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

Version: 3 Date: 30 July 2013

Reviewer: Donald Edmondson

Reviewer's report:

The Myocardial Infarction Stress Prevention Intervention (MI-SPRINT) trial, as described by the authors in this protocol, is an exciting new development in the field of psychosomatic medicine. It is designed to determine whether a brief early psychological intervention can reduce MI-triggered PTSD symptoms and secondarily cardiovascular risk factors. The results of this trial will be of broad interest to psychologists, psychiatrists, cardiologists, and internists, and could have an impact on the acute management of MI patients.

One major revision that would strengthen the current work would be a description of the cardiometabolic assessments that the authors plan to analyze as secondary outcomes.

All of the other suggestions that I make below should be considered discretionary, as they are meant to elicit the authors' thinking about aspects of the study design for the benefit of others in the field. Perhaps a brief section in the Discussion on Design Considerations would stimulate other researchers' thinking about how to interpret the results of this trial and how to design trials of their own.

1. Why have the authors chosen PTSD symptoms at 3 months post-MI, rather than 1 month, as the primary outcome? PTSD can be diagnosed at 1 month, PTSD symptoms at 1 month post-MI have been associated with recurrent cardiovascular events, and there may be greater variability in symptoms at 1 month.

2. Why have the authors chosen to exclude patients with severe depression, and how will that designation be made?

3. The potential for this intervention to reduce cardiovascular risk factors is very exciting. I wonder whether the intervention might offset recurrent CVD event risk. Will the authors test this in an exploratory analysis?

4. How will the authors deal with the changes in PTSD criteria in DSM-V?

5. The authors have designed a study comparing 2 active interventions. Did they consider simply comparing the trauma-focused intervention to usual care?
6. In the statistical analysis, the authors plan to replace missing items with the mean of completed items. Was there a discussion of other imputation techniques?

7. While this article may not be the most appropriate place to publish them, the information booklets for the two arms would be of great interest to many in the field, and seeing them would help researchers and clinicians to interpret the results of this trial and plan future research to offset PTSD risk.

8. Finally, as the authors note in the manuscript, the environment of medical care may influence both the acute stress that MI patients experience, as well as the development of PTSD symptoms after the event. Is there a way for the authors to retrospectively estimate CCU environment factors such as crowding or acuity of adjacent patients during participants’ CCU stay?

In conclusion, the authors should be commended for designing a timely and important trial to address a common and debilitating outcome of MI. I look forward to the results.

Level of interest: An article of outstanding merit and interest in its field

Quality of written English: Acceptable

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.