Protocol Title

A randomised, controlled trial of Eye Movement Desensitisation and Reprocessing via telehealth in Australian veterans with Posttraumatic Stress Disorder

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| **Protocol Number** | **2022/ETH00162** |
| **Coordinating Principal Investigator** | **David Graham** |
| **Signature:** | **Date:** |
|  |  |
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| **Protocol Version Number** | **1.0** |
| **Protocol Date** | **28/01/2022** |
| **Sponsor (if applicable)** |  |
| **Proprietary Notice (if applicable)** |  |

**Ethics Statement:**

The study will be conducted in accordance with the *National Statement on Ethical Conduct in Human Research* (2007) ([Link to National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)) , the *CPMP/ICH Note for Guidance on Good Clinical Practice* ([Link to CPMP/ICH](https://www.tga.gov.au/publication/note-guidance-good-clinical-practice-july-2000)) and consistent with the principles that have their origin in the Declaration of Helsinki. Compliance with these standards provides assurance that the rights, safety and well-being of trial participants are respected.

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| --- | --- |
| **Protocol Title** | A randomised, controlled trial of Eye Movement Desensitisation and Reprocessing via telehealth in Australian veterans with Posttraumatic Stress Disorder |
| **Protocol version** | 1.0 |
| **Objectives** | The primary objective of this RCT of Eye Movement Desensitisation and Reprocessing (EMDR) via telehealth in Australian veterans with Posttraumatic Stress Disorder (PTSD) is to:   1. Compare changes in PTSD symptom severity in veterans randomized to either EMDR delivered via telehealth or in person   The secondary objectives are to:   1. Compare changes in quality of life (QOL) in veterans randomized to either EMDR delivered via telehealth or in person; 2. Compare changes in functional disability in veterans randomized to either EMDR delivered via telehealth or in person; and 3. Compare adverse outcomes in veterans randomized to either EMDR delivered via telehealth or in person |
| **Study design** | Randomised, controlled trial delivered in two phases:   1. **Feasibility study**: a feasibility study will be conducted with at least twelve patients in order to demonstrate that EMDR can be delivered via telehealth and the data can be collected in accordance with the trial protocol, and to inform study size estimates for Phase B 2. **Randomised trial**: a randomised, controlled trial of patients undergoing treatment at the NCVH |
| **Planned sample size** | To be determined following an initial feasibility study of 12 patients |
| **Selection criteria** | 1. Attending the National Centre for Veterans’ Healthcare (NCVH) and considered suitable for EMDR; 2. Department of Veterans’ Affairs (DVA) accepted clinical diagnosis of PTSD, which have been confirmed by NCVH clinicians administering and trained in the Structured Clinical Interview for DSM 5 (SCID-5); 3. Age 18 years and older; 4. No prior treatment with EMDR; 5. No history of acquired brain injury from any cause; and 6. No active alcohol, benzodiazepine, or illicit substance use. |
| **Study Procedure** | Administer EMDR via telehealth or in person according to the standard EMDR protocol over a period of 8-12 weeks. |
| **Statistical considerations** | Sample size calculation will be determined based on the results of the initial feasibility study. Data will be analysed using the intention to treat principle by including patients who withdraw or exit from the study. For the purposes of statistical analysis, treatment will consist of a minimum of three sessions so that at least one active phase of treatment will be included. Kaplan-Meier event-free survival analysis curves using right-censoring will be used to analyse outcome measures. Categorical data will be compared using Fisher’s exact test and interval data will be compared using Mann-Whitney’s U test. Confounding variables will be controlled using appropriate statistical techniques. |
| **Time Period of Data Collection** | Veterans referred for EMDR over the period April 2022 – April 2024 will be offered inclusion in the study |
| **Duration of the Study** | Approximately two years, with an additional twelve month period to analyse data and prepare publications |
| **Funding (if applicable)** | N/A |
| **Sponsor (if applicable)** | N/A |

Protocol Version Control box

|  |  |  |
| --- | --- | --- |
| **Protocol**  **Version Number** | **Date** | **Summary of Changes** |
| 0.1 | 8/09/2021 | Initial draft |
| 0.2 | 29/09/2021 | Updated additional details in the study design, study variables, data collection, and anticipated burden to the NCVH. Further references added to support the selection of psychometric tools |
| 0.3 | 14/10/2021 | Updated with further clarity of overall protocol, and additional references to support background and exclusion criteria |
| 0.4 | 24/01/2021 | Re-formatted to meet HREC template requirements |
| 1.0 | 28/01/2021 | Updated with minor formatting changes and inclusion of appendices to finalise protocol for submission to HREC |

# 1. BACKGROUND AND INTRODUCTION

### 1.1. DISEASE/PROPOSED INTERVENTION BACKGROUND

Posttraumatic stress disorder (PTSD) is a syndrome of stress reactions that can develop after either direct or indirect exposure to a traumatic event. These reactions are categorised within four symptom clusters: intrusive symptoms (nightmares and flashbacks), avoidance symptoms, negative changes in thoughts and mood, and heightened arousal1. In addition, these symptoms must be present for at least one month and must cause psychological, social, or functional impairment. Despite the high prevalence of traumatic events2, the outcome is widely variable, and depends upon genetic factors, history of prior exposure, and physical injuries sustained at the time of the trauma.

The lifetime prevalence of PTSD varies between countries, but is seen in approximately 5-10% of the population3. Among serving Australian Defence Force (ADF) personnel, the 12 month prevalence of PTSD is 8.3%4. The recent “Mental Health and Wellbeing Transition Study” found that up to a half of transitioned ADF personnel[[1]](#footnote-1) have experienced a mental illness in the previous 12 months, and the lifetime prevalence of a mental illness is almost three quarters of transitioned ADF personnel5. With this in mind, it is not surprising that, among transitioned ADF personnel, the 12 month prevalence of PTSD is 17.7% and the lifetime prevalence of PTSD is 24.9%5.

There are a number of treatments available for PTSD, many of which involve an exposure component6. These include both psychological and pharmacological therapies, though there is limited evidence for the use of pharmacological treatment. Eye movement desensitisation and reprocessing (EMDR) and trauma-focused cognitive behavioural therapy (CBT) are both widely used and equally effective7. EMDR involves attention to the past, present, and future with a focus on disturbing memories and related events. Targeted memories are identified and the patient attends to those memories while simultaneously focusing on an external lateral stimulation, typically involving eye movements.

### 1.2. RATIONALE FOR PERFORMING THE STUDY

The COVID-19 pandemic has significantly altered the way in which mental health intervention has been delivered and telehealth has been rapidly implemented throughout Australia8. The increased demand in mental health services during the COVID-19 pandemic has conversely decreased the access to trauma-focused therapies, which has in turn increased the usage of application-based and online approaches to mental health9. Whereas there is an expanding range of telehealth technologies to support the management of mental illness, the results are mixed10. Despite the expanding evidence base of telehealth approaches to mental health, its role is ostensibly supportive of conventional mental health interventions11.

A number of companies have adapted EMDR to telehealth, but the evidence base remains limited. While there is a single observational trial of an unspecified form of self-directed online EMDR, there are currently no randomised, controlled trials12. However, from a clinical perspective at the National Centre for Veterans’ Healthcare (NCVH), the capacity to deliver EMDR via telehealth provides an opportunity to provide access to rural and remote patients, notwithstanding enabling preparedness for future pandemics. This trial will aim to investigate whether EMDR via telehealth is a safe and effective approach to treating PTSD among veterans.

# 2. HYPOTHESIS

This study will test the following null hypothesis in an outpatient setting with a nation-wide catchment:

*H0: the outcomes for veterans with PTSD undergoing EMDR via telehealth (intervention) are not inferior to the outcomes for veterans with PTSD undergoing in person EMDR (control).*

# 3. STUDY OBJECTIVES / AIMS

The research question of this study is: does delivering EMDR via telehealth to veterans with PTSD result in outcomes that are at least as good as delivering EMDR in person?

### 3.1. PRIMARY OBJECTIVES

The primary objective of the trial will be to compare changes in PTSD symptom severity in veterans randomized to either EMDR delivered via telehealth or in person.

### 3.2. SECONDARY OBJECTIVES

The secondary objectives of the trial will be to:

1. Compare changes in quality of life (QOL) in veterans randomized to either EMDR delivered via telehealth or in person;
2. Compare functional disability in veterans randomized to either EMDR delivered via telehealth or in person; and
3. Compare adverse outcomes in veterans randomized to either EMDR delivered via telehealth or in person.

# 4. STUDY DESIGN

### 4.1. DESIGN / STUDY TYPE

The trial will occur in two sequential phases.

1. **Feasibility study**: a feasibility study will be conducted with at least twelve patients in order to demonstrate that EMDR can be delivered via telehealth and the data can be collected in accordance with the trial protocol. In the absence of any literature on efficacy of EMDR delivered via telehealth, this phase will also allow an estimate of efficacy to inform study size estimates for Phase B.
2. **Randomised trial**: the randomised trial will be a randomised, controlled trial of patients undergoing treatment at the NCVH.

The randomised trial will consist of two intervention groups:

1. **Control group**: patients undergoing face to face EMDR.
2. **Telehealth** **group**: patients undergoing EMDR using remotEMDR, a commercial online platform that was developed using the standard EMDR protocol and provides HIPAA-compliant[[2]](#footnote-2) video link with therapist-controlled bilateral stimuli that can be delivered in visual, auditory, or tactile modalities.

The referring clinician will remain blinded to the allocation and will review the patient response to treatment on a fortnightly basis during treatment with EMDR. Fortnightly clinician reviews will be conducted in accordance with standard NCVH practice.

### 4.2. EXPECTED PARTICIPANT NUMBERS

A minimum of twelve participants will be required in the feasibility study and the randomised trial order to ensure adequate estimation of the regression variables13. Owing to the limited evidence base of EMDR via telehealth12, an estimate of study size will be determined after the feasibility study (Phase A) in order to ensure the study is adequately powered.

### 4.3. TIME PERIOD OF THE STUDY

The study will proceed over an approximately two year period, with an additional period of twelve months to analyse data and prepare publications. Typically, the NCVH commences EMDR with at least two to three patients per month. This will allow the feasibility study to be completed in approximately six to eight months; these patients will not be included in the randomised trial. A further 18 months will enable recruitment of up to approximately 40 participants.

The study time period is shown in Table 1 below.

**Table 1**. Study time period

|  |  |  |
| --- | --- | --- |
| **Task** | **Start Date** | **End Date** |
| **Ethics Submission** | Early January 2022 | End January 2022 |
| **Ethics Review and Approval** | Early February 2022 | End February 2022 |
| **Advertising** | March 2022 | March 2024 |
| **Recruitment** | March 2022 | March 2024 |
| **Conduction of EMDR interventions** | April 2022 | April 2024 |
| **Collection of data** | April 2022 | June 2024 |
| **Analysis of Feasibility Study data** | October 2022 | November 2022 |
| **Analysis of Randomised Trial data** | July 2024 | August 2024 |
| **Preparation of Feasibility Study report** | November 2023 | January 2024 |
| **Preparation of Randomised Trial report** | August 2024 | October 2024 |
| **Publication Draft for Feasibility Study** | January 2024 | March 2024 |
| **Publication Draft for Randomised Trial** | October 2024 | January 2025 |
| **Submission of Publications and Final Reports for Feasibility Study** | April 2024 | May 2024 |
| **Submission of Publications and Final Reports for** | January 2025 | February 2025 |

### 4.4. ENDPOINTS

The main result of the trial will be a non-inferiority finding in PTSD symptom severity in veterans who were randomized to EMDR delivered via telehealth in comparison with PTSD symptoms severity in veterans who were randomized to EMDR in person.

PRIMARY ENDPOINTS

The primary endpoint of the trial will be PTSD symptom severity in veterans who have undergone EMDR delivered via telehealth will not be significantly less than PTSD symptom severity in veterans who have undergone EMDR delivered in person. This will be assessed once sufficient numbers of participants have been enrolled to ensure the trial is adequately powered based on the estimates from the feasibility study.

SECONDARY ENDPOINTS

Secondary endpoints of the trial will be:

1. QOL in veterans who have undergone EMDR delivered via telehealth will not be statistically significantly less than the QOL in veterans who have undergone EMDR in person; and
2. Functional disability in veterans who have undergone EMDR delivered via telehealth will not be statistically significantly less than the functional disability in veterans who have undergone EMDR in person.

### 4.5. CENTRES

|  |  |
| --- | --- |
| **Site Name** | National Centre for Veterans’ Healthcare, CRGH |
| **Site Contact/Investigator** | Dr David Graham |
| **Study Procedures** | Recruitment, delivery of EMDR, data collection, data storage, data analysis |

# 5. STUDY PARTICIPANTS

### 5.1. INCLUSION CRITERIA

All patients attending the NCVH considered suitable for treatment of their PTSD with EMDR will be offered participation in the trial if they satisfy the inclusion and exclusion criteria:

1. Department of Veterans’ Affairs (DVA) accepted clinical diagnosis of PTSD, which have been confirmed by NCVH clinicians administering and trained in the Structured Clinical Interview for DSM 5 (SCID-5)[[3]](#footnote-3);
2. Age 18 years and older; and
3. Willingness to provide informed consent.

### 5.2. EXCLUSION CRITERIA

The following exclusion criteria will be used:

1. No prior treatment with EMDR;
2. No history of acquired brain injury from any cause, which may increase the risk of developing PTSD14 but the impact of acquired brain injury on treatment for PTSD with EMDR is currently unknown15; and
3. No active alcohol, benzodiazepine, or illicit substance use, which are common comorbidities among patients with PTSD16 but are generally considered relative contraindications for EMDR on the basis of their effects on long term potentiation17.

Patients may withdraw at any stage of treatment. Patients will exit the trial if they relapse into alcohol or substance use.

### 5.3 KEY ELEMENTS OF RECRUITING

Veterans are referred to the NCVH for multidisciplinary treatment over approximately three months. Veterans who are referred for treatment of their PTSD will be advised of the clinical trial if they are deemed suitable for EMDR and if they meet inclusion criteria. They will be offered an interview with the study lead to discuss details of the trial and for further screening of eligibility using a standardised checklist based on the inclusion and exclusion criteria (see Appendix).

The therapeutic relationship is central to the recruitment process that may influence recruitment as a stronger therapeutic relationship may increase the likelihood of a patient accepting referral for inclusion in the study. This may increase the likelihood of one clinician having a larger number of patients included in the study, which could potentially impact the study results. The mitigation of this risk is discussed in 6.3 below.

The co-location of the study lead within the same team will ensure rapid response between referral and recruitment and consent. Likewise, the involvement of the treating clinicians in the study will increase their likelihood of recruiting suitable patients, which will also enable patients to ask any follow up questions. Moreover, patients are generally referred for EMDR early in their treatment with the NCVH, which reduces the likelihood that they will be lost to follow up after referral for inclusion in the study, and inclusion in the study will not impact on their capacity to access EMDR through the NCVH. But it is important to keep in mind that veteran attitudes increase their likelihood to engage in clinical trials19; veteran altruism is likely to increase the number of participants recruited from NCVH.

### 5.4 CONFOUNDERS

Potential confounding variables include: sex, current age, military service branch (including special forces experience), combat exposure, exposure to moral injury[[4]](#footnote-4), and duration since trauma exposure. These will be

### 5.5 STUDY LIMITATIONS

This study will be limited to veterans presenting to the NCVH for treatment of PTSD. Though the NCVH has national reach into the veteran community, randomisation can only adequately occur with locally based veterans who can attend the NCVH in person, which geographically limits the study to Australian veterans who ostensibly live in Greater Sydney.

Comorbidity between PTSD and substance use disorder (SUD) is common, particularly among veterans16. Exclusion of patients with active substance use from the study will therefore limit the applicability of the study findings to this population group. Indeed, the limited evidence warrants further investigation with an appropriately controlled study.

Likewise, PTSD is a common comorbidity among veterans with a traumatic brain injury (TBI)20, and acquired brain injuries may increase the risk of developing PTSD14. Excluding patients with a history of comorbid PTSD and TBI from the study will limit the applicability of the study findings, but further investigation among this population can be conducted with a subsequent and appropriately controlled study.

# 6. STUDY PROCEDURES

### 6.1. STUDY FLOW CHART

The protocol design is illustrated in figure 1 below.

*Clinical evaluation of suitability for EMDR*

*Screening visit and explain RCT protocol*

*Randomisation*

*Exclude: fails inclusion criteria*

*Exclude: fails inclusion criteria, declines consent to participate*

*Control Group: weekly treatment (8-12 weeks)*

*Telehealth Group: weekly treatment (8-12 weeks)*

*Fortnightly blinded review*

*Fortnightly blinded review*

*Six weekly blinded telephone follow up (x4)*

*Data analysis*

**Figure 1**. *Protocol design*

### 6.2. INVESTIGATION PLAN

Patients will be referred after assessment for readiness for EMDR. EMDR will be delivered by an EMDR practitioner who has undergone accredited training in EMDR. This will be provided in person according to standardised EMDR protocols, and this will be provided via telehealth using remotEMDR.

The standard EMDR protocol involves a series of phases delivered in weekly sessions:

1. Identify targets for EMDR processing (90 minutes).
2. Safety planning and strategies for coping with emotional distress (90 minutes).
3. EMDR practitioner utilising eye movement techniques for bilateral stimulation, either in person or using remotEMDR (four to eight 60-90 minute sessions depending on clinical need).
4. Closure phase and commencement of a log for the following week to document any related material that may arise (60 minutes).
5. Re-evaluation phase to examine progress (60 minutes).

Data collection will be conducted by psychiatrists blinded to patient randomisation. Patients will be instructed not to disclose the arm of the trial to which they have been allocated, and assessing clinicians will be instructed not to ask. Treatment will occur over an 8-12 week period and will be conducted by an accredited EMDR clinician who will not be blinded from the allocation.

At randomisation, and at fortnightly intervals post-randomisation, psychiatrists will conduct a clinical review of patient progress, including any complications associated with treatment. This aligns with NCVH standard protocol. PCL-5, VR-36, and GAF will also be administered by trained clinicians (see Appendix). Each of these measures requires approximately five minutes to complete and will not significantly increase the clinical burden. Following completion of EMDR, four sixth-weekly post-treatment follow up telephone calls will be in order to administer PCL-5, VR-36, and GAF, and to determine whether any complications have emerged.

These interventions are summarised in Table 2 below for an 8 week course of EMDR.

**Table 2**. Study visits and procedures for an 8 week course of EMDR

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Clinic Visit (weekly)** | | | | | | | | | | | | | | **Follow Up (sixth weekly)** | | | |
| **Intervention** | **Enrol** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **1** | **2** | **3** | **4** |
| Participant Consent | ✓ |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Inclusion / Exclusion criteria | ✓ |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| EMDR |  |  | ✓ | ✓ |  | ✓ | ✓ |  | ✓ | ✓ |  | ✓ | ✓ |  |  |  |  |  |
| PCL-5 VR-36 GAF | ✓ | ✓ |  |  | ✓ |  |  | ✓ |  |  | ✓ |  |  | ✓ | ✓ | ✓ | ✓ | ✓ |
| Duration of Visit | 15 | 60 | 90 | 90 | 30 | 90 | 90 | 30 | 90 | 90 | 30 | 90 | 90 | 30 | 15 | 15 | 15 | 15 |
| Adverse Event & Serious Adverse Event Assessment |  |  | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |

### 

### 6.3. STUDY PROCEDURE RISKS

This study will not impact whether EMDR is offered at the NCVH, and therefore will not limit access to EMDR to Australian veterans attending NCVH. Any potential harms associated with EMDR re-triggering past trauma will not be increased through the conduct of this study over and above the clinical risks of delivering EMDR at the NCVH as this trial is designed to integrate with clinical practice. Indeed, Phase 2 of the standard EMDR protocol focuses on safety planning and strategies for coping with emotional distress. In the event that a participant has a significant deterioration in their mental state, established NCVH protocols will be followed to ensure that they have access to a local crisis team.

As noted in 5.3 above, the therapeutic relationship may influence recruitment and potentially impact the study results. However, this risk will be mitigated by including clinicians who have EMDR accreditation and therefore ensure adherence to the EMDR protocol regardless of which clinician is administering EMDR.

While comorbid PTSD and SUD is common among veterans, the evidence of EMDR in patients with comorbid PTSD and SUD is currently limited16. However, this does not preclude the provision of EMDR to this population in a clinical setting and therefore the study will not restrict access to EMDR among veterans presenting to the NCVH with comorbid PTSD and SUD.

Similarly, though comorbid PTSD and TBI is common among veterans, the impact of acquired brain injuries on EMDR is unknown15. Again, exclusion of this population from this study does not restrict access to the provision of EMDR to veterans presenting to the NCVH with comorbid PTSD and TBI.

### 6.4. PARTICIPANT RECRUITMENT AND SCREENING

|  |  |
| --- | --- |
| **Will participants be screened?** | Yes |
| **If yes, what data will be collected? (NB, if participant is not eligible, will data collected be destroyed or kept?) This should be mentioned in PIS/CF)** | All data collected in the initial screening session will be clinical data collected in line with standard NCVH protocol and kept in the participant’s paper file, eMR, and REDCap. This data will not be destroyed if the participant is not eligible as it will be clinical data used for clinical purposes |
| **Who will make initial contact with participants?** | Case manager will make the initial contact in line with standard NCVH protocol |
| **Who will perform the consent process? How will this be carried out?** | Study lead will book time with the participant to discuss the trial and provide them with PIS in person |
| **Will participants be consented verbally/explicitly/using eConsent?**  [SLHD Research Forms Link](https://www.slhd.nsw.gov.au/rpa/Research/forms.html) | Participants will be consented verbally and their decision recorded on eMR with the consent form uploaded to REDCap |
| **Will participants be given a specific time period to consider participating?** | Yes – one week between mental health appointments |
| **Review of existing databases or databanks (please identify the database/databank and the custodian)** | Study lead will review REDCap and the NCVH MS Teams and sharepoint sites, which are all hosted by SLHD |
| **Review of clinic files (please include who will be reviewing these files, for example a research coordinator).** | Study lead will review clinic paper files and eMR |
| **Advertisements (please include where the advertisement will be placed for example, in a newspaper, poster in a clinic or hospital foyer, radio announcements, website etc.)** | Advertising for the trial will occur within the NCVH during the initial assessment of participants for suitability |
| **Information Letter to Medical practitioners** | YES |
| **Explain how potential participants will be screened for the study** | Screening will occur in their mental health assessment by an NCVH psychiatrist in line with standard NCVH protocol. |
| **Any other potential recruitment methods.** | Nil |

### 6.5. PARTICIPANT ENROLMENT

Potential participants will be attending NCVH and found to be suitable for EMDR. They will be enrolled into the study after the informed consent process has been completed and they are assessed to meet all of the inclusion criteria and none of the exclusion criteria. Participants will enrolled into the study if they grant their consent. Participants will receive a study enrolment number and this will be documented in their medical record and on REDCap.

### 6.6. INFORMATION AND CONSENT

Potential participants and will be provided with an explanation of the study and its aims at a convenient time in person following their psychiatrist assessment. They will be provided with a PIS and given an opportunity to ask any clarifying questions. The discussion will be documented in eMDR. Potential participants will be offered a week to consider participation, which will be the standard duration of time between MH clinic appointments at NCVH. A signed CF will be required to proceed with participation in the study. The PIS and CF are included in Appendix.

### 6.7. RANDOMISATION PROCEDURE

Participants who meet inclusion criteria and provide their informed consent will be randomly assigned to either the control group or the teleheatlh group using stratified randomisation21 based on sex, military service branch, and combat exposure in order to ensure balancing of these potential covariates. Randomisation will be achieved using an online calculator.

### 6.8 END OF STUDY TREATMENT/WITHDRAWAL PROCEDURE

If a patient does not withdraw or is not withdrawn from treatment with the study, a 24 week post-treatment follow up period will follow their course of EMDR. If a patient withdraws or is withdrawn from the study, the patient and their treating clinician will elect whether they continue with EMDR using their allocated modality.

### 6.9. PATIENT WITHDRAWAL

Patients may withdraw at any stage of treatment and the reason will be recorded, including adverse outcomes. If a patient concludes their course of EMDR with the study and elects to continue with a further course of EMDR during the 24 week follow up period, then they will be withdrawn from the study. Patients will be withdrawn from the trial if they relapse into alcohol or substance use or if they are admitted to an inpatient mental health unit. If blinding has been breached, then the patient will be withdrawn from the trial as a dropout.

The study lead will be notified in the event of a patient withdrawing who will contact the patient for a debriefing session. Once withdrawn, no further data will be collected and the existing data will be analysed using the intention to treat principle.

# 7. OUTCOMES

### 7.1. DEFINITION OF OUTCOMES

The outcome variables will be symptom severity, QOL, functional capacity, and adverse outcomes. All outcome variables will be measured by validated measurement tools where appropriate:

1. **Symptom severity**: The PTSD Checklist for DSM 5 (PCL-5) will be used to report PTSD symptom severity. This has been selected as it has been validated in veterans18 and is simple to administer. Its wide use in the literature supports future meta-analyses.
2. **QOL**: The Veterans Short Form 36 (VR-36) will be used to report QOL outcomes. This has been selected as it is a validated tool in veterans22 and is simple to administer. Its wide use in the literature supports future meta-analyses.
3. **Functional capacity**: The Global Assessment of Function (GAF) will be used to report functional assessment. This has been selected as it has been validated in veterans23, however its use across facilities is limited24[[5]](#footnote-5).
4. **Adverse outcomes**: Admissions to mental health units, suicidality and suicidal behaviour, deliberate self-harm, and withdrawal from the trial due to alcohol or substance use (if applicable).

# 8. STATISTICAL METHODS

### 8.1. SAMPLE SIZE ESTIMATION

A minimum of twelve participants will be required in the feasibility study and the randomised trial order to ensure adequate estimation of the regression variables25. Owing to the limited evidence base of EMDR via telehealth12, an estimate of study size will be determined after the feasibility study (Phase A) in order to ensure the study is adequately powered.

### 8.2. STATISTICAL ANALYSIS PLAN

Data will be analysed using the intention to treat principle by including patients who withdraw or exit from the study. For the purposes of statistical analysis, treatment will consist of a minimum of three sessions in order to include at least one active phase of treatment. Statistical significance will be defined as p < 0.05.

Kaplan-Meier event-free survival analysis curves using right-censoring will be used to analyse PCL-5, SF-35V, and GAF scores based on 25% and 50% improvements in scores. Differences between groups assessed using log-rank tests. Cox proportional hazards regression used to control for differences in demographics and clinical characteristics.

Categorical data will be compared using Fisher’s exact test and interval data will be compared using Mann-Whitney’s U test. The following six clinical features will be modelled for the primary outcome using regression analysis: sex, current age, military service branch (including special forces experience), combat exposure, exposure to moral injury, and duration since trauma exposure.

### 8.3. INTERIM ANALYSES

Interim analyses will occur every six months to identify whether the study endpoints are being met:

1. Interim 1 will occur at the end of the Feasibility Study and will form the basis of the power analysis and an early publication of the observational study; and
2. Interim 2-4 will occur every six months during the Randomised Trial.

**9. DATA COLLECTION**

9.1. PARTICIPANT REGISTRATION

Participants will be provided with a registration number. The study lead will maintain a coding dictionary that links the patient registration number to a de-identified number associated with their REDCap data. The REDCap data will be used for analysis.

9.2. FORMS AND PROCEDURE FOR COLLECTING DATA

The following psychometric tests will be administered in paper form

1. PCL-5 is routinely administered to patients attending the NCVH at commencement and transfer of care. This is stored in the patient’s paper file and the results are uploaded onto REDCap. Participants in this trial will complete the PCL-5 in accordance with the study timeline in Table 2.
2. VR-36 will be added to the battery of tests administered at commencement and transfer of care at the NCVH. Th VR-36 will also be stored in the patient’s paper file and the data will be uploaded onto REDCap.
3. GAF will also be added to the battery of tests administered at the commencement and transfer of care at the NCVH. The GAF will be stored in the patient’s paper file and the data will be uploaded onto REDCap.

9.3. DATA FLOW

All forms for collecting data will be administered initially on the associated paper forms. The data will then be provided to the study lead who will upload the data to de-identified copies on REDCap using a coding dictionary stored on an SLHD encrypted drive. Only de-identified REDCap data will be used for analysis by blinded investigators to ensure appropriate blinding of results.

# 10. QUALITY CONTROL AND ASSURANCE

### 10.1. CONTROL OF DATA CONSISTENCY

Data consistency will be maintained by adherence to the PCL-5, VR-36, and GAF, which are standardised psychometric tests, and adherence to the EMDR protocol, which is a standardised protocol regardless of whether it is delivered in person or via telehealth.

### 10.2. AUDITS

The study lead and the co-investigators will meet with the NCVH Returned & Services League (RSL) Liaison Officer to perform interim audits every six months. The goal of these audits will be to monitor recruitment progress, adherence to the trial protocol and standardised EMDR protocol, and to identify any adverse outcomes associated with the study. This will coincide with the interim analyses to assess the progress of the study. Audits will involve a chart review of all participants who have had active treatment with EMDR over the previous six months, and to assess any follow up issues that may have emerged. The study lead will also contact participants via telephone to discuss their perspectives of the study. NCVH clinicians will be canvassed for any feedback associated with the study.

### 10.3. PROTOCOL AMENDMENTS

Any proposed protocol amendments will be discussed among the co-investigators and the RSL Liaison Officer based on findings of the interim audits. The merits of any proposed amendments will be debated against the impact on the trial. If an amendment is supported, then the study lead will submit any proposed amendments to the SLHD Ethics Committee and CRGH Governance Officer for review and approval.

# 11. ETHICS

### 11.1. INVESTIGATOR AUTHORISATION PROCEDURE

The study will commence once the initial approval process has been completed through SLHD Ethics and Governance authorisation. Updated documents will only be implemented once they have been reviewed and approved by the SLHD Ethics Committee and CRGH Governance Officer.

### 11.2. PATIENT PROTECTION

The study lead will ensure the study is completed in accordance with the guidelines set out in the National Statement on Ethical Conduct in Human Research26. This will be supported by regular study audits.

11.3 PARTNERING WITH CONSUMERS

The consumer involvement and engagement toolkit will be used to guide how the study can engage with veterans with PTSD who are receiving treatment with EMDR. The formal consumer representative is the NCVH RSL Liaison Officer, who has been approached for their opinion on the merits of the trial, particularly as it will allow the NCVH to continue to offer EMDR to veterans who are geographically isolated. Other representatives from the veteran community have yet to be approached, but will include representatives from Ex-Services Organisations (ESO).

Input from participants on the progress of the study will be canvassed during the biannual audits. The NCVH RSL Liaison Officer will be included in the audit process and on an *ad hoc* basis throughout the study. The RSL Liaison Officer will be asked for comment on reports and manuscript drafts so that perspectives from lived experience are included in the communication of results to the scientific community, as well as the development of plain language summaries.

As part of the consent process, participants will be given an opportunity to elect to receive a plain language summary of the study findings or a copy of any associated publications. When these are supplied to them, their feedback will be canvassed and incorporated into broader lessons for the NCVH team and suggestions for further research. Results will also be communicated through monthly NCVH education sessions, which will also provide an opportunity for further feedback from the veteran community on further research.

# 12. SAFETY

### 12.1. ADVERSE EVENT REPORTING

All adverse events will be reported as part of the publication of results and monitored through regular audits and interim analyses.

EMDR is a form of exposure therapy, and thereby can destabilise a patient’s mental state. Safety planning is integral to the delivery of EMDR (see 6.2 above), and distress coping strategies are developed and practiced with patients as part of the preparation for EMDR. Despite this preparation work, adverse events associated with EMDR include increased level of distress, increased anger, worsening of nightmares and sleep, increased anxiety symptoms, worsening of negative cognitions, deterioration of relationships, and increased alcohol or substance use. Serious adverse events include admissions to mental health units, increased suicidality and suicidal behaviour, and deliberate self-harm; death can result from suicidal behaviour.

While safety planning with EMDR delivered via telehealth occurs at a distance, the approach is the same as in-person. The availability of an therapist in-person does not improve the safety planning as the duration between therapy sessions is not contingent upon whether EMDR is delivered via telehealth or in-person. Moreover, as the study will be conducted with patients in the Greater Sydney Area, urgent appointments can be arranged to help with any distress associated with delivering EMDR.

Finally, the ethical acceptability of the protocol is associated with the ethical acceptability of EMDR, which is an established therapeutic technique. This study does not introduce any experimental psychological technique that could compromise the ethical acceptability of the study, nor does it restrict access to EMDR for any patients attending the NCVH.

### 12.2. SERIOUS ADVERSE EVENT REPORTING

Serious adverse events will be reported to the study lead who will contact the CRGH Governance Officer. The clinical director of admitting mental health hospitals will be contacted so that they are aware that the patient was participating in the study so that an RCA can be initiated if necessary. Local mental health teams will be contacted to provide close follow up in the event of increased suicidality, suicidal behaviour, or deliberate self-harm.

### 12.3. EARLY TERMINATION

The study will be terminated early if the interim analyses demonstrate significant difference in outcomes with sufficient power. If the study is terminated early, then participants will be informed and unblinded, and patients will be given the opportunity to choose to continue with the EMDR modality to which they’ve been randomised, or to switch to an alternative modality. The HREC will be notified and reports and papers will be prepared.

# 13. BLINDING AND UNBLINDING

NCVH psychiatrists referring patients to EMDR will be blinded to patient randomisation. Patients will be instructed not to disclose the arm of the trial to which they have been allocated, and assessing clinicians will be instructed not to ask. If blinding has been breached, then the patient will be withdrawn from the trial as a dropout.

# 14. CONFIDENTIALITY AND STORAGE AND ARCHIVING OF STUDY

REDCap will be used to store trial data, including all demographic data and clinical outcome data. This data will be retained for five years and electronic shredding will be used to destroy the data. This will be the responsibility of the study lead. There are no plans to share this data with any outside parties, or to retain it for follow on studies. In the event that a follow on study is planned, an amendment will be made and submitted to the SLHD HREC for approval.

The study lead will maintain a coding dictionary that links the patient registration number to a de-identified number associated with their REDCap data. This dictionary will be held on an encrypted SLHD network drive and destroyed along with the REDCap data.

Demographic data will be obtained from eMR and data from PCL-5, VR-36, and GAF will be administered by blinded clinicians in accordance with Table 2. This data will be provided to the study lead for de-identification and entry into REDCap. The paper copies of PCL-5, VR-36, and GAF will be stored in the patient paper files, and

De-identified data will be analysed by additional investigators with the aid of an SLHD biostatistician. Once analysis has been completed, the study lead will take responsibility for interpretation of the amalgamated data and subsequent communication of the results. All results will be reported in an amalgamated, de-identified form.

The Research Data Management Plan has been submitted with this protocol.

# 15. INDEMNITY

### 15.1. COMPENSATION

This trial will be conducted to align with standard clinical procedures at the NCVH using a treatment modality that is already being used with patients. Any compensation associated with the trial will therefore be incorporated under established clinical governance.

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# 17. APPENDICES

### 17.1. ELIGIBILITY CHECKLIST

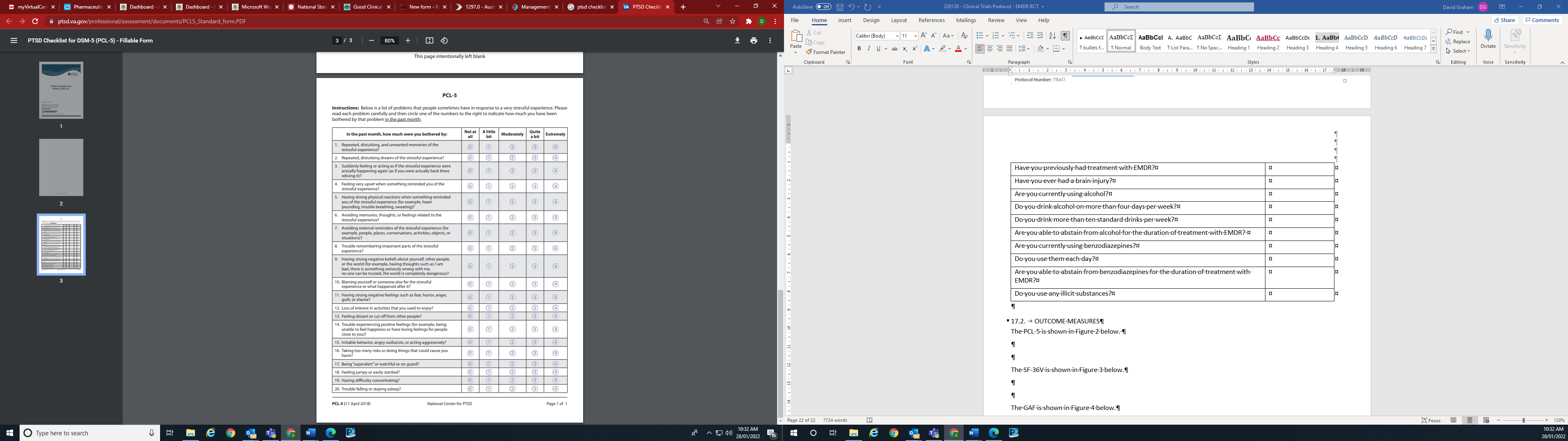
The standardised checklist of eligibility to be asked in the consenting process is shown in Table 3 below.

**Table 3**. Standardised eligibility checklist

|  |  |
| --- | --- |
| **Question** | **Response (Y/N)** |
| Are you a veteran? |  |
| Are you 18 years of age or older? |  |
| Do you have a DVA accepted diagnosis of PTSD? |  |
| Have you previously had treatment with EMDR? |  |
| Have you ever had a brain injury? |  |
| Are you currently using alcohol? |  |
| Do you drink alcohol on more than four days per week? |  |
| Do you drink more than ten standard drinks per week? |  |
| Are you able to abstain from alcohol for the duration of treatment with EMDR? |  |
| Are you currently using benzodiazepines? |  |
| Do you use them each day? |  |
| Are you able to abstain from benzodiazepines for the duration of treatment with EMDR? |  |
| Do you use any illicit substances? |  |

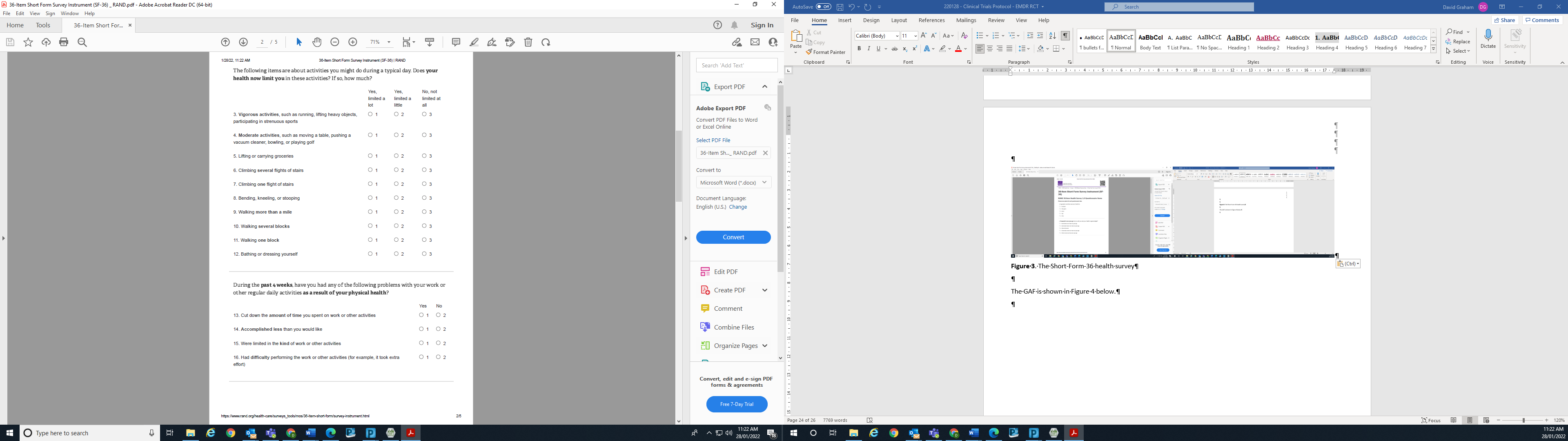
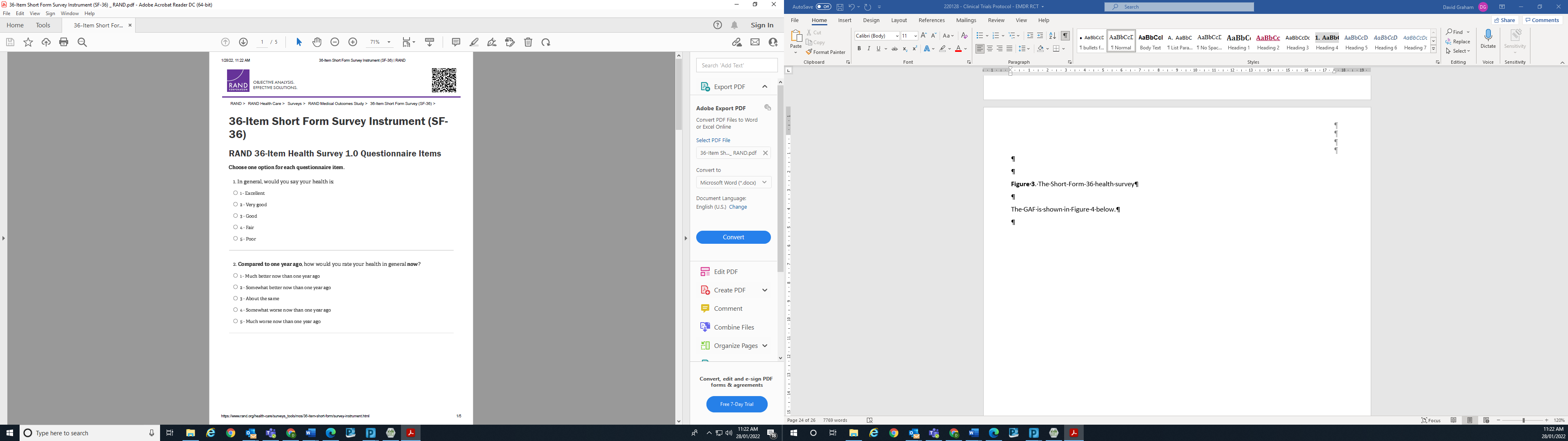
### 17.2. OUTCOME MEASURES

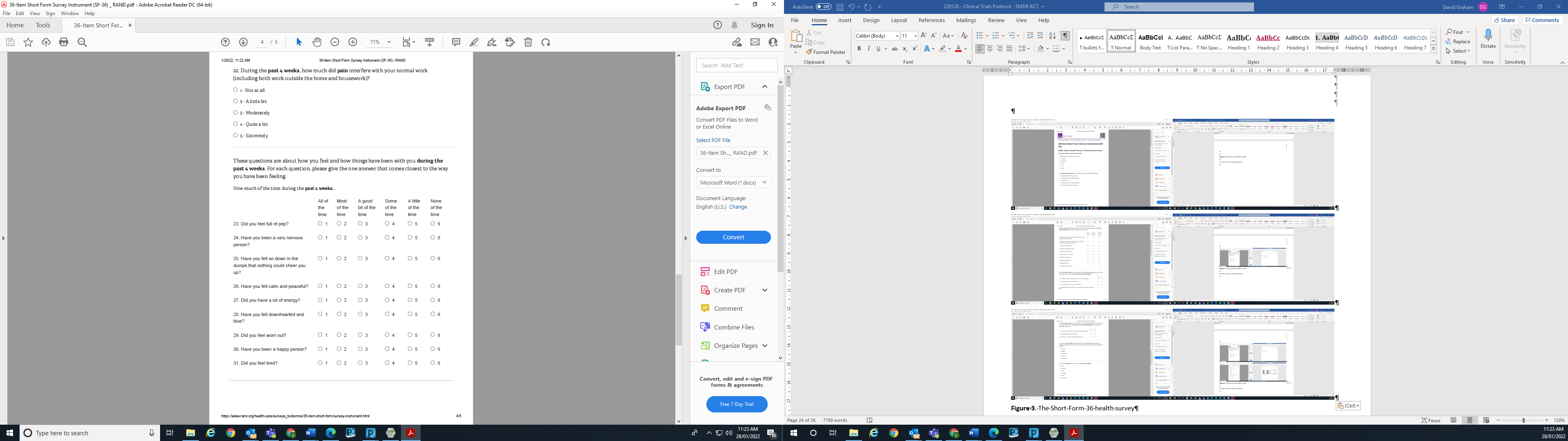
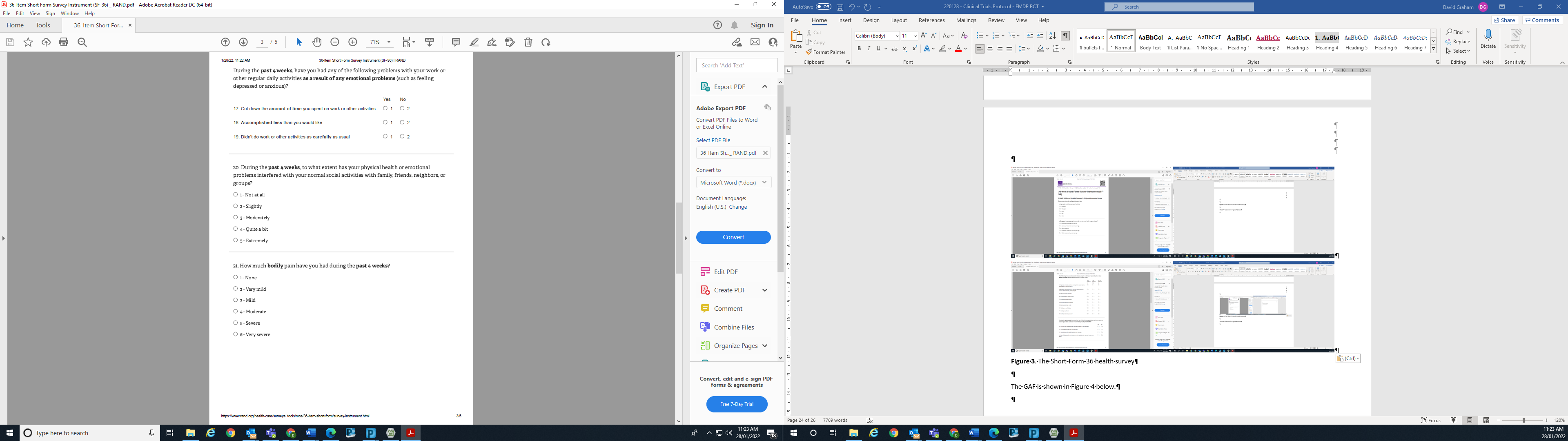
The PCL-5 is shown in Figure 2 below.

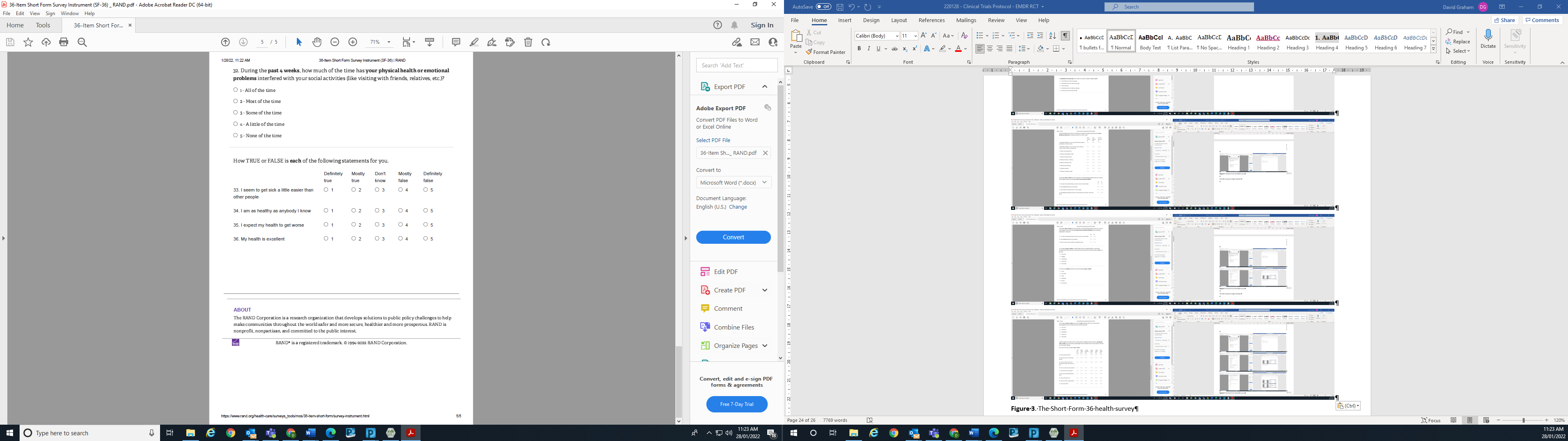


**Figure 2**. PTSD checklist for DSM5

The VR-36 has yet to be purchased by the NCVH, but it is based on the Short-Form-36 (SF-36), which is shown in Figure 3 below for illustration given it’s similarity to the VR-36.

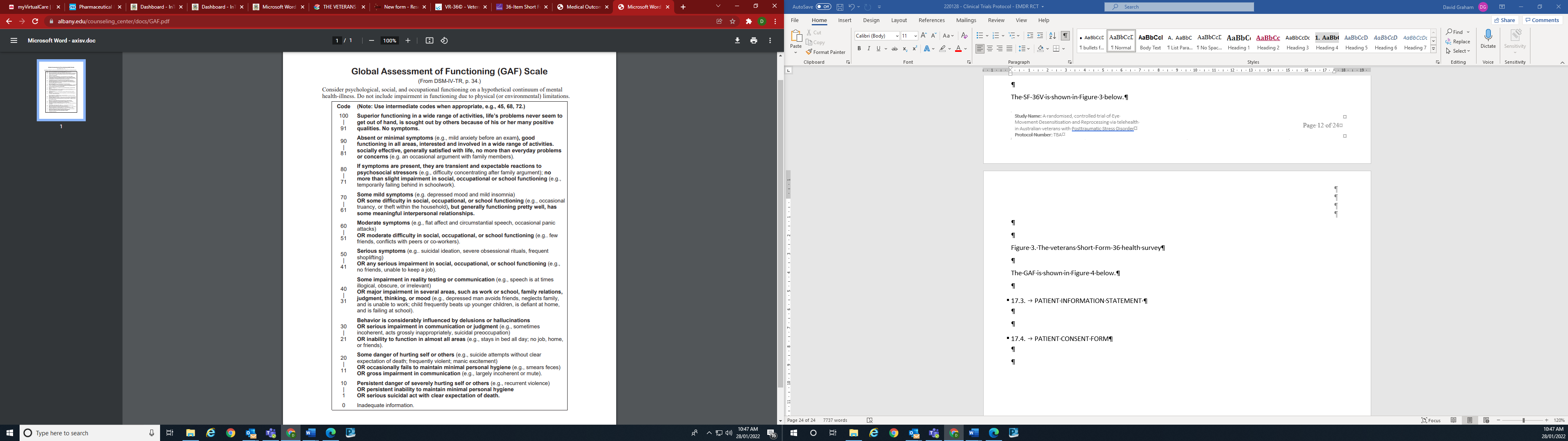






**Figure 3**. The Short-Form-36 health survey

The GAF is shown in Figure 4 below.



**Figure 4**. The Global Assessment of Functioning scale.

### 17.3. PATIENT INFORMATION STATEMENT

***A randomised, controlled trial of Eye Movement Desensitisation and Reprocessing via telehealth in Australian veterans with Posttraumatic Stress Disorder***

***“Virtual EMDR trial in Australian Veterans with PTSD”***

**PARTICIPANT INFORMATION SHEET**

|  |  |
| --- | --- |
| **Title** | *A randomised, controlled trial of Eye Movement Desensitisation and Reprocessing via telehealth in Australian veterans with Posttraumatic Stress Disorder* |
| **Short Title** | *Virtual EMDR trial in Australian Veterans with PTSD* |
| **Protocol Number** | *2022/ETH00162* |
| **Project Sponsor** | *Sydney Local Health District* |
| **Principal Investigator** | *Dr David Graham* |
| **Associate Investigators** | *Dr Charles Betts*  *Dr Gavin Angus-Leppan*  *Dr Cameron Korb-Wells* |
| **Location** | *National Centre for Veterans’ Healthcare, Concord Repatriation General Hospital* |

**1. Introduction**

You are invited to take part in a research study into / looking at the use of Eye Movement Desensitisation and Reprocessing (EMDR) delivered via telehealth in Australian veterans with Posttraumatic Stress Disorder (PTSD). The aim of the study is to see whether delivering EMDR by telehealth results in outcomes that are at least as good as delivering EMDR in person. Understanding this question will help us to build the evidence basis for delivering EMDR via telehealth, which will provide us with the opportunity to provide access to rural and remote patients, as well as to be prepared for future pandemics. You have been invited to take part in this study because you are currently attending the National Centre for Veterans’ Healthcare (NCVH) for treatment of PTSD and your treating team has identified that EMDR may be helpful for treating your PTSD.

The study is being conducted within this institution by:

* Dr David Graham, psychiatry registrar, NCVH
* Dr Charles Betts, psychiatrist, NCVH
* Dr Gavin Angus-Leppan, psychiatrist, NCVH
* Dr Cameron Korb-Wells, medical director, NCVH

This Participant Information Sheet (PIS) will tell you what is involved in the study and help you decide whether or not you wish to take part. Please read this information carefully. If there is anything you do not understand or if you feel you need more information about anything, please ask. Before you make a decision, please feel free to talk things over with a relative, a friend or your doctor.

**2. Study Procedures**

If you agree to participate in this study, you will be asked to sign the Participant Consent Form at the end of this document. You will then be asked to undergo weekly EMDR and randomly assigned to either in person or via telehealth over a period of 8-12 weeks. This will be delivered with the same standard of care regardless of whether you undergo EMDR via telehealth or in person as EMDR is delivered according to a standard protocol. While undergoing EMDR, we ask that you abstain from alcohol, benzodiazepines, or any illicit substances.

Each EMDR session will run for approximately 60-90 minutes. The initial EMDR session will focus on traumatic memories or dreams that will be used for EMDR. The next session will focus on safety planning. In the subsequent 4-8 sessions, your therapist will use eye movement techniques, either in person or using a web-based system called remotEMDR. The final two EMDR sessions will examine your progress from a therapeutic perspective.

Every two weeks, your NCVH psychiatrist will spend approximately 30 minutes with you to review your progress. They will not know whether you are undergoing EMDR in person or via telehealth and it is important for the purposes of the trial that you do not tell them. In these sessions, they will ask you to complete some questionnaires and the data in those questionnaires will be used to identify whether EMDR delivered via telehealth is at least as good as EMDR delivered in person.

The following information will be collected from your medical record for the purposes of analysis: sex, current age, military service branch (including special forces experience), combat exposure, exposure to moral injury, and duration since trauma exposure. This information will be collated with the other participants and so your privacy will be ensured.

If the study data will be used for future research purposes and / or shared with national and international collaborators, Ethics Approval will be required to be sought prior to access any non-identifiable data.

**3. Risks**

All treatments – whether for diagnosis or treatment, routine or experimental – involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown and unforeseeable. In spite of all precautions, you might develop complications from participating in this study.

EMDR is a form of exposure therapy, and therefore can cause distress which is why safety planning is an integral part of EMDR, and distress coping strategies are developed and practiced with patients as part of the preparation for EMDR. Despite this preparation work, risks associated with this study include: increased level of distress, increased anger, worsening of nightmares and sleep, increased anxiety symptoms, worsening of negative cognitions, deterioration of relationships, and increased alcohol or substance use. Serious adverse events include admissions to mental health units, increased suicidality and suicidal behaviour, and deliberate self-harm; death can result from suicidal behaviour.

If you wish to talk to someone outside the research team due to any distress caused to you by EMDR, you can contact your NCVH case manager during business hours, or Open Arms on 1800 011 046 or the Mental Health Access Line on 1800 011 511.

**4. Benefits**

While we intend that this research study furthers medical knowledge and may improve treatment of PTSD in veterans in the future, it may not be of direct benefit to you.

**5. Costs**

Participation in this study will not cost you anything, nor will you be paid.

**6. Voluntary Participation**

Participation in this study is entirely voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason by contacting Dr David Graham on 02 9767 8669. You and your therapist will elect whether to continue with EMDR in person or via telehealth, or to cease treatment. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the staff who are caring for you.

If you decide to withdraw from the study, we will not collect any more study-related information from you. If you want to withdraw please let us know and tell us what you would like us to do with the information we have collected from you up till then. If you wish, your information will be removed from our study records. It will not be included in the study results, unless we have analysed and published the results’

**7. Confidentiality**

All the information collected from you for the study will be treated confidentially and will be stored on a research database based in the Sydney Local Health District (SLHD) data centre. Only the researchersnamedwill have access to it. The information will be stored using unique ID codes that cannot be linked to your medical record.

The data will be analysed by the researchers at the NCVH. All data for use in journal publications and presentations will be de-identified – i.e. you or your information will not be identifiable. The files will be retained for fiveyears from the day the study is completed. Once the retention expires the files will be disposed of.

Data collected up until the time you withdraw may be included in the study. If you do not want them to do this, you must tell the researchers at the time of your withdrawal. The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable in such a presentation.

De-identified data will be stored on an online secure password protected research database accessed within the NCVHat Concord Repatriation General Hospitalsupported by SLHD Information Technology Department. Any identifiable hardcopy data will be stored on either a secure, password protected shared drive (supported by the hospital Information Technology Department) or in a locked cabinet in a locked office of the NCVH Operations Manager at Concord Repatriation General Hospital.

**8. Storage of Data**

The SLHD software licence for REDCap (Research Electronic Data Capture) will be used for to manage the collection and storage of research data. REDCap is a secure, web-based, non-commercial, data management tool designed for research purposes. Data collected by REDCap is stored on servers in the SLHD data centre. Data is securely backed-up, privately and confidently.

**9. Future use of Data**

The data collected in this project will not be used in future research studies.

**10. Further Information**

When you have read this information, Dr David Graham will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact them on 02 9767 8669.

This information sheet is for you to keep.

**11. Ethics Approval and Complaints**

This study has been approved by the Human Research Ethics Committee - CRGH of the SLHD. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9767 5622 and quote reference number 2022/ETH00162*.*

### 17.4. PATIENT CONSENT FORM

***A randomised, controlled trial of Eye Movement Desensitisation and Reprocessing via telehealth in Australian veterans with Posttraumatic Stress Disorder***

***“Virtual EMDR trial in Australian Veterans with PTSD”***

**PARTICIPANT CONSENT FORM**

I,\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *[full name]*

Of\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *[address]*

have read and understood the Participant Information Sheet on the abovenamed research study and   
  
have discussed the study with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[investigator responsible for conducting informed consent].

• I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

• I understand that my participation in this study will allow the researchers and others, as described in the Information for Participants, to have access to my medical record, and I agree to this.

• I understand that my de-identified data may be used for future research and I agree to this.

• I would like to receive a copy of the study results when they become available. My email address is: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

• I understand that, during the course of this study, my medical records may be accessed by the National Centre for Veterans’ Healthcare, by regulatory authorities, or by the Ethics Committee approving the research in order to verify results and determine that the study is being carried out correctly.

• I understand that the SLHD software license for REDCap (Research Electronic Data Capture) will be used to manage the collection and storage of my research data.

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

• I freely choose to participate in this study and understand that I can withdraw at any time.

• I also understand that the research study is strictly confidential.

• I hereby agree to participate in this research study.

• I consent to the storage and use of my information collected from me for use, as described in the relevant section of the Participant Information Sheet, for this specific research project

Participant Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­\_\_\_\_\_\_\_\_\_\_\_\_­\_\_\_\_\_\_\_\_

Participant Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Person conducting informed consent:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person conducting informed consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. The transition period with within the first two years of discharge from military service. Transitioned ADF personnel are those who have completed this transition period. [↑](#footnote-ref-1)
2. The US Health Insurance Portability Accountability Act (HIPAA) establishes standards for handling of sensitive patient data, and is equivalent to the Australian Privacy Act. All companies that produce products for delivering EMDR via telehealth maintain HIPAA-compliance. [↑](#footnote-ref-2)
3. SCID-5 is considered the gold standard for reliable psychiatric diagnosis against which other diagnostic tools are validated18 [↑](#footnote-ref-3)
4. A moral injury can occur in response to acting or witnessing behaviours that contradict one’s values or beliefs [↑](#footnote-ref-4)
5. While the Social and Occupational Functioning Assessment Scale (SOFAS) has also been used in the literature, it has similar limitations as the GAF and its validity in the veteran population has yet to be demonstrated22. [↑](#footnote-ref-5)