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Effects of the Informed Health Choices podcast on the ability of parents of primary school children in Uganda to assess claims about treatment effects: a randomised trial

Authors:

Daniel Semakula, Allen Nsangi, Andrew D. Oxman, Matt Oxman, Astrid Austvoll-Dahlgren, Sarah Rosenbaum, Angela Morelli, Claire Glenton, Simon Lewin, Margaret Kaseje, Iain Chalmers, Atle Fretheim, Doris Tove Kristoffersen, Nelson K. Sewankambo

College of Health Sciences, Makerere University, Kampala, Uganda (D Semakula MD, A Nsangi MSc, Prof N K Sewankambo MD)

Informed Health Choices Research Centre, Norwegian Institute of Public Health, Oslo, Norway (A D Oxman MD, M Oxman BJ, A Austvoll-Dahlgren PhD, S Rosenbaum PhD, A Morelli MA, C Glenton Dr.philos, S Lewin PhD, Prof A Fretheim PhD, Doris Tove Kristoffersen MSc)

University of Oslo, Oslo, Norway (D Semakula, A Nsangi, A Fretheim)

Infodesignlab, Oslo, Norway (A Morelli)

Health Systems Research Unit, South African Medical Research Council, Cape Town, South Africa (S Lewin)

Great Lakes University of Kisumu, Kisumu, Kenya (M Kaseje PhD)

James Lind Initiative, Oxford, UK (Sir I Chalmers DSc)

Address for correspondence:

Andy Oxman

Informed Health Choices Research Centre

Norwegian Institute of Public Health

PO Box 4404, Nydalen

N-0403 Oslo, Norway

Email: oxman@online.no

Telephone: +47 4825 4924

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Summary

Background

As part of the Informed Health Choices project, we developed a podcast called *The Health Choices Programme*, to help improve people's ability to assess claims about the benefits and harms of treatments. The target audience was parents of primary school children in Uganda. We evaluated the effects of the podcast on their ability to assess claims about the effects of treatments (any action intended to maintain or improve health).

Methods

We included parents of children participating in a linked trial of the Informed Health Choices primary school resources. We randomly allocated consenting parents to listen to a podcast or to typical public service announcements about health issues. The eight main podcast episodes included a story about a treatment claim, a concept essential to assessing claims about treatment effects, an explanation of how that concept applied to the claim, and a second example illustrating the concept. One of the episodes covered two concepts. The primary outcome, measured after listening to the entire podcast, was the mean score and the proportion of parents with passing scores on a test with two multiple-choice questions for each of the nine concepts (18 questions in total).

Results

The mean score for parents in the podcast group was 67.8% correct answers, compared to 52.4% in the public service announcements (control) group - an adjusted mean difference of 15.5% (95% CI 12.5% to 18.6%). In the podcast group, 70.5% of 288 parents had a predetermined passing score (≥ 11 out of 18 correct answers), compared to 37.7% of 273 parents in the control group - an adjusted difference of 34.0% more parents with a passing score (95% CI 26.2% to 40.7%). In the podcast group, 31.6% of parents mastered the concepts (≥ 15 out of 18 correct answers), compared to 6.2% of parents in the control group - an adjusted difference of 26.0% more parents (95% CI 15.2% to 39.1%).

Interpretation

Listening to the Informed Health Choices podcast led to a large improvement in the ability of parents to assess claims about the effects of treatments.

Funding

The trial was funded by the Research Council of Norway, Project number 220603/H10.

Trial registration

The trial was registered in the Pan African Clinical Trial Registry (www.pactr.org), PACTR201606001676150.

Introduction

The ability to obtain, process, and understand basic health information is crucial to making sound health choices.¹ Many people lack this ability, and commonly overestimate the benefits and underestimate the harms of treatments (any action intended to maintain or improve the health of individuals or communities).²⁻⁷ This can result in inappropriate use of health services and poor health outcomes.⁶

Providing reliable health information in mass media - including the Internet, radio, TV and print media – has the potential to affect health behaviours and healthcare use.⁸⁻¹¹ However, there are substantial barriers that prevent journalists from improving the scientific quality of their reports,¹² and evaluations have found major shortcomings of health stories in the media.¹³⁻²³ Therefore, audiences must be able to appraise the reliability of claims about treatment effects in the mass media, as elsewhere. This includes claims about the effects of drugs, surgery and other types of “modern medicine”; claims about lifestyle changes, such as changes to what you eat or how you exercise; claims about herbal remedies and other types of “traditional” or “alternative medicine”; claims about public health and environmental interventions; and claims about changes in how healthcare is delivered, financed and governed.

Sound health choices are especially important in low-income countries; the less people have, the less they can afford to waste. However, few studies have evaluated the effects of interventions to teach critical appraisal skills to patients or the public in any country.^{24,25} As part of the [Informed Health Choices](#) project, we developed a podcast called *The Health Choices Programme* to help fill this gap.

We began by identifying key concepts that people must understand and apply when assessing claims about treatments.²⁶ Together with journalists in Uganda, we assessed which of the concepts it is most important for the public to understand.²⁷ We prototyped, user-tested and piloted various mass media resources for facilitating critical appraisal of claims about treatment effects. We ended up with an educational podcast for teaching nine of the concepts to parents of primary school children.²⁸ The aim of this study was to test the effects of the podcast on the ability of listeners to apply those concepts.²⁹⁻³¹ The podcast complements learning resources that we developed to teach 12 of the key concepts to children in the fifth year of primary school in Uganda.³² All of the key concepts included in the podcast were included in the primary school resources, except for one (the third concept in Table 1).

We developed versions of the podcast in English and Luganda, two of the three official languages in Uganda, the third being Swahili. While direct translations of some terms were impossible, the structure and content of each version were the same. Luganda is the language of the Baganda, Uganda’s largest ethnic group.³³

The podcast is available online [here](#). We also gave them a [checklist](#) summarising the key messages in the podcast and a [song](#) (the Informed Health Choices theme song) to reinforce the messages of the podcast. The podcast had 13 episodes: an introduction to the series; eight main episodes; three short recap episodes, each of which summarised two of the first

six main episodes; and a conclusion. Each of the eight main episodes included a short story with an example of a treatment claim, an explanation of a key concept applied to the claim, and another example within the same story illustrating the concept. One of the episodes covered two key concepts.

The examples of claims were identified from scanning recent mass media reports and interviewing parents.²⁸ The eight main episodes introduced the concepts (Table 2). Each of the main episodes lasted about five to ten minutes. The first main episode covered two closely related concepts. The final structure, content, and presentation was informed by an iterative, user-centred design process.²⁸ This process involved user testing and consultation with stakeholders, including people in our target audience, and journalists.

Methods

Study design

We conducted a parallel group randomised trial comparing the Informed Health Choices podcast to a series of typical public service announcements about health issues. Ethics approval was obtained from the School of Medicine's institutional review board at Makerere University College of Health Sciences and the Uganda National Council for Science and Technology. The trial protocol is available [online](#).³⁴

Participants

The study was conducted in central Uganda. We recruited parents (or guardians) of children in the fifth year of primary school who were participating in a linked cluster-randomised trial of the Informed Health Choices primary school resources, which are designed to teach children to assess claims about treatment effects.³² Parents were recruited from both intervention and control schools. To be included they had to understand English or Luganda and consent to participate in the study. Parents were excluded if they were:

- unable to hear,
- not contactable by telephone,
- health researchers,
- participants in the development of the podcast,²⁸ or
- parents of children who participated in the development of the primary school resources.³⁵

We recruited a convenience sample of participants at parent meetings held at 20 intervention schools and 15 control schools between late August and early November 2016. Three additional meetings at control schools were cancelled due to parents being unable to attend at short notice. At the meetings, we (DS and AN) provided parents with information about the podcast trial and sought their consent to participate. This information was also included in consent forms in both English and Luganda. Parents who agreed to participate

were asked to sign a consent form before we randomly allocated them to the podcast or control group.

Randomisation and masking

We stratified the parents by highest level of formal education attained (primary school, secondary school, or tertiary education) and the allocation of their children's school in the trial of the primary school resources (intervention or control). We generated randomisation sequences with block sizes of four and six with equal allocation ratios within each block, using www.sealedenvelope.com. A statistician who was not a member of the research team generated the allocation sequence and, together with his team, prepared six randomisation lists (one for each combination of the two stratification variables) with unique codes. They labelled opaque envelopes with the unique codes, inserted slips of paper with the study group allocated to each code, and sealed them.

Because parents were recruited in groups (from parents' meetings) we allocated groups of participants at the end of each day on which a meeting was held. Upon return to the trial management office, the research assistant responsible for allocation opened the next available envelope in the stratum corresponding to each parent's education level and whether the child of that parent went to a school in the intervention or control arm of the primary school resources trial.³²

Due to the nature of the intervention, the research assistants who delivered the podcast, the principal investigators supervising them (DS and AN), and the study participants all knew whether the participants received the Informed Health Choices podcast or to the public service announcements. The statistician who analysed the study results also knew which study group had been assigned to the podcast and which to the public service announcements.

To ensure uniform performance in delivery of the podcast and the public service announcements, and in the assessment of outcomes, all study staff were trained before the start of the trial and received refresher training during the trial. We had standard operating procedures to guide interactions with participants.³⁴

Procedures

Participants in the podcast group listened to a series of episodes about how to assess claims about treatment effects. A description of the intervention using the GREET TIDieR checklist is attached as Appendix 1.³⁶

Participants in the control group listened to typical public service announcements about the same conditions that were used in the podcast (Appendix 2). We designed the announcements to be like typical ones heard on Ugandan radio. Participants could choose whether they wanted to listen to the podcast or the announcements in English or Luganda.

The podcast and the public service announcements were produced in collaboration with a Ugandan radio producer and actors.

Research assistants helped with recruitment, delivery of the podcast, follow-up, and administration of the test used as the outcome measure. They delivered episodes of the podcast or the public service announcements to the participants over a period of seven to ten weeks. Each research assistant was allocated about 25 participants to follow up through the duration of the study. To ensure that the participants listened to each episode (or announcement), the research assistants visited each participant once per week, delivering two episodes on portable media players.

Based on findings from developing the podcast, we thought that only one episode for each concept would be insufficient, so the research assistants played a recap of the previous two episodes at each visit before playing the new episodes. In addition to listening to the episodes delivered by the research assistants, we provided participants with the complete podcast and the song on MP3 players, so that they could replay them, as well as the theme song, at their convenience.

Outcomes

The primary outcome was measured as:

1. the mean score (percent of correct answers) on the test taken after listening to the entire podcast or all the public service announcements
2. the proportion of participants with a passing score

Secondary outcomes were:

1. the proportion of participants with a score indicating mastery of the concepts
2. for each key concept, the proportion of participants answering both questions correctly
3. intended behaviours and self-efficacy

The test included 18 multiple-choice questions from the [Claim Evaluation Tools](#) database - two for each of the nine key concepts (Appendix 3). The questions had between two and four response options, with an overall probability of answering 37% of the questions correctly by chance alone. We developed the questions based on extensive feedback from methodological experts, health professionals, teachers and members of the public.²⁹ We conducted two Rasch analyses to validate the test.^{30,31} Because many parents did not have English as their first language and many had poor reading skills, we developed a Luganda version of the test to be administered orally.³¹ We were careful to ensure that the examples used in the questions were different from what was used in the podcast, and that participants would be able to understand the language that was used without having listened to the podcast.

Eight additional multiple-choice questions were included, making 26 questions in total. These questions addressed four key concepts not covered by the podcast. They were included because the same test was used in the linked randomised trial evaluating the

primary school resources, and those key concepts were covered in the primary school resources.³² Responses to these eight questions were not included in the primary analyses of the podcast trial, since the podcast did not cover the concepts they address.

The test also included questions that assessed intended behaviours and self-efficacy (Appendix 3). In the podcast group, the test included questions that assessed satisfaction with the podcast.

We used an absolute (criterion-referenced) standard to set a passing score. Participants were counted as “passing” or “failing” depending on whether they met this pre-specified criterion. We used a combination of Nedelsky’s and Angoff’s methods to determine the cut-off for a passing score.³⁷ In addition, we determined a second cut-off for a score that indicated mastery of the nine concepts, using the same methods. The criterion for passing was a minimum of 11 out of 18 questions answered correctly. The criterion for mastery was a minimum of 15 out of 18 questions answered correctly.

The participants completed the tests individually after listening to all the podcast episodes or public service announcements. We will evaluate the effects of the podcast again after one year, using the same outcome measure. We will also attempt to measure effects on actual decisions, based on self-report.

The research assistants kept logs, including reasons for dropping out, and they recorded any unexpected adverse events.³⁸ In a process evaluation that will be reported separately, we have collected in-depth qualitative data from interviews and focus group discussions regarding potential adverse effects, as well as other potential benefits of the podcast.³⁸

Statistical analysis

We used the method described by Donner to calculate the sample size, based on calculation of odds ratios.³⁹ The smallest difference between the podcast and control groups that we wanted to be able to detect in the proportion of respondents with a passing score was 10 percentage points. Assuming 10% of the control group would achieve a passing score (based on data from a pilot study),²⁸ statistical power of 0.90, and a 2-sided P value of 0.05, we estimated that 397 participants were needed to detect an improvement of 10% in the podcast group. Studies of the effects of drug fact boxes and a primer to help people understand risk suggested that this was likely to be an adequate sample size.^{11,40} Allowing for a 20% loss to follow-up we estimated that we would need a sample size of 497 participants.

For the primary and secondary outcomes, we used fixed effect models with the stratification variables (education and allocation in the Informed Health Choices primary school trial) modelled as a fixed effect, using logistic regression for dichotomous outcomes and linear regression for continuous outcomes. Missing values were counted as wrong answers.

For intended behaviours and self-efficacy (Appendix 3), we dichotomized each outcome by combining, for example, 'very unlikely' with 'unlikely' and as 'likely' with 'very likely'; and we reported the proportion in each category.

We explored whether there were differences in the effects of the podcast for parents depending on whether they had a primary, secondary, or tertiary education level. We also explored whether there were differences in the effects of the podcast for parents who had a child in a school that received the Informed Health Choices primary school resources and those whose children were in a control school. These analyses adjusted for whether the child was in an intervention school and the parent's level of formal education respectively. We conducted stepwise backward regression of the full model comprising all main effects and second order terms of the explanatory variables - the parent's allocation (podcast or control), formal education level, and whether the child was in an intervention school - removing and adding one variable at a time. This resulted in a simple model with the main effects (explanatory variables) and without interactions (which were not statistically significant). Odds ratios from the logistic regression analyses were converted to risk differences using the control group odds as the reference, multiplying that times the odds ratio to estimate the intervention group odds, and converting the control and intervention group odds to proportions to calculate difference.

We calculated the adjusted standardised mean difference (Hedges' g) for comparison to effect sizes reported in meta-analyses of the effectiveness of other interventions to improve critical thinking.^{41,42}

The statistical analyses were performed with R (R Core Team, Vienna, Austria; version 3.3.2; using packages doBy, xlsx, tables, lme4, glm2, lsmeans, and sjstats).

There was no data monitoring committee. The trial was registered on 12 June 2016 in the Pan African Clinical Trial Registry (www.pactr.org): Trial identifier PACTR201606001676150. The data files for the study are provided in Appendix 4.

Role of the funding source

This trial was funded by the Research Council of Norway, Project number 220603/H10. The funder had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The principal investigator had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Out of 868 parents who agreed to participate, 675 could be reached by phone, which was necessary for follow-up; 334 of the 675 were randomly allocated to listen to the podcast and 341 were allocated to the public service announcements (control) group (Figure 1). In the podcast group, 288 parents (86.2%) completed the test after listening to the podcast, and in the control group, 273 (80.1%) completed the test after listening to the public service

announcements. The reasons for dropping out were similar in the podcast and control groups. The main reasons for dropping out of the study were: loss of interest, 18 (39.1%) and 28 (41.2%) in the podcast and control groups respectively); and not being able to contact the parents by phone, 21 (45.7%) and 25 (36.8%) respectively. Parents who dropped out were similar to the parents who completed the test with respect to education and sex. They were less likely to have said they had training in research (15.8% versus 32.1%).

The podcast and control groups were similar with respect to their preferred language, level of formal education, previous exposure to research, sex, and where they commonly seek healthcare (Table 3). Overall 87.7% of participants elected Luganda rather than English. About half the participants had no more than primary school education. About one third reported some training in research and about one quarter reported having previously participated in research. However, this may not accurately reflect how many had training or experience that was relevant to the key concepts that the podcast addressed. About three quarters were women. The participants reported most commonly seeking healthcare at government or private for-profit facilities. There were minor differences in where they reported that they would seek healthcare advice. Parents in the podcast group were less likely to seek advice from friends or relatives (16.0% versus 28.2%) and more likely to seek advice from health workers (81.9% versus 67.0%).

The mean score for parents in the podcast group was 67.8% compared to 52.4% in the control group. The adjusted mean difference (based on the regression analysis) was 15.5% (95% CI 12.5% to 18.6%; $p < 0.0001$) higher in the podcast than in the control group. The distribution of test scores is shown in Web figure 1. In the podcast group, 70.5% of the parents had a passing score (≥ 11 out of 18 correct answers), compared to 37.7% in the control group (Table 4). The adjusted difference (based on the odds ratio from the logistic regression analysis) was 34.0% more parents who passed (95% CI 26.2% to 40.7%; $p < 0.0001$) in the podcast than in the control group.

In the podcast group, 31.6% of the parents had a score indicating mastery of the nine key concepts (≥ 15 out of 18 correct answers) compared to 6.2% of the parents in the control group. The adjusted difference was 26.0% more parents in the podcast group who mastered the concepts (95% CI 15.2% to 39.1%; $p < 0.0001$).

For each concept addressed in the podcast, the proportion of parents who answered both questions correctly was higher in the podcast group than in the control group (Figure 2). For three out of the four concepts that were taught in the primary school resources,³¹ but not in the podcast, we detected little if any difference between the podcast and the control groups. For the fourth concept - that small studies in which few outcome events occur are usually not informative and the results may be misleading - 50.7% of the parents in the podcast group compared to 38.5% in the control group answered both questions correctly (adjusted difference 12.8%; 95% CI 4.2% to 21.2%).

We detected little if any difference between the podcast and control groups in how likely they would be to: find out the basis for a claim about treatment effects; find out if the claim was based on research; or agree to participate in research about an illness they might get

(Web table 5). Most (73% to 82% of both groups combined) responded likely or very likely to all three questions. However, more parents in the podcast group responded that they find it easy or very easy to assess: whether a claim is based on a research study (adjusted difference 15.5%; 95% CI 7.4% to 23.6%), where to find research-based information (15.4%; 95% CI 7.6% to 23.3%), how sure they can be about the results of research comparing treatments (29.4%; 95% CI 21.6% to 37.3%), and how relevant research comparing treatments is likely to be (10.4%; 95% CI 3.0% to 17.8%) (Web table 6).

The majority (76.4%) of parents who listened to the podcast found it 'easy' or 'very easy' to understand (Web table 7). Over 90% had positive views of the podcast with respect to how much they had liked it, how helpful they had found it, and how much they had trusted what they learned.

The podcast was effective across all three levels of education: primary school, secondary school, and tertiary education (Web table 8). We did not detect a clear relationship between level of education and the size of effect. Neither did we detect a clear relationship between having a child in a school that used the primary school resources and the size of the effect of the podcast on parents' scores (Web table 9). We found that having a child in a school that used the primary school resources had little if any effect on the parent's test scores (Web table 10).

The standardised mean difference (Hedges' *g*) was 0.83 (95% CI 0.65 to 1.00). None of the parents or research assistants who delivered the podcasts reported any adverse effects.

Discussion

Listening to the Informed Health Choices podcast improved the ability of parents of primary school children in Uganda to assess claims about treatment effects (Panel). So far as we are aware, this is the first randomised trial of using a podcast for non-formal education or health education, other than a podcast to aid weight loss.⁴²⁻⁵³ Systematic reviews of educational podcasts,⁴³ mobile learning,^{44,45} parental involvement in education,^{46,47} eHealth to improve health literacy,⁴⁸ mobile health (mHealth),⁴⁹⁻⁵² interactive media for parental education,⁵³ and narrative health promotion interventions⁵⁴ have not found studies that are directly comparable to ours. Although several interventions to improve the ability of non-health professionals to think critically about treatments have been evaluated, most of these have focused on one concept: that treatments usually have beneficial and harmful effects that need to be considered (the last concept in Table 1).²⁴ Other interventions designed to teach critical appraisal skills to non-health professionals include workshops, online courses, websites, books, and checklists. However, few of these have been formally evaluated.⁵⁵

A systematic review of strategies to teach people to think critically more broadly, which included 308 studies, found an average effect size (Hedges' *g*) of 0.33.⁴² The average effect size for interventions that were targeted at graduate and adult students was 0.21, as was the average effect size for interventions in health or medical education. The effect size for our intervention (0.83) is large in comparison. However, comparisons such as these must be

made cautiously due to differences in the interventions that were compared in these studies, the outcome measures, and the methods that were used.

In Figure 3, we compare the effects of the podcast on parents' abilities to assess claims about treatment effects to the effects of the Informed Health Choices primary school resources on their children's abilities and the children's teachers' abilities.³² The relative effects (odds ratios) were larger for the primary school resources than for the podcast. We expected this, given that the primary school intervention was multifaceted, interactive, and used more time (9 lessons totalling 12 hours) compared to the podcast (10 episodes totalling about 1.5 hours of listening). For passing scores, the absolute effect was largest for children and smallest for teachers, whereas for mastery scores it was largest for teachers and smallest for children. The absolute effect for parents was in the middle both for passing and mastery scores. Following the intervention, the proportion of parents and children in the intervention groups with a passing score in the two trials was similar (70.5% and 69.0% respectively).

The same test was used in both trials, but four concepts included in the test were not included in the main results for this trial. This was because they were addressed by the primary school resources, but not by the podcast. For three of those four concepts, the podcast had little if any effect, as would be expected (Figure 2). For the fourth concept - that small studies may be misleading - an effect was detected. Although we did not include this concept in the podcast, it ended up being explained in episodes about closely related concepts: that apart from the treatments being compared, the comparison groups need to be similar, and that the results of a single study can be misleading (Table 1).

Another difference between this trial and the trial of the primary school resources, and a limitation of this trial, is that the trial of the primary school resources was designed to be more pragmatic while the trial of the podcast was more explanatory.⁵⁶ To ensure that the parents listened to the podcasts, research assistants visited the parents six times and played all the episodes for the parents, in addition to giving the podcast to them on MP3 players. Furthermore, the parents in the podcast trial volunteered to participate, whereas all the children in a representative sample of schools were included in the trial of the primary school resources. Consequently, the effect estimates from this trial indicate the potential effects of the podcast amongst parents who choose to listen to them, not the effect of simply offering the podcast to a group of parents.

Another difference between this trial and the trial of the primary school resources is that we randomised individuals in this trial and schools in that trial. We did not measure the extent to which parents in the podcast group talked with parents in the control group or shared the podcast with them. However, to the extent that there was contamination, this would mean that the effect estimates are under-estimates.

Another limitation of this trial is that we both developed and evaluated the podcast. Independent evaluation in more pragmatic trials of this and similar interventions is warranted.⁵⁷

It is uncertain what the long-term impacts of listening to the podcast will be, whether it will have an impact on actual health choices and health outcomes, and how transferable the findings of this study are to other countries. We will measure outcomes again after one year, including impacts on actual decisions, based on self-report. We will user-test the podcast in Kenya and Rwanda in 2017, and we are developing a manual for adapting the podcast for other audiences.

The language, structure, stories and examples of the podcast were tailored to a specific target audience - parents of primary school children in Uganda. Nonetheless, we have shown that it is possible for adults in a low-income country, with a primary school education, to improve their ability to assess claims about treatment effects by listening to a podcast. More broadly, we have demonstrated the potential of a strategy that could be delivered through primary schools to improve the critical health literacy of parents, in conjunction with teaching the same essential life skills to their children.

We believe this study is widely relevant for two reasons. First, critical health literacy is essential for informed health choices, even if it is not sufficient for behavioural change. There is evidence that understanding of concepts can lead to improvements in health behaviours, although there have been few cognitive studies of conceptual change in health, especially in adults.⁵⁸ More importantly, regardless of whether improvements in critical health literacy alone result in behavioural changes, these improvements are necessary for people to be able to make informed choices about their own or their children's health and for effective public involvement and accountability in health policy decisions. Similarly, even though passive dissemination of a single podcast would have a smaller effect than what we found among parents who volunteered to participate and who listened to the entire podcast, we have shown that it can improve the critical health literacy skills of some. Whether this effect is sustained or not, it would be desirable to reinforce and build upon what was learned. Thus, either way, the podcast is an important step towards addressing a major public health challenge.

Second, although our study was conducted in a low-income country, we believe it is relevant for high-income countries. Unreliable claims about treatment effects are universal; they are not just a problem in low-income countries. For example, reviews of healthcare news stories have found major problems, including claims that are based on anecdotes, failing to differentiate association from causation, failing to distinguish surrogate outcomes from important outcomes, misleading reporting of relative effects, and failing to consider trade-offs between benefits and harms.⁵⁹ Health literacy is also a major problem in high-income countries,²⁻⁴ including the ability to assess information about the effects of treatments. For example, a survey of adults in Norway found that only one in five was able to differentiate association from causation, and health professionals did not perform better than non-health professionals.⁶⁰ Unfortunately, few interventions for teaching these skills have been rigorously evaluated.⁵⁵ Beyond showing the effectiveness of a podcast for teaching parents to assess treatment claims, we have demonstrated an approach to developing and evaluating learning resources that can and hopefully will be applied to other strategies for improving people's ability to assess treatment claims and make informed health choices.

Contributors

Daniel Semakula and Allen Nsangi are the principal investigators. They drafted the protocol with help of the other investigators and were responsible for the day-to-day management of the trial. Nelson Sewankambo and Andy Oxman had primary responsibility for overseeing the trial. All the investigators except for Doris Tove Kristoffersen reviewed the protocol, provided input, and agreed on this version. Matt Oxman together with Daniel Semakula had primary responsibility for developing the podcast. All the investigators contributed to the development. Astrid Austvoll-Dahlgren had primary responsibility for developing and validating the outcome measure. Daniel Semakula and Allen Nsangi had primary responsibility for data collection. Andy Oxman, Sarah Rosenbaum, Astrid Austvoll-Dahlgren, and Iain Chalmers were principal members of the coordinating group for the trial and, together with Nelson Sewankambo and the principal investigators, acted as the steering committee for the trial. They were responsible for final decisions about the protocol and reporting of the results.

Declaration of interests

All the authors declare that they have no competing interests.

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