Author's response to reviews

Title: Community-Based Navigators for Tobacco Cessation Treatment: a proof-of-concept pilot study among low-income smokers

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Author's response to reviews: see over
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Prof Asgeir R. Helgason
Mr Proel Vargas
BMC Public Health

Re: Manuscript ID 8215674191546365.

Dear Prof Helgason and Mr. Vargas,

We are submitting a revised version of the manuscript titled "Community-Based Navigators for Tobacco Cessation Treatment: a proof—of-concept pilot study among low-income smokers." We appreciate the reviewers' helpful comments and have made changes that we believe improve the manuscript and address the feedback. This letter provides point-by-point description of our responses.

Sincerely,

Reviewer 1:

Comment: The intervention in this study is very interesting in the way to reach smokers in special setting with high priority. The result is promising in moving people into more action and quit attempt and guidance in methods and support to stop smoking. The reading is interesting

Response: We thank the reviewer for these endorsements.

Comment: … background and method section needs to be more separated. For example line 104-106; 107-117; 126-140 is a mix.

Response: We have restructured the background and methods sections to make this separation.

Comment: In the Method section the paragraph “What to call navigators” and “Guide hiring” can be merged and moved up after “Study site.”

Response: We have made these changes.
Reviewer 1:

- Major Compulsory Revisions
1. It does not appear as though the authors took into account the different waves for many of the outcomes. It seems rather that they only reported both Wave 1 and Wave 2 for mean time to follow up, and not on any of the cessation outcomes. It is suggested that the authors report the outcomes for both waves, and then examine if there are any statistical differences between them, although that might be difficult because of the difference in sample size. They do need to account for the different waves in the outcomes, though, especially given the differences in sample size. There is also no discussion of what may account for the difference, which is important as well.

Response: Planned time to follow-up was intentionally changed from six months in Wave 1 to three months in Wave 2 in order to reduce attrition. Such adjustments based on formative (midstream) assessments are common in feasibility studies. We had noted the protocol change in the original manuscript (revised version lines 249-250) and have now added the phrase "to increase retention for outcome measurement" as the rationale (revised line 250).

We appreciate the reviewer's point that the waves might have enrolled different participants or led to different outcomes based either on time to follow-up or differences in the populations. To examine this possibility, we have now compared all study measures between waves, including participant characteristics (table 1), smoking and cessation history (table 2), and study outcomes (table 3). We tested binary outcomes for significant differences using Fisher's exact statistic, median outcomes using binomial tests, and mean outcomes using t-tests. We also modeled 7-day point abstinence as a logistic regression function of time to follow up. Power to detect significant differences was extremely low given the sample sizes (n=28 and n=12). (We do not know a reason for concern about unequal sample sizes.)

We found no significantly different outcome between waves, and only two baseline measures were different: Wave 1 participants were more likely to report first cigarette within 30 minutes of waking (79% vs. 42%, p=0.03) but also more likely to have baseline CO levels in the study range set as the criterion for abstinence (<10ppm; 29% vs. 8%).

In light of these results, we still show combined results in Table III; to avoid confusion, we have replaced wave-specific time to follow up in the table with combined time to follow up. We now note the absence of significant outcome differences between waves, along with the difference in time to follow up, at lines 307-308.

2. In the introduction, the authors discuss Motivational Interviewing as part of the role of the navigator, and motivation as a barrier to quitting. The discussion would benefit from a more nuanced discussion of the fluctuations in motivation among SED, and not just the population of smokers. Are there certain considerations that need to be taken into account when conducting MI with this population? The link between stressors of SED and fluctuations in motivation could be more
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Explicit.

Response: We agree with the reviewer that SED may interact with cessation motivation, and we discuss this indirectly at revised lines 82-99. We are unaware of studies of SED and cessation motivation stability, and although MI is appropriate for working with ambivalence, we have no knowledge or experience on which to discuss these points.

- Minor Essential Revisions
1. Some portions of the introduction are confusing and not worded well. For instance, the authors talk about “health coping resources”, but do not define the terms.
   Response: We have replaced the phrase "health-supporting coping resources" with a commonly used term, "healthy coping strategies."

2. The authors discuss the difficulty of adhering to cessation treatment in general, but do not explicitly discuss this in relation to SED (lines 100-103). It would be helpful to discussed why SED specifically have trouble adhering.
   Response: The demands of treatment that may challenge SED smokers are described at revised lines 93-96. We have added explicit discussion of this point at revised lines 97-99.

3. Daily smoking does not seem to be included as an inclusion criterion for the study, and the results section reports that 98% were daily smokers. The authors should provide some rationale for this decision in the methods section.
   Response: We have added the rationale with citation at revised lines 238-240.

4. Authors need to justify a 12-session protocol.
   Response: We have added the explanation at revised lines 211-213.

5. A discussion of the guides' previous experience regarding mental health counseling would be appropriate, given their responsibilities.
   Response: We have added explanation at revised lines 199-201 that guides were lay people who were not expected to have mental health counseling training or experience.

6. Authors did not exclude participants for endorsing psychotic symptoms. Was there a measure in place for determining if they were fit to participate?
   Response: Participants were already engaged in Head Start activities. We did not measure psychotic symptoms and relied on Head Start participation as establishing fitness to participate in smoking cessation.

7. A limitation that is not mentioned is that the authors have relied on self-reported mental health diagnoses, which can often be unreliable, especially in that population.
   Response: We have added this limitation at revised lines 406-407.

- Discretionary Revisions
1. Although not essential, it would be interesting/useful to examine the relation between the qualities of the guides and outcomes (duration of abstinence, motivation, etc.).
Response: We find this a very interesting question but feel the data are too sparse to support the suggested analysis.

2. Another interesting analysis could be to look at the relationship between mental health diagnoses and outcomes.
   Response: Again, a very interesting question but data are too sparse.

3. A discussion of which participants may be most likely to access which EST might be useful, and if the authors recommend any one treatment over another? This is not an essential revision, just a suggestion that would require additional analyses.
   Response: The authors endorse the published clinical guidelines for cessation treatment, which recommend offering cessation counseling and first-line cessation medication to every smoker who is ready to attempt quitting. The data are too sparse to associate characteristics with choice of treatment.

4. The discussion section talks about the unique stressors associated with quitting smoking among SED, but would benefit from a more extensive discussion on how to tailor smoking cessation treatments to SED (i.e. incorporating stress management techniques) within this context. This may be useful and will bolster the argument for tailored treatments for this population.
   Response: The reported study was funded under a national call to investigate this very question, how to tailor smoking cessation treatment to SED. In the current manuscript, we report our intervention design considerations at some length in order to contribute to this field, but the pilot study was not designed to assess efficacy and the field is not yet informed enough for us to feel confident addressing the larger question.

5. Lines 207-209 (methods) are somewhat confusing.
   Response: The words "[52%] of households" were inadvertently dropped and have been restored.