Author’s response to reviews

Title: Testing the Leadership and Organizational Change for Implementation (LOCI) intervention in Norwegian mental health clinics: A stepped-wedge cluster randomized design study protocol

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Point by point response to the editor

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<td>1a</td>
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<td>Identification as a randomized trial in the title</td>
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<td>2b</td>
<td>7</td>
<td>The hypotheses were included in the background section instead of the method section.</td>
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We added a sentence on how sample size was determined: “Based on the capacity of the project group, we calculated that we could include 47 clinics. We then calculated the power based on the sample size.”

A comment was added to describe the random allocation sequence:

“Allocation will be determined by an independent statistician using computer generated random number sequence”.

We added description of the type of randomization and allocation:

“Allocation will be determined by an independent statistician using computer generated random number sequence. The 15 adult clinics will be randomized into three cohorts of size five based on co-located or closely working clinics (to reduce the chances of contamination), number of practitioners (< 20 or >= 20), and the number of practitioners per LOCI leader (<15 or >= 15). For the seven health trusts encompassing the child clinics, a similar process will be used to assign them to three cohorts of size 2, 2, and 3. The variables that will be used in balancing are the total number of practices within the health trust, number of therapists trained to deliver TF-CBT, weighted centralization index, and number of municipalities served.”

We have added the following trial limitations:

“It is a strength that the design enables all clinics to receive the same implementation strategy, in addition to examining the effect of the LOCI program. However, the time gap between therapists receiving training in the PTSD treatment interventions and the leaders receiving training in the LOCI program might not be optimal for the implementation of the interventions in the last two cohorts. Moreover, even though clinics were randomized to avoid contamination between them, it might be a small chance of some contamination between clinics that are geographically close to each other.”

Role of funders was added with the following in the declarations: “The funders have no role in planning, designing, and analysing the results.”

Flowchart has been added on page 29.