Preventing intrauterine growth restriction and improving infant growth outcomes in Bangladesh

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Ethics Statement

This research was registered with the International Standard Randomised Controlled Trial Number (ISRCTN) registry (ISRCTN97447076). This research project received human research ethics approval from the following:

- James Cook University Human Research Ethics Committee (HREC), approval number #H4498;
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Statement of contribution by student

I, Briony Stevens, was the primary person responsible for the following thesis components:

- Conceptualisation and design of the research project.
- Study coordination of the entire project (2010 to 2015), including data collection, recruitment and training of local research staff and volunteers, liaison with key local stakeholders, financial management, progress updates to ethics committees, funding agencies and study communities.
- Coordination, design and development of consent forms, participant information sheets, project protocols (for each study phase), data collection tools, referral forms, Information Education Communication (IEC) tools, and design of supplement packaging.
- Coordination and design of training packages delivered to all research staff and volunteers.
- Management and coordination of the establishment and training of a local income generation group, who developed supplements for the longitudinal study.
- Coordination and management of data, data analysis, data interpretation and drafting of manuscripts (primary author of all manuscripts relating to this research project), and co-ordination of co-author contributions.

Please refer to statement of contributions from co-authors for responsibilities pertaining to publications.

Conflict of interest

Briony Stevens was employed by World Vision New Zealand from 2010 to 2012, and received a stipend to support study costs from 2013 to 2014. World Vision New Zealand was the main funding body of this research project from 2012-2015. World Vision New Zealand had no role in the design, analysis or writing of this thesis or articles published as a result of this work.

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Statement of the Contribution of Others

Nature of Assistance	Contribution	Names, titles and Affiliations of Co-Contributors
Intellectual support	Editorial assistance / Manuscript Preparation	Co-authors contributed editorial assistance to respective publications in the process of their critical reviews, as well as relevant academic expertise. Contribution is recognised where relevant by co-authorship, as per the NHMRC authorship guidelines. For relevant publications in this thesis which involved intellectual contribution by others, there is an explicit statement preceding the publication/chapter describing the contribution by others. In addition, Ms Melody Muscat and Ms Julie Parison, of James Cook University, provided editorial support for segments of Study 2. The anonymous reviewers for each peer-reviewed article provided additional editorial support. I employed Dr Christina Houen to copy edit the thesis.
	Supervision	Professor Petra Buettner was my Primary Advisor at James Cook University from November 2009 until her retirement in 2012; Associate Professor Kerrianne Watt was my Primary Advisor at James Cook University from 2012 until completion; Professor Jenni Judd was my Secondary Advisor at James Cook University; Professor Alan Clough was my Secondary Advisor at James Cook University;

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Statement of contribution by co-authors[1]

Chapter No.	Details of publication(s) on which chapter is based	Nature and extent of the intellectual input of each author, including the candidate
2	Stevens, B., Buettner, P., Watt, K., Clough, A., Brimblecombe, J., Judd, J. The effect of balanced protein energy supplementation in undernourished pregnant women and child physical growth in low- and middle-income countries: A systematic review and meta-analysis. Maternal and Child Nutrition. 2015; 4(11): 415–32. doi: 10.1111/mcn.12183	Stevens, Buettner and Judd co-developed the research question. Stevens conducted the search. Stevens and Judd assessed all selected full text articles for eligibility. Stevens and Judd assessed the quality of evidence for selected full text articles. Stevens and Buettner conducted the meta-analyses. Buettner, Watt and Stevens analysed and interpreted the data. Stevens wrote the first draft of the article, which was critically reviewed by Brimblecombe, Buettner, Watt, Clough and Judd. Stevens developed the figures and tables. All authors contributed to the editing of the final manuscript.
3	Stevens, B., Clough, A., Brimbecombe, J., Watt, K. and Judd, J. The use of a modified version of photovoice to identify maternal dietary consumption enablers and barriers in Northern Bangladesh. International Journal of Food, Nutrition and Public Health. 2016; 8 (1): 1-19.	Stevens and Judd developed the research question. Stevens collected the data and performed the data analysis with assistance from Judd. Stevens wrote the first draft of the article, which was critically reviewed and revised by Judd, Brimblecombe, Watt and Clough. All authors contributed to the editing of the final manuscript.

[1] Refer to appendix 1 for co-author consent to the inclusion of the publications in the thesis and acceptance of candidates' contribution to the manuscripts.

4	Stevens, B., Watt, K., Clough, A., Judd, J. and Brimblecombe, J. An exploration of maternal dietary diversity and household food security in undernourished pregnant women living in Northern Bangladesh. International Journal of Food, Nutrition and Public Health. 2015; 7 (2): 61-69.	Stevens and Clough developed the research question. Stevens collected the data and performed the data analyses. Stevens wrote the first draft of the article, which was revised after critical review from Judd, Brimblecombe, Watt and Clough. All authors contributed to the editing of the final manuscript.
5.	Stevens, B., Watt, K, Brimblecombe, J., Clough, A., Judd, J., and Lindsay, D. 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. 2016; (1): 1-9	Stevens developed the research question. Stevens coordinated the collection of data. Stevens performed the data analyses with assistance from Watt and Lindsay. Stevens wrote the first draft of the article, which was revised with editorial input and critical review from Judd, Watt Brimblecombe, Lindsay and Clough. All authors contributed to the editing of the final manuscript.
6.	Stevens, B., Watt, K, Brimblecombe, J., Clough, A., and Judd, J (2016). Development of a locally produced balanced protein energy food-based supplement, and its acceptance by undernourished pregnant women in northern Bangladesh. Journal of Hunger Environmental Nutrition, 2016; (1): 1-16.	Stevens developed the research question. Stevens collected the data and performed the data analyses with assistance from Watt. Stevens wrote the first draft of the article that was critically reviewed and revised by Judd, Watt, Brimblecombe and Clough. All authors contributed to the editing of the final manuscript.

7.	Stevens, B., Brimblecombe, J., Clough, A., Watt, K, Judd, J., and Lindsay, D. A village-matched evaluation of providing a local supplemental food during pregnancy in rural Bangladesh: A preliminary study**.** Under review.	Stevens developed the research question. Stevens coordinated the collection of data. Stevens performed the data analyses with assistance from Watt and Lindsay. Stevens wrote the first draft of the article, which was revised with editorial input and critical review from Judd, Brimblecombe, Watt, Lindsay and Clough. All authors contributed to the editing of the final manuscript.

Abstract

Background

Insufficient food intake during pregnancy is a major problem in many developing countries. The pregnancy period presents a key phase for ensuring the survival, growth and development of the offspring. When pregnant women are undernourished, extra food during pregnancy can improve birth outcomes and has the potential to improve the nutritional status of pregnant women. Bangladesh has among the highest rates of maternal and child undernutrition globally. Despite some improvement in maternal and child nutrition status, the World Health Organisation considers stunting and wasting rates high in terms of severity. While a number of studies have considered food-based supplements using locally available and preferred foods, evidence for effective community-based approaches for the treatment of maternal acute malnutrition is limited, particularly among rural population groups.

Objectives

The aim of this research was to develop an effective locally produced food-based supplement for undernourished pregnant women that prevents low birth weight (LBW). The research has a focus on undernourished pregnant women living in northern Bangladesh, a rural context. Bangladesh was selected due to continued high levels of maternal and child undernutrition. Consequently there is a public health imperative to address maternal and child undernutrition, and for new knowledge in this area to inform practice and policy. The overarching research question was: can locally produced food-based supplementation reduce LBW and improve infant growth outcomes when consumed by undernourished pregnant women?

Methods

This research was conducted in northern Bangladesh from 2013 until 2015. A multiphase design was used, while ensuring commitment to local-level applied research. This thesis comprises three phases and six sub-studies, encompassing six manuscripts (five published, and one under review). **Phase 1** consists of four sub-studies. Study 1 was a systematic review of the effect of balanced protein energy supplementation in undernourished pregnant women from low- and middle- income countries on child growth. Study 2 was a modified Photovoice study designed to explore perceptions on maternal diet of undernourished pregnant women in northern Bangladesh. Women were trained in Photovoice, and equipped with a digital camera. Photographs were used to evoke a narrative through an in-depth

interview process. Reflexive, thematic analysis was used. In Study 3, undernourished pregnant women in northern Bangladesh completed a questionnaire to identify women's dietary diversity (women's dietary diversity questionnaire) and household food security (an adaptation of the Household Food Insecurity Access Scale [HFIAS]). In Study 4, all pregnant women from targeted villages in northern Bangladesh were invited to participate in a survey to investigate the role of seasonality on maternal diet and household food security. Women were recruited over a two-year period, thus taking into consideration seasonal variances across the year. **Phase 2** was designed to assess the acceptability of a dietary supplement in undernourished pregnant women in Northern Bangladesh via a 30-day acceptability study (Study 5). An assessment and focus group at day 15 allowed for modifications to the initial supplement, and then a further assessment at day 30 allowed for testing acceptance of these modifications. The supplement developed in this study was used in Study 6. **Phase 3** (Study 6) was a cluster randomised controlled trial of undernourished pregnant women in Northern Bangladesh that was conducted to identify whether a locally produced prenatal food-based supplement improved anthropometric measures at birth and during early infancy. The intervention group received a locally produced balanced protein energy supplement (designed in Study 5). Intervention and control groups received basic nutrition education, antenatal and postnatal services.

Results

Phase 1

Study 1: The systematic review revealed that balanced protein energy supplementation significantly improved birth weight in babies of undernourished pregnant women from low and middle income countries. No significant benefit was observed on birth length or head circumference. The impact of intervention could not be determined for longer-term physical growth due to limited evidence. Additional research is required in low- and middle-income countries to identify impacts on longer-term infant growth.

Study 2: Eight major themes emerged from the Photovoice study: everyday foods consumed during pregnancy; liked foods influence on dietary consumption; household food production influences on dietary consumption; household food production providing both sustenance and income; need for a cash income in a subsistence community; family structure influences on dietary intake; understanding that nutrition is important though not sure why; and support provided by non-governmental

organisations. Study findings complemented the information obtained from Studies 1, 3 and 4, to better inform Studies 5 and 6.

Study 3: Half of the households in this survey were identified as food insecure, and two-thirds of women had inadequate dietary diversity, which may contribute to the burden of undernutrition and micronutrient deficiencies. The results of this study helped identify foods typically consumed by pregnant women, and informed the design of the supplement developed, tested and evaluated in Studies 5 and 6.

Study 4: The results of this study showed that seasonality was significantly associated with maternal dietary diversity and household food security. However, no significant differences in maternal nutrition status based on season were observed. The results of this study informed the design of the supplement used in Study 6, and supported the need for a locally developed food-based supplement in order to lessen the shock of lean seasons on household food security and maternal dietary diversity.

Phase 2

Study 5: A small business enterprise consisting of women from the targeted villages was established and women were trained to develop a balanced protein energy supplement using locally available, affordable and preferred foods as identified in Studies 2 and 3. The supplement developed in this study was used in Study 6. The establishment of a local business enterprise to produce the supplement built on local capacity and provided an income generation opportunity to the community.

Phase 3

Study 6: A randomised controlled trial of undernourished pregnant women revealed that a locally produced prenatal food-based supplement improved mid-upper arm circumference in early infancy. Thus, the proportion of wasting was lower in infants of supplemented mothers. Further, the supplement improved birth weight. While not significant, this was likely due to the sample size (type 2 error). The intervention reduced the risk of wasting at 6 months by 63.38%, and of LBW by 88·58%. Only three pregnant women require this intervention in order to prevent wasting at 6 months in one child, and seven need the intervention to prevent LBW of one child.

Conclusion

Bangladeshi pregnant women and children are urgently in need of sustainable community-led approaches to addressing undernutrition. This research has explored a new approach to addressing

undernutrition through the development of a locally produced food-based supplement. Findings from this research have the potential to influence practice and policy in Bangladesh. Program decision-makers have cheaper and more sustainable alternatives for the treatment of maternal acute malnutrition rather than using imported ready-to-use foods. Further research is required to confirm whether the approach presented in this thesis can be applied in other country contexts.

Table of Contents

Table of Figures

Acronyms and abbreviations

Acronym	Definition
ADP	Area Development Program
BBS	Bangladesh Bureau of Statistics
BDHS	Bangladesh Demographic Health Survey
BMI	Body Mass Index
Ca	Calcium
CI	Confidence Interval
CMAM	Community Management of Acute Malnutrition
COREQ	Consolidated Criteria for Reporting Qualitative Research
CONSORT	Consolidated Standards of Reporting Trials
D value	Cohen's d; or the odds ratio.
EPHPP QAT	Quality Assessment Tool for Quantitative Studies developed by the Effective Public Health Practice Project
FANTA	Food and Nutrition Technical Assistance
FAO	Food and Agriculture Organisation
FGD	Focus Group Discussion
g	Grams
GAM	Global Acute Malnutrition
HFIAS	Household Food Insecurity Access Scale

IDDS	Individual Dietary Diversity Score
IUGR	Intrauterine Growth Restriction
IQR	Interquartile Range
Kcal	Kilocalorie
Kg	Kilogram
LBW	Low Birth Weight
Mg	Magnesium
mg	Milligrams
MAM	Moderate Acute Malnutrition
MDG	Millennium Development Goal
MUAC	Mid-upper Arm Circumference
MICS	Multiple Indicator Cluster Survey
NGO	Non-Government Organisation
NIPORT	National Institute of Population Research training
NNT	Number Needed to Treat
ONDP	Optimal Nutrition During Pregnancy
PPM	Parts Per Million
P	Potassium
PICOS	Participants, interventions, comparisons, outcomes, and study design
P value	Probability value
PRISMA	Preferred Reporting Items for Systematic Reviews

RE	Retinol equivalents
RCT	Randomised Controlled Trial
RDI	Recommended Daily Intake
RRR	Relative Risk Reduction
RUTF	Ready to Use Therapeutic Food
SAM	Severe Acute Malnutrition
SD	Standard deviation
SGA	Small for Gestational Age
SPSS	Statistical Product and Service Solutions
TBA	Traditional Birth Attendant
UNICEF	United Nations International Children's Emergency Fund
WDDS	Women's Dietary Diversity Score
WHO	World Health Organisation
Zn	Zinc
µg	Micrograms

Glossary

Term	Definition
Amon	A type of rice typically cultivated from December to January
Ashbin	Month of the Bengali calendar; 15 September to 14 October
Boro	A type of rice typically cultivated from March to May
Choitro	Month of the Bengali calendar; 15 March to 14 April
Jute	Vegetable fibre that can be spun into coarse, strong threads
Kartik	Month of the Bengali calendar; 15 October to 14 November
Lesser monga	15 March to 14 April (Bengali calendar month: Choitro); also known as 'lesser lean season'
Lychee	*Litchi chinensis*; tropical/subtropical fruit tree
Main monga	The main monga occurs from 15 September to 14 November (Bangladeshi months of Ashbin and Kartik), prior to the main rice harvest. Also known as the 'lean season'
Mesta	Fibre crop commonly grown in Bangladesh
Monga	Bengali term referring to seasonal poverty, food insecurity and subsequent hunger in Bangladesh; also known as 'lean season'
Palm	Cultivated for palm oil production
Wood apple	Botanical name: *Limonia acidissima*; also known as bel fruit or elephant apple
Upazila	Geographical administrative division in Bangladesh; functions as a sub-unit of a district; sub-district
Union	Smallest administrative and local government units in Bangladesh

Preface

Motivation and personal background

In local level applied research it is considered important to place oneself in context, and it should be known that I am not a Bangladeshi. I was born in Australia and of British descent. My father worked in South East Asia and my family regularly visited him from Australia. This introduction from a young age exposed me to global inequities and challenges faced by many in low- and middle-income countries. My background is in public health nutrition, and I specialise in nutrition in emergencies. I hold qualifications in public health and health science, majoring in nutrition from the University of Sydney and Charles Sturt University respectively. I have a particular interest in nutrition programming in resource-poor settings, disasters and man-made humanitarian emergencies. My experience to date in public health nutrition includes holding multiple positions with progressive responsibilities with United Nations (UN) agencies and Non-Government Organisations (NGOs). I have spent the last ten years working in developing, disaster and man-made emergency contexts, and have country-specific experience including Cambodia, Bangladesh, Horn of Africa drought – Ethiopia, Typhoon Yolanda – Philippines, Typhoon Pam – Vanuatu, Gaza war – the Gaza Strip, Syrian refugee response – Jordan, the Yemen war – Yemen, the Borno State crisis – Nigeria, and the South Sudan response – South Sudan and Uganda.

I came to this research through my interest in better addressing child undernutrition. After graduating with a Master of Public Health in 2006, I travelled to Cambodia to start my career in public health nutrition in developing and emergency contexts. After a few years, I began to recognise the reliance on pre-packaged, imported ready-to-use products for the treatment of acute malnutrition in pregnant women and children. While effective, I questioned the sustainability of these products and why local alternatives were not encouraged. Often, ready-to-use foods are imported by United Nations agencies that work in the nutrition space. So, if funding is tight or a program ends, communities are unable to access these products. I also started to recognise that while evidence-based models were in place for the treatment of acute malnutrition in children (Community Management of Acute Malnutrition model, CMAM), there was no global consensus on the treatment of acute malnutrition in pregnant women.

In late 2009, I enrolled into a DrPH at JCU though was still unclear about the specifics of the research I wanted to conduct. In 2010, I found myself working in Bangladesh. Bangladesh was unlike any country I had worked in. Undernutrition in children and pregnant women were at unacceptable levels, and UN and NGO-led nutrition programs were not meeting the needs of the population. It was in

Bangladesh that I decided to research locally produced alternatives to address maternal undernutrition using a sustainable community-owned model. I was successful in gaining funding to support this research from World Vision New Zealand to pilot and test a locally produced food-based supplement that specifically targeted undernourished pregnant women in Bangladesh. Mostly, I continued to work full-time, however, in 2013 I focused on my research only, and lived in Bangladesh for a one-year period.

My candidature has been an incredibly rewarding journey. I was very lucky to have had the support of the Bangladeshi communities involved in this research, to secure needed funding, to have conducted this research, and to have strengthened my research skills. I hope that this research will better inform future nutrition programs that aim to address maternal undernutrition.

Chapter 1. Introduction

1.1 Overview

This introduction outlines maternal and child undernutrition globally, the impacts of maternal undernutrition on the foetus, causes to undernutrition, and prenatal food-based supplementation. This chapter sets the stage, provides the background and context for the research questions, positions my research and provides an overview of the thesis.

1.2 Maternal and child undernutrition in low- and middle- income countries

Article 25 of the Universal Declaration of Human Rights clearly states that all people have the right to a standard of adequate living for the health and wellbeing of self and family, which includes adequate access to food(1).[1] The message that food should be attainable by all is also proposed in many other international human rights treaties.[2] To ensure that global leaders recognise and endorse these human rights, both the World Food Summit in 1996 and the Millennium Summit in 2000 set quantified targets to halve the world's hungry by 2015. The international community worked hard to meet the Millennium Development Goals (MDGs) deadline; however, despite global efforts only two regions, South America and the Caribbean were able to reach MDG 1[3] and cut poverty and hunger by 50%. Efforts to reduce maternal and child undernutrition in sub-Saharan Africa, and south and west Asia remains static.

From 2012 to 2014, it was estimated that 60% of the world's 805 million chronically undernourished people were women. In sub-Saharan Africa and south and west Asia the prevalence of undernutrition in adult women (Body Mass Index <18.5) was above 10% (2). Maternal undernutrition is the leading cause of Intrauterine Growth Restriction (IUGR), which is measured using low birth weight (LBW) and small for gestational age[4] (SGA) as a proxy indicator (3). In 2010, 32.4 million babies were born SGA in low- and middle-income countries, with most born in India, Pakistan, Nigeria and

[1] Article 25 of the Universal Declaration of Human Rights (1) "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control. (2) Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection."

[2] Other international treaties include the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights, the Convention on the Elimination of All Forms of Discrimination Against Women, the International Convention on the Elimination of All Forms of Racial Discrimination, and the Convention on the Rights of the Child.

[3] MDG 1 – Eradicate extreme poverty and hunger; further information on the other MDGs can be found on the UNDP MDG webpage http://www.un.org/millenniumgoals

[4] Weight below the 10th percentile of a sex.

Bangladesh (4). SGA is associated with child undernutrition. In 2011, stunting[5] affected 165 million and wasting[6] affected 52 million children under the age of five years globally, with the highest rates in sub-Saharan Africa and South Asia (3).

1.3 Maternal undernutrition and Intrauterine Growth Restriction

Pregnancy and foetal growth are the two most vulnerable periods in a human's life. Maternal undernutrition (defined as pre-pregnancy Body Mass Index (BMI) <18.5, height <148cm, pre-pregnancy weight <45kg and/or low maternal weight gain) is associated with lowered birth weight (5). Newborns who are of LBW are at higher risk of becoming undernourished in the first five years of life (3) which may lead to irreversible outcomes such as: i) shorter adult height (6), ii) lowered immune function and subsequent malnutrition, iii) decreased cognitive function (7), and iv) an increased risk of chronic disease and maternal complications in later life (6). Newborns with LBW are likely to have had IUGR (8).

Intrauterine growth restriction (IUGR) is a result of the foetus not receiving the nutrients required for adequate growth, so that the foetus is SGA (9). During pregnancy, the body adapts and stores energy for the needs of the foetus, and stores fat for lactation. If a mother is undernourished, the body is unable to adapt, and placental growth is reduced by up to 50%, further limiting nutrient supplies to the foetus as fewer nutrients are able to cross the placental border (10, 11). When this occurs, the foetus will rob the mother of her own nutrient stores, regardless of her nutrient status (9). If the foetus still does not receive the nutrients required for adequate growth, it will become undernourished, resulting in IUGR.

1.4 Foetal malnutrition and disease

Maternal undernutrition negatively impacts on the development of the foetal immune system (12, 13). As a foetus, the principle components of the immune system begin to develop (12). Maternal malnutrition limits the nutrients needed for immune development leading to poor immune response to disease during childhood (12). Frequent disease results in a higher susceptibility to subsequent malnutrition which further affects the development of the immune system (13). This cycle is referred to as the 'disease and malnutrition cycle', which binds a child to malnutrition, and disease.

Maternal undernutrition and subsequent IUGR are not only linked with childhood disease, but also chronic disease in later life. The 'developmental origins of adult disease (Barker) hypothesis'

[5] Height for age z-score.
[6] Weight for height z-score and/or mid-upper arm circumference (MUAC) less than 12.5cm.

theorises that foetal structural and metabolic adaptations in response to maternal nutritional deprivation, followed by improved nutrition or rapid childhood weight gain, affects sensitivity to environmental factors later in life, increasing the risk of developing chronic disease (14-17).

1. 5 Underlying causes of maternal and child undernutrition

Undernutrition is both a cause and effect of poverty that combines generations of factors such as access to clean water and health care, low education and food insecurity.

In 1990, UNICEF developed a conceptual framework model outlining the causes of malnutrition in terms of how poverty, food insecurity and other factors affect nutritional status (18). The framework gives three main categories of underlying causes: 'immediate,' which operates at an individual level and includes insufficient dietary intake and infectious disease; 'underlying,' which operates at a household or community level and includes inadequate maternal and child care, and inadequate health services and health environment; and 'basic' which operates at a national or societal level and includes political ideology, formal and informal infrastructure and potential resources. This framework highlights the complexity of undernutrition whereby a variety of factors on different levels influence one another to determine the nutritional status of the individual. Maternal nutritional status is influenced not only by dietary preferences, but also by underlying conditions that affect household food security, care practices and access to health services such as political, economical, cultural and environmental structures.

1. 6 Prenatal supplementation in low- and middle-income countries and its effect on child growth

Food-based approaches to maternal supplementation aim to meet the energy gap experienced by many undernourished women. Balanced protein energy supplementation refers to supplementation where the protein provided is less than 25% of the total energy content (19). Recent systematic reviews have reported a significant positive effect of balanced protein energy supplementation on birth weight (5, 20); however, the impact on subsequent child growth is inconclusive, since few Randomised Controlled Trials (RCTs) have reported on this outcome (5).

The effect of balanced protein energy supplementation during pregnancy on subsequent child growth may depend on whether the mother enters pregnancy nourished or undernourished; the latter is a common circumstance in low-income countries. Thus, it is difficult to generalise the effect of balanced protein energy supplementation from low-, middle- and high-income countries (20).

Underweight women in studies from high-income countries are more likely to be suffering from acute malnutrition due to a sudden reduction in food intake. These women generally have nutrient stores available for foetal growth during the first trimester of pregnancy (9); however, acute malnutrition can result in a lowered weight in both mother and offspring. In contrast, women from studies in low-income countries are likely to suffer from chronic malnutrition with bouts of acute malnutrition during times of seasonal food shortages, consuming a low energy intake both before and during pregnancy while maintaining their usual physical workloads (21-25). Chronically malnourished mothers do not have nutrient stores, and have a much higher prevalence of delivering babies of LBW (9). Studies in Bangladesh (26), Gambia (27) and Taiwan (28) reported higher birth weight when maternal supplementation coincided with the months immediately after the lean season (26). These findings suggest that balanced protein supplementation is most effective when addressing an energy gap. Non-RCTs excluded from recent systematic reviews (5, 20) report positive effects from balanced protein energy supplementation on child growth in undernourished pregnant women when the supplement meets an energy gap (29, 30). In Guatemala, the authors of an RCT designed to investigate the effect of energy plus protein supplementation versus energy only, observed a positive impact of energy supplementation on growth when supplementation was provided to the mother and child (31). In Mexico, a quasi-experimental evaluation of a government conditional cash transfer program with high quality nutritional components (milk-based fortified foods) identified no difference in growth between children in intervention and comparison families aged 6 to 24 months. However, there was an increase in length and weight of children under 6 months (32). However, these results cannot be solely attributed to maternal supplementation, as the supplement was also received during lactation, and intervention households received cash transfers. A randomised trial in Bangladesh suggested that supplementation in early pregnancy compared to later pregnancy reduced the proportion of stunting from early infancy up to 54 months for boys, though not for girls (33).

There is no conclusive evidence on the timing of food interventions during pregnancy, as limited data are available. The Dutch famine study is often cited by researchers as evidence of the negative effect of malnutrition and undernutrition on foetal and infant growth; however, this study refers to acute malnutrition in a high-income country context and therefore does not provide evidence on the effects of chronic malnutrition of foetal and child growth (34-36). It is reported that if IUGR occurs in early pregnancy, the effects on foetal development are irreversible. However, if it occurs in the second half of pregnancy, it may be reversible with appropriate nutritional interventions (10, 11).

1.7 Research questions

The central question for this research is: Can locally produced food-based supplementation reduce LBW and improve infant growth outcomes when consumed by undernourished pregnant women? For the purposes of this thesis, 'locally produced' is defined as a supplement that uses locally available and preferred foods produced by the communities receiving the supplement. 'Improved infant growth outcomes' is defined as the locally produced supplement being effective in improving birth weight and infant weight and lean mass. My experience in working with maternal and child undernutrition in Bangladesh and other low-income countries is that while there is a slow improvement in the prevalence of maternal and child undernutrition rates, there is a reliance on imported ready-to-use foods. Subsequently, research funding allowed me to explore this issue. This research was based on the premise that maternal and child undernutrition must be sustainable.

1.8 Focus of the research

This research focuses on the development of a locally produced food-based supplement for undernourished pregnant women, and its efficacy in improving infant growth outcomes in rural Bangladesh. It also considers local food availability, the preferences and knowledge of pregnant women, and the supplement acceptance by these women.

The overarching research question was addressed through the following specific sub-questions:

1. In low- and middle-income countries, does balanced protein energy supplementation improve birth and infant growth outcomes, and what is the evidence for this?
2. What are the perspectives of pregnant women on maternal nutrition?
3. What is the nutritional situation in terms of dietary diversity and food security for pregnant women living in the targeted villages?
4. What form (composition and type) of locally produced supplement does the targeted population group accept?
5. Does the preferred supplement improve newborn/infant child growth outcomes?

The studies in this research build on and add to knowledge in the fields of supplementation and maternal and child undernutrition. Although several studies have explored the role of prenatal balanced protein energy supplementation and its association with child growth outcomes, there has been scant attention to the local production of these supplements. As such, this research presents additional

insights into the issues and challenges of developing a locally produced food-based supplement for undernourished pregnant women and its effect on infant growth.

This research focuses on maternal and child undernutrition in women of northern Bangladesh, a rural context. Thus, the research presented in this thesis is confined to Bangladeshi women living in rural areas rather than Bangladeshis or women in low-income countries in the broader sense. It was outside the scope of this research to discuss the establishment or feasibility of the small business enterprise that produced the supplement. It was also beyond the scope of this thesis to examine the effect of the supplement on maternal nutrition status, although this analysis will be conducted and published at a later date.

1.9 Overview of methods used

I used a multiphase mixed methods design for this thesis, as illustrated in Figure 1. All phases of this research were committed to local-level applied mixed methods research. Mixed methods research is defined as a

> "mixture of qualitative and quantitative approaches in many phases in the research process. As a method it focuses on collecting, analysing, and mixing both quantitative and qualitative data in a single or series of studies. Its central premise is that the use of quantitative and qualitative approaches in combination provides a better understanding of research problems than either approach alone." Cresswell 2007, page 5; (37)

When choosing the methods to use in this research, consideration was given to methods that were most likely to empower local communities. The specific method used for each of the sub-studies is discussed in detail in the relevant chapter of the thesis. Qualitative methods were used to better understand how pregnant women themselves perceive maternal nutrition, and thus informed the quantitative methods. The mixed methods approach used provided an expanded understanding of this thesis as a whole, and were informed mainly by Greene and Thorogood, and Creswell and Plano (37-39).

This research comprises three phases which were combined into a multiphase mixed methods design (38). Each phase addressed a research question in turn, and subsequently informed the next phase of the research. Phase one was the formative research phase and consisted of: a systematic review (Study 1); a qualitative study (Study 2); and two quantitative studies (Studies 3 and 4). Phase 2 focused on the development of an acceptable balanced protein energy supplement (Study 5). Phase 3 explored the

efficacy of the supplement developed on birth and infant anthropometric outcomes through a cluster randomised controlled trial (Study 6). As above, detailed methodology is described in each relevant chapter, however a brief overview of each phase and study is provided below for context.

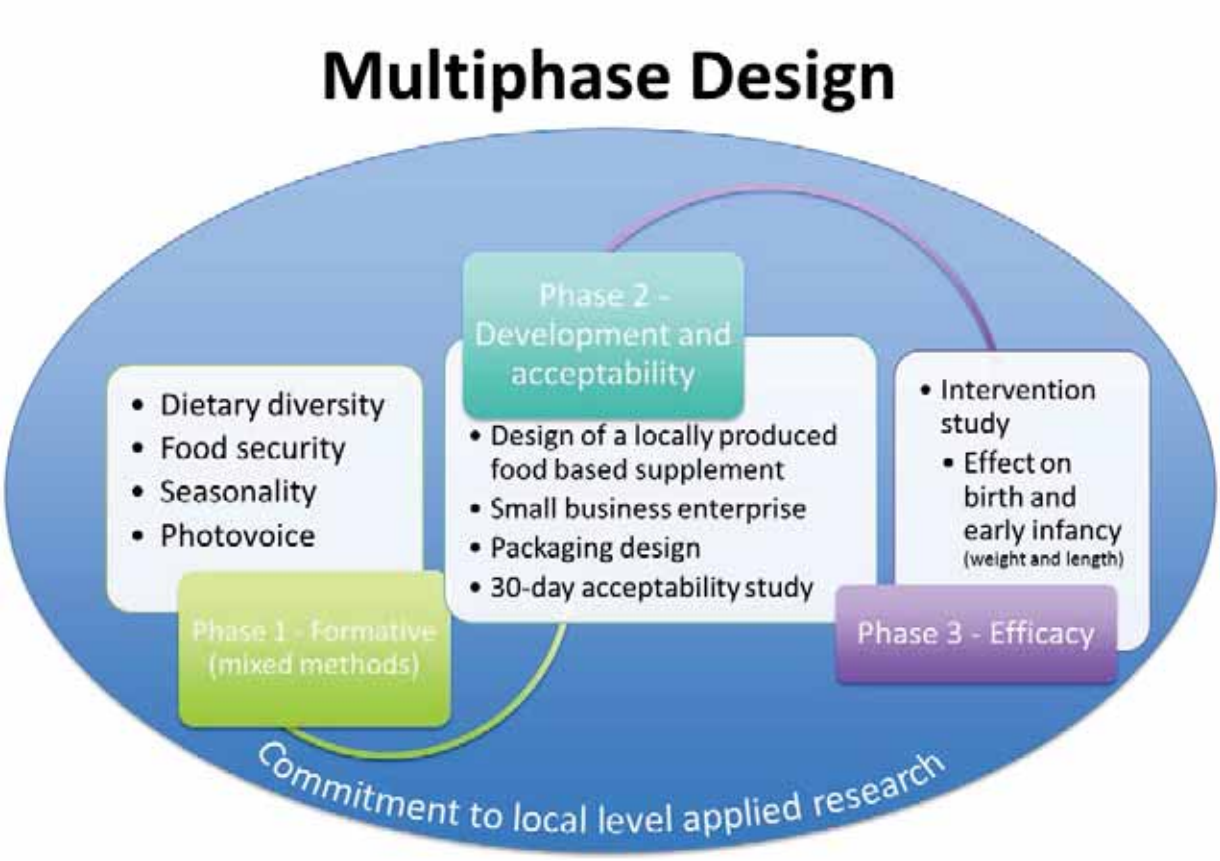

Figure 1 Design applied to thesis

1.9.1 Addressing the research questions

Phase 1

Question 1: In low- and middle-income countries, does balanced protein energy supplementation improve birth and infant growth outcomes, and what is the evidence for this?

Methodology: the methodology for addressing this question was a systematic review of peer-reviewed literature from low- and middle-income countries about balanced protein energy supplementation and its effect on birth and child growth outcomes (Chapter 2, Study 1). The search was conducted using

electronic databases and hand searching. The Preferred Reporting Items for Systematic Reviews (PRISMA) (40) checklist and the PRISMA Explanation and Elaboration Document (41) were used as an evidence-based guide to ensure the transparent and complete reporting of the review. Risk of bias was assessed using the Quality Assessment Tool for Quantitative Studies (42-44). Systematic reviews are a higher-level method for developing an evidence-base. A quantitative analysis was carried out using the program Comprehensive Meta Analyses (www.meta-analysis.com, USA, 2005)

Question 2 and 3: How do women perceive maternal nutrition? What is the nutritional situation in terms of dietary diversity and food security for pregnant women living in the targeted villages?

Methodology: Both qualitative and quantitative research methods were used to answer these questions (Studies 2, 3 and 4; Chapters 3, 4 and 5 respectively). All undernourished pregnant women in the selected villages were invited to participate. To answer Question 2, Photovoice methodology was used. Photovoice enabled women to document their daily lives through the use of photographs. This method draws from the theoretical literature on empowerment education for critical consciousness as developed by Paulo Freire (45), feminist theory as defined by Kathleen Weiler (46) and community-based approaches to documentary photography as defined by Wang (47). Participants were trained and equipped with a digital camera, and asked to record their individual views and experiences on maternal nutrition. These photographs were printed and used to evoke a narrative through an in-depth interview process. The Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist was used to ensure comprehensive reporting of this study (48). Thematic analysis was used to analyse and interpret the data sets (49, 50).

To answer Question 3, a structured survey was conducted (Study 3). The survey consisted of two validated tools for low-income and rural contexts: 1) the Household Food Insecurity Access Scale (HFIAS) and 2) the women's dietary diversity questionnaire. The survey was completed through face-to-face interviews to minimise issues associated with literacy and development of a rapport with participants. Data were analysed using Microsoft Excel and SPSS Statistics 23.0 ©, the HFIAS for Measurement of Food Access Indicator Guide (51) and the Guidelines for Measuring Household and Individual Dietary Diversity (52). This study was expanded into Study 4 where all pregnant women from targeted villages in northern Bangladesh were invited to participate in a cross-sectional survey to investigate the role of

seasonality on maternal diet and household food security. Women were recruited over a two-year period, thus taking into consideration seasonal variances across the year.

Phase 2

Question 4: What type of locally produced supplement is accepted by undernourished pregnant women living in northern Bangladesh?

Methodology: To answer Question 4, several approaches were applied and these formed Study 5 (Chapter 6). Data obtained from answering Questions 1 and 2 informed the initial composition of the supplement. A small business enterprise was then established to produce the supplement. To test the acceptance of the supplement, an acceptability study was conducted. The sample for the acceptability study was the same sample that participated in Chapter 3. Thus, all undernourished women identified as pregnant at the time of this study were invited to participate. For the acceptability study, a questionnaire was administered at days 15 and 30. The questionnaire consisted of open and closed questions. In addition to the questionnaire at day-15, a focus group discussion was conducted. The focus group added rich qualitative information and narrative that supported the quantitative analysis of the questionnaires. The day 15 questionnaire and focus group allowed for modifications to the initial supplement, and the assessment at day 30 allowed for testing acceptance of these modifications. Data from day 15 and day-30 were analysed separately, showing opinions at two different time points. Quantitative data were analysed using descriptive statistics with Microsoft Excel ©. Data from the focus group discussions were analysed and interpreted using thematic analysis (49, 50).

Question 5: Does the supplement effectively improve birth/infant growth outcomes?

Methodology: To answer this question, a cluster randomised controlled trial was conducted with undernourished pregnant women (Study 6, Chapter 7). Women in the intervention group received a daily serve of the supplement. Both the intervention and control groups received nutrition education messages, iron folic acid supplementation, and referral to antenatal and postnatal services. Women completed a structured questionnaire on enrolment to capture baseline information. Maternal height, weight and mid-upper arm circumference (MUAC) were measured on enrolment. Maternal height and MUAC were measured each month until delivery. Weight of the infant was recorded at birth, and each month until 6 months. Infant MUAC was recorded at 6 months. The Consolidated Standards of Reporting

Trials (CONSORT) statement was used to ensure comprehensive reporting of this study. Data quality was ensured by quality checks associated with the data entry process, double entry, and data cleaning. Data management was conducted using Microsoft Excel. Statistical analyses were performed using the statistical software package IBM SPSS, Version 23© (Armonk, NY, USA).

1.10 Developing the research

1.10.1 Community Engagement and Consultation

This research builds on my direct work experiences in low-income countries that experience high rates of acute malnutrition. Prior to conducting this research, I had experience working with remote Bangladeshi communities, including the sub district where this research took place. This prior experience of working in low-income country contexts and with Bangladeshi communities in particular, gave me an advantage when it came to commencing the community engagement for this research. I had an existing relationship with the World Vision field office (hereafter referred to as Pirganj Area Development Program, ADP) present in the area through my former position at World Vision New Zealand (NZ) where I coordinated NZ-generated funding for Bangladesh. World Vision had a good reputation with the communities under its coverage. In the former position, I would often visit New Zealand funded World Vision ADPs and see firsthand how funding was being used. Often, this involved reviewing the progress of activities against annual targets, visiting activities being conducted, holding focus groups and key informant interviews with communities, and providing capacity development activities as required.

For this research, the community engagement process began in early 2012. First, a sampling framework was developed to identify which communities would be involved in the intervention. The Pirganj ADP team assisted with organising preliminary meetings with the community leaders to identify their willingness to participate in this research. I was very lucky, as all villages selected for this research expressed interest in participating. Next, local health centres and NGOs were consulted. Information on this research was shared, and partnerships were established. I then engaged and consulted with the communities through community information sessions on the research. Every community member was invited to participate in these sessions. The sessions were interactive, firstly providing a background on the proposed research, then asking for community suggestions on how to improve the proposed research, and closing with Questions and Answers. After concluding the community information sessions, focus group discussions were held with pregnant women in each of the villages to explore

individual willingness to participate, thoughts on how to improve the research and other factors as discussed later in this thesis (Study 5).

1.10.2 Community Nutrition Volunteers

Based on previous experience and insight from other programs, I decided to establish a Community Nutrition Volunteer network to better support this research at a grassroots level. Based on expressions of interest, one Community Nutrition Volunteer was recruited from each of the targeted villages. In addition, one Community Nutrition Volunteer Coordinator was recruited to oversee the volunteers working in the intervention group, and one was selected to oversee the volunteers in the control group. The Community Nutrition Volunteers were provided with a stipend to reimburse for their work and time on the project. In addition, volunteers received information on this research, and basic training on all methods used (for Studies 2-6). The volunteers assisted with all aspects of data collection for Studies 2-6.

1.10.3 Research Assistance

I was very fortunate that a Masters student, Moniek, from Massey University, New Zealand, expressed interest in assisting this research, and conducted parallel research activities for her Master's thesis. In early 2012, she lived in Bangladesh for three months to assist with the initial set-up of this research project. During this time, Moniek also conducted qualitative research to explore the eating habits, taboos and superstition in the sub-district, which formed her own masters' thesis. While being separate from the research conducted for this thesis, Moniek's research contributed enormously by adding to the evidence base and informing the first and second phase (Studies 2-5) of my research.

1.10.4 Small Business Enterprise

To support development of the supplement, a small business enterprise was established. Very early in this research, a local food technologist who had heard about this research approached me. He expressed interest in being involved, and we recruited him to oversee the small business enterprise. The details of the small business enterprise are in Study 5. As a summary, under the guidance of the food technologist eight women were recruited from local communities, and using research funding, were equipped, trained and provided financing to produce the supplement. The food technologist ensured food safety and hygiene, and monitored the quality of the food purchased from the local markets.

1.10.5 Population and Setting

Bangladesh is a small disaster-prone country of 162 million people in South Asia, bordering with India and Myanmar. After independence from Pakistan in 1971, the country experienced cycles of famine, natural disasters and widespread poverty which today is amongst the highest rates globally. Bangladesh ranks 142 of 187 countries on the Human Development Index, and is thus classified as one of the least developed countries (53).

When I commenced planning my research and initial community engagement in 2011 and 2012, Bangladesh had among the highest rates of maternal and child undernutrition globally (54). Data at this time revealed that maternal undernutrition affected one in three women (defined as a Body Mass Index <18.5 kg/m2) (55), and LBW (< 2·5kg) affected one in five newborns (56). Among children aged 6 to 59 months, 43% were stunted and 17% wasted (57). In rural Bangladesh, extreme poverty[7] was three times higher than in urban areas, where women were less likely to access antenatal and postnatal services, and children suffered from higher rates of chronic malnutrition (45% and 36% in rural and urban areas, respectively) (55). A clear relationship between the maternal and child nutritional status had been identified. Children of older mothers were more likely to be stunted than children of younger mothers; children of mothers with no education were more likely to be stunted than other children; and children of undernourished mothers were more likely to be undernourished (55).

In Bangladesh, strong traditional practices influence maternal food consumption (59). Bangladeshi society is steeped in traditional beliefs, social and cultural structures, and is staunchly patriarchal. Dietary taboos and food aversions are widely practised, limiting the dietary consumption of pregnant women (59). Women traditionally eat last at a meal, resulting in the smallest share (59). While the purdah system of confining a woman to the home appears no longer common (60), women generally remain voiceless in household decision-making. Despite high levels of nutrition knowledge, the patriarchal society limits foods consumed, access to health care, and access to community events. In Bangladesh, the times of the year when there are seasonal fluctuations in income and employment are referred to as 'monga'. Monga occurs twice annually, with the main monga occurring from 15 September to 14 November (Bangladeshi months of Ashbin and Kartik), prior to the main rice harvest, and the lesser monga occurs from 15 March to 14 April (Bangladeshi month of Choitro) (61). During monga, Bangladeshis face seasonal food shortages that often result in household food shortages,

[7] Defined as earning less than $1.25 per day by the World Bank. See Ravallion, Chen, and Sangraula (2009) for further information on how the $1.25-a-day international poverty line was derived. 58. Ravallion M, Chen S, Sangraula P. Dollar a day revisited. The World Bank Economic Review. 2009.

particularly those in rural areas who rely on subsistence farming. The documented consequences of seasonal food shortages on the nutritional status of women in low-income countries include reduced energy expenditure, weight loss, insufficient weight gain, and subsequent LBW (22-24).

Figure 2 illustrates the districts in Bangladesh. Rangpur district is located in northern Bangladesh. Rangpur district covers an area of 2400·56 km^2, consists of 8 sub-districts, 83 unions, 1492 villages, and has 2,881,086 inhabitants [(62)]. The majority of the population are considered as rural, with only 15.37% living in urban areas (62). Literacy is at 48.6%,[8] and Islam is the main religion, followed by Hinduism and Christianity. Typical to other areas of Bangladesh, Rangpur district has a tropical monsoon climate with high temperatures, high humidity and heavy seasonal rainfall from June to November. Rangpur is reported as more vulnerable to seasonal food insecurity compared with other areas of Bangladesh(63). Rangpur's main employment is agricultural labour, though wages are low compared to neighbouring districts (61). The villages are typical of villages in northern Bangladesh and have dirt road access that is often inaccessible during the wet season. The main crops grown in Rangpur include rice (including Amon and Boro rice types), jute, mesta, wheat, pulses, oilseeds, spices, potato and sweet potato. The main fruits grown in Rangpur include mango, black berries, jackfruit, banana, coconut, organ, litchi, dates, guava, wood apples and palm (62).

Figure 3 illustrates the unions in Pirganj district. My research was conducted in twelve rural villages, in two unions of Pirganj sub-district of Rangpur District. Pirganj sub-district covers an area of 411·34 km^2, consists of 15 unions and 332 villages, and has 385,499 inhabitants (62). The majority of the population is Muslim, with a minority of people belonging to the Santal ethnic group who are predominantly Christian. The average household size is 3.78 and literacy rates are 45.4% (62). The villages are rural with dirt road access that is often inaccessible during the wet season. The population is largely dependent on subsistence farming and have limited experience with non-Bangladeshi foods.

[8] Defined as the ability to write a letter in any language, assessed from population 7 years and above. Bangladesh Population and Housing Census, 2011.

Figure 2 Map of Bangladesh. Map sourced from maps open source at mapsopensource.com

Figure 3 Map of Pirganj Upazila, Rangpur district. Map sourced from maps of Bangladesh, open source at mapsopensource.com

1.11 Thesis outline

Figure 4 is a concept map of this research as it is presented in this thesis. This thesis contains five manuscripts that have been published in international, peer-reviewed journals, and one that is currently under-review. These manuscripts form Chapters 2-7. Publications 1-5 are presented as published in a PDF format, and article 6 is presented as submitted. Consequently, there is some inevitable duplication within the thesis. Article 6 is under review, thus a PDF version is not presented in this thesis. Supplementary online material where related to a publication has been placed after each article. Each chapter starts with a succinct overview of the publication, and concludes with a summary of the

important points yielded from the research described in the chapter. These published papers (Chapters 2-7) are preceded by this Introduction. The thesis commences with this Introduction, and finishes with a Discussion section (Chapter 8) and Conclusion (Chapter 9) where the findings from all the studies are summarised in the context of strengths and limitations, and their implications, with suggestions for future research. The methodology for each publication is addressed within the corresponding chapter. My contribution to each study is stated in the Contribution of Authors table at the beginning of this thesis.

The findings from each phase are summarised in the Discussion (Chapter 8). A single Reference section (containing the references from the Introduction, Discussion and Conclusion) is placed after the chapters. The Appendices follow the Reference section, and contain a summary of outputs accomplished as part of my doctoral studies, the data collection tools used in these studies, and conference presentations documentation.

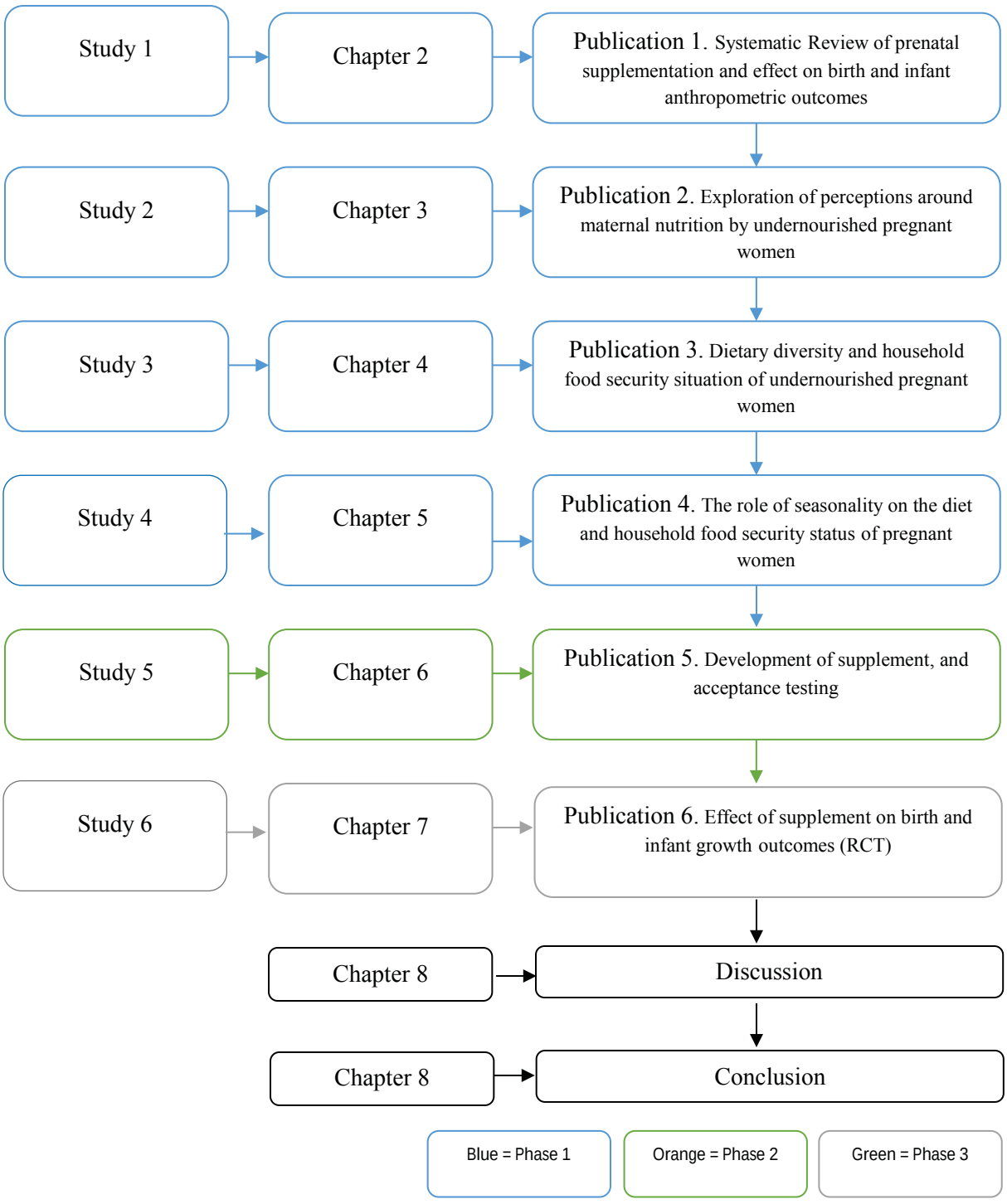

Figure 4 Concept map of thesis

1.12 Summary of chapters and corresponding publications

Study 1, Chapter 2: The effect of balanced protein energy supplementation in undernourished pregnant women and child physical growth in low- and middle-income countries: a systematic review and meta-analysis. Maternal and Child Nutrition. 2015; 4(11): 415–32. doi: 10.1111/mcn.12183

In this article, published by Maternal and Child Nutrition, I explore whether prenatal balanced protein energy supplementation has an effect on birth and child anthropometric outcomes particularly for low- and middle-income countries. This systematic review of the literature synthesised the evidence on how effective balanced protein energy supplementation is on improving birth and infant anthropometric outcomes. This review informed the design of this research in terms of what form of supplementation could potentially be effective.

Study 2, Chapter 3: The use of a modified version of Photovoice to identify maternal dietary consumption enablers and barriers in Northern Bangladesh. International Journal of Food, Nutrition and Public Health. 2016; 8 (1): 1-19.

Chapter 3 comprises the second published article in this thesis. This article, published in the International Journal of Food, Nutrition and Public Health, explores perceptions around maternal nutrition as experienced by undernourished pregnant women living in some of the villages selected for article 5. The information obtained from this study contributed to a deeper understanding of barriers and enablers that may influence maternal dietary consumption. This information contributed to Chapters 4 and 5.

Study 3, Chapter 4: An exploration of maternal dietary diversity and household food security in undernourished pregnant women living in Northern Bangladesh. International Journal of Food, Nutrition and Public Health. 2015; 7 (2): 61-69.

Chapter 4 comprises article 3, and is published in the International Journal of Food, Nutrition and Public Health. This chapter provides quantitative information on dietary diversity and household food security of undernourished pregnant women living in selected villages in northern Bangladesh. This information

contributed to recognition of commonly consumed food groups, and the levels of food security for these communities.

Study 4, Chapter 5: 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. 2016; (1): 1-9

The article that is the basis of this chapter is published with the Journal of Public Health Nutrition, and explores how seasonality may influence maternal nutrition. In particular, the chapter explores the role of seasonality on maternal anthropometric measures, dietary diversity and household food security. Other similar research explores seasonality by conducting cross-sectional studies at 2 or 3 time points. This study is unique as it uses the baseline of all pregnant women screened for the cluster randomised controlled trial, and provides information on the role of seasonality over a two year period.

Study 5, Chapter 6: Development of a locally produced balanced protein energy supplement, and its acceptance by undernourished pregnant women in northern Bangladesh. Journal of Hunger and Environmental Nutrition. 2016; (1): 1-16.

This chapter provides information on how the balanced protein energy supplement was developed, and the acceptability study that was conducted to test its acceptance by pregnant women. The manuscript has been published in the Journal of Hunger and Environmental Nutrition. This is an acceptability study and acted as an opportunity to modify the supplement (used in study 6) to better suit the expectations and acceptance of the participating women.

Study 6, Chapter 7: A village-matched evaluation of providing a prenatal local supplemental food and early infant growth in rural Bangladesh: A pilot study. Under review.

This chapter presents the evidence from a cluster randomised controlled trial with undernourished pregnant women from targeted villages in northern Bangladesh. The aim of this RCT is to investigate how the supplement affects birth and infant anthropometric outcomes. The resulting publication is currently under review.

1.13 Significance of this study

This is the first study to design a community-based model to prevent child undernutrition through prenatal supplementation. Each phase of the study is community-based. For example: the development of the supplement using locally available and preferred foods only; the use of community nutrition volunteers to screen pregnant women, collect monthly data and distribute the supplementary food; and the establishment of a small business enterprise to manufacture the supplement and then offer the supplement for sale after the study concluded. This study has the potential to influence future research and undernutrition projects that consider community ownership and sustainability.

Chapter 2. The effect of balanced protein energy supplementation in undernourished pregnant women and child physical growth in low- and middle-income countries: A systematic review and meta-analysis

2.1 Overview

At the time of this review there was no published synthesis of work on the effect of balanced protein energy supplementation consumed by undernourished pregnant women on birth and child anthropometric outcomes, specifically in low- and middle-income countries. This chapter explores the question: in low- and middle-income countries, does balanced protein energy supplementation improve birth and infant growth outcomes, and what is the evidence for this? This chapter synthesises the evidence for the effectiveness of balanced protein energy supplementation from low- and middle-income countries.

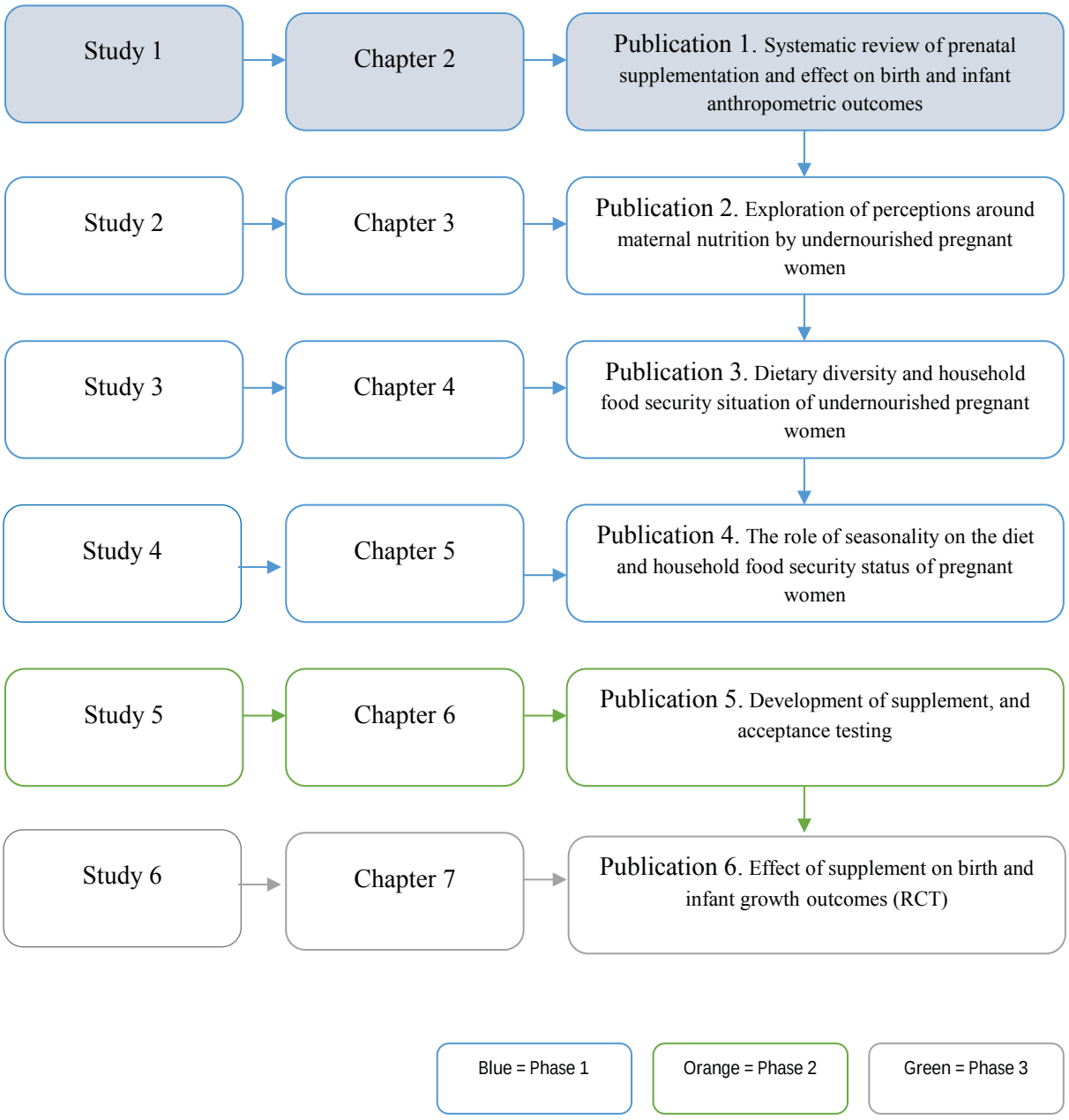

Figure 5 Study 1, Chapter 2 in relation to the thesis structure and multiphase design

This chapter comprises the following manuscript that has been published in an international, peer-reviewed journal:

Stevens, B., Buettner, P., Watt, K., Clough, A., Brimblecombe, J., Judd, J. The effect of balanced protein energy supplementation in undernourished pregnant women and child physical growth in low- and middle-income countries: A systematic review and meta-analysis. Maternal and Child Nutrition. 2015; 4(11): 415–32. doi: 10.1111/mcn.12183

The article is inserted as published (PDF). This article is among the top 10 downloaded articles from Maternal and Child Nutrition journal and has made a significant contribution to the literature by providing a synthesis of information specific to low- and middle-income countries. It is an open access article covered by a creative commons licence. Aspects of this study were presented in a conference poster at the Nutrition Society of Australia conference 2014. The peer-reviewed abstract is presented as an appendix at the end of this thesis.

2.2 Publication in Maternal and Child Nutrition

Maternal & Child Nutrition

DOI: 10.1111/mcn.12183

Review Article

The effect of balanced protein energy supplementation in undernourished pregnant women and child physical growth in low- and middle-income countries: a systematic review and meta-analysis

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Abstract

The beneficial effect of balanced protein energy supplementation during pregnancy on subsequent child growth is unclear and may depend upon the mother entering pregnancy adequately nourished or undernourished. Systematic reviews to-date have included studies from high-, middle- and low-income countries. However, the effect of balanced protein energy supplementation should not be generalised. This review assesses the effect of balanced protein energy supplementation in undernourished pregnant women from low- and middle-income countries on child growth. A systematic review of articles published in English (1970–2015) was conducted via MEDLINE, Scopus, the Cochrane Register and hand searching. Only peer-reviewed experimental studies analysing the effects of balanced protein energy supplementation in undernourished pregnant women from low- and middle-income countries with measures of physical growth as the primary outcome were included. Two reviewers independently assessed full-text articles against inclusion criteria. Validity of eligible studies was ascertained using the Quality Assessment Tool for Quantitative Studies (EPHPP QAT). In total, seven studies met the inclusion criteria. All studies reported on birthweight, five on birth length, three on birth head circumference, and one on longer-term growth. Standardised mean differences were calculated using a random-effects meta-analysis. Balanced protein energy supplementation significantly improved birthweight (seven randomised controlled trials, $n = 2367$; d = 0.20, 95% confidence interval, 0.03–0.38, $P = 0.02$). No significant benefit was observed on birth length or birth head circumference. Impact of intervention could not be determined for longer-term physical growth due to limited evidence. Additional research is required in low- and middle-income countries to identify impacts on longer-term infant growth.

Keywords: child growth, international child health nutrition, low-income countries, maternal nutrition, systematic review, underweight.

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Introduction

Rationale

The nutritional status of a woman during pregnancy influences the physical growth of the child. Undernutrition in pregnancy is associated with lowered birthweight, an indicator of intrauterine growth restriction (Stein *et al*. 2004). Low-birthweight babies have a substantially increased risk of stunting by 24 months of age (Martorell *et al*. 1998), leading to irreversible outcomes after 36 months of age, including (1) shorter adult height (Victora *et al*. 2008); (2) lowered immune function and subsequent malnutrition; (3) decreased cognitive function (Pitcher *et al*. 2006); and (4) an

increased risk of chronic disease and maternal complications in later life (Victora *et al*. 2008). Longer-term implications include diminished school achievements and lower adult income (Victora *et al*. 2008).

Little is known about the impact of balanced protein energy supplementation provided throughout pregnancy on birthweight and on the longer-term growth of the child, especially for undernourished women in low- and middle-income countries. A recent Cochrane review (Ota *et al*. 2012) identified that balanced protein energy supplementation during pregnancy significantly improves birthweight and birth length. However, impacts on longer-term growth remain inconclusive as few randomised control trials (RCTs) have reported on this outcome. Ota *et al*.'s review combined adequately nourished and undernourished women, and after stratification, no subgroup differences were identified in terms of birth anthropometrics. A similar review (Imdad & Bhutta 2011) argued that the effect is more pronounced in underweight women with no significant effect in adequately nourished women. Both systematic reviews combined studies from low, middle and higher income countries (Imdad & Bhutta 2011; Ota *et al*. 2012).

Non-RCT studies excluded from both Ota's and Imdad's reviews reported positive findings from maternal supplementation of undernourished women on longer-term growth when the supplement meets an energy gap (Winkvist *et al*. 1998; Tofail *et al*. 2008). Gestational weight gain is strongly associated with fetal growth (Ota *et al*. 2012) and pre-pregnancy weight below 45 kg, or height below 148 cm, are associated with poor fetal outcomes (Kelly *et al*. 1996). In Guatemala, the authors of an RCT, designed to investigate the effect of energy plus protein supplementation vs. energy only, observed a positive impact of energy supplementation on growth when supplementation was provided to mother and child (Lechtig *et al*. 1975). A randomised trial in Bangladesh suggested that supplementation in early pregnancy compared with later pregnancy reduced the proportion of stunting from early infancy up to 54 months for boys, although not for girls (Khan *et al*. 2011). Studies in Bangladesh (Shaheen *et al*. 2006), the Gambia (Ceesay *et al*. 1997) and Taiwan (Adair & Pollitt 1985) report higher birthweight when maternal supplementation coincided with the months immediately after the lean season (Shaheen *et al*. 2006). These findings suggest that balanced protein supplementation is most effective when addressing an energy gap.

The effect of balanced protein energy supplementation during pregnancy on subsequent child growth may depend upon whether the mother enters pregnancy adequately nourished or undernourished; the latter a common circumstance in low- and middle-income countries (Black *et al*. 2013). Thus, it is difficult to generalise the effect of balanced protein energy supplementation from low-, middle- and high-income countries (Imdad & Bhutta 2011). Underweight women in studies from high-income countries are more likely to be suffering from acute malnutrition due to a sudden reduction in food intake, which can result in a lowered weight in both mother and offspring. In contrast, women from studies in low- and middle-income countries are more likely to suffer from chronic malnutrition with bouts of acute malnutrition during times of seasonal food shortages,

Key messages

- First systematic review to-date that analyses the effect of balanced protein energy supplementation during pregnancy in undernourished women of low- and middle-income countries only.
- Between 1970 and 2015, seven unique studies measured the effect of balanced protein supplementation in undernourished pregnant women in low- and middle-income countries on child growth outcomes.
- In low- and middle-income countries, balanced protein energy supplementation has a statistically significant positive impact on the birthweight when the mother is undernourished.
- The impact of balanced protein energy supplementation for undernourished pregnant women on subsequent child growth in low- and middle-income countries remains inconclusive, as the evidence in these studies is not sufficient to determine the effectiveness.

consuming a low energy intake both before and during pregnancy while maintaining usual physical workloads. As reported by Imdad & Bhutta, the effects of balanced protein energy supplementation in undernourished women should not be generalised across low-, middle- and high-income countries. There is a need to review studies from low- and middle-income countries only.

This review identifies the effect of balanced protein energy supplementation during pregnancy on child physical growth in low- and middle-income countries and will identify the significance of targeting specific interventions to different economic contexts. The effect on child growth refers to the effect of balanced protein energy supplementation during pregnancy in undernourished women from low- and middle-income countries and:

1. birthweight,
2. birth length,
3. birth head circumference, and
4. longer-term growth (length/height, weight and head circumference up until 60 months of age).

Materials and methods

Protocol and registration

The PRISMA statement (Moher *et al*. 2011) and the PRISMA Explanation and Elaboration Document (Liberati *et al*. 2009) informed the methodology for this review. The search strategy, methods of analysis and inclusion criteria were specified in advance and documented in a protocol. The review is registered with the international prospective register of systematic reviews (PROSPERO) (Review number: CRD42013005115).

Eligibility criteria

Study

Peer-reviewed articles published in English from 1970 to 2015, describing experimental studies were included in this review – that is, RCTs, controlled before and after studies, and interrupted time-series analyses of routinely collected data. Comparisons with historical controls or national trends were excluded.

Participants

All studies from low- and middle-income countries involving participants who were identified as undernourished pregnant women. Low- and middle-income country classifications were based on the World Bank 2013 data.[1] This includes studies recruiting undernourished women only, or where within-study stratification was possible between adequately nourished and undernourished women. Undernutrition was not defined, and no common criteria were set. All degrees and definitions specified by each study were of interest, and included. Studies involving participants with groups living with HIV/AIDs and TB were excluded.

Intervention

Eligible studies focused on balanced protein energy supplementation during pregnancy with the outcome being infant and/or child growth. Balanced protein energy refers to macronutrient food-based supplements where the protein provided less than 25% of the total energy content (Kramer & Kakuma 2003). Interventions excluded were those with the primary objective of determining the effects of dietary advice to pregnant women, high protein supplementation (defined as interventions that provided more than 25% of total energy content) and isoenergetic protein supplementation (defined as a supplement where protein replaces an equal quantity of non-protein energy content). Single or multiple micronutrient supplementation studies were excluded unless a balanced protein energy supplement was provided in addition to the multiple micronutrients.

Comparison

Eligible studies had a measurable control so that the impact of the intervention could be assessed. Eligible

[1]The World Bank: Country and Lending Groups (2013). World Bank: Washington, DC. Available from: http://www.data.worldbank.org/country (Accessed 17 July 2013).

controls included 'alternative supplement', 'placebo' and 'no intervention'. Studies that compared a balanced protein energy supplement against a second balanced protein energy supplement were not included.

Outcome

To be eligible for the review, a study must have had published measures of at least one of the following as a primary outcome:

1. Anthropometric measures of the child up to 60 months, including length/height, weight and/or head circumference; and/or
2. Anthropometric measures of intrauterine growth including birthweight, birth length and/or birth head circumference

Information sources

Databases searched were Cochrane, Scopus and MEDLINE via Ovid electronic databases, between 11 March and 28 April 2013. An additional MEDLINE via Ovid search was conducted on 14 January 2015. Reference lists of eligible studies were also manually examined.

Search

The search consisted of four concepts: (i) food based supplementation; (ii) child growth; (iii) malnutrition/ deficiencies; and (iv) pregnancy.

Appendix S1 presents a summary of the search strategy for MEDLINE via Ovid. We used the following search strategy and MeSH using MEDLINE via Ovid: *Pregnancy AND *Nutrition Therapy; OR *Food; OR *Micronutrients; OR *Plants, Edible; OR *Nutrition Policy; AND *Nutrition Disorders; OR *Growth Disorders; *Body weight/ or foetal weight; OR *Anthropometry; OR *Nutritional physiological phenomena/ or *child nutritional physiological phenomena/ OR *diet/ or *hunger/ OR *maternal nutritional physiological phenomena/ OR *nutrition processes/ OR *nutritional requirements/ OR *nutritional status/ OR *physiological processes; AND *Infant. This search strategy was replicated and adjusted as needed for additional searches using Scopus and Cochrane.

Study selection

All identified records were assessed by title or abstract relevancy by one reviewer. Two reviewers independently assessed all selected full text articles for eligibility. Disagreements were resolved through discussion or, if required, through consultation with a third reviewer.

Data collection process

One reviewer extracted data pertaining to the outcomes of interest. Data were entered into spreadsheets and checked by the second reviewer. If data were unclear or not available in the selected paper, additional papers published using data from the same study were reviewed. To avoid duplication, all identified reports were grouped together by its unique study. To resolve inconsistencies, all identified reports under each study were considered.

Data items

We extracted information from each included study on (1) characteristics of the study (year of study implementation, site, design and sample size of intervention and control); (2) characteristics of study participants (age, socio-economic background, nutritional status, inclusion and exclusion criteria); (3) intervention (including type, nutrient composition, amount, duration and frequency); control group (control intervention – type, nutrient composition, amount, duration and frequency; placebo or no intervention); (4) outcome measure [birthweight, birth length, birth head circumference and longer-term growth (weight, height and head circumference)]; and (5) effect on outcome measure [birthweight, birth length, birth head circumference and longer-term growth (weight, height and head circumference)].

Risk of bias in individual studies

The quality of evidence was assessed using the Quality Assessment Tool for Quantitative Studies

developed by the Effective Public Health Practice Project (EPHPP QAT) and guided by the EPHPP reviewers' dictionary (Deeks *et al*. 2003; Thomas *et al*. 2004; Jackson et al. 2005). This tool was validated by Thomas *et al*. (2004) and judged suitable for use in systematic reviews of effectiveness in a review by Deeks *et al*. (2003). The tool calculates an overall methodological rating based on the strength of the study across six sections: (1) selection bias; (2) study design; (3) confounders; (4) blinding; (5) data collection methods; and (6) withdrawals and dropouts. Two sections, (7) intervention integrity and (8) statistical analyses, require consideration however are not included in the overall rating. Sections 1 to 6 received a component rating of 'strong', 'moderate' or 'weak'. A study identified as having two or more weak ratings was identified as weak, one weak rating was moderate and no weak ratings identified the study as strong.

Two reviewers independently completed this process and any discrepancies between the two reviewers with respect to the component ratings were resolved through discussion or, if required, through consultation with a third reviewer.

Summary measures

Random-effects models (Higgins, Green & Cochrane Collaboration 2008; Borenstein *et al*. 2010) were generated for each outcome (birthweight, birth length and birth head circumference). Results are reported as standardised mean differences (Cohen's d) with 95% confidence intervals and *P*-values. Forest plots were created for each outcome. All statistical analyses were carried out using the program Comprehensive Meta Analysis (http://www.Meta-Analysis.com, USA, 2005).

Synthesis of results and risk of bias across studies

We tested for heterogeneity using Q and I^2 statistics. Alpha of 0.05 or less was interpreted as significant. The I^2 test described the percentage of variation across studies that is due to significant heterogeneity rather than random chance. The thresholds outlined in the Cochrane Handbook were used for the interpretation of I^2 (Higgins, Green & Cochrane Collaboration 2008). To see if heterogeneity varied, sensitivity analyses separated studies identified as weak. For the purpose of the analysis, a Cohen's d score of zero was interpreted as no difference in effect; a result of 0–0.2 was interpreted as a small effect, 0.2–0.5 as a moderate effect and ≥0.8 as a large effect in favour of the intervention.

For cluster RCTs, samples sizes were adjusted in accordance to the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins, Green & Cochrane Collaboration 2008). Where no data on outcome-specific intra-cluster correlation coefficients were available, we assumed a value of 0.01 and adjusted the corresponding sample sizes according to the design effect. These methods are similar to those used by Ota *et al*. (2012).

We assessed the possibility of publication bias by evaluating funnel plots as well as calculating classic fail-safe N tests (Higgins, Green & Cochrane Collaboration 2008).

Additional analyses

Additional (subgroup) analyses were conducted to determine whether there were any differences in effect between (1) studies that included some kind of alternative intervention as the control group, and studies where no intervention at all as the control group and (2) studies that supplied micronutrient supplementation in addition to balanced protein energy supplementation as the intervention group, and studies where balanced protein energy supplementation only as the intervention group.

Results

Study selection

Figure 1 (a modified PRISMA flowchart) demonstrates the number of studies and results of the selection and screening process. The search of MEDLINE, Cochrane and Scopus provided 692 citations; 688 after removing duplicates. After screening by title and abstract relevancy, 23 articles were identified for full-text review. An additional 16 articles were identified

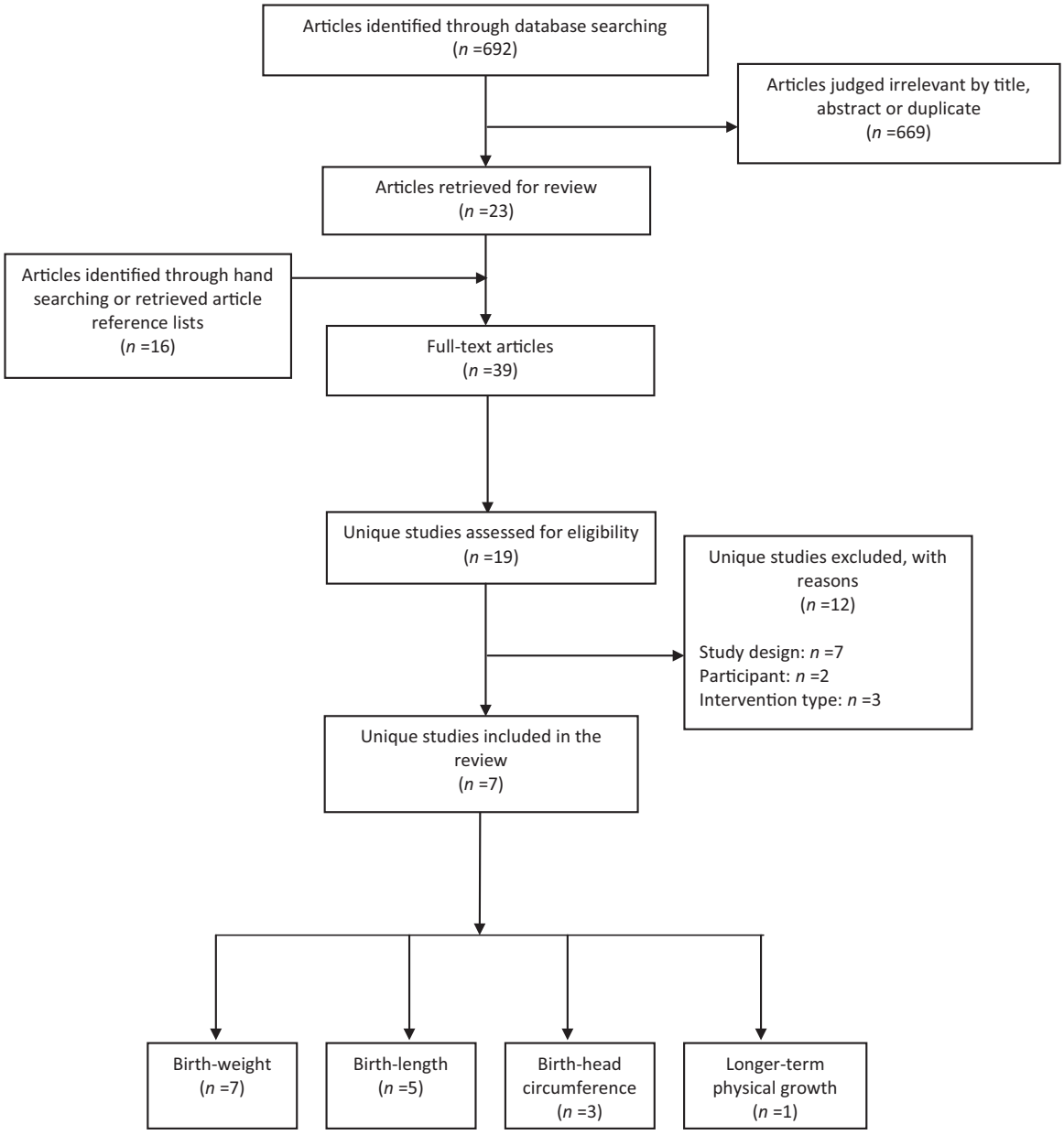

Fig. 1. Summary of search for selected articles (modified from PRISMA flowchart).

through manually searching the reference lists of retrieved articles, yielding a total of 39 articles. The 39 articles were categorised by unique study, and in total, 19 unique studies were identified. After reading the full text of these studies, 12 studies were excluded based on inclusion criteria (study design: 7; intervention type: 3; participants: 2). Therefore, a total of seven unique studies were included in the review. Table S1 presents the characteristics of the excluded studies.

Study characteristics

The seven studies included in the review are summarised in Table 1 (Mora *et al*. 1979; McDonald *et al*.

Table I. Characteristics of included studies

Allocated code	Study details		Subjects	Study group intervention	Control group	Intake	Outcomes relevant to systematic review
McDonald (a)	Year study initiated Site Study design Sample size intervention Sample size control	1967 Taiwan RCT 114 111	Selected based on low socio-economic rank, between ages 19 and 30 from 14 farming villages. Have at least one 'healthy' male child, in second or third trimester of pregnancy. Planning on having at least one more child.	Chocolate flavoured energy and nutrient-rich liquid supplement. Plus micronutrient supplement.	Received placebo beverage. First 4 years, 6 kcal day^{-1} and then 40 kcal day^{-1} as artificial sweetener replaced with sucrose. Micronutrients added in the last year near completion of study.	Two servings per day. Start: 3 weeks prior to birth of first child, End: after 15 months of lactation for the second.	Mean birthweight, gender sensitivity, birth length, infant weight, length and head circumference
	Findings No significant impact on low birthweight. Evidence of a threshold for the impact of caloric intake on birthweight where there is calorie gap. Effect of supplement greater during the hungry season, on birthweight of cohort 2 males of relatively thin mothers compared with control. Birthweight of the second male child was statistically higher than that of the first infant in the high supplement group. No effect on longer-term physical growth.					Issues No baseline data. 24-h dietary recall did not include snacks. Control supplementation changed after 4 years.	
Ceesay (b)	Year study initiated Site Study design Sample size intervention Sample size control	1989 Gambia Cluster RCT 1460 1037	Chronically undernourished women from 28 villages	Groundnut biscuit (groundnut, rice flour, sugar, groundnut oil). Feeding centre – direct observation daily by two birth attendants.	Received supplement after pregnancy	Two biscuits, 6 days a week. Start: 20 weeks pre-delivery.	Birthweight, birth length, head circumference
	Findings Supplement increased birthweight and head circumference in lean season only. Positive effects likely to be seen where women are malnourished.					Issues Data available until 36 months of infancy; however, the control received intervention post-delivery and lactating mothers were supplemented	
Girija (c)	Year study initiated Site Study design Sample size intervention Sample size control	1984 India RCT 10 10	Lower socio-economic women aged 20–33	50 g of sesame cake, 40 g of jaggery and 10 g of oil	No supplement	Servings and distribution not described. Start: second and third trimester.	Birthweight, birth length, head circumference
	Findings No significant impact on birthweight or length could be due to small sample size. Multiple correlation and multiple regression analyses showed that birthweight of the infant was positively associated with protein and energy intake.					Issues No information on compliance or dietary substitution. Energy and protein intake higher prior to supplementation in both groups. No SDs reported on post-natal anthropometric outcomes. Inadequate description of allocation.	
Huybregts (d)	Year study initiated Site Study design Sample size intervention Sample size control	2009 Burkina Faso RCT 641 655	Women of reproductive age	Lipid nutrient spread (LNS) comprise of 33% peanut butter, 32% soy flour, 15% vegetable oil and 20% sugar. Plus daily multiple micronutrient supplementation (UNIMMAP) meeting pregnancy recommended nutrient intake (RNI).	Multiple micronutrient tablet	1 serving daily. Produced by local women's association. Start: first or second trimester.	Birthweight, birth length, longer-term anthropometrics (weight and height)
	Findings Significant impact on birth length 0.5 cm ($P = 0.001$), hypothesised to be linked to the high fat content. Direct link unknown. Impact on weight though not significant.					Issues Control received multiple micronutrients, which are known to increase birthweight, reducing gap between control and intervention	

Table 1. Continued

Allocated code	Study details		Subjects	Study group intervention	Control group	Intake	Outcomes relevant to systematic review
Kardjati (e)	Year study initiated Site Study design Sample size intervention Sample size control	1992 Indonesia RCT 276 266	Nutritionally vulnerable women at 26–28 weeks of gestation	Protein energy drinks (sunflower, palm oil in text aid added to hot beverage) with casein and glucose	Control supplement of low protein energy drink 52 kcal and 6.2 protein	200 mL per serving. One package each day observed by fieldworker that delivered to house.	Birthweight, ongoing growth of child to 60 months
	Findings No impact on birthweight, although an increase in birthweight of the total sample (intervention and control) compared with baseline period. Supplementation proved beneficial if meeting an energy gap. Intervention children were significantly heavier than control children ($P < 0.05$). Intervention children were also taller throughout the first 5 years ($P < 0.05$ from 15 to 48 months, $P = < 0.05$ at both 3–12 and 60 months). Wasting was similar in both groups, although stunting was less prevalent in intervention children.					Issues Data suggest much higher calorie and protein intake in control than anticipated. Only children of mothers who had complied for at least 90 days were included in longer-term follow-up (attrition bias).	
Mora (f)	Year study initiated Site Study design Sample size intervention Sample size control	1975 Colombia RCT 207 200	Lower socio-economic women. Women recruited in first/second trimester and received supplement in third trimester of pregnancy. > 50% of children in household malnourished.	Weekly food basket for whole household (milk powder, bread and vegetable oil). Pregnant women instructed to consume usual diet and to treat supplementation as 'additional' food.	No supplement. Received measurements and health care	Food basket to be shared with whole household. Iron and vitamin A as a micronutrient tablet/capsule.	Birthweight
	Findings Significant correlation between maternal supplementation and weight gain during pregnancy in women giving birth to male offspring. Also significant impact on the mean birthweight of males although not females compared with control.					Issues Reported that women only got 9% of intended kcal intake; 150 of 850 women recruited in first/second trimester and received supplement. Supplement given to child at 3 months, therefore data on child growth not used in this review.	
Tontisirin (g)	Year study initiated Site Study design Sample size intervention Sample size control	1986 Thailand RCT 28 15	Non-smoking pregnant women age 16–30 from rural areas and of same socio-economic status. Selected from women who attended maternal health centres. First or second trimester. All in good health with low caloric intake.	Locally available supplementary food. Two formulas tested in two of the experimental groups; 1 group represented four potential formulas and the other a fifth formula. Each group provided similar caloric value.	No supplementation	Supplement provided as single serving packets, and consumed as a snack	Birthweight, birth length and birth head circumference
	Findings Significant impact on birthweight in both supplemented groups, although no significant impact on length or head circumference					Issues Number of women originally allocated not stated. Many statistical errors throughout report. Reported, as an RCT though would have been more suited as an acceptability study.	

RCT, randomised controlled trial.

1981; Girija *et al*. 1984; Tontisirin *et al*. 1986; Kardjati *et al*. 1988; Ceesay *et al*. 1997; Huybregts *et al*. 2009). More than one article was published describing the findings of three of these seven studies. Articles were categorised by the unique study's first published article lead author, as follows: Huybregts *et al*. (2009) (Lanou *et al*. 2014); Kardjati *et al*. (1988) (Kardjati *et al*. 1990; Kusin *et al*. 1992); and McDonald *et al*. (1981) (Wohlleb *et al*. 1983; Mueller & Pollitt 1984; Adair & Pollitt 1985). The studies are coded as follows (a) McDonald, (b) Ceesay, (c) Girija, (d) Huybregts, (e) Kardjati, (f) Mora, and (g) Tontisirin. Of the seven studies included in the review, six were RCTs (a, c, d, e, f, g) and one a cluster RCT (b). All studies were from low- and middle-income countries with the primary outcome to measure the difference in physical growth (weight, height, head circumference) between intervention and control groups of the child. The main inclusion criteria entailed pregnant women in second or third trimester from lower socio-economic groups. Included studies involved 2367 participants. In five of the studies (b, c, e, f, g), all women were identified as undernourished. Two of the five studies (a, d) included adequately nourished and undernourished women; however, within-study stratification was possible and data from nourished women were excluded.

Of the seven studies, one study (d) adjusted for gestational age, health centre- based recruitment and malaria prevention initiatives; one study (b) adjusted for sex, primiparity, Parkin score, gestational age, maternal parity, sex of the baby, and seasonality; three studies (a, e, f) conducted intergroup analyses on identified variables that may confound the main treatment–outcome relationship although did not adjust as no significant relationship were identified; and two studies (c, g) did not report on potential confounding variables.

The degree of undernutrition and its definition varied across studies. Two studies included all eligible participants without using an indicator to determine nutritional status, and the results were then stratified by adequately nourished and undernourished without providing the cut-off used to define undernourished (a, d). One study defined women as chronically malnourished or food insecure; however, the indicator used to define 'chronically malnourished' was not published (b). Three studies identified women as malnourished without a measure or definition provided (c, f, g). One study that identified women as nutritionally vulnerable failed to define undernutrition and did not use an anthropometric indicator (e).

Data from two studies included for the assessment of intrauterine growth were excluded for the assessment of child growth as one study supplemented the child from 3 months of age (f), and one study did not provide a measure of variation such as a standard deviation (c).

The seven interventions received are summarised in Table 2. The type of intervention received included a chocolate flavoured energy drink (a), groundnut biscuits (b), varying food baskets containing local produce (c, f, g), a lipid nutrient spread (d) and a protein energy drink (e). Selected studies had a diverse range of controls. Three studies were supplementation vs. control supplementation (a, d, e), one study provided the supplement to the control group on delivery of child (b), and three studies were supplementation vs. no intervention (c, f, g). Of the control supplements, two (a, e) were similar to the intervention in taste, colour and texture, with low amounts of energy, and the third was a multiple micronutrient supplement (d).

Risk of bias in individual studies

Figure 2 illustrates the quality of evidence using EPHPP ratings. Of the seven included studies, two were identified as strong (d, e), three studies (a, b, f) as moderate and two as weak (c, g). Two studies were not likely to be representative (c, g), two studies (c, g) did not report on the number of participants that agreed to participate in the study and two studies (a, c) did not report on methods of randomisation. The anthropometric staff were blinded in two studies (a, d) to reduce measurement bias, while the outcome assessor/s were aware of the exposure in two studies (b, e) and it was not possible to identify whether they were aware of exposure or not for three studies (c, f, g). Two studies (c, g) did not report withdrawals and dropouts in terms of numbers and/or reason per group and one study did not indicate the percentage of participants completing the study (g) (see Table 3 for further details).

Table 2. Nutrient composition of balanced protein energy supplementation

	Nutrients provided by supplement per day*								
	MacDonald Two cans	Ceesay Two biscuits	Girija One serve	Huybregts One serve	Kardjati One serve	Mora Average from weekly food basket	Tontisirin One serve		RNI† for pregnant women
							Formula 1	Formula 2	
Energy‡ (kJ)	3347	4247	1745	1559	1946	3582	1607	1456	9519§
Protein (g)	40	22	30	14.7	7.1	38.4	15	13.1	71¶
% Energy from protein**	20.0	8.7	<25††	15.8	6.1	17.9	15.6	15.1	10–35%‡‡
Fats§§ (g)	26.6	56		27.6	25.8		9.1	15.6	ND¶¶
% Energy from fat***	29.9	49.7		66.7	49.9	0.0	21.3	40.3	20–35%
Carbohydrates (g)	100			15.9	46.5				175†††
Vitamin A (μg RE)	5000			2936		6024			800‡‡‡
Cholecalciferol (μg)	10			5					5
Vitamin E (mg TE)				13					7.5§§§
Thiamine (mg)	1.6			1.6					1.4
Riboflavin (mg)	1.8			1.6					1.4
Niacin (mg)	20			21					18
Vitamin B6 (mg)	1.6			2					1.9
Folic acid (μg DFE¶¶¶)	0			461					600
Vitamin B12 (μg)	2			2.6					2.6
Pantothenic acid (mg)	7.36								6
Ascorbic acid (mg)	75			71					55
Calcium (mg)	1000	47		90			86.4	165.6	1200
Iron (mg)	12	1.8		35		18	7.02	3.9	NA****
Zinc†††† (mg)	0			17					10
Iodine (μg)	0			150					200
Selenium (μg)				65					30

TE, Tocopherol equivalents. *Blank cell indicates no available information. †Recommended Nutrient Intake (RNI) values as identified by WHO/FAO, 2004 (World Health Organization. & Food and Agriculture Organization of the United Nations. 2004). RNI is the daily intake that meets the nutrient requirements of almost all (97.5%) apparently healthy individuals in an age- and sex-specific population. RNI, as used above, is equivalent to that of the recommended dietary allowance (RDA) as used by the Food and Nutrition Board of the United States National Academy of Sciences. ‡1 kcal = 4.184 kJ. §Energy requirements based on a developing country profile (demography and anthropology) as defined by WHO, et al, 2004 (WHO et al. 2004). ¶Recommended Dietary Allowance sourced from the Food and Nutrition Board (U.S) (Institute of Medicine (U.S.). Panel on Macronutrients. & Institute of Medicine (U.S.). Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. 2005). RDA is the average daily dietary intake level; sufficient to meet the nutrient requirements of nearly all (97–98%) health individuals in a group. **Calculated by {total grams of protein × 4}{(total energy from protein)/(total energy in supplement) × 100} as recommended by WHO, et al, 2004 (WHO et al. 2004). ††Reported as a balanced protein energy supplement by Ota *et al.* (2012). Ota *et al.* had access to unpublished data. ‡‡Threshold as stated by WHO, et al, 2004 (WHO et al. 2004). §§Did not include linoleic or alpha-linolenic acid as no included study reported on this. ¶¶Based on energy from fat. ***Calculated by {total g of fat × 9} {(total energy from fat)/(total energy in supplement) × 100} as recommended by WHO, et al, 2004 (WHO et al. 2004). †††RDA sourced from the Food and Nutrition Board (U.S) (Institute of Medicine (U.S.). Panel on Macronutrients. & Institute of Medicine (U.S.). Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. 2005). ‡‡‡'Recommended safe intake' instead of RNI (Institute of Medicine (U.S.). Panel on Macronutrients. & Institute of Medicine (U.S.). Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. 2005). §§§No current evidence to suggest that vitamin E requirements during pregnancy differ from those of other adults. ¶¶¶Dietary folate equivalents: micrograms of DFE provided = {micrograms of food folate + (1.7 × micrograms of synthetic folic acid)}{[total grams of fat × 9]{(total energy from fat)/(total energy in supplement) × 100}. ****WHO/FAO recommends that iron supplements in tablet form be given to all pregnant women because of the difficulties in correctly assessing iron status in pregnancy. ††††Based on moderate availability.

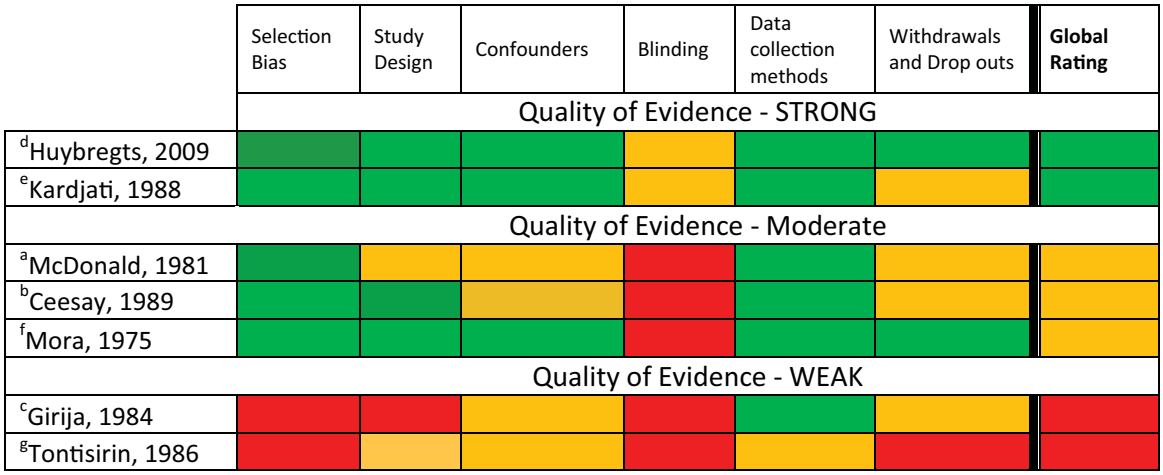

Fig. 2. EPHPP global ratings.

Risk of bias across studies

The classic fail-safe N test indicated that 27 additional negative studies were required to change the significance of the effect of supplementation on birthweight. The fail-safe test was not applicable to other findings (Higgins, Green & Cochrane Collaboration 2008). Funnel plots were considered as an unreliable source of judgement as there were only seven studies included in this review, which is below the recommended level of 10 studies for funnel plot analyses (Higgins, Green & Cochrane Collaboration 2008).

Results of individual studies/syntheses of results

Evidence of moderate to high heterogeneity between the seven included studies was observed, as indicated by the Q and I^2 values. This was also true for the stratified analyses on each of the outcome measures. The random effects models were used to estimate standardised mean difference as it was the most appropriate model due to the heterogeneity of the included studies (Borenstein *et al*. 2010).

Data on birthweight from undernourished mothers were available from all seven studies (intervention: $n = 1228$; control: $n = 1139$). While an increase in birthweight was observed in the intervention group for six of the seven studies (a, b, c, d, f, g), this was statistically significant in three studies only (b, f, g). For two of the seven studies, data were stratified by undernourished and adequately nourished (a, d). Data on adequately nourished were excluded, and only data on undernourished were included in the analysis. For one study (g), the intervention group received one of two potential supplements, but only one group (group 1) was used for the analysis. The pooled results from these studies indicate that supplementation had a significant moderate effect on birthweight [RCT = 7, intervention: $n = 1228$; control: $n = 1139$; d = 0.20, 95% confidence interval (CI): 0.03–0.38, $P = 0.02$]. No significant findings were identified

Table 3. Quality of evidence findings

Number of studies	Selection bias	Study design	Confounders	Blinding	Data collection methods	Withdrawals and dropouts	Intervention integrity	Analysis
Quality of evidence – STRONG								
2 [d, e]	Two studies recruited participants that are very likely to be representative of the target population. Number of individuals that agreed to participate reported for each study.	Two studies reported as RCTs and described as randomised. Methods of randomisation explained for each study and identified in review as appropriate.	Two studies reported no important differences between groups prior to the intervention.	The anthropometric outcome assessor(s) were not aware of the intervention/ exposure status of participants in one study (d). Could not identify whether participants were aware of the research question in two studies.	Data collection methods were identified as valid and reliable in two studies	Two studies reported on withdrawals and dropouts in terms of numbers and/or reasons per group. Two studies indicated the percentage of participants completing the study.	Two studies reported the number of participants received the allocated intervention. Unlikely that the subjects received an unintended intervention that may influence the results in two studies.	Unit of allocation at individual level for two studies. Analysis conducted at individual level for two studies.
Quality of evidence – MODERATE								
3 [a, b, f]	Three studies recruited participants that are very likely to be representative of the target population. Three studies reported the number of individuals that agreed to participate.	Two studies reported as RCTs (a, f) and one study as a cluster RCT (b). All studies described as randomised, methods of randomisation not reported for one study (a), and identified as appropriate for two studies (b, f).	Three studies reported no important differences between groups prior to the intervention.	The outcome assessor(s) were aware of the intervention or exposure status of participants for one study (b), not aware for one study (a), and was not reported for one study (f). Could not identify whether participants were aware of the research question in three studies.	Data collection methods identified as valid and reliable in three studies	Three studies reported on withdrawals and dropouts in terms of numbers and/or reasons per group. Three studies indicated the percentage of participants completing the study (a, b, f).	Three studies reported the number of participants that received the allocate intervention. Likely that participants received an unintended intervention that may influence results in one study (a).	Unit of allocation and analysis at individual level for two studies (a, f), and at community level for one study (b). Statistical methods identified as appropriate for three studies.
Quality of evidence – WEAK								
2 [c, g]	Two studies recruited participants that are not likely to be representative of the target population. Could not identify the percentage of selected individuals that agreed to participate in two studies.	Two studies reported as RCTs and as randomised. Methods not reported in one study (c), and not identified as appropriate (g).	Could not identify important differences between groups for one paper (c), and not reported in one paper (g)	Could not tell if the outcome assessor(s) were aware of the intervention or exposure status of participants for two studies and could not identify whether participants were aware of the research question for two studies	Data collection methods identified as valid and reliable in two studies	Two studies did not report on withdrawals and dropouts. One study indicated the percentage of participants completing the study (c) and could not identify for one study (g).	One study reported the number of participants that received the allocated intervention (c), and could not tell for one study (g). Unlikely that subjects received an unintended intervention that may influence results in two studies.	Unit of allocation and analysis at individual level for two studies. Statistical methods identified as appropriate for two studies.

RCTs, randomised controlled trials.

in the subgroup analyses of intervention vs. alternative intervention control group (a, b, d, e) (RCT = 4; intervention: $n = 997$; control: $n = 914$; d = 0.17, 95% CI: –0.06–0.40; $P = 0.15$), and subgroup analyses of intervention vs. no intervention control group (c, f, g) (RCT = 3; intervention: $n = 231$; control: $n = 225$; d = 0.41, 95% CI: –0.08–0.90, $P = 0.10$). However, a small and moderate impact in favour of the intervention was observed, respectively. In one of these studies (c), a higher percentage of energy from protein (>25%) was included in the intervention supplement even though the authors identified the supplement as balanced. When this study was excluded from the pooled analysis, the effect of supplementation was slightly reduced but remained significant (RCT = 6, intervention: $n = 1218$; control: $n = 1129$; d = 0.19, 95% CI: 0.01–0.37, $P = 0.04$). Two of the included studies also included micronutrient supplements in addition to balanced protein energy supplements as part of the intervention (a, d). When these studies were excluded from the pooled analysis, the effect of supplementation was reduced (RCT = 5; intervention: $n = 1109$; control: $n = 1030$; d = 0.18, 95% CI –0.04–0.39; $P = 0.11$). However, in one of these studies (d), the control group was given the micronutrient supplementation (and the intervention group was given balanced protein energy as well as micronutrient supplementation), so the observed effect size can be attributed to the balanced protein energy supplementation. When this study is included in the pooled results, a similar effect size is yielded, and approaches significance (intervention: $n = 1173$; control: $n = 1084$; d = 0.18; 95% CI: –0.01–0.37; $P = 0.06$). See Figure 3 for further details.

Data on birth length were available from five studies (a, b, c, d, g) (intervention: $n = 683$; control: 615). Of the five studies measuring the impact of supplementation on birth length, one study reported a statistically significant impact on birth length (d), two studies reported no significant impact although did identify an increase in length (c, a) and two studies reported no effect at all (b, g). For the meta-analyses, the data from two studies were stratified by undernourished and adequately nourished (a, d). Data on adequately nourished were excluded, and only data on undernourished were included in the analysis. For one study (g), only group 1 from the two supplemented groups was used for the analysis. The pooled results from these studies indicate that supplementation had a small effect in favour of the intervention, albeit not significant (RCT = 5, intervention: $n = 683$; control $n = 615$; d = 0.22; 95% CI: –0.04–0.50; $P = 0.10$). No significant findings were identified in the subgroup analyses of intervention vs. alternative intervention control group (RCT = 3, intervention: $n = 659$; control $n = 590$; d = 0.196; 95% CI: –0.10–0.49; $P = 0.18$) and subgroup analyses of intervention vs. no intervention control group (RCT = 2, intervention: $n = 24$, control: $n = 25$; d = 0.40; 95% CI: –0.47–1.27; $P = 0.37$). However, a small and moderate impact in favour of the intervention was observed, respectively. When the study (g) that included >25% of energy from protein was

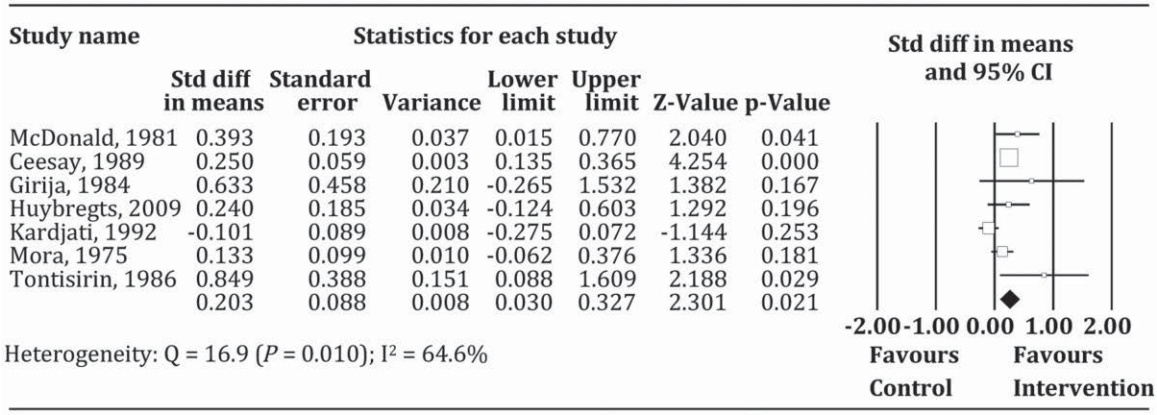

Fig. 3. Effect of balanced protein energy supplementation on birthweight ($n = 7$).

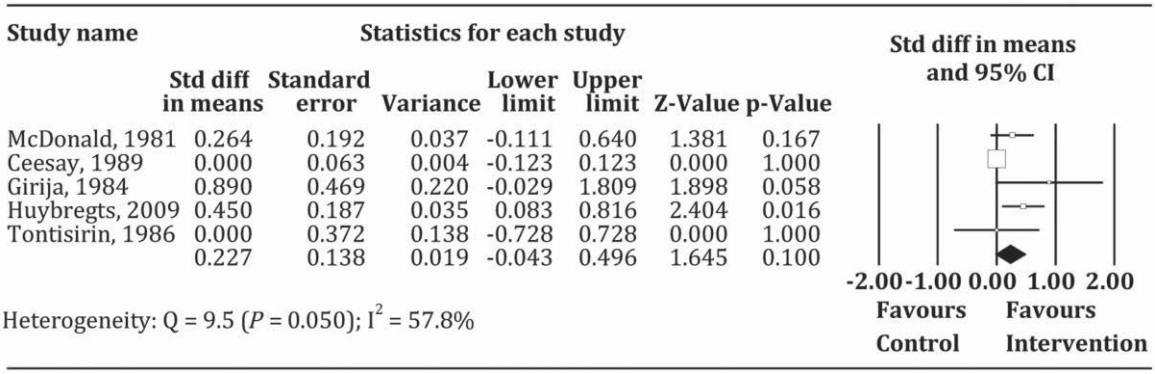

Fig. 4. Effect of balanced protein energy supplementation on birth length ($n = 5$).

excluded from the pooled analysis, the effect of the supplementation was reduced (RCT = 4, intervention: $n = 673$; control: $n = 605$; d = 0.17, 95% CI: –0.08–0.41, $P = 0.18$). When the two studies that also included micronutrient supplements in addition to balanced protein energy supplements as part of the intervention (a, d) were excluded from the pooled analysis, the effect of supplementation was reduced (RCT = 3; intervention: $n = 564$; control: $n = 506$; d = 0.14; 95% CI –0.27–0.55; $P = 0.51$). However, when the study (d) for which the control group was given the micronutrient supplementation (and the intervention group was given balanced protein energy as well as micronutrient supplementation) was included in the pooled results, the effect size increased but was still not significant (intervention: $n = 628$; control: $n = 560$; d = 0.24; 95% CI: –0.12–0.19; $P = 0.19$). See Figure 4 for further details.

Data on birth head circumference were available from three studies (b, c, g) (intervention: $n = 553$; control: $n = 499$). Stratification for two studies by undernourished and adequately nourished women was not possible (a, d) and therefore excluded from the analyses. Of the three studies measuring the impact of supplementation on head circumference, one study identified a statistically significant increase during the lean season only (b), one study identified a slight increase in intervention group, although not significant (g) and one study identified no effect (c). For one study (g), only group 1 was used for analysis. The pooled results from these studies indicate that supplementation had a small effect on birth head circumference in favour of the intervention, but this was not significant (RCT = 3, intervention: $n = 553$; control: $n = 499$; d = 0.17; 95% CI: –0.07–0.41; $P = 0.17$). This did not change when the study (g) with >25% of energy from protein was excluded from the analyses. Subgroup analyses of intervention vs. alternative intervention control group were not possible due to number of studies in analyse ($n = 1$). Subgroup analyses of intervention vs. no intervention control group identified a moderate impact in favour of the intervention, albeit not significant (RCT = 2, intervention: $n = 20$; control: $n = 24$; d = 0.26; 95% CI: –0.62–1.14; $P = 0.56$). See Figure 5 for further details.

Effect on longer-term growth

Only one study showed the impact of supplementation on the longer-term growth of a child (e). This study showed a significant difference for height until 60 months and weight until 24 months of age with a greater effect at 9 and 12 months, respectively. One additional study that measured impact of supplementation on longer-term growth however was excluded from analyses, as within-study stratification of infants born of mothers nourished or undernourished during pregnancy was not possible (a).

Discussion

Summary of evidence

The seven studies in this review included six (a, c, d, e, f, g) RCTs and one cluster RCT (b). We included one study (Tontisirin *et al.* 1986) not included in Ota

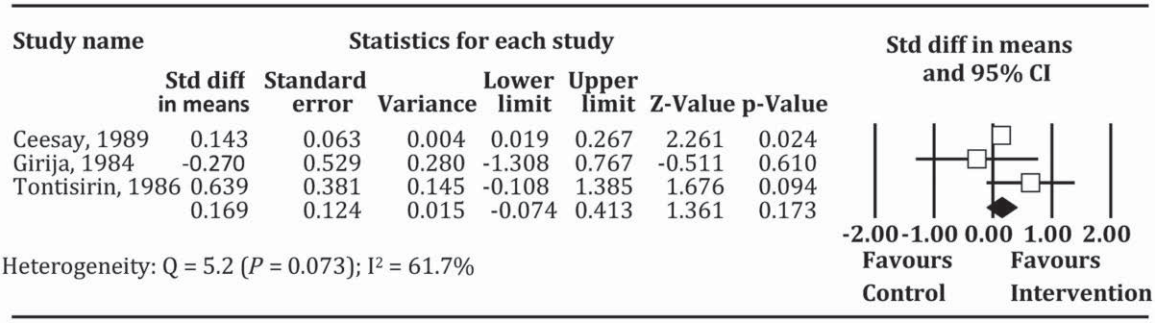

Fig. 5. Effect of balanced protein energy supplementation on birth head circumference ($n = 3$).

et al.'s (2012) review and three (Tontisirin *et al*. 1986; Kardjati *et al*. 1990; Huybregts *et al*. 2009) studies not included in the review of Imdad & Bhutta (2011). This review excluded all studies from high-income countries, which were included in the reviews of Ota *et al*. and Imdad & Bhutta.

Evidence from studies reporting on the impact of supplementation of undernourished pregnant women on fetal outcomes suggested a statistically significant positive effect on birthweight. As the interventions varied, the use of different controls is understandable; however, this creates some difficulties when pooling data and generalising the results across studies. Subgroup analyses identified that when no control supplement was used, the effect between the intervention and control increased from small to medium, indicating that supplementation has a greater impact when there is a larger energy gap to meet. This finding is supported by other studies (McDonald *et al*. 1981; Winkvist *et al*. 1998; Tofail *et al*. 2008).

We identified discrepancies in one study (Girija *et al*. 1984), between the manual calculations and published data (Imdad & Bhutta 2011; Ota *et al*. 2012), for the percentage of energy from protein for the intervention supplement. As reported in the Results section, when Girija's study was excluded from the pooled analyses, the effect sizes of the intervention were reduced for birthweight and birth length, and remained the same for birth head circumference. The changes in effect size were small, and this is likely because there were only 20 participants in the Girija study. This finding suggests that when compared to balanced protein energy supplements, a protein energy supplement with a higher percentage of energy from protein may have a positive effect on birthweight. Recent evidence from a Cochrane review contradicts this (Ota *et al*. 2012). In their review, Ota *et al*. identified that high-protein supplementation was associated with a significantly increased risk of small-for-gestational age babies. The energy from protein in the Girija study was 28.8%, and the energy from protein in the review by Ota and colleagues was 34.0% (Rush *et al*. 1980). Hence, the conflicting findings may suggest that protein energy supplementation is most effective when the percentage of energy from protein meets a certain threshold.

The impact of balanced protein energy supplementation for undernourished pregnant women on subsequent child growth in low- and middle-income countries remains inconclusive, as the evidence from one study is not sufficient to determine the effectiveness. This finding supports the results of Kramer and Kakuma's Cochrane review conducted in 2003 (Kramer & Kakuma 2003), which identified that there were an insufficient number of studies to draw a conclusion on the impact of balanced protein energy supplementation on longer-term child growth. Only one study reviewed reported on longer-term child growth outcomes, until 60 months of age. This study identified a significant increase in height and weight of the child, until 60 and 24 months, respectively. However, this study excluded poor compliers; thus, definitive conclusions cannot be made.

Limitations

The main limitations of this review are that the participant population, the form of supplement, the control

intervention and the outcome definitions are not consistent across studies. In addition, the definition of malnutrition varied across studies, and the differential effects of supplementation at these different levels are difficult to generalise. The quality of the studies varied, including the methods of randomisation, blinding of anthropometric staff, and reporting on withdrawals and dropouts. One study provided multiple micronutrient supplementation to the control (d), which is known to increase birthweight (Lumey *et al*. 1995), thus reducing a potential gap; one study provided the intervention to the woman pre-and post-pregnancy (a), making it difficult to identify the effect of supplementation during pregnancy only; four studies did not blind the anthropometric data collectors (c, e, f, g); three studies did not report on compliance (c, f, g); one study excluded poor compliers from analyses on longer-term growth and thus did not adhere to the intention-to-treat principle (e); and two studies provided a multiple micronutrient supplementation to the control (a, d).

Discrepancies across studies may have affected the findings. It is difficult to ascertain the direction of the impact of the sources of bias in the included studies on the results of these studies (and the meta-analyses completed for this review). For example, lack of blinding of anthropometric staff and excluding poor compliers from analyses may have improved the effect of the intervention. Conversely, poor compliance may reduce the effect of the intervention.

Low- and middle-income countries were classified using the 2013 World Bank data. While countries that transitioned from middle to high income from 1970 to 2013 were excluded, when conducting the systematic review, no studies from transitioned middle- to high-income countries were identified. Due to resource limitations, the studies were limited to English-language publications only. While studies were limited to English-language publications only, manually searching the reference lists of retrieved articles identified no additional publications in other languages.

Conclusion

Between 1970 and 2015, seven studies measured the effect of balanced protein supplementation of undernourished pregnant women in low- and middle-income countries on child growth outcomes. This review identifies that in low- and middle-income countries, balanced protein energy supplementation has a positive impact on the birthweight when the mother is undernourished. Scaling up this intervention would improve the nutritional status of otherwise nutritionally vulnerable children; however, additional research is required on the cost-effectiveness of the interventions compared with others. The effect of supplementation on longer-term physical growth remains inconclusive due to the small number of well-designed studies that have measured this outcome. The findings of this review support those reported in an earlier review (Ota *et al*. 2012). The opportunity exists to invest in new robust studies to identify whether protein energy supplementation targeting undernourished pregnant women affects the longer-term growth of a child in low- and middle-income countries.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

Contributions

BS, PB and JJ co-developed the research question. BS conducted the search. BS and JJ assessed all selected full text articles for eligibility. BS and JJ assessed the quality of evidence for selected full text articles. BS and PB conducted the meta-analyses. PB, KW and BS analysed and interpreted the data. BS wrote the first draft of the paper, which was revised with editorial input from JB, PB, KW, AC, JJ, and blind reviewers at

the Journal of Maternal and Child Nutrition. BS developed the figures and tables.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Table S1. Characteristics of excluded studies.

Appendix S1. Summary of search strategy for Medline via Ovid.

Appendix S2. PRISMA 2009 checklist.

2.3 Supplementary files

Table S1. Characteristics of excluded studies.

Study	Reason for exclusion
Agarwal 2000	Study type: evaluation study
Kaseb 2002	Participants: 'healthy' pregnant women. Study type (cluster-allocated/convenience sampling), without randomisation. Two sites — control and intervention.
Khan 2011	Study type: Early supplementation versus later supplementation. Main outcome: Timing of maternal intervention and impact on child physical growth.
Lechtig 1975	Study type: Originally a cluster RCT; however results based on observational findings. Initially designed to test impact of protein on birth weight, not energy. Both groups received energy supplementation (high versus low). In addition, children received supplement and child growth is measured against a historical control.
Mardones 1988	Isoenergetic supplementation (as defined by Kramer 2010). Considered by Mardones as 'balanced'. Intervention: milk power versus fortified milk powder. Difficult to interpret results as the milk powder supplement group had higher kcal, protein, fat, Ca, P, and similar levels of B vitamins, whereas the fortified milk contained higher Vitamin A, C, E, Mg, Zn, Iron. If anything, this study is showing the impact of iron supplementation on foetal growth.
Mardones 2008	Intervention: Similar to 1998, study involves two groups receiving similar intervention, with one being higher in micronutrient fortification. Difficult to identify results between food-based supplementation and fortification.
Mora 1981	Study design: Outcome child receives intervention. Impossible to determine effect from maternal supplementation on child growth.
Ortolano 2003	Study design: Results are based on findings from nationwide government nutrition program. Study designs include evaluation (Hossain), midterm evaluation (Ortolano) and observational (Shaheen). Participant: Nutrition program includes children as participants.
Prentice 1983	Historical control
Rivera 2004	Study type: Measuring impact of cash transfer program with a nutritional component. Participants include lactating women and children. Impossible to measure impact of food alone.
Ross 1985	Participants: Over-nourished women (mean weight 70 kg at 20 weeks). Identified as 'malnourished' though not referring to energy protein deficiency.
Shrimpton 2009	Study type: retrospective. Primary outcome: Trends in birth weight. No balanced protein energy supplement provided.

Appendix S1. Summary of search strategy for Medline via Ovid

Date of first search: 18/03/13

Step One:

- exp Pregnancy/
- exp Nutrition Therapy/
- exp Food/
- exp Micronutrients/
- exp Plants, Edible/
- exp Nutrition Disorders/
- exp Growth Disorders/
- exp body weight/ or foetal weight/
- exp Anthropometry/
- exp Infant/
- exp Nutrition Policy/
- Nutritional physiological phenomena/ or exp child nutritional physiological phenomena/ or exp diet/ or exp hunger/ or exp maternal nutritional physiological phenomena/ or exp nutrition processes/ or exp nutritional requirements/ or exp nutritional status/ or exp physiological processes/
- 2 or 3 or 4 or 5 or 11
- 6 or 7 or 8 or 9 or 12
- 1 and 10 and 13 and 14
- Limit 15 to (yr="1970–Current" and English and (clinical trial, all or clinical trial or controlled clinical trial or evaluation studies or randomised controlled trial) and (medline or oldmedline))

Step Two:

Articles identified through database searching: 491

Step Three:

Articles judged irrelevant by title, abstract or duplicate: 470

Step Four:

Articles retrieved for review: 21 papers.

Date of Second search: 14/01/2015

Step One:

Replication of above search strategy: 564

Step Two:

Articles judged irrelevant by title, abstract or duplicate: 542

Step Four:

Articles retrieved for review: 22 papers.

Appendix S2. PRISMA 2009 checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Provided on title page
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	Provided on abstract page
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	Page 1; line 03
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	Page 2; line 51-56
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Page 2; line 60-63
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	Page 3; line 66-101
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	Page 4; line 103-106
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Page 4; line 108-118

Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	Page 4; line 121-123
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	Page 4; line 126-130
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Page 4-5; line 133-140
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	Page 5; line 142-155
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Page 5; line 156-162
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	Page 5-6; line 164-178

2.4 Summary

- The beneficial effect of balanced protein energy supplementation during pregnancy on subsequent child growth is unclear and may depend on the mother entering pregnancy adequately nourished or undernourished.
- Systematic reviews to date have included studies from high, middle and low-income countries. However, the effect of balanced protein energy supplementation should not be generalised across countries of different income levels. This review focuses solely on the effect of balanced protein energy supplementation in undernourished pregnant women from low- and middle-income countries on child growth.
- A systematic review of articles published in English (1970 to 2015) was conducted via MEDLINE, Scopus, the Cochrane Register, and hand searching. Only peer-reviewed experimental studies analysing effects of balanced protein energy supplementation in undernourished pregnant women from low- and middle-income countries with measures of physical growth as the primary outcome were included.
- Two reviewers independently assessed full text articles against inclusion criteria. Validity of eligible studies was ascertained using the Quality Assessment Tool for Quantitative Studies developed by the Effective Public Health Practice Project (EPHPP QAT).
- In total, seven studies met inclusion criteria. All studies reported on birth weight, five on birth length, three on birth head circumference and one on longer-term growth. Standardised mean differences were calculated using a random-effects meta-analysis. Balanced protein energy supplementation significantly improved birth weight (7 RCTs, n= 2367; d= 0.203, 95% CI, 0.03-0.38, p=0.021). No significant benefit was observed on birth length or birth head circumference.
- Impact of intervention could not be determined for longer-term physical growth due to limited evidence. Additional research is required in low- and middle-income countries to identify impacts of balanced protein energy supplementation during pregnancy on longer-term infant growth.

2.5 Final word

The effectiveness of balanced protein energy supplementation during pregnancy on birth and early infancy anthropometric outcomes in low- and middle-income countries was examined in this systematic literature review. Findings were inconclusive due to the few papers exploring this topic. Consequently, I designed a study in Bangladesh, a low-income country context, to explore the effect of maternal balanced protein energy supplementation on infant anthropometric measures. Issues around the sustainability of locally available resources will be addressed after completion of this thesis.

Chapter 3. The use of a Modified Version of Photovoice to Identify Maternal Dietary Consumption Enablers and Barriers in Northern Bangladesh

3.1 Overview

This chapter explores perceptions around maternal nutrition as experienced by undernourished pregnant women themselves in order to better understand possible enablers and barriers to healthy eating during pregnancy. Initially, I planned to conduct focus group discussions to explore this topic, but I found that focus groups did not create an encouraging environment for participants to freely share their thoughts. Thus, I decided to use Photovoice as a data collection method because it enabled women to document and share their own views.

At the time there was no published data on perceptions of maternal nutrition for northern Bangladesh. Also there were no published data on the use of Photovoice in the field of nutrition in Bangladesh. I conducted this study (Study 2) as part of phase 1 (formative research) of the three phase multiphase design used for this research. This study, with Chapter 4 (Study 3), informed the development of the locally produced balanced protein energy supplement (phase 2, development of supplement; Chapter 6, Study 5), and the design of the randomised controlled study (phase 3, effectiveness of supplement on child anthropometric outcomes; Chapter 7, Study 6).

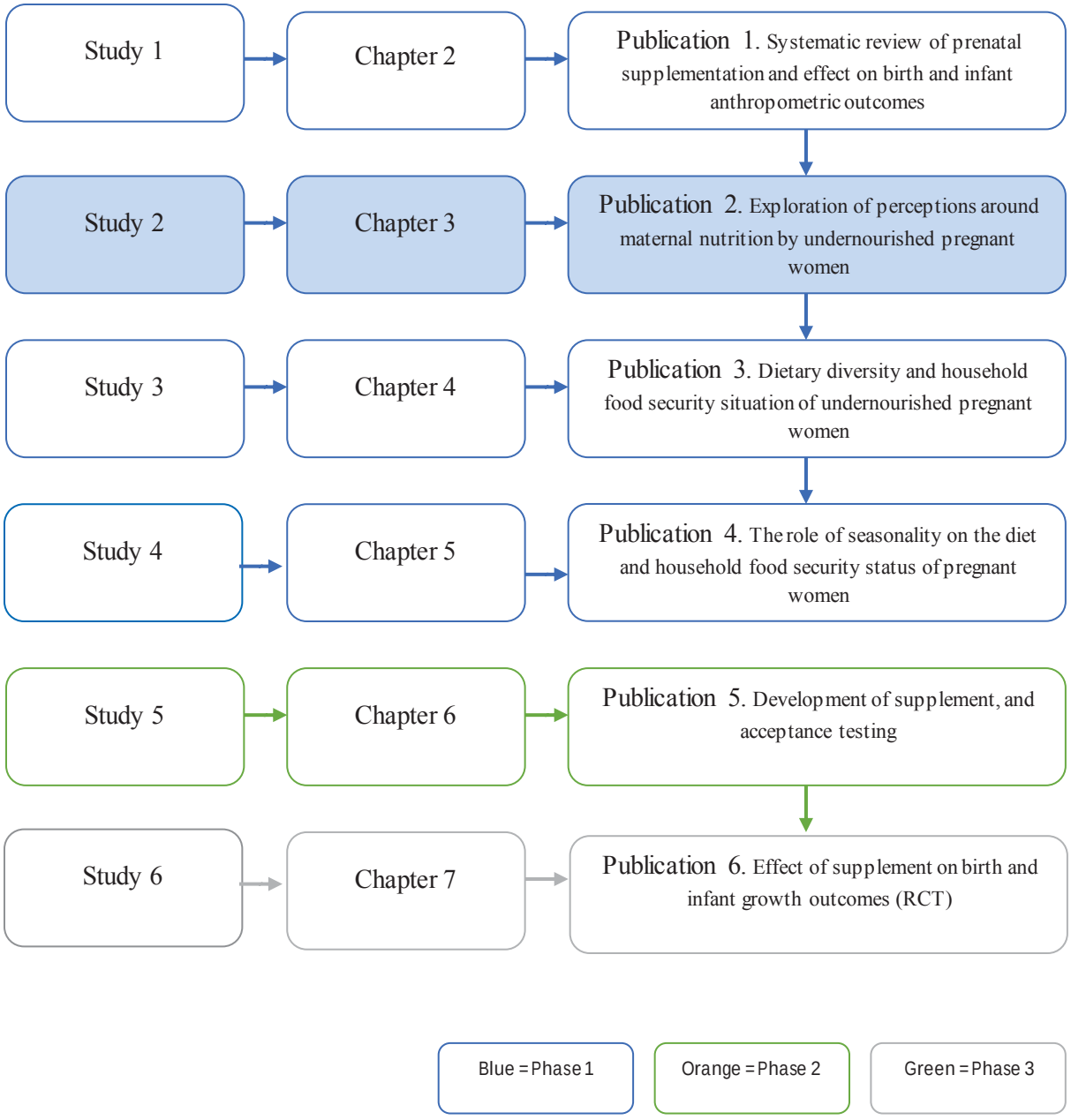

Figure 6 Study 2, Chapter 3 in relation to the thesis structure and multiphase design

This chapter is inserted as the published article (PDF):

Stevens, B., Clough, A., Brimbecombe, J., Watt, K. and Judd, J. The use of a modified version of photovoice to identify maternal dietary consumption enablers and barriers in Northern Bangladesh. International Journal of Food, Nutrition and Public Health. 2016; 8 (1): 1-19.

This study provides qualitative information on maternal nutrition in northern Bangladesh and the use of Photovoice in this particular context. To my knowledge, this was the first time Photovoice methodology was applied in Bangladesh for nutrition research. Because of this, I conducted an oral presentation on the use of Photovoice methodology in the context of a low-income country at a conference. The peer-reviewed abstract is presented as an appendix at the end of this thesis.

3.2 Publication in the International Journal of Food, Nutrition and Public Health

Int. J. Food, Nutrition and Public Health, Vol. 8, No. 1, 2016

THE USE OF A MODIFIED VERSION OF PHOTOVOICE TO IDENTIFY MATERNAL DIETARY CONSUMPTION ENABLERS AND BARRIERS IN NORTHERN BANGLADESH

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3.3 Summary

- Maternal undernutrition affects one in three women in Bangladesh, impacting on the health and nutrition of the child.
- My aim was to describe what maternal nutrition means to pregnant women living in rural areas of northern Bangladesh.
- Photovoice methodology was modified and used in two villages in northern Bangladesh between June and July 2012. Eight skilled community nutrition volunteers were trained as facilitators. Participants (n=10) were trained on the use of a digital camera. Participants then used digital cameras to record their individual views and experiences in relation to the research question "what does maternal nutrition mean to you?" Cameras were collected and pictures printed. The participants selected 98 photographs in total. The community nutrition volunteers led participants through an in-depth interview process where the photographs were used to evoke a narrative. Data were analysed qualitatively using thematic analysis.
- Eight major themes emerged: every day foods consumed during pregnancy; liked foods influence dietary consumption; household food production influences dietary consumption; household food production provides both sustenance and income; need for a cash income in a subsistence community; family structure influences dietary intake; understanding that nutrition is important though not sure why; and support provided by non-governmental organisations.
- These findings highlight that maternal dietary consumption is influenced by social, cultural and economic factors. Community-based nutrition interventions require nutrition-specific and sensitive approaches to address the root causes of undernutrition.

3.4 Final word

This study adds new knowledge on maternal nutrition through the eyes of undernourished northern Bangladeshi pregnant women. This study provides rich qualitative information on maternal nutrition and complements the following quantitative study that explores maternal dietary diversity and household food security (Study 3, Chapter 4).

Chapter 4. An exploration of maternal dietary diversity and household food security in undernourished pregnant women living in northern Bangladesh

4.1 Overview

This chapter explores household food security and the food groups consumed (and not consumed) by undernourished pregnant women living in one of the twelve villages selected to participate in the randomised controlled trial in Northern Bangladesh. This chapter comprises of Study 3. The data for this chapter came from the baseline questionnaires completed by women participating in the 30-day acceptability study (Study 5, Chapter 6). Thus, the participants are the same for Studies 3 and 5.

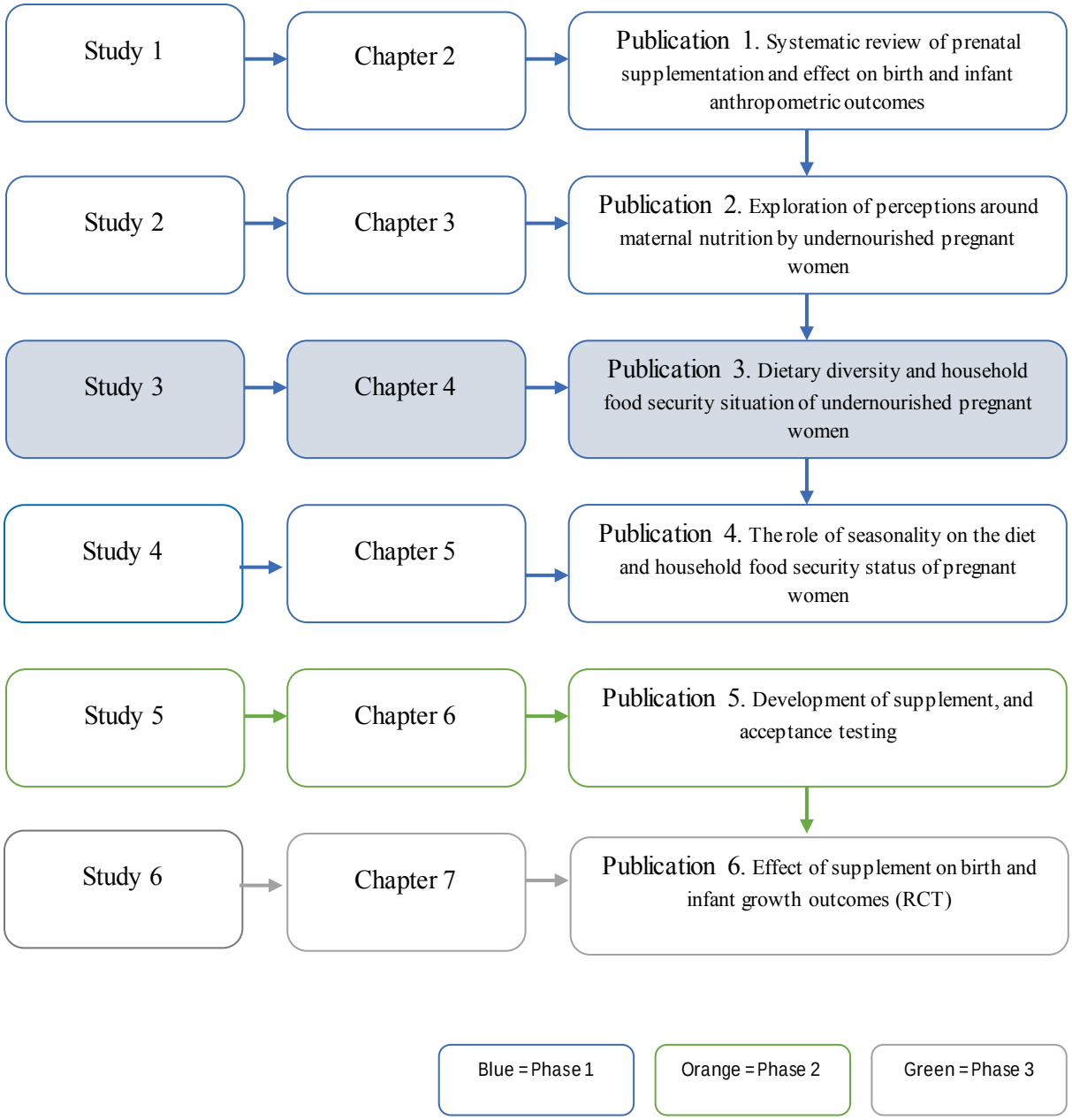

Figure 7 Study 3, Chapter 4 in relation to the thesis structure and multiphase design

This chapter is inserted as the published article (PDF):

Stevens, B., Watt, K., Clough, A., Judd, J. and Brimblecombe, J. An exploration of maternal dietary diversity and household food security in undernourished pregnant women living in Northern Bangladesh. International Journal of Food, Nutrition and Public Health. 2015; 7 (2): 61-69.

This article provides exploratory quantitative information on maternal nutrition in northern Bangladesh. In particular, the article provides information on dietary diversity and household food security. Together with the systematic literature review (Study 1), and the Photovoice study (Study 2), this study informed the design of the next phase of this research (development of the supplement; Study 5, Chapter 6). For example, ensuring that the composition of the supplement met addressed gaps in food groups consumed, while using locally available foods.

4.2 Publication in the International Journal of Food, Nutrition and Public Health

Int. J. Food, Nutrition and Public Health, Vol. 7, No. 2, 2015

AN EXPLORATION OF MATERNAL DIETARY DIVERSITY AND HOUSEHOLD FOOD SECURITY IN UNDERNOURISHED PREGNANT WOMEN LIVING IN NORTHERN BANGLADESH

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ABSTRACT

Purpose: Inadequate dietary intake during pregnancy is a major problem in many low-income countries. This study aimed to investigate dietary diversity of pregnant women in first, second or third trimester of pregnancy, and associations with household food security in a rural district of northern Bangladesh.

Design: In September 2012, skilled community nutrition volunteers (*n* 5 8) interviewed undernourished pregnant women (*n* 5 10) using a questionnaire which consisted of three components

1. demographics
2. household food security and
3. dietary diversity.

The Household Food Insecurity Access Scale (HFIAS) was adapted to explore household food access and the individual dietary diversity questionnaire to explore women's dietary diversity. Data were analysed using HFIAS and dietary diversity validated methodology.

Findings: This study found that half of households were identified as food insecure, and two thirds of women had inadequate dietary diversity, which may contribute to the burden of undernutrition and micronutrient deficiencies. There appeared to be no relationship among women with low dietary

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4.3 Summary

- Inadequate dietary intake during pregnancy is a major problem in many low-income countries. This study aimed to investigate the dietary diversity of pregnant women in first, second or third trimester of pregnancy, and associations with household food security in a rural district of northern Bangladesh.
- In September 2012, skilled community nutrition volunteers ($n = 8$) interviewed undernourished pregnant women ($n = 10$) using a questionnaire which consisted of three components: 1) demographics; 2) household food security; and 3) dietary diversity. The HFIAS was adapted to explore household food access and the women's dietary diversity questionnaire was used to explore women's dietary diversity. Data were analysed using HFIAS and dietary diversity validated methodology.
- In this study, half of the households were identified as food insecure, and two thirds of women had inadequate dietary diversity, which may have contributed to the burden of undernutrition and micronutrient deficiencies. There was no relationship between low dietary diversity scores and household food security. Additional research is required to identify the relationship between maternal nutrition status, dietary diversity scores and household food security.

4.4 Final word

In this exploratory study, maternal dietary diversity and household food security in the targeted villages of northern Bangladesh were identified. Chapter 5 explores the role of seasonality in dietary diversity and household food security of pregnant women in northern Bangladesh.

Chapter 5: The role of seasonality on the diet and household food security of pregnant women living in rural Bangladesh: A cross-sectional study

5.1 Overview

In this chapter I present the quantitative results of a multivariate analysis exploring the role of seasonality in dietary diversity and household food security among pregnant women.

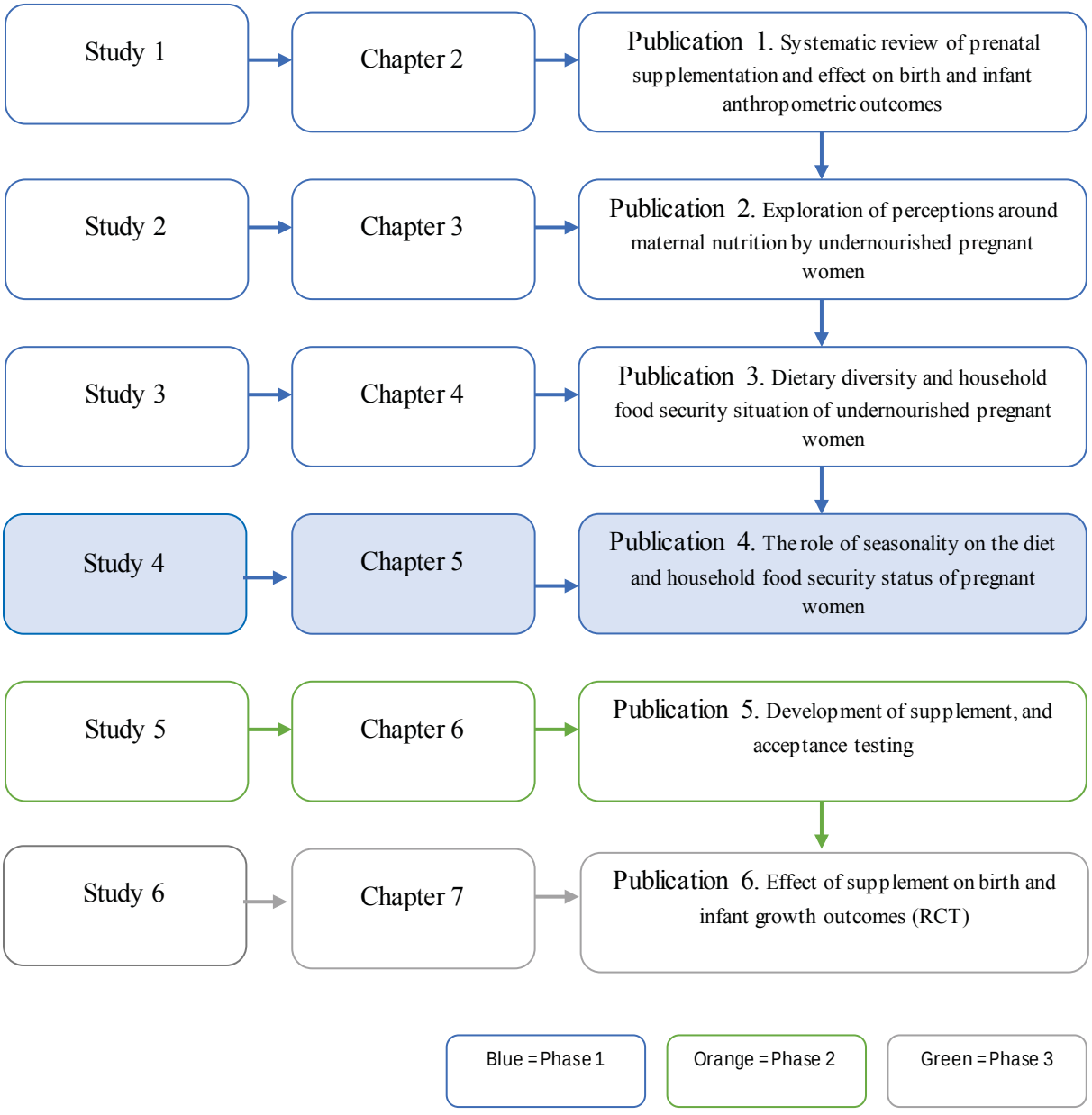

Figure 8 Study 4, Chapter 5 in relation to the thesis structure and multiphase design

This chapter is inserted as the published article (PDF):

Stevens, B., Watt, K., Brimbecombe, J., Clough, A., Judd, J. and Lindsay, D. 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. 2016; (1): 1-9. doi: 10.1017/S136898001600183X.

The above article presents quantitative information on the role of seasonality in dietary diversity and household food security among pregnant women living in northern Bangladesh. This study was published with the Journal of Public Health Nutrition. In September 2016, this article was the 9th most read article compared with other articles of similar age published with the Journal of Public Health Nutrition.

5.2 Publication in the Public Health Nutrition Journal

Public Health Nutrition: page 1 of 9 doi:10.1017/S136898001600183X

The role of seasonality on the diet and household food security of pregnant women living in rural Bangladesh: a cross-sectional study

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Abstract

Objective: To investigate the association of seasonality with dietary diversity, household food security and nutritional status of pregnant women in a rural district of northern Bangladesh.

Design: A cross-sectional study was conducted from February 2013 to February 2015. Data were collected on demographics, household food security (using the Household Food Insecurity Access Scale), dietary diversity (using the women's dietary diversity questionnaire) and mid-upper arm circumference. Descriptive statistics were used to explore demographics, dietary diversity, household food security and nutritional status, and inferential statistics were applied to explore the role of seasonality on diversity, household food security and nutritional status.

Setting: Twelve villages of Pirganj sub-district, Rangpur District, northern Bangladesh.

Subjects: Pregnant women (*n* 288).

Results: Seasonality was found to be associated with dietary diversity ($P=0{\cdot}026$) and household food security ($P=0{\cdot}039$). Dietary diversity was significantly lower in summer ($P=0{\cdot}029$) and spring ($P=0{\cdot}038$). Food security deteriorated significantly in spring ($P=0{\cdot}006$) and late autumn ($P=0{\cdot}009$).

Conclusion: Seasons play a role in women's household food security status and dietary diversity, with food security deteriorating during the lean seasons and dietary diversity deteriorating during the second 'lesser' lean season and the season immediately after. Interventions that aim to improve the diet of pregnant women from low-income, subsistence-farming communities need to recognise the role of seasonality on diet and food security and to incorporate initiatives to prevent seasonal declines.

Keywords
Maternal undernutrition
Bangladesh
Low-income country
Women's dietary diversity scores
Household Food Insecurity Access Scale

Birth weight is an important indicator of early childhood survival and health. Low-birth-weight babies are at an increased risk of stunting, infant mortality and morbidity, poor cognitive development, and chronic diseases such as diabetes and CVD later in life[1]. In low- and middle-income countries, maternal undernutrition contributes to intra-uterine growth restriction, which results in low birth weight[1,2]. Good nutrition during pregnancy is essential for ensuring fetal growth and development and subsequent childhood health and survival. While studies have identified effective supplementation interventions to address maternal undernutrition in low-income countries, the causes of maternal undernutrition in different contexts remain relatively unexplored[3,4]. To design programmes that address maternal undernutrition, organisations often assess food security and dietary diversity using tools that provide a snapshot of the situation at one point in time. Dietary diversity over a reference period acts as a proxy indicator of dietary quality and is associated with nutrient adequacy[5,6]. Household food security status reflects availability, accessibility and utilisation of food at a household level. Both dietary diversity and household food security are associated with access to and availability of foods, and seasonality is recognised as a key element of

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food availability in many low-income countries. While it may appear logical for seasonality to be associated with dietary diversity and household food security, programme decision makers rarely consider seasonality when designing new programmes to address maternal undernutrition.

Bangladesh has among the highest rates of maternal and child undernutrition globally. One in three pregnant women is undernourished (BMI <18·5 kg/m^2), one in five babies is born with low birth weight, and one in three children aged 6–59 months is stunted[7,8]. In Bangladesh, the times of the year when there are seasonal fluctuations in income and employment are referred to as '*monga*'. *Monga* occurs twice annually: the main *monga* occurs from 15 September to 14 November (Bangladeshi months of Ashbin and Kartik), prior to the main rice harvest, and the lesser *monga* occurs from 15 March to 14 April (Bangladeshi month of Choitro)[9]. During *monga* Bangladeshis face seasonal food shortages that often result in household food shortages, particularly among those in rural areas who rely on subsistence farming. The documented consequences of seasonal food shortages on the nutritional status of women in low-income countries include reduced energy expenditure, weight loss, insufficient weight gain and subsequent low birth weight[10–12]. Despite a number of studies exploring the role of seasonality on dietary diversity and household food security status at specific time points (often pre and post the lean or monsoon season), the role of annual seasonal variations on dietary diversity and household food security, especially among pregnant women, remains largely unknown[13,14]. By understanding seasonal fluctuations in dietary diversity and household food security among pregnant women, programme decision makers can better design interventions to address maternal undernutrition.

The aim of the present study was to investigate the role of seasonality on dietary diversity and household food security for pregnant women living in rural Bangladesh. We also explored relationships of seasonality with maternal nutritional status. We anticipate that these findings will highlight the importance of understanding seasonal variations in maternal dietary diversity and household food security and inform the design of future nutrition interventions in Bangladesh and other low-income contexts.

Methods

Study design

A cross-sectional study was conducted. Recruitment occurred over the period February 2013 to February 2015. The sample consisted of individuals from all villages previously selected for a cluster randomised controlled trial which aimed to measure the effect of a locally produced food-based supplement on reducing intra-uterine growth restriction in undernourished pregnant women. While the sample for the cluster randomised controlled trial consisted of undernourished pregnant women only, the current study looked at all pregnant women from these villages, regardless of their nutritional status. Therefore, participants for the current sample were from two purposively selected unions in Pirganj sub-district, one selected as the intervention and the other matched as the control. From the intervention union, eight villages were randomly selected using computer-generated random numbers. From the control union, four villages were purposively matched. The number of villages was determined based on average population number, prevalence and estimated incidence of pregnant women across the study period, and the required sample size. The data used for the current study come from surveys completed by consenting women confirmed to be pregnant within the twelve villages of interest.

Setting

The study was conducted in twelve rural villages of Pirganj sub-district of Rangpur District, located in northern Bangladesh. According to the 2011 Population and Housing Census, Pirganj sub-district covers an area of 411·34 km^2, consists of 332 villages and has 385 499 inhabitants[15]. The majority of the population is Muslim, with a minority of people belonging to the Santal ethnic group who are predominantly Christian. The average household size is 3·78 and the literacy rate* is 45·4 %[15]. The area has a tropical monsoon climate, and experiences high temperatures and humidity and heavy seasonal rainfall from June to November. Rangpur is commonly referred to as '*monga* prone' and reported as more vulnerable to seasonal food insecurity than other areas of Bangladesh[16]. Rangpur's main employment source is agricultural labour, although wages are very low compared with neighbouring districts[9]. The villages are typical of villages in northern Bangladesh and have dirt road access that is often inaccessible during the wet season. The communities are largely dependent on subsistence farming and have limited experience with non-Bangladeshi foods.

Participants and recruitment

In each of the selected villages, all women were invited to participate in the study if they: (i) were suffering no illness requiring medical referral; and (ii) were confirmed to be pregnant by a midwife, skilled community health volunteer or other health professional. Prior to the commencement of the study, eight female community nutrition volunteers and two (one male, one female) supervisors from the selected villages were trained on the basics of nutrition, study purpose and design. The community nutrition volunteers had at least a primary-school

* Defined as the ability to write a letter in any language, assessed among the population 7 years and above[15].

Public Health Nutrition

education, spoke the local dialect, and were aged between 21 and 49 years. Community nutrition volunteers compiled lists of all pregnant women in the twelve villages and produced village maps that determined the location of each woman's household. These women were identified through community discussions, door-knocking and snowballing. If the woman was interested, the community nutrition volunteer then verified that she met the inclusion criteria and referred the woman to a skilled health worker if the pregnancy was not yet confirmed. Women were given a brief overview of the project and invited to participate. Written or verbal (with thumbprint) consent to participate was obtained after participants heard the project information sheet read aloud. A copy of the information sheet in the local language was provided to participants for their further reference. Verbal consent was also obtained from the leaders of each village for inclusion of their village in the study.

The current project had human research ethical approval from the James Cook University (Australia) Ethics Committee (H4498) and the Bangladesh Medical Research Council (BMRC/NREC/2010-2013/58). The research was registered with the ISRCTN registry (ISRCTN97447076).

Data collection

The community nutrition volunteers assisted participants to complete a survey comprising: (i) background demographics; (ii) household food security; (iii) dietary diversity; and (iv) anthropometry. We used the validated Food and Nutrition Technical Assistance Project's Household Food Insecurity Access Scale (HFIAS) questionnaire and the validated FAO dietary diversity questionnaire to explore food security and dietary diversity, respectively[17–19]. The HFIAS questionnaire consisted of nine occurrence questions (conditions) and nine frequency-of-occurrence questions. With a recall period of 30 d, each occurrence question reflected a condition that represented an increasing level of severity of food insecurity (access) and the frequency-of-occurrence questions determined how often the condition occurred. The nine questions were grouped to form three domains to provide additional information on anxiety and uncertainty about household food supplies, insufficient quality and insufficient food intake and its physical consequences. The frequency-of-occurrence questions were also used to calculate scores, which were then grouped into two categories: food secure and food insecure[19]. The dietary diversity questionnaire consisted of thirteen questions that were later aggregated to form nine food groups. With a recall period of 24 h, this questionnaire allowed us to calculate the woman's dietary diversity score (WDDS), identify individual food groups consumed and calculate specific indicators of interest for micronutrient-rich food groups[20]. The study lead author adapted the HFIAS and dietary diversity questionnaires through community dialogue[21]. The HFIAS questionnaire was adapted to ensure a common understanding of certain words (e.g. a locally appropriate definition of 'household' and 'meal'). The dietary diversity questionnaire was adapted to reflect locally available foods. Questionnaires were translated into local terminology, back-translated and field-tested prior to use. In addition, an interviewer's guide was developed to provide additional information on each question, as well as examples to ensure that questions were understood appropriately.

Mid-upper arm circumference (MUAC) measurements were performed using the standardised procedures recommended by the WHO[22]. The community nutrition volunteer took duplicate measurements of the left arm measured to the nearest millimetre with adult MUAC tapes. Triplicate measurements were taken if a variation occurred between the two measurements. Maternal undernutrition was defined as MUAC $\leq$22·1 cm. MUAC was the preferred indicator to identify maternal undernutrition based on its association with low birth weight[23,24]. The cut-off was determined after a review of the evidence and a discussion with organisations conducting nutrition programmes and research in Bangladesh[24].

Statistical methods

The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) Checklist for cross-sectional studies was used to ensure comprehensive reporting of the present study. Data management was performed using the statistical software package IBM SPSS Statistics, Version 23.0©. Data quality was ensured by quality checks associated with the data-entry process, double entry and data cleaning.

Food insecurity

Household food insecurity was determined using the HFIAS for Measurement of Food Access: Indicator Guide, Version 3. Dichotomous occurrence and ordinal frequency categorical variables were created for each condition; frequencies for each food insecurity access domain (anxiety, food quality and food quantity) and HFIAS scores were used to identify the prevalence of different levels of household food insecurity[19].

Dietary diversity

Women's dietary diversity was determined using the FAO guidelines to measure household and individual dietary diversity[18]. Dietary diversity was summarised to create dichotomous occurrence variables for each food group and indicators of specific interest, and aggregated to create the WDDS[18]. The nine food groups were: (i) starchy staples; (ii) dark green leafy vegetables; (iii) vitamin A-rich fruits/vegetables; (iv) other fruits/vegetables; (v) organ meats; (vi) meat/poultry/fish; (vii) eggs; (viii) legumes/nuts/seeds; and (ix) milk/milk products. The WDDS were used as discrete quantitative variables and divided into

tertiles to distinguish diets of high, medium and low diversity. As there are no universally agreed cut-offs to define WDDS tertiles, we created tertiles based on recommendations in current literature[6]. After aggregating household food security and dietary diversity according to the respective guidelines, we analysed the means of the variables, with a higher HFIAS indicating more food insecure and a lower WDDS indicating lower dietary diversity. To explore consumption of vitamin A- and Fe-rich foods, indicators from specific related food groups were created[18].

Household food security, dietary diversity and nutritional status were used as dependent variables and differences in these variables were examined based on the season variable. Grouping questionnaires by the six Bangladeshi seasons (summer = 15 April–14 June; monsoon = 15 June–14 August; autumn = 15 August–14 October; late autumn = 15 October–14 December; winter = 15 December–14 February; spring = 15 February–14 April) created the season variable. We used inferential statistics to test for relationships and differences between the variables of interest.

Data were not normally distributed, so non-parametric tests were used. Questions related to food security, dietary diversity and anthropometry based on season were analysed using the Kruskal–Wallis one-way ANOVA by ranks test followed by the *post hoc* Mann–Whitney *U* test. Comparisons between frequencies of participants' responses on the dietary diversity and food security variables were analysed using the χ^2 test. Statistical significance was accepted at $P < 0{\cdot}05$.

Results

Participants

From February 2013 to February 2015, 289 pregnant women were identified as potentially eligible. One woman refused participation for unknown reasons. Thus, a total of 288 women were enrolled in the study.

Descriptive data

Background characteristics of the 288 women surveyed are presented in Table 1. The mean age of women was 25·3 (SD 5·7) years. Most women had attended school, with the majority reaching either primary or lower secondary education (42·0 and 42·4 %, respectively). The mean height of women was 148·5 (SD 7·7) cm, with almost half of women below 148 cm (47·4 %). The mean MUAC of women was 23·73 (SD 2·27) cm, with 29·7 % of women below 22·1 cm. Most women were in their second trimester (54·9 %) of their pregnancy. Of women in the first trimester (*n* 85), the mean BMI was 20·4 (SD 3·4) kg/m^2. One in three women reported that she was experiencing pregnancy for the first time (36·5 %).

Table 1 Background characteristics of participating pregnant women (*n* 288) from twelve villages in rural northern Bangladesh, February 2013–February 2015

Background characteristic	*n*	%	Mean	SD
Maternal age (years)			25·3	5·7
Trimester				
First	87	32·5		
Second	147	54·9		
Third	34	12·7		
Lived at village since birth	287	99·7		
Married	288	100·0		
Average household size			3·6	1·4
Male head of household	288	100·0		
School attendance				
Never attended	27	9·4		
Primary	121	42·0		
Lower secondary*	122	42·4		
Higher secondary†	16	5·6		
Tertiary	2	0·7		
Religion				
Islam	246	85·4		
Hindu	32	11·1		
Christianity	10	3·5		
Gravidity				
0	106	37·1		
1	121	42·3		
2	44	15·4		
≥3	15	5·1		
First pregnancy	105	36·5		
Still birth	11	3·8		
Miscarriage	19	6·6		
Woman works outside home, excluding housework	36	12·5		
Anthropometrics				
Maternal height (cm)			148·5	7·7
Maternal height <148 cm	136	47·4		
Maternal MUAC (cm)			23·7	2·3
Maternal MUAC <22·1 cm	85	29·7		

MUAC, mid-upper arm circumference.
*Grade 7–10.
†Grade 11–12.

Main results

Food security

Food security characteristics are presented in Table 2. The mean HFIAS score was 4·06 (SD 2·86; range 0–13 of a possible 27). Of the women, most were identified as food insecure (87·6 %), with 7·7 % identified as severely food insecure.

Dietary diversity

Over nine possible food groups, women's dietary diversity ranged from two to eight food groups. The mean number of food groups consumed was at 4·8 (SD 1·1), indicating low probability of adequate dietary intake[25]. Figures 1 and 2 illustrate the food groups consumed by pregnant women. To further explore the frequency of food groups consumed, Table 3 illustrates the food groups consumed by more than 50 % of women by WDDS tertile.

Seasonal variations in dietary diversity and household food security status

Table 4 presents the percentage of participants reporting consuming each food group (dietary diversity) and their

agreement with various statements in relation to household food security, based on season. The relevant medians and interquartile ranges for these analyses can be seen in Table 5. No significant differences in MUAC based on season were found ($P = 0{\cdot}130$). The median WDDS varied as a function of season ($H(5) = 12{\cdot}97$, $P = 0{\cdot}026$).

Table 2 Food security characteristics of pregnant women (*n* 288) from twelve villages in rural northern Bangladesh, February 2013–February 2015

Food security characteristic	*n*	%
HFIAS category		
Food secure	35	12·2
Mild household food insecurity	59	20·6
Moderate household food insecurity	171	59·6
Severe household food insecurity	22	7·7
HFIAS conditions		
Worry about food intake	111	38·5
Not able to eat preferred foods	195	67·7
Limited variety of foods	133	46·2
Eat unwanted foods	195	67·7
Eat small meals	147	51·0
Eat fewer meals	40	13·9
No food in house	11	3·8
Sleep hungry	9	3·1
Whole day without food	6	2·1
HFIAS domains		
Insufficient food quality	248	86·1
Insufficient food intake	162	56·4

HFIAS, Household Food Insecurity Access Scale.

Mann–Whitney *U* tests revealed that the median value for dietary diversity was significantly lower in summer than in late autumn ($U = 2202$, $r = 2{\cdot}19$, $P = 0{\cdot}029$) and winter ($U = 802{\cdot}5$, $r = 2{\cdot}21$, $P = 0{\cdot}027$) and significantly lower in spring than in late autumn ($U = 1286{\cdot}5$, $r = 2{\cdot}08$, $P = 0{\cdot}038$) and winter ($U = 463{\cdot}5$, $r = 2{\cdot}23$, $P = 0{\cdot}026$). Chi-square analyses revealed that the consumption of meat/poultry/fish varied as a function of season ($\chi^2 = 11{\cdot}74$, $P = 0{\cdot}039$). Based on the percentages presented in Table 4, it appears as though a greater proportion of women consumed meat/poultry/fish in late autumn and winter compared with other seasons. This may have contributed to the significantly higher number of women eating food groups rich in haem Fe during late autumn and winter compared with other months (see Table 4; $\chi^2 = 12{\cdot}9$, $P = 0{\cdot}034$).

A Kruskal–Wallis test determined that the median HFIAS score varied as a function of season ($H(5) = 11{\cdot}68$, $P = 0{\cdot}039$). Mann–Whitney *U* tests revealed that the median HFIAS score was significantly higher in spring than in the monsoon season ($U = 649{\cdot}5$, $r = -2{\cdot}73$, $P = 0{\cdot}006$) and late autumn ($U = 1181$, $r = -2{\cdot}61$, $P = 0{\cdot}009$). Further analyses of the HFIAS conditions based on season revealed a significant difference in the proportion of participants who reported having to eat a limited variety of foods due to a lack of resources ($\chi^2 = 12{\cdot}72$, $P = 0{\cdot}026$). The percentages reported in Table 4 suggest that more participants reported having to eat a limited variety of foods due to a lack of

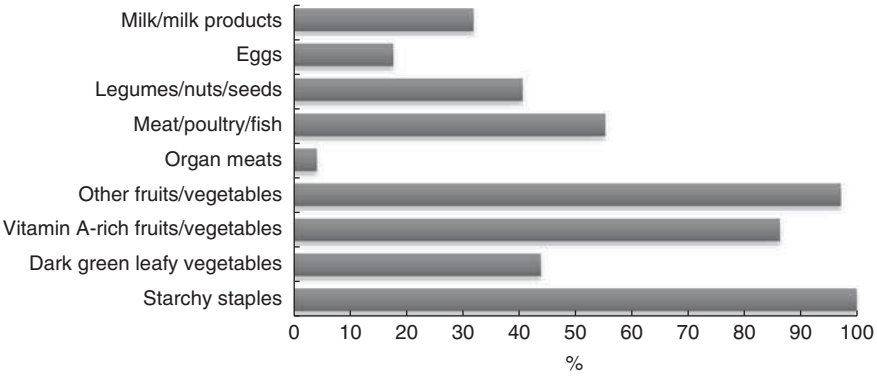

Fig. 1 Food groups consumed over a 24 h period by pregnant women (*n* 288) from twelve villages in rural northern Bangladesh, February 2013–February 2015

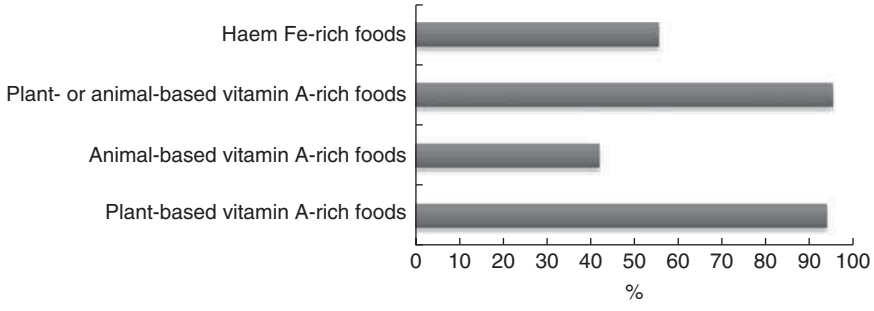

Fig. 2 Micronutrient-rich food groups consumed over a 24 h period by pregnant women (*n* 288) from twelve villages in rural northern Bangladesh, February 2013–February 2015

Table 3 Food groups, according to tertile of dietary diversity, consumed by ≥50 % of pregnant women (*n* 288) from twelve villages in rural northern Bangladesh, February 2013–February 2015

Lowest dietary diversity (≤4 food groups)	Medium dietary diversity (5 food groups)	High dietary diversity (≥6 food groups)
Starchy staples	Starchy staples	Starchy staples
Dark green leafy vegetables	Dark green leafy vegetables	Dark green leafy vegetables
Other vitamin-A rich fruits/vegetables	Other vitamin A-rich fruits/vegetables	Other vitamin A-rich fruits/vegetables
Other fruits/vegetables	Other fruits/vegetables	Other fruits/vegetables
	Meat/poultry/fish	Meat/poultry/fish
		Legumes/nuts/seeds
		Milk/milk products

Table 4 Percentage response to dietary diversity, food security and nutritional status questions as a function of season among pregnant women (*n* 288) from twelve villages in rural northern Bangladesh, February 2013–February 2015

	Season						
	Summer (*n* 89)	Monsoon (*n* 38)	Autumn (*n* 21)	Late autumn (*n* 62)	Winter (*n* 25)	Spring (*n* 53)	*P* value
Dietary diversity: food groups (%)							
Starchy staples	100·0	100·0	100·0	98·4	100·0	100·0	0·691
Dark green leafy vegetables	40·4	44·7	57·1	45·2	48·0	39·6	0·770
Vitamin A-rich fruits/vegetables	77·5	92·1	90·5	90·3	88·0	88·7	0·205
Other fruits/vegetables	98·9	97·4	95·2	93·5	100·0	96·2	0·426
Organ meats	2·2	5·3	9·5	3·2	8·0	3·8	0·457
Meat/poultry/fish	42·7	57·9	57·1	66·1	72·0	52·8	0·039
Legumes/nuts/seeds	42·7	15·4	8·5	25·2	10·2	21·5	0·638
Eggs	16·9	21·1	19·0	21·0	16·0	13·2	0·893
Milk/milk products	33·7	44·7	23·8	27·4	40·0	24·5	0·278
Plant-based vitamin A-rich foods	92·1	94·7	90·5	91·9	100·0	96·2	0·662
Animal-based vitamin A-rich foods	44·9	44·7	42·9	43·5	44·0	32·1	0·753
Haem Fe-rich foods	42·7	57·9	61·9	66·1	72·0	52·8	0·034
HFIAS conditions (%)							
Not able to eat preferred foods	65·2	63·2	76·2	61·3	68·0	79·2	0·336
Limited variety of foods	58·4	39·5	28·6	37·1	36·0	52·8	0·026
Eat unwanted foods	58·4	68·4	85·7	71·0	68·0	71·7	0·198
Eat small meals	66·3	36·8	52·4	37·1	60·0	47·2	0·040
Eat fewer meals	12·4	10·8	0·0	16·1	12·0	22·6	0·176
No food in house	5·6	2·6	0·0	1·6	8·0	3·8	0·628
Sleep hungry	1·1	0·0	0·0	4·8	8·0	5·7	0·197
Whole day without food	2·2	0·0	0·0	3·2	0·0	3·8	0·899
HFIAS domains (%)							
Worry about food intake	37·1	21·1	42·9	33·9	52·0	50·9	0·062
Insufficient food quality	87·6	84·2	90·5	80·6	84·0	90·6	0·692
Insufficient food intake	70·8	40·5	52·4	41·9	64·0	58·5	0·004
HFIAS category: food insecure (%)	89·9	83·8	90·5	93·9	84·0	92·5	0·619

HFIAS, Household Food Insecurity Access Scale.

Table 5 Median (and interquartile range (IQR)) dietary diversity score, food security score and mid-upper arm circumference (MUAC) as a function of season among pregnant women (*n* 288) from twelve villages in rural northern Bangladesh, February 2013–February 2015

	Season											
	Summer		Monsoon		Autumn		Late autumn		Winter		Spring	
	Median	IQR	Median	IQR	Median	IQR	Median	IQR	Median	IQR	Median	IQR
WDDS	5	1	5	2	5	2	5	2	5	2	4	1
HFIAS	4	4	3	4	4	4	3	5·5	4	5	4	4·5
MUAC	24·00	3·80	22·85	3·00	24·50	3·20	23·25	2·50	24·00	3·00	22·15	2·60

WDDS, woman's dietary diversity score; HFIAS, Household Food Insecurity Access Scale.

resources in the summer and spring seasons than all other seasons. The proportion of participants who reported having to eat a smaller meal than they felt they needed to because there was not enough food also differed significantly based on season ($\chi^2 = 17{\cdot}312$, $P = 0{\cdot}04$). Based on the percentages in Table 4, it appears as though

participants reported having to eat a smaller meal less often in the monsoon and late autumn seasons than in all other seasons.

Further analysis of the HFIAS domains revealed a significant difference in the proportion of participants who reported having insufficient food intake across the seasons ($\chi^2 = 46{\cdot}57$, $P = 0{\cdot}004$). From the percentages presented in Table 4, it appears as though participants are most concerned about not getting sufficient food intake in the summer and winter seasons.

Seasonal variations in anthropometry

A Kruskal–Wallis test revealed no significant differences in MUAC based on season ($H(5) = 8{\cdot}53$, $P > 0{\cdot}05$; see Table 5 for more detail).

Discussion

In northern Bangladesh, we found that dietary diversity and household food security were sensitive to seasonal variations, a finding which has been observed in similar studies[13,14]. Seasonality was significantly associated with dietary diversity and food security status of pregnant women. A common limitation in the use of the HFIAS and women's dietary diversity tools is that they capture a 'snapshot' of the situation and do not reflect seasonal variances. While a few studies have attempted to address this limitation, studies have traditionally been cross-sectional at two points in time[13,14]. Our study is unique as it recruited women over a 24-month period, taking into consideration seasonal variances across the year. A 2-year period was necessary to reach the required sample size to maximise the chance of finding a significant result. Contrary to findings reported elsewhere, we did not identify significant differences in maternal nutritional status based on season[14].

Women had higher dietary diversity in autumn and winter, corresponding with the first month of *monga* and the month between the main *monga* and lesser *monga*, respectively. The higher dietary diversity in autumn corresponded with a higher consumption of dark green leafy vegetables, vitamin A-rich fruits/vegetables and organ meats; while the higher dietary diversity in winter corresponded with a higher consumption of other fruits/vegetables, organ meats, meat/poultry/fish and milk/milk products. Late autumn and winter corresponded with a higher consumption of Fe-rich foods. Interestingly, these two seasons had the lowest consumption of legumes/nuts/seeds. This may be due to the higher consumption of fresh produce such as fruits, vegetables and meat. During these months, legumes, nuts and seeds may be stored for periods when fresh produce is no longer available or accessible. Women had lower dietary diversity in summer and spring, corresponding with the first month of the lesser *monga* and the month directly after the lesser *monga*. This may be due to households depleting food supplies during the main *monga* and having no reserves for the lesser *monga*. While the first *monga* may be considered the 'main' *monga* due to its longer duration, the effects of the lesser *monga* may be more detrimental on the nutritional status of pregnant women in the household.

We identified that household food insecurity peaked during *monga* (autumn) and lesser *monga* (spring). A similar study conducted in northern Bangladesh, but with a different target group, identified that the prevalence of both food insecurity and undernutrition was higher during the monsoon season compared with the dry season (winter)[14]. While our findings may differ, this is likely due to the study methodology; the other study conducted a survey at two points in time only (monsoon and winter) and therefore did not analyse the differences between other seasons. Our findings clearly illustrate fluctuations in dietary diversity and household food security across the seasons. Spring, which corresponds with the lesser *monga*, had high proportions of participants reporting both low variety of foods and food insecurity. By summer, we continued to see a high proportion of participants reporting low variety of foods, coupled with insufficient food intake, and consumption of smaller sized meals. By autumn, while dietary diversity was higher than in the previous season, household food insecurity remained high. Late autumn, which corresponds to the end of the main *monga*, appeared to be the most food-secure season where dietary diversity was at its highest and where food insecurity affected the lowest proportion of households for the year.

We did not identify a relationship between seasonality and maternal nutritional status (as measured by MUAC). Recent evidence from a similar study in a neighbouring district of Bangladesh contradicts this[14]. In that study, seasonality was associated with nutritional status. However, the target group in Hillbruner and Egan's study was children aged 6–72 months[14] and the target group in the present study was pregnant women. Hence, the conflicting findings may be due to differences in target group. The reason for seasonality not being associated with maternal nutritional status in the present study may be that the negative outcomes of seasonality on dietary diversity and household food security do not last long enough to be associated with maternal nutritional status in the Bangladeshi context. Alternatively, it may be that women are able to mitigate potential associations between seasonal variation and maternal nutritional status by adapting their diet accordingly. The WDDS and HFIAS tools are limited to identifying food groups consumed and classification of household food security status. By using a 24 h dietary recall tool, further analyses may have explored whether seasonal declines in maternal nutritional status were prevented through changes in the quantity of food consumed.

Study limitations

Our study had a number of limitations. First, the month of Ramadan resulted in difficulties finding an 'average' day

Public Health Nutrition

for the dietary diversity and household food insecurity questionnaires. To address Ramadan, participants observing Ramadan were rescheduled to complete the interview process on a 'normal' day, even if this meant waiting until after Ramadan. Second, we were unable to control for potential differences in seasonal impacts and differences in women across the 2-year enrolment period due to the small sample size. It is important to note, however, that while Bangladesh is disaster-prone, no natural disasters occurred in the study areas across the study period. Third, both the dietary diversity and household food insecurity questionnaires have a recall period (24 h and 30 d, respectively) which may have resulted in a recall bias. Participants may forget items, and particularly for the dietary diversity questionnaire, the time period may be insufficient to capture the typical food groups consumed by the participant and may capture episodic foods that are not typically consumed. Fourth, respondent bias may also be an issue. In population groups where food assistance or developmental aid assistance is frequent, participants may over-report food insecurity and under-report dietary diversity with the expectation of receiving assistance. Conversely, participants may modify their responses based on social desirability. Lastly, despite our active home visits by the community nutrition volunteers, the proportion of women included early in pregnancy was lower than desired, a limitation experienced by others[26].

Conclusion

In conclusion, the present study identified that seasonality was significantly associated with dietary diversity and household food security of pregnant women in Pirganj, Bangladesh. Women's household food security status was significantly worse during the two *mongas* and dietary diversity was significantly lower during the lesser *monga* and the month immediately after the lesser *monga*. While the highest annual levels of food security and dietary diversity occurred during the season after the main *monga*, indicating a quick recovery from the main *monga*, we identified a high proportion of food insecurity during the lesser *monga* and an even higher proportion of food insecurity in the season immediately after the lesser *monga*, potentially indicating that households struggled to recover from the lesser *monga*. While economic and nutritional support is required during *monga*, continued support is also required for the period between the lesser *monga* and the main *monga*. This support could be through behavioural change strategies, food banks and diversification of household food production. Support during this time may lessen the shocks of the two *mongas* on household food security and maternal dietary diversity.

Our study highlights the importance of measuring WDDS and HFIAS across the year in order to identify seasonal variations. By recognising these seasonal variations, policy makers and programme decision makers can design context-specific interventions to improve the diet of pregnant women while incorporating initiatives to prevent negative seasonal declines in food security and dietary diversity, thus contributing to better development outcomes for the mother and child.

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Public Health Nutrition

5.3 Summary

- This study aimed to investigate the association of seasonality with dietary diversity, household food security, and the nutrition status of pregnant women in a rural district of northern Bangladesh.
- The study was conducted in twelve villages of Pirganj sub-district, Rangpur District, northern Bangladesh. In total, 288 pregnant women participated in the study.
- A cross-sectional study was conducted from February 2013 to February 2015. Data were collected on demographics, household food security (using the HFIAS), dietary diversity (using the women's dietary diversity questionnaire), and mid-upper arm circumference (MUAC). Descriptive statistics were used to explore demographics, dietary diversity, household food security, and nutrition status, and inferential statistics were applied to explore the role of seasonality on diversity, household food security and nutrition status.
- Seasonality was found to be associated with dietary diversity ($p = 0{\cdot}026$), and household food security ($p = 0{\cdot}039$). Dietary diversity was significantly lower in summer ($p = 0{\cdot}029$) and spring ($p = 0{\cdot}038$). Food security significantly deteriorated in spring ($p = 0{\cdot}006$) and late autumn ($p = 0{\cdot}009$).
- Seasons play a role on women's household food security status and dietary diversity, with food insecurity deteriorating during the lean seasons and dietary diversity deteriorating during the second 'lesser' lean season and the season immediately after. Interventions that aim to improve the diet of pregnant women from low income, subsistence farming communities need to recognise the role of seasonality in diet, and food security and incorporate initiatives to prevent seasonal declines.

5.4 Final note

In the following chapter (5), I describe a locally-produced food-based supplement for undernourished pregnant women living in northern Bangladesh.

Chapter 6: Development of the locally-produced food-based supplement, and acceptance testing

6.1 Overview

This study explores the development of a locally produced food-based supplement, and its acceptance among undernourished pregnant women. I aimed to develop a supplement using locally available, affordable and preferred foods. Thus, the following study was informed by Studies 1, 2, and 3 (Chapters 2, 3, and 4 respectively).

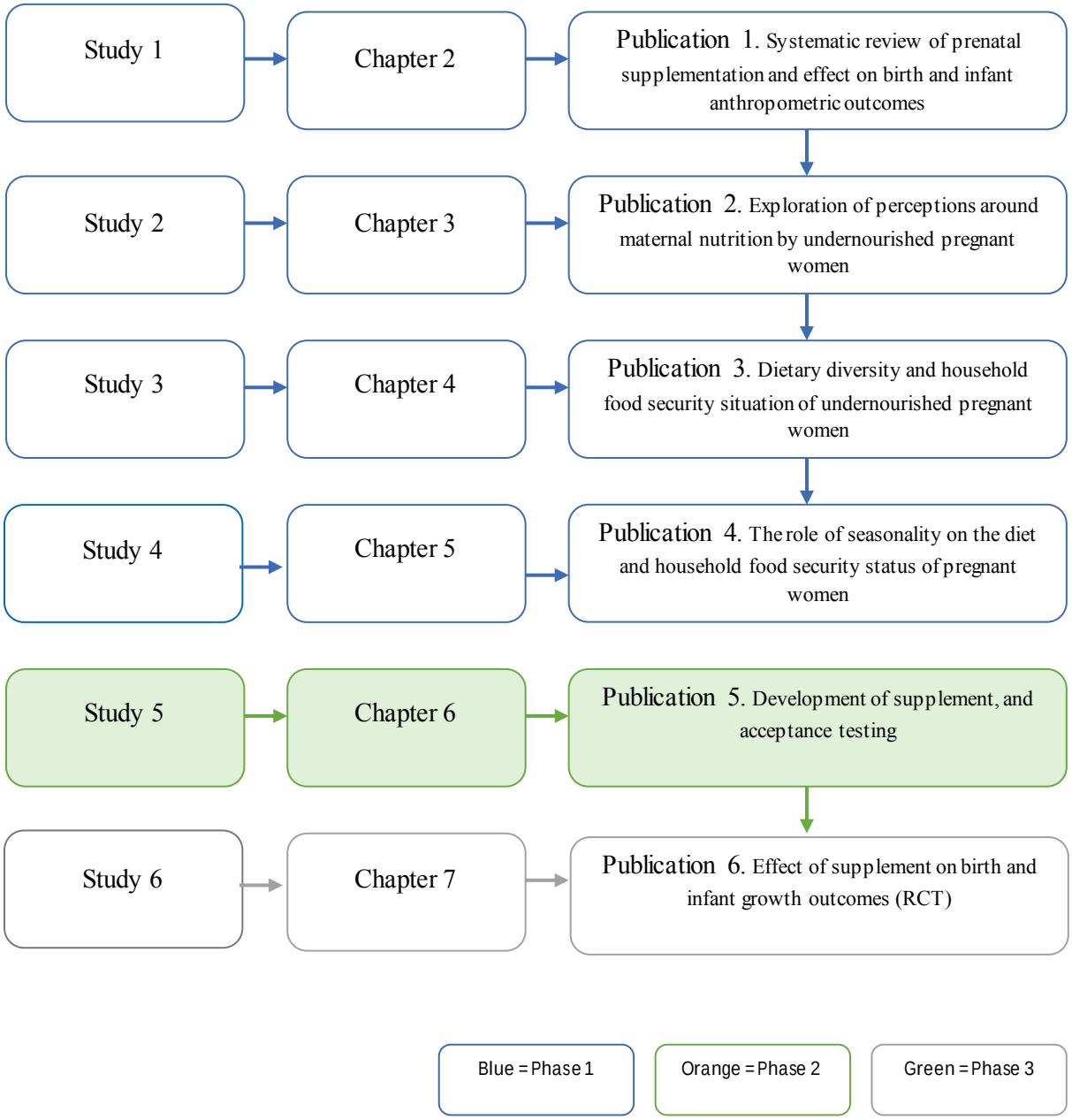

Figure 9 Study 5, Chapter 6 in relation to the thesis structure and multiphase design

6.2 Publication in the Journal of Hunger and Environmental Nutrition

This chapter is inserted as the published article (pdf), as published by *Taylor & Francis in* the Journal of Hunger Environmental Nutrition. The peer-reviewed published version of this article is available online: http://www.tandfonline.com/ 10.1080/19320248.2016.1227756.

This is the citation for the published article:
Stevens, B., Watt, K, Brimblecombe, J., Clough, A., and Judd, J (2016). Development of a locally produced balanced protein energy food-based supplement, and its acceptance by undernourished pregnant women in northern Bangladesh. Journal of Hunger Environmental Nutrition, 2016; (1): 1-16.

The above article presents qualitative information on the development of the supplement, and quantitative information on its acceptance. I elected to publish this study with the Journal of Hunger and Environmental Nutrition as the journal's scope explores innovative ways to address hunger and malnutrition in high-, medium- and low-income country contexts. Supplementary material supporting this article is presented prior to the chapter summary.

Journal of Hunger & Environmental Nutrition

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Development of a Locally Produced, Balanced Protein–Energy Food-Based Supplement and its Acceptance by Undernourished Pregnant Women in Northern Bangladesh

Briony Stevens, Kerrianne Watt, Julie Brimblecombe, Alan Clough & Jenni Judd

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Development of a Locally Produced, Balanced Protein–Energy Food-Based Supplement and its Acceptance by Undernourished Pregnant Women in Northern Bangladesh

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Supplemental data for this article can be accessed on the publisher's website.

6.3 Supplementary material

Characteristics of women that participated in the study

Characteristics (IQR, Interquartile range)	Women (*n* = 10)
Age (year, median ± IQR)	23 ± 7.5
Month of pregnancy (month, median ± IQR)	5.5 ± 1
Lived at village since birth (%)	100
Married (%)	100
Average household size	4.4
Male head of household (%)	100
Education (year, median ± IQR)	2.5 ± 5
Religion: Islam/Hinduism (%)	60/40
Husbands or father in-laws make financial decisions (%)	100
Husbands or father in-laws make decisions on food purchases (%)	100
Make own health care decisions (%)	20
First pregnancy (%)	30
Number of births (median ± IQR)	1 ± 3
Number of children alive (median ± IQR)	1 ± 2
Accessed skilled ANC services (%)	0
Received nutritional intervention during pregnancy (iron-folic acid) (%)	20

6.4 Summary

- Balanced protein energy supplementation can improve the nutritional status of pregnant women and birth weight. The cost of prenatal supplementation is often beyond the reach of mothers in low-income countries.
- In this study of undernourished pregnant women, a balanced protein energy supplement was developed using locally available, affordable and preferred foods, and tested for acceptance. A small business enterprise was established.
- A 30-day acceptability study was conducted among ten pregnant women between September and October 2012, in a rural district of northern Bangladesh.
- A questionnaire was administered at days 15 and 30 to assess women's perceptions and experience regarding compliance, organoleptic qualities, as well as personal and community attitudes towards the supplement and study.
- The primary outcome was compliance. All ten women completed the 15 and 30 day questionnaires. The supplement was redeveloped at day 15 based on feedback from the follow-up questionnaire, and formal and informal feedback. By day 30, women consumed an average of 29.7 packets of the supplement of the 30 packets received.
- We concluded that the redeveloped locally produced food-based supplement was well accepted by pregnant women. Study findings have contributed towards the design of an efficacy trial that is currently underway.

6.5 Final note

This study detailed the steps undertaken to develop a well-accepted, locally produced food-based supplement by undernourished pregnant women in Northern Bangladesh. The study contributed towards empowering the community to develop a supplement with community input. The following chapter (6) describes a pilot study, using a cluster randomised controlled trial design, to test the effect of the supplement on birth and infant weight, and mid-upper arm circumference.

Chapter 7. Prenatal food supplementation using locally available and preferred foods and postnatal growth in northern Bangladesh: a preliminary study

7.1 Overview

There is a need for more research exploring the link between maternal balanced protein energy supplementation and infant growth outcomes. In addition, I wanted to identify whether the locally developed balanced protein energy supplement could potentially improve birth weight and infant growth outcomes in supplemented undernourished mothers in rural northern Bangladesh. This was achieved by conducting a pilot cluster randomised controlled trial.

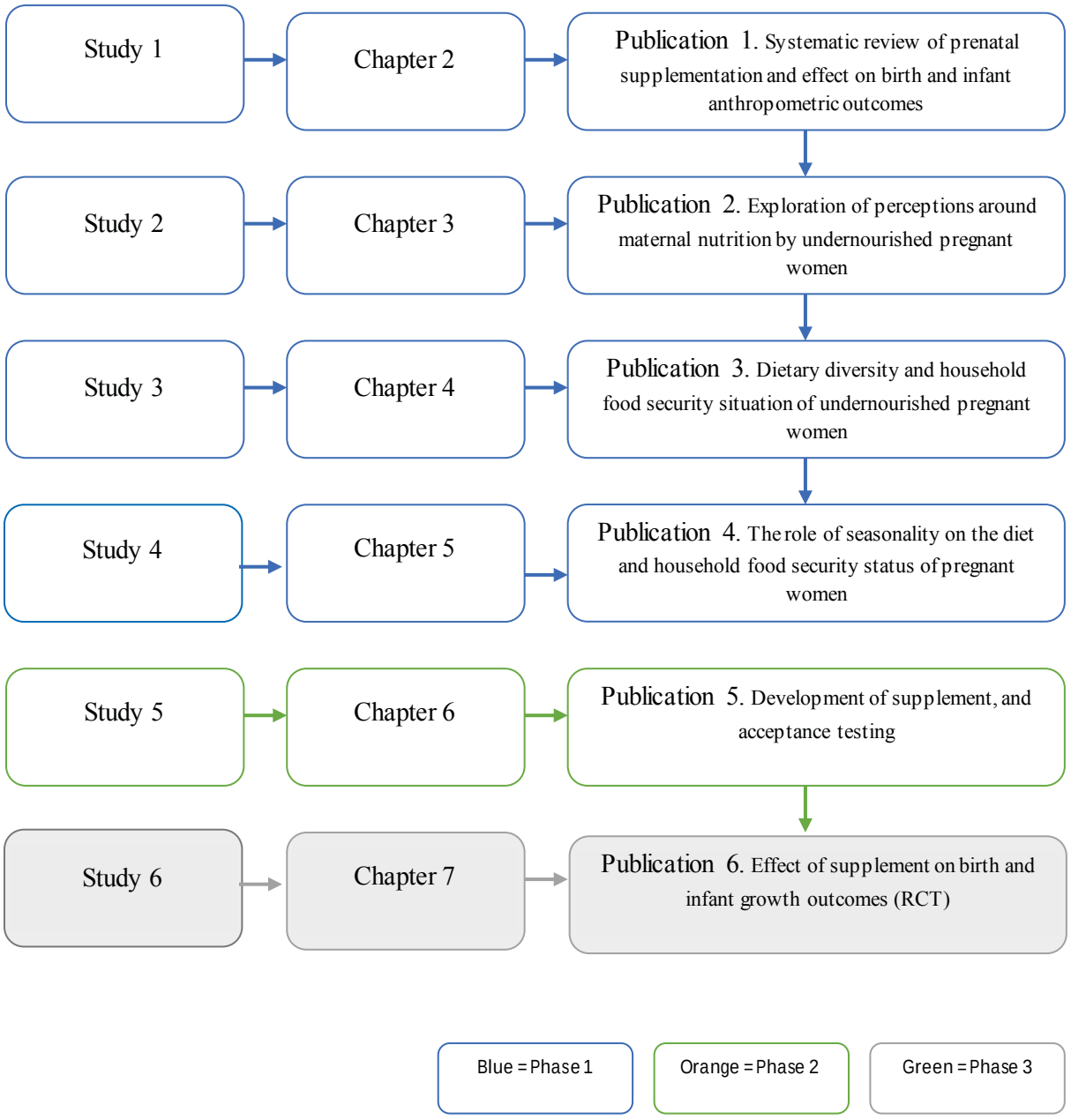

Figure 10 Study 6, Chapter 7 in relation to the thesis structure and multiphase design

This chapter has been submitted for publication in an international, peer-reviewed journal and is currently under review. The manuscript is inserted in the format required by the journal to which it was submitted. The citation will be:

Stevens, B., Watt, K, Brimblecombe, J., Clough, A., Judd, J and Lindsay, D. A village-matched evaluation of providing a prenatal local supplemental food and early infant growth in rural Bangladesh: A preliminary study.

This manuscript presents quantitative information on the effect of the locally produced supplement on birth and infant growth outcomes. Supplementary material supporting this manuscript is presented prior to the chapter summary.

7.2 Manuscript currently under review

A village-matched evaluation of providing a local supplemental food during pregnancy in rural Bangladesh: A preliminary study

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Abstract

Background: Prenatal balanced protein energy supplementation consumed by undernourished women improves mid-upper arm circumference in early infancy. This study aimed to identify whether locally produced maternal food-based supplementation improved anthropometric measures at birth and early infancy.

Setting: 12 villages (intervention: $n = 8$; control: $n = 4$) in Pirganj sub-district, Rangpur District, northern Bangladesh.

Design: A village-matched evaluation, applying principles of a cluster randomised controlled trial, of a locally produced supplemental food to 87 undernourished pregnant women. Daily supplements were provided.

Results: Anthropometric data at birth were available for 77 mother-infant dyads and longer-term infant growth data for 75 infants. Mid-upper arm circumference (MUAC) was significantly larger in infants of mothers in the intervention group compared with the control group at 6 months ($p<0.05$). The mean birth weight in babies of supplemented mothers (mean: 2·91 kg; SD: 0·19) was higher than in babies of mothers in the control group (mean: 2·72 kg; SD: 0·13), and these changes persisted until 6 months. Also, the proportion of low birth weight babies in the intervention group was much lower (event rate=0.04) than in the control group (event rate=0.16). However, none of these differences were statistically significant (p>0·05; most likely due to small sample size). The intervention reduced the risk of wasting at 6 months by 63.38% (RRR=0.6338), and of low birth weight by 88·58% (RRR=0.8858), with NNT of 2.22 and 6.32, respectively. Only three pregnant women require this intervention in order to prevent wasting at 6 months in one child, and seven need the intervention to prevent low birth weight of one child.

Conclusions: Locally produced food-based balanced protein energy supplementation in undernourished pregnant women in northern Bangladesh resulted in larger MUAC in infants at 6 months.

Further research, with larger sample sizes, is required to confirm the role of locally produced supplementation for undernourished pregnant women on weight and linear growth in newborns and infants.

Trial registration: This research was registered with the ISRCTN registry (ISRCTN97447076). This project had human research ethical approval from the James Cook University (Australia) Ethics committee (H4498) and the Bangladesh Medical Research Council (BMRC/NREC/2010-2013/58).

Keywords: Maternal undernutrition; Bangladesh; low-income country; balanced protein energy supplementation, low birth weight.

Background

Size at birth and growth in early infancy are important indicators of early childhood survival and health. Maternal undernutrition, an indicator of poor fetal growth, is associated with lowered birth weight [1]. Low birth weight babies have a substantially increased risk of stunting, infant mortality, and morbidity [2] [3]. Childhood undernutrition leads to increased susceptibility to infections and subsequent undernutrition [4]; shorter adult height [5]; decreased cognitive function [6]; and increased risk of maternal complications and chronic disease in later life [5, 7].

In a recent systematic review and meta-analysis, balanced protein energy supplementation among undernourished pregnant women was found to significantly improve birth weight in low and middle-income countries (d = 0·203, 95% CI, 0·03-0·38, p = 0·021) [8]. The impact on longer-term growth remains inconclusive because few randomised controlled trials (RCTs) have reported on this outcome [8]. An RCT in Indonesia showed a significant increase in height up to 60 months, and weight up to 24 months of age, with a greater effect at 9 and 12 months of age, respectively [9]. Positive findings have been reported in non-RCTs on longer-term growth from supplementation of undernourished pregnant women, especially when the supplement meets an energy gap [8, 10-12].

Although a number of studies have included food-based supplements using locally available and preferred foods [13-16], the evidence on effective approaches for the treatment of acute maternal malnutrition to improve growth outcomes at birth and early infancy is limited, and sustainability is rarely considered. The cost of food-based supplementation, even locally produced, is often beyond the reach of pregnant women in low-income countries, where undernutrition is most prevalent [17].

Bangladesh has among the highest rates of maternal and child undernutrition worldwide [18]. Maternal undernutrition affects one in three women (defined as a body mass index <18·5 kg/m^2) [19] and low birth weight (< 2·5 kg) affects one in five newborns [20]. Among children aged 6 to 59 months, stunting has declined from 51% in 2004 to 36% in 2014, and wasting has declined from 15% to 14% [21]. In rural Bangladesh, extreme poverty[i] is three times higher than in urban areas, women are less likely to access antenatal and postnatal services, and children suffer from higher rates of chronic malnutrition (43% and 36% in rural and urban areas, respectively) [23].

The purpose of this study was to identify whether a locally developed balanced protein energy supplementation for undernourished pregnant women in rural areas of northern Bangladesh, affected anthropometric measures at birth and during early infancy.

Methods

Setting and location

The study was conducted in the Pirganj sub-district of Rangpur District, northern Bangladesh. The Pirganj sub-district covers an area of 411·34 km^2, consists of 332 villages, and has 385,499 inhabitants [24]. As in other areas of Bangladesh, Rangpur has a tropical monsoon climate with high temperatures, high humidity and heavy seasonal rainfall from June to November. The villages are rural with dirt roads and are often inaccessible during the wet season. Rangpur is reported to be more vulnerable to seasonal food insecurity than other areas of Bangladesh [25]. Rangpur's main source of employment is agricultural labour though wages are low compared to neighbouring districts [26]. We previously identified that households were largely food insecure,

that the dietary diversity was poor, and that households relied on homestead food production for both sustenance and income [27, 28].

Study design

The study reported here was the third phase of a multiphase study design. All three phases were committed to local level applied research. The previous two phases were published accordingly [8, 27-30]. In summary, we used a multiphase design. Phase one consisted of formative research exploring maternal dietary preferences, and barriers and enablers to healthy eating in a sub-sample of the study locations. Phase two involved the development of a locally produced prenatal food based supplement. To achieve this, a small business enterprise was established, packaging was designed, and a 30-day acceptability study conducted. As reported here, the third phase consists of a pilot study testing the effectiveness of the locally developed supplement.

A village-matched evaluation, using principles of a cluster randomised controlled trial, was conduct. Recruitment occurred from February 2013 to February 2015. Rangpur district was selected based on its rural location. Pirganj sub-district was purposively selected for this study from eight sub-districts in Rangpur. Two of 15 unions[ii] from Pirganj were selected: one randomly selected as the intervention site using computer-generated random numbers, and the other was matched to the intervention union to act as the control. From the intervention union, eight villages of a possible 24 were randomized to receive the intervention using computer-generated random numbers. From the control union, four villages of a possible 30 were purposively matched to the intervention villages. Criteria for matched controls included similarities between socio-economics, demographics and agricultural produce. The number of villages was determined based on population, estimated

157 incidence of pregnant women across the study period, and the required sample size
158 [19, 23, 24]. The estimated sample size was targeted to detect a reduction of the
159 proportion of babies with LBW by 50% (from 38% to 19%), with 80% power and
160 alpha = 0·05.
161
162 *Participants and recruitment*
163 In the selected villages, the study recruited women who were (1) confirmed to be
164 pregnant (by skilled health professional); (2) undernourished, as defined by a mid-
165 upper-arm circumference (MUAC) ≤22·1cm[iii, iv]; and (3) not in need of a medical
166 referral. Exclusion criteria included (1) the delivery of twins (only singleton deliveries
167 included); and (2) a delivery outside of the study period.
168 Information on the study recruitment and community nutrition volunteers has
169 been published elsewhere [29]. In summary, trained community nutrition volunteers[v]
170 compiled lists of all pregnant women in the twelve villages and invited these women
171 to participate. Eligible women were given a brief overview of the project and written
172 or verbal (with thumbprint) consent to participate was obtained after the participants
173 had heard the project information sheet read aloud in their local language. Verbal
174 consent was also obtained from the leaders of each village to include their village in
175 the study.
176 Eight female community nutrition volunteers and two (one male and one
177 female) supervisors from the selected villages were trained on the basics of nutrition,
178 and the study purpose and design. The community nutrition volunteers had at least a
179 primary school education, spoke the local dialect, and were aged between 21 and 49
180 years.

Women in the intervention group received the intervention by visiting community nutrition volunteers at a designated community site. If the women were unable to visit the community nutrition volunteer, the volunteer would visit the household. All enrolled women in the intervention villages received one serving of the food-based supplement per day, within seven days of enrolment to term. Compliance to the food-based supplement was closely monitored through observation and discussion. Women from the control villages were unable to access the intervention supplement from the intervention villages due to the careful enrolment and follow-up process conducted by the community nutrition volunteers.

Supplement

Details on how the supplement was developed are published elsewhere [30]. In summary, a small business enterprise comprising of local women was established, and a food-based balanced protein energy supplement was developed. The supplement consisted of 27% pigeon pea, 35% banana, 16% sugar, 9% peanuts, 6% whole milk powder, 6% sesame seeds and 1% iodised salt. The supplement was pretested, and the most acceptable version of the supplement was selected for use in this intervention study. The composition and energy content of the supplement was designed to meet the estimated energy gap of undernourished pregnant women, while the protein provided was less than 25% of the total energy content [31]. Using locally procured ingredients, the supplement was prepared at a single centre by village women.

Nutrition screening, nutrition education, and antenatal and postnatal services

Women in intervention and control groups received identical services and support except for provision of the supplement. All pregnant women (regardless of study

206 enrolment) in the intervention and control groups were screened for undernutrition
207 through village-level monthly campaigns conducted by the community nutrition
208 volunteers. Referral pathways with existing government- and NGO-supported ante-
209 natal care (ANC) and post-natal care (PNC) services were established at the onset of
210 the study.
211 Regardless of study group, or nutrition status, all pregnant women living in the
212 villages selected to participate in this trial received iron-folic acid supplementation
213 through access to routine ANC and PNC services. In addition, all women were tested
214 for anaemia at a mobile clinic and were provided treatment if identified as anaemic.
215 The partnership with the mobile clinic was established for the purpose of this study.
216
217 *Data collection*
218 Upon enrolment, community nutrition volunteers collected the following data from
219 participants: 1) background demographics; 2) household food security; 3) dietary
220 diversity and 4) anthropometry. Household food insecurity was identified using the
221 validated Food and Nutrition Technical Assistance (FANTA) Household Food
222 Insecurity Access Scale (HFIAS) questionnaire (Version 3) [32, 33]. Women's
223 dietary diversity scores (WDDS) were determined using the validated Food and
224 Agricultural Organisations (FAO) dietary diversity questionnaire [34, 35].
225 Dichotomous variables were created to indicate the presence (or absence) of each
226 food group, then these were aggregated to compute a WDDS [35]. A higher HFIAS
227 score indicates greater food insecurity, and lower WDDS indicates lower dietary
228 diversity. The questionnaires were contextualised, translated into local terminology,
229 back-translated and field tested prior to use.
230 The community nutrition volunteers measured height, weight and MUAC at

231 participant enrolment and each month of the data collection period, using the
232 standardised procedures recommended by the World Health Organisation [36, 37].
233 Height was measured to the nearest millimetre (mm) with community-made adult
234 height boards, and weight to the nearest 100 grams (g) with digital SECA scales.
235 MUAC was measured to the nearest mm with adult MUAC tapes. Data on the
236 association between supplement and maternal weight and maternal MUAC will be
237 reported elsewhere. At birth, skilled health professionals[vi] recorded newborn length to
238 the nearest mm with a child length board, and weight to the nearest 100 g with a
239 beam-type scale. Where a skilled health worker was not present or able to complete
240 the measurement, community nutrition volunteers did so. Community nutrition
241 volunteers recorded infant weight and MUAC at 1, 3, and 6 months of age, or until
242 the end of the study. Weight at 6 months was measured using a calibrated digital scale
243 (SECA). Birth measurements were taken at the place of birth within 24 hours of
244 delivery. Longer-term measurements were taken at a designated community space, or
245 at the household. To ensure reliability, all anthropometric variables were measured
246 twice by the community nutrition volunteers, and once by the clinic staff, if the birth
247 occurred at a health centre. If the two measurements differed, a third measurement
248 was obtained to verify the correct measure. All weighing scales were calibrated daily.
249 Community nutrition volunteers recorded the occurrence of maternal mortality,
250 miscarriages, stillbirths, and loss to follow-up. The procedure was the same for all
251 participants, whether in the intervention or control group.
252
253 *Outcomes*
254 To identify whether a locally produced food-based supplement improved birth and
255 infant anthropometric measures, the primary outcomes included birth weight and

longer-term infant growth (weight and MUAC) at 1, 3, and 6 months. The secondary outcomes were preterm birth (defined as birth at <37 weeks of gestation), miscarriage (delivery of infant ≤20 weeks), stillbirth (delivery of an infant showing no signs of life ≥20 weeks), perinatal death (stillbirth or death of a live-born infant in the first 7 days after birth), and neonatal death (death within the first 28 days of life). We also measured acute malnutrition (wasting) in infants at 6 months. Wasting in infants was defined by a MUAC <12·5 cm [38].

Compliance was calculated by dividing the total number of days the supplement was taken under direct observation, by the total number of days possible, i.e., the number of days between enrolment and delivery. We defined loss to follow-up as a participant leaving the study area for a period longer than 2 consecutive weeks or delivering their infant in a place outside the study area.

Statistical methods

The Consolidated Standards of Reporting Trials (CONSORT) statement was used to ensure comprehensive reporting of this study. The data quality was ensured by quality checks associated with the data entry process, double entry, and data cleaning. Data management was conducted using Microsoft Excel. Statistical analyses were performed using the statistical software package IBM SPSS software, Version 23© (Armonk, NY, USA).

For categorical variables, between group differences were assessed as suggested by Donner and Klar (1994) [39].Categories were treated as event rates, and these were calculated for each cluster (e.g., proportion of babies with low birth weight in each cluster). Independent samples t-tests were then used to compare intervention and control groups, taking into account the clustering. For numerical variables, means

were calculated for each cluster, then independent samples t-tests were used to compare differences between intervention and control groups, accounting for clusters (as described in Campbell et al 2000) [40]. A p-value of <0·05 was considered statistically significant. To estimate the effect of the intervention, absolute measures of risk were also calculated. Specifically, Relative Risk Reduction (RRR), Absolute Risk Reduction (ARR), and Number Needed to Treat (NNT) were calculated in relation to the proportion of participants categorised as low birth weight (<2·5kg), and the proportion of participants with MUAC<12.5 at 6 months.

Ethics

This research was registered with the ISRCTN registry (ISRCTN97447076). This project had human research ethical approval from the James Cook University (Australia) Ethics committee (H4498) and the Bangladesh Medical Research Council (BMRC/NREC/2010-2013/58).

Results

Participation and recruitment

The participation and recruitment data are presented in Figure 1. From February 2013 to February 2015, 87 mothers were enrolled in the study: 58 in the intervention group and 29 in the control (Figure 1). Birth weight outcome data were available for 77 of 87 (88·5%) pregnant women (intervention: $n = 49$, control: $n = 28$) and infant anthropometric outcome data were available for 75 children (intervention: $n = 48$, control: $n = 27$). All births were singleton. No caesarean sections were recorded for the mothers in either group. The main reason for missing infant anthropometric outcome data was that the duration of the data collection phase did not adequately

allow for 6 months of follow up data to be collected from infants enrolled later in the study. Other reasons for missing longer-term growth data included mothers being unavailable to bring their child to the assessments due to household work or caring for their other children. The number of women lost to follow-up differed between groups (intervention: $n = 2$; control: $n = 0$). The reason that one woman was lost to follow-up was that she returned to her father's village to give birth; the other was unknown. Due to low numbers of preterm birth, miscarriage, stillbirth, perinatal death, and neonatal death, analyses on secondary outcomes were not conducted. Instead, these data were excluded from analyses (intervention: $n = 7$; control: $n = 1$). Two cases were excluded from longer-term analyses; one due to death (intervention), and one missing for unknown reasons (control). All infants identified with moderate or severe acute malnutrition were immediately treated.

Baseline characteristics and compliance

The background characteristics of the 87 enrolled women are presented in Table 1. There were no differences on demographic or anthropometric characteristics, dietary or food security, between the intervention and control groups at baseline ($p > 0{\cdot}05$), except that women in the intervention group were more religiously diverse (Muslim, Hindu, and Christian compared with 100% Muslim in the controls; $p < 0{\cdot}01$). The mean age of the women was 22·6 years (SD: 5·3). Most women attended school, with the majority reaching either a primary or lower secondary education level (37·6% and 47·1%, respectively). The mean height of the women was 148·5 cm (SD: 5·5), with more than half below 148 cm (52·6%), indicating chronic malnutrition. Most pregnancies were identified in the first or early second trimester (29·9% and 41·4%, respectively).

Compliance was high among the intervention group; almost all women consumed the full supplement on a daily basis (n = 57). One woman did not consume the supplement for a one-month duration during the third trimester, as she was not reachable and therefore did not receive the supplement. No women refused the supplement.

Main Results

Birth weight. The primary outcome data are presented in Table 2. Birth weight was higher in the intervention group (mean: 2·91; SD: 0·19) compared to the control group (mean: 2·72; SD: 0·13) but this was not significant (p >0·05). We grouped birth weight into two categories: healthy birth weight (≥2·50kg) and low birth weight (<2·50kg). Low birth weight occurred much less frequently in the intervention group (event rate = 0.04; ±0.10) compared to the control group (event rate=0.16 ±0.18), but this was not significant (p >0·05).

Infant weight. Although mean weight in the intervention group was higher than the control group at 1, 3, and 6 months, these differences were not statistically significant (p >0·05).

MUAC. The mean MUAC was significantly larger in the intervention group compared to the control group at 6 months (intervention mean: 12·83, SD: 0·62; control mean: 12·01, SD: 0·21 at 6 months; p <0·05).

We conducted analyses to explore the event rate of wasting at 6 months in the intervention and control groups. The event rate was significantly lower in the intervention group compared to the control group (intervention mean: 0·26, SD: 0·22; control mean 0·71, SD 0·21; p<0·05).

Absolute measures of risk were calculated to further describe the effect of the intervention, based on the proportion of participants categorized as low birth weight, and the proportion with MUAC<12.5 at 6 months. The intervention reduced the risk of low birth weight by 88·58% (RRR = 0·8858), and MUAC <12.5 at 6 months by 63.38% (RRR=0.6338). The absolute risk reduction was 15·82% for LBW, and 45% for MUAC<12.5-The Number Needed to Treat (NNT) was 6·32 (low birthweight) and 2.22 (MUAC<12.5). That is, 7 pregnant women need to experience this intervention in order to prevent low birth weight in one child, and 3 pregnant women need to experience the intervention in order to prevent wasting at 6 months in one child.

Discussion

In northern Bangladesh, we found that daily supplementation with a locally produced food-based balanced protein energy supplement during pregnancy among undernourished women resulted in infants with significantly larger MUAC measurements at 6 months and subsequently a lower event rate of wasting. Although a clear trend was observed of heavier babies at birth to 6 months in the intervention group compared to the control group, the difference was not significant (p >0·05).

MUAC reflects protein reserves and thus lean mass [42]. MUAC is an internationally recognised independent diagnostic criteria for acute malnutrition and is commonly used in the identification of children with a high risk of death who are in need of treatment [43]. Among pregnant women, MUAC cut-offs of <21 and <23 cm indicate risk of low birth weight [36]. Our data demonstrated that locally produced food-based balanced protein energy supplementation during pregnancy may contribute to preventing acute malnutrition in infants at 6 months of age as MUAC

measurements were larger in the intervention group compared to the control group. This finding is supported by several other studies showing an association between birth weight and later lean mass in children [44, 45]. However, we were unable to identify any studies that explored maternal supplementation and MUAC in infancy. A subsequent novel finding of our research was the noticeable difference in the event rate of wasting in the intervention group compared to the control group. These findings align with those reported by Mora and colleagues, who identified a lower proportion of children with severe acute malnutrition in the intervention group compared to their control group [46, 47]. Our data suggest that the fetal growth period is an important determinant of infant body composition. Importantly, only 3 pregnant women need to experience the intervention in order to prevent wasting at 6 months in one child.

Our study found that locally produced balanced protein energy supplementation reduced the proportion of low birth weight babies among undernourished pregnant women, albeit not significantly. The most likely reason for not seeing a significant difference between the two groups is due to the small sample size. These data show that the intervention reduced the risk of low birth weight by 88·58% (RRR = 0·8858), and that only seven pregnant women require this intervention in order to prevent low birth weight of one child. This finding is supported by a recent systematic literature review on balanced protein supplementation among undernourished pregnant women in low- and middle- income countries [8]. A recent study in Burkina Faso reported no effects on birth weight and suggested that this may have been due to the provision of multiple micronutrient supplementation to the intervention and control groups (which is also known to increase birth weight), the targeting of all pregnant women (nourished and

406 undernourished), or due to the energy content of the supplement [12]. Our study
407 provided iron-folic acid, nutrition education and enabled access to ANC and PNC
408 services to both groups. In our study, we enrolled undernourished women only and
409 provided a high-energy supplement. It has recently been suggested that multiple
410 micronutrient supplements have more of an effect on birth weight than iron-folic
411 alone [48]. We did not identify an association between maternal supplementation and
412 longer-term infant linear growth however, there was a trend for heavier infants in the
413 intervention group until 6 months. This may have been due to our small sample size
414 and study design, which resulted in our sample size decreasing with time.
415 Our study had a number of limitations. First, we calculated our sample size
416 based on the prevalence and estimated incidence using the most recent Demographic
417 Health Survey data [19]. Our calculation overestimated the number of women who
418 would be enrolled in this study. In addition, the study design included the enrolment
419 of pregnant women with subsequent follow-up over a 24-month period only. Funding
420 availability largely influenced this. These factors resulted in a gradual decrease in the
421 sample size, as we were unable to follow every infant born to an enrolled woman until
422 6 months of age. Further, the number of participants in each cluster, and in the overall
423 study, was relatively low. This low sample size is a likely explanation for the lack of
424 observed statistical significance in some of the results (e.g., birthweight), due to type
425 2 error. Second, it was initially planned that infant linear growth would be recorded.
426 However, due to delays in the procurement of infant height/length boards, we were
427 unable to include these data in the study. Third, due to the sensitivity around death,
428 the volunteers did not record anthropometric data for perinatal deaths. Fourth, the
429 monthly nutrition screening included a question on whether the mother experienced
430 an illness over the last 14 days, which may have resulted in recall bias. An illness has

the potential to affect anthropometric measurements, and may require referral to certain health services. Mothers may have forgotten an illness or when it occurred. Fifth, self-report may have been an issue for some of the measures, such as questions on household food security and dietary diversity. The monthly screening questions on whether the mother had received any other form of assistance from an NGO or other organisation, etc. In population groups where food assistance or developmental aid assistance are frequent, participants may over-report food insecurity and under-report dietary diversity with the expectation of receiving assistance. Conversely, participants may modify their responses based on social desirability. An additional limitation that potentially impacts on the interpretation of the study findings is the nature of the intervention. Unavoidably, women in the intervention group interacted at a higher frequency with community nutrition volunteers than women in the control group (as the supplement was accessed via community nutrition volunteers). We did attempt to control for this by providing nutrition education to both the intervention and control groups. However, it is possible that some of the observed effect of the intervention may be attributable to increased interaction with these volunteers. Lastly, despite the active home visits by the community nutrition volunteers, the proportion of women included early in pregnancy was lower than desired, a limitation that has been experienced by others [12].

Conclusion

In Rangpur district in northern Bangladesh, locally produced balanced protein energy supplementation, using a community-based small business enterprise, reduced wasting in children at 6 months when targeted to undernourished pregnant women. Further, this research illustrates how communities can be empowered to identify and

address maternal undernutrition. The intervention reduced the risk of wasting at 6 months by 63.38%, and of low birth weight by 88·58%. Only three pregnant women require this intervention in order to prevent wasting at 6 months in one child, and seven need the intervention to prevent low birth weight of one child. This supplementation thus contributed to better development outcomes for the mother and child. Our study findings highlight that programme decision-makers have alternatives to the commonly used Ready to Use Foods (RUFs) to treat acute maternal malnutrition, which may not be sustainable, cost effective or acceptable to some populations. While our study identified that the supplementation improved infant lean mass, we recommend that studies with larger sample sizes further explore this association. This study can inform future studies, with larger sample sizes, that aim to investigate the effect of maternal supplementation on longer-term infant growth (weight, length and MUAC).

Key messages

- Effective balanced protein energy supplementation for undernourished pregnant women can be locally produced.
- Communities can be empowered to develop effective balanced protein energy supplementation, identify maternal acute malnutrition, and provide treatment.
- Daily supplementation with a locally produced food-based balanced protein energy supplementation during pregnancy may contribute to reducing acute malnutrition in infants at 6 months of age. Further studies with larger sample sizes are required to explore this association.
- Further research using larger sample sizes is required to explore the effect of daily supplementation using locally produced food-based balanced protein

480 energy supplementation during pregnancy among undernourished women on a
481 baby's weight at birth ad early infancy.
482 • Findings from this study can inform, guide and motivate policies by providing
483 evidence on a sustainable nutrition intervention that improves birth weight.
484

Declarations

List of abbreviations

ARR: Absolute risk reduction

BMRC: Bangladesh medical research council

CI: Confidence interval

CONSORT: Consolidated standard reporting of trials

FANTA: Food and nutrition technical assistance

FAO: Food and agricultural organisation

G: Grams

HFIAS: Household food insecurity access scale

ISRCTN: International standard registered clinical social study number

IQR: Interquartile range

MUAC: Mid-upper arm circumference

MM: millimetres

NNT: Number needed to treat

P-value: Probability

RCT: Randomised controlled trial

SD: Standard deviation

RRR: Relative risk reduction

WDDS: Womens dietary diversity scores

Ethics approval and consent to participate

This research was registered with the ISRCTN registry (ISRCTN97447076). This project had human research ethical approval from the James Cook University (Australia) Ethics committee (H4498) and the Bangladesh Medical Research Council

(BMRC/NREC/2010-2013/58). Informed consent was obtained from all participants included in this study.

Consent for publication

Not applicable

Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests

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Authors contributions

Stevens oversaw the conception and design, with contributions from Brimblecombe, Clough and Judd. Stevens coordinated the collection of data. Stevens, Watt and Lindsay performed the data analyses. Stevens wrote the first draft of the paper, which was revised with editorial input from Judd, Brimblecombe, Watt, Lindsay and Clough for important intellectual content.

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750 **Table 1** Background characteristics of participants according to study group (N = 87)

	Intervention group (*n* = 58)				Control group (*n* = 29)			
Background characteristics	n	%	Median	IQR	n	%	Median	IQR
Maternal age (years)	31		21	10	18		22·5	7
Trimester								
First	23	41·1			10	38·5		
Second	26	46·4			13	50·0		
Third	7	12·5			3	11·5		
Average household (HH) size	58		3	2	29		3	2
Food purchase decision-maker								
Self	17	29·3			9	31·0		
Husband	33	56·9			17	58·6		
In-laws	8	13·8			3	10·3		
Own land for cultivation	30	51·7			19	67·9		
School attendance								
Never attended	3	5·3			2	7·1		
Primary	20	35·1			12	42·9		
Secondary	34	59·6			14	50·0		
Religion[1]								
Islam	39	67·2			29	100		
Hindu	13	22·4						
Christianity	6	10·3						
Parity								

Table continues over page
[1] ** = p <0.05

0	25	43·1			16	55·2		
1	26	44·8			12	41·4		
2	5	8·6			0	0		
≥3	2	3·4			1	3·4		
Stillbirth	0	0			1	3·4		
Miscarriage	5	8·6			1	3·4		
Anthropometrics								
Maternal height (cm)	58		148	7.5	28		147	10·5
Maternal height <148 cm	31	53·4			16	55·2		
Dietary diversity score	58		5	1	29		5	1·5
Food security status								
Food secure	1	2·1			3	10·7		
Food insecure	46	97·9			25	89·3		

Table continued from previous page.

Table 2 Weight (birth, 1, 3, and 6 months) and MUAC (6 months) of Intervention and Control Villages

	Intervention group (*n* = 8)		Control group (*n* = 4)		
Outcome	Mean	SD	Mean	SD	P
Weight (kg)					
Birth weight	2·91	0·19	2·72	0·13	0·13
1 month	3·88	0·35	3·44	0·33	0·06
3 month	5·64	0·74	4·87	0·49	0·09
6 month	7·01	0·89	6·53	0·67	0·37
MUAC (cm)					
6 month	12·83	0·62	12·01	0·21	0·03
Outcome[a]					P
Low birth weight	0·04	0.10	0·16	0.18	0·28
MUAC<12.5	0.26	0.22	0.71	0.22	0.01

[a]Event rate

[i] Defined as earning less than $1.25 per day by the World Bank. See Ravallion, Chen, and Sangraula (2009) for further information on how the $1.25-a-day international poverty line was derived. 22. Ravallion M, Chen S, Sangraula P: **Dollar a day revisited**. *The World Bank Economic Review* 2009.

[ii] Union is defined as the smallest rural administrative and local government unit in Bangladesh.

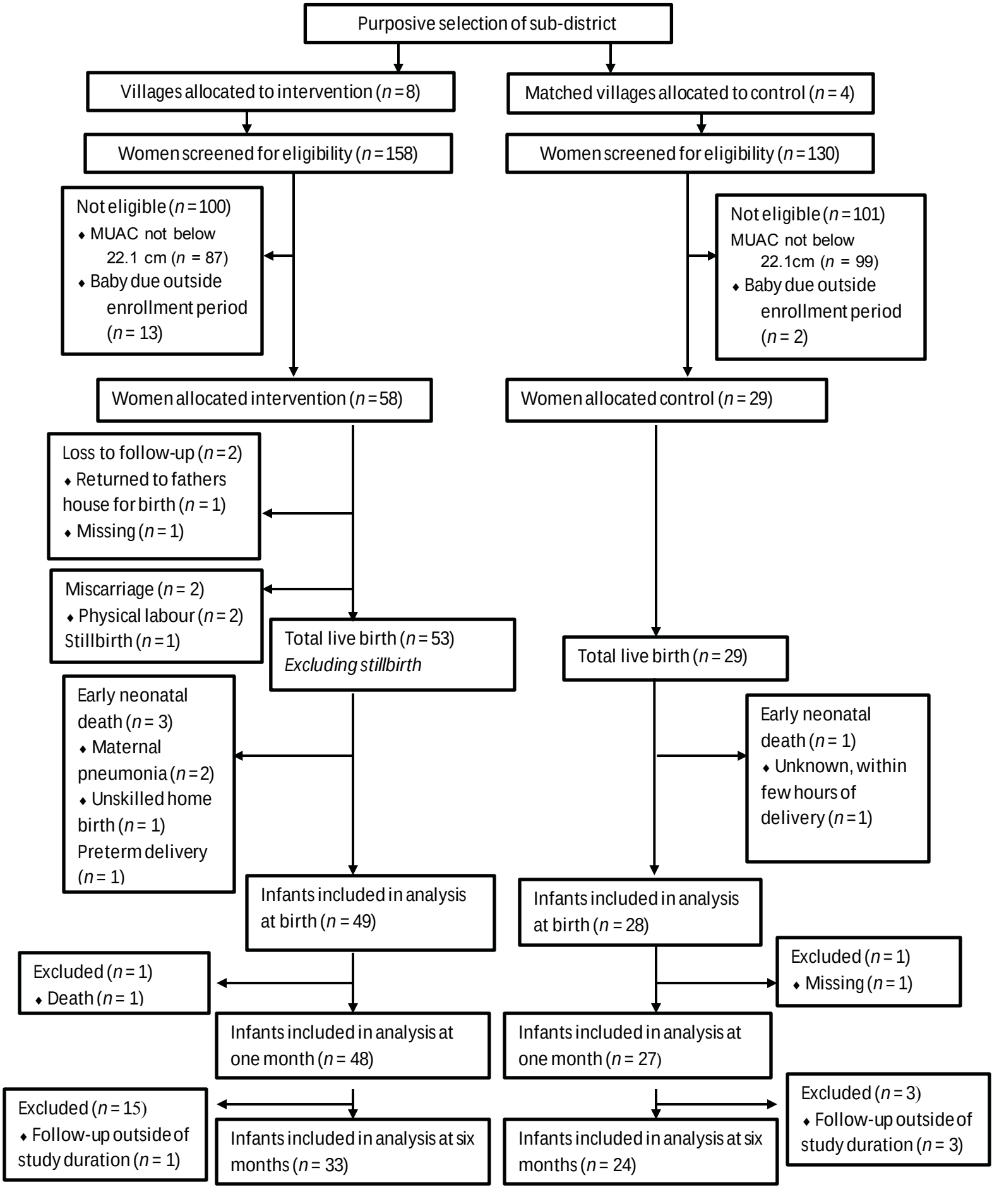
[iii] MUAC was the preferred indicator to identify maternal undernutrition based on its association with low birth weight. Ververs MT, Antierens A, Sackl A, Staderini N, Captier V. Which anthropometric indicators identify a pregnant woman as acutely malnourished and predict adverse birth outcomes in the humanitarian context? PLoS currents. 2013;5; WHO. Maternal anthropometry and pregnancy outcomes. A WHO Collaborative Study. Bulletin of the World Health Organization. 1995

[iv] Maternal undernutrition was defined by a MUAC ≤22·1 cm. The cut-off was determined after a review of the evidence and nutrition programmes and research in Bangladesh. The MUAC cut-off selected aligns with that commonly used by NGOs in Bangladesh at the time.

[v] Volunteers received a monthly stipend to compensate for time spent on this project and attended multiple trainings associated with this study.

s[vi] Defined as those that have received formal training

Figure 1: Trial profile of the study (Modified from CONSORT diagram)



7.3 Supplementary material.

Composition of the food-based balanced protein energy supplement per serving

Serving size 173 g Servings per packet 1		
Ingredients: Pigeon pea (48 g), banana (60 g), white sugar (28 g), peanuts (15 g), whole milk powder (10 g), sesame seeds (10 g), iodised salt (2 g)		
Nutrient	Amount per serving	Percentage of daily value (%)[1]
Calories (Kcal)	522	22
Protein (g)	19.5	31
Fat (g)	15.8	30
Calcium (mg)	270	45
Iron (mg)	5.5	6
Iodine (µg)	128	64
Vitamin A (µg RE)	105	18
Thiamine (mg)	0.53	53
Riboflavin (mg)	0.27	18
Niacin (mg)	6.1	38
Vitamin C (mg)	5	11

[1] Percentage daily value is based on a 2,405 Kcal/day diet

Village means for birth weight, weight at 1, 3, and 6 months, and MUAC at 6 months

	Intervention (village)								Control (village)			
Outcome	1	2	3	4	5	6	7	8	1	2	3	4
Weight (kg)												
Birth weight	3.20	2.78	2.93	2.61	3.00	3.10	2.70	2.94	2.75	2.80	2.54	2.84
1 month	4.44	3.50	3.88	3.59	4.13	4.13	3.47	3.96	3.47	3.000	3.52	3.79
3 month	6.05	4.81	5.15	5.43	6.55	6.80	4.94	5.38	4.38	4.60	5.01	5.50
6 month	7.63	6.29	5.90	6.55	7.85	-	6.63	8.25	6.92	5.60	6.50	7.09
MUAC (cm)												
6 months	12.44	13.79	12.50	12.77	12.10	-	13.57	12.65	11.80	12.00	11.94	12.30

7.4 Summary

- Aim: to identify whether a locally produced prenatal food-based supplement improved anthropometric measures at birth and infancy.
- Non-blinded, cluster randomised controlled trial with 87 undernourished pregnant women in 12 villages (intervention: *n* = 8; control: *n* = 4) in rural Bangladesh. Daily supplements were provided and community nutrition volunteers at each village verified compliance.
- Anthropometric data were available for the mother-infant dyad at birth (*n* = 77), and for infant growth (*n* = 75). The mean birth weight in babies of supplemented mothers (mean: 2·91 kg; SD: 0·19) was higher than in babies of mothers in the control group (mean: 2·72 kg; SD: 0·13) (*p* <0·05), and these changes persisted until 6 months, however were not significant (*p* >0.05). Mid-upper arm circumference (MUAC) was significantly larger in infants of mothers in the intervention group compared with the control group at 6 months (intervention mean: 12·83 cm, SD: 0·62; control mean: 12·01 cm, SD: 0·21; *p* <0·05).
- Locally produced food-based balanced protein energy supplementation in undernourished pregnant women in northern Bangladesh resulted in higher birth weight babies, though this was not significant. The proportion of LBW babies in the intervention group (event rate = 0.04) than in the control (event rate = 0.16), but this was not significant. The event rate of wasting in infants at 6 months (MUAC<12.5) was significantly lower in the intervention group (0.26) than the control group (0.71) (p<.01).
- Small sample size is a likely explanation for the lack of statistical significance in data on birthweight
- The intervention reduced the risk of wasting at 6 months by 63.38%, and of LBW by 88·58%, with NNT of 2.22 and 6.32, respectively. Only three pregnant women require this intervention in order to prevent wasting at 6 months in one child, and seven need this intervention to prevent LBW in one child
- Further studies with larger sample sizes are required to confirm the role of locally produced supplementation for undernourished pregnant women on longer-term physical growth and acute malnutrition in infants, and to explore generalisability

7.5 Final note

Locally produced balanced protein energy supplementation had positive effects on birth weight, and infant MUAC. This study was the last in a series of studies to develop an effective locally produced balanced protein energy supplement for undernourished pregnant women living in northern Bangladesh. The findings from all studies presented (Chapters 2-7) are presented in the following Discussion section (Chapter 8).

Chapter 8. Discussion

This thesis summarises the evidence from several studies that were conducted to develop a locally produced balanced protein energy supplement that effectively improves birth and infant growth outcomes. I used multiple methods, including a systematic review of the literature (Study 1), qualitative (Studies 2 and 5), and quantitative methods (Studies 3, 4, 5 and 6). Furthermore, at each phase of the study a commitment was made to apply local-level research to ensure community ownership of the research. This research addresses maternal and child nutrition through the development of a supplement, and also by better understanding the root causes of maternal undernutrition in northern Bangladeshi women. This thesis comprised three phases, each of which consisted of one or more sub-studies. The programme of research was designed to address five research questions. The findings of this programme of research are summarised in this discussion in the context of these five research questions, and in relation to previous research. I have integrated the findings from each of the studies. The implications of each separate study are discussed, as well as the overall programme of research. Recommendations for policy and practice, and implications for further research are described in the Conclusion (Chapter 9).

The five research questions are:

1. In low- and middle-income countries, does balanced protein energy supplementation improve birth and infant growth outcomes, and what is the evidence for this?
2. What are the perspectives of pregnant women on maternal nutrition?
3. What is the nutritional situation in terms of dietary diversity and food security for pregnant women living in the targeted villages?
4. What form (composition and type) of locally produced supplement does the targeted population group accept?
5. Does the preferred supplement improve newborn/infant child growth outcomes?

8.1 In low- and middle- income countries, does balanced protein energy supplementation improve newborn and infant growth outcomes, and what is the evidence for this?

A systematic literature review of seven studies from low- and middle-income countries was conducted to answer research question 1 (Study 1; Chapter 2). This systematic review identified that balanced protein energy supplementation had a statistically significant positive effect on birth weight, but no significant benefit was observed on birth length or birth head circumference. The effect of supplementation on infant growth was inconclusive due to a lack of published literature on this topic. At the time of this review there was no published synthesis of the effect of balanced protein energy supplementation consumed by undernourished pregnant women on birth and child anthropometric outcomes, specifically in low- and middle-income countries.

As the control supplements in each selected study varied, some difficulties were experienced when pooling data and generalising the results across studies. To address this difficulty, I conducted subgroup analyses to identify the effect when a control supplement was used and when no control supplement was used. When no control supplement was used, the effect between the intervention and control group increased, indicating that supplementation has a greater impact when there is a larger energy gap to meet. This finding was supported by other studies (29, 30, 64).

In addition, discrepancies were identified in one study (65) between the manual calculations performed and published data (5, 20) for the percentage of energy from protein for the intervention supplement. When this study by Giriga and colleagues was excluded from the pooled analyses, the pooled effect sizes of the intervention were reduced for birth weight and birth length, but remained the same for birth head circumference. The changes to effect size were small, probably because there were only 20 participants in the excluded study (65). This suggests that when compared to balanced protein energy supplements, a protein energy supplement with a higher percentage of energy from protein may have a positive effect on birth weight. Recent evidence from a Cochrane review contradicts this (5). In their review, Ota and colleagues identified that high-protein supplementation was associated with a significantly increased risk of small-for-gestational age babies. The energy from protein in the Girija study was 28.8%, and the energy from protein in the review by Ota and colleagues was 34.0% (66). Hence, the conflicting findings may suggest that protein energy supplementation is most effective when the percentage of energy from protein meets a certain threshold.

The impact of balanced protein energy supplementation for undernourished pregnant women on subsequent child growth in low- and middle-income countries remains inconclusive, as only one study was identified (67) that fulfilled the eligibility criteria in the systematic review. This study identified a significant increase in height and weight of the child until 60 and 24 months, respectively. However, this study excluded poor compliers, thus definitive conclusions cannot be made. One of the main conclusions of this systematic review is that additional research is required in low- and middle-income countries to identify impacts of balanced protein energy supplementation during pregnancy on longer-term infant growth. This was the main purpose of this programme of research.

8.2 What are the perspectives of pregnant women on maternal nutrition?

The second research question was addressed by study 2 (Chapter 3), which utilised Photovoice methodology to explore the perspectives of pregnant women on maternal nutrition.

Through the use of Photovoice, I identified that pregnant women in rural northern Bangladesh faced issues with availability in terms of household food production, and also with affordability of essential foods at the market place. Participants raised important concerns illustrating social determinants and socio-economic status that limited access to nutritious foods. Difficulties ranged from farming on rented land, reliance on businesses that yielded a modest income sufficient only for salt, oil and other food staples, or the sale of household produce to subsidise necessary expenditures such as school fees and clothing. Food insecurity limited household protein and fat consumption. However, milk consumption during pregnancy was common.

This study was novel, as it was the first published use of Photovoice for any topic in these study communities, and to my knowledge is the first time Photovoice has been used for nutrition research in Bangladesh. I found that the Photovoice method empowered participants to share their perspectives and understanding of nutrition and the barriers and enablers to healthy food choices. I used in-depth interviews as an alternative to focus group discussions, to ensure each participant was able to freely discuss their lived experiences, resulting in rich interview data. The participants reported that they believed they were contributing toward the research in a tangible way. At the same time, participants expressed that they did not view Photovoice as “research” and that the method was new and previously unknown to the community.

Together with Studies 3 (Chapter 4), 4 (Chapter 5) and 5 (Chapter 6), this research supported phase 2 and phase 3 of the programme of research conducted for the thesis. In particular, this study provided information on maternal dietary habits and preferences, and village specific information on food availability and affordability, as well as information on the role of social determinants and their

influence on dietary consumption, and on the role of the husband and in-laws on dietary consumption. This information was used to inform phase 2, and subsequently phase 3.

8.3 What is the nutritional situation in terms of dietary diversity and food security for pregnant women living in the targeted villages?

Studies 3 (Chapter 4) and 4 (Chapter 5) were conducted to answer this research question. An exploratory study of 10 women (Study 3, Chapter 4) from one of the 12 villages targeted for the intervention study (Study 6, Chapter 7) identified that the majority of undernourished pregnant women had an inadequate dietary intake and were from households identified as food insecure. While most women consumed animal or plant-based vitamin A food groups, only half consumed haem-iron rich foods. Current research indicated that women with lower dietary diversity scores are more likely to belong to the lowest quintiles of poverty indices (68). Due to the small sample size, no investigation was conducted to explore the association between dietary diversity and household food security status.

Household food security consists of three pillars: access, availability, and utilisation of food (69). I explored household food security in terms of access (financial). From the survey conducted (Study 3, Chapter 4) I identified that of the ten women enrolled, more than half of the women interviewed were from food insecure households, with a third who were severely food insecure and reportedly reduced the frequency or quantity of meals. A third of the women were from households that reportedly ran out of food stocks annually. These findings align with findings reported by the 2012 Bangladesh Demographic Health Survey (70). While nutrition education is of utmost importance to ensure that women know which foods to eat during pregnancy, consideration must be given to accessibility to these food items. Programs need to incorporate nutrition sensitive approaches that address the root causes of undernutrition, household income and homestead food production (3).

Dietary diversity questionnaires and scores assisted with identifying which nutrient-rich food groups were being consumed by enrolled women. Women who consumed an average of four food groups of a possible nine per day indicated a low probability of adequate dietary intake, which may have contributed to the burden of undernutrition and micronutrient deficiencies (71, 72). Almost all women consumed either a plant or animal-source vitamin A rich food; however only half of the women consumed haem-iron rich foods. Findings on low dietary diversity align to those reported in a similar study conducted in Bangladesh (73).

The demographic data from the survey suggested a strict patriarchal society. Pregnant women had a low level of education, were born and raised in the village that they currently resided in, and typically cared for the household. The men (husband or father in-law) were typically the household head, the main household income earners, and the financial decision-makers for household members, including decisions on health care and the purchase of food from the marketplace.

Study 4 (Chapter 5) investigated the association between seasonality and dietary diversity, household food security, and the nutrition status of pregnant women in a rural district of northern Bangladesh. This cross-sectional study was conducted in twelve villages of Pirganj sub-district, Rangpur District, northern Bangladesh, with 288 pregnant women, over a 2 year period. Data were collected on demographics, household food security (using the HFIAS), dietary diversity (using the women's dietary diversity questionnaire), and mid-upper arm circumference (MUAC). In this study, seasonality was found to be associated with dietary diversity and household food security. These data confirm that seasons play a role on women's household food security status and dietary diversity, with food insecurity deteriorating during the lean seasons and dietary diversity deteriorating during the second 'lesser' lean season and the season immediately after. Interventions that aim to improve the diet of pregnant women from low income, subsistence farming communities need to recognise the role of seasonality in diet, and food security and incorporate initiatives to prevent seasonal declines.

The information obtained from study 4 (Chapter 3) and Chapter 4 (Study 5) helped to inform the development of the supplement. The information contributed towards ensuring dietary diversification to help adequate dietary intake, and improving dietary quality in general (74).

8.4 What form (composition and type) of locally produced supplement does the targeted population group accept?

Based on the findings from phase 1 (Studies 1, 2, 3 and 4; Chapters 2-5) of this research, a supplement was developed. The acceptability of this supplement was tested with undernourished pregnant women in phase 2 of this research (Study 5, Chapter 6).

In the acceptability study, a supplement was developed and tested over a 30 day period. The Acceptability study included assessment of what pregnant women would be prepared to "spend" on the supplement. A survey was conducted midway, and subsequently, the supplement was redeveloped to meet the feedback received. By day 30, all women accepted the supplement. The

first version of the supplement, version 1.0, had a number of characteristics that contributed to reduced acceptance by the women. Overall, the reduced acceptance reflected the organoleptic properties of the supplement and individual preferences. I identified that while the target population commonly consumed lentils as part of their daily diet, the participants did not accept lentils as a dietary supplement. In contrast, Ahmed and colleagues identified that a lentil-based ready-to-use supplementary food (RUSF) was preferred by children 6-18 months of age (75). However, I identified that participants strongly disliked the smell of the lentils, which ultimately resulted in poor compliance and therefore, the supplement was modified at day 16 by replacing the lentils with pigeon pea.

The acceptability study findings identified high compliance with consumption among enrolled women. This high compliance was not expected due to family-sharing practices reported elsewhere (30). The reasons for achieving such high acceptability are likely to be due to the design of the acceptability study, as community nutrition volunteers observed the daily consumption of the supplement. In addition, community nutrition volunteers shared nutrition education messages, and all women in this particular cohort did not work outside of their household.

8.5 Does the preferred supplement improve newborn and infant growth outcomes?

This research question was addressed in phase 3 of the programme of research (Study 6, Chapter 7). I tested the efficacy of the supplement that was developed in phase 2 (Chapter 6) on improving infant growth outcomes through a (pilot) cluster randomised controlled trial. Eighty-seven women (intervention: n = 58; control: n = 29) from 12 villages (intervention: n = 8, average cluster size: n = 7; control: n = 4; average cluster size: n = 9) participated in the study. The primary outcomes included birth weight, infant weight and MUAC. Daily supplementation with a locally produced food-based balanced protein energy supplement during pregnancy resulted in heavier babies at birth Although a clear trend of heavier infants from birth to 6 months was observed in the intervention group compared to the control group, the difference was not statistically significant (most likely due to the small sample size). These findings align with other studies reporting that balanced protein energy supplementation significantly increases birth weight (76). Surprisingly, our study identified that the intervention group had significantly greater MUAC measurements at 6 months.

MUAC reflects protein reserves and thus lean mass (77). MUAC is an internationally recognised independent diagnostic criteria for acute malnutrition and is commonly used in the identification of children with a high risk of death who are in need of treatment (78). Among pregnant women, MUAC cut-offs of <21 and <23 cm indicate risk of LBW (79). The data from Phase 3 of this research (Study 6) demonstrated that locally produced food-based balanced protein energy

supplementation during pregnancy may contribute to preventing acute malnutrition in infants at 6 months of age, as MUAC measurements were consistently larger in the intervention group compared to the control group. While I was surprised to find a difference in MUAC measurements between the intervention and control groups, this finding is supported by a number of previous studies showing an association between birth weight and later lean mass in children (80, 81). However, I was unable to identify any studies that explored maternal supplementation and MUAC in infancy. Subsequently, another unexpected finding was the striking difference in the proportion of acute malnutrition in the intervention group compared to the control group. These findings align with those reported by Mora and colleagues, who identified a lower proportion of children with severe acute malnutrition in the intervention group compared to their control group (82, 83). My data suggest that the foetal growth period is an important determinant of infant body composition.

As well as increasing birthweight, this study also found that locally produced balanced protein energy supplementation reduced the proportion of LBW babies among undernourished pregnant women. A recent study in Burkina Faso reported no effects on birth weight (84). The authors suggested that this may have been due to the provision of multiple micronutrient supplementation to the intervention and control groups (which is also known to increase birth weight), the targeting of all pregnant women (nourished and undernourished), or to the energy content of the supplement (84). My study provided iron-folic acid to both groups and still detected a difference between them. In this study, the difference between groups was most likely due to multiple factors, including: enrolling undernourished women only, provision of a high-energy supplement; and provision of iron-folic acid as opposed to a multiple micronutrient supplement. Recent literature has shown that multiple micronutrient supplements have more of an effect on birth weight than iron-folic alone (85). In my study, no association with longer-term infant growth was identified. This is most likely due to the small sample size and recruitment method, which resulted in the sample size decreasing with time.

The intervention reduced the risk (RRR) of wasting at 6 months by 63.37%, and of LBW by 88·58% (ARR 15·82% for LBW, and 45% for MUAC<12.5).-Only three pregnant women require this intervention in order to prevent wasting at 6 months in one child, and seven need the intervention to prevent LBW in one child. This was the first known study to investigate the effect of a locally produced food-based balanced protein energy daily supplement on undernourished pregnant women in Northern Bangladesh on birth and infant outcomes. These findings need to be interpreted in the context of several limitations. Most notably, the sample size was small. The number of participants in each cluster, and in the overall study, was relatively low. This low sample size is a likely explanation for the lack of observed statistical significance in some of the results (e.g.,

birthweight), due to type 2 error.

8.6 Summary

In summary, the systematic review identified very few studies (n=7) that have been conducted in low and middle income countries to determine the effect of a balanced protein energy supplementation during pregnancy. At the time of this review there was no published synthesis of the effect of balanced protein energy supplementation consumed by undernourished pregnant women on birth and child anthropometric outcomes, specifically in low- and middle-income countries. This thesis set out to provide further evidence in this important area. Studies 2-4 (phase 1) were used to ascertain the nutritional situation in terms of dietary diversity and food security for pregnant women living in the targeted villages. Phase 2 of the research resulted in the development of a local produced food-based supplement, and tested its acceptability. Finally, phase 3 of this thesis was a cluster randomised controlled trial to determine the effect of the supplement on birth and infant growth. Birthweight was higher in the intervention group than the control group, and this trend persisted until 6 months, however was not statistically significant. MUAC was higher in the intervention group than the control at most time points. The intervention reduced the risk of LBW substantially (by 88.58%; only seven pregnant women require this intervention in order to prevent LBW of one child (NNT=7). However, further studies with larger sample sizes are required to confirm the role of locally produced supplementation for undernourished pregnant women on longer-term physical growth and acute malnutrition in infants, and to explore generalisability.

Chapter 9. Conclusion

In this Conclusion, I outline the strengths and limitations of this research, summarise my practice and policy recommendations and suggest areas for further research.

9.1 Strengths

This programme of research is novel for many reasons. It is the first study in which a community-based model has been used to prevent child undernutrition through prenatal supplementation. Each phase of the study is community-based. The supplement was developed using locally available and preferred foods; community nutrition volunteers were used to screen pregnant women, collect monthly data and distribute the supplementary food; and a small business enterprise was established to manufacture the supplement and then offer the supplement for sale after the study concluded. This study has the potential to influence future research and undernutrition projects that consider community ownership and sustainability.

The primary strength of this research lies in its unique approach to maternal supplementation in undernourished northern Bangladeshi women. My motivation for this research came from my experiences and observations over years of being a public health nutritionist in the humanitarian sector. This research was committed to local-level applied research, and the multiphase design ensured a community voice and empowerment. Research methods were specifically chosen to maximise participant engagement. Communities were involved in every step of this research, from its inception to owning the supplement developed. At no stage was a top-down approach applied. Therefore, the research is grounded in community ownership and built on my practical knowledge of the field.

At the onset of the research, I trained community nutrition volunteers to oversee the data collection processes. This approach empowered the communities and contributed to community ownership of the research, as the volunteers were hired locally and known by the participants. The community nutrition volunteers conducted the face-to-face interviews and questionnaires, trained participants on Photovoice methodology, and collected baseline data and monthly anthropometric measures from participants. All of the volunteers were female, allowing participants to freely discuss different topics. Two community nutrition supervisors oversaw the data collection of the volunteers, conducted quality checks, and assisted with data entry. I was personally involved in the capacity development of the community nutrition supervisors and volunteers, and oversaw the overall project coordination and community engagement. My involvement included supporting the thorough consultation processes with local community leaders, elders and members, either at

committee meetings, or through community-level meetings where entire villages were invited to participate. The research had significant support and contribution from a team of people, whom I have acknowledged at the front of this thesis.

Another strength of this research is the commitment to research sustainability through the research design. Sustainability was addressed through the identification of preferred locally available and affordable foods, the establishment of a small business enterprise, and ensuring affordability of the supplement for direct purchase by women from the small business enterprise once the research concluded. Sustainability was a particular priority of mine as I did not want to enter a community to conduct research and then leave. I wanted to design a research project that could potentially benefit the communities after the research concluded. I believe that this approach to research should become common practice, and that we should be placing community needs before our own research needs.

9.2 Limitations

The limitations of each study have been detailed in the respective chapters. A summary of the most important limitations is included here. Overall the main limitation affecting a number of studies was the small sample sizes. The small sample sizes in phases 1 and 2 resulted from a lack of funding, as the grants received were primarily to support phase 3 of this research — Study 6 (Chapter 7), and because of the civil and political unrest in Bangladesh. The small sample size for Study 6 (Chapter 7), resulted from an initial over-estimation of the pregnancy rate in the respective villages. Funding and civil/political unrest made it impossible to allow for a longer recruitment and follow-up period for the study. It is important to note that I successfully obtained funding to extend the lifespan of the research. However, while community volunteers continued the project, I did not extend the research component due to political insecurity and safety concerns. The response rates for each study were very high, indicating keen participation and interest from the communities. A larger sample size for Studies 3 and 4 may have resulted in stronger effect sizes (and significant associations). The sample size for Study 6 was calculated to detect a difference in birth weight (and as previously discussed, there were unintended errors associated with this calculation), thus I did not have a larger enough sample size to detect sub-group differences. A larger sample size for Study 6 may have resulted in more clinically meaningful impacts on birth and infant anthropometry.

In addition to small sample size, one of the limitations of this research is measurement bias associated with self-report of the data in several of the studies. In studies 3 and 4 (chapters 4 and 5), there may have been recall bias (resulting in under-reporting of food consumed), but there may also have been over-reporting of food insecurity and under-reporting of dietary diversity, which has

been reported in studies taking place in populations where food assistance or humanitarian aid programmes are frequent (with the expectation that food assistance may be consequently provided). In study 6 (chapter 7 - the RCT), if self-report bias was present, it was most likely non-differential in nature, and hence the impact would be an underestimate of the true impact of the intervention on the outcome measures [88]. Further, as the samples were taken from one area of northern Bangladesh, this limits transferability and generalisability to other areas of Bangladesh and low-income country contexts.

Another major limitation affecting Study 6 was that the height boards were not procured on time. This resulted in our inability to include data analyses on length as an anthropometric outcome. Infant stunting, as highlighted throughout the research, is a major concern to the global health community, and I was unable to report on this.

Finally, administration of the intervention unavoidably required women in the intervention group to interact with community nutrition volunteers much more frequently than women in the control group. In order to reduce this potential bias, all participants provided with nutrition education, however it is possible that this explained part of the observed effect of the intervention. There were no other known differences between women in the intervention and control groups (including health conditions that may impact on maternal and child health such as seasonal diarrhoea).

9.3 Relevance of the thesis

In the current climate, the global community is still looking for better ways to treat maternal undernutrition and prevent infant undernutrition. The publications generated from this research add new knowledge on how to address maternal undernutrition at a community level and subsequently prevent infant undernutrition. To-date, published articles from this research have been cited by other like-minded researchers who also seek innovative ways to address maternal undernutrition.

9.4 Summary of recommendations for practice and policy

My key recommendations are as follows:

9.4.1 Practitioner and service level

- Efforts to treat maternal undernutrition need to shift from 'aid' to 'community empowerment' and support the establishment of small businesses to produce locally produced food supplements;

- Researchers, policy makers and program decision makers need to understand local contexts when designing community based/owned programs to ensure more robust data collection and research outcomes.

9.4.2 Policy level

- Locally-produced balanced protein energy supplementation improves birth and infant growth outcomes in the context of Bangladesh;
- Nutrition interventions need to consider seasonal nutrition declines. Nutritional interventions need to take into consideration seasonal variances. Due to high levels of acute malnutrition year round, nutritional programs need to occur throughout the year and scaled up during months where there are seasonal food shortages. In addition, nutrition interventions during months affected by seasonal shortages can benefit from integrating with nutrition sensitive programs such as agricultural projects;
- To ensure community ownership, respective communities must be involved in all decision making processes;
- This thesis may inform, guide and motivate policies by providing evidence on a sustainable nutrition intervention that improves birth weight.

10.4 Further research and directions

There are many areas where further research is required to improve maternal and child nutrition outcomes.

The systematic review (Study 1, Chapter 2) identified an evidence gap for the effect of maternal balanced protein energy supplementation on child growth outcomes, particularly on weight and height. While my research identified that maternal balanced protein energy supplementation is effective for improving birth weight in the context of northern Bangladesh (Study 6, Chapter 7) it is important to keep in mind that I used a locally developed supplement. Thus, replication of the research design reported in this thesis may differ depending on the context in terms of food availability and preferences. In addition, further research with larger sample sizes is required to identify the effect of locally-produced supplementation on early infant weight and MUAC. This would also facilitate further sub-group analyses to explore the effect of supplementation, and how it might be modified by parity and gender of the baby. Sadly, I was unable to conduct a larger study due to financial resource restrictions. It is also recommended that additional work be completed to investigate the potential impact of other maternal nutritional factors, including supplement intakes. Specifically whether there were any differences in these

factors between the intervention and control groups, and whether this may have impacted on the observed results.

10.5 Final note

Bangladeshi pregnant women and children are urgently in need of sustainable community-led approaches to addressing undernutrition. This research has explored a new approach to addressing undernutrition through the development of a locally produced food-based supplement. Findings from this research have the potential to influence practice and policy in Bangladesh. Program decision makers have cheaper and more sustainable alternatives for the treatment of maternal acute malnutrition when compared to imported ready-to-use foods. Further research is required to confirm whether the approach presented in this thesis can be applied in other country contexts.

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Appendices

Appendix 1: PROSPERO Registration

Our systematic literature review (publication #1) was registered with the International prospective register of systematic reviews (PROSPERO). PROSPERO is an international database of prospectively registered systematic reviews in health and social care. Full registration can be viewed online at: http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42013005115#.VRKeUEuyNg0

UNIVERSITY of York
Centre for Reviews and Dissemination

NHS National Institute for Health Research

PROSPERO International prospective register of systematic reviews

Balanced protein energy supplementation for undernourished pregnant women in low income countries and child physical growth: A systematic review

Briony Stevens, Jenni Judd, Petra Buettner, Julie Brimblecombe, Kerrianne Watt, Alan Clough

Citation
Briony Stevens, Jenni Judd, Petra Buettner, Julie Brimblecombe, Kerrianne Watt, Alan Clough. Balanced protein energy supplementation for undernourished pregnant women in low income countries and child physical growth: A systematic review. PROSPERO 2013:CRD42013005115 Available from http://www.crd.york.ac.uk/PROSPERO_REBRANDING/display_record.asp?ID=CRD42013005115

Review question(s)
Does food based supplementation targeting undernourished pregnant women in low-income countries improve the physical growth of the child when compared to populations that do not receive supplementation?

Searches
We will conduct electronic database searches to identify studies. Limits are applied to English papers only, and limited to papers published between >1969 to 2013. This search will be applied to Cochrane, Scopus and MEDLINE via Ovid electronic databases. The first search was conducted on 11 March 2013 , and the last to be determined. The last search conducted will identify 'missed' or 'new' studies replicating the search methods to ensure accuracy. The 'snowball' technique will identify additional studies of interest related to the research area by manually examining the reference lists of selected studies from the electronic searches.

Types of study to be included
All experimental research including randomised controlled trials (RCTs), controlled before and after studies (CBAs), and interrupted time series analyses of routine data (ITS) are considered for this review. Comparisons with historical controls or national trends are excluded. Included studies are published in English. Only published material will be considered. Studies from 1970 to 2013 will be selected.

Condition or domain being studied
The effect of balanced protein energy supplementation in undernourished pregnant women is unclear. Systematic reviews to date have included studies from high, middle and low income countries. The form and degree of undernutrition fluctuates with the economic structure and political and ideological factors of a country and will likely influence the effect the supplement has on child physical growth.

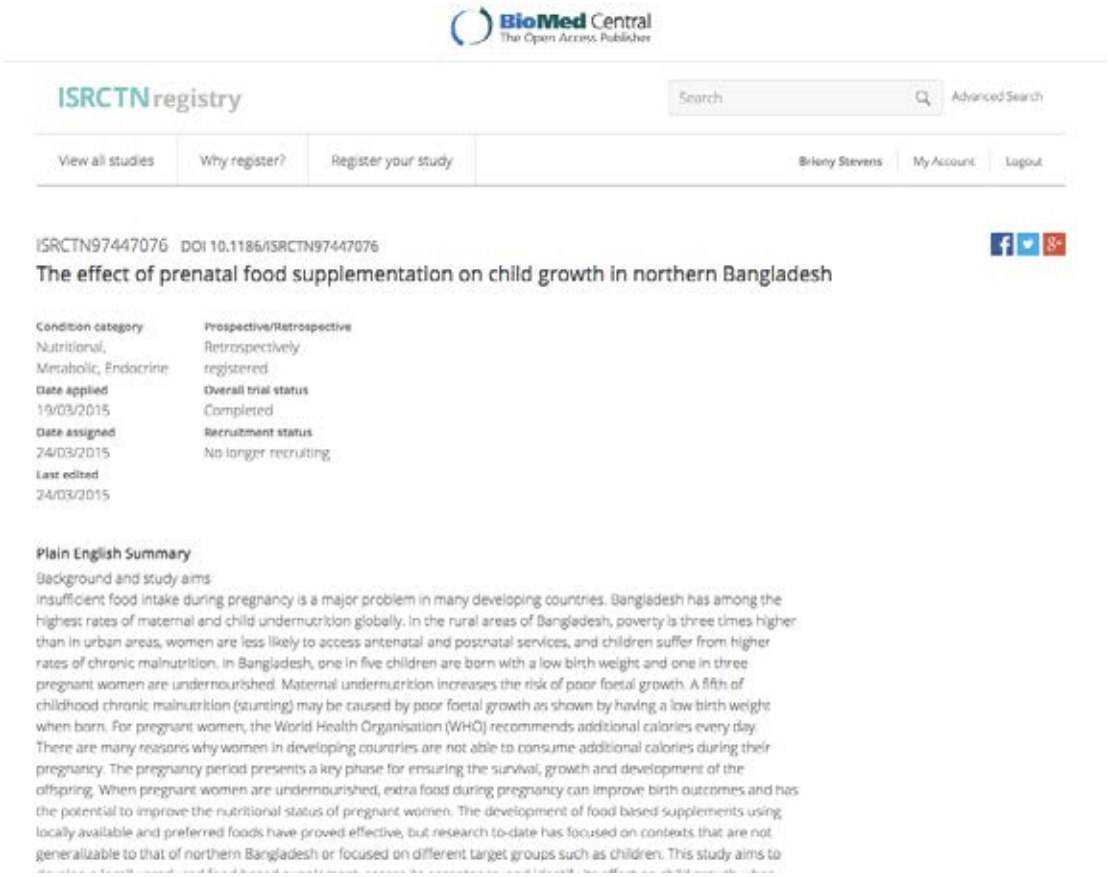
Participants/ population
Eligible participants are undernourished pregnant women. Undernourished is defined as below 50 kg in weight pre-pregnancy, under 150 cm in height, or as defined by the study authors. Studies that refer to supplementation in vulnerable groups such as those living with HIV/AIDs and TB are excluded.

Intervention(s), exposure(s)
Eligible studies focus on balanced protein energy supplementation during pregnancy with the outcome being infant and/or child growth. Balanced protein energy refers to supplements where the protein provides less than 25% of the total energy content. Excluded studies include interventions that have the primary outcome of dietary advice to pregnant women, high protein supplementation and isocaloric protein supplementation. Micronutrient supplementation studies are not eligible. Micronutrient studies include single or multiple micronutrients. Essential fatty acid studies are not eligible.

Comparator(s)/ control
Eligible studies have a measurable control to ensure that the impact of the intervention group can be analysed. Eligible controls include 'control supplement', 'placebo' and 'no intervention'. Studies that compare an intervention

Appendix 2: ISRCTN Registration.

The formative research, acceptability trial and longitudinal study were registered in the ISRCTN registry with the study ID: ISRCTN97447076. The ISRCTN registry is a primary clinical trial registry recognised by the World Health Organisation (WHO) and the International Committee of Medical Journal Editors (ICMJE) that registers clinical research studies, providing content validation, curation and a unique identification number necessary for publication. All study records in the database are freely accessible and searchable by the public. More information on ISRCTN can be found at: http://www.isrctn.com/



BioMed Central
The Open Access Publisher

ISRCTN registry

Search | Advanced Search

View all studies | Why register? | Register your study | Briony Stevens | My Account | Logout

ISRCTN97447076 DOI 10.1186/ISRCTN97447076

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

Condition category	Prospective/Retrospective
Nutritional, Metabolic, Endocrine	Retrospectively registered
Date applied	Overall trial status
19/03/2015	Completed
Date assigned	Recruitment status
24/03/2015	No longer recruiting
Last edited	
24/03/2015	

Plain English Summary

Background and study aims

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

Full registration can be viewed online at http://www.isrctn.com/ISRCTN97447076

Appendix 3: Ethical Approval

Ethics approval was obtained from the JCU ethical committee (H4498), and the Bangladeshi Medical Research Council (BMRC/NREC/2010-2013/58). This research was registered with the ISRCTN registry (ISRCTN97447076).

Ethics Application H4498

6216

Project title: **Maternal nutrition interventions and child development in Bangladesh**
Principal Investigator: **Stevens, Briony**
Start: **01-Mar-12** **End:** **01-Mar-15** **Approved:** **21-Mar-12**

Termination Dates	Notes	Date Approved
01-Mar-15	No extensions recorded	

Research participants 6216

1	Stevens, Briony	Student	P	01-Mar-12 to 01-Mar-15
2	Buttner, Petra	Staff	S	01-Mar-12 to 01-Mar-15
3	Clough, Alan	Staff	S	01-Mar-12 to 01-Mar-15

Amendment History		Date requested
20-Jun-12	Principal Investigator has requested to conduct 3 additional interviews that will contribute to the assessment for subject TM5524.Principal Investigator is only to use new data collected after amendment approved for TM5524 assessment.	20-Jun-12

Provisos	Date	Assessed by	Assessment
February 2012	29-Feb-12	Meeting	Approved
~			
February 2012	29-Feb-12	Meeting	Conditional Approval

The HREC deemed this study to be a category 3 study.
The HREC were concerned that the control group will only receive the intervention (nutritional diet) after 3 years. Please advise if there will be a mid intervention review, re: effectiveness of therapy. If not, please explain why a review will not be conducted. If a review is going to be conducted are there any plans to implement the intervention earlier for the control group, if it appeared to be working.
Please provide the roles and expertise of the supervisors. (The form that you have used has been superseded. Please check our website for the new form and see section 12.)
Please confirm if Dr. Babar is a co-investigator on the study as he is listed on the information sheet but not on the ethics application.
Please amend the information sheet to remove Sophie Thompson's name and replace with:
Human Ethics, Research Office
James Cook University, Townsville, Qld, 4811
Phone: (07) 4781 5011 (ethics@jcu.edu.au)
Please clarify how the middle arm circumference will be taken and how does this determine which participant will receive the intervention.

February 2012	29-Feb-12	Meeting	Pending

Pending

JAMES COOK UNIVERSITY AUSTRALIA

James Cook University
Townsville Qld. 4811 Australia
Tina Langford, Manager, Research Ethics & Grants
Research Services Ph: 47815011; Fax: 47815521
email: ethics@jcu.edu.au

Human Research Ethics Committee *APPROVAL FOR RESEARCH OR TEACHING INVOLVING HUMAN SUBJECTS*	Application ID H4498

PRINCIPAL INVESTIGATOR	Briony Stevens				Student
SCHOOL	Public Health & Tropical Medicine				
CO-INVESTIGATOR(S)					
SUPERVISOR(S)	Petra Buttner and Alan Clough				
PROJECT TITLE	Maternal nutrition interventions and child development in Bangladesh				
APPROVAL DATE:	**21/03/2012**	**EXPIRY DATE:**	**1/03/2015**	**CATEGORY:**	**2**

This project has been allocated Ethics Approval Number H4498, with the following conditions:

1. All subsequent records and correspondence relating to this project must refer to this number.

2. That there is NO departure from the approved protocols unless prior approval has been sought from the Human Research Ethics Committee.

3. The Principal Investigator must advise the responsible Human Ethics Advisor:
   - periodically of the progress of the project,
   - when the project is completed, suspended or prematurely terminated for any reason,
   - within 48 hours of any adverse effects on participants,
   - of any unforeseen events that might affect continued ethical acceptability of the project.

4. In compliance with the National Health and Medical Research Council (NHMRC) "National Statement on Ethical Conduct in Human Research" (2007), it is MANDATORY that you provide an annual report on the progress and conduct of your project. This report must detail compliance with approvals granted and any unexpected events or serious adverse effects that may have occurred during the study.

Human Ethics Advisor :	Parison, Julie
Email :	Julie.Parison@jcu.edu.au

This project was Approved by Meeting on 29 Feb 2012

Dr Anne Swinbourne
Chair, Human Research Ethics Committee

বাংলাদেশ চিকিৎসা গবেষণা পরিষদ
Bangladesh Medical Research Council
BMRC

Ref: BMRC/ERC/RPF-Bill/2012/ Date:

Bill

Briony Jayne Stevens
Health & Nutrition Manager
World Vision New Zealand &
Doctoral research students at
James Cook University Australia, 3rd Flags
Johnson Dr, Penrose, Auckland
New Zealand

Sl. No.	Title of Research Project	Principal Investigator & Address	Total Budget	Review and Processing Fee (RPF)		Total Tk.
				1 % up to 30.00 lakhs	0.5% of above 30.00 lakhs	
01	Maternal Nutrition and its role in child development in Bangladesh	Briony Jayne Stevens Health & Nutrition Manager World Vision New Zealand & Doctoral research students at James Cook University Australia, 3rd Flags Johnson Dr, Penrose, Auckland New Zealand	BDT 5,27,800/-	20,000/- (Minimum)	8,639/-	28,639/-
					Total Tk.	28,639/-

Taka (Twenty eight thousand six hundred thirty nine only)

The Amount of Tk. 28,639/- (Taka Twenty eight thousand six hundred thirty nine only) should be paid by A/C Payee Cheque in favour of Bangladesh Medical Research Council.

(Md. Afzal Hossain)
Accounts Officer

BMRC Bhaban, Mohakhali, Dhaka-1212, Bangladesh
Phone: +88 02 8828396, PABX +88 02 8819311, Fax: +88 02-8828820; E-mail: info@bmrcbd.org, Web: www.bmrcbd.org

Appendix 4: Supporting Documents - Ethics

JAMES COOK UNIVERSITY AUSTRALIA

World Vision

INFORMED CONSENT FORM

PRINCIPAL INVESTIGATOR	**Briony Stevens**
PROJECT TITLE:	**Exploration of the role of maternal nutrition in child growth in Bangladesh.**
ORGANISATION:	**World Vision**
SCHOOL	**Public Health**

I understand the aim of this research study is to explore the foods consumed during pregnancy, the role of eating habits and taboos; and the impact that the maternal diet has in relation to the development of the child. I consent to participate in this project, the details of which have been explained to me, and I have been provided with a written information sheet to keep.

I understand that my participation will involve an **interview/focus group discussion/questionnaire/pilot of intervention/intervention with anthropometry (please circle data collection method)** and I agree that the researcher may use the results as described in the information sheet.

I acknowledge that:

- taking part in this study is voluntary and I am aware that I can stop taking part in it at any time without explanation or prejudice and to withdraw any unprocessed data I have provided;
- that any information I give will be kept strictly confidential and that no names will be used to identify me with this study without my approval;
- confidentiality cannot be assured in focus groups.

(Please tick to indicate consent)

I consent to be interviewed		**Yes**		**No**
I consent for the interview to be audio taped		**Yes**		**No**
I consent to complete a questionnaire		**Yes**		**No**
I consent to participate in a focus group		**Yes**		**No**
I consent to participate in an intervention study that will involve to the consumption of an intervention during pregnancy, with pre and post pregnancy questionnaire, iron test; with follow up questionnaires and anthropometry with the off spring.		**Yes**		**No**
I consent to participating in an intervention study as a participant in the control group. I understand that I will not receive the intervention at this time.		**Yes**		**No**

Name: *(printed)*	
Signature:	**Date:**
Alternative mark or fingerprint	

PRINCIPAL INVESTIGATOR	Briony Stevens
PROJECT TITLE:	'Maternal Nutrition Interventions and Child Development in Bangladesh'
ORGANISATION:	World Vision
SCHOOL	Public Health

I understand the aim of this research is to explore my understanding of maternal nutrition practices. I consent to participate in this discussion, the details of which have been explained to me, and I have been provided with a written information sheet to keep. I understand that the results of the discussion will contribute towards doctoral research at James Cook University Australia and the design of a larger project.

I acknowledge that:

I consent to be interviewed		**Yes**		**No**
I consent for the interview to be audio taped		**Yes**		**No**

Name: *(printed)*	
Signature:	**Date:**
Alternative mark or fingerprint	

If you have any concerns regarding the ethical conduct of the study, please contact:
Human Ethics, Research Office
James Cook University, Townsville, Qld, 4811.
Phone: (07) 47815011, (ethics@jcu.edu.au)

JAMES COOK UNIVERSITY
AUSTRALIA

World Vision

Participant Information Sheets (Focus Group participants)

PROJECT TITLE: **Maternal Nutrition and its Role in Child Development in Bangladesh**

DATE:

Group Statement
You are invited to take part in a research project that explores the foods consumed during pregnancy, the role of eating habits and taboos; and the impact that the maternal diet has in relation to the development of the child in Bangladesh. The study is being conducted by **Briony Stevens, Programme Officer, World Vision New Zealand** and **respective staff members from World Vision Bangladesh, under the supervision of Dr Petra Buettner and Dr Alan Clough,** and will contribute towards a nutritional pilot study conducted by World Vision New Zealand and doctoral project in public health at James Cook University.

You have been invited to participate in this study because you have been identified as a valuable and influential member of your community, and of an elderly, reproductive age or pregnant population group. The purpose of this research is to understand your perception towards supplementary foods during pregnancy, their acceptability in your community, to identify possible barriers to adherence to providing supplementary foods to pregnant women. The collection of data and its analysis will inform and guide the development of the next phase of our research that will pilot supplementary food during pregnancy. This information will also guide us to develop tools to be used during the next phase of research.

If you agree to be involved in the study, you are invited to participate in a focus group discussion with 6 to 8 other participants that meet the same inclusion criteria. The questions we need to ask of the group will take approximately 2 hours. After we have finished, we will provide you with a meal to enjoy with the other women that have participated in the discussion. With your consent, and that of the groups, the discussion will be audio-taped electronically. The discussion is semi structured and will follow a set of predetermined questions. The discussion will be led by the key investigator, and will be conducted in your mother language through the support of a translator.

Taking part in this study is completely voluntary and you can stop taking part in the study at any time without explanation or prejudice. You may also withdraw any unprocessed data from the study.
As you are participating in a group discussion, we cannot guarantee that all information shared today can be kept confidential. We ask of each participant to keep the information from today's discussion confidential and not to share this with friends, family or community. We can confirm that all information you provide to the researcher and research team will be kept confidential and you will not be identified in any way when presenting the results of this research. If you, your family members or community has any concerns about the research during any part of the study, please feel welcome to voice your opinions to the translator or any World Vision staff member of the community leader, who will pass the information on to Briony, the lead investigator, who will address these concerns.

Thank you for your participation.

If you have any questions about the study, please contact either myself, Briony Stevens, or Dr Z.U Babar

Principal Investigator:

Briony Stevens
School of Public Health
James Cook University
Health and Nutrition Manager
World Vision New Zealand
Phone: +64 9 580 7708
Mobile: +64 21609221
Email: briony.stevens@jcu.edu.au

Co-Investigator:

Dr Z.U Babar
National Health and Nutrition Coordinator
World Vision Bangladesh
Phone: 88(02) 8815515 7
Email: zbabar@wvi.org

Briony Stevens

If you have any concerns regarding the ethical conduct of the study, please contact:
Human Ethics, Research Office
James Cook University, Townsville, Qld, 4811.
Phone: (07) 47815011, (ethics@jcu.edu.au)

JAMES COOK UNIVERSITY
AUSTRALIA

World Vision

Participant Information Sheets (Key Informants)

PROJECT TITLE: **Maternal Nutrition and its Role in Child Development in Bangladesh**

DATE:

INVITATION:
You are invited to take part in a research project that explores the meaning of maternal malnutrition by health staff in Bangladesh. The study is being conducted by **Briony Stevens, Programme Officer, World Vision New Zealand** and **respective staff members from World Vision Bangladesh, under the supervision of Dr Petra Buettner and Dr Alan Clough,** and will contribute towards a nutritional pilot study conducted by World Vision New Zealand and doctoral project in public health at James Cook University. Dr Babar, the National Health and Nutrition Coordinator for World Vision supports this project, and will be the Bangladeshi contact person if you would like to discuss anything further.

You have been invited to participate in this study because you have been identified as a health and nutrition focal person in your community (World Vision staff member). The purpose of this interview is to explore the meaning of malnutrition through your experience and understanding. These interviews will provide insight into the understanding and knowledge of malnutrition through the lived experiences of World Visions health staff. This information will inform and guide the development of the next phase of our research that will pilot supplementary food during pregnancy. This information will also guide us to develop tools to be used during the next phase of research.

If you agree to be involved in the study, you are invited to proceed with the one-on-one interview. The interview with your consent, will be audio-taped electronically, and should take approximately 1.5 hours of your time. The interview can either take place here, or a location of your choice. The interview is semi structured with a set agenda, we will interact and your responses will determine the information produced. If language or grammar is of an issue, you are free to request a Bangladeshi speaker to lead the interview, and I will observe.

Taking part in this study is completely voluntary and you can stop taking part in the study at any time without explanation or prejudice. A copy of the transcription will be provided to you for your review and you can provide and delete information if you chose to do so. You may withdraw any unprocessed data from the study.

This is a verbal interview conducted in English, with an Interpreter present if translation is needed. If you experience distress in any way, please inform the investigator, Briony Stevens, or the Interpreter and you will be referred to someone who can help you.

Your name and contact details will be strictly confidential however the information you disclose will be published under your organisations name. A disclaimer will be present indicating that the views of those interviewed may not be representative of the organisation. The data from the study will be used in research publications, conference presentations and for future programming reference. You will not be identified in any way in these publications.

Thank you for your participation.

If you have any questions about the study, please contact either myself, Briony Stevens, or Dr Z.U Babar

Principal Investigator:

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JAMES COOK UNIVERSITY
AUSTRALIA

World Vision

Participant Information Sheets (Questionnaire)

PROJECT TITLE: **Maternal Nutrition and its Role in Child Development in Bangladesh**

DATE:

INVITATION:
You are invited to take part in a research project that explores the foods consumed during pregnancy, the role of eating habits and taboos; and the impact that the maternal diet has in relation to the development of the child in Bangladesh. The study is being conducted by **Briony Stevens, Programme Officer, World Vision New Zealand** and **respective staff members from World Vision Bangladesh, under the supervision of Kerrianne Watt, Jenni Judd, Julie Brimblecombe and Dr Alan Clough,** and will contribute towards a nutritional pilot study conducted by World Vision New Zealand and doctoral project in public health at James Cook University.

You have been invited to participate in this study because you are a woman of reproductive age, pregnant or a mother. The purpose of this research is to understand your diet and nutritional status. The collection of data and its analysis will provide us with information on the nutritional situation of women in your community.

If you agree to be involved in this study, you will complete a questionnaire through discussion with an enumerator. The questionnaire will take approximately 1.5 hours and each question will be read out. Questions will include information about your family, your reproductive health and your diet and nutritional status.

Taking part in this study is completely voluntary and you can stop taking part in the study at any time without explanation or prejudice. You may also withdraw any unprocessed data from the study.

All information you provide will be kept confidential and you will not be identified in any way when presenting the results of this research. If you, your family members or community has any concerns about the research during any part of the study, please feel welcome to voice your opinions to the translator or any World Vision staff member of the community leader, who will pass the information on to Briony, the lead investigator, who will address these concerns.

Thank you for your participation.

If you have any questions about the study, please contact either myself, Briony Stevens, or Dr Z.U Babar

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World Vision Bangladesh
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Email: zbabar@wvi.org

Briony Stevens

Participant Information Sheet

Participant Information Sheet (Pregnant Women, Pirganj Bangladesh)

PROJECT TITLE: 'Maternal Nutrition Interventions and Child Development in Bangladesh' – Sub project: The use of Photo-voice to explore maternal nutrition practices in Pirganj, Bangladesh.

DATE:

INVITATION:

You are invited to take part in a research project that explores maternal nutrition practices in your community. The study is being conducted by **Briony Stevens, Programme Officer, World Vision New Zealand and student at James Cook University** and **respective staff members from World Vision Bangladesh, under the supervision of Alan Clough, Petra Buttner, Jenn Judd, and Julie Brimblecombe of James Cook University**. The findings from this research will lead to a publication on the use of photo-voice to explore nutrition practices, and will support the design of a larger nutrition project targeting pregnant women. This larger project, as you are aware, will contribute towards a doctoral research project being led by Briony Stevens. Dr Babar, the National Health and Nutrition Coordinator for World Vision supports this project, and will be the Bangladeshi contact person if you would like to discuss anything further.

You have been invited to participate in this study because you are pregnant, and live in a village that will soon be involved in a larger nutrition project. The purpose of this interview is to explore maternal nutrition through your experience and understanding. These interviews will provide insight into the foods consumed during pregnancy in your community.

If you agree to be involved in the study, you are invited to participate in training on the use of a camera, and to participate in a focus group discussion where we will look at these pictures. The training and discussion with your consent, will be audio-taped electronically, and should take approximately 2.5 hours of your time over two days. If language or grammar is of an issue, you are free to request a Bangladeshi speaker to lead the interview, and I will observe.

Taking part in this study is completely voluntary and you can stop taking part in the study at any time without explanation or prejudice. A copy of the transcription will be provided to you for your review and you can provide and delete information if you chose to do so. You may withdraw any unprocessed data from the study.

This is a verbal interview conducted in English, with an Interpreter present if translation is needed. If you experience distress in any way, please inform the investigator, Briony Stevens, or the Interpreter and you will be referred to someone who can help you.

Your name and contact details will be strictly confidential however the information you disclose will contribute towards a publication on the use of photo-voice.

Thank you for your participation.

If you have any questions about the study, please contact either myself, Briony Stevens, or Dr Z.U Babar

Principal Investigator:

School of Public Health
James Cook University
Health and Nutrition Manager
World Vision New Zealand
Phone: +64 9 580 7708
Mobile: +64 21609221
Email: briony.stevens@jcu.edu.au

Bangladeshi in-country support person:

Dr Z.U Babar
National Health and Nutrition Coordinator
World Vision Bangladesh
Phone: 88(02) 8815515 7
Email: zbabar@wvi.org

Briony Stevens

If you have any concerns regarding the ethical conduct of the study, please contact:
Human Ethics, Research Office
James Cook University, Townsville, Qld, 4811.
Phone: (07) 47815011, (ethics@jcu.edu.au)

JAMES COOK UNIVERSITY
AUSTRALIA

World Vision

Participant Information Sheets (acceptability study – Phase 2)

PROJECT TITLE: **Maternal Nutrition and its Role in Child Development in Bangladesh**

DATE:

INVITATION:
You are invited to take part in a research project that explores the foods consumed during pregnancy, the role of eating habits and taboos; and the impact that the maternal diet has in relation to the development of the child in Bangladesh. The study is being conducted by **Briony Stevens, Programme Officer, World Vision New Zealand** and **respective staff members from World Vision Bangladesh, under the supervision of Dr Petra Buettner, Dr Alan Clough, Jenni Judd, Julie Brimblecombe and Kerrianne Watt** and will contribute towards a nutritional pilot study conducted by World Vision New Zealand and doctoral project in public health at James Cook University.

You have been invited to participate in this study because you are a woman, are pregnant and living in an area that had been selected to participate in this study. The purpose of this research is to identify the acceptability of the proposed locally produced food-based supplement by pregnant women in your community and to identify acceptance, preparation, use, perceived benefits and perceived barriers. This will be analysed through the completion of a questionnaire at day-0, day-15 and at day-30. The collection of this information will assist the design of the next phase of this study that will explore the effect of the prenatal food-based supplement on birth and infant growth outcomes.

If you agree to be involved in this study, you will receive supplementary food for 30 days and will be asked to complete a questionnaire before receiving your first ration, after two weeks of receiving the ration, and after you have completed 30 days of receiving the ration. The questionnaire will take approximately 1 hour and each question will be read out. Questions will include information about how you accepted the food, your compliance,

Taking part in this study is completely voluntary and you can stop taking part in the study at any time without explanation or prejudice. You may also withdraw any unprocessed data from the study.

All information you provide will be kept confidential and you will not be identified in any way when presenting the results of this research. If you, your family members or community has any concerns about the research during any part of the study, please feel welcome to voice your opinions to the translator or any World Vision staff member of the community leader, who will pass the information on to Briony, the lead investigator, who will address these concerns.

Thank you for your participation.

If you have any questions about the study, please contact either myself, Briony Stevens, or Dr Z.U Babar

Principal Investigator:

Briony Stevens
School of Public Health
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Co-Investigator:

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World Vision Bangladesh
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Briony Stevens

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JAMES COOK UNIVERSITY
AUSTRALIA

World Vision

Participant Information Sheet

PROJECT TITLE: **Maternal Nutrition and its Role in Child Development in Bangladesh**

DATE:

INVITATION:
You are invited to take part in a research project that explores the foods consumed during pregnancy and the impact that the maternal diet has in relation to the development of the child in Bangladesh. The study is being conducted by **Briony Stevens, Programme Officer, World Vision New Zealand** and **respective staff members from World Vision Bangladesh, under the supervision of Dr Petra Buettner and Dr Alan Clough,** and will contribute towards a nutritional pilot study conducted by World Vision New Zealand and doctoral project in public health at James Cook University.

You have been invited to participate in this study because you are a woman, are pregnant and living in an area that has been selected to participate in this study. The purpose of this research is to identify whether a locally produced supplementary food (Pusti Khadda) eaten everyday by malnourished pregnant women improves the health outcome of their child. Dependant on your village location and your nutritional status, you may or may not receive Pusti Khadda.

If you agree to be involved in this study, you will be asked to complete a questionnaire (including anthropometric measurements and blood test) to determine whether you will receive Pusti Khadda. The questionnaire should take approximately 1.5 hours. Those who qualify will be required to eat one packet of Pusti Khadda every day; in addition to their usual diet. All women who agree to participate in this study will be involved in monthly monitoring (including anthropometric measurements and blood test) throughout their pregnancy and monitoring (including anthropometric measurements and blood test) of their child up to the age of two years. Each monitoring session should take approximately 30 minutes. If you agree to be involved in this study you will be supplied with educational materials and have the opportunity to attend monthly community meetings to discuss maternal nutrition and child care.

Taking part in this study is completely voluntary and you can stop taking part in the study at any time without explanation or prejudice. You may also withdraw any unprocessed data from the study.

All information you provide will be kept confidential and you will not be identified in any way when presenting the results of this research. If you, your family members or community has any concerns about the research during any part of the study, please feel welcome to voice your opinions to any World Vision staff member of the community leader, who will pass the information on to Briony, the lead investigator, who will address these concerns.

Thank you for your participation.

If you have any questions about the study, please contact either myself, Briony Stevens, or Dr Z.U Babar

Principal Investigator:

Briony Stevens
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James Cook University
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Cairns - Townsville - Brisbane – Singapore
CRICOS Provider Code 00117J

JAMES COOK UNIVERSITY AUSTRALIA

World Vision

TRANSCRIBER'S/TRANSLATOR'C CONFIDENTIALITY AGREEMENT

PRINCIPAL INVESTIGATOR	**Briony Stevens**
PROJECT TITLE:	**Exploration of the role of maternal nutrition in child growth in Bangladesh.**
ORGANISATION:	**World Vision**
SCHOOL	**Public Health**

I agree to translate and/or transcribe during the individual interviews, focus groups and the recordings provided to me.

I agree to keep confidential all the information provided to me.

I will not make any copies of the transcripts or keep any record of them, other than those required for the project.

Name: *(printed)*	
Signature:	**Date:**
Alternative mark or fingerprint	

If you have any concerns regarding the ethical conduct of the study, please contact:
Human Ethics, Research Office
James Cook University, Townsville, Qld, 4811.
Phone: (07) 47815011, (ethics@jcu.edu.au)

JAMES COOK UNIVERSITY
AUSTRALIA

World Vision

INFORMED CONSENT FORM

PRINCIPAL INVESTIGATOR:	**Briony Stevens**
PROJECT TITLE:	**Exploration of the role of maternal nutrition in child growth in Bangladesh.**
ORGANISATION:	**World Vision**
SCHOOL:	**Public Health**

I understand the aim of this research study is to explore the impact the maternal diet has in relation to the development of the child. I consent to participate in this project, the details of which have been explained to me, and I have been provided with a written information sheet to keep.

I understand that my participation will involve **questionnaires/ anthropometry data collection/ blood test** and may involve **consumption of 'Pusti Khadda'**, and I agree that the researcher may use the results as described in the information sheet.

I acknowledge that:

- taking part in this study is voluntary and I am aware that I can stop taking part in it at any time without explanation or prejudice and to withdraw any unprocessed data I have provided;
- that any information I give will be kept strictly confidential and that no names will be used to identify me with this study without my approval;

(Please tick to indicate consent)

I consent to participate in this study that will involve questionnaires, anthropometry measurements, blood test, monthly monitoring and possible consumption of 'Pusti Khadda'		**Yes**		**No**

Name: *(printed)*	
Signature:	**Date:**
Alternative mark or fingerprint	

Appendix 5: Data Collection Tools

Questionnaire #1. Components of the following questionnaire were used for phase 1, phase 2 and phase 3 of my research. Module 8 was specifically used for phase 2.

OPTIMAL NUTRITION DURING PREGNANCY – BASELINE QUESTIONNAIRE

CONFIDENTIAL

All information collected in this survey is strictly confidential and will be used for statistical purposes only

IDENTIFICATION INFORMATION

GEOGRAPHIC IDENTIFICATION

DIVISION _____

DISTRICT _____

UPAZILA _____

VILLAGE _____

ID HOUSEHOLD |__|__|

NAME OF PREGNANT WOMAN _____ |__|

HAS THE PREGNANT WOMAN BEEN SELECTED

TO RECIEVE NUTRITION INTERVENTION ? |__|

(YES = 1, NO = 2) (Answer after completion of survey)

INTERVIEW RECORD

Facilitator

Name _____

Signature _____

Date ___/___/___

Remarks _____

Supervisor

Name _____

Signature _____

Date ___/___/___

Remarks _____

Data entry

Name _____

Signature _____

Date ___/___/___

Remarks _____

INTERVIEWER VISITS

	1 (Day 1)	2 (Day 15)	3 (Day 30)	
DATE INTERVIEWERS NAME	_____ _____ _____	_____ _____ _____	_____ _____ _____	
NEXT VISIT: DATE TIME	_____ _____	_____ _____		TOTAL NUMBER OF VISITS _____
1.	2.			

Time	Start **|__|__|:|__|__|** Finish **|__|__|:|__|__|**

MODULE 1: HOUSEHOLD INFORMATION			
1.1	Name of respondent	……	
1.2	Are you currently pregnant?	1 = Yes 2 = No [__]	→ **If No, end survey here**
1.3	What month of your pregnancy are you currently in?	MONTH 98=DON'TKNOW [__][__]	
1.4	How long have you been continuously living in this community? If less than one year, record '00' in years	YEARS 97 = ALWAYS |__|__|	→ **If ALWAYS skip to Q1.6**
1.5	Just before you moved here, did you live in a city, town or village?	1= CITY |__| 2= TOWN 3 = VILLAGE	
1.6	What is your age?	YEARS 98 = DON'T KNOW |__|__|	
1.7	In what month and year were you born? (Ask for ID card to verify)	MONTH 98 = DON'T KNOW MONTH YEAR |__|__|__|__| 9998 = DON'T KNOW YEAR	
1.8	What is your current marital status?	1 = CURRENTLY MARRIED 2 = DESERTED |__| 3 = DIVORCED 4 = WIDOWED |__| 5 = OTHER	
1.9	How many people live in your household? (Household defined by those that share the same cooking space)	NUMBER OF PEOPLE |__|__|	
1.10	How many children and adults are currently living in the household who are between:		

AGE GROUP	MALE		FEMALE		AGE GROUP	MALE		FEMALE	
0 – 24 months	1.10.1	|__|__|	1.10.5	|__|__|	14– 18 years	1.10.9	|__|__|	1.10.12	|__|__|
25 – 59 months	1.10.2	|__|__|	1.10.6	|__|__|	18– 64 years	1.10.10	|__|__|	1.10.13	|__|__|
5 years – 11 years	1.10.3	|__|__|	1.10.7	|__|__|	64 years + (Elderly)	1.10.11	|__|__|	1.10.14	|__|__|

11 years – 14 years	1.10.4	|__|__|	1.10.8	|__|__|	

1.11	Who is your household leader?	1 = HUSBAND 2 = FATHER 3 = FATHER IN LAW 4 = OTHER _____ |__|	
1.12	Have you ever attended school?	1 = YES 2 = NO ⟶ |__|	**If NO, skip to Q1.15**
1.13	What is the highest level of school you attended?	1 = PRIMARY (CLASS 1 – 5) 2 = SECONDARY (CLASS 6 – 10) 3 = HIGHER SECONDARY (CLASS 11-12) 3 = GRADUATION (13-16) 5 = POST GRADUATION(CLASS 17) |__|	
1.14	What is the highest class you completed at that level?	CLASS |__|	
1.15	What is your religion?	1 = ISLAM 2 = HINDUISM 3 = CHRISTIANITY 4 = OTHER |__|	
1.16	Do you belong to an ethnic minority group?	1 = YES 2 = NO ⟶ |__|	**If NO, skip to Q2.1**
1.17	What is the name of your ethnicity group?	……	

MODULE 2: WEALTH RANKING

2.1	Aside from your own housework, do you work outside the home?	1 = YES 2 = NO ⟶ |__|	**If NO, skip to Q2.4**
2.2	What type of work do you do outside of home?	1 = RICE/CROP FARMER 2 = ANIMAL RAISING/SAL L PRODUCTS |__|__| 3 = FISHING 4 = WAGED LABOUR/ CASH INCOME 5 = SKILLED WORK 6 = SALARIED WORK 7 = SMALL BUSSINESS OWNER 8 = GATHER GOODS FROM FOREST 9 = HUNTING	

		10 = COLLECT FIREWOOD/CHARCOAL 11 = MONEY LENDING 12 = Other _____	
2.3	Whose land do you work on?	1 = OWN 2 = FAMILY OWNED 3 = RENTED 4 = SOMEONE ELSE OWNS LAND |__|	
2.4	Are you the main income earner in your household?	1 = YES 2 = NO ⟶ |__|	**If YES, skip to Q2.8**
2.5	If no, who is the main income earner?	1 = HUSBAND 2 = YOUR PARENTS 3 = PARENTS IN LAW 4 = CHILD 5 = OTHER _____ |__|	
2.6	What is their main income source?	1 = RICE/CROP FARMER 2 = ANIMAL RAISING/SALE Of ANIMAL PRODUCTS 3 = FISHING 4 = WAGED LABOUR/ CASH INCOME 5 = SKILLED WORK 6 = SALARIED WORK 7 = SMALL BUSSINESS OWNER 8 = GATHER GOODS FROM FOREST 9 = HUNTING 10 = COLLECT FIREWOOD/CHARCOAL 11 = MONEY LENDING 12 = Other _____ |__|__|	
2.7	Who's land does the main income earner work on?	1 = OWN 2 = FAMILY OWNED 3 = RENTED 4 = SOMEONE ELSE LAND 5 = OTHER |__|	
2.8	**Observe** and record the material of the house roof	1=BAMBOO,THATCH,GRASS, REED, HAY, LEAVES, EARTH OR OTHER TEMPORARY MATERIAL 2= IRON/ALUMINIUM, CEMENT, TILE (CLAY OR WOODEN) OR OTHER PERMENANT MATERIAL. |__|	
2.9	**Observe** and record the material of the house walls	1= BAMBOO, THATCH, GRASS, REED, HAY, LEAVES, EARTH OR OTHER TEMPORARY MATERIALS. 2= WOOD, CONCRETE, BRICK, STONE, IRON/ALUMINIUM, |__|	

		CEMENT OR OTHER PERMANENT MATERIALS	
2.10	Does the household have electricity from a power line in the house?	1 = YES 2 = NO |__|	
2.11	Who usually decides how your household money is spent?	1= SELF 2= HUSBAND |__| 3= YOUR PARENTS 4= PARENTS IN LAW 5= OTHER SPECIFY _____	
2.12	Who usually makes decisions about health care for yourself?	1= SELF |__| 2= HUSBAND 3= YOUR PARENTS 4= PARENTS IN LAW 5= OTHER SPECIFY _____	
2.13	Who usually makes decisions about health care for your children?	1= SELF |__| 2= HUSBAND 3= YOUR PARENTS 4 = PARENTS IN LAW 5= OTHER SPECIFY _____	
2.14	Who usually makes decisions about the purchase of daily household food?	1= SELF |__| 2= HUSBAND 3= YOUR PARENTS 4 = PARENTS IN LAW 4= OTHER SPECIFY _____	
2.15	Do you own land for cultivation?	1 = YES 2 = NO ⟶ |__|	**If NO, skip to Q2.19**
2.16	How much land do you own?	1 = LESS THAN 50 DECIMAL (HALF ACRE) 2 = 50 DECIMAL(HALF AN ACRE) 3 = 50 – 100 DECIMAL (HALF – ONE ACRE) 3 =100 DECIMAL(ONE ACRE) |__| 4 = MORE THAN 100 DECIMAL (MORE THAN ONE ACRE)	
2.17	How much of this land is used for agricultural produce? (income, trading or consuming)	1 = NONE ⟶ 2 = LESS THAN 50 DECIMAL (HALF ACRE) 3 = 50 DECIMAL(HALF AN ACRE) 4 = 50 – 100 DECIMAL (HALF – ONE ACRE) 5 =100 DECIMAL(ONE ACRE) |__| 6 = MORE THAN 100 DECIMAL (MORE THAN ONE ACRE)	**If NONE, skip to Q2.19**
2.18	Which crop did you grow last harvest?	1 = RICE ONLY 2 = RICE AND OTHER CROPS (SPECIFY) _____ 3 = OTHER CROPS (SPECIFY) _____	

2.19	Do you grow fruit or vegetables on your own property, around your house?	1 = YES 2 = NO |__|	**If NO, skip to Q2.23**
2.20	What is the number of different types of vegetables currently in your garden or on your land?	|__|__|	
2.21	What is the number of different types of fruit trees currently in your garden or on your land?	|__|__|	
2.22	What is the main use of fruits or vegetables grown in your garden?	1= HOME CONSUMPTION 2= SELL |__| 3= GIVE TO OTHERS 4= OTHER (SPECIFY)_____	
2.23	Does your household own any livestock, herds, or fish ponds?	1 = YES 2 = NO |__|	**If NO, skip to Q2.25**

2.24 How many of the following animals does your household own and what is their main use?

TYPE	NUMBER AVAILABLE		PRIMARY USE] 1 = Food 3 = Food and sale 2 = Sale 77 = Other	
Water buffalo	2.24.1	|__|__	2.24.2	|__|__|
Cows or bulls	2.24.3	|__|__	2.24.4	|__|__|
Horses	2.24.5	|__|__	2.24.6	|__|__|
Goats	2.24.7	|__|__	2.24.8	|__|__| |__|__|
Pigs	2.24.9	|__|__	2.24.10	
Chickens or ducks	2.24.11	|__|__	2.24.12	|__|__|
Fish, in fish ponds	2.24.13	|__|__	2.24.14	|__|__|

2.25	Does your household run out of rice in a normal year?	1 = YES |__| 2 = NO ⟶	**If NO, skip to Q2.27**
2.26	Between which months does your household run out of rice during a normal year?	MONTHS …… to ……..	
2.27	What is the main source for obtaining food for your household?	1= Own production, gathreing, hunting, fishing 2= Purchased 3= Borrowed, bartered exchanged for labour, gift from friends or relatives	

		4= Food aid 4 = Other |__|	

MODULE 3: HOUSEHOLD FOOD INSECURITY ACCESS SCALE (HFIAS) MEASUREMENT TOOL

For each of the following questions, consider what has happened in the past 30 days (four weeks). Consider if this happened: never (not even once), rarely (once or twice), sometimes (3-10 times) or often (more than 10 times)?

3.1	In the past four weeks, did you worry that your household would not have enough food? If yes, ask respondent, 'How often did this happen?'	0 = No ⟶ Skip to Q3.2 YES – 1 = Rarely (once or twice in the past 30 days) 2 = Sometimes (three to ten times in the past 30 days) 3 = Often (more than ten times in the past 30 days)	|__|
3.2	In the past four weeks were you or any household member not able to eat the kinds of foods you preferred to eat because of a lack of resources? If yes, ask respondent, 'How often did this happen?'	0 = No ⟶ Skip to Q3.3 YES – 1 = Rarely (once or twice in the past 30 days) 2 = Sometimes (three to ten times in the past 30 days) 3 = Often (more than ten times in the past 30 days)	|__|
3.3	In the past four weeks, did you or any household member have to eat a limited variety of foods due to a lack of resources? If yes, ask respondent, 'How often did this happen?'	0 = No ⟶ Skip to Q3.4 YES – 1. = Rarely (once or twice in the past 30 days) 2. = Sometimes (three to ten times in the past 30 days) 3. = Often (more than ten times in the past 30 days)	|__|
3.4	In the past four weeks did you or any household member have to eat some foods that you really did not want to eat because of a lack of resources to obtain other types of food? If yes, ask respondent, 'How often did this happen?'	0 = No ⟶ Skip to Q3.5 YES – 1. = Rarely (once or twice in the past 30 days) 2. = Sometimes (three to ten times in the past 30 days) 3. = Often (more than ten times in the past 30 days)	|__|
3.5	In the past four weeks did you or any household member have to eat a smaller meal than you felt you needed because there was not enough food? If yes, ask respondent, 'How often did this happen?'	0 = No ⟶ Skip to Q3.6 YES – 1. = Rarely (once or twice in the past 30 days) 2. = Sometimes (three to ten times in the past 30 days) 3. = Often (more than ten times in the past 30 days)	|__|

3.6	In the past four weeks did you or any other household member have to eat fewer meals in a day because there was not enough food? If yes, ask respondent, 'How often did this happen?'	0 = No ⟶ Skip to Q3.7 YES – 1. = Rarely (once or twice in the past 30 days) 2. = Sometimes (three to ten times in the past 30 days) 3. = Often (more than ten times in the past 30 days)	|__|
3.7	In the past four weeks was there ever no food to eat of any kind in your household because of lack of resources to get food? If yes, ask respondent, 'How often did this happen?'	0 = No ⟶ Skip to Q3.8 YES – 1. = Rarely (once or twice in the past 30 days) 2. = Sometimes (three to ten times in the past 30 days) 3. = Often (more than ten times in the past 30 days)	|__|
3.8	In the past four weeks, did you or any household member go to sleep at night hungry because there was not enough food? If yes, ask respondent, 'How often did this happen?'	0 = No ⟶ Skip to Q3.9 YES – 1. = Rarely (once or twice in the past 30 days) 2. = Sometimes (three to ten times in the past 30 days) 3. = Often (more than ten times in the past 30 days)	|__|
3.9	In the past four weeks, did you or any household member go a whole day and night without eating anything because there was not enough food? If yes, ask respondent, 'How often did this happen?'	0 = No ⟶ Skip to Q4.1 YES – 1. = Rarely (once or twice in the past 30 days) 2. = Sometimes (three to ten times in the past 30 days) 3. = Often (more than ten times in the past 30 days)	|__|
MODULE 4: MATERNAL HEALTH AND REPRODUCTION/MORTALITY			
4.1	Are you infected with HIV or AIDs? (Ask sensitively)	1 = YES 2 = NO |__|	

4.2	Do you have TB? (Ask sensitively)	1 = YES 2 = NO |__|	
4.3	Have you ever been pregnant before?	1 = YES 2 = NO |__|	**If NO, skip to Q5.1** →
4.4	How many children have you given birth to?	NUMBER OF CHILDREN |__|__|	
4.5	Have you ever given birth to a child who was born alive but later died?	1 = YES 2 = NO |__|	**If NO, skip to Q4.7** →
4.6	If yes, how many children have died?	NUMBER OF BOYS |__|__| NUMBER OF DAUGHTERS|__|__|	
4.7	Have you ever given birth to a baby that was not alive?	1 = YES 2 = NO	**If NO, skip to 4.9** →
4.8	If yes, how many children were not born alive?	NUMBER OF BOYS |__|__| NUMBER OF DAUGHTERS|__|__|	
4.9	Have you ever had a pregnancy that miscarriaged?	1 = YES 2 = NO |__|	**If NO, skip to 5.1**
4.10	When was the last time this occurred?	MONTH and YEAR ____/____	
MODULE 5: ANTE NATAL CARE			
5.1	Is this your first pregnancy?	1 = YES 2 = NO	
5.2	Have you experienced any difficulty with your vision during the day time?	1 = YES 2 = NO |__|	
5.3	During your current pregnancy, have you seen anyone for a medical check-up?	1 = YES 2 = NO	**If NO, skip to Q5.6**
5.4	If yes, who?	1 = DOCTOR 2 = NURSE |__| 3 = MIDWIFE 4 = SKILLED BIRTH ATTENDENT 5 = HEALTH ASSISTANT 6 = TRADITIONAL BIRTH ATTENDANT 7 = OTHER, IF OTHER, (PLEASE SPECIFY) ……	

5.5	How many checkups have been to in this current pregnancy?	Number of check ups |__||__|	
5.6	Have you received any vaccines during your pregnancy?	1 = YES 2 = NO	**If NO, skip to Q5.8**
5.7	What vaccines have you received during this pregnancy?	1 = TT (Tetanus) 2 = DPT (Diphtheria) 3 = Worm tablet 4 = Other (please specify ……	
5.8	During your current pregnancy, have you received any nutritional supplementation?	1 = YES 2 = NO |__|	**If NO, skip to MODULE 6**
5.9	What nutritional interventions have you receive?	1 = Iron tablet/syrup |__| 2 = Food suplement (rice, molasses, oil, pulse) 3 = Vitamin A supplementation 4 = Micronutrient powder 5 = Folic acid tablet 6 =Other, (PLEASE SPECIFY) |__| ……..	

MODULE 6: MATERNAL NUTRITIONAL STATUS

24 hour diet recall

"Was yesterday a celebration or feast day where you ate special foods or where you ate more, or less than usual?"	**1 = YES** **2 = NO** →	**If YES, arrange another time to complete the questionnaire.**

Please describe the foods (meals and snacks) that you ate over the previous 24 hours, whether at home or outside the h m

Start with the first food eaten in the morning. (List time, food items, cooking method and identify the amount in grams)

	Time	Food	Cooking method	**Amount**
6.0	Morning			
	Breakfast			
	Snack			
	Lunch			
	Snack			

	Dinner			
	Evening			

MODULE 7: MATERNAL NUTRITIONAL STATUS Individual Dietary Diversity Score (IDDS) FAO diversified. Adapted from FANTA HDDQ and Bangladesh DHS.			
Please use the foods listed in the 24 hour recall to indicate what food groups the participant consumed over the last 24 hours			
	FOOD GROUP	EXAMPLE	1 = YES 2 = NO
7.1	CEREALS	bread, noodles, biscuits, or any other foods made from millet, sorghum, maize, rice, wheat	
7.2	VITAMIN A RICH VEGETABLES AND TUBERS	pumpkin, carrots, squash, orange sweet potatoes, red capsicum, red chili pepper , red amaranth	

7.3	WHITE TUBERS AND ROOTS	white potatoes, arum root, parsnip, white radish or foods made from roots.	
7.4	DARK GREEN LEAFY VEGETABLES	Arum, green amaranth, pumpkin leaves, bottle guard leaves, spinach, carrot leaves, celery leaves, helencha leaves, Indian spinach, tamarind leaves,	
7.5	OTHER VEGETABLES	other vegetables including, onion, cucumber, eggplant, celery, tomato, snake gourd, bottle gourd, sweet gourd, bitter gourd, peas, lettuce, cauliflower, cabbage, ladies finger, green papaya, green banana, country (green) bean	
7.6	VITAMIN A RICH FRUITS	ripe mangoes, cantaloupe, dried apricots, dried peaches, orange papaya, guava, palm (tal), monkey jackfruit, watermelon, banana flower	
7.7	OTHER FRUITS	other fruits including, bananas, apples, grapes, pomegranate, jackfruit, berries, litchi, lemon, orange, mandarin, grapefruit, pineapple, jujube	
7.8	ORGAN MEAT (IRONRICH)	liver, kidney, heart or other organ meats or blood-based foods	
7.9	FLESH MEATS	beef, pork, lamb, goat, mutton, rabbit, wild game, chicken, duck, or other birds , pigeon	
7.10	EGGS		
7.11	FISH	fresh or dried fish (hilsa, bhetki, silver fish, ruhi) or shellfish, sweet or salt fish, smoked fish paste, fermented shrimp paste	
7.12	LEGUMES, NUTS AND SEEDS	beans, soybeans, chickpeas, peas(pulse), lentils, nuts(peanuts, cashew, pistachio), seeds (sesame, pumpkin, sunflower, jackfruit) or foods made from these	
7.13	MILK AND MILK PRODUCTS	milk, cheese, yogurt, milk powder or other milk products like curd, misti doi, UHT milk	
7.14	OILS AND FATS	oils, fats or butter added to food or used for cooking, ghee, coconut and coconut products mustard seed oil	
7.15		Palm oil (red/orange in colour), palm nut	

	RED PALM PRODUCTS		
7.16	Did you eat anything (meal or snack) OUTSIDE of the home yesterday? If yes, list food items below		1 = Yes 2 = No
	Food consumed outside of household in. Ensure each ingredient is listed.		

Thank you very much for participating in this part of the survey! We would now like to measure YOUR weight and check you for anaemia

MODULE 7: BASELINE MATERNAL ANTHROPOMETRY AND TECHNICAL MEASUREMENTS

Two measurements of heightand MUAC will be taken for each individual and if the difference is > 0.5 cm a third measurement should be taken and recorded

Is household salt iodized? (conduct rapid test of salt using rapid iodised salt testing kit) Yes = 1 No = 2 |__|

	FIRST	SECOND	THIRD
Weight	__ __.__		
Height	__ __.__	__ __.__	__ __.__
MUAC	__ __.__	__ __.__	__ __.__

Month of pregnancy (Circle)	FIRST SECOND THIRD FOURTH FIFTH SIXTH SEVENTH EIGHTH NINTH TENTH
Illness in last 14 day? If yes, what illness?	|__|

Codes for adult illnesses:

0=None	1=Acute respiratory infection
2=Diarrhoeal	3=Malaria/febrile
4=Joint	5=Urinal
6=Organ	7=Anaemia
8=Reproductive	9=Other, specify _____

Pre - pregnancy weight (if known)	__ __.__

To be included in Intervention and receive RUTF	Y = 1 N = 2 → |__|	If No, why not?	1 = Lives in Chatra, but MUAC >23cm |__| 2 = Lives in Bara-Alampur 3 = Other

MODULE 8: NUTRITIONAL AND ANTHROPOMETRIC MONITRING OF PREGNANT WOMAN (DAY 15 AND 30)									
	WEIGHT (kg)	LENGTH	*MUAC (cm)*	Oedema Yes=1 No=0		Cough Y = 1 N = 2	DIAHRROEA (3 or more watery stool in 24hr) Y = 1 N = 2	Febrile Illness, suspected malaria Y = 1 N = 2	Have you received any supplementary foods in the last month from other GOs or NGOs? Y = 1 N = 2
DAY 15	__ __. __	__ __. __	__ __. __	[___]		[___]	[___]	[___]	[___]
DAY 30	__ __. __	__ __. __	__ __. __	[___]		[___]	[___]	[___]	[___]

Photovoice Moderators Guide

Use of Photo-voice to explore maternal nutrition practices in Pirganj, Bangladesh

Part 1: Training

Materials: **10 x digital camera**
1 x laptop
Food items i.e. fruit

Introduction

Thank you for coming to this training. My name is Briony Stevens and these are my colleagues (state name and introduce any other members of the team that are present). I work with World Vision, and I am also associated with James Cook University in Australia.

We, World Vision, would like to understand more about maternal nutrition and our proposed project feasibility and packaging. We would like to understand the foods that are being consumed, what women prefer to eat, and what food women avoid and why. To do this, we would like to use digital cameras so that pregnant women can tell us a story about the foods in your community through the use of photos.

We will have just the one training group, and this session will take approximately an hour and a half and in order to ensure we do not miss anything that is said during the discussion the session is being recorded.

This training will give you the skills to use a camera, and we ask you to go to the house of pregnant women (from the names provided) and train them on the use of the camera and take 20 photos. We ask you to try and tell us your story through these pictures. The pregnant women can take photos of foods that they like, foods that they do not like, foods that they eat especially when pregnant or that they avoid. Anything at all.

You will collect these cameras and return to a WV staff member tomorrow morning and the photos will be printed. We will then conduct 2 or 3 discussion groups, using these photos to tell us a story. We ask you to identify a discussion time for tomorrow where the pregnant woman can be present and attend. If the pregnant woman cannot attend the discussion, please find a different pregnant woman.

Training

1. Who has used a camera?
2. Demonstration on how to use camera
3. Show how pictures transfer to computer
4. Show positioning of pictures, and objects.
5. Practical – walk around taking pictures of food.
6. Review of peoples photos and feedback
7. Questions and answers

Pirganj, Bangladesh

Understanding maternal nutrition through Photovoice June 2012

Attendance sheet, camera allocation and FGD allocation

Training Date: _____

Volunteer/nutrition assistant to write participant name, allocate a camera and arrange which FGD the participant will attend. Ensure that there are not more than 5 people per FGD

Nutrition Volunteer Name	Village	Pregnant woman name	Village	Camera number	Focus Group Discussion time (circle time – cap at 5 per group)
1					10:00am 11:30am 1:00pm
2					10:00am 11:30am 1:00pm
3					10:00am 11:30am 1:00pm
4					10:00am 11:30am 1:00pm
5					10:00am 11:30am 1:00pm
6					10:00am 11:30am 1:00pm
7					10:00am 11:30am 1:00pm
8					10:00am 11:30am 1:00pm
9					10:00am 11:30am 1:00pm
10					10:00am 11:30am 1:00pm

Use of Photo-voice to explore eating habits, attitudes and beliefs in Pirganj, Bangladesh

Phase 2: Focus Group Discussions

Materials: 10 x folder with photos (please write on back of photo the participant number)
Sticky tape

Introduction

Welcome and thank you for returning to this discussion group. As you are aware, my name is Briony Stevens, and I work with World Vision and I am also associated with James Cook University in Australia. We also have with us today (state name, and introduce any other member sof the team in the room). Today we will be running a total of 3 discussion groups to explore your understanding of issues related to maternal nutrition, your knowledge of the maternal diet, attitudes and beliefs, and we will also discuss a new project that World Vision is designing.

This focus group will last approximately one hour and in order to ensure that we do not miss anything that is said during the discussion the session is being recorded. The information gathered will be used in the context of this study and individuals will not be identifiable within the findings *(ask participants to sign consent sheet and attendance sheet, if anyone objects, then notes will have to be taken rather than session being recorded).*

Main Session (ensure all participants respond and react to their response appropriately)

Place all photos on the ground

Dietary consumption, understanding and beliefs:

1. (Using these photos) Can you show me which foods you consume during pregnancy?
   PROBE: Do you all consume these foods? If not, why not?

2. (Using photos) Are there any foods that you try to eat more of because you are pregnant?
   PROBE: Why do you try to eat more of these foods?
   Are there other foods that you try to eat that are not here?

3. (Using photos) Are there any foods here, or others if they come to mind, that you try to avoid during pregnancy
   PROBE: Why do you avoid these foods?

4. What is your understanding of maternal malnutrition?
   PROBE: Does this affect your community? Why/why not?

5. What can happen if women don't eat the right foods when pregnant?
   PROBE: Identify whether there is an understanding of micronutrient deficiencies, low birth weight, mortality.

Accessibility and availability:

6. Do you eat extra food when pregnant?
   PROBE: Why do you eat extra food/Or Why do you not eat extra food?

7. Who chooses which food items will be purchased for your household?

8. In what environment do you consume your food? With family? Without?

Existing services:

9. Have you ever seen or heard any messages or received advice about what to eat when pregnant?
   PROBE: Who shared this information with you?
   What was this information?
   How was this information used?

Supplementary food research

Now I will share with you the details of a project that will soon implement in your community. This project will involve extra food being provided to pregnant women that are identified as malnourished. We are still identifying which food items to use though will likely include rice, lentils, molasses, palm oil and salt.

If you were selected to receive this food……

Acceptability

10. Do you think that pregnant women will consume these food items?
    PROBE: If not, why not. If yes, why yes.

11. Would you be willing to consume this food item while pregnant in addition to your usual food intake?
    PROBE: If not, why not?

12. Would you be willing to pay a small amount of money for this food to improve your health while pregnant?
    PROBE: Ask why.

13. Can you think of reasons (barriers) that may prevent you from consuming this food item?
    PROBE: Husband, other children, elderly.

Packaging

14. We are thinking about putting the food into daily sachets. What design of the packet would be acceptable by the community?
    PROBE: Pictures or writing?
    Colours?
    What type of pictures?
    What information do you need on the packet?

Delivery

15. If you were receiving this extra while while pregnant, how would you like to collect it?
    PROBE: Door to Door, visit volunteer, community event…..

Messages

16. What type of information would you like to learn about with regard to what foods to eat during pregnancy?

17. How would you like to access this information?

- Community events? Posters? Through a volunteer?

Debrief

Thank you for your input into this project. Once all of the sessions are completed the recordings will be transcribed and analysed to identify any relevant patterns. Just to reiterate all of the information will be anonymous and we will share the findings with you once completed.

The findings from this research will assist with the design of our new nutrition project that supports pregnant women in your community, and will aid with the development of materials that aim to share information on which foods to eat during pregnancy.

Give out the information sheet which details the aims of the focus group and the contact details of World Vision.

Pirganj, Bangladesh:

Understanding maternal nutrition through photovoice June 2012

Attendance sheet, camera allocation and FGD allocation

Focus Group Date: _____

Focus Group Time: _____

Volunteer/research assistant to write participant name, tick if photos are present, tick if signed consent form, tick if received information sheet.

Participant's Name	Village	Photos present	Signed consent (tick or cross)	Received information sheet (tick or cross)
1				
2				
3				
4				
5				

Questionnaire #2. The following questionnaire was used for Phase 2 acceptability study, at days 15 and 30

Optimal Nutrition during Pregnancy

Assessment of the Feasibility, Acceptability and Compliance.

Day 15

Thank you for meeting with us today. We would like to ask you some questions about you using "Supplementary feeding product' over the last two weeks. Your answers are important to us and will help improve the product and the messages we are disseminating. There is no right or wrong answers so please tell us your honest opinion. If you cannot or do not want to answer any of the questions, just let me know and I will continue to the next question. This questionnaire should take approximately 1 hour. May we start the questions now?

1. Have you continued eating 'Supplementary food' every day?

Yes ➔ Skip to Q3 No

2. If no, why have you stopped?

_____
_____

3. How many packets have you consumed since the beginning of the program (collect used sachets)?

_____

4. Do you eat the whole 'Supplementary food' packet at one time?

Yes ➔ Skip to Q6 No

5. If no, what do you do with the food which is not eaten? (Given to others, eaten later)

_____
_____

6. What time in the day do you eat 'Supplementary food'?

_____

7. Do you mix 'Supplementary food' with any other foods?

Yes ➔ skip to Q9 No

8. What other foods do you eat it with?

_____
_____

9. Where do you store 'Supplementary food' in your home?

_____

10. Does the 'Supplementary food' mix together easily?

Yes No

11. Do you enjoy the texture (mouth feel) of the 'Supplementary food'?

Yes ➔skip to Q13 No

12. If no, why not?

_____
_____

13. Do you enjoy the taste of the 'Supplementary food'?

Yes ➔skip to Q15 No

14. If no, why not?_____
_____

15. Do you enjoy the smell of the 'Supplementary food'?

Yes ➔skip to Q17 No

16. If no, why not?

_____
_____

17. Is there any other type of food you would like in 'Supplementary food'?

Yes No ➔skip to Q19

18. If yes, what food?

_____
_____

19. Would you prefer molasses or sugar in 'Supplementary food'?

a. Sugar

b. Molasses

20. What do you think about the size of 'Supplementary food'?

a. Too small

b. Just right

c. Too big

21. Have you experienced any side effects (vomiting, diarrhea, headache, weakness etc) while taking 'Supplementary food'?

Yes No ➔skip to Q23

22. If yes, what side effects have you experienced?

_____
_____

23. Have your family members been supportive of you participating in this program and eating the 'supplementary food'?

Yes ➔skip to Q25 No

24. If no, what problems have you faced?

_____
_____

25. Have other community members, such as neighbours, local leaders, community health workers, been supportive of you participating in this program and eating the 'supplementary food'?

Yes ➔skip to Q27 No

26. If no, what problems have you faced?

_____
_____

27. Can you tell me any reasons why you should eat 'Supplementary food'?

Yes No ➔skip to Q29

28. If yes, what are some of the reasons?

_____
_____

29. Have you learnt anything new from the pamphlets the ONDP staff gave you?

Yes No ➔skip to Q31

30. If yes, what have you learnt?

_____
_____

31. Have you learnt anything new from meetings/sessions you have had with the ONDP staff?

Yes No ➔skip to Q33

32. If yes, what have you learnt?

_____
_____

33. Are there any changes you would make to the information materials (leaflet, flip chart, poster etc) used by the ONDP staff?

Yes No ➔skip to Q35

34. If yes, what changes would you make?

_____
_____

35. Is there any additional information about maternal, newborn and child health you would like to know?

Yes No ➔skip to Q37

36. If yes, what would you like to know?

_____
_____

37. What do you like/dislike about the packaging of 'Supplementary food'?

_____
_____

38. Would you continue taking 'Supplementary food' throughout your entire pregnancy if it were provided to you?

Yes ➔skip to Q40 No

39. If no, why not?

_____
_____

40. What are you overall thoughts or feelings about the Optimal Nutrition During Pregnancy project?

_____
_____

41. Do you have any questions about the Optimal Nutrition During Pregnancy project?

_____
_____

Thank you very much for your time. All of your answers are appreciated and valuable to this project. We are available in the future for any more questions you, your family or community may have.

Pregnancy Monitoring Card

Participants name _____

	Baseline survey (tick if complete)	24 hour recall (Tick if complete)	DDQ (Tick if complete)	Weight (kgs, 1 decimal place)			Height (cm, 2 decimal place)			MUAC (cm, 1 decimal place)			Receiving Pushti Khadda (Y = 1 N = 2)	Iodine (Indicate range)	Hb (g/L)	Odema (Y =1 N =2)	Cough in last 14 days (Yes =1 No =2)	Diarrhea in last 14 days (Y = 1 N = 2)	Fever in last 14 days (Y = 1 N = 2)	Received food or supplement in last month from GO or NGO (Y = 1 , N = 2
				1	2	Final	1	2	Final	1	2	Final								
Baseline																				
Month 2																				
Month 3																				
Month 4																				
Month 5																				
Month 6																				
Month 7																				
Month 8																				

Month 9																			
Month 10																			

Participant ID number _____

Child Monitoring Card

Childs name _____

Childs ID number _____

Mothers name _____

Mothers ID number _____

Household number_____

Date of birth _____

	Sex (M or F)	Apgar scale (Tick if complete)	Weight (kgs, 1 decimal place)			Length/ height (cm, 2 decimal place)			MUAC (cm, 1 decimal place)			Hb (g/L)	Odema (Y =1 N =2)	Cough in last 14 days (Y =1 N =2)	Diarrhea in last 14 days (Y =1 N =2)	Fever in last 14 days (Y =1 N =2)	Received food or supplement (excluding vitamin A, iron or PD Hearth) in last month from GO or NGO (Y = 1 , N = 2	24 hour recall (Tick if complete)	DDQ (Tick if complete)	Vitamin A supplementation received in last 30 days (Y = 1 , N = 2	Iron supplementation/ de-worming received in last 30 days (Y = 1 , N = 2	Child participated in PD Hearth sessions (Y = 1 , N = 2
			1	2	Final	1	2	Final	1	2	Final											
Birth																						

7 days																						
1 month																						
6 month																						
12 month																						
18 month																						
24 month																						

Appendix 6: Additional Documents Developed to Support Phase 3 Intervention Study

WEEKLY CHECKLIST FOR FACILITATORS TO CARRY OUT WITH EACH PARTICIPANT AND CHILD

Participant (pregnant woman) name _____

Participant (pregnant woman) ID number _____

Village name _____

Household ID number _____

Key village facilitator _____

Stage	Date	Checklist
Week 1 **(Month 1)**		☐Information sheet read aloud and given to participant ☐Consent obtained ☐Completed pregnancy monitoring card (baseline) including: ☐Baseline questionnaire complete ☐24 hour recall ☐Individual dietary diversity questionnaire ☐Blood test ☐Iodine test ☐Anthropometric measurements (weight, height, MUAC) ☐Received IEC/BCC materials ☐Read aloud pregnancy information sheet *If receiving Pusti Khadda* ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Read aloud Pusti Khadda instruction sheet ☐Received Pusti Khadda pictorial instruction sheet
Stage	**Date**	**Checklist**
Week 2-4		☐Attended monthly courtyard meeting

(Month 1)		*If receiving Pusti Khadda* ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets
Week 5-8 **(Month 2)**	_____	☐Completed pregnancy monitoring card ☐Attended monthly courtyard meeting *If receiving Pusti khadda* ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets

Stage	Date	Checklist
Week 9-12 **(Month 3)**		☐Completed pregnancy monitoring card ☐Attended monthly courtyard meeting *If receiving Pusti khadda* ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets
Week 13-16 **(Month 4)**	_____	☐Completed pregnancy monitoring card ☐Attended monthly courtyard meeting ☐Blood test ☐Iodine test *If receiving Pusti khadda* ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets

Stage	Date	Checklist
Week 17-20 **(Month 5)**		☐Completed pregnancy monitoring card ☐Attended monthly courtyard meeting *If receiving Pusti khadda* ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets
Week 21-24 **(Month 6)**	_____	☐Completed pregnancy monitoring card ☐Attended monthly courtyard meeting *If receiving Pusti khadda* ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets

Stage	Date	Checklist
Week 25-28 **(Month 7)**	_____	☐Completed pregnancy monitoring card ☐Attended monthly courtyard meeting ☐Blood test ☐Iodine test *If receiving Pusti khadda* ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets
Week 29-32 **(Month 8)**	_____	□ Completed pregnancy monitoring card ☐Attended monthly courtyard meeting *If receiving Pusti khadda* ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets

Stage	Date	Checklist
Week 32 – 36 **(Month 9)**	_____	☐Completed pregnancy monitoring card ☐Attended monthly courtyard meeting *If receiving Pusti khadda* ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets
Week 37+ **(Month 10)**	_____	☐Completed pregnancy monitoring card ☐Attended monthly courtyard meeting ☐Blood test *(as close to delivery as possible)* ☐Iodine test *If receiving Pusti khadda* ☐Received 3 Pusti Khadda packets

		☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets ☐Received 3 Pusti Khadda packets ☐Received 4 Pusti Khadda packets

Participant (child) name _____

Participant (child) ID number _____

Village name _____

Household ID number _____

Key village facilitator _____

Stage	Date	Checklist
Birth		☐Completed child monitoring card, including: ☐Sex ☐Date of birth ☐Apgar scale ☐Anthropometric (weight, length) ☐Received colostrum ☐Read aloud breastfeeding information sheet
Week 1 **(7 days)**		☐Completed child monitoring card
Week 2-4 **(Month 1)**		☐Completed child monitoring card
Week 4-24 **(Month 6)**		☐Completed child monitoring card
Week 25-56 **(Month 12)**		☐Completed child monitoring card
Week 57-72 **(Month 18)**		☐Completed child monitoring card
Week 72-96 **(Month 24)**		☐Completed child monitoring card

RECEIVING PUSTI KHADDA PACKET AND COMPLIANCE CHECKLIST

Participant name _____

Participant ID number _____

Village name _____

Household ID number _____

Key village facilitator _____

Date (DD/MM/YYYY)	Number of full packets given by facilitator	Facilitators name	Facilitator signature	Participants name	Participant signature	Number of empty packets received from participant

Community Nutrition facilitator

INSTRUCTION SHEET FOR THE USE OF PUSHTI KHADDA

WORLD VISION BANGLADESH

PIRGANJ ADP

OPTIMAL NUTRITION DURING PREGNANCY PROJECT

GENERAL MESSAGE

- Pusti Khadda is a nutritious food made from locally available ingredientsIt should be consumed by malnourished women during pregnancy in addition to their usual diet. Pushti Khadda will supply additional energy and nutrients during pregnancy to help the growth of a healthy baby.

STORAGE INSTRUCTIONS

- Store Pusti Khadda in a safe place where children cannot reach.
- If possible store in a sealed container
- Store in a cool, dry place.
- Keep all empty Pusti Khadda packets to give to village volunteer on their next visit to your home

EATING INSTRUCTIONS

- Wash your hands with water and soap before preparing the Pusti Khadda packet
- Eat one whole packet each day

- Tear/cut open all six ingredient packets, peel and add banana and mix together in a bowl until a paste is formed. Do not leave out any of the ingredients.
- Eat in-between usual meal times. Do not replace any meals with Pusti Khadda. It should be eaten as additional food to add to your usual diet.
- If the whole packet is not consumed within one sitting, cover the bowl and consume the left over amount within two hours
- Do not share Pusti Khadda with family members or friends. Only pregnant women should eat the whole Pusti Khadda packet each day.
- Please continue to eat packets during periods of illness.

COMMONLY ASKED QUESTION ABOUT THE ONDP PROJECT

What is the duration of the ONDP project?

Participants will be involved in the project for a maximum of two years and nine months. From the date of recruitment, the pregnant woman will be monitored on a monthly basis until she gives birth. Her child will then be monitored until the age of two.

Who is this project for?

The project intervention is directed to pregnant women; however the whole community will benefit and will have the opportunity to be involved in the project through community meetings, giving support to pregnant women and eating nutritious foods.

Who will receive Pusti Khadda?

Chatra union has been selected as the intervention area, and Bara-Alampur is the control. Pregnant women identified as malnourished (MUAC <22.1cm) will receive Pusti Khadda daily, until they give birth. If the project produces positive results, the intervention will be rolled out in Bara-Alampur after 1 year.

Why are women not receiving Pusti Khada packets?

As part of this project, we will be collecting information to say whether Pusti Khada packets improve the health of the malnourished pregnant woman and her baby. Therefore we need to make comparisons between those who receive the Pusti Khada, and those who don't. Chatra was randomly selected to receive Pusti Khada and Bara-Alampur was randomly selected as the control. If positive results

are shown after one year, malnourished pregnant women in Bara-Alampur will also start receiving Pusti Khada.

Will financial help be given during delivery period?

World Vision does not offer cash to participants; however World Vision will work with the community to improve health care access and work with individuals to save money for critical time periods.

KEY MESSAGES FOR PREGNANT WOMEN

- Rice alone is not enough during pregnancy. During this period, your body requires additional nutrients for the development of your baby.
- Pregnant women need to increase their food intake.
- It is important to eat foods rich in energy (rice, potato), foods for fighting against disease (vegetables and fruits) and foods to make you strong and for body-building (milk, eggs and fish).
- No foods should be restricted during pregnancy (apart from alcohol and cigarettes)
- Pregnant women should eat at least three meals each day and include snacks everyday
- Typical diet should include: Breakfast – rice/bread, vegetable x2/fish/egg curry and lentils; Lunch rice/bread, vegetables x2/fish/egg curry and lentils; Dinner rice/bread, vegetable x2/fish/egg curry and lentils, 2x snacks each day (fruit, cake, chanachur, bread, egg, dohtbaht, peanuts, roasted pumpkin seeds)
- Rice fry and muri are not nutritious snacks
- Do not eat a low amount so that the pregnancy belly will be small and delivery easy. Mother and child will be unhealthy and delivery will not be easier.
- During pregnancy, women need to eat one extra meal per day.
- Pushti Khadda will provide you with extra energy which will help you from getting tired, and for your babies development.

- Pushti Khadda will assist with the development of your babies brain and intelligence
- Pushti Khadda will decrease the chance of your baby getting sick after birth as it will strengthen its immune system.
- Pushti Khadda will decrease the chance of your baby from developing childhood malnutrition.
- If you get sick during pregnancy you must visit you doctor (village facilitator can help refer you to medical doctor).
  Pusti Khadda will give you strength and help with a smooth delivery
- You must visit your doctor at least four times during pregnancy to ensure that you and your baby are healthy.

KEY MESSAGES FOR BREASTFEEDING WOMEN

- Women who are breastfeeding should continue to eat an increased amount of food
- Breastfeeding women should eat at least three meals each day and include snacks everyday
- Typical diet should include: Breakfast – rice/bread, vegetable x2/fish/egg curry and lentils; Lunch rice/bread, vegetables x2/fish/egg curry and lentils; Dinner rice/bread, vegetable x2/fish/egg curry and lentils, 2x snacks each day (fruit, cake, chanachur, bread, egg, dohtbaht, peanuts, roasted pumpkin seeds)
- Rice fry and muri are not nutritious snacks
- Breastfeeding women should try to eat one extra meal each day
- A mother should initiate breastfeeding within the first hour of birth
- Colostrum does not need to be discarded (it does not cause diarrhoea nor is it ‘dirty‘) It is important to feed your baby colostrum for their immune health
- Women should eat as soon as possible after delivery to regain their strength. There are no food restrictions
- Fresh fruits, vegetables and legumes can be given to the mother after delivery.

- Women should exclusively breastfeed their baby up to 6 months. No extra food or water is needed
- A mother who is angry or frightened can breastfeed.
- A mother with a common illness should breastfeed.
- A mother who is pregnant can breastfeed.
- Breast milk looks thin and blue, especially at the beginning of a feed.
- Mothers can still breastfeed even if she has been separated from her baby for some time.
- A mother who breastfeeds can take most medications (check with health care provider).
- HIV positive mothers should exclusively breastfeed
- A sick infant should breastfeed more frequently.
- A malnourished mother can produce enough breast milk to feed her infant.
- No foods should be restricted during lactation (apart from alcohol and cigarettes)
- Women working in the fields can express milk and store it in a clean cup at room temperature for up to 6 hours.

Nutritional knowledge questionnaire

Monthly meeting

Facilitators _____
Village_____
Date_____
Number of women who attended _____

Identify <u>two</u> food sources rich in vitamin A
(vitamin A comes from animal foods such as milk, egg yolk, liver and oily fish and dark green leafy vegetables and yellow/orange fruits/vegetables such as mango, papaya, carrot, pumpkin)

Identify <u>two</u> food sources rich in iron
(Iron is found in red meat, liver and dark green leafy vegetables)

Identify <u>one</u> food source rich in iodine
(The best source of iodine is iodised salt but also found in fish and shellfish from the sea)

Identify <u>two</u> attachment and positioning techniques when breastfeeding
(Attachment - *Wide mouth with plenty of areola, babys chin should touch the breast, More areola above the babys mouth than below, Babys lower lip is turned outwards.*
Positioning – Baby held close to mothers body, babies whole body supported, baby approaches breast)

Child Referral Form

REFERRAL FORM FOR MALNOURISHED CHILDREN

Date: ___/___/___

Name of Division: _____

Name of District: _____

Name of Upazila: _____

Name of village: _____

Name of child: _____ Sex of Child: (circle) MALE/FEMALE

Age of child: (months) |__|__| Name of caretaker: _____

Name of caretaker: _____

Child diagnosed with (state the condition): _____

Presence of oedema: (circle) YES/NO Degree of oedema: (circle) 1st/2nd/3rd/4th

REFERRAL FORM FOR SICK PREGNANT WOMAN

Date: ___/___/___

Name of Referred Institution: _____

Address of Referred Institution: _____

Name of Division: _____

Name of District: _____

Name of Upazila: _____

Name of village: _____

Name of Woman: _____

Age of Woman: (years) |__|__| Name of Husband: _____

Woman diagnosed with (state the condition): _____

Figure 1. Packaging developed for the supplementary food used in phase 3 of this research

Figure 2. Village Nutrition Volunteers debriefing during phase 2; feasibility study

Figure 3. Community Nutrition Supervisors; overseeing community nutrition volunteers; at the supplementary food production center

Figure 4. Food technologist training women for the production of the supplementary food

Appendix 7: Conference Abstracts

International

- World Public Health Nutrition Conference Rio, Brazil, 2012
    - Oral presentation – 'Improving emergency nutrition capacity in Timor Leste'
    - Oral presentation – 'Womens Dietary Diversity Scores among undernourished pregnant women in northern Bangladesh'.

National

- Dietetics Association of Australia, 2012 – Poster – 'Scaling up Efforts to Address Malnutrition in Humanitarian Emergencies and Disasters'.
- Nutrition Society of Australia, 2013 – Poster – 'effect of balanced protein energy supplementation in undernourished women on child growth in low income countries'.
- Public Health Association of Australia, 2013 – oral presentation 'Perceptions on nutrition by undernourished pregnant women living in northern Bangladesh'.

Australasian Medical Journal [AMJ 2013, 6, 11, 580-685]
Proceedings of the Nutrition Society of Australia (2013) 37

Poster Session 2: Thursday 5 December

Group 7 – Public Health

P078

Using new technology to assess individual dietary intake at remote communities

SC Liberato[1,2], J Brimblecombe[1]
[1] Menzies School of Health Research, Darwin, NT, Australia. [2] School of Population Health, Division of Health Sciences, University of South Australia, SA, Australia.

Background
In order to investigate the relationship between diet and diseases is important to assess dietary intake. The use of new technologies has been shown to improve dietary assessment.
Objective
Aim to test the feasibility and practicability of assessing dietary intake using new technologies at individual level.
Design
This cross-sectional study was conducted in a remote community. All people aged 18y or older with interest in nutrition were invited to participate in the study. Flyers were delivered to Health centres, food stores, shire, Community Development Employment Program, aged care and local employment services. Three community workers helped with the recruitment by inviting people at their houses. Participants were trained on dietary data intake methodology including practice in collecting dietary intake from a child using 4-day dietary records and taking pictures of, or video recording, all foods given to the child. Two research team members visited participants' house daily sometimes twice a day to support data collection. Nutritional analysis was performed using Foodworks.
Outcomes
Eleven people completed the training and eight collected dietary intake, five over four days and three during one day. A total of 113 photos and 48 movies were taken. The number of photos and videos taken by mothers over 4 days ranged from three to 62 and from one to 16, respectively according to the participant. The average of pictures and videos taken by participants was 14 and 8, respectively. In total, 88 meals were recalled and 40% of the meals had the image recorded. The percentage of meals recorded by participant decreased from 51% in the first day to 26% in the fourth day. Around AU$2000,00 per participant was spent. Estimates of individual usual dietary intake were acceptable when compared to the energy expenditure average.
Conclusion
Estimates of individual usual dietary intake and use of new technology was well accepted by participants, particularly for one day, but very expensive. The findings from this study provide insights into the development of an appropriate approach for measuring individual dietary intake in remote communities.
Source of funding
This work was supported in part by the Menzies Small grant.

P079

Balanced protein energy supplementation for undernourished pregnant women in low-income countries and child physical growth: a systematic review

BJ Stevens[1, 2], J Judd[1], P Buettner[1], K Watt[1] A Clough[1], J Brimblecombe[3]
[1] James Cook University, Townsville, QLD, Australia [2] World Vision International [3] Menzies Institute, Darwin, NT, Australia

Background
The effect of balanced protein energy supplementation in undernourished pregnant women is unclear. While systematic reviews to date have included studies from high, middle and low-income countries, country-specific sociopolitical factors are confounders.
Objective
Assess the effect of balanced protein energy supplementation in undernourished pregnant women from low-income countries on child growth.
Design
A systematic review of articles published in English (1970 to 2013) was conducted using articles retrieved via MEDLINE, Scopus, the Cochrane Register, and hand searching. Only experimental research analysing effects of balanced protein energy supplementation in undernourished pregnant women from low-income countries with physical growth as the primary outcome were included. Two reviewers independently assessed full text articles against inclusion criteria. Validity of eligible studies was ascertained using the Quality Assessment Tool for Quantitative Studies developed by the Effective Public Health Practice Project (EPHPP QAT). PROSPERO registration number: CRD42013005115
Outcomes
Seven studies met inclusion criteria (n=2367). All studies reported on birthweight, five studies reported on birth length and birth head circumference and two studies reported on longer-term growth. Standardised mean differences were calculated using random-effects model. Balanced protein energy supplementation significantly improved birth weight (7 RCTs, n= 2367; P=0.021, 95% CI, 0.03-0.38). No significant benefit was observed on birth length or birth head circumference. Impact of intervention could not be determined for longer- term physical growth as only two studies reported on longer-term growth.
Conclusion
Balanced protein energy supplementation targeting undernourished pregnant women in low-income countries has a positive effect on birth weight. Additional research is required in developing countries to identify impacts on longer-term infant growth.
Source of funding
Not applicable.


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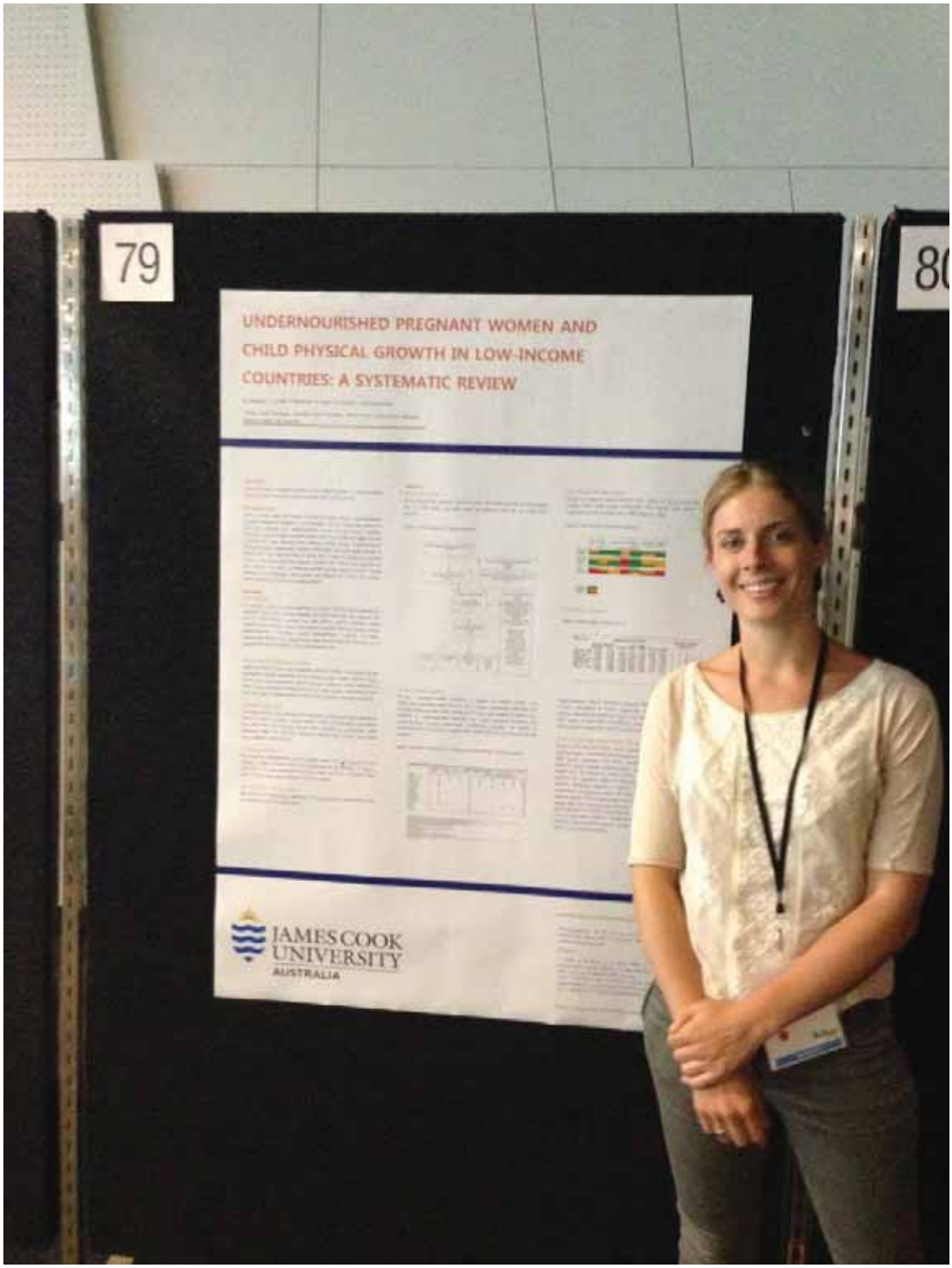
Abstracts
rates. This study monitored reformulation of Australian child-oriented food products (products marketed specifically to children) between 2009–2011.All child-oriented food products in a large supermarket were identified in 2009 and followed-up in 2011. Nutriere content data were collected at baseline and follow-up. Absolute and percentage change in energy, total fat, saturated fat, sugars, sodium and fibre was calculated. Two methods were used to assess the extent of reformulation: percentage change in single nutrients was assessed over time, and nutrient criteria were used to assess changes in overall healthiness of products over time. Of 120 products, 33% remained unchanged in nutrient composition from 2009–2011 and 67% underwent change. The proportions of positively and negatively reformulated products were similar for most nutrients surveyed, excluding sodium. Eighteen products (15%) were simultaneously positively and negatively reformulated for different nutrients. Using percentage change in nutrient content to assess reformulation, nearly half (n = 53) of all products were at least moderately reformulated and one third (n = 42) were substantially reformulated. The nutrient criteria method revealed 5 products (5%) were positively reformulated and none that had undergone negative reformulation. Positive and negative reformulation was observed to a similar extent among Australian child-oriented food products between 2009–2011, indicating little overall improvement in healthiness of child-oriented foods. This study highlights the need for comprehensive, targeted and standardised reformulation benchmarks to assess the extent of reformulation occurring in the food supply.
Contact author: Stephanie Savio – stephanie.savio@flinders.edu.au
162. ADDRESSING FOOD AND NUTRITION INSECURITY THROUGH ENHANCED COLLABORATIONS BETWEEN EMERGENCY FOOD RELIEF PROVIDERS
BROOKE SEARLE, REBECCA RAMSEY, DANIELLE GALLEGOS
Queensland University of Technology, Brisbane, QLD 4059, Australia
Food insecurity occurs when access to or availability of nutritious, safe and culturally-appropriate foods is compromised, or when such foods are unable to be accessed by socially-acceptable means. Food insecurity is associated with poor diet, obesity and chronic diseases such as dia-
230. SCALING UP EFFORTS TO ADDRESS MALNUTRITION IN HUMANITARIAN EMERGENCIES AND DISASTERS
BRIONY STEVENS
James Cook University, Townsville, QLD, Australia
Protecting the nutritional status of vulnerable groups affected by emergencies and complex disasters is a humanitarian right. A 2005 review, commissioned by the Inter-agency Standing Committee (IASC), identified that a lack of capacity in the humanitarian sector affected the quality and suitability of a humanitarian response and a humanitarian reform was introduced.
One initiative under the reform included the development of the cluster approach which consists of sectoral clusters which aim to strengthen coordination, response capacity, accountability and partnerships in a humanitarian response at a global and country level. In 2007, an in-depth nutrition in emergencies review, commissioned by the IASC Global Nutrition Cluster, identified two key nutrition in emergency (NiE) capacity gaps firstly, inadequate 'resident' capacity and secondly, a lack of nutritionists able to work within the complexities of emergencies. Those findings led to renewed efforts by UN agencies to ensure that nutrition is brought to a higher platform, both at a global and country level.
In 2010, RedR Australia supported these efforts through the deployment of emergency nutrition specialists to UN agencies. RedR Australia is a not-for-profit organisation which selects, trains, deploys and supports specialists deployed to humanitarian relief operations.
RedR Australia works with countries at the request of UN Agencies, often for an intensive period of one to six months. As part of RedR Australia's ongoing support to humanitarian operations worldwide, RedR is recruiting nutritionists with experience in emergencies to deploy to UN agencies, where requested.
Contact author: Briony Stevens – briony.stevens@my.jcu.edu.au
197. AN EVALUATION OF BEHAVIOUR, ATTITUDE, KNOWLEDGE AND BARRIERS TOWARDS A NUTRITION THERAPY PROTOCOL


79
UNDERNOURISHED PREGNANT WOMEN AND CHILD PHYSICAL GROWTH IN LOW-INCOME COUNTRIES: A SYSTEMATIC REVIEW
JAMES COOK UNIVERSITY
AUSTRALIA

Nutrition & Food Security (Delacombe) Chair: Heather Yeatman

4.00-4.15	**Health, Weight and Equity: Problem Representation in South Australia's Healthy Weight Policies - Louise Townend (WITHDRAWN)**
4.15-4.30	The impact of subsidised fruit and vegetables and mandatory folate-fortification on folate levels in Aboriginal children - Andrew Black
4.30-4.45	A 'Community of Practice' for public health nutritionists working with remote stores - Stacey Holden
4.45-5.00	Proving small stores can have a big impact: A qualitative process evaluation - Claire Palermo
5.00-5.15	The use of photovoice to identify maternal dietary consumption in rural Bangladesh - Briony Stevens
5.15-5.30	Food costs deter welfare dependent families' dietary choices: a population perspective - Christina Pollard
5.30-5.45	Public policy, food relief and food security in contemporary Australia - Rebecca Lindberg
5.45-6.00	Seasonal fresh food and a sense of place: Exploring farmers' markets in Sydney - Belinda Crawford

6.00-7.00pm **Combined conference welcome reception and Poster Session with Refreshments (Central Foyer)**

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