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The Low Birth Weight in South Asia Trial (LBWSAT): can birth weight in the plains of Nepal be cost-effectively increased using a behaviour change strategy (BSC) involving womens groups alone or by BCS with either a food or cash transfer?

Submission date
20/06/2013

Recruitment status
No longer recruiting

Registration date
12/07/2013

Overall study status
Completed

Last Edited
30/07/2018

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Around 28% of babies in southern Nepal are born low birth weight (<2500g). These babies have increased risk of dying in early life, of poor growth and cognitive (mental) development and of chronic disease later in life. We are conducting a study of 17, 000 pregnant women to compare different ways to increase birth weight in two districts of southern Nepal. Our goal is to find the most cost effective means of increasing birth weight by comparing birth weight in current programme areas with birth weight in areas where we conduct one of three combinations of strategies for increasing birth weight. Strategy one is a behaviour change strategy (BCS). This involves working with womens groups and other community members using a participatory learning and action approach to change womens eating behaviour during pregnancy so that they increase their intake of nutritious food. Strategies two and three combine this BCS with provision of a food supplement or a cash payment respectively. These transfers are provided unconditionally each month to pregnant women (i.e. they are not dependent on the pregnant woman attending antenatal care, or any meetings). The combined study areas that share the same strategy for improving birth weight will be compared with the combined study areas where no strategies for increasing birth weight are implemented. Findings should be useful to help governments and donors decide what policies to develop and fund for increasing birth weight in South Asia.

Who can participate?
We will recruit around 17,000 pregnant women and weigh around 13,000 babies from 80 study areas in Dhanusha and Mahottari districts in southern Nepal.

What does the study involve?
Eighty rural Village Development Committee areas have been selected and 20 allocated to each of the three strategies described above and 20 to current programmes (no new strategies) by a process called randomisation, which is like tossing a coin. Strategies to improve birth weight will run from August 2013 to July 2015. BCS comprises a series of open womens group meetings which pregnant women are encouraged to attend. A Female Community Health Volunteer will assist each group, supported by a nutrition mobiliser. The groups identify and prioritise problems associated with improving womens intake of nutritious food in pregnancy. Then groups draw-up and introduce strategies for addressing these problems. Food and cash transfers will be distributed to pregnant women through the womens group meeting or through home visits from the nutrition mobiliser. A woman will be eligible for up to 7 monthly supply of fortified food supplement during pregnancy or a cash transfer of NPR 750 each month or NPR 5,250 over the pregnancy. Over 2 years, all women of reproductive age (10-49 years) resident in the study areas will be invited to participate in monthly monitoring of whether they have had or missed their period. We will interview (and at certain times weigh or measure) women with a positive pregnancy test who agree to take part at enrolment (preferably 8-12 weeks gestation), at 32-35 weeks, within 72 hours of birth and at 4-6 weeks after birth. We will weigh babies within 24 hours of birth where possible, but at least within 72 hours. At the end of the study, we will compare the average birth weight in the study areas with current programmes only with the average birth weight in the three areas with different strategies. We will also compare other indicators such as: % born low birth weight (<2500g), % born preterm, maternal weight gain in pregnancy, eating behaviour in pregnancy, allocation of food in the household, access to and use of food or cash transfers, exposure to womens groups or other BCS activities, miscarriages /stillbirths, deaths and illness in pregnancy and in the first month of life.

What are the possible benefits and risks of participating?
Immediate direct benefits for living in BCS areas may include learning new information about pregnancy, diet and caring for a baby and improved health due to better diet or care. Women who participate in groups may be empowered by taking part. For women in food transfer and cash transfer intervention areas benefits may include increased intake of protein, energy, vitamins and minerals. In cash distribution areas women benefit directly by receiving up to NPR 5250 over their pregnancy for use on food or to contribute to other household expenses. We do not predict any increased risks to women participating in the trial. However, illness or death will be monitored and the trial stopped should any unexpected adverse outcomes be observed. We will protect data containing womens personal information and datasets used for analysis will not contain names of women.

Where is the study run from?
The Institute for Global Health at University College London is leading the study. Mother and Infant Research Activities (MIRA), a Nepalese NGO, is implementing the study in Nepal. Save the Children is assisting with setting up and evaluating social transfer systems. World Food Programme is providing a food supplement and advice about nutrition. Institute of Fiscal Studies is assisting with evaluation of transfers.

When is the study starting and how long is it expected to run for?
Recruitment system piloting and set-up ran from March to December 2013, interventions should run from January 2014 for up to 24 months and the trial analysis and trial publication should complete by September 2016. Participants enrol in the study from 8 weeks pregnant onwards and exit 4-6 weeks after delivery of their baby. Enrolment will run for 22 months to enable sufficient pregnant women to be exposed to the strategies and deliver their babies. However, it may take longer if birth rates fall or many women migrate out of study areas.

Who is funding the study?
Department for International Development (DFID) (UK)

Who is the main contact?
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Study website
http://www.ucl.ac.uk/igh/research/projects/all-projects/1VUP

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
The Low Birth Weight in South Asia Trial (LBWSAT): a cluster randomised controlled trial to determine the relative cost effectiveness of a participatory behaviour change strategy (BCS) alone, or BCS plus a food or cash transfer for increasing birth weight in plains Nepal compared with current programmes

Acronym
LBWSAT

Study objectives
Improved nutrition behaviour change strategies combined with a social transfer constitute a cost-effective approach to improving birth weight.
Research question: What are the relative impacts on birth weight and maternal nutrition, and the relative costs under experimental conditions: 1) enhanced nutrition behaviour change strategies (BCS) 2) BCS plus an unconditional cash transfer; 3) BCS plus a food supplement; compared with 4) current programmes?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nepal Health Research Council and UCL Research Ethics Committee, 14/09/2012.

Study design
Cluster randomised controlled 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 patient information sheet

Health condition(s) or problem(s) studied
Low birth weight

Interventions
Behaviour change strategy
We will work with womens groups already organised by the government-supported Female Community Health Volunteers (FCHVs) in each ward of 60 Village Development Committees (VDCs) 540 groups in total. Monthly womens group meetings will follow a participatory action cycle in which local maternal nutritional problems will be identified, prioritised, and addressed by the group and the community. Communities will then evaluate their approach and the cycle will continue in the re-identification and re-prioritization of problems. Through this process, local barriers to good maternal nutrition will be identified and addressed.
In addition literate group members called nutrition mobilisers, will be paid an incentive for supporting the running of the groups and distribution of transfers. They will visit pregnant women at home to counsel them on improving their diet, taking supplements, resting and attending ANC.
Groups will also organise outreach to men in their community and other household decision makers to orient them on improving maternal diet and using transfer appropriately.

Added 06/01/2014: The behaviour change strategy will include not only community women's groups following a participatory learning and action cycle but will be supplemented by home visits to pregnant women, delivered by an incentivised literate community volunteer called a 'nutrition mobiliser'. This will enable the food and cash transfers to be delivered unconditionally to women who do not attend groups and will also enable direct one-to-one counselling of pregnant women in all study arms.

Food supplement strategy
Womens groups will be the main distributing agent for the food, supported by an incentivised nutrition mobiliser who is an educated womens group member capable of keeping written records and checks on supplies. Groups will identify pregnant women early in their pregnancies and encourage them to come to the group to receive a monthly food transfer. If a pregnant woman does not attend the group, the nutrition mobiliser will make monthly visits to the woman to provide her with her food, explain to her how to and how much of it to prepare/eat and also to explain the importance of eating well in pregnancy.

Cash transfer strategy
Cash will be collected from district headquarter banks by user committees or implementing agency staff, and delivered by foot or by vehicle to beneficiary communities. Nutrition mobilisers will be responsible for distributing the cash at groups or on home visits to pregnant women and for maintaining proper records.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Birth weight accurate to 10g measured within 72 hours

Secondary outcome measures
1. Prevalence of low birth weight (% < 2500g)
2. Maternal weight gain during pregnancy (difference between first and third trimester weight, adjusted for gestation)
3. Preterm delivery (based on LMP)/gestational age at delivery
4. Miscarriages
5. Stillbirths
6. Neonatal mortality
7. Maternal morbidity during pregnancy
8. Neonatal morbidity
9. Maternal eating behaviour in pregnancy (eating down/less, maternal 24-hour dietary diversity score in early and late pregnancy, consumption of key micronutrient-rich foods, number of eating occasions per day, observance of food taboos and fasting)
10. Exposure to womens groups by pregnant women and family members (attendance, home visits and awareness-raising activities in the community)
11. Access to food transfer and recall of its use in the household
12. Access to cash transfers and how it was spent
13. Intra-household food allocation

Overall study start date
01/07/2012

Completion date
17/10/2015

Eligibility

Key inclusion criteria
Individual participant inclusion criteria:
1. All women of reproductive age who are permanent residents of the study areas are eligible for inclusion in menstrual monitoring.
2. All pregnant women identified within the surveillance system before 20 weeks gestation are eligible for inclusion in monitoring of pregnancy weight gain and diet and for receipt of transfers (in transfer areas).
3. All babies born to women permanently resident in the study clusters are eligible for inclusion in birth weight outcomes and 4-6 week interviews, so long as they can be weighed within 72 hours.
4. Any woman residing in behaviour change strategy areas may participate in womens groups and any family members of pregnant women may participate in groups for men or mother-in-laws.

Cluster (or study area) inclusion criteria:
1. Village Development Committee (VDC) in Dhanusha or Mahottari districts of Nepal with 4000 to 9000 estimated population
2. Received not previous womens group intervention using participatory learning and action approach
3. Does not contain a large town or municipality

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
17,000 pregnant women from whom we obtain at least 13,000 birth weights

Key exclusion criteria
Individual participant exclusion criteria:
1. Birth weight obtained more than 72 hours after birth
2. Woman temporarily resident in the study clusters (i.e. not spending most of her pregnancy in the area and/or not planning to be in the area when the baby is born)

Cluster (or study area) exclusion criteria:
1. Smaller than 4000, or larger than 9200 population
2. VDC contains a large town or municipality

3. VDC had a previous womens group implemented by MIRA between 2007 and 2011
4. Cluster has hills, borders the E-W highway in the north of the districts, or has large hills ethnicity population

Date of first enrolment
29/12/2013

Date of final enrolment
28/02/2015

Locations

Countries of recruitment
England

Nepal

United Kingdom

Study participating centre
University College London
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Sponsor information

Organisation
Department for International Development (DFID) (UK)

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Sponsor type
Government

ROR
https://ror.org/05rf29967

Funder(s)

Funder type
Government

Funder Name
Department for International Development

Alternative Name(s)
Department for International Development, UK, DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the Low Birth Weight South Asia Trial study will be stored in a publicly available repository called ReShare UK data service https://reshare.ukdataservice.ac.uk.
Individual level data for all variables presented in the trial results paper tables are available indefinitely as of March 2018. The data contain no personally identifiable information but do contain the pregnancy_id variable that was the unique identifier used to identify every participant in the study to enable checking of cases should queries arise. Access to the data will be provided by a committee comprised of scientists from UCL Institute for Global Health and Mother and Infant Research Activities (Nepal) to applicants who seek to undertake novel analyses that are not overlapping with those of existing users / owners of the data. Applicants can download the data sharing agreement form from the ReShare repository and email it to Naomi Saville on n.saville@ucl.ac.uk or email Naomi directly for a copy of the form. The data are not to be used for commercial purposes. The consent form for participants included the statement “I agree that my non-personal research data may be used by others for future research. I am assured that the confidentiality of my personal data will be upheld through the removal of identifiers”, which means that data may be used for secondary analyses.

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/10/2016		Yes	No
Results article	results	09/05/2018		Yes	No
Results article	results	01/09/2018		Yes	No