PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Protocol for Healthy Habits Happy Homes Scotland. Feasibility of a participatory approach to adaptation and implementation of a study aimed at early prevention of obesity.
AUTHORS	gillespie, jenny; Hughes, Adrienne; Gibson, Ann-Marie; Haines, Jess; Taveras, Elsie; Reilly, John

VERSION 1 - REVIEW

REVIEWER	Maria Maynard Leeds Beckett University
REVIEW RETURNED	11-Dec-2018

GENERAL COMMENTS	Thank you for the opportunity to review this protocol. The proposed study is in an area where ongoing research attention is essential, with early years intervention being a critical issue. A small number of suggested minor amendments are listed below - Article summary It might be useful to have another look at the statements as some (particularly 2 and 3) read more like objectives than strengths or limitations. - Introduction There is a great deal of text in this section, which might be at the expense of clarity in the subsequent sections. If the later suggestions are undertaken, the introduction is where the text could be reduced in order not to exceed the word count. For improved readability, some very long sentences in the introduction would benefit from being edited into shorter sentences. Avoid anthropomorphisms – e.g. ‘ a recent systematic review analysed..’ The study aims could be more clearly presented as an overall aim and a set of objectives - Methods and analysis P7 line 15: ‘The Standard Protocol Items….’ rather than this In ‘Patient and Public Involvement’, it would be useful to have brief description, with references, of the theoretical underpinning of the study (CBPR and co-production) before going on to the practical application that is given in this section. There is no mention of the workforce practitioners mentioned later – should they be viewed as separate form those who were involved in the research process. P7 Line 36 – I appreciate that the SPIRIT statement is being used but a clear aim is not stated here, and the aim is given in the introduction, so may be clearer to stick to the design and setting.

	P8 lines 8-36: Please provide brief detail of the type of workforce practitioners that took part. When and where did the meetings take place? Are there obesity prevalence data for the North East/ specific neighbourhoods to add to or replace the overall figures for Dundee? The need for the work to be carried out in the areas chosen is clear, but for example, were they the most deprived (certainly the neighbourhood with 96% of households in very deprived areas is), what were the close contenders (in other words I'm curious about the level of debate at the meetings, or was there fairly quick consensus?) – can this be discussed briefly in the text? The participatory meetings were presumably with those mentioned in Patient and Pubic Involvement – please link back to that section. Participant characteristics – Are there literacy issues with the target groups (which may be important with the content and delivery of the intervention, but also the control group)? There is no mention of ethnicity and this would be useful to know, including if it a majority White Scottish population in the target setting. Given that the original study was designed for minority ethnic groups, were the elements that are being used in the current study similarly effective across ethnic groups. It would be useful to state at the end of this section that the data generated from this phase will contribute to sample size power calculations for subsequent pilot/ definitive trials, if that is the case. P10. I feel the intervention ethos could be slightly better described in relation to the logic model – (i.e. references to raising awareness, increasing knowledge, improving motivation). The components could be more specific in places (increase physical activity, decrease screen time…), and are there specific targets/ aim to meet recommendations, etc? See comment above re literacy and the materials intended for the intervention and control groups. - Discussion As the authors state, CBPR is to date under-utilized in UK obesity prevention targeting pre-school children and therefore this study is a welcome opportunity for engagement, empowerment and ownership among the target communities. However, this approach is not without challenges e.g. equitable participation, generating commitment, and engagement with particular communities may produce an intervention, which may not suit other communities in wider dissemination. It would be valuable if the authors could briefly discuss/ acknowledge some of these challenges, and how they might tackle those challenges based on their experience/ knowledge.

REVIEWER	Kayla de la Haye University of Southern California, USA
REVIEW RETURNED	18-Jan-2019

GENERAL COMMENTS	This manuscript describes the protocol for adapting the Healthy Homes, Healthy Habits program for a disadvantaged population in Scotland, and a protocol that is being implemented to evaluate the feasibility, acceptability and primary efficacy of this adapted program in a sample of 40 families. My suggestions largely focus

	on providing more information about the following: the intervention components, the theoretical rationale for the intervention and measures, who is being recruited into the study, and the outcomes measures for this sample. Major comments 1. In the Introduction (p.5) can the authors provide more information about how the results of the systematic review that emphasized school, environmental and "empowerment" intervention are relevant to their trial? Do any of these strategies focus on families or in-home interventions? Also, on lines 30-32 can you provide more detail about the strategies found to be effective in pre-school children: i.e., is "skills acquisition" focused on parents, what type of skills were effective, and did behavior change focus on parents, children, or both? Overall, at the end of this paragraph the scientific rationale and argument for using home-based interventions that target the family to prevent obesity in early childhood is not clear. The theoretical rational for the program is also not evident in the manuscript: it is not clear if this program is targeting specific behavior change mechanisms (e.g., habit formation, change in knowledge or behavioral beliefs, etc.) and if these are being evaluated as part of the study. 2. The introduction and/or methods should provide more detail about the intervention that is being tested in this study. On P.5, lines 44-51 can you describe what "targeted family routines" sought to do? What behaviors did this program seek to change? 3. On P.8, lines 33-34: please describe in more detail how the materials from the original program were adapted. E.g., were there major changes in the target behaviors or behavior change mechanisms? 4. Clarify what the primary outcomes are for the trial. The methods describe "Outcome measures" (p.9) that include physical activity, sedentary behavior, and sleep, and anthropometric measures to assess adiposity. It is not clear how dietary intake/eating habits are assessed. In contrast to this, the Logic Model suggests that multiple outcomes will be treated as dependent variables including knowledge, confidence/skill/self-efficacy, motivation/intent for each of the 4 key behaviors. The Logic model does not list change in specific health behaviors as primary outcomes of the trial. Please clarify: what are the primary outcomes of the trial (including if these are parent, child or other family member outcomes), and how these are being measured (including measures of proximal outcomes such as knowledge, and behavioral beliefs). 5. Critical information about the sample and measures is missing from the manuscript. Please clarify who is enrolled into the trial, and what is measured for whom. E.g., The manuscript states that "families" from the target neighborhood will be enrolled: does this mean multiple family members are enrolled, or just one parent/caregiver? Is it an eligibility requirement that a child aged 2-5.5 is enrolled? And subsequently when describing the measures, clarify what is measured and for whom: i.e., are these same measures taken from ALL family members (including children) that are enrolled in the study? Does the parent/caregiver report on

	outcomes for children? What behaviors and anthropometric measures are taken for children? 6. The manuscript does not provide any hypotheses about the evaluation of feasibility or efficacy of the study. If the evidence base and theoretical model(s) justify this, the authors should include some hypotheses for their study aims. Minor comments The Abstract has several grammatical issues: the word “The” in missing in several sentences (e.g., line 29, line 45 (2 instances), line 53. P.4, line 32: Clarify what about the study is limited by the duration and sample size. P.4, line 58: I’d suggest starting a new sentence after “social inequalities”, and clarifying that “this data” is referring to a data set from the UK (clarify what this data set is). P.5, line 16: Is this systematic review looking at children 0-18 years? P.8, lines 8-25: This section could more concisely describe the neighborhood from which the sample is drawn. Overall, the manuscript has several long run-on sentences that could be edited.

REVIEWER	Tania Griffin University of Bath, UK
REVIEW RETURNED	18-Jan-2019

GENERAL COMMENTS	Dear Authors, Overall the manuscript is difficult to follow. It is presenting two phases of a study – the adaptation of the intervention and the planned study for testing it out. These two phases, especially in the methods section are not separated sufficiently to make it clear for the reader. I would recommend amending the manuscript to ensure the two separate phases of the project are clearly defined and presented sequentially. The results of the co-production are not clear and presented with vague terms such as ‘adaptation of existing materials’ without detail on what these adaptation were. The use of the term ‘translation’ is unusual. The term has two definitions – to translate text from one language to another, or to move something from one place to another. I have assumed (but can be corrected) that the intervention delivered in America was in English language therefore translation may refer to the movement of the intervention from America to Scotland but this does not encapsulate the process of adaptation through co-production and CBPR. The addition of word adaptation (which is used more often later in the manuscript) would help to make this a bit clearer. The name of the intervention is not clear – 4H for Scotland, 4H Scotland or 4H, Scotland or Dundee Family Health Study. It varies throughout. If it is now DFHS this should be reflected in manuscript title. The 4H intervention was 6-months but this

	adapted version is 4 months. It has not been explained why this has been shortened. It is not clear whether there are progression criteria for the feasibility study and how will it be decided whether the programme is successful. Several outcomes are presented but it is not explicitly clear which is the primary outcome of focus. Overall the study sounds interesting and one which will provide a useful contribution to the evidence on obesity programmes. The manuscript would benefit from being revised to ensure the processes are presented with more clarity to facilitate ease of reading and to present the study in its best light. Detailed comments: Abstract: It is not clear from the abstract that the paper is two parts – the participatory and co-production of the intervention adaptation and the implementation study. This is mentioned in the last few lines of 'methods' but it states 'could support development' – it is unclear what it means. I would advise using the introduction of the abstract to explain why the study is important (why target health behaviours?), Why Dundee? (what are obesity levels in Dundee), and why 4H intervention (successful in America – can it be implemented here?). Then the methods can be used to explain the co-production and also the implementation study. Page 3, line 28. - Remove the word 'participant' - - 4H for Scotland aims to recruit up to 40 participant families. - A 'range of measures' needs expansion or examples – this is ambiguous Line 29 - 'The intervention consists of…' sounds better than 'intervention consists of…' - The number 4 would be better as 'four' - Visits to 'the' family home - There is no mention of the SMS messages sent as part of the intervention in the abstract Line 34 - 'The control group will receive a standard care….' Introduction As a general comment the introduction is long and would benefit from being made more concise. Page 4, line 55. This is a long sentence which needs amending to change to two. Obesogenic environment needs the original reference. Page 5 line 39 onwards. It is not clear how many phone calls / texts were sent or how many home visits were made. Please add a little more detail. Were all the family present at the session? Line 51 – increased sleep duration and reduced TV viewing on weekend days – was this increased sleep on weekend days only? Page 6 – lines 10-25 - I understand the summary of what is trying to be explained here but it is long winded and becomes unclear. Lines 38-49 – I think this could be removed as it's not adding much to the introduction. If the authors think this is important it should be rephrased to ensure its clear what the link is. Lines 58-5 (page 7) – this is methods not introduction

	Page 7 - Line 23 – members of the public Line 38 – 'In order to' is superfluous – the sentence could start with 'To' Line 40 – CBPR – spell out the acronym here as it hasn't appeared for a while Splitting this section into two would be helpful to explain 1: the adaptation process and 2 : the planned implementation of the intervention. Much of the detail about Scotland deprivation and obesity is repeated from introduction and should be removed from the methods. Page 8 - line 8 'an iterative process of dialogue' - it is not clear what this means Page 9 - Line 9 – 'in order to' can be replaced with 'to' Line 9-12 – this sentence beginning 'This process offers an…' could be removed it is adding words to the manuscript but not much content. Line 30 – the logic model doesn't seem to link well to the text and seems an 'add on', this needs a little more clarification in the manuscript. Lines 39 – explain next to the measurements who will be conducting them. This is explained later in the paragraph but would benefit from being presented earlier. What will the primary outcome be and which are secondary outcomes? Line 54 – the questionnaire has been adapted from one used in the ToyBox study. Is the questionnaire still valid if it has been adapted – what was the process for adaption? Adding a little more detail or a reference would help. Page 10 - Lines 24-33. The researcher delivering the intervention has a lot of experience and is skilled at MI. If this was to be trialled as a larger RCT how would you train the facilitators who would be delivering the intervention? Would you only recruit those who have training in MI or can facilitators be trained to deliver 4H? Page 11 lines 7-10 - It is not clear what the SCOTT checklist will be used for. Is this to measure whether elements of the intervention were delivered as intended? Line 20 – 'parameters such as…' remove the term 'such as' and state the parameters you will be measuring. Line 29 – how many families do you aim to interview? Line 30 – 'experience of obtaining outcome measures' - it is not clear if this means the participants experience of working towards outcome measures such as increased PA or reduced BMI, or their experience of being measured? Line 42 – who will conduct the qualitative data analysis? Figure 2 - MI is used as an abbreviation but not explained on the diagram what this means (not key) - Follow-up measures (missing S) on the end of measures - Adding in the measures taken (BMI etc) in a key or in small font in the boxes would be useful for the reader.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1

The following key amendments have been made to the manuscript:

Strength and Limitations

- It might be useful to have another look at the statements as some (particularly 2 and 3) read more like objectives than strengths or limitations. We have reworded to become strengths and limitations.

Introduction

- There is a great deal of text in this section, which might be at the expense of clarity in the subsequent sections. If the later suggestions are undertaken, the introduction is where the text could be reduced in order not to exceed the word count. For improved readability, some very long sentences in the introduction would benefit from being edited into shorter sentences. Avoid anthropomorphisms – e.g. ' a recent systematic review analysed We have re-structured the introduction and reduced the number of long sentences and avoided anthropomorphisms.

- The study aims could be more clearly presented as an overall aim and a set of objectives We have amended the introduction so that the aims and objectives and later the outcome measures, are clearer and also edited the logic model to reflect this.

Methods

- Overall, we have made changes made to the order and content of methods improved readability and there are links to other sections of the paper and to the logic model

- P7 line 15: 'The Standard Protocol Items….' rather than this we have made change

- In 'Patient and Public Involvement', it would be useful to have brief description, with references, of the theoretical underpinning of the study (CBPR and co-production) before going on to the practical application that is given in this section. We have introduced a brief description of CBPR and co-production principles at an earlier stage to offer a basic theoretical rationale that can be built on in our future papers.

- There is no mention of the workforce practitioners mentioned later – should they be viewed as separate form those who were involved in the research process. We have used stage 1,2,3 to help describe the process and have added sentences to clarify further details e.g multi agency practitioners and location of meetings.

- P7 Line 36 – I appreciate that the SPIRIT statement is being used but a clear aim is not stated here, and the aim is given in the introduction, so may be clearer to stick to the design and setting. We have removed 'aim' as suggested regarding SPIRIT and have ensured that aims are clearly stated earlier.

- P8 lines 8-36: Please provide brief detail of the type of workforce practitioners that took part. When and where did the meetings take place? Now described in more detail.

- Are there obesity prevalence data for the North East/ specific neighbourhoods to add to or replace the overall figures for Dundee? ISD are able to provide a breakdown of childhood obesity

prevalence for each school, although this information is only issued to health boards for management purposes and there appears to be no other local data.

- The need for the work to be carried out in the areas chosen is clear, but for example, were they the most deprived (certainly the neighbourhood with 96% of households in very deprived areas is), what were the close contenders (in other words I'm curious about the level of debate at the meetings, or was there fairly quick consensus?) – can this be discussed briefly in the text? Whilst we agree that neighbourhood obesity data would be useful, unfortunately the data is not available from ISD in this form e.g obesity figures for each school are collected but ISD only release this to healthboards for management purposes. We have also added clarity in terms of the rationale for the North East area being selected, in view of the limited word count we have kept this brief and hope to offer further detail in future papers.

- The participatory meetings were presumably with those mentioned in Patient and Pubic Involvement – please link back to that section. Yes have now made this link and linked to logic model and stage 1-3.

- Participant characteristics – Are there literacy issues with the target groups (which may be important with the content and delivery of the intervention, but also the control group)? A description of Participant characteristics remains brief in view of limited words available. We intend to offer detailed insights in future papers i.e that will report results of stage 1 and 2 and the process evaluation – including barriers such as literacy or language.

- There is no mention of ethnicity and this would be useful to know, including if it a majority White Scottish population in the target setting. Given that the original study was designed for minority ethnic groups, were the elements that are being used in the current study similarly effective across ethnic groups. As above we intend to report on participant characteristics in future papers; process evaluation and results and ethnicity will be included as this data will be collected.

- It would be useful to state at the end of this section that the data generated from this phase will contribute to sample size power calculations for subsequent pilot/ definitive trials, if that is the case. We have offered a sentence to address the sample size, power calculation

- P10. I feel the intervention ethos could be slightly better described in relation to the logic model – (i.e. references to raising awareness, increasing knowledge, improving motivation). The components could be more specific in places (increase physical activity, decrease screen time…), and are there specific targets/ aim to meet recommendations, etc? See comment above re literacy and the materials intended for the intervention and control groups. We feel the intervention ethos is now clearly stated by rewording the introduction and methods to reflect the content of the logic model. We have made changes to the text and logic model to make it clearer that our intention is to assess against UK guidelines eg moving towards, meeting, exceeding guidelines recommendations for physical activity / movement.

Discussion

- As the authors state, CBPR is to date under-utilized in UK obesity prevention targeting pre-school children and therefore this study is a welcome opportunity for engagement, empowerment and ownership among the target communities. However, this approach is not without challenges e.g. equitable participation, generating commitment, and engagement with particular communities may produce an intervention, which may not suit other communities in wider dissemination. It would be valuable if the authors could briefly discuss/ acknowledge some of these challenges, and how they might tackle those challenges based on their experience/ knowledge. A sentence acknowledging the challenges has been added which we feel we could expand on in future papers.

Reviewer 2

Abstract

- We have made changes to grammatical issues in abstract

Introduction

- In the Introduction (p.5) can the authors provide more information about how the results of the systematic review that emphasized school, environmental and “empowerment” intervention are relevant to their trial?

- Also, on lines 30-32 can you provide more detail about the strategies found to be effective in pre-school children: i.e., is “skills acquisition” focused on parents, what type of skills were effective, and did behavior change focus on parents, children, or both. Overall, at the end of this paragraph the scientific rationale and argument for using home-based interventions that target the family to prevent obesity in early childhood is not clear. On page 5 – we have added a sentence to clarify the link with our study and the systematic review. We feel that the current study is an example of an empowerment approach where local people are involved in the research process. The use of motivational interviewing in the intervention further demonstrates empowerment by being client centred, and facilitating behaviour change.

- The theoretical rational for the program is also not evident in the manuscript: it is not clear if this program is targeting specific behavior change mechanisms (e.g., habit formation, change in knowledge or behavioral beliefs, etc.) and if these are being evaluated as part of the study. The introduction and/or methods should provide more detail about the intervention that is being tested in this study. On P.5, lines 44-51 can you describe what “targeted family routines” sought to do? What behaviors did this program seek to change? We have made clearer the basis of the original 4H study in relation to this study and outlined primary and secondary outcome measures. We have also added a sentence to provide further detail about e.g skills acquisition and made it clearer that this intervention is related to improvements in EBRB’s.We have made reference to the original 4H study to highlight that our intention is to make culturally relevant adaptations to this.

Methods

- 3. On P.8, lines 33-34: please describe in more detail how the materials from the original program were adapted. E.g., were there major changes in the target behaviors or behavior change mechanisms? Sentence to clarify changes more related to local language e.g N American – UK, no change to target beahiours or mechanisms. TV in bedroom not as relevant due to rapid change in use of handheld media devices in children,

- 4. Clarify what the primary outcomes are for the trial. feasibilityThe methods describe “Outcome measures” (p.9) that include physical activity, sedentary behavior, and sleep, and anthropometric measures to assess adiposity. Please clarify: what are the primary outcomes of the trial (including if these are parent, child or other family member outcomes), and how these are being measured (including measures of proximal outcomes such as knowledge, and behavioral beliefs). ‘ We ensured that the primary and secondary outcome measures are now described in more detail and that both qualitative and quantitative measures will be used e.g it is clearer that we are interested in family eating meals together in terms of diet.

- It is not clear how dietary intake/eating habits are assessed. In contrast to this, the Logic Model suggests that multiple outcomes will be treated as dependent variables ?? including knowledge, confidence/skill/self-efficacy, motivation/intent for each of the 4 key behaviors. The Logic

model does not list change in specific health behaviors as primary outcomes of the trial. We have made it clearer that objective measures will be of the pre-school child only and that parents will offer detail on diet and screen time subjectively via questionnaires. We have removed long sentences, made shorter and re-written elements of introduction to improve readability .There is now a clearer description of aims and objectives, outcome measures and relates to logic model

- 5. Critical information about the sample and measures is missing from the manuscript. Please clarify who is enrolled into the trial, and what is measured for whom. E.g., The manuscript states that "families" from the target neighborhood will be enrolled: does this mean multiple family members are enrolled, or just one parent/caregiver? Is it an eligibility requirement that a child aged 2-5.5.5 is enrolled? And subsequently when describing the measures, clarify what is measured and for whom: i.e., are these same measures taken from ALL family members (including children) that are enrolled in the study? Does the parent/caregiver report on outcomes for children? What behaviors and anthropometric measures are taken for children? 6. The manuscript does not provide any hypotheses about the evaluation of feasibility or efficacy of the study. If the evidence base and theoretical model(s) justify this, the authors should include some hypotheses for their study aims.

We have now described better the qualitative methods that will offer insights into acceptability and have added hypothesis to logic model. The logic model now aligns better with the written text in terms of outcomes and now clarifies that we are interested in movement toward or exceeding UK guidelines for EBRB's. The neighbourhood information as thought key, have re-worded to describe more succinctly.

Reviewer 3

General:

- Overall the manuscript is difficult to follow. It is presenting two phases of a study – the adaptation of the intervention and the planned study for testing it out. These two phases, especially in the methods section are not separated sufficiently to make it clear for the reader. I would recommend amending the manuscript to ensure the two separate phases of the project are clearly defined and presented sequentially. We have re-written elements of the paper to ensure that it clearly outlines the process and have used stage 1-3 with reference to the logic model which we feel improves readability.

- The results of the co-production are not clear and presented with vague terms such as 'adaptation of existing materials' without detail on what these adaptation were.

- The use of the term 'translation' is unusual. The term has two definitions – to translate text from one language to another, or to move something from one place to another. I have assumed (but can be corrected) that the intervention delivered in America was in English language therefore translation may refer to the movement of the intervention from America to Scotland but this does not encapsulate the process of adaptation through co-production and CBPR. The addition of word adaptation (which is used more often later in the manuscript) would help to make this a bit clearer.

- The name of the intervention is not clear – 4H for Scotland, 4H Scotland or 4H, Scotland or Dundee Family Health Study. We intent to report results and describe details regarding co-production and adaptations in a future paper and process evaluation and feel it is outwith the scope of this protocol paper to go into detail here. We have offered a clearer description of the ethos of co-production as a means to adapt materials etc.We have now consistently used 4HScotland throughout the paper. We have used the word 'adaptation' and removed 'translation' for consistency

- The 4H intervention was 6-months but this adapted version is 4 months. It has not been explained why this has been shortened. The length of the intervention remain the same as the original 4H and we have made this clearer in the paper and figure 2.

- It is not clear whether there are progression criteria for the feasibility study and how will it be decided whether the programme is successful.

- Several outcomes are presented but it is not explicitly clear which is the primary outcome of focus. ? We have outlined the qualitative and quantitative approaches that will be utilised in order to address the primary and secondary outcome measures (now written more clearly).

- Overall the study sounds interesting and one which will provide a useful contribution to the evidence on obesity programmes. The manuscript would benefit from being revised to ensure the processes are presented with more clarity to facilitate ease of reading and to present the study in its best light. We have re-written elements of the paper to ensure that it clearly outlines the process and have used stage 1-3 with reference to the logic model which we feel improves readability.

Abstract

- We have reworded the abstract and made clearer reference to a 3 stage model.

- We had added in some data regarding obesity rates in Scotland and use of SMS.

Introduction

- We have used the UK Foresight Report of 2007 to reference 'obesogenic'

- For reasons of keeping within the 4000 word count, we prioritised changes that would improve readability and clarity on key points linked to this protocol paper and felt that referring to the original 4H study would allow the reader to gain details e.g linked to phone calls / texts were sent or how many home visits were made.

- The section related to Berge et al was moved to the discussion

Methods

- We have added some detail to further describe the 'iterative' process

- We have now set out clearly the primary and secondary outcomes and explained that the researcher will take measurements.

- The logic model is now clearer and links better with the text.

- The toybox questionnaire is validated. Details of adaptations made for this study will be described in a future paper.

- It is the intention that a list of recommendations such as training requirements of researcher would be made in a future paper rather than in this protocol.

- We have provided clarity with regards to the qualitative methods that will be used to gain insights into acceptability.

Figure 1 the logic model has been renamed 4H Scotland and revised to ensure it links better with the text.

Figure 2 we have provided a key regarding MI and measures.

VERSION 2 – REVIEW

REVIEWER	Maria Maynard Leeds Beckett University
REVIEW RETURNED	18-Mar-2019

GENERAL COMMENTS	No additional comments. The authors appear to have made comprehensive improvements to the manuscript and the study should make a valuable contribution to the evidence base.