

**Effect of the Informed Health Choices
digital secondary school resources on the
ability of lower secondary students in
Kenya to critically appraise health claims:
protocol for a process evaluation**

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Colophon

Title	Effect of the Informed Health Choices digital secondary school resources on the ability of lower secondary students in Kenya to critically appraise health claims: protocol for a process evaluation (Version 5)
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Abstract

Background: People frequently make decisions about what can improve their health. They do this based on large amounts of information that they get from different sources, which include claims about what harms or improves health. People therefore need skills to assess the trustworthiness of health claims. The Informed Health Choices (IHC) Key Concepts framework was used to develop the 'Be Smart about your Health' secondary school resources to help students in lower secondary to assess health claims about the effects of treatments. We are evaluating these resources in a cluster randomized trial in 80 lower secondary schools in Kenya. This protocol is for a process evaluation that will be conducted alongside the trial. The objective of this evaluation is to explore the extent to which the intervention was delivered as planned; understand factors that facilitated or hindered the delivery and impact of the resources; and anticipated and unanticipated effects.

Study design: We will employ a mixed-methods design using quantitative and qualitative data. We will collect quantitative data from all schools (n=40) allocated to the intervention arm using lesson evaluation forms. Our qualitative data collection will include: (a) structured classroom observations in all schools (n=40), with at least one lesson observed in each school. In a sample of eight schools, we shall observe more than one lesson. (b) We will conduct focus group discussions (with students (n=4), teachers (n=1) and parents (n=4)). (c) Key informant interviews with policymakers in education (n=5), teachers (n=8), and with school principals (n=8)). We will purposively select these schools based on location (urban and rural) and ownership (private and public).

Data analysis: We will use framework analysis to analyze qualitative data and descriptive analysis to analyze quantitative data. We will summarize and appraise the confidence of the key findings from the qualitative data using a modified version of the GRADE-CERQual approach.

Background

Each day people make decisions about what can improve their health. Most of these decisions are informed by the very large amounts of information on what improves or harms health (sometimes called health claims) that people receive from different sources. Health information sources include websites; traditional information sources such as magazines, radio, and television; and social media such as Facebook. The basis for most of this information is unsubstantiated, unreliable, or untrustworthy [1].

Many adults and young people lack skills to assess the health claims that they encounter [2-5] Acting on unreliable health claims or choosing not to act on reliable ones may lead to unnecessary suffering or waste of resources. This is especially a problem in low-income countries, where people have few resources to waste on unreliable health claims. People need to have competencies to evaluate health information and make informed choices[6]. Educational interventions to improve people's ability to assess claims about treatments have been shown to be effective, at least in the short term [7]. For example, a primary school intervention was evaluated in a cluster randomized trial in Uganda and was found to be effective for improving the ability of 10-14 year-old children to assess health claims [8].

Teaching young people critical thinking skills early in life can lay a foundation for future learning. Such teaching may help to foster desirable dispositions (habits of the mind), such as questioning the basis for treatment claims, and help to prevent uncritical beliefs, which may be difficult to change as adolescents grow into adulthood[9]. Critical thinking is widely advocated globally [10, 11]. Kenya, among other countries, has recently adopted a competency-based curriculum that includes critical thinking as a core competency. However, critical thinking about health is not explicitly included in the curriculum or taught in Kenya [12] or many other countries [13-15]

To address this gap, the Informed Health Choices (IHC) network has developed and evaluated resources to enable adults and children in primary school to assess health claims and make informed health care choices. The resources are based on the IHC framework of Key Concepts that people should understand and apply when deciding whether to believe a claim about the effects of health actions (things that people do to care for their health or the health of others) and what decisions to make about their health [16, 17]. A process evaluation conducted alongside the randomized trial of the IHC primary school intervention in Uganda found that the resources were useful, but a lack of time in the timetable and the cost of printing the resources were barriers to scaling up use of the resources [18].

Building on the findings of the evaluation of the primary school intervention in Uganda and context analyses in Kenya, Rwanda, and Uganda, we have developed and pilot tested the 'Be Smart about your Health' digital secondary school resources that can be scaled up using the basic ICT technology available for teaching and learning in those countries. The resources were developed iteratively between 2020 and 2022, using human-centered design [19] together with teachers, students, and curriculum developers.

We will evaluate the effect of the resources on students' ability to assess health claims in a cluster randomized trial in Kenya [20], as well as in Rwanda and Uganda [21, 22]. This is a process evaluation study alongside the trial to explore aspects of the implementation process [23] and to identify factors affecting the implementation, impact, and potential scale up of using the 'Be Smart about your Health' secondary school resources. This protocol describes the objectives and methods for the process evaluation in Kenya.

Objectives

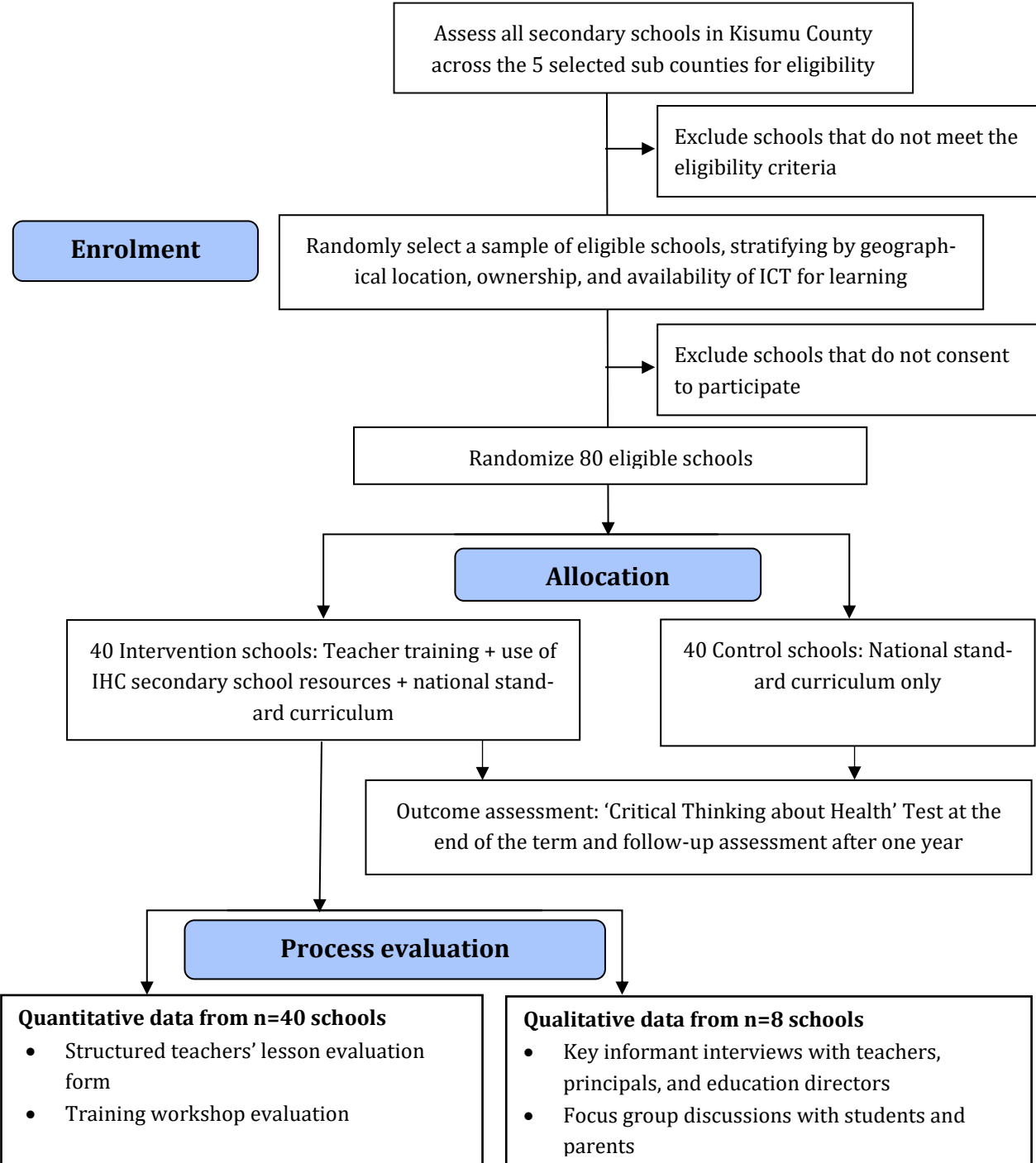
The objectives of this process evaluation are to:

1. Explore the extent to which the Be Smart about your Health secondary school resources was implemented as planned
2. Explore the factors that facilitated or hindered the delivery and impact of the Be Smart about your Health secondary school resources
3. Explore intended and unintended effects of the Be Smart about your Health secondary school resources

Methods

We will conduct the process evaluation alongside a two-arm, pragmatic cluster-randomized trial as illustrated in the flow diagram (Figure 1). The process evaluation will employ a mixed methods design utilizing a combination of quantitative and qualitative data.

Figure 1. Flow chart diagram



Study setting and location

This study will be conducted in the lower secondary schools randomized to the intervention arm of the trial. These schools will be randomly selected from the five sub-counties (equivalent to districts) (Kisumu East, Kisumu West, Kisumu Central, Nyakach, and Seme) in Kisumu County, western Kenya. Schools from these sub-counties are representative of public and private secondary schools found across Kenya. The schools follow the national secondary school curriculum.

Secondary school education in Kenya lasts four years. An annual academic calendar is for three school terms, where a single term is approximately 10-13 weeks. Teachers at secondary school level qualify after undergoing training by an accredited university or training institute. Nearly 95% of secondary school teachers hold a bachelor's degree and about 5% have a post-graduate qualification.

Students are intended to enroll in secondary school when they are about 13-14 years old and graduate when they are about 17-18 years. Students in lower secondary schools are expected to choose 12 out of 30 subjects. Health is taught in three subjects (home science, business studies, and physical education) but not specifically critical thinking about health. "Critical thinking and problem solving" is one of seven core competencies that cut across all subjects in the current curriculum. However, little time is devoted to teaching this competency and it is not assessed in examinations. The Kenyan government plans to gradually replace the curriculum with a new, competency-based curriculum by 2024.

The intervention

We have described the intervention using the GREET checklist for describing educational interventions (Additional file 1).

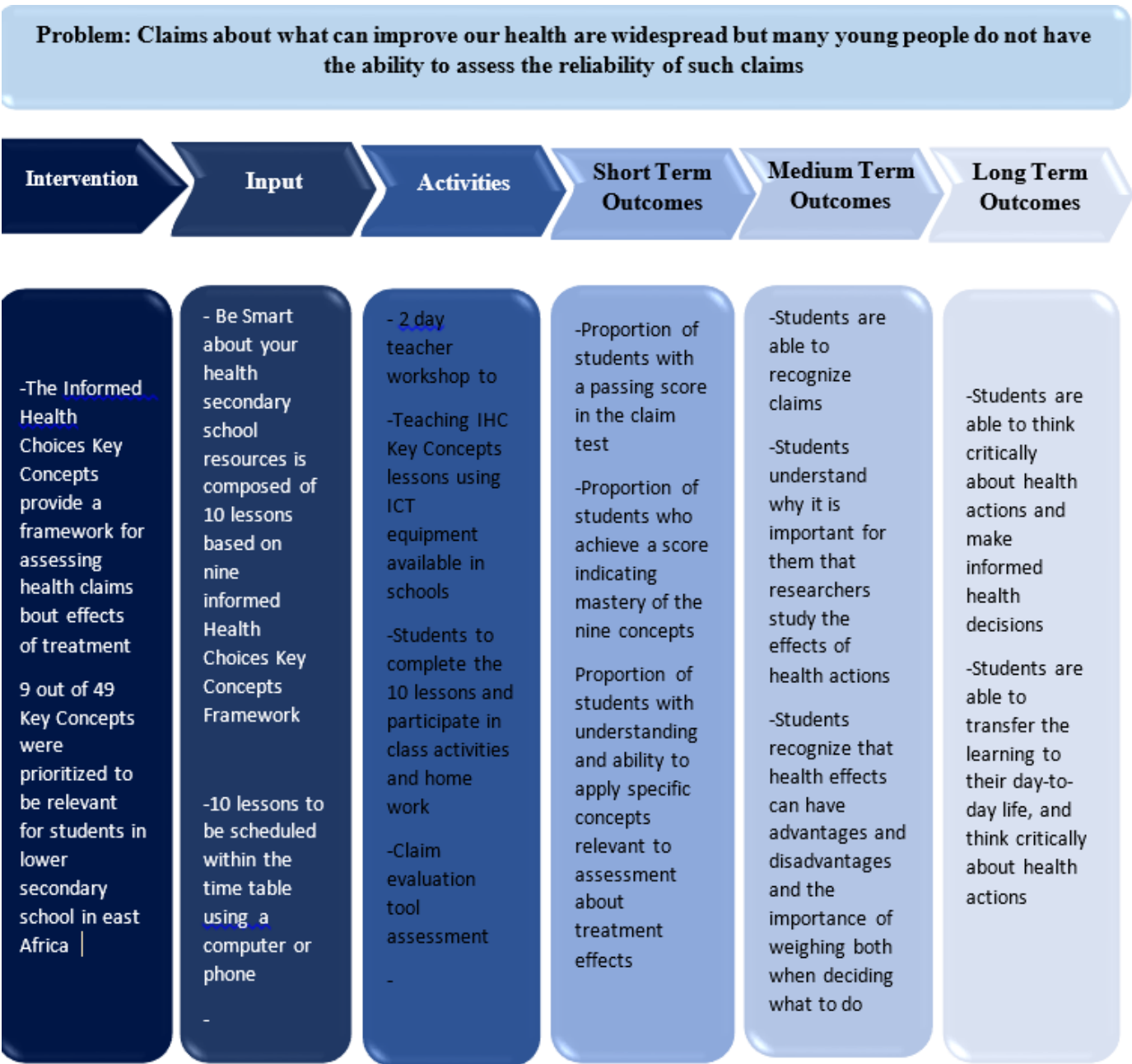
Schools assigned to the intervention arm will be asked to use the 'Be Smart about your Health' secondary school resources. The resources are based on nine prioritised Key Concepts that people need to understand and apply to critically assess health claims [24]. Teachers will be asked to complete the IHC lessons described in Table 1 in a single term (10-13 weeks). Each lesson is intended to take a single period (40 minutes) per week, but teachers are free to create time outside the timetable to complete the lessons. We will provide the teachers with a two-day training workshop one week before the trial to orientate them on the IHC intervention. Teachers in the intervention schools will download the resources using a computer or phone and use them to teach in a classroom setting. Both intervention and control schools will continue using the standard lower secondary school curriculum. Figure 2 shows a logic model for the intervention. Students and teachers in the participating schools will take the 'Critical Thinking about Health' Test (Additional file 2) at the end of the term when the resources are delivered.

We will offer the control arm schools a workshop and access to the secondary school resources after the one-year follow-up assessment.

Table 1. Lessons with learning goals

Lesson	Goals By the end of the lesson, students should be able to:
1. Health actions	<ul style="list-style-type: none"> • Identify health actions • Explain why it is important to think critically about health actions (why these lessons are important)
2. Health claims	<ul style="list-style-type: none"> • Identify claims about the effects of health actions
3. Unreliable claims	<ul style="list-style-type: none"> • Identify claims about the effects of health actions that are only based on personal experiences, how commonly-used something is, or how new or expensive something is • Explain why most such claims are unreliable
4. Reliable claims	<ul style="list-style-type: none"> • Explain why knowledge about the effects of health actions depends on comparisons • Explain why we need researchers to make the comparisons
5. Using what we learned (1)	<ul style="list-style-type: none"> • Remember what they learned in Lessons 1 to 4 • Use what they learned in these lessons in their daily lives • Recognise limits to what they have learned
6. Randomly-created groups	<ul style="list-style-type: none"> • Explain why groups of people in comparison should be similar at the start
7. Large-enough groups	<ul style="list-style-type: none"> • Explain what it means for comparisons between health actions to be large enough
8. Personal choices	<ul style="list-style-type: none"> • Identify advantages and disadvantages of health actions, for individuals
9. Community choices	<ul style="list-style-type: none"> • Identify advantages and disadvantages of health actions, for communities
10. Using what we learned (2)	<ul style="list-style-type: none"> • Remember what they learned in Lessons 1 to 9 • Use what they learned in these lessons in their daily lives • Recognise limits to what they have learned

Figure 2. Logic model of the “Be smart about your health secondary school resources”, an intervention for teaching lower secondary school students to think critically about health



Target population

This process evaluation will target all schools randomized to the intervention arm of the study. In these schools we will include form one students, teachers, school principals, county education officers, curriculum developers, and parents of selected students that participated in the intervention arm of the trial.

Sampling

For quantitative component of the evaluation, we will include data from all schools (n=40) assigned to the intervention arm. For the qualitative component of the evaluation, we will purposively select 8 schools (20%) that participated in the intervention arm. We will purposively select schools to include varied characteristics (ownership (public/private), geographic location (rural/urban), and the extent to which the IHC lessons were delivered as intended) to get a wide range of views from varied participants. In each school, we will include the school principal, the teacher that taught IHC lessons, 8-10 students and their parents. The students will be sampled based on performance in their end of term examination during the delivery of the learning resources. Finally, we will include five policy makers (curriculum developers and sub-county education directors) from the settings in which the trial is implemented.

Recruitment strategy

We will contact the school principals and teachers at the sampled schools to inform them of the objectives of this process evaluation and ask them to participate in this study. Together with the teachers, we will select the students that will participate, based on their performance in the Critical Thinking about Health Test. We will ask the principals to contact (by phone or letter) the parents of the sampled students and invite them to participate in the interviews. Finally, we will ask the county ministry education and the Kenya Institute of Curriculum Development to permit the officers that were involved in the IHC trial to participate in this study.

Data collection

We will collect data using the following tools: a teacher-training-workshop evaluation form to be completed by the teachers (Additional file 3), a lesson evaluation form to be completed by teachers after each lesson (Additional file 4), an observation guide (Additional file 5), interview guides for key informant interviews (Additional files 6-8) and focus group discussions (Additional files 9-11). We have adapted these data collection tools from the previous IHC primary school process evaluation. The revised tools will be piloted and then adjusted based on the feedback from the pilot. The questions in the tools are linked to the study objectives as shown in Table 2 and described in more detail below.

Table 2. Overview of data collection

Domain	Data collection method	Participants	Timing
Objective 1: To explore the extent to which the Be Smart about your Health secondary school intervention was implemented as planned.			
Fidelity: dose, coverage, delivery	Teachers' lesson evaluation form (Additional file 4)	All schools in the intervention arm (n=40)	During and post intervention
Fidelity: dose, coverage, delivery	Semi-structured Interviews with teachers (Additional file 6)	Teachers from n=10 schools from intervention arm	Post intervention
Fidelity: delivery (variation)	Structured lesson observation (Additional file 4)	Teachers from n=10 schools from intervention arm	During intervention
Objective 2: To explore factors that facilitated or hindered the delivery and impact of the Be Smart about your Health secondary school intervention			
Policy factors (scale up)	Semi-structured interviews (Additional file 8)	County education officials (n=5) Curriculum developers at the Institute of Curriculum Development (n=2)	During and post intervention
Contextual factors	Semi-structured interviews (Additional file 6)	Teachers (n=8)	Post intervention
Contextual factors	Semi-structured inter-views (Additional file 7)	School principals (n=8)	Post intervention
Objective 3: To explore intended and unintended effects of the Be Smart about your Health secondary school intervention			
Intended and unintended effects	Semi structured interview (Additional file 6)	Teachers (n=8)	Post-intervention
Intended and unintended effects	Focus group discussion (Additional files 10 and 11)	Students (n=4) Parents (n=4)	Post-intervention
Intended and unintended effects	Focus group discussion (Additional file 10) Structured class observations (Additional file 5)	Students (n=4)	Post-intervention

Objective 1: to explore the extent to which the Be Smart about your Health secondary school intervention was implemented as planned

We will explore if the resources were implemented as planned by describing three dimensions of fidelity: coverage, dose, and deviations. Coverage will be looked at as average student class attendance per IHC class, dose as lessons delivered, and 'deviations' as alterations that teachers made to achieve the lesson objectives. We will collect data using teachers' lesson evaluation forms, structured classroom observations (Additional file 5), and interviews with teachers (Additional file 6), as described in more detail below.

Teachers' lesson evaluation form: All teachers (n=40) in the intervention schools will be asked to complete an electronic lesson evaluation form (Additional file 4) after each IHC lesson taught. We will train teachers during the teacher training workshop on how to complete and submit the electronic forms using Google Forms. We will provide the teachers with Internet data bundles to cover costs connected to the trial and process evaluation.

Structured classroom observations: For the observations, we will collect data from all schools (n=40) and will observe at least one lesson in each school. In addition, we shall observe more than one lesson in a sample of eight schools. The principal investigator and trained research assistants will observe the lessons guided by a structured observation guide (Additional file 5). They will not participate in the classroom activities. The observers will adopt a 'marginal participant role' [25] to data collection, allowing observers to reflect on what was noted and summarise key findings from the observations.

Interviews with teachers: We will conduct interviews with teachers (n=8) that taught IHC lessons to gain an in-depth understanding of their experience delivering the intervention, using a structured interview guide (Additional file 6).

Objective 2: To explore the factors that facilitated or hindered the delivery and impact of the Be Smart about your Health secondary school intervention

We will explore factors that facilitated or hindered delivery and impact of the IHC secondary school resources. We will collect data using the teacher-training-workshop evaluation from (Additional file 3), key informant interviews and focus group discussions with teachers (Additional files 6 and 7), school principals (Additional file 7), and sub-county education directors (Additional file 8), as described in more detail below.

Teacher-training-workshop evaluation: At the end of the training workshop, we will ask all the trained teachers (n=40) to complete and submit an electronic training evaluation form (Additional file 3). We will evaluate teachers' training workshop experiences to explore the extent to which the training achieved its objective, and increased teacher's competence and their readiness to deliver the intervention.

Interviews with sub-county education directors, school principals and teachers: We will interview all the relevant ministry of education officials (sub-county education directors, teachers service commission and curriculum developers) (n=5) (Additional file 8). We will also interview school principals (n=8) (Additional file 7) and teachers (n=8) that used the IHC resources (Additional file 6) at the sampled schools. Two researchers (PhD fellow with a research assistant) will conduct the interviews.

Focus group discussions with teachers: We will conduct one face-to-face focus group discussions with teachers to understand factors that might have facilitated or hindered their use of IHC resources. We will invite teachers to a central place where we will conduct the discussion. Two researchers (a moderator and note taker) will conduct the discussions guided by an interview guide (Additional file 9). Prior to each discussion, the

moderator will provide a general overview of what the study is about and seek written permission to collect data and record the discussions or take pictures. We anticipate that the discussions will take approximately 1½ hours.

Objective 3: To explore intended and unintended effects of the Be Smart about Health secondary school intervention

Use of the IHC secondary school resources might have potential adverse and beneficial effects that will not be measured in the trial). We have developed a framework for identifying potential unintended effects (adverse outcomes or harms) and the potential ‘far transfer’ of learning (use in daily life of what is learned from the intervention as well as use in contexts other than health), and potential methods to evaluate those effects (Additional file 12). We will collect data using interviews and focus group discussions.

Interviews with teachers: We will conduct interviews with teachers (n=8) from the selected schools. We will use a semi structured interview guide (Additional file 6) to explore adverse outcomes (e.g., conflict with teachers, peers, or parents) and beneficial effects (e.g., constructive discussion).

Focus group discussions with students and parents: We will conduct focus group discussions with students (n=4) and their parents (n=4) to explore their perspectives regarding how the IHC resources may have influenced their behavior. Students will be sampled based on their performance in the ‘Critical Thinking about Health’ Test. Each discussion will involve 8-10 participants. We will conduct the discussions in the selected schools using an interview guide (Additional files 11 and 12).

Data analysis

We will clean and, where needed, anonymise all data prior to analysis. We will analyze data by objective. For qualitative data, we will use a 5-stage thematic framework approach for applied research [26]. We will start by transcribing all the audio files in verbatim and then verify these transcripts against the original audio-recording [27]. Subsequently, the principal investigator will read and reread the transcripts to familiarize themselves with the data sets. Next, two researchers will independently read at least one to two sampled transcripts from the datasets and code relevant statements using two standard coding frameworks (Additional file 12) used in a similar primary school IHC study. New emerging codes will be discussed for inclusion. We will share the coded data with the rest of the research team for review and agreement on the final codes. Using the agreed coding frameworks, we will code and rearrange the data according to the frameworks while being open to the inclusion of new codes as analysis progresses. We will compare findings from teachers’ lesson evaluation forms, structured classroom observations and interviews. We will then write a summary for each finding and determine if quantitative data support the finding.

For quantitative data we will use descriptive analysis to assess the extent to which the IHC resources were implemented as planned. We will calculate the proportion of lessons delivered by projectors/phone, the average time taken to teach the lessons, average student class attendance per lesson, and teaching strategies used in the delivery of these lessons. We will use Likert scale to rate the level of teachers' preparedness from the teacher training workshop and per lesson evaluation (1- poorly prepared, 7- well prepared), achievement of learning objectives of the Be smart about your health intervention (1 less covered- 7-fully covered). We will analyze fidelity both quantitatively and qualitatively.

Trustworthiness of findings

We will use a modified version of the GRADE-CERQual approach to assess our confidence in the key findings [28]. GRADE- CERQual is a systematic and transparent method for assessing the confidence in evidence from reviews of qualitative research and involving applying four components: methodological limitations, data adequacy, coherence and relevance [29]. Although CERQual has been designed for findings emerging from qualitative evidence syntheses, the components of the approach are suitable for assessing findings from a single study with multiple sources of qualitative data [18, 30]. We modified the components slightly, as follows:

- 1) Methodological limitations: the extent to which there are concerns about the sampling and collection of the data that contributed evidence to an individual finding,
- 2) Coherence of the finding: an assessment of how clear and compelling the fit is between the data and the finding that brings together these data,
- 3) Adequacy of the data contributing to a finding: an overall determination of the degree of richness and quantity of data supporting a finding and
- 4) Relevance: the extent to which the body of evidence supporting a finding is applicable to the context (perspective or population, phenomenon of interest, setting) specified in the study question.

Two of the study investigators (FC and BW) will independently use the approach to assess each finding and rate the confidence as being high, moderate, low, or very low. All findings will start as high confidence and will be downgraded if there are important concerns regarding any of the components described above [31].

Ethics and dissemination

We obtained ethics approval for the entire IHC study from Masinde Muliro University of Science and Technology Institutional Ethics Review Committee and a research permit

from the Kenya National Commission of Science and Technology Institute in 2019 (License number: NACOSTI/P/19/1986). We renewed the approval that covers the process evaluation.

We will obtain written consent from each study participants (over 18 years) (Additional file 13). The school principals will consent on behalf of the students (Additional file 14), and we will obtain written assent from the students (Additional file 15).

We will anonymize participants' identities to ensure confidentiality.

Competing Interests

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

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Protocol amendments

Any protocol modification will be recorded in a new version of the protocol and communicated to relevant parties, including the Ethics Review Committee.

Protocol contributors

Conceptualization: FC, MK, MM, SR, NA, SD, NL, MO, NKS, SER, and ADO. Methodology: FC, MM, KM, SCM, FC, SR, NA, SD, AA, NL, MO, LS, NKS, SER, and ADO. Writing original draft: FC. Writing, review, and editing: all authors.

Additional files

1. Description of the intervention (GREET checklist)
2. Critical Thinking about Health Test
3. Teacher-training-workshop evaluation form
4. Teachers' lesson evaluation form
5. Classroom observation guide
6. Teacher interview guide
7. Principals interview guide
8. Education Authorities Interview guide
9. Teacher focus group discussion guide
10. Student focus group discussion guide
11. Parent focus group discussion guide
12. Coding framework for potential harms and far transfer
13. Consent form for adults
14. Consent form for principals on behalf of students

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