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Nourishing the future: targeting infants and their caregivers to reduce undernutrition in rural China

Submission date
19/03/2013

Recruitment status
No longer recruiting

Registration date
15/04/2013

Overall study status
Completed

Last Edited
12/02/2024

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
There are high rates of iron deficiency anemia (IDA) among babies in Chinas rural areas, but since no single institution holds responsibility for the health and development of this critical age group, IDA and other undernutrition problems are commonly neglected. We have two objectives in this study. Our first objective is to measure the impact of providing a daily nutritional supplement packet with iron on the health and development of babies in our study. Our second objective is to compare how well two programs designed to encourage usage of the nutritional supplement packets work: one program in which the packets are simply given away for free, and another in which caregivers are offered a conditional cash transfer for using the packets.

Who can participate?
All babies in 189 villages in poor parts of rural Shaanxi Province (China), aged 6-12 months at the time of participation.

What does the study involve?
Villages will be randomly allocated to one of three groups: (1) a Control Group with no intervention; (2) a Free Supplement Group that receives nutritional training for caregivers and free daily nutritional supplements for babies; (3) a Text Messaging Group that receives the same interventions as the Free Supplement Group plus a daily text message reminding them to feed their baby the nutritional packet. These text message reminders will continue for the entire duration of the study (24 months).

What are the possible benefits and risks of participating?
The risks to the participants are lo. There is no risk of harm from the nutritional supplements. Participating babies may experience some discomfort during the hemoglobin blood test, but since the test only requires a few drops of blood taken using new and sterilized equipment, the risk of infection is minimal.

Where is the study run from?
189 villages in Shaanxi Province (China)

When is the study starting and how long is it expected to run for?
May 2013 to May 2015.

Who is funding the study?
Funding for the project is provided by the International Initiative for Impact Evaluation (3ie), the UBS Foundation, the Bank of East Asia, the Heinz Institute of Nutritional Sciences (HINS), and the Shanghai Charity Foundation.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Nourishing the future: targeting infants and their caregivers to reduce undernutrition in rural China - a cluster-randomized controlled trial

Study objectives
We focus on the undernutrition problem of iron deficiency anemia (IDA). Iron deficiency anemia is the most common nutritional deficiency worldwide, affecting approximately a quarter of the global population, mostly in developing countries. Prolonged iron deficiency impairs the production of hemoglobin, limiting the amount of oxygen that blood cells can carry to essential organs and, most importantly, to the brain. As a result, IDA can cause fatigue, poor attention, and prolonged physical impairment. A large body of literature also links iron deficiency with or

without anemia to impaired cognition and brain function. Iron deficient school-age children have been shown to have worse educational outcomes, including grades, attendance and attainment, than their better-nourished peers.

1. What is the impact on child health and development of offering caregivers a free daily nutrition supplement packet for their child?
2. What is the uptake rate of the nutrition supplements when caregivers are educated about nutrition and given the supplements free of charge?
3. How does the uptake rate of the nutrition supplements change when caregivers are sent a daily text message reminding them to feed the supplements to their babies?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Stanford University Human Subjects Research Institutional Review Board, 26/10/2012, ref: 25734

Study design
Cluster randomised single-blind controlled interventional multi-centre trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Iron deficiency anemia

Interventions
Control Group: No intervention.
Treatment Group 1: Free Supplement Arm
Families in the Free Supplement Arm will receive the following interventions:
- An in-depth nutritional training campaign, teaching caregivers (mothers, grandmothers and others) the importance of good infant nutrition, providing examples of a balanced diet, and informing about the role of nutritional supplements
- A nutritional supplementation program, in which families participating in the project will be offered free NurtureMate supplement packets

Treatment Group 2: Text Messaging Arm
Families in the Text Messaging Arm will receive the same two interventions as the Free

Supplement Arm, and also:
- All caregivers will be will be sent a daily text message reminding them to feed their baby the nutritional supplement

All treatments will last for 24 months, from May 2013 through May 2015.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Hemoglobin level, measured every 6 months using HemoCue 201+ fingerprick technology
2. Height and weight, measured every 6 months using WHO standard methodology
3. Cognitive development, measured by Bayley Scale of Infant Development (BSID) III test
4. Packet uptake rate, measured by monthly counts of empty nutritional packets and bi-annual List Randomization Technique (LRT) survey questions (to determine whether the caregiver respondent is lying about the number of packets fed to the infant participant)

Secondary outcome measures
1. Infant health, measured by a monthly survey of episodes of illness
2. Infant social emotional development, measured by the Ages and Stages Questionnaire: Social Emotional (ASQ:SE)
3. Caregiver nutritional knowledge, measured by a nutritional quiz administered every 6 months over the course of the study

Overall study start date
01/04/2013

Completion date
01/05/2015

Eligibility

Key inclusion criteria
All babies aged 6-12 months (at the start of the study) in the sample areas in rural Shaanxi Province

Participant type(s)
All

Age group
Neonate

Sex
Both

Target number of participants
1,890

Key exclusion criteria
Babies outside of the age range 6-12 months at the start of the study

Date of first enrolment
01/04/2013

Date of final enrolment
01/05/2015

Locations

Countries of recruitment
China

United States of America

Study participating centre
616 Serra Street
Stanford
United States of America
94305

Sponsor information

Organisation
Rural Education Action Program (REAP) (USA)

Sponsor details
616 Serra Street
Stanford
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94305

Sponsor type
Research organisation

Website
http://www.reapchina.org/

ROR
https://ror.org/00f54p054

Funder(s)

Funder type
Charity

Funder Name
International Initiative for Impact Evaluation (3ie)

Funder Name
UBS Foundation

Funder Name
Bank of East Asia

Funder Name
Heinz Institute of Nutritional Sciences

Funder Name
Shanghai Charity Foundation

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	19/01/2018		Yes	No
Results article		10/02/2024	12/02/2024	Yes	No