PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	A protocol for the process evaluation of a Structured E-parenting Support (STEPS) in the OPTIMA randomised controlled trial.
AUTHORS	Hedstrom, Ellen; Kostyrka-Allchorne, Katarzyna; French, Blandine; Glazebrook, Cristine; Hall, Charlotte; Kovshoff, Hanna; Lean, Nancy; Sonuga-Barke, Edmund

VERSION 1 – REVIEW

REVIEWER	Nunes, Maria vania Catholic University of Portugal, Institute of Health Sciences
REVIEW RETURNED	28-Nov-2023

GENERAL COMMENTS	I thank the editor for the opportunity to make this review. Here are some minor comments that I hope will be useful to the authors The formal and methodological aspects are very well designed, complying with all the standards. The process evaluation is very well conceptualized and a very solid methodological approach is in place. Therefore, my comments are only aimed at clarify some aspects. The first comment relates to the description of the app itself. Regarding content, it is understood that it was based on the NFPP, but it is not clear if there is any innovation. Concerning the design itself from a more technological perspective It is not entirely clear the level of interaction that the app allows. In the same note I would like to know how the digital buddies and the pre-programmed prompts will function. What are their limits?Could you further clarify these points? With the RCT already running, it was not clear to me when and how the introduction of PPI suggestions will be carried out. I would like to ask if you could provide additional clarification on the randomization process used, especially considering that participants come from different centers. Could you please clarify if digital proficiency of the parents was taken into consideration, and make a comment on this point? We understand the general interest in evaluating the perspective of clinicians, but it was not very clear what will be explored. In reality, the interest it to work before the child reaches the clinician. Could you provide further clarification on this? On a last note, when a child is enrolled in the study does is there any possibility of causing a delay in their entry into the system? I think this could be clarified. The dates are not in the manuscript. Thank you once more.

REVIEWER	Williams, Christopher University of Glasgow, Psychiatry
REVIEW RETURNED	31-Dec-2023

GENERAL COMMENTS	This protocol describes a process evaluation of an already funded NIHR grant- the Optima RCT. The study is already defined by that funding as valuable, needed and worthy of funding. The paper covers all/most of the key areas, but I recommend a few areas are expanded for added clarification, and the structure be modified slightly. 1). The content of the intervention is well described as part of the New Forest Parenting Programme. Regarding this I recommend the evidence base for that content (presumably a previous manual) is summarised, together with any previous feasibility or pilot data completed on the STEPS app. As there is an internal pilot, I assume a pilot of the RCT design has not been completed. 2). The ownership of IP of the New Forest Parenting Programme, and of modifications needed for the creation of the app should be clarified. A named developer (Bitjam) has created the programming. Who owns the programming? If the app is found to be helpful is there a clear route to commercialisation or will IP issues become problematic? Has the programming been done before this trial- or is funding going to the programmers to amend the programme? Finally, are any of the authors of this protocol/funded participants PI etc "owners" of IP in the STEPS Programme? This is not currently declared at the end of the paper under conflicts of interest and it would be best to clearly clarify this. 3). Support for the Programme: It is stated early in the paper that the package will be offered as a low intensity unsupported programme consisting of video, audio, text and downloadable resources, with what seems to be pop-up text (but apparently no push notification reminders - please clarify) but later (page 16 lines 9-10) that "we aim to provide support to parents awaiting clinical assessment). That might mean simply by providing the app rather than any support, but the process of "introducing" and "selling" use of the app needs clarification. is this by the clinician or researcher. The role of he "Digital Buddies" in the package should be expanded. Is this a video person with active response-linked advice? Or something more passive? 4). The benefits or not of introducing a consistent standard paragraph that is not overly "positive" introducing bias could be discussed. Brief training in using that introductory paragraph for both the arms would be helpful. It would be helpful ideally if clinicians were unaware of the arm before their assessment however it is appreciated this is likely to be hard to achieve. Will there be any attempt to achieve one or two sided blinding? It is implicitly assumed clinicians will ask/know hence the qualitative arm examining clinicians, but the researchers would be aware of the need to tease out objective differences observed by clinicians in how parents/children respond as there is a danger of response bias by clinicians guessing or being told that STEPS has been used. 5). Structure: I suggest the methodology of the clinician and parent interviews are clearly separated out/described - there is currently some mixing of how these two different pieces of research are conducted and reported (e.g. page 13, lines 31-32). 6). Evaluation questionnaires: It would be useful to define the questionnaires in the text with a brief description of their reliability/validity and especially known ability to measure change. This is especially important for the qualitative study more than this

	current evaluation. One element to test the reliability of is the extraction of data by the programmers of module use - and especially the time on a module. Modules are estimated to take 20 minutes of so each. However in this sort of work measuring time on a module is notoriously imprecise- eg windows are opened and left unattended while lunch is eaten, or forgotten about leading to errors. It would be worth testing the usefulness of this and whether to move to a simpler approach e.g. started a module/or not, and ended a module or not eg reached the last or last but one screen of a module. This should be discussed in the discussion as a potential source of error. 7). Thematic analysis. This needs more information about exactly what will happen. E.g. a single place to describe the recruitment of each group, offer of £20 incentive (currently only mentioned in the Topic Guide), and how recruited. The recordings of the 50 people will be online it seems of whom 10 will be clinicians. How will it be transcribed. By Who. Who will rate. Several people are mentioned as involved in the thematic analysis - researchers and also PPI members. There is no real mention of people doing this independently, then the process of how to come together to determine themes/tackling of disagreements. Will there be training for this - especially of PPI members- or will they be asked to comment after the researchers have done this process? A brief expansion of page 14 line 7 could say more about what will happen in the Framework analysis process. How long will recordings be kept - and when deleted? Finally, the Topic Guide should be tested in a small pilot with 2-3 people for length. It is stated the interviews will be 30-40 minutes in length. It is currently very long however. Has this been piloted. The guide for clinicians will also need to be different. It sees too long to fit 30-40 mins at present if people are allowed to talk. It might be better to focus in on key issues eg access to the package, what was used, the helpfulness or not, understandability and use in practice? 8). Other issues: a. Tables 2/3 - many abbreviations and the first time that evaluations are mentioned. much of this could be stripped from this protocol as the quantitive measures are generally unimportant here. b. Video and email interviews are planned. Will one or the other offer greater richness? Why not use just one approach? c. Implementation: Interviewing senior NHS managers/commissioners might be helpful - currently not mentioned. d. Clinician interviews: will you really gain from interviewing them unless they have experienced parents using he approach. Why not selectively interview clinicians with that experience? Also aim for saturation not just n=10.

VERSION 1 – AUTHOR RESPONSE

Reviewer comment responses

Comment 1: STEPS and its relationship to the New Forest Parenting Program (NFPP).
Reviewer 1 said: The first comment relates to the description of the app itself. Regarding content, it is understood that it was based on the NFPP, but it is not clear if there is any innovation. Concerning the

design itself from a more technological perspective It is not entirely clear the level of interaction that the app allows.
Reviewer 2 said: The ownership of IP of the New Forest Parenting Programme, and of modifications needed for the creation of the app should be clarified. A named developer (Bitjam) has created the programming. Who owns the programming? If the app is found to be helpful is there a clear route to commercialisation or will IP issues become problematic? Has the programming been done before this trial- or is funding going to the programmers to amend the programme? Finally, are any of the authors of this protocol/funded participants PI etc "owners" of IP in the STEPS Programme? This is not currently declared at the end of the paper under conflicts of interest and it would be best to clearly clarify this.

Response: Thank you, we realise that we need to be clearer about what STEPS is and how it is used, its relationship to the NFPP and also who owns the IP.
First, we have added a supplementary appendix (Appendix A) that describes STEPS in detail. This information is also included in the published OPTIMA trial protocol.
Second, we have rephrased the first paragraph on pages 4-5 to make clear that STEPS is not an online version of the NFPP. It is a standalone app, that draws on certain aspects of the NFPP, but also other more generic parenting interventions. Thus, the IP for the NFPP and STEPS are unrelated. We will work with our translational research team and technology transfer office to establish STEPS IP, in line with the terms outlined in the collaboration agreement. However, it is anticipated that KCL will be the lead party to take the IP forward together with SLaM and Solent NHS Trusts. We have also revised our Acknowledgment section to make clear our various roles in developing STEPS clearer. None of the authors will benefit financially from the development or evaluation of the app. The route to potential commercialisation will be informed by the findings from the process evaluation and the RCT, and implementation and commercialisation will be explored in OPTIMA phase III.

New text
“STEPS has been designed to support parents of children with ADHD-type symptoms that are accompanied by challenging behaviour and who are awaiting clinical diagnostic assessment. Its structure, content and approach are described in Appendix A. STEPS draws inspiration from some of the principles underpinning the New Forest Parenting Program (NFPP) (13), an established face-to-face parent program based on a long track record of research and clinical practice relating to parenting of child behaviour problems. However, its content, structure and approach, tailored to the digital delivery, are substantively different from the NFPP.”

Comment 2: The role of the parent buddies and other functions to increase engagement.

Reviewer 1 said: I would like to know how the digital buddies and the pre-programmed prompts will function. What are their limits? Could you further clarify these points?
Reviewer 2 said: Support for the Programme: It is stated early in the paper that the package will be offered as a low-intensity unsupported programme consisting of video, audio, text and downloadable resources, with what seems to be pop-up text (but apparently no push notification reminders - please clarify) but later (page 16 lines 9-10) that "we aim to provide support to parents awaiting clinical assessment). That might mean simply by providing the app rather than any support, but the process of "introducing" and "selling" use of the app needs clarification. is this by the clinician or researcher. The role of he "Digital Buddies" in the package should be expanded. Is this a video person with active response-linked advice? Or something more passive?

Response: STEPS incorporates a range of functions to optimise user engagement and the Buddies are a novel and central part of this. Each parent chooses a buddy, who will then provide signposting and guide them through the STEPS programme. These are parents played by 4 actors varying in their background and circumstances to create a better sense of personal connection and shared

understanding. However, the content of the intervention does not change depending on the buddy – it is the same for all app users. More information about the buddies is included in Table 3 - Logic Model, in the input and intervention section. Other app features designed to support engagement include, for example, text message notifications sent by the app. Appendix A includes more details of the parent buddies and the schedule of text message notifications.

Comment 3: Request to provide more information about the involvement of the PPI group.
Reviewer 1 said: With the RCT already running, it was not clear to me when and how the introduction of PPI suggestions will be carried out.

Response: Thank you for this comment. Apologies if we have not been sufficiently clear on this point. We have added some information on page 16 which describes in more detail when our PPI panel became involved in the study and also added more information about how their feedback shaped changes for the RCT. We have also referred the reader to a published paper which gives more information on the usability study of the app in which the PPI members were involved (Kostyrka-Allchorne et al., 2023).

New text
“The PPI group was established early on in the overall OPTIMA programme of research prior to any empirical work taking place. The group advised the team about how the design and functionality of the app could be optimised as part of the panel group discussions as well as individually in the usability study (26). This was implemented and piloted before the RCT. The PPI group also supported the team in ensuring that the trial procedures were acceptable to the participants and that any participant-facing documents were written in clear and accessible language. Finally, they also helped with the development of the schedules for the parent interviews.”

Comment 4: The randomization process.
Reviewer 1 said: I would like to ask if you could provide additional clarification on the randomization process used, especially considering that participants come from different centres.

Response: Thank you, this information has been added now on page 6.

New text
“Randomisation will be carried out online via a secure platform provided by Sealed Envelope in a 1:1 ratio and stratification by trial centre location (London, Nottingham, Southampton) using random permuted blocks procedure with varying block sizes. The randomisation system will use a unique identifying number.”

Comment 5: Parents’ digital proficiency.
Reviewer 1 said: Could you please clarify if digital proficiency of the parents was taken into consideration, and make a comment on this point?

Response: Thank you, for raising this important point. The app was designed and usability tested to ensure it is as easy as possible for parents to use. We have added some information about this on page 6. We have also described our screening process which ensured that those enrolled would be able to use the app.

New text
“In our previous study parents rated the app’s usability level as very high; the overall STEPS usability score on the System Usability Scale was 94.8 (SD 4.8) out of 100 (26). Moreover, feedback received was used to optimise the app in preparation for the trial. For example, we improved and simplified the registration process, improved video playback and added captions to videos. We also let parents

know that study administrators would be on hand to help with any technical issues if the app visual download guide was insufficient. As part of the screening process, researchers checked whether parents had a phone with an operating system that was compatible with the app and were sufficiently proficient in English to be able to use the app and understand it."

Comment 6: The role of clinicians
Reviewer 1 said: We understand the general interest in evaluating the perspective of clinicians, but it was not very clear what will be explored. In reality, the interest it to work before the child reaches the clinician. Could you provide further clarification on this?
Reviewer 2 said: It is implicitly assumed clinicians will ask/know hence the qualitative arm examining clinicians, but the researchers would be aware of the need to tease out objective differences observed by clinicians in how parents/children respond as there is a danger of response bias by clinicians guessing or being told that STEPS has been used.
Reviewer 2 said: Will you really gain from interviewing them unless they have experienced parents using he approach. Why not selectively interview clinicians with that experience? Also aim for saturation not just n=10.

Response: We realise that the protocol needs to be clearer about the role of the clinician in the trial and the purpose of the clinician interviews. Clinicians have no active involvement in the trial or the collection of outcome data. The clinician will not be asked to explore the individual parents' STEPS use or be notified which parents used STEPS. However, some parents could disclose they used the ap during a consultation. This information would not be sought by the team. The purpose of the interviews with clinicians is to get their general views about the impact of STEPS as a waitlist intervention, potential factors influencing parent engagement and barriers to effectiveness with the aim of facilitating implementation into clinical services. For clarity, we have now included the clinician interview schedule in Appendix B. We believe 10 clinician interviews to be sufficient as they will be analysed together with the 50 parent interviews, text box data provided by parents alongside the study questionnaire responses and PPI feedback using framework analysis. This flexible but rigorous method is used in health research to integrate qualitative data from different informants and sources. We have rewritten some of the sections on page 13 to address this. Furthermore, the schedule for the clinician interviews has now been added to the parent interview in Appendix B.

New text
"The clinicians who are interviewed have no active involvement in the trial, the STEPS intervention or the collection of outcome data. Some participants may disclose their use of the STEPS but the clinician is not asked to probe for this. The purpose of the interviews with clinicians is to get their views about the impact of STEPS, potential factors influencing parent engagement and perceived barriers to effectiveness with the aim of facilitating implementation into clinical services."

Comment 7: The process evaluation questionnaires.
Reviewer 2 said: It would be useful to define the questionnaires in the text with a brief description of their reliability/validity and especially known ability to measure change. This is especially important for the qualitative study more than this current evaluation. One element to test the reliability of is the extraction of data by the programmers of module use - and especially the time on a module.

Response: The process evaluation will use parent-reported baseline Social Communication Questionnaire (SCQ) and oppositionality and defiance subscale of the Swanson, Nolan and Pelham questionnaire (SNAP-IV ODD) for descriptive purposes and SNAP-IV ODD at Time 2 to explore impact (change in ODD). We have now included brief descriptions of their reliability and validity and for the SNAP-IV ODD sensitivity to change on page 14.

New text

“This SNAP-IV ODD subscale is a valid outcome measure for use in clinical trials.”
“The SCQ-L, used in this study to characterise the sample of participants receiving the intervention, has been found to have good internal consistency (Cronbach α=0.82). A cutoff =>15 differentiated young people with a clinical diagnosis of ASD from those without ASD (sensitivity = 0.70 and specificity = 0.67).”

Comment 8: Measuring the STEPS usage data.
Reviewer 2 said: Modules are estimated to take 20 minutes of so each. However in this sort of work measuring time on a module is notoriously imprecise- eg windows are opened and left unattended while lunch is eaten, or forgotten about leading to errors. It would be worth testing the usefulness of this and whether to move to a simpler approach e.g. started a module/or not, and ended a module or not eg reached the last or last but one screen of a module. This should be discussed in the discussion as a potential source of error.

Response: Thank you for this comment, we have added more information on how the STEPS usage data will be used. We added some text to the limitations section of this paper on page 17 relating to usage measurement. We have also added some more information on usage data extraction on page 14.

New Text
“Some caution must be exercised when analysing these data in terms of potential errors such as parents opening the app but not actually using it.”
“To establish intervention adherence, the number of completed STEPS modules will be measured (min = 0; max = 8), with completion of two modules constituting adherence to the intervention. Other collected app usage events will include: the number of started modules, the number of videos watched, the time spent watching videos (in seconds), the number of audio clips listened to and the time spent listening to audio clips (in seconds), the number of reflections recorded, the number of items saved to favourites, and the number of accessed text resources. These will be used to provide descriptive information about app usage patterns.”

Comment 9: The framework analysis approach.
Reviewer 2 said: This needs more information about exactly what will happen. E.g. a single place to describe the recruitment of each group, offer of £20 incentive (currently only mentioned in the Topic Guide), and how recruited. The recordings of the 50 people will be online it seems of whom 10 will be clinicians. How will it be transcribed. By Who. Who will rate. Several people are mentioned as involved in the thematic analysis - researchers and also PPI members. There is no real mention of people doing this independently, then the process of how to come together to determine themes/tackling of disagreements. Will there be training for this - especially of PPI members- or will they be asked to comment after the researchers have done this process?
A brief expansion of page 14 line 7 could say more about what will happen in the Framework analysis process. How long will recordings be kept - and when deleted?
Finally, the Topic Guide should be tested in a small pilot with 2-3 people for length. It is stated the interviews will be 30-40 minutes in length. It is currently very long however. Has this been piloted. The guide for clinicians will also need to be different. It sees too long to fit 30-40 mins at present if people are allowed to talk. It might be better to focus in on key issues eg access to the package, what was used, the helpfulness or not, understandability and use in practice?

Response: Thank you for your comments regarding the analytical process. We have added more detailed information on how the interview schedule was developed and tested, how we estimated the timings and clarified the incentive. We also have added information about data handling. These comments have been added across pages 12 and 13. We have also added the clinician interview to Appendix B. On page 15 more information about the team involved in the analysis of transcripts has

been added and we've expanded on framework analysis, we sincerely hope this helps to address your valid comments.

New text
"The interview schedule has been developed by a team of experienced qualitative researchers in collaboration with the OPTIMA Patient and Public Involvement (PPI) group. Once the team had finalised the interview schedule, the three researchers involved in conducting the interviews, piloted the interviews with members from the PPI group and colleagues. Initially up to an hour had been allocated for the interviews but the pilot showed that 30-45 was adequate time to cover all the questions. Furthermore, the PPI group felt that a decrease in the time required from the parents was more commensurate with the compensation for participation, a £20 Amazon gift voucher. The interview schedules remained dynamic and in the early stage of interviewing, the qualitative team worked together to adapt and add questions."
"All de-identified transcripts and email responses will be stored in electronic form on a KCL OneDrive for Business and SharePoint location. The original recordings or emails will be deleted from OneDrive for Business after transcription and analysis."
"Framework analysis is a flexible but rigorous method used in health research to integrate qualitative data from different informants and sources. It uses inductive or deductive approaches to identify, describe and interpret patterns. Three researchers will take part in both interviewing, transcribing and analysing transcripts with two senior members of the research team taking part in verifying a selection of transcripts. PPI members will work with the research team during the interpretation and verification stages of analysis. Specifically, PPI members will individually review a selection of transcripts to verify the researchers' interpretation of the data and also take part in group meetings to discuss codes and meanings. Although several members of the PPI team have prior experience in qualitative research, 2-3 hours of training on the introduction to qualitative research and how to read and code transcripts will be provided by the research team. Finally, the analysis will be overseen by experts in framework analysis and regular meetings between the researchers analysing the transcripts and the larger qualitative team, will ensure fidelity and cohesiveness in the coding process."

Comment 10: How enrolment affects treatment.
Reviewer 1 said: When a child is enrolled in the study does is there any possibility of causing a delay in their entry into the system? I think this could be clarified.

Response: Thank you, this has now been addressed on page 6.

New text
"Participation in the study will not impact routine clinical care received by the family or the time spent on the waitlist. There will be no restrictions on concomitant care, which will be monitored carefully during the trial through the Child and Adolescent Service Use questionnaire."

Comment 11: Study dates
Reviewer 1 said: The dates are not in the manuscript.

Response: Thank you for noticing this and the dates have now been added on pages 6 and 13.

Comment 12: Changing the structure of the methodology to add clarity to the clinician and parent interviews.
Reviewer 2 said: I suggest the methodology of the clinician and parent interviews are clearly separated out/described - there is currently some mixing of how these two different pieces of research are conducted and reported (e.g. page 13, lines 31-32).

Response: Thank you, clinician and parent interviews are now presented separately.

Comment 13: Standardization of introductory text
Reviewer 1 said: The benefits or not of introducing a consistent standard paragraph that is not overly "positive" introducing bias could be discussed. Brief training in using that introductory paragraph for both the arms would be helpful.

Response: A communication protocol was used by all researchers recruiting, consenting and following-up participants in the RCT. This included a set of structured communication templates specifying the text of emails and text messages sent to the participants, including information for parents about the nature of the study and that there was a 50-50 chance of receiving the intervention. We thank the reviewer for the suggestion and feel that this is a procedural detail that would be better reported in the main OPTIMA RCT paper.

VERSION 2 – REVIEW

REVIEWER	Nunes, Maria vania Catholic University of Portugal, Institute of Health Sciences
REVIEW RETURNED	19-Mar-2024

GENERAL COMMENTS	Thank you for the opportunity to review your study protocol. I appreciate your efforts in addressing the previous comments and providing clear and thorough responses. Based on the responses provided, I believe the protocol is now ready for publication in its current form. I look forward to seeing the finalized version in publication.

REVIEWER	Williams, Christopher University of Glasgow, Psychiatry
REVIEW RETURNED	19-Mar-2024

GENERAL COMMENTS	Thank you for the revisions that have been made. I think these add significantly to the clarity of the paper. The description especially strengthens understanding of the app and it's introduction, the PPI input and IP issues. My comments at this stage are relatively minor: 1. There are some minor elements of the paper that confuse me about the population. Are non-parents also allowed to use the app and be part of the study. Page 10 of the paper mentions use by grandparents and child minders. Are they part of the study - or just parents? 2. Support for the app is stated as unguided and low intensity. Automated texts are sent and also emails by research assistants. It's implied these only are practical/administrative in nature- can you confirm this is the case and does not include instruction on applying what is learned? (top of Page 11) 3. Page 14 - you have now helpfully confirmed a cut-off for acceptable engagement/adherence as just 2 of the 8 modules. This is a low bar - but at least now it is described. It could be argued it should be higher and some discussion of this in the strengths and limitations section of the Discussion would be helpful. 4. Page 6 participant recruitment is stated as May 2022-July 2023. I realise this was asked for by the other reviewer however for me Protocol papers would be more about describing what will happen, and the recruitment sales are more for the write up of the Results paper.

	5. My next comment is the use of the term Fidelity e.g. in Table 2 and also e.g. page 7. Fidelity is usually used to describe adherence to a model. It is not being used in this way here and I think that is misleading. The content of the package used is consistent (video and audio) so fidelity to delivery will occur. 6. You address the reviewer comment about only having 10 clinicians take part in the qualitative interviews. I would still suggest this number be reviewed again. Your argument is that you will combine their responses with the 50 parents- hence achieving more than saturation. I am not certain. You should be asking different questions of clinicians – e.g. about service implementation, barriers and facilitators for this etc. These are different and very important topics, and the topic guide in Appendix B confirms they are different for parents and clinicians. A decision for the research team I think, but you may not achieve saturation of these sorts of important NHS delivery issues – and they matter. You might well be able to shift interviewing and analysis resource if you introduced some flexibility into the number of parents being interviewed and removed the desire to interview 50. If instead you aimed for saturation it would almost certainly have smaller numbers- and your qualitative efforts could then widen the interviews with clinicians? 7. It is not until very late in the day that the social learning underpinnings of the package is described. It will be very helpful to readers to have added Appendix A- thank you. 8. There are a few typos: Page 13 line 2 – add missing word minutes. Page 14 3 lines from the bottom cut-off. 9. Page 19: I suggest any IP owners i.e.. authors who have written content are listed. Although it is correctly stated that no payments have been received in the development or evaluation of STEPS, they may well be if it is commercially made available and that does to me seem a competing interest that is best declared. Thank you for asking me to review this most interesting protocol paper. I hope these comments are helpful.

VERSION 2 – AUTHOR RESPONSE

Reviewer 2 comment responses

Comment 1

There are some minor elements of the paper that confuse me about the population. Are non-parents also allowed to use the app and be part of the study. Page 10 of the paper mentions use by grandparents and child minders. Are they part of the study - or just parents?

Response

Eligibility criteria to take part in the study are outlined in full in the trial protocol referenced on page 6 where the population is also noted to be parents. However, parents are able to talk about the app or show the app to extended family members/or friends and, in this way, we believe the STEPS app to have a wider impact on not only the parent involved in the study but also other key adults in the child's life. For clarity, we have changed the word 'engagement of' to 'impact on':

Impact on a broader range of family members and key adults (e.g., fathers/grandparents/childminders) (page 10)

Comment 2

Support for the app is stated as unguided and low intensity. Automated texts are sent and also emails by research assistants. It's implied these only are practical/administrative in nature- can you confirm this is the case and does not include instruction on applying what is learned? (top of Page 11)

Response

Communication from staff and automated text only serve to remind parents to use the app as well as support and encourage them. These instructions are practical in nature and parents are not given any further information on how to apply the learnings apart from anything gained within the actual app steps.

Comment 3

Page 14 - you have now helpfully confirmed a cut-off for acceptable engagement/adherence as just 2 of the 8 modules. This is a low bar - but at least now it is described. It could be argued it should be higher and some discussion of this in the strengths and limitations section of the Discussion would be helpful.

Response

We understand your concern which is certainly very relevant to any discussion of the OPTIMA trial primary and secondary outcome results that will be reported in the main trial results paper (from here referred to as the 'main trial paper'). However, the process evaluation is interested in the views of all participants offered STEPS and we will report the dosage of intervention for the whole group but will not be analysing any data by cut-off.

Comment 4

Page 6 participant recruitment is stated as May 2022-July 2023. I realise this was asked for by the other reviewer however for me Protocol papers would be more about describing what will happen, and the recruitment sales are more for the write up of the Results paper.

Response

Thank you for your comment. We hope it will be helpful to the reader to add some context to the recruitment process although as you state, more details on this will be published in the main trial paper.

Comment 5

My next comment is the use of the term Fidelity e.g. in Table 2 and also e.g. page 7. Fidelity is usually used to describe adherence to a model. It is not being used in this way here and I think that is misleading. The content of the package used is consistent (video and audio) so fidelity to delivery will occur.

Answer

In the context of our process evaluation fidelity captures "to what extent the intervention as delivered matched the delivery as planned" (Haynes et al., 15, p. 2). To further clarify, we have added feedback

from participants as this provides an important dimension to understanding how and why changes in delivery were made and their impact (page 8).

Fidelity Was the intervention delivered as intended including exploring adaptations or changes made during the study Data from captured via a secure web platform (SE) on trial expectations.

Recordings and minutes from regular PPI panel meetings.

Participant feedback on app communication/support

Trial expectations collected at baseline as multiple choice and free text boxes.

PPI panel feedback on suggestions for change/adaptations.

Participant responses to support material provided throughout the app usage (written instructions/video guides)

Comment 6

You address the reviewer comment about only having 10 clinicians take part in the qualitative interviews. I would still suggest this number be reviewed again. Your argument is that you will combine their responses with the 50 parents- hence achieving more than saturation. I am not certain. You should be asking different questions of clinicians – e.g. about service implementation, barriers and facilitators for this etc. These are different and very important topics, and the topic guide in Appendix B confirms they are different for parents and clinicians. A decision for the research team I think, but you may not achieve saturation of these sorts of important NHS delivery issues – and they matter. You might well be able to shift interviewing and analysis resource if you introduced some flexibility into the number of parents being interviewed and removed the desire to interview 50. If instead you aimed for saturation it would almost certainly have smaller numbers- and your qualitative efforts could then widen the interviews with clinicians?

Response

Thank you for your feedback on this. Clinician feedback is indeed important to gain an initial understanding of how STEPS can be implemented effectively in clinical services. This will be further used to inform the planned work that will be conducted in the final phase (Phase III) of the OPTIMA programme. Specifically, this work would focus on better understanding barriers and facilitators of STEPS UK-wide implementation. However, we will only proceed to PHASE III, if the current trial demonstrates statistically significant benefits of the app at 3-month follow-up in terms of reductions in child oppositionality and defiance (primary outcome).

As previously noted, we will encourage as many clinicians as wish to take part in interviews to come forward. The interviews are weighted towards participants to ensure we fully understand the impact of STEPS on parents.

Comment 7

It is not until very late in the day that the social learning underpinnings of the package is described. It will be very helpful to readers to have added Appendix A- thank you.

Response

Thank you, we appreciate your feedback.

Comment 8

There are a few typos:

Page 13 line 2 – add missing word minutes.

Page 14 3 lines from the bottom cut-off.

Response

Thank you, we have amended these errors.

Comment 9

Page 19: I suggest any IP owners i.e.. authors who have written content are listed. Although it is correctly stated that no payments have been received in the development or evaluation of STEPS, they may well be if it is commercially made available and that does to me seem a competing interest that is best declared.

Response

Thank you, we have added names of those involved in developing the STEPS app under the heading of competing interest, page 19.

VERSION 3 – REVIEW

REVIEWER	Williams, Christopher University of Glasgow, Psychiatry
REVIEW RETURNED	21-Apr-2024

GENERAL COMMENTS	Thank you for addressing the previous feedback. It's a nice paper and I wish you well with the research.