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

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ABSTRACT

Objectives Low birthweight significantly contributes to neonatal mortality, morbidities and psychosocial debilities throughout the course of life. A large proportion of infants (36–55%) in Bangladesh is born with low birthweight. Nutritional status of women during pregnancy is critical for optimal growth and development of the fetus. Nutrition education has been found to improve maternal nutritional status. Our study aims to determine whether nutrition education with a practical demonstration during pregnancy is an effective intervention for improving the birthweight of infants compared with standard nutrition education only.

Methods and analysis We will conduct a community-based cluster randomised controlled trial in one rural district of Bangladesh. Treatments will be allocated evenly between the study clusters (n=36). Participants in the intervention clusters receive 'balanced plate nutrition education' with a practical demonstration from community health workers 4–7 times throughout their entire pregnancy, starting from the first trimester. The control clusters will receive standard nutrition education delivered by public and other healthcare providers as per ongoing antenatal care protocol. Our sample size would be 900 pregnant women to determine 100 g differences in mean birthweight, considering 5% type 1 error, 80% power and an intra-cluster correlation coefficient of 0.03. The primary outcome of the trial is birthweight of the infants and the secondary outcomes include daily caloric intake and dietary diversity score among the pregnant women. Outcomes will be measured at enrolment, third to ninth month of gestation (monthly) and at delivery. Community health workers blinded to the study hypothesis will collect all data.

Ethics and dissemination The study was approved by the James P Grant School of Public Health, BRAC University Ethical Review Committee, Dhaka, Bangladesh. We will communicate the final results to relevant research and public health groups and publish research papers in peer-reviewed journals.

Trial registration number ACTRN12616000080426.

Strengths and limitations of this study

► This study may contribute to limited evidence regarding maternal nutrition education strategies to improve birthweight of infants.
► Identifying effective approaches in nutrition education is likely to contribute to reducing the burden of maternal malnutrition and poor birth outcomes.
► This replicable behaviour change communication approach can be scaled up and sustained through existing health systems with minimal investments.
► Prior piloting and adaptation are required to replicate this community-based intervention in other settings.
► The study is localised in one district of Bangladesh, so the results might not be representative or generalisable to all parts of Bangladesh or other countries.

INTRODUCTION
Background and rationale

Globally more than 20 million infants are born with low birthweight (LBW) (<2500 g) every year, 96% in low and middle-income countries.[1] Neonates weighing less than 2500 g are approximately three times more likely to die compared with those weighing 2500 g or more at birth, and the risk increases as birth- weight decreases. LBW indirectly accounts for 60% of the deaths among neonates and more than 13 million disability adjusted life years among children aged less than five years.[2] LBW significantly impacts on health throughout the life course; in childhood it causes hyperactivity and inattention, emotional and behavioural problems and poor educational attainment,[3] while in adulthood it leads to the development of chronic diseases[4] and lower economic productivity.[5]

Intrauterine growth restriction (IUGR) is the probable cause of LBW in babies born at term (≥37 weeks of gestation)[2]; this may be partly due to the impairment of the placental development and function in the presence of maternal undernutrition.[6] There is strong evidence that poor maternal nutrition during pregnancy leads to intrauterine growth restriction and thus LBW.[7–9] Thirteen percent of Bangladeshi women of reproductive age (15–49 years) are short statured (height <145 cm) and 19% are thin (body mass index <18.5 kg/m^2),[10] which indicates that these women enter pregnancy with chronic undernutrition. Moreover, in Bangladesh during pregnancy women consume far less than the recommended dietary energy. Alam and colleagues found that the average daily energy intake among Bangladeshi women in late pregnancy was 1464±416 kcal per day, much lower than the recommendation of ~2500 kcal.[11] Among women from low-income families, diets lack protein and micronutrients.[7] Dietary diversity, which is believed to be strongly associated with nutrient adequacy, was 4.5 (out of nine food subgroups) in women's regular diet in rural Bangladesh.[8] This nutritional deprivation during pregnancy may impair placental development, leading to reduced nutrient transfer to the fetus and ultimately to IUGR.[9] A longitudinal study conducted in Iran between 2009 and 2010 found that energy and protein intake was associated with the birthweight of infants. Pregnant women who consumed 1794±54 kcal per day gave birth to neonates with a mean birthweight of 2600 g, whereas pregnant women who consumed 2698±107 kcal gave birth to neonates with a mean birth- weight of 3600 g. Similarly, an increase in protein intake from 38.7±4.7 g to 72.8±7.4 g per day was associated with an increased birthweight from 2500 g to 3400 g.[12]

Antenatal nutrition education has been found to improve dietary behaviour and significantly increase total energy intake (from 2269 to 2431 kcal per day, p<0.05) among low-income pregnant women.[13] A systematic review examined the effect of antenatal nutrition education on birthweight of infants and found a significant increase in birthweight by 105 g. However, the stratified analysis showed that the effect was significant only for high-income countries and when nutrition education was provided with nutritional supplementation.[14] A Cochrane review reported a significant increase in birthweight among undernourished women who received nutrition education (difference in mean 490 g; 95% CI 428-552 g), while no significant increase was observed for adequately nourished women.[15] These findings are based on studies with some methodological weaknesses including small sample size or few events and quasi-experimental studies or randomised controlled trials with design or analysis limitations.

Bangladesh has had a large-scale community-based nutrition programme since 1995 and mainstreamed antenatal nutrition education and supplementation programmes since 2010.[16] Despite these programmes, the LBW rate still remains a public health concern, estimated at 36–55%.[17–19] In this context, innovative interventions are needed to accelerate reductions in LBW at the population level to achieve the Sustainable Development Goal targets of nutrition by 2030.[20] Shifting from conventional nutrition education and food supplementation to more effective enhanced nutrition education could be one of the potential sustainable ways of improving dietary behaviour during pregnancy and to increase birthweight at the population level.

Study objectives and hypothesis

We have designed a nutrition education intervention that actively teaches and empowers pregnant women to prepare their own balanced plate of food that includes an appropriate selection of items with maximisation of diversity and adequate portion size from foods readily available in their kitchen. The objective of the study is to compare the impact of this 'balanced plate nutrition education' approach with the standard nutrition education programme for pregnant women on their dietary behaviour and birthweight of their infants.

Our primary hypothesis is that women who receive 'balanced plate nutrition education' during pregnancy will deliver babies 100 g heavier than those who receive standard nutrition education. Secondary hypotheses are that 'balanced plate nutrition education' will increase daily caloric intake by 300 kcal and increase the dietary diversity score to at least five (out of nine food subgroups with minimum consumption of 15 g from each group) among pregnant women compared with standard nutrition education.

METHODS AND ANALYSIS
Study design

We will conduct a two-arm parallel community-based cluster randomised controlled trial with pregnant women. Women allocated to the intervention arm will receive the 'balanced plate nutrition education' with practical demonstrations and women in the control arm will receive standard nutrition education (figure 1). This is an effectiveness trial to be conducted through the existing health programme of BRAC (an NGO formerly known as Bangladesh Rural Advancement Committee or Building Resources Across Communities), a nationwide community-based healthcare intervention.

Formative research

We will conduct a food attributes exercise applying the ProPAN methodology.[21] In this regard, a group of qualitative interviews will take place with key target populations such as pregnant women, influential family members (eg., husbands, mothers and mother-in-laws of the pregnant women) to generate information about key foods taken during pregnancy, positive and negative characteristics attributed to key foods, and conditions and changes required for pregnant women to consume nutrient-rich foods that are not currently taken or
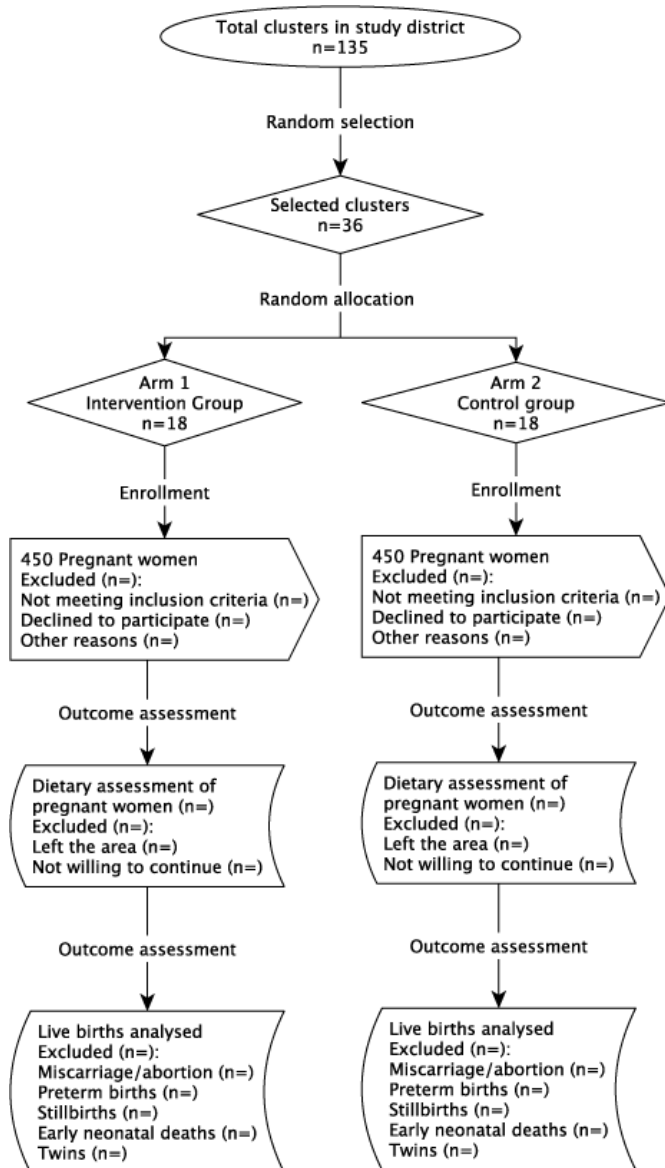
Figure 1 Study design

inadequately taken. These data will inform the design of the 'balanced plate nutrition education' intervention, which will then be pilot tested to assess its acceptability to the community and the feasibility of implementation prior to the commencement of the actual trial. We will conduct focus group discussions with pregnant women; their husbands, mothers and mother-in-laws; and *Shasthya Kormis* (community health workers of BRAC who are the major antenatal care providers in the respective community) in two different sites of the study area. The data will assist with understanding the cultural compatibility of the proposed approach along with identifying local norms, beliefs, priorities and any cultural food restrictions and prescriptions during pregnancy. Information about the availability of foods in different seasons will also be considered. The final messages will be developed, refining the menu by incorporating the results

of the pilot trial on local preferences, acceptability and seasonal variation.

Study setting
The proposed research will take place in the villages of Sherpur district, situated in the northern part of Bangladesh (figure 2). The total population of the district is approximately 1.4 million. The economy of Sherpur is mainly agriculture-based with 60% of the households engaged in farming. The adult literacy rate is 37.9% (male 40.2% and female 35.7%),[22] much lower than the national average of 56.1%.[23] Healthcare services such as maternity care are mostly provided by the public providers through healthcare facilities and outreach centres.

BRAC implements a community-based maternal, neonatal and child health programme in the study area, characterised by a prospective pregnancy surveillance system, home-based antenatal care (ANC) and other reproductive, neonatal and child healthcare. The trial uses the established pregnancy surveillance and home-based ANC system of BRAC. There are ~346 health volunteers (called *Shasthya Shebika*) who pay home visits to women of reproductive age and detect delayed or missed menstrual cycles. Women missing a menstrual cycle in the previous six weeks are screened for possible pregnancy using a urine test and, if the pregnancy is confirmed, start receiving ANC from the *Shasthya Kormis* (*SK*).

Study clusters
We have chosen clusters as the unit of randomisation instead of individuals for greater logistical convenience and to prevent contamination of the intervention. The unit of randomisation in our study is the population (~10 000) served by *SK* with a defined geographical area consisting of approximately five villages. The entire study district is divided into 135 exclusive clusters. Clustering will help minimise sharing of nutrition messages among pregnant women, which would occur if the intervention and control were administered among women from the same village or neighbouring villages. Clusters will be eligible for inclusion in the trial if the corresponding *SKs* have work experience for at least six months in the maternal, neonatal and child health programme in the specific region. Clusters will be excluded if there is any maternal nutrition intervention already in place.

Study population
The study population comprises pregnant women permanently residing in the study area. Permanent residency is defined by living in the study area for a minimum of six consecutive months preceding the recruitment.

Inclusion and exclusion criteria
We will consider women eligible for recruitment if they are:
► married and of reproductive age (15–49 years)
► pregnant with a duration of gestation of 7–12 weeks
► permanent residents of the study area.

Figure 2 Study site

We will exclude women who have:

► planned to deliver outside the study area
► been diagnosed with any chronic diseases, such as diabetes, hypertension and other diseases that may impact on their ability to participate in the trial.

Randomisation

Random selection of clusters

Sherpur district is divided into five sub-districts: Jhenaigati, Nakla, Nalitabari, Sherpur Sadar and Sreebardi containing 16, 19, 25, 49 and 26 clusters, respectively. We will use proportionate stratified sampling method to obtain 4, 5, 7, 13 and 7 clusters, respectively, from each of the five sub-districts proportionate (36/135) to their population size. For the first sub-district (Jhenaigati), we will select four

clusters from a list of the clusters in that area using random numbers generated by a computer program in MS Excel spreadsheet (using the RANDOM function), and apply the same method to the rest of the sub-districts until we obtain the 36 clusters. With this technique, we will be able to capture geographical variations across the district.

Allocation sequence and concealment

Once we have prepared the list of clusters, we will conduct a lottery to assign treatments between the two groups (intervention (group A) and control (group B)) in 1:1 ratio. We will write each cluster number onto 36 pieces of paper and put them into five different jars, one jar for each sub-district, based on the cluster selection made in the first step. The treatment sequence will alternate between A (intervention) and B (control), starting with A. One volunteer (not

involved with the study) will pick the papers blindfolded. For the first sub-district, there will be four pieces of paper and the treatment assignment sequence will be ABAB, which means the first number picked will go to treatment A and the next to treatment B and so on. For the second sub-district, the sequence would be ABABA, starting with where the first one ended. Subsequently, the sequence we will follow for the third, fourth and fifth sub-districts are BABABAB, ABABABABABABA and BABABAB.

Implementation

BRAC staff from the headquarters along with the Principal Investigator will select the clusters as described above, while BRAC local staff (at the study site) will conduct the lotteries to assign the treatments in the presence of other staff in the office. After obtaining consent from the *SK*s to take part in the study, the lists will be provided to the training unit to ensure appropriate training of the two groups. If any *SK* decides to withdraw from the study, she will be replaced by another *SK* randomly selected from the remaining *SK*s in the list.

Enrolment

Once clusters are finalised, *SK*s will start enrolling study participants, consented eligible pregnant women, from the study sites. Each *SK* has been given a minimum target to enrol 10 pregnant women per month until the individual target (25) is reached. Regular pregnancy identification system of BRAC will be used to reach pregnant women and approach them for obtaining the consent. The long-term involvement of *SK*s with the community enabled them to gain people's trust, which will help maximise enrolment and obtain the desired sample size within three months. However, if the target is not reached, the enrolment period will be extended with proper justification. Actual enrolment started on 1 October 2016 and will continue until 31 December 2016. The details of the enrolment schedule are shown in table 1.

Table 1 Time schedule of enrolment, intervention, assessment and process evaluation

	Study period										
	Pre-enrolment	Enrolment			Post-enrolment						
Time point (month)	*0*	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*
Enrolment:											
Cluster selection	X										
Allocation	X										
Eligibility screen	X										
Informed consent			◆——◆								
Enrolment			◆——◆								
Interventions:											
Balanced plate nutrition education				◆————————————◆							
Standard nutrition education				◆————————————◆							
Assessments:											
Baseline											
Sociodemographic information			◆——◆								
Nutrition knowledge assessment			◆——◆								
Follow-up											
Physical condition					◆————————◆						
Dietary assessment					◆————————◆						
Impact evaluation											
Birth outcome									◆——◆		
Birthweight measurement									◆——◆		
Process evaluation:											
Participants enrolled			◆——◆								
Nutrition messages delivered					◆————————◆						
Pregnancy identification		◆—————————————◆									
Antenatal care visit		◆—————————————◆									
Postnatal care visit		◆—————————————◆									

Box   Core contents of nutritional messages

1. Eat five times a day, three major meals and two snacks.
2. Eat 1.5 dishes of rice or 3 pieces (medium sized) of chapaties, 1 dish of vegetables, 1 egg or 1 dish of thick lentil in the morning.
3. Eat 1 piece or 1 dish of seasonal fruit(s) and 1 dish of milk product(s) as morning snack.
4. Eat 3 dishes of rice, 1 dish of vegetables, 1 dish of thick lentil and 1 piece of fish or meat or egg at lunch.
5. Eat 1 glass of milk, 1 dish of puffed rice mixed with molasses and 1 piece or 1 dish of seasonal fruit(s) in the evening snack.
6. Eat 2 dishes of rice, 1.5 dishes of vegetables, 1 dish of thick lentil, 1 piece of fish or meat or egg and 1 glass of milk or 0.5 dish of curd at dinner.
7. Drink at least 8 glasses of water.
8. Cook with oil.

Blinding (masking)

Allocation concealment is not possible due to the nature of the intervention. The participants, as well as the *SK*s, are aware of the intervention. However, both the participants and the *SK*s will be blinded to the study hypothesis. We will use objective and reliable outcomes, such as birthweight and food consumption, which are less prone to ascertainment bias. Finally, we will blind the data analysts by labelling the groups with non-identifying terms (e.g; A and B) until the final analysis.

Intervention

The study intervention, 'balanced plate nutrition education', is a method of teaching pregnant women to prepare properly balanced meals. The education session has two parts: one-to-one nutrition-specific counseling and practical demonstration. For counselling, *SK*s will use written and pictorial menus. The core contents of the counselling are included in box. The nutritional messages are developed with reference to the current Bangladeshi recommendations,[24] which incorporates the following: (a) intake of food-yielding at least 2500 kcal energy per day; (b) consumption of diversified food; (c) inclusion of animal sourced food in the diet, at least two servings per day; and (d) eating at least five times a day (five different plates for five meals). Rather than endorsing new or expensive foods, indigenous foods rich in iron, calcium and vitamins will be promoted in the study. Considering the high price and low consumption of protein-rich foods in general, both from the plant (ie, lentils) and the animal (ie, meat, fish, egg and milk) sources, we will advise the cheapest options for protein from animal source such as fish grown in local farms. There are varieties of inexpensive fish available in the market, such as tilapia, certain catfish (e.g., *pangas*) and carp (e.g., silver carp). We will motivate the pregnant women to consume an adequate amount of these fish by making them realise that these are equally as nutritious as other costly protein-rich foods. Five different menus will be developed for five daily meals yielding collectively 2500 kcal energy and essential micro- and macronutrients for the day (table 2). A pictorial menu (figure 3) and a pictorial food

Table 2   Five-meal menu for pregnant women (English)

Meal	Food	Quantity (one dish=250 mL)
Breakfast	Rice	1.5 dishes
	or	
	Chapati (medium size)	3 pieces
	Vegetables	1 dish
	Egg	1
	or	
	Lentil (thick)	1 dish
Mid-morning snack	Seasonal fruit(s)	1 piece/dish
	Milk product(s)	1 dish
Lunch	Rice	3 dishes
	Lentil (thick)	1 dish
	Leafy/non-leafy vegetables	1.5 dishes
	Meat/fish/egg	1 piece
Afternoon snack	Milk	1 glass
	Seasonal fruit(s)	1 piece/dish
	Puffed rice with molasses or Biscuits	1 dish 1 dish
Dinner	Rice	2 dishes
	Lentil (thick)	1 dish
	Leafy/non-leafy vegetables	1.5 dishes
	Meat/fish/egg	1 piece
	Milk or	1 glass
	Curd	0.5 dish

chart (figure 4) in the local language will be provided to all women, who are mostly illiterate or semi-literate.

Practical demonstration refers to exhibiting the meal preparation in front of the pregnant women and their family members in a participatory way. For this, participant women will be encouraged to share food from their own. If the available food items are not sufficient to make a balanced meal, then the neighbours will be asked to contribute. Sharing food between households is common and culturally acceptable in rural Bangladesh. *SK*s will measure portion sizes for carbohydrate, protein and vegetable groups using a local utensil (250 mL size dish) and display the assembled meal on a regular dinner plate. From this visual presentation, pregnant women will be able to actively identify the food groups where they should make a change. Pregnant women are then encouraged to make their own plate for each meal following the given menu. The *SK*s will invite the key influential family members to join the balanced plate preparation demonstration and the counselling sessions. The mother-in-law and/or mother of the pregnant woman (depending on where the

উপাদান		পরিমাণ
সকালের নাস্তা	ভাত	১১/২ বাটি (২৫০ মি.লি.+১২৫ মি.লি.)
	অথবা	অথবা
	আটার রুটি	৩টি (মাঝারি)
	সবজি ভাজি	১ বাটি (২৫০ মি.লি.)
	ডিম ভাজি	১টি
	অথবা	অথবা
	ঘন ডাল	১ বাটি (২৫০ মি.লি.)
নাস্তা (সকাল ১০-১১)	যে কোন মৌসুমি ফল (যেমন-কলা/আম/কাঁঠাল/পেয়ারা/পেঁপে ইত্যাদি)	১টি (মাঝারি)
	অথবা	অথবা
	গুড়-মুড়ি/গুড়-খই/বিস্কুট	১ বাটি (২৫০ মি.লি.)
দুপুরের খাবার	ভাত	৩ বাটি (২৫০ মি.লি.+২৫০ মি.লি.+২৫০ মি.লি.)
	ঘন ডাল	১ বাটি (২৫০ মি.লি.)
	শাক-সবজি	১ বাটি (২৫০ মি.লি.)
	মাছ/মাংস/ডিম	১ টুকরা (মাঝারি)
বিকেলের নাস্তা	দুধ	১ গ্লাস
	অথবা	অথবা
	দুধের তৈরি পায়েস/ফিরনি/পিঠা	১/২ বাটি (১২৫ মি.লি.)
রাতের খাবার	ভাত	২ বাটি (২৫০ মি.লি.+২৫০ মি.লি.)
	ঘন ডাল	১ বাটি (২৫০ মি.লি.)
	শাক-সবজি	১১/২ বাটি (২৫০ মি.লি.+১২৫ মি.লি.)
	মাছ/মাংস/ডিম	১ টুকরা (মাঝারি)

গর্ভবতী মহিলার একদিনের খাদ্য তালিকা (২৫০০ কিলোক্যালরী)

রান্নায় তেল ব্যবহার করুন। সম্ভব হলে খাবার পূর্বে খাবারের সঙ্গে ১ চা চামচ তেল যোগ করুন।

Figure 3 Five-meal menu for pregnant woman (*Bengali*).

women stay at the time of counselling/demonstration) and her husband (if he is available) will be invited. In the absence of the mother-in-law or mother, an influential senior female member will be invited. In addition to providing counselling on the maternal nutrition and balanced diet, the *SK*s will motivate these family members to provide support to the pregnant women for their adherence to the nutritional messages. We expect that their active support will create an enabling environment for the pregnant women to practise improved diet.

The intervention will commence in the first trimester (ideally before 12 weeks of gestation) and will continue every month until birth. Each pregnant woman will have 4–7 sessions throughout her entire pregnancy. The sessions will last for approximately 30–45 min.

Control intervention

Government health facilities provide nutrition education, following a national standard protocol, to all pregnant women seeking ANC. Pregnant women from both the control and the intervention groups will continue to have access to this service. This education is one-to-one advice, delivered by doctors or Family Welfare Visitors. The content usually includes the following advices: (a) taking extra food; (b) consumption of meat, fish, liver, egg, milk/milk products, lentils, colourful vegetables, fruits and oil; and (c) taking iron-folic acid (60 mg iron and 40 mg folic acid) and calcium (500 mg) supplements. The control group has the same frequency of contact with the *SK*s as the intervention group and receives antenatal care except for the 'balanced plate nutrition education'.

Outcomes
Primary outcome
The primary outcome of this study is the birthweight of the newborn infants. Community health volunteers notify births in the community within 24 hours. *SK*s visit the mother and baby, and conduct a postnatal check-up including weighing the baby. Birthweight is defined as the weight of an infant just after birth. Birthweight less than 2500 g is considered as low birthweight.

Secondary outcomes
The secondary outcome is the maternal dietary behaviour, which includes daily caloric intake and dietary diversity score. *SK*s will conduct dietary assessments with a semi-structured questionnaire, developed based on the list of foods used in the Food and Nutrition Technical Assistance II Project (FANTA-2).[8] This tool captures detailed information about all foods, beverages and dietary supplements consumed in the past 24 hours with quantity, from midnight to midnight the previous day. Prompts, such as a 250 mL size dish, will be used to improve estimation of portion size. We will estimate the approximate weight in grams using the conversion table from the Food Composition Table for Bangladesh (INFS 2013) to calculate the equivalent weight of the raw food and attainable calories.[25] We will combine all consumed food items in 10 groups as: (1) grains, white roots and tubers; (2) pulses (beans, peas and lentils); (3) nuts and seeds; (4) dairy; (5) meat, poultry and fish; (6) eggs; (7) dark green leafy vegetables; (8) other vitamin A-rich fruits and vegetables; (9) other vegetables; and (10) other fruits. Minimum dietary diversity, a dichotomous indicator, will be developed for referring higher micronutrient adequacy and diet quality.[7]

Other study parameters
Other study parameters include age, education and occupation of mother; age, education and occupation of husband; religion; family income; living children; previous pregnancy loss; gestational age; tetanus injection; ANC visit; and other healthcare services used.

Sample size calculation
A published randomised controlled trial in rural Bangladesh reported a mean±SD birthweight of 2531±415 g.[19] Holding this as a reference, we expect a 100 g increase in birthweight over the study period in the intervention group, resulting in a mean expected birthweight of 2631 g. Using standard sample size calculation formulae,[26] the estimated sample size will be 720 live births (from 36 clusters) to determine a 100 g difference in mean birthweight, assuming 5% type 1 error, 80% power and a 0.03
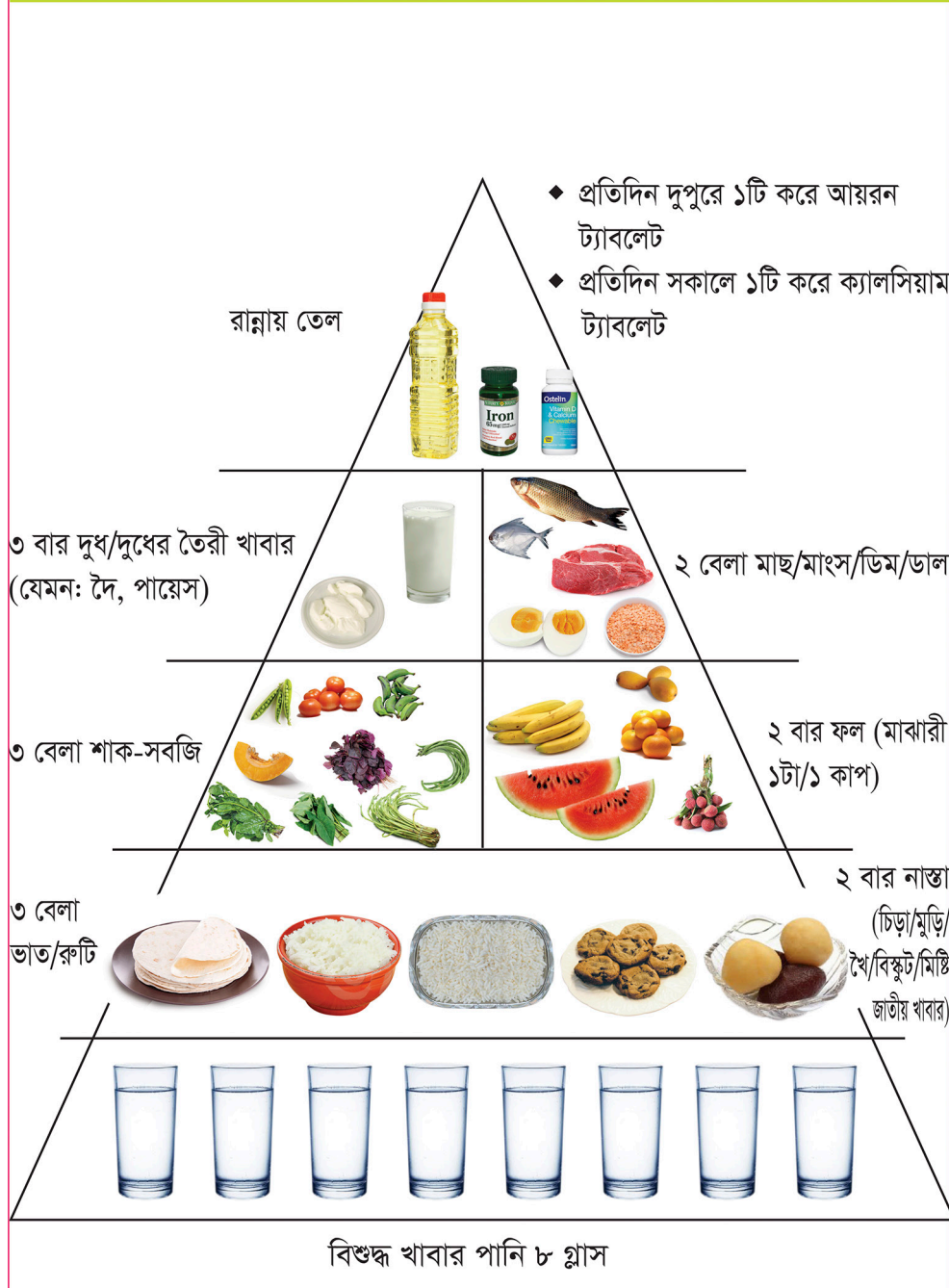
Figure 4 Pictorial food chart for pregnant women (*bengali*)

intra-cluster correlation coefficient (ICC) (based on a published ICC for birthweight from a trial conducted in rural China).[27] Inflating the sample by 5% for non-response, 10% for pregnancy loss and 10% for delivery outside the study area (unpublished data, based on our experience of conducting a large community-based trial in rural Bangladesh, ACTRN12612000588897), we require a sample of 900 pregnant women to retain 720 live births.

The estimated live births per cluster per month is approximately 19, based on the national rural crude birth rate of 23.3 per 1000 population.[28] Therefore, three months of recruitment will be sufficient to reach the required sample size. The estimated recruitment per cluster per month would be slightly more than eight.

Data collection method and schedule

At baseline, sociodemographic data and reproductive history will be collected from all pregnant women on enrolment. During the monthly follow-ups, information on health condition, current pregnancy status and healthcare services will be collected. We will conduct

longitudinal dietary assessment for 4–7 non-consecutive days. All live newborn infants' birthweights will be assessed within 72 hours of birth with a hand-held spring balance scale (Salter scale with a capacity of five kg and an accuracy of 100 g). Infants will wear only light clothes; the wrapping blanket will be taken off during weighing. The scale will be adjusted for the weight of the dress that the infant will be wearing before the process starts. *SK*s will collect the data during their regular scheduled visit to pregnant women and newborn children. A detailed schedule of assessment is shown in table 1.

Field supervisors will check 5% of the data randomly and notify a potential measurement problem. In addition, we will validate the dietary assessment data by repeating the assessment with independent interviewers in a subsample of participants (72; 36 each from intervention and control). Field supervisors, blinded to the outcome of interest, will also recapture 25% of the birthweight measures for data validity. The Salter scales used will be standardised every month. For institutional births, the recorded birthweights will be used.

Women will be designated as 'lost to follow-up' if they withdraw or move away and are untraceable for more than three consecutive visits. Information regarding the reasons for discontinuation will be recorded interviewing the relatives, neighbours or direct contact with the woman through mobile phones.

Data management

SKs will record the information in a paper book (one book for 25 participants), which will be transferred into an electronic file at the end of the intervention. The string variables will be coded with numeric values before inputting into Stata files. After completion of this process, the paper books will remain locked in the regional office of BRAC with access restricted to management staff only and will be destroyed after four years as per institutional guidelines. The research officer will de-identify the participants' data, code, clean and verify it (if needed). The principal investigator blinded to the trial arm will analyse the data.

Statistical analysis

All the women who are randomly assigned to either balanced plate or standard nutrition education will be analysed on an intention-to-treat basis. We will limit the birthweight data analysis to singleton liveborn infants, considering the strong relationship between multiple births and low birthweight.[29] Dietary data will be analysed if we have at least two rounds of dietary assessment (baseline and follow-up), irrespective of pregnancy outcome.

The differences in performance of key cluster personnel (SKs) are expected to induce differences in response to the intervention. This makes the data hierarchical in nature due to the assumption of non-independence among those who live in the same cluster; hence we will use multilevel models to examine outcomes. Births being nested within clusters, we will use mixed effects regression

models to measure the difference in effect (random intercept) between the treatment groups accounting for clusters and report the ICC. We will treat cluster as a random effect in the models, while the other explanatory variables will be treated as fixed effects. We will compare the distribution of prognostic factors between treatment groups and check for the effectiveness of randomisation. Any imbalance in the important prognostic factors will be adjusted by including them as covariates in the models.

We will use multivariable regression analysis to assess intervention effects holding other predictors constant, such as gestational age, infant sex, parity, age, socioeconomic status, education, the number of visits and time of the first visit after adjusting for the clusters.[30] To assess the treatment effect on dietary caloric intake and diversity over time, we will use data from each visit distributed across subjects. We will compute inter-rater reliability to measure the level of agreement using ICC statistic among multiple coders (data collectors, *SK*s and field supervisors).[31] The analysis will be performed with Stata software (version 13.1).

PROCESS EVALUATION

We will apply the Trials of Improved Practices (TIPs) methodology to identify causes of any non-compliance of the advice provided to the women. We will purposively select subsamples (approximately 20) of the households, keeping the geographical and sociocultural (e.g., religion and economic status) diversities in mind. *SK*s will demonstrate the balanced plate to the pregnant women of these households, provide counselling to consume the balanced meal similar to the plate and ask them to continue this practice for 1 week. At the end of the week in a follow-up visit, the SKs will interview the women and identify significant barriers to incorporating the balanced diet into their dietary practices. The TIPs findings will provide feedback to adjust the design of the communication technique based on the practical experience of the trial participants. The feedback will be shared in the monthly meetings to adapt the content and strategy of the communication. Apart from the TIPs, we will assess the progress of the study against some verifiable indicators including the number of pregnant women enrolled and the number of nutrition messages delivered. Ticking the boxes through direct observations will check the number of nutrition messages delivered to the pregnant women. Any deviation from the target will be investigated for recovery actions. Any decline in performance against some verifiable indicators (pregnancy identification, ANC and postnatal visits) will suggest probable task overload of *SK*s. We will record all the barriers faced in the process of programme development and implementation. The process evaluation schedule is shown in table 1.

DISCUSSION

This paper describes a protocol for a two-arm cluster randomised controlled trial consisting of an intervention in which pregnant women receive nutrition education that includes a practical demonstration on preparing a nutritionally balanced meal. Nutrition education for pregnant women is understood to influence nutrition-related knowledge and dietary behaviour, pregnancy weight gain and birthweight.[32]

This new approach using a practical demonstration is a unique and promising method of behaviour change communication. This intervention is easy to implement by the existing community health workers and its participatory nature engages the pregnant women involved. It does not require any additional props or tools that are not readily available. Unlike typical nutrition education, our approach is more visual and interactive, which makes it easier for the participants to understand the messages clearly. Importantly, it does not require any food supplementation, which makes this intervention highly scalable and more likely to be sustainable in resource-poor settings including Bangladesh.

Nutrition education, which has been defined as 'any combination of educational strategies, accompanied by environmental supports, designed to facilitate voluntary adoption of food choices and other food and nutrition-related behaviours conducive to health and well-being…' has essentially three phases or components: motivational phase, action phase and environmental component.[33] Our intervention addresses all the three components: verbal communication increases awareness and enhances motivation of the pregnant woman to adopt the intended behaviour; practical demonstration facilitates the ability to take action in practising a balanced meal; and communication with influential family members (husband, mother-in-law and mother) provides an enabling environment to support the woman's changed dietary behaviour. All of these three components are grounded in a health behaviour change communication theory, the 'Integrative Model of Behavioural Prediction'. According to this theory, a strong intention of a person to perform a behaviour, accompanied by the necessary skills and abilities to perform it, and a conducive environment results in the expected behaviour change.[34]

Using a practical demonstration in maternal nutrition education is a novel approach. However, this approach has been proved to be quite effective in other health education interventions. A study addressing oral health, provided a one hour lecture and practical demonstration to caregivers on oral hygiene, and measured the impact on oral infections (gingivitis and stomatitis). The results showed that gingivitis scores in the intervention group decreased to 0.28 units from a baseline of 1.37, and the rate of stomatitis in the intervention decreased from 17% at baseline to 4%.[35] Gill and O'May investigated the utility of a practical pouring exercise to inform participants of their daily limits of alcohol consumption and found that almost half of the participants (46%) were able to confirm exactly when they would exceed the limit. One-fifth of the participants thought that this practical pouring might influence their future alcohol drinking habit.[36]

Successful behaviour change is already observed in infant and young child feeding practices in Bangladesh with approaches like practical demonstration and counseling.[37] An educational tool for practical demonstration (food plate and nutrition messages) to improve dietary diversity during pregnancy has been tested in one project in Bangladesh with the intention of improving maternal nutrition.[38]

METHODOLOGICAL CONSIDERATIONS

Contamination due to communication between the service providers cannot be completely ruled out as the study will be conducted in one geographic region. However, we will ensure that *SK*s from the intervention and control groups do not meet each other. These two groups will receive training separately and have monthly meetings in distinct groups. There is no chance of overlapping at the community level as *SK*s work in distinct villages (villages are usually geographically separated by farm lands, canals and roads). Another limitation of the study is the multipurpose role of *SK*s who will provide the 'balanced plate nutrition education' intervention and also act as data collectors. We anticipate that blinding to study hypothesis will reduce some of the measurement bias.

ETHICS AND DISSEMINATION

The present study was approved by the James P Grant School of Public Health, BRAC University Ethical Review Committee, Dhaka, Bangladesh.

We will communicate the final results to BRAC programme and research professionals, James P Grant School of Public Health professionals and students, public health academics, researchers and students at the University of Sydney and other relevant national and international forums. Research papers based on the study will be published in peer-reviewed journals. Everyone who makes a substantial contribution to the conduct of the project and/or to publications including conception, design, analyses and interpretation of data will be an author. We will acknowledge other contributions, such as project staff, BRAC management team, research assistants and community people via acknowledgement in the publication. Any researcher having a particular interest in the relevant field will be considered to get access to the full protocol and participant level dataset if felt crucial.

TRIAL REGISTRATION

The trial is registered in the Australian New Zealand Clinical Trials Registry (ANZCTR) on 25 January 2016. The registration number is ACTRN12616000080426. The protocol has been amended on 28 November 2016 with the designated Trial Registry.

DECLARATIONS

Consent to participate

After pregnancy identification, informed consent will be obtained from all eligible participants before enrolling into the study. *SKs* will explain the nature and process of the study to the potential participants if they meet the inclusion criteria. For literate participants, the consent will be in a written form (a copy is attached in the Supplementary file 1) and for all others, it will be verbal. Participants will be assured about the confidentiality of data and will be allowed to withdraw at any time from the trial without any justification.

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