# Examining the acceptability and impact of a school-based helminth prevention educational package in the Lower Mekong Basin: Study protocol of a cluster-randomized control trial

Helminthiases, diseases caused by parasitic worms, are a major global public health concern, with one of the highest burdens found Southeast Asia (Wright et al., 2018). In Southeast Asia, and the Mekong region in particular, helminthiases are most commonly caused by soil-transmitted helminths (STH) –including Ascaris lumbricoides, Trichuris trichiura and hookworm– and Opisthorchis viverrini (OV), a fish-borne liver fluke (Kaewpitoon et al., 2015). Helminthiases are associated with physical and cognitive deficiencies, including stunting, malnutrition, anemia, and chronic pain (King, 2019). Chronic OV infection can also lead to cancers of the bile duct and bladder, classifying Opisthorchiasis as a biological carcinogen (Brindley PJ, 2015). Helminthiases can also have impacts beyond health, with chronic infections often inhibiting education attainment and economic growth, thereby affecting broader socioeconomic development (Weatherhead et al., 2017, World Health Organization, 2011). This is particularly pertinent given that low and middle income settings face a disproportionate burden of helminth infections (World Health Organization, 2022c, Utzinger et al., 2010, Ojja et al., 2018).

Helminth infection is a major public health issue in the Lower Mekong Basin (LMB), a region encompassing Northeast Thailand, Lao PDR, and Cambodia. WHO considers STH a public-health problem when more than 1% of at-risk populations have infections of moderate or high intensity (World Health Organization, 2012), although other studies have found light-moderate infections can also lead to major health impacts such as anemia (Ezeamama et al., 2005, Gyorkos and Gilbert, 2014, Brooker et al., 2008). Reported prevalence of STH infections has reached 31% (Adisakwattana et al., 2020), 70% (Hotez, 2009), and 71% (Conlan et al., 2012) in Thailand, Cambodia, and Lao PDR respectively. STH is transmitted via ingestion of egg-infested soil; this typically occurs via consumption of unwashed fruit, vegetables or contaminated water (World Health Organization, 2022d). Children may also play in contaminated soil, which can increase the risk of soil ingestion if children do not wash their hands before eating (World Health Organization, 2022d). LMB also has a high burden of OV, a foodborne trematode that is a biological carcinogen for bile duct cancer, cholangiocarcinoma (Fürst et al., 2012, Pullan et al., 2014). Humans become infected from ingestion of raw or fermented freshwater fish, a reservoir host for OV (Vonghachack et al., 2017). OV is estimated to affect at least 10 million people in the Lower Mekong Basin, the highest reported burden globally (Ziegler et al., 2013, Sripa et al., 2011).

The primary control strategy for STH and OV infection is mass drug administration (MDA). For STH, the World Health Organization (WHO) advocates periodic MDA for at-risk groups, such as preschool-aged children (2-4 years; PSAC) and school-aged children (5-12 years; SAC) using albendazole or mebendazole; to control OV, MDA for high burden groups using praziquantel is the recommended treatment (World Health Organization, 2022d, World Health Organization, 2022a).

However, while MDA is effective in treating helminthiases, it does not prevent reinfection. Moreover, there is increasing concern around the relationship between MDA and anthelmintic resistance. Anthelmintic resistance refers to nematodes’ decreased sensitivity to anthelmintics, allowing them to survive previously lethal treatment (Nipane et al., 2008). Several studies have implicated MDA in accelerating AR in livestock and other domestic animals (Kelleher et al., 2020, Fissiha and Kinde, 2021, Werkman et al., 2020), and there are growing calls to address this risk in humans (Tinkler, 2020, Vlaminck et al., 2018). In light of this, alternative STH and OV control methods such as water, sanitation, and hygiene (WASH) promotion and health education are needed.

Children are an important target group for helminth prevention and control strategies. Children are particularly vulnerable to STH infection (World Health Organization, 2012); several studies have reported high incidence of STH among PSAC and SAC, often with high infection intensity (Weatherhead et al., 2017, Ojja et al., 2018, González Quiroz et al., 2020, Mationg et al., 2021). In LMB specifically, Kaewpitoon et al. (2015) found that the overall helminth prevalence was 11.88% among SAC in 2015, however in some areas prevalence was as high as 16.08% (Kaewpitoon et al., 2015). SAC are also a well-placed group for intervention delivery, as schools are institutions trusted by children and their families, and can facilitate delivery to a large population, as recognized in WHO’s Global School Health Initiative (World Health Organization, 2022b). As such, schools play an important role in health promotion, education and intervention delivery (World Health Organization, 2022b).

In recent years, there has been a growing emphasis on the importance of acceptability in intervention success (Dwipayanti et al., 2017, Sekhon et al., 2017). Several studies have identified acceptability as a key indicator for initial and sustained use of a WASH intervention, although there remains a lack of consistency among acceptability measures and definitions employed in public health research (Dwipayanti et al., 2017, Sekhon et al., 2017, Heitzinger et al., 2020, Hussain et al., 2017, Sultana et al., 2018). In the absence of an existing definition and measure of acceptability, Hosking et al. (2022) advocated the use of The Theoretical Framework of Acceptability (TFA) (Sekhon et al., 2017). The TFA was developed to assess acceptability in healthcare interventions, and outlines seven component constructs of acceptability: “affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy”, and defines acceptability as “a multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention” (Sekhon et al., 2017).

## Magic Glasses

“Magic Glasses” is a school-based health educational package that was originally developed to reduce STH burden among schoolchildren in China in 2009-2011 (Bieri et al., 2013). The primary component of this package was a ~12-minute cartoon, “Magic Glasses”, which described transmission, symptoms, treatment and prevention of STH through the lens of Chinese schoolchildren. The original “Magic Glasses” led to a 50% decrease in STH incidence among intervention schools (OR 0.5, 95% CI 0.35-0.70, *p*<.0001). In 2016-2017, the “Magic Glasses” educational package was adapted for the Philippines, a region with estimated 33% STH prevalence (Mationg et al., 2022). “Magic Glasses: Philippines” led to a 60% reduction in the odds of any STH infection in intervention schools with a baseline prevalence <15% (aOR 0.4, 95% CI 0.20,0.70, *p*<.001) (Mationg et al., 2022).

For the LMB intervention, two versions of “Magic Glasses” will be developed: (1) “Magic Glasses: Lower Mekong”, an educational cartoon addressing STH infection, including transmission, symptoms, treatment and prevention, adapted from previous MG cartoons, and (2) “Magic Glasses: Opisthorchiasis”, an educational cartoon addressing OV infection, including transmission, symptoms, treatment and prevention. In addition, this study will assess the acceptability of the “Magic Glasses” intervention.

## Methods

### Study design

Our overarching hypothesis is that a school-based educational package targeting helminths will be acceptable to schoolchildren and their teachers, and that this educational package will increase students' knowledge of transmission, symptoms, treatment, and prevention of helminths, and increase healthy hygiene attitudes and behaviour.

We will test this hypothesis by conducting a matched cluster-randomized controlled trial, targeting schoolchildren in Years 4-6 in four randomly selected schools in each country. This trial is a sub-project of the ‘Helminth Elimination in the Lower Mekong’ project (HELM Project) aimed at reducing the burden of STH and OV in the Lower Mekong Basin.

Two schools in each country will be assigned to the *intervention* arm, in which the Magic Glasses health package, consisting of “Magic Glasses Lower Mekong (MGLM), a cartoon on transmission, symptoms, treatment, and prevention of STH”, and “Magic Glasses Opisthorchiasis” (MGO) and acceptability assessment will be delivered. The remaining two schools in each country will comprise the *control* arm of the study, and will receive the standard health education activities in accordance with local government guidelines.

### Study Setting

The trial will be conducted in Chonnabot district, Thailand; Preah Vihear province, Cambodia; and Savannakhet province, Lao PDR. To minimize the risk of contamination, all included schools will be at least three kilometres apart.

### Ethics Approval and Consent to Participate

The study protocol was submitted to and received ethical approval from the Australian National University Human Ethics Committee (approval number 2022/507), the Cambodia Ministry of Health National Ethics Committee for Health Research, the Lao PDR Ministry of Health National Ethics Committee for Health Research, and Khon Kaen University Ethics Committee for Human Research (record number 4.2.03:16/2565). Permission will be sought from the Department of Education in Cambodia, Thailand, and Lao PDR, and from the principals of all included schools prior to study commencement. Once schools have been identified and approved, parents or legal guardians of prospective participants will receive an information sheet outlining the procedure and purpose of the study and contact information, and a consent form (see attachments). Once informed consent is obtained, the study will be explained to prospective participants (schoolchildren) and their assent will be sought (see attachments).

**Follow-up Survey**

KAP Questionnaire

Figure 1. Trial Profile.

**-T‑**

**T0**

**T1**

**T2.1**

**T2.2**

**T3**

**Sentinel Cohort** (n=342)

**Sentinel Cohort** (n=342)

**Randomize within pairs**

**Control**

9 schools

**Intervention**

9 schools

**Select 18 schools, pair-matched (3 pairs per country)**

**Baseline Survey**

KAP Questionnaire

**Follow-up Survey**

KAP Questionnaire, acceptability FGDs, KIIs

**MGLM + MGO Screening 1**

Acceptability Questionnaire, FGDs, KIIs

**MGLM + MGO Screening 2**

### Confidentiality

All quantitative data will be collected on paper questionnaires, and will be de-identified prior to analyses. Qualitative data (KIIs, FGDs) will be recorded using audiotapes

## Intervention: Magic Glasses Lower Mekong and Magic Glasses Opisthorchiasis

The Magic Glasses health package will be comprised of two educational cartoons: MGLM, targeting STH, and MGO targeting OV. This will be supplemented with a comic pamphlet for each cartoon with key messages. MGLM and MGO have been developed for the Lower Mekong setting, informed by the previous “Magic Glasses” cartoons (Mationg et al., 2022, Bieri et al., 2013) and formative research.

### Formative research

The formative research was conducted in October to December 2021. Due to the COVID-19 pandemic, the measures used in previous “Magic Glasses” formative research (e.g., surveying schoolchildren on knowledge, attitudes, and practices (KAP); field observation and interviews) were not possible. As such, formative research for MGLM and MGO consisted of a desk review exploring (1) KAP and risk factors relating to STH (see attachments), and (2) KAP and risk factors relating to OV in Southeast Asia (see attachments).

### Production of the cartoons

The findings from the desk review in conjunction with “Magic Glasses” and “Magic Glasses Philippines” were used to develop the scripts for MGLM and MGO. Development of the scripts for MGLM and MGO took place from Cartoon development took place from March 2022 to August 2022. In line with previous “Magic Glasses”, the health messages of the cartoon were informed by developmental psychology theories including the Theory of Planned Behaviour (Ajzen, 1991), and Social Cognitive Theory (Schunk, 2012) to ensure they were engaging and effective. In order to ensure the cartoon style and backgrounds are relevant to SEA audience, the cartoons will be produced by a Thai animation company in Khon Kaen. Backgrounds and uniform details will be adapted to Cambodia and Lao PDR based on local expertise. Once cartoon production is complete, the audio for the videos will be recorded by voice actors in Khmer, Thai, and Lao.

### Pilot testing

Beta versions of MGLM and MGO will undergo pilot testing in one rural school and one urban school in each country in the Lower Mekong region, outside the main trial areas. MGLM and MGO will be presented to schoolchildren in Years 4-6, parents and teachers. Approximately 50 children per school will be recruited to complete the questionnaires (~20 per year). The cartoons will be delivered to schoolchildren and teachers in their classroom. The cartoons will be delivered to parents in a separate room at the school. Prior to commencing the pilot testing, consent and assent will be sought from prospective participants (see attachments).

Immediately following MGLM screening, schoolchildren in Years 4-6 will complete a an adapted acceptability questionnaire on the MGLM. Following acceptability questionnaire completion, a brief classroom discussion will be held to discuss impressions of the cartoon. Separate focus group discussions (FGD) will be then be conducted with 3-5 schoolchildren in each year to discuss comprehension and acceptability of the cartoon (see attachments). Feedback will also be sought from parents and teachers; one FGD will be held with 3-5 parents at each pilot school to review messaging, video, and audio content of MGLM and perceived acceptability. One teacher will be interviewed (KII) to review messaging, video, and audio content of the MGLM and perceived acceptability (see attachments). The same procedure will be followed for the MGO cartoon. It is estimated that pilot testing will take approximately 1-4 days in total, depending on availability of field workers for pilot testing administration.

To minimize confusion between the health messages for STH and OV, MGLM and accompanying assessments, and MGO and accompanying assessments will be delivered at separate times (e.g. MGLM in the morning, and MGO in the afternoon, or over consecutive days).

The content and style of MGLM and MGO will then be adapted in accordance with pilot feedback.

### Baseline and Intervention Delivery

Study commencement will be staggered across Thailand, Cambodia and Lao PDR, in order to align with the start of the school year in each country (see Figure 2). As such, the trial will be treated as independent in each country throughout the data collection period.

Figure 2. Anticipated study dates.

|  |  |
| --- | --- |
|  | Country  |
|  | Thailand | Cambodia | Lao PDR |
| Pilot testing | May 2023 | May 2023 | July 2023  |
| Baseline and intervention delivery  | June 2023 | June 2023 | August 2023 |
| Follow-up | February 2024 | March 2024 | June 2024 |

### Knowledge, attitudes and practices

At the start of the school year, all consenting participants in Years 4-6 at control and intervention schools will complete two questionnaires to ascertain baseline knowledge of STH and OV. The first questionnaire will include questions on demographic information and students’ knowledge of STH, including general knowledge, transmission, symptoms and treatment; attitudes and health education, and behavior. The second questionnaire will follow the same format to assess students’ knowledge of OV. To minimize confusion between the two infections, baseline questionnaires for STH and OV will be administered a week apart.

All children who completed the questionnaires at baseline will be recruited for follow-up at the end of the school year (~9 months after baseline). The baseline and follow-up questionnaires will employ the same study measurements and standard operating procedures (see attachments). The trial study design is shown in Figure 1.

### Intervention and acceptability assessment

Following STH baseline assessment, the MGLM intervention will be administered. MGLM will be presented to all schoolchildren and teachers at intervention schools (MGLM delivery 1). All students will also receive a comic summarizing the key messages of MGLM.

Immediately following the MGLM showing an acceptability questionnaire will be administered to all consenting students in Years 4-6 to assess acceptability of the cartoon. The questionnaire will contain questions adapted from TFA (Sekhon et al., 2017) to include age-appropriate language for the schoolchildren, and specific questions on STH. Following questionnaire completion, approximately five students in Years 4-6 at each intervention school will be asked to participate in a FGD to further examine acceptability of the MGLM cartoon (see attachments). KIIs will also be held with one teacher at each intervention school (from a non-science background where possible) to discuss perceived acceptability of the cartoons among the schoolchildren (see attachments).

Six to eight weeks after the first presentation of MGLM, the cartoon will be shown to the school audience again to reinforce the health messages of the cartoon (MGLM delivery 2).

Delivery of MGO and the associated acceptability assessment (see attachments) will commence on the same or following day (depending on school size) that the OV baseline questionnaire is completed (MGO delivery 1), and follow the same procedure delivery as used for MGLM.

 Six to eight weeks after the first presentation of MGO, the cartoon will be shown to the school audience again to reinforce the health messages of the cartoon ((MGO delivery 2).

All children who completed the acceptability questionnaires will be recruited for follow-up. FGDs will be held with schoolchildren in Years 4-6 to discuss the acceptability and effectiveness of the cartoons (see attachments). KIIs will be held with teachers (from a non-science background where possible) to discuss perceived acceptability and impact of the cartoons among the schoolchildren (see attachments).

## Outcome measures

The primary outcomes of the study are acceptability of the MGLM and MGO, and changes in knowledge of STH and OV, and their transmission, symptoms, treatment and prevention. The secondary outcomes are changes in self-reported attitudes and behavior (handwashing, food hygiene, toilet use, raw and fermented fish consumption). Control and intervention outcomes will be compared across countries, and between countries.

## Selection of schools

### Power calculation

Sample size was calculated to retain 80% power, assuming baseline knowledge of 30 percentage points (as reported in the original Magic Glasses study by Bieri et al. 2013) and a design effect of 2 to account for cluster sampling. Accounting for 10% attrition, it was estimated that a total of 227 participants would be needed to detect a difference of 5 percentage points in knowledge between intervention and control groups. As such, we will enroll a total of 228 schoolchildren in Years 4-6 (114 intervention, 114 control) in each country.

Six schools will be selected in each trial area, in consultation with the Department of Education in each respective country. All schools identified for this study will be outside the main HELM trial study sites. Once prospective sites have been identified, permission to conduct the study will be sought from the Principal of each selected schools. Following approval, schools within each country will be randomly allocated to control or intervention. Students in Years 4 and 5 will receive the information sheets and consent forms to provide to their parents or guardians. Once consent is obtained, students will also be provided with assent forms and information sheets for them to complete.

## Data Analyses

### Quantitative

Descriptive statistics will be computed to ascertain variable distributions.

Normality of distribution will be checked using the Shapiro-Wilk test, with significance set to *p*<.05 (2-sided).

In acceptability analyses, negatively worded statements will be reverse scored to align the direction of the scale. Spearman’s correlation coefficient will be used to assess criterion validity among different questionnaire items. Exploratory factor analysis with oblique rotation will then be performed to assess construct validity.

Changes in knowledge, attitudes, and self-reported behavior scores will be analyzed using a multiple linear regression model. Analysis will also assess differences in KAP between control and intervention schools at baseline and follow up Potential confounders such as age and sex will be incorporated. Spearman’s correlation coefficient will be used to estimate correlations among acceptability, knowledge, and self-reported behavior. Chi-square tests will also be used to measure associations between KAP and acceptability.

### Qualitative

Thematic analysis will be undertaken to determine the major categories in the qualitative data (KAP and acceptability FGDs and KIIs), in-line with Braun and Clarke’s approach(Braun and Clarke, 2006). Recordings will be transcribed vertabim by hand, and then translated to English. Once transcribed, an inductive approach will be employed to analysis the recordings of FGDs and KIIs. Codes will be generated as part of the initial review process, and entered into a standardized extraction table. Coded data will then be examined for key themes. Themes will be then be organized using thematic maps to identify key and shared concepts across themes. Once organized, themes will be reviewed and defined, and key extracts identified. Acceptability and KAP qualitative data will first be examined separately, and then reviewed together to identify shared themes.

All statistical analyses will be performed using IBM SPSS, Stata or SAS. Microsoft Excel will be used for qualitative data tables.

## Study outcomes

The expected outcomes are an understanding of the initial and sustained acceptability of the Magic Glasses cartoon, and a measurement of the effect of the Magic Glasses education package on improvements in KAP associated with STH and OV. As demonstrated by previous "Magic Glasses" interventions, these outcomes will promote healthy WASH knowledge and practices among schoolchildren in the Lower Mekong Basin.

## Strategies for limiting COVID-19 impacts on the study

This study requires face-to-face group interventions in order to be effective, however this also increases the risk of COVID-19 impacts on the sample population, and research staff, such as in the case of a COVID-19 outbreak in the trial area. Researchers considered an online delivery of the intervention, however as the project will take place in a resource-poor setting, this is not feasible. In order to minimize the risk of COVID-19 transmission, all research staff will wear appropriate personal protective equipment (e.g. face masks) and maintain hand hygiene. In the case of a COVID-19 outbreak, all research staff will adhere to local government guidelines.

## Discussion

MDA is the primary strategy to control STH and OV in high-burden regions, however this approach is limited by the need for recurring treatment to maintain protection (World Health Organization, 2022d, World Health Organization, 2022a), and the growing anthelmintic resistance (Kelleher et al., 2020, Fissiha and Kinde, 2021, Werkman et al., 2020). Previous “Magic Glasses” have demonstrated the effectiveness of a school-based educational cartoon in improving KAP among schoolchildren in China and Philippines, and reducing the STH burden (Mationg et al., 2022, Bieri et al., 2013). “Magic Glasses Philippines” demonstrated the generalizability of “Magic Glasses” to other regions with endemic infectious diseases (Mationg et al., 2022). “Magic Glasses” LMB health package will assess the translatability of “Magic Glasses” to other infectious diseases with different methods of transmission and prevention. In addition, this will be the first study to formally assess the acceptability of “Magic Glasses” intervention. It is hoped that this study will provide further support for “Magic Glasses”, and its role as a novel, engaging and cost-effective intervention in reducing the burden of STH and other infectious diseases.

## Attachments

* Desk review – OV
* Desk review – STH
* Acceptability forms (qualitative) – schoolchildren
* Acceptability forms (quantitative) – schoolchildren, teachers
* KAP questionnaire forms – schoolchildren
* Assent form – schoolchildren
* FGD guide – schoolchildren
* Informed consent form – parents
* Informed consent form – teachers
* KII guide – teachers
* Participant information sheet – parents
* Participant information sheet – teachers
* Pilot test forms – teachers, parents, schoolchildren
* Pilot test participant information sheet – parents
* Pilot test participant information sheet – schoolchildren

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