through bracketing the suspension of judgment. This is a fundamental concept to Husserlian philosophy, which ensures a trustworthy description of the phenomenon ([47](#_ENREF_47)).In order to ensure the credibility of this study, an audit trail of decisions taken throughout the data collection and analysis process will be maintained. Wolf ([59](#_ENREF_59)) states that “the audit trail helps to establish the credibility of qualitative studies and serves to convince the scientific community of their rigor”.

# STUDY TREATMENTS

* 1. **Treatment Arms**

There will initially be two ‘treatment groups’ (Intervention/EMDR and control/optimised standard care group). The treatments will take place on a weekly basis over 3 weeks, with some flexibility given the demands of the medically complex acute care setting. Patients in the control group who remain symptomatic will be offered the EMDR intervention after 3 months. This ‘cross over group’ will be in treatment for a further 3 weeks. So while most patients will be in treatment for 3 weeks, the cross over group will be in treatment for 6 weeks.

* 1. **Description of the Intervention/Treatment**

An explanation of both the EMDR and supportive counselling will be provided at the time of obtaining informed consent. This involves describing the nature of treatments to patients as well as giving a brief demonstration of the bilateral eye stimulation along with a disclaimer that “the intervention may or may not help the distress”.

**Table 3: Intervention table for cases, controls and non-participants of the Treatment Phase (P2)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Timeframe** | **Cases/EMDR group** | **Controls/optimised****Standard care group** | **Non participants/ standard care** |
| **2-4 weeks** | 1. Psychiatric and Social work assessment2. Consent3. Questionnaires:Impact of Event Scale-Revised (IES-R) COPE DS-16 Relationship Questionnaire (RQ)ABCD-Self Report, revised (ABSD-SRR)The Depression Anxiety & Stress Schedule (DASS) Measure of Alcohol use | 1. Psychiatric and Social work assessment2. Consent3. Questionnaires:Impact of Event Scale-Revised (IES-R) COPE DS-16 Relationship Questionnaire (RQ)ABCD-Self Report, revised (ABSD-SRR)The Depression Anxiety & Stress Schedule (DASS) Measure of Alcohol use3. Assessment:Burns Modified Adult Attachment Interview (BM-AAI)DES | 1. Psychiatric and Social work assessment |
| **Session 1** | 1. Targeted/specific trauma processing involving bilateral eye movement2. IES-R before and after each session | structured/optimised version of standard care i.e. counselling2. IES-R before and after each session | As determined by patient need and clinicians’ availability |
| **Session 2** | Targeted/specific trauma processing involving bilateral eye movement2. IES-R before and after each session | structured/optimised version of standard care i.e. counselling2. IES-R before and after each session | As determined by patient need and clinicians’ availability |
| **Session 3** | Targeted/specific trauma processing involving bilateral eye movement2. IES-R before and after each session | structured/optimised version of standard care i.e. counselling2. IES-R before and after each session | As determined by patient need and clinicians’ availability |
| **3 months post injury** | Questionnaires CAPS Interview | Questionnaires CAPS Interview | As per assessment and patient request |
| **6 months post injury** | Questionnaires Semi structured interview | Questionnaires Semi structured interview |  |
| **9 months post injury** | Questionnaires  | Questionnaires  | As indicated |
| **12 months post injury** | QuestionnairesBSHS-B | QuestionnairesBSHS-B | As indicated |
| **Annually for 5 years** | Questionnaires | Questionnaires | As indicated |

**Table 4: EMDR/A-TIP Intervention**

The Acute –Traumatic Incident Procedure (A-TIP)([36](#_ENREF_36)) is a simplified version of the Recent-Traumatic Events Protocol (R-TEP), which was modified from the standard eight phase EMDR protocol for early intervention following traumatic exposure ([13](#_ENREF_13)). It consists of 3 one hour sessions.

*Session One: Introduction & Stabilisation*

1. The A-TIP is administered within 3 sessions and ‘processing’ is confined to the recent event. These limitations are explained clearly and form part of the therapeutic contract before work commences.
2. The patient is asked to give a brief chronological narrative of the whole traumatic experience and then asked to rate their level of disturbance, which is referred to as SUD (subjective units of distress: 0 is no disturbance and 10 is maximum disturbance). The patient’s negative cognition associated with the event as well as their positive/adaptive belief is elicited and both are rated using the VoC scale (validity of cognition: 1 being totally false and 7 being totally true).
3. Patients are taught some basic relaxation and self-soothing strategies, to assure safety and containment as well as to adequately assess patients’ readiness for processing. Patients must have the ability to both tolerate their disturbance and regulate their responses. If this is not the case, more stabilisation work may need to be done before bilateral stimulation is introduced. Safe/calm place, container and breathing exercises will be used for this. These are evidence based exercises used to help patients feel or regain a sense of safety and reduce arousal and anxiety.
4. Patients are then asked to ‘walk through’ the story with continuous BLS (bilateral stimulation). This involves patients talking about their traumatic experience from beginning to end while having the bilateral eye stimulation.
5. Debrief & closure. Options for next session are discussed and if necessary affect management skills for stabilisation are revised.

*Session Two: Processing the disturbance*

1. The ‘worst part of the incident’ is assessed, including image that represents the event, sensory component, negative and positive belief, VoC: 1-7, emotions, SUD (0-10) and body location of disturbance. This is then processed using BLS until SUD are as low as possible. This is followed by the installation of the positive belief until the VoC is as high as possible. This is repeated for other disturbing aspects/fragments of the trauma, either in chronological or by level of disturbance.
2. Debrief and closure. Affect management skills if required.

*Session Three: Reevaluation& Future Action Planning*

1. Patients are re-evaluated, both globally, in terms of any changes, dreams, startle responses and triggers that may have arisen, and specifically in terms of the previous ‘targets’ processed. Any new or remaining disturbances are processed as in session two.
2. Patients are asked to imagine potential future aspects similar to the traumatic event and asked to hold their positive belief with that situation. The VoC is checked and then BLS is applied until the VoC moves to an adaptive level.
3. Exit interview and closure

**Table 5: Supportive Counselling Intervention:**

*Session One:*

1. Explanation of 3 session contact for supportive counselling.
2. Provide psycho-education re PTS and normal trauma reactions/what to expect
3. Explore patients concerns, coping and social supports.
4. Patients are taught some basic relaxation and self-soothing strategies, to help them manage their current post traumatic symptoms, assure safety and containment. Safe/calm place, container and breathing exercises will be used for this.

*Session Two:*

1. Exploration of patients’ ongoing concerns, allowing patients to reflect on how they have coped and made meaning of traumatic experiences.
2. More affect/stress management skills as required.

*Session Three:*

1. Exploration of patients’ ongoing concerns, allowing patients to reflect on how they have coped and made meaning of traumatic experiences.
2. More affect/stress management skills as required.
3. Debrief and closure: Participants, who remain symptomatic, will be offered the 3 sessions of EMDR. This will be explained as part of the debriefing and closure and arrangements for recruitment into the cross over group made if indicated.

**Timing of Intervention**

It is important to state that initial acute stress symptoms should be viewed as normal reactions to an overwhelming experience. These immediate responses will not be pathologised, but viewed as potentially adaptive attempts to restore equilibrium after traumatic exposure (11). Both types of intervention will only be offered when distress, via complaints or symptoms have not decreased to below moderate levels within 2-4 weeks of traumatic exposure. Research nevertheless suggests that high levels of PTS symptoms experienced at 2 weeks correlate with PTSD and this was found to be the most reliable predictor for PTSD (32). Due to the physical impediments to screening and psychological resolution in burns care, such as intense early (and traumatic) treatment and ICU admissions for many, this window for early treatment is extended to cover the 2-4 week window between the event and the time for diagnosis of PTSD at one month post injury. Interventions have been time sensitive in the small number of studies to date and time from injury will be closely monitored as a covariate.

# PARTICIPANTENROLMENT AND RANDOMISATION

* 1. **Recruitment**

Initially contact will be made through a ward nurse, Social Worker or Psychiatry trainees affiliated with the Burns Unit. These staff members will ask potential participants if they are interested in potentially participating in this project. Researchers will then provide potential participants who have indicated an interest with further information about what is involved. An information sheet will be provided to all potential participants and time spent to answer any questions people may have prior to giving consent so that an informed decision can be made. There will be no initial coercive influence from clinicians as researchers on identifying potential participants and no other aspect of treatment will be affected by refusal/agreement to participate. However routine C-L screening is already in place for clinical care.

All burn patients admitted to the SBIU will be asked to participate in the optimized screening and follow up phase of this study. Potential participants, identified as patients with high posttraumatic symptom scores (IES-R ≥ 26) will then be considered for participation in phase 2 of this study.

It is planned that intervention will start during or after week 2-4 in order to allow for natural recovery, but still within a time frame where chronicity might be avoided. Patients’ consent to participate in this study will be obtained after the nature of both possible interventions is explained and a disclaimer that “the intervention may or may not help the distress” is provided.

* 1. **Eligibility Criteria**
	2. **Inclusion Criteria**

All burns patients admitted to the SBIU will be eligible to participate in the first (screening) phase of this study. Of these patients, those with moderate to high levels of uncomplicated post-traumatic stress symptoms at 2-4 weeks post injury will be offered participation in the second/treatment phase of this study. Moderate to high levels of post-traumatic stress symptoms will be defined as an Impact of Event Scale Revised (IES-R) score ≥ 26. Patients with known psychiatric disorders other than previous PTSD or chronic complex trauma, schizophrenia, and previous substance abuse histories, and suicidal ideation may still be included, provided they have been screened by C-L psychiatry, assessed for dissociation and subsequently deemed safe and appropriate participants. Patients with self-inflicted burn injuries will not meet inclusion criteria. The window within which posttraumatic symptoms might begin to settle with natural coping is 2-4 weeks post injury. The aim is to tap participants who may not be settling within that time frame, but to study a group with some variability, not simply those who have an established PTSD diagnosis at 4 weeks post event.

A severe burn injury is defined as any burn injury requiring admission to a Severe Burn Injury Unit. Transfer criteria for admission to a burns unit in NSW are consistent with those of the Australian and New Zealand Burn Association (ANZBA) and the International Society for Burns Injuries (ISBI)([60](#_ENREF_60)).

Definition and medical retrieval of a severe burn injury is as follows:

* any intubated patient
* inhalation injuries with cutaneous burns
* head and neck burns
* hand, face or genital burns
* mid-dermal, deep dermal or full thickness burns >20%
* burns with significant co-morbidities
* associated trauma
* circumferential burn to limbs or chest that compromises circulation or respiration
* electrical condition injury with cutaneous burns
* chemical injury with cutaneous burns
* any burn involving hands, face or genital area
* all electrical and chemical burn injuries
	1. **Exclusion Criteria**
1. Patients younger than 18 years of age.
2. Medical or psychiatric issue that impairs the ability of the participant to give informed consent.
3. Patients with high levels of dissociation (DES score >40)
4. Patients suffering from acute grief reactions
5. Patients at risk of self-harm who cannot assure their safety.
6. Patients who remain in an unsafe environment/current abusive relationship.
7. Patients with complex chronic trauma histories that are unresolved (discernible signs of ongoing traumatic disorganization of reasoning, discourse and behaviour)
8. Patients that are required to give evidence or statements to the police or in a court of law.
9. Patients with self-inflicted burns

Patients younger than 18 years of age and those with issues that impair the ability to give informed consent will be excluded as their capacity for informed consent will be affected.

Patients with current and ongoing severe substance abuse, high levels of dissociation (DES score >40), those suffering from an acute grief reaction as well as patients with complex chronic trauma histories that are unresolved (discernible signs of ongoing traumatic disorganization of reasoning, discourse and behaviour) will also be excluded as this would require longer term support and stabilisation before being able to address the current (burn related) trauma safely.

Also patients at risk of self-harm who cannot assure their safety, those who remain in an unsafe environment/current abusive relationship and patients with a previous PTSD diagnosis will be excluded as these are contraindications for early EMDR intervention(14, 17, 18, ).

The Consultation-Liaison Psychiatry Team routinely screens Burns patients and will identify those with many of the above exclusions based on their routine bedside testing as necessary (Mental State Examination; Mini-Mental State Examination; Addenbrooks). Only patients cleared by the C-L Psychiatry team will undergo the further screening of a DES, BMAAI and CAPS which will determine the exclusions of high levels of dissociation, chronic complex trauma and prior PTSD which are exclusions particular to the this EMDR intervention.

* 1. **Informed Consent Process**

Only patients that have capacity to give informed consent to their medical treatment will be recruited into this research study. Assessment of this by the burns team and the from the Consultation-Liaison Psychiatry Team will include bedside assessments that current pain levels or trauma are not affecting patients’ cognition and decision making capacity. This is routinely ascertained on the SBIU via assessment and bedside testing (Mental State Examination; Mini-Mental State Examination; Addenbrooks). Again clearance by the C-L team will be required for offers to participate in the intervention study.

Patients will be given the relevant Patient Information Consent Form (PICF) to read (one for the screening study and then another for the intervention study) and given the opportunity to ask questions about any aspects of the studies. Patients are encouraged to talk with family and friends before deciding on whether to participate.

* 1. **Enrolment and Randomisation Procedures**

The participant will be enrolled into the study after the informed written consent process has been completed and the participant has met all inclusion criteria and none of the exclusion criteria. The participant will receive a study enrolment number and this will be documented in the participant’s medical record and on all study documents. Ms Kwiet will allocate patient study numbers but Dr McLean will be responsible for randomization from a random numbers protocol.

* 1. **Subject Withdrawal**
	2. **Reasons for withdrawal**

It is expected that some patients will withdraw and this is reflected in our initial sample size for phase 2 of this study. The reasons for withdrawing will be asked and included in the analysis. However, participants will be able to withdraw from the study at any time without giving a reason. Also the numbers of withdrawals from both groups and reasons stated will be compared and could be significant to the research.

* 1. **Handling of withdrawals and losses to follow-up**

The initial data of participants who withdraw will be kept and included in analysis. For phase 2 this is not anticipated to be problematic as long as sample size does not fall below 20 per group. Analyses will include an Intention to Treat Analysis. Participants from the control group who remain symptomatic will be offered the EMDR treatment after 3 months. This will not affect sample size, as immediate post treatment comparison and formal PTSD assessment at 3 months will be used for analysis.

Research shows that attrition rate for PTSD is high and this has been taken into account in the sample size calculation and is the reason for initial over recruiting by 100%.

* 1. **Replacements**

If group size was to fall below 20, then participants would have to be replaced (recruited to keep minimum sample size of 20 per group) to allow for meaningful statistical analysis. In this case, data would be analysed in stages to withhold the data of replaced participants and then included to compare both treatment completion and analyse on an Intention to treat basis. These results would be compared in the discussion of results.

* 1. **Trial Closure**

While the screening and outcome tracking phase of this study is over a period of 5 years, the treatment phase is only for 3 – 6 weeks with follow-up of up to 18 months. During this time any adverse events or where there is a concern about a patient’s safety, referral to C-L Psychiatry will be made for assessment and community follow up. Participants found to have or be at risk of developing mental health disorders, both during or at the end of this trial will also be referred to their local GP, as part of best practice and to ensure appropriate care.

The functioning and utility of the database will be reviewed and it is likely that we would seek to continue its operation as a function of normal burn injury care but with an opportunity to review and reduce the questionnaire protocol and the potential to seek external funding.

# STUDY VISITS AND PROCEDURES SCHEDULE

## Study Flow Chart

|  |
| --- |
| Part 1 - **Screening** all burns patients admitted to SBIU, RNSH Part 2 – Intervention RCT Study of suitable patients with PTS (IES ≥ 26)**Randomisation**  Control Group: Standard Care Interventional Group: EMDR **Treatment Phase:** 3 or 6 weeks, depending on cross over**Follow up phase:** 3 monthly in first year and annually for 5 years after |

# ADVERSE EVENT REPORTING

* 1. **Definitions**

**Adverse event**

Reported side effects from EMDR include feelings of marked distress during processing of traumatic memories, dissociation (especially in those with prior risk) and changes in recall of a particular event or image([61](#_ENREF_61)). This study aims to screen out those with prior risk, as this is considered best practice for safe use of EMDR([61](#_ENREF_61), [62](#_ENREF_62)).

During EMDR, traumatic memories are targeted for ‘processing’, with the aim of ‘resolving’ the traumatic material. Accessing these memories involves ’triggering’ or bringing up the related disturbances/feelings/sensations([62](#_ENREF_62)). This can cause the patient to feel some distress. It is important to note here that the EMDR is not ‘causing’ the distress, it is merely bringing it to awareness so that it can be processed. The actual traumatic memory may or may not be altered: sometimes patients are no longer able to recall a memory or picture at all and sometimes there is no change. This may have significant legal implications where participants are required to give evidence in a court of law or other legal proceedings. This has been attended to in the exclusion criteria. There is also a chance that EMDR may uncover memories of an event that had been forgotten or repressed. If this results in distress or disturbance the participant will be referred to Consultation-Liaison Psychiatry for assessment and follow up. Supportive counselling from the Social Work Department will also be available for participants in these cases.

Possible side effects can occur just the once or more frequently. They can occur immediately or within days of the treatment, as processing can continue beyond the session. For these reasons, participants will be closely monitored and given the opportunity to contact members of the research team if needed.

Any research can diagnose previously unrecognised conditions and this may affect insurance in the future. This will be explained to all participants. 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.

Studies have demonstrated EMDR to be safe and effective and the severity and likelihood of these adverse reactions occurring are low. Further, these adverse experiences can be minimised by careful screening and assessment of participants as well as addressing participants safety at all times.

# STATISTICAL METHODS

* 1. **Sample Size Estimation**

The SBIU sees over 200 patients a year and with most studies showing a prevalence of 20-25% of PTSD, and local unpublished data showing elevated PTS (McLean et al, unpublished data, 2014),we anticipate sufficient numbers especially as this project will treat those with significant symptoms rather than simply a formal PTSD diagnosis. If recruitment is unexpectedly slow the project will still continue to recruitment and treatment completion as it is the basis of the first part of Ms Kwiet’s part-time MPhil/PhD.

* 1. **Population to be analysed**

Adult burns patients admitted to the SBIU at RNSH are the target populations to be analysed.

* 1. **Statistical Analysis Plan**

**For the screening study**

We will aim to analyse data cohorts over time looking at predictors of post-traumatic symptoms, depression, anxiety and quality of life parameters, using regression and logistic regression models and MANCOVA models. We aim to recruit the majority of SBIU patients and follow them longitudinally, accruing approximately 200 patients per year. Our small prior study with a sample size of around 50 was able to show strong correlations between personality, coping style, mental health diagnoses and early high PTS and depression scores([8](#_ENREF_8)). We anticipate the larger numbers and longitudinal follow-up will strengthen the data and allow logistic regression models that will have predictive value longitudinally from baseline and early recovery data.

**For the interventional study**

We will be conducting a repeated measures analysis of within-subject and between group differences between the initial EMDR and TAU groups.

The effect size of EMDR in general has been shown to be substantial in many studies with a moderate to strong effect found of a Cohen’s d of 0.7 or more for comparisons of pre-and post-treatment means, and comparable early intervention studies demonstrating an even stronger effect of d ≥≥1.0.([10](#_ENREF_10), [12](#_ENREF_12), [23](#_ENREF_23), [27](#_ENREF_27)). Allowing for a possible lower effect size in this medically unwell group of 1.0 >d >0.9 with power of 0.8 and significance set at an alpha of 0.05 (two-tailed) then the minimum sample size is 17-20 in each group for an independent samples t-test. Dependent testing usually yields a higher power, because the interconnection between data points of different measurements are kept and is relevant here in the repeated measures design. This suggests that even smaller samples with a lower effect size may be able to be analysed with sufficient power. (http://www.psychometrica.de/effect\_size.html#transform). We plan to over recruit to allow for dropouts and medical complications that might interfere with the protocol, aiming to recruit 40 subjects in each arm of the intervention study, but planning for an early analysis at n=20. Larger numbers will support the sub-analysis with the crossover group, and some analysis of covariates. These kinds of smaller numbers aimed for in the early analysis have yielded results in pilot studies comparing a specific treatment with supportive therapy, for example 14 patients given Interpersonal therapy versus 12 patients given brief supportive psychotherapy ([63](#_ENREF_63)). All data will be screened for outliers, spurious and missing data and normality. The need for replacement of missing data will be considered. Repeated measures data sets offer more options for strategies such as auto regression to deal with missing data. However conservative analyses will be prioritised.

Analysis will proceed via a repeated measures M/ANCOVA models examining pre- and post-treatment differences both within subjects and between groups, subject to normal conditions for this testing being satisfied. All analyses will be conducted on the relevant SPPS software with significance testing set at an alpha level of 0.05 and two-tailed testing. The major independent variable is the type of treatment and the major dependent variable will be the posttraumatic symptoms as measured by the IES score. A secondary independent variable will be the delayed administration of EMDR in the crossover group. Relevant covariates will include: TBSA, site of burn, gender, age and time elapsed from burn to initial treatment and, for the analysis with the crossover group, time elapsed from burn until EMDR treatment. Models with follow-up outcomes will also be examined. Secondary dependent variables will be the prevalence of PTSD and the prevalence and severity of depressive and anxiety symptoms. Logistic regression will also be used to identify risk factors for at risk subgroups (such as PTSD or major depression on post-treatment measures) as the local study has found that certain factors (including Type D personality and insecure attachment style) have strongly predicted high PTS scores (McLean et al, unpublished data, 2014). Ms Kwiet will be supported and guided in this task of analysis in order to ground her statistical skills in practice by A/Prof McLean who is familiar with multivariate repeated measures analyses.

# DATA MANAGEMENT

* 1. **Data Collection**

Data will be collected by both questionnaires and interviews. The questionnaire data will be numbered with the patient’s study number to de-identify the data. Ms Kwiet will be the primary researcher involved in collection of the questionnaire data. Interview data will be recorded on sheets where relevant (eg Mental Health Diagnoses by the CL Psychiatry team). Some interviews will be recorded on portable digital recording devices, either laptop or i-Pad that will be password protected.

* 1. **Data Storage**

The original questionnaires collected will be stored as a paper copy in a locked filing cabinet in a limited access area in the Social Work Department in Ms Kwiet’s designated office. Should this space provision change, the SBIU has an office dedicated to the Psychosocial support team of Social Work and C-L Psychiatry and the paper copies can be stored there in locked filing cabinets.

The screening information obtained by questionnaire will be entered in the de-identified computerised psychosocial database by allocated subject number, although a master sheet will be kept in a separate file to allow re-identification if necessary for safety reasons. RCT study information will be handled similarly but entered into a separate data base.

All computer files will be password protected. Data will be backed up to 2 external hard drives, one each to be in the custody of A/Prof McLean and Ms Kwiet respectively and each pass-word protected to ensure that the database is not lost to file corruption or local hazards such as fire. Only the research team will handle the database and will monitor the accuracy of data with regular random checking of entries at data review meetings.

The related interview and session audio files will be stored on computer hard drive according to the study subject number and password protected. Where relevant for the qualitative subprojects the interviews will be transcribed confidentially, de-identified and stored under the study subject number in password protected computer files. These interviews will be retained for transcription as a subproject and this qualitative data will be available to A/Prof McLean, Dr Kornhaber and other researchers involved in the qualitative analysis.

* 1. **Study Record Retention**

The information obtained will be stored for a minimum of 15 years as per the NHMRC’s code for responsible conduct of research ([64](#_ENREF_64)).

# 11 ADMINISTRATIVE ASPECTS

* 1. **Confidentiality**

Data confidentiality will be maintained throughout this study in accordance with NSW Health policy pertaining to patient confidentiality and privacy laws. Personal Data will be stored in re-identifiable form and only members of the research team will have access to this.

Data collected will be securely retained in accordance with the Australian Code for the responsible conduct of Research([64](#_ENREF_64)), National Statement on Ethical conduct in Human Research.

The National Health and Medical Research Council (2007) state that “confidential information must only be used in ways agreed with those who provided it ([64](#_ENREF_64)). Participants’ anonymity will be strictly maintained. The information shared with the researcher will remain confidential; the researchers will be the only persons able to link the names of participants with the interviews. The digital recordings will be deleted on completion of the study in order to maintain anonymity. Participants’ names and any other potentially identifiable information will be removed from the research. To ensure anonymity, the participants’ identifiable information will be coded and stored on a separate password protected computer and deleted at the completion of this research. In the event that the research is to be published, no potentially identifying information will be contained within the research findings and the identity of the participants will not be released.

Data transcription:

The Audacity 1.3.11 (Beta) digital audio program (free, open source software for recording and editing sounds for Windows, Mac OS X and other operating systems) or the Pure Voice Recorder (i-pad) will be used to record interviews and thereafter transcribed into written form verbatim. Transcription of the data will be conducted by an external transcription agency specialising in qualitative research. This agency has no relationship with the study or the participants and the recordings will go to transcription with a study number and no external personal identification of the file.

* 1. **Independent HREC Approval**

NSLHD HREC

**11.3 Amendments to the protocol/project**

Any amendments to this protocol/project will be submitted to the relevant HREC.

**11.4 Protocol Deviations**

Any protocol deviations will be reported to the local HREC as well as the NSW Institute of Psychiatry.

**11.5 Participant Reimbursement**

Participants will not be reimbursed for any related expenses because they will meet with members of the research team when they are visiting RNSH for their clinic appointments and follow up. In cases of extreme hardship, the social work department may be able to assist with the cost of parking and transport, provided all other options have been explored.

**11.6 Financial Disclosure and Conflicts of Interest**

The NSW Institute of Psychiatry has provided Ms Julia Kwiet with a research fellowship worth $50.000. There is no conflict of interest declared.

# 12 USE OF DATA AND PUBLICATIONS POLICY

Results will be disseminated in scientific journals and other scientific media and presented at conferences and some of the results will form part of Ms Kwiet’s MPhil/PhD thesis submission. It is anticipated that the community of Burns survivors as well as the participants will be interested in the results and efforts will be made to reach these audiences and in this arena the use of digital media will be considered to support dissemination. It is also planned that the psychosocial database may have important information that may have a bearing on policy for provision of care and for funding and will be released where appropriate for this purpose. Publication policy has been discussed within the research team and will reflect the level of scholarly input into each project and the related background aspects of the project.

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