

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Evaluation of the COPING Parent online universal programme: Study protocol for a pilot randomised controlled trial
AUTHORS	Owen, Dawn; Griffith, Nia; Hutchings, Judy

VERSION 1 - REVIEW

REVIEWER	Marianne Simonsen Aarhus University, Denmark
REVIEW RETURNED	22-Aug-2016

GENERAL COMMENTS	<p>Referee report on Owen et al: Evaluation of an online parenting programme based on 'The Little Parent Handbook': Study Protocol for a pilot randomized trial</p> <p>This protocol outlines a pilot evaluation of a relatively cheap online universal parenting programme. The pilot is currently being carried out in North-West Wales. The researchers recruit parents of 3-8 year-olds via health visitors and school nurses and use a wait-list design in their evaluation. The primary outcome measures positive parent-child interactions through the Dyadic Parent-Child Interaction Coding System. The authors note that the intention is to recruit 60 parents (40 to intervention, 20 to wait-list control).</p> <p>Major comments: I appreciate the idea of providing parenting programmes to a broader group of parents; it is definitely possible that not only disadvantaged populations could benefit from guidance. Since the intervention is provided online, universal provision will also likely be feasible in a real world setting.</p> <p>My main reservations are the following: - I wonder about selection into the research project. Who are expected to sign up? Are they likely to resemble the average parent in North-West Wales? One could imagine that those who focus on positive parenting to begin with are more likely to sign up – but health visitors may also more strongly encourage more disadvantaged parents to sign up. In any case, it would be relevant to compare participants' observable characteristics to those of the overall population with 3-8 year-olds in North-West Wales. Would the authors have access to any aggregate information that would allow for such a comparison? This is important for predicting who would pick up the intervention if it were to be rolled out in full scale later but also for understanding the results. - While I like the idea of providing this programme to a broader population, such an evaluation usually requires larger samples because some groups may only benefit very little or not at all. The general idea of pilot RCTs is definitely meaningful but I worry that a</p>
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	<p>population of 60 will only give very weak indications of the effects of the programme and will not allow for sub-group analyses.</p> <p>- The study is concerned with short-term outcomes. It would be interesting, however, to track families for a longer period in a subsequent full-scale evaluation. Especially because it would be relevant to know if the intervention matters for child outcomes, and not only parent-child interactions, in the longer run. Is this the intention?</p> <p>- The motivation of the study focuses on several issues that are not necessarily well-linked – and it is not clear that they are linked to the intervention either. For example, there is much discussion of issues associated with kids' eased access to technology but also of challenges that are very different in nature such as divorce and low socio-economic status. I would like to see a more coherent motivation and discussion of which challenges the programme is likely to be able to address.</p> <p>- It would be relevant to know what other types of interventions and services are available in the region, especially to those with parenting challenges.</p>
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REVIEWER	<p>Sarah Rabbitt Assistant Professor Oberlin College Oberlin, OH USA</p>
REVIEW RETURNED	14-Sep-2016

GENERAL COMMENTS	<p>This manuscript describes the protocol for a pilot randomized controlled trial (RCT) of an online parenting program for parents of young children (3-8 years old). Both the protocol and the manuscript have many strengths; the protocol uses a treatment delivery platform (the internet) that removes barriers to accessing resources, the parenting program is based on effective behavioral principles, and many important methodological details are described in the manuscript. Below I offer specific feedback to clarify my ratings on the Review Checklist and make additional comments about ways to further improve the current manuscript.</p> <p>Statistical Analyses</p> <ul style="list-style-type: none"> • It would be helpful to provide more detailed information on plans to address missing data given the high likelihood that there will be parents who drop out of the program before completing it and, therefore, will not provide any follow-up data. • Based on the information on mediators and moderators noted earlier in the manuscript (p. 21-22), it appears that there are specific planned mediator and moderator analyses. These analyses should be described in more detail. <p>Study Limitations</p> <ul style="list-style-type: none"> • The authors note one specific limitation (the requirement to log into the online program each week and the potential for problems related to parent engagement). However, there are other limitations of the study that should be noted, including its small sample size and use of wait-list control condition instead of an alternative comparison group (e.g., attention controls). The manuscript would be improved with a more comprehensive discussion of limitations. <p>Supplementary Reporting</p>
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There are several items in the SPIRIT checklist that are either not addressed at all in the manuscript or inadequately addressed. These items are noted in the list below.

- 6b. The choice of the waitlist control as a comparison group is not explained in the manuscript. Given the variety of alternatives, the authors should explain why they selected this type of control group.
- 13. A participant timeline for each group (intervention and control) would be helpful to include as a figure.
- 14. There is not a clear explanation for the specific number of participants included in the protocol. How were these estimates (intervention group $n = 40$, control group $n = 20$) generated? In addition, the authors state their plans to recruit 60 participants, but it is very likely that some of those participants will not complete the program. Is the intention to enroll a total of 60 participants or to ensure that 60 participants complete the program? This should be clarified.
- 18 b. For parents who drop out of the program, will there be any efforts made to collect follow-up data?
- 21a-23. Minimal information is provided on the items related to monitoring of data. Are there any reasons that families may be discontinued from the program (e.g., a psychiatric or other medical emergency)?
- 31. The authors note plans to publish data in peer-review journals and to present data at conferences. However, it seems that they believe the information from this study would be helpful for healthcare professionals, health visitors, and school nurses as well (p. 23). How do the authors propose to share relevant findings with these groups?
- 32. A model consent form is not provided.

Other Comments and Recommendations

In addition to the information noted previously, the manuscript would benefit from addressing several other specific issues. These are listed below, organized by section of the manuscript.

Abstract

- Registration details should be added to end of the abstract.

Background

- The background section includes information about both universal programs and targeted programs. Because this is a universal program, it would be helpful if the authors re-focused the background section on universal programs and make a stronger argument for the need for such programs.
- This section is divided into several subsections. The number of subsections reduces the readability and coherence of the background. It would be helpful if the authors revised this section and removed the subheadings. The overall readability of to manuscript would be improved if subheadings were removed (or reduced) throughout the document.
- When presenting the aims and objectives (p. 9), the authors state that key objectives of the program include assessing the acceptability of the program. However, there are no specific hypotheses related to perceived acceptability or parent satisfaction and no measures related to these constructs. If specific data are being collected related to acceptability and satisfaction, add that information to the manuscript. If not, consider revising the document to remove references to the constructs.

Methods

	<ul style="list-style-type: none"> • In terms of inclusions and exclusion criteria, were families who were already receiving services or involved in treatment included in the program? If not, note that in the manuscript. If so, explain how you can be sure that participation in those services/treatments would not influence the study results. Are parents asked about their engagement in other programs/treatments? • The authors mention a feasibility study conducted in 2015 that informed the protocol design (p. 13) but provided no detailed information on that study. What was the design of that study? Were data collected and analyzed? <p>Study Outcomes</p> <ul style="list-style-type: none"> • For the parent-child observations, why are child categories not coded? It seems like potentially valuable information. The authors state that child variables are not coded because parent-report data (via questionnaire) will be used. However, both observational data and parent-report data could be gathered and analyzed in this study. If there is a compelling reason not to use observational child data, this should be included. <p>Discussion</p> <ul style="list-style-type: none"> • This section does not adequately describe plans for dissemination (e.g., how to get the program to health workers and school nurses). In fact, issues related to dissemination are not addressed in this section.
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1 comments

1. Reviewer 1 wanted to know who are expected to sign up to the study as it would be relevant to compare participants' observable characteristic to those of the overall population with 3-8 year olds in North-west Wales. Reviewer 1 was also interested whether the authors would have access to any aggregate information that would allow for such comparison?

The authors have no access to any aggregate information on the overall observable characteristics of parents in North Wales. However, the researchers will be collecting demographic information and baseline characteristics will be reported. Additionally, the percentage of parents recruited from both health visitors/school nurses and recruitment poster will be reported and their characteristics compared to the national population characteristics (i.e. unemployment and poverty). This will allow us to explore the background to the parents who signed up for this study in addition to how well they engaged with the programme. This point has been made clearer in the manuscript (page 10 – paragraph 2).

2. Reviewer 1 liked the idea of providing the programme to a broader population but felt that such as evaluation required a larger sample as some parents may benefit very little or not at all. Reviewer 1 felt that a sample of 60 parents would not be sufficient.

Unfortunately due to time and cost restraints associated with this PhD project, a larger sample size would have been difficult to recruit in the given time frame. This is a pilot study with the aim of further evaluation trials of the programme. After considering this feedback from reviewer 1, the authors have decided that a mediator/moderator analysis would be difficult to do given the small sample size and so have decided not to pursue with this. If funding allows for a larger scale trial in the future, perhaps this would be something worth considering. The mediator/moderator paragraph of the paper has been taken out.

3. Reviewer 1 expressed an interested in a longer-term follow-up, as it would be relevant to know if the intervention matters for child outcomes. Reviewer 1 has asked if this is the intention?

The authors agree that a longer-term follow-up would be beneficial in terms of both parent-child outcomes and child outcomes. However, again due to time and cost constraints with this PhD project, this would not be possible with this trial. However, if the results justified, funding could be sought for a longer-term follow-up. If a larger scale trial were to get funded in the future, this would certainly be considered.

4. Reviewer 1 expressed that she would like to see a more coherent motivation and discussion of which challenges the programme is likely to be able to address.

The authors found this comment helpful, and agreed that the introduction section in particular needed a more concise focus. The authors have worked on the introduction section in order to clarify the project's focus. The introduction is now more focused on the availability, cost and barriers of group parenting programmes and the challenges faced by parents who would like additional support but who are not experiencing severe child problem behaviours. The introduction discusses the benefits of providing an online intervention to parents in general. Changes made to the introduction are highlighted in purple text (page 3, paragraph 2 - page 7, paragraph 1).

5. Reviewer 1 stated that it would be relevant to know what other types of interventions and services are available in the region, especially to those with parenting challenges.

The authors agreed that this would be useful information to add to the introduction section. The authors have discussed the Flying Start initiative and discussed how only parents living in disadvantaged areas of wales with a child aged 4 years or younger are able to access the programmes, highlighting the challenges for some parents to access support (page 4 – paragraph 2). The role of health Visitors in providing universal support has also been discussed (page 5).

Reviewer 2 comments

1. Statistical Analysis – reviewer 2 felt it would be helpful to provide more detailed information on plans to address missing data.

More information has been added regarding the strategy for to address missing data (page 20 – paragraph 3). The authors will use multiple imputation to treat any missing data as a general-purpose approach to dealing with missing data.

2. Reviewer 2 wanted the authors to describe the planned mediator/moderator analysis in more detail.

Having read both reviewer's comments regarding mediator/moderator analysis, the authors agree that the small sample size would pose a challenge, therefore this section has been removed.

3. Study limitations – reviewer 2 felt that the manuscript would be improved with more comprehensive discussion of limitations.

The authors have added more limitations to the 'strengths and limitations' sub-heading (page 3 – paragraph 2). The limitations are, (1) potential loss of follow-up data, (2) recruitment of a small sample size and (3) funding and time constraints not allowing for a longer-term follow-up.

Supplementary Reporting

1. (6b) The choice of the waitlist control as a comparison group is not explained in the manuscript. Given the variety of alternatives, the authors should explain why they selected this type of control group.

The authors favored a control condition over an alternative treatment condition, as (1) the authors wanted all parents to access the 'Little Parent Handbook' online programme (page 19 – paragraph 3) and (2) an alternative treatment is not available (other than a treatment as usual health visitor intervention).

2. (13) A participant timeline for each group (intervention and control) would be helpful to include as a figure.

A participant timeline has been added to the manuscript (page 20).

3. (14) There is not a clear explanation for the specific number of participants included in the protocol. How were the estimated generated? Is the intention to enroll a total of 60 participants or to ensure that 60 participants complete the programme? This should be clarified.

The authors agreed that 60 was all that was feasible for this PhD study to explore initial outcomes in terms of engagement and use of positive parenting strategies. The aim is to enroll 60 parents. This point has been made clearer in the manuscript (page 19 – paragraphs 2 and 3).

4. (18b) For parents who drop out of the programme, will there be any efforts made to collect follow-up data?

All efforts will be made to collect follow-up data from participants. This has also been clarified in the manuscript (page 18 – paragraph 3).

5. (21a-23) Minimal information is provided on the items related to monitoring of data. Are there any reasons that families may be discontinued from the programme (e.g. a medical emergency).

There are no reasons for families being discontinued from the programme. The only exclusion criteria are not having a child in the 3-8 age range, having an adequate understanding of English and not having access to the internet (page 9).

6. (31) The authors note plans to publish data in peer-reviewed journals and to present data at conferences. However, it seems that they believe the information from this study would be helpful for healthcare professionals, health visitors and school nurses. How do the authors propose to share relevant findings with these groups?

Both parents recruited to the trial and healthcare professionals will be informed of the study results by means of a letter summarizing the outcomes of the programme. The authors have also agreed to present the main findings to health care professionals (health visitors/ school nurses and their managers) once the data becomes available. This has been added to the manuscript (page 21, paragraph 3 – page 22, paragraph 1). Additionally, information regarding the results of the trial will also be made available in our annual newsletter and website.

Other comments and Recommendations

1. Abstract – registration details (ISRCTN number) have been added to the end of the abstract (page 3)
2. Background – the introduction has been modified to focus more on universal parenting programmes (pages 3-7)
3. Background – the subheadings have been removed in order to increase readability and coherence of the background section (pages 3- 7)
4. Aims and objectives – the authors agreed that no measures of parent acceptability of the programme were taken and so this statement has been removed from the manuscript (page 7)
5. Methods – families who are already in receipt of services are also invited to participate in the study as this is not an exclusion criterion. Parents are also asked to disclose which service(s) they are receiving and the duration of the service. This has been clarified in the manuscript (page 9)
6. Feasibility study – the authors agreed that the feasibility study was not fully explained in the manuscript. The aim of the small-scale study was to gain user feedback in addition to testing the interactive features of the software. No measures were taken and participants were not randomised. This has been clarified in the manuscript (pages 11- 12)
7. Study outcomes – the authors decided not to code child categories on the observation measure as the intervention focuses on changing the behaviour of the parent. The authors felt it would be sufficient to measure child behaviour using self-report questionnaires only and focus the observation on parental behaviour. This has been added to the manuscript (page 16)
8. Discussion – the authors agree that this section did not adequately address the issues relating to dissemination. Currently, there are no future plans for dissemination (how to get the programme to health visitors and school nurses) and this has been added to the manuscript (page 22)

VERSION 2 – REVIEW

REVIEWER	Marianne Simonsen Aarhus University, Denmark
REVIEW RETURNED	15-Nov-2016

GENERAL COMMENTS	I am happy with the responses and have nothing further
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REVIEWER	Sarah Rabbitt Assistant Professor Oberlin College Oberlin, OH USA
REVIEW RETURNED	25-Nov-2016

GENERAL COMMENTS	This revised version of the manuscript has successfully incorporated several recommendations made in the review process and addressed many specific questions raised by the reviewers. At this point, my major concerns are listed below:
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• The sample size remains an important issue. While the authors added some information about the small number of participants (p. 19), the proposed sample size requires additional explanation. The authors are not recruiting a clinical sample in which one might expect to observe more substantial changes over the course of a brief intervention. In fact, their inclusion criteria do not include any requirements related to behavior problems in children. The authors note limitations related to time and resources as part of the reason only 60 parents will be recruited, and these practical concerns often dictate important study features like sample size. However, the authors still need to clearly articulate why they believe that their sample is adequate. What leads them to believe that effects can be detected with this small number of parents? Additional and more detailed information is required to justify the proposed sample size and defend its use to achieve the stated study goals.

• In describing the protocol for the online program, the authors note that parents can choose to receive text message reminders about their participation. Is this something that the authors will track? Related, can parent participation (e.g., number of logins to the website) be tracked by the research team? These seem like key variables to assess in an online program like this one. It is possible that the subset of parents that are most engaged will benefit from the program more than parents that do not actively participate. These are valuable data to have for a pilot RCT and could shape how these authors (and other researchers) run future trials. If the authors are not tracking these data, how do they plan to address issues related to participation/engagement differences across parents?

• The authors' plan for how to use the study's results requires additional attention in the manuscript. The authors note that the program (if effective) could be made available to school nurses and health visitors, but state that there are not plans for wider dissemination due to cost restrictions (p. 22). Even if the authors do not have specific funds for a large-scale dissemination, it is important for them to explain how a program like this might be used to help many children and families – not just the individuals that participate in this pilot RCT. I think the authors can make an argument for the value of programs like this one and offer specific suggestions of how it might be disseminated (even if they do not have the resources to execute those plans). Including this type of information would strengthen the manuscript and highlight the important implications of this work.

Minor Concerns:

• The authors used many subheadings in the Methods/Design section. It would be helpful for some of these sections to be combined (e.g., inclusion and exclusion criteria) to improve the flow and readability of this section of the manuscript.

• Some of the information included in the Outcomes section would be more appropriate in the Methods section. For example, the details and explanation of the sample size should be included with the description of the participants. The authors should review the material in this section and move some of it to the Methods/Design section. In fact, a separate Outcomes section may not be needed depending on how the authors reorganize the Methods section.

VERSION 2 – AUTHOR RESPONSE

Reviewer 2 comments

1. Reviewer 2 felt that additional and more detailed information is required to justify the proposed sample size and defend its use to achieve the stated study goals.

“Due to limited funds and time restrictions associated with recruitment and data collection, a larger sample size would be difficult to recruit within the time frame. Additionally, this is a pilot RCT with the aim of exploring initial outcomes (in terms of measures, delivery and acceptance of the programme) with a view to conducting a larger scale trial in the future. Results from this pilot trial will give researchers initial information regarding acceptability and delivery of the programme with parents of children aged 3-8 years and should be sufficient to explore initial outcomes in terms of encouragement in the use of positive parental strategies that would inform a power calculation for a larger definitive study.”

This pilot RCT is exploratory in nature, and the researchers are interested in initial outcomes with a view to conducting a larger scale trial. Researchers are interested in initial outcome measures in addition to exploring the delivery and acceptance of the programme. Delivery and acceptance information will inform researchers whether the LifeGuide software should be used again in the future or whether other options should be explored. We believe a sample of 60 is sufficient in giving us these early indications.

2. Reviewer 2 wanted the authors to clarify whether they could track text message prompting and individual usage data through LifeGuide?

“LifeGuide does not allow researchers to track how many messaged parents have received, however, researchers will calculate the number of text messages each participant has received depending on the programme schedule, e.g. if a parent has not logged on after three days of the chapter becoming available they will have received one text message, etc. Therefore it will be possible to monitor the level of prompting each participant receives.”

“LifeGuide allows researchers to track individual usage data, including the number of log in, time spent on each page and the number of chapters completed”

The authors have clarified that LifeGuide allows for the tracking of individual usage data including time spent on each page and the number of chapters completed by each participant. However, at this present moment, a limitation of LifeGuide is the ability to directly monitor text message prompting. However, as the text messages are sent on a schedule (i.e. participant receives a message after 5 days to say the next chapter is available etc.) the researchers will be able to calculate how many messages each participant has received. LifeGuide does however inform us if any messages have not been sent due to error, therefore we can cross reference with this data in order to work out exactly how many messages each participant received during the intervention. This data will be useful when exploring treatment engagement.

3. Reviewer 2 wanted the authors to make a clearer argument for the value of the programme in terms of wider dissemination, and make a specific suggestion for how it might be disseminated.

“If the trial suggests that there are significant benefits this would inform a bid for funds for a larger definitive RCT with the goal that the intervention could subsequently be made available to parents in general as a preventative programme. This programme could potentially be useful to parents who would like to receive additional support, but who are not living in targeted areas (such as Flying Start areas in Wales) where higher levels of parenting support are provided. A preventative universal programme available to all parents could potentially allow health care professionals more time and resources to target clinical (or at-risk) populations and also encourage parents to use well established positive parenting strategies to prevent child behaviour problems from forming. A universal preventative programme such as this could be useful in encouraging positive parenting practices for all parents.”

In Wales, parents living in more disadvantaged areas, for example Flying Start areas, have better access to parenting advice and support (i.e. access to additional targeted health visiting support). This programme could potentially be a preventative programme and be made available to parents in general as a means of providing them with evidence-based behavioral advice to encourage positive child behaviour.

Supplementary Reporting

4. The sub-headings in the methods section have been combined and some removed in order to increase the flow and readability of this section.

5. The outcome measures, data collection, randomization, blinding and statistical analyses sub-headings have been merged with the methods and design section (the outcomes sub-heading has therefore been removed), again in order to improve the flow and readability.

VERSION 3 – REVIEW

REVIEWER	Sarah M. Rabbitt Assistant Professor Department of Psychology Oberlin College Oberlin OH USA
REVIEW RETURNED	20-Feb-2017

GENERAL COMMENTS	<p>Specific comments on each of the main sections of the manuscript are provided below.</p> <p>General comments</p> <ul style="list-style-type: none"> • There are a number of small typos and errors throughout the manuscript. It would be helpful of the authors carefully reviewed the entire manuscript to identify and correct these small mistakes. <p>Strengths and Limitations</p> <ul style="list-style-type: none"> • For the final bullet point (related to follow-up data), the authors should revise this statement to note specifically the timeframe for follow-up data collection. This point is currently vague regarding the length of the follow-up period. <p>Background</p> <ul style="list-style-type: none"> • The first line of this section is somewhat confusing as it is currently written. The authors may consider revising this to ensure that
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	<p>readers clearly understand the points being made in this introductory statement.</p> <ul style="list-style-type: none"> • In their discussion of the spread of technology (p. 5), the authors need to update the data for computer use in the US. Data from 2015 and 2016 are available; these new data support the authors' argument that Internet use is widespread and accessible to a large and growing portion of the population. • In their review of web-based programs (p. 6), the authors include dated references (some more than 12 years old). There are many new programs that have been developed and evaluated in recent years. This section would be improved by including more updated references. <p>Methods/Design</p> <ul style="list-style-type: none"> • In describing the eligibility criteria (p. 8), the authors note that participants must be able to access the Internet using one of several devices. They list both an iPad and a tablet. Because an iPad is a specific example of a tablet, the authors should consider eliminating this item from their list. • For the list of topics covered in each chapter (p. 11-12), please note in a few words what is reviewed in the two revision chapters. For example, is the first revision (Chapter VI) a review of the first half of the program? Is the second revision (Chapter X) a review of the second half or a review of the entire program? • The bullet point including in the "Demographic information" subsection (p. 18) is not needed. • What specific efforts will the authors make to collect follow-up data? <p>Discussion</p> <ul style="list-style-type: none"> • The hypothesized results seem out of place at the end of this section. The authors should introduce these hypothesized results earlier in the section. Specifically, it would be helpful if these were provided before the discussion of how results will be disseminated. • The subheading "Proposed results" should be deleted. This heading is unnecessary in a discussion of this length.
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VERSION 3 – AUTHOR RESPONSE

Reviewer 2 comments:

The reviewer has recommended publication, but has also suggested some minor revisions to the manuscript. These changes have been made in addition to some others that the authors felt were needed in order to improve the quality of the manuscript particularly in the background section

1. "There are a number of small errors and typos throughout the manuscript".

The manuscript has been revised and all errors and typos corrected [entire manuscript].

2. "For the final bullet point in the strengths and limitations subheading, the authors should revise this statement to note specifically the timeframe for the follow-up data collection".

This bullet point has been amended [page 3].

3. "The first line of the background section is somewhat confusing as it is currently written"

After consideration of this comment and a previous reviewer comment regarding the background section of the manuscript, the authors have revised this entire section as they felt it was not concise enough and not in line with the rest of the paper. This section has been re-written in order to make it clear the background relating to the online universal parenting programme. We hope that the editorial

team agrees that these changes make the background more relevant [pages 3-6].

4. "The authors need to update the data for computer use in the US"

The authors have updated the UK data on internet use as 2016 data has become available since the last submission. The authors decided not to include data on the US as the study is conducted in North Wales and therefore we felt that data from the UK was sufficient in making this point [page 5].

5. "In the review of web-based programmes the authors have included dated references"

An updated reference has been included in order to improve this section [page 5]. The main reference list has also been updated with the changes made to the manuscript.

6. "An iPad is a specific example of a tablet, therefore the authors should consider eliminating this item from their list"

The item has now been removed [page 7].

7. "Please note in a few words what is reviewed in the two revision chapters"

Information regarding what is covered in both revision chapters has now been added [page 10].

8. "The bullet point included in the demographics subsection is not needed"

This bullet point has been removed [page 16].

9. "What specific efforts will the authors make to collect follow-up data?"

The authors have included additional information to clarify this point. Researchers will firstly contact parents via telephone to book an appointment to collect follow-up data. However, if this mode of communication is not successful, researchers will send a letter with an appointment card [page 17].

10. "It would be helpful if the hypothesized results were provided before the discussion of how results will be disseminated"

The hypothesized results have been moved as suggested by the reviewer.

Additionally, the authors have modified the discussion section slightly and have included the 'ethics and dissemination' subheading after the discussion in order to include the information on the dissemination of the trial results (previous reviewer comment) [pages 19-20].

11. "The subheading 'proposed results' should be deleted as it is unnecessary"

This heading has been deleted [page 20].