Author's response to reviews

**Title:** Recruiting South Asians to a lifestyle intervention trial: experiences and lessons from PODOSA (Prevention of Diabetes & Obesity in South Asians)

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**Author's response to reviews:** see over
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Dear Editor

Thank you for giving us the opportunity to respond to reviewer’s comments on our paper and resubmit a revised version. We have listed the reviewers’ comments below with our responses. We have responded to all comments and in most cases have addressed the queries by addition, clarification or deletion of text. There are only a few points for which we do not have data or information available to allow us to respond.

The main paper uses track changes to show our amendments. The changes to the tables and figure are highlighted in green.

On behalf of the authors I have re-submitted the paper and we are hoping it will be considered for publication.

Yours sincerely

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Reviewer: Janet Dunn

1. More detail in the methods section 3(b) Marketing Agency would be helpful. What was the marketing campaign they initiated?

**Response:** This involved regular email-shots to their large existing database of South Asian contacts, widespread poster distribution and access to local media, for example arranging radio interviews with the PI.

2. Table 1 and Figure 1 could be combined into Figure 1. At the moment it is not clear from Figure 1 how many people were randomised to each group. I know this is not the main purpose of this paper but it would complete the picture. I suggest the 4 bullet points for eligibility are included in the 'total potential participants....n>2089' box and some of the methods bullet points included in the text or after the 'recruits with IGT/IFG randomised into trial n=171' box with two extra boxes to demonstrate final numbers randomised in the two arms

**Response:** Footnotes have been added to Figure 1 and boxes added with the randomised allocation to the two trial groups. However we feel that Figure 1 will become too ‘busy’ if more is added and therefore prefer to keep Table 1 as a simple and clear description of the trial eligibility criteria and methods.

Reviewer: Vera Nierkens

**Major Compulsory revisions**

1. It is very interesting to read the experiences. However, I miss a clear research question. Is it only about the participation rates or also about difference between referral rate and participation rate or the efficiency of the recruitment methods used?

**Response:** Additional text on p6 in Background - The aim of the paper is to share our experiences of enrolling participants to the screening stage of the trial and to inormally compare referral rates from the different approaches used. We have also attempted to judge the efficiency of the methods used.

Methods

2. For me, it is insufficiently clear whether you want to describe the recruitment strategy as a whole or after the extra funding only. Could you clarify that, please?

**Response:** We have added in timescales and time point references in the methods section in the paragraph ‘Summary of our actual experience of recruitment’ and also in the results section which clarifies that we are describing the complete 27 month recruitment period.
3. The methods section included in the text too little details about concrete targets of recruitment methods and about the expected numbers of the “source population” per recruitment strategy. What was the aim of the different strategies? It become clear from the table now, that the marketing strategies are conducted for awareness, but not from the description in the text.

**Response:** As stated on p 8 at the end of the ‘Initial recruitment expectations and strategies’ section, ‘Our expectation was to find 50% of participants for the screening stage via the NHS and the other 50% via the community’.

We did not subdivide our targets further than this. We have added in text in pages 10-13 to give more detail about each method – see response to next reviewer’s point 4.

4. I do not understand the difference between method 1b and 1d. What is the extra contribution of method 1d?

**Response:** This has been clarified in the text to describe the difference. 1b involved writing to South Asian patients aged 35 years or older who did not have a diagnosis of diabetes recorded on the practice system. Method 1d was tested to try and identify our specific trial population ie South Asians over 35 years with disglycemia. See pages 10-11.

5. The description of method 2b is unclear for me: the first paragraph seems to be another method than the second paragraph.

**Response:** We have clarified that the first paragraph refers to our initial approach over the first few months of community recruitment and the second paragraph refers to the formal partnerships set up after we had obtained additional funding.

**Results**

6. In general I think the results section needs to be more structured to understand what you expected per recruitment method and what the result was.

7. The text would become clearer when in this section the numbers of Table 2 were used as well.

**Response:** The above two points have been addressed as described in the next reviewer’s points 9 and 10.

8. Could you please clarify the percentages? Especially in the text I, it was difficult to understand whether the percentages were the percentage of all people screened or the percentage of the source populations for example.

**Response:** Footnotes and amended headings have been added to table 2 to explain the numbers of referrals and numbers screened and that percentages are by column.
9. Regarding community recruiters: could you please describe how many community recruiters were asked to refer people? Without this information, it is difficult to interpret the comment about the five recruiters without referrals. Were these the 10 mentioned at 2b?

Response:
This paragraph now reads:
The paid community recruiters found the recruitment process harder than anticipated. Five of the 10 individuals did not refer any participants. The recruiters’ main reasons for this were a lack of time and limited access to the relevant population of South Asians living permanently in Glasgow or Edinburgh. As Table 2 shows, in total the community recruiters contributed approximately 29% of the referrals to PODOSA. Of the 618 names passed to the research team, collected over a period of about 18 months, around 55% were eligible, available and willing to be screened.

Discussion

10. For me, it seems that the first paragraph of the discussion describes new data about the numbers referred per method which is not described in the results section. Could you please add this to the results section?
Response:
The data on eligibility and availability for screening has been added to the results section.

11. The comparison with other trials is interesting, but will be more informative if you would describe some background characteristics of participants in other trials.
Response:
We have added information about the age range for the ProActive trial in England and the two Scottish studies referred to at the start of this paragraph.

12. The last sentence of the aforementioned paragraph seems to address another issue than the low response rates, i.e. the efficiency of recruiting via record systems because of extra restrictions in target population. This should be a separate paragraph.
Response: This has been done.

Discretionary revision

13. Regarding the media promotion, it would be interesting whether you know more about the perceptions of participants about this. Did / do they speak about this media promotion and did it raise awareness. If you have these data, I would prefer if you describe it in this paper.
Response: We do not have any information about recruits’ perceptions of the media promotion so are unable to add this to the paper.

Reviewer: Irene van Valkengoed
Reviewer's report:
I enjoyed reading this paper. I am impressed by all the efforts the authors had to undertake to for the PODOSA trial. There are definitely lessons to be learned from their experiences. I have some suggestions that I hope contribute to the discussion and interpretation.

Background
1. Throughout the background and the rest of the paper, it seems as if the UK is used as a “synonym” for Europe. However, although a study in the UK may provide some relevant insight for studies in other European countries, the UK may differ in several aspects from other European countries. This should be considered in the introduction, aim and – particularly – the discussion.

Response: On page 5-6 and in the conclusion we have narrowed the focus of our paper to the UK.

2. The paper seems to be about recruitment of South Asians in general, while a lot of focus is put on the evidence for lifestyle interventions for type 2 DM and the design of the PODOSA trial in the introduction. This description would fit better under methods (general description of the setting and design). These paragraphs also contain some information that could be considered results. For instance, the last sentence on how many were screened, could be omitted.
On the other hand, the information that is presented under the heading of ‘Overview of recruitment strategies’ does belong in the introduction.

Response: We have moved the 2 paragraphs about diabetes and other prevention trials, plus the design of PODOSA, to the beginning of the methods section under the heading ‘Trial setting and design’. We have omitted the sentence about numbers screened. See pages 6-8.

3. In this section, I do not understand the focus on ‘at the time of the trial design’, as it is meant to provide background information for the reader on the current state of the knowledge (what this paper adds) and not as a justification for choices that were made in the past (the justifications should be given under methods and discussed in the discussion, where relevant). This is also illustrated by the fact that the section refers to multiple papers that were published after PODOSA was set up.

Response: We have deleted the phrase ‘at the time of trial design’ so that this section is clearly about the current state of published evidence and highlighted the point that currently we are unaware of any published methodology on the topic of our paper.

Methods
4. In the first part (‘Initial recruitment…’), I would recommend the authors not only to discuss the expectations, but also the general design and approach of PODOSA. Then
the individual recruitment strategies can be discussed. I would like much more
detailed information about the methods used, e.g.: how were recruiters trained, what
type of information was given, were the invitations
targeted/tailored to the population or individual, what was the focus of the
promotional talks, were any materials tested (not piloted, but discussed)?

Response: We have moved the paragraphs about diabetes and other prevention
studies and the description of the trial design from the Background to Methods
section.

The following text has been added to the detailed descriptions of each recruitment
approach on pages 10-13

1a
The aim was to raise awareness of the study with the expectation that health care
professionals would refer potentially eligible patients to the research team.

2b
All the paid recruiters were given materials and training about diabetes, the risk for
South Asians, the trial eligibility criteria and the importance of confidentiality.

2c
The talks focussed on South Asians’ risk of developing type 2 diabetes, how it can be
prevented and what trial participation would involve.

3a
Our information leaflet used simple language to describe the study, explain that South
Asians are at high risk of developing diabetes, and provide the research team’s contact
details. It was translated into Urdu and Punjabi and all language versions were tested
for understanding within the community, using local contacts conversant in these
languages.

5. Please add some background information on the population (how many are able to
read? level of education?).

Response: On page 8 we say that our previous experience had shown us that a
significant proportion of the South Asian population in the two cities, especially in the
older age groups, speak and read little English.
We do not have further detailed data on levels of education within our specific target
population in Glasgow and Edinburgh.

6. Were all strategies planned ahead or were more added as the project progressed?
For instance, the re-design of the material. If this was done after the initial NHS
recruitment failed, this should be explicitly discussed.

7. Was the fee per person screened added later – for whom? Recruiters only or
organisations too?

Response: In the ‘summary of our actual experience of recruitment’ we have added
timescales to clarify the above two points - see page 9.
Also in 2b, on page13, the second paragraph now reads:

After securing additional funding, we set up formal partnerships with five local organisations, including: NHS or community health initiatives, a women and children’s Islamic teaching organisation and, the Muslim Council for Scotland, a national body to promote Muslim affairs in Scotland. We also identified 10 individual recruiters who were well known within their local communities. Contracts were agreed with the groups and individuals, based on a payment of £15 per referral actually screened. All the paid recruiters were given materials and training about diabetes, the risk for South Asians, the trial eligibility criteria and the importance of confidentiality.

8. Some of the information under ‘Summary of our actual experience of recruitment’ belongs in the results section. For example, p.6, parts of paragraphs 1 and 3 “Our experience showed that….or with small groups was relatively successful”. Please be more specific, as the text now makes me curious (how successful, what where the expectations then?).

Page 11, 2.a. Later on in the text, I read that there were more recruiters (5 of the community had not referred)? Were there 3 or more?

Response: In 2a page 12 we have clarified that this is a description of the snowballing effect by asking screening participants if family and friends might be interested in the study and passing on study information leaflets. This is different to 2b where formal agreements were set up with 5 organisations and 10 individuals to recruit for us in return for payment – we hope we have now corrected this misleading wording.

Results

9. The results would be easier to read with a reference to Table 2 and the numbers/labels used in the methods.

Response: The results has been structured in a similar way to the methods section using labels ie 1(a), 1(b) etc.

10. To determine the efficiency of a method, I would not only like to know how many persons were recruited (referred, eligible, screened) through that channel, but also in how much time and at which cost (work-load and financial). Recruiting 300 persons may sound much less efficient if it is done over a period of 2 years than 2 months.

Response: PODOSA was not set up or resourced to test the cost effectiveness of each recruitment method. Costs have not been calculated. We have added in timescales where appropriate to each method, given the percentage of referrals, from GPs and the community recruiters, who were eligible to be screened, but we do not have complete data recorded on all referrals/responders/names collected and whether eligible and actually screened. The unavailability of formal data on time and costs is acknowledged as a limitation in the discussion.
11. The information on retention is not directly relevant for the current aim. Unless the emphasis is placed on recruitment for the trial instead of for the screening throughout the text, the authors should also consider omitting the information on prevalence etc.

**Response:** This has been deleted on page 16

**Discussion**

12. The Summary of the findings is not clear. The information about referrals and screening cannot be easily deducted from Table 2.

13. Some of the information on the workload, experiences etc. could be considered a new result. The last sentence of the first paragraph in the discussion.

**Response:** The above two points have been addressed by reporting the percentages, where available, of referrals who were eligible to continue to be screened, in the results section. We have also added text in the results and discussion sections to refer to the percentage of total screened as displayed in column 4 of Table 2, so that readers can easily match the table with the text.

14. Was there an effect on the participation of using less professional materials during the NHS recruitment phase (if this was the case-see comment above).

**Response:** Our original wording was misleading as the same materials were used for both NHS and community recruitment throughout. We hope we have clarified this by adding in timescales throughout the methods and results sections and correcting the wording used about the redesign of our materials in 3b page 13.

15. The authors should keep in mind that the conclusion that community recruitment is better is based on a comparison with a suboptimal recruitment method via the NHS (no reminders, telephone contacts, possibly less professional materials used). This possibly limits the generalisability. Therefore the suggestion that – based on this study alone-Ethics committees-should encourage community recruitment seems quite bold. I think it should be considered as a serious option, but that much more information is needed before the focus is shifted (completely) to this method.

**Response:** We carried out a trial of reminder letters and have added this into the paper in the results section. And we have clarified about the materials in point 14 above.

Our recommendation was that ethics committees should encourage community recruitment from the outset as part of an overall recruitment program. In the discussion, Paragraph 1 on page 18 now reads

Overall, recruitment via the health service had limited success and was time and resource intensive. Ethics Committees should note this for future trials, and may wish
to encourage early direct contact for community recruitment [39] as part of a multi
pronged recruitment program tailored to the ethnic minority group under study.

16. Moreover, I believe that the data presented provide an indication, but are not
sufficient to fully judge the efficiency of the different methods (due to lack of
information on time investment and cost). This would require a more systematic and
direct comparison of methods, that incorporate all possible variations (with incentive
or without, with reminder or without reminder etc.).

**Response:** We agree with the points in the above two comments and have inserted a
paragraph at the end of the Discussion section to acknowledge limitations in our paper
and to explain the basis for our definitions of success or otherwise.

PODOSA was not designed to collect detailed data on resources, time and costs for
the recruitment process and therefore to formally compare each strategy. We
acknowledge this as a limitation to the conclusions that can be drawn from our
findings. However we have formed a judgement on the success of the different
approaches based on numbers referred, and informal estimates of time and cost
incurred by the research team, staff from other research networks and community
recruiters

17. Finally, I miss a critical discussion of how the findings that were specific for
PODOSA translate to other settings, locations (counties-the focus in the aim was
Europe), topics of research and possibly even populations with a different origin or
migration history.

**Response:**
The first paragraph of the Conclusion now reads:

We faced many challenges during the initial recruitment stage to PODOSA of the
kind that have delayed or stopped other trials in general populations [40]. As reports
of working with South Asian populations in the community in the UK are limited, we
hope our experience will help others and provide encouragement for further studies to
be undertaken in this and other UK ethnic minority populations. As others have
suggested [21,41], making generalisations for recruitment to other ethnic minority
groups may not be valid, however improving understanding in one population may
help raise awareness of possible recruitment issues for community trials in other
minority groups.

**Conclusions**

18. The conclusions do not match the aim. The high participation and retention rate in
the trial are truly excellent, but do not reflect the lesson that should/could be learned
from the information presented in the paper.

**Response:**
This has been deleted from the conclusion.
Figure 1
Please add footnotes about:
- The contacts that were not registered
- The reasons for exclusion?

**Response:** The following notes have been added to Figure 1:
1. Not all informal contacts with potential participants were recorded.
2. Ineligible: main reasons were did not satisfy waist size criteria or unavailable for screening visit.
3. Excluded: main reasons were unavailable for baseline visit within timeframe, or close family members already in the trial.

Table 2
Please add footnote
- What is difference between referral and screened?
- Was the initial target % for referrals or screened?
Comparing the figures in the columns is difficult as it is not clear how the % were calculated (total referred for the study and total screened in the study) and the referrals lists numbers with % between brackets.

**Response:** Footnotes have been added to table 2 to describe the difference between referrals and those actually screened:

Referrals*: total number of potentially suitable participants referred to research team or responded to invitation letters for the screening stage.
Screened: *1319 of 2089 referrals were eligible, available and willing to attend a screening visit to have blood glucose measured, percent of total number screened is given.

Criteria for judgement are poorly defined (although I understand that this is an opinion rather than a clear threshold): was the definition of “success” purely based on numbers referred or on more (e.g. labour intensive talks were considered moderately successful whereas resource intensive letters were not).
The success of community recruiters may depend greatly on personal motivation and skills (e.g. 5 had no referrals), and…. the financial incentive! The impression I get from Table 2 is that it is mainly the financial incentive that makes a difference. Could the NHS strategy have been more effective is professionals had been paid?

**Response:** These points have been addressed previously in points 14-16 above.