Prevention of Low Birthweight Infants Among Pregnant Women in Rural Bangladesh: A Cluster Randomized Controlled Trial

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Statement of Authentication

This is to certify that the content of this thesis is my own work. This thesis has not been submitted for any degree or other purposes.

I certify that the intellectual content of this thesis is the product of my own work and that all the assistance received in preparing this thesis and sources have been acknowledged.

Signature: 

Date: 28 August, 2018

Authors' Contribution

The work presented in this thesis was conducted by the candidate under the supervision of Professor Michael J. Dibley, Associate Professor Camille Raynes-Greenow and Dr Ashraful Alam from Sydney School of Public Health, the University of Sydney.

The candidate planned the research, designed the studies, prepared the protocol and evaluation tools, obtained ethics approval, conducted formative research followed by field trial, supervised the intervention and data collection, analyzed the data, interpreted results, drafted and revised the manuscripts for peer-reviewed journals for all studies presented in this thesis.

Ethical Clearance

The trial was ethically approved by the James P Grant School of Public Health, BRAC University Ethical Review Committee (ERC); Bangladesh (Ethics Reference No 53). The Sydney Medical School (funder) and Human Ethics committee, University of Sydney, Australia accepted the home country approval.

For secondary data analysis, BDHS data were obtained from the public domain with an approval from Demographic Health Survey (DHS) Programme, ICF International; USA. The survey was approved by the institutional review board of ICF Macro in Calverton, MD, USA.

Abstract

The low birthweight (LBW) prevalence in Bangladesh varies between 22-50%, which positioned Bangladesh 4th globally among the countries having highest burden of LBW. LBW imposes greater risk of mortality and morbidities among children under five and creates a long-term negative impact on development and wellbeing in adolescence and adulthood. Therefore, the objective of the research was to investigate the effects of 'balanced plate nutrition education' (nutrition education on balanced diet with practical demonstration of balanced plate) in combination with engagement of family decision makers, to reduce incidences of LBW infants among pregnant women by increasing birthweight. The specific objectives included developing the 'balanced plate nutrition education' intervention for rural pregnant women and measuring the effect of the intervention on birthweight of infants and incidences of LBW, and exploring the barriers of and household coping strategies related to compliance. It also examined the association of household food insecurity and size of infants at birth.

Both quantitative and qualitative methods were applied for this research. For the quantitative analysis, primary data were derived from a randomized controlled trial conducted in rural Bangladesh (Chapter 4) and secondary data from Bangladesh Demographic and Health Survey 2011 (Chapter 6). Statistical analyses were performed using multivariable linear and binomial regression with log link function. We adjusted for the clustered randomisation using generalised estimating equations (GEE). We constructed survey-weighted logistic regression models for BDHS data to account for different sampling probabilities and different response rate. A qualitative study was conducted in the trial area among the balanced plate nutrition education intervention recipients. We conducted in-depth interviews (n=10) with mothers of infants (0-6 months), focus group discussions (n=2) with their husbands and older women in the family and key informant interviews (n=4) with Shasthya Kormi (community health workers) of BRAC (an NGO in Bangladesh, formerly known as Bangladesh Rural Advancement Committee). Interviews were audio-recorded during collection, later transcribed in Bangla, and translated into English. The transcripts were manually coded and analysed using the thematic approach.

Chapter 4 demonstrated that pregnant women who received balanced plate nutrition education had heavier infants compared to those received standard nutrition education. The incidence of low birthweight (LBW) was also lower among women in the balanced plate group compared to the latter. The mean birthweight increased by 125.3 g (95% confidence interval (CI) 5·7, 244·9; p=0·04) and the risk of LBW was reduced by 54% (relative risk (RR) 0·46; 95% CI 0·28, 0·78; p=0·004) in the intervention compared to the comparison group. The effect of intervention was greater among adolescent mothers in terms of birthweight and incidence of LBW than the non-adolescent mothers mean difference 297·3 g; 95% CI 85·0, 509·6; p=0·006 and RR 0·31; 95% CI 0·12, 0·77; p=0·01).

Chapter 5 exhibited that accessing animal source food was the greatest barrier in practicing balanced diet. Perceived gap in understanding appropriate portion size and importance of diversified food for a pregnant woman were the other reported barriers. Mothers-in-law's authority and control over pregnant women's diet led to intra-household food mal-distribution with less nutritious food share for them. Active engagement of the family decision makers (husbands and elderly women in the family) in the nutrition counseling and demonstration session created an agreement on balanced diet for pregnant women. Husbands were inclined to finance more for purchasing nutritious foods such as cheap fishes, milk and fruits. Women were self-motivated to increase consumption of vegetables and animal source foods with right proportion of rice. Mothers-in-law's approval and husbands' voluntary contribution enabled women to practice the balanced diet.

Chapter 6 showed an inverse association between household food insecurity and perceived birth size of infants in Bangladesh. Infants from food insecure household were 36% more at risk of being small at birth compared to infants born in food secure households, which was aggravated by less utilization of antenatal care and first birth. There was an obvious regional variation of prevalence of smaller infants in geographically hard to reach areas; women in Sylhet and Chittagong districts were more vulnerable to give birth to smaller infants than mothers living in Barisal.

In conclusion, balanced plate nutrition education in pregnancy impacted on the birthweight of infants and incidence of LBW in rural Bangladesh. Practical demonstration of making balanced plate in combination with family engagement can create an enabling environment for pregnant women to adopt a balanced diet with self-motivation. Household food insecurity is major driver in determining fetal growth and subsequent size of infants at birth. The insights from this research will help to design nutrition behaviour change communications for pregnant women and target household with greatest need to improve perinatal nutrition for better child survival, growth, development and productivity in Bangladesh and other LMICs.

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This research would not have been possible without the personal and professional support and encouragement I received from countless friends, family, and colleagues. First and foremost, I would like to thank my dissertation supervisor Professor Michael J. Dibley for his intellectual and emotional support through this journey. I'm extremely grateful for his attentive, thoughtful and expert guidance and constant trust and confidence in my abilities and for allowing me to work independently. I want to express that it has been an invaluable experience to have Michael as a guide, who I not only admire, but trust as a colleague and a friend. I want to pay thanks to the people who helped me in my accomplishment.

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List of Abbreviations

AA	Arachidonic acid
ANC	Antenatal care
BDHS	Bangladesh Demographic and Health Survey
BINP	Bangladesh Integrated Nutrition Project
BMI	Body mass index
BRAC	Bangladesh Rural Advancement Committee
CHW	Community health workers
CI	Confidence interval
cRCT	Cluster randomised controlled trial
DHA	Docosahexaenoic acid
FAO	Food and Agriculture Organization
FGD	Focus group discussions
GWG	Gestational weight gain
HPNSDP	Health, Population, and Nutrition Sector Development Program
ICC	Intra-cluster correlation coefficient
IDI	In-depth interviews
IFA	Iron-folic acid
IUGR	Intrauterine growth restriction
KII	Key informant interviews
LBW	Low birthweight
LMIC	Low and middle-income countries
LNS	Lipid-based nutrient supplements
MDG	Millennium Development Goal
MMN	Multiple micronutrients
MNCH	Maternal, Neonatal and Child Health program
OR	Odds ratio
RCT	Randomised controlled trial
RR	Relative risk
SD	Standard deviation
SGA	Small-for-gestational age
WHO	World Health Organization

CHAPTER 1

INTRODUCTION

1.1 Rationale

1.1.1 Epidemiology of Low Birthweight (LBW)

Definition and Prevalence of LBW

The World Health Organization (WHO) defines birthweight as "the first weight of the foetus or newborn obtained after birth".[1] There is substantial evidence to consider birthweight as one of the most important indicators of health. From an evolutionary perspective, birthweight expresses the foetal accumulation of nutrients through hormonal control over maternal resistance.[2] From a biomedical perspective, birthweight is a strong predictor of early life mortality and morbidity[3], associated with developmental and psychosocial problems in childhood and a wide variety of morbidities in adulthood, and being carried forward inter-generationally.[4] Epidemiologically, birthweight is a proxy measure for foetal growth.[5] From a societal perspective, nutrition in early life is essential to the foundation of human capital.[4]

Low birthweight (LBW) is a weight at birth of less than 2500 g irrespective of the gestational age of the infant.[1] LBW includes very low birthweight (less than 1500 g) and extremely low birthweight (less than 1000 g) infants. LBW is a major public health problem. Globally, approximately 16% of infants are born LBW, which represents more than 22 million LBW infants per year.[6] Over 95% of these infants are born in low and middle-income countries.[7] In South Asia, about one quarter (28%) of all infants are born with LBW. In sub-Saharan Africa, and Latin America and the Caribbean, LBW rates are estimated to be 13% and 9%, respectively.[8] However, there is a high probability that the incidence of LBW is underestimated, as almost 50% of all newborns are not weighed at birth.[8]

Two major factors mostly determine birthweight: duration of gestation and intrauterine growth rate of the foetus. Either a shorter gestation period than optimum or retarded growth in utero or a combination of both could result in LBW. Thus LBW can arise from preterm birth (birth before 37 completed weeks of gestation) or small-for-gestational-age (SGA) infants born at term or a combination of both—preterm and SGA newborns.[9] SGA, or intrauterine growth restriction (IUGR), is a birthweight less than the 10th percentile for gestational age.[10] In a population where the LBW rate

exceeds 10%, SGA infants represent the majority of LBW infants; whereas, with a lower rate (5% to 7%), preterm infants who have appropriate growth for their gestational age constitute the majority of the LBW infants.[3] The mean gestational age and foetal growth are lower in developing countries and underprivileged populations compared to developed countries and privileged populations. The incidence of preterm birth (<37 weeks gestation) ranges from 7.1% to 22.3% in developing countries, whereas, it is about 5% in developed countries.[11]

Considering the rate and number of infants born SGA, the situation is dire in South Asia. The prevalence of SGA infants reached almost 50% in Pakistan and India wherein only 6.9% in Germany, 5.4% in Denmark and 4.2% in Finland.[7 12] In 2010, most SGA infants were born in India, Pakistan, Nigeria, and Bangladesh.[7] In low-income and middle-income countries (LMIC) in 2010, an estimated 32·4 million infants were born SGA, of them 10·6 million infants were term LBW and 7.4 million were preterm LBW (Table 1).[7]

Table 1: The 2010 top ten countries with the highest numbers of LBW infants[a].

	Countries	Livebirths	LBW births	LBW prevalence
1	India	27,000,000	7,507,200	27.8
2	Pakistan	4,700,000	1,232,800	26.2
3	Nigeria	6,300,000	740,900	11.8
4	Bangladesh	3,000,000	656,100	21.9
5	China	17,000,000	398,400	2.3
6	Indonesia	4,400,000	485,300	11.0
7	Ethiopia	2,600,000	530,400	20.4
8	Philippines	2,300,000	459,500	20.0
9	Democratic Republic of Congo	2,900,000	275,800	9.5
10	Sudan	1,400,000	438,600	31.3

LBW and Risk of Mortality

Low birthweight indirectly contributes to about 60% of all neonatal deaths.[13] Infants born at term weighing 1500–1999 g were 8·1 (95% CI 3·3, 19·3) times more likely to die from all causes during the neonatal period, and those weighing 2000–2499 g were 2·8 (95% CI 1·8, 4·4) times more likely to die than those weighing more than 2499 g

[a] 7. Lee AC, Katz J, Blencowe H, et al. National and regional estimates of term and preterm babies born small for gestational age in 138 low-income and middle-income countries in 2010. *The Lancet Global health* 2013;1:e26-36.

at birth.[13] LBW Infants account for two thirds of all neonatal deaths and very low birthweight account for half.[3]

The Lancet Maternal and Child Nutrition Series estimated 817,000 neonatal and 418,000 infant deaths (1–11 months) attributed to SGA from a pooled-analysis of population-based cohort studies in LMICs in Asia, sub-Saharan Africa, and Latin America in 2011. Asia had the largest burden (Figure 1).

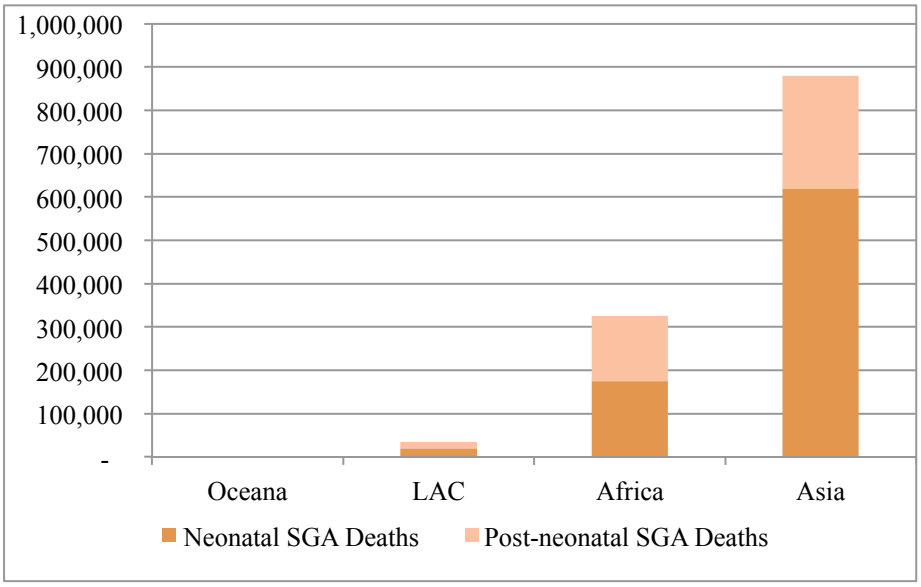

Figure 1. Neonatal and infant deaths attributable small for gestational age births by United Nations region in 2010. *(Source: Black et al. 2013)*

There is a distinct gradient of the relationship between birthweight and the infant mortality rate. Variations in mortality rates characterise different birthweight categories. Epidemiological observations indicate that infant mortality rates increase rapidly for newborns weighing less than 2500 g at birth.[3]

Wilcox and Russell plotted curves of birthweight-specific mortality using one million white singleton births and the corresponding 21,000 foetal deaths in 1968 and 1.75 million white singleton births and the corresponding 49,000 early neonatal deaths in the United States during 1960. Their first plot showed that the relationship between foetal mortality and birthweight depicts a parabolic curve (Figure 2, A). The shape of the curve indicates that the risk of death is higher for infants with a birthweight less than 3000 g and those with a birthweight of more than 4000 g. The second curve of first-week mortality (Figure 2, B) shows a dose-response relationship or linear association of birthweight and risk of mortality.[14] However, the magnitude of the

problem is higher at the low-birthweight end where there are more infants because the distribution of birthweight is not symmetrical but rather skewed towards lower birthweights.[15]

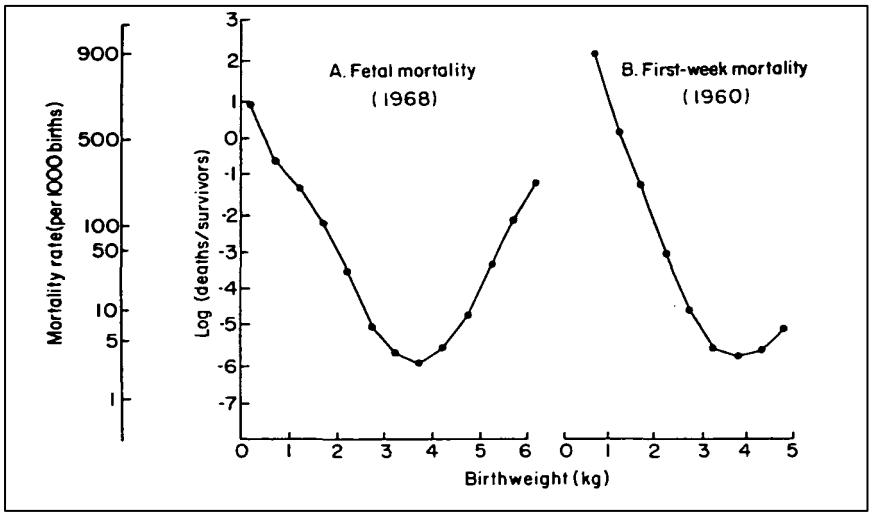

Figure 2. Birthweight specific mortality curves. *(Source: United States Whites, 1968 and 1960)*

LBW and Risk of Growth and Developmental Failure

LBW children have a broad spectrum of poor growth, health, and developmental outcomes. Although the majority of the LBW children have normal outcomes, the rate of subnormal growth, illnesses, and neurodevelopmental problems are higher compared to normal weight children. There is an inverse association between birthweight and the likelihood of stunting in childhood.[16] LBW infants have poor immune function and a higher risk of morbidity, making them more vulnerable to linear growth faltering in the post-neonatal period.[17] The risk of stunting was 1.74 (95% CI 1.38, 2.19) times higher among children born with LBW than those born with normal weight.[18] One-fifth of all stunted children are LBW (95% CI 0.14, 0.24).[19] The growth velocity is even lower among the IUGR infants compared to preterm LBW.[20]

LBW infants who survive, are less likely to have catch-up growth and are more likely to experience developmental deficits.[21] The developmental sequelae include mild problems in cognition, attention, and motor functioning, while a small proportion has an intellectual disability and, or cerebral palsy.[22] Among school-age children (7-11 years), those born with LBW showed significantly more emotional behaviour symptoms, conduct disorders and hyperactivity/inattention.[23] They were also more

likely to have a learning disability, receive special education and repeat school years.[24] These behaviour problems and cognitive impairment extend into adolescence and early adulthood.[25 26]

LBW and Risk of Chronic Diseases in Adulthood

Infants undernourished in-utero are at risk of chronic diseases as adults, notably when they become exposed to the nutrient-rich postnatal environment and a sedentary lifestyle.[27] The Barker 'foetal origins of chronic disease hypothesis'[28] of the early 1990s was initially based on the epidemiological relationship between LBW and the subsequent development of cardiovascular disease in adults. We now know of the association of LBW with many other diseases, such as obesity, type-2 diabetes mellitus, stroke, osteoporosis, insulin resistance and schizophrenia.[29] The hypothesis suggests that limiting food resources during a vulnerable period of intrauterine growth and development may cause physical and metabolic adaptations of the foetus that predispose the infant to disease in adult life. The hypothesis is now called the "developmental origins of health and disease (DOHaD)".[27] This hypothesis holds that a stressful in-utero environment alters the developmental programming of the foetus when rapid foetal cell division is in progress in various tissues of the body. During these 'critical periods', insufficient supply of nutrients and oxygen causes permanent adaptive responses, or foetal programming, which alters organ growth, structure, physiology, and metabolism.[30 31] Dependent on the type, timing, and duration, this stress may compromise growth of those organs, developing in the affected time window, or preclude the fetus reaching genetically determined maximum growth. Animal models with dietary restriction of both global nutrition or isocaloric protein undernutrition administered during gestation have demonstrated that an association between IUGR and reduced nephron number, altered vascular function and increased blood pressure.[32] Utero-placental insufficiency induced permanent changes in glucose homeostasis leading to type-2 diabetes in adult mice.[33]

Social and Economic Cost of LBW

LBW is subject to economic burden from four points of view: premature deaths in infancy, health care costs of LBW infants and children, special education requirements for school-age children and loss of productivity in adults.[34] For a 1988 birth cohort in the United States, there was an estimated excess cost of $5.5 - 6 billion

associated with LBW. Health care expenses accounted for nearly 75% of the costs, and special education, as well as increased grade repetition, accounted for 10% of the costs.[35] Evidence also suggests that LBW children require additional outpatient care and hospitalisation during their childhood.[34] Adults, born small are more likely to have reduced earnings and productivity compared to those born normal weight due to lower cognitive achievement or stature. In a population-based cohort of extreme LBW survivors who were born between 1977 and 1982 in central-west Ontario, Canada, the reported weekly earnings were 27% lower in the extreme LBW group than their normal weight counterparts.[36]

1.1.2 Trends of LBW

There is a mixed trend globally in the incidence of LBW infants. In the majority of developed countries it is rising (compared between 1990 and 2015) because of (i) an increase in the number of multiple births, partly as a result of the rise in fertility treatments; (ii) an increased age of mothers at childbirth; and (iii) an increase in smoking among young women.[37 38] The percentage of infants who had LBW declined between 2001 and 2009, from 6.4% to 6.0% in New South Wales, Australia. It then increased slowly until 2016 when it was at 6.4% (Figure 3).[39]

An analysis of trends in LBW in developing countries is difficult because of the lack of comparable data over time. A limited analysis based on data from 20 developing countries, covering about half the population (excluding China) indicated that the incidence was roughly constant between 1990 (LBW rate 24%) and 2000 (LBW rate 23%).[6] There was a similar trend observed in South Asia between the late 1960s and late1980s.[11] Hospital-based data have revealed a marginal but positive (52 to 126g) improvement in birthweight resulting in a greater reduction of LBW prevalence (by 8% to 12% but by 22% in one report). The improvement in birthweight is probably due to increases in both gestation and intrauterine growth. The mean improvement in gestation was again marginal (0.3 to 0.8 weeks). However, these marginal changes in mean gestation resulted in greater reduction in preterm birth rates (by 4 to 5%).[11]

Three consecutive National Family Health Surveys (NFHS) of India depicted a decreasing prevalence of LBW babies in India from 1992 to 2006. However, the fall in prevalence reported was sluggish despite a large number of maternal and child

health programmes implemented during the period.[40] The consensus is that in developing countries, particularly in South Asia, an overwhelming majority of LBW infants have full-term gestation but are growth restricted (IUGR).[40]

The experience from some countries, where there are records of low birthweight over a long period, as in Sri Lanka, shows that the prevalence changes only slowly.

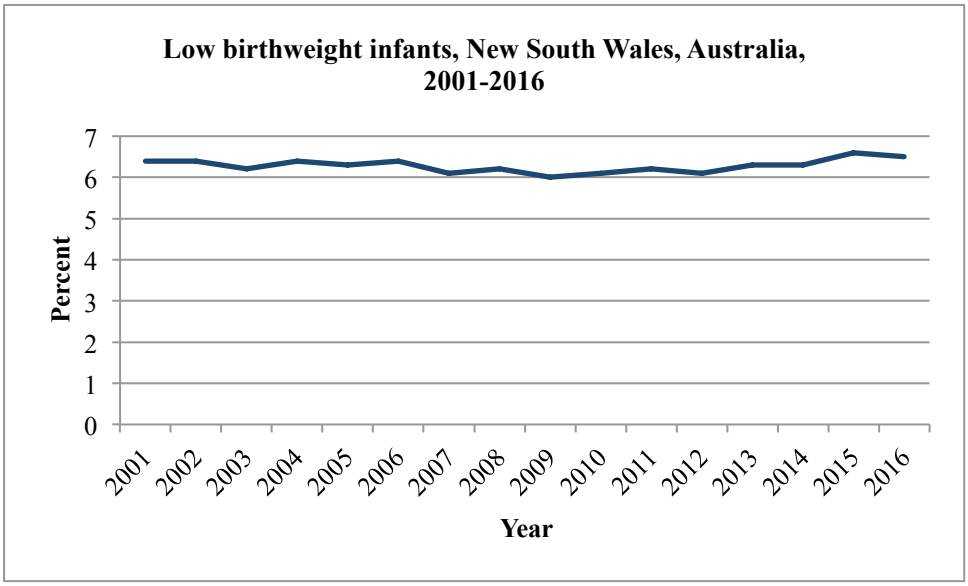

Figure 3. Trend of prevalence of low birthweight in New South Wales, Australia. *(Source: www.healthstats.nsw.gov.au. Accessed 13 July 2018).*

1.1.3 Theoretical Framework of Factors Associated With LBW

This research adopts a conceptual framework of Black et al. (2008) drawing on mostly social factors associated with maternal and child undernutrition, and Kramer's (1987) depiction of biological determinants of intrauterine growth in developed and developing countries[10 13] (Figure 5). An overview of the biological factors influencing prenatal growth and development is shown in Figure 6.[27] The diagram shows there is a substantial overlap between several of the factors, i.e., their effects on intrauterine growth are not independent. For example, gestational weight gain and caloric intake are highly interrelated since the latter is one of the major determinants of the former.[10]

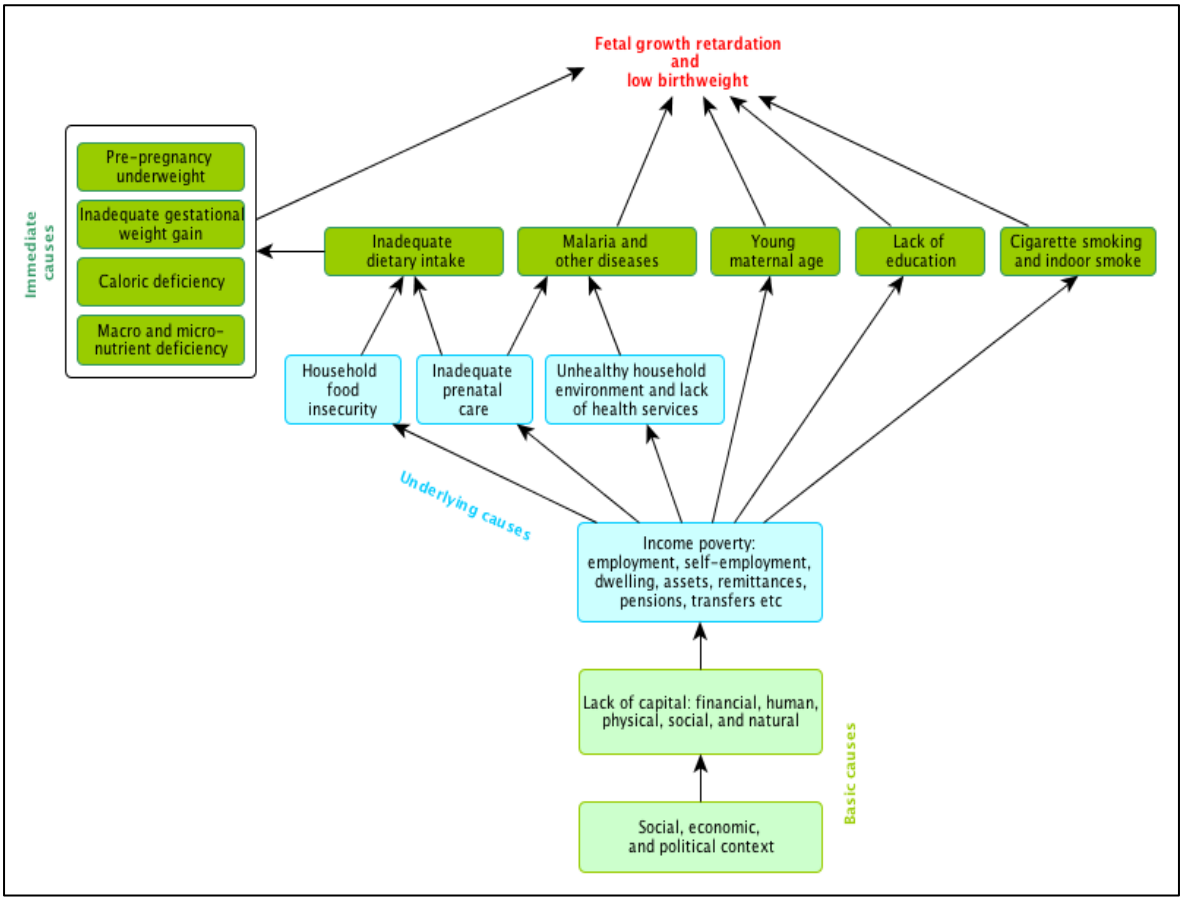

Figure 3. Conceptual framework for factors associated with low birthweight. *(Source: Black et al. 2008, Kramer 1987)*

Factors commonly associated with IUGR differ worldwide. In industrialised countries, the causes of IUGR include smoking, alcohol consumption, and pre-eclampsia, in addition to low maternal weight and weight gain. Whereas, the aetiology in developing countries is more often related to low maternal weight and weight gain due to poor nutrition of the mother before and during pregnancy and maternal infections.[41] Other factors include infant sex, maternal height, maternal age, parity, birth interval, previous pregnancy loss, malaria, prenatal care, socioeconomic status and food security.[10 42]

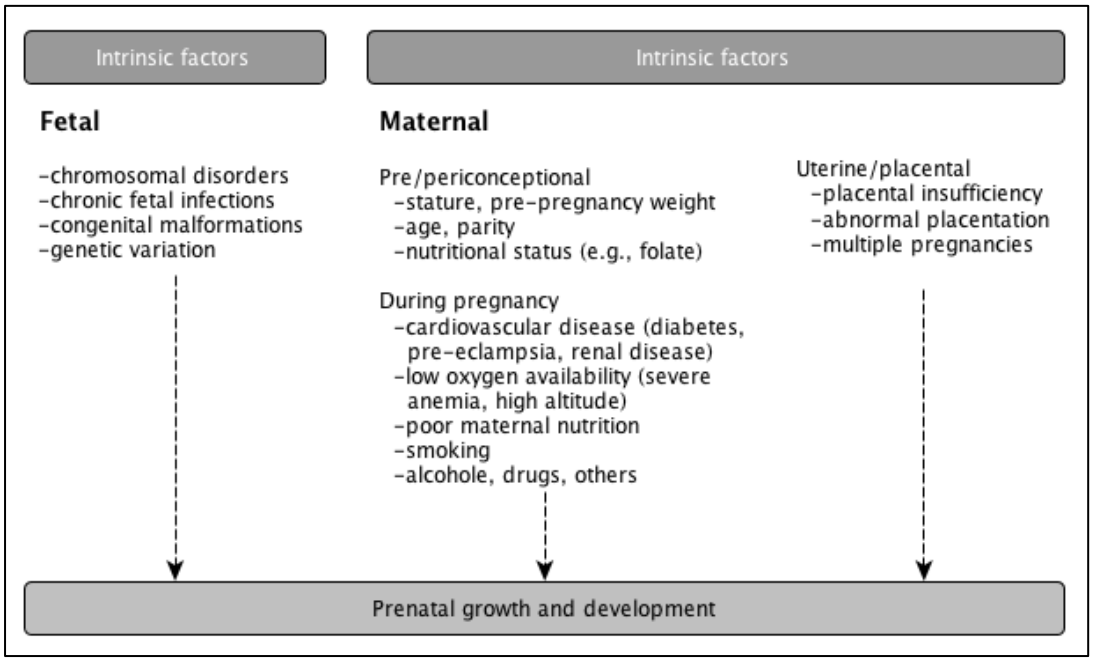

Figure 4. Biological factors influencing prenatal growth and development. *(Source: Muskiet 2010)*

Poor Maternal Nutritional Status

Maternal undernutrition, which may have originated in childhood, adolescence or during pregnancy, is associated with LBW infants. Among the proximal determinants, maternal nutritional status displays a linear relationship with LBW. Epidemiological evidence suggests that the relative risk of LBW decreases by 5% for each 1 cm increase in height, and decreases by 8% for each unit increase in BMI.[43] Maternal height <145 cm (short stature) puts infants at risk of LBW.[44] [19]

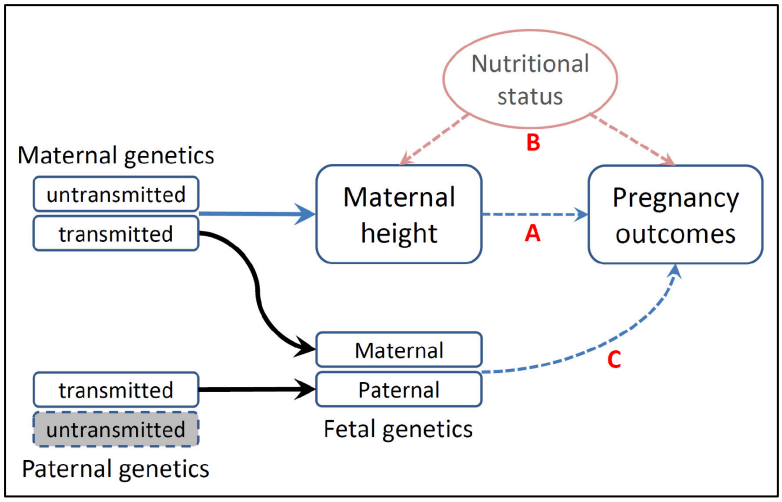

Figure 5. Schematic representation of various causal mechanisms that can lead to the observational associations between maternal height and pregnancy outcomes. *(Source: Zhag et al. 2015)*

A systematic review and meta-analysis by Han et al. demonstrated an almost doubling of the risk for short-statured women to give birth to LBW infants in contrast to women with the reference height (RR 1.81; 95% CI 1.47, 2.23). Height <150 cm was considered to be a significant predictor of LBW (OR 2.24; 95% CI 1.24, 3.47 for < 156 cm). Genetic and environmental factors contribute to the association between maternal height and LBW, although the exact pathway is not understood.[45] Foetal genetics (with contributions from maternal and paternal genotype) mainly determines the association between maternal height and foetal growth parameters.[46] Short-statured women are more likely to pass on to their foetus a genetic predisposition for reduced growth. Anatomically a short statured woman has a smaller uterus, which imposes physical limitations on the growth of the uterus, placenta, and foetus (Figure 5).[45]

Maternal pre-pregnancy underweight (BMI <18.5) is highly correlated with the risk of delivering LBW infants (OR 1.47; 95% CI 1.27, 1.71; p <0.001).[47] [19] The 'WHO collaborative study on maternal anthropometry and pregnancy outcomes' reported that mothers in the lowest quartile of pre-pregnancy weight carried an elevated risk of IUGR and LBW (OR 2.55; 95% CI 2.3, 2.7 and OR 2.38; 95% CI 2.1, 2.5), compared to the upper quartile.[48] The association between maternal underweight and LBW might be explained directly by a lack of nutrients or indirectly through other associated factors such as smoking, poor diet or medical illness. In developed countries, smoking imposes a risk of maternal underweight and LBW. In developing countries, it is likely that a higher proportion of underweight women belong to the lower socioeconomic classes. These women are engaged in strenuous manual labour or possibly have an ethnic or genetic predisposition towards thinness.[49]

Maternal weight gain is not uniform throughout the pregnancy period, it is minimal during the first trimester and close to linear through the second and third trimesters until birth. Strauss et al. reported an increased risk of IUGR with low second and third-trimester weight gain irrespective of maternal BMI. Low weight gain in the second trimester was associated with a relative risk of IUGR 1.8 (95% CI 1.3, 2.6) to 2.6 (95% CI 1.6, 4.1), and 1.7 (95% CI 1.3, 2.3) to 2.5 (95% CI 1.7, 3.8) in the second and third trimester respectively.[50] Grivell et al. found a relative relationship between pregnancy weight gain and SGA infants with respect to maternal pre-pregnancy BMI.

The rate of SGA infants was lower among low BMI women with higher weight gain and high BMI women with lower weight gain.[51]

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Nutritional Deficiencies

Foetal growth depends on the availability of nutrients in maternal circulation and the ability to transport these nutrients into the foetal circulation. The foetus is at the end of a supply line via the placenta that ensures delivery of nutrients from the maternal/uterine circulation to the foetus. The indirect link between maternal and foetal nutrition is mediated by the mother's dietary intake; her metabolism and endocrine status; partitioning of nutrients among storage, use, and circulation; the capacity of circulating transport proteins; and cardiovascular adaptations to pregnancy which determine uterine blood flow.[52] Maternal undernutrition not only reduces global nutrient availability, but also diminishes nutrient transport due to reduced surface area of the placenta, and compromised vasculogenesis and angiogenesis, which contributes to foetal growth retardation. [53] Macronutrients (fat, protein, carbohydrates) deliver energy and important building blocks to ensure the entire body composition of the foetus, whereas, micronutrients keep the process of continuous construction and re-construction running.

Total Energy

Evidence for the consequences of energy deprivation during pregnancy comes from a variety of sources including famine studies, food supplementation and food restriction trials in animals. The effects of starvation on the size of infants at birth were

discernible in the 18-month Leningrad siege, in the 6-month Dutch famine, and in the acute food shortage in Wupperthal, Germany, during the post-war chaos of 1945.[57] During the Dutch famine, per capita food availability was progressively reduced from 6,700 kilojoule/day in September 1944 to below 4,200 kilojoule/day between January and April 1945. Mothers who were exposed to the food deprivation in their third trimester gave birth to infants 327 g (9%) lighter than the pre-famine period.[58] Birthweight recorded in Wupperthal, Germany for the period of 1937-1948 revealed an abrupt fall by 185 g after a year of acute food shortage.[59] The 6 months siege of Leningrad resulted a 529 g fall in birthweights for boys and 542 g for girls.[60]

Protein

Amino acids – the structural building blocks for all proteins, are critical for foetal growth and development. Epidemiological studies in humans have deduced that perinatal protein deficiency gives rise to low birthweight, and these individuals are at greater risk for development of the metabolic syndrome in adult life.[61] Maternal protein restriction in animal models causes IUGR. The offspring had a reduced growth of organs, such as the liver, muscles and pancreas. They also showed impaired metabolic programming that persisted into adulthood and exhibited a phenotype characterised by metabolic dysfunction. In adult life, these animals tend to have glucose intolerance, dyslipidemia, and increased visceral obesity. Moreover, Barker's hypothesis suggests that foetal programming prepares for a nutritionally scarce postnatal environment producing a "thrifty" phenotype that is capable of foetal energy conservation (Hales and Barker 2001). Unfortunately, these metabolic adaptations become harmful when the foetus is born into a nutritionally rich environment and store energy rather than spend it because of the energy conserving programming that occurred during development.[61]

Essential Fatty Acids

Dietary fat has long been considered a concentrated source of energy, providing metabolic efficiency to support adipose tissue growth and to spare protein for accretion of lean tissue during development.[62] Adverse fatty acid supplies during foetal and infant development alters the fatty acid composition of tissue lipids with the potential to disrupt cellular environments, with short and long-term implications for cell structure and function. The essential fatty acids - docosahexaenoic acid

(DHA) and arachidonic acid (AA) are structural components of membrane phospholipids, modulators of gene expression and precursors of (neuro) protectins. DHA and AA are notably abundant in the central nervous system and play important roles in foetal and infant neurodevelopment.[63] The critical role of DHA in neurogenesis, however, suggests that the adverse effect of inadequate DHA in gestation and the first few months after birth is more difficult to overcome than deficiencies occurring later on. Several human and animal trials established a positive relation between neonatal brain DHA and cognitive and behavioural performance.[63] An animal model of IUGR described by Sinclair and Crawford suggested that a mild deficiency in essential fatty acids in spite of normal caloric intake induced a drop of 25-30% in foetal weights in rats.[64]

Micronutrient

Iron, iodine, vitamin D and folate are micronutrients, which might become critical during first 1000 days of life. As the symptoms of deficiencies of micronutrients develop late, it is termed as "hidden hunger". Worldwide more than 2 billion people, primarily women and children are affected by hidden hunger.[65]

Iron

Iron is an important component of haemoglobin that carries oxygen from the lungs to organs throughout the body. During pregnancy, foetal demand for iron increases maternal daily iron requirements from <1 to 2.5 mg/d in early pregnancy and 6.5 mg/d in the third trimester. If the woman's diet is deficient in iron, foetal requirements can be met only by additional contributions of iron from maternal stores causing the mother to develop iron deficiency anemia.[66] The link between maternal anaemia and infant birthweight is well established. A systematic review and meta-analysis of epidemiological studies found that maternal anaemia was associated with low birthweight with an adjusted odds ratio of 1.23 (95% CI 1.06, 1.43).[67] Although we do not know the exact pathway, there are several potential biological mechanisms through which anaemia or iron deficiency could affect birthweight. Anaemia (by causing hypoxia) can induce maternal and foetal stress, stimulating the synthesis of (CRH) and foetal cortisol production, which may inhibit longitudinal growth of the foetus. Iron deficiency also increases oxidative damage to erythrocytes and increases

the risk of maternal infections, which again can stimulate the production of corticotropin-releasing hormone.[68]

Folic Acid/Folate

Folate plays a crucial role in the one-carbon metabolism for physiological nucleic acid synthesis and cell division, regulation of gene expression, amino acid metabolism and neurotransmitter synthesis. During pregnancy, increased folate intake is required for rapid cell proliferation and tissue growth of the uterus and the placenta, growth of the foetus and expansion of the maternal blood volume.[69] The recommended daily allowance for folate for pregnant women is 600 μg/d.[70] A systematic review identified the importance of maternal folate status on birthweight, in particular during pregnancy.[69 71] According to Fekete and Berti (2012) a neonate whose mother has a folate intake of 500 μg per day is predicted to have a birthweight that is 2% higher than a neonate whose mother has a folate intake of 250 μg per day.[69] Folate deficiency, which can lead to megaloblastosis and cell death, particularly of highly proliferative somatic cells, will result in adverse consequences to the foetus during gestation. This effect is more profound on highly proliferative embryonic neural tube and neural crest cells resulting in neural tube defects. Animal models demonstrated that the folate-deficient murine foetuses exhibited a net loss of cells by ~20% in various regions of the brain.[72]

Iodine

Iodine is critical for the production of thyroid hormone - thyroxine (T4) and triiodothyronine (T3). In pregnancy iodine requirement increases markedly to supply the foetus with thyroid hormones in the first trimester, before it can produce its own. The thyroid hormones are essential for development of the foetal brain.[73] However, thyroid hormones are required for the general accretion of foetal mass. They also trigger development of somatic tissues from early in gestation. Thyroid hormones act directly through anabolic effects on foetal metabolism and the stimulation of foetal oxygen consumption. They also act indirectly by controlling the bioavailability and effectiveness of other hormones and growth factors that influence foetal development such as the catecholamines and insulin-like growth factors.[74] A longitudinal study compared the incidence of LBW between two groups of pregnant women – iodine-

sufficient and iodine-insufficient and found a higher rate of LBW in the iodine-insufficient group (19.9% vs. 12.3%; p 0.04).[75]

Vitamin B-12

Low serum vitamin B-12 concentration during pregnancy is associated with a significantly higher risk of IUGR. During pregnancy, vitamin B-12 has a potential role for synthesis of phospholipids, proteins, myelin, catecholamines, DNA and RNA using plasma homocysteine. A deficiency in vitamin B-12 has shown to be associated with elevated homocysteine which is a risk factor for recurrent spontaneous abortion, intra-uterine death, abruption placenta, neural tube defects and LBW.[76]

Maternal Gestational weight gain

Maternal gestational weight gain is a unique and complex biological phenomenon that supports the functions of growth and development of the foetus. Gestational weight gain is influenced not only by changes in maternal physiology and metabolism, but also by placental metabolism. Changes in protein and nitrogen metabolism occur in early pregnancy, presumably in response to pregnancy-related hormones. Changes in carbohydrate and lipid metabolism occur to ensure a continuous supply of nutrients to the growing foetus. Weight loss or no gestational weight gain as a result of dietary caloric insufficiency induces certain maternal hormonal and metabolic responses leading to foetal growth restriction.[77]

The magnitude of association between maternal gestational weight gain and infant birthweight is strong, especially the relative risk of SGA with low gestational weight gain. The entire birthweight distribution shifts downwards with reduced gestational weight gain, increasing the risk of SGA as the mean birthweight rises. The Institute of Medicine has recommended gestational weight gain guidelines based on pre-pregnancy BMI categories developed by the World Health Organization (Table 2). Among adolescents, in general, gestational weight gain tended to be higher compared with adult women (means ranged from 14.6 to 18.0 kg in the US). From a population perspective, obese women usually gain less weight than non-obese women do. Total gestational weight gain in multiple pregnancies is generally higher than in singleton pregnancies with means ranging from 15 to 31 kg.[77] A randomized controlled trial in Vietnam found that overall, three-quarters of women gained gestational weight below

the IOM guidelines, and these women were 2.5 times more likely to give birth to a SGA infant.[78]

Table 1. Institute of Medicine weight gain recommendation for pregnancy

Pre-pregnancy Weight Category	Body Mass Index (kg/m^2)	Recommended Range of Total Weight (kg)
Underweight	<18.5	12.7-18.1
Normal Weight	18.5–24.9	11.3-15.9
Overweight	25–29.9	6.8-11.3
Obese	≥30	5.0-9.1

Pre-pregnancy BMI is intermediary in the association between maternal gestational weight gain and birthweight. In addition to pre-pregnancy BMI, the only other factor that appears to impact the association between gestational weight gain and birthweight is the gestation, e.g., during the first, second or third trimester.[79] Maternal weight at earlier gestations has the greatest association with foetal growth. A one standard deviation (SD) increase in gestational weight in the first 20 weeks was associated with a 43% reduction in SGA risk (95% CI 0.46, 0.70) compared to later gestational period (≥30 weeks).[78] Brown et al. reported a 31 g ($p<0.001$) predicted newborn weight in the first trimester and 26 g ($p<0.001$) in the second trimester, with 1 kg maternal weight gain.[80] The gestational weight gain effect on birthweight is stronger among underweight women compared to the normal weight counterparts. Offspring of underweight women were found to be same size at birth to the offspring of normal weight women when they gained optimum gestational weight.[81]

Food Insecurity

Prenatal diet affects gestational weight gain. The translation of nutritional change (caloric intake) into maternal-weight change and then into birthweight change was demonstrated in the Dutch famine study where women went through extreme hunger (Figure 6). This phenomenon supported a causal pathway from diet to weight gain to birthweight. Outside famine, effects are modest and conditional on baseline nutrition, timing, and content of diets (high protein), possibly infant sex (male) and energy expenditure.[82]

Food security is necessary for nutrition security. The Food and Agriculture Organization defined food security as, "… when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food which meets their dietary needs and food preferences for an active and healthy life".[83] Food insecurity is defined as "whenever the availability of nutritionally adequate and safe food or the ability to acquire acceptable foods in socially acceptable ways is limited or uncertain." Globally 805 million people were considered food insecure (2012–2014), of them more than one-third, lived in South Asia (276 million).[84]

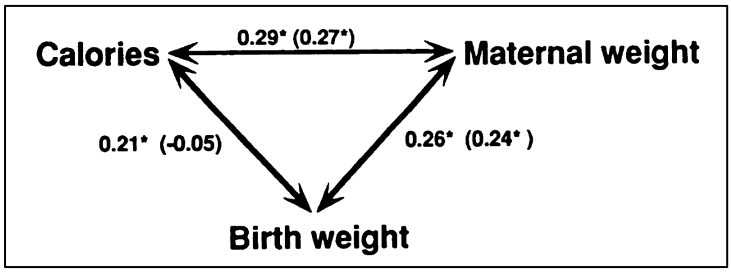

Figure 6. Correlation between caloric intake, maternal weight gain and birthweight

Women and children are the worst victims of food insecurity. Household food security is a strong predictor of maternal nutritional status. Maintaining a sufficient nutrient-dense diet in an environment of food insecurity is difficult, and this has important implications for maternal nutrition and foetal growth. A study in the US demonstrated that food insecurity was associated with reduced energy, vitamins and minerals intake. Energy intake was 50% of the recommended daily allowance among those from food insecure households. For calcium, iron, vitamin E, magnesium, and zinc, the mean intakes were of women below two-thirds for this group.[85]

A population-based study in Ghana found that the BMI for women from food-secure households was 1.4 kg/m^2 significantly higher than the BMI for women from food insecure households (95 % CI 0.54, 2.35; p 0.002). Women in food-secure households were more likely to consume a more nutrient rich diet, e.g., milk, pulses, oily and sugar-based foods than those food insecure.[86] Dietary diversity among pregnant women gradually declined with the severity of household food insecurity, predisposing women to micro and macro nutrient deficiencies.[87]

Pregnancy and lactation require a modest increase in energy but greater increase in vitamin and mineral intake. For pregnant women to gain an appropriate amount of

weight and meet their nutrient requirements, dietary changes to promote high nutrient density and appropriate energy intake is required. Unfortunately, the lack of nationally representative data on pregnant women limits understanding of dietary trends among food insecure population.[88]

There is a lack of evidence and understanding of the quantitative effects of food insecurity in resource-poor settings, on pregnancy outcomes such as LBW. It is assumed that other than through maternal diet and the nutritional pathway, adverse coping strategies (such as reduced intake of certain foods) and poor mental health status (anxiety and depression) can lead to LBW.[85] Food insecurity as a psychosocial stressor was found to increase the risk of LBW by three times (OR 3.2, 95% CI 1.4, 7.2) in the US.[42] There is a positive correlation between food insecurity and prevalence of LBW.[89]

Maternal Stress

Maternal stress affects placental and foetal physiology through the release of catecholamines, which results in placental hypo-perfusion and consequent restriction of oxygen and nutrients to the foetus, leading to foetal growth impairment and/or precipitation of preterm delivery.[90] An alternative hypothesised pathway is the suppression of immune processes through immune activation via hormonal and neuronal pathways, such as catecholamines or cortisol, and neuropeptides, like plasma beta-endorphin. Apart from hormonal factors, direct neuronal influences from the hypothalamus on the immune system enhances the susceptibility to infections, such as chorioamnionitis, which can induce preterm rupture of membranes and pre-term delivery. The epidemiological association between maternal stress exposure and birthweight have yielded mixed results, which might be due to differences in methodology.[91] Literature reviews of prospective studies examining the relationship between stress and LBW suggest that certain types of stressors such as major life events and chronic stressors are good predictors of LBW.[92 93]

1.1.4 Interventions to Prevent and Reduce LBW

Affordable, accessible and appropriate health care is critical for preventing and treating LBW.[94 95] Maternal nutrition is a modifiable risk factor of public health importance that can be integrated into efforts to prevent adverse birth outcomes such

as LBW, particularly among low-income populations who are at greater risk. In 2012, the World Health Assembly agreed on six global nutrition targets including a 30% reduction of the LBW rate by 2025.[96] Based on existing evidence embracing both proximate and distal determinants of optimal fetal and child growth and development, the Lancet Maternal and Child Nutrition series proposed a conceptual framework (Figure 7) for nutrition-specific and nutrition-sensitive interventions. This framework outlined the dietary, behavioural, and health determinants of optimum nutrition, growth, and development, and how they are affected by underlying food security, resources, and environmental conditions.[97]

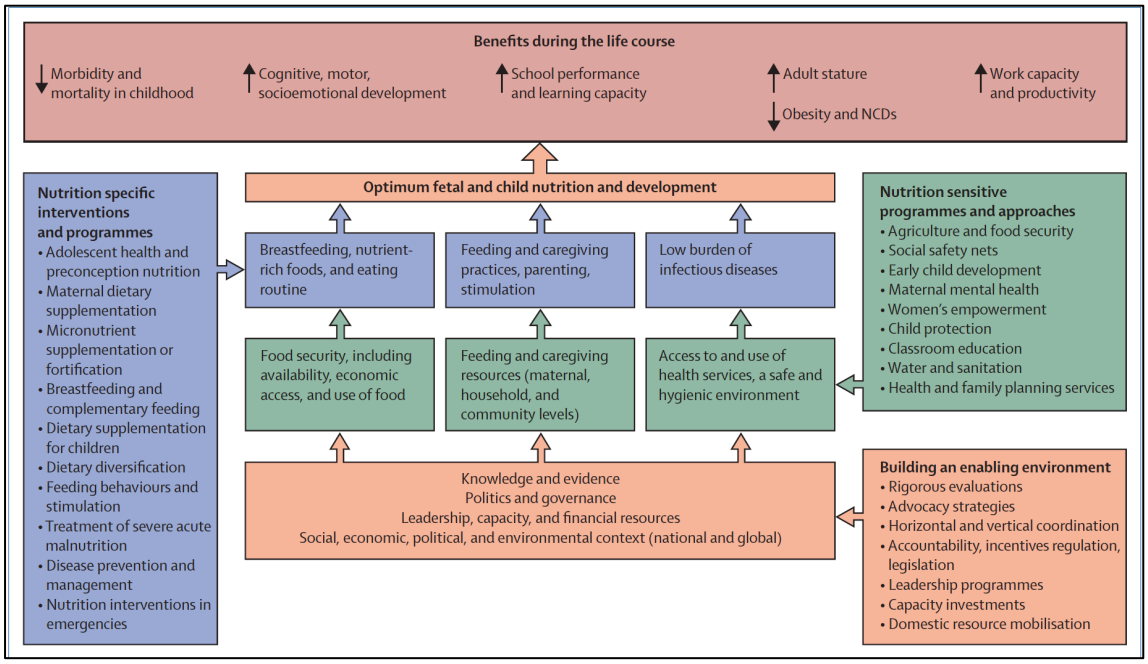

Figure 7. Conceptual framework for nutrition. (Source: Gillespie et al. 2014. based on the 1990 UNICEF Conceptual Framework)

Maternal Nutrition Interventions

Nutrition before conception and during pregnancy is important to ensure a healthy pregnancy outcome. "The first 1000 days" is an international public health priority aimed at improving nutrition for the mother and child between a woman's pregnancy and her child's second birthday. The provision of the right nutrition during this 1000-day window can help ensure the child has the potential to live a healthy life and reduces the financial and social costs of poor health over the life course. There is a clear need to identify the best nutrition interventions for pregnant women aimed at preventing adverse neonatal and infant outcomes. Nutrition interventions could

consist of nutrition counselling and, or education, food supplementation, fortified food products, or a combination of these interventions.[98]

Maternal Nutrition Education

Nutrition education and counselling is a widely used strategy to improve the nutritional status of women during pregnancy. The strategy focuses primarily on promoting a healthy diet by increasing the diversity and amount of foods consumed, promoting adequate weight gain through sufficient and balanced protein and energy intake, and promoting consistent and continued use of micronutrient supplements, food supplements or fortified foods.[99] There are five systematic reviews and, or meta-analyses investigating the impact of maternal nutrition education on gestational weight-gain and birth outcomes, which are discussed below.

Ota et al. (2017) systematically reviewed the evidence from 23 systematic reviews of randomised controlled trials focusing on nutritional interventions before and during pregnancy to reduce LBW. These authors found one review, which included 17 RCTs or cluster-RCTs reporting a 96% (RR 0.04; 95% CI 0.01, 0.14) reduction in LBW with nutritional education to increase energy and protein intake compared with no nutritional education in pregnancy. However, the positive evidence came from only one study (300 pregnant women) in Bangladesh.[100] The effect of dietary counselling during pregnancy was not consistent across trials. Other systematic reviews failed to achieve significant results from dietary counselling on birthweight because some studies showed an increase in birthweight with dietary counselling, while others showed a decrease.[98] Dietary counselling interventions significantly increased birthweight without reducing the risk of LBW. Girard and Olude (2012) found a significant increase in the mean birthweight (105.2 g; 95% CI 17.7, 192.7) without any significant impact on LBW.[101] Stratified analysis showed that birthweight was significantly increased among undernourished women (mean difference) 489.8 g; 95% CI 427.9, 551.6) compared to adequately nourished women (mean difference 15.0; 95% CI 76.3, 106.3).[102] Interventions trying to increase dairy intake in pregnant adolescents also tended to have stronger effects.[98] When stratified by study site, nutrition education significantly increased birthweight in high-income countries (64.8 g; 95% CI 1.7, 128.0). In low and middle-income countries (LMIC) the effect appeared more substantial but failed to reach significance (151.7 g; 95% CI -80.6,

384.0), likely due to the small number of studies. Significant gains in birthweight were also achieved when nutrition education was provided with nutritional support (225.7 g; 95% CI 148.8, 302.7) but not when provided alone or with other health messages.[101] Gresham et al. reported a significant increase in mean birthweight with food and fortified food products in pregnancy (standardised mean difference 0.27; 95% CI 0.14, 0.40; p 0.01).[98] Of the randomised controlled trials, there were only five delivered at the community level[103-107], while the rest were healthcare centre based.[108-114] No studies from LMICs delivered education on balanced diet or used practical demonstrations; only three studies[103 106 112] from high-income countries included education on balanced diet.

Nutrition education can successfully improve dietary practices and consumption of specific macro and micronutrients. Nutritional education significantly increased energy and protein intake (mean difference 7.0 g/d; 95% CI 3.0, 11.0) without any consistent impact on pregnancy outcomes.[102 115] A significantly higher proportion of women reported positive dietary changes and/or adherence to an 'appropriate' or 'good' diet with nutrition education.[101] Nutrition education also significantly improved gestational weight gain by 0.45 kg (95% CI 0.12, 0.79) and reduced the risk of anaemia by 30% (95% CI 0.58, 0.84).[101] The effect of nutrition education on gestational weight gain was greater when provided with nutrition support, for example, food or micronutrient supplements or nutrition safety nets (mean weight gain difference 0.15 kg; 95% CI 0.0, 0.29) or when studies were conducted in high-income settings (mean weight gain difference 0.76 kg; 95% CI 0.20, 1.31).[101]

Protein Energy Supplementation

The World Health Organization recommends a balanced energy and protein dietary supplementation for pregnant women in undernourished populations to reduce the risk of stillbirths and SGA.[116] Studies have demonstrated a reduced risk of SGA (21%) with balanced protein-energy supplementation, on the other hand, an increased risk (56%) with high protein supplementation.[100] During pregnancy extra energy is required for the growth of the foetus, placenta and various maternal tissues, such as the uterus, breast and fat stores.[44] Protein is deposited predominantly in the foetus (42%), but also in the uterus (17%), blood (14%), placenta (10%), and breasts (8%). An estimated 925 g protein deposition is associated with a 12.5 kg gestational weight

gain.[117] Therefore, balanced protein-energy supplementation for pregnant women could be one of the ways to improve pregnancy outcomes in low-income countries where a significant proportion of women enter pregnancy undernutrised.[118]
Trials that primarily altered energy, protein, and fat composition in diets showed better birthweight outcomes. Systematic reviews and meta-analysis showed that balanced protein-energy supplementation increased birthweight by 41 - 73 g and reduced the risk of LBW by 21- 32%.[44 98 102] This is supported by another meta-analysis reporting a concomitant increase in maternal weight gain.[115] These effects were more pronounced in undernourished women compared with adequately nourished women.[44 98 115] High-protein supplementation was associated with a small and non-significant increase in maternal weight gain and a non-significant reduction in mean birthweight but a significant increase in risk of SGA birth.[115] Furthermore, trials on isocaloric protein supplementation alone (without energy supplementation) could not demonstrate any benefit to pregnant women or their infants.[115] Dietary interventions conducted in low-income countries showed a significantly greater increase in birthweight (94 g vs 49 g) and reduction in the incidence of LBW compared to high-income countries.[98]

Lipid-based Nutrient Supplementation

The anticipated risk of LBW in developing countries is high considering the lower level of lipid intake. Approximately 80% of the population's diet contains less than 15% lipid, whereas the WHO recommendation is 30%.[64] Interventions intended to increase lipid intake found mixed results in relation to increase birthweight and lowering incidence of LBW. An RCT in Bangladesh showed that lipid-based nutrient supplements (LNS-20 g/d, containing 118 kcal) for pregnant women significantly increased birthweight (2629 ± 408 vs 2588 ± 413 g; p 0.007) than those women who received iron-folic acid supplements. LNS reduced the risk of newborn stunting (length-for age z score <-2) (18.7% vs 22.6%; RR: 0.83; 95% CI: 0.71, 0.97) and LBW (36.0%; 95% CI 32.9, 39.3 vs 39.5%; 95% CI 37.6, 41.4). The effects of LNS on newborn stunting were greatest in infants born to women with household food insecurity.[119] Adu-Afarwuah et al. reported similar findings with a greater mean birthweight increase (85 g; p 0.04) and a lower risk of LBW (RR: 0.61; 95% CI 0.39, 0.96; p 0.032).[120] LNS supplementation was significantly associated with reduction in inadequate gestational weight gain (57.4%) compared to other supplements such as

iron-folic acid (63.1%) and multiple micro-nutrients (MMN) (67.2%).[121] However, similar supplementation in rural Malawi and Gambia did not find any strong association between LNS supplementation and mean birth size.[122 123] The results so far have been equivocal with no evidence of a positive effect on birth size, except some evidence among younger women, those with household food insecurity and primiparous women.[120 123]

Micronutrient Supplementation

Micronutrients are essential for normal physiological function, growth and development. Deficiencies of micronutrients such as vitamin A, iron, iodine and folate are particularly common during pregnancy due to increased nutrient requirements of the mother and developing foetus. Lopes et al. conducted a systematic review of randomised controlled trials focusing on nutritional interventions before and during pregnancy to reduce LBW. Micronutrient supplementation such as vitamin A, iron and folic-acid, low dose calcium, zinc, and multiple micro-nutrient (MMN) resulted in a reduction in the prevalence of LBW.[100]

The WHO recommends daily oral iron and folic acid supplementation with 30 - 60 mg of elemental iron and 400 μg (0.4 mg) folic acid for pregnant women to prevent maternal anaemia, puerperal sepsis, low birthweight, neural tube defects, and preterm birth.[124]A case-control study in Spain showed that iron supplementation (80 mg ferrous sulphate) was associated with a lower risk of LBW (OR 0.58; 95% CI 0.34, 0.98).[125] Similar results were reported by an RCT in the US with a significant increase in mean birthweight (206 ± 565 g; p 0.010).[126] There is strong biological plausibility for a causal link between maternal anaemia and LBW. Iron supplementation reduced maternal anaemia at term by 70% (RR 0.30; 95% CI 0.19, 0.46), iron-deficiency anaemia by 67% (RR 0.33; 95% CI 0.16, 0.69).[127] However, a Cochrane review failed to establish any significant association between iron supplementation with foetal birthweight or LBW.[127] Folic-acid (15 mg/day) supplementation alone was also not associated with LBW.[125]

Compared to iron only or iron-folic acid, MMN supplementation is effective in increasing mean birthweight. A Cochrane review reported a significant decrease in the number of newborns with LBW (RR 0.88; 95% CI 0.85, 0.91) with MMN (with

iron and folic acid or only iron) supplementation in pregnancy.[128] Another meta-analysis reported a similar reduction in LBW and 22.4 g increase in mean birthweight (95% CI 8.3, 36.4; p = 0.002).[129] In low-income countries, MMN supplementation resulted in a small increase in birthweight and a reduction in the prevalence of LBW (10%) compared to iron-folic acid alone.[130] Although most current evidence shows that giving MMN (containing 13–15 different micronutrients, including iron and folic acid) supplements to pregnant women may reduce the risk of LBW and SGA compared with iron-folic acid supplementation alone, it is not recommended as a regular supplementation considering some evidence of risk.[131]

Social Support Interventions

Limited success in reducing LBW through medical interventions, coupled with evidence of association between psychosocial factors and pregnancy outcomes, have led to an interest in preventing LBW by implementation of psychosocial interventions. A Cochrane review examined the effect of 'additional support' during pregnancy, defined by some form of emotional support (e.g. counselling, reassurance, sympathetic listening) with or without additional information or advice; or both, on perinatal outcomes. Social support interventions for at-risk pregnant women were not associated with reductions in the numbers of preterm or LBW babies. Considering the theoretical rationale for the strong links between social support, stress, and health, it has been argued that the social support might not be sufficiently powerful to improve the outcomes of the pregnancy. However, pregnant women need and deserve to have the help and support of caring family members, friends, and health professionals to reduce life stress that can cause other pregnancy complications.[132]

Health-care providers could reach out to partners, family and peers who could provide the pregnant woman with consistent daily support, a role beyond their clinical domain to address LBW besides antenatal visits.[133] In low resource settings, community health workers (CHW) have the potential to become an important resource for continuing support for women and children.[134] Social support from a woman in one's community, who has a similar socioeconomic background and is experiencing similar life stresses, may be qualitatively different from support from a healthcare professional, who has broad professional knowledge and experience, but may not share the same socioeconomic background or life concerns, and who often provides

other professional services as well as support.[135] Moreover, an adequately functioning social network may buffer possible harmful effects of stress exposure and help pregnant women to cope with stressful physiologic stimulation.[136]

1.1.5 Conclusions

In 2012, the World Health Assembly Resolution endorsed a comprehensive implementation plan for maternal, infant and young child nutrition, which specified six global nutrition targets; the third target was to achieve a 30% reduction in the number of LBW infants by the year 2025. This would translate into a 3% relative reduction per year between 2012 and 2025 and a reduction from approximately 20 million to about 14 million infants with LBW globally.[96] Affordable, accessible and appropriate healthcare intervention is imperative to achieve the target of preventing and treating LBW.[96]

Currently, there is an emerging interest in prenatal micronutrient and food supplementation for prevention of LBW infants. However, limited data is available from low-income countries, where the prevalence is highest. In addition to food and micronutrient supplementation, there is a growing recognition that it is necessary to investigate non-supplemental strategies, such as nutrition education, which is sustainable and scalable in resource poor setting. Strong data to support the effect of prenatal nutrition education on foetal growth is still lacking, especially in low-income countries. Of the few randomised controlled trials conducted in LMICs, the majority were health centre based or through skilled counsellors (doctors, nurses, midwives or health staff), and none included education on balanced diet. To date no study has explored the effect of community-based balanced diet education in LMICs to prevent LBW infants.

The incidence of LBW in Bangladesh is one of the highest in the world. Bangladesh was ranked 4th in terms of the global burden of LBW infants.[137] Although Bangladesh is progressing towards improved child survival, child deaths have been increasingly concentrated in the earliest months of life. Between the 1989-1993 and 2010-2014 periods, infant mortality declined by 56 percent, from 87 to 38 deaths per 1,000 live births. An almost 20 percent further reduction in infant mortality is needed to achieve the Health, Population, and Nutrition Sector Development Program (HPNSDP) target

of 31 deaths per 1,000 live births.[138] Bangladesh launched the Integrated Nutrition Program (1995-2002) to promote large-scale maternal and child nutrition characterised by nutritional counselling complemented by supplementary feeding for pregnant women and young children in rural areas. The project's goal was to reduce LBW by 50% over a 5-year period.[139] There was no overall impact of the program observed on birthweight or maternal weight gain.[140] This warrants more research to explore efficient ways to reduce the incidence of LBW in Bangladesh, and thus neonatal mortality. The association between food security and infants' size at birth also needs further investigation for developing future public health programs with special attention to those who are food insecure.

1.2 Research Aims

The research aim is to develop and test a nutrition specific intervention for pregnant women to improve birthweight and reduce the incidence of low birthweight in Bangladesh.

The specific aims are:

a) To develop nutrition behaviour change communication tool – the 'balanced plate nutrition education with practical demonstration' intervention for rural pregnant women.
b) To examine the impact of the balanced plate intervention on birthweight of infants.
c) To explore the barriers of complying with the balanced plate intervention and household coping strategies.
d) To investigate the association of household food insecurity with size of infants at birth.

1.4 Thesis Outline

The thesis consists of seven chapters. Chapter 1 and 2 are the overview of the research that include the introduction (**Chapter 1**) and the background of the research (**Chapter 2**).

1.3 Main Approaches

In this thesis, I have used both quantitative and qualitative methods to answer the research questions.

The thesis reports a randomized controlled trial conducted in a rural district of Bangladesh to investigate the impact of the balanced plate intervention on infant birthweight. **Chapter 3** consists of the protocol of the balanced plate trial (Publication 1) and discusses the trial methods in detail. **Chapter 4** (Manuscript 1) discusses the statistical analysis methods and the trial findings. In **Chapter 5,** an analysis of data from the qualitative study explores the influence of the balanced plate intervention, barriers to compliance and household coping strategies to overcome the barriers (Manuscript 2). Data for the qualitative analyses are from focus group discussions (FGD), in-depth interviews (IDI) and key informant interviews (KII) from a qualitative study conducted in one rural district (Sherpur) in Bangladesh among the trial participants and community health workers. I also examined the association between household food security and infants' size at birth analysing data from the Bangladesh Demographic and Health Surveys 2011, which I present in **Chapter 6** (Paper 2).

Chapter 7 summarises the main findings, and the strengths and limitations of the research, and provides recommendations for policy implications and future research directions.

CHAPTER 2

RESEARCH BACKGROUND

2.1 Bangladesh

Bangladesh, officially called 'The People's Republic of Bangladesh' is located in the tropics in South Asia and has a total area of 147,570 sq. km.[141] The country is bounded by India on the west, north, and northeast, Myanmar on the southeast, and the Bay of Bengal on the south (Figure 8). Eighty percent of its area consists of floodplains created by more than 300 rivers and channels, including three major rivers: the Ganges, the Brahmaputra, and the Meghna. Rivers are the most important geographical characteristic in Bangladesh and are the soul of life for the vast majority of Bangladeshi households. Topographically, the country is almost entirely a fertile alluvial plain. Hills rise above the plain only in the Chittagong Hill Tracts in the far southeast and the Sylhet division in the northeast.

Figure 8. Map of South Asia. *(Source: University of Texas Libraries)*

Annual flooding during the monsoon season causes devastation and suffering. In addition to flooding, other natural calamities plague Bangladesh such as cyclones, tidal surges, droughts and tornadoes. Bangladesh is a subtropical country with three main seasons, March through May is the hot season, when the climate is characterised

by heat, increasing humidity, and scattered storms. June through September is the monsoon season, characterized by regular rainfall and rising rivers; and October-February is a cool season, characterized by drier air and cooler temperatures.[142] Administratively, Bangladesh is divided into eight divisions, 64 districts and 491 sub-districts.[143]

The total population in Bangladesh is estimated to be ~160.8 million (2016) with more than 1,090 persons per sq. km.[144] Bangladesh is one of the most densely populated countries in the world. The population is growing at an annual rate of 1.37%. According to the Bangladesh Demographic and Health Survey (BDHS) 2014, total fertility has declined from more than 6 children per woman in 1991 to 2 births per woman in 2014.[138] Despite the remarkable decline in fertility rates, Bangladesh is characterized by a young age structure (33% of the population are less than 15 years of age) and thus has a 'built-in population momentum'.[145]

In Bangladesh 65% (2015) of the population resides in rural areas; which was more than 73% in 2005.[146] Bangladesh experienced faster urbanization between 2000 and 2010. Over that period, the share of Bangladesh's population living in urban settlements increased by 1.69% a year, yet the pace of urbanization still falls short of the pace in the East Asia and Pacific region.[147] The majority (~88.8%) of the people are Muslim and over 98% of the people speak Bangla.[142]

Bangladesh has made remarkable progress in reducing poverty, supported by sustained economic growth. Based on the international poverty line of $1.90 per person per day, it reduced poverty from 44.2 percent in 1991 to 13.8 percent in 2016/17. In parallel, life expectancy at birth (72 years), literacy rates (57.2%)[142] and per capita food production have increased significantly. Progress was underpinned by more than 6% growth over the decade and up to 7.3% in 2016/2017. Rapid growth enabled Bangladesh to reach the lower middle-income country status in 2015. In 2018, Bangladesh fulfilled all three eligibility criteria for graduation from the UN's Least Developed Countries (LDC) list for the first time and is on track for graduation in 2024.[148]

2.2 Prevalence of LBW in Bangladesh

The prevalence of LBW in Bangladesh is one of the highest in the world, and it was ranked 4th in terms of global burden of LBW infants.[137] However, the extent of LBW in the country has not been well surveyed or documented since 2004, largely because most women deliver at home (63%)[138], which makes the large scale data collection of birthweights difficult, and because most areas of the country lack the equipment or practice of measuring birthweight at home or at the community level. Table 3 shows the results of several small[149 150] and large-scale[151-154] regional surveys and two nationwide studies[155 156] in Bangladesh that have estimated the prevalence of LBW between 1983 to 2007. The prevalence ranged from 15.2% in an urban government maternity hospital to 55.3% in a northern rural district of Bangladesh.

Table 2. Findings of previous studies in Bangladesh on infant birthweight

Location	Year of data collection	Sample size	Mean birthweight in g (SD/95% CI)	Prevalence of LBW (%)
Institution-based survey	1983	624	2,593 (480)	45.4
Urban slum	1993-95	1,654	2,516 (404)	46.4
Institution-based survey	2002	316	2,889 (468)	15.2
Nationwide survey	2003	3,085	2,632 (433)	35.6
Rural Bangladesh	2003	252	2,550 (380)	48.0
Nationwide survey (rural areas)	2004	692	2,780 (2750, 2810)	20.7
Rural northern Bangladesh	2001-2007	13,709	2,446 (420)	54.4
Rural northern Bangladesh	2004-2007	16,290	2,433 (425)	55.3
Rural Bangladesh (Matlab)	2001-2009	3,267	2,694 (2680, 2708)	31%

Although this data has a wide range of estimates, of LBW in Bangladesh, approximately one third to half of infants are still LBW, and LBW is more prevalent in poverty-stricken rural districts and urban slums.

The prevalence of undernutrition was markedly higher in children with LBW than those with normal birthweight (stunting: 51% vs 39%; wasting: 25% vs 14% and underweight: 52% vs 33%). While controlling for the known risk factors, children with LBW had significantly increased risk of becoming malnourished compared to their normal birthweight counterparts for stunting, wasting and underweight (stunting: RR 1.2; 95% CI 1.2, 1.3, wasting: RR 1.7; 95% CI 1.5, 1.9 and underweight: RR 1.5; 95% CI 1.4, 1.6). The observed associations were not modified by factors known to

reduce the prevalence of undernutrition, such as increased maternal education, better household socio-economic conditions or longer birth-interval.[157]

2.3 Nutritional Status of Women in Bangladesh

Bangladeshi women suffer from multifaceted nutritional deficiencies. A nationally representative survey indicated a co-existence of acute and chronic undernutrition among women of reproductive age; 13% are short statured (height <145 cm) and 19% are thin (BMI <18.5 kg/m^2).[138] The observed change in nutritional status has been slow. Comparisons between the 2004, 2007, 2011, and 2014 BDHSs indicate a slight reduction in the proportion of women whose height is less than 145 cm, from 16% in 2004 to 13% in 2014. At the same time, the mean BMI has increased from 20.2 (2004) to 22.3 (2014). Consequently, the proportion of women with a BMI below 18.5 has decreased from 34% (2004) to 19% (2014). However, overweight also increased between 2004 and 2014 (Figure 9).[138]

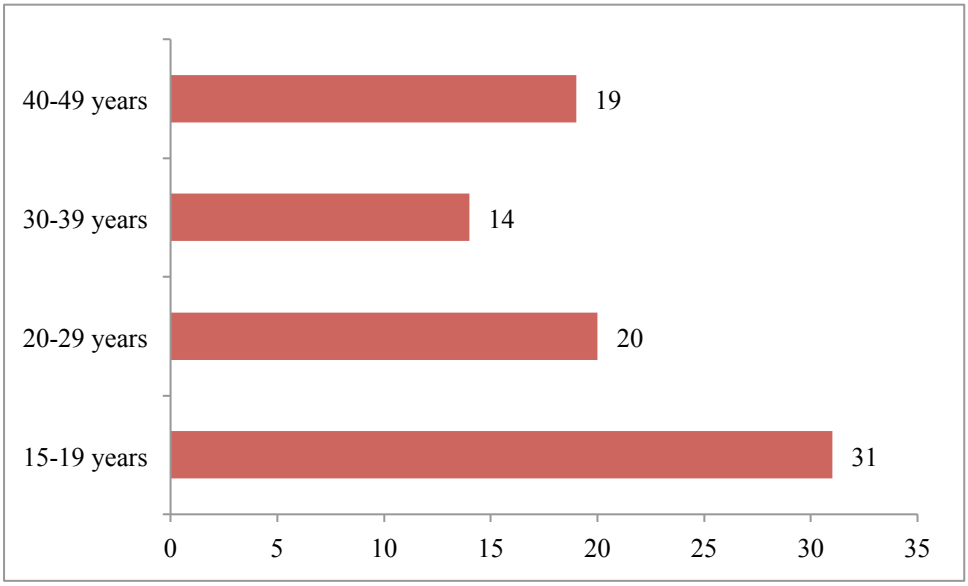

Figure 9. Trends in nutritional status of ever-married women, 2004-2014. (Source: BDHS 2014)

Undernutrition is highly skewed towards adolescents and low-income groups. Ever-married women aged 15-19 are more likely to be thin or undernourished compared with women in other age cohorts (Figure 10). The proportion of overweight women increases with age. Rural women are more likely than urban women to be undernourished (21% vs 12%), whereas urban women are twice as likely to be overweight or obese compared with rural women (36% vs 19%).[138]

The prevalence of anaemia among non-pregnant, ever-married women was 41.3% (urban: 37.2 % and rural: 43.5 %); of them 35.5% had mild anaemia (haemoglobin level 10.0-11.9 g/dL), 5.6% had moderate anaemia (haemoglobin level 7.0-9.9 g/dL), and 0.2% had severe anaemia (haemoglobin level <7.0 g/dL).[158] Iron deficiency anaemia is as high as 40% (haemoglobin <11.0 g/dL) among pregnant women despite high (77.5%) intake of iron folic acid supplements[159], which may be aggravated by low serum vitamin A (<30 g/dL) (45%), zinc (55%) and folate (18%) and vitamin B 12 (49%) levels.[160 161 162 163]

The nutritional status is worse among pregnant women, especially among rural and low-income groups. The prevalence of undernutrition was 63% in rural and 45% in urban pregnant women.[164] Undernutrition is inequitably distributed across the economic classes. More than three quarters of pregnant women in the low-income groups were classified as underweight as opposed to 13% in the high income group.[165] Among rural women, the total gestational weight gain was 5.6 kg, which is lower than values reported in other Asian countries (Taiwan, 7.6 kg; India, 6.5 kg; East Java, 6.0 kg), and lower than the WHO recommendations.[166]

Dietary surveys revealed that food consumption in pregnancy in terms of quantity and quality is far below the recommendation. The reported maternal daily energy intake at 5 – 7 months of gestation was 1,464 (±416) kcal[167], while the recommendation for an average weight Bangladeshi pregnant women is 2,265 kcal in the second trimester and 2,455 kcal in the third trimester.[168] The overall mean diet diversity score was as low as 4.28, with least consumption from three food groups including dairy foods, eggs, and dark green leafy vegetables.[169] A large proportion of pregnant women did not consume eggs (49%), milk (25%), meat (31%), liver (83%), large fish (32%), small fish (39%) and pumpkin (52%) in the last two trimesters; while about 25% of them consumed dark green leafy vegetables and 64% fruits for at least four servings a week.[160] Knowledge on the importance of nutrition during pregnancy and its impact on birthweight were very low. Only a quarter of the women reportedly knew that undernutrition during pregnancy might cause LBW. One in every five women had no knowledge about nutritious foods. About one third women mentioned that vegetables were the most nutritious foods, whereas, another third believed that its milk, egg, meat and fish which are most nutritious.[159]

2.4 Determinants of Maternal Nutrition Practices

Maternal malnutrition is not simply the result of limited food resources or cultural practices preventing women from eating nutritiously, but rather is the consequence of a complex interplay of many factors including knowledge of nutritional foods; women's status in the family and society and limited financial stability.[170 171] In South Asia factors that hindered women from maintaining adequate nutritional practices in pregnancy includes low socio-economic status (42.4%), inadequate knowledge about food (20.4%), ignorance (13.1%), lack of husbands' support (12.6%) and forgetfulness (11.5%).[172]

Knowledge alone is not necessarily translated into practice due to social and economic barriers that women face. Despite having knowledge, more than half of the pregnant women did not increase dietary intake from their pre-pregnancy state due to discriminatory food allocation (90%), lack of decision-making power (85%), lack of family support (67%), economic/access constraints (50%), illness (46%), not wanting a large baby (20%), large family size (7%), and not feeling comfortable to increase dietary intake (7%).[173] Interpersonal communication with a support network surrounding the women enhanced their self-efficacy in achieving recommended practices.[172] A large-scale maternal nutrition intervention in Bangladesh demonstrated that at the household level, delivering interpersonal counselling and community mobilization improved maternal dietary diversity and micronutrient supplement consumption through increasing the husband's support.[174 175]

Household size is significant because it may tell us about the competition for food within the family. Mothers will tend to serve the children and the husband before serving themselves.[171] In households with less food, mothers often miss out food. Nearly 66% of mothers reportedly consumed no more than half of a standard plate.[176] Consumption of certain groups of food might be affected by availability and food preference. Limited production and market availability and seasonality of production were identified to limit the consumption of fruits and vegetables during pregnancy. Gastrointestinal irritations or fear of having a large baby lead to avoidance of certain foods and intake volume.[177] Food preference during pregnancy is driven equally by both internal and external factors. Internal factors are related to biological factors of pregnancy (i.e., immobility, ailments or nausea) and motivation, whereas, social and

cultural norms act as external influencers.[178]

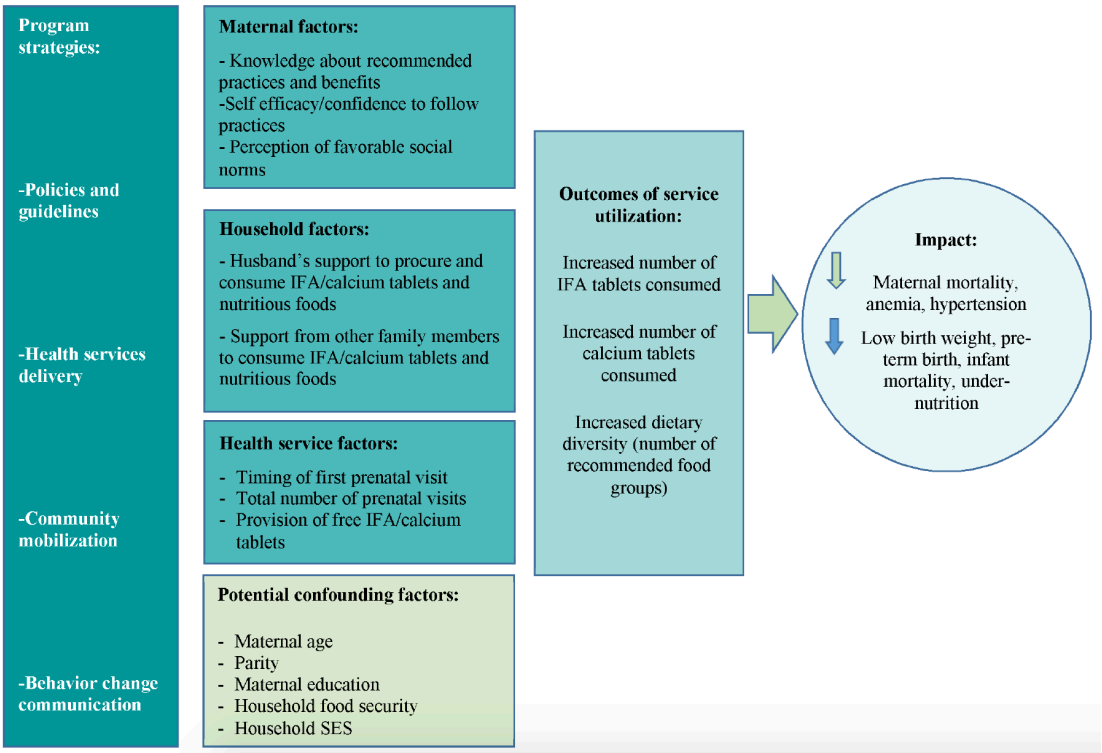

Figure 6. Conceptual framework of factors influencing maternal nutrition practices in Bangladesh. (*Source: Nguyen 2017)*

Gender discrimination is widely recognised as a primary underlying cause of undernutrition across South Asia, including Bangladesh[179], resulting in high rates of women's undernutrition across social classes.[180] Child marriage leads to early pregnancy and child bearing and this is in turn is related to nutrition, particularly the nutritional status of the newborn, and hence LBW.[181 182] Although there has been some reduction in child marriage in the last two decades, the prevalence remains high. Two thirds of girls are married by 18 years of age, and one third are already married by 15 year old.[138]

2.5 Food Security Situation in Bangladesh

Food security is a core element in the struggle against poverty. Food security or insecurity has several dimensions, such as the level of food aggregation (national, household or individuals), seasonal production of staples, nutritional balance in the diet, people's access to and utilization of food, and temporal uncertainty of supplies often caused by natural disasters or price increases.[183] Over the past three decades, Bangladesh has made significant progress in increasing domestic production of food

grains. The average per capita dietary energy supply has increased from 1,800 kcal in 1970s to 3,055 kcal in 2009. Rice alone provides 76% of the total calories and 66% of total protein requirement. Despite self-sufficiency in rice production, food insecurity at the household level remains widespread due to access barriers such as low income and price increases. The country's food insecure (<2,122 kcal/person/day) population is now estimated at 65 million (nearly half or 45% of the population) and nearly one quarter are deemed severely food insecure (<1,805 kcal/person/day).[184] Between 1985/86 and 2000 the proportion of people below the poverty line dropped by 10%, while average consumption of calories slightly increased and consumption of protein practically remained unchanged.[183] A major shift in demand from inferior foods towards more varied and higher value foods requires an improvement of gross national income and food purchasing ability.[185]

There are substantial variations in calorie consumption among regions and wealth groups. At the household level food distribution among the members is not necessarily equal. Generally, women and children have less access to food than adult males.[179] The per capita consumption of meat and eggs by rural consumers falls far short of the requirement. The high consumption of cereals but low intake of pulses and other animal-based proteins results in a high level of anaemia and other micro nutrient deficiencies.[183]

Food security in Bangladesh has been adversely affected by both disasters and recent escalating food prices.[186] [187] Population growth and urbanisation also have serious blows on the food supply and access for Bangladesh because of loss of agricultural land, fragmentation of land and land development projects in fragile environments that constantly affect food production. Impacts of climate change on food security are global concerns, but they represent a particular threat for Bangladesh.[184] The prevalence rates of food insecurity, wasting, and inadequate growth were all significantly higher during the monsoon season as compared to the dry season. Dietary diversity and lost work due to the weather were identified as specific pathways through which the season affected household food security.[188] In Bangladesh, a seasonal fluctuation in income and employment, referred to as 'monga' occurs prior to the main rice harvest in ecologically vulnerable and economically weak parts of northwest.[189] During monga, seasonal food shortages result in

household food insecurity and low dietary diversity, particularly among rural women.[190] Women's reduced access to wealth and poor literacy are also associated with household food insecurity and poor dietary diversity.[191]

2.6 Antenatal Nutrition Interventions in Bangladesh

The Government of Bangladesh identifies nutrition as a crosscutting issue and key to poverty reduction. Expanded nutrition services are being integrated into the health sector through the Health, Population and Nutrition Sector Development Program, and through the National Nutrition Service.[192] In 2012, Bangladesh joined the 'Scaling Up Nutrition' movement guiding work in multi-sectoral and multi-stakeholder space.[193] Nutrition has been covered in two consecutive 'Poverty Reduction Strategy Papers' and under the fifth 'Five Year Plan'. Nutrition specific intervention prior to the 6th 'Five Year Plan' was the Bangladesh Integrated Nutrition Project (BINP) (1995-2000) and National Nutrition Programme (NNP) (2003-2011), managed by Ministry of Health and Family Welfare under Health and Population Sector Programme and Health, Population and Nutrition Sector Programme. The BINP was implemented in 40 out of 460 thanas (administrative areas) in the country with the aim to reduce malnutrition, particularly among women and children, by ensuring household food security and through behavioural changes related to food intake, infant feeding, growth monitoring and caring practices. Pregnant women who have BMI<18.5 kg/m^2 on first presentation received supplementary food (2,512 kJ or 600 kcal/d) for six days per week for up to 6 months, distributed through the community nutrition centres located in villages. A longitudinal study in the BINP areas reported that food supplementation did not lead to enhanced pregnancy weight gain or a reduction in the prevalence of low birthweight. The identified reasons of failures were inefficient targeting of eligible women, failing to start supplementation on time and to failure to achieve full compliance.[166]

Under the 6th 'Five Year Plan', The Government of Bangladesh has developed a Health, Population and Nutrition Sector Development Program (2011-2016), including an operational plan for mainstreaming and scaling up nutrition services nationally through the National Nutrition Services, which intends to reduce the prevalence of undernutrition, especially among women and girls. By focusing on the first '1,000 days' (the period from conception to a child's second birthday), the

government aims to ensure universal access to nutrition services.[194] Nutrition specific interventions include iron-folate supplementation to pregnant and lactating women and adolescent girls, postpartum vitamin A supplementation, supplementary feeding for malnourished and marginalised pregnant and lactating women, nutrition education for diet diversity and increasing awareness about proper nutrition.[195]

2.7 Conclusion

Given the nutritional condition of the women of Bangladesh and its consequence on birth outcomes (especially LBW) it is pertinent that a more effective intervention is essential to bring down the LBW rate. Despite several government initiatives the rate is still highest in the world. Based on the evidence, we can conclude that maternal nutrition education intervention could be one of the potential solutions to resolve the problem. Therefore, we tested the effectiveness of the balanced plate nutrition education intervention to find a context specific scalable intervention in a resource poor setting.

REFERENCES

1. World Health Organization. International Statistical Classification of Diseases and Related Health Problems, Tenth Revision. World Health Organization, Geneva, 1992.
2. Haig D. Genetic conflicts in human pregnancy. *The Quarterly Review of Biology* 1993;68(4):495-532.
3. McCormick MC. The Contribution of Low Birth Weight to Infant Mortality and Childhood Morbidity. *The New England Journal of Medicine* 1985;312(2):82-90.
4. Victora CG, Adair L, Fall C, et al. Maternal and child undernutrition: consequences for adult health and human capital. *Lancet* 2008;371(9609):340-57. doi: 10.1016/S0140-6736(07)61692-4
5. Camerota M, Bollen KA. Birth Weight, Birth Length, and Gestational Age as Indicators of Favorable Fetal Growth Conditions in a US Sample. *PloS one* 2016;11(4) doi: 10.1371/journal.pone.0153800
6. United Nations Children's Fund and World Health Organization. Low Birthweight: Country, regional and global estimates. New York: UNICEF, 2004.
7. Lee AC, Katz J, Blencowe H, et al. National and regional estimates of term and preterm babies born small for gestational age in 138 low-income and middle-income countries in 2010. *The Lancet Global health* 2013;1:e26-36.
8. United Nations Children's Fund. Undernourishment in the womb can lead to diminished potential and predispose infants to early death 2014 [Available from: http://data.unicef.org/topic/nutrition/low-birthweight/ accessed 7 May 2018.
9. Pollack RN, Divon MY. Intrauterine Growth Retardation: Definition, Classification and Etiology. *Clinical Obstetrics and Gynecology* 1992;35(1)
10. Kramer MS. Determinants of low birth weight: methodological assessment and meta-analysis. *Bulletin of the World Health Organization* 1987;65(5):663-737.
11. Sachdev HPS. Low Birth Weight in South Asia. *Int J Diab Dev Countries* 2001;21:13-31.
12. Black RE, Allen LH, Bhutta ZA, et al. Maternal and child undernutrition: global and regional exposures and health consequences. *Lancet* 2008;371:243-60.
13. Wilcox AJ, Russell IT. Birthweight and Perinatal Mortality: II. On Weight-Specific Mortality. *International journal of epidemiology* 1983;12(3):319-25.
14. Wilcox AJ, Russell IT. Birthweight and Perinatal Mortality: I. On the Frequency Distribution of Birthweight. *International journal of epidemiology* 1983;12(3):314-18.
15. Adair L, Guilkey D. Age-specific determinants of stunting in Filipino children. *Journal of Nutrition* 1997;127:314-20.
16. Raqib R, Alam DS, Sarker P, et al. Low birth weight is associated with altered immune function in rural Bangladeshi children: a birth cohort study. *American Journal of Clinical Nutrition* 2007;85(3):845–52.
17. Aryastami NK, Shankar A, Kusumawardani N, et al. Low birth weight was the most dominant predictor associated with stunting among children aged 12–23 months in Indonesia. *BMC Nutrition* 2017;3(16)
18. Black RE, Victora CG, Walker SP, et al. Maternal and child undernutrition and overweight in low-income and middle-income countries. *The Lancet*;382(9890):427-51. doi: 10.1016/s0140-6736(13)60937-x

19. Cruise M. A longitudinal study of the growth of low birth weight infants. I. Velocity and distance growth, birth to 3 years. *Pediatrics* 1973;51(4):620.
20. Martorell R, Ramakrishnan U, Schroeder D, et al. Intrauterine growth retardation, body size, body composition and physical performance in adolescence. *European Journal of Clinical Nutrition* 1998;52(Suppl 1):S43-52.
21. Hack M, Klein NK, Tayl HG. Long-term developmental outcomes of low birth weight infants. *The Future of Children-Spring 1995* 1995;5(1):176- 96.
22. Gupta ND, Deding M, Lausten M. The effect of low birth weight on height, weight and behavioral outcomes in the medium-run. *Economics and human biology* 2013;11(1):42-55.
23. Fletcher JM. The medium term schooling and health effects of low birth weight: Evidence from siblings. *Economics of Education Review* 2011;30(3):517-27.
24. Kormos CE, Wilkinson AJ, Davey CJ, et al. Low birth weight and intelligence in adolescence and early adulthood: a meta-analysis. *Journal of Public Health* 2013;36(2):213–24. doi: https://doi.org/10.1093/pubmed/fdt071
25. Taylor HG, Margevicius S, Schluchter M, et al. Persisting behavior problems in extremely low birth weight adolescents. *Journal of developmental and behavioral pediatrics : JDBP* 2015;36(3) doi: 10.1097/DBP.0000000000000139.
26. Muskiet FAJ. Chapter 2 Pathophysiology and Evolutionary Aspects of Dietary Fats and Long-Chain Polyunsaturated Fatty Acids across the Life Cycle. In: Montmayeur J, le Coutre J, eds. Fat Detection: Taste, Texture, and Post Ingestive Effects. Boca Raton (FL): CRC Press/Taylor & Francis 2010.
27. Barker D. In utero programming of chronic disease. *Clinical Science* 1998;95(2):115-28.
28. Godfrey KM, Barker DJ. Fetal nutrition and adult disease. *American Journal of Clinical Nutrition* 2000;71(5 Suppl):1344S-52S. doi: 10.1093/ajcn/71.5.1344s
29. Godfrey K, Robinson S. Maternal nutrition, placental growth and fetal programming. *Proceedings of the Nutrition Society* 1998;57:105-11.
30. Alexander BT. Fetal programming of hypertension. *Am J Physiol Regul Integr Comp Physiol* 2006;290:R1–R10. doi: 10.1152/ajpregu.00417.2005.
31. Ojeda NB, Grigore D, Alexander BT. Intrauterine Growth Restriction: Fetal Programming of Hypertension and Kidney Disease. *Advances in Chronic Kidney Disease* 2008;15(2):101-06.
32. Simmons RA, Templeton LJ, Gertz SJ. Intrauterine Growth Retardation Leads to the Development of Type 2 Diabetes in the Rat. *Diabetes* 2001;50(10):2279-86. doi: https://doi.org/10.2337/diabetes.50.10.2279
33. Yajnik C. Obesity epidemic in India: Intrauterine origins? *The Proceedings of the Nutrition Society* 2004;63:387–96.
34. Alderman H, Behrman JR. Estimated Economic Benefits of Reducing Low Birth Weight in Low-Income Countries. Washington, DC: The World Bank, 2004.
35. Lewit EM, Baker LS, Corman H, et al. The Direct Cost of Low Birth Weight. *The Future of Children* 1995;5(1)
36. Goddeeris JH, Saigal S, Boyle MH, et al. Economic Outcomes in Young Adulthood for Extremely Low Birth Weight Survivors. *Pediatrics* 2010;126(5):e1102-e08.
37. OECD Family Database. Low birth weight 2017 [Available from: http://www.oecd.org/els/family/CO_1_3_Low_birth_weight.pdf accessed 8 May 2018.

38. Ohmi H, Hirooka K, Hata A, et al. Recent trend of increase in proportion of low birthweight infants in Japan. *International journal of epidemiology* 2001;30(6):1269-71.
39. Child Trends Data Bank. Low and Very Low Birthweight Infants: Indicators of Child and Youth WEll-Being 2018 [cited 2018 May 16]. Available from: https://www.childtrends.org/wp-content/uploads/2016/12/57_Low_Birth_Weight.pdf.
40. Bhat BV, Adhisivam B. Trends and Outcome of Low Birth Weight (LBW) Infants in India. *Indian Journal of Pediatrics* 2013;80(1):60-62. doi: 10.1007/s12098-012-0922-6
41. Anuranga C, Wickramasinghe R, Rannan-Eliya RP, et al. Trends, inequalities and determinants of low birth weight in Sri Lanka. *Ceylon Medical Journal* 2012;57:61-69.
42. Walker SP, Chang SM. Handbook of Growth and Growth Monitoring in Health and Disease. New York, NY: Springer 2012.
43. Borders BAE, Grobman WA, Amsden LB, et al. Chronic Stress and Low Birth Weight Neonates in a Low-Income Population of Women. *The American College of Obstetricians and Gynecologists* 2007;109(2):331-38.
44. Imdad A, Bhutta ZA. Maternal Nutrition and Birth Outcomes: Effect of Balanced Protein-Energy Supplementation. *Paediatric and Perinatal Epidemiology* 2012;26(Suppl. 1):178–90.
45. Han Z, Lutsiv O, Mulla S, et al. Maternal Height and the Risk of Preterm Birth and Low Birth Weight: A Systematic Review and Meta-Analyses. *J Obstet Gynaecol Can* 2012;34(8):721–46.
46. Zhang G, Bacelis J, Lengyel C, et al. Assessing the Causal Relationship of Maternal Height on Birth Size and Gestational Age at Birth: A Mendelian Randomization Analysis. *PLoS Med* 2015;12(8):e1001865. doi: 10.1371/journal.pmed.1001865
47. Yu Z, Han S, Zhu J, et al. Pre-Pregnancy Body Mass Index in Relation to Infant Birth Weight and Offspring Overweight/Obesity: A Systematic Review and Meta-Analysis. *PloS one*;8(4):e61627. doi: 10.1371/journal.pone.0061627
48. Energy Requirements of Pregnancy. Human energy requirements - Report of a Joint FAO/WHO/UNU Expert Consultation. Rome: FAO, 2001.
49. Han Z, Mulla S, Beyene J, et al. Maternal underweight and the risk of preterm birth and low birth weight: a systematic review and meta-analyses. *International journal of epidemiology* 2011;40:65–101. doi: 10.1093/ije/dyq195
50. Strauss R, Dietz W. Low maternal weight gain in the second or third trimester increases the risk for intrauterine growth retardation. *The Journal of Nutrition* 1999;129(5):988-93.
51. Grivell R, Dodd J, Robinson J. The prevention and treatment of intrauterine growth restriction. *Best Practice & Research Clinical Obstetrics and Gynaecology* 2009;23:795–807.
52. Abu-Saad K, Fraser D. Maternal Nutrition and Birth Outcomes. *Epidemiologic Reviews* 2010;32:5-25.
53. Triunfo S, Lanzone A. Impact of maternal under nutrition on obstetric outcomes. *Journal of endocrinological investigation* 2015;38(1):31-8.
54. Myron W. Nutrition, pre- and postnatal development: Plenum Press 1979.
55. Stein Z, Susser M. The Dutch Famine, 1944-1945, and the Reproductive Process. I. Effects on Six Indices at Birth. *Pediatric Research* 1975;9:70-76.

56. Bergner L, Susser MW. Low Birth Weight and Prenatal Nutrition: An Interpretative Review. *Pediatrics* 1970;46(6)
57. Antonov A. Children born during the siege of Leningrad in 1942. *Journal of Pediatrics* 1947;30:250-9.
58. Oke SL, Hardy DB. Effects of Protein Deficiency on Perinatal and Postnatal Health Outcomes. *Physiology and Pharmacology Publications* 2017;101
59. Innis SM. Fatty acids and early human development. *Early Human Development* 2007;83:761–66.
60. Kuipers RS, Luxwolda MF, Dijck-Brouwer JDA, et al. Intrauterine, postpartum and adult relationships between arachidonic acid (AA) and docosahexaenoic acid (DHA). *Prostaglandins, Leukotrienes and Essential Fatty Acids* 2011;85:245–52.
61. Robillard PY, Christon R. Lipid Intake During Pregnancy In Developing Countries: Possible Effects of Essential Fatty Acid Defficiency on Fetal Growth. *Prostaglandins Leukotriens and Essential Fatty Acids* 1993;48:139-42.
62. Biesalski HK, Jana T. Micronutrients in the life cycle: Requirements and sufficient supply. *NFS Journal* 2018;11:1-11.
63. Steer PJ. Maternal hemoglobin concentration and birth weight. *American Journal of Clinical Nutrition* 2000;71(suppl):1285S–7S.
64. Figueiredo ACMG, Gomes-Filho IS, Silva RB, et al. Maternal Anemia and Low Birth Weight: A Systematic Review and Meta-Analysis. *Nutrients* 2018;10(601) doi: 10.3390/nu10050601
65. Allen LH. Biological Mechanisms That Might Underlie Iron's Effects on Fetal Growth and Preterm Birth. *The Journal of Nutrition* 2001;131(2):581S–89S. doi: https://doi.org/10.1093/jn/131.2.581S
66. Fekete K, Berti C, Trovato M, et al. Effect of folate intake on health outcomes in pregnancy: a systematic review and meta-analysis on birth weight, placental weight and length of gestation. *Nutrition journal* 2012;11(75)
67. FAO and FHI 360. Minimum dietary diversity for women: a guide for measurement. Rome, 2016.
68. Uitert EMv, Steegers-Theunissen RgPM. Influence of maternal folate status on human fetal growth parameters. *Molecular Nutrition & Food Research* 2013;57:582–95.
69. Antony AoC. In utero physiology: role of folic acid in nutrient delivery and fetal development. *American Journal of Clinical Nutrition* 2007;85(Suppl):598S–603S.
70. León G, Murcia M, Rebagliato M, et al. Maternal Thyroid Dysfunction during Gestation, Preterm Delivery, and Birthweight. The Infancia y Medio Ambiente Cohort, Spain. *Paediatric and Perinatal Epidemiology* 2015;29:113–22. doi: 10.1111/ppe.12172
71. Forhead A, Fowden A. Thyroid hormones in fetal growth and prepartum maturation. *Journal of Endocrinology* 2014;221(3):R87-R103. doi: 10.1530/JOE-14-0025
72. Charoenratana C, Leelapat P, Traisrisilp K, et al. Maternal iodine insufficiency and adverse pregnancy outcomes. *Maternal and Child Nutrition* 2016;12:680–87.
73. Muthayya S, Kurpad A, Duggan C, et al. Low maternal vitamin B12 status is associated with intrauterine growth retardation in urban South Indians. *European Journal of Clinical Nutrition* 2006;60:791–801.

74. Institute of Medicine (US) and National Research Council (US) Committee to Reexamine IOM Pregnancy Weight Guidelines. Composition and Components of Gestational Weight Gain: Physiology and Metabolism. In: Rasmussen K, Yaktine A, eds. Weight Gain During Pregnancy: Reexamining the Guidelines. Washington (DC): National Academies Press (US) 2009.
75. Young MF, Nguyen PH, Addo OY, et al. Timing of Gestational Weight Gain on Fetal Growth and Infant Size at Birth in Vietnam. *PloS one* 2017;12(1):e0170192. doi: 10.1371/journal.pone.0170192
76. Institute of Medicine (US) and National Research Council (US) Committee to Reexamine IOM Pregnancy Weight Guidelines. Consequences of Gestational Weight Gain for the Child. In: Rasmussen K, Yaktine A, eds. Weight Gain During Pregnancy: Reexamining the Guidelines. Washington (DC): National Academies Press (US) 2009.
77. Brown J, Murtaugh M, Jacobs DJ, et al. Variation in newborn size according to pregnancy weight change by trimester. *American Journal of Clinical Nutrition* 2002;76(1):205-9.
78. Zanardo V, Mazza A, Parotto M, et al. Gestational weight gain and fetal growth in underweight women. *Italian Journal of Pediatrics* 2016;42(74) doi: 10.1186/s13052-016-0284-1
79. Susser M. Maternal weight gain, infant birth weight, and diet: causal sequences. *American Journal of Clinical Nutrition* 1991;53:1384-96.
80. FAO. The state of food security in the world. Rome: Food and Agriculture Organization, 2000.
81. FAO, IFAD, WFP. The State of Food Insecurity in the World 2014. Strengthening the enabling environment for food security and nutrition. Rome: FAO, 2014.
82. Ivers LC, Cullen KA. Food insecurity: special considerations for women. *The American journal of clinical nutrition* 2011;94(suppl):1740S–4S.
83. Saaka M. How is household food insecurity and maternal nutritional status associated in a resource-poor setting in Ghana? *Agriculture & Food Security* 2016;5(11)
84. Na M, Mehra S, Christian P, et al. Maternal Dietary Diversity Decreases with Household Food Insecurity in Rural Bangladesh: A Longitudinal Analysi. *The Journal of Nutrition* 2016;146:2109–16.
85. Institute of Medicine (US) and National Research Council (US) Committee to Reexamine IOM Pregnancy Weight Guidelines. Descriptive Epidemiology and Trends. In: Rasmussen K, Yaktine A, eds. Weight Gain During Pregnancy: Reexamining the Guidelines. Washington (DC): National Academies Press (US) 2009.
86. Savard N, Levallois P, Rivest LP, et al. Impact of individual and ecological characteristics on small for gestational age births: an observational study in Quebec. *Chronic Diseases and Injuries in Canada* 2014;34(1):46-54.
87. Copper R, Goldenberg R, Das A, et al. The preterm prediction study: maternal stress is associated with spontaneous preterm birth at less than thirty-five weeks' gestation. National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. *amirican journal of Obstetrics and GynecologO* 1996;175(5):1286-92.
88. Paarlberg KM, Vingerhoets AJM, Passchier J, et al. Psychosocial Factors and Pregnancy Outcome: A Review With Emphasis On Methodological Issues. *Journal of Psychosomatic Research* 1995;39(5):563-95.

89. Schetter CD, Tanner L. Anxiety, depression and stress in pregnancy: implications for mothers, children, research, and practice. *Current Opinion in Psychiatry* 2012;25(2):141–48.
90. Stanevaa A, Bogossianb F, Pritchardc M, et al. The effects of maternal depression, anxiety, and perceived stress during pregnancy on preterm birth: A systematic review. *Women and Birth* 2015;28(3):179-93.
91. WHO. Promoting Optimal Fetal Development : Report of a Technical Consultation. Geneva: WHO, 2003.
92. Kavle JA, Landry M. Addressing barriers to maternal nutrition in low- and middle- income countries: A review of the evidence and programme implications. *Maternal and Child Nutrition* 2018;14(e12508) doi: 10.1111/mcn.12508
93. WHO. Global Nutrition Targets 2025: Low Birth Weight Policy Brief. World Health Assembly Resolution 656, 2012.
94. The Lancet. Maternal and Child Nutrition: Executive Summary of The Lancet Maternal and Child Nutrition Series, 2013.
95. Gresham E, Byles JE, Bisquera A, et al. Effects of dietary interventions on neonatal and infant outcomes: a systematic review and meta-analysis. *The American journal of clinical nutrition* 2014;100:1298–321.
96. WHO. Nutrition counselling during pregnancy 2017 [Available from: http://www.who.int/elena/titles/nutrition_counselling_pregnancy/en/ accessed 28 May 2018.
97. Lopes KdS, Ota E, Shakya P, et al. Effects of nutrition interventions during pregnancy on low birth weight: an overview of systematic reviews. *BMJ Global Health* 2017;2(e000389) doi: 10.1136/bmjgh-2017-000389
98. Girard AW, Olude O. Nutrition education and counselling provided during pregnancy: effects on maternal, neonatal and child health outcomes. *Paediatric and Perinatal Epidemiology* 2012;26(s1):191-204.
99. Ota E, Hori H, Mori R, et al. Antenatal dietary education and supplementation to increase energy and protein intake (Review). Cochrane Database of Systematic Reviews: John Wiley & Sons, Ltd, 2015.
100. Widga AC, Lewis NM. Defined, in-home, prenatal nutrition intervention for low-income women. *Journal of the American Dietetic Association* 1999;99(9):1058-62.
101. Graham AV, Frank SH, Zyzanski SJ, et al. A clinical trial to reduce the rate of low birth weight in an inner city black population. *Family medicine* 1992;24(6)
102. Olds D, Henderson CJ, Tatelbaum R, et al. Improving the delivery of prenatal care and outcomes of pregnancy: a randomized trial of nurse home visitation. *Pediatrics* 1986;78(1)
103. Briley C, Flanagan NL, Lewis NM. In-home prenatal nutrition intervention increased dietary iron intakes and reduced low birthweight in low-income African-American women. *Journal of the American Dietetic Association* 2002;102(7):984-87.
104. Kafatos AG, Tsitoura S, Pantelakis SN, et al. Maternal and infant health education in a rural Greek community. *Hygie* 1991;10
105. Heins HC, Nance NW, McCarthy BJ, et al. A Randomized Trial of Nurse-Miswifery Prenatal care to Reduce Low Birth Weight. *Obstetetrics and Gynecolology*;75(3):341-45.

106. Nikièma L, Huybregts L, Martin-Prevel Y, et al. Effectiveness of facility-based personalized maternal nutrition counseling in improving child growth and morbidity up to 18 months: A cluster-randomized controlled trial in ruralBurkina Faso. *PloS one* 2017;12(5):e0177839.
107. Sweeney C, Smith H, Foster JC, et al. Effects of a nutrition intervention program during pregnancy. *Journal of Nurse-Midwifery* 1985;30(3):149-58. doi: http://dx.doi.org/10.1016/0091-2182(85)90280-0
108. Akter SM, Roy SK, Thakur SK, et al. Effects of third trimester counseling on pregnancy weight gain, birthweight, and breastfeeding among urban poor women in Bangladesh. *Food and Nutrition Bulletin* 2012;33(3):194-201.
109. Kafatos AG, Vlachonikolis IG, Codrington CA. Nutrition during pregnancy: the effects of an educational intervention program in Greece. *American Journal of Clinical Nutrition* 1989;50(5):970-79.
110. Mclaughlin JJ, Altermeier WA, Christensen MJ, et al. Randomized trial of comprehensive prenatal care for low-income women: effect on infant birthweight. *Pediatric* 1992;89(128)
111. Jahan K, Roy SK, Seema M, et al. Short-term nutrition education reduces low birthweight and improves pregnancy outcomes among urban poor women in Bangladesh. *Food and Nutrition Bulletin* 2014;35(4):414-21.
112. Kramer M, Kakuma R. Energy and protein intake in pregnancy (Review). *Cochrane Database of Systemic Reviews* 2003(4):CD000032.
113. WHO. Balanced energy and protein supplementation during pregnancy 2017 [cited 2018 27 May]. Available from: http://www.who.int/elena/titles/energy_protein_pregnancy/en/.
114. Butte NF, King JC. Energy requirements during pregnancy and lactation. *Public Health Nutrition* 2005;8(7a)
115. Walker SP. Nutritional issues for women in developing countries. *Proceedings of the Nutrition Society* 1997;56:345-56.
116. Mridha MK, Matias SL, Chaparro CM, et al. Lipid-based nutrient supplements for pregnant women reduce newborn stunting in a cluster-randomized controlled effectiveness trial in Bangladesh. *American Society for Nutrition* 2016;103:236-49.
117. Adu-Afarwuah S, Lartey A, Okronipa H, et al. Lipid-based nutrient supplement increases the birth size of infants of primiparous women in Ghana. *American Journal of Clinical Nutrition* 2015;101:835–46.
118. Adu-Afarwuah S, Lartey A, Okronipa H, et al. Maternal Supplementation with Small-Quantity Lipid-Based Nutrient Supplements Compared with Multiple Micronutrients, but Not with Iron and Folic Acid, Reduces the Prevalence of Low Gestational Weight Gain in Semi-Urban Ghana: A Randomized Controlled Trial. *The Journal of Nutrition* 2017;147:697–705.
119. Ashorn P, Alho L, Ashorn U, et al. The impact of lipid-based nutrient supplement provision to pregnant women on newborn size in rural Malawi: a randomized controlled trial. *American Journal of Clinical Nutrition* 2015;101:387–97.
120. Johnson W, Darboe MK, Sosseh F, et al. Association of prenatal lipid-based nutritional supplementation with fetal growth in rural Gambia. *Maternal & child nutrition* 2016;13:e12367. doi: 10.1111/mcn.12367
121. WHO. Daily iron and folic acid supplementation during pregnancy 2017 [Available from: http://www.who.int/elena/titles/daily_iron_pregnancy/en/ accessed 29 May 2018.

122. Palma S, Perez-Iglesias R, Prieto D, et al. Iron but not folic acid supplementation reduces the risk of low birthweight in pregnant women without anaemia: a case–control study. *J Epidemiol Community Health* 2008;62:120–24. doi: 10.1136/jech.2006.052985
123. Cogswell ME, Parvanta I, Ickes L, et al. Iron supplementation during pregnancy, anemia, and birth weight: a randomized controlled trial. *American Journal of Clinical Nutrition* 2003;78(773–81)
124. Peña-Rosas J, De-Regil L, Garcia-Casal M, et al. Daily oral iron supplementation during pregnancy. *Cochrane Database of Systematic Reviews* 2015(7):CD004736.
125. Haider BA, Bhutta ZA. Multiple-micronutrient supplementation for women during pregnancy. *Cochrane Database of Systematic Reviews* 2017(4):CD004905. doi: 10.1002/14651858.CD004905.pub5
126. Osrin D, Vaidya A, Shrestha Y, et al. Effects of antenatal multiple micronutrient supplementation on birthweight and gestational duration in Nepal: double-blind, randomised controlled trial. *Lancet* 2005;365:955–62.
127. Fall CHD, Fisher DJ, Osmond C, et al. Multiple micronutrient supplementation during pregnancy in low-income countries: A meta-analysis of effects on birth size and length of gestation. *Food and Nutrition Bulletin* 2009;30(4 Suppl):S533–S46.
128. WHO. Multiple micronutrient supplementation during pregnancy 2017 [Available from: http://www.who.int/elena/titles/micronutrients_pregnancy/en/ accessed 29 May 2018.
129. Hodnett E, Fredericks S, Weston J. Support during pregnancy for women at increased risk of low birthweight babies (Review). *The Cochrane Library* 2010(6)
130. Lu MC, Tache V, Alexander GR, et al. Preventing low birth weight: is prenatal care the answer? *Journal of Psychosomatic Research* 1995;39(5):563–95.
131. Namazzi G, Okuga M, Tetui M, et al. Working with community health workers toimprove maternal and newborn health outcomes: implementation and scale-up lessons from eastern Uganda. *Global health action* 2017;4(sup4):1345495.
132. Hodnett ED, Fredericks S, Weston J. Support during pregnancy for women at increased risk of low birthweight babies. *Cochrane Database of Systematic Reviews* 2010(6):CD000198. doi: 10.1002/14651858.CD000198.pub2.
133. Paarlberg KM, Vingerhoets AJM, Passchier TJ, et al. Psychosocial Factors and Pregnancy Outcome: A Review With Emphasis on Methodological Issues. *Journal of Psychosomatic Research* 1995;39(5):563-95.
134. Lee AC, Kozuki N, Cousens S, et al. Estimates of burden and consequences of infants born small for gestational age in low and middle income countries with INTERGROWTH-21st standard: analysis of CHERG datasets. *BMJ* 2017;358(j3677)
135. National Institute of Population Research and Training (NIPORT), Mitra and Associates, ICF International. Bangladesh Demographic and Health Survey 2014. Dhaka, Bangladesh, and Rockville, Maryland, USA: NIPORT, Mitra and Associates, and ICF International, 2016.
136. Pelletier D, Shekar M, Du L, et al. The Bangladesh Integrated Nutrition Project. Effectiveness and lessons. Washington, DC: World Bank, 2005.

137. Victora CG, Barros FC, Assunção MC, et al. Scaling up maternal nutrition programs to improve birth outcomes: A review of implementation issues. *Food and Nutrition Bulletin* 2012;33(2)
138. The World Bank. World Development Indicators database 2018 [cited 2018 1 June]. Available from: http://databank.worldbank.org/data/views/reports/reportwidget.aspx?Report_Name=CountryProfile&Id=b450fd57&tbar=y&dd=y&inf=n&zm=n&country=BGD.
139. Bangladesh Bereau of Statistics (BBS). Statistical Pocketbook Bangladesh 2015: Bangladesh Bureau of Statistics, Ministry of Planning 2016.
140. Bangladesh National Portal. bangladesh.gov.bd [cited 2018 1 June]. Available from: https://bangladesh.gov.bd/site/page/fc63120c-63e9-406f-904a-48e399ca0f79/District Portals.
141. Bangladesh Bereau of Statistics (BBS). Report on Bangladesh Sample Vital Statistics 2016. Ministry of Planning, 2017.
142. Islam A. Population Momentum In Bangladesh: Centre for Policy Dialogue (CPD) 2000.
143. The World Bank. The World Bank Data 2018 [Available from: https://data.worldbank.org/indicator/SP.RUR.TOTL.ZS accessed 1 June 2018.
144. The World Bank. Leveraging Urbanization in Bangladesh 2015 [Available from: http://www.worldbank.org/en/country/bangladesh/brief/leveraging-urbanization-bangladesh accessed 1 June 2018.
145. The World Bank. The World Bank In Bangladesh: Overview 2018 [Available from: http://www.worldbank.org/en/country/bangladesh/overview accessed 31 May 2018.
146. Canosa CA. Intrauterine Growth Retardation in India and Bangladesh. *Intrauterine Growth Retardation* 1989;18
147. Dhar B, Mowlah G, Nahar S, et al. Birth-weight status of newborns and its relationship with other anthropometric parameters in a public maternity hospital in Dhaka, Bangladesh. *Journal of Health and Population Nutrition* 2002;20(1):36-41.
148. Christian P, lemm RK, Shamim AA, et al. Effects of vitamin A and b-carotene supplementation on birth size and length of gestation in rural Bangladesh: a cluster-randomized trial. *American Journal of Clinical Nutrition* 2013;97:188–94.
149. Klemm RDW, Merrill RD, Wu L, et al. Low-birthweight rates higher among Bangladeshi neonates measured during active birth surveillance compared to national survey data. *Maternal and Child Nutrition* 2013;11(4):583-94.
150. Arifeen SE, Black RE, Caulfield LE, et al. Infant growth patterns in the slums of Dhaka in relation to birth weight, intrauterine growth retardation, and prematurity. *American Journal of Clinical Nutrition* 2000;72:1010–7.
151. Bangladesh Bureau of Statistics & unicef. National Low Birth Weight Survey of Bangladesh, 2003-2004. Dhaka, 2005.
152. Ahmed T, Roy SK, Alam N, et al. National Nutrition Programme Baseline Survey 2004 Report. Dhaka: ICDDR,B: Centre for Health and Population Research, 2005.
153. Rahman MS, Howlader T, Masud MS, et al. Association of Low-Birth Weight with Malnutrition in Children under Five Years in Bangladesh: Do Mother's Education, Socio- Economic Status, and Birth Interval Matter? *PloS one* 2016;11(6):e0157814. doi: 10.1371/journal.pone.0157814

154. Kamruzzaman M, Rabbani MG, Saw A, et al. Differentials in the prevalence of anemia among non-pregnant, ever-married women in Bangladesh: multilevel logistic regression analysis of data from the 2011 Bangladesh Demographic and Health Survey. *BMC women's health* 2015;15(54) doi: 10.1186/s12905-015-0211-4
155. Salim F, Begum N. Nutritional Status and Knowledge about Nutrition during Pregnancy among Pregnant and Postpartum Women. *Northern International Medical College Journal* 2015;6(2)
156. Ahmed F, Mahmuda I, Sattar A, et al. Anaemia and vitamin A deficiency in poor urban pregnant women of Bangladesh. *Asia Pacific J Clin Nutr* 2003;12(4):460-66.
157. Lindström E, Hossain MB, Lönnerdal B, et al. Prevalence of anemia and micronutrient deficiencies in early pregnancy in rural Bangladesh, the MINIMat trial. *Acta Obstetricia et Gynecologica Scandinavica* 2011;9(1):47-56.
158. USAID. Bangladesh National Anemia Profile: SPRING; [cited 2018 31 May]. Available from: https://www.spring-nutrition.org/sites/default/files/publications/anemia-profiles/spring_nap_bangladesh.pdf.
159. Ahmed F. Anaemia in Bangladesh: a review of prevalence and aetiology. *Public Health Nutrition* 2000;3(4):385-93.
160. Hossain B, Sarwar T, Reja S, et al. Nutritional Status of Pregnant Women in Selected Rural and Urban Area of Bangladesh. *Journal of Nutrition and Food Science* 2013;3:219. doi: 10.4172/2155-9600.1000219
161. Islam MZ, Akhtaruzzaman M, Lamberg-Allardt C. Nutritional status of women in Bangladesh: comparison of energy intake and nutritional status of a low income rural group with a high income urban group. *Asia Pacific Journal of Clinical Nutrition* 2004;13(1):61-68.
162. Nahar S, Mascie-Taylor N, Begum HA. Impact of targeted food supplementation on pregnancy weight gain and birth weight in rural Bangladesh: an assessment of the Bangladesh Integrated Nutrition Program (BINP). *Public Health Nutrition:* 2008;12(8):1205–12.
163. Alam DS, Raaij van JMA, Hautvast JGAJ, et al. Energy stress during pregnancy and lactation: Consequences for maternal nutrition in rural Bangladesh. *European Journal of Clinical Nutrition* 2003;57(1):151-6.
164. Nahar Q, Choudhury S, Faruque MO, et al. Desirable Dietary Pattern for Bangladesh: National Food Policy Capacity Strengthening Programme, 2013.
165. Shamim AA, Mashreky SR, Ferdous T, et al. Pregnant Women Diet Quality and Its Sociodemographic Determinants in Southwestern Bangladesh. *Food and Nutrition Bulletin* 2016;37(1):14-26.
166. Piasecki AM. Maternal Nutrition Practices and Perceptions in Bihar, India. Emory University, 2013.
167. Alemayehu MS, Tesema EM. Dietary Practice and Associated Factors among Pregnant Women in Gondar Town North West, Ethiopia, 2014. *International Journal of Nutrition and Food Sciences* 2015;4(6):707-12. doi: 10.11648/j.ijnfs.20150406.27
168. Ogechi AC, Hamdalat OO. Factors Influencing the Nutritional Practice of Pregnant Women Living in a Semi-Urban Region of Ogun State, Nigeria. *Saudi Journal of Medicine* 2017;2(5):114-20. doi: 10.21276/sjm.2017.2.5.1

169. Shannon K, Mahmud Z, Azim A, et al. The Social and Environmental Factors Underlying Maternal Malnutrition in Rural Bangladesh: Implications for Reproductive Health and Nutrition Programs. *Health Care for Women International* 2008;29:826–40.
170. Nguyen PH, Kim SS, Sanghvi T, et al. Integrating Nutrition Interventions into an Existing Maternal, Neonatal, and Child Health Program Increased Maternal Dietary Diversity, Micronutrient Intake, and Exclusive Breastfeeding Practices in Bangladesh: Results of a Cluster-Randomized Program Evaluation. *The Journal of Nutrition* 2017 doi: 10.3945/jn.117.257303.
171. Nguyen PH, Sanghvi T, Kim SS, et al. Factors influencing maternal nutrition practices in a large scale maternal, newborn and child health program in Bangladesh. *PloS one* 2017;12(7):e0179873. doi: 10.1371/journal.pone.0179873
172. Wycliffe K. Social Factors Influencing Nutrition Status of Expectant Women Admitted At Pumwani Maternity Hospital, Nairobi, Kenya. *International Journal of Science and Research (IJSR)* 2013;4(10):533-35.
173. Zerfu TA, Umeta M, Baye K. Dietary habits, food taboos, and perceptions towards weight gain during pregnancy in Arsi, rural central Ethiopia: a qualitative cross-sectional study. *Journal of Health, Population and Nutrition* 2016;35(22) doi: 10.1186/s41043-016-0059-8
174. Skinner A-L. Pregnancy outcome in South Asian women: Factors affecting diet and nutrition, 2012.
175. Haddad L, Peña C, Nishida C, et al. Food Security and Nutrition Implications of Intrahousehold Bias: A Review of Literature. Washington DC: Food Consumption and Nutrition Division 1996.
176. Haddad L. Women's status: Levels, determinants, consequences for malnutrition, interventions and policy. 1999.
177. Gibbs C, Wendt A, Peters S, et al. The impact of early age at first childbirth on maternal and infant health. *Paediatrics Perinatal Epidemiology* 2012;26(Suppl 1)
178. Yu SH, Mason J, Crum J, et al. Differential effects of young maternal age on child growth. *Global health action* 2016;9(31171)
179. IMF. Bangladesh: Poverty Reduction Strategy Paper. Washington, D.C.: International Monetary Fund, 2005.
180. Habiba U, Abedin MA, Hassan AWR, et al. Food Security and Risk Reduction in Bangladesh. Tokyo, Japan: Springer 2015.
181. Chen Y, Lu C. A Comparative Analysis on Food Security in Bangladesh, India and Myanmar. *Sustainability* 2018;10(405) doi: 10.3390/su10020405
182. Akter S, Basher SA. The impacts of food price and income shocks on household food security and economic well-being: Evidence from rural Bangladesh. *Global Environmental Change* 2014;25:150–62. doi: 10.1016/j.gloenvcha.2014.02.003
183. Faridi R, Wadood SN. An Econometric Assessment of Household Food Security in Bangladesh. *The Bangladesh Development Studies* 2010;XXXIII(3)
184. Hillbruner C, Egan R. Seasonality, household food security, and nutritional status in Dinajpur, Bangladesh. *Food and Nutrition Bulletin* 2008;29(3):221-31.
185. Zug S. Monga - Seasonal Food Insecurity in Bangladesh - Bringing the Information Together. *Journal of Social Studies* 2006;111

186. Stevens B, Watt K, Brimbecombe J, et al. The role of seasonality on the diet and household food security of pregnant women living in rural Bangladesh: a cross-sectional study. *Public Health Nutrition*;20(1):121–29.
187. Harris-Fry H, Azad K, Kuddus A, et al. Socio-economic determinants of household food security and women's dietary diversity in rural Bangladesh: a cross-sectional study. *Journal of Health, Population and Nutrition* 2015;33(2)
188. USAID. Bangladesh Nutrition Profile 2014 [cited 2018 2 June]. Available from: https://www.fantaproject.org/sites/default/files/download/Bangladesh-Nutrition-Profile-Mar2014.pdf.
189. Scaling Up Nutrition. Bangladesh, 2017.
190. USAID. Bangladesh: Nutrition Profile 2014 [cited 2018 2 June]. Available from: https://www.usaid.gov/sites/default/files/documents/1864/USAID-Bangladesh_NCP.pdf.
191. Hussain AMZ, Talukder M, Ahmed T. Nutrition Background Paper to inform the preparation of the 7th Five Year Plan, 2015.

CHAPTER 3

PAPER 1

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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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

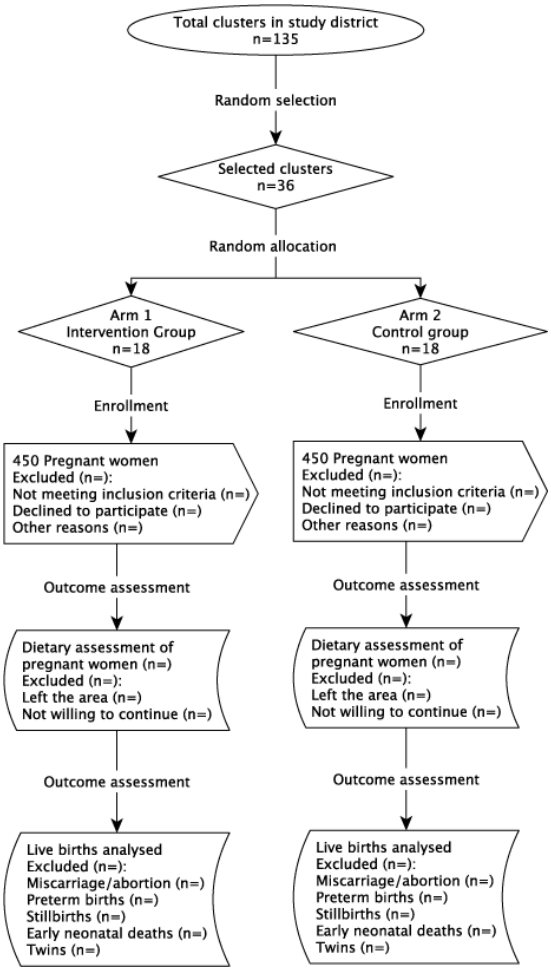

Figure 1 Study design

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.

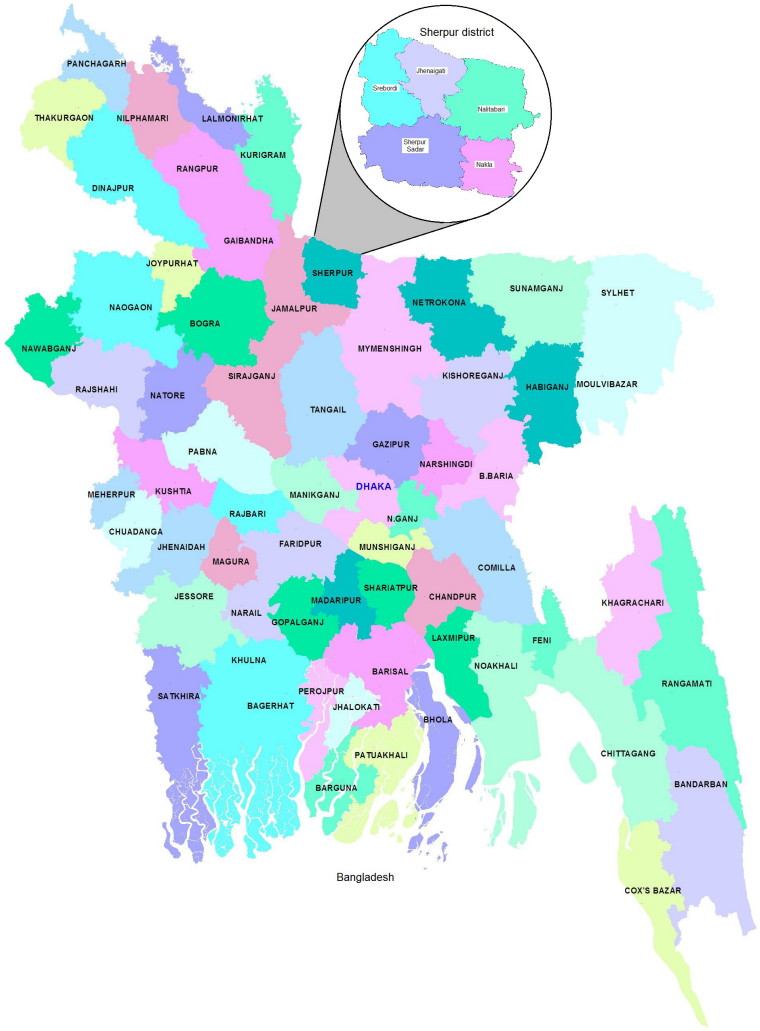

Figure 2 Study site

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 *SKs*, are aware of the intervention. However, both the participants and the *SKs* 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, *SKs* 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 chart (figure 4) in the local language will be provided to all women, who are mostly illiterate or semi-literate.

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

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. *SKs* 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 *SKs* 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

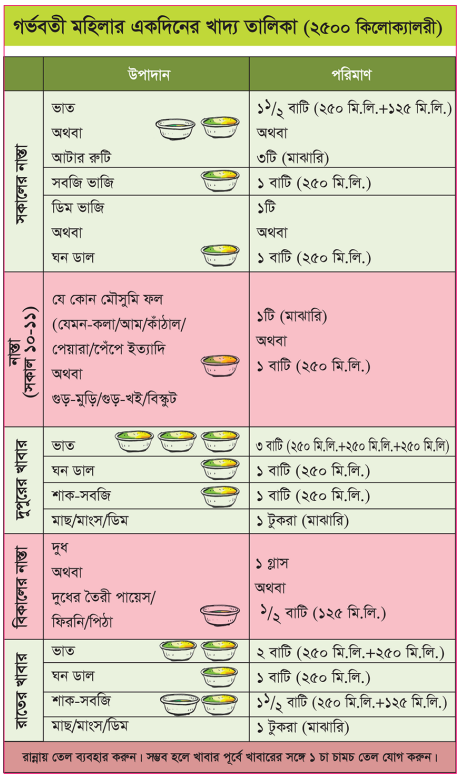

Figure 3 Five-meal menu for pregnant woman (*Bengali*).

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 *SKs* 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 *SKs* 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. *SKs* 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. *SKs* 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

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. *SK*s 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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Contributors MC conceived the overall study and wrote the first draft of the protocol and this manuscript and CRG critically reviewed it. MJD provided critical input regarding study design, sample size calculation, and outcome evaluation and statistical analysis plan. AA provided crucial input on formative research and process evaluation design, and contributed to addressing the reviewers' comments and revision of the paper. MC and CRG obtained funding for the intervention. All authors critically reviewed and approved the final version of the manuscript and agree to be accountable for all investigations necessary to resolve questions related to accuracy or integrity of all or any part of the work.

Competing interests None declared.

Ethics approval James P Grant School of Public Health, BRAC University Ethical Review Committee.

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES

1. United Nations Children's Fund and World Health Organization. *Low birthweight: country, regional and global estimates*. New York: UNICEF, 2004.
2. Black RE, Allen LH, Bhutta ZA, *et al*. Maternal and child undernutrition: global and regional exposures and health consequences. *Lancet* 2008;371:243–60.
3. Gupta ND, Deding M, Lausten M. The effect of low birthweight on height, weight and behavioral outcomes in the medium-run. *Econ Hum Biol* 2013;11:42–55.
4. Victora CG, Adair L, Fall C, *et al*. Maternal and child undernutrition: consequences for adult health and human capital. *Lancet* 2008;371:340–57.
5. Goddeeris JH, Saigal S, Boyle MH, *et al*. Economic outcomes in young adulthood for extremely low birthweight survivors. *Pediatrics* 2010;126:e1102–e1108.
6. Triunfo S, Lanzone A. Impact of maternal under nutrition on obstetric outcomes. *J Endocrinol Invest* 2015;38:31–8.
7. Smith CA . undefined Effects ofmaternal under nutrition upon the newborn infant in Holland (1944-1945) .*The Journal of pediatrics* 1947;30:229–43.
8. AkitakeY, KatsuragiS, HosokawaM *et al*, Moderate maternal food restriction in mice impairs physical growth, behavior, and neurodevelopment of offspring*Nutrition Research* 35 1 76 87 2015;:–.
9. KramerMS . Determinants of low birth weight: methodological assessment and meta-analysis *Bulletin of the World Health Organization* 65 5 663 737.1987
10. National Institute of Population Research and Training (NIPORT), Mitra and Associates, and ICF International. 2013. Bangladesh Demographic and Health Survey 2011. Dhaka, Bangladesh and Calverton, Maryland, USA: NIPORT, Mitra and Associates, and ICF International.
11. Alam DS, Van Raaij JM, Hautvast JG, *et al*. Energy stress during pregnancy and lactation: consequences for maternal nutrition in rural Bangladesh. *Eur J Clin Nutr* 2003;57:151–6.
12. National Institute of Population Research and Training (NIPORT), Mitra and Associates, ICF International. *Bangladesh Demographic and Health Survey 2014*. Dhaka, Bangladesh and Rockville, Maryland, USA: NIPORT, Mitra and Associates and ICF International, 2016.
13. Islam MZ, Akhtaruzzaman M, Lamberg-Allardt C. Nutritional status of women in Bangladesh: comparison of energy intake and nutritional status of a low income rural group with a high income urban group. *Asia Pac J Clin Nutr* 2004;13:61–8.
14. Alam DS, Van Raaij JM, Hautvast JG, *et al*. Energy stress during pregnancy and lactation: consequences for maternal nutrition in rural Bangladesh. *Eur J Clin Nutr* 2003;57:151–6.
15. FAO and FHI 360. *Minimum dietary diversity for women: a guide for measurement*. Rome: FAO, 2016.
16. Arimond M, Torheim LE, Wiesmann D. *Dietary diversity as a measure of the micronutrient adequacy of women's diets: results from rural Bangladesh site*. Washington, DC: Food and Nutrition Technical Assistance II Project (FANTA-2), FHI 360, 2009.
17. Gluckman PD, Sizonenko SV, Bassett NS. The transition from fetus to neonate--an endocrine perspective. *Acta Paediatr Suppl* 1999;88:5–11.
18. Tabrizi FM, Saraswathi G. Maternal nutrient intake and maternal serum micronutrients and their relation to birthweight: a longitudinal study. *Int J Collab Res Intern Med Publ Health* 2011;3:617–32.
19. Widga AC, Lewis NM. Defined, in-home, prenatal nutrition intervention for low-income women. *J Am Diet Assoc* 1999;99:1058–62.
20. Ota E, Hori H, Mori R, *et al*; *Antenatal dietary education and supplementation to increase energy and protein intake (review)*. John Wiley & Sons: Cochrane Database of Systematic Reviews, 2015.
21. Victora CG, Barros FC, Assunção MC, *et al*. Scaling up maternal nutrition programs to improve birth outcomes: a review of implementation issues. *Food Nutr Bull* 2012;33(2 Suppl):S6–S26.
22. *Monitoring the Situation of Children and Women Project. National low birthweight survey of Bangladesh, 2003-2004*. Dhaka: Bangladesh Bureau of Statistics, 2005.
23. Klemm RD, Merrill RD, Wu L, *et al*. Low-birthweight rates higher among Bangladeshi neonates measured during active birth surveillance compared to national survey data. *Matern Child Nutr* 2015;11:583–94.
24. West KP, Shamim AA, Mehra S, *et al*. Effect of maternal multiple micronutrient vs iron-folic acid supplementation on infant mortality and adverse birth outcomes in rural Bangladesh: the JiVitA-3 randomized trial. *JAMA* 2014;312:2649–58.
25. United Nations General Assembly. 2014. Report of the Open Working Group of the General Assembly on Sustainable Development Goals.
26. *ProPAN: Process for the Promotion of Child Feeding*. Washington, DC: PAHO, 2013.
27. *District Statistics 2011: Sherpur*. Bangladesh Bureau of Statistics (BBS) Statistics andInformatics Division (SID), Ministry of Planning, Government of the People's Republic of Bangladesh, 2013.
28. *Population and Housing Census 2011*. Socio-Economic and Demographic Report: Bangladesh Bureau of Statistics (BBS) Statistics and Informatics Division (SID), Ministry of Planning, 2012.
29. Nahar Q, Choudhury S, Faruque MO, *et al*. *Desirable Dietary Pattern for Bangladesh*. National Food Policy Capacity Strengthening Programme, 2013.
30. Shaheen N, Rahim ATM, Mohiduzzaman M, *et al*. *Food Composition Table for Bangladesh*. Institute of Nutrition and Food Science, Centre for Advanced Research in Sciences, University of Dhaka, 2013.
31. Hayes RJ, Moulton LH. *Cluster randomised trials*. Boca Raton: CRC Press, 2009.
32. Zeng L, Dibley MJ, Cheng Y, *et al*. Impact of micronutrient supplementation during pregnancy on birthweight, duration of gestation, and perinatal mortality in rural western China: double blind cluster randomised controlled trial. *BMJ* 2008;337:a2001–15.
33. Frenkel H, Harvey I, Newcombe RG. Improving oral health in institutionalised elderly people by educating caregivers: a

randomised controlled trial. *Community Dent Oral Epidemiol* 2001;29:289–97.
34 Beiguelman B, Colletto GMDD, Franchi-Pinto C, *et al*. Santa Casa de Misericórdia de São Paulo. Birthweight of twins: 1. The fetal growth patterns of twins and singletons. *Genet Mol Biol* 1998;21:151–4.
35 Lee J. Long-term effects of low birthweight. *Agricultural Res* 1999;47:10.
36 Hallgren KA. Computing inter-rater reliability for observational data: an overview and tutorial. *Tutor Quant Methods Psychol* 2012;8:23–34.
37 Akter SM, Roy SK, Thakur SK, *et al*. Effects of third trimester counseling on pregnancy weight gain, birthweight, and breastfeeding among urban poor women in Bangladesh. *Food Nutr Bull* 2012;33:194–201.
38 Contento IR. Nutrition education: linking research, theory, and practice. *Asia Pac J Clin Nutr* 2008;17 Suppl 1:176–9.
39 Fishbein M, Yzer MC. Using Theory to Design Effective Health Behavior Interventions. *Communication Theory*. 2003;13:164–83.
40 Gill J, O'May F. Practical demonstration of personal daily consumption limits: a useful intervention tool to promote responsible drinking among UK adults? *Alcohol Alcohol* 2007;42:436–41.
41 International Food Policy Research Institute. Rapid improvements in infant and young child feeding practices resulting from a large-scale program: Alive & Thrive's approach and results in Bangladesh. 2015.
42 Shamim AA, Tegenfeldt K, Aradhya K, *et al*. *Designing a food plate for dietary counselling of pregnant women in Bangladesh*. ENN: SHIKHA project, 2016.
43 National Institute of Population Research and Training (NIPORT), Mitra and Associates, and ICF International. *Bangladesh Demographic and Health Survey 2011*. Dhaka, Bangladesh and Calverton, Maryland, USA: NIPORT, Mitra and Associates, and ICF International, 2013.1999;88:5–11;88:5–11.

CHAPTER 4

PAPER 2

The impact of an antenatal balanced plate nutrition education intervention on infant birthweight: a cluster randomised controlled trial in rural Bangladesh

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Summary

Background: Low birthweight (LBW) is strongly associated with neonatal morbidity and mortality. Evidence that nutrition education improves diet during pregnancy and reduces LBW is still weak. We investigated the effect of a nutrition education intervention for pregnant women in improving birthweight of infants in a low-income population.

Methods: We conducted a parallel, two-arm, cluster-randomised controlled trial in five sub districts of Sherpur district of Bangladesh between July 2015 to June 2016, in which we randomly assigned 36 clusters in equal ratio to receive the intervention or standard care. The participants in the intervention group received balanced plate nutrition education and practical demonstration starting from their 1st trimester until delivery. Eligible participants were pregnant women with ≤12 weeks gestation. The primary outcome was mean birthweight and incidence of LBW. We registered the trial with the Australian New Zealand Clinical Trials Registry, number ACTRN12616000080426.

Findings: We included all assigned participants in the intervention (445) and the comparison (448) groups in the analyses. The mean birthweight increased by 125.3 g (95% confidence interval (CI) 5·7, 244·9; p=0·04) and the risk of LBW was reduced by 54% (relative risk (RR) 0·46; 95% CI 0·28, 0·78; p=0·004) in the intervention compared to the comparison group. In post hoc analyses we observed a greater improvement in birthweight and reduction in LBW amongst adolescent mothers (mean difference 297·3 g; 95% CI 85·0, 509·6; p=0·006 and RR 0·31; 95% CI 0·12, 0·77; p=0·01).

Interpretation: A community-based balanced plate nutrition education was effective in increasing birthweight and reducing the incidence of LBW in a rural population of Bangladesh.

Funding: James P. Grant School of Public Health; Bangladesh, and Sydney Medical School; Australia.

Introduction

Birthweight is an extremely powerful predictor of an individual infant's survival.[13] Birthweight less than 2500 g, defined as low birthweight (LBW), is a major determinant of infant mortality, childhood growth and development, and adulthood wellbeing.[13 196] In general, the lower the weight, the higher the infant's risk of mortality.[14] An estimated 606,500 neonatal deaths occur annually in low and middle-income countries due to small for gestational age, a form of LBW, which accounts for 22% of all neonatal deaths.[137] South Asia has the largest burden, with the highest prevalence of LBW globally (34%).[137] Bangladesh is ranked fourth in the global burden of LBW.[7]

LBW is strongly associated with under-nutrition in mothers. According to one estimate, about half of all intrauterine growth restriction (IUGR) in developing countries is attributable to low maternal weight and stature at conception and low weight gain during pregnancy.[10] The development of the fetus in utero depends on the availability and supply of nutrients from the mother, which in turn depends on her nutrient stores and dietary intake.[94] Maternal under-nutrition induces suboptimal placental growth; thereby influencing the rate of nutrient delivery through the placenta, and altering fetal hormones contributing to restricted fetal development.[53] Consistent with this mechanism is the high prevalence of LBW in rural Bangladeshi women who suffer from a chronic shortfall of food energy throughout pregnancy.[165] In South Asia, intra-household food distribution is inequitable between women and men with lower energy share, consumption of animal source food and dietary adequacy in women, which persists regardless of pregnancy.[197]

Three meta-analyses have assessed the impact of nutrition interventions on birthweight. The first one conducted in 1993 by Boyd and Windsor found that women, who received nutrition education, significantly increased consumption of protein and certain vitamins, and the birthweight of their infants by 300 g. However, the studies included in this meta-analysis lacked statistical power or did not report estimates of effect size.[198] The second meta-analysis conducted by Girard and Olude in 2012

found a 105 g (95% confidence interval (CI) 18, 193) increase in mean birthweight with nutrition education and counselling in pregnancy. When stratified by study site, the effect appeared more substantial but failed to reach significance in low and middle-income countries (152 g; 95% CI 81, 384), likely due to the small number of studies.[101] The third meta-analysis conducted by Gresham et al. in 2014 reported that dietary counselling interventions significantly increased birthweight in three of the studies (149 g; p=0·039), but two had a small sample size, and another had methodological limitations.[199]

Research in context

Evidence before this study

We searched PubMed, the Cochrane Central Register of Controlled trials and hand-searched references from published articles up to 31 December 2017 to identify randomized controlled trials assessing prenatal nutrition education interventions for birthweight improvement. The search terms were 'birthweight', 'low birthweight', 'LBW', 'birth outcome', 'nutrition education', 'nutrition counseling', 'nutrition intervention', 'dietary education', 'prenatal', 'antenatal', 'pregnancy', and 'pregnant woman'. We found 15 completed and three ongoing trials investigating the impact of antenatal nutrition education on birthweight. Most of these studies were from Europe, North America, and China; only six studies were from low and middle-income countries (LMIC), two from Bangladesh, one each from Nepal, Burkina Faso and Malawi. Of the completed trials, four had been delivered at the community level, while the rest were either healthcare centre based and one used mobile messages. None of the interventions in studies from LMICs delivered balanced diet education or used practical demonstrations. Three studies (two in USA and one in Greece), claimed to use a balanced diet model, but did not elaborate on portion size or the combination of food groups. The majority of the studies were focused on weight gain, increased dietary intake and consumption of some specific nutritious foods. Interventions were mostly delivered with nurse-midwives or nutritionists or trained counselors. Evidence is conflicting on the effects of these interventions on birthweight; eight of them were positive, one negative and three found no impact.

Added value of the study

This study is the first to assess the effectiveness of an antenatal nutrition education with practical demonstration delivered by community health workers to improve birthweight and reduce LBW in a LMIC. We demonstrated that the balanced plate intervention beginning in the first trimester of pregnancy can increase mean birthweight and reduce the prevalence of LBW infants in the intervention group compared to the comparison group.

Implications of all the available evidence

The balanced plate intervention delivered through community health workers to improve birthweight is a pragmatic approach. This is particularly important in the context of the double burden of malnutrition, and the shortage of adequate human health resources, as this intervention is scalable at a national level through the existing health system. This strategy is also replicable in other LMICs that have a similar strong community health work force.

Despite three reviews, the evidence for nutrition education to improve diet during pregnancy, for multiple maternal and neonatal health indicators including birthweight, is still relatively weak. Most of the evidence comes from quasi-experimental studies or RCTs with design or analysis limitations.[101] Moreover, most studies were from high-income countries where pregnant women received counselling from professional dieticians or nutritionists.[199] There is a clear need to explore the effect of nutrition specific and nutrition-sensitive interventions further to achieve the global goal of a 30% reduction in the rate of LBW by 2025.[100]

Therefore, our study aimed to investigate the impact of antenatal nutrition education and practical demonstration of a balanced diet on birthweight of infants in a low-income population.

The trial is registered with Australian New Zealand Clinical Trials Registry (ANZCTR) (number ACTRN12616000080426).

Methods

Study design and participants

The balanced plate nutrition intervention trial was a two-arm, parallel, community-based, cluster randomised controlled trial (cRCT) conducted in rural Bangladesh. It was designed to establish the effectiveness of community-based nutrition education with a practical demonstration on how to consume a balanced diet in pregnancy to improve infants' birth weight and reduce the incidence of LBW. The James P. Grant School of Public Health; BRAC University Ethical Review Committee; Dhaka; Bangladesh approved the study protocol. Participants gave verbal (non-literate) or written informed consent.

We have previously described the study design and the sampling frame.[200] In brief, we conducted the study in the northern rural district of Sherpur, which scores poorly on the human development index, and has a higher percentage of the population belonging to the lowest economic quintile (37·1%) compared to the national average (21·7%).[201] The child survival status, including neonatal mortality (46 per 1000 live

births) and under-five mortality rates (73 per 1000 live births) are also higher compared to the national average (32 and 56/1000 live births respectively).[202] Administratively, Sherpur is divided into five sub-districts: Jhenaigati (population 160,452), Nakla (189,685), Nalitabari (251,361), Sherpur Sadar (497,179) and Sreebardi (259,648).

Sources of maternal and child health services in Sherpur are public and private hospitals and other formal and informal practitioners. Pregnant women, self-reporting to a hospital or formal practitioner (such as a doctor, nurse or Family Welfare Visitor) for antenatal care receive nutrition education as part of the routine antenatal counselling. BRAC (a national NGO; formerly known as Bangladesh Rural Advancement Committee) implements a community-based Maternal, Neonatal and Child Health (MNCH) program in rural areas, characterised by a prospective pregnancy surveillance system and basic antenatal care (ANC) led by CHWs, who are known as *Shasthya Kormi*. One *Shasthya Kormi* serves an area of ~10,000 people along with ten health volunteers (known as *Shasthya Shebika*). The *Shasthya Kormi* are local village women who have a basic qualification of 10-years schooling; received training on health, nutrition and sanitation issues for six weeks followed by bi-monthly refresher training. In the study, a cluster was the catchment area of one *Shasthya Kormi,* which provided logistical convenience and minimised intervention spill over into the control group. Any *Shasthya Kormi* having had at least six months of work experience in BRAC's MNCH program was considered eligible. Eligible individual participants were pregnant women aged 15-49 years, gestational age 12 weeks or less, permanently residing in the study area, not expecting to move out (to parents' residence) of the area until birth, and who consented to participate in the study. We excluded pregnant women with diagnosed chronic diseases. We conducted the trial in collaboration with BRAC MNCH program.

Randomisation and masking

Before enrolment, we assigned each *Shasthya Kormi* with a random identification number, allocated using a program in Excel (RANDBETWEEN function). The random groups were denoted as A/B, with 18 clusters in each group, and stratified by sub-districts. All pregnant women served by the same *Shasthya Kormi* received either the intervention or standard care as per the allocation of *Shasthya Kormi* to a

treatment group. The *Shasthya Kormi* used the already established pregnancy identification system in which the *Shasthya Shebika* using monthly menstrual surveillance to identify new pregnancies. Women with delayed menstrual periods for six weeks or more underwent a urine test for pregnancy. A *Shasthya Kormi* visited each confirmed pregnant woman, screened her for eligibility and enrolled her after written (literate) or verbal (not literate) consent. Recruitment took place between August and December 2016.

Due to the nature of the intervention, we could not mask families or the research team to the group allocation; however, we blinded those assessing primary and secondary outcomes to the study hypothesis. We also used an objective outcome (birth weight), which was less prone to ascertainment bias. The intervention was assigned randomly at the cluster level, and we assessed the outcomes at the individual level.

Procedures

After randomisation, the *Shasthya Kormi* from the intervention clusters received two days of training on the balanced plate nutrition education intervention, including lectures on balanced nutrition and counselling techniques. They also had opportunities to practice their nutrition counselling skills in the community under the supervision of the trainers. The *Shasthya Kormi* in both clusters received one-day training on consent taking and data collection. The *Shasthya Kormi* visited all enrolled pregnant women once a month to provide antenatal counselling that included standard nutrition advice. In the intervention clusters, the balanced plate intervention replaced the standard nutrition advice. A culturally appropriate daily meal menu and a pictorial food chart were produced based on the currently recommended diet for Bangladeshi pregnant women.[168] The menu contained foods from all seven-food groups (cereal, lentil, animal protein, vegetables, fruits, milk and oil) giving a daily 2500 kcal energy, and included essential micro and macronutrients. The balanced plate that we used for the demonstration was a combination of foods in appropriate portion size, essential to meet the requirements of a pregnant woman. Before the trial commenced, we conducted focus groups with pregnant women and family decision makers to identify locally preferred foods and any local dietary restrictions in pregnancy. Before implementation, the menu was pilot tested in two sites to assess community acceptability and the feasibility to incorporate it into the *Shasthya Kormi'* usual ANC

services.

The intervention was delivered individually through face-to-face contact. *Shasthya Kormi* visited women during their leisure time, usually between breakfast and lunchtime, and selected the best place in their home, reasonably free from outside interruptions and convenient, to demonstrate the meal preparation. They welcomed other family members to all parts of the sessions.

In the first part of the session pregnant women received information about a balanced diet and the benefit for maternal and fetal health; in the second part, they learnt how to prepare a meal or "balanced plate" through demonstration. *Shasthya Kormi* demonstrated what a balanced meal or balanced plate looked like on a plate with food using the prescribed menu. Pregnant women shared foods from their kitchen for the demonstration, in some cases neighbours also voluntarily contributed if any essential food was missing. Different combinations of food were tried and displayed on a plate, with appropriate alternatives, for example, meat (as a source of protein), the most expensive food, was replaced by relatively cheaper options such as eggs or the cheapest farm fishes (tilapia, carps and pungas). *Shasthya Kormi* gave more emphasis to food items commonly missed in the regular diet, such as milk, fruits and coloured vegetables. Women were also encouraged to increase the frequency of meals, for example, taking at least three major meals (breakfast, lunch and dinner) and two snacks (morning and evening). A bowl commonly found in most homes (a dish with a capacity of 250 ml) was used to demonstrate the measurement. Family decision makers, such as husbands, mothers, mothers-in-law and other elderly family members were invited to observe the demonstration sessions and to assist the pregnant woman to make a balanced plate.

Delivering the intervention took approximately ~45 minutes, with 10 minutes for individual counselling, 10 minutes for household counselling and 25 minutes for a demonstration which was diminished gradually when women eventually learned how to make the balanced plate. A handout with a pictorial food chart and a written menu were provided to the women in the intervention group to help them recall the messages (see protocol paper for details[200]).

The home visits started at enrolment and continued until birth or pregnancy

termination. ANC from other sources was not discouraged. During the follow-up visits, *Shasthya Kormi* inquired about which messages had been practised and re-emphasised the messages not adhered to after discussing with the women and their families. Husbands were encouraged to re-allocate the family budget to purchase more nutritious food and mothers-in-law were motivated to re-distribute family food to increase the share for their pregnant daughters-in-law.

One field supervisor supervised the 36 *Shasthya Kormi*, who recorded all their field activities with dates in a register. The field supervisor conducted follow-up interviews with 5% of the participants to confirm the visit occurred and measure protocol adherence.

Shasthya Kormi collected background demographic, socio-economic and reproductive data on enrollment from women. The same staff also did birthweight measurements during the first postnatal visit within 72 hours of birth after being notified by the *Shasthya Shebika*. Families notified all births or pregnancy loss (miscarriage, abortion and stillbirth) immediately to the nearby *Shasthya Shebika*.

Pregnant women in the usual care group received the same frequency of home visits as in the intervention group and standard nutrition advice except for the balanced plate demonstration. The standard advice included recommendations to take extra food; consume meat, fish, liver, eggs, milk/milk products, lentils, colourful vegetables, fruits and oil; and to take iron-folic acid (60 mg iron and 400 μg folic acid) and calcium (500 mg) supplements.

Outcomes

The primary outcome was birthweight of the infants, and LBW was defined as birthweight less than 2500 g. All infants born alive and at home were weighed using a 5 kg spring balance Salter scale (with an accuracy of 100 g) by *Shasthya Kormi* in case of home births. The scales were standardised every month during the monthly refresher training meetings. The refresher trainings were scheduled to happen once in every month which were the only opportunity to check the instruments used by Shasthya Kormi. Mothers, who birthed in health facilities, self-reported the birthweight measured at the facility.

Shasthya Kormi recorded any fetal loss during pregnancy, birth outcome, other delivery information, and any neonatal and maternal death during the routine monthly home visits with structured forms. We defined stillbirths as fetuses delivered at 28 weeks' gestation or later with no signs of life and recorded as occurring before the onset of or during labour. We defined neonatal deaths as deaths among live-born infants occurring within 28 days of delivery. MNCH program staff as per usual practice, re-interviewed all women who had a stillbirth or neonatal death to validate the reported information.

Statistical analysis

To estimate the sample size, we assumed a mean birthweight of 2531 g with 415 g standard deviation in the control group based on the findings of a trial in a similar setting in Bangladesh,[203] and an expected 100 g increase in birthweight in the intervention group. We also assumed a β of 0·8, a two-sided α of 0·05, an intra-cluster correlation coefficient (ICC) of 0·03[204] and 36 clusters (based on logistics). The sample size was estimated to be 360 live births in each treatment group with ten live births from each cluster. Accounting for 5% non-response, 10% pregnancy losses and 10% losses to follow-up (unpublished data, based on a large scale community-based trial in rural Bangladesh, ACTRN12612000588897), the total required sample was 900 pregnant women.

The analyses used the intention to treat principle, with two-tailed statistical tests and a P value less than 0·05 taken as significant. We assessed the balance of potential confounders between treatment groups by calculating the means or proportions of each factor within study arm and comparing them with t-tests or χ^2 tests, as appropriate. We summarised the main trial outcomes of birthweight and LBW as means and proportions respectively, within each study arm. We estimated the mean difference in birthweight using linear regression and estimated the relative risk for LBW by binomial regression with log link function. For both outcomes, we included study arm as a covariate in the model. We adjusted for the clustered randomisation using generalised estimating equations (GEE) assuming an exchangeable correlation structure and applying the sandwich estimator to standard errors. Furthermore, we also adjusted for any unbalanced baseline characteristics between the two study

groups, by including the characteristic as a covariate in the models.

We conducted post hoc subgroup analyses for age and education. We divided the participants into adolescents (<20 years) and non-adolescents (≥20 years), and educated (primary, secondary and higher) and non-educated (no schooling) groups. A p-value for interaction (<0·001) was used to assess whether there was a significant effect difference between the study groups for sub-groups, using regression model. We used Stata version 13·1 for all analyses.

Role of the funding source

The funders had no role in study design, participant selection, data collection, and data analyses. The corresponding author had full access to the data in the study and final responsibility for the decision to submit for publication.

Results

We identified 2154 newly pregnant women from August 2015 to February 2016 in the selected clusters. Of these women, 937 did not meet the eligibility criteria (603 had a gestation of >12 weeks, 147 were not permanent residents, and 187 had planned to move out of the study area for childbirth) and 324 declined to participate. We recruited the remaining 893 women from 36 clusters, 445 in 18 intervention and 448 in 18 comparison clusters. Two *Shasthya Kormi* dropped out from the intervention clusters in the middle of the trial, but we replaced them within two months. We lost 65 participants during follow-up, 44 (9·9%) in the intervention and 21 (4·7%) in the comparison group. The plausible reason for a greater number of losses in the intervention arm was due to the dropout of the two intervention *Shasthya Kormi*. There were 42 pregnancy losses (abortion or stillbirth), and six neonatal deaths within 24 hours of birth. Birthweight data were missing for 40 participants, 31 and 9 in intervention and comparison groups respectively (Figure 1).

There were no significant differences between individuals in the intervention and comparison groups regarding background demographic, socioeconomic and reproductive characteristics, except the age and gestational age at enrolment (Table 4).

The mean age (standard deviation (SD)) in the intervention group was 23·1 years (4·7), and in the comparison group, 24·0 years (4·4). Approximately, 21·0% and 16·7% of women were teenagers in the intervention and comparison groups at enrolment. The mean gestational age at enrolment was 10·1 (3·2 SD) and 9·6 (3·2) weeks in the intervention and comparison groups.

We found a statistically significant increase in mean birth weight and a reduction in LBW in the intervention compared with the comparison group (Table 5). The estimated difference in mean birthweight between the groups was 125·3 g (95% CI 5·7, 244·9; p=0·04), adjusted for clustering, age and gestation at enrolment. The estimated relative risk (RR) of LBW was 54% lower in the intervention compared to the comparison group (RR 0·46; 95% CI 0·28, 0·78; p=0·004), adjusted for clustering, age and gestation at enrolment. The estimated ICCs for birthweight and LBW were 0·14 and 0·07 respectively. The results adjusted for clustering, but not adjusted for age and gestation at enrollment were very similar (Appendix 1).

We conducted post hoc subgroup analyses of age, and education (Table 6). We found a statistically significant difference in the treatment effect on birthweight by age group - adolescent vs non-adolescents (p-value for interaction 0·01). The mean birthweight difference between the intervention and comparison groups was greater in the adolescent than the non-adolescent mothers (297·3 g; 95% CI 85·0, 509·6; P = 0·006; vs 90·0 g; 95% CI -23·4, 203·2; p=0·096). The effect of the intervention on reducing LBW was greater among adolescent mothers than non-adolescents (for adolescent mothers RR 0·31; 95% CI 0·12, 0·77; p=0·01 vs for non-adolescent mothers RR 0·52; 95% CI 0·29, 0·95; p=0·033), although this difference was not statistically significant (p-value for interaction 0·22). There was no evidence of modification of the treatment effect by levels of education.

Independent personnel observed 5% of the balanced plate demonstration sessions and checked the boxes for message delivery, use of the visual aids (menu and food chart), demonstration, and problem-solving and counselling. Approximately, 6-7 messages were delivered (out of 8) in 80% of the participants. The time taken for the demonstrations gradually decreased with increasing numbers of visits. Counselling the family members was largely dependent on their availability; husbands were

present in only 15-20% of the sessions, but other family members were present in more than 80% of the home visits.

Discussion

We have demonstrated that community-based, antenatal nutrition education with a practical demonstration that teaches how to eat a balanced diet using food available in the home, can increase infant birthweight and reduce the incidence of LBW in rural Bangladesh. The effect of the intervention was greater in adolescent mothers than in the older women both in increasing birthweight, and decreasing LBW. The findings are important because they provide evidence of a food-based intervention to increase birthweight. The approach is sustainable and can be implemented in a community-based health care system. It also provides a way to directly address gender biased inequitable intra household food distribution.

The response of our nutrition education intervention appears to be greater than that from more other approaches to improving birthweight through micronutrient supplements. A large cluster RCT (22,405 pregnancies) in Bangladesh compared the impact of antenatal multiple micronutrients with iron–folic acid supplementation on birth outcomes, and found a 54 g (95% CI 41, 66) increase in birthweight and a 12% reduction (RR 0.88; 95% CI 0·85, 0·91; p<0·001) in the risk of LBW infants.[203] Another cluster RCT of lipid-based micronutrient supplementation (20 g per day, 118 kcal, containing essential fatty acids, and 22 vitamins and minerals) study showed a 41 g birthweight increment without a significant effect on LBW (RR 0·93; 95% CI 0·84, 1·02).[119] Providing micronutrient supplements, even with additional food energy, is unlikely to address the essential problem of insufficient food intake in pregnancy related to food taboos and inequitable intra-household food distribution. In contrast an observational study evaluating the National Nutrition Program in Bangladesh reported a 118 g increase in birthweight with daily 608 kcal food supplements combined with iron-folic acid sustained for more than 4 months compared to women receiving the supplements for a shorter period of time.[205] Although this evidence is weaker than our trial is does lend support to finding food based solution to this problem.

Despite the earlier evidence of a positive impact of nutrition education on pregnancy outcomes, little attention has been paid to the approach to the delivery of the nutrition education, which is particularly important with rural women with lower levels of literacy and empowerment. These women require dietary counselling which is easy to comprehend and recollect, realistic to practice, and more importantly sanctioned by the community. A review of over 300 studies on nutrition education found that it is more likely to be effective when it focused on behaviour and action rather than knowledge alone, and if it was grounded in theory.[206] According to the Integrated Theoretical Model, "any given behaviour is most likely to occur if one has a strong intention to perform the behaviour if a person has the necessary skills and abilities required to perform the behaviour, and if there are no environmental constraints preventing behavioural performance".[207] Our balanced plate intervention was designed to embrace all three aspects of this approach to impact positively on dietary behaviour. Our study adopted an innovative counselling technique including a practical demonstration of a balanced diet using food from the participants' kitchen and engaging family decision makers. A similar kind of nutrition counselling intervention was found effective in increasing age-specific complementary feeding practices in rural Bangladesh.[208]

In Bangladesh, the main source of nutrition education for pregnant women is ANC. Amidst a huge shortage of human health resources, the time dedicated to nutrition advice is insufficient to offer quality counselling,[209] thus, engaging CHWs in delivering dietary advice is an appropriate approach to complement the health services as suggested by the WHO.[210] In our study, we integrated the balanced plate intervention into the existing ANC package delivered by BRAC through *Shasthya Kormi.* The same staff in a recent intervention demonstrated their successful interpersonal counselling on breastfeeding and complementary feeding.[211] Previously we also found that CHWs can positively influence family decision makers such as mothers-in-law and husbands to help increase pregnant women's iron-folic acid consumption. [212]

The evidence presented from this trial is robust despite some limitations. A key strength of the study is its cluster, randomised controlled trial design with sufficient statistical power to detect the expected changes in birthweight and incidence of LBW.

The unblinded nature of the intervention was counterbalanced by using an objective outcome and blinding the participants and data collectors to the aims and hypotheses. The trial had a very high follow-up rate (93%). The analyses used an intention-to-treat principle and adjusted for unbalanced baseline factors and clustering. Our intervention design, which was informed by well-designed qualitative formative research, was logistically simple and culturally appropriate, therefore, is ready for integration into existing health-care systems in low and middle-income countries, such as Bangladesh, where CHWs are part of the primary health-care system. Key to our success to increasing birthweight was that we conducted the trial within the existing antenatal care framework. The delivery strategy resonates with the recommendations of the Lancet series on Maternal and Child Nutrition to achieve adequate coverage of nutrition-specific interventions by reaching populations in need.[213] However, we acknowledge some limitations. First, the *Shasthya Kormi*, who provided the intervention, also collected birthweight data. Measuring birth weight is a routine task of these staff in both intervention and control clusters and with the *Shasthya Kormi* blinded to the study outcome, we would expect a non-differential bias. Secondly, use of the *Shasthya Kormi* client catchment areas as clusters might have introduced some contamination, with the possibility of exchange of information between the *Shasthya Kormi*. If this had been the case, our results would have moved towards the null. However, we only trained those *Shasthya Kormi* assigned to the intervention arm, and we conducted all refresher training in separate groups. These precautions helped to minimise the risk of contamination. Thirdly, we were not able to measure quantified food intake of the women in the trial and intra-household food distribution, which might have proved evidence about the pathway to the impact we observed.

The results of this study indicate that our balanced plate nutrition education during pregnancy increases birthweight and reduces the incidence of LBW. Our trial offers a pragmatic strategy to confront the problem of LBW in resource-poor settings. We have designed a CHW-led intervention for pregnant women, which is feasible to implement in a context where there is shortage of human health resources. The intervention is simple, easy to implement and scalable through existing public and private community health infrastructure.

Contributors

MC conceived the overall study, developed study design and data collection method, conducted literature search and data analysis, interpreted data, and wrote the first draft of the manuscript. MJD provided critical input regarding study design, sample size calculation, and outcome evaluation and the statistical analysis plan. KA provided practical guidance in formulating the implementation strategy. AA provided crucial input on formative research and process evaluation design. PK provided technical support for data analyses. CRG and MC obtained funds for the intervention. CRG contributed to all drafts and approved the final version for submission. MJD, KA, PK and AA critically reviewed the manuscript and approved the final version for submission. MC, MJD, CRG, PK, KA and AA agreed to be accountable for all investigations necessary to resolve questions related to accuracy or integrity of all or any part of the work.

Declaration of interests

We declare no competing interests.

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References

1. Black RE, Allen LH, Bhutta ZA, et al. Maternal and child undernutrition: global and regional exposures and health consequences. *Lancet* 2008;371:243-60.
2. Cesar G Victora, Linda Adair, Caroline Fall, et al. Maternal and child undernutrition: consequences for adult health and human capital. *Lancet* 2008;371:340-57.
3. Wilcox AJ, Russell IT. Birthweight and Perinatal Mortality: II. On Weight-Specific Mortality. *International journal of epidemiology* 1983;12(3):319-25.
4. Lee AC, Kozuki N, Cousens S, et al. Estimates of burden and consequences of infants born small for gestational age in low and middle income countries with INTERGROWTH-21st standard: analysis of CHERG datasets. *BMJ* 2017;358(j3677)
5. Lee AC, Katz J, Blencowe H, et al. National and regional estimates of term and preterm babies born small for gestational age in 138 low-income and middle-income countries in 2010. *The Lancet Global health* 2013;1:e26-36.
6. Kramer MS. Determinants of low birth weight: methodological assessment and meta-analysis. *Bulletin of the World Health Organization* 1987;65(5):663-737.
7. WHO Technical Consultation Towards the Development of a Strategy for Promoting Optimal Fetal Development. Promoting Optimal Fetal Development : Report of a Technical Consultation Geneva: WHO; 2003 [accessed March 18 2017.
8. Triunfo S, Lanzone A. Impact of maternal under nutrition on obstetric outcomes. *Journal of endocrinological investigation* 2015;38(1):31-8.
9. Islam MZ, Akhtaruzzaman M, Lamberg-Allardt C. Nutritional status of women in Bangladesh: comparison of energy intake and nutritional status of a low income rural group with a high income urban group. *Asia Pacific Journal of Clinical Nutrition* 2004;13(1):61-68.
10. Harris-Fry H, Shrestha N, Costello A, et al. Determinants of intra-household food allocation between adults in South Asia – a systematic review. *International Journal for Equity in Health* 2017;16(107) doi: DOI 10.1186/s12939-017-0603-1
11. Boyd NR, Jr., Windsor RA. A meta-evaluation of nutrition education intervention research among pregnant women. *Health education quarterly* 1993;20(3):327-45. [published Online First: 1993/01/01]

12. Girard AW, Olude O. Nutrition education and counselling provided during pregnancy: effects on maternal, neonatal and child health outcomes. *Paediatric and Perinatal Epidemiology* 2012;26(s1):191-204.
13. Gresham E, Collins CE, Mishra GD, et al. Diet quality before or during pregnancy and the relationship with pregnancy and birth outcomes: the Australian Longitudinal Study on Women's Health. *Public Health Nutrition* 2016;19(16):2975–83.
14. Lopes KdS, Ota E, Shakya P, et al. Effects of nutrition interventions during pregnancy on low birth weight: an overview of systematic reviews. *BMJ Global Health* 2017;2(e000389)
15. Chowdhury M, Raynes-Greenow C, Alam A, et al. Making a balanced plate for pregnant women to improve birthweight of infants: a study protocol for a cluster randomised controlled trial in rural Bangladesh. *BMJ Open* 2017;7(e015393)
16. Sen B, Ali Z. Spatial Inequality in Social Progress in Bangladesh. *The Bangladesh Development Studies* 2009;XXXII(2)
17. Bangladesh District Level Socio-demographic and Health Care Utilization Indicators: National Institute of Population Research and Training (NIPORT), Dhaka, Bangladesh, MEASURE Evaluation, UNC-CH, USA, and ICDDR,B, 2011.
18. Nahar Q, Choudhury S, Faruque MO, et al. Desirable Dietary Pattern for Bangladesh: National Food Policy Capacity Strengthening Programme, 2013.
19. West Jr PK, Shamim AA, Mehra S, et al. Effect of Maternal Multiple Micronutrient vs Iron–Folic Acid Supplementation on Infant Mortality and Adverse Birth Outcomes in Rural Bangladesh: The JiVitA-3 Randomized Tria. *JAMA* 2014;312(24):2649-58.
20. Zeng L, Cheng Y, Dang S, et al. Impact of micronutrient supplementation during pregnancy on birth weight, duration of gestation, and perinatal mortality in rural western China: double blind cluster randomised controlled trial. *BMJ* 2008;337(7680):1211 - 15.
21. Mridha MK, Matias SL, Chaparro CM, et al. Lipid-based nutrient supplements for pregnant women reduce newborn stunting in a cluster-randomized controlled effectiveness trial in Bangladesh. *American Society for Nutrition* 2016;103:236-49.

22. Shaheen R, Francisco Ad, Arifeen SE, et al. Effect of prenatal food supplementation on birth weight: an observational study from Bangladesh1–. *The American journal of clinical nutrition* 2006;83:1355–61.
23. Contento IR. Nutrition education: linking research, theory, and practice. *Asia Pac J Clin Nutr* 2008;17(1):176-79.
24. Fishbein M, Yzer MC. Using Theory to Design Effective Health Behavior Interventions. *Communication Theory* 2003;13(2):164-83.
25. Sanghvi T, Haque R, Roy S, et al. Achieving behaviour change at scale: Alive & Thrive's infant and young child feeding programme in Bangladesh. *Maternal & child nutrition* 2016;12(Suppl. 1):141-54.
26. Ahmed SM, Hossain MA, Chowdhury AMR, et al. The health workforce crisis in Bangladesh: shortage, inappropriate skill-mix and inequitable distribution. *Human Resources for Health* 2011;9(3)
27. WHO. Community health workers: What do we know about them? Geneva, 2007.
28. Alive & Thrive. Alive & Thrive's approach and results in Bangladesh: Rapid improvements in infant and young child feeding practices resulting from a large-scale program, 2015.
29. Alam A, Rasheed S, Khan NU, et al. How can formative research inform the design of an iron-folic acid supplementation intervention starting in first trimester of pregnancy in Bangladesh? *BMC public health* 2015;15(374)
30. Bhutta ZA, Das JK, Rizvi A, et al. Evidence-based interventions for improvement of maternal and child nutrition: what can be done and at what cost? *The Lancet* 2013;382:452-77.

Tables and Figures

Table 3. Baseline characteristics of clusters, households and participants by treatment group

	Intervention group (n=445)	Comparison group (n=448)
No of clusters	18	18
Mean (SD) population in clusters in 2016	9775 (2007)	9639 (1763)
Mean (SD) no of households in clusters	2315 (288)	2321 (419)
Mean (SD) no of women of reproductive age	2639 (542)	2631 (481)
Mean (SD) pregnant women enrolled in clusters	24.7 (1.0)	24.9 (0.5)
Maternal age (years):		
Mean (SD)	23·1 (4·7)	24·0 (4·4)
15-19	90 (21·0)	71 (16·7)
20-34	329 (76·5)	346 (81·2)
>34	11 (2·6)	9 (2·1)
Missing	15	22
Women's education:		
No education	96 (22·1)	107 (24·5)
Primary	287 (66·1)	272 (62·4)
Secondary	32 (7·4)	36 (8·3)
Higher	19 (4·4)	21 (4·8)
Missing	11	12
Monthly family income (SD) in USD $	91·7 (53·6)	90·1 (55·1)
Missing	27	26
Husband's education:		
No education	154 (35·6)	171 (39·9)
Primary	216 (49·9)	196 (45·7)
Secondary	40 (9·2)	40 (9·3)
Higher	23 (5·3)	22 (5·1)
Missing	12	19
Parity:		
Mean (SD)	1·7 (1·2)	1·9 (1·3)
0	38 (10·5)	50 (12·1)
1	143 (39·4)	128 (31·1)
≥2	182 (50·1)	234 (56·8)
Missing	82	36
Previous pregnancy loss		
Yes	71 (19·6)	104 (25·2)
No	292 (80·4)	308 (74·8)
Missing	82	36
Gestation at enrolment (week)	10·1 (3·2)	9·6 (3·2)
Missing	58	12

Figures are numbers (percentage) unless stated otherwise

Table 4. Birth outcomes with adjusted difference or relative risk of intervention compared to comparison

Birth outcomes	Mean (SD)/No of infants (%)	Adjusted difference or relative risk (95% CI)[a]	P value
Birth weight (g)			
Intervention	2861·0 (444·5)	125·3 (5·7 - 244·9)	0·04
Comparison	2736·8 (432·5)	Reference	
Low Birthweight			
Intervention	37 (9·7)	0·46 (0·28 - 0·78)	0·004
Comparison	87 (21·9)	Reference	

[a]Birthweight was analysed using linear regression, low birthweight (LBW) was analysed using binomial regression with a log link. All models were adjusted for clusters using generalized estimating equation (GEE) models assuming exchangeable correlation structure and applied sandwich estimator to standard errors. Results presented were also adjusted for age and gestation at enrolment. Sample size for adjusted analysis was n=722 due to 37 missing values in age and 70 in gestation at enrolment.

Table 5. Sub-group analyses for age and education status

	Age group						
	Adolescent (<20 years) (n=695)			**Non-adolescent (≥20 years) (n=161)**			
	Mean (SD)/No of infants (%)	Adjusted difference or relative risk (95% CI)[a]	P value	Mean (SD)/No of infants (%)	Adjusted difference or relative risk (95% CI)	P value	P value for interaction
Birth weight (g)							
Intervention	2916·3 (473·7)	297·3 (85·0-509·6)	0·006	2847·6 (443·8)	90·0 (-23·4-203·2)	0·096	0·009
Comparison	2637·5 (484·5)	Reference		2762·6 (401·5)	Reference		
Low Birthweight							
Intervention	6 (7·5)	0·31 (0·12-0·77)	0·01	31 (10·8)	0·52 (0·29-0·95)	0·033	0·22
Comparison	17 (26·6)	Reference		62 (19·8)	Reference		
	Educational status						
	Educated (primary or higher) (n=667)			**Un-educated (no-education) (n=203)**			
	Mean (SD)/No of infants (%)	Adjusted difference or relative risk (95% CI)	P value	Mean (SD)/No of infants (%)	Adjusted difference or relative risk (95% CI)	P value	P value for interaction
Birth weight (g)							
Intervention	2859·0 (446·0)	112·9 (-13·6, 239·5)	0·08	2869·5 (463·1)	170·4 (23·3-317·5)	0·023	0·66
Comparison	2758·0 (437·3)	Reference		2693·3 (341·4)	Reference		
Low Birthweight							
Intervention	29 (9·0)	0·44 (0·25-0·77)	0·004	11 (13.4)	0·57 (0·28-1·16)	0·11	0·42
Comparison	59 (19·9)	Reference		22 (24.7)	Reference		

[a]Birthweight was analysed using linear regression, low birthweight (LBW) was analysed using binomial regression with a log link. All models were adjusted for clusters using generalized estimating equation (GEE) models assuming exchangeable correlation structure and applied sandwich estimator to standard errors. Results presented were also adjusted for age and gestation at enrolment.

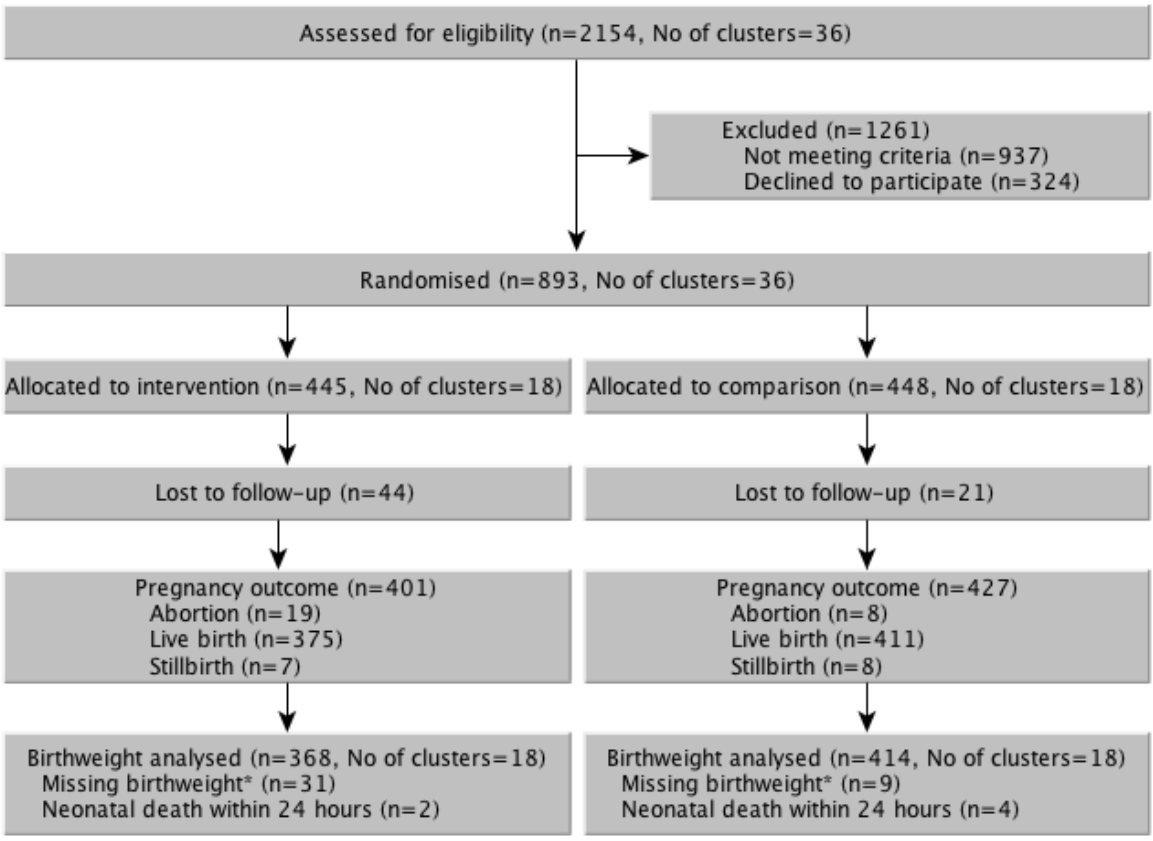

Figure 7. Trial flow chart

*Birthweight missing for live births

CHAPTER 5

PAPER 3

A qualitative study to understand the barriers and coping strategies to comply with balanced plate nutrition education intervention in rural Bangladesh

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Under review at PLOS ONE

Abstract

Maternal under-nutrition with chronic energy and micronutrient deficiencies is widely prevalent in south-central Asia. Nutritional deficiency in pregnancy is associated with intrauterine growth retardation (IUGR) and low birthweight (LBW). Under-nutrition is usually associated with an inadequate intake that might result from lack of access and unavailability of food, improper utilization or inequitable intra-household distribution of food. The selection, allocation and consumption of food are highly regulated by social, cultural, environmental and economic factors. A wide range of restrictive practices exists on the perinatal diet in Asia, Latin America and Africa affecting the eating behaviour of pregnant women. External influence such as advice and social judgment could potentially influence eating choices. Therefore, we have developed a nutrition behaviour change communication intended to promote balanced diet in pregnancy to increase birthweight of the infants in rural Bangladesh and tested the impact with a cluster randomized controlled trial (cRCT). We conducted a process evaluation with the aim to explore the barriers and coping strategies to comply with the intervention of the individual, family and societal, and providers' perspectives.

We conducted focus group discussions (FGD) with pregnant women's husbands and older women (mothers and mothers-in-law). In-depth interviews (IDI) were applied to collect data from recently delivered mothers, husbands, and older women who received the intervention. Key informant interviews (KII) were conducted with BRAC *Shasthya Kormi* (community health worker-CHW) who provided balanced plate demonstration.

We found that the balanced plate nutrition education helped women through practical demonstration to learn about a balanced meal considering appropriate portion sizes and diversity of foods. The family decision makers, such as husbands and mothers-in-law, considered adopting a healthier diet as a tactic to protect the newborn and the mother from health complications that might safeguard a healthier baby. We also found that rural Bangladeshi pregnant women needed the active involvement of CHWs in mobilizing social support to create an enabling environment essential to bring change in dietary habits with self-motivation.

Background

Around 211 million women are pregnant each year, mostly in developing countries [214]. Despite many efforts, 10.6 million children and 529,000 mothers die mostly from avoidable causes [214]. Maternal and child under-nutrition indirectly contributes to 3·5 million deaths and 35% of the disease burden in children younger than 5 years and 11% of total global DALYs [13]. Maternal short stature and iron deficiency anaemia account for at least 20% of maternal mortality [13]. Maternal under-nutrition with chronic energy and micronutrient deficiencies is mostly prevalent in south-central Asia. The situation is considered critical in India, Bangladesh, and Eritrea where the prevalence of low body-mass index (less than 18·5 kg/m²) in women is around 40% [13]. Nutritional deficiency in pre-pregnancy and pregnancy is associated with adverse outcomes such as low birthweight (LBW), preterm birth, and intrauterine growth retardation (IUGR) that have consequences for survival, development, quality of life, and health care costs [215].

Nutritional requirements in pregnancy vary and guidelines differ between countries. The Royal College of Obstetricians and Gynaecologists recommend a 200 kcal increase in daily energy intake in the third trimester – an approximate 10% increase from the 1940 kcal/day recommendation for a non-pregnant adult woman [216]. Under-nutrition is usually associated with inadequate intake but can also be associated with increased nutritional requirements or losses, or impaired ability to absorb or utilize nutrients [217]. Inadequate intake can result from lack of access and unavailability (food insecurity) or improper utilization in quality and quantity and inequitable intra-household distribution of food [218]. The selection, allocation and consumption of food is highly regulated by social, cultural, environmental and economic factors [219].

Changes in eating behavior in pregnancy are obvious and are restructured by physical (nausea and vomiting) and emotional feelings (unplanned or unsupported pregnancy) [220]. A wide range of restrictive practices on perinatal diet exists in Asia, Latin America and Africa based on the notions of food being beneficial or harmful with little cross-cultural agreement [221]. Food restrictions affect eating behaviors of pregnant women and lead to frustration and a perceived loss of control. Whereas, adoption of a healthier diet results in self-fulfillment and empowerment regarding

own health and well-being of babies [222]. External influences such as advice and social judgment can potentially influence eating choices. In the life course perspective, pregnancy is a transition period that offers a window of opportunity for women to change towards a healthier diet which can improve the health and well-being of both mother and baby [222]. Pregnant women express motivation to change eating habits if the changes improve outcomes or reduce risks for their babies [220].

We developed a nutrition behaviour change intervention intended to promote a balanced diet in pregnancy and increase birthweight of infants in rural Bangladesh and tested the impact with a cluster randomized controlled trail (cRCT). Before onset of the trial, we conducted formative research to understand current attitudes, perceptions and practices around diet in pregnancy, which contributed to development of the balanced plate intervention. During the later part of the trial, we conducted a process evaluation to explore barriers and coping strategies around adopting a balanced diet during pregnancy from both individual, family and societal, and provider perspectives.

Cluster randomised controlled trail (cRCT)

A two-arm parallel cRCT was conducted in villages of the Sherpur district of Bangladesh. A total of 36 clusters were randomly selected and randomly assigned to one of two treatments. Clusters were defined by an area of ~10,000 population served by one community health worker (known as Shasthya Kormi) of BRAC (an NGO, formerly known as Bangladesh Rural Advancement Committee). Twenty-five pregnant women were enrolled from each cluster; 445 in a balanced plate nutrition education group (intervention) who received nutrition counseling and practical demonstrations from conception till delivery and 448 in a standard nutrition education group (comparison). It was hypothesized that infants would be 100 g heavier in the intervention than the comparison group. Trained Shasthya Kormi visited all women once each month to provide antenatal care services including nutrition education (either balanced plate or standard nutrition education). The balanced plate nutrition education was characterized by a combination of counseling on balanced diet, food diversification and demonstration of making a balanced plate with appropriate portion sizes from foods available in women's kitchens. Family decision makers were also involved and motivated to support pregnant women in adopting a healthy diet through

purchasing more nutritious food and/or women friendly intra-household food distribution. We conducted formative research using interviews with focus groups of women, family members and Shasthya Kormi to generate information on food availability, seasonality, cultural dietary restrictions and proscriptions, and neighborhood/community food sharing. The information assisted us in designing the balanced plate intervention.

Methods

Study population and sampling

We used a stratified purposeful sampling method [223] to identify eligible participants from two study sites. The study population was selected from a list of pregnant women and recently delivered mothers provided by the BRAC MNCH program. We selected pregnant women regardless of gestational age, with no chronic disease (such as, diabetes and hypertension) and permanently resident in the area and recently delivered mothers who had delivered within the last three months and had a live child. Husbands, mothers and mothers-in-law of pregnant or recently delivered women were selected using the same list. Shasthya Kormi had been selected randomly from the intervention clusters.

Three qualitative methods – in-depth interviews (IDI), focus group discussions (FGD) and key informant interviews (KII) were applied (Table 5). We conducted four FGDs - two with pregnant women, one with husbands, and one with mothers and mothers-in-law. The evaluation research included 10 IDIs with recently delivered mothers, one FGD with husbands, and one with older women who received the balanced plate intervention. KIIs were conducted with four BRAC Shasthya Kormi who provided the balanced plate demonstration.

Table 6. Methods and sample size

Method	Type of respondents	Number
In-depth interviews	- Mothers of infants	10
Focus group discussions	- Pregnant women	2
	- Older women	1
	- Husbands	1
Key informant interviews	- Shasthya Kormi	4

Data collection

We used semi-structured interview guidelines for data collection. Separate guidelines were developed for IDI, FGD and KII and translated into Bengali. MC designed the guidelines after a literature review, and in consultation with AA and a nutritionist. In July 2015, the interview guidelines were pretested (by MC and an anthropologist) with four pregnant women and two of husbands in the study area. Guidelines were revised based on their responses and feedbacks. Interviewers were trained after finalization of the questionnaire and guidelines. Data collection took place from November-December 2016. With the help of the local BRAC staff, MC filtered one potential respondent from each registry book of Shasthya Kormi considering the eligibility criteria. Participants were individually approached for informed consent after explaining the purpose of the study, confidentially of the information and their right to withdraw. Verbal consent was obtained from all participants and the family decision makers (if present). We also obtained consent to record interviews with a digital recorder. Interviews typically lasted 30 to 40 minutes. Coded numbers were used to maintain the anonymity of data.

FGDs were also conducted to gather opinions of family decision makers on the balanced plate intervention and how this brought changes in the household budget allocation to food and intra-household food distribution. Discussion topics included – 1) advantages and disadvantages of balanced plate education and demonstration, 2) constraints of accessing desirable food and the strategies to overcome constraints, and 3) the role of older women in controlling pregnant women's food share in the household.

A major goal was to understand changes in dietary practices of pregnant women, the influence of balanced plate intervention on family decision makers, and the barriers and enabling factors that contributed to adopting a balanced diet in pregnancy. IDIs were used to elicit information about how women made choices of what and how much to eat. Discussion was focused on three topics: 1) views on balanced plate counselling, 2) benefits of balanced plate demonstration as a tool of nutrition education, and 3) role of husband, mother or mother-in-law in steering food accessibility and intra-household food distribution.

To explore health providers' perspectives of community acceptance of the balanced plate intervention, we interviewed Shasthya Kormi who provided the service in the intervention clusters. The major discussion points were: 1) role of Shasthya Kormi in promoting pregnant women's health and nutrition in the community, 2) community perception of the balanced plate intervention and 3) coping strategy of managing additional tasks within regular work schedules.

Data analysis

We audio-recorded all interviews and discussions. They were transcribed and translated into English for analysis by the first author (MC). We used both inductive and deductive coding approaches. We used priori codes to identify text related to the research questions and added additional codes to the codebook based on new themes that emerged during coding. Initially MC manually coded one IDI and one FGD transcripts following the data collection guidelines and developed a draft codebook that were checked by a senior qualitative researcher (AA) to improve inter-coder reliability. Subsequently MC coded all the transcripts maintaining the flexibility of modifying the codebook by adding any new themes that emerged throughout the coding process. Subsequently, text pertaining to each thematic code was compiled into separate files. These files were read and re-read by MC and analyzed using thematic approach [224]. Through iterative discussions among the research team, the data were analyzed to find variations, similarities and emerging trends in themes.

Results

Experience of balanced plate nutrition education

Everyone interviewed expressed that they liked the demonstration of making the balanced plate. The most common reason was that, this was a new method and different from other nutrition education they had experienced. The conventional way of education was lecturing, sometimes with visual aids such as pictures or flipcharts.

" Thai is a modern method, I have never seen something like this before. She (Shasthya Kormi) talked about different kinds of nutritious foods, why they are important and how they will benefit our child. We all participated in a process of measuring foods and then put on a plate. I think this is innovative." – A husband

Participants found the practical demonstration more interesting because it was participatory and needed active involvement in gathering essential food items, measuring food and displaying it on a plate. They did not have to buy anything that should be used in the plate. All they used was foods from their own kitchen, which made them feel comfortable with the process. Moreover, measuring food was also innovative and allowed participants to see the exact amount of food they had to eat, which was clearer than their previous knowledge of 'more' food that pregnant women were advised to eat.

"My daughter-in-law does not want to eat, she does not feels to. Now she would realize how little she is eating. She has to eat that much shown on a plate. Now she will listen to what I say (for eating more)." – A mother-in-law

Pregnant women considered visual presentation effective in recalling messages and easy to apply in practice. For example: one pregnant woman explained that initially she used the 'bowl' that was shown to measure the food but later developed her own method of measuring similar portion sizes with spoons. The display of the food on a plate made a visual impression on her memory. Later she repeated the same plate from memory without seeing the menu or using the measuring bowl.

"Rozina apa (Shasthya Kormi) showed me how to make my plate. She used a bowl from my kitchen and measured rice, curry, lentil and other foods and put together on a plate. First couple of days I also tried that way but later I realized that I know how much rice makes two bowls, I don't need to measure it now. I can do it with spoon." – A pregnant woman

"Visual display made it easy for me to recall what components must be on the plate. For example: now I know in my plate there should be either meat or fish or egg. I should eat lentil regularly which I was not habituated before." – A pregnant woman

During demonstration sessions, if household did not have all groups of foods essential to make a balanced meal, neighbours came forward with a contribution. Sharing food is a common culture in the society. Participants, their family and neighbours showed overwhelming interest to make a perfect plate with all essential components.

Barriers to and coping strategies of practicing the balanced plate messages

Monetary constraints

Monetary constraint was the primarily mentioned cause of non-compliance in practicing the balanced diet. All participants were from low-income families, hence found it difficult to allocate extra money for purchasing some nutritious foods missing in their regular menu. Shasthya Kormi' repeated contact with pregnant women, husbands and mothers-in-law motivated husbands to try several strategies to overcome this issue. A significant effort was reported by families to either reallocate the existing budget and/or put effort into earning more to spend on food. Husbands expressed that they were influenced by the counselling and demonstration and were convinced that pregnant women should eat more food and diversified food. They changed their shopping patterns to accommodate more healthy food either within their existing budget or by stretching the budget. Some husbands said they had channeled some expenses that they thought unnecessary (e.g, ready made snacks) to buy more fish, milk and fruits. Others said that they were working to earn extra money to invest in nutrition. One husband shared his experience of managing the extra budget:

"Suppose my previous weekly budget was taka 1500. Now I need additional taka 200/300 per week. I work some extra hours to manage the extra amount of money my family needs now. I have no problem with it." – A husband

Women also echoed what husbands said. Though not aware about the exact budget and the additional expenditure on food, they found that their husbands were buying more of the foods suggested by Shasthya Kormi and did it voluntarily.

"He (husband) bought more foods while I was pregnant. He did not wait for me to tell him what to buy." - A recently delivered mother

Inequitable intra-household food distribution

The food share of a woman in the family depended on the mother-in-law's approval, her husband's support and her position in the family. It was not socially acceptable for a woman to eat 'good' food and have a big share. To be a 'good wife or daughter-in-law', they had to eat last and eat leftovers, mostly rice with scant curry. This was

accepted as normal practice. However, the mothers-in-law differed and insisted their daughters-in-law eat more so the baby would be healthy. At the same time, they also believed that eating 'too much' would make the baby bigger and cause a complicated delivery. However, there was no clear concept about what constituted 'too much'. When women were asked about the role of their mothers-in-law on their diet, there were mixed responses. Some women said that their mothers-in-law did not bother about what they ate; others told that their mothers-in-law asked them to eat more. However, the best share of food always went to the male household heads. One elderly woman said that they were the one who earn, so they had to eat more to stay healthy.

"My son is the person who had to work all day long to feed the whole family. Where would he get energy for work if he does not eat more? Can they do it if they do not eat meat/fish?"

Shasthya Kormi played a crucial role in negotiating an equitable distribution of food in favor of pregnant women. As a member of the same community Shasthya Kormi have a unique position to deal with sensitive issues like intra-household food distribution. Creating and utilizing personal connections with elderly female members helped. One woman said,

"This is my 3rd child. I feel craving for food all the time. My mother in law watches me and does not allow me to eat full stomach. She says the baby will get big. So I asked apa (Shasthya Kormi) to talk to her but without letting her know that I told her about it. She might get angry if she comes to know. I found afterwards that my mother in law is not preventing me from eating some more." – A recently delivered mother

Unaffordability of animal source food

Most women reported that their husbands liked the idea of their eating a balanced diet and the prescribed foods. Husbands also tried to buy as much of the foods as they could afford. However, buying expensive food like meat regularly was not possible so it was purchased once/twice in a week/month. Compared to beef, chicken was less

expensive and available from local poultry farms. Beef was usually only available on market days (once/week).

“Previously my husband used to buy meat once in 2-3 months. Now he brings it at least 1-2 times in a month. I know it is expensive and not affordable to him, still he buys, even in small quantity.” – A pregnant woman

Participants commended the advice of replacing meat with cheaper options of fish or egg. With a notion that meat was one of the most nutritious foods, the information of fish and egg being similar in nutrient value was new. Families usually eat fish quite often but a small quantity goes to women. When advised, all families tried to increase the amount of fish in their daily menu. There was a misconception that cheap-farmed fish like tilapia, carp and catfishes were not as nutritious as other big fishes. However, the Shasthya Kormi informed them that farmed fish were equally as good as others and families should increase these fish consumption without buying expensive animal protein like big fish or meat. However, families reported increased meat consumption based on affordability. Another noticeable change was a regular consumption of egg. Egg was considered to be a substitute for meat and fish and women rarely cooked egg along with meat or fish but, after counselling, many women regularly ate an egg in the morning or as a snack. Almost half of the families had their own chickens, however, eggs were mostly given to the children. Similar practices were reported for milk which was considered as a food for younger children. After counseling, women were encouraged and supported by their husbands and mothers-in-law to drink milk. If they did not have their own cow, husbands bought it even in small quantities.

“My husband used to buy milk for me. You know it is expensive, so he could not buy a lot. Everyday he bought quarter liter of milk and made sure I drank it.” – A recently delivered mother

One woman reported that her teen school-going daughter, who was also present during nutrition counseling, insisted that she drank her share of milk. She told her mother,

"Mother, you need more of it (milk) now than me. The baby will get better nutrition and be in good health."

A mother-in-law also told that she insisted her daughter-in-law who was a minor and had completely lost her appetite, to at least drink milk which would give her strength.

Misconception about fruits and vegetables

Participants were aware that fruits were 'good' food; especially imported fruits such as apple, orange and grapes which families used to buy in some special occasions or when someone in the family was sick. From the counseling they understood that local fruits like guava, jujube, banana, and mango were equally 'good' and pregnant women should eat these seasonal fruits. Many families had their own trees or even these were cheap and available in the local market. Women said that they preferred acidic fruits because they improved their appetite. After nutrition counseling husbands bought fruits regularly, at least 1-3 times a week.

Colored vegetables like pumpkin, tomato and carrot were scant in regular diets. The commonly consumed vegetables were gourds, eggplant, cauliflower, cabbage, radish and legumes. Participants opined that according to knowledge, leafy vegetables were the main source of nutrients in pregnancy. However, the amount of vegetables consumed varied widely depending on economic status; women belonging to poor families used to consume less than those better off. In poor families, one food item had to be shared by all members, leaving very little for women. After the intervention, women asked their husbands to buy more pumpkin and tomatoes from the market and they also collected more leafy vegetables from their local vicinity.

Disproportionate portion size

In the regular diet, the proportion of foods was dominated by rice. Women used to consume a large portion of rice everyday with scant other foods. Despite having some knowledge of 'good' foods, they had apparently no knowledge about portion size before the visual display of the balanced plate. Mothers of infants confirmed that they knew about how much rice they should eat in each meal from Shasthya Kormi. However, some reported that the amount shown was not enough and they used to eat more, while the others said that they used to eat less before counseling. The reasons

of eating down were mostly related to loss of appetite, acidity, fullness, bloating and indigestion. However, some of them increased overall intake of all varieties of foods or intake of rice after listening the importance of adequate eating during pregnancy.

Women said that seeing the relative portion size on the plate, they figured out themselves where in their own diet they had to make changes to make it balanced. However, this was not an easy task for those who used to eat a lot of rice. Women reported that they gradually adjusted their portion size (some women increased and some reduced) with an increase in vegetables, lentils and animal protein (the size of the piece of meat/fish), and adding milk (not everyone) and fruits.

"That small amount of rice is not sufficient for me. I ate more than what Jahanara apa (Shasthya Kormi) showed me to eat." - A recently delivered mother

Role of community health workers

Shasthya Kormi were one of the most trusted sources of health and nutrition information, especially for women and children in the community. They were educated women who received training from BRAC, the organization they were linked with, and were held accountable for the advice they give. Most pregnant women said that Shasthya Kormi were easy to reach and could be called for help any time. Moreover, women preferred to talk to women, specifically about reproductive health. From a financial point of view, no consultation fee was attached to their services, which made it more affordable. Above all, the participants had the confidence in Shasthya Kormi for their long-term connection with the community.

"Jahanara apa (Shasthya Kormi) has been working in our village for years and we know her very well. She is my relative too. She is seeing (ANC visit) pregnant women for a long time. So I am happy to see her and I am sure she is the best person to help me here." - A pregnant woman

Shasthya Kormi played an active role in changing women's dietary behaviour through engaging with elderly women in the community. For those not willing to comply with a balanced diet out of confidence with their regular practice or lacking trust in guidance, Shasthya Kormi brought influential elderly females or peers who had just

became mothers in from the neighborhood. Pregnant women were motivated when they talked to these groups about how they ate and changed their own diet habits in pregnancy. Moreover, Shasthya Kormi were community members and many of them are mothers too, this gave them an extra weight to talk about pregnancy issues in light of their own motherhood experiences.

Discussion

Our study demonstrated a rise in nutrition awareness and practice among pregnant women in the study areas, in line with that reported in other low and middle-income countries [95 225]. The novel finding in this study was the description of the entire process that pregnant women went through to adopt a balanced diet, highlighting the importance of social support and active involvement in the education. We found that the balanced plate nutrition education helped women through practical demonstration to learn about a balanced meal considering appropriate portion sizes and dietary diversity. The family decision makers, such as husbands and mothers-in-law, considered adopting a healthier diet to protect the newborn and the mother from complications necessary to have a healthier baby. We also found that rural Bangladeshi pregnant women needed active involvement of CHWs in mobilizing social support to bring change in dietary habits with self-motivation.

Both women and families liked the participatory approach of balanced plate preparation because it was different and it allowed them to actively engage. It indicated that people actually like to contribute with their own ideas rather than only being instructed to follow some pre-fixed advices. Parents valued pregnancy and everybody craved for a good outcome both for mother and baby. The women regarded pregnancy as a special time and desired good nutrition practices to improve the health and growth of their baby. This desire was followed by an increased consumption of food considered ‘good’, in addition to their regular diet [226]. Researchers argued that carrying out an intended behaviour change requires one’s confidence in their ability to do so. In an investigation into pregnant women’s self-efficacy relating to physical activity and healthy diet, self-efficacy was found to predict both during pregnancy [227]. A favourable environment with social support, family support and support from others such as health professionals is a pre-requisite

to self-efficacy [228]. A study investigating the social environment influencing diet quality found that social capital and tolerance of diversity positively influenced adherence to a Mediterranean diet pattern. The results were interpreted to show that social capital leads to feelings of obligation, reciprocity and self-control, which result in greater motivation to follow a healthy diet [228]. Similar success in infant and young child feeding practices, and greater intake of micronutrient supplements and dietary diversity were observed when health providers positively influenced women along with husbands and mothers-in-law to overcome cultural practices that contradicted recommended best practices [229 230].

Pregnancy is a physiologically and psychologically unique period; consequently there may be many behavioral determinants that shape dietary patterns. Pregnancy-induced nausea and vomiting may cause food avoidance and preferences, and pica, cravings and food aversions are also associated with pregnancy [228]. Nutrition knowledge alone often does not lead to dietary behavior change. In China, nutrition education directed to postpartum mothers did not bring desired behavior change because their mothers or mothers-in-law cared them during the "sitting month" (first 30 or 40 days postpartum) without allowing freedom to decide their own care including diet. This study recommended targeting family members, rather than only women, to obtain optimum benefits from nutrition education intervention [231].

In our study, the women and the family members went beyond the suggestions they were given by the *Shasthya Kormi* through innovations and finding ways to overcome barriers to access nutritious foods. For example, some husbands said that they went to fishing to catch small fish that were equally nutritious as big fish. In a society where rice contributes around 70% of total energy with little animal protein and vegetables [168], it is difficult to encourage people to reverse their dietary patterns. However, women were self-motivated to modify their diet after they observed the imbalanced food proportions in their meal. This provides a significant message for future interventions in improving intervention uptake i.e., engaging the participants not only in designing but also in implementing the intervention.

Our intervention had a positive impact on spousal communication and men's active responsibility towards their wives' nutrition. For example, a husband said that he

worked extra hours to pay for the increased cost (Taka 200/300 per week) of buying nutritious food and he was self-motivated. In most developing counties, women do not have control over their health and nutrition and tend to have less effort for their own needs. Women with less influence or power within the household and the community are unable to guarantee fair food distribution in their households [232]. Interventions focusing on gender equality through intra-family-dialogue may improve women's decision-making power on their own health. Addressing couples in our intervention encouraged the parents to be equally responsible for their newborns, for example, men recognized the importance of purchasing nutritious food, whereas, women felt they should eat more of those. Similar behaviour was observed among parents of children where fathers increased their participation in household chores related to childcare and feeding [233]. Addressing women's issues acknowledges the instrumental role of men by closing the gender gap. Both men and women need to be involved in this process, recognizing their respective roles and needs, and fostering mutual awareness and partnership [234].

The community's eagerness to be involved in the intervention was reflected in their striving to cope with the barriers to complying with the balanced diet messages such as accessing animal source food. Apart from changing maternal dietary behaviors, we found improvements in community support such as neighbours' contribution with food items and that the health workers social roles created enabling environments for maternal nutrition. *Shasthya Kormi* negotiated with husbands and mothers-in-law on behalf of the women to allow them to eat better, which was not included in their project duties. Consideration of CHW's social roles for better community health has been suggested by social scientists in a broader sense [235].

In our study setting, the main source of nutrition education for pregnant women was public and private providers or health care facilities through ANC visits. Doctors are the major provider of ANC in both rural and urban areas in Bangladesh [138] amidst a huge shortage and unequal distribution of health resources. The ratio of doctors to 10,000 population is only 1.1, which is far below the WHO recommended standard [209]. It is not surprising that in public health care facilities, the average consultation time offered by a doctor to a woman seeking maternal or newborn care is as little as 8.9 (± 4.8) minutes [236]. This consultation time is supposed to cover medical examinations,

advice on birth preparedness, breast feeding and newborn care, and education on personal hygiene, rest, safer sex, family planning, and diet and supplements [237]. Thus, quality of care was an issue felt by health care providers [238]. Moreover, in an assessment of the implementation status of Bangladesh national nutrition services, none of the providers were trained in national nutritional and dietary advice at the time of interview [239]. Thus, it is likely that pregnant women receive only very brief nutrition messages from doctors, if they receive any, which is insufficient to impact on dietary behaviour. The "WHO Global Strategy on Human Resources for Health (HRH): Workforce 2030" encourages countries to adopt a diverse, sustainable skills mix, harnessing the potential of community-based workers in healthcare [240]. The 2013 Lancet Maternal and Child Nutrition Series also emphasized CHW-led interventions at scale to reach more populations [241]. In this study we have demonstrated the undeniable role of the *Shasthya Kormi* as health providers and social promoters in addressing maternal undernutrition in rural Bangladesh.

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References

1. World Health Organization. International Statistical Classification of Diseases and Related Health Problems, Tenth Revision. World Health Organization, Geneva, 1992.
2. Haig D. Genetic conflicts in human pregnancy. *The Quarterly Review of Biology* 1993;68(4):495-532.
3. McCormick MC. The Contribution of Low Birth Weight to Infant Mortality and Childhood Morbidity. *The New England Journal of Medicine* 1985;312(2):82-90.
4. Victora CG, Adair L, Fall C, et al. Maternal and child undernutrition: consequences for adult health and human capital. *Lancet* 2008;371(9609):340-57. doi: 10.1016/S0140-6736(07)61692-4
5. Camerota M, Bollen KA. Birth Weight, Birth Length, and Gestational Age as Indicators of Favorable Fetal Growth Conditions in a US Sample. *PloS one* 2016;11(4) doi: 10.1371/journal.pone.0153800
6. United Nations Children's Fund and World Health Organization. Low Birthweight: Country, regional and global estimates. New York: UNICEF, 2004.
7. Lee AC, Katz J, Blencowe H, et al. National and regional estimates of term and preterm babies born small for gestational age in 138 low-income and middle-income countries in 2010. *The Lancet Global health* 2013;1:e26-36.
8. United Nations Children's Fund. Undernourishment in the womb can lead to diminished potential and predispose infants to early death 2014 [Available from: http://data.unicef.org/topic/nutrition/low-birthweight/ accessed 7 May 2018.
9. Pollack RN, Divon MY. Intrauterine Growth Retardation: Definition, Classification and Etiology. *Clinical Obstetrics and Gynecology* 1992;35(1)
10. Kramer MS. Determinants of low birth weight: methodological assessment and meta-analysis. *Bulletin of the World Health Organization* 1987;65(5):663-737.
11. Sachdev HPS. Low Birth Weight in South Asia. *Int J Diab Dev Countries* 2001;21:13-31.
12. The World Bank Data. 2018 [Available from: https://data.worldbank.org/indicator/SH.STA.BRTW.ZS?end=2012&locations=FI-DK-DE&start=2012&view=bar&year_high_desc=false accessed December 31 2018.
13. Black RE, Allen LH, Bhutta ZA, et al. Maternal and child undernutrition: global and regional exposures and health consequences. *Lancet* 2008;371:243-60.
14. Wilcox AJ, Russell IT. Birthweight and Perinatal Mortality: II. On Weight-Specific Mortality. *International journal of epidemiology* 1983;12(3):319-25.
15. Wilcox AJ, Russell IT. Birthweight and Perinatal Mortality: I. On the Frequency Distribution of Birthweight. *International journal of epidemiology* 1983;12(3):314-18.
16. Adair L, Guilkey D. Age-specific determinants of stunting in Filipino children. *Journal of Nutrition* 1997;127:314-20.
17. Raqib R, Alam DS, Sarker P, et al. Low birth weight is associated with altered immune function in rural Bangladeshi children: a birth cohort study. *American Journal of Clinical Nutrition* 2007;85(3):845–52.
18. Aryastami NK, Shankar A, Kusumawardani N, et al. Low birth weight was the most dominant predictor associated with stunting among children aged 12–23 months in Indonesia. *BMC Nutrition* 2017;3(16)

19. Black RE, Victora CG, Walker SP, et al. Maternal and child undernutrition and overweight in low-income and middle-income countries. *The Lancet*;382(9890):427-51. doi: 10.1016/s0140-6736(13)60937-x
20. Cruise M. A longitudinal study of the growth of low birth weight infants. I. Velocity and distance growth, birth to 3 years. *Pediatrics* 1973;51(4):620.
21. Martorell R, Ramakrishnan U, Schroeder D, et al. Intrauterine growth retardation, body size, body composition and physical performance in adolescence. *European Journal of Clinical Nutrition* 1998;52(Suppl 1):S43-52.
22. Hack M, Klein NK, Tayl HG. Long-term developmental outcomes of low birth weight infants. *The Future of Children-Spring 1995* 1995;5(1):176- 96.
23. Gupta ND, Deding M, Lausten M. The effect of low birth weight on height, weight and behavioral outcomes in the medium-run. *Economics and human biology* 2013;11(1):42-55.
24. Fletcher JM. The medium term schooling and health effects of low birth weight: Evidence from siblings. *Economics of Education Review* 2011;30(3):517-27.
25. Kormos CE, Wilkinson AJ, Davey CJ, et al. Low birth weight and intelligence in adolescence and early adulthood: a meta-analysis. *Journal of Public Health* 2013;36(2):213–24. doi: https://doi.org/10.1093/pubmed/fdt071
26. Taylor HG, Margevicius S, Schluchter M, et al. Persisting behavior problems in extremely low birth weight adolescents. *Journal of developmental and behavioral pediatrics : JDBP* 2015;36(3) doi: 10.1097/DBP.0000000000000139.
27. Muskiet FAJ. Chapter 2 Pathophysiology and Evolutionary Aspects of Dietary Fats and Long-Chain Polyunsaturated Fatty Acids across the Life Cycle. In: Montmayeur J, le Coutre J, eds. Fat Detection: Taste, Texture, and Post Ingestive Effects. Boca Raton (FL): CRC Press/Taylor & Francis 2010.
28. Barker D. In utero programming of chronic disease. *Clinical Science* 1998;95(2):115-28.
29. Godfrey KM, Barker DJ. Fetal nutrition and adult disease. *American Journal of Clinical Nutrition* 2000;71(5 Suppl):1344S-52S. doi: 10.1093/ajcn/71.5.1344s
30. Godfrey K, Robinson S. Maternal nutrition, placental growth and fetal programming. *Proceedings of the Nutrition Society* 1998;57:105-11.
31. Alexander BT. Fetal programming of hypertension. *Am J Physiol Regul Integr Comp Physiol* 2006;290:R1–R10. doi: 10.1152/ajpregu.00417.2005.
32. Ojeda NB, Grigore D, Alexander BT. Intrauterine Growth Restriction: Fetal Programming of Hypertension and Kidney Disease. *Advances in Chronic Kidney Disease* 2008;15(2):101-06.
33. Simmons RA, Templeton LJ, Gertz SJ. Intrauterine Growth Retardation Leads to the Development of Type 2 Diabetes in the Rat. *Diabetes* 2001;50(10):2279-86. doi: https://doi.org/10.2337/diabetes.50.10.2279
34. Alderman H, Behrman JR. Estimated Economic Benefits of Reducing Low Birth Weight in Low-Income Countries. Washington, DC: The World Bank, 2004.
35. Lewit EM, Baker LS, Corman H, et al. The Direct Cost of Low Birth Weight. *The Future of Children* 1995;5(1)
36. Goddeeris JH, Saigal S, Boyle MH, et al. Economic Outcomes in Young Adulthood for Extremely Low Birth Weight Survivors. *Pediatrics* 2010;126(5):e1102-e08.
37. OECD Family Database. Low birth weight 2017 [Available from: http://www.oecd.org/els/family/CO_1_3_Low_birth_weight.pdf accessed 8 May 2018.

38. Ohmi H, Hirooka K, Hata A, et al. Recent trend of increase in proportion of low birthweight infants in Japan. *International journal of epidemiology* 2001;30(6):1269-71.
39. Centre for Epidemiology and Evidence. HealthStats NSW Sydney: NSW Ministry of Health; 2018 [Available from: http://www.healthstats.nsw.gov.au/Indicator/mab_lbw/mab_lbw accessed 13 July 2018.
40. Bhat BV, Adhisivam B. Trends and Outcome of Low Birth Weight (LBW) Infants in India. *Indian Journal of Pediatrics* 2013;80(1):60-62. doi: 10.1007/s12098-012-0922-6
41. Walker SP, Chang SM. Handbook of Growth and Growth Monitoring in Health and Disease. New York, NY: Springer 2012.
42. Borders BAE, Grobman WA, Amsden LB, et al. Chronic Stress and Low Birth Weight Neonates in a Low-Income Population of Women. *The American College of Obstetricians and Gynecologists* 2007;109(2):331-38.
43. Anuranga C, Wickramasinghe R, Rannan-Eliya RP, et al. Trends, inequalities and determinants of low birth weight in Sri Lanka. *Ceylon Medical Journal* 2012;57:61-69.
44. Imdad A, Bhutta ZA. Maternal Nutrition and Birth Outcomes: Effect of Balanced Protein-Energy Supplementation. *Paediatric and Perinatal Epidemiology* 2012;26(Suppl. 1):178–90.
45. Han Z, Lutsiv O, Mulla S, et al. Maternal Height and the Risk of Preterm Birth and Low Birth Weight: A Systematic Review and Meta-Analyses. *J Obstet Gynaecol Can* 2012;34(8):721–46.
46. Zhang G, Bacelis J, Lengyel C, et al. Assessing the Causal Relationship of Maternal Height on Birth Size and Gestational Age at Birth: A Mendelian Randomization Analysis. *PLoS Med* 2015;12(8):e1001865. doi: 10.1371/journal.pmed.1001865
47. Yu Z, Han S, Zhu J, et al. Pre-Pregnancy Body Mass Index in Relation to Infant Birth Weight and Offspring Overweight/Obesity: A Systematic Review and Meta-Analysis. *PloS one*;8(4):e61627. doi: 10.1371/journal.pone.0061627
48. Energy Requirements of Pregnancy. Human energy requirements - Report of a Joint FAO/WHO/UNU Expert Consultation. Rome: FAO, 2001.
49. Han Z, Mulla S, Beyene J, et al. Maternal underweight and the risk of preterm birth and low birth weight: a systematic review and meta-analyses. *International journal of epidemiology* 2011;40:65–101. doi: 10.1093/ije/dyq195
50. Strauss R, Dietz W. Low maternal weight gain in the second or third trimester increases the risk for intrauterine growth retardation. *The Journal of Nutrition* 1999;129(5):988-93.
51. Grivell R, Dodd J, Robinson J. The prevention and treatment of intrauterine growth restriction. *Best Practice & Research Clinical Obstetrics and Gynaecology* 2009;23:795–807.
52. Abu-Saad K, Fraser D. Maternal Nutrition and Birth Outcomes. *Epidemiologic Reviews* 2010;32:5-25.
53. Triunfo S, Lanzone A. Impact of maternal under nutrition on obstetric outcomes. *Journal of endocrinological investigation* 2015;38(1):31-8.
54. Bendich A, Deckelbaum RJ. Preventive Nutrition. Totowa, NJ: Humana Press 2001:387-413.

55. Bloomfield FH. How Is Maternal Nutrition Related to Preterm Birth? *Annual Review of Nutrition* 2011;31:235–61.
56. Zhang Y, Zhou H, Perkins A, et al. Maternal Dietary Nutrient Intake and Its Association with Preterm Birth: A Case-control Study in Beijing, China. *Nutrients* 2017;9(221)
57. Myron W. Nutrition, pre- and postnatal development: Plenum Press 1979.
58. Stein Z, Susser M. The Dutch Famine, 1944-1945, and the Reproductive Process. I. Effects on Six Indices at Birth. *Pediatric Research* 1975;9:70-76.
59. Bergner L, Susser MW. Low Birth Weight and Prenatal Nutrition: An Interpretative Review. *Pediatrics* 1970;46(6)
60. Antonov A. Children born during the siege of Leningrad in 1942. *Journal of Pediatrics* 1947;30:250-9.
61. Oke SL, Hardy DB. Effects of Protein Deficiency on Perinatal and Postnatal Health Outcomes. *Physiology and Pharmacology Publications* 2017;101
62. Innis SM. Fatty acids and early human development. *Early Human Development* 2007;83:761–66.
63. Kuipers RS, Luxwolda MF, Dijck-Brouwer JDA, et al. Intrauterine, postpartum and adult relationships between arachidonic acid (AA) and docosahexaenoic acid (DHA). *Prostaglandins, Leukotrienes and Essential Fatty Acids* 2011;85:245–52.
64. Robillard PY, Christon R. Lipid Intake During Pregnancy In Developing Countries: Possible Effects of Essential Fatty Acid Defficiency on Fetal Growth. *Prostaglandins Leukotriens and Essential Fatty Acids* 1993;48:139-42.
65. Biesalski HK, Jana T. Micronutrients in the life cycle: Requirements and sufficient supply. *NFS Journal* 2018;11:1-11.
66. Steer PJ. Maternal hemoglobin concentration and birth weight. *American Journal of Clinical Nutrition* 2000;71(suppl):1285S–7S.
67. Figueiredo ACMG, Gomes-Filho IS, Silva RB, et al. Maternal Anemia and Low Birth Weight: A Systematic Review and Meta-Analysis. *Nutrients* 2018;10(601) doi: 10.3390/nu10050601
68. Allen LH. Biological Mechanisms That Might Underlie Iron's Effects on Fetal Growth and Preterm Birth. *The Journal of Nutrition* 2001;131(2):581S–89S. doi: https://doi.org/10.1093/jn/131.2.581S
69. Fekete K, Berti C, Trovato M, et al. Effect of folate intake on health outcomes in pregnancy: a systematic review and meta-analysis on birth weight, placental weight and length of gestation. *Nutrition journal* 2012;11(75)
70. FAO and FHI 360. Minimum dietary diversity for women: a guide for measurement. Rome, 2016.
71. Uitert EMv, Steegers-Theunissen RgPM. Influence of maternal folate status on human fetal growth parameters. *Molecular Nutrition & Food Research* 2013;57:582–95.
72. Antony AoC. In utero physiology: role of folic acid in nutrient delivery and fetal development. *American Journal of Clinical Nutrition* 2007;85(Suppl):598S–603S.
73. León G, Murcia M, Rebagliato M, et al. Maternal Thyroid Dysfunction during Gestation, Preterm Delivery, and Birthweight. The Infancia y Medio Ambiente Cohort, Spain. *Paediatric and Perinatal Epidemiology* 2015;29:113–22. doi: 10.1111/ppe.12172

74. Forhead A, Fowden A. Thyroid hormones in fetal growth and prepartum maturation. *Journal of Endocrinology* 2014;221(3):R87-R103. doi: 10.1530/JOE-14-0025
75. Charoenratana C, Leelapat P, Traisrisilp K, et al. Maternal iodine insufficiency and adverse pregnancy outcomes. *Maternal and Child Nutrition* 2016;12:680–87.
76. Muthayya S, Kurpad A, Duggan C, et al. Low maternal vitamin B12 status is associated with intrauterine growth retardation in urban South
Indians. *European Journal of Clinical Nutrition* 2006;60:791–801.
77. Institute of Medicine (US) and National Research Council (US) Committee to Reexamine IOM Pregnancy Weight Guidelines. Composition and Components of Gestational Weight Gain: Physiology and Metabolism. In: Rasmussen K, Yaktine A, eds. Weight Gain During Pregnancy: Reexamining the Guidelines. Washington (DC): National Academies Press (US) 2009.
78. Young MF, Nguyen PH, Addo OY, et al. Timing of Gestational Weight Gain on Fetal Growth and Infant Size at Birth in Vietnam. *PloS one* 2017;12(1):e0170192. doi: 10.1371/journal.pone.0170192
79. Institute of Medicine (US) and National Research Council (US) Committee to Reexamine IOM Pregnancy Weight Guidelines. Consequences of Gestational Weight Gain for the Child. In: Rasmussen K, Yaktine A, eds. Weight Gain During Pregnancy: Reexamining the Guidelines. Washington (DC): National Academies Press (US) 2009.
80. Brown J, Murtaugh M, Jacobs DJ, et al. Variation in newborn size according to pregnancy weight change by trimester. *American Journal of Clinical Nutrition* 2002;76(1):205-9.
81. Zanardo V, Mazza A, Parotto M, et al. Gestational weight gain and fetal growth in underweight women. *Italian Journal of Pediatrics* 2016;42(74) doi: 10.1186/s13052-016-0284-1
82. Susser M. Maternal weight gain, infant birth weight, and diet: causal sequences. *American Journal of Clinical Nutrition* 1991;53:1384-96.
83. FAO. The state of food security in the world. Rome: Food and Agriculture Organization, 2000.
84. FAO, IFAD, WFP. The State of Food Insecurity in the World 2014. Strengthening the enabling environment for food security and nutrition. Rome: FAO, 2014.
85. Ivers LC, Cullen KA. Food insecurity: special considerations for women. *The American journal of clinical nutrition* 2011;94(suppl):1740S–4S.
86. Saaka M. How is household food insecurity and maternal nutritional status associated in a resource-poor setting in Ghana? *Agriculture & Food Security* 2016;5(11)
87. Na M, Mehra S, Christian P, et al. Maternal Dietary Diversity Decreases with Household Food Insecurity in Rural Bangladesh: A Longitudinal Analysi. *The Journal of Nutrition* 2016;146:2109–16.
88. Institute of Medicine (US) and National Research Council (US) Committee to Reexamine IOM Pregnancy Weight Guidelines. Descriptive Epidemiology and Trends. In: Rasmussen K, Yaktine A, eds. Weight Gain During Pregnancy: Reexamining the Guidelines. Washington (DC): National Academies Press (US) 2009.
89. Savard N, Levallois P, Rivest LP, et al. Impact of individual and ecological characteristics on small for gestational age births: an observational study in Quebec. *Chronic Diseases and Injuries in Canada* 2014;34(1):46-54.

90. Copper R, Goldenberg R, Das A, et al. The preterm prediction study: maternal stress is associated with spontaneous preterm birth at less than thirty-five weeks' gestation. National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. *amirican journal of Obstetrics and GynecologO* 1996;175(5):1286-92.
91. Paarlberg KM, Vingerhoets AJM, Passchier J, et al. Psychosocial Factors and Pregnancy Outcome: A Review With Emphasis On Methodological Issues. *Journal of Psychosomatic Research* 1995;39(5):563-95.
92. Schetter CD, Tanner L. Anxiety, depression and stress in pregnancy: implications for mothers, children, research, and practice. *Current Opinion in Psychiatry* 2012;25(2):141–48.
93. Stanevaa A, Bogossianb F, Pritchardc M, et al. The effects of maternal depression, anxiety, and perceived stress during pregnancy on preterm birth: A systematic review. *Women and Birth* 2015;28(3):179-93.
94. WHO. Promoting Optimal Fetal Development : Report of a Technical Consultation. Geneva: WHO, 2003.
95. Kavle JA, Landry M. Addressing barriers to maternal nutrition in low- and middle- income countries: A review of the evidence and programme implications. *Maternal and Child Nutrition* 2018;14(e12508) doi: 10.1111/mcn.12508
96. WHO. Global Nutrition Targets 2025: Low Birth Weight Policy Brief. World Health Assembly Resolution 656, 2012.
97. The Lancet. Maternal and Child Nutrition: Executive Summary of The Lancet Maternal and Child Nutrition Series, 2013.
98. Gresham E, Byles JE, Bisquera A, et al. Effects of dietary interventions on neonatal and infant outcomes: a systematic review and meta-analysis. *The American journal of clinical nutrition* 2014;100:1298–321.
99. WHO. Nutrition counselling during pregnancy 2017 [Available from: http://www.who.int/elena/titles/nutrition_counselling_pregnancy/en/ accessed 28 May 2018.
100. Lopes KdS, Ota E, Shakya P, et al. Effects of nutrition interventions during pregnancy on low birth weight: an overview of systematic reviews. *BMJ Global Health* 2017;2(e000389) doi: 10.1136/bmjgh-2017-000389
101. Girard AW, Olude O. Nutrition education and counselling provided during pregnancy: effects on maternal, neonatal and child health outcomes. *Paediatric and Perinatal Epidemiology* 2012;26(s1):191-204.
102. Ota E, Hori H, Mori R, et al. Antenatal dietary education and supplementation to increase energy and protein intake (Review). Cochrane Database of Systematic Reviews: John Wiley & Sons, Ltd, 2015.
103. Widga AC, Lewis NM. Defined, in-home, prenatal nutrition intervention for low-income women. *Journal of the American Dietetic Association* 1999;99(9):1058-62.
104. Graham AV, Frank SH, Zyzanski SJ, et al. A clinical trial to reduce the rate of low birth weight in an inner city black population. *Family medicine* 1992;24(6)
105. Olds D, Henderson CJ, Tatelbaum R, et al. Improving the delivery of prenatal care and outcomes of pregnancy: a randomized trial of nurse home visitation. *Pediatrics* 1986;78(1)
106. Briley C, Flanagan NL, Lewis NM. In-home Prenatal Nutrition Intervention Increased Dietary Iron Intakes and Reduced Low Birthweight in Low-Income

African-American Women. *Journal of the American Dietetic Association* 2002;102(7):984-87. doi: http://dx.doi.org/10.1016/S0002-8223(02)90225-7
107. Kafatos AG, Tsitoura S, Pantelakis SN, et al. Maternal and infant health education in a rural Greek community. *Hygie* 1991;10
108. Heins HC, Nance NW, McCarthy BJ, et al. A Randomized Trial of Nurse-Miswifery Prenatal care to Reduce Low Birth Weight. *Obstetetrics and Gynecolology*;75(3):341-45.
109. Nikièma L, Huybregts L, Martin-Prevel Y, et al. Effectiveness of facility-based personalized maternal nutrition counseling in improving child growth and morbidity up to 18 months: A cluster-randomized controlled trial in ruralBurkina Faso. *PloS one* 2017;12(5):e0177839.
110. Sweeney C, Smith H, Foster JC, et al. Effects of a nutrition intervention program during pregnancy. *Journal of Nurse-Midwifery* 1985;30(3):149-58. doi: http://dx.doi.org/10.1016/0091-2182(85)90280-0
111. Akter SM, Roy SK, Thakur SK, et al. Effects of third trimester counseling on pregnancy weight gain, birthweight, and breastfeeding among urban poor women in Bangladesh. *Food and Nutrition Bulletin* 2012;33(3):194-201.
112. Kafatos AG, Vlachonikolis IG, Codrington CA. Nutrition during pregnancy: the effects of an educational intervention program in Greece. *American Journal of Clinical Nutrition* 1989;50(5):970-79.
113. Mclaughlin JJ, Altermeier WA, Christensen MJ, et al. Randomized trial of comprehensive prenatal care for low-income women: effect on infant birthweight. *Pediatric* 1992;89(128)
114. Jahan K, Roy SK, Seema M, et al. Short-term nutrition education reduces low birthweight and improves pregnancy outcomes among urban poor women in Bangladesh. *Food and Nutrition Bulletin* 2014;35(4):414-21.
115. Kramer M, Kakuma R. Energy and protein intake in pregnancy (Review). *Cochrane Database of Systemic Reviews* 2003(4):CD000032.
116. WHO. Balanced energy and protein supplementation during pregnancy 2017 [cited 2018 27 May]. Available from: http://www.who.int/elena/titles/energy_protein_pregnancy/en/.
117. Butte NF, King JC. Energy requirements during pregnancy and lactation. *Public Health Nutrition* 2005;8(7a)
118. Walker SP. Nutritional issues for women in developing countries. *Proceedings of the Nutrition Society* 1997;56:345-56.
119. Mridha MK, Matias SL, Chaparro CM, et al. Lipid-based nutrient supplements for pregnant women reduce newborn stunting in a cluster-randomized controlled effectiveness trial in Bangladesh. *American Society for Nutrition* 2016;103:236-49.
120. Adu-Afarwuah S, Lartey A, Okronipa H, et al. Lipid-based nutrient supplement increases the birth size of infants of primiparous women in Ghana. *American Journal of Clinical Nutrition* 2015;101:835–46.
121. Adu-Afarwuah S, Lartey A, Okronipa H, et al. Maternal Supplementation with Small-Quantity Lipid-Based Nutrient Supplements Compared with Multiple Micronutrients, but Not with Iron and Folic Acid, Reduces the Prevalence of Low Gestational Weight Gain in Semi-Urban Ghana: A Randomized Controlled Trial. *The Journal of Nutrition* 2017;147:697–705.
122. Ashorn P, Alho L, Ashorn U, et al. The impact of lipid-based nutrient supplement provision to pregnant women on newborn size in rural Malawi: a

randomized controlled trial. *American Journal of Clinical Nutrition* 2015;101:387–97.
123. Johnson W, Darboe MK, Sosseh F, et al. Association of prenatal lipid-based nutritional supplementation with fetal growth in rural Gambia. *Maternal & child nutrition* 2016;13:e12367. doi: 10.1111/mcn.12367
124. WHO. Daily iron and folic acid supplementation during pregnancy 2017 [Available from: http://www.who.int/elena/titles/daily_iron_pregnancy/en/ accessed 29 May 2018.
125. Palma S, Perez-Iglesias R, Prieto D, et al. Iron but not folic acid supplementation reduces the risk of low birthweight in pregnant women without anaemia: a case–control study. *J Epidemiol Community Health* 2008;62:120–24. doi: 10.1136/jech.2006.052985
126. Cogswell ME, Parvanta I, Ickes L, et al. Iron supplementation during pregnancy, anemia, and birth weight: a randomized controlled trial. *American Journal of Clinical Nutrition* 2003;78(773–81)
127. Peña-Rosas J, De-Regil L, Garcia-Casal M, et al. Daily oral iron supplementation during pregnancy. *Cochrane Database of Systematic Reviews* 2015(7):CD004736.
128. Haider BA, Bhutta ZA. Multiple-micronutrient supplementation for women during pregnancy. *Cochrane Database of Systematic Reviews* 2017(4):CD004905. doi: 10.1002/14651858.CD004905.pub5
129. Osrin D, Vaidya A, Shrestha Y, et al. Effects of antenatal multiple micronutrient supplementation on birthweight and gestational duration in Nepal: double-blind, randomised controlled trial. *Lancet* 2005;365:955–62.
130. Fall CHD, Fisher DJ, Osmond C, et al. Multiple micronutrient supplementation during pregnancy in low-income countries: A meta-analysis of effects on birth size and length of gestation. *Food and Nutrition Bulletin* 2009;30(4 Suppl):S533–S46.
131. WHO. Multiple micronutrient supplementation during pregnancy 2017 [Available from: http://www.who.int/elena/titles/micronutrients_pregnancy/en/ accessed 29 May 2018.
132. Hodnett E, Fredericks S, Weston J. Support during pregnancy for women at increased risk of low birthweight babies (Review). *The Cochrane Library* 2010(6)
133. Lu MC, Tache V, Alexander GR, et al. Preventing low birth weight: is prenatal care the answer? *Journal of Psychosomatic Research* 1995;39(5):563–95.
134. Namazzi G, Okuga M, Tetui M, et al. Working with community health workers toimprove maternal and newborn health outcomes: implementation and scale-up lessons from eastern Uganda. *Global health action* 2017;4(sup4):1345495.
135. Hodnett ED, Fredericks S, Weston J. Support during pregnancy for women at increased risk of low birthweight babies. *Cochrane Database of Systematic Reviews* 2010(6):CD000198. doi: 10.1002/14651858.CD000198.pub2.
136. Paarlberg KM, Vingerhoets AJM, Passchier TJ, et al. Psychosocial Factors and Pregnancy Outcome: A Review With Emphasis on Methodological Issues. *Journal of Psychosomatic Research* 1995;39(5):563-95.
137. Lee AC, Kozuki N, Cousens S, et al. Estimates of burden and consequences of infants born small for gestational age in low and middle income countries with INTERGROWTH-21st standard: analysis of CHERG datasets. *BMJ* 2017;358(j3677)

138. National Institute of Population Research and Training (NIPORT), Mitra and Associates, ICF International. Bangladesh Demographic and Health Survey 2014. Dhaka, Bangladesh, and Rockville, Maryland, USA: NIPORT, Mitra and Associates, and ICF International, 2016.
139. Pelletier D, Shekar M, Du L, et al. The Bangladesh Integrated Nutrition Project. Effectiveness and lessons. Washington, DC: World Bank, 2005.
140. Victora CG, Barros FC, Assunção MC, et al. Scaling up maternal nutrition programs to improve birth outcomes: A review of implementation issues. *Food and Nutrition Bulletin* 2012;33(2)
141. The World Bank. World Development Indicators database 2018 [cited 2018 1 June]. Available from: http://databank.worldbank.org/data/views/reports/reportwidget.aspx?Report_Name=CountryProfile&Id=b450fd57&tbar=y&dd=y&inf=n&zm=n&country=BGD.
142. Bangladesh Bereau of Statistics (BBS). Statistical Pocketbook Bangladesh 2015: Bangladesh Bureau of Statistics, Ministry of Planning 2016.
143. Bangladesh National Portal. bangladesh.gov.bd [cited 2018 1 June]. Available from: https://bangladesh.gov.bd/site/page/fc63120c-63e9-406f-904a-48e399ca0f79/District Portals.
144. Bangladesh Bereau of Statistics (BBS). Report on Bangladesh Sample Vital Statistics 2016. Ministry of Planning, 2017.
145. Islam A. Population Momentum In Bangladesh: Centre for Policy Dialogue (CPD) 2000.
146. The World Bank. The World Bank Data 2018 [Available from: https://data.worldbank.org/indicator/SP.RUR.TOTL.ZS accessed 1 June 2018.
147. The World Bank. Leveraging Urbanization in Bangladesh 2015 [Available from: http://www.worldbank.org/en/country/bangladesh/brief/leveraging-urbanization-bangladesh accessed 1 June 2018.
148. The World Bank. The World Bank In Bangladesh: Overview 2018 [Available from: http://www.worldbank.org/en/country/bangladesh/overview accessed 31 May 2018.
149. Canosa CA. Intrauterine Growth Retardation in India and Bangladesh. *Intrauterine Growth Retardation* 1989;18
150. Dhar B, Mowlah G, Nahar S, et al. Birth-weight status of newborns and its relationship with other anthropometric parameters in a public maternity hospital in Dhaka, Bangladesh. *Journal of Health and Population Nutrition* 2002;20(1):36-41.
151. Christian P, lemm RK, Shamim AA, et al. Effects of vitamin A and b-carotene supplementation on birth size and length of gestation in rural Bangladesh: a cluster-randomized trial. *American Journal of Clinical Nutrition* 2013;97:188–94.
152. Klemm RDW, Merrill RD, Wu L, et al. Low-birthweight rates higher among Bangladeshi neonates measured during active birth surveillance compared to national survey data. *Maternal and Child Nutrition* 2013;11(4):583-94.
153. Arifeen SE, Black RE, Caulfield LE, et al. Infant growth patterns in the slums of Dhaka in relation to birth weight, intrauterine growth retardation, and prematurity. *American Journal of Clinical Nutrition* 2000;72:1010–7.
154. Persson LAk, Arifeen S, Ekstro¨m E-C, et al. Effects of Prenatal Micronutrient and Early Food Supplementation on Maternal Hemoglobin, Birth Weight, and

Infant Mortality Among Children in Bangladesh: The MINIMat Randomized Trial. *JAMA* 2012;307(19):2050-59.
155. Bangladesh Bureau of Statistics & unicef. National Low Birth Weight Survey of Bangladesh, 2003-2004. Dhaka, 2005.
156. Ahmed T, Roy SK, Alam N, et al. National Nutrition Programme Baseline Survey 2004 Report. Dhaka: ICDDR,B: Centre for Health and Population Research, 2005.
157. Rahman MS, Howlader T, Masud MS, et al. Association of Low-Birth Weight with Malnutrition in Children under Five Years in Bangladesh: Do Mother's Education, Socio- Economic Status, and Birth Interval Matter? *PloS one* 2016;11(6):e0157814. doi: 10.1371/journal.pone.0157814
158. Kamruzzaman M, Rabbani MG, Saw A, et al. Differentials in the prevalence of anemia among non-pregnant, ever-married women in Bangladesh: multilevel logistic regression analysis of data from the 2011 Bangladesh Demographic and Health Survey. *BMC women's health* 2015;15(54) doi: 10.1186/s12905-015-0211-4
159. Salim F, Begum N. Nutritional Status and Knowledge about Nutrition during Pregnancy among Pregnant and Postpartum Women. *Northern International Medical College Journal* 2015;6(2)
160. Ahmed F, Mahmuda I, Sattar A, et al. Anaemia and vitamin A deficiency in poor urban pregnant women of Bangladesh. *Asia Pacific J Clin Nutr* 2003;12(4):460-66.
161. Lindström E, Hossain MB, Lönnerdal B, et al. Prevalence of anemia and micronutrient deficiencies in early pregnancy in rural Bangladesh, the MINIMat trial. *Acta Obstetricia et Gynecologica Scandinavica* 2011;9(1):47-56.
162. USAID. Bangladesh National Anemia Profile: SPRING; [cited 2018 31 May]. Available from: https://www.spring-nutrition.org/sites/default/files/publications/anemia-profiles/spring_nap_bangladesh.pdf.
163. Ahmed F. Anaemia in Bangladesh: a review of prevalence and aetiology. *Public Health Nutrition* 2000;3(4):385-93.
164. Hossain B, Sarwar T, Reja S, et al. Nutritional Status of Pregnant Women in Selected Rural and Urban Area of Bangladesh. *Journal of Nutrition and Food Science* 2013;3:219. doi: 10.4172/2155-9600.1000219
165. Islam MZ, Akhtaruzzaman M, Lamberg-Allardt C. Nutritional status of women in Bangladesh: comparison of energy intake and nutritional status of a low income rural group with a high income urban group. *Asia Pacific Journal of Clinical Nutrition* 2004;13(1):61-68.
166. Nahar S, Mascie-Taylor N, Begum HA. Impact of targeted food supplementation on pregnancy weight gain and birth weight in rural Bangladesh: an assessment of the Bangladesh Integrated Nutrition Program (BINP). *Public Health Nutrition:* 2008;12(8):1205–12.
167. Alam DS, Raaij van JMA, Hautvast JGAJ, et al. Energy stress during pregnancy and lactation: Consequences for maternal nutrition in rural Bangladesh. *European Journal of Clinical Nutrition* 2003;57(1):151-6.
168. Nahar Q, Choudhury S, Faruque MO, et al. Desirable Dietary Pattern for Bangladesh: National Food Policy Capacity Strengthening Programme, 2013.

169. Shamim AA, Mashreky SR, Ferdous T, et al. Pregnant Women Diet Quality and Its Sociodemographic Determinants in Southwestern Bangladesh. *Food and Nutrition Bulletin* 2016;37(1):14-26.
170. Piasecki AM. Maternal Nutrition Practices and Perceptions in Bihar, India. Emory University, 2013.
171. Alemayehu MS, Tesema EM. Dietary Practice and Associated Factors among Pregnant Women in Gondar Town North West, Ethiopia, 2014. *International Journal of Nutrition and Food Sciences* 2015;4(6):707-12. doi: 10.11648/j.ijnfs.20150406.27
172. Ogechi AC, Hamdalat OO. Factors Influencing the Nutritional Practice of Pregnant Women Living in a Semi-Urban Region of Ogun State, Nigeria. *Saudi Journal of Medicine* 2017;2(5):114-20. doi: 10.21276/sjm.2017.2.5.1
173. Shannon K, Mahmud Z, Azim A, et al. The Social and Environmental Factors Underlying Maternal Malnutrition in Rural Bangladesh: Implications for Reproductive Health and Nutrition Programs. *Health Care for Women International* 2008;29:826–40.
174. Nguyen PH, Kim SS, Sanghvi T, et al. Integrating Nutrition Interventions into an Existing Maternal, Neonatal, and Child Health Program Increased Maternal Dietary Diversity, Micronutrient Intake, and Exclusive Breastfeeding Practices in Bangladesh: Results of a Cluster-Randomized Program Evaluation. *The Journal of Nutrition* 2017 doi: 10.3945/jn.117.257303.
175. Nguyen PH, Sanghvi T, Kim SS, et al. Factors influencing maternal nutrition practices in a large scale maternal, newborn and child health program in Bangladesh. *PloS one* 2017;12(7):e0179873. doi: 10.1371/journal.pone.0179873
176. Wycliffe K. Social Factors Influencing Nutrition Status of Expectant Women Admitted At Pumwani Maternity Hospital, Nairobi, Kenya. *International Journal of Science and Research (IJSR)* 2013;4(10):533-35.
177. Zerfu TA, Umeta M, Baye K. Dietary habits, food taboos, and perceptions towards weight gain during pregnancy in Arsi, rural central Ethiopia: a qualitative cross-sectional study. *Journal of Health, Population and Nutrition* 2016;35(22) doi: 10.1186/s41043-016-0059-8
178. Skinner A-L. Pregnancy outcome in South Asian women: Factors affecting diet and nutrition, 2012.
179. Haddad L, Peña C, Nishida C, et al. Food Security and Nutrition Implications of Intrahousehold Bias: A Review of Literature. Washington DC: Food Consumption and Nutrition Division 1996.
180. Haddad L. Women's status: Levels, determinants, consequences for malnutrition, interventions and policy. 1999.
181. Gibbs C, Wendt A, Peters S, et al. The impact of early age at first childbirth on maternal and infant health. *Paediatrics Perinatal Epidemiology* 2012;26(Suppl 1)
182. Yu SH, Mason J, Crum J, et al. Differential effects of young maternal age on child growth. *Global health action* 2016;9(31171)
183. IMF. Bangladesh: Poverty Reduction Strategy Paper. Washington, D.C.: International Monetary Fund, 2005.
184. Habiba U, Abedin MA, Hassan AWR, et al. Food Security and Risk Reduction in Bangladesh. Tokyo, Japan: Springer 2015.
185. Chen Y, Lu C. A Comparative Analysis on Food Security in Bangladesh, India and Myanmar. *Sustainability* 2018;10(405) doi: 10.3390/su10020405

186. Akter S, Basher SA. The impacts of food price and income shocks on household food security and economic well-being: Evidence from rural Bangladesh. *Global Environmental Change* 2014;25:150–62. doi: 10.1016/j.gloenvcha.2014.02.003
187. Faridi R, Wadood SN. An Econometric Assessment of Household Food Security in Bangladesh. *The Bangladesh Development Studies* 2010;XXXIII(3)
188. Hillbruner C, Egan R. Seasonality, household food security, and nutritional status in Dinajpur, Bangladesh. *Food and Nutrition Bulletin* 2008;29(3):221-31.
189. Zug S. Monga - Seasonal Food Insecurity in Bangladesh - Bringing the Information Together. *Journal of Social Studies* 2006;111
190. Stevens B, Watt K, Brimbecombe J, et al. The role of seasonality on the diet and household food security of pregnant women living in rural Bangladesh: a cross-sectional study. *Public Health Nutrition*;20(1):121–29.
191. Harris-Fry H, Azad K, Kuddus A, et al. Socio-economic determinants of household food security and women's dietary diversity in rural Bangladesh: a cross-sectional study. *Journal of Health, Population and Nutrition* 2015;33(2)
192. USAID. Bangladesh Nutrition Profile 2014 [cited 2018 2 June]. Available from: https://www.fantaproject.org/sites/default/files/download/Bangladesh-Nutrition-Profile-Mar2014.pdf.
193. Scaling Up Nutrition. Bangladesh, 2017.
194. USAID. Bangladesh: Nutrition Profile 2014 [cited 2018 2 June]. Available from: https://www.usaid.gov/sites/default/files/documents/1864/USAID-Bangladesh_NCP.pdf.
195. Hussain AMZ, Talukder M, Ahmed T. Nutrition Background Paper to inform the preparation of the 7th Five Year Plan, 2015.
196. Cesar G Victora, Linda Adair, Caroline Fall, et al. Maternal and child undernutrition: consequences for adult health and human capital. *Lancet* 2008;371:340-57.
197. Harris-Fry H, Shrestha N, Costello A, et al. Determinants of intra-household food allocation between adults in South Asia – a systematic review. *International Journal for Equity in Health* 2017;16(107) doi: DOI 10.1186/s12939-017-0603-1
198. Boyd NR, Jr., Windsor RA. A meta-evaluation of nutrition education intervention research among pregnant women. *Health education quarterly* 1993;20(3):327-45. [published Online First: 1993/01/01]
199. Gresham E, Collins CE, Mishra GD, et al. Diet quality before or during pregnancy and the relationship with pregnancy and birth outcomes: the Australian Longitudinal Study on Women's Health. *Public Health Nutrition* 2016;19(16):2975–83.
200. Chowdhury M, Raynes-Greenow C, Alam A, et al. Making a balanced plate for pregnant women to improve birthweight of infants: a study protocol for a cluster randomised controlled trial in rural Bangladesh. *BMJ Open* 2017;7(e015393)
201. Sen B, Ali Z. Spatial Inequality in Social Progress in Bangladesh. *The Bangladesh Development Studies* 2009;XXXII(2)
202. Bangladesh District Level Socio-demographic and Health Care Utilization Indicators: National Institute of Population Research and Training (NIPORT), Dhaka, Bangladesh, MEASURE Evaluation, UNC-CH, USA, and ICDDR,B, 2011.

203. West Jr PK, Shamim AA, Mehra S, et al. Effect of Maternal Multiple Micronutrient vs Iron–Folic Acid Supplementation on Infant Mortality and Adverse Birth Outcomes in Rural Bangladesh: The JiVitA-3 Randomized Tria. *JAMA* 2014;312(24):2649-58.
204. Zeng L, Cheng Y, Dang S, et al. Impact of micronutrient supplementation during pregnancy on birth weight, duration of gestation, and perinatal mortality in rural western China: double blind cluster randomised controlled trial. *BMJ* 2008;337(7680):1211 - 15.
205. Shaheen R, Francisco Ad, Arifeen SE, et al. Effect of prenatal food supplementation on birth weight: an observational study from Bangladesh1–. *The American journal of clinical nutrition* 2006;83:1355–61.
206. Contento IR. Nutrition education: linking research, theory, and practice. *Asia Pac J Clin Nutr* 2008;17(1):176-79.
207. Fishbein M, Yzer MC. Using Theory to Design Effective Health Behavior Interventions. *Communication Theory* 2003;13(2):164-83.
208. Sanghvi T, Haque R, Roy S, et al. Achieving behaviour change at scale: Alive & Thrive's infant and young child feeding programme in Bangladesh. *Maternal & child nutrition* 2016;12(Suppl. 1):141-54.
209. Ahmed SM, Hossain MA, Chowdhury AMR, et al. The health workforce crisis in Bangladesh: shortage, inappropriate skill-mix and inequitable distribution. *Human Resources for Health* 2011;9(3)
210. WHO. Community health workers: What do we know about them? Geneva, 2007.
211. Alive & Thrive. Alive & Thrive's approach and results in Bangladesh: Rapid improvements in infant and young child feeding practices resulting from a large-scale program, 2015.
212. Alam A, Rasheed S, Khan NU, et al. How can formative research inform the design of an iron-folic acid supplementation intervention starting in first trimester of pregnancy in Bangladesh? *BMC public health* 2015;15(374)
213. Bhutta ZA, Das JK, Rizvi A, et al. Evidence-based interventions for improvement of maternal and child nutrition: what can be done and at what cost? *The Lancet* 2013;382:452-77.
214. World Health Organization. The World Health Report: 2005: Make every mother and child count. Geneva, 2005.
215. Abu-Saad K, Fraser D. Maternal Nutrition and Birth Outcomes. *Epidemiologic Reviews* 2010;32
216. Ho A, Flynn AC, Pasupathy D. Nutrition in pregnancy. *Obstetrics, Gynaecology and Reproductive Medicine* 2016;26(9):259-64.
217. Hanson MA, Bardsley A, De-Regil LM, et al. The International Federation of Gynecology and Obstetrics (FIGO) recommendations on adolescent, preconception, and maternal nutrition: "Think Nutrition First". *International Journal of Gynecology and Obstetrics* 2015;131(s4):s213-s53.
218. Reinhard I, Wijayaratne KBS. The Use of Stunting and Wasting as Indicators for Food Insecurity and Poverty. Integrated Food Security Programme, Trincomalee. Sri Lanka, 2000.
219. Gittelsohn J, Vastine AE. Sociocultural and Household Factors Impacting on the Selection, Allocation and Consumption of Animal Source Foods: Current Knowledge and Application. *The Journal of nutrition* 2003;133:4036S–41S.

220. Paterson H, Hay-Smith EJC, Treharne GJ. Women's experiences of changes in eating during pregnancy: A qualitative study in Dunedin, New Zealand. *New Zealand College of Midwives Journal* 2016(52)
221. Raman S, Nicholls R, Ritchie J, et al. Eating soup with nails of pig: thematic synthesis of the qualitative literature on cultural practices and beliefs influencing perinatal nutrition in low and middle income countries. *BMC pregnancy and childbirth* 2016;16(192)
222. Bianchi CM, Huneau J-F, Le Goff G, et al. Concerns, attitudes, beliefs and information seeking practices with respect to nutrition-related issues: a qualitative study in French pregnant women. *BMC pregnancy and childbirth* 2016;16(306)
223. Patton M. Qualitative evaluation and research methods. Beverly Hills, CA: Sage 1990:169-86.
224. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology* 2006;3(2):77-101.
225. Piirainen T, Isolauri E, Lagstro¨m H, et al. Impact of dietary counselling on nutrient intake during pregnancy: a prospective cohort study. *British Journal of Nutrition* 2006;96:1095–104.
226. de Sa J, Bouttasing N, Sampson L, et al. Identifying priorities to improve maternal and child nutrition among the Khmu ethnic group, Laos: a formative study. *Maternal & child nutrition* 2013;9(4):452–66.
227. Cramp A, Bray S. A prospective examination of exercise and barrier self-efficacy to engage in leisure-time physical activity during pregnancy. *Annals of behavioral medicine* 2009;37(3):325-34. doi: 10.1007/s12160-009-9102-y
228. Doyle I-M, Spallek J. Determinants of dietary behaviour during pregnancy. *Public Health Forum* 2016;24(3):231–33.
229. Kavle JA, Mehanna S, Saleh G, et al. Exploring why junk foods are 'essential' foods and how culturally tailored recommendations improved feeding in Egyptian children. *Maternal & child nutrition* 2015;11:346–70.
230. Nguyen PH, Frongillo EA, Sanghvi T, et al. Engagement of Husbands in a Maternal Nutrition Program Substantially Contributed to Greater Intake of Micronutrient Supplements and Dietary Diversity during Pregnancy: Results of a Cluster-Randomized Program Evaluation in Bangladesh. *The Journal of Nutrition* 2018;148:1–12.
231. Liu N, Mao L, Sun X, et al. The effect of health and nutrition education intervention on women's postpartum beliefs and practices: a randomized controlled trial. *BMC public health* 2009;9(45) doi: https://doi.org/10.1186/1471-2458-9-45
232. Oniang'o R, Mukudi E. Nutrition and Gender. In Nutrition: A Foundation for Development. Geneva, 2002.
233. USAID. Engaging Men to Improve Nutrition and Gender Equality, 2017.
234. FAO. Gender and Nutrition (draft) 2012 [cited 2018 26 May]. Available from: http://www.fao.org/fileadmin/user_upload/wa_workshop/docs/Gender-Nutrition_FAO_IssuePaper_Draft.pdf.
235. Nichter M, Nichter M. Anthropology and international health: Asian case studies: Gordon & Breach 1996.
236. Chowdhury S, Hossain SA, Halim A. Assessment of quality of care in maternal and newborn health services available in public health care facilities in Bangladesh. *Bangladesh Medical Research Council Bulletin* 2009;35:53-56.

237. Ministry of Health and Family Welfare, Government of People's Republic of Bangladesh. Maternal Health Standard Operating procedures (SOP), 2013.
238. Islam F, Rahman A, Halim A, et al. Perceptions of health care providers and patients on quality of care in maternal and neonatal health in fourteen Bangladesh government healthcare facilities: a mixed-method study. *BMC Health Services Research* 2015;15(1):237. doi: 10.1186/s12913-015-0918-9
239. Saha KK, Billah M, Menon P, et al. Bangladesh National Nutrition Services: Assessment of Implementation Status. Washington, DC: World Bank 2015.
240. WHO. WHO guidelines on health policy and system support to optimize community based health worker programmes 2018 [cited 2018 26 May]. Available from: http://www.who.int/hrh/community/en/.
241. Bhutta ZA, Das JK, Rizvi A, et al. Evidence-based interventions for improvement of maternal and child nutrition: what can be done and at what cost? *The Lancet*;382(9890):452-77. doi: 10.1016/s0140-6736(13)60996-4
242. ProPAN: Process for the Promotion of Child Feeding. Washington, D.C. : PAHO, 2013.

CHAPTER 6

PAPER 4

Household Food Security and Birth Size of Infants: Analysis of the Bangladesh Demographic and Health Survey 2011

Chowdhury M, Dibley MJ, Alam A, Huda TM, Raynes-Greenow C.

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ORIGINAL RESEARCH

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CURRENT DEVELOPMENTS IN NUTRITION

Household Food Security and Birth Size of Infants: Analysis of the Bangladesh Demographic and Health Survey 2011

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Abstract

Background: More than one-third of the population in Bangladesh is affected by household food insecurity in a setting where child survival and well-being are under threat. The relation between household food security and birth size of infants is an important area to explore given its explicit effect on mortality and morbidity.

Objective: Our study aims to estimate the association between household food security and birth size of infants.

Methods: For the analysis we used a nationally representative cross-sectional survey of 8753 households with a live birth between 2006 and 2011, collected under the Bangladesh Demographic and Health Survey (BDHS) 2011. We investigated the association of small birth size with the following potential explanatory variables: sex of the child; birth interval; mother's age at birth, height, body mass index (BMI), anemia status, parity, previous pregnancy loss, antenatal care visits, exposure to television, and participation in health care decisions; cooking fuel; parents' education level; region; place of residence; and wealth index using Pearson's chi-square test. We then constructed a multivariable logistic regression model of birth size on food security after controlling for all potential confounders as well as the cluster sampling design. The odds ratio (OR) was reported for each of the covariates; a P value <0.05 was interpreted as statistically significant.

Results: A total of 1485 (17.3%) children were reported as small at the time of birth and more than one-third of households (35.7%) experienced some degree of food insecurity. Mothers from food-insecure households had 38% higher odds of having small-size infants compared to food-secure households (adjusted OR: 1.38; 95% CI: 1.19, 1.59; $P < 0.001$).

Conclusion: Household food security is one of the key factors associated with small birth size. Interventions to increase birth size should target women belonging to food-insecure households. *Curr Dev Nutr* 2018;2:nzy003.

Introduction

Birth size significantly impacts newborn survival and subsequent health and well-being. Low birth weight (LBW) (<2500 g) indirectly contributes to 60% of newborn mortality (1). Those who survive are at increased risk of developmental delays, cognitive and behavioral problems, subnormal growth, and diseases in later life (2–5). Therefore, preventing LBW may be an important consideration for countries in development transition.

Factors contributing to LBW are multidimensional and complex in nature and vary by geography (6). Findings from studies have suggested that several sociodemographic, reproductive, and nutritional factors contribute to LBW; however, the impact of household food security on LBW has yet to be examined (7–10). Household food security is a factor that is closely linked with household nutrition, which could impact on birth weight. There is scant evidence of a relation

Keywords: birth size, food security, perinatal nutrition, BDHS, Bangladesh

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Abbreviations used: ANC, antenatal care; BDHS, Bangladesh Demographic and Health Survey; EA, enumeration unit; LBW, low birth weight.

between household food insecurity and LBW, especially in low-income countries. Only one study conducted in the United States has shown that food-insecure women are 3 times more likely to give birth to LBW infants [OR: 3.2 (95% CI: 1.4, 7.2)] (11). However, the definition of food insecurity differs between developed and developing country contexts. In the United States, the NHANES III (1988–1994) reported that, among adults, food insecurity resulted in consumption of a less-healthy diet and deficiency in nutrients (12). In developed countries the prime concern is quality of food rather than quantity or accessibility, whereas for developing countries both quality and accessibility are issues. Despite the lack of evidence and understanding of the quantitative effects of food insecurity on birth weight in resource-poor settings, there is evidence that food insecurity worsens diet quality among women of childbearing age, reduces micronutrient intake, and reduces energy consumption by 50% (13). There is strong evidence that poor maternal nutrition during pregnancy leads to intrauterine growth restriction, and thus LBW (6, 14–17). More precisely, maternal nutrition affects the weight of the fetus during the last half or last trimester of pregnancy (17).

In Bangladesh, ~41% of households live in a food-insecure environment; although food insecurity is more prevalent among the poor, it extends to the higher-economic quintiles (18). Dietary diversity is reduced during pregnancy and the early postpartum period among food-insecure households. This is largely due to reductions in all types of animal-source foods, especially dairy products, eggs, meat, and fish (2). The average daily protein requirement in pregnancy is 71 g. Low maternal protein intake in the second and third trimesters is associated with decreased birth weight (3). In 2010, Bangladesh was ranked fourth in the global burden of LBW (19), and over half of Bangladeshi infants were born with LBW (20). Therefore, our aim is to investigate the association between household food security and infant's size at birth, which has not previously been examined in a low- and middle-income country. These findings are important for policy makers who are developing strategies to reduce LBW, and consider household food insecurity as one of the important determinants.

Methods

This study used data from the Bangladesh Demographic and Health Survey (BDHS) 2011, which was based on a 2-stage stratified sample of households. In stage 1, 600 enumeration units (EAs) were selected with a probability proportional to the EA size, giving 207 clusters in urban and 393 in rural areas. In stage 2, a systematic sample of 30 households on average was selected per cluster, from urban and rural areas separately, and for each of the 7 regions of Bangladesh. Reproductive histories were collected from all married women aged 12–49 y. The survey asked female respondents about all their births. In order to reduce recall bias, detailed information regarding childbirth was asked only for the children aged <60 mo (21). We used birth data for women who had singleton live births in the last 5 y preceding the survey for our analysis.

Variables

We examined infant birth size as the categoric outcome variable, 1 = small; 0 = not small. In the BDHS, direct measurement of birth weight is not available, because birth weight is unknown for many babies, particularly for those born at home. However, the survey collected information on mothers' perception of the size of the infants at birth, which was used as a proxy for birth weight; this is commonly done in developing countries (22). For brevity from here on we will refer to this as infant birth size. In the BDHS mothers ranked their children on a scale of "very small," "smaller than average," "average," "larger than average," and "very large" at birth. We considered "very small" and "smaller than average" as "small," and "average," "larger than average," and "very large" as "not small."

The main exposure variable was the household food security score. The World Food Summit in 1996 defined food security as "when all people, at all times, have physical and economic access to sufficient safe and nutritious food to meet their dietary needs and food preferences for a healthy and active life" (23). The BDHS used a broader definition specifying the availability of food and a person's access to it. The BDHS asked the following 5 questions to all ever-married women aged 15–49 y about the last 12 mo: *1*) how often they ate 3 square meals (full stomach meals) a day: *2*) how often they skipped entire meals; *3*) how often they personally ate less food; *4*) how often they or any family members had to eat grains other than rice (which is a staple food); and *5*) how often their family had to ask for food from relatives or neighbors. Each question was assigned a score ranging from 0 to 3, with 0 corresponding to "never," 1 to "rarely," 2 to "sometimes," and 3 to "mostly/often." The question about "square meals" was coded in reverse to be consistent with other items, in which higher frequency indicates more severe food insecurity. All the food-frequency responses were summed into a single score for each ever-married woman. The composite score ranged from a minimum of 0 to a maximum of 15, which was then classified into 4 categories: 0 = "food secure," 1–5 = "mild food insecurity," 6–10 = "moderate food insecurity," and 11–15 = "severe food insecurity" (21). We examined the internal consistency ("reliability") of the food security Likert questions that formed the food insecurity scale by calculating Cronbach's α.

We considered the relevant child, mother, and household level covariates as explanatory variables in our analysis. The child covariates included sex of the child, birth interval, and year and month of birth. The maternal covariates included mother's age at birth, height, BMI, anemia status, parity, any previous pregnancy loss, number of antenatal care (ANC) visits, education, participation in health care decision making, and exposure to television. The household level covariates included father's education, place of residence, region, access to clean cooking fuel, and wealth index.

We grouped together continuous variables using clinical and epidemiologic cut-offs and treated these as categoric variables by creating dummy variables with the lowest group serving as the reference group to check the validity of linearity assumption. For example, ANC visit and parity as category better fitted the model, thus we converted these into categoric variables. Based on WHO recommendation on the basic ANC model, the number of ANC visits was categorized into 3 groups: no visit, 1–3 visits, and ≥4 visits (24). We divided mother's parity into 3 categories: first birth, parity 1–4, and parity ≥5. For both parents' education the reference group we chose was the highest group (higher education group). The BDHS defines birth interval as the length of time between 2 successive live births, whereas the WHO recommendation is based on birth-to-pregnancy intervals (25). We calculated mother's age at birth by deducting the child's age from the mother's age

(self-reported). Height, BMI, and anemia status were the measures taken at the time of the interview. Any previous pregnancy with either stillbirth or abortion or miscarriage was termed as previous pregnancy loss. Considering the health risks, type of cooking fuel was categorized into clean fuel (electricity, liquid petroleum gas, natural gas, and biogas) and polluting fuel (coal, lignite, kerosene, charcoal, wood, straw or shrubs or grass, agricultural crop, animal dung, and others). In the BDHS, wealth is used as a measure of economic status, which is constructed using coefficients and assets, services, and amenities that are specific to urban and rural areas, thought to be correlated with a household's economic status (26). Wealth index was generated with a statistical procedure known as principal components analysis, which puts the individual households on a continuous scale of relative wealth known as the wealth index score. From this, the national-level wealth quintiles are obtained by assigning the wealth index score for each household member, ranking each person by his or her score, and then dividing the ranking into 5 equal categories, each comprising 20% of the population (21). We have created a year-month variable combining year of birth (e.g., 2010) with month of birth (e.g., 02), so a child born in Feruary 2010 would have a year-month variable value of 201002.

Statistical analysis

The BDHS 2011 used individual sampling weights to account for different sampling probabilities and different response rates. Since the sample is a 2-stage stratified cluster sample (household and cluster), sampling weights were calculated separately for each sampling stage and cluster based on sampling probabilities (21). For univariable and multivariable analysis we applied STATA's survey estimation procedures (svy command) in order to account for the 2-stage cluster sampling design. We constructed a table reporting unweighted frequencies of participants with weighted percentages and weighted proportion of outcomes for each level of the variables, i.e., child, mother, and household (**Table 1**).

We examined the data to see if a mother had >1 singleton birth in the data set, to adjust for common maternal and environmental factors influencing pregnancy outcomes; however, we found no such births in our data.

We constructed survey-weighted logistic regression models to specify the dichotomous dependent variable [small (yes = 1; no = 0)] as the function of a set of explanatory variables. The survey-weighted logit model reported estimates of model parameters after correcting the variance estimates, using information from the survey design. Univariable survey-weighted logistic regression reported crude ORs along with the 95% CI. Considering the large sample size and epidemiologic evidence, all variables, irrespective of statistical significance, were entered into the base model (multivariable survey-weighted logistic regression model) except mother's anemia status and birth interval. Mother's anemia status was assessed on a subsample of the population ($n = 2674$), and birth interval had 3095 missing values (mothers who had only one birth). Variables entered into the baseline model were checked for collinearity, which potentially can produce unstable estimates or nonconvergence. We investigated for any strong associations among the variables by finding the correlation between continuous variables and by cross-tabulating categoric variables. Parity and mother's age was found to be moderately correlated ($r = 0.7$) and the latter was excluded from the baseline model. All the continuous variables were checked for linearity assumption, in contrast to the models in which the specific variables were treated as categoric variables. The final decision was made based on the Akaike information criterion (AIC) and the Bayesian information criterion (BIC); the models with the lowest values of these 2 criteria were assumed to provide a better-fitting model. Nonsignificant variables (that were neither confounders nor otherwise needed in the model) were removed one at a time using a backward elimination process, starting with the least-significant overall P value to get the final model. We ruled out the possibility of any interaction between the main exposure (food security) and other variables by including interaction terms for birth month and region in the model; and with a backward elimination process, sequentially eliminated all insignificant interaction terms ($P > 0.001$), starting with the least-significant one. In the multivariable model, the adjusted OR with 95% CI was reported for all variables. Statistical significance was considered at $P < 0.05$ levels.

We have investigated the sensitivity of retrospective recall of household food security status by restricting the analysis to births occurring within 1 y of interview, the recall period for the food security questionnaire. We adjusted for season of birth by entering a year-month of birth variable and checked whether the effect of food security on small birth size is stronger. We classified the year-month of birth variable as lean-season (October–December) and nonlean-season births (January–September) to test the effect of seasonal food shortages on food security and birth size. Mothers who had been exposed to lean season in their third trimester were examined separately. As the lean season is predominantly a feature of some of the districts of the northwestern part of Bangladesh, we restricted our analysis to Rangpur (a region in the northwest) in a lean season in a separate model. The STATA 13 software package was used for all statistical analyses.

Results

There were 8753 children aged <5 y born between 2006 and 2011 who had birth size data in the BDHS 2011; of these, 8588 were singleton births. A total of 1485 (17.3%; 95% CI: 16.2%, 18.5%) children were reported as being born small by their mothers. The male:female sex ratio among the children was 51:49. The majority of the births (83%) had a birth interval of ≥2 y. The mean ± SD age of mothers at the time of pregnancy was 23 ± 6 y; almost a third of the mothers (32%) were in their teens and were having their first birth (28%). The mean ± SD height of mothers was 151 ± 6 cm; 13% of the mothers were short statured (<145 cm); more than a quarter of mothers (27%) were thin [BMI (kg/m^2) <18.5]; and close to half (45.3%) of the mothers had some degree of anemia at the time of the survey. Eighteen percent of the mothers had a history of pregnancy loss. Around two-thirds of the mothers reported having had an ANC visit in the recent pregnancy, but of them only 41% had ≥4 visits. The majority of the mothers were literate (80%); this rate was slightly higher than that of the fathers (70%). Sixty percent of mothers reported participating in maternal health care decisions either alone or with their husbands, and 58% were exposed to television. Almost 80% of mothers were living in rural areas, 44% belonged to the poorest families, and only 11.8% of the families cooked with clean fuel (Table 1).

More than a third of households in our sample (35.7%) experienced some degree of food insecurity in the 12 mo preceding the survey. A

TABLE 1 (*Continued*)

Factors	*n* (weighted)	Relative frequency, %	Mean ± SD	Small birth size,[2] %
Place of residence			N/A	
Urban	1915	22.2		15.0
Rural	6715	77.8		18.0
Cooking fuel			N/A	
Clean fuel	912	11.8		13.5
Polluting fuel	6819	88.2		18.2
Household wealth index			N/A	
Poorest	1727	20.0		19.4
Poorer	1727	20.0		18.9
Middle	1726	20.0		17.1
Richer	1727	20.0		17.0
Richest	1725	20.0		14.4

[1]Missing values for anemia, birth month, birth interval, ANC, cooking fuel, BMI, height, participation in healthcare decision, nutrition score, husband's education, and exposure to TV were 5914, 3842, 3095, 1343, 886, 190, 186, 146, 21, 6, and 2, respectively. ANC, antenatal care; N/A, not applicable.
[2]Small birth size is defined as birth size "small" and "not small."
[3]Thin, normal, and overweight are defined as BMI (in kg/m^2) <18.5, 18.5–24.9 and ≥25.0, respectively.
[4]Mild anemia is defined as hemoglobin concentrations 10.0–11.9 g/dL (nonpregnant) and 10.0–10.9 g/dL (pregnant), and moderate to severe anemia is defined as hemoglobin concentrations ≤9.0 g/dL (pregnant and nonpregnant).

high proportion of households experienced ≥1 of the specific conditions that were used to assess food insecurity; nearly 1 in 5 mothers did not eat 3 square meals/d (18.8%) or had skipped an entire meal (18.6%) in the previous 12 mo. More than one-fifth (22%) of the mothers ate less because there was not enough food available for them to eat during the 12 mo before the survey (Table 2). The Cronbach's α of 0.91 indicates a high level of internal consistency for the Likert scale used in the BDHS. The 5 questions in this questionnaire all reliably measure the same latent variable "feeling of food insecurity."

Table 3 shows that mothers from food-insecure households were 37% more likely to give birth to small infants compared to food-secure mothers (OR: 1.37; 95% CI: 1.20, 1.57; $P < 0.001$). Once adjusted for clustering and other variables in the model, the effect remained unchanged (OR: 1.37; 95% CI: 1.18, 1.59; $P < 0.001$). Compared to males, female infants had 41% higher odds of being smaller at birth (OR: 1.41; 95% CI: 1.24, 1.62; $P < 0.001$) after adjusting for other factors. Mother's parity was found to mitigate small birth size: compared to first birth there were lower odds of delivering small infants in subsequent births (OR: 0.81; 95% CI: 0.70, 0.94; $P = 0.006$). The results showed that the small size at birth was decreased by 6% (OR: 0.94; 95% CI: 0.91, 0.97; $P < 0.001$) for every additional ANC visit. We observed a significant association between birth size and geographical region. Mothers from Chittagong and Sylhet regions had higher odds of having small infants compared to those from Barisal (OR: 1.62; 95% CI: 1.21, 2.18; $P = 001$ and OR: 1.71; 95% CI: 1.31, 2.24; $P < 0.001$ for Chittagong and Sylhet, respectively). In the subgroup analysis, ANC visit appeared low among mothers of Sylhet and Chittagong (not shown in the table).

The relation between food security and birth size was similar in the interview year and the preceding years, indicating that the food security status of households remained mostly unchanged over the previous 5-y period. We observed only a small increase in the effect of food security on birth size (7%) when the model was adjusted for year-month of birth variable. Similarly, we did not find any change in effect of food security on birth size when adjusted for lean season (mothers exposed to lean season in their third trimester). We also could not establish any effect of lean season on birth size even in the most vulnerable region affected by seasonal food production variation (Rangpur). Some of the other regions were found to be at risk of having more small-size infants (Chittagong and Sylhet). The odds of small birth size were significantly higher in both food-insecure poor households (OR: 1.39; 95% CI: 1.11, 1.76; $P = 0.005$) and food-insecure nonpoor households (OR: 1.32; 95% CI: 1.08, 1.62; $P = 0.007$) compared to the respective food-secure groups. We observed a gradient in the rate of small birth size along the wealth quintiles; however, there was no evidence of an association between wealth and birth size after controlling for food security.

Discussion

The prevalence of small birth size in the study sample was 17.3%, which varied by household food security status. The odds of having smaller infants were higher for food-insecure households, female children, lower birth orders, mothers who had fewer ANC visits, and those who were living in Chittagong or Sylhet regions. The other plausible determinants

TABLE 2 Household experience of specific food insecurity–related conditions

	Never, *n* (%)	Rarely (1–6 times this year), *n* (%)	Sometimes (7–12 times this year), *n* (%)	Mostly/often (few times each month), *n* (%)
Had 3 square meals	44 (0.7)	219 (3.5)	219 (14.0)	5052 (81.8)
Skipped entire meals	5047 (81.9)	793 (12.6)	242 (3.8)	105 (1.6)
Ate less food	4827 (78.4)	878 (13.8)	346 (5.7)	136 (2.1)
Ate wheat or rice substitute	5136 (83.6)	735 (11.6)	239 (3.8)	77 (1.1)
Asked for food from relatives or neighbors	4171 (66.6)	1338 (22.0)	491 (8.6)	187 (2.8)

TABLE 3 Effects of household food security on birth size of infants[1]

Factors	Crude OR (95% CI)	*P* value	Adjusted OR (95% CI)[2]	*P* value
Food security				
Food secure	Reference			
Food insecure	1.37 (1.20, 1.57)	<0.001**	1.38 (1.19, 1.59)	<0.001**
Sex of child				
Male	Reference			
Female	1.35 (1.19, 1.53)	<0.001**	1.41 (1.24, 1.62)	<0.001**
Birth interval	1.01 (0.98, 1.05)	0.47	—	
Mother's age at birth	1.00 (0.98, 1.01)	0.57	—	
Mother's height	0.99 (0.97, 1.00)	0.013*	—	
Mother's BMI	0.97 (0.95, 0.98)	<0.001**	—	
Mother's anemia status				
No anemia	Reference			
Mild anemia	0.95 (0.74, 1.23)	0.72	—	
Moderate to severe anemia	1.11 (0.71, 1.74)	0.64	—	
Parity				
First birth	Reference			
Subsequent births	0.94 (0.81, 1.08)	0.35	0.81 (0.70, 0.94)	0.006*
Previous pregnancy loss				
No	Reference			
Yes	1.20 (1.01, 1.43)	0.035*	—	
ANC visit	0.93 (0.90, 0.96)	<0.001**	0.94 (0.91, 0.97)	<0.001**
Mother's education				
No education	1.85 (1.37, 2.50)	<0.001**	—	
Primary	1.64 (1.21, 2.23)	0.002*	—	
Secondary	1.64 (1.22, 2.21)	0.001*	—	
Higher	Reference			
Mother's participation in health care decision				
No	Reference			
Yes	0.81 (0.71, 0.93)	0.003*	—	
Mother's exposure to television				
Not at all	Reference			
≤1 time/wk	0.96 (0.83, 1.10)	0.55	—	
Father's education				
No education	1.49 (1.18, 1.90)	0.001*	—	
Primary	1.40 (1.12, 1.75)	0.003*	—	
Secondary	1.31 (1.03, 1.67)	0.031*	—	
Higher	Reference			
Region				
Barisal	Reference			
Chittagong	1.64 (1.23, 2.20)	<0.001**	1.62 (1.21, 2.18)	0.001*
Dhaka	1.23 (0.93,1.63)	0.14	1.20 (0.90, 1.60)	0.21
Khulna	1.20 (0.90, 1.61)	0.22	1.10 (0.81, 1.49)	0.54
Rajshahi	1.22 (0.90, 1.65)	0.19	1.13 (0.83, 1.54)	0.45
Rangpur	1.00 (0.74, 1.35)	0.98	1.00 (0.73, 1.37)	1.00
Sylhet	1.78 (1.36, 2.32)	<0.001**	1.71 (1.31, 2.24)	<0.001**
Place of residence				
Urban	Reference			
Rural	1.25 (1.05, 1.48)	0.01*	—	
Cooking fuel				
Clean fuel	Reference			
Polluting fuel	1.43 (1.11, 1.84)	0.005*	—	
Household wealth index				
Poorest	1.43 (1.15, 1.78)	0.001*	—	
Poorer	1.39 (1.11, 1.73)	0.004*	—	
Middle	1.23 (0.99, 1.53)	0.06	—	
Richer	1.22 (0.97, 1.52)	0.09	—	
Richest	Reference			

[1] *Significant at $P < 0.05$; **Significant at $P < 0.001$. ANC, antenatal care.
[2] The multivariable model was adjusted for sex of child, parity, ANC visit, and region.

not found significant in this paper were mother's age at birth, height, BMI, anemia status, birth interval, previous pregnancy loss, exposure to television, and participation in health care decisions, and the cooking fuel used in the household; and both parents' education; place of residence; and household wealth status.

We found that the children belonging to food-insecure households were more likely to be small at birth than those belonging to food-secure households. It is well established that household food security is strongly associated with child nutrition. A study conducted among 6858 urban poor children in Kenya found that the risk of stunting increased by 12% among children from food-insecure households (27). Infants in food-insecure households in Bangladesh were found to receive poor-quality feeding between the ages of 6 and 12 mo ($n = 1343$) compared to infants in food-secure households (28). Women are more vulnerable to food insecurity; they may reduce their intake of certain foods to cope with household food insufficiency and to protect other family members, especially children (13). Food insecurity in terms of food shortage imposes additional stress on pregnant women (29). Pregnant women from food-insecure households had almost 3 times higher odds of having prenatal depressive symptoms compared to food-secure women (30). Reduced nutrient intake during pregnancy due to food shortage in conjunction with depression results in poor placental development and reduced nutrient transfer from the mother to the fetus (27, 31). And any such nutritional insult in pregnancy results in suboptimal fetal growth, leading to small birth size (or LBW) (6, 7).

Food insecurity can be chronic or transitory for some households. The transitory food-insecure do not consume adequate food during the lean season as a result of production losses or price hikes (32). Monga, a period of seasonal food insecurity in Bangladesh, is defined by lack of access to food due to loss of income preceding a major harvest between mid-September and mid-November (33). In our analysis we did not find any association between monga and food security or birth size, even in the most monga-prone regions, which might be the result of interventions to dampen seasonal price hikes and increase nonfarm income in those regions. Over the past 2 decades seasonal price hikes have been halved by the expansion of the harvesting season and the introduction of high-yielding varieties of rice (34).

In 2007–2008, Bangladesh experienced soaring prices of staple cereals, which threw millions into the urgent-hunger category (35). However, our data failed to demonstrate any evidence of an association between food security status of households or risk of small birth size at specific birth years.

Our findings suggested a significant regional variation in Bangladesh, with 2 regions, Sylhet in the north and Chittagong in the south, showing an increased risk of small birth size. This finding is not surprising for Sylhet, which has historically low ANC coverage, low child nutrition, and high neonatal mortality (36). On the other hand, Chittagong is doing well in 2 out of 3 of these measures. This difference cannot be explained by the economic situation either. The incidence of poverty is lower in those regions compared to the national level (31.5% national compared to 26.2% in Chittagong and 28.1% in Sylhet) (37). The probable explanation could be the challenges people face in accessing health care services due to the difficult topography (hilly areas and wetlands).

In this study, it is apparent that food security status was more efficient in predicting small birth size than was wealth status. We did not find any association between wealth status and birth size when controlling for food security, although wealth status was a strong predictor of food security and birth size.

The strength of our study is that it is based on a nationally representative sample survey that used a standardized methodology, and is able to examine geographic or regional variations in birth size. This is the first study, to our knowledge, to investigate the impact of household food security on birth size of infants in Bangladesh. The main limitation of the DHS data is that it is retrospective, covering the 5 y preceding the survey for almost all indicators except food security. For food security indicators, the recall period was 1 y prior to the interview; however, we included children born in the last 5 y. Therefore, we restricted our analysis to the births in the last year (coinciding with the food security recall period) and found no difference in coefficients from earlier years, indicating that the food security of most of the families seems not to have changed over the 5-y period. However, the sensitivity analysis (although useful and reassuring) does not completely fix the misaligned temporality, because restricting the analysis to births within 1 y of interview means that some of these births occurred before the full food security exposure period was completed. The second limitation is that the data could not establish significant seasonal variation in food insecurity, especially major trends, e.g., the food shortages of 2007–2008 and seasonal food shortages. As it was a nationwide survey, this study could not capture the seasonal effects of food insecurity on birth size, which are localized in several districts in northwestern Bangladesh and areas adjacent to rivers subject to flooding (38, 39). The third limitation is that due to unavailability of data, we could not examine the already well-known relation between gestational age and birth size in our analysis. The fourth limitation is the lack of precise birth weight data. In Bangladesh, birth weight is often not measured due to the large number of home births. We used mothers' perceived size of infants at birth as a proxy for birth weight. Some studies have reported that perceived birth size was associated with birth weight (9, 40).

From these findings, we conclude that infants born to food-insecure households were more at risk of being smaller at birth, which was aggravated by less utilization of ANC. The first-time pregnant mothers and those from Sylhet and Chittagong were more vulnerable to giving birth to smaller infants. Infant size at birth is an important predictor of early-life survival and future growth, development, and productivity. The findings from the present study, therefore, emphasizing the need for a comprehensive intervention strategy to alleviate household food insecurity and increase health care utilization. Further investigation is necessary to identify the factors responsible for small birth size among primiparous mothers and mothers living in Sylhet and Chittagong, and to address them accordingly. Maternal and infant nutrition condition in Bangladesh is in a critical state and needs immediate intervention to protect mothers and their unborn children from the dire consequences of undernutrition.

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References

1. Black RE, Allen LH, Bhutta ZA, Caulfield LE, de Onis M, Ezzati M, Mathers C, Rivera J. Maternal and child undernutrition: global and regional exposures and health consequences. Lancet 2008;371:243–60.
2. Gupta ND, Deding M, Lausten M. The effect of low birth weight on height, weight and behavioral outcomes in the medium-run. Econ Hum Biol 2013;11(1):42–55.
3. Hack M, Klein NK, Taylor HG. Long-term developmental outcomes of low birth weight infants. Future Child 1995;5:176–96.
4. Fletcher JM. The medium term schooling and health effects of low birth weight: evidence from siblings. Econ Educ Rev 2011;30:517–27.
5. Goddeeris JH, Saigal S, Boyle MH, Paneth N, Streiner DL, Stoskopf B. Economic outcomes in young adulthood for extremely low birth weight survivors. Pediatrics 2010;126:e1102–e8.
6. Kramer MS. Determinants of low birth weight: methodological assessment and meta-analysis. Bull World Health Organ 1987;65:663–737.
7. Kabir A, Merrill RD, Shamim AA, Klemn RDW, Labrique AB, Christian P, West Jr KP, Mohammed N. Canonical correlation analysis of infant's size at birth and maternal factors: a study in rural northwest Bangladesh. PloS One 2014;9:e94243.
8. Hosain GMM, Chatterjee N, Begum A, Saha SC. Factors associated with low birthweight in rural Bangladesh. J Trop Pediatr. 2005;52(2):87–91.
9. Khanal V, Sauer K, Karkee R, Zhao Y. Factors associated with small size at birth in Nepal: further analysis of Nepal Demographic and Health Survey 2011. BMC Pregnancy Childbirth 2014;14(32).
10. Sebayang SK, Dibley MJ, Kelly PJ, Shankar AV, Shankar AH, the SUMMIT study group. Determinants of low birthweight, small-for-gestational-age and preterm birth in Lombok, Indonesia: analyses of the birthweight cohort of the SUMMIT trial. Trop Med Int Health 2012;17:938–50.
11. Bryant BAE, Grobman WA, Amsden LB, Holl JL. Chronic stress and low birth weight neonates in a low-income population of women. J Am Coll Obstetr Gynecol 2007;109:331–8.
12. Bhattacharya J, Currie J, Haider S. Poverty, food insecurity, and nutritional outcomes in children and adults. J Health Econ 2004;23:839–62.
13. Ivers LC, Cullen KA. Food insecurity: special considerations for women. Am J Clin Nutr 2011;94(Suppl):S1740S–S.
14. Kader M, Perera NKP. Socio-economic and nutritional determinants of low birth weight in India. North Am J Med Sci 2014;6:302–8.
15. Boyd NR, Windsor RA. A meta-evaluation of nutrition education intervention research among pregnant women. Health Educ Behav 1993;20:327–45.
16. Girard AW, Olude O. Nutrition education and counselling provided during pregnancy: effects on maternal, neonatal and child health outcomes. Paediatr Perinat Epidemiol 2012;26(Suppl 1):S191–204.
17. Smith CA. Effects of maternal under nutrition upon the newborn infant in Holland (1944-1945). J Pediatr 1947;30:229–43.
18. Szabo S. The World Bank. 2014 [Available from: http://blogs.worldbank.org/endpovertyinsouthasia/bangladesh-likely-achieve-its-2021-universal-food-security-target.
19. Lee AC, Katz J, Blencowe H, Cousens S, Kozuki N, Vogel JP, Adair L, Baqui AH, Bhutta ZA, Caulfield LE, et al. National and regional estimates of term and preterm babies born small for gestational age in 138 low-income and middle-income countries in 2010. Lancet Glob Health 2013;1:e26–36.
20. Klemm RDW, Merrill RD, Wu L, Shamim AA, Ali H, Labrique A, Christian P, West KP Jr. Low-birthweight rates higher among Bangladeshi neonates measured during active birth surveillance compared to national survey data. Matern Child Nutr 2013;11:583–94.
21. National Institute of Population Research and Training (NIPORT), Mitra and Associates, ICF International. Bangladesh Demographic and Health Survey 2011. Dhaka, Bangladesh, and Rockville, MD: NIPORT, Mitra and Associates, and ICF International; 2013.
22. Islam MM. An evaluation of use of maternal recalled birth size as a proxy measure of birth weight. Matern Child Health J 2014;18:1462–70.
23. Pinstrup-Andersen P. Food security: definition and measurement. Food Sec 2009;1:5–7.
24. WHO recommendations on antenatal care for a positive pregnancy experience. Geneva: World Health Organization; 2016 [available from: http://apps.who.int/iris/bitstream/10665/250796/1/9789241549912-eng.pdf?ua=1.
25. Report of a WHO technical consultation on birth spacing. Geneva: World Health Organization; 2005 [available from: http://apps.who.int/iris/bitstream/10665/69855/1/WHO_RHR_07.1_eng.pdf.
26. Rutstein SO, Johnson K. The DHS Wealth Index. Calverton, MD: ORC Macro; 2004.
27. Diego MA, Field T, Hernandez-Reif M, Schanbergandez S, Kuhn C, Gonzalez-Quintero VH. Prenatal depression restricts fetal growth. Early Hum Dev 2009;85:65–70.
28. Saha KK, Frongillo EA, Alam DS, Arifeen SE, Persson LA, Rasmussen KM. Household food security is associated with infant feeding practices in rural Bangladesh. J Nutr 2008;138:1383–90.
29. Hadley C, Patil CL. Food insecurity in rural Tanzania is associated with maternal anxiety and depression. Am J Hum Biol 2006;18:359–68.
30. Hromi-Fiedler A, Bermúdez-Millán A, Segura-Pérez S, Pérez-Escamilla R. Household food insecurity is associated with depressive symptoms among low-income pregnant Latinas. Matern Child Nutr 2011;7:421–30.
31. King JC. A summary of pathways or mechanisms linking preconception maternal nutrition with birth outcomes. J Nutr 2016;Supplement:1437–44.
32. World Bank. What are the links between agricultural production and food security? http://siteresources.worldbank.org/INTWDRS/Resources/477365-1327599046334/8394679-1327606607122/WDR08_07_Focus_C.pdf (accessed Jul 25, 2017).
33. Zug S. Monga - seasonal food insecurity in Bangladesh - bringing the information together. J Soc Stud 2006;111.
34. Ministry of Food and Disaster Management & World Food Programme-Bangladesh. Food security in Bangladesh. Dhaka, Bangladesh; 2005.
35. Nath NC. Food Security of Bangladesh: Status, Challenges and Strategic Policy Options. 19th Biennial Conference of the BEA; Dhaka, Bangladesh; 2015.
36. National Institute of Population Research and Training (NIPORT), Mitra and Associates, ICF International. Bangladesh Demographic and Health Survey 2014. Dhaka, Bangladesh, and Rockville, MD: NIPORT, Mitra and Associates, and ICF International; 2016.
37. Bangladesh Bureau of Statistics. Report of the Household Income & Expenditure Survey 2010. Dhaka: Statics Division, Ministry of Planning; 2011.
38. Shaheen R, de Francisco A, El Arifeen S, Ekström E-C, Persson LÅ. Effects of prenatal food supplementation on birth weight: an observational study from Bangladesh. Am J Clin Nutr. 2006;83:1355–61.
39. Na M, Mehra S, Christian P, Ali H, Shaikh S, Shamim AA, Labrique AB, Klemm RD, Wu LSF, West KP Jr. Maternal dietary diversity decreases with household food insecurity in rural Bangladesh: a longitudinal analysis. J Nutr 2016;146:2109–16.
40. Titaley CR, Dibley MJ, Agho K, Roberts CL, Hall J. Determinants of neonatal mortality in Indonesia. BMC Public Health 2008;8:232.

CHAPTER 7

SUMMARY AND CONCLUSION

7.1 Key Findings and Potential Significance

This body of work provides novel information about the prevention of LBW among pregnant women in rural Bangladesh with an innovative behaviour change communication approach - the balanced plate nutrition education with a practical demonstration by *Shasthya Kormi* (CHW). The findings demonstrated a marked improvement in birthweight of infants and a reduction in the incidence of LBW compared to standard nutrition education in the study population. The effect of the intervention was greater among adolescent mothers than the older women. We believe the intervention investigated in this trial has important implications for public health nutrition programs to improve maternal nutrition and prevent low birth weight.

The study also found that the balanced plate nutrition education and practical demonstration helped women to learn about preparing a nutritionally balanced meal considering appropriate portion sizes and food diversity. Family decision makers, such as husbands and mothers-in-law, considered adopting a healthier diet as a condition to protect the newborn and mother from complications and achieve an improved pregnancy outcome. This study also highlights the assistance rural Bangladeshi pregnant women obtain from the active involvement of *Shasthya Kormi* in mobilising social support to bring change in household food distribution.

The study described in Chapter 6 also demonstrated that household food security was one of the key factors associated with small birth size. Mothers from food-insecure households had a greater risk of delivering smaller infants compared to food-secure households. Findings from the present study suggest that interventions to increase the birth size of infants should target women in food-insecure households.

7.2 Strengths of the Study

This study is the first to explore the effectiveness of community-based balanced diet nutrition education with a practical demonstration to pregnant women and their families to influence birthweight of infants in a resource-poor setting. An important aspect of the study was the formative study during the design phase followed by qualitative process evaluation. The findings of the formative research informed the design of the intervention and assessment tools. The process evaluation helped keep

the intervention on-track and understand and interpret the contextual factors of the impact of the intervention.

A key strength of the study was its cluster randomised controlled design with sufficient statistical power to detect changes in birthweight. The unblinded nature of the intervention was counterbalanced by using an objective outcome and blinding the participants and data collectors to the study aims and hypotheses. The probability of selection bias in this trial was low because of broad inclusion criteria and random allocation of the clusters to the trial treatments. The trial had a very high follow-up rate (93%). The analyses used an intention-to-treat principle and adjusted for unbalanced baseline factors and clustering. Our intervention was logistically simple and culturally appropriate, therefore, is ready for integration into existing health-care systems of Bangladesh. Furthermore, the intervention after contextual modification is appropriate for use in other LMICs.

Existing *Shasthya Kormi* who provide ANC to pregnant women delivered the balanced plate intervention, without having to involve any extra staff. The delivery strategy resonates with the recommendations of the Lancet series suggesting more efficient community-based delivery platforms for scaling up coverage of nutrition interventions potential to reach poor populations through demand creation and household service delivery.

The findings of this cluster RCT alone had a limited capacity to establish the causal pathway of nutrition education on birthweight. Therefore, we conducted a qualitative study to explore whether the balanced diet intervention caused any changes in dietary behaviour, and if so, what the changes were and how the changes occurred. We studied factors that re-shaped pregnant women's dietary behaviour from both individual and societal perspectives. We found that our practical demonstration of the balanced plate increased the women's and key family members' literacy and awareness of a balanced meal especially about appropriate portion sizes and dietary diversity as a means of safeguarding health of the newborn and the mother. The findings also revealed the role of social support, which can be mobilized through an active involvement of local CHWs, to bring about the pregnant women's self-motivation leading to dietary behavior changes.

7.3 Limitations of the Study

Results of the study are based on a carefully conducted cluster randomised controlled trial. However, we acknowledge some limitations. First, the *Shasthya Kormi*, who provided the intervention, also collected the birthweight data, which was the primary outcome. Measuring birthweight is a routine task of these staff, however as we blinded the *Shasthya Kormi* to the study outcome, we would expect non-differential bias. Secondly, use of the *Shasthya Kormi*'s catchment areas as clusters may have introduced some contamination, with the possibility of exchange of information between the *Shasthya Kormi*. If this had been the case, our results would have moved towards the null. To overcome this we only trained those *Shasthya Kormi* assigned to the intervention arm, and we conducted all refresher training in separate groups. These precautions helped to minimise the risk of contamination. Thirdly, we were not able to measure quantified food intake of the women in the trial and intra-household food distribution that might have proved evidence about the pathway to the impact we observed.

7.4 Implications for Policy

The results of the studies presented in this thesis provide an evidence base for reducing LBW in infants in low-income settings, who are at higher risk of mortality and morbidities. The robust evidence generated by this study should inform decision makers at the national, regional and global level who are developing policies for improved maternal nutrition with special attention to most vulnerable groups. The findings indicate that nutrition education with a demonstration of food preparation for pregnant women and family decision makers is effective in increasing birthweight and reducing LBW infants in rural Bangladesh. We observed a great impact from the intervention among adolescent mothers indicating that the intervention was more beneficial for this vulnerable group. The significant association of food insecurity and birth size underscores the need for targeted strategies for food insecure populations.

Culturally specific design of communication materials such as face-to-face demonstrations and visual presentation of a balanced meal, food prescriptions based on availability and cultural preferences, cheaper alternatives to expensive foods and engaging family decision-makers were the critical behaviour change techniques

leading to the adoption of the promoted dietary practices for pregnant women. The participatory nature of the intervention was indispensable in creating greater motivation among pregnant women to create a balanced meal. We also found that the CHWs played a critical role in generating social support for the pregnant women using their standing in the community by negotiating with husbands and mothers-in-law. The insights from the qualitative study will help to design nutrition behaviour change communications addressing the social dynamics around pregnant women's diet and self-efficacy to practice a balanced diet.

Amidst a huge shortage of human health resources, engaging CHWs in delivering dietary advice is an appropriate approach to complement the established ANC program. The intervention is simple, easy to implement and scalable through existing public and private community health infrastructure. Neither CHW-led balanced diet education nor practical demonstrations have previously been evaluated as a means to improve birthweight and prevent LBW in other LMICs. Bangladesh has a good community-based public healthcare infrastructure complemented by NGOs and private sectors to deliver nutrition services. The balanced intervention combined with social support could replace the standard nutrition advice for pregnant women.

Identifying populations at greatest risk of low birth weight, as well as those that are most likely to face barriers in access to health and nutrition interventions is a global priority and fundamental for the success of achieving the 30% reduction in the number of infants born with LBW by the year 2025. Nutrition programmes should be cognizant of the beliefs and preferences of women concerning their health, the unbalanced gender relations and power distribution within families. The inequalities between groups of women based on socio-economic status, age and residential segregation are also important. Therefore, the implementation of evidence-informed interventions will be more effective and have a greater impact on health equity if context-specific implementation reaches those who need it most. Bangladesh has a high burden of maternal malnutrition distributed across socio-economic classes and regions, which is partially caused by inequitable access to health and nutrition services. This research will help design efficient nutrition interventions that will benefit families at risk of having LBW. Mainstreaming the intervention into the existing community healthcare network would make the intervention more sustainable.

We conducted this research within the infrastructure of BRAC, the largest NGO in Bangladesh and the world, and there has a high likelihood of implementation at scale.

7.5 Future Research Directions

Community-based nutrition education to prevent LBW infants among pregnant women is a neglected area of research, and therefore there are very few studies to date that have evaluated the efficacy, acceptability and cost-effectiveness of such interventions in LMICs. Moreover, there is little understanding of how to deliver those interventions effectively in diverse settings and within the wide range of existing health systems. Areas of future research should include the following:

- Implementation research is needed to study the processes used in the implementation of intervention as well as the contextual factors that affect these processes, for policymakers and health system managers. The study should include follow-up measures beyond the intervention period to explore sustainability.
- An RCT that compares the efficacy of balanced plate nutrition education that includes food insecure pregnant women in both the intervention and control groups.
- A large-scale effectiveness trial that implements the balanced plate intervention within a health system compares it to standard care and includes measures for a cost-effectiveness analysis.
- A comprehensive RCT that examines the intermediary pathways of impact through dietary assessment, anthropometry and blood biometry.
- We have proposed a trial on preconception balanced plate intervention in adolescent girls to the National Health and Medical Research Council (NHMRC) 2018 round.

7.5 Conclusions

Our trial findings present a great opportunity to reduce the prevalence of LBW infants in Bangladesh by shifting tasks from skilled providers to community health workers. We recommend nutrition programmes add balanced diet education for pregnant women to improve the nutrition of the fetus, the first lap of the “first 1000 days” of life which is known as the “critical windows of opportunity” to ensure optimum fetal and child growth and development.

This research also shows that household food insecurity is the major driver for having smaller infants, which is fairly common among relatively wealthier families too. This finding suggests that nutrition-sensitive programmes are essential for ensuring sustainable food and nutrition security not only among the poor but also among the wealthier households.

The findings from the qualitative research indicate the importance of social support for pregnant women to successfully change their dietary behaviour. Besides knowledge, self-motivation and an enabling environment are critical for translating knowledge into action. Visual demonstration of a balanced plate can help women interpret portion size and food diversity enabling them to develop a self-strategy to steer their eating habits. Engaging men throughout the process of behaviour change might improve spousal communication and assure men's active participation in women's nutrition. Inequitable intra-household food allocation can be altered to increase pregnant women's share of nutritious foods in the family by mobilising the mothers-in-law's support.

Nutrition education with a pragmatic approach like a demonstration of a balanced plate of food in a community setting targeting pregnant women along with family decision makers would benefit women to adopt a healthier dietary habit. This intervention can also create a congenial in-utero environment for the fetus to optimally grow and thrive with full potential postpartum. In summary, this research recommends integration of balanced diet nutrition education during pregnancy with a social support programme irrespective of wealth status with special attention to food insecure households and adolescents to ensure better maternal nutrition and subsequent improvement in infant nutrition.

APPENDICES

Appendix 1: Unadjusted models

Birth outcomes	Adjusted difference or relative risk (95% CI)[a]	P value
Birth weight (g)		
Intervention	127.5 (11.1 - 243.9)	0.032
Comparison	Reference	
Low Birthweight		
Intervention	0.44 (0.25 - 0.75)	0.003
Comparison	Reference	

[a]Birthweight was analysed using linear regression, low birthweight (LBW) was analysed using binomial regression with a log link. All models were adjusted for clusters using generalized estimating equation (GEE) models assuming exchangeable correlation structure and applied sandwich estimator to standard errors.

Appendix 2. Consent form of the trial

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

Information regarding socio-economic and demographic condition will be collected from all enrolled pregnant women from both the control and intervention arms at the beginning of the project.

ID No: | | | | |

Day		Month		Year			

Date:

Pregnant woman's name: _____ Husband's name: _____

Upazila: _____ ☐ Name of Shasthya Shebika: _____ ☐

Union: _____ ☐ Name of Shasthya Kormi: _____ ☐

Village: _____ ☐ Name of PO: _____ ☐

Respondent:

1.1	Pregnant woman who received nutrition intervention
1.2	Pregnant woman who did not received nutrition intervention

INFORMED CONSENT

Assalamu Alaikum/Adab,

I work for an organization named, BRAC. It is known that during pregnancy women should take adequate diet for betterment of the infants and women themselves. To improve nutritional knowledge and practice and thus increase weight of the infants, the researchers are intended to implement a new initiative and are going to conduct some research in your locality. Under this research project, we will record information on pregnancy related issues from you. I assure you that, all information will be used for research purpose only and will be kept confidential.

You have every right to leave the interview at any time. In the circumstances, do you give your consent to collect information from you?

Has agreed ☐ 1 Has not agreed ☐ 2

INTERVIEWED BY: _____ SIGNATURE: _____

Appendix 3. Ethics approval for the trial from James P Grant School of Public Health, BRAC University (Bangladesh)

BRAC UNIVERSITY

JPG SCHOOL OF PUBLIC HEALTH
JAMES P. GRANT

KNOWLEDGE AND KNOW-HOW FOR HEALTH EQUITY

Date: 25 May, 2015

Ethics Reference No: *Please quote this ref on all correspondence*	**53**
Project Title:	**Making balanced plate for pregnant women to improve birth weight of infants: a cluster randomized controlled trial in rural Bangladesh**
Principle Investigator:	**Morseda Chowdhury**
Co Investigators:	**Michael J Dibley, Dr. Camille Raynes-Greenow, Ashraful (Neeloy) Alam**

Thank you for submitting your application which was considered by the James P Grant School of Public Health, BRAC University Ethical Review Committee (ERC). The following documents were reviewed:

1. Ethical Review Checklist
2. Research Proposal
3. Consent Form
4. Questionnaires

The Ethical Review Committee approves this study from an ethical point of view upon the addressing by the researchers of the concerns as raised by the ERC affiliates.

Approval is given for three years. Projects, which have not commenced within two years of original approval, must be re-submitted to ERC. You must inform ERC when the research has been completed.

Any serious adverse events or significant change which occurs in connection with this study and/or which may alter its ethical considerations must be reported immediately to the ERC.

Approval is given on the understanding that the 'Guidelines for Ethical Review' are adhered to.

Yours sincerely,

Professor Malabika Sarker
Acting Dean, Director of Research and Chair of ERC,
James P Grant School of Public Health,
BRAC University

68, Shahid Tajuddin Ahmed Sharani, Level-6, icddr,b Building, Mohakhali, Dhaka-1212, Bangladesh
Phone:880-2-9827501-4 Fax:880-2-8810383 http://sph.bracu.ac.bd; www.jpgsph.org

Appendix 4: Quantitative Questionnaire

MAKING A BALANCED PLATE FOR PREGNANT WOMAN TO IMPROVE DIETARY BEHAVIOUR OF MOTHER DURING PREGNANCY AND BIRTH WEIGHT OF INFANTS: A CLUSTER RANDOMISED CONTROLLED TRIAL IN RURAL BANGLADESH

This questionnaire will be used to collect data from all enrolled pregnant women at the end of the study from both intervention and control arms. The source of data will be SK's register.

ID No: | | | | |

Date:

Day		Month		Year			

Pregnant woman's name: _____Husband's name: _____

Upazila: _____ ☐ Name of Shasthya Shebika: _____ ☐

Union: _____ ☐ Name of Shasthya Kormi: _____ ☐

Village: _____ ☐ Name of PO: _____ ☐

Respondent: 1.1 Pregnant woman who received nutrition intervention
1.2 Pregnant woman who did not received nutrition intervention

Sl No	Indicator	Answer	
	Date of pregnancy identification		
1.2	Last menstrual period (LMP)		
1.3	Expected date of delivery (EDD)		
1.4	Dates of ANC visit by SK		
1.5	Dates of ANC at facilities		
1.6	Date of abortion		
1.7	Date of delivery		
1.8	Place of delivery Facility Home	 Govt. Hospital NGO/private hospital BRAC Health Center BRAC CSBA Doctor Nurse Other CSBA SACMO Medical assistant	

		Shasthya Shebika Trained TBA (BRAC) Other (untrained)	
1.9	Mode of delivery	Vaginal C - section	
	Delivery outcome	Live birth Still birth	
	Complete TT vaccination		
	Received Albendazol		
	Month of receiving Albendazole		
	Time of starting IFA tablets		
	Number of IFA tablets received		
	PNC	Within 24 hours Within 48 hours Within 72 hours After 72 hours	
	Pregnancy related complication	During pregnancy During delivery During postpartum	
	Received treatment from facility/provider		
	Maternal death	Home On transit Facility	
	Cause of death		
	Neonatal Health		
	Gestational age	< 37 wks ≥37 wks	
	Birth weight	Taken Not taken	
	Time of birth weighing	Within 24 hrs Within 48 hrs Within 72 hrs	
	Essential newborn care	Dried and wrapped Initiation of breast feeding within 1 hour of birth	
	Complication	Birth asphyxia Neonatal sepsis Others	
	Date of neonatal death		

	Cause of death		

Section 2: Reproductive History

Sl No	Questions	Answer	Code	Skip to
2.1	How many children have you ever conceived? (Total number of conception including current one)	_____Number Don't know	 99	
2.2	*Outcome of conception	Live birth _____number Abortion _____number MR _____ number Still birth _____ number IUD _____ number	1 2 3 4 5	
2.3	What is the age of last child?	___ ___year___ ___month		
2.4	*How many of your live children have died and at what ages?	None Neonate (0-28 days) ___ number Within one year ___ number Within two year ___ number Within five year ___ number Others: _____ (Explain) Total Number ___		

* Multiple answers

Appendix 5: Qualitative Questionnaire (IDI – Pregnant Woman)

MAKING A BALANCED PLATE FOR PREGNANT WOMAN TO IMPROVE DIETARY BEHAVIOUR OF MOTHER DURING PREGNANCY AND BIRTH WEIGHT OF INFANTS: A CLUSTER RANDOMISED CONTROLLED TRIAL IN RURAL BANGLADESH

In-depth Interview (IDI) with Pregnant Women

Informed Consent Form

Date: __ __/__ __/__ __ __ __

Protocol Title: Making a balanced plate for pregnant woman to improve dietary behaviour of mother during pregnancy and birth weight of infants: a cluster randomised controlled trial in rural Bangladesh.

Principle Investigator's name: Morseda Chowdhury

Organization: BRAC

Purpose of the research
Assalamualaikum/Adab, we work at BRAC. We are doing a research titled Nutrition counselling to pregnant women by practical demonstrations to improve birth weight: a cluster randomised controlled trial in rural Bangladesh.
In Bangladesh approximately four in ten infants are born too small, which is related to neonatal death. These infants also suffer from other problems in later life, e.g., psychosocial, emotional problems and develop risks of diabetes and hypertension in adulthood. About one fourth of the women aged 15-49 years are undernourished. It is well evidenced that poor maternal nutrition during pregnancy leads to low birthweight. The proposed research will develop a nutrition counselling package for the pregnant women to be delivered by BRAC community health workers (CHW) during regular antenatal visits aiming to improve dietary behaviour of the pregnant women. An innovative way of communication; practical demonstration method will be used to show how to prepare a plate with balanced diet with diversified food. The impact of counselling will be assessed on neonatal birth weight and maternal dietary behaviour.

Why are you invited to participate in the study?
We are assessing the feasibility and acceptability of this method of nutrition counselling to pregnant women and testing the food plate as an instrument within local norms and context. As you are a pregnant woman, you have the wisdom of maintaining nutrition of yourself throughout your pregnancy. Thus, we are inviting you to participate in this focus group discussion. Your knowledge and information will guide us to further refine our approach and tools of this project.

Methods and procedures [What is expected from the participants of the research study]
If you agree to participate in this study, we will ask you some questions regarding the approach we are going to use and we will also ask you about the combination of an ideal food plate and your personal perceptions, feelings and attitudes regarding this study.
The whole procedure may take about two hours, but you do not have to stay for the whole time. You can leave whenever you want. We can arrange a meeting later if you find it convenient.

We would like to record the interview digitally and take notes so that we don't forget the valuable information you give. Again, you do not have to be recorded if you are not comfortable.

Risk and benefits

There will be no risks related to your participation in this study. All information obtained from the interview will be kept strictly confidential and will be used for the purpose of this research only. Participation in this study may not benefit you directly, but the information we will obtain, will be very useful to further enhance the quality of nutritional information given to pregnant women and will potentially improve the nutritional status of pregnant mothers and newborns in Bangladesh.

Privacy, anonymity and confidentiality

We do hereby affirm that privacy, anonymity and confidentiality of information and your identity will be strictly maintained. None, other than the investigators of this research and Ethical Review Committee (ERC) would have an access to the information. The questioning will be done in a place where your answers cannot be heard by other people. We would be happy to answer any questions about the study.

Future use of information

Anonymous or abstracted information and data may be shared with other researchers within and outside the country. However, this will not conflict with or violate the maintenance of privacy, anonymity and confidentiality of participants in any way.

Right not to participate and withdraw

Your participation in the study is voluntary, and you have the sole authority to decide to take part or opt out. You do not have to answer any question that you do not want to. You would also be able to withdraw yourself during the interview without showing any reason. Refusal to participate in the research will not cause you any harm. We may again get back to you later for a second visit, if needed. If you participate in the first visit, that does not mean you are obliged to do so for the second time.

Principle of compensation

As mentioned earlier, your participation in this study is completely voluntary and you will not get any payment for participating in this research.

Answering your questions/contact information

If you have any questions, I will be happy to answer them. In case you ever want to contact someone from the office we work for, I can write down the telephone number of the BRAC Health Nutrition and Population Programme (HNPP) at BRAC in Dhaka. You should call this number and ask for Dr. Tapash Roy, who is the Programme Head for the programme where the study is being conducted at HNPP, BRAC: (02) 9881265, ext 3517.

If you wish to contact with me, I can write the information down for you. Please contact The University of Sydney, School of Public Health, room no: 124, Mobile +61470642799, email: morsheda.c@brac.net.

If you agree to our proposal of enrolling yourself in our research, please indicate that by putting your signature or your left thumb impression at the specified space below. Thank you for your cooperation.

Participant: I certify that all the above information was adequately explained to me and I understood the explanation

_____	_____
Signature or left thumb impression of participant	Date
_____	_____
Signature or left thumb impression of the witness	Date
_____	_____
Signature of the PI or her representative	Date

(NOTE: In case of representative of the PI, she shall put her full name and designation and then sign)

Guideline for IDI with pregnant woman

Facilitator's note: Greet the participant; introduce yourself and your note taker– follow normal practices as you would do in any social setting. You should take consent to audio-record the discussion and ensure the anonymity of the information.

The following question route is a list of key topics that need to be discussed. Additional probing might be necessary to generate adequate data.

IDI thematic area

[*We need to collect some demographic and reproductive information about each participant.*]

1. Demographic information:
   - 1.1. Age
   - 1.2. Education
   - 1.3. Religion, Caste (if it is appropriate to ask in public)
   - 1.4. Occupation
2. Reproductive information:
   - 2.1. Current gestational age
   - 2.2. Para
   - 2.3. Gravida

   [Note Taker: Take detailed notes of demographic information in your note book.]
3. Diet during pregnancy:
   - 3.1. What did you get animal protein (meat, fish and poultry), egg, vegetables, fruits and milk from?
   - 3.2. Did you face any obstacles to buy those food items? What are those? How did you overcome the obstacles?
   - 3.3. How did you come to know about the menu? Who counselled you? How frequently had you been counselled?
   - 3.4. Do you think you have taken more than you intended to after having been counselled?
   - 3.5. What food items and how much have you taken extra?
   - 3.6. Did you find any physical or social barrier to consume that extra amount of food?
   - 3.7. Did your family members encourage/help you to consume extra diet?
   - 3.8. Did your husband buy any food items especially for you? What are those? How frequently he used to buy them?
   - 3.9. Did your mother/mother in law allowed you to take the suggested amount and types of food?
   - 3.10. Did she cook any items especially for you?
   - 3.11. How many glasses of water you used to take in a day? Who recommended the amount?
   - 3.12. Did you take iron-folic acid tablets? How frequently you took in a week? Who recommended the dose? Where did you get it? Do you have to pay for it?
   - 3.13. Did you find any side effects of it? How did you overcome those?
   - 3.14. Did you take iron-folic acid tablets? How frequently you took in a week? Who recommended the dose? Where did you get it? Do you have to pay for it?
   - 3.15. Did you find any side effects of it? How did you overcome those?
   - 3.16. Did you take any other drugs? Who recommended those? Why?

4. Practical demonstration approach:
    4.1. Did the Shasthya Kormi counsel you with a practical demonstration? Did she show how to make your plate for every meal?
    4.2. Was it effective for learning? Did you change your dietary behaviour after receiving the counselling? If yes, at what extent? If not, why?
    4.3. In the practical demonstration what food SK used? Did you have all the food items at your own home? Did you asked any food items from neighbours to complete the plate? What are the items you have to ask for?
    4.4. Did the SK counsel your husband and mother/in law? How frequently she used to counsel them?
    4.5. Do you think counselling your husband and mother/in law were effective? Why? Explain.
    4.6. Did they change their attitudes towards your diet? What are changes you have noticed?
    4.7. Would you recommend same nutritional counselling with practical demonstration for the wellbeing of other pregnant women? Why?

5. Food menu:
    5.1. Do you think the proposed menu is sufficient/excessive/insufficient for you? If excessive/insufficient how much is that?
    5.2. Did you eat all the suggested varieties and amount of food? If not, why?
    5.3. Did you find any food unavailable in the market? Why? What are those?
    5.4. Are there any cultural taboo attached to any suggested food? What are those?

6. Role of mother/in law:
    6.1. Were there any barriers from your mother/in law for consuming any particular food item/s?
    6.2. Did your mother/in law help/encourage you to follow the suggested menu? If yes, how? If no, why?
    6.3. Why do you think your mother/mother in law encouraged to follow the diet, for you or for the baby?

7. Role of husband:
    7.1. Were there any barriers from your husband for consuming any particular food item/s?
    7.2. Did your husband help/encourage you to follow the suggested menu? If yes, how? If no, why?
    7.3. Why do you think your husband encouraged to follow the diet, for you or for the baby?
    7.4. How much extra money do you think your husband had to spend for your additional diet? Did he do it willingly?

Appendix 6: Qualitative Questionnaire (FGD – Pregnant Woman)

MAKING A BALANCED PLATE FOR PREGNANT WOMAN TO IMPROVE DIETARY BEHAVIOUR OF MOTHER DURING PREGNANCY AND BIRTH WEIGHT OF INFANTS: A CLUSTER RANDOMISED CONTROLLED TRIAL IN RURAL BANGLADESH

Focus Group Discussion (FGD) with Pregnant Women

Informed Consent form

Date: __ __/__ __/__ __ __ __

Protocol Title: Making a balanced plate for pregnant woman to improve dietary behaviour of mother during pregnancy and birth weight of infants: a cluster randomised controlled trial in rural Bangladesh.

Principle Investigator's name: Morseda Chowdhury
Organization: BRAC

Purpose of the research:

Assalamualaikum/Adab, we work at BRAC. We are doing a research titled Nutrition counselling to pregnant women by practical demonstrations to improve birth weight: a cluster randomised controlled trial in rural Bangladesh.
In Bangladesh approximately four in ten infants are born too small, which is related to neonatal death. These infants also suffer from other problems in later life, e.g., psychosocial, emotional problems and develop risks of diabetes and hypertension in adulthood. About one fourth of the women aged 15-49 years are undernourished. It is well evidenced that poor maternal nutrition during pregnancy leads to low birthweight. The proposed research will develop a nutrition counselling package for the pregnant women to be delivered by BRAC community health workers (CHW) during regular antenatal visits aiming to improve dietary behaviour of the pregnant women. An innovative way of communication; practical demonstration method will be used to show how to prepare a plate with balanced diet with diversified food. The impact of counselling will be assessed on neonatal birth weight and maternal dietary behaviour.

Why are you invited to participate in the study?
We are assessing the feasibility and acceptability of this method of nutrition counselling to pregnant women and testing the food plate as an instrument within local norms and context. As you are a pregnant woman, you have the wisdom of maintaining nutrition of yourself throughout your pregnancy. Thus, we are inviting you to participate in this focus group discussion. Your knowledge and information will guide us to further refine our approach and tools of this project.

Methods and procedures [What is expected from the participants of the research study]
If you agree to participate in this study, we will ask you some questions regarding the approach we are going to use and we will also ask you about the combination of an ideal food plate and your personal perceptions, feelings and attitudes regarding this study.
The whole procedure may take about two hours, but you do not have to stay for the whole time. You can leave whenever you want. We can arrange a meeting later if you find it convenient.
We would like to record the interview digitally and take notes so that we don't forget the valuable information you give. Again, you do not have to be recorded if you are not comfortable.

Risk and benefits

There will be no risks related to your participation in this study. All information obtained from the interview will be kept strictly confidential and will be used for the purpose of this research only. Participation in this study may not benefit you directly, but the information we will obtain, will be very useful to further enhance the quality of nutritional information given to pregnant women and will potentially improve the nutritional status of pregnant mothers and newborns in Bangladesh.

Privacy, anonymity and confidentiality

We do hereby affirm that privacy, anonymity and confidentiality of information and your identity will be strictly maintained. None, other than the investigators of this research and Ethical Review Committee (ERC) would have an access to the information. The questioning will be done in a place where your answers cannot be heard by other people. We would be happy to answer any questions about the study.

Future use of information

Anonymous or abstracted information and data may be shared with other researchers within and outside the country. However, this will not conflict with or violate the maintenance of privacy, anonymity and confidentiality of participants in any way.

Right not to participate and withdraw

Your participation in the study is voluntary, and you have the sole authority to decide to take part or opt out. You do not have to answer any question that you do not want to. You would also be able to withdraw yourself during the interview without showing any reason. Refusal to participate in the research will not cause you any harm. We may again get back to you later for a second visit, if needed. If you participate in the first visit, that does not mean you are obliged to do so for the second time.

Principle of compensation

As mentioned earlier, your participation in this study is completely voluntary and you will not get any payment for participating in this research.

Answering your questions/contact information

If you have any questions, I will be happy to answer them. In case you ever want to contact someone from the office we work for, I can write down the telephone number of the BRAC Health Nutrition and Population Programme (HNPP) at BRAC in Dhaka. You should call this number and ask for Dr. Tapash Roy, who is the Programme Head for the programme where the study is being conducted at HNPP, BRAC: (02) 9881265, ext 3517.

If you wish to contact with me, I can write the information down for you. Please contact The University of Sydney, School of Public Health, room no: 124, Mobile +61470642799, email: morsheda.c@brac.net.

If you agree to our proposal of enrolling yourself in our research, please indicate that by putting your signature or your left thumb impression at the specified space below. Thank you for your cooperation.

Participant: I certify that all the above information was adequately explained to me and I understood the explanation

_____	_____
Signature or left thumb impression of participant	Date
_____	_____
Signature or left thumb impression of the witness	Date
_____	_____
Signature of the PI or her representative	Date

(NOTE: In case of representative of the PI, she shall put her full name and designation and then sign)

Guidelines

Facilitator's note: Greet the participants, introduce yourself and your note taker, ask everyone's name and introduce them all to each other – follow normal practices as you would do in any social setting. Please provide a concise description of this research in simplistic general terms, understandable to the participants. Tell them that, this is not a test and all views are equally important and we would like to hear all perspectives. Then, explain the major topics you are going to discuss during the FGD. You may also provide some ground rules that should be followed by all participants, such as, not attacking anyone personally; everyone should try to stay until the end of the session, etc. You should take consent to audio-record the discussion and ensure the anonymity of the information. If you have arranged food/snack and/or transport reimbursement, inform the participants.

The following question route is a list of key topics that need to be discussed. Additional probing would be necessary to generate the discussion in a logical flow.

FGD question route

[*We need to collect some demographic and reproductive information about each participant. You will need to decide when and how this isbest done. In some cultures it is rude to ask people their age, education and occupation at the start. You can choose how to collect this information – maybe at recruitment, but it is important information to collect for each participant.*]

1. Demographic information:
   - 1.1. Age
   - 1.2. Education
   - 1.3. Religion, Caste (if it is appropriate to ask in public)
   - 1.4. Occupation
2. Reproductive information:
   - 2.1. Current gestational age
   - 2.2. Para
   - 2.3. Gravida

   [Note Taker: Take detailed notes of demographic and reproductive information in your note book.]
3. Diet during pregnancy:
   - 3.1. What food do the pregnant women in this region usually eat when they are pregnant?
   - 3.2. In your opinion, does a pregnant woman need to take different foods compared to when she was not pregnant? Please explain why or why not?
   - 3.3. Do pregnant women in this region make changes in their diet? If yes, what changes they make and how? If no, why they don't make any change?
   - 3.4. Is there any barrier to accessing food required for a pregnant woman? Please explain. [Prompt: Cost, baby will be too big, don't think necessary, etc.]
   - 3.5. Is there any norm to restrict any type of or amount of food to a pregnant woman? What are they and what is the possible reason?

4. Practical demonstration approach:

[Please describe and demonstrate the counselling technique we are going to test in this research. Make a food plate for pregnant woman with food cooked in the neighbouring households. Ask them to actively bring different varieties of food prepared for their own families. Now, make a plate using that food items and show how a plate for a pregnant woman should look. Then, explain the different

varieties of food along with the quantity and function in body and over the baby. Tell them that, this is the way we are going to counsel a pregnant woman to improve her nutrition behaviour and practice.]

4.1. Do you like the way we are going to counsel the pregnant woman? Please explain why you liked/not liked the approach.
4.2. Do you think it will be effective to make any change in behaviour and practice? Please explain why.
4.3. Do you suggest any modification (inclusion/exclusion) of the messages? Please explain what are those and why.
4.4. Do you think that the plate is adequate or too much for a pregnant woman? What should be the adequate amount?

5. Food menu:

[Please show the participants the daily menu and narrate exactly the messages that will be delivered to a pregnant woman in terms of promoting diversified food. Then, invite the participants' opinion about the menu and content of the messages; like, suggested food in terms of availability, accessibility and cultural context.]

5.1. Do you think the menu includes a complete list of all food that a pregnant woman should take? Please explain why/why not.
5.2. Do you find any food locally not available or only seasonally available? What are those?
5.3. Do you think any food advised here culturally prohibited/harmful to a pregnant woman or the baby? Please explain.

Appendix 7: Qualitative Questionnaire (FGD – Husband)

MAKING A BALANCED PLATE FOR PREGNANT WOMAN TO IMPROVE DIETARY BEHAVIOUR OF MOTHER DURING PREGNANCY AND BIRTH WEIGHT OF INFANTS: A CLUSTER RANDOMISED CONTROLLED TRIAL IN RURAL BANGLADESH

Focus Group Discussion (FGD) with Husbands of Pregnant Women

Informed Consent Form

Date: __ __/__ __/__ __ __ __

Protocol Title: Making a balanced plate for pregnant woman to improve dietary behaviour of mother during pregnancy and birth weight of infants: a cluster randomised controlled trial in rural Bangladesh.

Principle Investigator's name: Morseda Chowdhury

Organization: BRAC

Purpose of the research

Assalamualaikum/Adab, we work at BRAC. We are doing a research titled Nutrition counselling to pregnant women by practical demonstrations to improve birth weight: a cluster randomised controlled trial in rural Bangladesh.

In Bangladesh approximately four in ten infants are born too small, which is related to neonatal death. These infants also suffer from other problems in later life, e.g., psychosocial, emotional problems and develop risks of diabetes and hypertension in adulthood. About one fourth of the women aged 15-49 years are undernourished. It is well evidenced that poor maternal nutrition during pregnancy leads to low birthweight. The proposed research will develop a nutrition counselling package for the pregnant women to be delivered by BRAC community health workers (CHW) during regular antenatal visits aiming to improve dietary behaviour of the pregnant women. An innovative way of communication; practical demonstration method will be used to show how to prepare a plate with balanced diet with diversified food. The impact of counselling will be assessed on neonatal birth weight and maternal dietary behaviour.

Why invited to participate in the study?

We are assessing the feasibility and acceptability of this method of nutrition counselling to pregnant women and testing the food plate as an instrument within local norms and context. As you are husband of a pregnant woman, you have the wisdom of maintaining nutrition of her. Thus, we are inviting you to participate in this focus group discussion. Your knowledge and information will guide us to further refine our approach and tools of this project.

Methods and procedures [What is expected from the participants of the research study]

If you agree to participate in this study, we will ask you some questions regarding the approach we are going to use and we will also ask you about the combination of an ideal food plate and your personal perceptions, feelings and attitudes regarding this study.

The whole procedure may take about two hours, but you do not have to stay for the whole time. You can leave whenever you want. We can arrange a meeting later if you find it convenient.

We would like to record the interview digitally and take notes so that we don't forget the valuable information you give. Again, you do not have to be recorded if you are not comfortable.

_____ _____

Signature or left thumb impression of the witness Date

_____ _____

Signature of the PI or her representative Date

(NOTE: In case of representative of the PI, she shall put her full name and designation and then sign)

Guideline for FGD with husbands

Facilitator's note: Greet the participants, introduce yourself and your note taker, ask everyone's name and introduce them all to each other – follow normal practices as you would do in any social setting. Please provide a concise description of this research in simplistic general terms, understandable to the participants. Tell them that, this is not a test and all views are equally important and we would like to hear all perspectives. Then, explain the major topics you are going to discuss during the FGD. You may also provide some ground rules that should be followed by all participants, such as, not attacking anyone personally; everyone should try to stay until the end of the session, etc. You should take consent to audio-record the discussion and ensure the anonymity of the information. If you have arranged food/snack and/or transport reimbursement, inform the participants.

The following question route is a list of key topics that need to be discussed. Additional probing would be necessary to generate the discussion in a logical flow.

FGD question route

[*We need to collect some demographic information about each participant. You will need to decide when and how this is the best done. In some cultures it is rude to ask people their age, education and occupation at the start. You can choose how to collect this information – maybe at recruitment, but it is important information to collect for each participant.*]

1. Demographic information:
   1.1. Age
   1.2. Education
   1.3. Religion, Caste (if it is appropriate to ask in public)
   1.4. Occupation
   1.5. Number of alive children
   [Note Taker: Take detailed notes of demographic information in your note book.]
2. Diet during pregnancy:
   2.1. What do your wives eat during pregnancy? Is it different from usual diet? If yes, at what extent?
   2.2. Do you think the diet is sufficient for her and the baby? Please explain.
   2.3. Are there any barriers for the pregnant women to access food especially animal protein (poultry, fish and meat), egg, milk and fruits? What are those?
3. Practical demonstration approach:

[Please describe and demonstrate the counselling technique we are going to test in this research. Make a food plate for an imaginary pregnant woman with food cooked in the neighbouring households. Ask them to actively bring different varieties to food prepared for their own families. Now, make a plate using that food items and show how a plate of a pregnant woman should look like. Then, explain the different varieties of food along with the quantity and function in body and over the foetus. Tell them that, this is the way we are going to counsel a pregnant woman to improve her nutrition behaviour and practice.]

   3.1. Did you like the way BRAC Shasthya Kormis (SK) counselled the pregnant women, mother/in laws and husbands? Please explain.
   3.2. Did you find it effective to improve knowledge about diet of pregnant women? Please explain.
   3.3. Do you think that the plate was adequate for a pregnant woman? Please explain.
4. Food menu:

[Please show the participants the daily menu and narrate exactly the messages that will be delivered to a pregnant woman in terms of promoting diversified food. Then, invite the participants' opinion about the menu and content of the messages; like, suggested food in terms of availability, accessibility and cultural context.]

4.1. Do you think the menu included a complete list of all food that a pregnant woman should take? Please explain.
4.2. Did you find any food locally not available or only seasonally available? What were those?
4.3. Do you think any food culturally prohibited/harmful to a pregnant woman of the foetus? Please explain.

5. Role of a husband:
   5.1. How did you help your pregnant wife to consume the suggested food?
   5.2. Did you take part in the decision of your wife's diet?
   5.3. Did you spend some money exclusively for your pregnant wife's food? How much?

Appendix 8: Qualitative Questionnaire (FGD – Mother-in-law)

MAKING A BALANCED PLATE FOR PREGNANT WOMAN TO IMPROVE DIETARY BEHAVIOUR OF MOTHER DURING PREGNANCY AND BIRTH WEIGHT OF INFANTS: A CLUSTER RANDOMISED CONTROLLED TRIAL IN RURAL BANGLADESH

Focus Group Discussion (FGD) with Mother/in law

Informed Consent Form

Date: __ __/__ __/__ __ __ __

Protocol Title: Making a balanced plate for pregnant woman to improve dietary behaviour of mother during pregnancy and birth weight of infants: a cluster randomised controlled trial in rural Bangladesh.

Principle Investigator's name: Morseda Chowdhury

Organization: BRAC

Purpose of the research:

Assalamualaikum/Adab, we work at BRAC. We are doing a research titled Nutrition counselling to pregnant women by practical demonstrations to improve birth weight: a cluster randomised controlled trial in rural Bangladesh.
In Bangladesh approximately four in ten infants are born too small, which is related to neonatal death. These infants also suffer from other problems in later life, e.g., psychosocial, emotional problems and develop risks of diabetes and hypertension in adulthood. About one fourth of the women aged 15-49 years are undernourished. It is well evidenced that poor maternal nutrition during pregnancy leads to low birthweight. The proposed research will develop a nutrition counselling package for the pregnant women to be delivered by BRAC community health workers (CHW) during regular antenatal visits aiming to improve dietary behaviour of the pregnant women. An innovative way of communication; practical demonstration method will be used to show how to prepare a plate with balanced diet with diversified food. The impact of counselling will be assessed on neonatal birth weight and maternal dietary behaviour.

Why are you invited to participate in the study?
We are assessing the feasibility and acceptability of this method of nutrition counselling to pregnant women and testing the food plate as an instrument within local norms and context. As you are a mother/in law, you have the wisdom of maintaining nutrition of your daughter/in law and yourself while pregnant. Thus, we are inviting you to participate in this focus group discussion. Your knowledge and information will guide us to further refine our approach and tools of this project.

Methods and procedures [What is expected from the participants of the research study]
If you agree to participate in this study, we will ask you some questions regarding the approach we are going to use and we will also ask you about the combination of an ideal food plate and your personal perceptions, feelings and attitudes regarding this study.
The whole procedure may take about two hours, but you do not have to stay for the whole time. You can leave whenever you want. We can arrange a meeting later if you find it convenient.

We would like to record the interview digitally and take notes so that we don't forget the valuable information you give. Again, you do not have to be recorded if you are not comfortable.

Risk and benefits

There will be no risks related to your participation in this study. All information obtained from the interview will be kept strictly confidential and will be used for the purpose of this research only. Participation in this study may not benefit you directly, but the information we will obtain, will be very useful to further enhance the quality of nutritional information given to pregnant women and will potentially improve the nutritional status of pregnant mothers and newborns in Bangladesh.

Privacy, anonymity and confidentiality

We do hereby affirm that privacy, anonymity and confidentiality of information and your identity will be strictly maintained. None, other than the investigators of this research and Ethical Review Committee (ERC) would have an access to the information. The questioning will be done in a place where your answers cannot be heard by other people. We would be happy to answer any questions about the study.

Future use of information

Anonymous or abstracted information and data may be shared with other researchers within and outside the country. However, this will not conflict with or violate the maintenance of privacy, anonymity and confidentiality of participants in any way.

Right not to participate and withdraw

Your participation in the study is voluntary, and you have the sole authority to decide to take part or opt out. You do not have to answer any question that you do not want to. You would also be able to withdraw yourself during the interview without showing any reason. Refusal to participate in the research will not cause you any harm. We may again get back to you later for a second visit, if needed. If you participate in the first visit, that does not mean you are obliged to do so for the second time.

Principle of compensation

As mentioned earlier, your participation in this study is completely voluntary and you will not get any payment for participating in this research.

Answering your questions/contact information

If you have any questions, I will be happy to answer them. In case you ever want to contact someone from the office we work for, I can write down the telephone number of the BRAC Health Nutrition and Population Programme (HNPP) at BRAC in Dhaka. You should call this number and ask for Dr. Tapash Roy, who is the Programme Head for the programme where the study is being conducted at HNPP, BRAC: (02) 9881265, ext 3517.

If you wish to contact with me, I can write the information down for you. Please contact The University of Sydney, School of Public Health, room no: 124, Mobile +61470642799, email: morsheda.c@brac.net.

If you agree to our proposal of enrolling yourself in our research, please indicate that by putting your signature or your left thumb impression at the specified space below. Thank you for your cooperation.

Participant: I certify that all the above information was adequately explained to me and I understood the explanation

_____	_____
Signature or left thumb impression of participant	Date
_____	_____
Signature or left thumb impression of the witness	Date
_____	_____
Signature of the PI or her representative	Date

(NOTE: In case of representative of the PI, she shall put her full name and designation and then sign)

Guideline for FGD with mother/in laws

Facilitator's note: Greet the participants, introduce yourself and your note taker, ask everyone's name and introduce them all to each other – follow normal practices as you would do in any social setting. Please provide a concise description of this research in simplistic general terms, understandable to the participants. Tell them that, this is not a test and all views are equally important and we would like to hear all perspectives. Then, explain the major topics you are going to discuss during the FGD. You may also provide some ground rules that should be followed by all participants, such as, not attacking anyone personally; everyone should try to stay until the end of the session, etc. You should take consent to audio-record the discussion and ensure the anonymity of the information. If you have arranged food/snack and/or transport reimbursement, inform the participants.

The following question route is a list of key topics that need to be discussed. Additional probing would be necessary to generate the discussion in a logical flow.

FGD question route

[*We need to collect some demographic information about each participant. You will need to decide when and how this is the best done. In some cultures it is rude to ask people their age, education and occupation at the start. You can choose how to collect this information – maybe at recruitment, but it is important information to collect for each participant.*]

1. Demographic information:
   1.1. Age
   1.2. Number of pregnancy/ies
   1.3. Religion, Caste (if it is appropriate to ask in public)

   [Note Taker: Take detailed notes of demographic information in your note book.]

2. Diet during pregnancy:
   2.1. What do the pregnant women eat in your locality?
   2.2. In your opinion, does a pregnant woman need to change her dietary behaviour during pregnancy? Please explain why.
   2.3. What changes do you think a pregnant should make?
   2.4. What did you eat during your pregnancies? Did you eat animal protein (poultry, meat and fish), egg, milk and fruits every day? Was there any restriction in any type of food or in amount?
   2.5. Is there any norm to restrict food or any type of food to a pregnant woman? What are they and what is the possible reason?
3. Practical demonstration approach:

[Please describe and demonstrate the counselling technique we are going to test in this research. Make a food plate for an imaginary pregnant woman with food cooked in the neighbouring households. Ask them to actively bring different varieties to food prepared for their own families. Now, make a plate using that food items and show how a plate of a pregnant woman should look like. Then, explain the different varieties of food along with the quantity and function in body and over the foetus. Tell them that, this is the way we are going to counsel a pregnant woman to improve her nutrition behaviour and practice.]

3.1. Do you like the way BRAC Shasthya Kormis (SK) are going to counsel the pregnant women? Please explain why.
3.2. Do you find it effective to bring any change in dietary behaviour and practice? Please explain how.
3.3. Do you suggest any modification (inclusion/exclusion) of the messages or in technique? Please explain.
3.4. Do you think that the plate is adequate for a pregnant woman? If not, why? What should be the adequate amount?

4. Food menu:

[Please show the participants the daily menu and narrate exactly the messages that will be delivered to a pregnant woman in terms of promoting diversified food. Then, invite the participants' opinion about the menu and content of the messages; like, suggested food in terms of availability, accessibility and cultural context.]

4.1. Do you think the menu includes a complete list of all food that pregnant women should take?
4.2. Do you find any food locally not available or only seasonally available? What are those?
4.3. Do you think any food culturally prohibited/harmful to a pregnant woman of the foetus? Please explain.
4.4. Is there any barrier to accessing these foods by pregnant women? Please explain.

5. Role of a mother/mother in law:
5.1. Do you think a mother/in law has the responsibility to actively participate in the decision making process of a pregnant woman's diet in a family? What are the roles? If not, why?
5.2. Who do you think should decide on the diet of a pregnant woman?
5.3. How was your diet influenced by your mother/in law?

Appendix 9. Reviewers' comments with responses for manuscript "Making a balanced plate for pregnant women to improve birthweight of infants: a study protocol for a cluster randomised controlled trial in rural Bangladesh" (Chapter 3)

Editorial Query

- SPIRIT Checklist Item 9: Do you have any specific strategies for achieving adequate participant enrolment to reach the target sample size? Contrary to what the checklist indicates, this item does not appear to be reported on page 9.

Response: The strategy we have adopted is to leverage the long-term rapport of BRAC health workers (Shasthya Kormi) in the community. Our experience shows that people have trust on their intension to do good for the community. Women also feel comfortable to disclose pregnancy status with Shasthya Kormi who have been working in same community for years. Therefore, we expect that the refusal of enrolment will be minimum for this study. Strategies for achieving adequate participant enrollment to reach sample size are explained in page 9, paragraph 3 in the revised manuscript. The revised paragraph reads as follows:

"Once clusters are finalized, SKs will start enrolling study participants (pregnant women) from the study sites. Over the three months recruitment period, we will enroll eligible pregnant women who give informed consent. SKs are given a target to enroll minimum 10 pregnant women per month until the individual target (25) is reached. Pregnancy identification is part of a regular program of BRAC. We will utilize this system to reach pregnant women to enroll them into the study. The long-term involvement of SKs with the community enabled them to gain people's trust, which will help us maximise enrollment and get desired sample size within three months. However, if the target is not reached, the duration of enrolment will be extended with proper justification."

Reviewer 1

The proposal is generally well written. However, I have some suggestions to make it better:

- For formative research I suggest that you use Food attribute exercise from PROPAN methodology.

Response: This is a very useful comment and we have made the following changes to the manuscript on page 6, paragraph 3. The following text added:

"A food attributes exercise will be conducted adapting the Process for the Promotion of Child Feeding (ProPAN) methodology. We will conduct a group of qualitative interviews with key target population such as pregnant women, influential family members (i.e. husbands and mother or mothers-in-law of the women) to generate information about i) key foods taken during pregnancy, ii) positive and negative characteristics attributed to key foods and iii) conditions and changes required for the pregnant women to consume nutrient-rich foods that are not currently taken or 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 commencement of the actual trial."

- For the process evaluation, I suggest that you use TIPs methodology to understand the quality of advice provided

Response: We thank the reviewer for this useful suggestion. We have now decided to include a Trial of Improved Practices (TIPs) for process evaluation to understand the quality of advice and acquire information on conditions hindering the compliance. The following texts have been added in page 17, paragraph 3 of the revised manuscript:

"We will apply Trials of Improved Practices (TIPs) methodology to identify causes of any non-compliance of the advices provided to the women. We will purposively select sub-samples (approximately 20) of the households for the TIPs, keeping the geographical and socio-cultural (i.e. religion and economic status) diversities in mind. Shasthya Kormi (SKs) 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 one week. At the end of the week in a follow up visit, the SKs will interview the women and identify significant barriers to incorporate balanced diet, that were suggested during the counselling, into the dietary practices of the pregnant women. The TIPs findings will provide feedback to adjust the design of the balanced plate nutrition education 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 communication."

- Please explain how you would like to include family decision makers in the counselling sessions

Response: This is an important issue raised by the reviewer and we have explained the process more elaborately on page 13, paragraph 1 of the revised manuscript. The revised texts read as follows:

"The SKs will invite the key influential family members to join the balanced plate preparation demonstration and the counselling sessions. The mother-in-law or mother of the pregnant woman (depending on where the women stays at the time of counselling/demonstration) and her husband (if he is available) will be invited. In absence of the mother-in-law and the mother, an influential senior female member will be invited. The SK will counsel these family members along with the targeted pregnant woman. In addition to providing the counselling on the maternal nutrition and balanced diet, the SK will motivate these family members to provide support to the pregnant women for her adherence to the counselling messages. We expect that their active support would create an enabling environment for the pregnant women to practice improved nutrition by adhering to the counselling messages."

- How are you going to prevent SKs from learning from each other?

Response: We would like to assure the reviewer that we have taken certain steps in preventing SKs from learning each other. In this regard we have made the following changes to the manuscript on page 19, paragraph 3. The revised paragraph reads as follows:

"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 SKs 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 SKs work in distinct villages, with each SK covering 5 villages on an average (villages are usually geographically separated by fields, canals and roads)."

- How are you planning to deal with food insecure households where protein is heavily restricted?

Response: We will suggest the cheapest options of protein for the women in the food insecure households. At the same time, we want to ensure optimal consumption of available protein. Thus we have made the following changes to the revised manuscript on page 11, paragraph 2:

"Considering the high price and low consumption of protein-rich foods in general, both from plant (i.e. lentils) and animal (i.e. 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 fishes available in the market like tilapia, certain catfish (*pangash*) and carps (silver carp). We will motivate the pregnant women to consume adequate amount of these fishes by making them realise that these are equally nutritious as other costly protein-rich foods."

Reviewer 2

This manuscript reports on the protocol for a randomized trial assessing the efficacy of a "balanced plate" educational intervention for improving dietary intake among pregnant women in Bangladesh. The topic is an important one and the study is described in a minimal manner. There are a number of issues the authors should address.

- In the first paragraph of the Methods and Analysis section under the subsection on Study Design there is an incomplete sentence at the end of the paragraph.

Response: We would like to thank the reviewer to pointing out this mistake. The text has been corrected in the revised manuscript on page 6, paragraph 2 by completing the sentence. The revised sentence reads as follows:

"Women, allocated in the intervention arm, will receive the 'balanced plate nutrition education' with practical demonstration and women, in the control arm, will receive standard nutrition education only (Figure 1)."

- The randomization procedures are very unclear and this section needs to be rewritten so it is understandable. As currently written, I have no idea how this was done.

Response: We have re-written the section 'Randomization' to the revised manuscript on page 8, paragraph 3 and page 9, paragraph 1 & 2. The revised paragraphs read as follows:

"Random selection of clusters: We will use proportionate stratified sampling to ensure the selected clusters are representative of the study population of the five sub-districts. We will select clusters from each strata or sub-district, proportionate to its population size. One cluster covers approximately 10,000 population. We will prepare lists of clusters for each of the five different strata that total to 16, 19, 25, 49 and 26 clusters from Jhenaigati, Nakla, Nalitabari, Sherpur Sadar and Sreebardi sub-districts respectively. We will then randomly select the clusters proportionally (36/135) from each strata to obtain 4, 5, 7, 13 and 7 clusters, respectively. From a list of random numbers, generated by a computer program in MS Excel spreadsheet (using RANDOM function), we will select, for example, 4 clusters for the first stratum (Jhenaigati), and apply the same method to the rest of the strata until we obtain the 36 clusters. With this technique we will be able to capture geographic variations across the district.

Sequence generation and allocation concealment: Once we have prepared the list of clusters we will conduct a lottery to assign treatments in two groups (A=intervention and B=control) in 1:1 ratio. At first we will write each cluster number onto 36 pieces

of paper and put them into 5 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 4 pieces of papers 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 district, the sequence would be ABABA, starting with where the first one ended. Subsequently the sequence we will follow for sub-district third, fourth and fifth are BABABAB, ABABABABABABA and BABABAB.

Implementation: BRAC staff from headquarters along with the principal investigator will select the clusters as described above, while BRAC local staff (at study site) will conduct the lotteries to assign the treatments in the presence of other staff in the office. After obtaining consent from the SKs 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 randomly selecting another SK from the remaining list in that sub-district."

- I am concerned that the authors are using Salter spring scales for measurement of birthweight as their primary outcome. These scales are notoriously difficult to read accurately, fluctuate wildly with movement of the infant and are difficult to calibrate. I would strongly recommend they switch to a electronic infant scale for the trial duration. No mention is made of what clothing will be worn by the infant during weighing.

Response: We must appreciate the concern raised by the reviewer regarding the justification to use salter scale. We do not agree with the reviewer's comments that the use of salter scale is extremely difficult. We would argue that repeated training, long-term use and quality control could make users skilled enough to use it correctly. Slater scales have been introduced to BRAC programs since 2005 and Shasthya Kormi (community health worker of BRAC) receive regular training on it. The machines have been checked for reproducibility and validity at regular intervals. Apart from that, supervisory staff directly observes weighing process and check boxes for following the steps correctly.

We would also disagree to switching to an electric scale for a small-scale research like ours, rather than using existing resources.

We have addressed reviewer's comments on clothing of newborn during weighing and have made the following changes to the revised manuscript on page 15, paragraph 3. The following text added:

"Infants will wear only light clothes; any extra wrap or heavy clothes (jumper) 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."

- I am surprised that the pilot qualitative work on the acceptability of the intervention in the community was not done prior to the start of the study. How do the investigators know this intervention will actually be accepted by the women in the intervention arm? How will they measure the fidelity of the intervention delivery?

Response: We agree that pilot work is essential prior to implement any new intervention in the community. This has been explained under the Formative research heading and we have revised this section to the manuscript on page 6, paragraph 3. The paragraph read as follows:

"A food attributes exercise will be conducted applying ProPAN methodology,[242]. We will conduct a group of qualitative interviews with key target population such as pregnant women, influential family members (i.e. husbands and mother or mothers-in-law of the women) to generate information about i) key foods taken during pregnancy, ii) positive and negative characteristics attributed to key foods and iii) conditions and changes required for the pregnant women to consume nutrient-rich foods that are not currently taken or 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 commencement of the actual trial. Among the pilot study participants from two different sites, we will conduct focus group discussions with

pregnant women, their husbands and mothers or mother in laws and Shasthya Kormi (service providers). The data will assist with understanding the cultural compatibility of the approach, along with identifying local norms, beliefs, priorities and any cultural food restrictions in pregnancy. Information about the availability of food in different seasons will also be considered. The final messages will be developed, refining the menu by incorporating the results of the pilot on local preferences, acceptability and seasonal variation."

- Given the delivery of the intervention is being done by routine BRAC staff, would the authors claim this to be an efficacy or effectiveness trial?

Response: We would argue that this is very much an effectiveness trial where we have incorporated nutrition intervention into existing system, rather than testing the efficacy of this intervention in a controlled environment. We have mentioned this into the manuscript on page 6, paragraph 2. The following text added:

"This is an effectiveness trial to be conducted through the existing health program of BRAC. This program is complementing community part of national health system across Bangladesh."

Appendix 10. Reviewers' comments with responses for manuscript "Household food security and birth size of infants: analysis of Bangladesh Demographic and Health Survey 2011" (Chapter 4)

Reviewer 1

- The authors did this analyses using BDHS 2011 data whereas there are updated data (BDHS 2014) available. The main questions here is that are these findings presented in the manuscript still valid? Are there any changes as the country has migrated from low-income to lower middle-income category?

Response: BDHS 2014 did not collect data on household food security indicators; therefore, we could not include those data in our analysis.

Bangladesh has only just graduated from low to lower middle-income status and the findings of this paper are still pertinent to the current situation. This is based on the following justification: as of July 2016, low-income economies are defined as those with a GNI per capita of $1,025 or less in 2015; lower middle-income economies are those with a GNI per capita between $1,026 and $4,035. The current GNI of Bangladesh is $1,330 (calculated using the World Bank Atlas method), which is slightly above the cut off value of the low-income status (https://data.worldbank.org/indicator/NY.GNP.PCAP.CD?locations=BD). Bangladesh is yet to graduate from the least developed country (LDC) status due to lagging behind in income and human asset index, though it has achieved the economic vulnerability index (https://bdnews24.com/economy/2015/11/26/bangladesh-to-remain-ldc-until-2024-un-review). Though the rate of poverty has been declining at a steady rate over the last two and a half decades, the income inequality has, in fact, widened further. Once again, Bangladesh appears to be among the worst performing countries with only 1.2 percent share of public expenditure on health in GDP (http://www.thedailystar.net/op-ed/bangladesh-all-set-be-middle-income-country-7867090.

- Household food security – BDHS used a five-point scale to measure household food security status. Although there are similarities between questions of this

scale and the household food insecurity access scale (HFIAS), which is a well-recognized measure for household food security status and has been widely used in many countries including Bangladesh. This is not to say that other measures of household food security cannot be used but the main question here is whether the significant associations between household food security and low birth weight found in this study will remain the same if other measure of household food security were used. Also, I would suggest to check internal consistency of this scale by examining Cronbach's alpha.

Response: The BDHS 2011 developed the food insecurity questions using the 2011 Nepal DHS food insecurity module and Household Food Insecurity Access Scale (HFIAS) indicators. BDHS used a definition specifying the availability of food and a person's access to it asking five questions (eat three square meals, skip entire meals, eat less food, family members have to eat grains other than rice and family have to ask for food from relatives or neighbours) over the last 12 months. Whereas, HFIAS is comprised of nine questions to assess the level of anxiety and uncertainty of the participants about household food supply, insufficient quality of food and insufficient food intake (worry about food, unable to eat preferred foods, eat just a few kinds of foods, eat foods they really do not want to eat, eat a smaller meal, eat fewer meals in a day, no food of any kind in the household, go to sleep hungry, go a whole day and night without eating). It indicates that there are some commonalities in questions used in two scales; however, it is difficult to say whether the same association would exist if we used HFIAS along with BDHS indicators. To our knowledge, no such study investigated the association between food security and an outcome variable using different scales of food insecurity.

Thank you for the very useful suggestion about checking internal consistency of the food insecurity scale. We have incorporated internal consistency check of the food security Likert scale calculating Cronbach's alpha. We have added following texts in the manuscript in lines 81-90 and lines 206-209 in the manuscript.

"We examined the internal consistency ("reliability") of the food security Likert questions that formed the food insecurity scale by calculating Cronbach's alpha."

"The score of Cronbach's alpha (0.91) indicates a high level of internal consistency for the Likert scale used in BDHS. The five questions in this questionnaire all reliably measure the same latent variable 'feeling of food insecurity'."

- Birth size – it is well known the rationale for using perceived size at birth as birthweight data are not available in many countries. The main issue here is that this is the main outcome variable and based on data from perception and memory recall (long sometime). Was there any validly check for birth size data?

Response: Thank you for the raising the very pertinent issue. The BDHS, like all DHS's does not collect birthweight data. Records of birthweight are seldom available in developing countries. Maternal perceived birth size is often the only available source of birthweight information for use in retrospective epidemiological studies. The validity of maternal perceived birth size could be measured by sensitivity and specificity tests. In absence of paired birthweight data in BDHS 2011 we could not perform these tests in our analysis.

- (Ln27-31): Justification for this study which is described in the last paragraph should be strengthened – why this study is important? Is there any knowledge gap? How will results from this study contribute to the existing knowledge?

Response: We have amended lines 28-38 and added evidence of the knowledge gap and how the result of the study will contribute to the existing gap. The revised texts read as follows:
"Dietary diversity is reduced during pregnancy and the early postpartum period among food insecure households. This is largely due to reductions in all types of animal source foods, especially dairy products, eggs, meat, and fish (Na M et al. 2016). The average daily protein requirement in pregnancy is 71 g. Low maternal protein intake in the second and third trimesters is associated with decreased birth weight (Abu-Saad & Fraser 2010)."…. "Therefore, our aim is to investigate the association between household food security and infant's size at birth, which has not previously been examined in a low and middle-income country. These findings are

important for policy makers who are developing strategies to reduce LBW and consider household food insecurity as one of the important determinants."

Reviewer 2

- The major limitation, acknowledged by the authors, related to misaligned temporality. That is, the analysis used outcomes (i.e. perceived birth size) for women in 5 years preceding survey but exposure data (i.e. household food insecurity in previous 12 mo). And even the sensitivity analysis does not truly "fix" the misaligned temporality because both perceived birth size and household food insecurity are obtained during the same time period. Ideally, the exposure (i.e. household food security status) should be assessed before perceived birth size is assessed.

Response: We do agree with the reviewer. However, there is evidence that food insecurity recall more than 12 months prior to the outcome may be valid. A study in a rural district of Bangladesh found a consistent negative association between food insecurity and dietary intake, nutritional status and household socioeconomic status, which was assessed more than a year before the food security questionnaire was assessed (Na M et al. 2016). There is good evidence that dietary consumption and nutritional status have not changed between 2006 and 2011 (the outcome recall period). Per capita calorie intake in Bangladesh in 2005 was 2,239 kcal and in 2010 it was 2,318 kcal (HIES 2010). The average protein intake was 63 and 66 g respectively in 2005 and 2010. The Gini Co-efficient was 0.47 (2005) and 0.46 (2010) indicating almost no change in nutrition consumption inequity. Child nutritional status also changed very little from 2005 to 2011; stunting was 43% vs 41%, wasting 17% vs 16%, under-weight 41% vs 36% (BDHS 2007 and 2011). However, we have acknowledged the problem in the discussion and added following texts in lines 302-305:

"However, the sensitivity analysis (although useful and reassuring) does not completely fix the misaligned temporality, because restricting the analysis to births within one year of interview means that some of these births occurred before the full food security exposure period was completed."

- Use of "birth size" term. The authors should clarify that the outcome being assessed is "perceived" birth size—that is the size of the newborn at birth as perceived by the mother and not an objective birth size measure. This should be clarified throughout the manuscript.

Response: We have addressed the suggestion on clarifying the "perceived birth size". We incorporated following text in lines 58-61 in the method section:
"However, the survey collected information on mothers' perception of the size of the infants at birth, which was used as a proxy for birthweight; this is commonly done in developing countries (22). For brevity from here on we will refer to it as infant birth size."

- Statistical analysis methods clearly described and appropriate methods used—including adjusting for cluster sampling design, examining potential effect modifiers, and examining potential lean season effects. The authors should be commended on attempting to conduct sensitivity analysis by restricting the outcome data used so that it better aligns with the relevant exposure period. However, even this attempt does not address the temporality issue completely because restricting the analysis to births within one year of interview means that some of these births occurred before the full food security exposure period was completed. This should be noted as a limitation in the manuscript.

Response: Thank you for the suggestion. We have noted this issue as a limitation in the manuscript and added following texts in lines 307-310:
"However, the sensitivity analysis (although useful and reassuring) does not completely fix the misaligned temporality, because restricting the analysis to births within one year of interview means that some of these births occurred before the full food security exposure period was completed."

- Line 62: Please clarify what the scores 0-3 correspond to—i.e. never, rarely, sometimes, mostly/often.

Response: We have re-written the 2nd paragraph in page 5 of the manuscript from lines 73-79. The new texts read as follows:
"Each question was assigned a score ranging from 0-3; 0 corresponding to "never", 1 "rarely", 2 "sometimes" and 3 "mostly/often". The question about ''square meals" was coded in reverse to be consistent with other items, where higher frequency indicates more severe food insecurity. All the food frequency responses were summed into a single score for each ever-married woman. The composite score ranged from a minimum of '0' to a maximum of '15', which was then classified into four categories: 0 'food secure', 1-5 'mild food insecurity', 6-10 'moderate food insecurity' and 11-15 'severe food insecurity' (21)."

- Lines 197-199: The data do not provide any information about household food security status in the 1-4 years preceding the survey, only during the 12 m preceding the survey. Unless the authors can show that food security status remains stable in a given set of households over time, it is speculative to say that food security status remains mostly unchanged over the past 5 years.

Response: Please see response above number 13 where we explained that food security is a stable measure over time.

- It is also important to note that birth size is highly influenced by gestational age, but information on gestational age at birth was not available to the authors.

Response: We do agree that this is one of the limitations of our study and mentioned such in the manuscript. The following texts was added in lines 307-308:
"It is well known that birth size is highly influenced by gestational age; however, due to unavailability of data we could not examine the relationship in our analysis."

- The absence of a lean season effect (Monga season) on perceived birth size is surprising. The discussion mentions potential effects of interventions to soften seasonal price hikes, expansion of harvest season and use of high- yielding rice varieties. However, this would suggest that the food insecurity in Bangladesh is mostly chronic and stable within households which is unlikely to be true. See Na

M et al J Nutr 2016 which reveal strong seasonable effects related to maternal diet.

Response: *Seasonal effect on birth size:* "Monga" is related to the seasonal food insecurity in several districts in north-western Bangladesh. It is also a problem in other parts of the country, although generally less severe. The biggest group of people affected by monga are those families whose income mainly depends on agricultural labour and marginal farming. People try to prevent food insecurity by using various coping strategies, for example, open new income sources or to increase their income in normal times (Zug 2006). A study conducted in one subdistrict in Bangladesh (Shaharasti) reported a significant seasonal variation in birthweight. The main occupation of the population is agriculture. The area is located adjacent to a river that annually causes moderate to severe flooding, which might affect harvest and food security, though the study did not report on household food security or maternal dietary intake (Shaheen et al. 2006). Na M et al. also found that compared with winter, women in summer, on average, consumed ~1 more food group, but failed to report the change in total caloric intake and did not record birthweight either. We can conclude that seasonal food insecurity in localized and might not be generalizable. Being a nation wide survey the BDHS 2011 could not capture the localized seasonal effects of food insecurity on birth size.

Stability of food insecurity: Na M et al. (2016) concluded that household food insecurity is stable and extends further in time than anticipated. They found a negative association between food insecurity and dietary intake during pregnancy, maternal nutritional status, and household socioeconomic status, which was assessed more than 1 year before the food security questionnaire was assessed (Na M 2006).

Appendix 11. Do-file of the manuscript "Making a balanced plate for pregnant women to improve birthweight of infants: a study protocol for a cluster randomised controlled trial in rural Bangladesh" (Chapter 3)

********** Full model **********

xi: svy: logistic size foodsec sex birthint_c age_c height_c bmi_c parity_c i.anemia pregloss anc_c ib3.edu deci tv ib3.edufa i.reg res fuel wealth_c_1000

*** Excluding sub-sample anemia***

xi: svy: logistic size foodsec sex birthint_c age_c height_c bmi_c parity_c pregloss anc_c ib3.edu deci tv ib3.edufa i.reg res fuel wealth_c_1000

*** Excluding birthint with large missing values***

xi: svy: logistic size foodsec sex age_c height_c bmi_c parity_c pregloss i.anc ib3.edu deci tv ib3.edufa i.reg res fuel wealth_c_1000

********** Baseline model **********

xi: svy: logistic size foodsec sex age_c height_c bmi_c parity_c pregloss anc_c ib3.edu deci tv ib3.edufa i.reg res fuel wealth_c_1000

********** Checking for correlation & collinearity **********

correlate age_c height_c bmi_c parity_c anc_c wealth_c_1000
collin age_c height_c bmi_c parity_c anc_c wealth_c_1000

****Cross tabulations****

tab foodsec sex, row chi2
tab foodsec pregloss, row chi2
tab foodsec edu, row chi2

```
tab foodsec reg, row chi2
tab foodsec res, row chi2
tab foodsec fuel, row chi2
tab foodsec edufa, row chi2
tab foodsec deci, row chi2
tab foodsec tv, row chi2
tab deci edu, row chi2
tab tv edu, row chi2
tab edufa edu, row chi2
tab res fuel, row chi2

********** Final model - backward elimination **********

*** Starting with the least significant one I have eliminated deci, wealth, bmi,
pregloss, res, height, age, fuel, edu and tv one at a time

xi: svy: logistic size foodsec sex parity_c anc_c i.reg

********** Checking linearity assumption **********

logistic size foodsec i.anc sex i.reg i.parity
estat ic
logistic size foodsec anc_c sex i.reg i.parity
estat ic
logistic size i.parity anc_c foodsec sex i.reg
estat ic
logistic size parity_c anc_c foodsec sex i.reg
estat ic

********** FINAL MODEL **********

xi: svy: logistic size foodsec sex i.parity anc_c i.reg
```

********** Sensitivity analysis **********

***** Sensitivity of food security-Restricting the analysis into births in food security recall period and excluding year *****

xi: svy: logistic size foodsec sex i.reg i.parity anc_c if birth_int_dif==1

**** Adding year-month of birth variable****

xi: svy: logistic size foodsec sex birth_yr_mo i.parity i.anc i.reg

***** Effect of lean season-adding mongabirth and dropping birthmonth****

xi: svy: logistic size foodsec sex i.reg i.parity i.anc if mongabirth==1

**** Effect of food insecure region-adding mongareg and dropping region***

xi: svy: logistic size foodsec sex mongareg i.parity i.anc

****** Adding monga_mo_reg and dropping region*******

xi: svy: logistic size foodsec sex monga_mo_reg i.parity i.anc

******** Comparing food security and poverty********

xi: svy: logistic size foodsec sex i.parity anc_c i.reg if wealth==1| wealth==2

xi: svy: logistic size foodsec sex i.parity anc i.reg if wealth==3| wealth==4| wealth==5

Appendix 13. Do-file of the manuscript "Household Food Security and Birth Size of Infants: Analysis of the Bangladesh" (Chapter 6)

```
**********Checking missing outcome balance**********

misstable summarize age edu f_inc h_edu parity prev_pregterm gest_wk if outmis==0
& treat==1
misstable summarize age edu f_inc h_edu parity prev_pregterm gest_wk if outmis==0
& treat==2
tab outmis_bi treat, col chi2
xtgee outmis_bi treat, family(poisson) link(log) corr(exchangeable) vce(robust) eform

********** Table 4: Baseline characteristics **********

ttest age, by(treat)
tab agecat treat, col chi2
tab edu treat, col chi2
ttest f_inc, by(treat)
tab h_edu treat, col chi2
ttest parity, by(treat)
tab parity_cat treat, col chi2
tab prev_pregterm treat, col chi2
ttest gest_wk, by(treat)

* Table 5 - model adjusted for randomization, age, parity and gestation at enrollment*

xtset cluster
ttest weight, by(treat)
xtgee weight ib2.treat age gest_wk, vce(robust) nolog
estat wcorrelation
tab lbw_bi treat, col chi2
xtgee lbw_bi ib2.treat age gest_wk, family(poisson) link(log) corr(exchangeable)
vce(robust) eform
estat wcorrelation
```

********** Adolescent sub-group analysis **********

********** Adolescent (<20 years) **********

***** Birthweight*****

```
ttest weight if ado==1, by(treat)
xtgee weight ib2.treat age gest_wk if ado==1, vce(robust) nolog
```

**** intercation ****

```
xtgee weight ib2.treat i.ado#i.treat i.ado, vce(robust) nolog
```

****** LBW *****

```
tab lbw_bi treat if ado==1, col chi2
xtgee lbw_bi ib2.treat age gest_wk if ado==1, family(poisson) link(log)
corr(exchangeable) vce(robust) eform
```

**** intercation ****

```
xtgee lbw_bi ib2.treat i.ado#i.treat i.ado, family(poisson) link(log) corr(exchangeable)
vce(robust) eform
```

********** Non- adolescent (>=20 years) **********

****** Birthweight ******

```
ttest weight if ado==0, by(treat)
xtgee weight ib2.treat age gest_wk if ado==0, vce(robust) nolog
```

****** LBW ******

```
tab lbw_bi treat if ado==0, col chi2
xtgee lbw_bi ib2.treat age gest_wk if ado==0, family(poisson) link(log)
corr(exchangeable) vce(robust) eform
```

```
*************** Education sub-group analysis ***************
********************** Educated ***************
****** Birthweight ******

ttest weight if edu_bi==1, by(treat)
xtgee weight ib2.treat age gest_wk if edu_bi==1, vce(robust) nolog

**** interaction ****

xtgee weight ib2.treat i.edu_bi i.edu_bi#i.treat, vce(robust) nolog

****** LBW ******

tab lbw_bi treat if edu_bi==1, col chi2
xtgee lbw_bi ib2.treat age gest_wk if edu_bi==1, family(poisson) link(log)
corr(exchangeable) vce(robust) eform

**** interaction ****

xtgee lbw_bi ib2.treat i.edu_bi i.edu_bi#i.treat, family(poisson) link(log)
corr(exchangeable) vce(robust) eform

****************** Un-Educated **********************

ttest weight if edu_bi==0, by(treat)
xtgee weight ib2.treat age gest_wk if edu_bi==0, vce(robust) nolog

****** LBW ******

tab lbw_bi treat if edu_bi==0, col chi2

xtgee lbw_bi ib2.treat age gest_wk if edu_bi==0, family(poisson) link(log)
corr(exchangeable) vce(robust) eform
```

********** Unadjusted model **********

```
xtgee weight ib2.treat, vce(robust) nolog
xtgee lbw_bi ib2.treat, family(poisson) link(log) corr(exchangeable) vce(robust)
eform
xtgee weight ib2.treat if ado==1, vce(robust) nolog
xtgee lbw_bi ib2.treat if ado==1, family(poisson) link(log) corr(exchangeable)
vce(robust) eform
```