

Reinfection rates of soil-transmitted helminth infections among school aged-children following a single or a 4- monthly health hygiene education: an open label clinical trial



Study Protocol

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BACKGROUND

Soil-transmitted helminth (STH) infections (*Ascaris lumbricoides*, *Trichuris trichiura*, and hookworm) are important neglected tropical diseases.¹ It is widely spread in tropical and subtropical regions with an estimation of 1.5 millions individuals affected in 2018. This infection occurs in 267 millions pre-school children and 568 millions of school-aged children.² In Indonesia, the prevalence of STH ranges from 45 to 65%, and in poor sanitation areas the prevalence increases to 80%.^{3,4}

Several factors have been associated with the high prevalence of helminthiasis including poor personal hygiene such as handwashing habit, access to good sanitation, and water availability.⁵ Ideal disease prevention and control measures should include those aforementioned, nevertheless without good education those interventions may cause recurrent infections.⁶

The primary aim of this study is to evaluate the effectiveness of video health hygiene education on STH reinfection rates among school-aged children. The secondary objectives of this study include:

1. To determine the prevalence of STH infections among school-aged children prior to intervention
2. To evaluate the knowledge of STH prevention measures among school-aged children before and after intervention

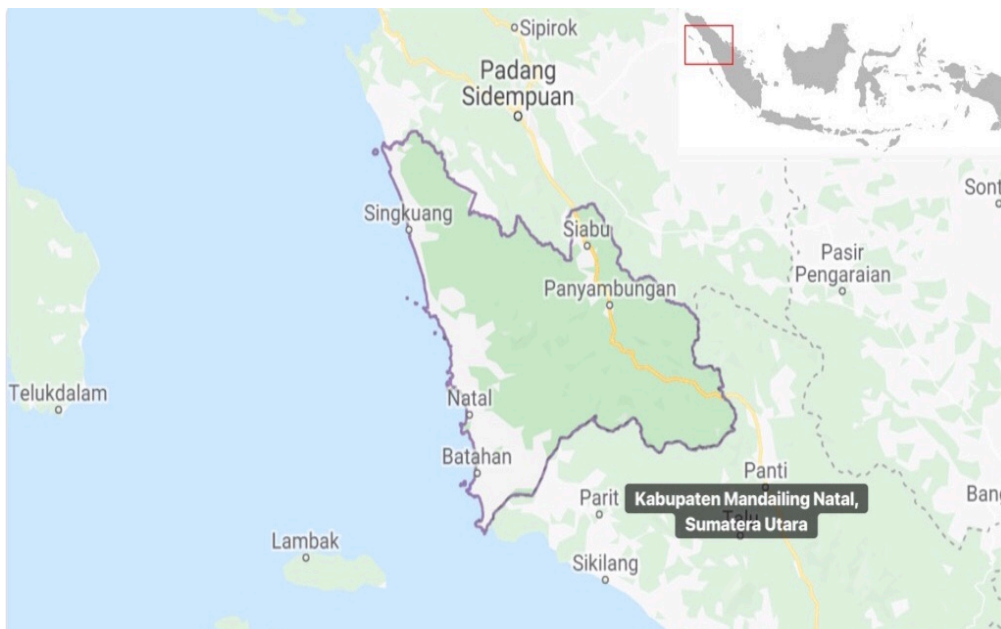
METHODS

Study Design

This is an open label clinical trial comparing the effectiveness of single and repeated video health hygiene education among school-aged children.

Plate and Time

The study is done in Singkuang Elementary School and Sikapas Elementary School in Mandailing Natal district, North Sumatera province, Indonesia from March 2019 to March 2020.



Gambar 1. Mandailing Natal district of North Sumatera province, Indonesia

Subjects

Subjects are children who have negative results on Kato Katz examination after receiving 400 mg of albendazole for 3 days.

Sample size

The sample size of this study was calculated using the following formula:

$$n1 = n2 = \frac{(Z\alpha\sqrt{2PQ} + Z\beta\sqrt{P1Q1 + P2Q2})^2}{(P1 - P2)^2}$$

dimana:

n1 : sample size for study arm with intervention

n2 : sample size for study arm without intervention

Z α : 95% significant value = 1,96

Z β : 80% power = 0.842

P1 : Significant differences, 0,62

P2 : STH prevalence 0.75

Q1 : 1-P1 = 0.38

Q2 : 1-P2 = 0.25

P : $\frac{1}{2}$ (P1+P2) = 0.69

Q : 1-P = 0.31

According to above formula, the minimum sample size for each arm with 10% add is 216 children.

Inclusion criteria

1. Student with negative result on Kato Katz examination after receiving 400 mg of albendazole for 3 days

Exclusion criteria

1. Parents who did not give consent
2. Severe malnutrition
3. Co-infected with other helminth infections

Ethics

Parents or guardians will receive a participant information sheet and an informed consent form in Bahasa Indonesia. This study has been approved by the Health Ethical Research Committee of Faculty of Medicine, Universitas Sumatera Utara (#177/TGL/KEPK FK USU-RSUP HAM/2019).

Study Protocol

1. Consent will be sought from the parents or guardians of children with negative results on Kato Katz examination after receiving 400 mg of albendazole for 3 days.
2. Each student will be asked to fill in a questionnaire comprising of knowledge on helminthiasis, attitude and practice on STH prevention.
3. Observation on the cleanliness of both hands' nails will be done.
4. Education on health hygiene and helminthiasis prevention will be given in a form of video.
5. Two schools will be selected to receive either single or repeated education every 4 months
6. At month 4, stool examination using Kato Katz examination will be performed and similar questionnaire will be given and observation on the nails of the students will be done again.

7. Treatment using albendazole will be given to children infected with STH on Kato Katz examination
8. Re-education will be given to study arm A (school 1) and no intervention will be given to study arm B (school 2)
9. At month 8, stool examination using Kato Katz examination will be performed and similar questionnaire will be given and observation on the nails of the students will be done again.
10. Treatment using albendazole will be given to children infected with STH on Kato Katz examination
11. Re-education will be given to study arm A (school 1) and no intervention will be given to study arm B (school 2)
12. At month 12, stool examination using Kato Katz examination will be performed and similar questionnaire will be given and observation on the nails of the students will be done again.
13. Treatment using albendazole will be given to children infected with STH on Kato Katz examination
14. Re-education will be given to study arm A (school 1) and no intervention will be given to study arm B (school 2)
15. All results will be recorded, statistical analysis will be performed to determine association between single or repeated education and re-infection occurrence

Study Procedures

a. Kato Katz examination

- a) Use gloves to prevent infection
- b) Label a glass slide according to the stool pot ID
- c) Place a small amount of faecal sample on an absorbable paper and press a wire net on top
- d) Using spatula, scrape the sieve faecal material through the screen so that only the debris remains
- e) Scrape up some of the sieved faeces to fill the hole in the template, avoiding air bubbles and leveling the faeces off to remove any excess.
The estimate weight of the faecal is 41.7 mg
- f) Carefully lift off the template and place it on the glass slide
- g) Place one piece of the cellophane, which has been soaked overnight in methylene blue glycerol solution, over the faecal sample
- h) Place a clean slide over the top and press it downwards to spread the faeces in circle. Carefully remove the slide by gently sliding it sideways to avoid separating the cellophane strip.
- i) Place the slide under a microscope and examine the whole area in a systematic zigzag pattern
- j) Record the number and the type of each egg of each species on a recording form alongside the sample number
- k) Multiply the number of eggs by the appropriate number to give the number of eggs per gram (epg) – the standard measurement to assess the intensity of infection

Intensity of ascariasis = Numbers of positive eggs x 1000/R

Intensity of trichuriasis = Numbers of positive eggs x 1000/R

Intensity of hookworm = Numbers of positive eggs x 1000/R

*R = faecal weigh according to the template (mg)

Intervention

Education will be given in a form of video with a length of 12 minutes, the education comprises of health promotion in helminthiasis including etiology, risk factors, clinical symptoms, treatment and prevention.

Education will be given to all children on month 0, and repeat education will only be given to study arm 1 at month 4 and 8.

Treatment

Children with positive results on Kato Katz examination will receive treatment according to the findings. Single infection with *A. lumbricoides* or hookworm will be treated with 400 mg of albendazole single dose. Single infection with *T. trichiura* will be treated with 3 days of daily dose 400 mg of albendazole.

In case of mixed infection, coinfection of *A. lumbricoides* and hookworm will be treated with single dose 400 mg of albendazole. While mixed infection of *A. lumbricoides* or hookworm with *T. trichiura* will be treated with 3 days of daily dose 400 mg of albendazole.

Analysis

Primary outcome of this study is the proportion of children with STH infection at month 12 in each group. Secondary outcomes include baseline prevalence of STH infection; knowledge of children prior intervention and at months 4, 8 and 12.

Data will be analysed using SPSS v22, 2010, using confidence interval of 95% and significant value is set at 0.05.

Monitoring

This study will be registered to clinicaltrials.gov and complies with international guidelines for clinical trial reporting. Experienced staff including senior physician will be recruited to perform the study, to monitor participants closely and to ensure that the rights, safety and the wellbeing of the human subjects in the study are in accordance with the study protocol, ICH and GCP guidelines.

Reporting

At the end of the study, the investigator will prepare a report to be reviewed by advisors and later to be shared with the Provincial Health Office of North Sumatera. The results of the study will also be presented in several conferences and will be published in a scientific journal.

DAFTAR PUSTAKA

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