Development and evaluation of learning resources

An educational podcast to improve the ability of parents of primary school children in Uganda to assess claims about treatment effects: Process evaluation protocol

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An educational podcast to improve the ability of parents of primary school children in Uganda to assess claims about treatment effects: Process evaluation protocol

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Date
January 2017
Abstract

Background: People are constantly confronted with claims about the effects of treatments. Yet they may lack the ability to understand and apply key concepts that are essential for assessing such claims. As part of the Informed Healthcare Choices project, we have developed and evaluated - in a randomised trial - an educational podcast for improving people’s ability to critically assess claims about the effects of treatments. This protocol is for a process evaluation to assess the fidelity of the intervention; and to explore why the podcast did or did not have the intended effects, ways to scale up use of the podcast, and potential beneficial and adverse effects not measured in the trial.

Methods: This will be a multi-method study using both qualitative and quantitative data. We will collect data from observations, interviews and focus group discussions with parents. The interviews and focus group discussions will be audio-recorded, transcribed and together with notes from observations be coded by two of the investigators. We will summarise the findings on fidelity using descriptive statistics. We will use the framework analysis approach to analyse qualitative data fitting frameworks for each objective and thematic analysis for data outside the frameworks. We will use a logic model approach to link the findings of this process evaluation with the findings of the podcast trial. We will assess our confidence in the findings using a modified version of the GRADE-CERQual approach.

Discussion: This process evaluation will provide information that will help us better understand the results of the podcast trial as well as factors that influenced the impact of the podcast. The findings will guide further development, adaptation, evaluation, and implementation of the podcast.
**Background**

Claims about what we should do to improve our health are common in the mass media and elsewhere. Many people do not have sufficient ability to understand basic health information, and many more do not have sufficient capacity to assess claims about the benefits and harms of treatments. This problem is common in both high and low-income countries. Individuals who are unable to understand and apply health information correctly are prone to making inappropriate health choices and may experience poor health outcomes consequently. There is a need to support people in assessing the reliability of claims about treatment effects and making informed health choices. To respond to this need the Informed Health Choices (IHC) project is developing and evaluating materials that could potentially help people understand and apply key concepts that are necessary for assessing claims about treatment effects and making informed health choices [1]. By “treatment” we mean any action intended to improve the health of individuals or communities. This includes doing something – such as exercising, vaccinating, using contraception, wearing glasses, eating a specific diet - and not doing or avoiding something - such as avoiding contact with known allergens or avoiding actions or situations that could have adverse health effects.

As part of the IHC project, we have prepared a podcast for the parents of primary school children in Uganda. We designed the podcast to help improve their ability to assess claims about treatment effects. Each episode in the podcast comprises a story about a treatment claim, a message about one key concept that is important for people to understand to be able to assess that claim, an explanation and another example illustrating the concept. Alongside the podcast we a song and a checklist to help reinforce the messages of the podcast.

As part of this undertaking, we are conducting a two-arm, parallel group randomised trial to evaluate the effects of the IHC podcast on parent’s ability to assess claims about the benefits and harms of treatments [2]. In a linked trial, we are assessing the effectiveness of IHC primary school resources in improving the ability of children in the fifth year of primary school to assess claims about the benefits and safety of treatments [3]. Participants in the podcast trial and the accompanying process evaluation are parents of primary school children in schools in the central region of Uganda, which participated in the IHC primary school resources trial.
This protocol describes the methods we will use in the process evaluation that will be carried out alongside the podcast trial.

**Objectives**

1. To assess the fidelity of the intervention (whether the intervention was delivered and used as intended)
2. To explore factors that may have influenced the impact of the podcast, including why the resources did or did not have intended effects and to explain any variations in effects
3. To explore ways to scale up use of the podcast including how the implementation of the podcast could be improved
4. To identify potential adverse and beneficial effects of the IHC podcast not measured in the trial
Method

Study design

This will be a multi-method study using both qualitative and quantitative data. We will conduct interviews and focus group discussions with study participants, and use observations made by research assistants and the principal investigators (DS and AN).

Frameworks underlying this process evaluation

We have developed three frameworks that we will use to guide the collection and analysis of the data in this process evaluation. The first addresses the fidelity of the intervention (Table 1). The second addresses other factors that could affect the impact of the podcast (Table 2). The third addresses potential adverse and beneficial effects of the podcast (Table 3).

Fidelity of the podcast

We have adapted Carroll and colleagues’ framework for implementation fidelity [4] to explore factors related to adherence to implementation procedures for the podcast (Table 1).

Table 1. Considerations for assessing fidelity of the podcast

<table>
<thead>
<tr>
<th>Domain</th>
<th>Factors</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adherence</td>
<td>Delivery of the podcast, MP3 player, IHC theme song and checklist</td>
<td>The extent to which we delivered the podcast to the parents as planned. Research assistants were to visit participants six times and to play all the episodes and recaps of previous episodes for the participants. In addition, we gave the participants MP3 players with the podcast and a song (the IHC theme song) reinforcing the general message of the podcast, which they could listen to at their convenience. We also gave the participants a checklist summarising the key messages from the podcast.</td>
</tr>
</tbody>
</table>
|               | Listening to the podcast                                                | • The number of podcast episodes that parents listened to  
• The extent to which participants completed listening to each episode 
• The time interval between episodes |
|               | Repetition                                                              | • The number of recaps that participants listened to 
• The number of times participants listened to each episode 
• The number of times participants listened to the episodes on their own (in the absence of research assistants) 
• Whether and how participants used the checklist |
We also will consider the extent to which the test used as the primary outcome measure [5,6] was administered as intended. Research assistants were to administer the test as an audio questionnaire and record the responses of participants on paper questionnaires.

**Factors that could affect the impact of the podcast**

Table 2 summarises the factors that could influence the impact of the podcast. This framework has been developed by reviewing relevant frameworks for factors affecting health promotion activities, mass media campaigns, health innovations, health education and guideline implementation [7-12] and a related framework that we are using in the process evaluation of the IHC primary school resources [13]. We will use the framework to guide the collection and analysis of data for the second and third objectives.

<table>
<thead>
<tr>
<th>Domain</th>
<th>Factors</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Target audience</strong></td>
<td>Education</td>
<td>The extent to which the listener has sufficient background knowledge to understand the key messages</td>
</tr>
<tr>
<td></td>
<td>Amount of podcast that was heard</td>
<td>The extent to which the listener listens to all of the podcast or reasons for not doing so</td>
</tr>
<tr>
<td></td>
<td>Motivation to listen and learn</td>
<td>Listener's motivation to listen and learn</td>
</tr>
<tr>
<td><strong>Attitudes</strong></td>
<td></td>
<td>Listener’s attitudes towards learning, towards authorities, towards science, or towards critical thinking</td>
</tr>
<tr>
<td><strong>Beliefs</strong></td>
<td></td>
<td>Listener’s beliefs about the content (e.g. what treatments work or the concepts) or beliefs that are in conflict with the content</td>
</tr>
<tr>
<td><strong>Preferences or experiences</strong></td>
<td></td>
<td>Listener’s preferences for or experiences with healthcare generally or specific types of healthcare and information about treatments that influences the listener’s interest, attitudes or beliefs</td>
</tr>
<tr>
<td><strong>Listeners expectations</strong></td>
<td></td>
<td>The extent to which what listeners expect - for example because of other messages or programs (e.g. public service announcements) - affects their ability to understand the key messages (e.g. expecting to be told what to do)</td>
</tr>
<tr>
<td><strong>Self-efficacy</strong></td>
<td></td>
<td>The extent to which listeners feel competent and confident about being able to learn and use the messages</td>
</tr>
<tr>
<td><strong>Access to healthcare and information about treatments</strong></td>
<td><strong>Clarity of the podcast</strong></td>
<td>Availability or unavailability of healthcare generally or specific types of healthcare and information about treatments that influences the listener’s interest, attitudes or beliefs</td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td></td>
<td>The extent to which the language and key messages are clear and understandable</td>
</tr>
<tr>
<td></td>
<td><strong>Value of the podcast</strong></td>
<td>The extent to which the podcast is valued by the listeners</td>
</tr>
<tr>
<td>Domain</td>
<td>Factors</td>
<td>Explanation</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Length</strong></td>
<td></td>
<td>The extent to which the length of each episode and the number of episodes is adequate or too long</td>
</tr>
<tr>
<td><strong>Effort</strong></td>
<td></td>
<td>The amount of effort required to listen and learn the key messages</td>
</tr>
<tr>
<td><strong>Entertainment</strong></td>
<td></td>
<td>The extent to which the podcast is interesting (does not bore the listeners), is well produced with good sound, and presents content in a way that appeals to the listeners</td>
</tr>
<tr>
<td><strong>Appropriateness of the podcast</strong></td>
<td></td>
<td>The extent to which podcast is appropriate for the target audience (parents), relevant to them, and engages them (including the examples that are used and the stories)</td>
</tr>
<tr>
<td><strong>Chanel of communication</strong></td>
<td></td>
<td>The extent to which the type of media used (podcasts delivered by a research assistant) facilitates or hinders listening to the podcasts and reflecting on them</td>
</tr>
<tr>
<td><strong>Credibility of the podcast</strong></td>
<td></td>
<td>The extent to which the listeners perceive the podcast as credible</td>
</tr>
<tr>
<td><strong>Environment</strong></td>
<td><strong>Listening environment and technology</strong></td>
<td>The extent to which there are distractions, good acoustics, other listeners that help or hinder listening, and the technology used to play the podcasts functions appropriately</td>
</tr>
<tr>
<td></td>
<td><strong>Time constraints</strong></td>
<td>The extent to which there is sufficient time to listen to the podcast</td>
</tr>
<tr>
<td></td>
<td><strong>Access to the podcast</strong></td>
<td>The extent to which the research assistants delivering the podcasts in the trial facilitate or hinder listening to the podcasts and reflecting on them</td>
</tr>
<tr>
<td></td>
<td><strong>Listening pattern</strong></td>
<td>The extent to which the frequency of visits and the number of episodes listened to each visit facilitates or hinders listening to the podcasts and reflecting on them</td>
</tr>
<tr>
<td></td>
<td><strong>Competing priorities</strong></td>
<td>The extent to which other priorities limit listening to the podcast and reflecting on the key messages</td>
</tr>
<tr>
<td></td>
<td><strong>Competing messages</strong></td>
<td>The extent to which other messages in the media are in conflict with or reinforce the messages and examples used to illustrate the messages</td>
</tr>
<tr>
<td></td>
<td><strong>Attitudes and beliefs of others</strong></td>
<td>Attitudes or beliefs of family, friends, neighbours, colleagues, authorities or others that influence the listener’s interest in the key messages</td>
</tr>
<tr>
<td></td>
<td><strong>Political environment</strong></td>
<td>Elements of the political environment that affect listening to the podcast and learning the key messages; e.g. the extent to which the political environment discourages or encourages questioning of information and ideas</td>
</tr>
</tbody>
</table>
Potential adverse and beneficial effects

Use of the IHC podcast might have adverse or beneficial effects that were not measured in the trial, for example on relationships, beliefs, attitudes and behaviours. We have developed an initial list of potential effects that we will explore (Table 3). This list is based on pilot and user testing of the podcast and the IHC primary school resources, discussions with other researchers about potential benefits and harms, and wider discussions about the benefits and harms of interventions to promote evidence-informed decision-making. We will use this framework as a guide to the collection and analysis of data for the fourth objective of this process evaluation.

Table 3. Potential adverse and beneficial effects of the podcast

<table>
<thead>
<tr>
<th>Potential adverse effects</th>
<th>Corresponding beneficial effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Distrust of health professionals or conflict between participants and health professionals.</td>
<td>• Appropriate questioning of health professionals, better understanding and better healthcare</td>
</tr>
<tr>
<td>• Conflict between religious beliefs and scientific principles</td>
<td>• Engagement of participants and others in discussion about religious beliefs and science</td>
</tr>
<tr>
<td>• More difficult decision-making about healthcare</td>
<td>• More thoughtful and informed decisions about healthcare</td>
</tr>
<tr>
<td>• Nihilism or cynicism</td>
<td>• Healthy scepticism and appreciation of science</td>
</tr>
<tr>
<td>• Anxiety or discomfort with uncertainty</td>
<td>• Understanding and acceptance of uncertainty</td>
</tr>
</tbody>
</table>

Other potential beneficial effects

| • Impacts on children or others | The podcast might indirectly improve children’s understanding and ability to apply the concepts being learned by the parents or the podcast might be shared with others in the household or other contacts of the study participants. |
| • Awareness of the basis for claims about treatment effects | Participants becoming more aware and thinking critically about the basis for claims about treatment effects |
| • Attitudes and behaviours towards evidence of treatment effects | Participants desiring and asking for evidence supporting claims about treatment effects |
| • Awareness, attitudes and behaviours in relation to other types of causal claims | Participants becoming more aware and thinking critically about the basis for causal claims not related to treatments, and desiring and asking for evidence supporting those claims |
| • Questioning more | Participants asking more questions and not taking things for granted |
| • Engagement in informed discussions about policies | Participants becoming more engaged in discussions about health policies, and desiring and asking for evidence supporting claims about health policies |
| • Impacts on other types of decisions | Participants making more thoughtful and informed decisions about interventions or activities that are not related to health |
Participants

Participants will be parents in the intervention arm of the podcast trial. In the trial, participants can choose whether to listen to the podcast in English or Luganda, the two most commonly spoken languages in central Uganda. We will include participants who chose to listen to the podcast in either language. This is likely to be highly correlated with the participants' education level. Because English is used in schools, the more education that participants have, the more likely they are to listen to the podcast in English.

To capture the opinions, views and experiences of a wide range of participants, we will purposively sample parents to obtain a range of characteristics based on:

- the participants’ highest level of education (primary school, secondary school, or tertiary education) and
- whether their children were in a school that was in the intervention or control arm of the IHC primary school resources trial

Data collection

The figure below summarises the methods for data collection for each objective, data analysis, and the expected results. Data collection for fidelity will start at the commencement of the trial while data collection for the other objectives will start after completion of the trial follow-up period.
Figure 1. Schematic summary of the podcast trial process evaluation: objectives, methods and anticipated outcomes

**OBJECTIVES**

1. Fidelity of the intervention
2. Factors that influenced the impact of the podcast
3. Potential adverse and beneficial effects
4. Ways to scale up the intervention

**METHODS**

**Data collection**
- Observation of the podcast trial implementation processes for fidelity
- CLAIM Questionnaire
- Interviews and focus group discussions with parents and research assistants

**Data analysis**
- Quantitative analysis of implementation fidelity
- Quantitative analysis of variation in effects of the podcast
- Qualitative framework analysis of:
  1) barriers and facilitators-including implementation fidelity
  2) adverse and beneficial effects
  3) scaling up
- Qualitative thematic analysis of data on scaling up

**EXPECTED RESULTS**
- A quantitative assessment of fidelity of the podcast
- Explanations of any variations in effects of the podcast
- Possible explanations of why the podcast worked or did not work
- Any identified potential adverse effects
- Any identified potential beneficial effects
- Ways to scale up the podcast
- Implementation considerations for scaling up the podcast
Interviews with participants

We will conduct two kinds of interviews: 1) brief semi-structured post-episode interviews to explore people’s experiences with each episode, and 2) in-depth post-intervention interviews after participants have had an opportunity to listen to all the episodes and completed the test. In conducting the post-intervention interviews, we will start with a couple of interviews and use the issues emerging from those data to revise the questions in the interview guide to be explored in subsequent interviews and in the focus group discussions.

Post-episode interviews with parents

Post-episode interviews will be conducted immediately after each episode. The research assistants will ask parents for their immediate perceptions about the episodes at the end of each visit, using an episode evaluation form (Appendix 1). The evaluation form will have general questions regarding how well they listened to and understood the episodes, their perceptions about the episode, as well the environment in which they listened.

Post-intervention interviews with parents

Following completion of the trial follow-up period we will conduct face-to-face interviews to explore participants’ experiences regarding the podcast using an interview guide for this activity (Appendix 2). The interview guide will have questions related to barriers and facilitators (Table 2), and strategies for scaling up use of the podcast. It will also include questions about potential adverse and beneficial effects (Table 3). The interview guide will include prompts for each of the domains and factors in the frameworks above. The interviewees will be asked to reflect on their experience and perceptions from their different perspectives. These interviews will be done after parents listen to all the episodes and complete the test.

The planned number of interviews (approximately 18 parents and 3 focus group discussions) is largely pragmatic. There is some evidence that suggests that it is possible to reach saturation with somewhere between 6 and 12 interviews [14]. However, the concept of saturation has been criticised for being too vague to operationalise and rules of thumb may not be empirically justified [15]. We will make a judgement, based on the emerging data, about whether more interviews or focus groups are needed. In making this judgement, we will consider the variation in issues emerging from the interviews and focus groups and the extent to which we can explain these variations. However, due to time and resource constraints, and in order not to end up with very large volumes of data that cannot be easily managed or analysed [15], we are unlikely to conduct more than 30 interviews and 6 focus group discussions.
**Observation**

The podcast trial will employ 29 field research assistants, one trial coordinator and a data manager. Each field research assistant will follow-up an average of 20 participants by delivering the podcast episodes to them at their preferred listening venue and time. The principle investigators (DS and AN) will hold regular weekly meetings with the research assistants and have regular random phone calls to each of the field research assistants and field visits to observe for their progress, identify and resolve any challenges, and identify and document good practices.

During weekly follow-up visits the research assistants will make notes of all attempts to contact parents, including when they were contacted and when they listened to the podcast episodes for that week. This data will be recorded in a study log (Appendix 3). The research assistant will keep a log for each participant allocated to him or her. In addition, each research assistant will have a checklist to map progress of all participants allocated to him or her (Appendix 4). These documents will be kept by the research assistants and will be submitted when a participant completes study follow-up procedures (in the case of the study log), and after all participants allocated to a research assistant have completed follow-up procedures (in the case of the checklist).

At the weekly meetings research assistants, will share their field experiences and report the number of participants, among those allocated to them, who have completed listening to specific episodes of the podcast and plans for having others complete the pair of episodes for the week. At each weekly meeting the data submitted by research assistants will be captured on a tracking sheet for episodes and episode evaluation interviews completed (Appendix 5). The principal investigators (DS and AN) will use a weekly tracking sheet for research assistants’ progress on participants’ visits (Appendix 6) to document the number of participants who are still in the trial, the number dropped out since the last visit, and the reasons for dropping out. They will also keep a notebook where they record observations from field visits, informal consultations, weekly meetings, and other contacts with study participants and research assistants.

**Focus group discussions with parents**

We will use focus group discussions with parents to explore barriers and facilitators to using the resources, and potential adverse and beneficial effects. We shall organise three focus group discussions with parents: one each for parents whose highest level of education is primary school, secondary school, and tertiary education. These will focus primarily on barriers and facilitators to implementation and understanding of the content of the podcast. Each focus group discussion will involve four to six participants, with clear ground rules (includ-
ing confidentiality) agreed in advance. Each group will be moderated by a facilitator using a guide (Appendix 7) and assisted by an observer (note taker).

**Focus group discussions with research assistants**

The principal investigators will organise at least one focus group discussion with the research assistants who delivered the podcast to parents to explore their experiences delivering the podcast and interacting with parents. We will use an interview guide designed for this purpose (Appendix 8).

**Interviews with the principal investigators**

DS and AN are responsible for implementing the intervention. Given the importance of their role in the trial and the process evaluation, two of the other investigators (CG and SL) will interview them to document their thoughts and experiences and how these may have influenced decisions they made in the process evaluation (reflexivity).

**Data collection methods for each objective**

1. **Fidelity of the intervention**

Data collection for fidelity will start concurrently with the trial. Some of the data will be quantitative as outlined in Table 1 while the rest will be qualitative. We will use data from observations made by the research assistants and principal investigators (DS and AN), as well as interviews and focus group discussions with parents and the research assistants.

2. **Why the podcast did or did not have intended effects**

To explore barriers and facilitators to the impact of the podcast we will conduct interviews and focus group discussions with participants. The interview guides we will use will be based on the barriers and facilitators framework in Table 2 above.

3. **Ways to scale up use of the podcast**

In addition to questions and prompts regarding barriers and facilitators, we will include questions on scaling up the podcast in the interview guides for interviews and focus group discussions with participants.

4. **Potential adverse and beneficial effects**

To assess potential adverse and beneficial effects of listening to the podcast we will include questions in the interview guides for interviews and focus group discussions with participants, using the framework for barriers and facilitators outlined in Table 2.
**Quality assurance during data collection**

All study staff participating in the collection of data will receive training on methods for qualitative data collection including procedures for conducting interviews and focus group discussions. We will pre-test all data collection tools and adjust them as needed. In addition, we will conduct mock interviews amongst investigators and research assistants to familiarize ourselves with the interview questions and to ensure that questions are asked in the same way, apart from variation in follow-questions based on participants’ responses.

**Analysis**

We will transcribe all audio interviews verbatim into a Microsoft Word document. To prevent loss of data during transcription it is reasonable to maintain the data in the language in which it was collected. However, some transcripts in Luganda will be translated to English if this is found to be useful in analysis. This notwithstanding, all the coding will be done in English. Observational notes and other records will be converted into electronic text by entering them into appropriate electronic data entry sheets, using word processor software such as Microsoft Word for observation, notes and spreadsheets software for count data such as that from the weekly tracking sheets. We will use framework analysis [16] to the analysis of the qualitative data for each of the relevant objectives in five stages.

*Stage 1. Familiarization with the transcribed data*

Two investigators (DS and AN) will listen to all the interviews while reading through the transcripts to familiarize themselves with the study data and to check that important information was not left out during transcription. They will then immerse themselves in the data by reading the transcripts repeatedly with the study objectives in mind. They will make side notes of their first impressions of the data.

*Stage 2. Developing and refining the analytical framework*

We will use the frameworks shown in Tables 1-3 as a starting point for developing the final analytical frameworks. At the initial stage, we will carefully read through the first two or three transcripts, line by line. Guided by each of the frameworks we will highlight text that might be helpful for answering our study questions and apply codes that describe our interpretation of the information in the transcript, based on the categories in our frameworks. We will generate new codes for any text that does not seem to fit those categories.
We will compare the results from the initial coding exercises, discuss any differences and similarities in the additional coding, and agree on labels to use and a common coding scheme. We will keep notes on how we developed the codes and how we arrived at the final codes to be used for analysis. We will assign each code an abbreviation for easy identification and easy application to the data.

**Stage 3. Indexing the data: applying the analytical framework**

The principal investigators (DS and AN) will re-read the data and apply the agreed-upon codes manually to all the transcripts. The revised analytical framework developed in Stage 2 will be applied to all the interviews and focus group discussion transcripts and observational data. We will be careful to categorise data appropriately with the study objectives in mind, looking for factors influencing the implementation and impact of the intervention, and adverse and beneficial effects.

**Stage 4. Summarising data into the analytical framework matrix**

We will create tables into which we will chart the summarized data for each framework, with framework factors in columns and participants in rows. We will ensure that the data are organized systematically while reducing the volume and retaining the meanings derived from the data. The table will contain distilled summaries of the findings from different stakeholder perspectives and will include references to illustrative quotations.

**Stage 5. Mapping and interpretation of the data**

We will note early and subsequent interpretations of the data as the analysis unfolds. We will identify common characteristics - including similarities and differences in the data from the different participants - and different domains of factors, interpreting and describing interesting scenarios where needed, and mapping connections between the data. We will define concepts, map the nature of phenomena, create typologies and find associations between themes as a way of developing explanations for the findings. The process of mapping will be influenced by the themes that emerge from the data in relation to the objectives.

**Analysis of data for specific objectives**

1. **Fidelity of the intervention**

This will be a descriptive analysis of the extent to which the podcast was delivered and listened to as intended. We will have data from observations by the research assistants for all the parents in both arms of the trial. We will summarise these data quantitatively, using a modification of Carroll and colleagues’ conceptual framework (Table 1), which defines fidelity (or adherence) as a...
1. The combination of content, frequency and duration of delivery, and coverage [4]. Qualitative data from the research assistants’ observations, interviews with participating parents, and focus group discussions with the parents will be analysed qualitatively using framework analysis to identify possible barriers and facilitators that might explain variation in fidelity.

2. Why the podcast did or did not have intended effects and variation in effects

We will use framework analysis to qualitatively explore factors that might have influenced the impact of the intervention using the framework in Table 2. We will explore quantitatively the extent to which fidelity (listening to all the episodes as intended) is related to the effect of the intervention and might explain variation in its effects. We will use scores from the test (Appendix 9) as the dependent variable. We will use the number of episodes that were listened to and the number of times the podcast was listened to as independent variables. We will also explore the effect of other factors on the impact of the podcast. We will first test the effect of fidelity by bivariate regression analysis. Because fidelity might be correlated with the two other effect modifiers that are specified in the trial protocol (education level and whether the participants’ children were in the intervention group of the IHC primary school resources trial), we will then use backward stepwise regression analysis, including all three pre-specified variables and potential interactions in the mixed model, after adjusting for clustering (since multiple parents will be recruited from different schools). This will allow us to explore the extent to which each factor modifies the effect when controlling for the other factors. We will interpret and report these analyses cautiously, using explicit criteria for subgroup analyses to assess the credibility of any factors that appear to explain variation in effects [17, 18].

We will also identify possible barriers and facilitators that might have mediated the effectiveness of the intervention, as described in the analysis for the second objective. However, we will not have sufficient data to explore quantitatively whether any of those factors might explain variation in the effects of the intervention.

3. Ways to scale up use of the podcast

We will use framework analysis to qualitatively explore barriers and facilitators to scaling up use of the podcast, starting with the framework in Table 2. Factors outside the framework will be analysed using thematic analysis.
4. Potential adverse and beneficial effects

We will use framework analysis to qualitatively explore potential adverse and beneficial effects, starting with the framework in Table 3.

Quality assurance during analysis

All transcripts will be reviewed by at least two researchers before the commencement of analysis. All translations made during transcription will be re-examined and compared to the audio recordings to ensure that the original meaning is not lost during translation. We will have an audit trail of analysis to help identify and minimize possible bias in addition to tracking variability between researchers performing the analysis.

Integration of the findings of the process evaluation with the findings of the trial

We will use a logic model approach to organise the findings of this process evaluation with the findings of the trial. First, the principal investigators (DS and AN) will organise the findings into chains of events that might have led to the outcomes of the trial and any relevant potential outcomes that we will explore, starting with those listed in Table 3. Findings and outcome measures will be categorised as follows:

- Components or planned elements of the intervention
- Intermediate outcomes that the components might lead to, such as fidelity
- Important outcomes, including the primary outcome measures and other outcomes that are considered important
- Moderators, or barriers and facilitators, that could affect the relationship between the components of the intervention and intermediate or important outcomes

The investigators will then organise these elements into chains of events, discuss these and revise them iteratively until there is agreement on a final model.

Appraisal of the certainty of the findings of the process evaluation

We will summarize the key findings of the process evaluation for each objective. For each key finding from the qualitative analyses we will assess our confidence in the finding using a modified version of the GRADE-CERQual approach [19]. Although CERQual has been designed for findings emerging from qualitative evidence syntheses, we anticipate that several components of the approach will also be suitable for findings based on multiple sources of qualitative data (ob-
servations; interviews with parents, research assistants, and the lead investigators; and focus group discussions with parents).

**Ethical considerations**

This study has a low risk of harm to participants. We will seek consent for participants’ involvement in the process evaluation activities. Only consenting participants will be included. All data will confidential and will be reported anonymously.
References


