Making a balanced plate for pregnant women to improve birthweight of infants: a cluster randomised controlled trial in rural Bangladesh

1. **Background**

More than 20 million infants worldwide are born with low birthweight (LBW) (<2500 g), 95.6% of them in developing countries [[1](#_ENREF_1)]. LBW can indirectly contribute to neonatal deaths, altogether accounting for about 60% of neonatal deaths. During the neonatal period infants are 2.8 times more likely to die while weighing less than 2000 g compared to those weighing more than 2499 g at birth and the risk increases further with decrease in birthweight. LBW accounts for 337,047 deaths (3.3%) and 13,536,000 DALY (3.1%) among under 5 children [[2](#_ENREF_2)]. There is significant evidence of medium and long term impacts of LBW on physical and cognitive development and wellbeing; the medium term effects include psychosocial and emotional problems and lower educational attainment. Long term effects include increased risks of developing diabetes and hypertension in adulthood [[3-8](#_ENREF_3)].

Intrauterine growth restriction is the probable cause of LBW in case of babies born at term (37 weeks of gestation) [[2](#_ENREF_2)]. Nutritional status of women around pregnancy is important for optimum growth and development of fetus [[9](#_ENREF_9)]. There is strong evidence that poor maternal nutrition during pregnancy leads to low birthweight [[10-14](#_ENREF_10)]. An animal study showed that moderate maternal food restriction in mid-pregnancy induced intrauterine growth restriction and LBW in offspring of mice [[15](#_ENREF_15)]. Generalized maternal undernutrition stricken Northwestern Holland during the winter of 1944-1945 (famine period) resulted in lower weight of the infants compared to pre-famine period [[16](#_ENREF_16)]. The cause of foetal growth restriction is partly due to impairement in placental development and function in presence of maternal under nutrition [[17](#_ENREF_17)].

Several studies had proven that improvement in maternal nutrition can result in increase in birthweight of infants. A systematic review assessesed the effect of balanced protein energy supplementation in undernourished pregnant women from low and middle income countries and found significant mean difference in birthweight (d 0.20, 95% CI 0.03–0.38, P 0.02) [[18](#_ENREF_18)]. Maternal dietary behaviour again found to be improved with nutrition education during pregnancy. A cochrane review reported that, antenatal nutritional advice with the aim of increasing energy and protein intake is effective in increasing protein intake (mean difference +6.99 g/day, 95% CI 3.02 to 10.97) [[19](#_ENREF_19)], which was supported by another meta-analysis conducted earlier (1993) [[20](#_ENREF_20)]. found nutrition education successful in changing dietary behavior, including ingestion of more protein and improved birth weight by 300 g [[13](#_ENREF_13)]. A meta-analyses conducted in 2012 for the effect of nutrition education and counselling (NEC) on maternal, neonatal and infant health outcomes reported that, NEC generally improved maternal dietary practices and consumption of specific macro and micronutrients and adherence to appropriate diet, reduced the risk of anaemia by approximately 30% (0.70 [95% CI 0.58, 0.84]) and increased mean birthweight by 105 g [95% CI 17.73, 192.67]. But, the association between NEC and risk of LBW failed to achieve significance [[21](#_ENREF_21)].

LBW affects 36-55% of all infants in Bangladesh, whereas the public health problem threshold is only 15% [[22-24](#_ENREF_22)]. It had been reported that 25-54% pregnant women in Bangladesh are moderately malnourished [1,2] with 47% chronic energy deficiency (BMI<18.5 kg/m2) [[25](#_ENREF_25)], 50% from anaemia (Hb<11.0 g/dl) [[26](#_ENREF_26)] and substantial amount other micronutrients (vitamin A, B 12, D, folate, iodine and zinc) [3-7]. A study conducted in Bangladesh found that the average energy intake of pregnant women was 1,464±416 (252) kcal/day [[27](#_ENREF_27)] which is much lower compared to recommended daily allowance of 2,500 kcal/day.

In this proposed research, a group of pregnant women will be counseled to consume appropriate amount and types of food starting from first trimester and continued till delivery. Each pregnant woman will be counseled separately to follow a diet chart. The technique that will be used for education is practical demonstration of plates containing balanced diet made up of readily available food at households. The impact will be assessed on maternal dietary behaviour and birthweight of infants.

**Aim**

The study aims to collect evidence of whether nutrition education and counselling during pregnany can improve birth weight of infants in rural Bangladesh.

**Hypothesis**

*Primary hypothesis*

The primary hypothesis of the research would be; nutrition education and counseling starting from first trimester of pregnancy, and sustained for at least six months will increase birth weight by 100 g compared to standard program.

*Secondary hypothesis*

The secondary hypothesis would be; nutrition education and counseling will-

i) increase daily energy consumption in third trimester by at least 300 kcal, and

ii) increase daily dietary diversity score to at least five varieties of food in third trimester compared to standard program.

**Research Design and Method**

*Research Design*

A cluster randomized controlled trial will be conducted to test the impact of nutrition education and counseling during pregnancy on birthweight of infants. The outcome will be compared with standard antenatal care program. There will be two arms of the study; in one arm there will be nutrition education and counseling on; a) consumption of food yielding at least 2,500 kcal energy every day, b) consumption of food from all seven groups (rice/chapati, vegetables, lentil, fish/meat, egg, milk/milk products and fruits), at least five every day, c) inclusion of animal sourced food at least in two servings in a day, and d) eating at least five times in a day; three major meal and two snacks. The other arm will contain standard antenatal care program including advice on; a) taking extra food, b) consumption of meat, fish, liver, egg, milk/milk products, lentils, colorful vegetables, fruits and oil, c) iron-folic acid (60 mg iron and 40mg folic acid) and calcium (500 mg) tablet supplementation. A qualitative study will be conducted to explore the socio-cultural norms, attitude and practices regarding maternal nutrition in both intervention and control areas. The cluster design will reduce chance of contamination.

*Research site*

The proposed research will take place in a rural district of Bangladesh; Sherpur where BRAC has already been implementing a project called, “Improving Maternal Neonatal and Child Survival (IMNCS)” project. The major components of the project are community based services including family planning, pregnancy related care, safe delivery, neonatal care, <5 child care. Besides this there is Government provided nationwide antenatal care program.

*Sample Size and Power*

Sample size and power for the trial was estimated with the following assumptions:

* The expected mean birth weight in control clusters 2,622 g [18]
* The expected difference in mean birthweight between intervention and control groups 100 g (2,622 in control and 2,722 in intervention)
* The standard deviation 415 g [25]
* Power 80% and 5% two-sided alpha
* Intra-cluster correlation coefficient (ICC) 0.03 [19]
* The number of clusters 36

Using the standard [[1]](#footnote-1)formulae [20] the sample size required would be 720 from 36 clusters. Assuming 95% participation, 10% pregnancy loss and 10% delivery outside the study site (based on the experience in the Shonjibon Trial; APP1026864 - CIA-Dibley), 900 samples would be adequate to retain 720.

In this randomised controlled design treatment will be allocated at CHW cluster level. In the study area BRAC has 135 CHWs (*Shasthya Kormi*); of them 36 has been selected random and proportionately from all five sub-districts. Treatment has been assigned randomly to half (18) of the selected CHWs. Each selected CHWs will enroll 25 pregnant women and provide nutrition education and counseling starting from the date of initiation of the project.

*Inclusion criteria*

Key inclusion criteria includes:

* Pregnant women
* Age between 15-49 years
* First trimester of pregnancy (first 1-3 months)
* Permanent resident of study area

*Exclusion criteria*

Key exclusion criteria includes:

* Have plan to deliver outside the study area
* Diagnosed with chronic diseases like diabetes, hypertension, etc.
* Twin pregnancy

lling to volunteer

*Feasibility and acceptibility study*

A quick feasibility and acceptability study will be conducted to test the proposed diet plan and method of practical demonstration. Two focus group discussions will be conducted, one with pregnant women and another with mother/in laws of pregnant women in the proposed study area. This will enable us to understand the compatibility of the proposed diet plan in contrast to the local norms, beliefs, priorities and restrictions in diet in pregnancy. Information about availability of food in different seasons will also be gathered. Thus the final messages will be prepared refining the menu by incorporating local preferences, acceptability and seasonal variation. The training materials will be developed accordingly and CHWs will be trained on this new menu afterwards.

*Intervention design*

The ongoing IMNCS project ofBRAC provides community based anenatal care to all pregnant women. BRAC CHWs visit each pregnant women once in every month. During these visits CHWs will show the pregnant women how to make a plate of balanced diet with readily available food at households for each meal. They will prepare the meal infront of pregnant women and her family and show the exact measurement of a balanced meal with diversified food. They will use a 250 ml bowl to make a plate with adequate amount of food giving 2,500 Kcal from all four groups. At the same time they will promote locally available food rich in iron, calcium and vitamins. They will emphasize at least two servings of protein per day. A flyer containing the menu, both written and pictorial will be provided to each pregnant woman. CHWs will check the compliance of adherence to proposed diet plan by paying periodic surprise visit to pregnant women during meal time and observe the consumption pattern. In case of non-compliance, they will reinforce counselling the issues difficult to follow. Especially, if the issue is lack of access to particular food (e.g., animal source food), SKs will negotiate with the husbands to purchase that particular food. In case of very impoverished family, program will connect them with ‘Ultra-poor program’ of BRAC to avail financial support. CHWs will keep counseling pregnant women in control group following the standard approach. A daily food chart will be developed following the WHO and Institute of Nutrition and Food Security, Dhaka University, Bangladesh guidelines which will be used as BCC tool and job aid.

*Monitoring plan*

During monthly visits SKs will collect longitudinal data regarding dietary knowledge and practices from all enrolled pregnant women in intervention and control areas to monitor the compliance of dietary practice. Program Organizers (field supervisors of BRAC) and Research Officers (field supervisors of the project) will ensure data quality by direct observation of the data collection and cross checking 10% of the records with pregnant women.

***Main messages:***

*CHWs will use a bowl measuring 250 ml to show the amount of food a pregnant women should take. She will also provide a printed menu to all pregnant women containing the list of food with measurement for all five meals and a picture of different varieties of food. They will show them practically how to select and measure food and make a plate of balanced diet. The following are the messages-*

1. *Eat five times a day; three major meal and two snacks.*
2. *Eat 1.5 bowls rice or 3 pieces (medium sized) chapaties, 1 bowl vegetables, one egg or 1 bowl thick lentils in the morning.*
3. *Eat 1 piece seasonal fruits and 1 bowl milk products as morning snacks.*
4. *Eat 3 bowls rice, 1 bowl vegetables, 1 bowl thick lentils and 1 piece fish or meat or egg in lunch.*
5. *Eat 1 glass of milk, 1 bowl puffed rice and 1 piece seasonal fruits in the evening snacks.*
6. *Eat 2 bowls rice, 1.5 bowl vegetables, 1 bowl thick lentils, 1 piece fish or meat or egg and 1 glass of milk or .5 bowl curd in dinner.*
7. *Drink at least 8 glasses of water everyday.*

Table 1: Daily meal plan for pregnant woman (2500 kcal)

|  |  |  |
| --- | --- | --- |
|  | Food items | Quantity |
| Breakfast | Rice  Or  Ruti/chapatti | 11/2 bowl (250 ml + 125 ml)  Or  3 pieces (medium) |
| Vegetable fry (colored vegetables) | 1 bowl (250 ml) |
| Egg fry  Or  Thick pulse | 1 piece  Or  1 bowl (250 ml) |
| Mid-morning snacks  (10-11 am) | Seasonal fruits (e.g. banana/ mango/ jackfruit/ guava etc.) | 1 piece/ 1bowl (medium) |
| Mill products (rice cake, etc.) | 1 bowl (250 ml) |
| Lunch | Rice | 3 bowls (250 ml + 250 ml + 250 ml) |
| Thick pulse | 1 bowl (250 ml) |
| leafy/non-leafy vegetables | 11/2 bowl (250 ml + 125 ml) |
| Meat/fish/egg | 1 piece (medium) |
| Afternoon snacks | Milk | 1 glass (250 ml) |
| Seasonal fruits | 1 piece/ 1bowl (medium) |
| Puffed rice with molasses/biscuits | 1 bowl (250 ml) |
| Dinner | Rice | 2 bowls (250 ml + 250 ml) |
| Thick pulse | 1 bowl (250 ml) |
| leafy/non-leafy vegetables | 1bowl (250 ml) |
| Meat/fish/egg | 1 piece (medium) |
| Milk  Or  Curd | 1 glass (250 ml)  Or  1/2 bowl (125 ml) |

**Evaluation plan**

*Outcome assessment*

The primary outcome of interest is;

1) the difference in mean birth weight among babies born to mothers in intervention and control.

The secondary outcome of interests are;

2) the difference in mean daily energy intake and

3) the difference in mean dietary diversity score among pregnant women in third trimester between intervention and control.

Outcome assessments will be conducted on the cohorts of pregnant women and their infants in intervention and control groups. After enrollment all pregnant women will be followed up till delivery. Dietary assessment will be conducted at the third trimester with a group of trained interviewers. They will use 24 hours recall method to collect data on varieties of food consumed with quantity. After delivery all pregnant will be visited by Program Organizers within 72 hours and babies will be weighed. Only the singleton term live births will be included in the study and all preterm births (before 37 completed weeks) and twin births will be excluded from analysis.

*Measurements*

Birth weight: Program Organizers receive intensive training on postnatal check up and birth weighing. There is a system in place to inform about any births in the study area to BRAC CHWs and thus Program Organizers. An incentive attached to attend deliveries at home makes the system effective. Families contact CHWs via mobile phones as soon as the woman gets into labour. CHWs conduct uncomplicated deliveries at home, provide first postnatal care with taking birth weight and inform Program Organizers over phone to get the baby weighed again. Salter scale with 100 g precision will be used for this purpose. For hospital/institutional births, recorded birthweight will be used. In case on un-weighed babies Program Organizers will take birthweight if mother and baby come back home within 72 hours. Hand held 5 kg spring balance scale (Salter scale) with 100 g precision will be used to weigh the infants.

Dietary assessment:Maternal dietary intake will be measured using food frequency instrument (based on ‘Food Composition Table for Bangladesh’, INFS, 2013). Interviewers will collect 24 hour recalls of dietary history using standard methods in a randomly selected sub-sample of 72 pregnant women at their third trimester from each groups. The total available energy from each food will be calculated using references from ‘Food composition table for Bangladesh’, INFS 2013[[28](#_ENREF_28)]. Dietary diversity score will be developed in ferenece to the technical guideline of FHI 360 [[29](#_ENREF_29)]. We will display a 250 ml bowl to facilitate estimation of portion sizes and increase the reliability of estimation for individual food items consumed. From this the weight of different food items will be calculated. A conversion table from ‘Food Composition Table for Bangladesh’ will be used to calculate the equivalent weight of the raw food. Information on the habitual dietary pattern of each participant will be collected using a 7-day food frequency questionnaire enlisting a wide range of food items.

The sub-sample was calculated using following assumptions;

* The expected mean energy intake in control clusters 1,464 kcal/day
* The expected difference in mean birthweight between intervention and control groups 300 kcal (1,464 kcal/day in control and 1,764 kcal/day in intervention)
* The standard deviation 416 kcal [25]
* Power 80% and 5% two-sided alpha
* Intra-cluster correlation coefficient (ICC) 0.03 [19]
* The number of clusters 36

Using the standard [[2]](#footnote-2)formulae the sample size required would be 72 from 36 clusters (36 each in control and intervention).

*Outcome indicators*

The key outcome indicators are;

* Percentage of pregnant women consumed 2,500 kcal energy per day,
* Mean energy intake by pregnant women,
* Percentage of pregnant women consumed five or more varieties of food per day,
* Mean dietary diversity score of pregnant women,
* Percentage of infants born with birthweight 2,500 g or more
* Mean birthweight of infants and
* Percentage of LBW infants

*Case Definitions*

Birthweight: Weight of a newborn at birth is called birthweight. In this study weight will be allowed to take within 72 hours of birth. Mean birth weight will be calculated taking average of birthweights of all infants born alive among the enrolled pregnant women.

Dietary behaviour: Dietary behaviour will include information regarding daily intake of food energy, consumption of different varieties of food, amount of food and frequency of feeding.

**Qualitative study**

To understand the factors influencing the dietary behavior and practices among pregnant women and acceptability of intervention to the family members will be explored at the end of the intervention at the intervention arm. To ensure scientific rigor and increase the reliability of data, we will employ data triangulation through several methods of qualitative research; in-depth interview (IDI) and focus group discussion (FGD) with diversified categories of respondents. For example, if in the quantitative data, we find any type of food is being consumed less, the qualitative data from pregnant women will tell us whether there is any constraint in consuming that kind of food in pregnancy. Similarly, the FGD data will also tell us about the social norms and preception towards that particular food.

*In depth interview*

IDI with pregnant women will be conducted to explore the practices, perceptions, attitude and beliefs regarding pregnant woman’s diet, perceptions of the importance of nutrition during pregnancy, sources of nutrition information, attitude and acceptability towards the new messages and counseling technique. A purposive sampling will be used for in-depth interviews. A list of pregnant women will be collected from SKs intervention areas and sample will be selected based on gestational age; e.g., samples will be taken from each trimester; first, second and third. The number of IDI will depend on data saturation point.

*Focus Group Discussion*

FGD will be conducted with husbands of the enrolled pregnant women to understand their attitude towards the proposed intervention, their roles in ensuring nutrition of their pregnant wives and barriers in compliance with proposed diet. Five focus group discussion will be organised in five upazilas of the intervention district.

Based on the evidence from qualitative health research literature, we are confident that this will generate sufficient data to capture the diversity of individual perceptions and practices related to the research interest.

**Schedule of data collection**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Component | When | Measurements | Method/tool | By Whom |
| Assessment at enrolment | 1st trimester (within 12 weeks of gestation) | Socio-economic data,  details of reproductive history | Health records | SKs |
| Follow-up | 4-9th month of pregnancy | Blood pressure, anaemia, jaundice, oedema, chronic illnesses, pregnancy complications, service utilization, dietary intake, iron and calcium supplementation | Questionnaire, pregnancy record, blood pressure apparatus, 24-hour dietary recall | SKs |
| Primary outcome | Within 72 hours of birth | Birthweight, gestational age, physical assessment, cord care, initiation of brest feeding, maternal and infant complications | Standard anthropometric methods as described in measurements | Program Organizers |
| Secondary outcome | 3rd trimester (7-9th month of pregnancy) | Estimation of amount of different food items consumed | 24-hour dietary recall and 7-day Food Frequency Questionnaire | Trained interviewers |

**Statistical Analysis**

Data analysis will be conducted at mother and newborn level adjusting for the cluster randomization [6]. Primary analyses will compare the mean birthweight of full-term live birth infants and daily energy intake and dietary diversity score of mothers using Pearson’s chi-square tests at 95% confidence intervals. Secondary analyses will examine each outcome variable with multivariate linear regression to assess the net effect of independent variable on dependent variables. Odds ratio will be used to interpret the results at p-value less than 0.05 for statistical significance. Stata® software will be used for all analyses.

In case of qualitative study interviews and FGDs will be recorded using digital audio recorders. Interviewers and note takers will take additional notes of the key terms. The researchers involved in data collection will transcribe verbatim, the audio-recorded interviews and discussions, and expand the field notes in *Bengali* (the language spoken by the respondents and the chief investigator). Data will be organised and coded using NVivo® 10 software. Thematic analysis will be conducted to find variations, similarities and emerging trends in the themes that would be developed through the coding process.

**Timeline**

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| Activity | Year 1 | | | | | | | | | | | | Year 2 | | | | | | | | | | | |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| **1st Phase** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Protocol development & obtain ethical approval |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Recruitment of personnel |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Feasibility study |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Development of training materials |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Print BCC tools and job aids |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Development of registers and data collection tools |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Training of CHWs |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **2nd Phase** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Enrolment of participants |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Intervention |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Monthly data collection |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Data entry-quarterly |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **3rd Phase** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Dietary assessment |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Qualitative data collection |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Data management and analysis |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Report writing |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**Ethics**

Ethical approval will be sought from the Ethical Review Committee of James P. Grant School of Public Health, BRAC University, Dhaka, Bangladesh. Informed verbal consent will be collected for individual participants before enrolling into the study. Participants will be assured about confidentiality of data and will be allowed to leave the study without justification.

Benefits to participants include the provision of extensive behaviour change communications on monthly basis and opportunities to receive dietary counseling. The control clusters will not be directly benefitted through the trial. However, it is justifiable to run this trial considering the expected long term benefits of the programme to be upscale.

BRAC CHWs will explain the nature and process of the trial to potential participants as they register their pregnancies if they meet the inclusion criteria. CHWs will be trained to obtain verbal informed consent.

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1. Clustersampsi, mu1(2622) mu2(2722) sd1(415) sd2(415) k(36) rho(0.03) [↑](#footnote-ref-1)
2. Clustersampsi, mu1(1464) mu2(1764) sd1(416) sd2(416) k(36) rho(0.03) [↑](#footnote-ref-2)