Author’s response to reviews

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 comment #1:

It is still unclear why treatment acceptability is not assessed directly rather than only being referred from factors such as retention and attendance. Why not ask patients what they think of the intervention and study procedures?

Answer:

In addition to factors such as retention and attendance, we will use the Treatment Acceptability and Preference Questionnaire to assess TOPP-Trauma acceptability. We have added specifications with regard to this questionnaire under the section Feasibility. This validated questionnaire includes four acceptability attributes (i.e., perceived effectiveness, appropriateness, suitability, and convenience). An open-ended questions was also added at the end of the questionnaire to gather input on the modifications required to improve intervention acceptability. We added details on how we will analyse data collected with this questionnaire in the Data Analysis section.
Reviewer comment #2:

The use of the TAU rather than a time-and-attention control is somewhat justified, but the limitation section should note this as a limitation of any inference regarding clinical outcomes. Such factors should be useful in informing design decisions regarding a full scale efficacy trial.

Answer:

We acknowledged the use of an educational pamphlet only for the control group as a limitation in the Study Limits section. Although patients at high risk for opioid chronic consumption likely require the implementation of strategies from qualified health professionals, we mentioned that we will consider the contribution of the attention received in the interpretation of findings and that we will plan for a three-arm full-scale RCT to control for the effect of this factor when testing the efficacy of TOPP-Trauma.