Author’s response to reviews

Title: Metacognitive therapy vs. eye movement desensitization and reprocessing for posttraumatic stress disorder: Study protocol for a randomized controlled trial.

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Author’s response to reviews:

Dear Editor Dr. Jochen Raimann

Thank you for accepting a revised version of our paper. I declare that all authors have agreed to accept authorship of this manuscript and they have all permission to access the reported data that is collected in the study.

Here are our comments to the reviewer in chronological order:

Reviewer #1:

(1)  Thank you for the opportunity to review this protocol for an RCT of MCT vs EMDR. MCT for PTSD has produced promising results in previous trials. Yet, there is still a lack of sufficiently powered RCTs that investigate the effects of MCT vs relevant control groups. As such, this study is highly important, as it will strengthen our knowledge on the effectiveness of MCT compared to a frequently used, evidence-based treatment, namely EMDR.

COMMENT: Thank you!
(2) I believe the following could be clarified:

In the abstract, for clarity please add "follow-up" after 3 and 12 months --> 3 and 12 months follow-up.

COMMENT: Done, page 2

(2) In the section regarding participants, it is stated that patients with severe depression are excluded. How is this defined and determined?

COMMENT: MDD was assessed in a clinical interview using ADIS-IV pre-treatment, and also the patients were checked for suicidality and severity of depression. No patients were excluded at pre assessment for severe MDD or acute suicidality.

(3) PDS: the scoring of the PDS could be described more clearly. From the text it is not clear that the symptom severity score comprises the 17 items related to DSM-IV symptoms.

COMMENT: We agree- and we have tried to simplify the text- see page 6.

Reviewer #2: This is a valuable study, important to the field of PTSD treatment.

I have a few minor comments:

(1) Background on EMDR should be updated with the latest theories and findings.

a. The authors indicate that "There is currently no empirically supported model of the therapeutic mechanisms of EMDR: however, there is a theory that, over the past years, has received

b. The authors presume that EMDR works because of "overlaps with core components of CBT, such as imaginal exposure and cognitive restructuring of negative trauma-related cognitions", however in a meta-analysis by Lee & Cuijpers (2012) it was demonstrated that the eye movements have significant additional value.

COMMENT: We believe that this position, although with mounting evidence, is debatable. Although the theory of EMDR posits that negative, trauma-related cognitions (and emotions and behavioral responses) are due to inadequately processed memories of traumatic life events, there is still a substantial focus on cognitions as part of the reprocessing of traumatic memories [1, 2]. Furthermore, there is still substantial controversy whether bilateral eye movements lead to better treatment outcomes [3] or not [4, 5]. The meta-analysis by Lee and Cuijpers [3] indicated that EMDR treatment with eye movements was somewhat superior to EMDR without eye movements (d = 0.27, 95% CI [0.07-047]), although it is important to note that the studies included in the meta-analysis had high risk of bias and that the meta-analysis has been heavily criticized [4]. On this background, Sack et al. [6] conducted a fairly rigorous and stringent RCT comparing three conditions in the treatment of PTSD: (1) EMDR with bilateral eye movements to EMDR vs. (2) EMDR without bilateral eye movements but with eyes fixated on a nonmoving object vs. (3) EMDR without the explicit task of fixating eyes on an external object. Sack et al. reported that EMDR with bilateral eye movements or with eyes fixated on a non-moving object achieved somewhat better outcome compared to EMDR without the explicit task of fixating eyes on an external object. According to Sack et al. their results indicate that a potential explanation for the treatment effects of EMDR is the explicit training of dual attention in session. However, it is important to note that dismantling trials such as the one by Sack et al. does not in itself provide sufficient evidence regarding potential mediators and mechanisms for treatment outcome [7]. As such, we will still maintain that we do not have satisfactory knowledge about mediators of treatment outcome for EMDR specifically or trauma-focused treatments in general. This is in line with a recent review comparing the commonalities and differences between a number of effective treatments for PTSD, where the authors concluded that “[a] better understanding of underlying mechanisms of action is clearly needed” [1].

However, based on what reviewer #2 have pointed to- we have now incorporated the following paragraph in our manuscript: “A number of theories explaining the potential mechanisms underlying the effects EMDR has been proposed [e.g. 8]. The importance of bilateral eye movements are often highlighted, but there is still substantial controversy whether bilateral eye
movements are of importance [3] or not [4-6]. It is also important to note that dismantling randomized controlled trials comparing EMDR with and without bilateral eye movements does not in itself provide sufficient evidence regarding potential mediators and mechanisms for treatment outcome [7]. To the best of your knowledge, to date there has not been conducted any RCTs of EMDR that incorporate the investigation of potential mediators of treatment outcome as outlined by Kazdin [7]. As such there is still a pressing need for trials investigating potential mediators of treatment outcome of trauma-focused treatments generally and EMDR specifically [1].” See this comment inserted on page 3 and 4.

2. It is not clear from the introduction what MCT actually is; please elaborate a bit more (1-2 sentences) on how MCT targets metacognitive beliefs.

COMMENT: We have now added a few sentences- see page 4: “Metacognitive beliefs are beliefs and theories people have about their thinking and how to regulate their thoughts. It could be beliefs that thoughts have a special meaning (i.e. sinful thoughts) or that thoughts may be harmful or uncontrollable. The metacognitive beliefs are hypothesised to underlie an unhelpful response style consisting of worry, rumination and threat monitoring, and other coping strategies such as attempting to fill gaps in memory”

3. It is hypothesized (h2) that MCT will outperform EMDR. Please provide the relevant references (showing differences in effect sizes)

COMMENT: Normann’s [9] meta analysis of MCT is a useful source showing the ES for MCT of PTSD. The ES and recovery rates reported for MCT are high, with 80% recovery and ES between .97 and 2.8. See Normann, Emerik and Morina, 2014 [9] for an meta-analysis of MCT. This reference is now included on page 5, bottom. In addition, Wells et al (2015) showed that MCT performed significantly better than PE in an RCT, and this make us hypothesise that MCT will perform better than EMDR also, as EMDR and PE has shown similar effects in meta-analyses. These references are included in the paper now.

4. Patients with psychotic symptoms, alcohol or drug abuse, suicidality will be excluded from participation. How will these symptoms/disorders be assessed?

COMMENT: These patients will be assessed pre-treatment by using ADIS-IV.

5. Patients will be subjected to stratified randomization according to presence and severity of borderline personality traits (p6-top). At the same time patients with borderline personality
disorder will be excluded (p6-participant section). This (possible) discrepancy should be clarified.

COMMENT: We wrote the text to illustrate that many patients with PTSD also have some BPD features, but not the full diagnosis. Those with 4 criteria fulfilled were included in the stratified randomisation- and we have included this in the text in parenthesis, see page 6, first paragraph.

Thank you!

Additional references included: