Informed Health Choices

Does the use of the Informed Health Choices teaching resources improve the secondary students' ability to critically think about health in Uganda? A cluster randomised trial protocol

Ssenyonga R et al.

IHC Working paper, April 2022

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Colophon

Title Does the use of the Informed Health Choices teaching resources improve the secondary students' ability to critically think about health in Uganda? A cluster randomised trial protocol

Authors Ssenyonga, Ronald
Oxman, Andrew D.
Nakyejwe, Esther
Mugagga, Solomon K.
Nsangi, Allen
Semakula, Daniel
Chesire, Faith
Mugisha, Michael
Lewin, Simon
Rosenbaum, Sarah
Oxman, Matt
Kaseje, Margaret
Sewankambo, Nelson K.

Corresponding author(s) Ssenyonga, Ronald
rssenyonga12@gmail.com
Makerere University College of Health Sciences
P. O. Box 7072, Kampala, Uganda

Keywords critical thinking, health literacy, education, secondary school, randomized trial, adolescents, Uganda

Citation Ssenyonga R, Oxman AD, Nakyejwe E, Mugagga SK, Nsangi A, Semakula D, Chelagat F, Mugisha M, Lewin S, Rosenbaum S, Oxman M, Kaseje M, Sewankambo NK. Does the use of the Informed Health Choices teaching resources improve the secondary students' ability to critically think about health in Uganda? A cluster randomised trial protocol. IHC Working Paper. 2022. http://doi.org/10.5281/zenodo.6560218

Date April 2022

Abstract

Background

To make well-informed choices, people must possess skills to assess the trustworthiness of health-related claims. It is important that young people learn to assess the reliability of claims to inform decisions, both when making their own choices and as citizens participating in a democracy. This trial aims to evaluate the effect of the Informed Health Choices (IHC) teaching resources on secondary school students' ability to assess health-related claims and make informed choices.

Methods

This will be a two-arm cluster-randomised trial. We will randomise 80 lower secondary schools to evaluate the IHC secondary school digital teaching resources. The resources for teachers include 10 lessons to be delivered in a single school term, using lesson plans developed for classrooms equipped with only a blackboard or with a projector. Teachers in the intervention arm will be invited to a three-day teacher training workshop. Teachers in the control schools will continue teaching the national curriculum. Uganda's National Curriculum Development Centre introduced a new competence-based curriculum in 2020. This curriculum has critical thinking as one of seven generic skills to be taught across all subjects. The curriculum does not explicitly include critical thinking about health. The IHC lessons address nine prioritised key concepts. We will use multiple choice questions – two for each key concept - to evaluate the student's ability to assess claims and make informed choices. We will measure the proportion of students with a passing score at the end of the school term, and again after one year to assess retention of what was learned.

Expected results

Based on previous work done in Ugandan primary schools, we anticipate that the use of the teaching resources will lead to a large improvement in the lower secondary school students' ability to assess claims and make informed health choices.

Background

Increased access to health information through the Internet and other sources creates opportunities for people to use evidence when making choices, but also poses a challenge to verify the reliability of information they access. People need to be able to appraise and use information about the effects of health actions (interventions that might affect our health). Health professionals and researchers, charlatans, governments and international organisations, journalists and advertisers, family, friends, and teachers all make claims about the effects of health actions. These include claims about the effects of drugs, surgery, and other types of "modern medicine"; lifestyle changes, such as changes to what you eat or how you exercise; herbal remedies and other types of "traditional" or "alternative medicine"; public health and environmental interventions; and changes in how healthcare is delivered, financed, and governed. Many claims are unreliable, and people's beliefs in unreliable claims can lead to unnecessary suffering and wasted resources [1-5]. Conversely, failure to believe and act on reliable claims also leads to unnecessary suffering and inefficient use of resources [6-8]. Health professionals and public health campaigns typically tell people what they should do without empowering them to assess the basis for those recommendations. But mistrust of researchers, research, and health professionals is common [9-11]. Moreover, experts frequently disagree, and the opinions of experts are frequently not based on reliable evidence [12, 13]. Consideration of who makes a claim is not a reliable basis for assessing the trustworthiness of the claim.

The effect of education on health and decision-making patterns appears to be related to critical thinking [14]. Critical thinking about health actions (and other types of actions) depends on understanding and applying principles (key concepts) to assess claims about health actions and using that knowledge to make informed choices [15 16] . However, science education in schools often tends towards rote learning rather than critical thinking. Although teaching critical thinking is widely advocated generally, and specifically for health, intentions and practice are still far apart [17-19]. Consequently, people are frequently unable to assess the trustworthiness of treatment claims and make informed health choices [18-21].

A randomised trial in Uganda, conducted in 120 primary schools with over 10,000 children, showed large improvements in the ability of school children, and teachers to assess claims about health actions [20]. Follow-up data showed that the learning was retained for at least one year [21]. In the primary school trial, resources were designed to teach 12 key concepts to children [22]. The primary outcome measure was an evaluation tool using multiple-choice questions to measure the children's ability to apply the concepts [23-26].

In the primary school project process evaluation [27] and a context analysis conducted for this project [28], teachers and policymakers in Uganda expressed a need for resources to improve learners' ability to think critically about health actions. However, the cost of the printed primary school resources, was a major barrier to scaling up their use. Although this cost was only $4 (USD) per student, this was 14% of the annual government educational expenditure of $29.4 per student [20]. Using digital rather than printed learning-resources could substantially reduce the cost of distributing teaching resources, provided they can be accessed in schools with widely varying Information and Communication Technology (ICT) resources. In this trial, we will evaluate the effect of using digital IHC teaching resources on the ability of lower secondary school students to assess the reliability of claims about the effects of health actions and to make informed health choices. The teaching resources have been developed in Kenya and Rwanda, as well as in Uganda. Parallel trials using the resources will be conducted in the three countries and a prospective meta-analysis is planned to synthesize the findings of the three trials.

Rationale

Democracy and well-informed policy decisions depend on a scientifically literate population. In addition, personal choices about one's health affect public health and resource use. Some young people in lower secondary schools will become health professionals, researchers, and policymakers. It is therefore crucial that they learn basic skills they will need to make informed choices. Use of well-designed teaching-resources can help to ensure individuals, citizens, and future health professionals and policymakers are scientifically literate and enabled to make well-informed choices.

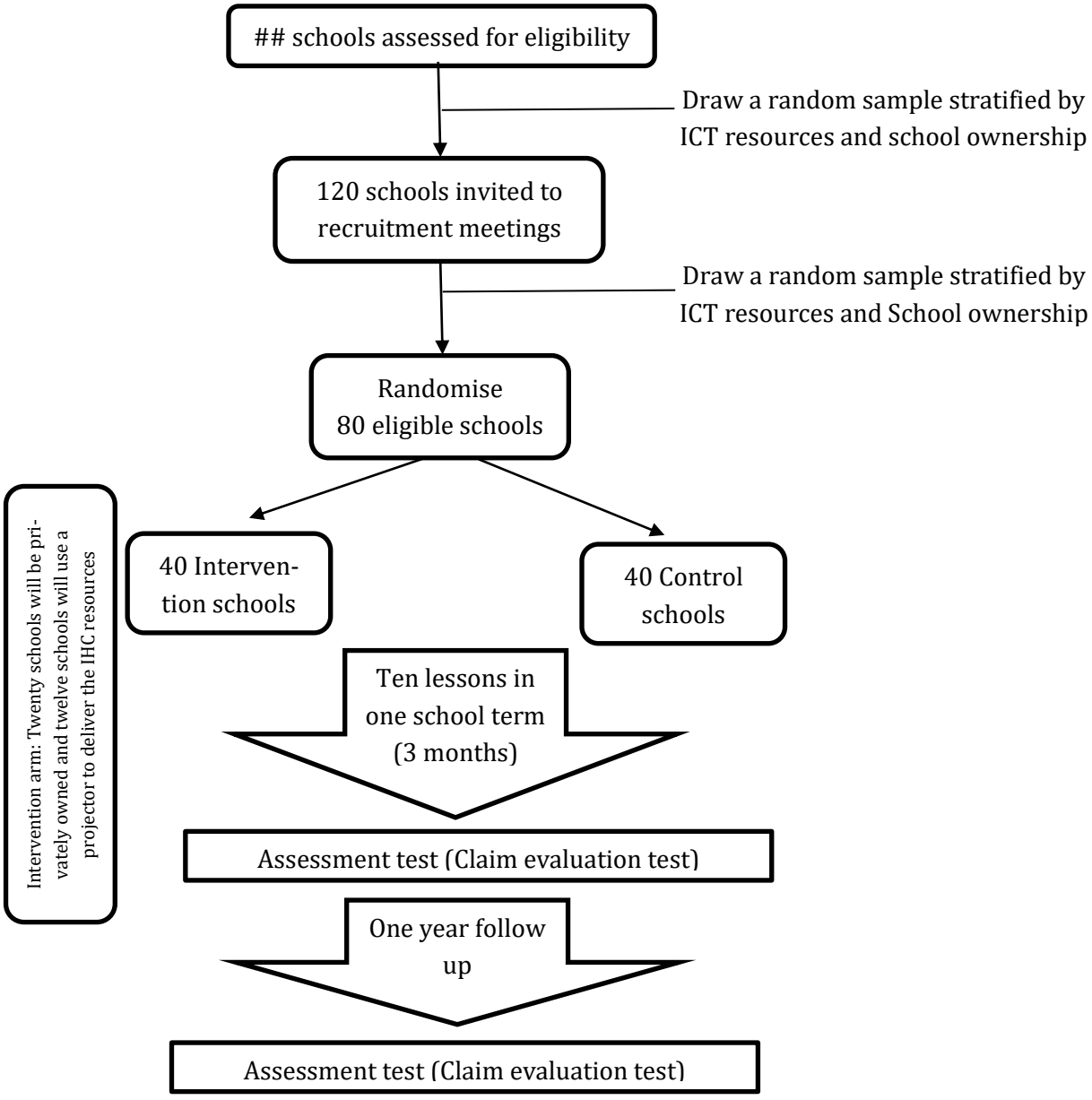
We aim to equip lower secondary school students with skills to recognise and question claims about the effects of health actions and to make informed health choices. We are targeting secondary school students because they have time to learn, and learning to think critically early in life lays a foundation for future learning.

Method

Design

This is a two-arm cluster-randomised trial (Figure 1). Schools randomised to the intervention arm will use the IHC secondary school resources. Schools in both the control and intervention arms will conduct the standard curriculum. For schools that have more than one stream for the form two class, we will randomly select one stream to include in the trial.

Figure 1: Study flow chat



Objectives

The primary objective of this study is to measure the effect of using the IHC teaching resources on lower secondary students' ability to assess claims about the effects of health actions and make informed health choices.

Secondary objectives are to measure the effects of using the teaching resources on the students':

- mastery of the 9 IHC key concepts addressed in the resources
- ability to apply each of the 9 concepts
- intended behaviours and self-efficacy
- self-reported behaviours
- overall academic achievement in O-level compulsory subjects: biology, chemistry, physics, mathematics, English, history & political education, and geography.
- retention of what they learned one year after the intervention

In addition, we will measure effects on the teachers' ability to assess claims about the effects of health actions and make informed health choices and their mastery of the 9 concepts (Additional file 1).

Trial site and population

We will conduct the trial in six districts (Luwero, Wakiso, Mpigi, Mukono, and Kampala, and Kayunga) half of which will be in rural and the other half in urban areas of these districts. These districts contain schools that have similar characteristics to those found across Uganda. The trial participants will be students in form 2 of lower secondary schools of Uganda and their teachers. The typical age of year 2 students in lower secondary school is 13-17. The IHC lessons will be taught as separate lessons added to the standard Biology lessons.

We will include secondary schools that have a lower (ordinary) level section that teaches the national curriculum. Only schools for which the head teacher and teachers selected by the head teacher provide written consent to participate. Teachers must have a computer or smart phone with an Internet connection to be included in the trial. We will exclude special needs schools for students with auditory and visual impairments, schools that participated in user-testing or piloting of the IHC learning resources, and adult only education schools (schools where individuals usually over the age of 18 years go for secondary education).

Recruitment and retention of schools

Working with district education officers, we will access lists of all registered secondary schools in their respective districts as of April 2022. A sampling

frame shall be generated after applying the exclusion criteria described above. We will randomly select a total of 120 schools from the six districts using the Random Number Generator App (https://www.random.org/). We will select schools within four strata (type of school ownership: public vs government; and ICT resources: projector used in learning vs no projector). We shall then visit the schools to engage the headteachers and deliver their invitation letters for the recruitment meeting. To increase attendance for recruitment meetings, we will send text message reminders and make phone calls. At the recruitment meetings, we will present the trial objectives, obtain consent, and review time commitments expected from the schools.

During the trial, we will make phone calls and monthly visits to study schools (both in the intervention and control arms). During these interactions, we will ask teachers questions about activities in the school. This information will be used in a process evaluation. These questions and interactions are not intended to influence delivery and compliance with the allocated interventions. The telephone engagements with teachers in the trial are intended to improve retention in both the control and intervention group. We will ask about coverage of the national biology curriculum over the school term in both study arms; the number of biology, math, and chemistry lessons; the teaching strategies used in delivering biology lessons; and challenges faced in implementing the new curriculum.

The interventions

We present a description of the intervention using the GREET checklist in Additional file 2. Schools in both the control and intervention groups will continue teaching the national standard curriculum, which does not include teaching critical thinking about health. No additional materials will be provided to the control schools.

Random allocation

A statistician who is not a member of the research team will randomise schools to either the intervention or control arm using a computer-generated block randomisation sequence via the Sealed Envelope, an Internet-based, password-protected platform [29]. We will conceal the allocation by assigning codes to the schools.

The schools will be stratified by two variables: type of school ownership (public or private) and the availability of ICT resources (at least one projector available for teaching or access to the Internet by teachers with no other ICT teaching resources). Half of the schools in the trial will be public/government owned and

the others will be privately owned. Based on findings from the context analysis [31], 30% of the schools have projectors. .

Outcome assessment

The primary outcome measure is the proportion of students with a passing score on the Critical Thinking about Health Test (Additional file 3), which we will use to measure the students' ability to apply the nine key concepts addressed by the intervention. The test includes two questions for each of the concepts. The criterion for passing, which was determined by an independent group of judges (Additional file 4) is at least nine correct answers out of the 18 questions

Secondary outcome measures are the:

- mean score (percentage of correct answers) on the Critical Thinking about Health Test
- proportion of students with a score indicating mastery of the concepts (at least 14 correct answers out of 18 questions (Additional file 4)
- proportion of students who answer both questions correctly for each of the nine concepts
- students' intended behaviours and self-efficacy measured using questions included in the Critical Thinking about Health Test
- self-reported behaviours
- overall academic performance in O-level compulsory subjects: biology, chemistry, physics, mathematics, English, history & political education, and geography
- proportion of teachers with a passing score, their mean score, and the proportion with a score indicating mastery of the concepts using the Critical Thinking about Health Test

All the outcomes other than self-reported behaviours will be measured at the end of the school term during which the intervention is delivered and again after one year to assess retention of what was learned. Self-reported behaviours will only be measured after one year. These will be measured using a questionnaire that is designed based on findings of a process evaluation, which will explore use of what was learned in the students' daily lives.

The Critical Thinking about Health Test includes 18 multiple-choice questions (MCQs) from the Critical Thinking about Health Test item bank, two for each of the Key Concepts included as learning goals in the IHC secondary school resources. We developed the item bank after searching for other appropriate outcome measures to evaluate the IHC primary school resources [23]. The item bank has been developed based on extensive qualitative and quantitative

feedback from methodological experts, health professionals, teachers, and members of the public [24]. It includes 3-4 MCQs for each of the 49 IHC Key Concepts. To develop the Critical Thinking about Health Test, we started with the MCQs for the nine concepts. To ensure applicability and acceptability of the test, we conducted cognitive interviews with students, adults, and people with methodological expertise in Kenya, Rwanda, and Uganda. Based on the interviews, we made minor revisions to some of the questions and selected three MCQs for each concept. We then validated the Critical Thinking about Health Test using Rasch analysis. For the Rasch analysis, we administered a test that included the 27 MCQs to at least 250 secondary school students and 250 adults in each of the three countries (Kenya, Rwanda, and Uganda). The adults included health professionals, teachers, and other members of the public. Based on the Rasch analysis we selected the two MCQs for each Key Concept (Additional file 5).

Far transfer and adverse effects

If students are unable to transfer skills that they learn to other contexts, the value of education is limited. The more different the transfer context is from the learning context, the "further" the transfer. However, far transfer often is not measured and there is uncertainty about how to evaluate far transfer.

Similarly, adverse effects of educational often are not measured. Educational interventions can have unintended harms and benefits as well as the intended beneficial effects. In separate studies, we are identifying potential "far transfer" effects and potential harms and benefits, and we are developing measures to evaluate those effects (Additional file 6).

Blinding

The researchers, students, and trial statistician will not be blinded when conducting the analysis. All the participants in the trial will be informed of the purpose of the study. The head teachers and the district education officers will be informed of the purpose of the study when they are recruited. The teachers in both arms of the trial will be informed of the purpose of the study prior to the delivery of the intervention. Students in both arms of the trial will be informed of the purpose of the Critical Thinking about Health Test when they are asked to complete it. They and their teachers will be informed that they will be told their scores at the end of the trial.

We will monitor the risk of contamination by adding questions to the Critical Thinking about Health Test for teachers in the intervention schools, asking whether teachers in the intervention schools shared the IHC resources or taught in schools other than those randomised to the intervention. We will add similar

questions to the test taken by teachers in the control schools, asking whether they accessed and used the resources.

Safety monitoring for potential harms and adverse events

We will monitor, record, and report any perceived adverse events reported by teachers and students. Adverse events are an increase in undesirable outcomes or decrease in desirable outcomes attributed to an intervention [30]. Teachers will be instructed to report possible adverse effects to the investigators or, if relevant, to the Makerere University School of Medicine Research and Ethics Committee and Uganda National Council of Science and Technology (Additional file 7). Following a review of the reported adverse events and findings of a process evaluation, we will measure potential adverse effects after one year. These will be measured quantitatively using a questionnaire. No serious adverse events were reported in the trial or process evaluation of the IHC primary school resources [20, 22, 27] or piloting the secondary school resources, and they are unlikely to occur during the trial. Teachers, will receive electronic forms for safety monitoring and adverse events (Additional file 7) via email and the completed forms will be collected electronically using surveyCTO [31].

Data collection and management

Research assistants will administer the Critical Thinking about Health Test using paper copies (Additional file 3) and scan standardised answer sheets using ZipGrade software [32]. We will download the assessment scores from ZipGrade and import the data into R software to check for completeness and consistency and produce a final dataset for analysis. To reduce the number of unclear or missing values, the research assistants will check all paper questionnaires at the schools and correct these immediately before scanning them.

We will collect demographic data using electronic questionnaires. This will include school characteristics, including: location (rural, urban), ownership (public, private), and ICT (at least one projector, no projector); teachers' education (certificate or diploma, university degree) and years of experience. We will also collect students' scores on all subjects (English, mathematics, history & political education, geography, physics, biology and chemistry) studied in the school term before the trial (for a planned subgroup analysis in the prospective meta-analysis), at the end of the trial, and one year after the trial.

Electronic questionnaires will be pre-programed with skip logics, plausible ranges and required fields. Data will be stored securely on SharePoint and backed up on a weekly basis. Hard copies will be filed under lock and key. The

final dataset will be shared with the IHC team members at the Norwegian Institute of Public Health in Oslo.

Sample size

We have used the University of Aberdeen Health Services Research Unit's Cluster Sample Size Calculator to calculate the sample size [33], applying the following assumptions: 75 students per cluster; a 20% difference in proportions between intervention and control; an alpha of 1%; and a power of 90%; and using an intraclass correlation coefficient (ICC) of 0·19 based on the ICC from a similar intervention in a randomised trial in primary schools [20]. We estimated that we would need 40 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 Critical Thinking about Health Test), we estimated that we needed a minimum of 40 schools in each group.

Statistical Analysis

We will use 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. We will conduct an intention to treat analysis with all results analysed as randomised. Missing values will be counted as wrong answers. The statistical analysis will be conducted using R studio software (run on R version 3.5.2). For the secondary outcomes we will calculate odds ratios for the proportion of students with a score indicating mastery of the concepts and the proportion of students who answered both questions for each concept correctly. We will convert odds ratios from logistic regression analyses to adjusted differences [34]. The mean scores, passing scores and mastery scores for the teachers will be analysed without a random effects term.

Ethical considerations

Ethics approval for this study has been obtained from the School of Medicine research ethics committee at the Makerere University College of Health Sciences and from the Uganda National Council for Science and Technology. We will obtain informed consent from head teachers on behalf of the school and students (Additional file 8) and teachers (Additional file 9). Students will be orally informed about the trial, and we will ask the head teachers to facilitate a parent-teacher meeting at which the study team can explain the trial. The head teachers also will be given printed information about the trial to distribute to the parents.

We will not obtain consent from individual students or their parents. The intervention poses minimal risk and no more risk than other teaching materials, almost none of which have been rigorously evaluated [35]. Refusal of informed consent by individual students or their parents, in effect, would be meaningless once the decision to participate has been 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 [36]. Individual students and their parents will have the same right to refuse participation as they do for other lessons or tests in secondary schools.

Trial management

The in-country lead investigator (RS) will act as the overall project coordinator assisted by AN and DS. The steering group for the trial in Uganda will include RS, NKS, LN, MK, SR, AO, MM and FC. RS will be directly responsible for the day-to-day management of trial activities. He will obtain letters of approval and permission as applicable. The letters will be sought from the appropriate line ministries to introduce the study team to the district education offices and lower secondary schools. We will use the list of all lower secondary schools in the study districts and review them with the education officers to generate a complete sampling frame from which we will select eligible schools to recruit.

RS will work with the in-country team to coordinate staff recruitment, training of teachers and research assistants, and ensure proper trial documentation.

All investigators and research assistants will be required to participate in Human Subject Protection training and certificates will be kept on file. A delegation of responsibilities log will be kept and updated as needed to ensure smooth governance of the trial.

Reporting and dissemination of results

The findings will be written up and published in a peer reviewed journal. We will share the results of the trial with all the participating schools and education officers, the networks of teachers and students who have been engaged in the project [37], and our national and international advisory groups. If the teaching resources are found to be effective, we will make the intervention available to the control schools We also will share a summary of the findings with key institutions, including the Uganda National Curriculum Development Centre; the relevant Ugandan Government departments (Ministry of Health; Ministry of Education and Sports; Ministry of Gender, Labour and Social Development), the Ugandan schools association, UNICEF-Uganda, WHO-Afro, and any other institution or agency that expresses interest in this study.

Discussion

Use of the IHC secondary school resources may have positive effects on the ability of secondary school learners in Uganda to assess claims about effects of health interventions, similar to what was found in the primary school trial conducted in Uganda [20].

A strength of this study is including a representative sample of schools and biology teachers in those schools who teach students in the first and second year of lower secondary school. This is a pragmatic trial designed to measure the effects of introducing the IHC secondary school resources into the national curriculum under circumstances as similar as possible to the way in which new material is introduced into the curriculum. For example, the teacher workshops will be led by fellow teachers, and we have designed the resources to fit into the national curriculum [28]. Teachers selected by their head teachers in a random sample of schools will deliver the intervention. The training of teachers, which is modelled after typical teacher training workshops that use a cascading approach, and the workshop materials as well as a teachers' guide are included in the resources (Additional file 10). This should enable scaling up and sustainability of the intervention in Ugandan schools if use of the IHC teaching resources is found to be effective.

The resources might have a positive effect on other measures of academic achievement and how learners apply the learning to their daily lives. We will measure outcomes using standard end-of-term tests.

A limitation of this study is that the test used as the outcome measure is aligned with the intervention ("treatment-inherent"). The test measures the ability to apply the concepts that the IHC learning resources are designed to teach. Treatment-inherent outcome measures are associated with larger effect sizes than independent measures [38]. However, the multiple-choice questions are 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. We have ensured that the examples in the questions are different from those used in the learning resources. We have also ensured that students in both the control and intervention schools are able to understand the language used in the test, which differs from language used in the resources (e.g., using "treatment" instead of

"health action" and "research study" instead of "comparison between health actions", and defining key terms in the test instructions (Additional file 3).

Neither the teachers nor the students will be shown the test or similar multiple-choice questions before taking the test. The outcome measure, which was developed by our group for this study (Additional file 5) includes 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 [24], and we have validated the test using Rasch analyses (Additional file 5). A group of independent judges determined the cut-off scores for passing and mastery scores (Additional file 4).

A second limitation is that Uganda's lower secondary schools have varied characteristics (access to resources like teachers, reading material, school computer laboratories) [28] . Therefore, it would have been desirable to sample schools from each of the fifteen sub-regions of the country to obtain a national representative sample of schools. However, financial and practical considerations prohibit this.

We will measure intended behaviours and, after one-year, self-reported behaviours. However, a third limitation is that we will not be able to measure actual health choices. We will explore this in a process evaluation, but this will still be limited because most of the students will not be making many of their own health choices.

Conclusion

We have reported all the items in the SPIRIT checklist in this protocol (Additional file 11), and this study is large enough and rigorous enough to reliably detect what we consider to be a meaningful effect of the digital IHC secondary school resources on young people's ability to appraise claims about health actions. The smallest important effect that the trial is designed to detect is based on the assumptions that at least half (50%) of the students in the intervention schools must achieve a passing score on the Critical Thinking about Health Test (compared to an anticipated 30% of students in the control schools). Use of the resources can potentially enable students to make informed health decisions as they grow older. The schedule of trial events is presented in Additional file 12.

Declarations

Stakeholder engagement

We have sought and will continue to seek input from stakeholders throughout this project [37]. The stakeholders include the national advisory panel (national curriculum committee or education board and education authorities) and teacher and student networks established to provide input and feedback. The results and interpretation of this study will be shared with these networks and advisory groups before publication.

Funding

This research is funded by the Research Council of Norway (https://www.forskningsradet.no/en/), project number 284683, grant no:69006 awarded to ADO. The funders have no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing interests

The authors declare that they have no financial or any other competing interests.

Availability of data

The final de-identified dataset and analysis code for the trial will be made available on Zenodo.org.

Protocol registration

This protocol has been registered in the Pan African Clinical Trial Registry: Trial number PACTR202204861458660. Registered on 14th April 2022.

Protocol amendments

Any protocol modification will be communicated to relevant parties, including the Ethics Review Committee and Trial Registry.

Contributions to the protocol

RS prepared the first draft of this protocol. All the authors provided feedback and approved the final version. RS is the guarantor.

Acknowledgements

We would like to thank the other members of our research team for their contributions to this project. We also are grateful to the teachers, students, curriculum specialists, and members of our national and international advisory groups who have contributed to this project, and particularly to Robert Boruch, Shaun Treweek, and Merrick Zwarenstein for reviewing a draft of this protocol.

Additional files

1. Prioritised IHC concepts
2. Description of the intervention using the GREET checklist
3. Critical Thinking about Health Test
4. Determination of cut-offs for passing and mastery scores
5. Development and evaluation of the Critical Thinking about Health Test
6. Evaluating “far transfer” of learning, and evaluating and monitoring potential harms
7. Safety monitoring and adverse events form
8. Informed consent form for head teachers
9. Informed consent form for teachers
10. Teacher training workshop
11. SPIRIT checklist
12. Schedule of trial events

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