Effects of the Informed Health Choices primary school intervention on the ability of children in Uganda to assess the reliability of claims about treatment effects: a cluster-randomised controlled trial

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Summary

Background **Claims about what improves or harms our health are ubiquitous. People need to be able to assess the reliability of these claims. We aimed to evaluate an intervention designed to teach primary school children to assess claims about the effects of treatments (ie, any action intended to maintain or improve health).**

Methods **In this cluster-randomised controlled trial, we included primary schools in the central region of Uganda that taught year-5 children (aged 10–12 years). We excluded international schools, special needs schools for children with auditory and visual impairments, schools that had participated in user-testing and piloting of the resources, infant and nursery schools, adult education schools, and schools that were difficult for us to access in terms of travel time. We randomly allocated a representative sample of eligible schools to either an intervention or control group. Intervention schools received the Informed Health Choices primary school resources (textbooks, exercise books, and a teachers' guide). Teachers attended a 2 day introductory workshop and gave nine 80 min lessons during one school term. The lessons addressed 12 concepts essential to assessing claims about treatment effects and making informed health choices. We did not intervene in the control schools. The primary outcome, measured at the end of the school term, was the mean score on a test with two multiple-choice questions for each of the 12 concepts and the proportion of children with passing scores on the same test. This trial is registered with the Pan African Clinical Trial Registry, number PACTR201606001679337.**

Findings **Between April 11, 2016, and June 8, 2016, 2960 schools were assessed for eligibility; 2029 were eligible, and a random sample of 170 were invited to recruitment meetings. After recruitment meetings, 120 eligible schools consented and were randomly assigned to either the intervention group (n=60, 76 teachers and 6383 children) or control group (n=60, 67 teachers and 4430 children). The mean score in the multiple-choice test for the intervention schools was 62·4% (SD 18·8) compared with 43·1% (15·2) for the control schools (adjusted mean difference 20·0%, 95% CI 17·3–22·7; p<0·00001). In the intervention schools, 3967 (69%) of 5753 children achieved a predetermined passing score (≥13 of 24 correct answers) compared with 1186 (27%) of 4430 children in the control schools (adjusted difference 50%, 95% CI 44–55). The intervention was effective for children with different levels of reading skills, but was more effective for children with better reading skills.**

Interpretation **The use of the Informed Health Choices primary school learning resources, after an introductory workshop for the teachers, led to a large improvement in the ability of children to assess claims about the effects of treatments. The results show that it is possible to teach primary school children to think critically in schools with large student to teacher ratios and few resources. Future studies should address how to scale up use of the resources, long-term effects, including effects on actual health choices, transferability to other countries, and how to build on this programme with additional primary and secondary school learning resources.**

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Introduction

Good health depends partly on people making good choices. Good choices depend on health literacy—ie, people's ability to obtain, process, understand, and judge the reliability of relevant health information. However, people often lack the ability to judge the reliability of information about the effects of treatments, and they tend to overestimate treatment benefits and underestimate treatment harms.[1] Low health literacy is associated with poor health outcomes and poor use of health-care services.[2] Improving health literacy, and particularly people's ability to assess claims about treatment effects, has the potential to reduce unnecessary suffering and to save billions of dollars every year.[3–5]

Most health information offers instructions or claims without adequate information for people to make informed choices. Meanwhile, much health and science education, which could teach people to assess

Research in context

Evidence before this study

At the start of the project (June 21–22, 2013), we searched the Cochrane Library, MEDLINE (Ovid), and ERIC for any quantitative study that measured the ability of participants to assess claims about the effects of treatments. We also contacted key researchers working in related research areas. We did not include reports in languages other than English or the Scandinavian languages. We did not find any studies that evaluated a primary school intervention to teach children to critically appraise treatment claims or make informed health choices, in any country.

A systematic review (Abrami and colleagues, 2015) of the effects of strategies for the development and enhancement of critical thinking skills at any age and in any setting found 49 studies of such strategies for teaching children aged between 6 and 10 years. However, none of these strategies focused specifically on health literacy. An overview (Evans, 2015) of six systematic reviews of educational interventions in low-income and middle-income countries included 227 studies that reported learning results. None of these studies addressed health or science literacy, or critical thinking more broadly. Systematic reviews (Austvoll-Dahlgren, 2016; Nordheim, 2016) of teaching children critical appraisal skills in relation to health have not identified studies that evaluate the effects of strategies for teaching these skills to primary school children.

Added value of this study

This is the first randomised trial to evaluate any intervention to improve the ability of primary school children anywhere to assess claims about treatments. We found a large effect: an increase of nearly 50% in the proportion of children with a passing score on a test that measures their ability to assess treatment claims. This corresponds to an effect size that was well above the average for other critical thinking interventions for any type of student in any country. No adverse events were reported. As with any school activity, the time that is used for this intervention (13 h over a 12-week school term) must be taken away from other activities. The cost of the intervention (about US$4 per child) is substantial relative to current levels of expenditures per primary school child in Uganda and other low-income countries.

Implications of all the available evidence

It is uncertain what the long-term effects of using the Informed Health Choices primary school resources are, what if any effect the programme will have on actual health choices and outcomes, or how transferable the findings of this study are to other regions and countries. Additionally, although the cost of the intervention is small, it is a substantial cost compared with the cost of school in Uganda. Nonetheless, being able to think critically about treatment claims (and generally) has an intrinsic value. School authorities, teachers, and children in the study indicated that they consider it important. We recorded a large effect on critical thinking about treatment effects, which was the primary outcome. Future research should address how best to scale up use of the resources, their suitability and effects in other countries, and how to build on these resources with additional primary and secondary school resources.

health claims, tends towards rote learning rather than critical thinking.[6] Economically disadvantaged people suffer disproportionately if they are unable to make informed health choices, as they can least afford to waste resources.

Teaching primary school children how to assess claims about the effects of treatments might be an effective strategy for several reasons. First, children are capable of learning about fair tests (ie, controlled investigations) and critical appraisal.[7] Indeed, teaching these basic skills is already part of school curricula in some countries.[8] Second, by targeting primary school children, it is possible to reach a large segment of the population (before many leave the education system and become difficult to reach). Large numbers of children drop out after primary level in low-income countries.[9] Third, teaching children at primary school level to assess claims about treatments can capitalise on the time these children have available for learning. Conversely, young people and adults have increasing demands on their time and it becomes increasingly difficult to teach them to think critically about treatment claims if they lack a foundation. They have less time to learn and must learn more at once. Moreover, erroneous beliefs, attitudes, and behaviours developed during childhood might be resistant to change later, when children become adults.[10] Fourth, teaching critical thinking skills to young children improves their academic achievement, and these effects are larger for low-achieving children.[11,12] Finally, learning to think critically about treatment claims can prepare children to contribute to well informed health policies as citizens, as well as to make their own personal health choices.

Although primary school children are taught about fair tests and critical thinking in some countries,[8] the focus is not on health or assessing claims about the effects of treatments. The aim of this study was to test the effects of using learning resources on the ability of children to assess claims about the effects of treatments. In a separate paper,[13] we will report a process evaluation in which we investigate factors that might have influenced the effect of the intervention, ways of scaling up effective use of the resources, and other potential beneficial and harmful effects of using the resources.

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Methods

Study design

In this two-group cluster-randomised trial, we included 120 primary schools in the central region of Uganda. 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. We obtained approval to do the trial from the Ugandan Ministry of Education before recruiting study participants.

Participants

Primary schools in Uganda normally fall under a regional authority headed by a district education officer, who is the primary contact between the Ministry of Education and the schools in that region. For this study, we obtained an introductory letter from the Permanent Secretary at the Ministry of Education introducing us to the district education officers in the region. We informed the district education officers about the project and asked them to provide us with a list of all primary schools in the region. We used this list as our sampling frame to identify eligible schools.

We used a multistage sampling technique in which we first drew a random sample of four districts from all 24 districts in the region (appendix 1). In the second stage, we randomly sampled schools proportionately from lists of the selected districts, stratifying by school location (urban, semi-urban, or rural) and ownership (private or public). With the help of the district education officers we generated a list of 2029 eligible schools in those four districts. We excluded eight international schools, five special needs schools for children with auditory and visual impairments, four schools that had participated in user-testing and piloting of the resources, 160 infant and nursery schools, and one school for adult education. For practical reasons, we also excluded 753 schools that were difficult for us to access in terms of travel time. We then randomly selected 170 of the remaining schools.

We (AN and DS) visited schools that were selected for recruitment, taking with us a letter of introduction from the respective district education officer. We provided the head teacher of each school with information about the study and obtained written consent from them on behalf of their school to take part in the study. We also obtained written consent from the primary-5 (year 5 of primary school) teachers identified by the head teachers. Within each participating school, we included all year-5 children. The official starting age for year-5 children in Uganda is 10 years, but many children are older than this. We did not obtain assent from individual children or consent from their parents. The intervention posed minimal risk and no more risk than other teaching materials, almost none of which have been evaluated. Informed consent by individual children or their parents, in effect, would be meaningless once the decision to participate was taken by the head teacher and the teachers, who have the responsibility and authority to make decisions about lesson plans and the administration of tests. Individual children and their parents had the same right to refuse participation as they do for any other lesson or test in primary schools.

Randomisation and masking

We randomly allocated schools (1:1) to the intervention or control group using a computer-generated sequence with block sizes of four and six and equal allocation ratios within each block. We used stratified randomisation to help ensure equal distribution of schools for two variables: school ownership (public and private) and geographical location (urban, semi-urban, and rural). A statistician who was not a member of the research team, together with his assistants, generated six randomisation lists (one for each combination of the two variables) with unique codes. They labelled opaque envelopes with the unique codes, inserted cards with the study group allocated to each code in the envelopes, and sealed them.

For the **random number generator** see http://www.sealedenvelope.com

After obtaining consent from 120 schools, two research assistants selected each school from a list of the schools and identified the appropriate randomisation list to be used for that school, based on its geographical location and ownership. They assigned the next available code from that list to each school and then opened the corresponding envelope to determine whether the school was assigned to the intervention or control group. No changes to allocation were made during or after this process.

See Online for appendix 1

We informed the participating head teachers and year-5 teachers about the purpose of the study in the consent form (available with the protocol), which they signed before being randomly allocated. After randomisation, they knew whether they were in the intervention or control group. The consent form included information about the outcome measure, stating that it "consists of multiple-choice questions that assess an individual's ability to apply concepts that people must be able to understand and apply to assess treatment claims and to make informed health-care choices". We did not show them the test until the end of the school term. Children in both groups of the trial were informed of the purpose of the test used as the primary outcome measure when their teachers asked them to complete it at the end of the term. Because the teachers and children wanted to know their scores, they put their names on the tests and were told that they and their teachers would be told their scores. The statistician who analysed the data did not know which group was the intervention and control group when he did the primary analyses, but this became obvious due to the magnitude of the effect.

Procedures

We first identified the key concepts that people need to understand and apply when assessing claims about treatments.[14] Together with teachers in Uganda, we established which of those concepts were relevant for primary school children (appendix 1). We started with a list

Panel 1: 12 key concepts covered by the Informed Health Choices primary school resources

Claims
- Treatments might be harmful
- Personal experiences or anecdotes (stories) are an unreliable basis for assessing the effects of most treatments
- Widely used treatments or treatments that have been used for a long time are not necessarily beneficial or safe
- New, brand-named, or more expensive treatments may not be better than available alternatives
- Opinions of experts or authorities do not alone provide a reliable basis for deciding on the benefits and harms of treatments
- Conflicting interests may result in misleading claims about the effects of treatments

Comparisons
- Evaluating the effects of treatments requires appropriate comparisons
- Apart from the treatments being compared, the comparison groups need to be similar (ie, "like needs to be compared with like")
- If possible, people should not know which of the treatments being compared they are receiving
- Small studies in which few outcome events occur are usually not informative and the results may be misleading
- The results of single comparisons of treatments can be misleading

Choices
- Treatments usually have beneficial and harmful effects

The concepts are shown here as they are described in the key concepts list, which was not designed as a learning resource, and not as they were presented to the children in the primary school resources (appendix 1).

of 32 key concepts, divided into six groups:[15] recognising the need for fair comparisons of treatments, judging whether a comparison of treatments is a fair comparison, understanding the role of chance, considering all the relevant fair comparisons, understanding the results of fair comparisons of treatments, and judging whether fair comparisons of treatments are relevant.

We consulted with Ugandan teachers, who found all six groups of concepts to be relevant for year-5 children. Based on these consultations with the teachers, we judged that 24 of the 32 concepts could be learned by primary school children. These final judgments were made by members of the research team in a face-to-face meeting using informal discussion to reach a consensus.

We developed the resources iteratively between 2013 and 2015, using idea generation and prototyping, pilot testing with non-participatory observation, user-test interviews with children and teachers, and feedback from a network of teachers (appendix 1). We found that there were too many concepts to teach in a single school term. We therefore considered the importance and difficulty of each concept, informed by data from the piloting and user testing. Based on these considerations, we selected 12 concepts (panel 1).

The resulting learning resources included a textbook, a teachers' guide, exercise books, a poster, activity cards, and a song. The textbook (appendix 1) of a story told in a comic book format (figure 1), instructions for classroom activities, exercises, a checklist summarising the concepts in the book, and a glossary of key words with definitions in English and translations to Luganda and Swahili. In addition to the textbooks, we provided intervention schools with a guide for each teacher, exercise books for each child, a poster of the checklist for the classroom, and activity cards for the seventh lesson (appendix 1). We also provided them with the "Think carefully about treatments" song on an MP3 player (appendix 1). The lyrics of this song are another reminder of the key messages in the book. Panel 2 lists the contents of the book and the teachers' guide. Appendix 1 provides a description of the intervention using the GREET TIDieR checklist.

There are three school terms per year in Ugandan primary schools, each lasting between 12 and 14 weeks. Teaching periods last 40 min. We designed the resources to be used over 9 weeks, with one double period (80 min) per week, during a single term, and 1 h to complete the test at the end of the term. There was an expectation on the part of the head teachers and teachers that any content displaced by the lessons would be compensated, so that time was not taken away from other lessons. Each school decided how to do this.

At least 1 week before the trial began, and before the introductory workshop, we gave teachers' guides to the teachers in the intervention schools, enabling them to familiarise themselves with the content and prepare a plan for delivering the lessons. We invited all participating teachers in the intervention group to attend a 2 day introductory workshop. At the workshop, we (AN and DS) informed them about the study objectives and procedures, including the general nature of the outcome measure; went through all nine lessons outlined in the primary school resources; and addressed any questions or concerns that arose.

We monitored delivery of the intervention, in accordance with guidelines of the Ministry of Education school supervisory timetable. These allow for follow-up of newly introduced programmes within schools. One of the investigators (AN or DS) or a research assistant observed one lesson in each of the classes in the intervention schools. If there were not enough textbooks, we provided these; if schools were behind schedule in completing the lessons, we explored why; and we addressed any administrative issues relating to the conduct of the trial. We observed how the teachers taught the lessons, but we did not provide feedback or advice to the teachers.

We also encouraged the teachers to make summaries for themselves after reading each chapter in the teachers' guide in preparation for the lesson, and we asked them to hand these in to the study team after the intervention period. We did this to help ensure that the teachers read the teachers' guide in preparation for the lessons, as well as to collect data for the process evaluation.

We contacted the schools allocated to the control group at the beginning of the school term, and invited year-5

Figure 1: **An excerpt from the comic book story in the textbook**

teachers to a 2 h introductory meeting in each district. At these meetings, we informed them about the study procedures, including the general nature of the test that we would be using as the outcome measure. We told them that they would receive the primary school resources at the end of the study. We did not introduce them to the resources or invite them to an introductory workshop.

Children in both groups of the trial completed the test in their classrooms at the end of the term. Research assistants delivered the tests a few hours before exam time and collected them immediately after the exam. They ensured that the children had sufficient time to complete the test (1 h, as is current practice for primary school exams in Uganda). All reading materials, including the Informed Health Choices poster, were removed from the class during exam time. The children (where possible) had spacing that is at least double the usual sitting class spacing, and the test was completed individually without assistance, under supervision of the teachers and observed by the research assistants. Most teachers completed the test at the same time as the children. We contacted teachers who were not available on the day of the exam to arrange completion of the questionnaire on another day. The children and the teachers were aware that missing answers would be scored as wrong.

Outcomes

The primary outcome was measured at the individual participant level as: the mean test score (percentage of correct answers) on the test taken at the end of the term and the proportion of children with a passing score. The secondary outcomes were the proportion of children with a passing score for a subgroup of children who received an audio version of the test in Luganda; the proportion of children with a score indicating mastery of the concepts; for each concept, the proportion of children who answered both questions correctly; the children's intended behaviours and self-efficacy; and the children's attitudes towards science and school. Additionally, we have reported the following, which were not specified in the protocol: mean scores, passing scores, and mastery scores for the teachers, the standardised mean difference for the children, and the cost of the intervention

The test at the end of the term included 24 multiple-choice questions (two for each concept) from the Claim Evaluation Tools database (appendix 1).[16] The questions had between two and four response options, with an overall probability of answering 39% of the questions

Panel 2: **Contents of the textbook and the teachers' guide**

The Health Choices Book: learning to think carefully about treatments, a health science book for primary school children

Introduction
- Lesson 1: Health, treatments, and effects of treatments

John and Julie learn about CLAIMS about treatments
- Lesson 2: Someone's experience using a treatment
- Lesson 3: Other bad bases for claims about treatments (part 1)
- Lesson 4: Other bad bases for claims about treatments (part 2)

John and Julie learn about COMPARISONS of treatments
- Lesson 5: Comparisons of treatments
- Lesson 6: Fair comparisons of treatments
- Lesson 7: Big enough fair comparisons of treatments

John and Julie learn about CHOICES about treatments
- Lesson 8: Advantages and disadvantages of a treatment

Review
- Lesson 9: Review of what is most important to remember from this book

Teachers' guide

The teacher's guide includes an introduction to the project and the resources, and the following for each lesson, in addition to the embedded chapter from the textbook:
- The objective of the lesson
- A lesson preparation plan
- A lesson plan
- A list of materials that the teacher and children will need
- A synopsis of the story
- Keywords in the chapter
- Review questions to ask the children after reading the story
- Extra examples for illustrating the concepts
- Background about examples used in the story
- Teacher instructions for the classroom activity
- Answers and explanations for the activity
- Answers and explanations for the exercises
- Background information, examples, and keyword definitions for teachers

correctly by chance alone. We developed the questions based on extensive feedback from methodological experts, health professionals, teachers, children, and members of the public.[16] We conducted two Rasch analyses to validate the test.[17,18] Most year-5 school children in Uganda do not have English as their first language and many have poor reading skills. Because we were concerned that this might affect their scores on the test, we also developed a Luganda version of the test to be administered orally to a subgroup of children in each school to estimate the effect of literacy on test scores.[18] We asked the teachers at each school to select 15 children who had already taken the written test in English and who were competent in Luganda. In schools with small classes, the Luganda version was received by all the children who met those two criteria and were present on the day of the oral test.

Two additional multiple-choice questions were included, making 26 in total. These were included because the test used in this trial was also used in a linked randomised trial evaluating a podcast given to the parents of some of the children at the end of the term.[19] These two extra questions addressed the concept: "a treatment outcome may be associated with a treatment, but not caused by the treatment". This concept was not covered in the primary school resources and responses to the two extra questions were not included in the primary analyses.

The test included questions that assessed intended behaviours, self-efficacy ("an individual's conviction of their own capability to complete a task or perform a particular behaviour in order to realise goals"), and attitudes (appendix 1). There were four questions that assessed reading skills. We used the answers to those four questions as a covariate in exploratory analyses. In the intervention group, the test included questions that assessed satisfaction with the resources.

We used an absolute (criterion referenced) standard to set a passing score (appendix 1). Children were counted as "passing" or "failing" depending on whether they met this prespecified criterion. We used a combination of Nedelsky's and Angoff's methods to determine the cutoff for a passing score. Additionally, using the same methods, we determined a second cutoff for a score that indicated mastery of the 12 concepts. The criterion for passing was a minimum of 13 of 24 questions answered correctly. The criterion for mastery was a minimum of 20 of 24 questions answered correctly.

We will report comparisons of academic achievement using end of term examinations as well as attendance between children in the two groups in the process evaluation in a separate report.[13]

We have reported three additional outcomes that were not specified in the trial protocol: the teachers' scores on the test, which was planned as part of the process evaluation; the standardised mean difference for the children's test scores, which allows comparison with effect sizes from other studies; and the cost of the intervention. We estimated the cost of the intervention, based on the actual printing costs, and estimated costs for delivery of the materials, teacher workshops, and teachers' time. We assumed the teaching materials, apart from the exercise book and the test, would be used over 5 years; the training workshops for the teachers would not need to be repeated during this time; and an interest rate of 5%, giving an annualisation factor of 0·23.

All the outcomes were measured at the end of the school term in which the intervention was implemented. We will measure the sustainability of the effects after 1 year. We asked teachers to record unexpected adverse events and problems that might pose risks to the children or others, and asked them to report these to the investigators or to the Makerere University College of Health Sciences, Institutional Review Board.

Teachers in the intervention group of the trial were given the contact information of the principle investigators (AN and DS) at the start of the trial and instructions for recording adverse events and problems in journals that they were asked to keep for the process evaluation. For the process evaluation, which will be reported separately, we have collected in-depth qualitative data from interviews and focus group discussions regarding participants' views of the intervention, potential adverse effects, as well as other potential benefits of the intervention.

Statistical analysis

We used the University of Aberdeen Health Services Research Unit's Cluster Sample Size Calculator to calculate the sample size, applying the following assumptions: 70 children per cluster; an intraclass correlation coefficient of 0·5, based on ICCs from a meta-analysis of randomised trials of school interventions and an international comparison of ICCs for educational achievement outcomes, which suggested the ICC might be very high;[20,21] 0% as the proportion of children expected to achieve a passing score without the intervention, based on findings from pilot testing; 10% as the smallest difference we wanted to be able to detect; an alpha of 0·05; and a power of 90%.Based on these assumptions, we estimated that we would need 50 schools in each group. Allowing for a loss to follow-up of up to 10% (for schools where it might be impossible to administer the tests at the end of the term), we estimated that we needed a minimum of 55 schools in each group.

For the primary and secondary outcomes, we used mixed models with a random effects term for the clusters and the stratification variables modelled as fixed effects, using generalised logistic regression for dichotomous outcomes and linear regression for continuous outcomes. The statistical analyses were done with R (R Core Team, Vienna, Austria; version 3.3.2). All the children and teachers who completed the test were included in the analyses. Missing values were counted as wrong answers. We converted odds ratios from logistic regression analyses to adjusted differences using the intervention group percentage as the reference for the main outcomes and the control group percentage as the reference for the secondary outcomes.

We did two post-hoc sensitivity analyses suggested by external reviewers to explore the risk of bias due to attrition, which was larger in the control schools than in the intervention schools. First, we did a weighted analysis using inverse probability weighting. In this analysis, the children in each school were given a weight equal to the inverse of the proportion of children in the school that completed the test. Second, we calculated upper and lower bounds for the mean difference in test scores using the Lee bounds approach.[22] These are constructed by trimming the group with less attrition at the upper and lower tails of the outcome (test score) distribution respectively. In this analysis, the sample was trimmed in the intervention schools so that the proportion of children included in the analysis was equal for both groups. We did not adjust for covariates in this analysis.

For each outcome, we have reported the proportion, mean and standard deviation or count and percentage for each group, the estimated difference, the estimated confidence interval for the difference, and the p value from the statistical models. For questions about intended behaviours and self-efficacy, we dichotomised the responses in the analysis (eg, very unlikely or unlikely *vs* very likely or likely), and reported the number and percentage of children for each of the response options.

Based on data from the pilot studies, we anticipated that many of the children would have poor reading skills, and that this might impede their ability to comprehend the content of the textbook and to answer the multiple-choice questions. We explored whether there were differences in the effect of the intervention for children with advanced reading skills (all four literacy questions answered correctly) versus basic reading skills (both basic literacy questions correct and one or two of the advanced literacy questions wrong) versus lacking basic reading skills (one or both basic literacy questions wrong).

We calculated the adjusted standardised mean difference (Hedges' g) so that we could put the effect of the intervention in the context of effect size reported for other interventions to improve critical thinking or learning in primary schools.[11,20,23] We calculated an adjusted Hedges' g and its 95% confidence interval using formulae described by White and Thomas.[24]

We intended to do a second subgroup analysis to explore whether having a parent who listened to the podcast improved the scores of the children and whether there was an interaction between the effect of the podcast and the primary school resources. However, because of delays in starting the podcast trial, the parents allocated to listen to the podcast did not do so until after the children had completed the tests. There was no data monitoring committee. Appendix 2 provides data files for the study.

See Online for appendix 2

This trial is registered with the Pan African Clinical Trial Registry, number PACTR201606001679337.

Role of the funding source

The funder had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The principal investigator (AN) had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between April 11, 2016, and June 8, 2016, 2960 schools in Uganda were assessed for eligibility. After recruitment meetings, 120 schools consented and were randomly assigned to either the intervention (n=60) or control group (n=60). All 120 schools provided data and were included in the analysis. Figure 2 shows the

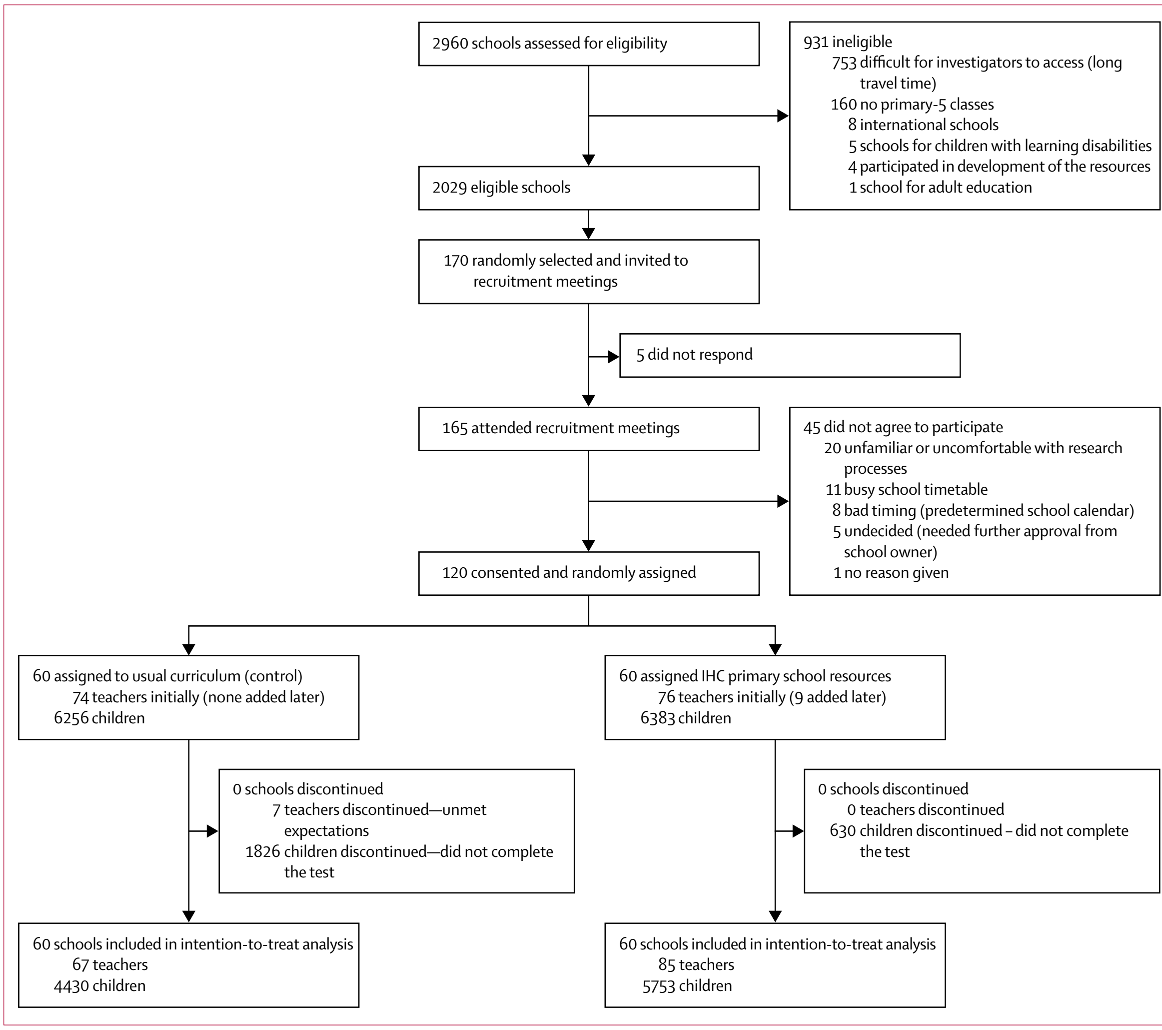

Figure 2: **Trial profile**

reasons for non-inclusion, the flow of the schools, teachers, and children through the study. Most of the schools in both the intervention and control groups were urban or semi-urban (table 1). There were more public schools in the control group (55% *vs* 50%). There were more teachers with a university degree and fewer with a teaching diploma in the intervention schools (12% *vs* 5% and 41% *vs* 49%), and there were more teachers who taught science as their main subject in the intervention group (80% *vs* 73%; table 1). These minor differences seem unlikely to have biased the results. In the sensitivity analysis, the Luganda test was administered in 114 schools. Six control schools declined (five because of a lack of time, and one because no children reportedly spoke Luganda).

All 60 schools in the intervention group delivered all nine of the lessons. The timing of the lessons varied. Some schools (mostly boarding schools) did the lessons early in the morning or in the evening. Others taught the lessons when the usual science lessons were scheduled or when co-curricular activities like drama and sports were scheduled. These schools compensated for what was missed by doing the missed activities early in the morning or in the evening.

We initially asked each head teacher to select one year-5 science teacher, but some schools had more than one teacher who taught year-5 science, so there were more than 60 teachers in both the intervention and control schools. Six intervention schools that had more than one year-5 class (with a different teacher for each class) identified altogether nine more teachers for whom they requested training. No teachers were added in the control schools, since the teachers in the control schools did not receive training. All 85 teachers in the intervention schools and 67 (91%) of the teachers in the control schools completed the same test that the children took at the end of the term.

Altogether, 10 183 children completed the test. More children completed the test in the intervention schools (5753 [90%] of 6383) than in the control schools (4430 [71%]

of 6256). This was most likely because teachers in the intervention schools were more motivated to request that the children stay at the end of the term to take the test, having committed time and energy to the intervention, than teachers in the control schools, who taught the usual curriculum. There was no appreciable difference in the proportion of girls (45%) or the median age of children in the two comparison groups (11 years, IQR 10–12). Most of the children answered all the questions. The proportion of missing values (unanswered questions) for each question was between 0·5% and 4·3% and the number of missing values was similar between the intervention and control schools (p=0·964; appendix 1).

The average score for children in the intervention schools was 62·4% (SD 18·8) compared with 43·1% (15·2) in the control schools. The adjusted mean difference (based on the regression analysis) was 20·0% (95% CI 17·3–22·7; p<0·00001) higher in the intervention than in the control group. Appendix 1 shows the distribution of test scores. In the intervention schools, 3967 (69%) of 5753 children had a passing score (≥13 of 24 correct answers), compared with 1186 (27%) of 4430 in the control schools (table 2). The adjusted difference (based on the odds ratio from the logistic regression analysis) was 50% more children who passed (95% CI 44–55; p<0·00001) in the intervention than in the control group.

The average score for the 1616 children who completed the test orally in Luganda was 66·3% in the intervention schools compared with 49·7% in the control schools. The adjusted difference was 15·8% (95% CI 12·7–19·0), which was slightly smaller than the adjusted mean difference for the written test (table 3). We did two additional sensitivity analyses to assess the potential risk of bias from attrition—ie, children who did not take the test. There was very little difference between the results of the weighted analysis, using inverse probability weighting, and the primary analysis (table 3), suggesting that the results are robust. In the second analysis, we calculated Lee bounds for the mean difference in test scores. This resulted in a lower (worst case) and upper (best case) mean difference of 14·2% and 24·6%, respectively (95% CI 13·4–25·5). This indicates that even with the worst-case scenario, the average test score in the intervention schools was still 14·2% higher than in the control schools (with a lower confidence limit of 13·4%). Moreover, the worst-case scenario, which removed 19% of the children with the highest test scores from the intervention group, is unlikely. This is equivalent to assuming that the children in the control schools who did not take the test would have had scores that corresponded to the top 19% of the children in the intervention schools, had they taken the test. Attrition for each strata of school (based on ownership and location) and test scores for each stratum are summarised in appendix 1.

In the intervention schools, 19% of the children had a score indicating mastery of the 12 key concepts (≥20 of 24 correct answers) compared with 1% of the children in the control schools. The adjusted difference was 18% more children in the intervention schools who mastered the concepts (95% CI 18–18; p<0·00001).

For each concept, the proportion of children who answered both questions correctly was higher in the intervention schools than in the control schools, including for the concept that was not covered in the primary school resources (p<0·00001 for all 13 concepts after a Bonferroni correction for multiple comparisons; figure 3).

Children in the intervention schools were more likely to respond that they would find out what a claim was based on (adjusted difference 10·6%, 95% CI 6·2–14·7); find out if a claim was based on research (10·8%, 6·3–15·1); and participate in a research study if asked

	Control schools	Intervention schools
Schools		
Schools (selected from the central region of Uganda)	60	60
Location		
Rural	8 (13%)	6 (10%)
Semi-urban	15 (25%)	14 (23%)
Urban	37 (62%)	40 (67%)
Ownership		
Public	33 (55%)	30 (50%)
Private	27 (45%)	30 (50%)
Teachers		
Teachers (initially identified by head teachers)	74	76
Completed tests*	67 (91%)	85 (100%)†
Education‡		
Certificate	30 (45%)	39 (46%)
Diploma	33 (49%)	35 (41%)
University degree	3 (4%)	10 (12%)
Main subject taught		
Science	49 (73%)	68 (80%)
Sex		
Women	29 (43%)	34 (40%)
Children		
Children (enrolled in year-5 at the start of the term)	6256	6383
Completed tests*	4430 (71%)	5753 (90%)
Median completed tests per class§	60 (40–95)	61 (43–89)
Sex		
Girls	1973 (45%)	2599 (45%)
Median age (years)	11 (10–12)	11 (10–12)

Data are n, n (%), or median (IQR). *Questions about the characteristics of the teachers and children were included in the test completed at the end of the school term. †Head teachers were initially asked to identify teachers who taught science to children in the fifth year of primary school. However, some schools had more than one year-5 class. Six intervention schools with more than one year-5 class (with a different teacher for each class) requested that nine additional teachers be included altogether. ‡There was one missing value in each group for this variable. §The average class size at the start of the term was 84 children in both groups.

Table 1: **Characteristics of the participants**

	Control schools (60 schools, 4430 children)	Intervention schools (60 schools, 5753 children)	Adjusted difference*	Odds ratio†	ICC
Primary outcome					
Mean score	43·1% (15·2)	62·4% (18·8)	20·0% (17·3–22·7)	..	0·18
Children with a passing score (≥13 of 24 correct answers)	1186 (27%)	3967 (69%)	50% (44–55)	9·3 (6·6–13·2)	0·19
Secondary outcome					
Children with a mastery score (≥20 of 24 correct answers)	38 (1%)	1070 (19%)	18% (18–18)	35·3 (20·6–60·7)	0·21
Teachers' scores‡					
Mean score	66·7% (14·3)	84·6% (17·1)	18·3% (12·9–23·3)	..	..
Teachers with a passing score (≥13 of 24 correct answers)	58 (87%)	83 (98%)	11% (4–13)	7·2 (1·5–35·3)	..
Teachers with a mastery score (≥20 of 24 correct answers)	10 (15%)	61 (72%)	57% (37–70)	14·4 (6·2–33·1)	..

Data are % (SD), % (95% CI), or n (%). ICC=intraclass correlation coefficient. *The adjusted difference is based on mixed models with a random-effects term for the clusters and the stratification variables are modelled as fixed effects, using logistic regression for dichotomous outcomes and linear regression for continuous outcomes. p<0·0001 for all four comparisons. † The odds ratios from the logistic regressions for passing scores and mastery scores have been converted to differences based on the intervention school proportions and the odds ratios calculated using the intervention schools as the reference (the inverse of the odds ratios shown here). ‡There were 67 teachers in the control schools and 85 in the intervention schools.

Table 2: **Main results**

	Adjusted difference*	SMD† or OR
Primary analysis	20·0% (17·3–22·7)	SMD 1·16 (1·00–1·32)
Weighted analysis	20·0% (17·3–22·7)	SMD 1·08‡ (0·93–1·22)
Lee bounds	14·2–24·6% (13·5–25·5)	..
Oral examination in Luganda§	15·8% (12·7–19·0)	SMD 0·99 (0·79–1·20)
Passing score (≥13 out of 24 correct answers)		
Primary analysis	49·8% (43·8–54·6)	OR 9·3 (6·6–13·2)
Weighted analysis	50·0% (44·1–54·8)	OR 9·5 (6·7–13·4)

Data are % (95% CI) unless stated otherwise. SMD=standardised mean difference. OR=odds ratio. *The adjusted difference is based on mixed models with a random-effects term for the clusters and the stratification variables modelled as fixed effects, using logistic regression for dichotomous outcomes and linear regression for continuous outcomes. p<0·0001 for all analyses. The ORs from the logistic regressions for passing scores have been converted to differences based on the intervention school proportions and the ORs calculated using the intervention schools as the reference (the inverse of the ORs shown here). †Adjusted Hedges' g. ‡The effect size is different from the primary analysis, despite the adjusted mean difference being the same, because of a difference in the intraclass correlation coefficient. §Administered to 769 children in the control schools (mean 49·7% [SD 15·6]) and 847 children in the intervention schools (66·3% [15·7]).

Table 3: **Sensitivity analyses**

(7·8%, 3·7–11·9), compared with children in the control schools (appendix 1).

Children in the intervention schools were more likely to consider it easy to assess whether a claim is based on research (adjusted difference 15·0%, 95% CI 10·9–19·0) compared with children in the control schools (appendix 1). They were less likely to consider it easy to assess how sure they could be about research results (adjusted difference –4·1%, 95% CI –1·0 to –7·3). We detected little if any difference in how easy they thought it was to find information about treatments based on research, or to assess how relevant research findings are likely to be to them. We also detected little if any difference in attitudes towards school or science. At least 90% of the children overall indicated a positive attitude in response to all four questions (appendix 1). Most children (4864 [85%] of 5753) in the intervention schools had positive views of the textbook (appendix 1).

None of the teachers or research assistants who observed the lessons reported any adverse events. Although the intervention had positive effects regardless of reading skills (appendix 1), there was an interaction between levels of reading skills and the effects of the intervention. As we hypothesised, the beneficial effects of the intervention were larger for children with better reading skills.

In an analysis that was planned for the process evaluation, but not included in the protocol for the trial, we found that most teachers in both the control and the intervention groups (87% and 98%, respectively) had a passing score on the same test that the children took at the end of the term (adjusted difference 11%, 95% CI 4–13; table 2). The teachers in the intervention group were much more likely to have a score indicating mastery of the concepts (72% *vs* 15%; adjusted difference 57%, 95% CI 37–70).

We calculated the effect size (standardised mean difference) for the children for comparison with other studies (table 3). The effect size (Hedges' g) was 1·16 (95% CI 1·00–1·32) based on the primary analysis. It was slightly less (1·08; 95% CI 0·93–1·22) based on the weighted analysis. We estimated that the average annual

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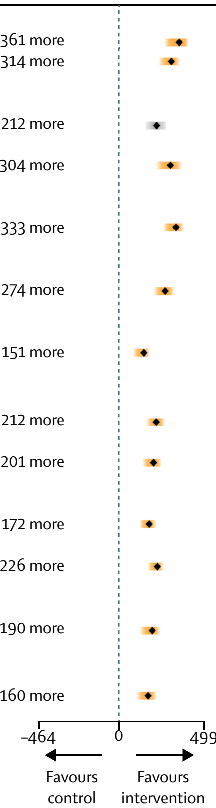
	Control schools % correct* (n=273)	Intervention schools % correct* (n=288)	Adjusted difference%† (95% CI)	Difference* per 1000	Odds ratio (95% CI)	ICC‡
Claims						
Treatments might be harmful	21·0 (n=930)	52·1 (n=2999)	36·1 (28·6–42·9)	361 more	5·0 (3·7–6·7)	0·12
Personal experiences or anecdotes (stories) are an unreliable basis for assessment of the effects of most treatments	14·5 (n=643)	41·5 (n=2387)	31·4 (25·0–37·0)	314 more	5·0 (3·8–6·3)	0·11
A treatment outcome might be associated with a treatment, but not caused by the treatment§	6·9 (n=306)	28·3 (n=1630)	21·2 (16·7–27·7)	212 more	5·3 (4·2–7·1)	0·09
Widely used treatments or treatments that have been used for a long time are not necessarily beneficial or safe	16·0 (n=708)	40·6 (n=2335)	30·4 (23·6–38·3)	304 more	4·5 (3·4–6·3)	0·15
New, brand-named, or more expensive treatments might not be better than available alternatives	33·1 (n=1467)	62·7 (n=3609)	33·3 (27·6–39·2)	333 more	4·0 (3·1–5·3)	0·11
Opinions of experts or authorities do not alone provide a reliable basis for deciding on the benefits and harms of treatments	27·1 (n=1201)	51·2 (n=2944)	27·4 (21·7–33·7)	274 more	3·2 (2·6–4·2)	0·10
Conflicting interests might result in misleading claims about the effects of treatments	19·8 (n=875)	34·6 (n=1990)	15·1 (10·4–19·6)	151 more	2·2 (1·8–2·6)	0·07
Comparisons						
Evaluation of the effects of treatments requires appropriate comparisons	6·9 (n=306)	28·3 (n=1630)	21·2 (16·7–27·7)	212 more	5·3 (4·2–7·1)	0·10
Apart from the treatments being compared, the comparison groups need to be similar (ie, like needs to be compared with like)	14·6 (n=640)	34·5 (n=1987)	20·1 (14·7–25·8)	201 more	3·1 (2·4–4·0)	0·09
If possible, people should not know which of the treatments they are receiving‡	19·8 (n=877)	34·6 (n=1988)	17·2 (12·4–22·3)	172 more	2·4 (1·9–2·9)	0·06
Small studies in which few outcome events occur are usually not informative and the results may be misleading	21·9 (n=970)	42·5 (n=2445)	22·6 (17·6–27·3)	226 more	2·9 (2·3–3·4)	0·07
The results of single comparisons of treatments can be misleading	22·6 (n=1000)	37·5 (n=2155)	19·0 (12·9–25·1)	190 more	2·4 (1·9–3·1)	0·10
Choices						
Treatments usually have beneficial and harmful effects	27·1 (n=1201)	41·1 (n=2364)	16·0 (10·4–22·4)	160 more	2·0 (1·6–2·6)	0·10



95% CI
95% CI for key concept not included in learning resources
Point estimate

Figure 3: **Results for each key concept**
*There were two multiple-choice questions for each concept. The proportions are for the percentage of children who answered both questions correctly. †The adjusted difference is based on mixed models with a random effects term for the clusters and the stratification variables modelled as fixed effects, using logistic regression. All the p values are less than 0·0001 after being adjusted for multiple comparisons. The odds ratios from the logistic regressions have been converted to differences based on the control school proportions and the odds ratios shown here. ‡Intraclass correlation coefficient. §This concept was not included in the learning resources or counted in the average, pass, or mastery scores.

cost of the intervention, including teachers' time, would be approximately US$400 per school, and $4 per child (appendix 1).

Discussion

Use of the Informed Health Choices primary school resources had a large effect on the ability of primary school children in Uganda to assess claims about treatment effects. This effect was larger for children with better reading skills, but the intervention was effective for children lacking basic reading skills, as well as for children with basic or advanced reading skills. This effect was achieved even though the learning materials and the tests were in English, which was not the children's first language. Based on findings from pilot testing both the resources and the test used to measure the outcomes, we were surprised by the size of the effect, which is also large in comparison to other education interventions in primary schools in low-income and middle-income countries,[20] and other interventions to teach critical thinking for all ages in high-income countries.[11] In addition, the intervention had a positive effect on the children's intended behaviours and the teachers' mastery of the key concepts.

We have not found any directly comparable studies. Other interventions in primary schools have been found to have a positive effect on critical thinking, but these studies have been conducted in high-income countries and neither the interventions nor the outcome measures are directly comparable.[11] Nonetheless, the effect size for this study (a standardised mean difference of 1·16) is well above the average effect size reported for other critical thinking interventions (0·33 [SD 0·55]; appendix 1).[11] It is larger than any of the effect sizes reported in a systematic review of interventions to improve learning in primary schools in low-income and middle-income countries for interventions with teacher training and for interventions with instructional materials.[20] It is also larger than the effects reported in a second systematic review for learning outcomes for structured pedagogy programmes in low-income and middle-income countries.[23] However, most of those studies used reading or maths tests as the outcome measure rather than a test that was explicitly designed to measure skills that were the focus of the intervention. Only two of the studies of structured pedagogy programmes measured cognitive or problem solving skills. Therefore, it is not appropriate to compare our results with the studies in these reviews.

The systematic review of interventions to improve learning in primary schools in low-income and middle-income countries found that instructional materials alone may not improve learning, and that they are more likely to be effective when combined with teacher training and a well articulated instructional model.[20] However, the second systematic review of structured pedagogy programmes, all of which included teacher training and many of which provided learning resources, found a large range of effects.[25] Possible explanations for a lack of effect in some studies, identified by the investigators, include teachers sometimes not being knowledgeable or experienced enough to fully understand their training or not implementing the lessons as intended or as often as planned. Another possible explanation was that the investigators did not consider key contextual factors, such as limited resources and high student-to-teacher ratios.[23]

It is uncertain how effective the Informed Health Choices primary school resources would be without the teacher training and support from the school authorities and teachers. The more than 85% of teachers in the control schools (without training) who had passing scores on the test used as an outcome measure suggests that the teachers were knowledgeable enough to understand the training. That 72% of the teachers in the intervention schools had scores indicating mastery of the concepts, compared with 15% of the teachers in the control schools, suggests that the training, together with their teaching experience during the term, was effective. Over 2 years of pilot and user-testing the learning resources, and collaborating with a network of teachers, helped to ensure that our intervention took account of contextual factors, including large student-to-teacher ratios, crowded classrooms, and scarce resources.

No adverse events were reported by any of the head teachers, teachers, children, or parents. Potential adverse effects that were hypothesised before the trial, but were not observed, are summarised in appendix 1. These will also be explored further in the process evaluation.

A limitation of this study is the number of children that did not take the test used to measure outcomes at the end of the term and the difference in the proportion of children that completed the test in intervention schools (90%) and control schools (71%). Attrition is a common problem in randomised trials of education interventions.[20,25] The most likely reason for the difference in attrition in this study is that, having invested time and energy in the lessons, teachers in the intervention schools put more effort into making sure that children in their classes completed the test.

Our study does not meet the attrition standard suggested by the What Works Clearinghouse (WWC).[26] However, that standard is based on tolerating a maximum bias of 0·05 standard deviations, and it is highly sensitive to the maximum level of bias that a systematic review is willing to accept.[27] The effect size for this study (1·16) is more than 20 times the WWC maximum tolerable bias. Although we cannot rule out some degree of bias due to attrition, it is highly unlikely that bias modified the observed effect substantially relative to the size of the effect. The sensitivity analyses that we did support this conclusion (table 3).

There were also more teachers who completed the test in the intervention schools. This was probably because although we initially asked the head teachers to identify one year-5 teacher, some schools had more than one class. We subsequently included all the teachers who taught science to a year-5 class in the intervention schools, but not in the control schools.

Another limitation of this study is that the test used as the outcome measure was aligned with the intervention ("treatment-inherent"). That is, the test measured the ability to apply the concepts that the resources were designed to teach. Treatment-inherent outcome measures are associated with larger effect sizes than independent measures.[28] It is also problematic to compare the effect size from this study with studies in which both comparison groups were taught the subject being tested. Because of this, it is inappropriate to compare the effect of our intervention on our outcome measure to the effects of other interventions on independent measures, such as reading or maths tests. Similarly, one should be cautious when comparing our results to the effects of other interventions to teach critical thinking. The systematic review of critical thinking interventions, noted above, found larger effects for outcome measures developed by one or more of a study's authors for use in the study (0·65, 95% CI 0·52–0·78) than for well established measures of critical thinking (0·40, 0·26–0·53).[11]

Because there was no pre-existing outcome measure suitable for our study,[14] we used an outcome measure that was developed by us for this study.[16–18] However, we used multiple-choice questions from a database of questions that independent research methodologists judged to have face validity, and end-users judged to be relevant and acceptable;[18] we validated the test in two Rasch analyses;[17,18] and a group of independent judges determined the cutoff scores for passing and mastery scores. The multiple-choice questions were designed to require critical thinking on the part of the test-takers and could not be answered by simply repeating content from the learning resources (appendix 1). We were careful to ensure that the examples used in the questions were different from those used in the learning resources, and that the children would be able to understand the language that was used without having used the resources. Neither the teachers nor the children were shown the test or similar multiple-choice questions before taking the test.

What the long-term effects of using the Informed Health Choices primary school resources are; whether they will have an effect on actual health choices and outcomes; whether they will have an effect on other measures of academic achievement; and how transferable the findings of this study are to other countries remain uncertain. We will measure the effects on standardised end-of-term examinations in a process evaluation. We will also measure outcomes again after 1 year. This will provide some indication of the degree to which the learning is sustained. Although we measured intended behaviours, it was not possible to measure actual health choices. We will explore the effects on actual choices when we measure outcomes after 1 year, but this will still be limited since most of the children will not be making many of their own health choices, and their choices will be self-reported.

We have piloted and user-tested an earlier version of the resources in Kenya and Rwanda, and we will pilot and user-test translated versions of the current version of the resources in those countries in 2017. User-testing and trials in other countries are needed. The cost of the intervention (approximately $4 per child) is substantial in light of government expenditure per primary school student ($29·4) and estimates of the direct costs of primary school education in Uganda.[9,29] We will explore ways of scaling up the use of the intervention in the process evaluation. Together with school authorities, we will try to find ways of covering the costs of scaling up use of the resources in Uganda.

In addition to the inherent educational value of the resources, there are three arguments for considering using these learning resources or similar approaches to teach these skills to primary school children.

First, low health literacy is consistently associated with poor use of health services and poor health outcomes.[2] Improving critical health literacy is likely to improve those outcomes, even though it is uncertain what if any effect use of these resources alone will have on health outcomes. Second, whether the effect on learning is sustained or not, it would be desirable to reinforce what was learned and to introduce additional key concepts, building on what was learned. Use of these resources should be viewed as a first step in a spiral curriculum (appendix 1). It is important to introduce these key concepts at a young age to lay a foundation for future learning and to reduce the development of misconceptions that become resistant to change later.[10] Third, teaching critical thinking is likely to have a positive effect on academic achievement, in addition to its direct effect on critical thinking skills.[11,12] Teaching critical thinking in connection with claims about treatments engages both children and teachers. As noted by a girl in an international school that piloted an earlier version of the learning resources: this is about "things we might actually use instead of things we might use when we are all grown up and by then we'll forget". An illustration of this was provided by a girl in another class at the same school: "When I was grocery shopping with mom, mom was like, 'Buy this toothpaste! It's new and it's really good!' I looked at another one and it was exactly the same, so I actually bought the cheaper one."

In summary, we believe we have shown reliably that it is possible to teach critical appraisal of treatment claims on a large scale in a low-income country. We have not compared our approach to another because, as far as we are aware, there is currently no other evaluated approach for doing this.[14,30] We believe that the Informed Health Choices primary school resources are an important first step towards enabling children to make informed health decisions as they grow older, as patients, future health professionals, citizens, and future policy makers.

Contributors

AN and DS were the principal investigators. They drafted the protocol with help from the other investigators, and were responsible for the day-to-day management of the trial. NKS and ADO had primary responsibility for overseeing the trial. All the investigators reviewed the manuscript, provided input, and agreed on this version. MO and SR had primary responsibility for developing the primary school resources. AM shared primary responsibility for developing the teachers' guide. All the investigators other than YD contributed to the development of the resources and to the protocol. AA-D had primary responsibility for developing and validating the outcome measure. AN and DS had primary responsibility for data collection. YD did the statistical analysis. The Norwegian Institute of Public Health, recipient of the grant from the Research Council of Norway, is the coordinating centre for the Informed Health Choices project. ADO, SR, AA-D, and IC were principal members of the coordinating group for the trial and, together with NKS 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

We declare no competing interests.

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