

## PEER REVIEW HISTORY

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### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	The adaptation and uptake evaluation of an SMS text message smoking cessation programme (MiQuit) for use in antenatal care
<b>AUTHORS</b>	Naughton, Felix; Cooper, Sue; Bowker, Katharine; Campbell, Katarzyna; Sutton, Stephen; Leonardi-Bee, Jo; Sloan, Melanie; Coleman, Tim

### VERSION 1 - REVIEW

<b>REVIEWER</b>	Severin Haug Swiss Research Institute for Public Health and Addiction, Switzerland
<b>REVIEW RETURNED</b>	25-Jun-2015

<b>GENERAL COMMENTS</b>	<p>This is a well-written, straightforward manuscript on a rarely investigated but highly relevant topic: the uptake and acceptance of a text message-based smoking cessation Intervention in routine antenatal care.</p> <p>Minor revisions suggested:</p> <ol style="list-style-type: none"> <li>1. Within the abstract an results section the number of persons (n) should be reported in addition to each percentage. This would give a better impression of the small sample size of persons receiving the intervention.</li> <li>2. The conclusions based on the results sound very optimistic and I would prefer a more balanced discussion, particularly concerning the "very low costs" of the intervention. Development and continuous maintenance of text message-based interventions also require qualified staff. Furthermore, it is still an open question whether the use of other smoking cessation aids might have decreased in SMS program participants.</li> </ol>
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<b>REVIEWER</b>	Lorien Abrams George Washington University, USA
<b>REVIEW RETURNED</b>	I have licensed Quit4baby to Voxiva Inc. 16-Jul-2015

<b>GENERAL COMMENTS</b>	The authors present a study of how much uptake there is of a SMS program for smoking cessation in pregnant women after the distribution of a leaflet. Uptake is an import question, as few studies have been conducted looking at the integration of SMS programs in routine medical services, especially among pregnant smokers, and
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	<p>pregnant smokers are resistant to receiving counselor provided programs. So the question is very important.</p> <p>My enthusiasm is tempered by some weaknesses in the methods and analysis plan. While they have a clear count of the number of enrollees in the SMS program, the estimates of rates of uptake seem confusing. Why in the extended period—do they look at 9 months of activation but only 8 months of pregnant bookings (n=2356) , unlike the strict period where it is 6 months of booking and 6 months of registrations. It seems that that extra month of activation in the extended period adds extra enrollees in the program, without out accordingly increasing the number of pregnant bookings, thus artificially increasing their enrollment rate, their primary outcome. It seems the rules they create for themselves in handling the difficulty of estimating the rate and not uniformly applied to the strict and extended periods.</p> <p>Another weakness that is not acknowledged is the significance of the finding that very few people successfully enrolled in the program (n=11) and then went on to stay in the program through its length (n=6), which is currently underplayed. While I appreciate the emphasis on uptake in the most narrow sense (requests to join the program), uptake in a broader sense—uptake after registering—should be considered as key. Half the people who tried to enroll could not . Another big group unsubscribed soon after joining the program. These findings should temper the authors' enthusiasm in the conclusions. Even if the difficulties enrolling can be sorted out, the fact that half did not like it and stopped the program soon after enrolling is a big problem and is at odds with the conclusion that the program resulted “in a small but potentially impactful uptake rate by pregnant smokers.” A willingness to stay in the program is also a major finding on uptake—high rates of stopping the program “prematurely”— and should be clearly presented as such in the discussion and conclusions. I disagree that disengagement is the same as the NHS disengagement, and therefore can be discounted, because in the case of SMS the dose —several text messages—is very different than an hour of counseling.</p> <p>Pg . 4. Please describe briefly what is the SSSPs?What kind of service is it?</p> <p>Confidence intervals should not be used around defined events. For example, in the abstract it says 56% texted a quit date to the system and 46% (CI 21-72%) stopped the programme prematurely”. How is this CI calculated? Why only around one texting stop and not quit data ? I think the CI make no sense, especially because we are talking about a defined event with 6 people who texted STOP.</p> <p>All percentages should be presented with counts so that the reader can appreciate the small numbers involved which make effects not stable and mis-represent magnitude of effects. (e.g. yes 67% completed the tailoring questions but really that's only 5 people). Please make the corrections in the abstract and body of the manuscript.</p> <p>The authors have no conclusions about the practicality of 12 tailoring variables. Given that many could not get through them, might they suggest that 12 is too many outside of a research context.</p>
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## VERSION 1 – AUTHOR RESPONSE

Reviewer 1

1. Within the abstract and results section the number of persons (n) should be reported in addition to each percentage.

Response: Thank you. We have now ensured that the number of persons are now stated for all descriptive data in the abstract, although we had already listed the actual number of participants for all descriptive data relating to MiQuit uptake or usage in the results sections. Please note that we have also changed the percentages (and corresponding CIs) provided in the abstract and text to whole numbers rather than to one decimal place, given that they reflect relatively small numbers (percentages and CIs that are below 1 are presented to one decimal place). We have also corrected a rounding error for the discontinuation rate throughout the manuscript (was presented as 46%, now changed to 45%).

2. The conclusions based on the results sound very optimistic and I would prefer a more balanced discussion, particularly concerning the "very low costs" of the intervention. Development and continuous maintenance of text message-based interventions also require qualified staff.

Response: Thank you for this comment. On re-reading the main conclusion, we have added the words "estimated" when describing the findings so it now reads "...resulted in 3-4% of estimated pregnant smokers (word corrected from 'women') requesting to receive text message cessation support" (pg. 17). We have also added the words "though small" in the sentence at the beginning of the discussion: "...demonstrated that a significant, though small, minority of pregnant smokers in one site were sufficiently interested..." (pg. 14). The remaining conclusions in the discussion and abstract we feel represent the findings and are cautious and suggestive only e.g. "(abstract conclusion): "...resulted in a small but potentially impactful uptake rate by pregnant smokers", "If demonstrated to be effective... Delivering self-help by text message could therefore make an important contribution to the reduction of maternal and infant complications..." "findings suggest that a large definitive trial testing MiQuit efficacy would be a rational use of resource fund". We have also revised how we compare our discontinuation rate with that of NHS face-to-face cessation support (see reviewer 2 point 6).

We describe the cost of the promotion of MiQuit (i.e. making the leaflet and supplementary materials available), rather than the intervention itself, as "very low" as these costs were small (graphic design, printing and admin time to insert into booking folders) relative to other forms of promotion such as those that require health professional time. In the original manuscript we described the intervention costs as "cheap" (abstract) and "low" (discussion) citing the £3.20 per participant cost from a recent trial. However, we agree that there are costs associated with maintenance - we have now added the following words into the discussion "...plus maintenance costs" after citing the £3.20 cost (pg. 16).

3. It is still an open question whether the use of other smoking cessation aids might have decreased in SMS program participants.

Response: Thank you for this important point. We have now added the following sentence to the future research paragraph in the discussion: "Finally, it is important to establish whether uptake of text messaging support might decrease use of other cessation support." (pg. 17)

Reviewer 2

4. While they have a clear count of the number of enrollees in the SMS program, the estimates of

uptake seem confusing. Why in the extended period do they look at 9 months of activation but only 8 months of pregnant bookings (n=2356)...it seems that the extra month of activation in the extended period adds extra enrollees in the program, without accordingly increasing the number of pregnant bookings, thus artificially increasing their enrollment rate, their primary outcome?

Response: Thank you for this point. The leaflets, the promotional materials considered to be the primary generator of uptake activation requests, were available to midwives only for 6 months and the supplementary materials left on clinic desks/poster were potentially available for a further 2 months (8 months total). The research team checked to ensure that materials were no longer available after 8 months. As indicated in the methods section, we originally intended to only explore uptake for the initial 6 months i.e. when the leaflet was made available. However, as stated in the paper there were a significant number of activations in the three months after all the leaflets were distributed – potentially due to exposure to the supplementary materials or a delay in sign up as a result of receiving the leaflet/supplementary materials. As the shortcode (and keyword combination) was unique to the study materials, these 'late' sign ups could only be due directly or indirectly to the materials made available, during the 8 month period. To use a 9-month period for the denominator does not seem logical given that the extra month of pregnant women would not have been directly exposed to the promotional materials. We have added the following into the section in the methods that describes the 8-month period of availability to help clarify this: "... i.e. when pregnant women had direct access to the materials" (pg. 11). We provide this 'extended' period together with the a priori and more conservative 'strict' period to provide a range of uptake estimates and we use this range when summarising the findings.

5. Another weakness is...that very few people successfully enrolled in the program (n=11) and then went on to stay in the program through its length (n=6), which is currently underplayed. While I appreciate the emphasis on uptake in the most narrow sense (requests to join the program), uptake in a broader sense - uptake after registering - should be considered as key. Another big group unsubscribed soon after joining the program. These findings should temper the authors' enthusiasm in the conclusions. Even if the difficulties enrolling can be sorted out, the fact that half did not like it and stopped the program soon after enrolling is a bit problem and is at odds with the conclusion...A willingness to stay in the program is also a major finding on uptake - high rates of stopping the program "prematurely" - and should be clearly presented as such in the discussion and conclusions.

Response: Thank you. The reviewers point relates to the discontinuation rate (5 out of 11 - 45%). We cannot say that those who discontinued using MiQuit prematurely did so because they did not like the programme. The feasibility trial of MiQuit found that only 2 out of 8 participants discontinuing MiQuit support said they found the text message support annoying (we have now added this into the text on page 17). Furthermore, we cite a recent study that found "...non-pregnant smokers who discontinue cessation text message support are found to be more likely to have engaged in quitting smoking and subsequently relapsed than not have attempted to quit at all." (pg. 17). Therefore, discontinuation of the MiQuit programme does not necessarily imply or reflect disengagement with attempting to stop smoking. We have now added that "Further insight into premature discontinuation rates of text message support in real-world contexts is therefore required." (pg. 16) In the study conclusion we simply repeat the main finding that "...3-4% of estimated pregnant smokers request to receive text message support." We have now simplified the text in the conclusion relating to discontinuation rates so it simply states "Almost half chose to discontinue the text support before programme completion." Following this, we have now added "However, further research is required to better understand the reasons why some recipients of text support discontinue it prematurely". We feel that, taking these changes into account, our conclusions do not go beyond the findings or evidence or that the discontinuation rate is underplayed.

6. I disagree that disengagement is the same as the NHS disengagement, and therefore can be

discounted, because in the case of SMS the dose - several text messages - is very different than an hour of counselling.

Response: Thank you for raising this. We agree and have amended the text describing the NHS disengagement rate so it states: "While this is similar to the 44% discontinuation rate of routine SSSP support, using a definition of those not attending a 4-week follow-up appointment,[7] these rates may not be directly comparable given the difference in the type of support provided, effort required to discontinue them and reasons for doing so." We have also removed the section in the conclusion referring to the comparability of discontinuation in MiQuit with NHS rates (see point 5).

7. Please describe briefly what is the SSSPs? What kind of service is it?

Response: Thank you. We have added the following text providing more detail about what support is routinely provided with a reference of a recent survey of the support provided by SSSPs: "The SSSPs typically provide face-to-face behavioural support in combination with nicotine replacement therapy with follow-up visits or phone calls.[6]" (pg. 4).

8. Confidence intervals should not be used around defined events. For example, in the abstract it says "56% texted a quit date to the system and 46% (CI 21-72%) stopped the programme prematurely". How is this Ci calculated? Why only around one texting stop and not quit data?

Response: Thank you. The confidence intervals were calculated using the Wilson Score method without continuity correction. We have included confidence intervals as they provide an indication of the uncertainty regarding the sample estimate for the population values of our findings. For example, if we carried out our investigation using the same sampling method for different samples, assuming the results would follow a normal distribution, the CI tells us that 95% of the time the true discontinuation rate in the population would be between 21 and 72%. We consider the use of confidence intervals for this type of data is becoming increasingly common in medical research and would argue that their inclusion adds to rather than detracts from the paper. In light of the reviewer's comment, we have removed the confidence interval for the proportion of participants completing tailoring questions as it represents a less important parameter than initiation and discontinuation and makes the abstract and findings section more consistent.

9. All percentages should be presented with counts.

Response: Thank you. This has now been addressed (see reviewer 1 point 1)

10. The authors have no conclusions about the practicality of 12 tailoring variables. Given that many could not get through them, might they suggest that 12 is too many outside of a research context.

Response: Thank you for this useful point. We have added to the lessons learned sentence highlighting this: "Lessons learned... include... the consideration of using fewer than 12 tailoring questions when pregnant smokers initiate completion of these by text message rather than website.

## Correction

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Naughton F, Cooper S, Bowker K, *et al.* Adaptation and uptake evaluation of an SMS text message smoking cessation programme (MiQuit) for use in antenatal care. *BMJ Open* 2015;5:e008871.

The final sentence was omitted from the Funding section. The full funding section should read:

**“Funding** This work was funded by the National Institute for Health Research (NIHR) under its Programme Grant for Health Research scheme (grant reference RP-PG-0109-10020). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department Health.”

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