# **Campbell Systematic Reviews - PROTOCOL**

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# Eye Movement Desensitization and Reprocessing (EMDR) for Posttraumatic Stress Disorder (PTSD) in Combat Veterans

# PROTOCOL

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# 1 Background

# **1.1 DESCRIPTION OF THE CONDITION**

#### 1.1.1 Definition

Posttraumatic Stress Disorder (PTSD) can develop after exposure to a traumatic event or experience, including those experienced during combat. According to the *Diagnostic and Statistical Manual of Mental Disorders* American Psychiatric Association, 2000, PTSD is an Axis I Anxiety Disorder, and in order to be diagnosed with PTSD, a person must have experienced, witnessed, or confronted death or serious bodily injury to oneself or other and responded with intense fear, helplessness, or horror. Symptoms appear in three clusters, i.e., re-experiencing, avoidance/numbing, and hyper-arousal; must last greater than one month; and cause significant clinical distress or impairment in social, occupational, or other functioning American Psychiatric Association, 2000. According to the *International Classification of Diseases* World Health Organization, 1992, in order to be diagnosed with PTSD, a person must have been exposed to a stressor, experience symptoms of re-experiencing and avoidance, and either an inability to recall or two or more symptoms of hyper-arousal, within six months of the stressor.

## 1.1.2 Epidemiology

PTSD was initially defined as a mental health disorder by the DSM-III in 1980 (American Psychiatric Association, 1980). The lifetime prevalence of PTSD was estimated to be approximately 7% to 9% in community samples in the United States (Y ehuda, 2004). More recent estimates obtained from probability samples found PTSD to be diagnosable in 8.6% of African Americans, 6.5% among Caucasians, 5.6% among Hispanics Americans, and 1.6% of Asian Americans (Asnaasi et al., 2010), and range from 0.3% to 6.1% in other countries (Kessler & Ustun, 2008).<sup>1</sup> One sample of Norwegians survivors (n = 63) of a natural disaster (a tsunami in Thailand) found 36.5% to meet PTSD criteria som e 2.5 years later (Hussain, Weisaeth & Heir, 2011). PTSD was diagnosable among 28% of U.S. adolescents

<sup>&</sup>lt;sup>1</sup> Prev alence rates not directly comparable due to methodological differences.

with severe emotional disorders (Mueser & Taub, 2008). Given the military conflicts in Iraq, Afghanistan, and around the world, the risk of developing PTSD due to combat exposure and effective treatments for it, remains an important policy and practice topic. In the United States, there is preliminary evidence that from 10% to 17% of combat-deployed service members to Iraq and Afghanistan have PTSD symptoms (Smith et al., 2008) and some estimates as high as 30% (Atkinson et al., 2009). These figures suggest that the diagnosis of PTSD is a serious health problem.

#### **1.2 DESCRIPTION OF THE INTERVENTION**

EMDR was introduced as a treatment modality about twenty five years ago (Shapiro, 1989). EMDR has eight treatment phases. The first three stages include: 1) history taking; 2) preparation (introduction to the EMDR protocol, coping strategies and affect management techniques) and 3) assessment (bringing to mind an image of a traumatic incident, identifying beliefs and emotions associated with that incident, rating the degree of disturbance felt in recalling the traumatic incident, and rating the validity of preferred cognitions about oneself). During the next phase desensitization the core component of the intervention is implemented. It involves using a dual attention/bilateral stimulation procedure that aims to reprocess the disturbing emotions and cognitions associated with the traumatic incident. The client is instructed to keep in mind the image, beliefs and cognitions while simultaneously visually tracking the therapist's fingers as they are moved back and forth in front of the client in a prescribed manner. (Bilateral tactile taps or auditory tones are used instead of eye movements for clients who have difficulty visually tracking.) Bilateral stimulation is also used during the next two phases - installation and body scan - which aim to install a positive cognition to replace the negative cognition associated with the trauma and to reprocess any remaining bodily sensations. During the next phase closure the client is advised about what to do between sessions if experiencing distress. The final phase re-evaluation occurs at the start of the next session and involves identifying and reprocessing any residual material from the previous session or that arose between sessions. The length of treatment sessions varies, but typically lasts from 60 to 90 minutes. The number of treatment sessions also varies, ranging between 5 and 15 sessions.

#### **1.3 HOW THE INTERVENTION MIGHT WORK**

Early interest in EMDR was based more on Shapiro's (1989) initial findings than on an a priori theoretical foundation. Various explanations subsequently were postulated as to why and how it might work. The most prominent, and current, explanation is based on the adaptive information processing (AIP) model. According to this model, PTSD symptoms result from trauma-related images, thoughts, emotions and physical sensations becoming dysfunctionally stored in the brain's memory networks. It is postulated that implementing bilateral stimulation while the client focuses on those images, thoughts, emotions and physical sensations will facilitate access to and processing of the maladaptively stored information.

It is believed that access to and reprocessing of the dysfunctionally stuck material is likely to be faster and less anxiety inducing with the use of bilateral stimulation than with the use of alternative cognitive-behavioral interventions, such as exposure therapy. Those proffering that belief, however, disagree as to why that may be so, and their explanations are speculative. Some preliminary neurobiological evidence suggests that the bilateral stimulation might arouse parts of the brain associated with PTSD symptoms and memory tasks (Rauch et al., 1996; Zoler, 1998; Levin, Lazrove & van der Kolk, 1999; Amen, 2001). There are at least nine discrete neurobiological mechanisms of action which have been proposed for EMDR, mechanisms supported by varying levels of research (see Bergman, 2010). The available evidence for each of these is of uneven quality leading one reviewer to conclude: "Thus far, the definitive discovery and articulation of the underlying mechanisms of eye movement desensitization and reprocessing...has been ...elusive" (Bergman, 2010, p. 22). This unsatisfying conclusion is similar to that reached by Gunter and Bodner (2009) - "Despite much theorizing and speculation, EMDR's mechanism of action remains unspecified" (p. 161).

Despite the theoretical claims made for the underlying mechanisms of action of EMDR, controlled outcome and dismantling studies have demonstrated that there is no convincing evidence that eye movements themselves contribute to treatment outcome (Cahil, Carrigan & Frueh, 1999, Servan-Schreiber et al., 2006). This suggests that although EMDR may produce some beneficial results, these are likely not obtained via the originally hypothesized neurobiological or other mechanisms of action. At present there is some consensus that EMDR works, at least in part, because of its incorporation of traditional methods of exposure therapy involving anxiety-evoking stimuli, and to the role of placebo influences. EMDR may produce benefits beyond those attributable to these two parsimonious mechanisms of action, but strong evidence of this is lacking.

#### **1.4 WHY IT IS IMPORTANT TO DO THIS REVIEW**

The treatment of PTSD with EMDR has been studied extensively. A U.S. Institute of Medicine report (2008) titled *Treatment of posttraumatic stress disorder: An assessment of the evidence* concluded that "the evidence is inadequate to determine the efficacy of EMDR in the treatment of PTSD" (p. 112). A recent Cochrane Systematic Review (Bilson & Andrew, 2009) generally found both EMDR and Exposure Therapy to be both effective and comparable, but no subgroup analysis was conducted on clients suffering from PTSD secondary to combat trauma. Two meta-analyses on the effectiveness of EMDR on clients with PTSD also found this approach to be useful (Davidson & Parker, 2001; Bradley et al., 2005), but in neither meta-analyses were military combat-related subgroup analyses conducted.

At present, no systematic review has examined outcome studies specifically focusing on the effectiveness of EMDR on PTSD related to exposure to military combat. It is important to focus on combat veterans because EMDR is being recommended as a treatment for PTSD (Russell, 2006; Cook, Biyanova & Coyne, 2009; Wesson & Gould, 2009; VA/DOD, 2010) despite limited and equivocal evidence for its use with this specific population. Russell (2008) describes clinician and administrative resistance to the utilization of EMDR as a therapy for combat veterans. If EMDR is truly an effective intervention, this resistance is a disservice to members of the military. However, even EMDR experts themselves acknowledge that "...the evidence is stronger for the beneficial effect of EMDR on persons with single-event civilians trauma than on multiply traumatized treatment-refractory chronically ill war veterans" (Chemtob, Tolin, van der Kolk & Pitman, 2000, p. 569) We also note that "...some experts believe that combat veterans with PTSD are less responsiv to treatment that survivors of other traumas" (Foa, Keane & Freidman, 2000, p. 542), which raises the importance of examining the literature specific to the effectiveness of EMDR with military combat-related PTSD. If EMDR is not an effective therapy for persons with combat-related PTSD, then its adoptive is premature, if not an actual disservice to members of the military and to veterans.

Albright and Thyer (2010) authored one narrative review on the issue of the effectiveness of EMDR among military combat veterans diagnosed with PTSD, and found that the evidence was insufficient to recommend this approach. However Albright and Thyer's (2010) paper was not conducted according to the high standards required of a Campbell Collaboration systematic review, hence their proposal, added by other experts, to complete the current protocol to provide a more comprehensive and credible appraisal.

# **2** Objective of the review

The primary objective is to complete a systematic review of experimental and quasiexperimental studies of EMDR for combat veterans with PTSD.

The secondary objective is to synthesize the results of these studies to assess the effect of EMDR on reducing PTSD in combat veterans.

# **3 Methods**

# 3.1 CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

#### 3.1.1 Types of studies

#### **Design**

The review will include experimental and parallel cohort experimental or quasiexperimental evaluations of EMD/EMDR provided to reduce PTSD in combat veterans. Studies will be eligible for review if they (1) used random assignment to create treatment and comparison or control groups or (2) used parallel cohort designs<sup>2</sup> in constructing a comparison/control group. Single-group designs and single-subject designs will be excluded. All studies since 1987 will be included, which is the year Francine Shapiro first conceptualized EMDR (Shapiro, 1989; 1997).

#### 3.1.2 Types of participants

Study participants will include adults, 18 years of age and older, who are military combat veterans meeting the DSM (III, III-R, IV, IV-R) or ICD (9, 10) criteria for PTSD. Males and females will be included. Combat veterans from all countries will be included. Military is defined as an organization authorized by a nation to use force in defending or attacking perceived threats. Combat is broadly defined as armed or unarmed conflict between military forces in war and might include being attacked or ambushed, receiving incoming artillery, rocket, or mortar fire, being shot at or receiving small-arms fire, shooting or directing fire at the enemy, etc. (Hoge et al., 2004, p. 18). Veteran is defined as a person who has served in the

<sup>&</sup>lt;sup>2</sup> These designs use stratification by subgroup during the randomization process to ensure balanced randomization among them. So, for example, participants not meeting randomization criteria can be assigned to a treatment option and followed prospectively in parallel to the randomized groups.

military. This review focuses on military veterans who participated in combat (rather than, for example, witnessed combat).

# 3.1.3 Types of interventions

The intervention of interest is EMD/EMDR (Shapiro, 1989) that is provided to individual clients. It will be compared with placebo treatment condition, no treatment condition, or alternative treatment conditions. Studies that compare EMD/EMDR to pharmacological, physical, or psychological treatments and studies that combine treatments will also be considered.

# <u>Setting</u>

All settings (e.g., VA Hospitals, outpatient clinics, private-practice, theatre of war, etc.) will be accepted.

# 3.1.4 Types of outcomes

The primary outcome is a level of PTSD symptoms (e.g., intrusive flashbacks, recurring dreams, avoidance of activities associated with the stressor, etc.). The primary outcome will be assessed in terms of the independent rating of severity of traumatic stress symptoms using a standardized measure. The standardized measure will be a structured diagnostic interview or one or more self-report questionnaire(s).

Structured diagnostic interviews will include the Structured Clinical Interview for DSM-IV (First, Spitzer, Williams, & Gibbon, 2000), the Clinician Administered PTSD Scale (Blake et al., 1990), the PTSD Interview (Watson et al., 1991), or the PTSD Symptom Scale Interview (Foa et al., 1993).

Self-Report Questionnaires will include the Impact of Event Scale Horowitz (Wilner, & Alvarez, 1979), the Impact of Event Scale -- Revised (Weis & Marmar, 1997), Mississippi Scale for Combat-Related PTSD (Keane, Caddell, & Taylor, 1988), Keane PTSD Scale of the MMPI-2 (Keane, Malloy, & Fairbank, 1984), Posttraumatic Diagnostic Scale (Foa et al., 1997), PTSD Checklist (Weathers et al., 1993), or the Distressing Event Questionnaire (Kubany, Leisen, Kaplan, & Kelly, 2000).

# 3.2 SEARCH METHODS FOR IDENTIFICATION OF STUDIES

## 3.2.1 Electronic searches

All electronic searches will be limited to research reported since 1987, which is when Francine Shapiro first conceptualized EMDR (Shapiro, 1989; 1997). Electronic searches will include the following bibliographic databases:

- 1. ACP Journal Club;
- 2. ASSIA: Applied Social Sciences Index and Abstracts;
- 3. CINAHL with Full Text;
- 4. Cochrane Central Register of Controlled Trials (CENTRAL);
- 5. Cochrane Database of Systematic Review;
- 6. DARE;
- 7. Dissertation Abstracts/Digital Dissertations;
- 8. EMBASE;
- 9. MEDLINE;
- 10. PILOTS;
- 11. PsycINFO;
- 12. Science Citation Index Expanded; and
- 13. Social Services Abstracts.

#### 3.2.2 Search terms

The following search terms will be used in finding the relevant studies for inclusion in the review. Search terms will be modified to meet the requirements of individual databases in regard to differences in fields.

#### EMDR OR

("Eye movement desensitization and reprocessing") OR

("Eye movement desensitization reprocessing") OR

EMDOR

("Eye movement desensitization") OR

AND

PTSD OR

(Posttraumatic\*)OR

(Post-traumatic\*) OR

AND

COMBATOR

WAR\* OR

("Armed conflict") OR

MILITARY OR

VETERAN\* OR

No language restrictions or geographical restrictions will be applied.

#### 3.2.3 Searching other resources

<u>Correspondence</u>

Attempts to contact relevant authors and experts will be made. Snowball sampling of key informants (authors and experts) will be attempted to identify relevant, unpublished work.

#### Grey Literature

- 1. Book Chapters
- 2. Conference Abstracts or Proceedings of the APA, EMDRIA, and ISTSS
- 3. Dissertations
- 4. Government Reports
- 5. Personal Network
- 6. Relevant Professional Organizations' Forums and Listservs (e.g., EMDR Institute, Inc.)
- 7. Research Reports

The following web sites will also be searched:

- 1. Agency for Healthcare Research and Quality (www.ahrg.gov);
- 2. ClinicalTrial.gov (www.clinicaltrial.gov);
- 3. Department of Veteran Affairs (www.va.gov);
- 4. EMDR Institude, Inc. (www.emdr.com);
- 5. EMDR International Association (www.emdria.org);
- 6. Grey.net (www.greynet.org);
- 7. National Institute of Mental Health (www.nimh.nih.gov); and
- 8. Government agencies outside the USA.

#### Hand-searching

The following journals will be hand-searched:

- 1. Journal of EMDR Science and Practice;
- 2. Journal of Psychological Trauma: Theory, Research, Practice, and Policy;
- 3. Journal of Traumatic Stress; and
- 4. Journal of Traumatology.

#### Reference Lists

Reviewers will check the reference lists of all relevant articles that are obtained,

including those from previously published reviews. Potentially relevant articles that are identified will be retrieved and assessed for possible inclusion in the review.

## **3.3 DATA COLLECTION AND ANALYSIS**

Citations and abstracts downloaded from electronic searches will be entered into the bibliographic software, Zotero.

#### 3.3.1 Selection of studies

The screening of the studies will follow a three-stage procedure. Each subsequent stage consists of increasing scrutiny based on the exclusion and inclusion criteria of the review.

#### <u>Stage 1</u>

The first stage will consist of an initial screening by two reviewers to determine whether a study might be appropriate for the review based on the report's title and abstract. The screening form is found in Appendix 1. If the reviewers disagree or there is not enough information to determine the appropriateness of the study based on its title and abstract, then full text articles will be retrieved.

### Stage 2

The second stage will consist of a stricter screening of the full text of the articles by two reviewers to determine whether a study will remain in the review based on the exclusion and inclusion criteria. Specific reasons for exclusion will be documented for each report. The screening form is found in Appendix 2. Any disagreements will be resolved by a third reviewer. Reliability coefficients on initial inter-rater agreement will be provided.

## 3.3.2 Data extraction and management

The third stage will consist of a data extraction form to record data from the studies that have made it past the previous stages. Study details will be extracted by two reviewers using a standardized form found in Appendix 3. Differences between coders will be identified and resolved by referral to the source material, and if needed, by consulting a third reviewer. Reliability coefficients on initial inter-rater agreement will be provided.

## 3.3.3 Assessment of risk of bias in included studies

Methodological quality will be assessed independently by two authors (DLA & BAT) using the Cochrane Collaboration's tool for assessing risk of bias (Higgins, 2011). Any disagreements will be resolved by discussion and, if necessary, disagreements will be arbitrated by a third author (BJB). The tool will be used to assess the following domains: sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other sources of bias (e.g., treatment fidelity, stopping the trial early, changing methods during the trial, etc.).

The quality of the trials will be presented in a risk of bias table where, for each question-based entry, the judgement ('Yes' for low risk of bias; 'No' for high risk of bias, or 'Unclear') of the authors will be followed by a text box providing details on

the available information that lead to each judgment. The sources of bias that we will assess are:

#### Adequate Sequence Generation

Randomization will be rated as follows:

- 1. 'Yes' when participants were allocated to treatment conditions using randomization such as computer-generated random numbers, a random numbers table, or coin-tossing;
- 2. 'Unclear' when the randomization method was not clearly stated or unknown; or
- 3. 'No' when the randomization method did not use any of the above methods.

#### Allocation Concealment

Allocation concealment will be rated as follows:

- 1. 'Yes' when participants and researchers were unaware of participants future allocation to treatment condition until after decisions about eligibility were made and informed consent was obtained;
- 2. 'Unclear' when allocation concealment was not clearly stated or unknown; or
- 3. 'No' when allocation was not concealed from either participants before informed consent or from researchers before decision about inclusion were made or allocation concealment was not used.

### <u>Blinding</u>

It is not possible to blind either those who deliver EMD/EMDR or those who receive it due to the nature of the intervention. Given that many of the secondary outcome measures are likely to be self-report, it is therefore probable that blinding of outcome assessments will be low in the included studies. Quality of blinding will be determined primarily by whether those who assessed and coded outcome measures were blind to treatment conditions, and the quality of blinding will be rated as follows:

- 1. 'Yes' when assessors were blind to the treatment conditions;
- 2. 'Unclear' when blinding of assessor was not reported and information was not available from researchers; or
- 3. 'No' when assessors were not blinded to treatment conditions.

## Addressing Incomplete Outcomes

Assessment will take into account whether researchers used intention-to-treat (ITT) analyses by including measures from all the participants, even those that did not participate fully in the treatment protocol and did not complete outcome measures. Those studies where the researchers did not use ITT analyses and it is not possible to conduct them with the available data will be identified. Sensitivity analyses will be used to determine bias from these studies and any potential bias will be discussed. When attrition between groups differs within studies, sensitivity analyses will also

be used to determine whether those studies bias the results of the meta-analysis. The adequacy of the way the authors of the trials dealt with missing data will be rated as follows:

- 1. 'Yes' when all participants were included in outcome analyses including those who withdrew from the trial or intention-to-treat analysis can be performed using available data;
- 2. 'Unclear' when information about whether ITT analyses were performed was not available and cannot be acquired by contacting the researchers of the study; or
- 3. 'No' when ITT analyses were not performed and cannot be done using available data.

#### Selective Reporting

The authors will try to get all available reports on included studies and track outcomes (and cases) across reports. The likelihood that the authors of the trial omitted some of the collected data when presenting the results will be determined and will be rated as follows:

- 1. 'Yes' when all collected data seems to be reported;
- 2. 'Unclear' when it is not clear whether other data was collected and not reported; or
- 3. 'No' when the data from some measures used in the trial are not reported.

#### **Treatment Fidelity**

The assessment will also take into account whether the researchers took any steps to ensure that practitioners maintained fidelity to the treatment protocol by using, for example, treatment manuals, training sessions, and supervision.

#### Other Potential Sources of Bias

Assessment will determine whether any other bias is present in the trial, such as stopping the trial early, changing methods during the trial, or other anomalies.

#### 3.3.4 Measures of treatment effect

#### Dichotomous Data

Dichotomous data will be converted into odds ratios (OR) with 95% confidence intervals.

#### Continuous Data

Continuous data will be converted into mean differences (MD) or standardized mean differences (SMD) if different scales have been used and they cannot be converted to the same scale, and presented with 95% confidence intervals.

#### <u>All Data</u>

When necessary, we will convert dichotomous data, correlation coefficients, *F* ratios, *t*-values, and chi-square values into SMDs. Hedges' *g* will be used to correct for small sample bias. If there are dichotomous and continuous measures of the same outcomes (within or across studies), we will convert to odds ratios (OR) and then to *d*. Data will be inspected for skewness in the distribution.

#### 3.3.5 Unit of analysis issues

The authors will take into account the unit of analysis of the trials to determine whether individuals were randomized in groups, whether individuals may have undergone multiple interventions at once, whether results were reported at multiple time points, and whether there were multiple treatment groups.

#### Cluster Randomized Trials

It is possible that participants will be randomized to groups in clusters, either when data from multiple participants are included (creating a cluster within the locality), or when participants are randomized by locality or region. For trials that use clustered randomization, results will be presented with proper controls for clustering (robust standard errors or hierarchical linear models). If appropriate controls are not used and it is impossible to obtain the full set of individual participant data, the data will be controlled for clustering using the procedures outlined in Higgins, Deeks, & Altman (2008). That is, when outcome measures are dichotomous, the number of events and the number of participants per study arm will divided by the design effect [1 + (1 - m) \* r], where m is the average cluster size and r is the intra-cluster correlation coefficient (ICC). When outcome measures are continuous, the number of participants per trial arm will be divided by the design effect, while leaving the mean values unchanged. To determine the ICC, the reviewers will use estimates in the primary trials on a study-by-study basis. However, where these values are not reported, the reviewers will use external estimates of the ICC that are appropriate to each trials context and average cluster size by contacting the authors. If the authors are not available, the reviewers will seek statistical assistance from the Cochrane and Campbell Methods' Group.

#### Multiple Time Points

When the results are measured at multiple time points, each outcome at each point will be analyzed in a separate meta-analysis with other comparable studies taking measures at a similar time point post-intervention. These will be grouped together as follows: immediately post-intervention, 1-5 months, 6-11 months, 12-23 months, 24-35 months, etc.

#### Studies with Multiple Treatment Groups

For studies where there are multiple treatment (intervention) groups, data from the same group will not be analyzed twice. The treatment condition will be selected for meta-analysis according to which one match the inclusion criteria. The comparison condition will be placebo treatment, no treatment, or alternative treatment. These comparisons will be analyzed separately. For studies with multiple comparisons, each comparison will be analyzed.

# 3.3.6 Dealing with missing data and incomplete data

When data are missing, we will attempt to contact the author(s) of the primary studies and try to obtain missing information. We will address the potential impact of missing data on the findings of the review in the discussion section.

## 3.3.7 Assessment of heterogeneity

Statistical heterogeneity in the outcome measures will be assessed using the Q-statistic and the associated *p*-value for each analysis. Random effects variance components will be reported.

The heterogeneity among included studies will also be examined through the use of the chi-square test, where a low p-value indicates heterogeneity of treatment effects. The I<sup>2</sup> statistic (Higgins et al., 2003) will be used to determine the percentage of variability that is due to heterogeneity rather than sampling error or chance.

The authors will discuss the possible reasons for any heterogeneity and conduct sensitivity analyses accordingly, where data permit. Subgroup analyses may be used to investigate this further, as described below.

## 3.3.8 Assessment of publication bias

Publication and small sample bias will be assessed with trim-and-fill analysis (Duval, 2000), along with other techniques, i.e., funnel plots to assess for the potential existence of small study bias (Higgins, 2011) depending on how many studies are in the analysis. In the event of asymmetry, the reviewers will seek input from methodologists, including the Cochrane and Campbell Methods' Groups, on appropriate analyses.

## **3.4 DATA SYNTHESIS**

Data synthesis will be conducted using RevMan (The Cochrane Collaboration, 2008) and with Comprehensive Meta- Analysis 2 (Borenstein et al., 2005).

The random effects model will be used for pooling results. If the fixed effects model fits, the between-studies random effects variance will be small or 0, and the random effects model simplifies to the fixed effects model. The random effects model is:

$$T_i = \theta_{\star} + \mu_i + e_i, \tag{1}$$

where  $T_i$  is the observed effect,  $\theta$ . Is the population average,  $\mu_i$  is the between-studies variation, and  $e_i$  is the sampling error.

If between-studies variation is negligible, then the  $\mu_i$  drops out (= 0) and we have:

$$T_i = \theta_{\cdot} + e_i, \qquad (2)$$

which is the fixed effects model.

Results for randomized and quasi-experimental designs will be pooled and reported separately. If a study reports two or more separate measures of the same outcome, then an average of the measures will be computed. Results of each outcome measure will be reported in Forest plots.

If a study has multiple outcome measures, then each measure will be analyzed separately before deciding if it is appropriate to combine effect sizes as a SMD.

# 3.4.1 Subgroup analysis, moderator analysis and investigation of heterogeneity

We expect subgroup analysis will be underpowered; however, we hope to explore the following subgroups using the ANOVA analogue:

- 1. Active versus placebo versus no-treatment controls;
- 2. High quality versus low quality studies; and
- 3. Structured diagnostic interviews versus self-report questionnaires versus both.

#### 3.4.2 Sensitivity analysis

Sensitivity analysis will be performed to explore the influence of the following factors on effect size:

- 1. Repeating the analysis excluding unpublished studies;
- 2. Repeating the analysis taking account of risk of bias elements, as specified previously (i.e., sequence generation, allocation concealment, blinding,

addressing incomplete outcomes; selective reporting, treatment fidelity, and other potential sources of bias); 3. Repeating the analysis excluding outliers; and

- 4. Repeating the analysis excluding studies using the filter: formal affiliation with EMDR and/or the EMDR Institute, Inc. and/or Francine Shapiro.

# 4 Acknowledgements

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# **6** Appendices

#### 6.1 SCREENING: STAGE 1

- 1. Does the sample consist of adults who are military combat veterans? Yes No Unclear
- 2. Is EMD/EMDR used with this sample? Yes No Unclear
- 3. Is there an experimental or parallel cohort (comparison or control group) design? Yes No Unclear
- 4. Are the outcomes related to PTSD? Yes No Unclear

#### 6.2 SCREENING: STAGE 2

- 1. Does the study use a comparison that includes placebo treatment condition or no treatment condition? Y es No Unclear
- 2. Are the outcome measures either a recognized structured diagnostic interview or self-reported questionnaire as indicated in the protocol? Yes No Unclear

#### **6.3 EXTRACTION**

#### **Report Characteristics**

- 1. First author (Last, initials):
- 2. Year of publication:
- 3. Source (e.g., dissertation, journal, book chapter, etc.):
- 4. Volume:
- 5. Pages:
- 6. Country conducted in:
- 7. Language published in:
- 8. Funding source, if any:
- Does the author(s) acknowledge any potential conflict of interest
  a. If yes, please provide the conflict(s)

#### Characteristics of Setting and Participants

- 1. Setting (e.g., outpatient clinic, hospital, military base, etc.)
- 2. Country in which sample was obtained (list all)
- 3. Number/percentage of Males:
- 4. Number/percentage of Females:
- 5. Number/percentage White:
- 6. Number/percentage Black:
- 7. Number/percentage Other:
- 8. Age in years (mean, SD, min and max):

9. Please provide a concise explanation of the procedure used to recruit participants:

#### Sampling

- 1. Sampling strategy:
  - a. Probability and stratified probability
  - b. Quasi-probability (e.g., birth dates)
  - c. Census (e.g., all combat veterans in a PTSD program)
  - d. Convenience sample
  - e. Can't tell
- 2. Sample size for treatment at the time of:
  - a. Initial
  - b. Random assignment
  - c. Pre-test
  - d. Post-test
  - e. Each follow-up
- 3. Units that the sample size for treatment represents:
  - a. Persons
  - b. Groups
  - c. Facility
  - d. Other (please provide)
  - e. Unclear
  - Sample size for control/comparison(s) at the time of:
    - a. Initial

4.

7.

- b. Random assignment
- c. Pre-test
- d. Post-test
- e. Each follow-up
- 5. Units that the sample size for control/comparison(s) represents:
  - a. Persons
  - b. Groups
  - c. Facility
  - d. Other (please provide)
  - e. Unclear
- 6. Was power assessed? Yes No Unclear
  - a. If yes, a priori or post hoc
  - Group assignment mechanism:
    - a. Random assignment
    - b. Haphazard assignment
    - c. Other nonrandom assignment
    - d. Can't tell
- 8. Assignment mechanism:
  - a. Self-selected into groups
  - b. Selected into groups by others on a basis related outcome (e.g.,
  - participants with higher intensity of PTSD placed in the treatment group) c. Selected into groups by others not known to be related to outcome (e.g.,
  - randomized experiment)
  - d. Can't tell
- 9. Equating variables
  - a. None
  - b. Prior PTSD
  - c. Other (please list)
  - d. Can't tell

#### <u>Design</u>

1. Experimental design: Yes No Unclear

#### 2. Specify design used:

#### Outcome Measure(s)

- 1. PTSD measure used:
  - a. Structured diagnostic interview (go to question 2)
  - b. Self-report questionnaires (go to question 3)
  - c. Both (respond to both questions 2 and 3)
- 2. If structured diagnostic interview, then select measure(s) used:
  - a. Structured Clinical Interview for DSM-IV
  - b. Clinician Administered PTSD (CAPS) Scale
  - c. PTSD Interview
  - d. PTSD Symptom Scale Interview
  - e. Other (please list)
- 3. If self-report questionnaires, then select measure(s) used:
  - a. Impact of Event Scale
  - b. Impact of Event Scale-Revised
  - c. Mississippi Scale for Combat-Related PTSD
  - d. Keane PTSD Scale of the MMPI-2
  - e. PTSD Diagnostic Scale
  - f. PTSD Checklist
  - g. Distressing Event Questionnaire
  - h. Other (please list)
- 4. Reliability coefficient for PTSD measure(s)
- 5. Metric for reliability coefficient
  - a. Internal consistency
    - b. Split-half
    - c. Test-retest
    - d. Can't tell
  - e. None given
- 6. Source of reliability coefficient estimate:
  - a. Current sample
  - b. Citation from another study
  - c. Can't tell
  - d. None given

#### Intervention Data

- 1. What was the duration (in days, weeks, months) of the intervention (mean, SD, min and max)?
- 2. Were manuals used? Yes No Unclear
  - a. Please elaborate.
- 3. Were fidelity checks used? Yes No Unclear
  - a. Please elaborate.
- 4. Was EMDR administered by a trained individual? Yes No Unclear
  - a. Level of education (e.g., high school, college, masters, Ph.D., other, unknown)
  - b. Discipline (e.g., counseling, medicine, psychology, social work, other, unknown)
  - c. Level of EMD/EMDR training (basic, Level 1, Level II, etc.)
  - d. Affiliated with the EMDR Institute, Inc., EMDR International Association, etc.

#### <u>Results</u>

- 1. Attrition in control: Yes No Unclear
  - a. If yes, how many?
- 2. Attrition in treatment: Yes No Unclear

- a. If yes, how many?
- 3. How many participants were excluded?
- 4. Was there follow-up? Yes No Unclear
  - a. If yes, how long?
  - b. If yes, how many?
  - Please provide effect size(s) and confidence interval(s)
- Please provide effect size(s)
  Data effect size is based on

#### Quality Assessment

- 1. Was there adequate sequence generation (selection bias)? Yes No Unclear
- 2. Was allocation adequately concealed (selection bias)? Yes No Unclear
- 3. Was knowledge of the allocated interventions adequately prevented during the study (detection bias)? Yes No Unclear
  - a. Participants and personnel
  - b. Outcome assessors
- 4. Were incomplete outcome data adequately addressed (attrition bias)? Yes No Unclear
- 5. Are reports of the study free of suggestion of selective outcome reporting (reporting bias)? Yes No Unclear
- 6. Was the study apparently free of other problems that could put it at a risk of bias? Yes No Unclear

# 7 Contribution of authors

David Albright drafted the background, objectives, and method sections of the protocol. Bruce Thyer reviewed and suggested changes to the protocol. Betsy Becker reviewed and suggested changes to the method section. Allen Rubin reviewed and suggested changes to the background section.

# **8 Declarations of interest**

Mr. Albright and Dr. Thyer have a narrative review on this topic published in the journal, *Behavioral Intentions*. Dr. Rubin has published nine articles on EMDR; none of them focusing on the military or combat veterans. Otherwise, none reported.

# **9 Sources of support**

## 9.1 INTERNAL SOURCES

No sources of support provided.

### 9.2 EXTERNAL SOURCES

No sources of support provided.