"The Magic Glasses Philippines": a cluster randomised controlled trial of a health education package for the prevention of intestinal worm infections in schoolchildren

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Summary

Background Soil-transmitted helminths (STH) cause substantial disease and disability globally. Health education has proven complementary to school-based drug administration programs for STH control. We determined the generalizability of the impact of "The Magic Glasses" health education package for STH prevention in schoolchildren in Laguna province, the Philippines, having previously shown its positive impact in China.

Methods We conducted a cluster-randomised controlled trial, in schoolchildren, aged 9–10 years, across 40 schools over one year. Schools were randomly assigned either to the "Magic Glasses Philippines" health education intervention package (consisting of a cartoon video, classroom discussions, drawing and essay competition) complementing the standard health education activities of the Philippines Departments of Health and Education, or to a control group, which involved only the standard health education activities. The primary trial outcomes were the proportion of STH infected schoolchildren and their knowledge, attitude and behaviour of STH assessed in both groups at baseline and through two follow-up surveys undertaken immediately prior to the semi-annual national mass administration of albendazole. The outcomes between the study arms were compared using generalized estimating equation models, accounting for clustering at the school level. The trial is registered with Australian New Zealand Clinical Trials Registry number: ACTRN12616000508471

Findings At follow-up assessments, the mean knowledge and behaviour scores in the intervention group were, respectively, 5·3 (95% confidence interval [CI]:4·2—6·5; p=<0.001) and 1·1 (95% CI: 0·4—1·7; p=0.002) percentage points higher than the control group. There was no overall effect on helminth infections (any STH; adjusted odds ratio [aOR]:1·0; 95% CI: 0·8—1·3; p=0·856), *Ascaris lumbricoides;* aOR:1·0; 95% CI: 0·7—1·6; p=0·894, or *Trichuris trichiura;* aOR:1·7; 95% CI: 0·9—1·6; p=0·315) but sub-group analysis showed a 60% reduction in the odds of any STH infection resulting from the "Magic Glasses" intervention in schools with a baseline prevalence ≤15% (aOR: 0·4; 95% CI: 0·2—0·7; p=0·001).

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Interpretation The health-education package demonstrated a modest but statistically significant impact on the students' overall STH knowledge and changes in their behaviour but was only effective in preventing STH infections in intervention schools where the baseline prevalence was ≤15%.

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Keywords: Soil-transmitted helminths; randomised controlled trial; school-based health education intervention; Magic Glasses Philippines; integrated control

Research in context

Evidence before this study

The World Health Organization promotes school-based soil-transmitted helminth (STH) control through mass drug administration (MDA). Although MDA is effective in reducing the worm burden in at-risk populations, this approach has a limited impact on parasite transmission. Poor hygiene practices together with environmental contamination of STH eggs can result in rapid reinfection. Thus, the need for preventive measures such as behaviour changes facilitated through health education and improved sanitation could complement MDA programs for sustainable control of STH infections. We searched the PubMed and Scopus Databases for studies assessing the effectiveness of health education interventions on STH infection, using the terms "health education" or "health education intervention" and "soil-transmitted helminths" or "STH" or "intestinal worms" and "impact" or "effectiveness". In several identified publications, a positive effect of health education in the control of STH infections has been demonstrated.

In 2013, we developed a novel and effective health educational package: "The Magic Glasses" for the prevention of STH in Chinese schoolchildren. A cluster-randomised controlled trial (RCT) demonstrated that the package increased students' knowledge about STH, led to behaviour change, and resulted in 50% efficacy in preventing worm infections among the Chinese schoolchildren. We subsequently adapted this public health intervention to the Philippine context and again rigorously evaluated it via a RCT in circa 2000 schoolchildren in order to determine the generalizability of the package in another Asian country highly endemic for intestinal worm infections.

Added value of this study

In this study, we assessed the effectiveness of "The Magic Glasses Philippines" health education intervention on schoolchildren aged 9-10 years old in Laguna province, the Philippines, an area with high STH prevalence. The health education intervention was informed by extensive formative research, is culturally appropriate, and led to a statistically significant modest improvement in STH knowledge and behaviour. The primary analysis showed no reduction in overall STH infections, which may have been due to the high level of STH egg contamination in this environmental setting driving infection risk. However, sub-group analysis demonstrated a significant reduction of STH infections in intervention schools where the baseline prevalence did not exceed 15%. This suggests that the impact of the health intervention on STH infections was mediated by the prevalence or force of STH infection at baseline. This result is consistent with the Magic Glasses trial we undertook in China where the health educational package reduced the infection rate in children within one school year when the baseline prevalence was approximately 10%.

Implications of all the available evidence

The RCT outcomes provide added support to the concept that the Magic Glasses health education package improves knowledge and behaviour, and that it is applicable in different geographical settings. Its impact in preventing STH infections in schools with an endemic prevalence ≤15% suggests that in low transmission areas (with 15% or less prevalence), health education and MDA can reduce infection whereas MDA alone will not. However, in areas with higher prevalence, the health educational package plus additional measures such as high levels of MDA coverage and improved water and sanitation infrastructure and services will be necessary.

Introduction

Soil-transmitted helminthiases are among the most common of the neglected tropical diseases (NTDs), with 1·45 billion people infected with at least one species worldwide [1]. In 2019, the global burden due to soil-transmitted helminths (STH) (*Ascaris lumbricoides*, hookworm, and *Trichuris trichiura*) was estimated at 1.97 million disability-adjusted life years (DALYs) [2]. It is estimated that more than 300 million pre-school age children (Pre-SAC) aged 1-4 years and 748 million school-age children (SAC) aged 5-14 years are infected with STH globally [3]. The prevalence and intensity of *A. lumbricoides* and *T. trichiura* tend to peak in SAC and decline in adults while hookworm infections tend to rise monotonically with increasing age, plateauing in adulthood [4,5]. For hookworm infection, males have been shown to be more commonly infected than females but this is not the case for *A. lumbricoides* or *T. trichiura* infections [4]. The difference in age-and sex-related STH infection patterns was attributable to behavioural and environmental exposure factors rather than the differences in susceptibility to infection [4].

As children are at high risk of infection and long-term morbidity, the World Health Organization (WHO) recommends that they be targeted for drug treatment (deworming) [1,6]. Children chronically infected with STH have been shown to experience malnutrition, anaemia and stunted growth (resulting from nutritional deficiency) [7,8]. Other long-term effects associated with STH include: impeded intellectual development; cognitive and educational deficit [7,9]; and reduced productivity and economic prosperity [10,11]. Heavy infections and polyparasitism (infection with multiple STH species) are associated with higher morbidity rates, and increased vulnerability to other infections [12,13].

Mass preventive chemotherapy with benzimidazoles (albendazole, mebendazole) is the mainstay of intestinal worm control, but this approach does not prevent re-infection as a stand-alone intervention [14-17]. Complementary measures, such as improvements in personal hygiene through health education and improved sanitation, are thus needed to prevent re-infection as part of an integrated approach leading to the sustainable control of intestinal worms [18,19]. The integration of health education in school-based deworming programs is recommended by WHO [6] to reduce STH infections and re-infection risks through hygiene awareness and behaviour modifications. As shown in a number of studies, health education strategies are associated with increased knowledge [19−24] and acceptability of deworming [21], and uptake and maintenance of WASH interventions. [25] In addition, the positive impact of health education intervention on STH infections in children has been demonstrated in some of these reports. [19,20,22-24] Thus, the role of effective and low-cost health educational interventions in the long-term control of worm infections cannot be overemphasized.

STH are a serious public health problem in the Philippines [26,27] with some 45 million children at risk of infection, requiring preventive chemotherapy in 2019 [28]; of these, 24% are Pre-SAC and 76% are SAC [29]. Despite the launch of a nationwide school-based helminth control program more than a decade ago, intestinal worms are still highly endemic in the Philippines, with prevalences among PSAC and SAC ranging from 24.9-97.4% [30].

We developed and successfully tested a video-based health education package, "The Magic Glasses", to prevent intestinal worm infections in Chinese schoolchildren. [20] The cluster-randomised controlled trial (RCT) demonstrated that the package increased students' knowledge about STH, led to behaviour change, and resulted in 50% efficacy in preventing worm infections among the Chinese schoolchildren. [20] We culturally adapted the Magic Glasses video for the Philippines, and undertook a new cluster-RCT in Laguna province schools to determine the generalisability of the earlier findings in a different geographical setting and ethnic group and to provide evidence for translation of the package into public health policy and practice in the wider Asian region and beyond.

Methods

The full description of the trial procedures can be found in the published study protocol [31] and the supporting CONSORT checklist is available as additional supporting information; see Checklist S1.

Study setting and design

We undertook an unmatched, cluster-RCT targeting schoolchildren aged 9-10 years, in 40 schools (40 clusters) in Laguna province (Figure 1). Laguna province is located on the island of Luzon, in the Calabarzon region of the Philippines, where the STH prevalence averages ~33%. [32] Schoolchildren aged 9-10 years were chosen since they are the target population recommended by WHO for assessing STH burden in the community [33,34]; and this is the minimum age for us to accurately assess the impact of the intervention on Knowledge, Attitude and Practices (KAP).

The trial was conducted over one year (June 2016 through July 2017). Twenty schools were randomly assigned to the "intervention" group, in which the "Magic Glasses Philippines" health education package was delivered, together with the standard health education activities. These form part of the Water, Sanitation, and Hygiene in Schools (WinS) Program for the promotion of correct hygiene and sanitation practices among schoolchildren, endorsed by the Philippines Department of Health (DOH) and the Department of Education (DepEd) [35] and incorporated in the "Health" curriculum in Grade 4 (See Supplementary Information 1 for additional information). The other 20 schools comprised the "control" group of the study, where only the standard DOH/DepEd's health education activities were implemented. School facility survey was conducted prior to the trial, whereby Grade 4 classrooms in all 40 schools included in the Magic Glasses RCT were visited and assessed for the presence of toilets, water facilities, and hand washing areas, and their functionality.

The primary trial end-points were the proportion of students infected with STH and knowledge of intestinal worms, their transmission, symptoms, treatment and prevention, measured every five months through two follow-up surveys. The first and second follow-up surveys were conducted 5 and 10 months, respectively after the baseline procedures and the delivery of health

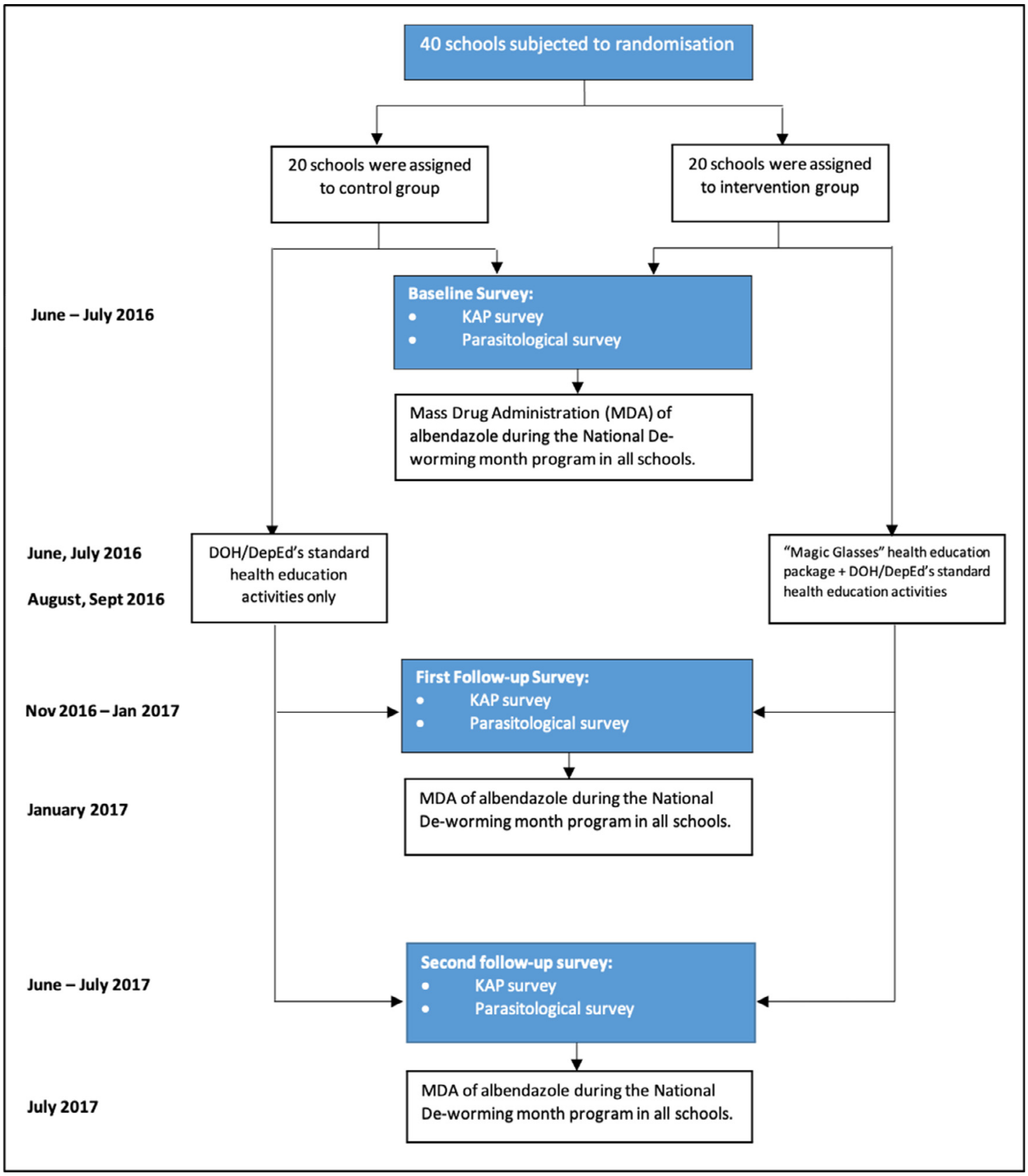

Figure 1. Trial profile. Flow diagram showing the trial study design and timeline of activities including baseline, follow-up surveys and intervention delivery, and Knowledge, Attitude and Practice (KAP), and parasitologic surveys among schoolchildren in Laguna Province, the Philippines.

The figure was adapted from Mationg MLS, Williams GM, Tallo VL, Olveda RM, Aung E, Alday P, Reñosa MD, Daga CM, Landicho J, Demonteverde MP, Santos ED, Bravo TA, Angly Bieri FA, Li Y, Clements ACA, Steinmann P, Halton K, Stewart DE, McManus DP, Gray DJ. Determining the Impact of a School-Based Health Education Package for Prevention of Intestinal Worm Infections in the Philippines: Protocol for a Cluster Randomized Intervention Trial JMIR Res Protoc 2020;9(6):e18419. doi: 10.2196/18419 https://www.researchprotocols.org/2020/6/e18419/;

education in the intervention schools and the baseline procedures in the control schools. The secondary trial endpoint was a change in self-reported hygiene behaviour (hand washing, use of toilets, food hygiene) measured by a KAP questionnaire.

Study oversight

The study protocol was approved by the Institutional Review Board of the Research Institute for Tropical Medicine (RITM), the Philippines (approval number: 2013–16) QIMR Berghofer Medical Research Institute Human Ethics Committee, Australia (approval number: P1271), and the Australian National University Human Ethics Committee (approval number: 2014/356). The trial is registered with the Australian New Zealand Clinical Trials Registry (registration number: ACTRN12616000508471). Prior to commencement, permission to undertake the study was obtained from the Philippines DepEd. Then details of the study were provided to the principals and parents of students of each school involved. Both written parental consent and children's assent were obtained prior to the enrolment of children. Staff training workshops were held before commencement of the trial (for details, see the study protocol [31]).

All authors assumed full responsibility for the design of the study; the collection, analysis, interpretation, and completeness of the data; and the reliability of this report adhering to the published study protocol [31].

Intervention package

"The Magic Glasses" educational cartoon video targeting Chinese schoolchildren was culturally adapted and developed for the Philippines setting using the same approach used in its original production [31,36]. The cultural adaptation of the video involved three major activities including the formative research to inform the development of the video, production and pilot testing, and revision (for details, see the study protocol [31]).

The educational intervention package comprised the 15-minute cartoon informing schoolchildren about the transmission and prevention of STH, complemented with classroom discussions, distribution of a pamphlet summarizing the key messages in the cartoon, and essay-writing and drawing competitions to reinforce the messages. Details of the implementation of the educational package are provided in (Table 1). The cartoon video is available as additional supporting material.

Mass drug administration (MDA) of Albendazole. Following the baseline survey, the recruited students across both the control and intervention schools received the WHO recommended single oral dose of 400 mg of albendazole given as MDA during the semi-annual National De-Worming Month program. Albendazole MDA of schoolchildren in the intervention schools occurred simultaneously with the delivery of the Magic Glasses intervention. Follow-up surveys were undertaken immediately prior to the next round of the de-worming program.

Study procedures

Baseline parasitological and KAP surveys were undertaken with participating students within four weeks after the initial caregiver's meetings at all schools in the trial. The two types of survey that had been performed at baseline were repeated at the two five monthly follow-ups. Stool samples were requested from all participants at baseline and at the first and second follow-up (Figure 1). All students received a stool collection kit (stool container, gloves, an applicator stick and instructions on how to collect a stool sample) and were instructed to collect a total of two stool samples on any morning of four prescribed collection days. The samples were immediately processed and examined on the same day at each school using the Kato–Katz (KK) technique using triplicate KK thick smears (41·7 mg of stool/smear) [48]. To ensure validity and accuracy of the results, 10% percent of all slides were randomly selected and re-examined by a reference microscopist on each collection day. The quality control showed an agreement of 98·4% to 100% for the three surveys (Supplementary Tables 1-3).

On completion of the baseline, and the first and second follow-ups, the parasitologic results were communicated to all parents in writing, with a recommendation for immediate drug treatment (if necessary) at the local health centre and/or a request to partake in the school deworming activity when all participating students were offered albendazole. The school principal, teachers and/or assisting nurses at each school monitored the students for treatment compliance and recorded any side effects experienced resulting from the drug treatment. The KAP questionnaire comprised multiple-choice as well as open-ended questions regarding demographics; health characteristics; medical history; previous health education and knowledge about intestinal worms including their modes of transmission, and the symptoms and treatment of infection; the student's attitude toward STH; self-reported hygiene practices with respect to using the toilet, hand-washing, handling of food, and the wearing of shoes; and household characteristics relating to household water sources and household assets. The questionnaire was developed in English, translated into Tagalog, and back translated into English to ensure accuracy. It was piloted in March 2015 in two schools outside the main trial area.

Statistical analysis

The study was designed to have 80% power to detect the intervention effect, using an intervention efficacy of

Date	Educational Component	Aim
May 2016	Research Staff Training	The research staff were oriented on how to deliver the health education package
June 2016	Baseline Survey	
June-July 2016	• Video shown twice • Student questions • 10–15 min classroom discussion	Inform about STH transmission and prevention Repeat key messages and answer students' questions
	• Distribution of pamphlet (comic)	Key messages as take-home message
	• Draw"ing competition	Practice and reinforce new knowledge
	Students draw warning signs for risk areas to warn others about worms.Three best drawings are given awards	
July-August 2016	• Participants received treatment at school (as part of the National Deworming Month program)	
August-September 2016	• Video shown twice again • Student questions • 10–15 min classroom discussion based on student questions	Reinforce knowledge about STH transmission and prevention Repeat key messages and answer students' questions
August-September 2016	• Essay competition	Practice and reinforce new knowledge
	Write story about own actions taken to prevent worm infection	
November 2016-January 2017	First Follow-up Survey	
January-February 2017	Participants received treatment at school (as part of the National Deworming Month program)	
June-July 2017	Second Follow-up Survey	
July-August 2017	Participants received treatment at school (as part of the National Deworming Month program)	

***Table 1*: Details of the implementation of the Magic Glasses health education package targeting STH in the intervention schools**
This table was adapted from Mationg MLS, Williams GM, Tallo VL, Olveda RM, Aung E, Alday P, Reñosa MD, Daga CM, Landicho J, Demonteverde MP, Santos ED, Bravo TA, Angly Bieri FA, Li Y, Clements ACA, Steinmann P, Halton K, Stewart DE, McManus DP, Gray DJ. Determining the Impact of a School-Based Health Education Package for Prevention of Intestinal Worm Infections in the Philippines: Protocol for a Cluster Randomized Intervention Trial JMIR Res Protoc 2020;9(6):e18419. doi: 10.2196/18419 https://www.researchprotocols.org/2020/6/e18419/;

30%. Calculations assumed an infection prevalence of 18%, a design effect of 1.5 to account for the cluster effect, and a predicted annual 10% student loss-to-follow-up. The sample size calculation determined the requirement of 20 clusters for each study group (40 in total), and corresponded to 1,520 study participants (assuming 38 participants per cluster).

Study participants who completed both the KAP questionnaire and provided a stool sample at baseline were included in the fixed cohort for follow-up over the course of the trial. The final analysis sets were restricted to: 1) students with a stool sample tested at baseline and at least one follow-up stool result; and 2) students who completed a KAP questionnaire at baseline and at least one follow-up KAP questionnaire (Figure 2). Descriptive analyses were conducted at each time point to determine participation and the prevalence and intensity of *A. lumbricoides* and *T. trichiura* infection.

The scores for the knowledge, attitude and behaviour components in the KAP questionnaire were calculated as percentages of a total of 31, 7 and 29, respectively; differences between groups are expressed in percentages points. For the intervention assessment, the binary primary outcome was STH infection status at the follow-up surveys, with a positive infection being defined as the presence of *A. lumbricoides* and/or *T. trichiura*. These were analysed using a logistic regression model, to calculate an odds ratio for an estimate of the

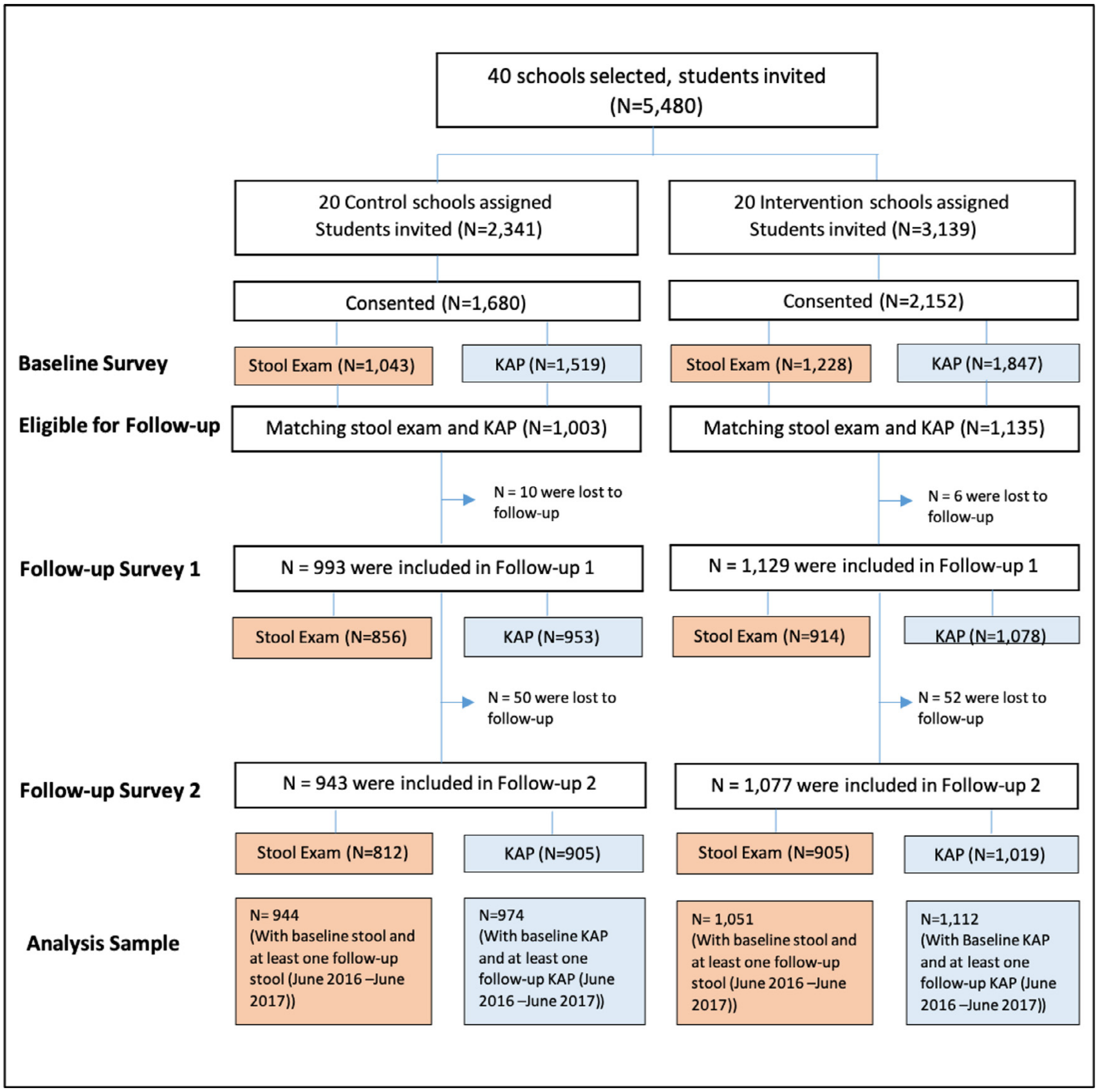

Figure 2. Trial recruitment, follow-up, and retention of study participants.

A spatial sampling frame was used for randomization: schools were randomly selected from the list of schools within three kilometres radius of each other. Twenty schools were randomly assigned to the intervention group and another twenty schools were randomly assigned to the control group. A total of 3,366 students were enrolled in the study, of whom 2,138 with matching stool results and KAP (knowledge, attitudes, and practices) data at baseline were included as a fixed cohort for follow-up over the course of the trial. During the whole study period, 118 students were lost to follow-up, while the number of students who were transferred to other schools from the control and intervention groups were 60 and 56, respectively. Two students in the intervention group were reported deceased during the first follow-up survey.

intervention effect. Data from the KAP questionnaire, including the individual components, were analysed by linear regression. Generalized-estimating-equation (GEE) models were used to take account of clustering within schools and repeated measurements on the same individuals over time. The link function was specified as "logit" for the dichotomised outcome. In addition to allocation group and follow-up time, we included age (as continuous variable), sex and rural/urban status of schools (based on the Philippines Statistical Authority (PSA) rural/urban classification of barangays (villages) where the school was located) as covariates. These variables were adjusted because of their importance as potential confounders.

For STH infection outcomes (i.e., any STH species; *A. lumbricoides* and *T. trichiura*), unadjusted models for follow-ups 1 and 2, and combined time points, used only baseline infection prevalence as a covariate. The adjusted models included age, sex, baseline infection prevalence and rural/urban status of schools. In the assessment of scores for each KAP component, adjusted models for follow-ups 1 and 2 and the combined time points included age, sex and rural/urban status of schools as covariates. In both the unadjusted and adjusted models for follow-ups 1 and 2 and the combined time points, baseline attitude and behaviour scores were included as covariates for attitude and behaviour outcomes. A Spearman test was used to estimate correlations among self-reported behaviour, knowledge and attitude.

A sub-group analysis was undertaken to evaluate the intervention effect separately for schools with ≤ 15% and >15% STH prevalence. This was decided during the data analysis in light of the higher endemicity in the study area compared with the previous study in China, where the prevalence reported was approximately 10%.[20] The 15% prevalence cut-off point used was the median STH baseline prevalence of schools included in the trial. The sub-group analysis was carried out using GEE with the inclusion of an interaction between 'study group' and 'STH prevalence level in school' in the model. A significant p value for the interaction parameter estimate indicated that the intervention effect in the two strata were significantly different.

The proportion of schoolchildren dewormed prior to and after the intervention was further assessed with McNemar's test used to determine the impact of the intervention on deworming uptake in the intervention schools.

Data were entered in duplicate using a customised Microsoft Access database [37]. Electronic copies of all entered data were saved offline and back-up paper duplicates were stored in a locked cabinet at RITM in the Philippines. All data management and analyses used SAS (r) Proprietary Software 9.4 (TS1M3) [Copyright (c) 2002–2012 by SAS Institute Inc., Cary, NC, USA, Licensed to the AUSTRALIAN NATIONAL UNIVERSITY – EAS, Site 10004431].

Role of funding source

The funders of the study had no role in study design, data collection and analysis, interpretation of data, decision to publish, or preparation of the manuscript. All authors had full access to all the data in the study and had the final responsibility to submit for publication.

Results

Participants

Of those who consented (3,832), 2,138 with matching KAP data and who provided at least one stool sample (1,003 in the control group and 1,135 in the intervention group) were included as part of the fixed cohort for study follow-up. Over the course of the trial, 116 students (60 in the control group and 56 in the intervention group) enrolled in the trial were lost to follow-up (LTFU) because of relocation to another school; two students in the intervention group were reported deceased due to natural causes during the first follow-up (total LTFU=118). The numbers of participants whose stool samples were tested and those with KAP data at each follow-up are shown in Figure 2. The final analysis set which included those with a baseline and at least one follow-up stool assessment, comprised 1,995 students (944 in the control group and 1,051 in the intervention group); and those with baseline and at least one follow-up KAP data set, comprised 2,086 students (974 in the control group and 1,112 in the intervention group) (Figure 2). Baseline information for participating children included in the final analysis set collected for the intervention and control groups is presented in Table 2.

Prevalence and intensity of STH infection

Table 3 shows the percentage of students infected with intestinal worms. At baseline, the infection prevalence across the study was 23% (Range: 2–68%, 95% Confidence Interval [CI]: 21·2–24·9) for any STH, 17% (Range: 0–57%, 95% CI: 14·9–18·2) for *A. lumbricoides* and 13% (Range: 0–52%, 95% CI: 11·3–14·2) for *T. trichiura*. We did not find any individuals infected with hookworm.

The prevalence of any STH infection was 20·1% (95% Confidence Interval [CI]: 17·6–22·7) in the control group versus 25·8% (95% CI 23·1–28·4) in the intervention group; the prevalence of *A. lumbricoides* was 14·9% (95%CI: 12·6–17·2) versus 17·9% (15·7–20·3); and the prevalence of *T. trichiura* was 11·1% (95% CI: 9.1–13·1) versus 14·3% (95% CI: 12·2–16·4). There were significant differences in the prevalence of infection at baseline between the control and intervention groups for any STH (p=0·001), *A. lumbricoides* (p=0·039) or *T. trichiura* (p=0·020); between males and females (p=0·022); between age groups 7–9 years and >10 years (p=0·026); and between rural and urban schools (p=0·021). Intensity of infection, assessed as the geometric mean number of eggs per grams of faeces and using the WHO categorization [38], indicated 66% of the positive samples were low-intensity *A. lumbricoides* infections in the control group versus 62% in the intervention group; with *T. trichiura*, 96% and 91% were categorized as low intensity infections in the control and intervention groups, respectively.

After adjustment for baseline STH prevalence, student age and sex, and the rural/urban status of schools, the primary analysis at the first follow-up showed that the health education intervention had no overall effect on infection with any STH (odds ratio [OR] in the intervention schools, 1·0; 95% CI: 0·7–1·4, p=0·984), *A. lumbricoides* (OR:1·2; 95% CI: 0·7–2·0; p=0·558) or *T.*

Characteristics	KAP cohort			Stool cohort		
	Overall(n=2,086) n (%)	Control (n=974) n (%)	Intervention (n=1,112) n (%)	Overall(n=1,955) n (%)	Control(n=944) n (%)	Intervention (n=1,051) n (%)
Sex						
Male	975 (46·7)	461 (47·3)	514 (46·2)	926 (47·4)	442 (46·8)	484 (46·1)
Female	1,111 (53·3)	513 (52·7)	598 (53·8)	1069 (54·7)	502 (53·2)	567 (53·9)
Age group						
Mean (SD*); median	8·9 (0·86); 9·0	8.9 (0.9); 9·0	8·9 (0·9); 9·0	8·9 (0·85); 9·0	8·9 (0·89); 9·0	8·9 (0·81); 9·0
7-9 years	1851 (88·7)	860 (88·3)	991 (89·1)	1776 (90·8)	835 (88·5)	941 (89·5)
>10 years	232 (11·1)	112 (11·5)	120 (10·8)	216 (11·0)	107 (11·3)	109 (10·4)
Missing	3 (0·1)	2 (0·2)	1 (0·1)	3 (0·2)	2 (0·2)	1 (0·1)
Rural/Urban status of school						
Urban	1507 (72·2)	724 (74·3)	783 (70·4)	1439 (73·6)	702 (74·4)	737 (70·1)
Rural	579 (27·8)	250 (25·7)	329 (29·6)	556 (28·4)	242 (25·6)	314 (29·9)

***Table 2*: Baseline characteristics of study participants included in the final analysis set which included those with a baseline and at least one follow-up stool assessment and those with baseline and at least one follow-up KAP data**

*Standard Deviation

Study Outcome	Total no. of students (N)	Control schools		Intervention schools		Odds Ratio, (95% CI)*			
						Crude model [†]		Adjusted model [‡]	
		n	% (95% CI)	n	% (95% CI)	OR (95% CI)	P-value	OR (95% CI)	P-value
Any STH									
Prevalence at baseline	1,995	944	20·1 (17·6—22·7)	1,051	25·8 (23·1—28·4)	1·4 (1·1—1·7)	0·003	1·4 (1·2—1·8)	0·001
% infected at FU1	1,770	856	16·4 (13·8—18·8)	914	19·7 (17·1—22·2)	0·9 (0·6—1·6)	0·823	1·0 (0·7—1·4)	0·984
% infected at FU2	1,717	812	18·8 (16·2—21·5)	905	21·3 (18·6—23·9)	1·0 (0·7—1·4)	0·912	1·0 (0·6—1·3)	0·997
Combined effect (FU1 and FU2)	—	—	—	—	—	1·0 (0·8—1·3)	0·923	1·0 (0·8—1·3)	0·856
Ascaris lumbricoides									
Prevalence at baseline	1,995	944	14·9 (12·6—17·2)	1,051	17·9 (15·7—20.3)	1·3 (0·9—1·6)	0·068	1·3 (1·0—1·6)	0·039
% infected at FU1	1,770	856	10·4 (8·4—12·6)	914	14·0 (11·8—16.3)	1·1 (0·7—1·9)	0·672	1·2 (0·7—2·0)	0·558
% infected at FU2	1,717	812	13·9 (11·5—16·3)	905	15·1 (12·8—17.5)	1·0 (0·6—1·4)	0·735	1·0 (0·6—1·5)	0·828
Combined effect (FU1 and FU2)	—	—	—	—	—	1.1 (0·8—1·4)	0·655	1·0 (0·7—1·6)	0·894
Trichuris trichiura									
Prevalence at baseline	1,995	944	11·1 (9·1—13·1)	1,051	14·3 (12·2—16·4)	1·3 (1·0—1·7)	0·036	1·4 (1·1—1·8)	0·020
% infected at FU1	1,770	856	9·7 (7·7—11·8)	914	11·6 (9·5—13·8)	1·0 (0·6—1·6)	0·994	1·1 (0·7—1·7)	0·783
% infected at FU2	1,717	812	9·5 (7·5—11·5)	905	13·0 (10·8—15·4)	1·3 (0·8—2·1)	0·351	1·3 (0·9—2·0)	0·232
Combined effect (FU1 and FU2)	—	—	—	—	—	1·1 (0·9—1·5)	0·698	1·7 (0·9—1·6)	0·315

***Table 3*: Proportion of STH infections in the control and intervention schools; odds ratios (95% confidence intervals) and *P*-values for intervention effects on any STH, *A. lumbricoides* and *T. trichiura* (primary analysis), derived from logistic regression using generalized-estimating-equation models, Laguna Province, The Philippines, June 2016-June 2017**

* Odds ratios (OR) for the intervention schools as compared with the control schools are shown for the prevalence of infection. CI denotes confidence Interval.

† Values in the baseline model for any STH, *A. lumbricoides* and *T. trichiura* were adjusted for clustering, while values in follow-ups (FU) one, two, and the combined time points models were adjusted for clustering and baseline infection status for any STH, *A. lumbricoides* and *T. trichiura*, respectively.

‡ Values in the baseline model for any STH, *A. lumbricoides* and *T. trichiura* were adjusted for clustering, age group, sex and rural/urban classification of school, while values in the FUs one, two, and the combined time points models were adjusted for clustering, age group, sex, rural/urban status of schools and baseline infection status for any STH, *A. lumbricoides* and *T. trichiura*, respectively.

trichiura (OR:1·1; 95% CI: 0·7–1·7; p=0·783) (Table 3). A similar picture was evident on assessing the intervention effect at follow-up two and the combined effect at both time points. For any STH, the OR in the intervention schools, based on the intervention effects at follow-up two, was 1·0, 95% CI: 0·6–1·3, p=0·997; and 1·0, 95% CI: 0·8–1·3, p=0·856 at the combined time points. For *A. lumbricoides*, the OR in the intervention schools, based on the intervention effects at follow-up 2, was 1·0; 95% CI: 0·6–1·5; p=0·828; and 1·0, 95% CI: 0·7–1·6, p=0·894 at the combined time points. For *T. trichiura*, the OR in the intervention schools, based on the intervention effects at follow-up two, was 1·3; 95% CI: 0·9–2·0; p=0·232 and 1·7; 95% CI: 0·9–1·6; p=0·315 at the combined time points (Table 3).

It is notable that the subgroup analysis indicated a different and significant intervention effect between schools with baseline STH prevalences of ≤15% and >15% (Table 4). The percentage of students infected with any STH was reduced from 9·6% (95% CI: 6·3–12·9) at baseline to 5·3% (95% CI: 2·6–7·9) at the first follow-up in the intervention schools with a STH prevalence of ≤15%. The adjusted OR in these intervention schools, was 0·3 (95% CI: 0·2–0·7; p=0·002, unadjusted OR, 0·4; 95% CI: 0·2–0·8; p=0·006). In contrast, the percentage of students infected in the control schools with a STH prevalence >15%, however, remained unchanged from 10·8% (95% CI: 8·2–13·4) at baseline to 11·1% (95% CI: 8·4–13·8) at first follow-up. The intervention had no apparent effect on the OR of schools with a STH prevalence >15% (adjusted OR: 1·2; 95% CI: 0·9–1·8; p=0·257).

Similarly, at the second follow-up, compared with the baseline prevalence, the percentage of students infected with any STH was lower in the intervention schools with a STH prevalence of ≤15% compared with the control schools. The percentage of students infected with any STH was 12·4% (95% CI: 9·4–15·3) in the control schools and 7·3% (95% CI: 4·2–10·3) in the intervention schools (adjusted OR in the intervention schools, 0·5; 95% CI: 0·3–0·9; p=0·022; unadjusted OR, 0·5; 95% CI: 0·3–0·9; p=0·023). The intervention had no detectable effect on the OR of schools with STH prevalence >15% (adjusted OR: 1·0; 95% CI: 0·7–1·5; p=0·949).

When data from both follow-ups were combined, the health education intervention was shown effective in preventing intestinal worm infection (adjusted OR: 0·4; 95% CI: 0·3–0·7; P=<0·001) in schools with baseline STH prevalence of ≤15%. For schools with baseline STH prevalence >15%, the corresponding OR was 1·1; 95% CI: 0·8–1·5; p=0·459. Interaction tests between baseline prevalence (categorised as ≤15% or >15%) and the percentage of students infected at either follow-up or at both follow-ups showed that the intervention effect differed significantly for the two baseline prevalence groups (Table 4). Similar results were evident after running the models using the individual species (i.e., *A. lumbricoides* and *T. trichiura*) as study outcomes (Supplementary Tables 4 and 5).

Knowledge, attitude, and practices

Overall changes over time in the individual component scores on the KAP questionnaire are shown in Table 5. Regarding the knowledge component, the differences in the adjusted scores between the control and intervention groups increased over time. At baseline, there were no significant differences in the knowledge scores between the intervention and control groups (42·4; 95% CI: 41·4–43·3 vs. 43·2; 95% CI: 42·1–44·3; p=0·237); between children aged 7–9 years and ≥10 years (p=0·569); and between children in rural and urban schools (p=0·544). Baseline knowledge scores, however, differed by sex, with females achieving higher scores than males (44·5; 95% CI: 43·6–45·5 vs. 40·8; 95% CI: 39·7–41·7; p=<0·001). After adjusting for age group, sex, and rural/urban status of schools, the knowledge scores were 5·2 (95% CI: 3·7–6·6; p=<0·001) and 5·4 (95% CI: 4·2–6·8) percentage points higher in the intervention than in the control group at the first and second follow-up surveys, respectively. Similar results were observed in the overall model (assessment of intervention effect at the combined time points); students in the intervention schools scored 5·3 (95% CI: 4·2–6·5) percentage points higher than those from the control schools (56·8; 95% CI: 55·7–57·9 vs 51·5; 95% CI: 50·3–53·7; p=<0·001).

Attitude scores were significantly higher (p=0·001) in the intervention group at baseline. Baseline attitude scores were also significantly higher in females than males (p=0·024) and in students attending urban compared with rural schools (p=<0·001), but were not significantly different by age group (p=0·238). At the first follow-up assessment, the attitude score was significantly higher in the intervention group compared with the control group (63·0; 95% CI: 61·5–64·6 vs. 60·3; 95% CI: 58·6–62·0; p=0·001) after adjustment for covariates. At the second follow-up assessment, the attitude scores, however, remained unchanged in the intervention group (63·2; 95% CI: 61·5–64·8), with higher scores observed in the control group (66·3, 95% CI: 66·5–68·2) (p=0·001). The overall model assessing intervention effects at the combined time points did not show a significant difference between the attitude scores in the intervention and control groups (63·1; 95% CI: 61·9–64·3 vs 63·2; 95% CI: 61·9–64·6; p=0·850).

Reported behaviour scores at baseline were significantly different between the intervention and control groups (p=<0·001). At the first follow-up assessment, there was no significant improvement in the behaviour scores observed in students who received the intervention after covariate adjustments were made (87·3; 95% CI: 86·5–88·1 vs. 86·4; 95% CI: 85·6–87·2; p=0·052).

Variable	Total no. of students (N)	Control schools		Intervention schools		Odds Ratio, (95% CI) *			
						Crude model †		Adjusted model ‡	
		n	% (95% CI)	n	% (95% CI)	OR (95% CI)	P-value	OR (95% CI)	P-value
Any STH									
Prevalence at baseline	1,995	944	20·1 (17·6—22·7)	1,051	25·8 (23·1—28·4)	—	—	—	—
<15%	877	565	10·8 (8·2—13·4)	312	9·6 (6·3—12·9)	0·8 (0·6—1·4)	0·583	0·9 (0·6—1·5)	0·741
>15%	1,118	379	34·0 (29·3—38·8)	739	32·6 (29·2—35·9)	0·9 (0·7—1·2)	0·632	1·0 (0·7—1·2)	0·720
Interaction §						0·9 (0·6—1·6)	0·811	1·0 (0·6—1·7)	0·909
% infected at follow-up 1 (FU1)	1,770	856	16·4 (13·8—18·8)	914	19·7 (17·1—22·2)	—	—	—	—
<15%	780	515	11·1 (8·4—13·8)	265	5·3 (2·6—7·9)	0·4 (0·2—0·8)	0·006	0·3 (0·2—0·7)	0·002
>15%	990	341	24·3 (19·8—28·9)	649	25·6 (22·2—28·9)	1·2 (0·8—1·7)	0·454	1·2 (0·9—1·8)	0·257
Interaction §	—	—	—	—	—	0·3 (0·2—0·7)	0·006	0·3 (0·1—0·6)	0·001
% infected at Follow-up 2 (FU2)	1,717	812	18·8 (16·2—21·5)	905	21·3 (18·6—23·9)	—	—	—	—
<15%	761	486	12·4 (9·4—15·3)	275	7·3 (4·2—10·3)	0·5 (0·3—0·9)	0·023	0·5 (0·3—0·9)	0·022
>15%	956	326	28·5 (23·6—33·4)	630	27·4 (17·8—30·9)	1·0 (0·7—1·4)	0·862	1·0 (0·7—1·5)	0·949
Interaction term §	—	—	—	—	—	0·5 (0·3—1·0)	0·067	0·5 (0·3—1·0)	0·049
Combined effect (FU1 and FU2)	—	—	—	—	—				
<15%	—	—	—	—	—	0·5 (0·3—0·7)	0·002	0·4 (0·3—0·7)	0·001
>15%	—	—	—	—	—	1·1 (0·8—1·4)	0·728	1·1 (0·8—1·5)	0·459
Interaction §	—	—	—	—	—	0·4 (0·2—0·7)	0·004	0·4 (0·2—0·7)	0·001

***Table 4*: Proportion of any STH infections in the control and intervention schools with STH prevalence above and below 15%; odds ratios (95% confidence intervals) and *P*-values for intervention effects on any STH stratified by above or below 15% STH prevalence, derived from logistic regression using generalized-estimating-equation models, Laguna Province, The Philippines, June 2016-June 2017**

* Odds ratios (OR) for the intervention schools as compared with the control schools are shown for the prevalence of infection. CI denotes confidence Interval.

† Values in the baseline model were adjusted for school clustering, while values in follow-up (FU) one, two, and the combined time points models were adjusted for clustering and baseline infection status for any STH.

‡ Values in the baseline model were adjusted for school clustering, age group, sex and rural urban classification of school, while values in FUs one, two, and the combined time point models were adjusted for clustering, age group, sex, rural/urban status of schools and baseline infection status for any STH.

§ Interaction term is the ratio of the effect odds ratio for schools with <15% STH prevalence to the effect odds ratio for schools >15% STH prevalence.

Variable	No. of students	Control schools		Intervention schools		Intervention effect; Intervention vs. Control (95% CI) *			
						Crude model†		Adjusted model ‡	
		n	Mean score (95% CI)	n	Mean score (95% CI)	Mean difference (95% CI)	P-value	Mean difference (95% CI)	P-value
Knowledge score									
Baseline	2,086	974	43·2 (42·1—44·3)	1,112	42·4 (41·4—43·3)	-0·7 (-2·1—0·7)	0·295	-0·8 (-2·2—0·6)	0·237
Follow-up 1	2,031	953	49·4 (48·1—50·8)	1,078	54·6 (53·2—55·9)	5·4 (4·0—6·9)	<0·001	5·2 (3·7—6·6)	<0·001
Follow-up 2	1,924	905	53·9 (53·6—55·2)	1,019	59·4 (58·1—60·6)	5·6 (4·3—6·9)	<0·001	5·4 (4·2—6·8)	<0·001
Combined effect FU1 and FU2	—	—	51·5 (50·3—53·7)		56·8 (55·7—57·9)	5·5 (4·3—6·7)	<0·001	5·3 (4·2—6·5)	<0·001
Attitude score									
Baseline	2,086	974	57·5 (55·6—59·4)	1,112	61·0 (59·3—62·8)	3·3 (1·4—5·3)	0·001	3·5 (1·6—5·5)	0·003
Follow-up 1	2,031	953	60·3 (58·6—62·0)	1,078	63·0 (61·5—64·6)	2·8 (1·2—4·5)	0·005	2·7 (1·1—4·4)	0·001
Follow-up 2	1,924	905	66·3 (64·5—68·2)	1,019	63·2 (61·5—64·8)	-3·2 (-4·9 to -1·5)	0·001	-3·1 (-4·9 to -1·4)	0·001
Combined effect FU1 and FU2	—	—	63·2 (61·9—64·6)	—	63·1 (61·9—64·3)	-0·1 (-1·4—1·2)	0·858	-0·1 (-1·4—1·2)	0·849
Behaviour score									
Baseline §	2,084	973	82·2 (81·0—83·3)	1,111	84·5 (83·3—85·6)	2·3 (1·2—3·4)	<0·001	2·3 (1·1—3·4)	<0·001
Follow-up 1	2,031	953	86·4 (85·6—87·2)	1,078	87·3 (86·5—88·1)	0·8 (-0·02—1·6)	0·057	0·8 (-0·01—1·6)	0·052
Follow-up 2	1,924	905	85·9 (84·9—86·8)	1,019	87·1 (86·3—87·9)	1·2 (0·4—1·9)	0·005	1·3 (0·4—2·0)	0·003
Combined effect FU1 and FU2	—	—	86·1 (85·4—86·8)	—	87·2 (86·6—87·9)	1·1 (0·4—1·7)	0·002	1·1 (0·4—1·7)	0·002

***Table 5*: Differences in scores of knowledge, attitude and practices (KAP) questionnaire in the control and intervention schools, Laguna Province, The Philippines, June 2016—June 2017**

* Scores on the KAP questionnaire were calculated as percentages of a total points for Knowledge, n=31; Attitude, n=7; and Behaviour, n=29); the scores shown are mean scores. Differences between the groups are expressed as percentage points.

† The intervention effect is the difference in model-based estimated scores, accounting for clustering. Values in follow-ups (FU) one, two, and the combined time points models for the overall KAP score, attitude score and behaviour score were adjusted for baseline overall KAP score, attitude score and behaviour score, respectively.

‡ The adjusted values for baseline models in the overall KAP score and individual KAP component score were adjusted for age group, sex, and rural/urban status of schools. Models for the follow-ups one, two and the combined time points for overall KAP score, attitude score and behaviour score were adjusted for age group, sex, rural/urban status of schools and baseline overall KAP score, attitude score and behaviour score, respectively. For knowledge score, models for follow-ups one, two, and combined time points were adjusted for age group, sex, and rural/urban status of schools only.

§ Two students had missing behaviour scores (one student in intervention schools and one student in control schools) at baseline.

In the second follow-up assessment, a 1·3 percentage points increase was observed among students in the intervention group compared with the control group (87·1; 95% CI: 86·3–87·9 vs. 85·9; 95% CI: 84·9–86·8; p=0·003) after adjustment of the same covariates. Overall, the model for the intervention effects at the combined time points showed a statistically significant modest increase in the behaviour scores among students in the intervention compared with the control group (87·2; 95% CI: 86·6–87·9 vs. 86·1; 95% CI: 85·4–86·8; p=0·002).

Correlations between the different domains of the KAP questionnaire revealed significant positive correlations between knowledge and attitude scores (Spearman rank-correlation coefficient rho (r)=0·207, p=<0·001 at follow-up one and r=0·151, p=<0·001 at follow-up two); knowledge and behaviour scores (r=0·186, p=<0·001 at follow-up one and r= 0·168, p= <0·001 at follow-up two); and attitude and behaviour scores (r=0·118, p=<0·001 at follow-up one and r=0·087, p=<0·001 at follow-up two).

Deworming coverage

At baseline, 77% of students in the control group and 75% of those in the intervention group were dewormed (p=0·098). The rate of deworming increased by 7% in the intervention group at the first follow-up assessment, following the delivery of the intervention (McNemar's test statistics=10·5; p=0·001); while in the control group, there was a 4% increase (not statistically significant, McNemar's test statistics=2·5; p=0·114) (Supplementary Table 6).

Discussion

This cluster-randomised controlled trial demonstrated that the "Magic Glasses Philippines" health education package had no overall effect in preventing STH infections among Filipino schoolchildren after 10 months' follow-up. This lack of effect may have been due to a high level of STH egg contamination in this environmental setting driving infection risk [39] given *A. lumbricoides* and *T. trichiura* can produce considerable numbers of ova that can remain viable in the soil for several months under favourable conditions [40]. It is noteworthy that the baseline prevalence for any STH was higher and so there was a greater force of infection in the Philippines study setting compared with our earlier China Magic Glasses intervention trial where the baseline prevalence was ~10% [20]. As in the Chinese trial [20], the Magic Glasses package did improve knowledge and behaviour among schoolchildren who received the health education intervention, but this improved hygiene practice did not result in fewer infections overall. However, the subgroup analysis showed that the "Magic Glasses Philippines" was indeed effective in preventing STH infections in intervention schools where the baseline prevalence did not exceed 15%. This suggests that the impact of the health intervention on worm infections was mediated by STH prevalence at baseline or the force of STH infection driving contamination of the environment with parasite eggs leading to an increased risk of infection within the Philippines study area. These findings are in concordance with those of the Chinese Magic Glasses trial where the health educational package reduced the infection rate in students within one school year when the baseline prevalence was approximately 10% [20].

Another important finding was the significantly increased deworming uptake in the intervention schools at the first follow-up after the delivery of the health educational package, an outcome that could synergize with the current national school-based deworming program in the Philippines, given recent reports of declining MDA coverage due to fear of treatment and side-effects, and poor communication within the national MDA program [30,41,42].

The strengths of this study include the rigorous study design, large sample size, the high response and follow-up rates and statistical adjustments for school clustering, repeated measures and potential confounders. Given direct observation of the school children's behaviour (particularly relating to handwashing) was not logistically feasible, a possible limitation was the self-reporting of STH-associated hygiene behaviour which may have been overestimated; this in turn may have introduced a measurement error [43], considering this method relies on a participant's level of understanding, transparency and memory. However, the reliability and validity of self-reporting among children aged >8 years have been shown to be good in health-related questionnaires [44,45]. Another potential limitation was the use of the Kato-Katz procedure in the detection of STH infections, especially in low prevalence and low intensity settings. Recent studies have shown that whereas this method is reliable for *A. lumbricoides* and *T. trichiura* diagnosis, it is less sensitive for diagnosing hookworm infection, particularly when faecal slides are not prepared and read rapidly [46,47]. The absence of hookworm infections in the present study was unsurprising considering the low hookworm prevalence (6.8%) determined by a more highly sensitive qPCR assay in Laguna province previously reported [32].

The positive effect of the Magic Glasses intervention package in preventing STH infections in schools with an endemic prevalence ≤ 15% implies that in low transmission areas (with prevalence 15% or less), health education and MDA can reduce infection levels whereas MDA alone will not. However, in areas with higher prevalence, the health educational package plus additional measures such as increased levels of MDA coverage and improved water and sanitation infrastructure and services will be necessary. These findings are in line with the current WHO guidelines for the community control of soil-transmitted helminthiases [6].

The trial outcomes provide added support to the concept that the Magic Glasses health education package is applicable to different geographical settings. Maximising its effectiveness will necessitate that it is delivered in a culturally appropriate and acceptable manner. The early and consistent involvement of the community, health education officials, health workers, teachers, parents and schoolchildren was key in the development of the health education package through rigorous assessment of the risk factors and the knowledge, attitudes and practices associated with soil-transmitted helminthiases [20,31].

Despite the inclusion of correct hygiene and sanitation practices into the Philippines DepEd's Policy and Guidelines for the Comprehensive Water, Sanitation, and Hygiene in Schools (WinS) Program in the elementary school curriculum [35], there is still inadequate recognition of the public health significance and community problem of STH. The sensitive cultural adaptation of the Magic Glasses cartoon video lends considerable support for integration of such a health education package into the school curriculum and/or the WinS program [35]; and into the ongoing national deworming program in the Philippines, thereby complementing the current approach for the control of STH infections in school-age children advocated by the WHO [6]. The application of health education to increase knowledge of STH and the benefits of MDA could increase treatment acceptance, clarify misconceptions and advance MDA implementation in schoolchildren. Accordingly, the Magic Glasses could be readily incorporated into the Philippines national program for soil-transmitted helminthiasis control; in areas with >15% prevalence, additional WASH measures will be required to augment MDA and the video based health education intervention. The school-based health education package is also appropriate for consideration as a scalable approach to mitigate infection risk both in ongoing and future deworming programs in endemic regions with appropriate level of infrastructure to deliver the "Magic Glasses" intervention.

Contributors

DJG, DPM, GMW designed the study. All authors contributed to the trial operations. MLM, DJG, VLT, RO, FAAB, EA, PA, MDR, CMD, JL, MPD, EDS, and TAB, undertook the fieldwork. MLM and GMW undertook the analyses. MLM wrote the first draft of manuscript. All authors contributed to the drafting of the manuscript.

Declaration of Competing Interest

All authors declare no competing interests.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.lanwpc.2021.100312.

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