

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

Submission date 19/03/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/03/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 25/04/2023	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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

Contact name

Ms Briony Stevens

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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 hypothesise 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

Study design

Cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Treatment

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

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 measure

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

Secondary outcome measures

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)

Overall study start date

21/03/2012

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

Age group

Mixed

Sex

Female

Target number of participants

12 community-level clusters. 165 participants in intervention group; 165 participants in control group

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

Sponsor details

School of Public Health, Tropical Medicine and Rehabilitation Sciences
James Cook University
Townsville
Australia
4810

Sponsor type

University/education

Website

www.jcu.edu.au

ROR

<https://ror.org/04gsp2c11>

Funder(s)

Funder type

Charity

Funder Name

World Vision (New Zealand)

Results and Publications

Publication and dissemination plan

1. Stevens B., Brimblecombe, J., Buettner, P., Watt, K., Clough, A., and Judd, J. The effect of balanced protein energy supplementation in undernourished pregnant women and child physical growth in low- and middle-income countries: a systematic review and meta-analysis, Maternal and Child Nutrition, in press.
2. Stevens, B., Clough, A., Brimblecombe, J, and Judd, J. The use of a Modified Version of Photovoice to Identify Maternal Dietary Consumption Enablers and Barriers in Northern Bangladesh, journal tbc.

3. Stevens, B., Brimblecombe, J., Clough, A., Watt, K, and Judd, J. Acceptability testing of a balanced protein energy supplement using locally available foods for pregnant women in Northern Bangladesh, journal tbc.

4. Stevens, B., Brimblecombe, J., Clough, A., Watt, K, and Judd, J. Dietary diversity of pregnant women and seasonality in northern Bangladesh, journal tbc.

5. Stevens, B., Brimblecombe, J., Clough, A., Watt, K, and Judd, J. Effect of prenatal supplementary food on child physical growth, journal tbc.

Intention to publish date

30/03/2016

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