Author’s response to reviews

Title: A type II implementation-effectiveness hybrid quasi-experimental pilot study of a clinical intervention to re-engage people living with HIV into care, ‘Lost & Found’: an implementation science protocol

Authors:

Joseph Cox (joseph.cox@mcgill.ca)
Blake Linthwaite (blake.linthwaite@mail.mcgill.ca)
Kim Engler (kimcengler@gmail.com)
David Lessard (david.lessard2@mail.mcgill.ca)
Bertrand Lebouché (bertrand.lebouche@mcgill.ca)
Nadine Kronfli (nadine.kronfli@mcgill.ca)

Version: 3 Date: 25 Oct 2019

Author's response to reviews:

Hamde Nazar
Pilot and Feasibility Studies

October 23, 2019

Dear Hamde Nazar and Lehana Thabane,

Re: PAFS-D-19-00134

A type II implementation-effectiveness hybrid quasi-experimental pilot study of a clinical intervention to re-engage people living with HIV into care, 'Lost & Found': an implementation science protocol. Joseph Cox, MD MSc FRCPC; Blake Linthwaite, MScPH; Kim Engler, PhD; David Lessard, PhD; Bertrand Lebouché, MD PhD; Nadine Kronfli, MD MPH DTM & H FRCPC
Thank you again for your review and related comments/questions. I am re-submitting the protocol taking into consideration your feedback, with tracked changes in the re-submitted documents and direct responses to your comments below.

As a non-randomized pilot study (a type of study which falls under the umbrella of feasibility studies), we wrestled with how best to present the overall ‘feasibility of implementation of the intervention’ as you propose. The concern is related to “feasibility” as a distinct implementation outcome in our work vs. feasibility studies as “an overarching concept for studies assessing whether a future study, project or development can be done” (Eldridge 2016). To make this distinction, therefore, we refer to the “viability” rather than “feasibility” of the project to propose a larger trial as an overall objective of our study. Please let us know if you have any concerns with this approach. With this in mind, here are direct responses to your comments:

1) Abstract: The statements of the objectives need to clearly state that the primary aim is to assess feasibility of implementation of the intervention.

RESPONSE: A statement to this effect has been added on page 2, in the background section of the abstract.

2) Similarly, the primary objective(s) of the study needs to be framed appropriately as to evaluate feasibility and acceptability of implementation of the intervention.

RESPONSE: We have added statements on page 11 to clarify that our two primary aims contribute to the overall objective “to determine the viability of a multisite stepped-wedge cluster randomized trial.”

3) Please state the criteria for evaluation of the success of feasibility.

RESPONSE: Explicit statements about evaluating viability for a larger trial have been added to pages 17 and 20.
4) Please justify the sample size, and this needs to be based on the primary feasibility objectives.

RESPONSE: A statement about sample size has been added to page 20.

5) Please refer to general guidance for pilot and feasibility studies for non-randomized studies to ensure that you have covered all the key aspects, and include an adapted checklist with the submission: https://pilotfeasibilitystudies.biomedcentral.com/track/pdf/10.1186/s40814-019-0499-1

RESPONSE: Thank you for this helpful resource. We have submitted the CONSORT extension checklist along with the protocol.

Again, thank you for this additional feedback. I hope the revised manuscript is acceptable for publication in Pilot and Feasibility Studies.

Best wishes,

Joseph Cox, MD MSc FRCP(C)
Associate Professor