Reviewer’s report

Title: We Can Quit2 (WCQ2): A community-based intervention on smoking cessation for women living in disadvantaged areas of Ireland: study protocol for a pilot cluster randomised controlled trial.

Version: 0 Date: 07 Jan 2019

Reviewer: Christine Bond

Reviewer's report:

Thank you for asking me to review this interesting protocol. I have many small comments to make that I would ask the authors to address in a revised version of the paper these are summarised below.

1. In the abstract/method, the description of the clusters is confusing and I would prefer the wording used in the main paper to be used here ie to say 'four matched pairs of districts (eight clusters)'.

2. Also in the abstract line 63, whilst I understand why it is 97 per arm, this does not make sense when you're multiplying 25 x 8.

3. The background is well described justifying the study. However I feel there should be more in the background to clarify what standard practices is and the principal difference that is being introduced with the intervention.

4. Line 162, I would delete 'planned'

5. Line 191 refers to the cluster recruitment which seems to be dependent on the local area advisory groups. These LAGS need to be explained more clearly. How many are there in the whole of Ireland, how big they in terms of population, what is the size of the potential target population ie the number of women who are could be eligible, and how were the four LAGS selected out of all the possible LAGs. The ordering of this section, from line 191 to 207 also needs reflecting on as at the moment it isn't quite logical/chronological.

6. Line 208 onwards -again this paragraph on eligibility criteria could be rationalised so that the first reference to eligibility criteria would say 'fluent English speaker', making the text in line 205 redundant.

7. Line 213 there is a typo "who are have been prescribed'. And it is not clear from later how people already on nicotine replacement therapy or bupropion or e-cigarette are managed within the study.
8. Line 225 this refers to the sample size and again it would be good if the likely eligible population in the district were quantified, and the percentage of these which the 39 who were initially recruited represents as well as citing the 74% of those followed up.

9. Lines 236 - 238 refer to needing to understand recruitment and retention rates for the usual care group, but given the randomisation is after recruitment it is only retention rates in the usual care group that need to be assessed.

10. I wonder if the Consort extension for Pilot and Feasibility studies, has also been used in drafting this protocol.

11. Lines 246-48 Approach for managing withdrawal of consent and subsequent exclusion needs justifying, as removing these participants from the sample affects the intention-to-treat analysis, and normally Ethics will allow you to use data collected up until that point.

12. Line 251-255 needs to make clear exactly how the intervention will be promoted in order to raise awareness and for people to self-select into the program

13. Line 280 -287 the tenses in this paragraph are muddled. There is a reference to 'who will have developed' and 'will have been' and I think that this should be 'who will develop' and 'will be'. A protocol should be in the future tense

14. Line 286-287 I am not sure that it is appropriate to inform the participants of their 'allocation' group as this suggests they are being told they are in the 'intervention' or 'usual care' group; rather they will be informed of the support program they will be receiving but it shouldn't be labelled as intervention or usual.

15. It is only in line 290 that the intervention per se is described and I personally think this should come earlier.

16. And line 293 I would suggest the intervention is developed based on evidence from the US study rather than a hypothesis

17. Line 309, what is combination nicotine replacement therapy, what happens to people on the varenicline, what happens to people on e-cigarettes

18. Line 334 should make clear that the completion of the online training program has to be within six months of the start of the program delivery, I assume.

19. Line 347 it seems premature to say that the community facilitators 'tend to be ex smokers'. As this is a protocol this would not be known at this point, and maybe it would be better to say X smokers/?smokers would not be excluded as community facilitators. Should it be explained how these CFs are recruited. They are central to the intervention
20. Line 355  the description of the control arm needs to be clear earlier who are the providers of the standard program. I'm also confused that it is stated that the service model is not available in all areas, so is providing this program one of the criteria for selecting a district.

21. Somewhere the difference between intervention and usual care needs to be more clearly articulated as the standard service seems to use many of the same techniques. What is the USP of the intervention. Is it using the CFs? Or the group option? What is the theoretical framework underpinning this?

22. Line 385- isn't the primary outcome the recruitment rate? And in this paragraph shouldn't an outcome be an estimation of the percent of the potential eligible population -this would be needed to plan a definitive trial

23. Line 397 the base line needs to be more clearly defined. Is the quit date set (which is implied) or the first appointment. Using the quite date- defined presumably by the smoker/participant is open to bias

24. Should the number of session attended be a secondary outcome?

25. The process evaluation is poorly described with insufficient detail. I wonder if a full protocol for the process evaluation should be separate. For example it is unclear who will be observed, interviewed, how many, how selected.

26. What quality of life measure will be used

27. Line 458-9 refers to checking of 20% of data and correcting errors. Is there any threshold of errors that would prompt checking all the data ?

28. Line 490 'an' should be 'a'.

29. Line 495 DT- as a general point note and correct inconsistent use of full labels and abbreviations across the paper

30. Line 496 and I see that whilst a HE component is planned for in the main study it is not mentioned in the pilot trial protocol

31. Line 504 and line 507 - How valid are initial results? What does this statement really mean?

32. Line 515 0 I am not clear what this line means . Should 'development of' be deleted?

33. Line520-522 also needs rewording for clarity

34. Line 539 'efforts' feels pejorative

35. Lines 545 -6 First time waves mentioned and does this mean that the pilot trial has already commenced? I think this should not be reported here. Potential limitations should only refer to
published literature and previous rather than ongoing experience. Also what do lines 553-4 mean?

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