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The effect of prenatal food supplementation on child growth in northern Bangladesh

Submission date
19/03/2015

Recruitment status
No longer recruiting

Registration date
24/03/2015

Overall study status
Completed

Last Edited
25/04/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Insufficient food intake during pregnancy is a major problem in many developing countries. Bangladesh has among the highest rates of maternal and child undernutrition globally. In the rural areas of Bangladesh, poverty is three times higher than in urban areas, women are less likely to access antenatal and postnatal services, and children suffer from higher rates of chronic malnutrition. In Bangladesh, one in five children are born with a low birth weight and one in three pregnant women are undernourished. Maternal undernutrition increases the risk of poor foetal growth. A fifth of childhood chronic malnutrition (stunting) may be caused by poor foetal growth as shown by having a low birth weight when born. For pregnant women, the World Health Organisation (WHO) recommends additional calories every day. There are many reasons why women in developing countries are not able to consume additional calories during their pregnancy. The pregnancy period presents a key phase for ensuring the survival, growth and development of the offspring. When pregnant women are undernourished, extra food during pregnancy can improve birth outcomes and has the potential to improve the nutritional status of pregnant women. The development of food based supplements using locally available and preferred foods have proved effective, but research to-date has focused on contexts that are not generalizable to that of northern Bangladesh or focused on different target groups such as children. This study aims to develop a locally produced food based supplement, assess its acceptance, and identify its effect on child growth when consumed by undernourished pregnant women.

Who can participate?
Undernourished pregnant women living in northern Bangladesh.

What does the study involve?
Using group discussions, photographs and interviews, we explored the diet of pregnant women living in northern Bangladesh. This information was used to develop a food based supplement which uses locally available and preferred foods. We asked pregnant women to participate in a small study so that we could measure the acceptance of the supplement, and modify it if required. Women consumed the locally developed supplement, and shared their experiences through the completion of a questionnaire at day 15 and day 30. The results informed the next phase of the study. The composition of the supplement was influenced by the preferences of

women in the selected communities and the local availability of foods that are accessible year-round. The production of the supplement involved the establishment of a local business enterprise, building on local capacity and providing an income generation opportunity to the community. We conducted a study to see if the food based supplement had an effect on child physical growth when consumed by women that were undernourished. We screened all women in the selected villages on a monthly basis for undernutrition. Undernourished pregnant women were invited to participate in the study and written consent was obtained. In eight randomly selected intervention villages the women received the supplement until delivery of the child. We selected four control villages to ensure that they were as similar to the intervention villages as possible, and to ensure that the control villages had limited/no exposure to the intervention. All women in the selected communities (intervention and control), undernourished and nourished, also received maternal nutrition education, antenatal and postnatal care services, and iron-folic acid supplementation. The child was measured (weight, length, head circumference) at birth, 1, 3, 6 and 12 months.

What are the possible benefits and risks of participating?
Participation in this study may result in improved nutritional status of the participant and her child. There are no expected risks in participating.

Where is the study run from?
The research site is in northern Bangladesh, and coordinated by James Cook University (Australia)

When is the study starting and how long is it expected to run for?
March 2012 to March 2015

Who is funding the study?
World Vision (New Zealand).

Who is the main contact?
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Contact information

Type(s)
Public

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Study information

Scientific Title
Effect of prenatal balanced protein energy supplementation on child physical growth in northern Bangladesh: a cluster randomised controlled trial

Study objectives
A fifth of childhood stunting may be attributable to poor foetal growth as shown by being born small for gestational age (SGA) (Black et al. 2013), thus we hypothesis that prenatal balanced protein energy supplementation targeting undernourished women (Middle Upper Arm Circumference [MUAC] <22.1) will decrease childhood stunting by up to 20%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Human Research Ethics Committee, James Cook University, ref: H4498
2. Bangladesh Medical Research Council (BMRC), ref: BMRC/NREC/2010-2013/58

Primary study design
Interventional

Study design
Cluster randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Maternal undernutrition (defined as Middle Upper Arm Circumference <22.1)

Interventions
Balanced protein energy supplementation; where the protein provided less than 25% of the total energy content (Ota et al. 2012). No micronutrients were added to the mix.

The study consists of three phases.

Phase 1: Formative research (focus groups, photovoice, systematic literature review) exploring the dietary preferences and food security situation of pregnant women living in northern Bangladesh. This research informs which food items would be appropriate and acceptable for the development of a supplementary food. In addition, the research informs the development of IEC/BCC materials and tools.

Phase 2: Development of a balanced protein energy supplement using locally available foods, and 30-day acceptability trial. Acceptance of the supplement measured at two timepoints in its development (day 15 and day 30). An assessment and focus group at day 15 allowed for modifications to the initial supplement, and an assessment at day 30 allowed for testing

acceptance of these modifications. The results of the 30-day trial will inform Phase 3 of this research. The composition of the supplement was influenced by the organoleptic preferences of women in the selected communities, and the local availability of foods that are accessible year-round. The production of the supplement involved the establishment of a local business enterprise, building on local capacity and providing an income generation opportunity to the community.

Phase 3: Cluster randomised controlled trial of the locally developed supplement in 12 villages in northern Bangladesh. All women in the selected villages are screened on a monthly basis. Undernourished pregnant women are invited to participate in the research project and written consent is obtained. In eight randomly selected intervention villages the women received the supplement until delivery of the child. We selected four control villages to ensure that they were as similar to the intervention villages as possible, and to ensure that the control villages had limited/no exposure to the intervention. All women in the selected communities (intervention and control), undernourished and nourished, also received maternal nutrition education, antenatal and postnatal care services, and iron-folic acid supplementation. The child was measured (weight, length, head circumference) at birth, 1, 3, 6 and 12 months.

Intervention Type
Supplement

Primary outcome(s)
1. Birth weight (salter scales) at birth.
2. Birth length (calibrated length board) at birth
3. Birth head circumference (measuring tape) at birth
4. Longer term growth (length/weight and head circumference) at 1, 3, 6 and 12 months of age

Key secondary outcome(s)
1. Maternal weight gain (salter scales) each month
2. Maternal dietary diversity (measured used the validated Womens Dietary Diversity Questionnaire developed by Food And Nutrition Technical Assistance FANTA)

Completion date
21/03/2015

Eligibility

Key inclusion criteria
1. Written informed consent
2. Confirmed to be pregnant
3. Undernourished as defined by a mid-upper-arm circumference (MUAC) ≤22.1 cm
4. Did not require medical referral

Participant type(s)
Other

Healthy volunteers allowed
No

Age group

Mixed

Sex
Female

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
21/03/2012

Date of final enrolment
21/03/2015

Locations

Countries of recruitment
Bangladesh

Study participating centre
Rangpur District, Northern Bangladesh
Bangladesh
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Sponsor information

Organisation
James Cook University

ROR
https://ror.org/04gsp2c11

Funder(s)

Funder type
Charity

Funder Name
World Vision (New Zealand)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/07/2018		Yes	No
Results article		30/08/2016	25/04/2023	Yes	No