Reviewer's report

Title: Feasibility of a Tapering Opioids Prescription Program for Trauma Patients at High Risk of Chronic Consumption (TOPP-Trauma): Protocol for a Pilot Randomized Controlled Trial

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Reviewer: Brent Moore

Reviewer's report:

The manuscript presents the protocol for a randomized clinical pilot trial of a behavioral counseling intervention. The context of the study is distinctive because the study is aimed at prevention of OUD in trauma patients. The design and methods are generally standard for clinical trials of behavioral interventions. However, there are several concerns regarding the study and the manuscript.

1. The manuscript needs better clarification and justification for the study. The background/introduction needs more information on the justification for this specific study rather than the broad review of characteristics of the opioid crisis, and the broad overview of interventions. Presentation of the closely related studies using iPACT-E-Trauma would be useful given that the content is stated to be the same as TOPP-Trauma. Justification for face-to-face counseling is needed and why the iPACT-E-Trauma is not sufficient. In addition, justification for a pilot trial rather than a full randomized clinical trial should be clearly stated.

2. Similarly, there is confusion in presentation of the purpose of the study. The title states that the focus is on the feasibility, while the methods include section on primary and secondary outcomes, with the focus being that the primary outcome will be morphine equivalent dose. There is discussion of research methods feasibility, but limited discussion of feasibility of delivery of the intervention. How will the outcome of the study determine whether a larger-scale trial is truly feasible? Because the control group does not have counseling sessions, feasibility for variables such as session attendance cannot be compared across condition and thus need to be established a priori. Justifiable a priori levels can also be set for patient acceptability, engagement, and treatment completion. These measures can be informed by the prior studies with the same content delivery (iPACT-E). Feasibility could be established by addressing whether patient engagement is at or above the level of those prior trials or some other justifiable level.

3. If feasibility is the study focus, justification for the use of a randomized clinical trial is needed. Most evaluations of feasibility of behavioral interventions can be evaluated in a single arm trial, so additional justification is needed.
4. It is odd that patient acceptability is not evaluated as a potential indicator of study feasibility.

5. The use of a treatment-as-usual control group should be justified for the pilot RCT. The study has the potential for a clear time-and-attention bias which generally inflates the estimated effect size, particularly in a small-scale trial. Was there a rationale for not including a time-and-attention control condition?

6. Although there is general information on the assessments included, and the program broadly, there's insufficient detail on what will actually occur in the counseling sessions. How will the 15-minute sessions be structured, what content will be covered in each of them, and what will be the goal of each session? Is there a level of counseling engagement that corresponds to a sufficient dose of the intervention? How will fidelity of counseling delivery be measured. Fidelity is commonly examined in pilot studies of counseling interventions. How will you know that the counseling is being delivered competently?

7. The assessments include evaluation of opioids at community pharmacies and non-opioid analgesics but stated components of the intervention are the use of non-pharmacological strategies for pain management, health promotion strategies, and return to preferred activities. It is unclear why these are not being assessed.

8. The sample size justification should not only focus on collecting data for effect size estimation, but also on whether there will be sufficient data to determine feasibility.

The paper could use some additional editing and proofreading.

1. It is odd to see p values in a background/introduction, and unclear how they are informative given the citation to published work.

2. The subheadings do not add sufficient information to the background section.

3. There are a number of typos in the manuscript. (e.g., line 131,343,

4. Inclusion of the number of patients in the pilot study should be provided in the last paragraph of the introduction.

5. Given that many readers may be focused on opioid use disorders, and have psychiatric backgrounds, clarification that trauma is physical traumatic injury could be helpful to
differentiate from psychological traumatic injury. In the inclusion criteria, examples of traumatic injury would be useful.

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