Reviewer's report

Title: MI-SPRINT (Myocardial Infarction - Stress PRevention INTervention): Study protocol of a randomized-controlled interventional trial to reduce the incidence of posttraumatic stress after acute myocardial infarction through psychological counseling

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Reviewer: Ian M Kronish

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The manuscript “MI-SPRINT: Study protocol of a randomized controlled interventional trial to reduce the incidence of posttraumatic stress after acute myocardial infarction through psychological counseling” describes the protocol for a randomized trial comparing the effectiveness of two early (in-hospital) psychological interventions aimed at reducing MI-triggered PTSD symptoms. One of the interventions involves a 45 minute individual counseling session that targets MI-triggered traumatic reactions. The other intervention is a 45 minute counseling session that focuses on the general role of psychosocial stress in coronary heart disease without explicit reference to the potential for traumatic reactions. The primary outcome is PTSD symptom severity at 3 months.

The authors provide a nice review of the evidence linking PTSD with adverse outcomes after MI and hence provide a good rationale for performing this trial. Relying on early brief interventions to prevent PTSD after other types of trauma, they provide good justification for their choice of their trauma-focused intervention. They also succinctly describe key components of the intervention, addressing the majority of the items in the CONSORT checklist. Nevertheless, their description of their protocol could be improved by addressing the following comments:

Major compulsory revisions

1. The abstract states that the aim of study is to examine whether psychological counseling reduces the development of post-traumatic stress. However, both groups receive counseling. While the use of an active control group can be considered a strength of the study, it would be helpful if the authors clarify their main hypothesis. Is it to test whether trauma-focused counseling is more effective than non-trauma focused counseling? The title might also make this distinction more explicit.

2. The primary outcome measure was confusing. In the abstract and measures sections, they state that an interviewer-rated measure will be used. However, in their sample size calculation, they refer to the self-rated PDS.

3. The intervention is the most novel aspect of their report. Additional details about the interventions should be provided. Was there a manual developed? According to any specific theories? Was there any monitoring to ensure
adherence to the intervention protocol? While the level of training of those delivering the intervention was specified, how much training on each specific intervention took place prior to beginning the trial?

Minor essential revisions
1. The abstract should state the statistical test used for their primary outcome. 2. What measure was used to assess MI-triggered distress (a key inclusion criteria)? Was it a single-item question? Please provide additional details.
3. Please state whether there was an assessment as to the effectiveness of blinding of outcomes assessors?
4. Please state whether the analysis will be based on the intention to treat principle.
5. In Table 2, please specify what T0, T1, T2 refer to.

Discretionary revisions
1. Consider providing additional detail on definition of NSTEMI and NSTEMI in study. Did a study cardiologist confirm determinations? Based on chart reviews?
2. It wasn’t clear on what basis the authors assumed that patients would have a 1.0 point reduction on the PDS in the control group. It might be helpful to show how much power they had to detect various differences in the change scores in PTSD symptoms between intervention and control groups.
3. The authors’ primary analysis will compare the differences between the 2 groups after accounting for baseline differences in sociodemographic, clinical, and received psychotherapy. This, however, may take away some of the benefits of the randomization. It may be more appropriate to do a primary analysis without accounting for these covariates, and a sensitivity analysis with their inclusion.
4. The authors provide scant detail as to which measures will be used for their key secondary outcomes. They provide a Table with numerous measures. It might be helpful to state which of these are key secondary outcomes and which are exploratory. Given the numerous measures, there is possibility for type 1 error in finding significance in one or more of these outcome measures.
5. The discussion of the persistence of PTSD to 12 months in the sample size discussion was confusing as the primary outcome on which the study was powered was 3 months and the outcome is on PTSD symptoms not PTSD diagnosis. Consider reframing this section.
6. While the writing is acceptable, there were several grammatical errors that made the manuscript difficult to follow in places.

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a
statistician.

Declaration of competing interests:

I declare that I have no competing interests.