PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (see an example) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below. Some articles will have been accepted based in part or entirely on reviews undertaken for other BMJ Group journals. These will be reproduced where possible.

ARTICLE DETAILS

TITLE (PROVISIONAL)	The development, feasibility and acceptability of a school-based obesity prevention programme: Results from three phases of piloting.
AUTHORS	Lloyd, Jennifer; Wyatt, Katrina; Creanor, Siobhan; Logan, Stuart

VERSION 1 - REVIEW

REVIEWER	***Dr Peymane Adab*** Senior clinical Lecturer Public Health, Epidemiology & Biostatistics The University of Birmingham UK Competing interests I am principal investigator for a cluster randomised controlled trial of childhood obesity prevention in the West Midlands, funded by the NIHR-HTA programme.
REVIEW RETURNED	19-Jan-2011

THE STUDY	This paper tries to address a complex issue and is a laudable study of the development of an obesity prevention intervention for children. I think the authors have done a great job of trying to summarise the work done in this single paper - but because of the complexity of the study, all aspects are relatievely superficially reported. The authors refer to the MRC framework for complex interventions, but do not really describe how the various phases in the study address the phases described in the framework. It is not completely clear how the intervention was developed. Whilst there is justification for the messages incorporated in the intervention package, it is not clear how they decided on the method for delivery, nor what the rationale is for the "80:20 message". In terms of outcomes - each phase of the study has its own outcomes, and these are implied in the results. However, a more explicit description of the outcome for each phase and a clearer linking of findings from one phase leading to the next is lacking. I think this is in part because there is so much to report in this paper, and the complexity makes it difficult to report in a single paper.
RESULTS & CONCLUSIONS	This study falls between reporting of a process, and reporting of research findings - so it is difficult to assess. However, I think this is inevitable with writing up of the developmental phases of a complex intervention. Table 1 seems unnecessary, and would be better presented in the text and a figure. Table 2 needs to include the numbers as well as % in the columns and is difficult to follow. I am not sure why the data are presented by sex rather than by control/intervention schools. Presumably the data are from the exploratory trial? I can understand why the authors want to report the wider outcomes

	of the exploratory trial and the details of the focus group findings elsewhere - but I am not sure what the presentation of baseline data from the exploratory trial adds to the main outcomes for this particular paper. It is difficult to conclude that an intervention has now been fully developed just from the findings presented in this paper and more cross-referencing to the literature and to previous childhood obesity prevention trials is needed. Why is this study different from previous trials, and how generalisable are the findings? What would be the implications of now taking this forward to a full randomised controlled trial? Reference to the MRC framework for complex interventions needs to be more explicit. There is no discussion of the limitations of the study nor acknowledgement that the intervention could have been developed in other ways had they chosen to do so. I think the discussion is the major section where more work is needed.
REPORTING & ETHICS	I don't think there are any checklists/guidelines for the reporting of phase I and II studies of complex interventions. Therefore it cannot be compared against any checklist. There is no mention of ethics approval - but I assume there was some ethical review, and this simply needs to be stated in the article.

REVIEWER	***Manfred Muller*** University of Kiel, Christian Albrechts Universität zu Kiel The reviewer has no competing interests.
REVIEW RETURNED	24-Jan-2011

GENERAL COMMENTS	This is a first and exploratory study on feasibility, acceptance and first effects of a school-based prevention program fighting against childhood overweight. The authors came out with some favorable results suggesting definitive trials. Although the study seems to be well and very carefully done the authors missed some fundamental issues (i.e. ethical approval and appropriate statistics including a power analysis). In addition they did not adequately refer to previous studies. It remains unclear how the present data add to the present state of the art. Furthermore it remains to be explained how the authors improved their strategies compared with previous prevention experiences. There is extensive literature on the issue of school-based prevention of childhood overweight. Worldwide there are at least 12 international good quality and so-called reference studies (including Janet James study on carbonated drinks as well as Pinky Sahotas well known APPLE's study from Leeds which both have been published in the BMJ before) and a total number of 19 systematic review articles (from which only 1 is cited in the text) with additional 2 review of reviews. Going through the present ms there is considerable ignorance of previous studies. This is especially true for the well known barriers of prevention including SES, mother's weight and sex. The authors provide no idea how they can overcome these barriers. The article lacks a view on the greater dimensions or contexts of the obesity issue. To get in the authors should refer to EU strategies including the well known EPODE program as an example of community-based prevention (E.g. Childhood obesity: Thin living, Hannah Westley, BMJ 2007;335:1236; Obesity: Steps to a leaner Europe, Rory

	Watson, BMJ 2007;335:1238 and also PHN 2009.). School-based prevention cannot work in isolation. The limited effectiveness of school-based prevention of childhood overweight is well documented in a number of long-term studies following the effects over periods of 4,8 and 12 years. If one wants to re-start the story he or she has to tackle limited effectiveness first and then should make clear whether there is a new idea or concept or not. The ms should be improved and submitted to an Obesity journal. The systematic and well documented approach in program development is appreciated and is of value.

REVIEWER	***Dr Louise Hardy PhD, MPH(Hons) | Research Fellow*** Physical Activity, Nutrition and Obesity Research Group (PANORG) | Prevention Research Collaboration THE UNIVERSITY OF SYDNEY Level 2, K25 Medical Foundation Building | The University of Sydney | NSW | 2006
REVIEW RETURNED	07-Feb-2011

THE STUDY	This paper describes a proof of concept for a chil obesity program - detailled description of the participants and the methods of the statistical analyses are not required.
GENERAL COMMENTS	The manuscript is well written and describes a 'proof of concept' regarding the development, feasibility and acceptability of their school-based child obesity program 'Healthy Lifestyle Programme' (HeLP). To date there has been considerable investment in child obesity prevention studies with many showing little improvement in outcome measures that are sustainable. To this end, proof of concept trials, pilot and feasibility studies provide a promising, less costly, avenue to ascertain the potential efficacy of interventions which encourage behaviours that prevent obesity. While I commend the authors for submitting a proof of concept manuscript I do feel there are major gaps in the paper. Firstly, I realise the constraint of the word limit may impact on the inclusion of details, however I do feel that a wee bit more information on the development and implementation of HeLP would be useful. I suggest this because the key intervention points in child obesity programmes are generally consistent targeting key modifiable behaviours (i.e., reduce soft drink, decrease screen time etc), but it is information how these are successfully developed implemented, taken up and a programs sustainability which are of prime importance. In my opinion the authors should consider publishing their focus group work and how this informed the development of their program. In its current state, the manuscript does not provide enough information on how this program would be more efficacious than another school-based program. To this end, I do not want to deter the authors from publishing their proof of concept of a program, rather more detail is warranted at this stage.

	I have made specific comments below which I hope the author will consider and find useful. Specific comments Page/Line - 8/10 I think it would be useful to mention upfront whether HeLP was delivered only within schools, and was that only primary schools, or were there also other delivery settings outside of school? I feel this is important as one of the 'failing' points of sustainability for many school-based interventions is buying into curriculum time. Understanding how a program engages schools is important. Page/Line - 8/50 Again the setting where focus groups were undertaken and where these were held separately for students and teachers. What was the aim of the focus groups – to ascertain knowledge, attitudes and behaviours, or was it ascertain which behaviours could be leveraged? Did focus groups assist in the development of the intervention. Page/Line - 8/52 Was the questionnaire completed by parents about the study (ie intervention actions, acceptability etc) or about their child's behaviour? Page 9 The authors state the intervention is based on 3 key messages however they fail to describe how these messages were delivered to students and to parents (via research team, external providers, research team?) and the intervention products i.e., was it written material, interactive sessions etc. Information on the engagement of key stakeholders (who and how) would be useful. How were families engaged? Page/Line - 10/6-14 It would be useful to the reader to have more information about the focus groups. For example defining the indifferent group (and was that 4 participants, or 4 focus groups. Weer interviews with staff and head teacher held separately or together and again was n the number of participants or groups. Further, what was the aim of the focus groups – to feedback on the delivery of the intervention or participant's knowledge and awareness? Page/Line - 10/30 Is there a difference between primary and junior school?

	Page/Line - 11/24 It is interesting that the authors state that HeLP is for children, schools and families, yet the intervention was restricted to Year 5 students. Perhaps the authors would consider further explanation of this given whole of school approaches that starts with Kindergarten children may have great efficacy as such programmes become imbedded into a schools culture. Can the intervention be adapted to other Year groups? Page/Line - 11/35 How did HeLP promote family engagement with the school? Page/Line - 11/45 Did any of the activities include change to the school environment? Eg ban soft drinks from school vending machines, increase physical activity lessons? etc Page/Line - 14/22 I do feel that information relating to the development of the intervention and how intervention components were derived from the focus groups is key information and probably should be published ahead of this paper. This would allow the reader to have a good understanding of what was done. Page/Line - 14/40-47 How feasible are external providers to deliver the intervention? Can the intervention be implemented on an equity issue (ie who pays, particularly in low income areas?)

VERSION 1 – AUTHOR RESPONSE

Below we address each comment from the reviewers in turn with details of where the manuscript has been amended.

Reviewer 1
1.1 The authors refer to the MRC framework for complex interventions, but do not really describe how the various phases in the study address the phases described in the framework. It is not completely clear how the intervention was developed.

We have added some more information regarding how the intervention was developed using the MRC framework and tried to make it more explicit as to how each phase fed into the next phase during the development and piloting by providing user views for each phase and their implications for the subsequent phase. (results p11-13).

1.2 Whilst there is justification for the messages incorporated in the intervention package, it is not clear how they decided on the method for delivery, nor what the rationale is for the "80:20 message".

We have added in the rationale for all the messages including the ‘80:20’ concept in the

‘development, feasibility and piloting methods’ section (p7). The methods of delivery and the underlying process of behavior change are detailed in table one (revised), however further details of the underlying change mechanisms (behavior change techniques) linked to each delivery method are detailed in the intervention mapping paper which is referenced.

1.3 In terms of outcomes - each phase of the study has its own outcomes, and these are implied in the results. However, a more explicit description of the outcome for each phase and a clearer linking of findings from one phase leading to the next is lacking. I think this is in part because there is so much to report in this paper, and the complexity makes it difficult to report in a single paper.

We have split up the results section of each phase into ‘user views’ and ‘implications’ for the subsequent phase in order to provide a more detailed description of the outcome of that phase and how it informed the next phase of development (p11-13). In addition we have replaced table 1 (feasibility data) with a table detailing the intervention components, processes of behavior change and methods of delivery in order to provide a summary of the intervention package.

1.4 This study falls between reporting of a process, and reporting of research findings - so it is difficult to assess. However, I think this is inevitable with writing up of the developmental phases of a complex intervention.

Table 1 seems unnecessary, and would be better presented in the text and a figure.

We have deleted table 1 (feasibility data) adding the information into the body of the manuscript (p13)

1.5 Table 2 needs to include the numbers as well as % in the columns and is difficult to follow. I am not sure why the data are presented by sex rather than by control/intervention schools. Presumably the data are from the exploratory trial?

Table 2 has been substantially amended and presented by randomized group (rather than gender). We understand that the original table was difficult to follow and have altered it to detail only demographic and weight status (BMI) data.

1.6 I can understand why the authors want to report the wider outcomes of the exploratory trial and the details of the focus group findings elsewhere - but I am not sure what the presentation of baseline data from the exploratory trial adds to the main outcomes for this particular paper.

We agree with the reviewer and have deleted the baseline data related to the behavioural questionnaires and objectively measured physical activity in the ‘summary of baseline data’ section (results p15).

1.7 It is difficult to conclude that an intervention has now been fully developed just from the findings presented in this paper and more cross-referencing to the literature and to previous childhood obesity prevention trials is needed.

We have expanded upon the findings from each phase and the discussion has been substantially amended to show how the intervention was developed. Additional references to other obesity prevention trials have been added into the background (p6) and the discussion (p17).

1.8 Why is this study different from previous trials, and how generalisable are the findings? What would be the implications of now taking this forward to a full randomised controlled trial?

Similarly the discussion now includes consideration of how ‘HeLP’ differs from previous trials and its

potential generalisability (p17 and p19).

1.9 Reference to the MRC framework for complex interventions needs to be more explicit. There is no discussion of the limitations of the study nor acknowledgement that the intervention could have been developed in other ways had they chosen to do so. I think the discussion is the major section where more work is needed.

We have made more explicit reference to the MRC framework in the background (p6) and have expanded on the 'strengths and limitation' section after the abstract (p4) and have also discussed limitations in the discussion (p19).

1.10 There is no mention of ethics approval - but I assume there was some ethical review, and this simply needs to be stated in the article.

Ethical approval for each phase is detailed at the end of the manuscript (p20).

Reviewer2
2.1 This is a first and exploratory study on feasibility, acceptance and first effects of a school-based prevention program fighting against childhood overweight. The authors came out with some favorable results suggesting definitive trials. Although the study seems to be well and very carefully done the authors missed some fundamental issues (i.e. ethical approval and appropriate statistics including a power analysis).

The paper states that ethical approval was obtained (as above). As these phases are concerned with developing the intervention and determining its feasibility and acceptability it is not appropriate to conduct a statistical analysis as the exploratory trial was not powered to determine effectiveness. The exploratory trial was conducted to assess the acceptability and feasibility of the trial design, outcome measures and of the intervention for schools, children and their families to inform the design of the definitive evaluation. The anthropometric data collected in the exploratory trial will inform the sample size calculation for the definitive evaluation hence the results we present in this paper are merely descriptive. A comment to clarify this has been added to the discussion.

2.2 In addition they did not adequately refer to previous studies. It remains unclear how the present data add to the present state of the art. Furthermore it remains to be explained how the authors improved their strategies compared with previous prevention experiences.

The discussion section has been expanded and how this intervention differs to others has been considered and makes reference to other school-based interventions.

2.3There is extensive literature on the issue of school-based prevention of childhood overweight. Worldwide there are at least 12 international good quality and so-called reference studies (including Janet James study on carbonated drinks as well as Pinky Sahotas well known APPLE's study from Leeds which both have been published in the BMJ before) and a total number of 19 systematic review articles (from which only 1 is cited in the text) with additional 2 review of reviews. Going through the present ms there is considerable ignorance of previous studies. This is especially true for the well known barriers of prevention including SES, mother's weight and sex. The authors provide no idea how they can overcome these barriers.

In order to present the 3 development and evaluation phases of HeLP within the word limit of this manuscript, rather than discussing individual school-based prevention trials we have referred to the most recent systematic review evidence which includes the trials mentioned above as well as other

school-based interventions We acknowledge that SES and parental weight status are known risk factors for childhood obesity, however, we are explicit that we are taking a population approach to prevention and, in developing the Programme in schools with children from varying socio-economic backgrounds, we are confident that the activities are appropriate and able to engage regardless of individual circumstances. In addition, we were mindful when developing the intervention, that should there be evidence of effectiveness, it would be possible to roll the programme out in all schools within the National Curriculum for key stage 2 as commented on in the discussion (p18).

2.4 The article lacks a view on the greater dimensions or contexts of the obesity issue.
To get in the authors should refer to EU strategies including the well known EPODE program as an example of community-based prevention (E.g. Childhood obesity: Thin living, Hannah Westley, BMJ 2007;335:1236; Obesity: Steps to a leaner Europe, Rory Watson, BMJ 2007;335:1238 and also PHN 2009.). School-based prevention cannot work in isolation. The limited effectiveness of school-based prevention of childhood overweight is well documented in a number of long-term studies following the effects over periods of 4, 8 and 12 years. If one wants to re-start the story he or she has to tackle limited effectiveness first and then should make clear whether there is a new idea or concept or not.

In the background (p6) we have now referenced community based interventions and, in the discussion, show how a Programme such as 'HeLP' can form part of such an approach (p17).

Reviewer 3

3.1 While I commend the authors for submitting a proof of concept manuscript I do feel there are major gaps in the paper. Firstly, I realise the constraint of the word limit may impact on the inclusion of details, however I do feel that a wee bit more information on the development and implementation of HeLP would be useful. I suggest this because the key intervention points in child obesity programmes are generally consistent targeting key modifiable behaviours (i.e., reduce soft drink, decrease screen time etc), but it is information how these are successfully developed implemented, taken up and a programs sustainability which are of prime importance.

The methods (p8-10) and results sections (p11-13) have been substantially amended to detail the outcomes of each phase and the implication of these for these for the refinement and evaluation of help. In addition, we have now included a table (Table 1) detailing methods of delivery and the underlying process of behavior change.

3.2 In my opinion the authors should consider publishing their focus group work and how this informed the development of their program. In its current state, the manuscript does not provide enough information on how this program would be more efficacious than another school-based program. To this end, I do not want to deter the authors from publishing their proof of concept of a program, rather more detail is warranted at this stage.

In the results section (p11-13) we have now included some additional detail regarding the focus groups and their findings. It was beyond the scope of this paper to include detailed quotes from all the qualitative data we have collected from the three phases of development, however, we have tried to present an overview of the views of teachers, children and their parents in the 'User Views' sections accompanying each phase.

3.3 8/10 I think it would be useful to mention upfront whether HeLP was delivered only within schools, and was that only primary schools, or were there also other delivery settings outside of school?

In the abstract (p2) we now make it clear that the intervention is delivered solely within schools and the addition of Table 1 outlining the intervention components and who delivers them further clarifies

the context of the Programme.

3.4 I feel this is important as one of the 'failing' points of sustainability for many school-based interventions is buying into curriculum time. Understanding how a program engages schools is important.

We completely agree with this comment and have supplemented part of the discussion (p18) to show how the Programme dovetails with National Curriculum objectives for this age group. The user views for phase 2 (p12) show how the Programme is able to engage the schools and is feasible and acceptable to the teachers.

3.5 8/50 Again the setting where focus groups were undertaken and where these were held separately for students and teachers. What was the aim of the focus groups – to ascertain knowledge, attitudes and behaviours, or was it ascertain which behaviours could be leveraged? Did focus groups assist in the development of the intervention.

We have now clarified the purpose for collecting the qualitative data (interviews with children and parents, focus groups with children) in the 'development, feasibility and piloting methods' section (p8) and the 'implications' section of the results (p11-13) show how these findings informed the refinement and evaluation of the Programme. We have also provided some additional detail on the sampling strategy used for the focus groups in the methods (p8-10).

3.6 8/52 Was the questionnaire completed by parents about the study (ie intervention actions, acceptability etc) or about their child's behaviour?

Similarly the questionnaires responses from parents were part of the process evaluation (p7) to determine whether the Programme was acceptable and feasible.

3.7 The authors state the intervention is based on 3 key messages however they fail to describe how these messages were delivered to students and to parents (via research team, external providers, research team?) and the intervention products i.e., was it written material, interactive sessions etc.

Table 1, which has been added to the revised manuscript, presents the components of the intervention, methods of delivery and who delivers them. In addition the discussion now expands upon some of our delivery methods.

3.8 Information on the engagement of key stakeholders (who and how) would be useful.

Key stakeholders included teachers, headteachers, children and their parents. More detail on the views of these stakeholders in the 'user views' section of the results section and in the discussion to demonstrate how they were engaged has been added.

3.9 How were families engaged? 11/35 How did HeLP promote family engagement with the school?

More information in the discussion (p17-18) has been added regarding how families were engaged.

3.10 It would be useful to the reader to have more information about the focus groups. For example defining the indifferent group (and was that 4 participants, or 4 focus groups. Were interviews with staff and head teacher held separately or together and again was n the number of participants or groups. Further, what was the aim of the focus groups – to feedback on the delivery of the intervention or participant's knowledge and awareness?

We have provided some additional detail on the sampling strategy used including the number of focus groups and children participating in each one in the methods section (p8-10) and in the three figures.

3.11 Is there a difference between primary and junior school?

In England, a primary school starts from Reception (4-5 yr olds) and goes up to Year 6 (11-12 year olds), whereas a Junior school starts from Year 3 (7-8 yr olds) and goes up to Year 6.
So as not to confuse an international audience we have now only used the term primary school.

3.12 It is interesting that the authors state that HeLP is for children, schools and families, yet the intervention was restricted to Year 5 students. Perhaps the authors would consider further explanation of this given whole of school approaches that starts with Kindergarten children may have great efficacy as such programmes become imbedded into a schools culture. Can the intervention be adapted to other Year groups?

Although our development work has shown that year 5 were more receptive to the messages and more able than the other year groups within primary school to engage their families and translate the messages into behavior changes, several of the activities have a whole school focus in order to try and create a healthy lifestyles culture within the school. In answer to the question regarding other year groups we would suggest that the focus remains on year 5 and by creating awareness of the Programme throughout the school younger year groups will hopefully look forward to and engage in the Programme once they are in year 5.

3.13 Did any of the activities include change to the school environment? Eg ban soft drinks from school vending machines, increase physical activity lessons? Etc

Although the intervention was not developed to directly alter the school environment in the ways mentioned above, the development work in creating a receptive context at the level of the school, a crucial component of the intervention, led to the schools themselves adopting new practices and these have been added to the discussion.

14/22 I do feel that information relating to the development of the intervention and how intervention components were derived from the focus groups is key information and probably should be published ahead of this paper. This would allow the reader to have a good understanding of what was done.

We have tried to show how the focus groups informed and further developed the Programme in this revised manuscript.

14/40-47 How feasible are external providers to deliver the intervention? Can the intervention be implemented on an equity issue (ie who pays, particularly in low income areas?)

We agree these are important points which we have considered fully throughout the development of the Programme and continued stakeholder involvement (Public Health, Local Authority, Community Pediatricians) will inform implementation of the Programme should a full trial demonstrate effectiveness and cost effectiveness.

VERSION 2 - REVIEW

REVIEWER	***Prof.Dr.M.J.Müller***
REVIEW RETURNED	10-Mar-2011

THE STUDY	The study population has not been described in detail and essential data on SES or parental weight are missing. outcome is described in terms of body weight, but the effect of the intervention on food intake, physical activity and TV consumption are not presented. Since the authors have performed a healthy lifestyle intervention changes in lifestyle rather than body weight should be taken as primary outcomes.There are no informations about statistics.
RESULTS & CONCLUSIONS	The authors should focus on feasibility and acceptability, data on effectiveness should be omitted.
REPORTING & ETHICS	The authors did not mention ethical issue, it is unclear whether the protocol was approved by the local ethical committee.

REVIEWER	***Peymane Adab***
REVIEW RETURNED	01-Apr-2011

THE STUDY	This is a complex paper and does not completely fit with a particular commonly used design. However, there is a need for such papers, and the authors have made a good attempt to describe the process of developing a complex health intervention.
GENERAL COMMENTS	The authors have addressed most of the comments made on the first draft in this revision.

VERSION 2 – AUTHOR RESPONSE

Please see our responses below.
At present, author SC is credited with critical revision only. As per the definition of authorship provided by the International Committee of Medical Journal Editors, that is insufficient to qualify for authorship. Please therefore add SC to an acknowledgements section, or amend the contributor ship statement if SC did in fact undertake more work than is currently reported.

We have amended the author contributions section on page 21.

Reviewer Muller's comment re. ethics approval appears to be answered by the ethics statement at the end of your paper.

Reviewer(s)' Comments to Author:
Reviewer: Prof.Dr.M.J.Müller
no conflicts of interests

The study population has not been described in detail and essential data on SES or parental weight are missing. outcome is described in terms of body weight, but the effect of the intervention on food intake, physical activity and TV consumption are not presented.

As we have tried to clarify, the intervention was designed to engage schools, children and their families of varying socio-economic and weight status. In the proposed full trial we will look at school SES (using number of children eligible for free school meals), gender and individual children's BMI for possible differential intervention effects. As phase 3 was only an exploratory trial we felt that, for this paper, we needed to demonstrate that we were able to collect such data. Table 2 presents the baseline characteristics of the children only and not their parents as the intervention is tailored to the individual child and their circumstances with a crucial aim of engaging the parents to support their

child in healthy lifestyle behaviours. Whilst we acknowledge that parental weight status is strongly associated with a child's BMI, we felt that the ethical considerations of weighing and measuring parents outweighed any potential benefit of having this information; moreover, such measurements could well be counterproductive in creating the conditions for behaviour change within the family.

Since the authors have performed a healthy lifestyle intervention changes in lifestyle rather than body weight should be taken as primary outcomes. There are no informations about statistics.

The primary outcomes for the three phases of piloting have been developing and determining the feasibility and acceptability of the HeLP Programme. We understand, therefore that we perhaps should not include any outcome data. However, we have only included data on proportions overweight and obese (calculated using Coles, 1990 UK reference curves for children (25)) in order to demonstrate 'proof of concept' because the definitive trial will be powered on changes in BMI sds at 24 months. We have tried to make it clear in the paper that this is not an effectiveness study.