Reviewer's report

Title: ENTER: Rationale and design of a cluster-randomized controlled trial evaluating a collaborative smoking cessation intervention in primary care

Version: 1 Date: 19 August 2015

Reviewer: Sophia Papadakis

Reviewer’s report:

This study reports on the rationale and design of a clustered randomized trial of a smoking cessation intervention for heavy smokers or those with COPD/CHD. The study design is sound and well described. Below is a list of suggested revisions that would further strengthen the paper that should be addressed prior to publication.

Major Revisions

1. Please provide additional detail on economic analysis, it is clear a cost-utility analysis is being planned. Please provide perspective (patient, health care system, insurer) and what/how costs will be calculated of the intervention but also if appropriate the medical costs savings.

2. Para 285 – please provide more details on effect size assumptions. The calculations used are based on 30% abstinence rate at 12-months. This appears to be consistent with eval of program (as per discussion) reference this in the sample size justification and/or if it is based on another source then note that. I did not see reference to what we assumed cessation rate would be in control group – this should be added and it was unclear to me if this was considered in the sample size calculation. If I am correctly understanding the assumption is 10% in control 30% intervention with difference of 20%. If this is the case – make this more overt so we are not guessing.

3. Para 290 – please provide a source to support the ICC of 0.05.

4. Please identify how patients lost to follow-up will be treated in the analysis ie. Assumed to have returned to smoking, replaced with imputation, removed from analysis.

Minor Essential Revisions

5. Title page – add country to institutional affiliations

6. Para 165 – inclusion criteria, please provide rationale for inclusion of only heavy smokers and/or suffer from COPD or heart disease.

7. Para 175 – provide detail on how presence COPD and/or heart disease will be assessed ie. standardized test, physician diagnosis, event etc.
8. Para 230 - 1st sentence, repetitive, please remove

9. Please add declaration of conflict of interest statements for co-authors.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests.