Reviewer's report

Title: Feasibility and acceptability of a multiple risk factor intervention: The Step Up randomized pilot trial

Version: 1 Date: 27 December 2010

Reviewer: Kristin Schneider

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Reducing multiple disease risk factors is critical to reducing disease rates, but is a relatively understudied area. Pilot studies like the proposed project are important for informing intervention efforts and directing further research. This study has a number of strengths including its high follow-up completion rate, the integration of evidence-based treatments for depression, and the clarity and quality of writing. There are a few limitations that should be acknowledged and addressed to strengthen this manuscript’s contribution to the field.

Major Compulsory Revisions

The authors do an excellent job of stressing that this is a pilot trial, not powered to detect differences in risk factor outcomes, and recommend caution when interpreting their results. However, they focus exclusively on the positive trending outcomes of change for the intervention condition, neglecting the fact that the control may have actually done better in some instances, though differences are not statistically different. For example, while intervention participants reported a greater increase in moderate intensity physical activity, control participants reported a greater increase in vigorous intensity physical activity. Combining minutes of moderate and vigorous activity results in a greater total for the control compared to the intervention group. The authors should consider a more balanced presentation of these results if they are going to mention that “several of the observed measures appeared to trend in the expected direction.”

In the statistical analyses section the authors state that the analyses were "intent to treat", yet t-tests and chi-squares were used for the analyses which do not allow for missing data, and there were participants who did not complete the follow-ups. For smoking abstinence, missing data was reported as smoking (as described in the assessment section), but it is unclear what was used for the other outcome variables. The authors should consider using analyses that allow for missing data or at a minimum, report the type of imputation that was used.

The authors make the point in the discussion that only 13% of the participants who were contacted about the study were deemed eligible and note that this may reflect the challenge of recruiting individuals with 3 risk factors. However, according to the baseline mean and the fact that some participants were recruited with physical activity levels that they would need to “maintain”, a significant percentage of participants may have only met two of the risk factors (smoking and moderate depression symptoms). Certainly, since this is
self-reported data and individuals tend to over-report their participation in moderate physical activity, it is likely that individuals who were reporting > 150 minutes of physical activity were not getting the recommended amount, which may explain why the authors switched to the IPAQ criteria for eligibility. Clarification of how many participants met two risk factors and how many met three is recommended.

Minor essential revisions
In the methods, mention that 7-day point prevalence abstinence is self-reported.

In the results section under the “Impact on mood, smoking and physical activity” heading, please clarify in the sentence beginning “Although group differences were not statistically significant,” that you are referring to the mean SCL-90 scores.

The step up workbook and the homework assignments had the lowest ratings for being helpful. I’m wondering if there are other specific ways the authors are considering improving the use of these components or if they have insight as to why these components were rated the lowest.

The fact that depressive symptoms significantly improved for the intervention participants compared to the control participants raises a few questions that the authors could consider addressing.

1) Might the significant change in depressive symptoms, compared to the other behaviors argue for addressing mood prior to improving other risk factors? Or is it premature to raise this issue based on the fact that the risk factor outcomes were not powered to detect differences?

2) Participants, if taking an antidepressant, were only required to be on it for one month. It is likely that a percentage of those individuals taking an antidepressant for just over a month may have had their dose increased or switched medications. Additionally, participants not taking a medication at baseline may have started a medication during the 6 month study. Do the authors have any data on medication changes and whether those changes were equally distributed between the two conditions?

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests.