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Deworming and Health Education: A project to address intestinal worms in rural Guizhou province

Submission date	Recruitment status	[_] Prospectively registered
09/04/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/04/2013	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/04/2013	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Our team's 2010 survey of poor, rural areas of Guizhou Province found rates of infection with soil transmitted helminths (STHs) to be around 40%. But Chinese government officials are not convinced that STH infection poses any real problem to Chinese schoolchildren. The goal of this study is to see whether an intensive campaign to reduce STH infection has any impact on child health or cognitive performance.

Who can participate?
Our sample will include both school-aged (9-11 years) and preschool-aged (3-5 years) children in the sample villages.

What does the study involve?
The study will have one intervention group and one control group with no intervention. The intervention involves administration of two rounds of albendazole treatment for all village children over age 3 years, health education training for both children and their parents, and an invitation to a health training session led by a local Centers for Disease Control and Prevention (CDC) official.

What are the possible benefits and risks of participating?
All children participating in the study will be dewormed (children in the control group will be dewormed at the conclusion of the endline survey), and families in the intervention group will also have the opportunity to learn about the dangers of STH infection and ways to prevent it. The risks of participating in the study are minimal - albendazole is safe with minimal side effects, mainly limited to mild stomach cramps as the STHs die and are expelled from the host body.

Where is the study run from?
110 villages in poor parts of rural Guizhou Province.

When is the study starting and how long is it expected to run for?
The study will begin in May, 2013, and will continue for 12 months until May, 2014.

Who is funding the study?
The study is funded by grants from the International Initiative for Impact Evaluation (3ie), the UBS Optimus Foundation, and Stanford University.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Deworming and Health Education: A cluster-randomized single-blind controlled trial to address soil-transmitted helminths in rural Guizhou province

Study objectives
The goal of this study is to see whether an intensive campaign to reduce STH infection has any impact on child health or cognitive performance.

This project involves treatment of children with soil-transmitted helminth infection (Ascaris, hookworm, Trichuris). Depending on the number of worms harbored, infection with parasitic intestinal worms can cause a range of symptoms, including diarrhea, general sickness and weakness, impaired cognitive development, stunted growth, and chronic intestinal blood loss.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval was provided by the Stanford University Human Subjects Research Institutional Review Board on the 15th September 2012 (ref: 25027)

Study design
Interventional cluster-randomised single-blind controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Soil-transmitted helminth infection

Interventions
Villagers in the intervention group will participate in the following activities:
1. All village children over age 3 years will be administered two 400 mg tablets of albendazole: one tablet at the start of the project, and another one after 6 months. The local CDC (with help of the village doctor) will be responsible for medication distribution and administration.
2. All parents of sampled children will receive one-on-one health education training from a trained project team member.
3. All school-aged children in our sample will receive health education training from a trained project team member
4. All parents of children in the village will be invited to a health training session led by a local CDC official with the help of the village doctor.

Villagers in the control group will not participate in any study interventions (no treatment).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Albendazole

Primary outcome(s)
1. Soil-transmitted helminths (STH) infection rate, measured by a Kato-Katz smear test
2. Child height and weight
3. Student academic performance, measured by performance on a standardized Trends in International Mathematics and Science Study (TIMSS) test
4. Educational readiness for preschool-aged children, measured by performance on a standardized test of educational readiness
5. Cognitive processing, as measured by performance on a test of executive function

Measured at baseline and at end line (12 months after baseline).

Key secondary outcome(s))
1. Hemoglobin levels, measured by HemoCue 201+ technology
2. Worm burden [eggs per gram (epg)]

Measured at baseline and at endline (12 months after baseline).

Completion date
21/04/2014

Eligibility

Key inclusion criteria
All school-aged (9-11 years) and preschool-aged (3-5 years) children living in our sample villages in poor parts of rural Guizhou Province will be included in the study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
9 years

Upper age limit
11 years

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
21/04/2013

Date of final enrolment
21/04/2014

Locations

Countries of recruitment
China

United States of America

Study participating centre
616 Serra Street
Stanford

United States of America
94305

Sponsor information

Organisation
Stanford University (USA)

ROR
https://ror.org/00f54p054

Funder(s)

Funder type
Charity

Funder Name
International Initiative for Impact Evaluation (3ie) (USA)

Funder Name
UBS Optimus Foundation

Funder Name
Stanford University Global Underdevelopment Action Fund (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes