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Intervention to fight anemia and improve well-being in a very low income setting: Selling Double Fortified Salt (DFS) and Free DFS

Submission date
17/01/2014

Recruitment status
No longer recruiting

Registration date
06/02/2014

Overall study status
Completed

Last Edited
06/02/2014

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Iron deficiency anemia has been linked to low productivity in adults, slowing of cognitive (mental) and physical growth among children and, in the elderly, increased risk of cognitive impairment and physical disability, as well as decreased muscle strength. While iron deficiency anemia has been recognized to be a serious public health problem in developing countries for several years, not much progress has yet been made against it.
Distributing iron supplements appears to be an impractical policy in resource-poor settings where the public health systems do not have the capacity to maintain a large-scale distribution system. Iron supplementation of foods is therefore an attractive alternative, it requires no additional effort on the part of the consumer, and can be done relatively cheaply in centralized locations. Double Fortified Salt, with iron and iodine, offers an inexpensive and attractive solution to the widespread iron deficiency anemia in rural Bihar (an Indian state), as salt is consumed by every society, there are strong existing supply chains, and it is centrally fortified. The aim of this study is to examine the impact of the availability and provision of Double Fortified Salt on health outcomes and economic productivity among the rural population of Bhojpur District, Bihar.

Who can take participate?
Households in a village in Bhojpur District, India.

What does the study involve?
400 villages will be randomly allocated to one of two groups: the control group, where the shops will not sell Double Fortified Salt, or the intervention group, where shops will sell Double Fortified Salt. An information campaign will be carried out in each village to tell households about the product.
15 households in each village of all the 400 villages will be randomly selected to complete surveys and tests.
In another part of the study we will deliver Double Fortified Salt free at home to 434 households in a subset of villages (62) where the salt is also being sold, and households decide if they want to cook with it or not. We can compare their outcomes in individuals in the 496 households who

are not given free salt (in the same 62 villages) as well as to individuals in the 3,000 households in villages where we neither sell nor give away Double Fortified Salt.

What are the possible benefits and risks of participating?
Individuals may develop stronger awareness of anaemia and its effects, which we believe is at a low level presently. Respondents will also be sold Double Fortified Salt at a discount and will have higher iron content in their diet if they choose to use it. Over the period of this study, this should result in decrease in anemia levels as well as in the symptoms of anemia.
Individuals that participate in the survey will be screened for extreme levels of anemia and will be given information about treatment if they are deemed to have an excessively low hemoglobin count. Individuals also receive a printed report on their physical health checks.
Households in the free DFS arm will also receive free salt for over one year, if they choose to accept it.
Given the diet in the study area, which is low in iron and high in phitates that prevent iron absorption, the fact that consumption of salt doesn't increase radically over time, and the limited amount of iron, there are no concerns of overconsumption of iron. Double Fortified Salt is approved for use in India as a food supplement, and is used in some state programs (for example in school meals). It is certified to be in compliance with Indian National Institute of Nutrition guidelines, is endorsed by a committee of the Indian Council for Medical Research, and has been approved for the study by the Government of Bihar.
Individuals participating in this study may suffer minor pain associated with hemoglobin testing. The test will involve pricking the fingertip with a sterile lancet. This procedure is very quick and involves very little pain or discomfort. Trained field officers will perform it using sterile equipment and hygienic practices.
The maximum economic harm done to households is the loss of a few rupees for purchasing slightly more expensive salt.
Some aspect of the data collected is private: the interviews will be conducted in private, and the electronic and paper version of the data will be carefully kept.

Where is the study run from?
The study takes place in 400 villages of Bhojpur District in the state of Bihar in India.

When is the study starting and how long is it expected to run for?
The study started in April 2011 and is expected to run until August 2014.

Who is funding the study?
National Institutes of Health (USA), Department for International Development (UK), International Initiative for Impact Evaluation (3ie) (USA), The International Food Policy Research Institute (USA).

Who is the main contact?
Prof. Sharon Barnhardt, Principal Investigator (PI)
The co-PIs are Profs. Abhijit Banerjee and Esther Duflo from the Massachusetts Institute of Technology, USA

Contact information

Type(s)
Scientific

Contact name

Prof Sharon Barnhardt

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Additional identifiers

Protocol serial number
DFS

Study information

Scientific Title
Intervention to fight anemia and improve well-being in a very low income setting: Selling Double Fortified Salt (DFS) and Free DFS: a cluster randomized controlled field trial

Acronym
DFS

Study objectives
1. Making Double Fortified Salt available for sale in small shops in villages in Bihar will significantly increase the hemoglobin level and reduce Iron Deficiency Anemia of people who live in those villages (compared to villages where Double Fortified Salt is not available for sale).
2. Giving Double Fortified salt to households in villages in Bihar where it is available for sale will significantly increase the hemoglobin level and reduce Iron Deficiency Anemia of people in those households (compared to people in the same villages who are not given free Double Fortified Salt or to people who live in villages where Double Fortified Salt is not made available for sale).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Massachusetts Institute of Technology COUHES 08/11/2011, ref.: 1101004293. Updated 26/04/2013 for free DFS.
2. Institute for Financial Management and Research, 02/05/2011, ref.: IRB00007107; FWA00014616; IORG0005894. Updated 26/04/2013 for free DFS.
3. Indian Council for Medical Research,10/01/2012, ref.: 5/7/1008/Indo/FRC/2011-RHN.

Study design
Cluster-randomized controlled field trial

Primary study design
Interventional

Study type(s)

Prevention

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

Interventions
400 Villages are randomized to:
1. 200 control villages
2. 200 sales treatment villages: Within sales treatment, 7 households in each of 62 villages get free salt distribution

Double Fortified Salt: Formulated by the National Institute of Nutrition (Hyderabad), produced by Tata Chemical Ltd. (Mumbai).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Hemoglobin level measured by hemocue, anemia according to age/sex/pregnancy benchmarks. This is measured at baseline and endline. Endline is approximately 15-18 months after the beginning of salt distribution to stores.

Key secondary outcome(s))
1. Body mass index (BMI)
1.1. Weight measured twice (and a third time if difference between first two trials is more than 0.5 kg) by enumerators during survey in the home using flat scales.
1.2. Height measured twice (and a third time if difference between first two trials is more than 0.5 cm) by enumerators during survey in the home using stadiometers for adults and child mats for infants.
2. Mid-Upper Arm Circumference is measured twice (and a third time if difference between first two trials is more than 0.5 cm) by enumerators during survey in the home using Seca Measuring Tapes
3. Number of Activities of Daily Living that can be completed: Enumerator, as a part of survey in the home, records the respondent's self-reported rating (1-4 in increasing order of difficulty in doing a task) of ease with which he/she can do a set of six activities of daily living
4. Self-reported health: Enumerator, as a part of survey in the home, records the respondent's self-reported rating (1-4 in increasing order of worsening state of health) of the current state of his or her health
5. Queens College Step Test
6. Time to walk 4 meters: Enumerator, as a part of survey in the home, records the time taken (using a stopwatch) by a respondent to walk 4 meters (marked out on the ground outdoors using a measuring tape)
7. Time to sit and stand up 5 times in a row: Enumerator, as a part of survey in the home, records the time taken (using a stopwatch) by a respondent to sit and stand up 5 times in a row from a chair
8. Depression index based on the CES-D from self-reports on mental states
9. The Lucknow Development Screen for infant development
10. Memory batteries for children (digit spans from PGI Memory Scales and block tapping test

from the NIMHANS child neurpsoychology tests)
11. Memory for adults (four subtests of the PGI Memory Scale)
12. Hindi Mental State Exam for adults over 50
13. School attendance and performance, work attendance, value of consumption, and time use including hours of work: Self reported by the respondent at a survey in the home

Completion date
01/08/2014

Eligibility

Key inclusion criteria
For the marketing (sales) experiment, all persons living in the village are included. Households choose to purchase and consume Double Fortified Salt (or not) in the treatment clusters. Individuals who consume meals made in homes that purchase Double Fortified Salt will consume supplemental iron. There are no inclusion criteria for individuals.

For the free distribution of Double Fortified Salt arm, 7 households were randomly selected from the 15 households who were also randomly selected to be measurement households in the treatment villages. Individuals in these households will consume supplemental iron if the person responsible for cooking chooses to use the free Double Fortified Salt and if the individual consumes meals made at home.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
There are no exclusion criteria for individuals.

Date of first enrolment
04/04/2011

Date of final enrolment
01/08/2014

Locations

Countries of recruitment
India

Study participating centre
Indian Institute of Management - Ahmedabad
Ahmedabad
India
380015

Sponsor information

Organisation
Abdul Latif Jameel Poverty Action Lab (J-PAL) South Asia (India)

ROR
https://ror.org/04dtrtr74

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health (NIH) (USA), P01 AG005842-26 (subproject 6)

Funder Name
Department for International Development (UK), Component Code 114506-103

Funder Name
International Initiative for Impact Evaluation (3ie) (USA), OW3: 1205

Funder Name
The International Food Policy Research Institute (IFPRI) (USA), 2011X437.JPA

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