

**Effects of the Informed Health Choices  
secondary school intervention on the  
ability of lower secondary students in  
Kenya to think critically about health in-  
formation and choices: Protocol for a  
cluster-randomized trial**

*Chesire F et al.*

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# Colophon

<i>Title</i>	Effect of the Informed Health Choices secondary school intervention on the ability of lower secondary students in Kenya to think critically about health information and choices: Protocol for a cluster-randomized trial
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# Abstract

**Background:** There is an overabundance of claims about the advantages and disadvantages of health interventions. Many people are unable to assess the reliability of these claims. Acting on unreliable health claims or failing to act on reliable advice can lead to waste of resources and unnecessary suffering. There is a global focus on teaching critical thinking, including in the new Kenyan curriculum, however, critical thinking about health is not taught in Kenyan schools.

The study planned for in this protocol is an evaluation of the effects of the Informed Health Choices secondary school intervention on the ability of lower secondary school students in Kenya to think critically about health information and choices. The intervention consists of providing teachers with digital teaching resources and training them to deliver the intervention to students. The intervention covers 10 lessons that address nine key concepts.

**Methods:** This study is a cluster-randomized trial. We will stratify lower secondary schools by ownership and geographical location, and randomly select 80 of them. We will randomly allocate the schools to either the intervention or control group. The intervention schools will teach the 10 lessons in one academic term alongside the Kenya national secondary school curriculum. The control schools will continue teaching the national secondary school curriculum. The primary outcome measure will be a test with multiple-choice questions from the Claim Evaluations Tools item bank. The test will include two items for each of the nine concepts covered by the teaching resources. The primary outcome will be the proportion of students attaining a predetermined passing score.

**Trial registration:** Pan African Clinical Trial Registry, trial identifier: PACTR202204883917313. Registered on 05/04/2022.

# Background

There is a massive amount of information about how to care for one's health, much of which is unreliable [1]. Many people are unable to assess the reliability of such information [2, 3]. People believing and acting on unreliable health claims contributes to overuse of ineffective or harmful health interventions [4] and underuse of helpful health interventions [5]. A health intervention is any preventive, therapeutic, rehabilitative, or palliative action intended to improve the health or wellbeing of individuals or communities [6].

Critical appraisal of health information is an essential skill for the public, including children and adolescents, not just health professionals [7, 8]. Critical appraisal skills help people to assess health information and make informed health decisions.

Educational interventions to teach people critical appraisal skills can improve people's abilities to assess health information. However, there is a paucity of rigorous evaluations of interventions intended to teach critical appraisal skills to laypeople [9, 10]

Schools in low- and middle-income countries have the potential to act as powerful behaviour modifiers not only by promoting specific, currently recommended health behaviours [11], but by teaching adolescents how to appraise health claims they encounter in their daily lives, now and in the future [12]. Review of studies of effects of school-based educational interventions to teach adolescents to critically appraise health claims found that such interventions may have an effect on knowledge and skills required for critical appraisal of health claims [9]

There are several reasons for teaching critical appraisal skills to adolescents. First, they might carry the skills through to adulthood [13]. Second, they are frequent users of social and mass media, where they are exposed to many health claims [13], and many of them might be poorly equipped to evaluate the trustworthiness of online health information [14]. Third, there is a global focus on teaching critical thinking, which is considered a 21<sup>st</sup> century competency [15, 16]. Critical thinking is central in the new Kenyan curriculum [17], but critical thinking specifically about health is not taught in Kenyan schools [18].

To address this problem, the Informed Health Choices Network has developed a framework for teaching people to think critically about health claims and choices[19]. This framework includes concepts, competencies, and dispositions that people need to assess the reliability of claims and research evidence about the effects of health interventions and make well-informed health decisions [19]. The concepts provide a starting point for developing teaching and learning resources that can help people assess health claims and make informed health choices, and evaluation tools to measure people's ability to do this. Most of these concepts are also relevant for other fields, besides health care[20].

The framework was used to develop and evaluate the IHC primary school resources. A cluster-randomized trial showed that using those resources had a large effect on children's ability to assess health intervention claims[21]. A process evaluation found that teachers, children, parents, and education authorities experienced the resources as important and relevant [3, 22]. However, lack of time in school schedules and the cost of printing the resources were barriers to scaling up their use [22].

We conducted a context analysis in Kenya, to explore how we can address the barriers and scale-up use of IHC resources in Kenyan secondary schools if deemed to be effective [18]. We found there was interest in the resources from stakeholders including teachers and curriculum developers, and that the resources can be integrated within the curriculum. We also found that few secondary schools have computers with a reliable Internet connection, and students have limited Internet access. Therefore, making digital resources that can be accessed with basic ICT equipment can reduce the cost of printing and can be widely used at low cost if they are shown to be effective. Parallel context analyses in Rwanda and Uganda also indicated an interest in the resources [23, 24].

Building on the findings from the IHC primary school intervention and the context analyses, we have developed and piloted digital IHC resources for lower secondary schools in Kenya, Uganda, and Rwanda. The resources address nine IHC Key Concepts (Box 1), prioritized by curriculum developers, teachers, and researchers in the three countries (Additional file 1) We used a human-centred design approach to develop the resources iteratively between 2020 and 2022 together with teachers, students, and curriculum developers [25]. Using the resources, we aim to equip students and teachers with skills to recognize and appraise health claims and make informed health decisions. This protocol is for a cluster-randomized trial to evaluate the effects of the IHC secondary school intervention in Kenya.

***Box 1: Prioritised IHC Key Concepts to be used in the secondary school resources***

1. Treatments can cause harms as well as benefits.
2. Large, dramatic effects are rare.
3. Personal experiences or anecdotes alone are an unreliable basis for most claims.
4. Treatments that are new or technologically impressive may not be better than available alternatives.
5. Widely used treatments or those that have been used for decades are not necessarily beneficial or safe.
6. Identifying the effects of treatments depends on making comparisons.
7. Small studies may be misleading.
8. Comparison groups should be as similar as possible.
9. Weigh the benefits and savings against the harms and costs of acting or not.

## **Objectives**

**Primary:** To evaluate the effects of the IHC secondary school intervention on the ability of Kenyan secondary school students to critically appraise claims about health intervention effects and make informed health choices.

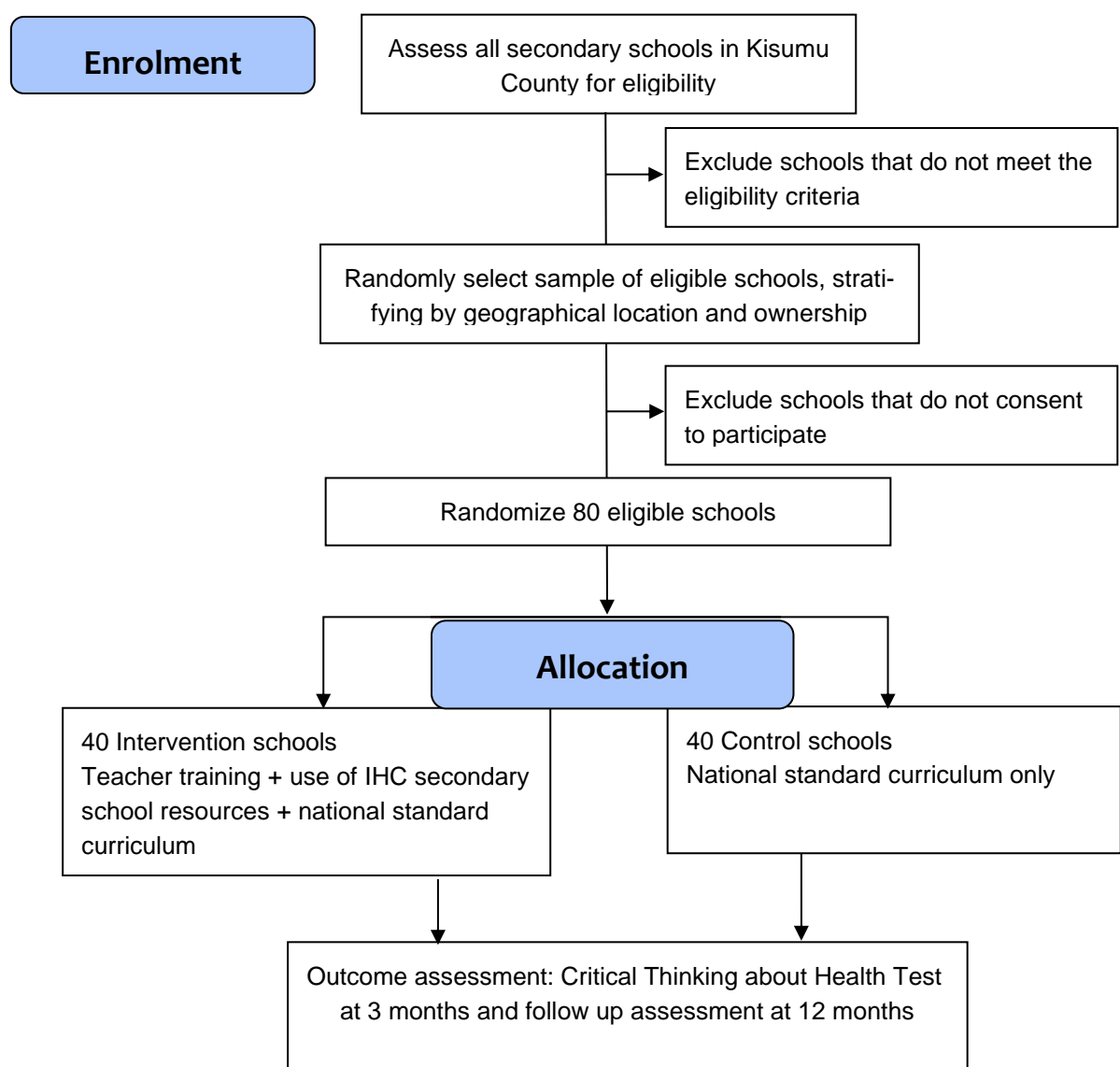
**Secondary:** To evaluate the effects of using the resources on students' intended behaviours, self-efficacy, and academic achievement, and on teachers' ability to critically appraise claims about health intervention effects and make informed health choices.

# Methods

## Design

This is a two-arm, cluster-randomized trial) that adopts superiority trial (not a non-inferiority) trial. (Figure 1).We will stratify and randomize schools based on ownership (public/private) and geographical location (rural/urban). Schools allocated to the intervention arm will receive training and use the IHC secondary school resources in addition to the teaching of other subjects in the curriculum. The intervention schools will be compared to schools that will not receive training or IHC resources but will continue to teach the national secondary school curriculum.

**Figure 1. Flow diagram**



## **Study setting and location**

According to the 2019 education report [26], there are 10,487 secondary schools in Kenya, of which 85% are publicly owned. This study will be conducted in lower secondary schools from 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 is four years. An annual academic calendar is for three school terms, where a single term is approximately 10-13 weeks. Teachers that teach this 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 [26].

Students are intended to enrol 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 3 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[27]. The Kenyan government plans to gradually replace the curriculum with a new, competency-based curriculum by 2024.

## **Study population**

This study will target form one (first year) students and their teachers in public and private schools in Kisumu County. We target form one students for two reasons. First, we want to follow up with the students after one year to assess whether they retained what they learned. Due to changes in the academic calendar necessitated by the COVID-19 pandemic prevention guidelines, the form-one students will be the only students intended to be in secondary school for the whole study period. Second, other forms are busy preparing for their national examinations.

## ***Inclusion and exclusion criteria***

We will include public and private schools that follow the national standard curriculum in Kisumu County. The principals of schools invited to participate, and teachers selected by the principals must sign a written consent form (Additional files 2 and 3) before enrolling the school in the study. Teachers enrolled in the



intervention arm must have access to an Internet connection and a computer or a smartphone. All form one students in the consented schools will be eligible to participate.

We will exclude schools that participated in the user testing and piloting of the secondary school resources. Schools in sub-counties that are prone to floods or insecurity due to inter-ethnic cattle rustling, and special needs schools for children with hearing and vision impairments will also be excluded. The inclusion and exclusion criteria are listed in Table 1.

**Table 1. Inclusion and exclusion criteria**

	<b>Inclusion criteria</b>	<b>Exclusion criteria</b>
<b>Schools</b>	<ul style="list-style-type: none"> <li>• follow the national curriculum</li> <li>• have electricity</li> <li>• consent to participate</li> </ul>	<ul style="list-style-type: none"> <li>• participated in the user testing or piloting of the IHC resources</li> <li>• special needs schools</li> <li>• international schools</li> <li>• located in sub-counties (districts) prone to floods and insecurity</li> </ul>
<b>Teachers</b>	<ul style="list-style-type: none"> <li>• form one teachers selected by the principal</li> <li>• have a smartphone or laptop computer</li> <li>• teach a subject related to health or critical thinking (home science, biology, physical education, English, or business studies)</li> </ul>	
<b>Students</b>	<ul style="list-style-type: none"> <li>• form one students</li> </ul>	<ul style="list-style-type: none"> <li>• students that choose not to participate</li> </ul>

### ***Sampling strategy***

We will use multistage sampling to select schools. First, we will purposively select five sub-counties (Kisumu East, Kisumu Central, Kisumu West, Nyakach, and Seme) out of the seven in Kisumu County. We will exclude 2 sub-counties (Nyando and Muhoroni) since they are prone to floods or insecurity due to inter-ethnic cattle rustling. Second, we will stratify schools by ownership (private/public) and geographical location (rural/urban). Finally, we will randomly select 80 schools from the four strata by sub-county. The number of schools will be proportionate to the number of eligible schools in each sub-county.

### ***Recruitment and retention of schools***

Together with the sub-county education directors, we will invite principals of the selected schools to attend face-to-face meetings. In these meetings, the research team will introduce the study objectives and discuss specific phases and

methods of the study, outcome measurement, and the one-year follow-up assessment. We will also discuss criteria for selecting teachers and form one class to participate in the trial; obtaining informed consent from the selected teachers; plans for teacher training workshops; scheduling of lessons within the timetable; and plans for a process evaluation. Finally, we will seek their consent to participate in the study. For principals that decline to consent, we will replace their schools with eligible schools from the same strata, using the same recruitment and consenting process as above.

We will make two follow-up visits and phone calls to participating schools (both intervention and control arms) to improve retention of form one classes in the study. During the visits, we will collect information about the implementation of the IHC resources. We will call the control schools to inquire about activities or programs that are running in the participating class to improve critical thinking. The information collected will be used to assess fidelity in a process evaluation, for which a separate protocol is being prepared.

## **Random allocation and concealment**

We will stratify and randomize eligible schools that consent to participate based on ownership (public/private) and geographical location (rural/ urban). To ensure a balance of school characteristics in the intervention and control arms, we will use block randomization to allocate schools. An independent statistician not involved in recruitment of schools will use [www.sealedenvelope.com](http://www.sealedenvelope.com) to generate the allocation sequence and allocate the schools [28]. The principal investigator will assign unique codes to the schools and provide the statistician with the codes to ensure that the allocation is concealed. The statistician will then prepare the randomization list with the unique codes and corresponding allocation group for each participating school. The final list of selected schools will not be changed after random allocation by the statistician.

## **Blinding**

Because of the nature of the intervention, it will not be possible to blind the research team, teachers, or students. We will introduce the study objectives to teachers in both arms of the trial. When the test that is the primary outcome measure is administered, we will tell students in both arms of the trial the purpose of the test.

## Sample size

We have estimated the sample size based on the IHC primary school intervention trial results, using the University of Aberdeen Health Services Research Unit's Cluster Sample Size Calculator[29] and the assumptions shown in Table 2.

**Table 2. Sample size calculation**

	Assumptions
Students per cluster	40 according to Kenya education statistics [26]
The proportion of students expected to achieve a passing score without the intervention	30% based on a cluster-randomized trial of the IHC primary school resources in Uganda [21]
Detectable difference	20% based on the difference between 30% passing and at least half of the students passing being the minimally important difference
Statistical significance	0.01
Power	90%
Intraclass correlation coefficient	0.19 based on the cluster-randomized trial of the IHC primary school resources in Uganda [21]
Loss to follow-up	10%

Based on the assumptions in Table 2, we will need a minimum of 74 schools to participate in the trial. Allowing for a loss to follow-up for schools where it might be impossible to administer the assessment at the end of the term. We will recruit 80 schools.

## The intervention

We have described the intervention using the GREET checklist for describing educational interventions (Additional file 4). The 'Informed Health Choices secondary school resources' cover nine IHC Key Concepts (Box 1). Classes at schools randomized to the intervention arm will be asked to complete the lesson goals described in Table 3 in a single term (10-13 weeks). Each lesson is intended to take a single period (40 minutes) per week. Teachers are free to decide how to fit the 10 lessons into the regular school timetable or create time outside the timetable to complete the lessons.

**Table 3. Lessons with learning goals**

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

### ***Delivery of the intervention***

The teachers in the intervention arm of the trial will receive a two-day training workshop a week before the trial. Four teachers that participated in the pilot of the secondary school resources will train the participants. We will observe them as they train and correct any mistakes, such as misapplying the Key Concepts. The workshop aims to provide a standard orientation of the IHC intervention (Additional file 5). In the workshop we will discuss:

- 1) an overview of the lessons, including the nine Key Concepts, why they are important, the learning goals, how the lessons are organized, and how to use the resources
- 2) the classroom activities and how to teach each lesson,
- 3) scheduling and preparing for the lessons,
- 4) information about the trial, including plans to administer a test at the end of the term and after one year, and other plans for data collection

Teachers in the intervention schools will need a computer or phone with Internet connection to access the resources. They can use a projector if they have

one. Before the workshop, we will give them a URL link to the resources and Internet bundles to cover any costs associated with accessing the resources. Teachers in the intervention schools will be asked to complete a brief report after each lesson, including whether the lesson was taught using the projector or the blackboard version. We will ask the participating schools to share their timetable including the scheduling of the outcome measure. We will measure fidelity of IHC intervention using quantitative and qualitative data collection approaches including class observations (observe IHC lessons in 8 schools), student class attendance (all IHC lessons taught) and interviews. This information will be used in the process evaluation.

The IHC secondary school resources and training will not be made available to schools in the control arm during the study period. However, they could get the URL from someone in the intervention arm. We will explain to them why they should not do this. We will offer them a workshop and access to the resources after the one-year follow-up assessment.

## **Outcome assessment**

We will use the Critical Thinking about Health Test (Additional file 6) to assess the ability of the students to think critically about health claims and choices. The test was derived from the Claim Evaluation Tools item bank which contains multiple-choice questions (MCQs) that assess an individual's understanding of and ability to apply IHC Key Concepts[30]. The item bank was developed after searching for other appropriate outcome measures to evaluate the IHC primary school resources and not finding one[31].

The item bank has been developed based on extensive qualitative and quantitative feedback from curriculum developers, health professionals, teachers, and members of the public [30]. It includes 3-4 MCQs for each of the 49 IHC Key Concepts. To develop the primary outcome measure we started with 27 MCQs for the nine concepts addressed in the IHC secondary school intervention and conducted cognitive interviews with children, adults, and curriculum developers in Kenya, Rwanda, and Uganda. We made minor revisions and determined the reliability and validity of the test using Rasch Analysis [32] based on responses from 250 secondary school students and 250 adults in each country (Additional file 7).

Based on this analysis, we selected 18 MCQs for the final questionnaire (two for each of the nine concepts). Each MCQ has three response options. In addition to the 18 MCQs, we will include questions that measure intended behaviours and self-efficacy, using Likert response options (Additional file 6).

## **Outcomes**

The primary outcome measure is the difference between the intervention and control schools in the proportion of children with a passing score. We used a combination of Nedelsky's and Angoff's methods [33, 34] to determine a cut-off for passing and mastery scores (Additional file 8). The cut-off for passing is at least nine correct answers out of the 18 MCQs.

Secondary outcome measures are:

- the mean difference in scores
- the difference in the proportion of students with a score that indicates mastery of the nine Key Concepts (at least 14 correct answers out of 18 MCQs)
- the difference in the proportion of students that answer both questions correctly for each Key Concept
- the difference in students' intended behaviours and self-efficacy
- potential beneficial and adverse effects of the IHC secondary school intervention
- the difference in the proportion of teachers with a passing score and the first two secondary outcomes (the average score and the proportion of teachers with a score that indicates mastery of the nine Key Concepts)
- the difference in scores on academic achievement measured using national examinations and end of term examination

Both primary and secondary outcomes will be measured at the end of the term during which the IHC intervention is delivered and one year later. Both students and teachers in the participating schools will be asked to complete the same questionnaire. The students' marks will not be used for grading, but the students will be told their scores after the one-year follow-up assessment.

## **Data collection and management**

At the beginning of the trial, we will train research assistants on how to seek consent and administer the questionnaires. The research assistants will deliver printed copies of the *Critical Thinking about Health Test*, including answer sheets and the exam instructions to each school on the exam day. The test will be administered by the research team both to the teachers and the students in intervention and control schools. Individual students and teachers will be assigned a study code which will be written on the answer sheets. Additionally, students will be instructed to write their age and sex on the answer sheet. The research team will collect then scan the answer sheets using Zip Grade[35]. All participants from both arms will complete the same questionnaire one year after intervention delivery. We will provide participants with their scores after the one-year follow-up.

## Measures of academic achievement

Research assistants will collect data on academic achievement for each participating students in the intervention and control arms. End of term examination results will be collected after the school term when the intervention is delivered and after one year (Table 5). These data will be used to assess the impact of the intervention on academic achievement. In addition, we will collect national examination results for primary school education. Those data will be used in a planned subgroup analysis as part of a prospective meta-analysis [36]. We will not account for absentees and dropouts in the process evaluation. We will address this by conducting the two sensitivity analyses described in the data analysis section.

**Table 5. Measures of academic achievement**

Before intervention	After intervention
Overall mean grade score for academic year 2021 of the national Kenya Certificate of Primary Education (KCPE) exams (used for joining secondary school)  The above mean score is based on five subjects examined (maths English, Swahili, science, and social studies, and religious education) in KCPE.	Overall mean grade score of end-of-term examination results for 12 subjects examined during the school term of intervention.  Students choose subjects from five categories depending on school and examining body requirements. The five categories are as follows:  <b>Compulsory subjects:</b> English, Kiswahili, mathematics  Science subjects: chemistry, physics, biology  <b>Humanity subjects:</b> geography, history and government, Christian religious, education, Islamic religious education, Hindu religious education  <b>Applied sciences:</b> computer studies, agriculture, home science, art and design, woodwork, metalwork, building construction, power mechanics, electricity, drawing and design, aviation technology  Technical subjects: business studies, French, German, Arabic, Kenya sign language, music

## Descriptive data

Research assistants will collect data about the study participants (teachers and students) and school characteristics as shown in Table 4. The data collection tool (Additional file 9) will include questions about gender (for both teachers and students), level of education, years of experience, and subjects taught (for teachers. The school characteristics will include ownership (public/private), and geographical location (rural/urban) available for teaching. These data will be checked for completeness at the time they are collected. Research assistants will make follow-up telephone calls or visit schools to collect any missing data. The data will be entered in the study database. We will de-identify all data in the

study database, before conducting the analysis. The database will be kept on a secure server that can be accessed only by the study investigators. The study investigators will review the completeness of data and instruct the research assistants to collect missing or incomplete data.

**Table 4. Descriptive characteristics**

	<b>Characteristics</b>	<b>Description</b>
<b>Schools</b>	Location	Rural Semi-urban Urban
	Ownership	Public Private
	ICT	At least one projector No projector
<b>Teachers</b>	Education	Certificate Diploma University degree
	Experience	Years teaching secondary school
	The main subject taught	Science Other
	Gender	Female Male
<b>Learners</b>	Gender	Female Male
	Age	

### ***Far transfer of learning***

In separate studies, we are identifying the potential “far transfer” of learning (use of what is learned in daily life) and potential harms. We are developing methods to evaluate those effects (Additional file 10).

## **Safety monitoring for potential harms and adverse effects**

We will monitor and report potential harms of the intervention, although serious harms are unlikely. The IHC intervention might have undesirable effects (for example, IHC teaching and assessment might waste time and draw student’s away from other curriculum activities) to students at the participating schools. We will ask teachers to report adverse effects to the research team using an electronic questionnaire (Additional file 11). We will give contact details (phone and email address) at the start of the trial and instructions for recording adverse events. We will review the reported adverse events and findings of a process evaluation and measure them after one year.



## **Data analysis**

We will use descriptive statistics to calculate the frequencies, percentages, measures of central tendency for demographic and baseline characteristics. For comparisons between students in the intervention and control schools, we will use hierarchical mixed models. We will analyse dichotomous data using multi-level logistic regression with clusters (schools) as random effects and strata variables (ownership and geographical location) modelled as fixed effects. Multi-level linear regression will be used for continuous outcomes. We will dichotomize responses for questions on intended behaviours and self-efficacy, and we will report the proportions of students for each of the response options, odds ratios, adjusted differences (based on the odds ratios), and the corresponding confidence intervals. For continuous outcomes, we will report the means, standard deviations, mean difference, and corresponding confidence intervals. We will report the intraclass correlation coefficient for all student outcomes.

## ***Sensitivity analysis***

We will conduct two sensitivity analyses to explore the risk of bias due to attrition, which may be larger in the control schools than in the intervention schools [21]. First, we will do a weighted analysis using inverse probability weighting. In this analysis, the students in each school will be given a weight equal to the inverse of the proportion of students in the school that completed the CTH Test. Second, we will calculate upper and lower bounds for the mean difference in test scores using the Lee bounds approach [36]. These are constructed by trimming the group with less attrition at the upper and lower tails of the outcome (test score) distribution respectively. We will not adjust for covariates in this analysis.

## **Trial management**

The Norwegian Institute of Public Health, the recipient of the grant from the Research Council of Norway, is the coordinating centre for this trial and parallel trials being conducted in Rwanda and Uganda [36]. The members of both the steering committee and the coordinating teams for the trial are LN, MK, NS, SR, and AO.

We will create a database where we will keep all the study documents, including the protocol, ethics approvals, letters, consent forms, data collection forms for participants, and the data management plan. We will create a file for each participating school, labelled with the unique school code. In each school file, we will keep students' and teachers' names and codes, timetable, answer sheets for the test, and teacher evaluation reports. The documents will be destroyed after five years.

The principal investigator (FC) is responsible for final decisions about the protocol and reporting of the results. She will be responsible for overseeing recruitment, data collection, and data management. Trained research assistants will be responsible for collecting consent forms, and data from each school.

The timeline for the trial is shown below (Figure 2). Recruitment of schools began in February 2022, the *Informed Health Choices* lessons will be taught in the intervention schools between April and June 2022 and evaluated in June 2022 beginning with control schools, and the outcome assessment will be conducted in January 2023 as outlined in Figure 2.

**Figure 2: Trial timeline**

	2022																												2023
	FEB				MAR				APR				MAY				JUN				JUL				AUG				JUN
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1
<b>Enrolment</b>																													
Authorization by County education office																													
Sampling of schools for the trial																													
Meeting with school heads to consent and recruit teachers																													
<b>Allocation</b>																													
Random allocation of schools to intervention & control arms																													
Workshop/training for teachers (Intervention group)																													
Meeting with Teachers (Control Group)																													
<b>Intervention</b>																													
Delivery of IHC lessons and class observation																													
Claim Evaluation assessment																													
Data cleaning and entry																													
Process Evaluation interviews																													
<b>One year follow up</b>																													

### Post recruitment retention strategies

Schools that agree to participate will schedule the IHC teaching and assessment within their timetables. Teachers that agree to teach will give their consent before allocation.

We will explain the aim of the trial and the importance of completing the 10 lessons and the assessment test at recruitment meetings with the school directors and the introductory meetings with teachers. We will follow up with each participating school during the intervention, the outcome assessment, and after one year. We targeted the form one students since they will be the only students that will still be in school during the study period.

### Ethical considerations and informed consent

This study will be conducted by the protocol and regulatory requirements of conducting human studies in Kenya. We obtained ethics clearance from Masinde Muliro University of Science and Technology Institutional Ethics Review Committee and the Kenya National Commission of Science and Technology Institute in 2019 (Licence number: NACOSTI/P/19/1986), renewing the permit yearly.

Further approvals were sought from ministry of education and teachers service commission at national levels and county levels.

At school level, the principal investigator will seek written consent from school principals of all participating schools and selected teachers before randomization. We will ask the principals to consent on behalf of students enlisted to participate and introduce the study to students of the selected class. Further, we will ask the principals to inform the school management boards and parent-teachers association about the study (the length, purpose, and objectives of the intervention; any benefits or risks the school might incur).

Principals have the responsibility and authority to make decisions about lesson plans and the administration of tests. We will not obtain consent from individual students or their parents. However, individual students will have the right to refuse participation as they do for any other lessons or tests. We anticipate that this study will pose minimal risk to the students.

## **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.

## **Competing Interests**

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

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## **Availability of data and other materials**

We will publish the trial protocol before the trial starts on Zenodo.org, an open access repository. We will invite key stakeholders that participated in the trial to a workshop where we will disseminate the study findings. We will also sub-

mit reports of the results after the first outcome measure and the one-year follow-up to a relevant journal for publication and dissemination. We will remain the custodians of the 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: PACTR202204883917313. Registered on 05/04/2022.

## **Protocol amendments**

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

## **Protocol contributors**

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

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# Additional files

Additional file 1 Prioritisation of Informed Health Choices Key Concepts

Additional file 2 School principal consent form

Additional file 3 Teacher/ adult consent form

Additional file 4 GREET checklist

Additional file 5 Teacher training workshop

Additional file 6 Critical Thinking about Health Test

Additional file 7 Development and evaluation of the Critical Thinking about Health Test

Additional file 8 Determination of cut-offs for passing mastery scores

Additional file 9 Descriptive statistics

Additional file 10 Evaluating “far transfer” of learning, and evaluating and monitoring potential harms

Additional file 11 Safety Monitoring and Adverse Events reporting Form

Additional file 12 SPIRIT checklist