PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Design and baseline characteristics of the PODOSA (Prevention of Diabetes & Obesity in South Asians) trial: a cluster, randomised lifestyle intervention in Indian and Pakistani adults with impaired glycaemia at high risk of developing type 2 diabetes
AUTHORS	Douglas, Anne; Bhopal, Raj; Bhopal, Ruby; Forbes, John; Gill, Jason; McKnight, John; Murray, Gordon; Sattar, Naveed; Sharma, Anu; Wallia, Sunita; Wild, Sarah; Sheikh, Aziz

VERSION 1 - REVIEW

REVIEWER	Paramjit Gill Reader in Primary Care University of Birmingham I have worked with both Professors Bhopal and Sheikh in the past and currently working with Professor Bhopal on a childhood obesity prevention trial.
REVIEW RETURNED	15-Nov-2012

THE STUDY	General comments: This paper describes a challenging trial and is not a protocol paper as it reports initial results. In its current state, it lacks clarity and detail for the reader to replicate the study. Specific comments: 1. The authors describe a cluster randomised trial of lifestyle intervention in promoting weight loss. However, the current title/acronym PODOSA does not reflect this as it also includes preventing diabetes. I understand that as originally planned, a family intervention was to be undertaken to prevent diabetes at those at high risk. 2. In addition the title needs to include 'cluster' as this is missing. 3. In the abstract, the intervention states lifestyle provided by dietitian and implies diet only and physical activity needs to be inserted as stated in the text. 4. The rationale for using a cluster trial is not clear in the Background section and is mentioned as part of study questions (p5). The Background section cites individual based interventions in preventing diabetes and need to reflect change in trial question in promoting weight loss and evidence for a family intervention. 5. It is also noted that no feasibility/pilot data is shown to demonstrate response and other process measures before starting the full trial. Was one undertaken?

	6. Sample size calculations: What was the basis for effect size? In addition, there is a notable lack of a intracluster correlation coefficient (ICC) as highlighted by the 2010 Consort Statement on reporting cluster RCTs [Campbell MK et al. CONSORT statement: extension to cluster randomised trials. BMJ2004;328:702-8 and Campbell et al BMJ 2012;345:e5661 doi: 10.1136/bmj.e5661 Published].The latter was published on-line 4 September 2012. 7. How was blinding assured ? Who enrolled/assigned the clusters after randomisation? Was the intervention delivered independently and were the dietitians blind to randomisation. 8. In terms of measurements undertaken this is not clear if all participants had these at the same time and exactly what they had. On p8 under measurements for volunteer members of the family it states that no blood tests were done but further down the page (Data collection and handling) an OGTT was undertaken and blood stored. Was this for all participants or just the intervention group? Also the authors refer to 'cardiometabolic risk factors which will be the subject of a subsequent paper' without listing these risk factors. A table listing all baseline and outcome measures at various times would greatly help the reader. 9. It is also not clear who undertook baseline and outcome measures (p8) as it seems trained nurses undertook key endpoint variables at the 3-year visits and not at baseline? 10. How many dietitians were used and were they present throughout the intervention for each group? Was any standardisation undertaken? 11. The dietitians toolkit (p7) consisted of culturally adapted resources is mentioned on p7 and this needs to be detailed in terms of what this consisted of and any references cited. The authors state that '...a paper on the cultural adaptation has been submitted' but no details are provided. This needs to be clear and fully described in this paper. In addition references need to be provided for the 'Chester Step Test' and evidence for statement on 'educational and motivational purposes' (p7). 12. On p8, a very broad overview of the methods is given and this needs further details in terms of sampling the participants; number for interviews/focus groups; handling of the data; theoretical framework for analysis/interpretation of results. Also clarification of what '...experience-centred, culturally-orientated narrative methods' mean.
RESULTS & CONCLUSIONS	Only the initial baseline main results have been reported - not the outcome measures. However some discussion statements do need further support i.e. p10 ‘the very high level of support from within the wider South Asian community"; p11 'PODOSA is one of the first culturally adapted randomised intervention trials in South Asians in the UK'; p11 'PODOSA is important for weight control and diabetes' but no data is given here for this!
REPORTING & ETHICS	Main items described above and include inserting cluster into title and stating if ICC used or not as per Consort Statement. References to current Consort Statements are given above.

	Note that the authors state that a paper has been submitted for publication (p7) but do not provide it for reviewers.
GENERAL COMMENTS	This is an important trial and this paper needs further clarification and detail to enable the reader understand the conduct of the trial.

REVIEWER	Rantell, Khadija University College London
REVIEW RETURNED	21-Dec-2012

GENERAL COMMENTS	This is an interesting trial. This paper should be as a description of the protocol of the trial (published protocol) with the addition of baseline information about the participants characteristics. The outline of this paper was reviewed in relations to the extended consort statement for cluster randomised trial (Marion Campbell et al 2012). This paper needs revising and resubmission. The major findings are that there statement about primary (not really stated) and secondary trial objectives are not clear and the statistical methodology in relation to these difficult to assess because the level of inference is not explicit (cluster of individuals). There is also a lack of information to be able to reproduce the sample size and clear statement about trial schedule and time lines (who collect what and when). The inclusion of volunteer families deserves further explanation. There is also insufficient information about the cluster eligibility. Minor findings include: logical flow of text and presentation of results. Title The title should specify that it is a clustered randomised trial. Background The background should include rational for using cluster randomised trial for example to minimise contamination and or for practical reasons. On page 5 line 37, the author tried to justify the use of cluster trial, so this section should be part of the background and not methods. It is not clear whether the objective of the trial pertain to cluster level i.e. family or individual within the family or both. Although the information on page 5 suggests that it is the cluster level that is of interest, the subsequent analyses outline suggest that the authors are interested in both. The objectives of the trial should be sited in the background section to. Method Design This section should include information and definition of what constitutes a cluster, how they were selected and how was the intervention applied to the cluster. Some of this information, but not all, comes later on page 6 line 38… but it needs to be first. On page 5 line 8, the authors stated that the original protocol

	underwent a substantial amendment because of difficulty of recruitment, with consequence on the primary outcome. This is a good opportunity to expands on this and explain how and if these changes had impacted the choice of the number and size of clusters. The purpose of including volunteers has not been made clear in relation to the design of this trial. Participants The criteria given on page 6 relate to individuals. As this is clustered randomised trial two eligibility criteria are required: clusters and individuals within clusters. The eligibility criteria for clusters should also be given. Intervention Page 6 lines 47 to 52 should come under this section along with a description of the each of the two interventions. Page 6 lines 55 to 59 are irrelevant in this section. This type of information should come either in the Discussion or may be background. The information about the role of the dieticians is relevant although the writing need some re-organisation for example: Training, visit schedule, information given…The author stated that the family were seen by the same dietician for the duration of the study (page 7 line 4). This is an unrealistic assumption. A table or a chart of trial schedule would be helpful. Outcomes A description of the outcomes should be given in the same order as the research hypothesis, with indication as to whether they pertain to the cluster level, individual level or both as this has implication on the appropriate analysis of the outcome data. Also these families have been followed up for 3 years and need to state explicitly whether the measurement at the final visit will be used as the endpoints. On page 5, the authors state the following. The authors talked about principal and secondary questions. The research questions need to be described in terms of primary and secondary so that a judgement can be made in relation to study power and whether any adjustment for multiple outcomes is necessary. Primary outcome (principal research questions): • Evaluate change in weight loss (outcome= weight): a change in mean weight between the two groups (i.e. clusters) from baseline but did not specify if it is at the 3 years. • Evaluate Cost effectiveness (based on which variables? See page 7 lines 32 to 50) • Factor that assist recruitment, adherence with advice given, and retention in the trial. This is about the trial feasibility and ideally should have been part of a “pilot” phase. On page 8, the authors described the process of laboratory assessment but stated that these data will be analysed in a separate

	paper. It is not clear whether the information collected as part of this trial is related to any of the outcomes of the trial. Sample size Description of sample size was given on page 6 lines 26 to 31. The information provided is not complete and does not allow re-calculation of the sample size. The sample size was given for weight loss, which suggests that this is trial primary outcome and it needs to stated clearly. More specifically this section should include: method of calculation, number of clusters, cluster size(s) (equal or unequal sizes?), a coefficient of intracluster correlation (ICC) and 95% confidence interval of ICC. When dealing with a cluster trial, a design effect is applied. More information is needed if competing primary outcomes are of interest. The author should also state the software used for sample size calculation. The author may want to check the following paper: A simple sample size formula for analysis of covariance in cluster randomized trials by Teerenstra. Randomisation / allocation The author used blocked stratified randomisation, with varying block sizes. Stratifications factors were: location, ethnic group, number of IGT/IFG recruits per family. This is appropriate choice for this type of trial, especially if the number of clusters is small. On page 6 line 42, the authors talked about the allocation to the treatment group being done independently by the statistician to avoid bias in recruitment. This means that the allocation concealment was applied at the cluster level. The clusters were identified and recruited before randomisation. This is a good strategy to minimise selection bias. Implementation The random allocation was generated by the statistician. Information about who enrolled clusters and who assigned clusters to interventions need to be specified as well as the mechanism by which the individual participants within clusters were included as this can be a potential source of bias, for example using complete enumeration would mean that all members of the family who are identified as eligible can be included. On page 6 line 41, the authors state that consent was obtained from all members of the family. The author need to specify whether a cluster (i.e. family) was only included if its eligible member gave their consent and whether consent was sough before or after randomisation. The timing in relation to randomisation and the level at which the consent is sought are important as this may lead to attrition bias. Blinding On page 8 lines 53, the author stated that the research nurse who was blinded to the allocation group recorded independently a set of key anthropometric measures. Justification as to why blinding was

	not applied at the cluster level and who reported/measured key outcomes. Statistical method Statistical method for comparing intervention groups and how clustering was taken into account. Identification of the level of inference (individuals or cluster) is not clear. On page 9 line 20, the author talked about and ITT analysis at the individual level. This is confusing as the outcome is relating to the cluster level. Need to be consistent. Lines 35 to 41, included a statement of the statistical methods to be used but not specifying the research questions or outcome these relate to. The authors stated that they will use a random effect model to analysis the primary outcome (presumably the weight) and that the will adjust for stratification factors (ethnicity and allocation). This is an appropriate method of analysis. Essentially, this is a one type of analysis and the author should simply state that adjustment will be made for baseline value (presumably weight) and stratification factors (ethnicity and location). It is not clear when the number of IGT/IFG recruits per family (1 or > 1) is not adjusted for in the analysis. Comments on the cost effectiveness analysis and qualitative analysis are outside my remit. Results . Participant flow Figure 1 – consort diagram indicates that there are 156 cluster (78 to intervention) again the inclusion of 124 volunteer family is not clear in the context of this trial (page 5 line 28). The following information need to be added to the chart: • Number of received intervention and analysed for primary outcome(s) • Losses and exclusion (with reasons) after randomisation at cluster level and participant level, Baseline data On the title, the authors state that they will give a description of the baseline characteristics. The authors provided a description of baseline characteristics on Tables 1 and 2. The information presented in Table 1 should be given at individual cluster and individual cluster by intervention groups. This is important in order to check whether there are any imbalances. The information presented in Table 2 relates to volunteer's characteristics; a similar presentation by individuals and clusters is also required for each intervention groups. Again, it is not clear what the role of this volunteer family is in relation to the trial objectives.

VERSION 1 – AUTHOR RESPONSE

Reviewer: Paramjit Gill
Reader in Primary Care
University of Birmingham

I have worked with both Professors Bhopal and Sheikh in the past and currently working with Professor Bhopal on a childhood obesity prevention trial.

General comments:
This paper describes a challenging trial and is not a protocol paper as it reports initial results. In its current state, it lacks clarity and detail for the reader to replicate the study.

Specific comments:
1. The authors describe a cluster randomised trial of lifestyle intervention in promoting weight loss. However, the current title/acronym PODOSA does not reflect this as it also includes preventing diabetes. I understand that as originally planned, a family intervention was to be undertaken to prevent diabetes at those at high risk.

Response: We have added text to explain further about our change to the primary outcome. As further explanation, which we have not added to the paper, by 2009 when this change was made our PODOSA acronym was recognised and well known by both the South Asian and health care communities, and the Investigators agreed it could well cause confusion if we changed this mid- way through the study. We considered it was still applicable despite the change in primary outcome.

2. In addition the title needs to include 'cluster' as this is missing.
Response: We have added cluster to our article title

3. In the abstract, the intervention states lifestyle provided by dietitian and implies diet only and physical activity needs to be inserted as stated in the text.
Response: We have added text in the abstract to clarify this.

4. The rationale for using a cluster trial is not clear in the Background section and is mentioned as part of study questions (p5). The Background section cites individual based interventions in preventing diabetes and need to reflect change in trial question in promoting weight loss and evidence for a family intervention.
Response: We have inserted text to clarify the reasons for selection a cluster design in the background (pages 4-5)

5. It is also noted that no feasibility/pilot data is shown to demonstrate response and other process measures before starting the full trial. Was one undertaken?
Response: Such studies were not carried out for reasons discussed with the funders (NPRI) at the time of the grant application. We did carry out pilot work for the main procedures and we have added this on page 8 (measurements and data collection)

6. Sample size calculations: What was the basis for effect size?
In addition, there is a notable lack of a intracluster correlation coefficient (ICC) as highlighted by the 2010 Consort Statement on reporting cluster RCTs [Campbell MK et al. CONSORT statement: extension to cluster randomised trials. BMJ2004;328:702-8 and Campbell et al BMJ 2012;345:e5661 doi: 10.1136/bmj.e5661 Published].The latter was published on-line 4 September 2012.
Response: We have added text in the sample size paragraph (page 7) to explain that as we have minimal clustering it was not necessary to take this into account when calculating sample size for our amended primary outcome. The formal statistical analysis of the primary and secondary outcomes will

respect the cluster randomised design. We have corrected our omission in the statistical analyses section that we will report ICC.

7. How was blinding assured ? Who enrolled/assigned the clusters after randomisation?
Was the intervention delivered independently and were the dietitians blind to randomisation.
Response: We have elaborated the paragraph about randomisation (page 7) and allocation of intervention to clarify that
a) there was central randomisation carried out by an independent (to recruitment) member of the research team and
b) the dietitians and families did not know to which group they would be allocated during the complete recruitment and baseline stages.
Blinding of this type of intervention is not possible, as in the other main diabetes prevention trials, and this has been added to the text.

8. In terms of measurements undertaken this is not clear if all participants had these at the same time and exactly what they had. On p8 under measurements for volunteer members of the family
it states that no blood tests were done but further down the page (Data collection and handling) an OGTT was undertaken and blood stored. Was this for all participants or just the intervention group?
Also the authors refer to 'cardiometabolic risk factors which will be the subject of a subsequent paper' without listing these risk factors.
A table listing all baseline and outcome measures at various times would greatly help the reader.

Response: A new table (Table 1) has been added detailing timepoints for measures by trial arm. The measurements' paragraph describing measurements for main participants and family volunteers has been moved to before the description of the interventions on page 8 which we think provides a better flow for the reader.

9. It is also not clear who undertook baseline and outcome measures (p8) as it seems trained nurses undertook key endpoint variables at the 3-year visits and not at baseline?

Response: please see point 10 below

10. How many dietitians were used and were they present throughout the intervention for each group? Was any standardisation undertaken?

Response: We have clarified on page 8 about the research dietitians continuation throughout the trial and also that they carried out all measurements and data collection at all time points. We have clarified that an additional set of measurements were performed at 3 years by independent nurses blinded to group, to counteract any potential observer bias.

11. The dietitians toolkit (p7) consisted of culturally adapted resources is mentioned on p7 and this needs to be detailed in terms of what this consisted of and any references cited. The authors state that '...a paper on the cultural adaptation has been submitted' but no details are provided. This needs to be clear and fully described in this paper. In addition references need to be provided for the 'Chester Step Test' and evidence for statement on 'educational and motivational purposes' (p7).
Response: The Reference for Chester step test has been added. Also we have given further details about our submitted (now provisionally accepted) cultural adaptation paper and expanded on information about the resources used by the dietitians. As our submitted paper describes in detail the resources used we would prefer not to include much detail in this methods paper.

12. On p8, a very broad overview of the methods is given and this needs further details in terms of sampling the participants; number for interviews/focus groups; handling of the data; theoretical

framework for analysis/interpretation of results. Also clarification of what '...experience-centred, culturally-orientated narrative methods' mean.
Response: We have expanded details about the qualitative work on pages 9-10 giving an outline of methods employed. The intention is to submit a paper on this qualitative work, during 2013, along with the main results from the trial and health economic analysis.

Only the initial baseline main results have been reported - not the outcome measures. However some discussion statements do need further support i.e. p10 ‘the very high level of support from within the wider South Asian community''; p11 'PODOSA is one of the first culturally adapted randomised intervention trials in South Asians in the UK'; p11 'PODOSA is important for weight control and diabetes' but no data is given here for this!

Response: We have amended the first paragraph of the discussion and provided references to support these assertions.

Main items described above and include inserting cluster into title and stating if ICC used or not as per Consort Statement. References to current Consort Statements are given above.
Response: These comments have been addressed in points 2 and 6 above.

Note that the authors state that a paper has been submitted for publication (p7) but do not provide it for reviewers.
This is an important trial and this paper needs further clarification and detail to enable the reader understand the conduct of the trial.
Response: We have attached the paper provisionally accepted by Health Promotion International for the reviewers’ information.

Reviewer: 2
If you have any further comments for the authors please enter them below.
Design and baseline characteristics of the PODOSA (Prevention of Diabetes & Obesity in South Asians) trial: a randomised lifestyle intervention in Indian and Pakistani adults with impaired glycaemia at high

Reviewer: Khadija Rantell
University College London

This is an interesting trial. This paper should be as a description of the protocol of the trial (published protocol) with the addition of baseline information about the participants characteristics. The outline of this paper was reviewed in relations to the extended consort statement for cluster randomised trial (Marion Campbell et al 2012). This paper needs revising and resubmission.

The major findings are that there statement about primary (not really stated) and secondary trial objectives are not clear and the statistical methodology in relation to these difficult to assess because the level of inference is not explicit (cluster of individuals). There is also a lack of information to be able to reproduce the sample size and clear statement about trial schedule and time lines (who collect what and when). The inclusion of volunteer families deserves further explanation. There is also insufficient information about the cluster eligibility.

Minor findings include: logical flow of text and presentation of results.

Title

The title should specify that it is a clustered randomised trial.

Response: This has been added.

Background
The background should include rational for using cluster randomised trial for example to minimise contamination and or for practical reasons. On page 5 line 37, the author tried to justify the use of cluster trial, so this section should be part of the background and not methods.

Response: The paragraph from page 5 has been moved to the background section which hopefully clarifies why we chose a cluster design for the trial.

It is not clear whether the objective of the trial pertain to cluster level i.e. family or individual within the family or both. Although the information on page 5 suggests that it is the cluster level that is of interest, the subsequent analyses outline suggest that the authors are interested in both. The objectives of the trial should be sited in the background section to.
Response: We have added specific details of the trial outcomes on page 6. The clustering has been explained in the background section, pages 4-5 and on page 7.

Method
Design

This section should include information and definition of what constitutes a cluster, how they were selected and how was the intervention applied to the cluster. Some of this information, but not all, comes later on page 6 line 38… but it needs to be first.

Response: Eligibility criteria for family volunteers and the definition of a 'cluster' has been added to the methods section on page 7.

On page 5 line 8, the authors stated that the original protocol underwent a substantial amendment because of difficulty of recruitment, with consequence on the primary outcome. This is a good opportunity to expands on this and explain how and if these changes had impacted the choice of the number and size of clusters.
Response: This has been addressed in the sample size paragraph page 7.

The purpose of including volunteers has not been made clear in relation to the design of this trial.
Response: The reason for focusing on the family and including family volunteers has been clarified in the background section paragraph 4.

Participants

The criteria given on page 6 relate to individuals. As this is clustered randomised trial two eligibility criteria are required: clusters and individuals within clusters. The eligibility criteria for clusters should also be given.
Response: This has been clarified as described in the first point under 'methods' above.

Intervention
Page 6 lines 47 to 52 should come under this section along with a description of the each of the two interventions.

Page 6 lines 55 to 59 are irrelevant in this section. This type of information should come either in the Discussion or may be background. The information about the role of the dieticians is relevant

although the writing need some re-organisation for example:
Training, visit schedule, information given…The author stated that the family were seen by the same dietician for the duration of the study (page 7 line 4). This is an unrealistic assumption. A table or a chart of trial schedule would be helpful.

Response: The text about composition of families and definition of a cluster has been moved to earlier in this section and is now much clearer for the reader.
Lines 55-59 have been deleted. We have explained that 3 of our 4 dietitians did in fact remain with the study for the full 5.5 years and they followed their allocated families for the full 3 years. One dietitian left the study in 2009 and her families were distributed amongst the other 3 dietitians.

Outcomes

A description of the outcomes should be given in the same order as the research hypothesis, with indication as to whether they pertain to the cluster level, individual level or both as this has implication on the appropriate analysis of the outcome data. Also these families have been followed up for 3 years and need to state explicitly whether the measurement at the final visit will be used as the endpoints. On page 5, the authors state the following. The authors talked about principal and secondary questions. The research questions need to be described in terms of primary and secondary so that a judgement can be made in relation to study power and whether any adjustment for multiple outcomes is necessary.

Primary outcome (principal research questions):

• Evaluate change in weight loss (outcome= weight): a change in mean weight between the two groups (i.e. clusters) from baseline but did not specify if it is at the 3 years.
• Evaluate Cost effectiveness (based on which variables? See page 7 lines 32 to 50)
• Factor that assist recruitment, adherence with advice given, and retention in the trial. This is about the trial feasibility and ideally should have been part of a “pilot” phase.
Response: We have added a paragraph stating the primary and secondary outcomes of the study and added some text to clarify ‘costs’.
As in our response to the first reviewer pilot studies were not carried out for reasons discussed with the funders (NPRI) at the time of the grant application. However pilot work of the main trial procedures (ie OGTT and the screening and baseline visits was undertaken).

On page 8, the authors described the process of laboratory assessment but stated that these data will be analysed in a separate paper. It is not clear whether the information collected as part of this trial is related to any of the outcomes of the trial.

Response: We have removed the sentence about analyses of the frozen samples as this work is not part of the PODOSA protocol and will be carried out at a later date subject to a new grant application.

Sample size

Description of sample size was given on page 6 lines 26 to 31. The information provided is not complete and does not allow re-calculation of the sample size. The sample size was given for weight loss, which suggests that this is trial primary outcome and it needs to stated clearly. More specifically this section should include: method of calculation, number of clusters, cluster size(s) (equal or unequal sizes?), a coefficient of intracluster correlation (ICC) and 95% confidence interval of ICC. When dealing with a cluster trial, a design effect is applied. More information is needed if competing primary outcomes are of interest. The author should also state the software used for sample size calculation. The author may want to check the following paper: A simple sample size formula for

analysis of covariance in cluster randomized trials by Teerenstra.

Response: Please see our response to first reviewer's comment no. 6. For further explanation, by incorporating the clustering into the model the number of recruits per family will be incorporated by default, whereas location and ethnicity will be incorporated explicitly as covariates. We have added the software used for sample size calculations.

Randomisation / allocation
The author used blocked stratified randomisation, with varying block sizes. Stratifications factors were: location, ethnic group, number of IGT/IFG recruits per family. This is appropriate choice for this type of trial, especially if the number of clusters is small.

On page 6 line 42, the authors talked about the allocation to the treatment group being done independently by the statistician to avoid bias in recruitment. This means that the allocation concealment was applied at the cluster level. The clusters were identified and recruited before randomisation. This is a good strategy to minimise selection bias.

Implementation

The random allocation was generated by the statistician. Information about who enrolled clusters and who assigned clusters to interventions need to be specified as well as the mechanism by which the individual participants within clusters were included as this can be a potential source of bias, for example using complete enumeration would mean that all members of the family who are identified as eligible can be included.
Response: We have clarified in the randomisation paragraph that all members of a family gave consent and completed a baseline visit prior to randomisation. This is also shown in the new Table 1.

On page 6 line 41, the authors state that consent was obtained from all members of the family. The author need to specify whether a cluster (i.e. family) was only included if its eligible member gave their consent and whether consent was sough before or after randomisation. The timing in relation to randomisation and the level at which the consent is sought are important as this may lead to attrition bias.

Response: This is shown in Table 1 and is described in the randomisation paragraph on page 7.

Blinding
On page 8 lines 53, the author stated that the research nurse who was blinded to the allocation group recorded independently a set of key anthropometric measures. Justification as to why blinding was not applied at the cluster level and who reported/measured key outcomes.
Response: This point has been addressed in Randomisation and allocation of interventions paragraph on page 7.

Statistical method

Statistical method for comparing intervention groups and how clustering was taken into account. Identification of the level of inference (individuals or cluster) is not clear.

On page 9 line 20, the author talked about and ITT analysis at the individual level. This is confusing as the outcome is relating to the cluster level. Need to be consistent. Lines 35 to 41, included a statement of the statistical methods to be used but not specifying the research questions or outcome these relate to.

The authors stated that they will use a random effect model to analysis the primary outcome (presumably the weight) and that the will adjust for stratification factors (ethnicity and allocation). This is an appropriate method of analysis. Essentially, this is a one type of analysis and the author should simply state that adjustment will be made for baseline value (presumably weight) and stratification factors (ethnicity and location). It is not clear when the number of IGT/IFG recruits per family (1 or > 1) is not adjusted for in the analysis.

Response: Please see our response to first reviewer's comment no. 6. For further explanation, by incorporating the clustering into the model the number of recruits per family will be incorporated by default, whereas location and ethnicity will be incorporated explicitly as covariates. We have corrected our omission in the statistical analyses section page that we will report ICC. We have detailed in the paper the software used for sample size calculations.

Comments on the cost effectiveness analysis and qualitative analysis are outside my remit.

Results

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Participant flow

Figure 1 – consort diagram indicates that there are 156 cluster (78 to intervention) again the inclusion of 124 volunteer family is not clear in the context of this trial (page 5 line 28).

Response: Additional text in the methods section pages 5 and 7 has we think clarified this point and we have amended Figure 1 to clarify how individuals were grouped into clusters and how and when family volunteers were recruited.

The following information need to be added to the chart:

• Number of received intervention and analysed for primary outcome(s)
• Losses and exclusion (with reasons) after randomisation at cluster level and participant level,

Response: This will be reported in the main trial results paper, this is because we are keen to focus this paper on design and methods only and not to report results. The main paper will report baseline characteristics by randomised group and the final numbers receiving the intervention and in the main analyses. We are guided in this area by our trial statistician Prof. Gordon Murray who is an expert on trials methodology.

Baseline data

On the title, the authors state that they will give a description of the baseline characteristics.

The authors provided a description of baseline characteristics on Tables 1 and 2. The information presented in Table 1 should be given at individual cluster and individual cluster by intervention groups. This is important in order to check whether there are any imbalances. The information presented in Table 2 relates to volunteer's characteristics; a similar presentation by individuals and

clusters is also required for each intervention groups. Again, it is not clear what the role of this volunteer family is in relation to the trial objectives.
Response: Please see response to the previous point and also we hope we have now clarified in the paper about the role of the family volunteers.