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Overcoming China's anaemia puzzle in poor rural elementary schools

Submission date	Recruitment status	[_] Prospectively registered
04/05/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/05/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/07/2013	Haematological Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Nutrition and educational performance in rural Chinas elementary schools: A multi-site cluster randomised controlled trial in Shaanxi province

Study objectives

This study hypothesises that there is low haemoglobin count (which is known to be correlated with iron deficiency) among fourth-grade students in poor areas of Shaanxi province (Northwest China), and that the source of the problem is either nutritional deficiency, lack of information on nutritional practices, or intestinal worm infection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Stanford University Human Subjects Research Institutional Review Board approved on 27th January 2009 (IRB protocol number 15962)

Study design
Interventional multi-site cluster randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Iron-deficiency anaemia

Interventions
Control Condition 18 Schools
No intervention in these schools.

Deworming Intervention Only 12 Schools
400 mg of albendazole given in a single, oral dose to all students in the school by home room teacher (unless students meet exclusion criteria)

Nutrition Supplement Intervention Only 12 Schools
Multivitamin tablets containing 5 milligrams of iron given orally, daily for 5 months by home room teacher.

Each month we supplied teachers with 5 weeks worth of multivitamins with mineral supplements and disposable paper cups. During the first class period after the first meal of the day students always first go to their home room class. At least one period before the class, the teacher was supposed to boil a large kettle of water and let it cool. As soon as all of the students were in class, the teacher would hand out two disposable paper cups to each student. A multivitamin with mineral supplements was placed in one cup. The other cup was filled with water. The teacher would dispense the multivitamin with mineral supplements and water one student at a time and watch them take it. On each Friday afternoon, students would be given two multivitamins with mineral supplements to take home for the weekend. They were supposed to take one on Saturday and one on Sunday. Almost all parents that we talked to (during the spot checks) knew about the weekend protocol. Multivitamins with mineral supplements were dispensed from November to June. There was about a three week period during winter break when no multivitamins with mineral supplements were dispensed.

Deworming + Nutrition Supplement Treatment 12 Schools
In 12 schools, students were given a 400 mg albendazole dose orally and also received the 5 mg iron dosage daily.

Information Treatment Only 12 Schools
One of four letters (depending on students haemoglobin level) detailing the students specific anaemia status was sent home to parents or guardian two weeks after the baseline survey. The letter was sent home with the student and there was a follow up check by the home room teacher that parents received the letter. No other intervention or follow up was conducted.

The letter was written to describe to each parent what anaemia was and its known consequences. Parents were then told their own childs haemoglobin (Hb) level. Their anaemia status was given as 1 of 4 categories: severely anaemic (Hb levels below 115 g/L); moderately anaemic (Hb levels between 115 and 120 g/L); not anaemic, but borderline (Hb levels between 120 and 130 g/L); or not anaemic (Hb levels 130 g/L or higher). Anaemic students were then told that they should consult a doctor and that anaemia is often associated with poor diet and that parents should strive to give their children a balanced diet that contains at least one ounce of meat per day.

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Albendazole, iron tablets, multivitamins

Primary outcome(s)
Haemoglobin concentrations, obtained by finger prick testing using HemoCue 201+ point of-care diagnostics, measured during the baseline (October 2008) and during the evaluation survey, nine months after the start of the treatments (June 2009)

Key secondary outcome(s))
The secondary outcome variable of our study came from a standardised math test that we administered ourselves at baseline (October 2008) and nine months after the start of the treatments (June 2009). The math test was based on questions drawn from a pool of questions that were originally created for The Trends in International Mathematics and Science Study (TIMSS). Enumerators required students to finish the 29 question test in 30 minutes. No extra time was given.

Completion date
01/07/2009

Eligibility

Key inclusion criteria
All fourth grade students (both male and female students ages 9 12 years) in 66 randomly selected rural primary schools in eight of the poorest counties in China's Shaanxi province, in Chinas northwest region.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
9 years

Upper age limit
12 years

Sex
All

Key exclusion criteria
1. Students found to be extremely anaemic (sent directly to a doctor for treatment) or low body weight
2. Students identified as having thalassaemia
3. Students not meeting inclusion criteria

Date of first enrolment
01/10/2008

Date of final enrolment
01/07/2009

Locations

Countries of recruitment
China

United States of America

Study participating centre
616 Serra Street, Encina Hall
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Sponsor information

Organisation
Stanford University (USA)

ROR
https://ror.org/00f54p054

Funder(s)

Funder type
Other

Funder Name
LICOS Centre for Institutions and Economic Performance (Belgium)

Funder Name
Stanford University alumnus private donor (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?
Results article	results	01/05/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes