UNIVERSITEIT GENT

FACULTY OF BIOSCIENCE ENGINEERING

Kissa Bupopelo Martin Kulwa

Dietary strategies to improve feeding practices, dietary adequacy and growth of infants and young children in rural Tanzania

Thesis submitted in fulfilment of the requirements for the degree of Doctor (PhD) in Applied Biological Sciences

2016

"The ultimate measure of a man is not where he stands in moments of comfort and convenience, but where he stands at times of challenge and controversy."

Martin Luther King, Jr. (1929-1968)

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Bless the Lord oh my soul, and all that is within me, bless His Holy name (Psalm 103:1).

Kissa

Abbreviations

BMI	Body Mass Index
CHW	Community Health Workers
CONSORT	Consolidated Standards of Reporting Trials
ES	Effect Size
FAO	Food and Agriculture Organization of the United Nations
GMP	Growth Monitoring and Promotion
IYCF	Infant and Young Child Feeding
IYCN	Infant and Young Child Nutrition
LAZ	Length-for-age Z-scores
NBS	National Bureau of Statistics (of Tanzania)
PAHO	Pan American Health Organization
SD	Standard Deviation
TDHS	Tanzania Demographic Health Survey
UNICEF	United Nations Children's Fund
URT	United Republic of Tanzania
USD	United States Dollar, currency for the United States of America
VHW	Village Health Workers
vs.	versus, as compared to
WAZ	Weight-for-age Z-scores
WFP	World Food Programme (of the United Nations)
WHO	World Health Organization
WLZ	Weight-for-length Z-scores

Summary

Undernutrition continues to affect many children below the age of five years in low- and middle-income countries. Stunting, also commonly referred as linear growth faltering or retardation, is the most prevalent manifestation of undernutrition compared to wasting and underweight. A global reduction in the prevalence of undernutrition has been reported albeit regional variations. The number of stunted children is increasing steadily in sub-Saharan Africa. The 2010 Tanzania Demographic Health Survey showed unacceptably high levels of stunting, wasting and underweight among children below the age of five years; 42.0%, 4.8% and 15.8%, respectively. Children below the age of three years, children in rural areas and those living in the southern and central regions of the country were the most affected. Consequences of undernutrition during the formative years include poor growth, increased risk of and prolonged morbidity, mortality, delayed cognitive and motor development. Promotion of optimal feeding, health and growth during the first two years of life is a matter of immediate concern. Interventions to improve feeding and nutrition of infants during this period include promotion of breastfeeding, communication and education on complementary feeding behaviours, provision of food supplements, single and multiple micronutrients supplementation, reduction of diseases through appropriate hygiene practices, management and treatment of severe acute malnutrition. Reviews of previous interventions have reported that interventions with an educational component can effectively improve complementary feeding behaviours, dietary intake and child growth. There is limited information on the implementation and evaluation of evidence- and theory-based, culturally appropriate nutrition education interventions to improve diets and growth of rural infants in Tanzania.

The aim of this thesis was to: 1) characterise dietary and growth patterns of infants and young children living in rural Tanzania, and 2) develop and evaluate the effectiveness of a nutrition education package on feeding practices, dietary adequacy and growth of infants and young children in rural Tanzania. It was hypothesised that the nutrition education package would improve feeding practices, dietary adequacy and growth as compared to the routine health education given at health facilities. To accomplish these objectives, the research was organised into two studies: two cross-sectional studies to establish the nutrition- and health-related problems in a rural area and guide decisions on improvement, and an intervention study to improve dietary practices and growth.

A cross-sectional survey involving 496 infants (age 1-12 months) was conducted in six villages of Mpwapwa district in 2009 (**Chapter 2**). The study assessed feeding practices and nutritional status of children, and determined the macronutrient and selected micronutrient contents in commonly-consumed complementary meals. Implications for dietary adequacy and nutritional status of the studied children are reported. The same cohort of infants (n=374, age 9-20 months) was revisited

in 2010 to evaluate progress in their nutritional status after the first survey. Results of the 2009 survey showed that mean age of introduction of complementary foods (3.30±1.45) was earlier than the recommended age of six months. Porridge was the main complementary meal and the porridge samples contained relatively high water content, increasing the likelihood of reduced nutrient content. Mean number of meals consumed including snacks were lower than the age-specific World Health Organization recommendations. There was limited inclusion of nutrient-dense foods (e.g. legumes, animal-source foods, vegetables) in the meals. Small meal portion sizes, limited variety and the generally low nutrient content of meals increased the risk of not meeting the recommended nutrients intakes. Prevalence of stunting in 2009 and 2010 was 33.5% and 59.3%, respectively. Morbidity due to acute respiratory illness (ARI) was 63.9% in 2009 and 56.4% in 2010. Diarrhoea affected 48.4% children in 2009 and 36.4% in 2010. Overall prevalence of anaemia was 36.1% in 2009 and 36.7% in 2010. Results of the cross-sectional surveys demonstrated a need for a nutrition intervention to improve dietary practices, health and growth in infants and young children in rural Tanzania. While interventions to improve feeding, health and growth exist, it is imperative that they are contextualised to enhance feasibility and sustainability.

Intervention Mapping and Theory of Planned Behaviour provided systematic frameworks for the design, development and evaluation of a nutrition education package (**Chapter 3**). The package had three components: 1) education, counselling and cooking demonstration with mothers, 2) training of village health workers (VHW) to counsel mothers and family members during monthly home visits, and 3) supervision of the trained village health workers. Training and education materials were also developed for respective participants. A cluster randomised controlled trial was implemented for six months in Mpwapwa district to evaluate the effectiveness of the package. Eighteen villages were randomly allocated to either routine health education (control, n=9) or nutrition education package (intervention, n=9). Routine health education is a standard government health service for children below the age of five years, offered monthly by health staff at health facilities. It offers education to mothers during growth monitoring and immunisation contacts. The sessions are usually short (10-15 minutes) and focus on general health issues including child feeding, prevention of diseases such as malaria and importance of immunisations. Primary outcome was length-for-age Z-scores. Secondary outcomes included weight, weight-for-length Z-scores, intakes of energy, fat, iron and zinc from complementary foods, meal frequency and dietary diversity. A process evaluation was also carried out to provide insights into the nature of the processes leading to intervention effectiveness or ineffectiveness.

A total of 370 infants aged 6-7 months (control: n=186; intervention: n=184) participated in the intervention trial starting December 2014. Findings of the trial are presented in **Chapter 4**. At baseline, inadequate feeding practices and nutrient intake, morbidity, anaemia and poor growth were widespread. After intervention, mean change in feeding frequency was modestly higher in the intervention than control group (1.63 vs. 1.27, p=0.051). Mean change in dietary diversity was

significantly higher in intervention than control group (2.03 vs. 1.50, p=0.005). Infants in the intervention group had higher intakes of energy (+43.8 kcal, p=0.019) and fat (+2.7g, p=0.033) than infants in the control group. No effect was observed for iron and zinc intakes. The intervention resulted in significant mean change in length (0.47cm, 95% CI: 0.01, 0.92, p=0.043) and length-for-age Z-scores (0.20 Z-score, 95% CI: 0.29, 0.38, p=0.022) in intervention compared with the control group. The intervention had no differential effects on mean changes in weight, weight-for-length and weight-for-age Z-scores.

Chapter 5 presents results of the process evaluation. Fidelity, recruitment, reach, dose and contextual factors were reported for each package component. The package components and elements (training VHW, education and cooking demonstration with mothers, home visits, supervision of VHW) were implemented across the intervention villages as planned. The intervention was well received with good dose and was well accepted by VHW, mothers and their families. VHW knowledge on IYCF increased significantly during the two training sessions (1st session: +5.7-point, p<0.001; 2nd session: +4.1-point, p=0.003). Between midtrial and end of trial, the majority of mothers tried the promoted recipes at home (89.8% and 94.6%) and some tried all the recommended feeding and health practices (37.7% and 66.1%). Barriers to adoption of the recommended practices included high maternal workload, cultural beliefs on feeding choices and inadequate household income. **Chapter 6** discusses the implications of the findings and recommendations for further research.

In conclusion, this PhD research demonstrated that inadequate dietary practices and poor nutrition are consistently widespread in infants and young children in rural settings. Further, the nutrition education package adds to the evidence that practical nutrition education incorporating cooking demonstrations and regular home visits can improve feeding practices, dietary intake of macronutrients and growth, better than the routine health education delivered at health facilities. Child health status, socio-cultural and household factors played a significance role in influencing intervention outcomes. Barriers to intervention effects included high infant morbidity, high maternal workload, inadequate household income and mothers' habitual and cultural influences on feeding choices. The research calls for a review of routine health education for the delivery of quality nutrition services and improvement of child health services for reducing morbidity burden. There is also a need for joint strategies with other sectors (e.g. agriculture-livestock production, marketing-roads infrastructure, income generation initiatives) to address the underlying causes of child undernutrition.

Samenvatting (summary in Dutch)

Ondervoeding blijft een probleem voor veel kinderen onder de leeftijd van vijf jaar in landen met lage en middelhoge inkomens. Dwerggroei, ook bekend als vertraagde lineaire groei, is de meest voorkomende vorm van ondervoeding in vergelijking met acute ondervooeding (vermagering) en ondergewicht. Wereldwijd werd een globale daling van de prevalentie van ondervoeding vastgesteld zij het met regionale verschillen. Het aantal kinderen met groeiachterstand neemt gestaag toe in Afrika bezuiden de Sahara. Het Tanzaniaanse demografische gezondheidsonderzoek in 2010 bracht onaanvaardbare hoge niveaus aan het licht van dwerggroei, vermageringszucht en ondergewicht bij kinderen onder de leeftijd van vijf jaar; respectievelijk 42,0, 4,8 en 15,8 percent. Kinderen jonger dan drie jaar, wonende in de plattelandsgebieden en in de zuidelijke en centrale delen van het land werden het zwaarst getroffen. De gevolgen van ondervoeding tijdens de eerste levensjaren zijn onder meer slechte groei, verhoogd risico op een aanhoudende morbiditeit, mortaliteit, en vertraagde cognitieve en motorische ontwikkeling. Het bevorderen van een optimale voeding, gezondheid en groei tijdens de eerste twee levensjaren is een zaak van direct belang. Interventies om de voeding van zuigelingen te verbeteren gedurende deze periode omvatten promotie van borstvoeding, communicatie en voorlichting over aanvullende voeding, beschikbaarheid van voedingssupplementen, het toevoegen van enkelvoudige en meervoudige micronutriënten, vermindering van ziekten via passende hygiënepraktijken, beheer en behandeling van ernstige acute ondervoeding. Recensies van eerdere interventies hebben gemeld dat interventies met een educatieve component effectief het aanvullende voedingsgedrag, de voedselopname en de groei kunnen verbeteren. Er is slechts beperkte informatie beschikbaar over de uitvoering en evaluatie van de op bewijs- en theorie gebaseerde, van cultuur-sensitieve nutritionele voorlichtingsinterventies ter verbetering van de diëten en groei van de zuigelingen in de rurale gebieden van Tanzania.

Het doel van dit proefschrift was: 1) het in kaart brengen van de voedings- en groeipatronen van de zuigelingen en jonge kinderen woonachtig op het platteland van Tanzania en 2) het ontwikkelen en evalueren van de effectiviteit van een 'voedingsvoorlichting' pakket omtrent voedingspraktijken, nutritionele adequaatheid en groei van zuigelingen en jonge kinderen in het landelijke Tanzania. Er werd vertrokken van de hypothese dat het 'voedingsvoorlichting' pakket een betere impact zou hebben op het voedingspatroon, de nutritionele adequaatheid en de verbetering van de standaard gezondheidsvoorlichting welke gegeven wordt in de gezondheidscentra. Om deze objectieven te verwezenlijken, werd het onderzoek opgesplitst in twee studies: een eerste studie naar de voeding- en gezondheid gerelateerde problemen in een ruraal gebied om zo beslissingen voor verbetering van deze problemen op de juiste weg te helpen en een interventie studie ter verbetering van de voedingspraktijken en groei.

In 2009 werd een cross-sectioneel studie uitgevoerd onder 496 kinderen (leeftijd 1-12 maanden), wonende in zes dorpen van het Mpwapwa district in 2009 als onderdeel van de eerste studie (**hoofdstuk 2**). Het onderzoek beoordeelde de voedselpraktijken en voedingstoestand van de kinderen en analyseerde het macro- en micro nutriënten gehalte van de meest verbruikte aanvullende maaltijden. Implicaties voor de voedingsadequaatheid en voedingstoestand van de bestudeerde kinderen werden gerapporteerd. Dezelfde cohorte van zuigelingen (n=374, leeftijd 9-20 maanden) werd een tweede maal bezocht in 2010 om hun vooruitgang te meten inzake voedingstoestand sinds het eerste onderzoek. Uit de resultaten van het onderzoek in 2009 bleek dat de gemiddelde leeftijd waarop de aanvullende voedingsmiddelen (3,30±1,45) werden toegediend te vroeg was in vergelijking met de aanbevolen leeftijd van zes maanden. Pap was de belangrijkste aanvullende maaltijd en de monsters ervan hadden een relatief hoog watergehalte, waardoor de kans op verminderde nutriënten-inname verhoogde. Het gemiddeld aantal gebruikte maaltijden, inclusief de hapjes, lag lager dan de leeftijdsspecifieke, Wereldgezondheidsorganisatie aanbevelingen. He gebruik van nutriënt-rijke voedingsmiddelen (bijv. peulvruchten, dierlijke voedingsmiddelen, groenten) tijdens de maaltijden. Kleine portiegroottes, een beperkte variëteit en de over het algemeen lage nutriëntgehalten van de maaltijden verhoogt het risico van het niet voldoen aan de aanbevolen nutriënten opname. De prevalentie van dwerggroei in 2009 en 2010 was respectievelijk 33,5% en 59,3%. De morbiditeit ten gevolge van acute respiratoire aandoeningen was 63,9% in 2009 en 56,4% in 2010. 48,4% van de kinderen in 2009 en 36,4% in 2010 hadden last van diarree. De algemene prevalentie van anemie was 36,1% in 2009 en 36,7% in 2010. Uit de resultaten van de cross-sectionele onderzoeken blijkt dat er een dringende nood is aan een voedingsinterventie ter verbetering de voedings- praktijken, gezondheid en groei bij zuigelingen en jonge kinderen wonend in de rurale gebieden van Tanzania. Alhoewel er interventies ter verbetering van de voeding, gezondheid en groei al lopende zijn, blijkt het noodzakelijk dat zij in hun contextx geplaats worden om zo de haalbaarheid en duurzaamheid te versterken.

Het in kaart brengen van de interventie en de theorie van gepland gedrag, verschaften systematische kaders voor het opstellen van een ontwerp, de ontwikkeling en de evaluatie van een voedingsopleidingspakket (**hoofdstuk 3**). Het pakket bevatte drie onderdelen: 1) de scholing, advisering en kookdemonstratie met moeders, 2) trainingen voor gezondheidswerkers in het dorp voor adviseren van moeders en familieleden tijdens maandelijkse huisbezoeken, en 3) supervisie van de opgeleide dorp gezondheidswerkers. Aangepaste training- en scholingsmaterialen werden dan ook ontwikkeld voor de respectieve deelnemers. Gedurende zes maanden werd een controle test met een gerandomiseerd cluster van deelnemers uitgevoerd in Mpwapwa district, ter evaluatie van de doeltreffendheid van het pakket. 18 dorpen, lukraak geselecteerd, werden betrokken ofwel in de gebruikelijke (routine) gezondheidsscholing (controle groep, n=9), ofwel in een interventie met het voedingsscholingspakket (interventie groep, n=9). Routine gezondheidsscholing, maandelijks aangeboden door de gezondheidswerkers in de

gezondheidscentra, behoort tot de standard gezondheidszorg activiteiten voor kinderen beneden de leeftijd van vijf jaar. Het biedt scholing aan voor moeders tijdens groei monitoring en immunisering contactmomenten. De sessies zijn meestal kort (10-15 minuten) en concentreren zich op algemene gezondheidsproblemen zoals voeding, preventie van ziektes zoals malaria en het belang van vaccinaties. Het hoofdresultaat van deze sessies was de Z-scores van lengte-voor-leeftijd. Secundaire uitkomsten waren gewicht, Z-scores van gewicht-voor-lengte, inname van energie, vet, ijzer en zink uit aanvullende voedingsmiddelen, frequentie van maaltijden, en diversiteit in diëten. Procesevaluatie heeft ook plaatsgevonden om inzicht te bieden in de aard van de processen die leiden tot de effectiviteit van de interventie.

Een totaal van 370 zuigelingen van 6-7 maanden oud (controle: n=186; interventie: n=184) hebben deelgenomen aan het onderzoek van de interventie die in december 2014 begon. De bevindingen van het onderzoek worden besproken in **hoofdstuk 4**. Voor de start van de interventie waren problemen als inadequate voedingsgewoontes en inname van voedingsstoffen, morbiditeit, anemie en groeiachterstand wijdverspreid. Na de interventie, was de gemiddelde wijziging in voedingsfrequentie lichtjes hoger in de interventiegroep in de controlegroep (1,63 vs. 1,27, p=0,051). De gemiddelde wijziging in diversiteit van de voeding was significant hoger in de interventie- dan in de controlegroep (2,03 vs. 1,50, p=0,005). Zuigelingen in de interventiegroep verbruikten meer energie (+43,8 kcal, p=0,019) en vet (+2,7 g, p=0,033) dan zuigelingen in de controlegroep. Geen enkel effect werd waargenomen voor de inname van ijzer en zink. De interventie leidde tot een significante gemiddelde wijziging in de lengte (+ 0,47 cm, 95% CI: 0,01, 0,92, p=0,043) en de Z-scores voor lengte-voor-leeftijd (0,20 Z-score, 95% CI: 0,29, 0,38, p=0,022) in de interventiegroep versus de controlegroep. De interventie had geen differentiële effecten op de gemiddelde wijzigingen in gewicht, gewicht-voor-lengte en gewicht-voor-leeftijd Z-scores.

Hoofdstuk 5 toont de resultaten van de procesevaluatie. Trouw, rekrutering, bereik, dosis en context gebonden factoren werden besproken voor elk onderdeel van het pakket. De onderdelen en elementen van het pakket (het opleiden van degezondheidswerkers in het dorp, voorlichtingvan en kookdemonstraties met moeders, huisbezoeken, supervisie van degezondheidswerkers in het dorp) werden overeenkomstig de planning uitgevoerd in de interventiedorpen. De interventie werd goed ontvangen en werd goed geaccepteerd zowel door de gezondheidswerkers in het dorp, als de moeders en hun gezinnen. De kennis van de gezondheidswerkers in het dorp over voeding voor zuigelingen en jonge kinderen is aanzienlijk toegenomen tijdens twee opleidingssessies (1e sessie: + 5,7-punt, p<0,001; 2e sessie: + 4,1-punt, p=0,003). Halfweg en op het het einde van het onderzoek, had de meerderheid van de moeders de aanbevolen recepten thuis geprobeerd (89,8% en 94,6%). Sommigen probeerden zelfs alle aanbevolen voeding- en gezondheidspraktijken (37,7% en 66,1%). Barrières voor het stipt volgen van de aanbevolen praktijken werden onder andere de hoge werklast van de moeders, culturele

opvattingen over voedingskeuzes en het ontoereikend gezinsinkomen. **Hoofdstuk 6** bespreekt de gevolgen van de bevindingen en aanbevelingen voor verder onderzoek.

Tot slot, dit PhD onderzoek heeft aangetoond dat inadequate voedingsgewoonten en slechte voeding consistent en wijdverspreid zijn bij zuigelingen en jonge kinderen op het platteland. Verder werd bewezen dat een praktisch, nutritioneel voorlichtingspakket (met daarin kookdemonstraties en regelmatige huisbezoeken) een bijdrage kan leveren voor betere resultaten op vlak van sommige voedingsgewoonten, de inname van macro-nutriënten en groei in vergelijking met de routine gezondheidsvoorlichting gegeven in de gezondheidscentra. De gezondheidsstatus van het kind, de kenmerken of gedragingen van hun moeders en huishoudens spelen een significante rol in het beïnvloeden van de interventie uitkomsten. De belangrijkste barrières voor betere interventie-uitkomsten zijn: de hoge morbidtiet bij zuigelingen, de hoge werklast van hun moeders, ontoereikend inkomen van het gezin, en moeders gewoonte- en culturele invloed op de keuze van de dieetsamenstelling. Dit onderzoek dringt aan op een verbetering van de huidige standaard gezondheidsvoorlichting met het oog op het leveren van kwaliteitsvolle voedingsdiensten en het verbeteren van de gezondheidsdiensten voor kinderen om zo de morbiditeitsproblematiek bij kinderen te verminderen. Het pleit ook voor de noodzaak van gezamenlijke strategieën met andere sectoren (bijvoorbeeld landbouw-veeteelt, marketing-wegeninfrastructuur, inkomsten generende initiatieven) om zo de onderliggende oorzaken van ondervoeding van kinderen aan te pakken.

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Chapter 1. General introduction and outline of thesis

1.1 Understanding the problem of growth faltering

Human growth varies in the timing of critical periods (i.e. infancy, childhood) within the whole pattern of growth, as well as in the magnitude and rate of change coincident with the period (1). A high growth rate is observed from foetal life to infancy, followed by slow deceleration up to puberty. Puberty starts with an increased rate of growth. After peak height velocity has been reached a deceleration is noted until growth ceases (2). These processes are variable within a single child and between different children of the same or opposite sexes (1). The growth process is under the control of the endocrine system. Hormone-binding proteins, growth factors and their binding proteins, as well as the stage of maturity, quantity of the hormone and growth factor receptors on the target cells play a critical role (3). Some limitation is imposed on an individual's maximum height by genetic imprinting in very early development (4). In addition to foetal, maternal and placental characteristics, environmental factors contribute to growth faltering. Environmental factors such as parents' illiteracy, overcrowding, poor hygiene, childhood morbidity, a high disease load, meals of inadequate nutrients and contaminated foods have been linked to the faltering process (3, 5). High infection rates in the first year of life have been associated with post-neonatal mortality in developing countries (6). Infections damage the gastro-intestinal mucosa, leading to malabsorption and increased permeability to antigens and bacteria. The systemic effects of infections, mediated by cytokines, result in extra losses of nutrients (7). Adverse political instability, civil wars and social unrest have also been linked to high prevalence of growth faltering through disruption of livelihood activities such as crop production; which in turn reduce availability and accessibility to food.

Longitudinal studies have shown that growth faltering commences during the intrauterine period and extends to postnatal life (8-12). Growth faltering during the postnatal period is commonly assessed using physiological growth, body weight and length; and classified using growth references or standards of which the 2006 WHO Child Growth Standards are the most current in use (13). Length is measured in supine position for children younger than 24 months-old whereas height is measured while standing for children aged 24 months or older. The classification compares each child's value to that of the WHO reference child of the same age and sex. Children falling two standard deviations (SD or Z-scores) below the population median value are categorised as either too short relative to age (i.e. low length- or height-for-age Z-scores), having low weight relative to length or height (i.e. low weight-for-length or weight-for-height Z-scores) or having low weight relative to age (i.e. low weight-for-age Z-scores). Children falling three standard deviations below the population median value in any of these indices are categorised as severely stunted, severely wasted or severely underweight. These indices are commonly used to describe the growth as well as the nutritional status indicators: stunting, wasting and underweight, respectively, both at the individual and population level (14). Under field conditions and in some surveillance programmes in low income countries, weight is more frequently used to monitor growth than is length or height, because of ease of measurement. It is usually plotted against age

on the child's health clinic card. Notwithstanding its usefulness for rapid detection of growth failure, underweight is a composite indicator which does not distinguish between stunting and wasting (15). Other growth indices which are available but not commonly used are body mass index-for-age, head circumference-for-age, arm circumference-for-age, subscapular skinfold-for-age and triceps skinfold-for-age (13).

Undernutrition and frequent illnesses during childhood underlies most of the stunting, wasting and underweight prevalence globally. Stunting captures more prolonged or chronic exposure to undernutrition and repeated illnesses, whereas wasting captures recent inadequacies, although chronic undernutrition or illness can also cause this condition. Deficiencies of micronutrients such as vitamin A, iron, iodine, zinc, folic acid, and vitamin B_{12} often co-exist with stunting and wasting. These deficiencies manifest as reduced immunity, night blindness, reduced learning ability, fatigue, pallor and goitre (14).

1.1.1 Global and national burden of stunting, wasting and underweight

Undernutrition continues to affect many children below the age of five years in low-income countries (16-19). Stunting, also commonly referred as linear growth faltering or retardation, is the most prevalent manifestation of undernutrition globally as compared to wasting and underweight. In 2015, there were 159 million children who are stunted and 50 million wasted (19). Although stunting is more widespread than wasting and underweight (18-20), their co-existence with micronutrient deficiencies and morbidity in deprived environments increase the vulnerability to poor health and even mortality. A global reduction in the prevalence of undernutrition has been reported (19). Between 1990 and 2014, prevalence of stunting in children below the age of five years declined from 39.6% to 23.8%. Similarly, underweight prevalence decreased from 25% to 15% between 1990 and 2013. The number of wasted children also decreased from an estimated 58 million in 1990 to 52 million in 2011, and further to 50 million in 2014. Africa has reported a smaller relative decrease in prevalence of stunting as compared to Southern and South-eastern Asia (42.3% to 32.0% vs. 47.6% to 25.1%). Despite the trend towards reduction in undernutrition, stunting remains a major public health problem in sub-Saharan Africa. The number of stunted children has steadily increased, from 44.8 million in 1990 to 57.3 million in 2014 (19, 21). The 1990-2020 nutrition projections showed that if the current trend in Africa continues, not much improvement is anticipated for the 2010-2020 period. Given population growth, this translates into increasing numbers of stunted children (20).

High rates of stunting have also been documented in the Tanzania Demographic and Health Surveys (TDHS). Prevalence of stunting among children below the age of five years was 42% in the 2010 national survey (22). The prevalence increased with age, from 18.3% among infants below the age of 6 months to 55.0% among those aged 18-23 months-old, then declining to 38.9% at 48-59 months-old. Highest stunting rates were found among children residing in rural areas (44.5%)

as compared with those residing in urban areas (31.5%). Children living in the southern highlands, central and southern regions of the country had the highest stunting rates compared to those residing in other regions (46-51% vs. 31-43%). Prevalence of wasting and underweight among children below the age of five years also remain at unacceptable levels, 4.8% and 15.8%, respectively (22). Before the new 2006 WHO Child Growth Standards replaced the old National Center for Health Statistics/World Health Organization international growth reference, prevalence of stunting was equally high; 42.6% in 1992, 43.4% in 1996, 43.8% in 1999 and 37.7% in 2004-2005 (22, 23).

1.1.2 Consequences of undernutrition, stunting and wasting

Literature has shown strong evidence that undernutrition has immediate and long-term consequences on health and development (18, 24). The immediate consequences of undernutrition during the early years include poor growth (commonly manifesting as stunting or wasting), increased risk of and prolonged morbidity, mortality, delayed cognitive and motor development (18, 24-27). The increased risks of death and disease and their individual association with wasting and stunting have been documented (17, 28, 29). Both stunting and wasting are associated with increased risk of mortality, which increases progressively with the degree of the deficit (30-32). McDonald and colleagues (29) have estimated that a moderately stunted child was 2.3 times, and the severely stunted child 5.5 times more likely to die than the non-stunted child. They also estimated that a moderately wasted child was 3.4 times, and a severely wasted child 11.6 times more likely to die than the non-wasted child. A child who was both stunted and wasted was 12.3 times more likely to die (29, 30). Evidence also suggests that episodes of wasting negatively affect stunting, undermining child growth and development (30). Stunting and wasting have been documented to also share other important health implications. Wasting leads to reduced immune function and in some cases mucosal damage lowering resistance to colonisation and invasion by pathogens (33, 34). Stunting has been found to be associated with heightened risk of death from infectious diseases, particularly diarrhoea, pneumonia and measles (17).

Concurrent short-term consequences include economic burden related to increased health expenditures and the opportunity costs incurred in caring for sick children (18, 24-27). In the long-term, stunting has been linked to poor schooling performance and learning capacity, poor intellectual performance, decreased work capacity and productivity and reduced overall economic productivity (18, 24, 35, 36). These consequences have been documented to extend into adulthood, creating an intergenerational cycle of poverty and reduced human capital (24, 37). Children born to stunted parents were themselves at increased risk of shorter adult height, lower cognitive and developmental quotients, poor reproductive outcomes and greater risk of poor health during adolescence and adulthood (24, 38). Women who were themselves stunted during early childhood tended to have stunted offspring or offspring of lower birthweight (15). These

effects highlight the importance of investing in healthy growth, especially in environment characterised by a high burden of infectious diseases and a low-resources health care system (39).

1.1.3 Causes and risk factors for stunting and wasting during the postnatal period

Much has been done to improve the understanding of causes and risk factors for stunting and wasting (18, 40). Causes of childhood growth faltering are multifactorial, and foetal growth restriction has been identified as an important contributor to stunting and wasting (18). Cross-sectional and longitudinal studies focusing on children below the age of five years have shown other determinants of optimum growth and development, to include immediate, underlying (or proximal) and basic factors operating at different levels of causation (41). Immediate causes include inadequate feeding practices to support the rapid growth and development, infectious diseases and their interactions. Political, economic and social systems operate as basic causes at the national level, whereas underlying factors such as food insecurity, maternal factors, inadequate care, poor access to health care, unsafe food and water and poor hygiene and sanitation services play a crucial role at the household and family levels (41, 42).

Factors that contribute to stunted growth and development include inadequate infant and young child feeding practices (limited in quantity, quality, variety); infectious diseases (depending on severity, duration, recurrence) and subclinical infections resulting from poor access to healthcare, hygiene and sanitation and poor maternal health and nutrition (31). Other factors include household poverty, food insecurity, caregiver neglect, non-responsive feeding practices and inadequate child stimulation. The main underlying causes of wasting include poor access to appropriate, timely and affordable health care, inadequate feeding practices (e.g. exclusive breastfeeding, low quantity and quality of complementary food) and care, household food insecurity and lack of a sanitary environment, including inadequate access to safe water, sanitation and hygiene services (32).

Although stunting and wasting appear to have similar causal factors, these factors overlap and interact to compromise growth differently and the contribution of the different factors can vary widely between contexts (40, 42). The use of the 2006 WHO growth standards rather than the older 1976 WHO/National Centre for Health Statistics (NCHS) reference has changed the overall prevalence, prevalence by age and interpretation of causes of stunting and wasting (40, 43, 44). Recognising the importance of these discrepancies and the need to appraise contextual variations between stunting and wasting, researchers are revisiting the data for proper interpretation.

In Tanzania, recent analysis of the 2010 TDHS have identified risk factors for stunting among children aged 0-23 months and those aged 0-59 months (45). Risk factors for being stunted in children below the age of two years included mothers having a primary education or lower, mothers' age below 20 or above 40 years at child birth, being a male child, perception that the

child was very small at birth and using unprotected source of drinking water. Risk factors for being stunted in children below the age of five years included mothers having a primary education or lower, belonging to a poor wealth index, mother being underweight (BMI below 18.5 kg/m^3), child not breastfeeding, being a male child, maternal perception that a child was very small at birth and using unprotected source of drinking water. The risk of severe stunting among children below the age of five years was significantly higher in male children, children whose mothers and their partners had a primary education level or lower, children delivered by a non-health professional (e.g. traditional birth attendant), mothers being underweight (BMI below 18.5 kg/m^3), mother perceiving the child was very small at birth and using unprotected source of drinking water (45). Another analysis of the 2010 TDHS found stunting and wasting to be significantly associated with mother's educational level (46). Higher levels of maternal education reduced the odds of child stunting and wasting. The threshold level of maternal education associated with reduced prevalence of stunting was more than ten years of schooling whereas the threshold level for wasting was five to seven years of education.

Previous and recent studies carried out in different parts of the country have found association between stunting and low birth weight, malaria, maternal underweight and low income (47); low maternal education and child's age above 24 months (48); younger mother, younger head of household and low income (49); and mothers spending more days farming during the agricultural season (50). These findings continue to confirm the need to scale up interventions before, during and after pregnancy and the preschool years.

1.2 Interventions to improve growth of infants and young children

The economic rationale for investing in young children goes beyond improving quality of life during early childhood. It hinges on the principle that the benefits of these investments persist into school age and beyond (51). The period during pregnancy and from birth to two years has been recognised as a critical window for the promotion of optimal growth, health, and behavioural development (18). Interventions which address this critical window include those that improve maternal nutrition, prevent neonatal morbidity and mortality and promote health and growth, both during early and late infancy.

Interventions which address maternal nutrition and birth outcomes (e.g. anaemia, small-for-gestational age, neonatal mortality) have included micronutrients supplementation (multiple, two or single nutrients), food or beverage supplementation with balanced energy-protein (protein providing less than 25% of the total energy content), nutritional education and advice, and food vouchers. Interventions addressing disease prevention and treatment during pregnancy includes malaria prophylaxis and prevention (i.e. insecticide treated bednets), deworming and screening and treatment of infectious diseases (e.g. HIV). Evidence on intervention effectiveness is variable; depending on context, study population, composition of supplements, co-supplementation of

macronutrient and micronutrients and outcome studied (52, 53). Interventions involving multiple micronutrients supplementation were associated with a significant reduction in small-for-gestational age (SGA) births in comparison with iron-folate administration. The authors suggested that the multiple micronutrient supplementations to address maternal anaemia and SGA, must be accompanied by the provision of skilled care at delivery and health facility births to offset potential increase in the risk of obstructed labour and birth asphyxia (53).

Interventions for neonates aim to increase breastfeeding and improve care of preterm and SGA infants (18). These include delayed cord clamping, vitamin K administration (largely restricted to births in health facilities) to prevent bleeding, vitamin A supplementation, and baby-friendly hospital initiatives (BFHI) including a Kangaroo mother care approach. The Kangaroo mother care has been defined as the early skin-to-skin contact between mother and baby at birth or soon thereafter, early initiation and continued breastfeeding, parental support and early discharge from hospital (54). Delayed cord clamping (i.e. allowing continued blood flow from the placenta to the baby for a longer duration) in term neonates led to significant increase in newborn haemoglobin and serum ferritin concentration at six months of age and lower risk of complications after birth. Although vitamin K administration is associated with reduced clinical bleeding at 1–7 days of life, there is insufficient or variable evidence of public health significance, particularly in low- and middle-income countries or population-based programmes (18). A review of five studies showed a 14% significant reduction in the risk of infant mortality at six months in neonates supplemented with vitamin A compared to control (52). A review of 16 trials conducted in health facilities to evaluate the effect of Kangaroo mother care in preterm neonates reported a 40% reduction in the risk of mortality, a 58% reduction in hospital-acquired infections or sepsis, and increase in some measures of infant growth and breastfeeding (55). Although Kangaroo mother care might also beuseful for home deliveries, there is not yet evidence of effectiveness in community settings.

Exclusive breastfeeding (EBF) during the first six months promotes growth during early infancy and WHO recommends exclusively breastfeeding for the first six months of life to achieve optimal growth, development and health (56). Breast milk during infancy has a significant positive impact on child growth and development and decreases the risk for many acute and chronic diseases, including infections such as diarrhoea and respiratory tract infections during infancy (57, 58). A review of 53 interventions to promote breastfeeding have demonstrated a significant 43% increase in exclusive breastfeeding and any breastfeeding rates at 4-6 weeks and at 6 months (58). A relatively greater impact in EBF rates at 4-6 weeks postpartum was reported in developing countries than in the developed countries, 89% versus 20%, respectively. Incidence of EBF at six months increased significantly, six times in developing countries and 1.3 times in developed countries. Breastfeeding interventions included in the review involved: 1) formal curriculum or structured education (one-to-one or group sessions) directed at mothers or other family members; 2) professional support within health system (BFHI implementation at mass level,

training of health professionals, individual support during hospital stay or outpatient clinics, social support from health professionals [home visits, telephone]); and 3) social support by peers or lay persons (home visits, telephone).

The afore-mentioned interventions have demonstrated their beneficial effects during the first part of the critical window of opportunity (i.e. pregnancy, at birth, early infancy). The fact that they can feasibly be conducted in developing countries setting provides sufficient justification for large scale programming and political commitment. The importance of addressing the remaining part of the continuum (i.e. infancy and early childhood) is critical to the overall child health and survival. The largest part of the critical window has been reported to be the period of transition from exclusive breastfeeding to consuming a wide range of foods in addition to breast milk, commonly from 6 to 24 months (59). This transition period is commonly referred to as complementary feeding period. Complementary feeding refers to the timely introduction of safe and nutritious foods in addition to continued breastfeeding (56). It is a complex set of behaviours, comprising timing of introduction, food choices and dietary diversity, preparation methods, quantity, feeding frequency, responsiveness to infant cues, and safe preparation and storage of foods. Each behaviour has context-specific barriers, making recommendations for behaviour change difficult to apply as a 'one package fits all' model (60). The complementary feeding period is critical in developing countries because stunting, micronutrient deficiencies and common childhood illnesses also peak during this period (61). Infants and young children are particularly vulnerable due to increased nutrient needs relative to intake coupled with limited quality and quantity of complementary foods (26, 60, 62).

1.3 Energy and nutritional needs during the complementary feeding period

Breast milk intake continues to make a substantial contribution to the energy and nutrient intakes of infants and young children in developing countries after the age of 6 months. Total daily average energy requirements for healthy children are 615 kcal at 6-8 months, 686 kcal at 9-11 months, and 894 kcal at 12-23 months of age (59). In developing countries, the average expected energy intake from complementary foods is approximately 200 kcal at 6-8 months, 300 kcal at 9-11 months and 550 kcal at 12-23 months of age (26, 63). These values represent 33%, 45%, and 61% of total energy needs, respectively. Achieving these intakes requires that both feeding frequency and energy density of the foods be adequate. Other factors that may influence amounts consumed include child's appetite, caregiver feeding behaviours, and characteristics of the diet, which may include palatability (taste, flavour, consistency), density of nutrients relative to energy, bioavailability of micronutrients and overall dietary patterns (59, 62).

Amount of protein needed from complementary foods increases from 2 g/day at 6-8 months to 5-6 g/day at 12-23 months. The percentage of energy from fat in complementary foods that would be needed to achieve a level of 30-45% of energy from fat in the total diet depends on the level of

breast milk intake and the fat content of the breast milk (59). Breast milk is usually rich in fat, approximately 30-50% of energy (62). Infants in developing countries who consume average amount of breast milk with a normal fat concentration of 38 g/L require 0-34% at 6-8 months, 5-38% at 9-11 months and 17-42% at 12-23 months of energy from fat in complementary foods (26). If breast milk intake is high (609 kcal/d at 6-8 mo, 601 kcal/d at 9-11 mo, and 602 kcal/d at 12-23 mo), no additional fat from complementary foods is needed (26). To achieve at least 30% of energy from fat in the total diet, the amount of fat needed from complementary foods is zero at 6-8 months, approximately 3 g/day at 9-11 months and 9-13 g/day at 12-23 months, assuming average breast milk intake of 413 kcal/d (62). The quality of the fat is equally important since good sources of dietary fat (e.g. from fish, eggs, liver, groundnut paste, vegetable oil) also supply fat-soluble vitamins and essential fatty acids.

Because of the rapid rate of growth and development during infancy, micronutrient needs are high during the first 2 years of life. The amount of iron provided by breast milk is relatively low, approximately 0.2 mg/day, with the net amount needed from other sources being 9-10 mg/day at 6-8 months and 5-7 mg/day at 12-24 months (59, 63). The percentage of the recommended nutrient intake needed from complementary foods varies widely. This depends on the concentration of a nutrient in breast milk and its bioavailability at the intestinal level. Nutrients for which at least 75% must come from foods include iron (97-98%), zinc (80-87%) and vitamin B_6 (80-90%) (62). Because the amount of iron and zinc needed from complementary foods is high relative to the usual content of such foods, iron and zinc are usually the most limiting nutrients (59, 63, 64). Thus, complementary diets need to contain foods rich in these nutrients or be fortified. The WHO and FAO recommended iron intake of 9.3 mg/day at 6-12 months (65) while the United States of America recommended 11 mg/day at 7-12 months (66), assuming 10% bioavailability from complementary foods. Iron requirements range from 5.8 mg/day at 12-24 months (65) to 7 mg/day at 1-3 years (66). Children aged 6-8, 9-11, and 12-23 months would require foods with iron contents of at least 4.5, 3.0 and 1.0 mg per 100 kcal, respectively (59).

As is the case for iron, amount of zinc provided by breast milk is relatively low, 0.4 to 0.6 mg/day; with the remainder (3.5-3.7 mg/day) needed from other sources (59, 63). Recommendation for zinc intake as described by WHO and FAO (65), assuming moderate bioavailability, is 4.1 mg/day at 7-24 months of age. Children aged 6-8, 9-11, and 12-23 months would require foods with zinc contents of at least 1.6, 1.1, and 0.6 mg per 100 kcal, respectively (59).

Meals of infants and young children in developing countries are predominantly plant-based. The meals present great challenges in ensuring energy and nutrients density and adequate intakes. Porridge, the most common complementary meal, is made from plain cereals and starchy roots and tubers. Porridge and other cereal-based foods are thinly-prepared and are infrequently made with oil, fat or oilseeds. The meals also lack nutrient-dense foods such as animal-source foods and

legumes. This reduces the energy and nutrient density of the meals; making infants at increased risk of not meeting their nutritional requirements. Such inadequacies are further exacerbated if infants receive very few feedings per day (64). Other dietary-related challenges in plant foods include the presence of food-inherent organic components (e.g. phytate, polyphenols), and their interactions with nutrients (67). The organic components have received significant attention, particularly in complementary feeding, because they form insoluble complexes with some micronutrients (e.g. iron, zinc, calcium) at the physiological pH conditions of the small intestine, thus making them unavailable for absorption and re-absorption of the endogenously-excreted micronutrients (67). Household strategies to reduce the content or counteract the inhibiting effects of the components on micronutrients bioavailability include germination, soaking, microbial fermentation and roasting; and they have been tried in developing countries (68-70).

1.4 Complementary feeding interventions

Previous complementary feeding interventions were largely micronutrient (multiple, two or single nutrient) and food (or beverage) supplementation. With increased understanding of the risk factors, these interventions were complemented with other strategies. As stunting is increasingly becoming the focus of global efforts, much has been done to improve the understanding of the feasible and effective interventions to address stunting and other manifestations of undernutrition (71-73). Interventions during the complementary feeding period include promotion of breastfeeding; strategies to promote complementary feeding with or without provision of food supplements; and single and multiple micronutrients supplementation. Others include reduction of diseases by promoting appropriate hygiene practices; management and treatment of severe acute malnutrition; and general supportive strategies to improve family and community nutrition. Indicators for measuring complementary feeding practices and compare progress across countries are present (74) and there is a growing body of scientific basis for efficacy and effectiveness of various interventions and strategies (60, 75-77). Reviews of interventions conducted in developing countries demonstrated a wide use of a combination of strategies. These included supplementary feeding with or without micronutrients fortification, health services improvement, culturally-appropriate group nutrition education, interpersonal counselling or communication, home visits, and mass media.

1.4.1 Interventions to improve feeding practices, food and recipes, dietary intakes and growth

Interventions to improve feeding practices and dietary intakes were reviewed by Caulfield and colleagues in 1999 (75). This was the first review on complementary feeding interventions. They included five trials and 16 programmes conducted between 1970 and 1997 in 14 developing countries. These interventions were developed after formative research, which included 1) ethnographic studies on health and nutrition benefits and practices, 2) assessment of existing diets, practices, potential for improvement and obstacles, 3) trials of new feeding practices, feasible alternatives and reactions to new products and behaviours, and 4) development of overall

strategies based on findings from steps 1 to 4. None of the interventions reported underlying theories to guide on intervention development. The interventions varied with respect to: 1) approach (food-beverage supplementation, feeding advice, or both); 2) types of foods and drinks offered (milk-based drinks, semi-solid/solid snacks); 3) delivery mechanisms (ready-to-eat foods, processed blends, raw ingredients); 4) study population (age at the beginning of interventions [birth to 9 months]); and 5) baseline nutritional status (apparently healthy to undernourished); 6) duration (3 months to 3 years); and 7) number of children (70 to 200). They also varied in objectives (primary outcomes [growth, morbidity, child development, micronutrient intake, micronutrient status]); and evaluation of outcomes (pre-post or post alone designs, participants vs. non-participants in a programme, matching communities at baseline and pre-post design). Whereas delivery of and compliance to the trials were tightly controlled and small in scale, the programmes were large in scale and implemented mostly as growth monitoring initiatives (75). A variety of communication approaches were used by each programme to impart messages: mass media (songs, instructional videos, drama, radio messages, mobile loud speakers); printed materials (recipe booklets, calendar with recipes, leaflets, posters, feeding guides, counselling cards); training community health workers (CHW); one-on-one counselling between CHW and mothers; mothers' support groups, lactation and cooking demonstrations. Among the five trials, one used an educational approach where feeding advice and cooking demonstrations were provided to mothers, and this was conducted in Bangladesh (78).

Results of the five trials showed that increasing intakes of complementary foods is an efficacious approach to reducing child malnutrition. Energy intake from complementary foods increased by 65 - 300 kcal/day and growth improved in terms of length- or height-for-age (range: -0.04 to +0.35 Z-score units) and weight-for-age (range: -0.25 to +0.46 Z-score units). Not surprisingly, the Bangladesh trial demonstrated lower increase in energy intake compared to trials which offered food supplementation (+65 vs. +83-317 kcal/day); however, change in weight-for-age was comparable between the two approaches (+0.46 vs. +0.25 to +0.44 Z-score units). Although none of the programmes used randomisation procedures to identify programme and comparison communities, the programmes resulted in improved maternal recall of knowledge on optimal feeding and frequency of feeding (75). Energy intake from complementary foods increased by 70 - 165 kcal/day and growth improved in terms of height-for-age (range: +0.30 to +0.87 Z-score units) and weight-for-age (range: -0.08 to +0.50 Z-score units). Overall, the trials and programmes resulted in increased growth rates of children by 0.10 to 0.50 SD, translating to absolute reductions in the prevalence of undernutrition of 2 - 4% and 5 - 19%, respectively.

1.4.2 Interventions using high-energy, micronutrient fortified complementary foods

Interventions to improve dietary intakes, micronutrient status and growth of infants were again reviewed by Dewey and Adu-Afarwuah in 2008 (60), nearly ten years after the first review was reported by Caulfield and colleagues (75). This second review covered 29 efficacy trials and 13

effectiveness studies or programme reports conducted between 1996 and 2006 in 25 developing countries. The authors grouped the studies according to the component forming the significant part of the intervention: provision of food offering extra energy (with or without micronutrient fortification), with or without education; micronutrient fortification; increasing energy density; and education. Naturally, the design and duration of the interventions and baseline nutritional status of children differed across the studies. The authors measured the magnitude of the intervention effect using effect size; expressed as the mean change of the intervention group minus the mean change in the control group divided by the pooled standard deviation of change for both groups (60). The effect sizes (ES) were categorised as small (~0.2), medium (~0.5) or large (~0.8).

Studies (7 trials, 1 programme) which provided high-energy complementary foods gave fortified or unfortified cereal or cereal-legume and/or fish blends, fat-based spreads or condensed milk (60). These studies were associated with the overall mean ES of 0.47 (range: -0.04 to 1.81) for linear growth and 0.60 (range: -0.02 to 2.99) for weight. Because the effects were inflated by high ES (weight: 2.99, length: 1.81) from one trial, excluding it resulted in modest size of 0.28 (range: -0.04 to 0.69) for linear growth and 0.26 (range: -0.02 to 0.57) for weight. Studies (2 trials, 6 programmes) that combined provision of high-energy complementary food with education gave supplementary food (e.g. micronutrient fortified milk-based, flour mix of local ingredients) and education (e.g. intensive nutrition education, counselling, health services) to mothers and/or families. These studies resulted in larger ES for growth in trials (length: 0.29, range 0.25 to 0.32; weight: 0.49, range 0.32 to 0.66) than for programmes (length: 0.09, range 0.00 to 0.14; weight: 0.21, range 0.18 to 0.24). The smaller effects in the programmes were attributed to technical and logistical difficulties that hampered implementation.

Studies (6 trials) in which complementary foods were fortified with additional micronutrients provided multiple micronutrient supplements (sprinkles™, crushable tablets, fat-based products [mainly peanuts]) to home-prepared complementary foods (cereal-legume mixes) or milk formulations during central processing (60). The average ES were 0.12 (range: -0.02 to 0.45) for length and 0.11 (range: -0.22 to 0.37) for weight. Intervention children who received milk powder fortified with multiple micronutrients demonstrated significant change in length velocity (0.51 cm/year), weight velocity (0.21 kg/year), weight-for-age Z-scores (+0.20 Z-score units) and height-for-age Z-scores (+0.19 Z-score units) after one year of intervention as compared to those receiving non-fortified milk (79).

Studies (5 trials) involving simple food processing technologies to increase energy density and mineral solubility used industrially-prepared amylase or amylase-rich flour obtained from cereal (e.g. wheat, maize) germination. Children received a cereal-legume-oil blend containing amylase-rich flour, wheat porridge with industrial amylase or processed (soaked, germinated, roasted)

cereal-legumes blends. Among the interventions that used processed cereal-legumes blends was conducted in rural Tanzania (80). The double-blind, randomised controlled trial provided processed flour contained germinated finger millet, germinated kidney beans, roasted-peanuts and mango purée or unprocessed blend of the same ingredients. The study improved energy density and mineral solubility, however there was no significant impact on growth and haemoglobin concentration. Overall, the average ES of food processing studies was 0.23 (range: -0.25 to 0.71) for linear growth and 0.35 (range: -0.13 to 1.37) for weight.

1.4.3 Interventions providing nutrition education

The 2008 review by Dewey and Adu-Afarwuah identified six intervention trials and four effectiveness studies or programmes which offered nutrition education about complementary feeding or had a significant educational component without food supplementation (60). These studies were conducted in Brazil (2), China (1), India (3), Madagascar (1), Malawi (1), Nicaragua (1) and Peru (1). Similar to the first review (75), main nutrition education approaches were learner-centred group education, individual counselling and demonstrations; and the education activities were home-, community- or facility-based. Educational strategies included: 1) training of community-based workers (CBW) or volunteers who delivered educational messages to mothers and caregivers in their homes, community centres or during clinic attendance; 2) training health facilities staff (health workers, physicians) who then offered specific counselling to caregivers during clinic consultations; and 3) training both CBW and health facility staff to conduct counselling at various points of contact. The studies used a variety of nutrition-health education and communication strategies, depending on context, to disseminate knowledge and information on complementary feeding. The strategies included interpersonal communication (e.g. individual counselling, home visits), group training, demonstration on preparation of improved recipes, regular growth monitoring at health clinics, treatment of childhood diseases and community involvement (e.g. family members, health care providers). In Nicaragua, families received health services and cash transfers in addition to education. None of the reviewed interventions reported the use of theoretical models or frameworks to guide intervention development.

Educational messages promoted during the interventions varied widely. They focused on texture, quality and quantity of complementary foods, feeding frequency, hygienic methods of food preparation and storage, feeding during and after illness and basic childcare skills. Duration of the nutrition education interventions ranged from 2 to 24 months and intensity varied from twice a week for three months, monthly to 3-months intervals. The most common educational messages included: 1) maintained breastfeeding during complementary feeding; 2) use of thicker porridges instead of thinner porridges or soups; 3) use of animal-source foods; 4) increasing dietary diversity; 5) use responsive feeding; and 6) hygiene for food preparation and storage. Taken all 10 studies together, education about complementary feeding demonstrated a modest weight gain which resulted in a non-significant effects on weight. Similarly, no effect was found on length,

except for studies in Peru (81) and India (82) where significant effects on length were 1 cm (p=0.0003) and 0.32 cm (p=0.035) higher than control group, respectively (60). Overall, the educational interventions had a mean ES of 0.20 (range: 0.04 - 0.64) for linear growth and 0.28 (range: -0.06 - 0.96) for weight. Compared to nutrition education interventions, interventions combining education and food supplementation (2 trials, 6 programmes) had an average ES of 0.17 (range: 0 - 0.32) for linear growth and 0.35 (range: 0.18 - 0.66) for weight.

Additional evidence of the effectiveness of nutrition educational interventions on complementary feeding practices in developing countries was reported by Shi and Zhang in 2011 (76). In this third review, the authors identified 15 studies conducted from 1998 onwards which used nutrition education or counselling as an intervention strategy. Nine out of the 15 studies were included in the Dewey and Adu-Afarwuah review (60). The six additional studies were conducted in Bangladesh, China, Iran, Pakistan and Vietnam. Similar nutrition educational approaches and strategies were used. Overall, the studies resulted in greater impacts on caretakers' feeding behaviours (e.g. meal frequency, dietary diversity, food hygiene), better maternal nutritional knowledge, children's dietary intake (e.g. energy, protein, fat) and growth (weight or height gain) than comparison children (76). Despite substantial heterogeneity (e.g. nutrition education vs. nutrition education plus food supplementation, involving mothers vs. mothers plus other stakeholders, weekly vs. monthly contacts, age at enrolment [birth to 25 months], etc), overall results showed improved mothers' knowledge and feeding behaviours and energy and nutrients intake. Intervention effects on growth varied: some studies improved both length and weight while others found improvements in length or weight alone. Length gain varied from 0.32 to 1.6 cm whereas weight gain ranged from 250 to 830 g.

Another review on the effectiveness of maternal education and provision of complementary foods on child nutrition was conducted by Imdad and colleagues in 2011 (77). This review analysed studies conducted in developing countries until early February 2010. Eight studies focused on maternal education alone about complementary feeding practices. While all the eight studies were included in the review by Dewey and Adu-Afarwuah (60), seven out of the eight studies were included in the Shi and Zhang review (76). This fourth review supported the evidence that nutrition education can improve child nutritional status and growth; and that the interventions should be culturally sensitive, accessible and integrated with local resources (77). The authors used weighted mean difference (WMD), also called 'standard mean difference' or 'effect size' to pool intervention effects. Nutrition education alone led to a significant positive impact on height gain (WMD 0.21 SD, 95% CI 0.01-0.41) and weight gain (WMD 0.30 SD, 95% CI 0.05-0.54) in the intervention group as compared to control group. Provision of appropriate complementary food, with or without nutrition education, resulted in a significant increase in length (WMD 0.26 SD, 95% CI 0.08-0.43) and weight (WMD 0.34 SD, 95% CI 0.11-0.56).

1.4.4 Use of theoretical frameworks in the design of nutrition education interventions

Communication and counselling for behaviour change is increasingly being used in nutrition programming to provide tailored messages and supportive environment that persuades mothers and communities to make positive nutrition behaviour changes (83). Theoretical models or frameworks guide the setting of behaviour change goals, identification of educational strategies appropriate for the goals, selection of factors to target in the intervention and determination of variables that explain how nutrition education interventions positively affect knowledge, attitude and behaviour (84, 85). It is well accepted that effective health promotion programmes are informed by theory, research and practice (84). The theories are concerned with how people make behavioural choices and the general idea is that people decide what to do based on the extent to which they expect that their choices will produce results that they value (86). They address strategies of change at the individual, interpersonal, and community levels (87). Clear description about the processes used to bring change and how they were implemented (e.g. messages given, medium used, who delivered it) are often tied to specific theories of change. This is useful for examining evidence of success including possible influencing factors that may explain why and how nutrition education worked, thus provide guidance on how to make nutrition education more effective (83, 85). Strategies forming the basis of interventions and programs to change behaviour need to focus on theories of behaviour change, evidence for success and failure of past attempts, and in-depth understanding of the audience.

A description about a combination of theory and evidence to identify what and how to change behaviour was lacking in most of the reviewed nutrition education interventions. This may imply that a certain framework where dissemination of nutrition knowledge and skills impact on attitude and behaviour change was being used. Interventions which stated the use of a theoretical model or framework to guide intervention development and foster behaviour change were conducted in Vietnam, Iran, Peru and China. The Vietnam study reported in 2002 the use of a Positive Deviance/Hearth approach, a community-based rehabilitation and behaviour change model to identify behaviours practiced by the mothers or caretakers of well-nourished children from poor families and to transfer such positive practices to others in the community with malnourished children (88-90). The approach was initiated by Save the Children in Vietnam in the 1970s, and has since been implemented by other organisations. The study in Iran reported use of Hubley's Behavioural change model in 2004 as a theoretical model for behaviour change to guide intervention development (91). The theory posits that individual beliefs about the consequences of behaviours and the value placed upon each consequence lead to personal attitudes or judgements, and combined with the subjective norms of the community and enabling factors (e.g. income, housing, water supply, food production), they contribute to behavioural intention and change. Based on the theory, the authors trained influential members of families and communities (i.e. tribal or community leaders) to change subjective norms of the indigenous nomadic people. The study reported a greater improvement in knowledge and attitudes scores among intervention

mothers and that maternal attitudes were significantly correlated with child weight and length gains.

The Peru study reported in 2006 and 2007 to have used principles of social cognitive theory and formative research to implement a multi-component nutrition education intervention in health centres (92, 93). The theory recognises that behaviour is dynamic, and a person's behaviour and the environment in which the behaviour is performed are in continual interaction. The intervention targeted behavioural capacities, cognitive characteristics of individuals and collective groups (e.g. self/collective efficacy), and social and physical environments. The study reported improvement in health centre activities, caregiver exposure to and recall of key messages; and these were significant determinants of improved feeding behaviours and child growth (81, 93). The China study reported use of theory of planned behaviour (TPB) in 2009 as the fundamental framework to evaluate whether an educational intervention changed mothers' knowledge, attitudes, subjective norm, self-efficacy and intentions related to infant feeding (94). The study found a positive association between intention and other psychosocial variables (maternal knowledge, attitudes, self-efficacy) related to infant feeding behaviours. All the authors concluded that theories and approach used were appropriate for their audience and context in addressing psychosocial factors which influence infant feeding behaviours. All the three intervention studies reported improvements

Based on the present evidence, it can be concluded that theoretically-based interventions and those that were based on formative research or knowledge-attitude-behaviour framework resulted in significant improvements in feeding behaviours, and modest or lack of effect on growth. The magnitude of intervention effects cannot be explained by use or lack of use of a theoretical model alone, but also by other factors related to individual children, context, intervention design and delivery. Future inclusion of theoretical models will benefit nutrition education interventions in explaining the mechanisms of behaviour change hence contribute to effective nutrition programmes.

1.4.5 Practical implications for the complementary feeding interventions

The findings from these interventions have several implications for the design of future trials to improve complementary feeding. Formative research conducted before the intervention contributed to the success of the trials by identifying feeding practices, nutrient intakes, initial nutritional status, availability of nutrient-rich local foods and extent of household food insecurity. This is partly due to the designing of culturally-appropriate interventions which address identified needs. The potential for an impact on growth appeared to be greater with interventions using key educational messages and multiple channels, provision of complementary foods with or without fortification, alone or in combination with other strategies and increased energy density than with interventions based on micronutrients fortification alone (60). In areas of high prevalence of

household food insecurity, provision of additional food, not education alone, facilitated the ability of families to follow complementary feeding guidelines (60).

In a rural Tanzania context, a double-blind, randomised controlled food supplementation trial was conducted to improved quality of complementary foods (80). The study provided processed flour (germinated finger millet, germinated kidney beans, roasted-peanuts and mango purée) to intervention infants or unprocessed blend of the same ingredients to control infants for six months. The study improved energy density and mineral solubility; however there was no significant impact on intakes of some nutrients, growth and haemoglobin concentration. This study is examined with respect to sustainability, funding, logistics and hygiene in rural communities. An approach to modify feeding behaviour and increase consumption of nutrient-dense food blends based on what is available would enhance the overall dietary adequacy which is usually limited in multiple nutrients. Existing opportunities (e.g. functioning health system, household-community resources) are also explored when considering delivery of an intervention which can have an impact long after the intervention ends.

Culturally-appropriate nutrition education coupled with multiple communication techniques has shown to be an effective strategy to improve feeding practices, nutrient intakes and growth (60, 75). Specifically, effective interpersonal communication strategies and involvement of other stakeholders (family and community members, health facility staff) are important elements of the educational interventions aiming to modify caregivers' feeding behaviours and to facilitate and maintain the behaviour change. Implementation through existing health care services ensures greater sustainability of the intervention (81). For a considerable impact and sustainability, methodological aspects of interventions need to contextualise these factors. Appropriate evaluations are still needed for better evidence to inform programming and make a difference.

1.5 The need for process evaluation of interventions

Complementary feeding interventions encompass a wide variety of strategies designed to improve not only the quality and quantity of these foods but also multiple feeding and health behaviours. Documenting the extent to which research and programmatic efforts have been able to improve complementary feeding and, what can be learned and applied in future efforts (95, 96), is therefore critical to improved nutrition of children. In countries where resources are limited and basic public health problems are prevalent, documentation of intervention implementation and process is significant to promote effective programmes.

Evaluation of intervention implementation can provide formative data to improve intervention by identifying factors that may enhance or impede implementation and acceptability (97). This information can be incorporated into successive interventions activities in an iterative process to ensure effective intervention operations (97). Implementation evaluation can improve the

interpretability of data collected (i.e. internal validity of impact evaluation) by ensuring the intervention being evaluated has been properly implemented (95, 98). Implementation evaluation can also provide information for use in dose-response analyses (98). Process evaluation assesses the quality and quantity of intervention implementation, including the extent to which the intervention is being delivered and received, whether this delivery is 'as planned' by developers and the acceptability to the target audience (99). Process information may be obtained via the collection of qualitative or quantitative data (100).

1.6 Relevance of the present research to Tanzania

Prevalence of undernutrition in infants and young children has remained consistently high in rural Tanzania despite the routine health education service given at health facilities. As previously described, 42% of Tanzanian children below the age of five years suffer from stunting and 16.5% suffer from severe stunting. Younger children (aged 0-23 months) and children residing in rural areas and the southern highlands, central and southern regions of the country are the most affected (22). Although breastfeeding is nearly universal with 96.9% of children reported to have been breastfed and median duration of breastfeeding is relatively long (21 months), only 50% of infants under the age of six months were exclusively breastfed, implying that the other half were introduced to complementary foods earlier than the recommended age of six months. Early introduction of fluids other than breast milk before the age of six months is mainly caused by inadequate nutritional knowledge (e.g. importance of breast milk during the first 6 months, risks of giving other liquids), cultural and religious beliefs (e.g. young babies cry because they are hungry and need to be fed), low maternal education, and maternal perceptions of insufficient breast milk (101). Predictors of exclusive breastfeeding vary widely within regions in the country. Urban or rural differences, maternal age, employment status, educational level, knowledge and attitude on breastfeeding practices before and after delivery, mode of delivery, birth weight of the infant, health system practices and community beliefs have been shown to influence the prevalence of EBF (102-105).

The 2010 TDHS (22) showed that complementary feeding practices according to WHO criteria (74) were inadequate. The 2010 survey showed that among the breastfed children aged 6-23 months, only 38.6% were fed the minimum meal frequency (i.e. 2 times per day at 6-8 months-old, 3 times per day at 9-23 months-old) and 61.2% were given meals made from three or more food groups during the 24 hours preceding the survey. Infants who received the minimum acceptable diet (i.e. receiving the minimum meal frequency and minimum dietary diversity of 4 or more food groups) was 24.3%. Among the breastfed children aged 6-35 months, 29.8% and 61.5% consumed iron-rich and vitamin A-rich foods 24 hours preceding the survey (22).

The focus of this research was Dodoma, one of the central regions greatly affected by stunting. At 56%, Dodoma has the highest prevalence of stunting in the country (22). Feeding practices were

found to be inadequate (22). Among the breastfed children aged 6-23 months residing in the central regions, proportion of children who consumed the minimum meal frequency, received meals from three or more food groups and received the minimum acceptable diet was 25.7%, 49.8% and 8.7%, respectively. Proportion of breastfed children (6-35 months) who consumed iron-rich and vitamin A-rich foods was low, 12.2% and 60.8%, respectively.

In Tanzania where environmental factors (e.g. household incomes, transport and food market infrastructure, cultural beliefs, etc) leading to increased risk of undernutrition may remain relatively the same for some period of time, implementation of effective interventions is a matter of immediate concern. The country is committed to the improvement of infants and young child feeding, and national programmes such as vitamin A and iron supplementation, malarial prevention and integrated management of childhood illnesses (IMCI) are in place (106-109). Little attention has been paid, although well acknowledged, to the significance of nutritional knowledge, skills and attitudes at the household and community level. Mothers need practical knowledge, sustainable guidance and support to maintain optimal behaviours, thus ensuring their children continue to receive the best possible start in life. This research addressed the complementary feeding practices with a nutrition education perspective in a rural area with high rates of undernutrition. Findings from the formative studies conducted in the area, together with existing opportunities, were used to design an intervention to improve complementary feeding practices.

1.6.1 Objectives of the research

Objectives of the PhD research were to: 1) characterise dietary and growth patterns of infants and young children living in rural Tanzania; and 2) develop and evaluate the effectiveness of a nutrition education package on feeding practices, dietary adequacy and growth of infants and young children in rural Tanzania. It was hypothesised that the nutrition education package would improve feeding practices, dietary adequacy and growth as compared to routine health education given at health facilities. The hypothesis was tested in a cluster-randomised controlled trial organised in 18 villages in Mpwapwa district, Tanzania. The trial was registered at Clinicaltrials.gov as NCT02249754.

The PhD research addressed four specific objectives:

1. Assess feeding practices, nutrient content of complementary meals, and their implications for dietary adequacy and nutritional status
2. Develop a theory- and evidence-based nutrition education package for delivery in a rural community setting
3. Evaluate the effectiveness of a nutrition education package in improving feeding practices, dietary adequacy and growth as compared to routine health education
4. Describe the implementation and process evaluation of the nutrition education package

1.6.2 Presentation of the research setting

Tanzania

United Republic of Tanzania is a sub-Saharan country located in the eastern part of Africa. Tanzania lies south of the equator and shares borders with Kenya and Uganda to the north; Rwanda, Burundi and the Democratic Republic of Congo to the west; Zambia and Malawi to the south west; and Mozambique to the south. The Indian Ocean borders the eastern side (110). The country is composed of Tanzania Mainland (25 regions) and Tanzania Zanzibar (the Isles, 5 regions), with Dodoma as the capital city and Dar-es-Salaam as the commercial centre. According to the 2012 national census (111), Tanzania has 44,928,923 people. Majority of the population (70.4%) live in rural areas. Literacy rate is 71.8%. Proportion of population below the basic needs poverty line for the 2011/2012 period was 28.2% (33.3% in rural areas). Per capita gross domestic product (GDP) at current prices in 2014 was estimated to be USD 1,044, with agriculture and mining contributing 35.1% (110). While manufacturing, electricity, gas and water contributed 20.8% of GDP, services sector (e.g. wholesale and retail trade, communication and technology) contributed 44.2%. The 2010 TDHS reported the under-five and infant mortality rates during the 2006-2010 period to be 81 and 51 deaths per 1,000 live births, respectively (22, 112).

Mpwapwa District (in Dodoma region)

The research was carried out in Mpwapwa district, Dodoma region. The region is located in central Tanzania Mainland, and it lies at latitude 4° to 7^{0} South and longitude 35° to 37° East (113). It covers an area of 41,310 square kilometers, equivalent to 5% of the total land area of Tanzania. The region has 2,083,588 people (111). Administratively, the region is divided into seven districts, namely, Bahi, Chamwino, Chemba, Dodoma Municipal, Kondoa, Kongwa and Mpwapwa. Much of the region is a plateau (altitude 1,040 metres above sea level) with a savanna type of climate. The region is predominantly semi-arid. Monthly average rainfall was 32.9 mm and 40.8 mm in 2010 and 2014, respectively (110, 112). The main economic activities in the region include agriculture (famously known for cultivation of grapes), livestock keeping and small scale trading.

Mpwapwa district lies between 915 and 1,200 meters above sea level. It covers an area of 7,485 square kilometres. Total population in 2012 was reported to be 305,056 (111, 113). The district is characterised by a long dry season (May to mid-November) and a short single wet season (November to March). Monthly rainfall varies between 50 and 300 mm. Farmers experience one crops harvest period between mid-March and June. Crops cultivated include sorghum, pearl millet, maize, groundnuts, cowpeas, pigeon peas, Irish potatoes, sunflower and sesame. Traditional rearing of cattle, goats, chicken and pigs is commonly practiced, mainly as a source of income.

The district health system makes child health services available through a government-run network of 43 dispensaries, two health centres and one district hospital (114). These services are complemented by faith-based non-governmental organisations (two health centres, three

dispensaries) and government parastatals (two dispensaries). In addition, each village is served by two to five volunteer village health workers (VHW). The VHW assist health facility staff during immunisation and child growth monitoring activities. The main health problems existing in the district as identified in the District Health Plans for the 2007-2008 and 2008-2009 periods include maternal mortality, malaria morbidity and mortality, under-five mortality, high prevalence of eye infections, including trachoma and inadequate hygiene and sanitation (114). In-patient admissions and deaths per diagnosis during the July 2007-March 2008 period showed that severe and complicated malaria, uncomplicated malaria, anaemia, perinatal and neonatal conditions and pneumonia were the leading causes of deaths among children below the age of five years.

1.7 Outline of the thesis

This thesis is based on a longitudinal observational study and a cluster randomised controlled trial. The observational study, designed as two cross-sectional studies, was conducted in six villages in 2009 and repeated in 2010. **Figure 1** presents a map of the study area showing villages which participated in the observational study. The cluster randomised trial was conducted in 18 villages between 2014 and 2015. While the observational study involved all infants below the age of one year, the trial involved infants aged 6 months. **Figure 2** presents a map of the study area depicting villages which participated in the trial.

Chapter 1 of the thesis sets the background of the PhD research and presents its justification and objectives. **Chapter 2** presents findings of the observational study conducted to assess infant feeding practices, nutrient content of complementary meals, and their implications for dietary adequacy and nutritional status. Based on findings from Chapter 2, a multicomponent nutrition education package was developed, and this is described as a study protocol in **Chapter 3.** The effectiveness of the nutrition education package as compared to the routine health education was evaluated in a cluster randomised trial. **Chapter 4** reports on the effectiveness of the nutrition package on meal frequency, dietary diversity, dietary intake and nutritional status among infants from 6 to 12 months of age. **Chapter 5** describes the process evaluation of the nutrition education package. In **Chapter 6**, main findings of the previous chapters are summarised and discussed in a broader perspective and implications for practice and future research are given.

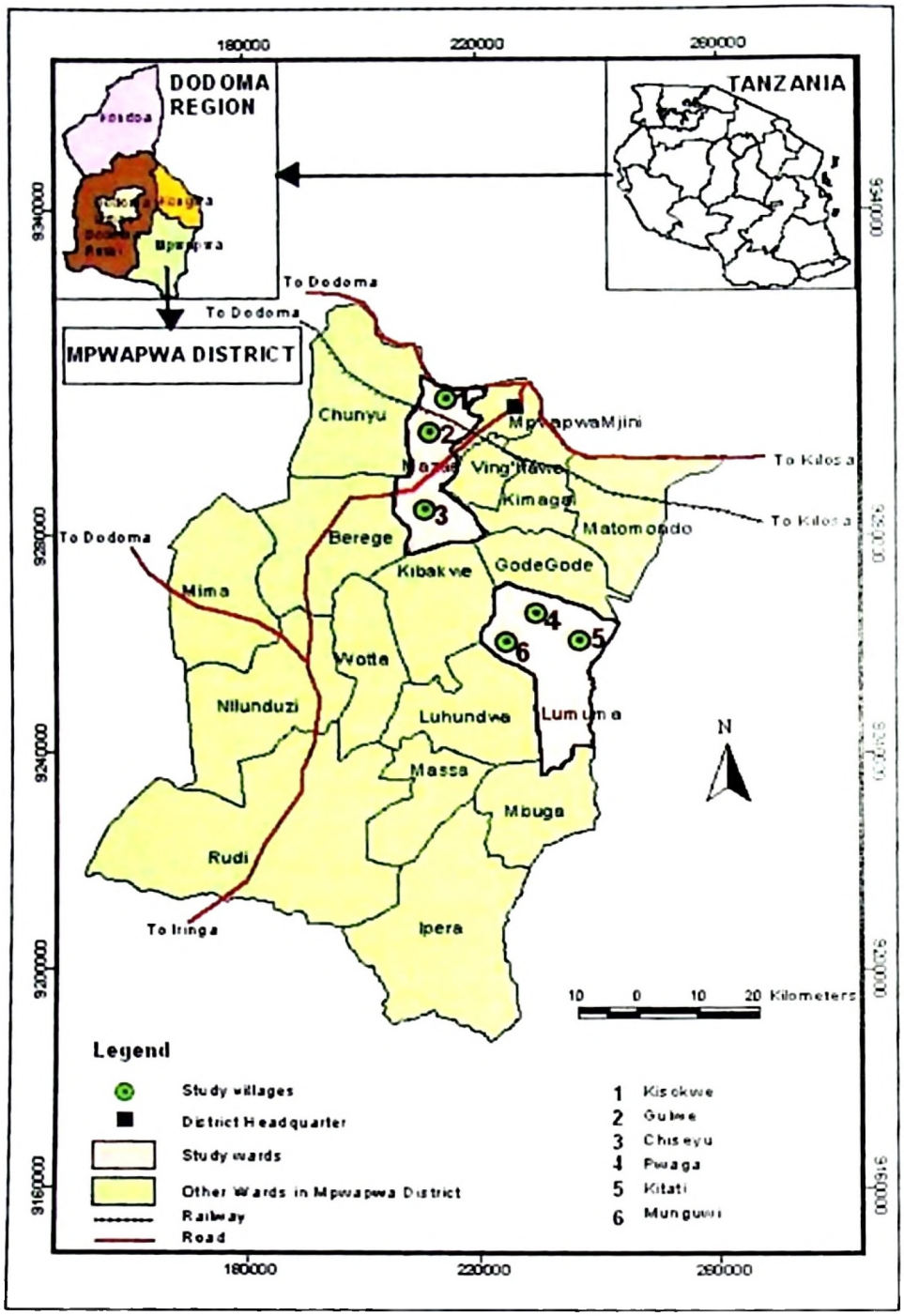

Figure 1. Location of the research area in Mpwapwa, Tanzania: villages participating in the observational study (2009-2010)

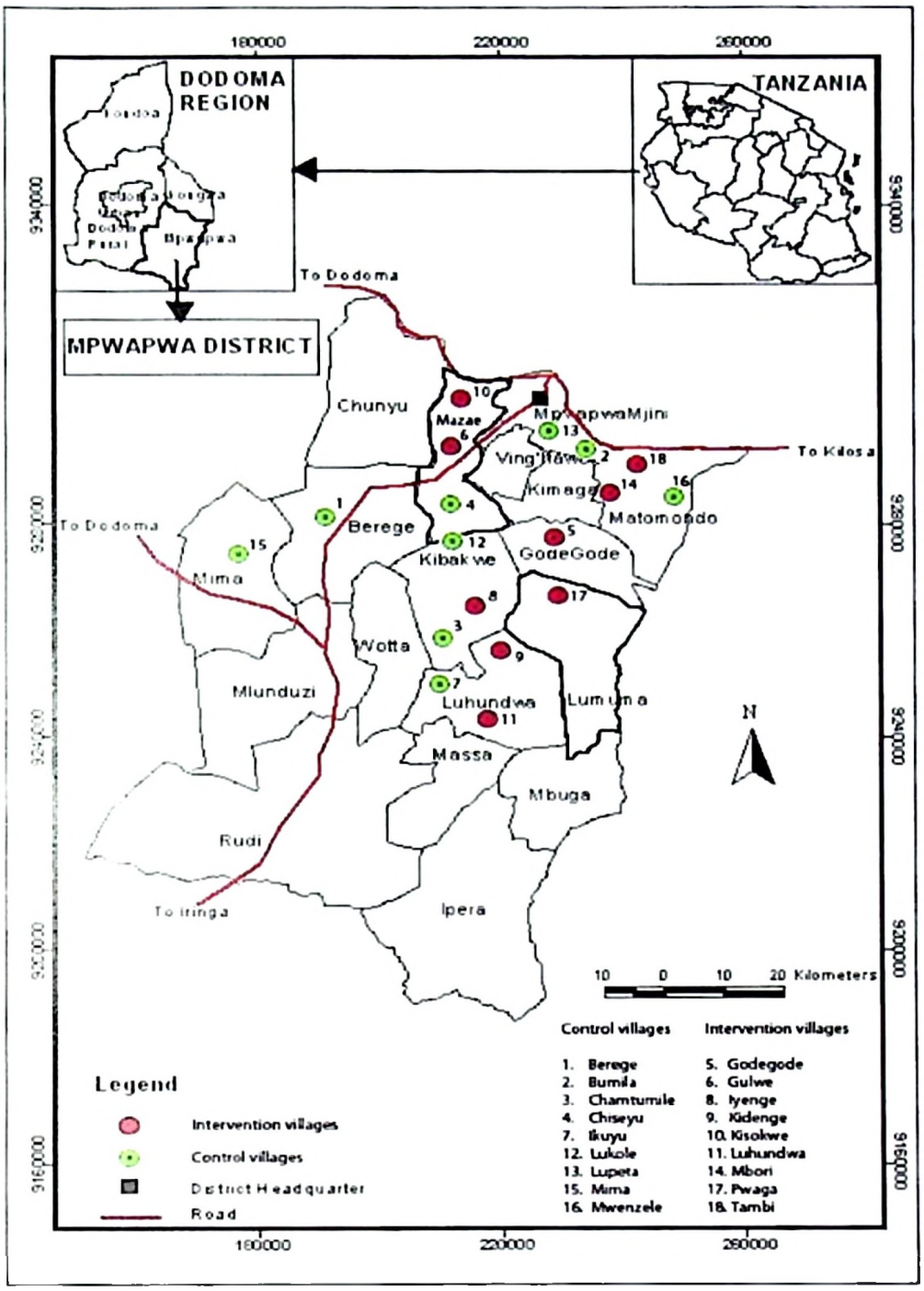

Figure 2. Location of the research area in Mpwapwa, Tanzania: villages participating in the cluster randomised controlled trial (2014-2015)

All research activities described in this thesis were carried out by the author within the framework of student's doctoral programme of Ghent University. The author is a former graduate in applied human nutrition. Data collection tools were reviewed by a nutrition and food research scientist from Sokoine University of Agriculture (SUA). Undergraduate and diploma-level students with human nutrition, food and agricultural sciences background assisted with the data collection. Collection of qualitative data was assisted by a social scientist from SUA. Food science and laboratory technologists assisted with analyses of food samples. A medical technologist prepared and assessed body fluid samples. Expert individuals in nutrition programming and curricular development working in government institutions reviewed the design and content of the training-education resources. Two medical officers who are members of the district health management team and a district nutrition officer assisted in conducting training sessions. A SUA nutrition graduate assisted in conducting education and counselling sessions. The district nutrition officer assisted in conducting supportive supervision and collection of process evaluation data.

Chapter 2. Diets, dietary practices and nutrition of infants and young children in rural central Tanzania: a cross sectional study

This chapter has been redrafted after:
Kulwa KBM, Mamiro PS, Kimanya ME, Mziray R, Kolsteren PW. Feeding practices and nutrient content of complementary meals in rural central Tanzania: implications for dietary adequacy and nutritional status. *BMC Pediatrics* 2015; 15:171

2.1 Summary

Objective: Stunting and micronutrient deficiencies are significant health problems among infants and young children in rural Tanzania. This chapter presents findings from a study in rural Tanzania which assessed feeding practices, nutrient content of complementary meals, and their implications for dietary adequacy and nutritional status.

Methods: A cross-sectional study was conducted in six randomly selected villages in Mpwapwa district, Tanzania during the post-harvest season. Data were collected from all households with infants below the age of one year. Information on feeding practices were collected by a structured questionnaire. Dietary consumption was assessed by an interactive 24-hour food recall. Anthropometric measurements were collected using standardised procedures. Forty samples of common meals were collected and analysed for proximate composition, iron, zinc and calcium. Results were expressed per 100 g dry weight.

Results: Proportion of infants below the age of six months who were exclusively breastfed was 40%. Mean age of introduction of complementary foods was earlier (3.30±1.45 [range: 1-6]) than the recommended age of six months. Mean number of meals consumed per day including snacks was 1.74±0.73; with 6-8 months-old infants having lower number of meals (1.66±0.65) than 9-11 months-old infants (1.84±0.71). Porridge was the main complementary meal and contained relatively high moisture content. Energy, protein and fat content in porridge ranged from 40.67-63.92 kcal, 0.54-1.74% and 0.30-2.12%, respectively. Iron, zinc and calcium contents (mg/100 g) in porridge were 0.11-2.81, 0.10-3.23, and 25.43-125.55, respectively. Median portion sizes were small (porridge: 150-350 g; legumes and meats: 39-90 g). Very few children (6.67%) consumed animal-source foods. Low number of meals, meals having low nutrient content, small portion size and limited variety reduced the contribution of meals to daily nutritional needs. Prevalence of stunting and morbidity were relatively high.

Conclusions: Findings of the study highlight inadequate feeding practices, low nutritional quality of meals and high prevalence of stunting. Feasible strategies are needed to address the dietary inadequacies and chronic malnutrition of rural infants.

Key words: Tanzania, complementary foods, feeding practices, energy, iron, zinc

2.2 Introduction

Widespread undernutrition in low-income countries continues to exert enormous cost in terms of survival among infants and young children (24, 71). Chronic undernutrition (defined as stunting) and micronutrient deficiencies are significant health problems among infants and young children in Tanzania. Prevalence of stunting among children aged 6-59 months in the 2005 and 2010 national surveys was 37.7% and 42%, respectively (22, 23). Children in rural areas were more affected than their urban counterparts. Coexistence of micronutrient deficiencies with undernutrition has been demonstrated in cross-sectional studies (47, 115). National data has also shown inadequate consumption of micronutrient-rich foods. Proportion of children (6-35 months-old) who consumed iron-rich foods was 29.8%, whereas that of vitamin A-rich foods was 61.5% (22). Inadequate dietary intakes and poor feeding practices directly affect the nutritional status of children in the country. This situation is aggravated by household food insecurity.

Households in rural Tanzania depend on rain-fed, small subsistence farming for their livelihoods. Inadequate rains and erratic rainfall patterns (delayed timing, low frequency) are widespread in semi-arid central regions of the country. This is common in Dodoma and Singida. It affects the timing of crop harvests and amount of food stocks. Dwindling food stocks, increasing food prices and seasonal shifting of maternal workload towards casual labour are apparent during the post-harvest season (116). It was reported that 45-55% of households in central regions were food insecure in 2006, whereas over one-third of households with tenuous access to food were reported in 2010 (116). Proportion of households receiving food aid in Dodoma was 66.6%.

These challenges demonstrate that many households in Dodoma are vulnerable to food insecurity. This situation provided a context in which to evaluate the extent to which household dietary vulnerability modifies feeding practices, diets and nutritional status among infants and young children. The present study was undertaken to assess feeding practices, nutrient content of complementary meals, and their implications for dietary adequacy and nutritional status in rural Dodoma.

2.3 Methods

The study was conducted in Dodoma Region, central Tanzania Mainland. Mpwapwa district was selected by simple random sampling. The district lies between 915 and 1,200 meters above sea level. It covers an area of 7,485 square kilometres and the total population in 2003 was 253,602 (113). The district is characterised by a long dry season (May to mid-November), a short single wet season (November to March) and monthly rainfall variability of between 50 and 300 mm. Farmers experience single staggered harvest between mid-March and June. Subsistence farming and traditional rearing of animals are the primary economic activities (114).

A cross sectional study was conducted in six randomly selected villages. All households with infants below the age of one year were eligible and invited to participate in the study. Purpose and nature of the study activities were explained to parents and those who agreed to participate gave verbal informed consent. A total of 496 infants were recruited and participated in the study. Ethical clearance was obtained from the National Institute of Medical Research, Tanzania.

Household, maternal and infant characteristics were collected using a structured questionnaire (**Appendix 2.1**). Household and maternal characteristics included household size, type of household, number of meals per day, status of household food sufficiency between seasons, maternal age, education and place where the study infant was delivered. Mothers provided information on infant breastfeeding and complementary feeding practices. Feeding practices were compared to WHO infant and young child feeding (IYCF) recommendations and indicators (26, 74). Four core IYCF indicators were used, namely *exclusive breastfeeding under 6 months* (i.e. Proportion of infants 0-5 months of age who are fed exclusively with breast milk); *introduction of solid, semi-solid or soft foods* (i.e. Proportion of infants 6-8 months of age who receive solid, semi-solid or soft foods); *minimum dietary diversity* (i.e. Proportion of children 6-23 months of age who receive foods from 4 or more food groups); and *minimum meal frequency* (i.e. Proportion of breastfed and non-breastfed children 6-23 months of age, who receive solid, semi-solid, or soft foods including milk feeds for non-breastfed children the minimum number of times or more). The minimum number of times is defined as 2 times per day at 6-8 months-old and 3 times per day at 9-23 months-old. Comparison of the IYCF practices and WHO indicators' minimum dietary diversity and minimum meal frequency is limited to infants below the age of one year instead of the WHO-recommended criteria of 6-23 months-old due to age limit entailed by the study population.

Children were weighed with minimum clothing using an infant-hanging weighing scale (Salter model 235, CMS Weighing Equipment, London). Child's recumbent length was taken using a portable wooden infant/child length board (Shorr Productions, Perspective Enterprises, Missouri). Standardised anthropometric procedures (117) were followed. Nutritional status indices (Z-scores for length-for-age [LAZ], weight-for-length [WLZ], weight-for-age [WAZ]) were computed using the 2006 WHO Child Growth Standards in the ANTHRO Software v3.0.1 (ANTHRO, WHO, Geneva). Indicators of nutritional status (stunting, wasting, underweight) were defined as Z-scores below -2 standard deviations (SD) of the median values of the reference data. Chi-squared test for categorical variables and bivariate analysis for continuous variables were used to test if there were any significant associations or relations between nutritional status and feeding practices indicators.

Food intake was assessed by an interactive 24-hour dietary recall (118). Mothers recalled all foods and fluids consumed by their children during the previous 24 hours, ingredients and amounts used in meal preparation and quantities of consumed foods/fluids. Calibrated cylinders, digital food

weighing scales (BOECO BEB 61, 5 kg capacity 1 g precision; Hamburg, Germany) and visual aids of fresh foods were used to facilitate quantity estimation. Frequently consumed meals were identified and information on ingredients and preparation methods were compiled. Amounts consumed (i.e. portion size in grams per meal) were recorded and expressed as median values. Due to several variations in meal ingredients and preparation methods, it was not possible to collect samples of all meals for laboratory analysis. Focus group discussions (n=6) were conducted to reach an agreement on which meals were common and what were their ingredients, amounts, preparation and cooking methods. After consensus, a guide on the selected meals and methods was developed in order to standardise meals preparation for sample collection. Eighty mothers who participated in the 24-hour dietary recall were randomly recruited to prepare the meals in small groups (119). Ingredients were obtained locally and cooking time was documented. Local preparation and cooking practices were maintained.

After cooking, five samples per meal were weighed in digital scales (BOECO BLC-3000, 3 kg capacity, 1 g precision; Hamburg, Germany) and collected for laboratory analysis. Because calcium content in water contributes to calcium content in meals and dietary intake (120), water used for cooking was randomly collected from six community sources for calcium analysis. Underground protected wells were the major sources of water for majority of the households.

Five hundred grams of each meal was packed in labelled trace element-free air-tight plastic containers (for semi-solid or solid) and bottles (for fluids). Water samples (500 ml) were packed in glass bottles and sealed. The samples were transported in ice-packed cooler boxes to the laboratory of the Department of Food Science and Technology, Sokoine University of Agriculture, Morogoro. Meal samples were kept at -18^{0}C and water samples at 5^{0}C for 3 days then transported in ice-packed cooler boxes to the Tanzania Food and Drugs Authority (TFDA) laboratory, Dar-es-Salaam. Meal samples were stored at -18^{0}C for 1 month awaiting analysis. Water samples were analysed for calcium within 14 days from the time of collection. On the day of analysis, meal samples were thawed at room temperature and homogenised using a stainless-steel blender (Copley Scientific, Nottingham, UK). For each nutrient parameter, 100 gram of homogenised sample was taken for analysis. All analyses were carried out in independent duplicate samples. Values were reported as mean ± standard deviation.

Proximate composition of samples was carried out using the AOAC Official Methods of Analysis (121), with analysis of moisture (method 925.04), ash (method 938.08), fat (method 954.02), crude fibre (method 985.29) and protein (method 981.10). Moisture content was determined by air drying in oven at 105^{0}C. Ash was determined after combustion of sample in a muffle furnace (Carbolite CWF 1200) at 550^{0}C for 4-6 hours. Crude fat was obtained using a Soxhlet method. Crude fibre was determined after digestion with sulphuric acid and sodium hydroxide and ashing in muffle furnace at 600^{0}C. Crude protein was determined by Auto-Kjedahl method (Kjeltec 2300,

FOSS). Conversion of nitrogen values to protein was calculated using a factor of 6.25 for meat, fish, maize and beans; 6.38 for milk; 6.31 for millet; 5.95 for rice; and 6.25 for other meals where a conversion factor is not specified (122). Available carbohydrate was calculated by percentage difference between 100 and sum of the fat, protein, moisture, ash and fibre values. Energy content of sample meal was calculated using the Atwater factors (123) and expresses as kcal/100g dry weight. Proximate composition results (%/100 g) were expressed per 100 g dry weight. Energy density was calculated by dividing energy content (kcal) to weight (g) of a meal.

Concentrations of calcium, iron and zinc were determined individually in the aliquots of air-dried, ashed acid-dissolved samples using Graphite-Furnace Atomic Absorption Spectrometry (GFAAS, 6300, Shimadzu, Tokyo, Japan) according to AOAC methods (121). For calcium determinations, lanthanum chloride (1% w/v) was added to both standards and samples to suppress interference from phosphorus (124, 125). Mineral content less than 0.06 mg/100 g were categorised as trace according to suggested analytical limits (122). Standards were prepared from stock standard solutions of zinc, iron and calcium (Scharlau, Scharlab SL, Spain). Results, mg/100 g, were expressed per 100 g dry weight.

To minimise risk of contamination, all glassware and plastic ware were acid-washed and rinsed with deionised water before use. Sterile disposable powder-free plastic gloves were worn when handling samples. All chemicals and solvents used were of analytical grade. Reagent blanks helped to monitor purity of the reagent used. Duplicate measurements falling within 10% of their mean were accepted to be showing satisfactory agreement. Analysis was repeated if the agreement was outside 10% of the mean for the duplicates (126). Analyses of in-house reference materials were used for quality assurance. Maize flour was used for analyses of moisture, ash and protein; soybean oil was used as in-house control sample for fat; whole wheat flour for fibre; and rice flour (Standard Reference Material 1568a) for the minerals.

2.4 Results

Data available for analyses included 496 for household and maternal characteristics, 492 for anthropometric measurements and 406 for dietary assessment (meals, beverages, or both). Four infants lacked length measurements because they were constantly crying and fussing that it was impossible to establish supine length. Of the 496 recruited infants, 390 infants consumed soft, semi-solid or solid foods a day before the survey, whereas 106 did not, instead they received breast milk alone or breast milk plus any water-based drinks; and were therefore excluded in dietary diversity assessment. Of the 496 recruited infants (0-11 months-old), 99.6% were breastfed 24 hours before the survey. Proportion of infants below the age of six months (n=175) who were exclusively breastfed was 40.0%. Mean age of introduction of complementary foods was 3.30±1.45 (range: 1-6). Majority (93%) of the infants aged 6-8 months were receiving soft, semi-solid or solid foods. Mean number of meals consumed including snacks was 1.74±0.73

(range: 1-4). Mean number of meals per day increased with age: 1.45±0.74 for 0-5 months-old infants, 1.66±0.65 for 6-8 months-old and 1.84±0.71 for 9-11 months-old infants. Of the 253 infants who met the WHO criteria for assessing meal frequency (i.e. six months or older, consumed a meal during the previous day), 44.7% met the minimum meal frequency. A higher proportion of 6-8 months-old infants met the minimum meal frequency than the 9-11 months-old infants. Mean number of individual food items consumed (i.e. food variety) was 2.27±1.43 (range: 1-8). Very few children (6.67%) consumed animal-source foods. Proportion of infants (6-11 months-old) who met the WHO minimum dietary diversity criterion of 4 or more food groups was 4.6%. The infants consumed 1 to 5 food groups. Prevalence of stunting, wasting and underweight were 33.7%, 2.4% and 12.0%, respectively. There were no significant associations or relations between nutritional status and any of the IYCF indicators. Other infant, maternal and household characteristics are shown in **Table 2.1.**

Table 2.1 Characteristics of infants 0-11 months of age (n=496), mothers and households participating in the study

Characteristic	N	n (%)	mean (SD)
Infant			
Age (months)	496		
0-5		175 (35.3)	
6-8		157 (31.7)	
9-11		164 (33.1)	
Sex (male)	496	247 (49.7)	
Sex (female)		249 (50.3)	
Stunting	492	166 (33.7)	-1.48 (1.32)[1]
0-5 mo		37 (7.5)	
6-8 mo		48 (9.7)	
9-11 mo		81 (16.5)	
Wasting	492	12 (2.4)	0.47 (1.33)[1]
0-5 mo		4 (0.8)	
6-8 mo		6 (1.2)	
9-11 mo		2 (0.4)	
Underweight	492	59 (12.0)	-0.61 (1.20)[1]
0-5 mo		14 (2.8)	
6-8 mo		20 (4.1)	
9-11 mo		25 (5.1)	
Feeding frequency	405		1.74 (0.73)
1		172 (42.5)	
2		169 (41.7)	
3		62 (15.3)	
4		2 (0.5)	
Introduction of soft, semi-solid, solid foods at 6-8 mo	157		
Breast milk, other foods and fluids		146 (93)	
Breast milk alone		11 (7)	
Infants meeting recommended feeding frequency[2]	253		
6-8 mo		92 (59.4)	
9-11 mo		21 (21.4)	
Infant dietary diversity	390		1.66 (0.88)
1-3 food groups		372 (95.4)	
4 or more		18 (4.6)	
Maternal			
Maternal age	496		26.57 (7.16)
Maternal education (years)	496		4.84 (3.05)
No education		198 (39.9)	
Primary		291 (58.7)	
Secondary and above		7 (1.4)	
Place infant was delivered	496		
Health facility		290 (58.5)	
Home		206 (41.5)	
Household			
Household size	496		5.26 (1.96)
Male-headed households	496	412 (83.1)	
Eating frequency	496		2.14 (0.54)
1		42 (8.5)	
2		342 (69.0)	
3		112 (22.6)	
If food is sufficient between seasons	496		
Yes		153 (30.8)	
No		343 (69.2)	

[1]Mean and standard deviation of the Z-scores for length-for-age (LAZ), weight-for-length (WLZ) and weight-for-age (WAZ), respectively. [2]WHO indicator: minimum meal frequency (2 times/day at 6-8 months-old, 3 times/day at 9-23 months-old).

Porridge was the main complementary meal. Common types of flour used in porridge preparation were maize, sorghum, pearl millet and finger millet. Detailed description of porridge ingredients and preparation methods are shown in **Appendix 2.2**. Flour was mixed with water in a flour to water ratio ranging from 1:4 to 1:9. Cow's milk was added in porridge or consumed as a beverage after dilution with water supposedly to make it 'light' for infants to consume. Other meals included staple foods eaten together with a relish (stew or sauce). The staples included stiff porridge (or *ugali* in *Kiswahili*) and white rice. Relish was based on beef, fish, sardines, fermented milk, kidney beans and green-leafy vegetables. Detailed description of staple and relish ingredients and preparation methods are shown in **Appendix 2.3**. Relish was prepared as a family meal, from which a portion was served to the infant. Being a dry season, fresh vegetables were obtained from locally-irrigated farm plots, whereas dried vegetables were obtained from households' stock of previous harvest. Preparation of dried vegetables usually involves harvesting of fresh leaves during the rainy season, de-stalking, open sun-drying, and storage in air-tight clay pots until consumption during the dry season.

Proximate composition of porridge samples and portion sizes estimated from the 24-hour dietary recall among infants aged 6-11 months are presented in **Table 2.2.** Porridge samples had high moisture content. Porridge containing groundnuts or cow's milk had slightly higher protein content than others. Fat content was slightly high in composite porridge and whole maize porridge made with groundnuts, cow's milk or sunflower oil. Composite porridge contained the highest amount of calculated energy.

Table 2.3 presents proximate composition for staples, accompanied relish and meal portion sizes estimated from the 24-hour dietary recall. Protein content was higher in whole maize ugali than other staples. Relish based on beef and fish contained higher amounts of protein, fat and energy compared to others. Inclusion of groundnuts in jute mallow leaves contributed to slight increase in fat compared to a similar relish without groundnuts.

Iron, zinc and calcium contents in porridge are shown in **Table 2.4**. Iron content was lowest in dehulled and soaked maize porridge and highest in whole finger millet porridge. Zinc content was highest in the composite porridge. Iron, zinc and calcium contents in staples and relish are presented in **Table 2.5**. Beef was a rich source of zinc, whereas dried jute mallow leaves contained highest amount of iron. Mean calcium levels of domestic water samples collected in the area was 120.97 mg/L (range: 115.50 – 129.02).

Table 2.2 Proximate composition and energy content of porridge varieties

Type of porridge and ingredients	Median portion[a]	n[b]	Moisture (%/100 g)	Energy (kcal/100 g)	Ash	Fat	Protein	Available Carbohydrate	Fibre
					(% per 100 g dry weight)				
Whole maize flour, Sugar	215	58	83.94±0.59	53.07	0.85±0.01	0.91±0.02	1.00±0.01	10.21	3.09±0.03
Whole maize flour, Groundnuts, Salt	215	58	83.25±0.58	54.55	1.05±0.01	1.20±0.02	1.33±0.01	9.61	3.56±0.04
Whole maize Groundnuts, Salt, Sugar	215	58	83.82±0.59	51.40	0.93±0.01	0.95±0.02	1.19±0.01	9.53	3.58±0.04
Whole maize flour, Baobab flour	215	58	84.16±0.60	47.45	0.96±0.01	0.76±0.01	0.96±0.01	9.19	3.97±0.04
Whole maize flour, Baobab flour, Sugar	215	58	84.40±0.61	47.40	0.89±0.01	0.68±0.01	0.59±0.01	9.74	3.70±0.04
Whole maize flour Sunflower oil, Salt	215	58	83.54±0.58	61.70	0.98±0.01	2.12±0.04	0.99±0.01	9.656	2.71±0.03
Composite flour (Whole maize flour, Finger millet flour, Sardines, Groundnuts)[c]	315	10	82.24±0.57	63.92	0.97±0.01	1.84±0.04	1.35±0.01	9.88	3.72±0.04
Whole maize flour, Cow's milk, Salt	215	79	86.30±0.60	45.43	0.83±0.01	1.17±0.02	1.04±0.01	7.69	2.97±0.03
Dehulled maize flour, Salt	245	74	85.74±0.60	49.68	0.57±0.00	0.48±0.01	0.66±0.01	10.69	1.86±0.02
Dehulled maize flour, Groundnuts, Sugar	245	74	84.15±0.59	52.37	0.83±0.01	0.73±0.01	1.04±0.01	10.41	2.85±0.03
Dehulled maize flour, Cow's milk, Salt	245	74	88.37±0.63	40.67	0.68±0.00	0.81±0.02	1.29±0.01	7.05	1.80±0.02
Dehulled and soaked maize flour, Salt	220	27	86.48±0.61	47.54	0.54±0.00	0.30±0.01	0.54±0.01	10.68	1.46±0.02
Dehulled and soaked maize flour, Groundnuts, Salt	220	27	86.53±0.61	47.18	0.57±0.00	0.66±0.01	1.02±0.01	9.30	1.93±0.02
Dehulled and soaked maize flour, Baobab, Sugar	220	27	86.68±0.61	46.00	0.82±0.01	0.51±0.01	0.71±0.01	9.65	1.63±0.02
Dehulled and soaked maize flour, Cow's milk, Sugar	220	27	86.85±0.62	49.56	0.51±0.00	0.63±0.01	0.99±0.01	9.98	1.03±0.01
Whole sorghum flour, Salt	187.5	44	84.53±0.59	47.87	0.98±0.01	0.76±0.01	1.47±0.01	8.80	3.47±0.04
Whole sorghum flour, Groundnuts, Salt	187.5	44	84.61±0.60	48.03	0.86±0.01	1.10±0.02	1.74±0.02	7.79	3.90±0.04
Whole pearl millet flour, Salt	227.5	10	84.25±0.59	45.46	0.97±0.01	0.79±0.02	1.35±0.01	8.24	4.41±0.05
Whole pearl millet flour, Groundnuts, Salt	227.5	10	83.95±0.59	45.27	0.98±0.01	0.85±0.02	1.48±0.01	7.93	4.81±0.05
Whole finger millet flour, Sugar	227.5	10	83.47±0.58	46.16	1.03±0.01	0.86±0.02	1.50±0.01	8.12	5.03±0.06
Fresh cow's milk, Water, Sugar	150	10	86.83±0.62	66.89	0.54±0.00	3.27±0.06	2.29±0.02	7.07	NA

Data are expressed as mean±SD on a dry-weight basis. NA-not analysed.

[a] Infant median portion sizes in grams per meal recorded from the 24-hour dietary recall among infants aged 6-11 months.

[b] Number of infants reported to have consumed the meal on the day of the 24-hour dietary recall. Infants who had 2 or more meals per day consumed same or a different type of porridge.

[c] Consumed by 9-11 months-old infants only.

Table 2.3 Proximate composition and energy content of cooked staple and accompanied relish

Meal type	Median portion[a]	n[b]	Moisture (%/100 g)	Energy (kcal/100 g)	Ash	Fat	Protein	Available Carbohydrate	Fibre
					(% per 100 g dry weight)				
Staple									
Whole maize *ugali*	110	66	62.51±0.44	138.68	0.89±0.01	1.28±0.02	4.38±0.04	27.41	3.53±0.04
Dehulled maize *ugali*	140	66	66.15±0.46	129.01	0.60±0.00	0.59±0.01	2.08±0.02	28.85	1.74±0.02
Dehulled and soaked maize *ugali*	140	66	69.12±0.48	120.44	0.53±0.00	0.39±0.02	0.28±0.00	28.96	0.73±0.01
Whole sorghum stiff *ugali*	110	66	63.65±0.45	129.33	0.97±0.01	0.96±0.02	3.85±0.04	26.31	4.26±0.05
Rice cooked	105	2	63.84±0.45	145.03	0.88±0.01	1.61±0.03	4.18±0.04	28.45	1.04±0.01
Relishand ingredients									
Beef, Tomatoes, Onions, Oil, Salt	65	10	65.86±0.46	190.13	2.05±0.01	12.91±0.25	18.05±0.16	0.44	0.69±0.01
Dried fish, Tomatoes, Onions, Oil, Salt	90	2	62.57±0.44	191.49	2.45±0.02	10.44±0.20	23.84±0.22	0.54	0.16±0.00
Dried sardines, Tomatoes, Onions, Oil, Salt	82.5	4	63.59±0.44	173.45	2.00±0.01	7.48±0.14	26.20±0.24	0.32	0.40±0.00
Fermented cow's milk	150	3	89.20±0.62	58.30	1.26±0.01	4.03±0.08	2.70±0.02	2.81	NA
Beans, Tomatoes, Onions, Oil, Salt	90	12	71.35±0.49	98.13	2.18±0.01	2.06±0.04	3.70±0.03	16.20	4.51±0.05
Bean, Onions, Oil, Salt relish	72.5	12	71.22±0.49	95.75	2.19±0.01	1.47±0.03	4.68±0.04	15.95	4.49±0.05
Chinese cabbage, Tomatoes, Onions, Oil, Salt	54	44	71.84±0.50	106.32	3.11±0.02	8.21±0.16	2.35±0.02	5.75	8.74±0.10
Sweet potato leaves, Tomatoes, Onions, Oil, Salt	54	44	74.47±0.52	73.41	4.14±0.03	4.17±0.08	1.27±0.01	7.69	8.26±0.10
Fresh cowpea leaves, Tomatoes, Onions, Oil, Salt	54	44	71.35±0.49	129.61	3.04±0.02	9.78±0.19	4.75±0.04	5.64	5.44±0.06
Dried cowpea leaves, Tomatoes, Onions, Oil, Salt	50	44	75.04±0.53	111.76	2.34±0.01	9.81±0.19	3.08±0.03	2.79	6.94±0.08
Pumpkin leaves, Tomatoes, Onions, Oil, Salt	54	44	74.80±0.52	85.28	5.08±0.03	6.27±0.12	3.19±0.03	4.01	6.64±0.08
Dried jute mallow leaves, Ground nuts, Salt	54	44	76.80±0.54	66.56	4.83±0.03	1.98±0.04	2.52±0.03	9.67	4.21±0.05
Dried jute mallow leaves, Salt	50	44	75.47±0.53	64.34	5.62±0.03	1.41±0.03	3.42±0.03	9.49	4.59±0.05
Kale leaves, Tomatoes, Onions, Oil, Salt	50	44	72.56±0.51	103.96	4.88±0.03	7.93±0.15	2.17±0.02	5.98	6.48±0.07

Data are expressed as mean±SD on a dry-weight basis. NA-not analysed.

[a]Infant median portion sizes in grams per meal recorded from the 24-hour dietary recall among infants aged 6-11 months.

[b]Number of infants reported to have consumed the meal on the day of the 24-hour dietary recall. Infants who had 2 or more meals per day consumed same staple, same relish or a different type of relish.

Table 2.4 Calcium, iron and zinc content of porridge and contribution to recommended intakes

Type of porridge and ingredients	Calcium	Iron	Zinc	Calcium		Iron		Zinc	
	(mg/100 g dry weight)			mg/portion	% RNI[a]	mg/portion	% RNI[a]	mg/portion	% RNI[a]
Whole maize flour, Sugar	25.43±1.37	0.45±0.02	0.29±0.01	8.78	2.2	0.16	1.7	0.10	2.4
Whole maize flour, Groundnuts, Salt	78.72±4.25	0.57±0.03	0.36±0.01	28.35	7.1	0.21	2.2	0.13	3.1
Whole maize flour, Groundnuts, Salt, Sugar	34.08±1.84	0.48±0.02	0.25±0.01	11.86	3.0	0.17	1.8	0.09	2.2
Whole maize flour, Baobab flour	55.98±3.02	0.24±0.01	0.17±0.00	19.06	4.8	0.08	0.9	0.06	1.4
Whole maize flour, Baobab flour, Sugar	95.13±5.14	ND	0.10±0.00	31.91	8.0	NA	NA	0.03	0.8
Whole maize flour, Sunflower oil, Salt	106.96±5.78	0.37±0.02	0.17±0.00	37.85	9.5	0.13	1.4	0.06	1.5
Composite flour (Whole maize flour, Finger millet flour, Sardines, Groundnuts)	68.14±3.68	1.49±0.07	0.50±0.01	38.12	9.5	0.83	9.0	0.28	6.8
Whole maize flour, Cow's milk, Salt	74.27±4.01	0.35±0.02	0.25±0.01	21.87	5.5	0.10	1.1	0.07	1.8
Dehulled maize flour, Salt	74.12±4.00	0.24±0.01	Trace	25.90	6.5	0.08	0.9	NA	NA
Dehulled maize flour, Groundnuts, Sugar	72.07±3.89	0.38±0.02	0.20±0.00	27.99	7.0	0.15	1.6	0.08	1.9
Dehulled maize flour, Cow's milk, Salt	85.33±4.61	0.19±0.01	Trace	24.31	6.1	0.05	0.6	NA	NA
Dehulled and soaked maize flour, Salt	78.43±4.24	0.08±0.03	0.13±0.00	23.33	5.8	0.02	0.3	0.04	0.9
Dehulled and soaked maize flour, Groundnuts, Salt	87.82±4.74	ND	0.19±0.00	26.02	6.5	NA	NA	0.06	1.3
Dehulled and soaked maize flour, Baobab, Sugar	103.96±5.61	ND	ND	30.46	7.6	NA	NA	NA	NA
Dehulled and soaked maize flour, Cow's milk, Sugar	125.55±6.78	ND	Trace	36.32	9.1	NA	NA	NA	NA
Whole sorghum flour, Salt	81.40±4.40	0.77±0.04	Trace	23.61	5.9	0.22	2.4	NA	NA
Whole sorghum flour, Groundnuts, Salt	103.57±5.60	0.75±0.04	Trace	29.89	7.5	0.22	2.3	NA	NA
Whole pearl millet flour, Salt	57.57±3.11	2.05±0.10	0.23±0.01	20.63	5.2	0.73	7.9	0.08	2.0
Whole pearl millet flour, Groundnuts, Salt	97.97±5.29	2.29±0.11	0.35±0.01	35.77	8.9	0.84	9.0	0.13	3.1
Whole finger millet flour, Sugar	93.61±5.06	2.81±0.14	0.44±0.01	35.20	8.8	1.06	11.4	0.16	4.0
Fresh cow's milk, Water, Sugar	60.12±3.25	ND	0.18±0.00	11.88	3.0	NA	NA	0.04	0.9

[a]Proportion of the recommended nutrients intake (RNI) for iron (9.3 mg/day, medium bioavailability), zinc (4.1 mg/day, moderate bioavailability) and calcium (400 mg/day) for 6-11 month-old infantsbased on WHO/FAO mineral requirements (65).

Data are expressed as mean±SD on a dry-weight basis. ND, not detected. Trace-values less than 0.06 mg/100 g dry weight.

NA, not applicable because mineral levels were either not detected or values were trace (less than 0.06 mg/100 g dry weight).

Table 2.5 Calcium, iron and zinc content of staple and relish and contribution to recommended intakes

Meal type	Calcium	Iron	Zinc	Calcium		Iron		Zinc	
	(mg/100 g dry weight)			mg/portion	% RNI[a]	mg/portion	% RNI	mg/portion	% RNI
Staple									
Whole maize *ugali*	11.40±0.62	2.04±0.10	0.97±0.02	4.70	1.2	0.84	9.0	0.40	9.8
Dehulled maize stiff *ugali*	8.70±0.47	0.82±0.04	0.87±0.02	3.98	1.0	0.38	4.0	0.40	9.7
Dehulled and soaked maize *ugali*	8.70±0.47	ND	0.62±0.01	3.82	1.0	NA	NA	0.27	6.6
Whole sorghum *ugali*	10.50±0.57	3.23±0.16	0.60±0.01	3.85	1.0	1.18	12.7	0.22	5.4
White rice cooked	19.10±1.03	ND	0.33±0.01	7.25	1.8	NA	NA	0.13	3.1
Relish and ingredients									
Beef, Tomatoes, Onions, Oil, Salt	191.70±10.35	7.39±0.36	1.61±0.03	53.75	13.4	2.07	22.3	0.45	11.0
Dried fish, Tomatoes, Onions, Oil, Salt	178.00±9.61	3.01±0.15	0.11±0.00	61.56	15.4	1.04	11.2	0.04	0.9
Dried sardines, Tomatoes, Onions, Oil, Salt	114.40±6.18	2.93±0.14	0.17±0.00	34.36	8.6	0.88	9.5	0.05	1.2
Fermented cow's milk	216.80±11.71	0.08±0.00	Trace	35.12	8.8	0.01	0.1	NA	NA
Beans, Tomatoes, Onions, Oil, Salt	80.40±4.34	1.78±0.09	0.20±0.00	20.61	5.2	0.46	4.9	0.05	1.2
Bean, Onions, Oil, Salt relish	70.70±3.82	1.75±0.09	0.08±0.00	14.96	3.7	0.37	4.0	0.02	0.4
Chinese cabbage, Tomatoes, Onions, Oil, Salt	125.30±6.77	7.24±0.35	0.14±0.00	19.05	4.8	1.10	11.8	0.02	0.5
Sweet potato leaves, Tomatoes, Onions, Oil, Salt	106.80±5.77	7.59±0.37	0.06±0.00	10.11	2.5	0.72	7.7	0.01	0.1
Fresh cowpea leaves, Tomatoes, Onions, Oil, Salt	103.90±5.61	5.79±0.28	Trace	16.64	4.2	0.93	10.0	NA	NA
Dried cowpea leaves, Tomatoes, Onions, Oil, Salt	164.90±8.91	4.22±0.21	Trace	20.58	5.1	0.53	5.7	NA	NA
Pumpkin leaves, Tomatoes, Onions, Oil, Salt	141.50±7.64	7.04±0.35	0.07±0.00	19.26	4.8	0.96	10.3	0.01	0.2
Dried jute mallow leaves, Ground nuts, Salt	81.10±4.38	15.11±0.74	0.10±0.00	11.12	2.8	2.07	22.3	0.01	0.3
Dried jute mallow leaves, Salt	136.20±7.36	17.02±0.83	Trace	10.55	2.6	1.32	14.2	NA	NA
Kale leaves, Tomatoes, Onions, Oil, Salt	97.80±5.28	2.75±0.13	0.07±0.00	11.95	3.0	0.34	3.6	0.01	0.2

[a] Proportion of the recommended nutrients intake (RNI) for iron (9.3 mg/day, medium bioavailability), zinc (4.1 mg/day, moderate bioavailability) and calcium (400 mg/day) for 6-11 month-old infants based on WHO/FAO mineral requirements (65).

Data are expressed as mean±SD on a dry-weight basis. ND-not detected. Trace-values less than 0.06 mg/100 g dry weight.

NA, not applicable because mineral levels were either not detected or values were trace (less than 0.06 mg/100 g dry weight).

2.5 Discussion

This present study has highlighted inadequate feeding practices, low nutrient content of complementary meals, low dietary contribution to nutritional requirements and high prevalence of chronic undernutrition (i.e. stunting) among infants in rural Dodoma.

Although majority of infants were breastfeeding as recommended, many infants were introduced to liquids and foods earlier than the recommended age of six months. Early introduction of complementary foods is a common practice in Tanzania (22); 60% in this study as compared to national levels of 33.4% and 63.5% among 2-3 and 4-5 months-old infants, respectively. Meal frequencies including snacks were lower than the recommended values of 2-3 for 6-8 months-old and 3-4 times for 9-11 months-old breastfed infants (26). Majority of infants aged 6-8 months met the WHO IYCF indicator of receiving semi-solid or soft foods. High prevalence of 92.3% for introduction of solids, semi-solid or soft foods was also reported among young children in Tanzania (127). Very few 6-11 months-old infants met the minimum dietary diversity criterion of 4 or more food groups. A similar finding was reported in Ethiopia where 6.3% of the children (6-24 months-old) achieved the minimum dietary diversity (128). The mean number of individual foods consumed (i.e. food variety) was low. Limited food accessibility, low availability and lack of nutritional knowledge, could have caused the observed inadequacies (41). Household food insecurity has been documented to compromise the quality and quantity of complementary foods given to infants, ultimately affecting their nutritional status (129-131).

Although moisture content of porridge samples were within 81-87% reported in Benin (132) and Africa (133), the flour:water ratios (1:4 - 1:9) used in preparations were higher than those (1:2 - 1:3) reported in Malawi, Ghana, Ethiopia, and other Asia Pacific countries (64). Because water content is an important determinant of levels of other food components (122), high water content in our porridge samples contributed to high moisture content and reduced nutrient content. Energy contents of porridge samples reported here were lower than those (91.0 - 130.3 kcal) indexed in the Tanzania Food Composition Tables (134) probably because of higher water content and relatively smaller amounts of sugar used in our samples than 13 - 50g reported in Tanzania Tables. Prolonged consumption of watery or thin porridges exposes infants to inadequate energy and nutrient intakes and chronic malnutrition.

Inclusion of groundnuts, cow's milk or baobab fruit pulp in porridge was desirable in that they enhanced energy, protein and calcium contents and overall dietary quality. The ingredients are readily available in the study area. Nevertheless, amount of ingredients used were small and milk was diluted with water before use. Dilution of milk with water was perceived by mothers to make it 'light' for the infants to consume. These factors would limit their nutritional benefits. Consumption of traditionally fermented sour milk may be nutritionally beneficial; however the milk poses a great health risk because it was not boiled. Raw milk can easily be contaminated by pathogenic bacteria if kept for too long at ambient temperature. Because the fermentation

process is spontaneous and uncontrolled, quality of sour milk may be variable; affecting taste and consequently reducing amount to be consumed.

There was limited inclusion of other nutrient-dense foods (e.g. legumes, beef, fish, sardines, vegetables) in the meals. In addition, few infants consumed these foods. Low consumption of animal source foods (ASFs) has also been reported in developing countries, resulting in inadequate dietary intake and poor growth (135-137). Low consumption of ASFs may be attributed to household food insecurity, high cost of foods, or inadequate nutritional knowledge. Due to inadequate maternal knowledge, mothers withhold these foods until infants grow sufficient number of teeth for chewing. Opportunities to increase their consumption need to be promoted. These include pounding or milling, manual grinding and mashing of raw/fresh, raw/dried and cooked foods. With the exception of one composite porridge made from a mixture of cereal, legume and animal source flour, use of composite flour was rare in this area. Formulations of mixed flours have been reported to achieve a desired nutrient content and protein complementarity (138), protein digestibility and lower viscosity as compared to single cereals (139).

Cooked staples constituted a major part of a meal and were good sources of energy. Maize is the main staple in most Tanzania communities. Although sweet potatoes, cassava and round potatoes are also consumed, they were not available at the time of the study. Types of relish reported here reflect common Tanzanian diets. Kidney beans were the only legumes available during the study. Availability of sun-dried leafy vegetables ensured their supply and consumption during the dry season. Open sun-drying method, commonly practiced in the study area and central Tanzania (140), will need to be improved in order to enhance adequate nutrient retention.

Environmental factors, grain pre-treatment prior to dehulling, extraction rates of dehulling machines, leaching of minerals in water during soaking and eventual discarding of soaking water could have accounted for reduced (or undetectable) levels of protein, fat, fibre, iron and zinc in meals made from dehulled or dehulled and soaked cereal flours. Calcium levels in cooking water were generally high and water samples had elevated taste of hardness. Notwithstanding the addition of calcium-rich foods in porridge (e.g. cow's milk, baobab fruit pulp), amounts of calcium in cooking water rather than calcium intrinsic to food ingredients could be responsible for the high levels in the porridge samples. It is therefore difficult to ascertain whether the enhanced calcium contents in porridge were due to water or calcium-rich foods.

Median portion sizes for porridge were slightly higher than 115 g reported for maize-based porridge and 90 g for maize ugali among 6-12 months infants in South Africa (141). Overall meal portion sizes were lower than the documented gastric capacity of 249 and 285 g/meal for 6-8 and 9-11 months infants, respectively (59). Inadequate portion sizes will most likely translate to inadequate dietary intake. Energy density (kcal/g) and portion size (g) of foods have been identified as two properties of foods that can modulate energy intake (142). When portion sizes

were expressed in amounts of energy that could be obtained per median portion, relish made from ASFs provided higher amounts than other meals. Porridge made from composite flour provided highest energy per portion. Calculated energy densities of porridges (0.41-0.64 kcal/g) were lower than the minimum densities (0.71 kcal/g, 6-8 months-old; 0.84 kcal/g , 9-11 months-old) required to meet recommended energy from complementary foods for infants receiving two meals per day (26). Energy densities of porridge in most developing countries have been reported to be low (0.25-0.50 kcal/g) due to addition of large quantities of water to achieve a drinkable consistency (143).

When compared to energy required from complementary foods (26), relish made from ASFs will contribute more energy (26-33%) than staple (24-30%), porridge (6-18%) and beans and leafy vegetables (3-13%) to 200 kcal/day required by 6-8 months-old infants. Likewise, ASFs will contribute more energy to 300 kcal/day required by 9-11 months-old infants. Although nutritional deficits by porridge may be addressed by consumption of staple ugali with relish, relish portion size would need to be increased to provide sufficient energy and other nutrients. It is also imperative that caregivers increase feeding frequency and include nutrient-rich foods in porridge.

Porridge made from composite flour provided highest amounts of zinc per portion, probably because its portion size was larger and had slightly high zinc content. Relish based on jute mallow leaves or beef provided highest amounts of iron. Compared to iron and zinc requirements (9.3 mg/day and 4.1 mg/day respectively) for 6-11 months-old infants (59, 65), none of the studied infants would be able to meet more than 25% RNI from porridge if it was consumed twice per day. A feasible option to increase iron and zinc content in porridge would be to add locally available iron- and zinc-dense foods (e.g. dried and ground jute mallow leaves, sweet potato leaves, beans, cowpeas), increase frequency of consuming these foods and increase portion sizes as the child grows.

Inadequate feeding practices and limited dietary supply observed here could have contributed to the chronic nature of malnutrition. Although the prevalence of stunting was high, there was lack of significant associations or relations between stunting and feeding practices. Limited food availability and accessibility during the post-harvest season could have aggravated this situation. The influence of seasons on decreased household food supply and limited dietary intake has also been documented in settings similar to this study (144-146).

2.6 Conclusion

The study shows that inadequate feeding practices, low nutrient content of complementary meals, decreased dietary contribution to nutritional requirements and high prevalence of chronic undernutrition (i.e. stunting) are very common among infants in rural Dodoma during the post-harvest season. Inclusion of groundnuts, cow's milk or oil in porridge improves energy, protein and fat contents. Composite porridge and relish based on ASFs provide higher energy, protein and fat per portion than other meals. Relish made from beef, fish, sardines, dried jute mallow leaves,

sweet potato leaves, beans and cowpeas are better sources of iron, zinc and calcium than other meals. These data provide a foundation for promoting best dietary practices (increased meal frequency, inclusion of nutrient-dense foods, adequate portion sizes, increased food variety) using feasible strategies such as nutrition education and counselling.

Chapter 3. Development of a nutrition education package to improve feeding practices, dietary adequacy and growth of infants and young children in rural Tanzania

This chapter has been redrafted after:
Kulwa KBM, Verstraeten R, Bouckaert KP, Mamiro PS, Kolsteren PW, Lachat C. Effectiveness of a nutrition education package in improving feeding practices, dietary adequacy and growth of infants and young children in rural Tanzania: rationale, design and methods of a cluster randomised trial. *BMC Public Health* 2014; 14:1077

3.1 Summary

Background: Strategies to improve infant and young child nutrition in low- and middle- income countries need to be implemented at scale. Successful strategies were contextualised and packaged into a feasible intervention for implementation in rural Tanzania. Motivations to behaviour change that can optimise delivery of the package included mothers' willingness to modifying practices; support of family members; seasonal availability and accessibility of foods; established set-up of village peers and functioning health system.

Objective: This chapter provides a background and description of the development processes and evaluation design of a nutrition education package aimed to improve feeding practices, dietary adequacy and growth of infants in rural Tanzania.

Methods: The education package is comprised of four components: 1) education and counselling of mothers, 2) training community-based nutrition counsellors and monthly home visits, 3) sensitisation meetings with health staff and family members, and 4) supervision of community-based nutrition counsellors. Infants will be recruited at 6 months of age. Duration of the intervention is nine months; six months of intensive intervention and three months of observation with no on-going intervention. A parallel cluster randomised controlled trial will be conducted in 18 rural villages of a district in central Tanzania. Nine villages will be randomised to intervention group and nine to control group. The control group will receive routine health education offered monthly by health staff at health facilities. Routine health education, a standard government health service for children below the age of five years, is offered monthly by health staff at health facilities. It offers education to mothers, mainly focusing on child feeding, prevention of diseases such as malaria and importance of immunisations. The intervention group will receive a nutrition education and counselling package in addition to the routine health education.

Primary outcome will be mean change in linear growth as length-for-age Z-scores; and secondary outcomes will include changes in weight-for-length Z-scores; mean intake of energy, fat, iron and zinc from complementary foods; proportion of children consuming 4 or more food groups and the recommended number of semi-solid/soft meals and snacks per day; maternal level of knowledge and performance of recommended practices. These will be assessed at baseline and when infants are aged 9, 12 and 15 months. Process evaluation will document reach, dose and fidelity of the intervention and context at 8 and 15 months. Multilevel mixed-effects models will be used to analyse effects of the package on outcomes.

Conclusion: Results of the trial will provide evidence of the effectiveness of the nutrition education package in community settings of rural Tanzania. They will provide recommendations for strengthening the nutrition component of health education in child health services.

Trial registration: ClinicalTrials.gov Identifier: NCT02249754, September 25, 2014.

Keywords: nutrition education, complementary feeding, growth, Tanzania, cluster randomised trial, process evaluation, intervention mapping, theory of planned behaviour

3.2 Introduction

Stunting and micronutrient deficiencies are significant health problems among rural infants and young children in the southern and central regions of Tanzania. Poor breastfeeding practices, inadequate dietary intake from complementary foods, high rates and repeated episodes of diseases, maternal inadequate nutritional knowledge and household food insecurity have been associated with stunting in Tanzania (47, 102, 147, 148). Overall, only 2 out of 10 Tanzanian children are fed in accordance with the recommended infant and young child feeding (IYCF) practices (22). Among the breastfed children (6-23 months-old), 61% were given foods from three or more food groups, 39% were fed the minimum number of times, 30% consumed iron-rich foods and 62% consumed vitamin A-rich foods.

Two cross-sectional surveys were conducted in Dodoma, one of the central regions with high rates of malnutrition, to closely examine feeding practices, diets and nutritional status of infants and young children and guide decisions on improvement. The first survey, conducted in 2009 during the post-harvest season, involved 496 households with infants aged 1 to 12 months. The second survey revisited the same households and infants in 2010 during the harvest season. Results of the surveys indicated high prevalence of stunting; 33.5% in 2009 and 59.3% in 2010. Morbidity due to acute respiratory illness (ARI) was 63.9% in 2009 and 56.4% in 2010. Diarrhoea affected 48.4% children in 2009 and 36.4% in 2010. Prevalence of anaemia was high (11 - 60% in 2009; 20 - 75% in 2010). Complementary fluids and foods were introduced at the median age of 3.0 months and 90% of all surveyed children had received these foods earlier than the recommended age of 6 months. Feeding frequencies (1.7 in 2009 and 2.4 in 2010) were lower than the age-specific World Health Organization (WHO) recommendations (26). Portion sizes for different types of relish/sauce were small. Similar findings in low- and middle- income countries (LMIC) have been documented in rural areas and have progressively worsened throughout the first year of life (62, 129, 149-151).

Systematic reviews of complementary feeding interventions have provided evidence of well adopted feeding practices, improved food recipes, increased dietary adequacy and growth and reduced prevalence of anaemia and morbidity (60, 75-77). The interventions included a combination of strategies, namely culturally-appropriate group nutrition education, individual counselling, interpersonal communication, home visits and mass media (81, 82, 152-155). Great impact and sustainability of the interventions were achieved through participatory approaches and community involvement (156-158).

The two cross-sectional studies conducted in Dodoma showed that age-specific, systematic and locally relevant interventions are needed to ensure that rural children receive the best possible start in life. To address the nutrition and health situation, intervention strategies were identified and contextualised according to, among other factors, local dietary patterns, meal preparation, food beliefs and preferences, food availability and cost and ability to change attitudes. The strategies were packaged as a nutrition education package. Opportunities that could optimise successful delivery of the package and encourage behaviour change include willingness to

modifying some feeding options, seasonal availability and accessibility of foods, established set-up of village peers and existence of health centres and health staff in some villages. This chapter describes the rationale, design and methods of a cluster randomised controlled trial to evaluate the effectiveness of a nutrition package in rural Tanzania.

The primary objective of the intervention trial is to implement and evaluate the effectiveness of a nutrition education package in improving infant and young child feeding practices, dietary adequacy and growth. The trial hypothesises that the nutrition education package will be more effective than the routine health education. The primary outcome will be linear growth as assessed by change in length-for-age Z scores. Secondary outcomes will include feeding practices, nutrients intake and level of knowledge on recommended practices. Results of the trial are expected to provide evidence to the effectiveness of the package in community settings and, where appropriate, recommendations to strengthen the nutrition component of health education in child health services.

3.3 Methods

3.3.1 Development of the nutrition education package

Intervention Mapping and Theory of Planned Behaviour (159, 160) provided a planning model and theoretical framework, respectively, for the design and development of the package and the intervention. The Intervention Mapping model integrates theory, empirical findings from the literature and information collected from the target population to develop culturally appropriate and theoretically sound interventions (161, 162). The model has been used successfully to develop health behaviour interventions (163, 164). This study applied consecutively and iteratively the six steps of Intervention Mapping, as described in the next sections.

Step 1: Needs assessment. Needs assessment involved a literature study on complementary feeding strategies conducted in low- and middle-income countries, a review of secondary data on child health and the cross-sectional studies conducted in 2009 and 2010 in the study area. Key informant interviews, focus group discussions, food market surveys and household surveys were conducted to obtain in-depth insight into the nutrition and health situation of infants and young children, community and household factors, parents' motivations and behaviours that facilitate and constrain infant and young child feeding and health.

Step 2: Identifying intervention performance and change objectives. Results from Step 1 were used to identify behaviours, motivations, barriers, predisposing and enabling factors associated with inadequate dietary intake, morbidity and poor growth. A conceptual framework illustrating expected behaviours and mediating factors for improvement of child growth was developed (**Appendix 3.1**). Aspects that will be implemented by the intervention are also presented. The overall intervention objective "improve feeding practices, dietary adequacy and growth of infants and young children (6-15 months)" was formulated and divided into sub-objectives and behavioural performance objectives (i.e. target behaviours that have to be accomplished by the

target group to achieve the intervention objective). A matrix of intervention objectives and behavioural performance objectives, classifying individual and environmental determinants as mediating mechanisms and modifying conditions was developed (**Appendix 3.2**). Discussions with district health experts and village health committees helped to refine the intervention further.

Step 3: Selection of theory-based intervention methods and techniques. Theoretical methods considered to influence changes of performance objectives (i.e. target behaviours) were identified and practical strategies were selected to put the theoretical methods into practice (163). Systematic reviews (60, 75, 76), individual nutrition education and counselling interventions (81, 153) and summary of theoretical methods (163) were used in the selection of existing methods and techniques, and the development of new strategies which fitted our intervention and behavioural objectives. The Theory of Planned Behaviour was used as the main focus of behavioural change during the selection of theory-based methods and strategies (165). The theory has been widely employed in health and nutrition behaviour change studies (160, 166, 167), including infant feeding (168-170). The theory facilitates an understanding of how behavioural intentions influence actual behaviour change, with skills, abilities and environmental factors acting as important moderators of change.

The theoretical methods were translated into practical strategies and these were related to the levels of the intervention. An example includes a behavioural objective and outcome expectation of "adding mashed animal-source food to infant meals at least 3 times per week would provide nutrients to make a child grow well and offer protection against common illnesses." A mother will be willing and more likely to apply the recommendation using the following methods and techniques:

- the individualisation method to provide opportunities for mothers to have personal questions and concerns about child feeding answered (e.g. what to feed, how to feed) or instructions paced according to individual progress;
- cognitive skills training with guided practice to influence self-efficacy;
- tailoring to increase practical knowledge on selection and preparation of new food recipes; and
- mobilising social support (e.g. trained peers, sensitised family members and health facility staff) to offer encouragement and support, and likely to help the mother to maintain optimal child feeding practices.

Step 4: Developing the intervention and pre-testing. The intervention objectives, selected methods and strategies were combined and a nutrition education package was developed. The nutrition education package is composed of four components, namely 1) education and counselling of mothers, 2) training community-based nutrition counsellors and monthly home visits, 3) sensitisation meetings, and 4) supervision of community-based nutrition counsellors. Draft versions of the package were discussed with district health and nutrition experts, village health committees and fine-tuned by the research team. Behavioural change at the individual level is

intended for mothers of rural infants aged 6 months through education and counselling sessions and cooking demonstrations. Based on local typical meals, the intervention will promote preparation and consumption of a variety of foods. Behavioural change at the family level will consist of sensitisation meetings with family members of targeted infants. This will help to create a nutrition-promoting environment. At the community level, the intervention will train community-based peers such as village health workers, lay counsellors and resource persons to support mothers and families through home visits. In addition, sensitisation meetings with health facility staff will help to reinforce and support mothers' behaviour change.

Training and educational resources were developed to support the implementation of the package **(Appendix 3.3)**. These include: 1) Training guide for community-based nutrition counsellors, 2) Manual for community-based nutrition counsellors, 3) Educational plan for mothers, 4) Information booklet for mothers and families, and 5) Counselling cards. The resources contained topics on breast feeding, complementary feeding, selection and preparation of locally available foods, feeding during illness, healthcare-seeking, hygiene and home environment sanitation. In addition to these topics, resources for nutrition counsellors included topics on communication skills, behaviour change communication and counselling skills. The developed resources were pre-tested with a convenient sample to assess whether the content and format were realistic, understandable, culturally appropriate, visually appealing and motivating.

Step 5: Implementation plan of intervention. The intervention strategy is centred on the child with their mothers as the primary target group. To stimulate lasting behaviour change, ensure continuity, and enhance linkage between communities and health facilities, secondary target groups have been incorporated in the intervention. These include family members (fathers, grandmothers, school-going siblings), community-based nutrition counsellors and healthy facility staff. Supportive structures such as district health management team and village health committees were be consulted regularly to enhance intervention support and feedback.

Step 6: Evaluation plan of intervention. The effectiveness of the nutrition education package is evaluated in a cluster randomised controlled trial, whereby villages will be randomly allocated to receive a nutrition education package or routine health education. The intervention group will receive the nutrition education package, whereas the control group will continue to receive routine health education given monthly at health facilities. Children aged 6 months and their families will be recruited and followed up for 9 months. Extensive process evaluation will also be performed to document reach, dose and fidelity of the intervention trial.

3.3.2 Study design

The intervention will be conducted in Mpwapwa district in Dodoma region, central Tanzania. Dodoma is among the regions in the country with the highest prevalence of stunting, 44.4% in 2005 and 56.0% in 2010 (22, 23). Detailed characteristics of the region and district have been described in Chapter 1 **(section 1.6.2)**.

The intervention trial will use a parallel cluster-randomised controlled trial design (**Figure 3**) and will be conducted and reported in line with the CONSORT recommendations for cluster randomised trials (171). Because the intervention will be delivered in community settings and encourage collective participation at household settings, to minimise contamination and facilitate logistical convenience in delivery, the unit of randomisation will be the village. Villages will be randomly assigned to either the intervention or control study groups. The intervention duration will be 9 months. Infants will be recruited when aged 6 months and followed up until they attain 15 months. The first six months will be of intensive intervention and the remaining three months of observation with no on-going intervention.

The control group will continue to receive routine health education, a standard government health service for children below the age of five years, offered monthly by health staff at health facilities. Routine health education offers education to mothers during growth monitoring and immunisation contacts. The sessions are usually short (10-15 minutes) and focus on general health issues including child feeding, prevention of diseases such as malaria and importance of immunisations.

The intervention group will receive the nutrition education package in addition to the routine health education. Mothers and caregivers will receive 3 sessions of education and counselling on optimal infant and young child feeding and health, when the child reaches 6 months, 9 and 12 months. Nutrition counsellors will receive training at baseline and the session will be repeated after 6 months. After training, the nutrition counsellors will conduct monthly home visits to counsel and support mothers and their families. Supervisory visits will be conducted by the research team after every 2 months to assess counsellors' work. Separate sensitisation meetings with families and health staff responsible for child health will be conducted at baseline and meeting will be repeated after 6 months.

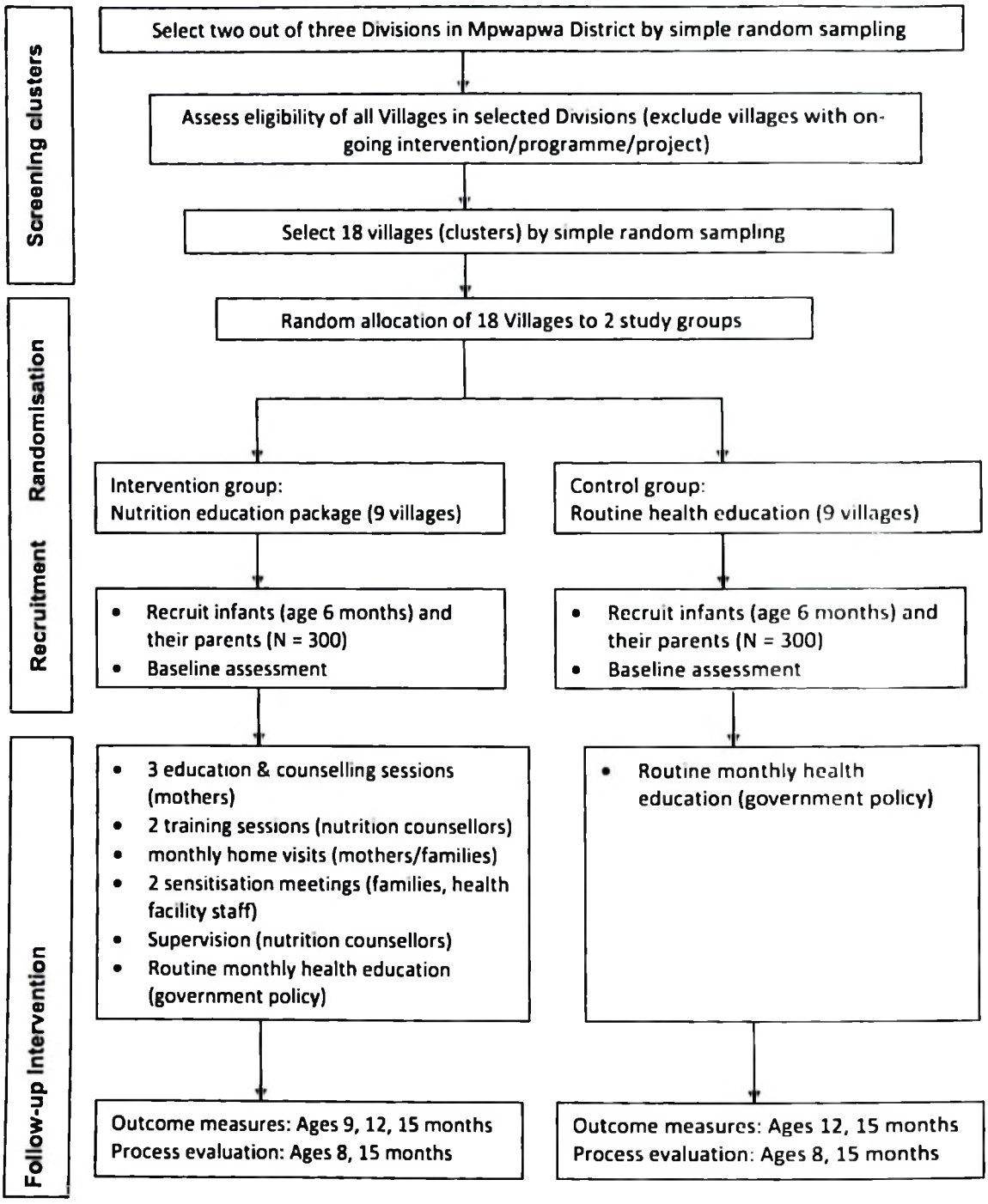

Figure 3. Trial profile

3.3.3 Cluster randomisation and sample size estimation

A village forms a unit of randomisation for the trial, while infants and their parents within the village will form units of observation. Two out of three divisions (Kibakwe, Mpwapwa, Rudi) in the district will be selected by simple random sampling. A list of all villages in the selected divisions will be compiled, and villages found to have an on-going intervention or project will be excluded.

Eighteen villages will be selected from the list by simple random sampling. The preselected villages will be listed alphabetically. A simple randomisation with a 1:1 allocation will be used to randomise villages to either control or intervention group. A list of random numbers will be generated in MS Excel 2007 and the generated values will be fixed by copying them as "values" next to the alphabetic list of the preselected villages. These will then be arranged in ascending order according to the generated random numbers: and the first 9 will be selected as intervention clusters and the last 9 as control clusters.

Generation of allocation sequence and randomisation of clusters will be done by a statistician blinded to study groups and not participating in the research. Data collectors will be masked of the village allocation by not informing them of the allocation, not being part of trial implementers and not being residents in any of the villages. Nutrition counsellors who will receive training and be tasked to conduct home visits may know they are in the intervention or control group; and because of this they will not participate in data collection. Mothers will only know from the research information sheet that they are participating in a research, but they will not be aware of group allocation.

The sample size will be calculated for unmatched cluster-randomised trials (172) as follows:

$$c = 1 + (Z_{\alpha/2} + Z_{\beta})^2 \times ([\sigma_0^2 + \sigma_1^2] / n + k^2 [\mu_0^2 + \mu_1^2]) / (\mu_0 - \mu_1)^2$$

whereby:

c is the number of clusters required in each treatment group; $Z_{\alpha/2}$ is the standard normal distribution corresponding to the 95% degree of confidence on a two-sided test; Z_{β} is the standard normal distribution corresponding to 80% power; σ_0 and σ_1 are the within cluster standard deviations of the outcome variable in the presence and absence of intervention, respectively; n is the minimum number of individuals sampled in each cluster; k is the coefficient of variation of true means between clusters within each group; and μ_0 and μ_1 are the within cluster population means in the presence and absence of intervention, respectively.

As there is no information available on the intra-cluster coefficient of variation, the estimate for the between-cluster coefficient of variation (k) was based on conservative estimates of ≤ 0.25 and 0.15-0.25 experienced in similar health and nutrition studies (172, 173). A coefficient of variation between clusters (k) of 0.1 was assumed and 30 infants per cluster based on district's estimates of birth rates. Data from the 2009 survey were used to make assumptions on change of values of the primary outcome length-for-age Z-scores (LAZ): a mean LAZ of -1.5 and a standard deviation of 1.3 in the control group. From the formula, 8.9 (~ 9) clusters will be needed to detect at least a 0.35 difference in LAZ between intervention and control groups, with the power of 80% (Z_{β}=0.84) and a statistical significance of 5% ($p<0.05$; $Z_{\alpha/2}$ = 1.96, two-tailed test). A total of 270 infants will be enrolled in each study group. Allowing for a 10% loss to follow-up, a sample size of 297 infants, i.e. 33 per village, will be required. A total of 594 (~ 600) infants will be recruited.

3.3.4 Recruitment, baseline information and ethical considerations

After cluster randomisation, sub-village leaders will identify all infants aged 6 months and their parents in a systematic door-to-door survey. Parents of identified infants will be invited to a meeting where the nature and purpose of the trial and eligibility criteria will be explained. Thereafter, the infants will be screened for eligibility. Inclusion criteria will be breastfeeding infants aged 6 months; parents (or caregivers) are residents in the sampled village and have no plans to move away during the intervention period. Exclusion criteria will be infants with obvious congenital or chronic abnormalities impairing feeding or physical growth measurements; have oedema; are severely ill or have clinical complications warranting hospitalisation. Parents/guardians and infants who meet the inclusion criteria, agree to participate in the trial and give a written informed consent will have their infants recruited in the trial. Baseline information of recruited infants and their parents/guardians will be collected using a structured questionnaire. The information will include household's, parents' and infant's characteristics. Structured interviews with village and sub-village leaders will also be conducted to collect village information (i.e. population, health facility, water supply, schools, livelihoods, resources, economic opportunities).

The trial will be explained verbally and in a written formal letter to district administrative and health officials. Approval to include the selected villages in the trial will be sought from village authorities. After identification of eligible infants in each cluster, their parents/guardians will be invited to a meeting where nature and purpose of the trial will be explained. The information sheet and informed consent document will be tailored to the study group (intervention or control) to which a particular cluster was allocated (174). Parents/guardians who agree to participate in the trial will be requested to sign a written informed consent. A verbal consent will be requested from parents or guardians who are unable to read and/or write and an impartial witness will be present when the verbal consent is given. Informed consent will also be sought from nutrition counsellors and health facility workers in intervention villages. During the course of the trial, infants reported to be ill in both study groups will be referred to health facilities where they usually receive treatment free of charge according to Ministry of Health regulations. Households that do not participate in the intervention group will receive education and counselling resources at the end of intervention. Ethical clearance was obtained from the National Institute of Medical Research (Tanzania), Institute of Tropical Medicine (Belgium) and University of Antwerp (Belgium).

3.3.5 Delivery of the nutrition package

Component 1: Education and counselling of mothers

This component aims to impart rural mothers and caregivers with action-oriented knowledge, skills, behaviour and attitude that will motivate their ability to adopt optimal infant and young child feeding and health care practices. Nutrition education and counselling will be conducted with mothers of recruited infants in three sessions. The first session will be conducted when infants are 6 months-old. The second and third sessions will be conducted when infants are aged 9 and 12 months, respectively. Each session is expected to last 2 to 3 hours. The content is consistent with

age-specific feeding recommendations made by WHO (26, 175) and timed to coincide with child's age at 6, 9 and 12 months. The sessions will be centred on feeding, health, hygiene and sanitation. Distribution of sessions and topic coverage is presented in **Table 3.1**. Theoretical sessions (Part 1)

Table 3.1 Description of nutrition education topics delivered during the training of village health workers and education of mothers in rural Mpwapwa District, Tanzania, 2014-2015[1]

Training VHW[2]		Educating and counselling Mothers[3]		
Session 1 **Child at 6 months**	**Session 2** **Child at 12 months**	**Session 1** **Feeding your child at 6-8 months**	**Session 2** **Feeding your child at 9-11 months**	**Session 3** **Feeding your child at 12-23 months**
Module 1 1.Optimal nutrition and health during the first two years of life	Discussions on the completed intervention **Module 1** 1.Optimal nutrition and health during the first two years of life	**Part 1:** Group education	Feedback/review of previously set goals **Part 1:** Group education	Feedback/review of previously set goals **Part 1:** Group education
2.Food groups and diversification of diets	2.Food groups and diversification of diets	Breastfeeding your baby	Breastfeeding your baby	Breastfeeding your baby
3.Complementary feeding practices at 6-24 months 4.Child health and preventive measures	3.Complementary feeding practices at 6-24 months 4.Child health and preventive measures	Meal diversity, frequency, consistency, amount, responsive style)	Meal diversity, frequency, consistency, amount, responsive style)	Meal diversity, frequency, consistency, amount, responsive style)
Module 2 1.Communication skills (channels, skills to communicate effectively, barriers)	**Module 2** 1.Communication skills (channels, skills to communicate effectively, barriers)	Locally available foods for preparation of nutritious meals	Locally available foods for preparation of nutritious meals	Locally available foods for preparation of nutritious meals
2.Behaviour change communication (types, determinants, stages, interventions, barriers)	2.Behaviour change communication (types, determinants, stages, interventions, barriers)	Feeding your baby during and after illness	Feeding your baby during and after illness	Feeding your baby during and after illness
3.Counselling skills (approaches, characteristics, skills for individual and group counselling, counselling process, negotiation) 4.Use of counselling tools I	3.Counselling skills (approaches, characteristics, skills for individual and group counselling, counselling process, negotiation) 4.Use of counselling tools I	Hygiene (safety, handling, storage of food) and home sanitation	Hygiene (safety, handling, storage of food) and home sanitation	Hygiene (safety, handling, storage of food) and home sanitation
5a.Field practice on counselling and negotiation 5b.Review and feedback of Field practice	5a.Field practice on counselling and negotiation 5b.Review and feedback of Field practice	Healthcare-seeking and disease prevention	Healthcare-seeking and disease prevention	Healthcare-seeking and disease prevention
Module 3 1.Use of counselling tools II	**Module 3** 1.Use of counselling tools II	Utilisation of child health services and compliance to treatment	Utilisation of child health services and compliance to treatment	Utilisation of child health services and compliance to treatment
2.Home visits tasks, supervision	2.Home visits tasks	**Part 2:** Cooking demonstration	**Part 2:** Cooking demonstration	**Part 2:** Cooking demonstration
3.Conclusion	3.Conclusion	**Part 3:** Individual counselling	**Part 3:** Individual counselling	**Part 3:** Individual counselling

[1]Modified from Kulwa *et al* (2014) (176) to include modules taught to VHW. [2]Session 1 took place in November 2014 and session 2 in July 2015. [3]Sessions 1, 2 and 3 took place in December 2014, March 2015 and June 2015, respectively.

will be followed by cooking demonstrations (Part 2) and counselling for mothers who have individual concerns (Part 3).

Direct (teacher-directed), interactive (discussion, sharing) and experiential (learner-centred, activity-oriented) instructional strategies will guide the approach of delivering education sessions. Talks, group discussions, group work exercises, demonstrations, role plays, storytelling, simulation, case studies and problem solving will be used to impart knowledge and skills, enhance maternal attitude and self-efficacy. For example, the topic "Locally available foods for preparation of nutritious meals" will apply the following teaching methodologies:

i. a lecture/talk will explain about nutrients in foods and their role in promoting growth and good health, and mothers will role play nutritional benefits;
ii. group work will involve mothers in identification and grouping of locally available foods for making typical household meals;
iii. mothers will be presented with case studies of meals to evaluate inadequacies, discuss and apply problem solving skills to overcome the inadequacies;
iv. key recommendations (**Table 3.2**) for inclusion of varieties of foods to increase content and intake of nutrient density of meals will be summarised in a lecture and mothers encouraged to make implementation goals; and
v. cooking demonstrations will show how food varieties can be used to prepare nutritious meals.

Cooking demonstrations aim to show how different food items can be used to prepare nutritious meals, illustrate appropriate amount and consistency of meals and demonstrate responsive feeding. Procedures for preparing nutritious meals based on promoted recipes (**Appendix 3.4**) will be described during the sessions. The recipes are based on meat, legumes, vegetables and root/tuber, and the foods can be eaten alone as a complete meal or eaten with cooked staple (stiff porridge ugali, rice, green banana, cassava). Under the guidance of the researcher, mothers of recruited infants and community-based nutrition counsellors will centrally prepare meals based on proposed recipes. One portion will be fed on-site and another given for feeding at home on the same day. Responsive feeding styles will be practiced by mothers during the feeding sessions and observed. For each cooking session, recipes will be alternated to reduce monotony, improve texture and flavour, and stimulate reflex chewing. Mothers will be encouraged to try the recipes and other feeding recommendations at home. Information booklets containing topic content, recipe examples and promoted recommendations will be distributed after the first session.

After cooking demonstrations, mothers will be invited for individual counselling. The counselling sessions will include listening, learning about their difficulties and assessing the situation, providing relevant information, and building mother's confidence to modify behaviours and overcome barriers. The mother will be referred to nutrition counsellors in her village for support and follow-up during the monthly home visits. Follow-up visits at home will be done by

Table 3.2 Key recommendations and messages for promoting optimal feeding and health practices

1	Continue to breastfeed your child on demand, during the day and night throughout the first and second years. Breastfeed first before giving other meals.
2	Start giving soft and thick meals in addition to breast milk when child completes 6 months, then continue with mashed and semi-solid meals. Increase variety, amount and consistency of food as he/she becomes used to eating and chewing different foods.
3	Prepare a thick porridge made from a combination of cereal flours. Enrich the porridge by adding groundnuts, milk, egg or legume. Thin porridge does not contain adequate nutrients to support your baby to grow well and stay healthy.
4	Give undiluted cow's milk to your child at least 3 times per week.
5	Cook, mash, and add one or more ingredients from legumes (e.g. beans, pigeon peas, bambara groundnuts, cowpeas) in each meal.
6	Cook, mash and feed animal source foods (e.g. eggs, beef, pork, chicken, liver, fish, sardines) at least 3 times per week.
7	Cook, mash, and feed vegetables (e.g. leafy vegetables, pumpkin, avocado) in each meal.
8	Feed your child a fruit (e.g. papaya, ripe banana, mango, orange) after a meal at least once per day.
9	Increase frequency of feeding meals per day (2-3 times at 6-8 months, 3-4 times at 9-11 months, 3-4 times at 12-23 months). Feed 1-2 snacks (e.g. fruit, bread with groundnut paste) between two major meals.
10	Encourage your child to eat with patience and love. Encourage a sick child to drink and eat more frequently during illness. Provide extra food after illness to facilitate quick recovery.
11	Wash your hands with soap before preparing meals or before feeding children. Wash your hands with soap after visiting the toilet, and after cleaning a child who has defaecated.
12	Learn to recognise early danger signs and symptoms of childhood diseases. Promptly take a sick child to the nearest health facility for examination and treatment.
13	Ensure that your child completes a full course of prescribed medications. Return for a follow-up visit at the health facility when required or if child's condition is not improving.
14	Keep your home environment clean. Use preventive measures to protect your child and family from diseases.

community-based nutrition counsellors. After completion of each session (Part 1, 2, and 3), mothers will be encouraged to set achievable goals (i.e. to prompt intention to try the recommendations). Feedback regarding the set goals will be reviewed during the next education session.

Component 2: Training community-based nutrition counsellors and monthly home visits

This component aims to empower community-based nutrition counsellors with action-oriented knowledge and skills to effectively counsel and negotiate with mothers and families to adopt recommended practices. In each intervention village, 2 individuals will be recruited and trained to carry out four major tasks: 1) counsel and support mothers and their families during home visits, 2) refer infants identified with danger signs of illnesses and malnutrition to health facilities, 3) supervise cooking demonstrations during the education sessions and 4) mobilise mothers for outcome assessments. Potential individuals will be nominated by village leaders in their respective villages, and the research team will interview and recruit the most suitable candidates. To be selected, a candidate has to be aged between 25 and 45 years, be a resident in the village with no plans of leaving within a year, has completed at least 7 years of formal education and has personal

experience in infant feeding. In addition, the candidate will have to demonstrate that they have time, are eager to participate in the trial and willing to undertake home visits.

All recruited nutrition counsellors will be centrally trained for 3 days. The first training session will be conducted at the beginning of the intervention whereas the second session of similar content will be repeated 6 months later (i.e. when infants are aged 12 months). The training will contain three modules (**Table 3.1**). Module 1 will focus on orientation and introduction, why nutrition matters during the first two years of life, feeding principles and practices, use of locally available foods to make nutritious complementary meals, child health and preventive measures. Module 2 will focus on communication skills, behaviour change communication, counselling skills and negotiation, problem solving (trying different solutions to common problems), use of counselling resources, field practice and feedback on field practice. Module 3 will focus on home visits tasks and procedures, use of counselling resources, supervisory visits and training evaluation. A standardised test with multiple and open-ended questions will be given before and after training to test knowledge and attitudes about child feeding and health. The training methodology will include lectures, small group activities and discussions, plenary discussions, demonstrations, role plays, and hands-on field practice with mothers in villages which will not be part of the intervention. Theoretical training will be followed by practical exercises designed to test performance. During the practice sessions, they will be observed and their skills discussed for improvement during plenary sessions. After training, counsellors will be issued counselling resources (counselling cards, workbook, family card, referral slip, counselling manual) as home visiting tools.

The nutrition counsellors will begin home visits immediately after their training. Each nutrition counsellor will be assigned 10-12 mothers residing in their village and each mother will be individually visited and counselled. They will make home visits once per month for 9 months of the intervention period. Mothers with sick children or children with feeding problems will be offered additional visits. The counselling will take place at home to ensure other family members can also take part in the sessions. The counsellors will be responsible for keeping home visits records in workbooks. These will include:

- behaviour adopted by mothers;
- issues discussed, barriers, next/missed appointments;
- referrals to health facilities given to infants with danger signs of childhood illnesses; and
- in-depth information of best-case and worst-case household circumstances for lessons learned during the intervention.

Achievements and unresolved difficulties during the visits will be discussed during supervisory or monitoring visits.

Component 3: Supervision of community-based nutrition counsellors

The aim of supervising nutrition counsellors is two-fold: 1) to reinforce theoretical knowledge, counselling and practical skills learned during training, and 2) to give support and feedback needed

to address child nutrition challenges in their communities. The supervision is important to support the implementation of monthly home visits for future reporting. In future, health staff working at facilities located in the villages or district nutrition officers can periodically supervise the counsellors. Supervisory visits coupled with observed counselling sessions, review of home visits workbooks and discussions on feedback will be made by the research team to assess the quality of counsellors' work. An observation checklist for individual counselling will be used to assess practice on interpersonal skills, active listening, effective use of counselling resources, offer referrals appropriately, promote problem-solving among mothers, and discuss practical solutions. Counsellors will receive a simple score of 2 = "Yes, sufficient" or 1 = "Yes, limited" if a correct practice is observed, and 0 = "None at all" if the practice is not done. Supervisory visits will take place in the villages at 2-weeks interval in the first 2 months of intervention, and thereafter visits will be made at 2-month interval.

Component 4: Sensitisation meetings

Sensitisation meetings will be held in intervention villages in the form of presentations and discussions with selected groups likely to influence the success and sustainability of the intervention. These include family members and health facility staff.

The aim of sensitising family members is to improve their knowledge and attitude on child nutrition issues so as they can ensure dietary adequacy and optimal growth. A 1 to 2 hours sensitisation meeting will be held with fathers, grandmothers and older siblings of recruited infants. The structure of the meeting will consist of four parts: Intervention rationale, content and activities; why nutrition matters during the first two years of life; promoted recommendations and their role in supporting mothers; and importance of adherence to intervention for its success. The meetings will take place twice: at baseline and 6 months into the intervention.

The aim of sensitising health facility staff is to improve their knowledge and attitude on feeding practices so as they can counsel mothers and caregivers during routine well-baby and sick-child visits. In villages where a health facility exists, two potential health workers will be nominated by their resident in-charge of the health facility to participate in sensitisation meetings. A 3 to 4 hours sensitisation meeting will take place in respective villages. At the meeting, the intervention will be outlined and its implications for community infants and young child discussed. Other topics for presentation and discussion will include why nutrition matters during the first two years of life; feeding principles and practices, use of locally available foods to make nutritious complementary meals, and key messages to share with the mothers. The meetings will take place twice: at baseline and 6 months into the intervention.

3.3.6 Data collection and measuring impact of the intervention package

Procedures for the collection of information are standardised. Data collection forms (structured questionnaires, observation checklists, etc.) were translated into the local language, Kiswahili. The accuracy of the translation was checked by back translation into English. The questionnaires were

pre-tested with 20 mothers in a neighbouring district to determine whether the items were adequate, clear and culturally appropriate. Revisions and modifications were applied accordingly. Data collectors will administer the forms in Kiswahili. After data collection, all filled forms will be manually checked for completeness and consistency. To enhance blinding, precise objectives of the study and village allocation to trial will not be disclosed to data collectors, nutrition counsellors will not be responsible for data collection, and data collection schedule will be randomised.

Primary outcome

The primary outcome of the study will be linear growth as assessed by mean change in LAZ at 6-12 and 6-15 months of age. Data will be collected at baseline, and ages 9, 12 and 15 months in the intervention group, whereas data will be collected at baseline, and ages 12 and 15 months in the control group.

Secondary outcomes

- Mean change in weight and weight-for-length Z-scores (WLZ)
- Mean intake of energy, fat, iron and zinc from complementary foods
- Proportion of children consuming foods from 4 or more food groups
- Proportion of children consuming the recommended number of semi-solid/soft meals and snacks per day
- Maternal level of knowledge and practice of recommended feeding and health practices

Anthropometry: Recumbent length will be measured to the nearest 0.1 cm using a portable wooden infant/child length board (Shorr Productions, Perspective Enterprises, Portage, Missouri) with a fixed head and sliding foot piece. Children will be weighed with light clothing to the nearest 10 g using a digital infant weighing scale (Salter model 235, CMS Weighing Equipment, London). The weighing scale and length board will be placed on a flat surface to ensure correct measurements. Each measurement will be done in duplicate and the mean value calculated. Child's age will be recorded from the health card or birth certificate. Standardised anthropometric procedures (117) will be observed. Nutritional status indices LAZ and WLZ will be computed for each child by comparing the child's measurements with the reference values of the WHO 2006 child growth standards using ANTHRO software v3.0.1 (ANTHRO, WHO, Geneva). Data will be collected at baseline, 9, 12 and 15 months in intervention group, whereas in control group, data will be collected at baseline, 12 and 15 months.

Dietary intake: Intake of specific nutrients (energy, protein, fat, iron, zinc) will be assessed at baseline and 12 months in intervention and control groups using interactive 24-hour dietary recall (118). Mothers will be asked to recall all foods and fluids consumed by their children in the previous 24 hours. Information on time, type of meal, ingredients used, amount of total dish, and amount consumed will be documented. Amounts will be determined using a digital food balance (TANITA kitchen scale, KD-400, maximum weight 5 kg, precision 1 g), household and other

common utensils (e.g. spoons, cups, bowls), and visual aids (e.g. fresh foods). Daily intake of nutrients will be calculated using the 2008 Tanzania Food Composition Tables (134). Nutrients intake will be compared to international recommendations (59, 63).

Dietary diversity assessment: Information from the interactive 24-hour food recall will be used to generate number of food groups consumed by children at baseline and 12 months. At 9 and 15 months, a structured questionnaire will be used to document type of meals consumed by children in the previous 24 hours. Meals of each child will be separated into their ingredients and the number of food groups consumed generated as recommended by Dewey and colleagues (177). The food groups includes: (1) cereals, tubers and roots; (2) legumes, nuts and seeds; (3) milk and milk products; (4) meat, fish, poultry, liver/organ meats; (5) eggs; (6) vitamin A-rich fruits and vegetables; (7) other fruits and vegetables; and (8) oils and fats. Sum of total number of food groups consumed will be generated for each child. Proportion of children consuming meals from 4 or more food groups will be determined at ages 9, 12 and 15 months in intervention villages and at 12 and 15 months in control villages.

Feeding frequency: Number of semi-solid/soft meals and snacks consumed per day will be collected using a structured questionnaire. Proportion of children consuming the recommended number of semi-solid/soft meals and snacks per day according to WHO (26, 74) will be determined at ages 9, 12, and 15 months in intervention villages and at 12 and 15 months in control villages.

Maternal knowledge of recommended practices: The intervention will promote adoption of key feeding and health care recommendations during the education and counselling sessions and home visits. Maternal recall of key recommendations will be assessed using a list of structured and open-ended questions generated from the list of key recommendations. Spontaneous recall questions will be used (e.g. What signs of illness would indicate that your child was very sick and is in need of urgent attention/treatment?), as well as prompted recall (e.g. Have you heard anything about children requiring more food and fluids during illness?). This will be followed by a query on messages associated with the practice. Mothers will receive a simple score of 1 for each correct response and 0 for a wrong response.

Maternal practice of key recommendations: Maternal practice of key recommendations will be assessed using a structured questionnaire and structured observation. Direct questions based on education lessons and the 11-item key recommendations will be asked to mothers. For example, a recommendation to "Wash your hands with soap before preparing meals or before feeding children," mothers will be asked to name occasions when they wash their hands with soap, why they should wash their hands, and how they wash their hands. For recommendations on consumption of specific foods (e.g. undiluted cow's milk, legumes, etc), a 7-day food frequency questionnaire will be used to determine consumption frequency of the specified food items. The list of such food items will be read to mothers and asked whether they had fed those items in the

previous 7 days. Pre-coded categories will include never, once per week, 2-4 times per week, 5-6 times per week, once per day, 2-3 times per day, 4 or more times per day (178).

Information on maternal recall and practice of key recommendations will be collected in intervention villages at ages 9, 12 and 15 months.

Other measurements

Information on factors that may influence the effectiveness of intervention is collected at baseline in both intervention and control groups. A structured questionnaire will be used to collect household, parents (or caregivers) and child characteristics, and other factors that may confound outcomes:

- Household: headship, composition, housing, fuel for cooking and lighting, water availability, and sanitation
- Maternal and paternal: age, education, marital status, occupation and level of child support
- Child: birth order, birth weight, early infant feeding [breast feeding, exclusive breast feeding, age at first introduction of fluids/foods] and types of the fluids/foods, child health [place of delivery, past immunisations, morbidity and healthcare-seeking, haemoglobin concentration]
- Child health during the intervention period
    - Immunisation status will be verified using a child's health card at 9 months.
    - Child morbidity and healthcare-seeking practices within two weeks before the visit will be assessed through maternal recall of signs and symptoms related to acute respiratory infections, diarrhoea, and fever; duration and severity; treatment sought; prompt use of medication; place of treatment; type of transportation used to reach the health facility; reasons for not attending a health facility; mother's ability to identify danger signs of childhood illness; and mother's perceptions of appropriate care after being presented with scenarios of sick children with danger signs. Acute respiratory infections will be defined as the presence of mucopurulent nasal discharge with or without cough, difficulty breathing, fast breathing than usual, breathing with severe noise or wheezing or difficulty inhaling. Diarrhoea will be defined as three or more liquid or semi-liquid stools in 24 hours. Fever will be based on maternal report of elevation of infant's body temperature above normal. Morbidity and healthcare-seeking data will be collected at baseline and at ages 9, 12, and 15 months in intervention group, whereas the same information will be collected at baseline and at age 12 months in the control group.
    - Haemoglobin concentration will be determined using a portable battery-operated electronic Haemoglobin Photometer (HemoCue Hb 201+, Angelhom, Sweden). Non-fasting blood samples will be obtained from a finger prick of each child between 08.00 and 10.00 hours using sterile butterfly lancets. A drop of blood will be placed in a sterile microcuvette and inserted in the machine for immediate reading. The machine will be calibrated daily with a reference microcuvette provided with the machine. A trained and skilled clinician working at the Mpwapwa District Hospital will be responsible for collection of blood samples and haemoglobin determination. Haemoglobin

concentration will be assessed at baseline and age 12 months in both intervention and control groups. Children found to be anaemic (haemoglobin concentration below 11.0 g/dl) during the assessments will be referred to the nearest health facility for treatment free of charge, and later, closely followed up to monitor compliance to treatment and advice.

- Seasonality: pre-harvest, harvest, post-harvest and rainy or dry season

3.3.7 Process evaluation

A process evaluation will be conducted to document the intervention implementation process so as to 1) assess whether the intervention activities are implemented as planned (i.e. fidelity), 2) evaluate the extent to which the intervention reaches the intended mothers and their families (i.e. reach), 3) determine the degree to which targeted mothers are exposed to intervention components and extent to which they use intervention resources (i.e. exposure or dose received), and 4) describe the setting (i.e. contextual factors, facilitators, barriers, contamination) into which the intervention is being implemented that may have an influence on intervention effectiveness (99, 179). Detailed process evaluation objectives, data sources and indicators are presented in **Table 3.3**. Process evaluation data will be collected two months after baseline (when infants are 8 months-old) and end of intervention (when infants are 15 months-old). Structured and semi-structured interviews, review of records (e.g. training and education attendance sheet, activity logs, training test scores, etc) and structured observations will be carried out with intervention participants (mothers, nutrition counsellors, health workers).

A process evaluation will also be conducted in control villages when infants are aged 8 and 15 months-old to identify and describe actions, events and context which may reveal new interventions, evidence of contamination or other factors external to the intervention. The information will be collected from village leaders and health workers through structured interviews and observations.

3.3.8 Monitoring of intervention, trial status and schedule of intervention activities

Data on the primary and secondary outcomes of the study will be collected through periodic monitoring and at the end of study. A list of intervention activities and their schedules is developed to facilitate the development of a monitoring plan for assessment of intervention progress. The activity monitoring plan will document delivery of intervention activities on weekly and monthly basis. The research team will visit intervention villages every 2 weeks in the first 2 months of intervention, and thereafter visits will be made at 2-months interval. Researchers will log and report all activities related to the delivery and quality of training, education, supervision and sensitisation meetings using monitoring tools (e.g. forms, logs, observation checklists, supervisory reports). Nutrition counsellors will document home visits in workbooks. Actions or events external to the intervention which happen in the intervention villages will be documented in event forms and semi-structured interviews.

Table 3.3 Planned process evaluation objectives, data collection methods and indicators

Objectives and data sources	Description of process indicators	Characteristic of process indicator
Assess whether the intervention activities are implemented as planned		
Activity logs	Number of taught modules and sessions held with nutrition counsellors	Fidelity
	Number of education and counselling sessions and taught lessons held with mothers	
	Number of reading resources distributed to targeted groups	
	Number of home visits conducted by nutrition counsellors	
	Number of sensitisation meetings held with families	
	Number of sensitisation meetings held with health facility staff	
Supervisory reports	Review of counsellors' workbooks (completeness, validity of information, referrals, appointments kept or missed)	Fidelity and dose delivered
Registration forms	Number of community-based nutrition counsellors trained	Fidelity
	Number of health facility staff sensitised	
Pre- and post-test scores	Performance of nutrition counsellors in knowledge and skills gained during training	Fidelity and dose delivered
Evaluation forms	Quality of training sessions (adequacy of delivery methods, time allocated to sessions, usefulness of materials and field practice, attitude to training)	
Structured observations	Nutrition counsellor's skills during home visits on interpersonal skills, use of reading resources, problem-solving, confidence in counselling mothers	
Evaluate the extent to which the intervention reaches the intended mothers and families		
Activity logs	Number of recruited infants in intervention and control villages. Number dropped out. Reasons for dropping out	Reach (participation rate)
Attendance records	Number of mothers attending each education and counselling session (plus cooking demonstration)	
	Number of family members present in sensitisation meetings	
	Number of mothers visited/attended during home visits	
Determine the degree to which targeted mothers are exposed to intervention components and extent to which they use intervention resources		
Attendance records	Number of mothers attending each education session	Dose received (exposure)
	Number of mothers with information booklets	
Structured observations	Observation of mothers' attentiveness, interest/keen (e.g. asked/answered questions, give examples) during education and counselling sessions	
	Observation of mothers' feeding style (e.g. responsive feeding) during cooking demonstration sessions	
	Amount of meal consumed by infants at cooking demonstration sessions	
Semi-structured interviews	Number of mothers who could recall (spontaneously, and/or prompted) key behaviours learned in education sessions and home visits	
	Number of mothers who could recall (spontaneously and/or prompted) messages in information booklet	
Semi-structured interviews	Mothers' perception on usefulness and preference (by ranking) of intervention aspects (education sessions, sensitisation meetings, home visits, booklet).	Dose received (satisfaction)
	Mothers' level of satisfaction with counsellors' services	
Investigate setting into which intervention is being implemented that may influence intervention effectiveness		
Semi-structured interviews	Interviews with nutrition counsellors about any ongoing interventions (e.g. competing programmes), perception regarding intervention delivery, strengths, challenges, and	Context, facilitators, barriers, contamination

	suggestions for improvement	
	Interviews with village and sub-village leaders about village profile during baseline	
Structured interviews	Interviews with residence in-charge of health centre on presence (and number) or absence of health staff who attended sensitisation meetings	
Structured observations	Observation of health facility staff conducting health education sessions in intervention and control villages	

The trial is planned to begin in September 2014 with the training of community-based nutrition counsellors. This will be followed by recruitment of infants and parents, collection of baseline information, education and counselling session, sensitisation meetings and home visits. In between, supervision, monitoring and data collection will be conducted. A summary of activities and measurements planned during the intervention period are presented in **Table 3.4**.

Table 3.4 Schedule of intervention activities and measurements during the study period

Activities and measurements	Child's age (in months) and time points of data collection									
	6[a]	7	8	9[b]	10	11	12[c]	13	14	15[d]
Activities in Intervention group										
Train community-based nutrition counsellors	X						X			
Education and counselling of mothers	X			X			X			
Sensitisation meetings	X						X			
Home visits by counsellors	X	X	X	X	X	X	X	X	X	X
Supervision of community-based nutrition counsellors	X	X			X			X		
Monitoring	X	X			X			X		
Measurements										
Covariates	X^{I+C}									
Child anthropometry	X^{I+C}			X^{I}			X^{I+C}			X^{I+C}
Child feeding practices (frequency, diversity)	X^{I+C}			X^{I}			X^{I+C}			X^{I+C}
Child food intake (24-hr recall)	X^{I+C}						X^{I+C}			
Child morbidity & healthcare-seeking	X^{I+C}			X^{I}			X^{I+C}			X^{I}
Child haemoglobin concentration	X^{I+C}						X^{I+C}			
Maternal recall and practice of feeding recommendations				X^{I}			X^{I}			X^{I}
Process evaluation data			X^{I+C}							X^{I+C}

[a]Baseline. [b]Follow-up 1. [c]Follow-up 2. [d]End of intervention. X^{I+C} Measurements taken in Intervention and Control groups, X^{I} Measurements taken in Intervention group alone.

3.3.9 Data management and analysis

Data will be entered in Epi-data version 3.1 and consistency analysed by range checks of data values. Data will be analysed using STATA release 12.0 (STATA Corporation, Texas, 2007). Frequency distributions will be run to identify outliers. Impact evaluation data will be compared between intervention and control villages using hierarchical or multi-level models and presented at the cluster and individual levels. The methods will provide adjustment for potential covariates and confounders at the cluster and individual levels. Data will be analysed by intention to treat.

Linear mixed models will be used for continuous outcomes (e.g. growth parameters) with cluster, household, and child as random effects to account for clustered observations. Generalised linear mixed models will be used for discrete outcomes (e.g. frequency of specific food intakes, practices, etc.). Random effects logistic regression analyses, taking clustering into account, will be used where appropriate. Values of $p<0.05$ will be considered statistically significant.

The process evaluation data will use both inductive and deductive approaches (180) to analyse qualitative data. The data will include structured observation checklists, in-depth interviews, and documents. From these, frequent, major, or significant themes inherent in raw data will be identified and coded. After coding, the transcripts will be entered in and analysed using NVivo version 10 (QSR International, Australia). Content will be analysed in terms of countable concepts/objects e.g. descriptive statistics, or in the broadest terms (e.g. majority, some, very few). Direct quotations from the group discussions will also be provided. Key analytical categories will be identified and interpreted to explore all aspects of intervention delivery, identify factors contributing to intervention success or failure, if intervention results have been affected by implementation process, and document encountered barriers. Within the intervention group, outcomes will be compared between groups of people with high and low scores for a process evaluation characteristic.

3.4 Discussion

By offering age-specific, practical problem-solving education and counselling on feeding and health care practices, and ensuring continuous support, it is expected that the nutrition education package will result in a larger impact on dietary adequacy, growth and health than could be achieved through routine health education alone. The package will look into improving the quality of nutrition education, interpersonal skills needed to communicate nutrition recommendations and capacity of families to act on nutrition recommendations. The package will achieve these through the implementation of its components: education and counselling mothers; training community-based nutrition counsellors and monthly home visits; sensitisation meetings with families and health facility staff; and supervision of community-based nutrition counsellors. With respect to the multi-component nature of this intervention, understanding of outcome results and implementation pathway need to be well documented. Implementation or process data are critical to understand what, how and why an intervention works or does not work. For a successful intervention to be replicated, data on implementation are necessary (99). In developing country settings, where resources are limited and basic public health problems prevalent, knowledge of implementation is critical to promote effective programmes, their replication and expansion (92).

This intervention study is in line with a global focus on infant and young child nutrition. In addition, infant and young child feeding is one of the priority areas specified in the Tanzania's National Nutrition Strategy (July 2011-June 2016). The intervention has included components that are likely to enhance maintenance of behaviour after completion of intervention. Mothers, caregivers and family members who participate in the intervention will serve as future reference

points for other households. To influence long-lasting behaviour change, trained community-based nutrition counsellors will remain a valuable resource to their respective villages and district. Sensitised health facility staff will apply gained knowledge and attitudinal change to counsel mothers during routine well-baby and sick-child visits. The intervention components can feasibly be integrated into existing health services and district health plans. If successful, the approach used to deliver the nutrition education package could be easily and inexpensively scaled and disseminated in other rural villages in the country.

3.5 Limitations

This study has some limitations. First of all, potential risks may arise due to lack of double blinding. Parents of study infants and nutrition counsellors allocated to intervention group may be aware of the allocated arm. To minimise this limitation, data collectors will be kept blinded to village allocation and will not be residents in intervention or control villages. Intervention implementers will not be part of the team collecting outcome data. The second limitation is that self-reporting measurements such as maternal recall of recommended practices may overestimate nutrition outcomes and behaviours due to recall bias. In this trial, the recall period will be relatively short (past week or past two weeks) to optimise the reliability of self-reports. Thirdly, the intervention duration of 9 months is relatively short to assess change of certain behaviour and the sustained effects. However, it was observed in previous trials that similar outcome measures demonstrated change within 6 months of intervention (60), and the effects were sustained 3 and 12 months after intervention (181). This trial is designed to assess outcomes within the common intervention duration of 6 months as well as follow-up measurements to allow evaluation of short and mid-term effects.

Chapter 4. Effectiveness of the nutrition education package on feeding practices, nutrients intake and growth of infants and young children in rural Tanzania: results of a cluster randomised trial

This chapter has been submitted as:
Kulwa KBM, Mamiro PS, Kolsteren PW. Effectiveness of a nutrition education package on feeding practices, nutrients intake and growth of infants and young children in rural Tanzania: results of a cluster randomised trial.

4.1 Summary

Objectives: Undernutrition is a significant public health problem in rural Tanzania. The objective of the study was to evaluate the effectiveness of a nutrition education package on feeding practices, nutrient intake and growth of infants (6-12 months) in rural Tanzania.

Methods: A cluster randomised controlled trial with 18 villages randomly allocated to routine health education (control, n=9) or nutrition education package (intervention, n=9) from 6 to 12 months of age was conducted. Components of the package included 1) education and counselling with mothers, 2) training of village health workers (VHW) to counsel mothers and families on monthly home visits and 3) supervision of trained VHW. Feeding practices, morbidity, weight, length and food intake were measured at 6 and 12 months. The primary outcome of the study was mean change in LAZ from baseline to end of trial (6-12 months). Secondary outcomes included mean changes in weight, WLZ, intakes of energy, fat, iron and zinc from complementary foods, proportion of children meeting the minimum dietary diversity and the minimum meal frequency. Changes in the primary and secondary outcome values between the two data points were analysed with the use of multilevel mixed-effects models, with baseline characteristics as the covariates, study group as fixed effect, and the village as a random effect.

Results: A total of 370 infants from 18 villages participated at the beginning of trial. Data of 246 infants from the 18 villages was available for analysis at the end of trial. Mean change in feeding frequency was modestly higher in intervention than control group (1.63 vs. 1.27, p=0.051). Mean change in dietary diversity was significantly higher in intervention than control group (2.03 vs. 1.50, p=0.005). Higher proportion of infants in the intervention than control group consumed meals made from 4 or more food groups (71.8% vs. 45.3%, p=0.002). Infants in intervention group consumed more energy (β=43.8 kcal, p=0.019) and fat (β=2.7g, p=0.033) than infants in control group. No effect was observed for intakes of iron (β=-0.2 mg, p=0.765) and zinc (β=0.2 mg, p=0.277). The intervention resulted in significant mean change in length (β=0.47cm, 95% CI: 0.01, 0.92, p=0.043) and LAZ (β=0.20 Z-score, 95% CI: 0.29, 0.38, p=0.022) in favour of intervention group. The intervention had no differential effects on mean changes in weight (β=0.11 kg, 95% CI: -0.08, 0.29, p=0.266), WLZ (β=-0.03 Z-score, 95% CI: -0.25, 0.19, p=0.810) and WAZ (β=0.14 Z-score, 95% CI: -0.00, 0.28, p=0.054). Acute respiratory infection (ARI) was the single most common illness among the infants at baseline and end of trial. A high proportion of infants in both groups suffered from multiple illnesses (combining diarrhoea, fever and ARI).

Conclusion: The nutrition education package resulted in better feeding and growth outcomes than routine health education. Depending on the context, future interventions need to incorporate other elements such as treatment of sick infants, initiation of household income generation schemes and general improvement of home food environment to ensure direct or indirect impact on infants and young child nutrition.

Trial registration: ClinicalTrials.gov Identifier: NCT02249754

Keywords: nutrition education, complementary feeding practices, growth, infant, nutrients, morbidity, Tanzania, village health worker

4.2 Introduction

Pregnancy and the first two years of life are recognised as critical windows for promoting optimal growth, health and development of children. Longitudinal studies have shown that poor growth (deficits in weight or length/height), micronutrient deficiencies and common childhood illnesses peak during the first two years (26, 182). Undernutrition is still a significant problem in the sub-Saharan Africa (SSA), Tanzania included. Prevalence of stunting, wasting and underweight in the SSA in 2014 was 36.3%, 6.3% and 16.5%, respectively (19, 21). In Tanzania, the 2010 TDHS data showed that prevalence of undernutrition increased with age, peaking during the complementary feeding period (6-23 months) (22). Prevalence of stunting among children below the age of 6 months, 6-8, 9-11, 12-17 and 18-23 months was 18.3%, 20.6%, 28.1%, 43.2% and 55.0%, respectively. Prevalence of underweight in children aged 6-8, 9-11, 12-17 and 18-23 months was 13.3%, 16.8%, 16.0% and 20.5%, respectively. Wasting was however more prevalent in younger children: 10.9%, 8.6%, 7.0% and 7.1% in children aged 6-8, 9-11, 12-17 and 18-23 months, respectively (22).

It is well recognised that causes of childhood growth faltering are multifactorial (14, 18, 41, 183) and much has been documented regarding risk factors, consequences and the significance of consequences to future child development (15, 17, 24). Studies carried out among young children in the country have shown that inadequate breastfeeding and complementary feeding practices and high morbidity (47, 102, 147, 148, 184), inadequate dietary intake, high rates and repeated episodes of diseases, inadequate nutritional knowledge, low maternal education, heavy farm workload and household food insecurity (47, 49, 50, 184) were associated with stunting. Analyses of nationally-representative data have similarly shown that inadequate feeding practices, male child, young child's age, low level of father/mother education, low maternal BMI, maternal perception that child's birth size is small and poor household economic status were risk factors for undernutrition (22, 45, 127).

Intervention strategies which improve infant and young child feeding and growth have been reviewed by various authors (60, 72, 75-77). Culturally-appropriate group nutrition education, individual counselling, interpersonal communication, home visits and mass media were the most feasible and effective components. Their significance on child outcomes depended on characteristics of the target population (e.g. age, initial prevalence of undernutrition), availability of energy-dense and micronutrient-rich local foods, health care, water and sanitation, extent of household food insecurity and poverty. With the high levels of undernutrition in the country and Tanzania being classified among the 24 countries with the largest burden of stunting (14), the importance of improving nutrition of infants and young children is a matter of immediate concern. Limited complementary feeding interventions have been conducted in Tanzania (80) despite the recognised need, urgency and evidence on feasible strategies.

To address the nutritional problems in the country, two cross-sectional surveys were conducted in Dodoma, one of the central regions with high rates of malnutrition, to closely examine feeding

practices, diets and nutritional status of infants and young children and guide decisions on improvement. The first survey was conducted in 2009 and involved 496 infants aged 1-12 months (176, 185). The same cohort (n=374) was revisited in 2010. Findings from the surveys showed high prevalence of stunting (34% in 2009; 59% in 2010). Prevalence of wasting and underweight in 2009 was 2.4% and 12.0%, respectively; whereas in 2010, wasting and underweight prevalence was 2.2% and 16.8%, respectively. Morbidity due to acute respiratory illness (ARI) was 64% in 2009 and 57% in 2010. Diarrhoea affected 48% children in 2009 and 37% in 2010. Overall prevalence of anaemia was 36.1% and 36.7% in 2009 and 2010 respectively. Meal frequency (adjusted for clustering) was 1.8±0.8 in 2009 and 2.45±0.7 in 2010). Proportion of children receiving foods the minimum number of times or more was 44.7% and 52.9% in 2009 and 2010, respectively. Portion sizes for different types of relish or sauces were small. These findings led to the development of a nutrition education package centred on feeding, cooking demonstrations, health, hygiene and sanitation, consistent with age-specific international and national feeding and health recommendations (26, 107, 175, 186).

This chapter reports findings of a cluster-randomised controlled trial conducted for six months to evaluate the effectiveness of the nutrition education package among infants (6-12 months) in rural Tanzania. Details of the trial protocol are found in **Chapter 3**. It was hypothesised that the nutrition education package will be more effective than the routine health education in improving feeding practices, dietary adequacy and growth.

4.3 Methods

4.3.1 Study setting, design and randomisation

The study was conducted in rural villages of Mpwapwa district, Dodoma region in central Tanzania. Dodoma is among the central regions affected by high prevalence of stunting. The region is predominantly semi-arid, characterised by a short, single wet season (November to March) and a long dry season (May to mid-November). Subsistence farming, traditional rearing of animals and small scale trading are the primary economic activities in the district. Crops cultivated include sorghum, pearl millet, maize, groundnuts, cowpeas, pigeon peas, round potatoes, sunflower and sesame (114). The area has a wide mix of ethnic groups, including the Gogo, Kaguru, Hehe, Bena and Tiriko. Kiswahili, one of the national languages, is widely spoken, in addition to ethnic languages. Common water sources include natural springs connected to village taps, protected communal wells, unprotected hand-dug shallow wells and rivers. The rural roads are not tarmac, with some being impassable during rainy seasons or due to broken down bridges; and in some area the roads are too steep for vehicles to pass.

Mpwapwa district health system is constituted of 43 dispensaries, 2 health centres and 1 district hospital (114). Each village is served by two to five volunteer village health workers (VHW). The VHW assist health facility staff in various activities, ranging from child growth monitoring to health education. Main health problems existing in the district during the 2007-2008 and 2008-2009 periods included maternal mortality, malaria morbidity and mortality, under-five mortality, high

prevalence of eye infections and inadequate hygiene and sanitation (114). In-patient admissions and deaths per diagnosis during the July 2007-March 2008 period showed that malaria, anaemia and pneumonia were the leading causes of deaths among children below the age of five years.

Effectiveness of the nutrition education package was evaluated using a cluster-randomised controlled trial. The unit of randomisation was the village. The package was delivered to groups of mothers at the village level by the research team and village health workers for 6 months (i.e. from the time infants were 6 months-old to when they reach 12 months-old). The study was conducted between November 2014 and July 2015. Detailed study setting and design has been described in Chapter 3 (**sections 3.3.2**).

From a list of 70 villages in the district, 18 villages met eligibility criteria (**Figure 4**). Computer-generated random numbers were assigned to each village. Villages were randomised to two groups in a 1:1 allocation. Generation of allocation sequence and randomisation of villages was done by a researcher not participating in the trial. Eighteen villages were randomly allocated to control group (n=9 villages) or intervention group (n=9 villages). The control group continued to receive routine health education, a standard government health service for children below the age of five years, offered monthly by health staff at health facilities. The intervention group received the nutrition education package in addition to the routine health education.

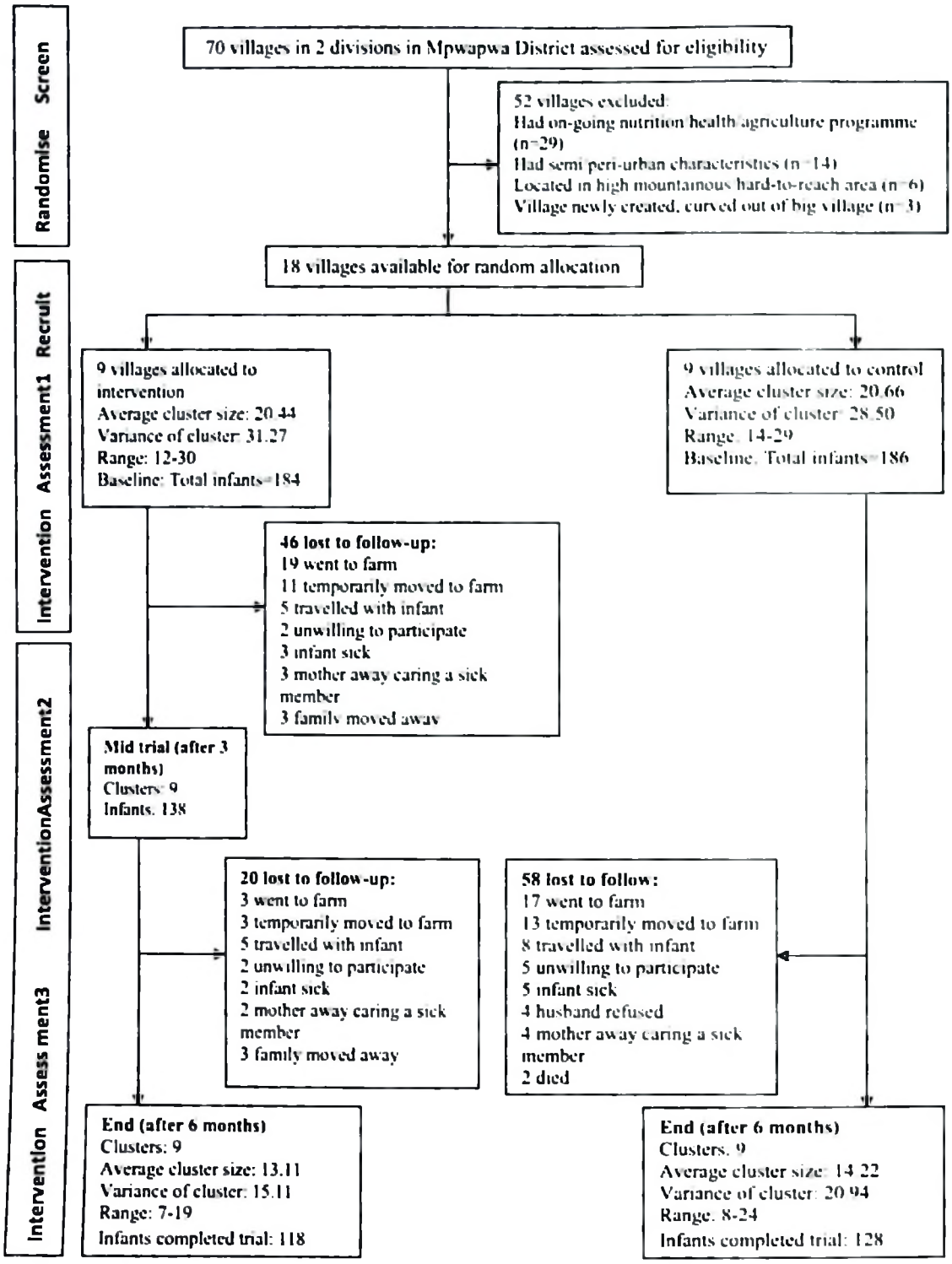

Figure 4. Flow chart of the trial

4.3.2 Study participants, recruitment and ethical considerations

The education package was delivered to groups of mothers and village health workers (VHW) for 6 months (i.e. from the time the infants were 6 months-old to when they reach 12 months-old). VHW were nominated by village leaders, and the research team interviewed them to ascertain

their availability, readiness and willingness to participate in the trial. VHW in control group were responsible for mobilising mothers for outcome assessments whereas VHW in intervention group received training to build their capacity to counsel and support mothers and families. VHW, sub-village leaders and health facility staff, identified and listed all infants between the ages of 6 and 7 months from village and health facility registers. Infants without congenital or chronic abnormalities impairing feeding or physical growth measurements, oedema, severe illness or clinical complications warranting hospitalisation were recruited (176). Permission to conduct the trial was sought and obtained from the district administrative and health officials and permission for village participation was sought and obtained from village authorities. VHW and parents of eligible infants were informed of the nature and purpose of the study, and were provided with study information sheet tailored to the participants and study group (174). VHW and parents who agreed to participate gave their consent and signed a written informed consent. This study was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving human subjects were approved by the Tanzania's National Institute of Medical Research (NIMR/HQ/R.8a/Vol.IX/943), Institute of Tropical Medicine (ITM/IRB/AB/ac/879/13, Belgium) and University of Antwerp (B300201317997, Belgium). The trial was registered with ClinicalTrials.gov, number NCT02249754, https://clinicaltrials.gov/show/NCT02249754.

4.3.3 Components of the nutrition education package

Intervention Mapping and Theory of Planned Behaviour provided frameworks for the design and development of the package (159, 160). The nutrition education package was an integrated package with three core components: 1) education and counselling with mothers, 2) training of village health workers (VHW) to deliver key recommendations to mothers and family members during monthly home visits and 3) supervision of the trained village health workers. Sensitisation meetings, which were initially designed as a standalone component, were incorporated in other components for ease in delivery. Sensitisation meetings with family members were incorporated in home visits as it was possible to have an audience with family members at home rather than in a separate meeting. Sensitisation meetings with health staff were incorporated in education sessions with mothers because they could be present when the sessions were delivered in the villages.

The education content for mothers (and families) and training content for VHW was centred on age-specific international feeding recommendations, healthcare-seeking practices, hygiene and sanitation. In addition, VHW received training on communication and counselling skills, and behaviour change communication. Key recommendations promoted during the intervention included continuing to breastfeeding on demand; preparing thick porridge using a combination of cereal flours and other nutrient-dense foods (e.g. groundnuts, egg or milk, dried vegetable flour); inclusion of nutrient-dense foods (e.g. undiluted cow's milk, legumes, animal-source foods, green leafy and other vegetables, fruits); age-specific feeding frequency; feeding during illness and recovery; and hygiene during food preparation and feeding. Detailed key recommendations are given in Chapter 3 (**Table 3.2**). Recipes promoted during the cooking demonstrations were based

on cereals (maize + sorghum or pearl millet or finger millet), legumes (beans or cowpeas), nuts (groundnuts or oilseeds), meat (pounded beef, deboned sardines or fish), undiluted milk, green-leafy vegetables (fresh or dried), orange-yellow vegetables/fruits (pumpkin or carrots, mango) and other fruits (banana, orange, avocado). Training and education resources developed together with the package (**Appendix 3.3**) were used during the intervention. These included: 1) a manual for VHW; 2) a set of illustrated counselling cards to be used by VHW; and 3) an illustrated information booklet for mothers and families. Detailed description of the package components were given in Chapter 3 (**section 3.3.5**). The next sections only highlight the key aspects of each component.

Education and counselling of mothers (December 2014, March 2015, June 2015). Three sessions were held with mothers; the first session was conducted after collection of baseline data, the second session three months thereafter and the last session three months later. Detailed schedule of the sessions are found in Chapter 3 (**Table 3.1**). The education part lasted between 1½ and 2¼ hours, whereas the cooking part lasted between 2 and 2½ hours. The sessions took place within the health facilities. Each session consisted of a theoretical part, cooking demonstrations and counselling of mothers with individual concerns. Mothers, VHW and the research team centrally prepared the meals. After meal preparation, infants and mothers consumed one portion and the remaining portion was packed for feeding at home. Mothers were encouraged to try the recipes and the key recommendations at home. Information booklets containing promoted recipes and recommendations were distributed during the first session, and were required to bring it to each session. Mothers continued to receive support from VHW during the monthly home visits.

Training of VHW (November 2014, July 2015) and monthly home visits. A total of 18 VHW were recruited, two in each intervention village, and trained to carry out four major tasks: 1) counsel and support mothers and their families during monthly home visits, 2) refer infants with danger signs of illnesses and malnutrition to health facilities, 3) supervise cooking demonstrations during the education sessions and 4) mobilise mothers for outcome assessments. Their 3-days training consisted of three modules (**Table 3.1**). Counselling resources (manual, cards, workbook) were distributed and used throughout the training. After training and when mothers had received the first education session, VHW began the home visits. Each VHW visited 6 to 15 mothers per month, and this depended on the number of recruited infants per village. Each mother was individually visited and counselled at home to allow other family members who were available to take part in the sessions.

Supervision of VHW (every 2 weeks in the first 2 months and 2-months interval thereafter). Supervision of VHW was supportive; whereby after supervisor's observation of VHW conducting a counselling session, feedback on well- and less-performed skills and challenges to address child feeding and health practices in the community were discussed. Detailed assessment of VHW performance which was evaluated during the supervisory visits is given in **Chapter 5**.

The package was delivered in Kiswahili by the research team and members of the district heath management team (DHMT) with expertise in child health and nutrition and VHW training, including the district nutrition officer (DNUO), to enhance application and sustainability. The trained VHW conducted monthly home visits for six months starting January 2015. Each mother received six monthly home visits. The intervention implementers were the same throughout the trial. Intervention activities were monitored every 2 weeks in the first 2 months of trial, and thereafter at 2-months interval. Control villages were visited at 2-months interval.

4.3.4 Data collection and outcomes

Data collection forms (questionnaires, observation checklists) were prepared in English and translated to Kiswahili, one of the official national language. The forms were back translated to English to ensure accuracy of translation and no loss of information. The structured questionnaires were pre-tested with 20 mothers in a neighbouring district and modified. Data collectors administered the questionnaires in Kiswahili. After data collection, all filled forms were manually checked for completeness and consistency. A 5-days training of data collectors was conducted in which study procedure and tools were discussed and exercises were done with in a non-participating village. A refresher 2-days training was repeated before each round of data collection. The same data collection team was maintained throughout the trial. To enhance blinding, data collection team were masked of the village allocation and the team was not part of trial implementers or residents in any of the villages. Recruited VHW were not responsible for data collection.

Intervention duration constitutes 6 months of intervention and 3 months of no intervention. Data collection time points for outcome measures were baseline (at 6 months, *December 2014*) and end of intervention (at 12 months, *June 2015*), and *January* and *July 2015* for process data. Midtrial assessment was only conducted in intervention group to investigate if the nutrition education package was delivered as planned and identify corrective measures if required.

Primary and secondary outcomes. As described in Chapter 3 (**section 3.3.6**), mean change in LAZ was the primary outcome, while mean change in weight, WLZ, energy, fat, iron and zinc from complementary foods, proportion of children consuming foods from 4 or more food groups, proportion of children consuming the recommended number of semi-solid/soft meals and snacks per day and maternal practice of key recommendations were the secondary outcomes.

Baseline information. Structured questionnaires, adapted from the Tanzania Demographic and Health Surveys and FAO guidelines for measuring household and individual dietary diversity (22, 23, 187), were used to collect information on village profiles and infant-mother-father-household characteristics at baseline in intervention and control groups. Information on village profiles (sub-villages, population size, water supply, seasons in which the data was collected, presence of health facility and schools) was collected from village and sub-village leaders. The infant-mother-father-household questionnaire was administered to both parents or the mother in case of father's

absence at baseline (**Appendix 4.1**) and at the end of trial (**Appendix 4.2**). Infant characteristics included sex, date of birth, birth weight, birth order, immunisation status, age at first introduction of fluids/foods, breast feeding and complementary feeding practices, anthropometric measurements, dietary intake, morbidity and haemoglobin concentration. Maternal characteristics included age, marital status, level of education, reading ability, occupation, place of delivery of index child, birth order and attendance to well-baby clinics. Father's characteristics included age, level of education, reading ability and occupation. Household characteristics included sex of household head, composition, ownership of assets, housing conditions, source of water, meal frequency and dietary diversity.

Principal component analysis (PCA) was used to construct a proxy wealth index for household socio-economic status (188, 189). The socio-economic status (SES) index was based on a number of assets owned (land, house, livestock, draft animals, plough, donkeys, motorcycle, bicycle, television, radio, mobile phone, sewing machine, furniture, generator), housing conditions (materials used to construct roof, walls, floor), source of water and number of people per sleeping room (a proxy for household crowding). These variables were selected because of their importance as indicators of household SES asset ownership and housing conditions in the country (22, 45, 190). The socio-economic status (SES) index was based on a number of assets owned, housing conditions, source of water and number of people per sleeping room (a proxy for household crowding). The wealth index was divided in five quintiles, from lowest to highest household wealth (lowest-1st-poorest, 2nd-poorer, 3rd-middle, 4th-rich, highest-5th-richest). This classification was used in accordance with previous studies (45, 127, 190, 191).

Anthropometric measurements. Weigh and length were measured following the standardised procedures (117) described in Chapter 3 (**section 3.3.6**). Nutritional status indices, length-for-age Z-scores (LAZ), weight-for-length Z-scores (WLZ) and weight-for-age Z-scores (WAZ) were computed using the WHO 2006 growth standards within the ANTHRO software (ANTHRO version 3.2.2, 2011, http://www.who.int/childgrowth/software/en/). Infants were classified as stunted, wasted or underweight if their LAZ, WLZ or WAZ, respectively, was -2 standard deviations (SD) below the median values of the reference data.

Food intake, dietary diversity and meal frequency. Methods used to collect information on dietary intake, dietary diversity and meal frequency were described in Chapter 3 (**section 3.3.6**). An interactive 24-hour dietary recall (118) was used to document foods/fluids consumed 24 hours before the survey. Portion sizes of consumed meals were determined by calibrating home utensils with the graduated plastic measuring cylinders or cups and digital food weighing scales (BOECO BEB 61, 5 kg capacity, 1 g precision; Hamburg, Germany). Visual aids of fresh foods (e.g. tomatoes, onions) were used to facilitate quantity estimation. Data was entered in Lucille, a food intake programme developed by Ghent University (http://www.foodscience.ugent.be/nutriFOODchem/foodintake, Belgium). Daily nutrients intakes were calculated using the 2008 Tanzania Food Composition Tables (134).

Food intake data generated from the 24-hour food recall (118) was separated into ingredients to enable the determination of dietary diversity. Ingredients were grouped into seven food groups as defined by WHO (74) and the sum total calculated for each child. Information on meal frequency was obtained from mothers and recorded in structured questionnaires as the number of semi-solid/soft meals and snacks consumed per day. Mean dietary diversity and meal frequency were calculated. Four age-specific WHO infant and young child feeding indicators were used to assess feeding practices (74). The indicators, minimum dietary diversity, minimum meal frequency and minimum acceptable diet, were used to generate the proportion of children meeting the minimum criteria. Definitions of indicators have been described in Chapter 2 (**section 2.3**). The assessment of feeding practices was limited to infants aged 6-12 months instead of the 6-23 months age criteria described by the indicators.

Morbidity assessment and healthcare-seeking practices. Morbidity definitions, indicators and methods used to collect the information were described in Chapter 3 (**section 3.3.6**). Morbidity questions were adapted from the UNICEF multiple indicator cluster surveys MICS2 and MICS5 (192). An index for morbidity burden (i.e. having more than one illness) was created to enable the investigation of effect of multiple illnesses on intervention outcomes. Infants were categorised as having no illness, one illness, or two and more illnesses.

Haemoglobin concentration Haemoglobin concentration was measured as described in Chapter 3 (**section 3.3.6**). The haemoglobin values were classified into anaemia levels using WHO guidelines (193). Anaemia was defined as haemoglobin concentration <110 g/L. Anaemia severity was further classified as mild (90-109 g/L), moderate (70-89 g/L) and severe (<70 g/L). Infants found to be anaemic during the assessments were referred to a health facility nurse/staff on duty for treatment, and were closely followed up to monitor compliance.

Maternal practice on key recommendations. Maternal practice of key recommendations was assessed using a structured questionnaire containing a list of recommended practices promoted during the intervention. Consumption of selected nutrient-dense foods promoted during the intervention was assessed using a 7-day food frequency questionnaire. The FFQ was adapted from previous studies assessing energy and nutrient intakes of infants aged 12 months (194, 195). Because the purpose of FFQ was to assess pattern, portion sizes were not included. The food list was developed from the 2009 survey in the study area, and baseline food intake collected during the 2014 trial showed similar foods were still being consumed. From this list, nutrient-dense foods to be promoted by the intervention were identified and compiled. Selection of the foods was based on the nutrient composition and availability in the area (185) and the Tanzania food composition tables (134). Frequency of consumption was pre-coded as: never, once per week, 2-4 times per week, 5-6 times per week, once per day, 2-3 times per day, 4 or more times per day (178).

4.3.5 Sample size estimation and data analysis

Sample size recommendation of Hayes and Bennett for unmatched cluster-randomised trial (172) was used to estimates number of villages and village size. With no information on intra-cluster coefficient of variation, the estimate for the between-cluster coefficient of variation (k) was based on conservative values of ≤ 0.25 and 0.15-0.25 experienced in similar health and nutrition studies (172, 173). A coefficient of variation between clusters (k) of 0.1 and 30 infants per cluster was assumed. Data from the 2009 survey were used to make assumption on change of values of the primary outcome length-for-age (LAZ): a mean LAZ of -1.5 and a standard deviation of 1.3 in the control group. Nine villages were needed to detect at least a 0.35 difference in LAZ between intervention and control groups, with the power of 80% (Z_β=0.84) and a statistical significance of 5% ($p<0.05$; $Z_{\alpha/2} = 1.96$, two-tailed test).

Data forms were reviewed in the field for accuracy, consistency, and completeness. Data were entered in EpiData version 3.1 and checked for consistency using range checks of data values and original forms. Data was exported and analysed in Stata/IC release 12.1 (StataCorp, College Station, Texas). Data were expressed in number (and proportion), median (and interquartile range) and mean (and standard deviation), accounting for cluster design using the survey *'svy'* command in Stata. Baseline characteristics of infants-parents-households lost to follow-up were compared to those of the study groups (i.e. intervention vs. lost, control vs. lost) after adjusting for clustering using the user-written *'clttest'* (for continuous variables) and *'clchi2'* (for categorical variables) commands in Stata. Frequency of consumption of selected foods promoted during the intervention was analysed by ordered logistic regression after cluster adjustment. Data analyses were done by intention to treat (196).

The primary outcome of the study was mean change in LAZ from baseline to end of trial (6-12 months). Secondary outcomes included mean changes in weight, WLZ, intakes of energy, fat, iron and zinc from complementary foods, proportion of children meeting the minimum dietary diversity and the minimum meal frequency. Analyses of effect of intervention included infants with data at baseline and end points (197). Changes in the primary and secondary outcome values between the two data points were analysed with the use of multilevel mixed-effects models, with baseline characteristics as covariates, study group as fixed effect, and the village as a random effect. The multilevel mixed-effects models were used to account for the clustered nature of the study design and correlated observations within villages. General linear mixed-effects regression models (*'xtmixed'* command in Stata) were used for continuous outcomes and generalised linear mixed-effects logistic regression models (*'xtmelogit'* command in Stata) for binary outcomes. All models used village as a random intercept. An "empty" or "null" model was first estimated with primary or secondary outcome as the only variable and village as a random intercept, to estimate the variance at the village level. Secondly, the study group was added as the only explanatory variable and village as a random effect to estimate the intervention effect on the outcomes. Results to show the magnitude of change are presented numerically (Table 4.6) and graphically (Figures 5a, 5b, 5c, 5d, 5e, 5f, 5g) as absolute differences (and whether the change between the

groups is significant) between baseline and end of trial and as unadjusted or crude models. Lastly, covariates of biological importance (e.g. baseline value, sex, age, morbidity, meal pattern, energy or nutrients intake, maternal age) were added to the models, one at a time in a forward selection approach, to test the effect of the variable on the outcome (198, 199). Covariates of statistical significance ($p<0.05$) in the bivariate analysis were included in the models. Confounders (e.g. household dietary pattern and wealth index) were kept in the models irrespective of their statistical significance. This procedure was repeated until all potential variables were entered into the models. As each variable was added, goodness-of-fit of the models was examined using the likelihood-ratio test and the Akaike-Schwarz information criterion (198, 200). The Akaike-Schwarz information criterion was used to select the optimal covariance structure (198). Residual distributions were assessed and graphically visualised for normality. Food frequency data which was not part of the study outcomes, was collected at one time point (end of intervention) to demonstrate maternal practices on feeding nutritious meals promoted by the intervention. Ordered logistic regression (*'ologit'* command in Stata) without covariates but study group as the only determinant and adjusted for clustering, was performed for food frequency data. This unadjusted analysis reported the odds ratio (OR), 95% confidence interval and p-value for the model for each food. Values of $p<0.05$ were considered statistically significant.

4.4 Results

4.4.1 Village summaries

Village summaries are presented as cluster summaries in **Table 4.1**. All previously randomised villages completed the trial. There was balance in baseline village characteristics between intervention and control villages. Mean age of recruited infants was 6.4±0.2 months.

Table 4.1 Village characteristics by clusters at baseline in Mpwapwa District

Characteristics	Intervention villages	Control villages
Village population	4924.55 ± 1319.30[1]	4817.88 ± 1360.48
Number of recruited children	20.44 ± 5.59	20.66 ± 5.33
Child age (mo)	6.43 ± 0.12	6.38 ± 0.09
Child sex		
Male	84 (45.6)	94 (50.5)
Female	100 (54.4)	92 (49.5)
Weight (kg)	7.60 ± 0.24	7.67 ± 0.19
Length (cm)	64.80 ± 0.85	65.21 ± 0.58
Nutritional status, Z scores		
LAZ	-1.11 ± 0.37	-0.94 ± 0.34
WLZ	0.69 ± 0.24	0.63 ± 0.15
WAZ	-0.22 ± 0.24	-0.16 ± 0.25
Household size	5.16 ± 0.54	5.57 ± 0.49
Household meal frequency	2.48 ± 0.17	2.44 ± 0.17
Household dietary diversity score	5.12 ± 0.47	5.24 ± 0.47

Total number of villages was 18, nine in each study group. [1]mean ± SD, number (percentage), all such values. No significant differences were found between the groups.

Overall, 16.9% (62/367) of infants were stunted, 4.6% (17/367) underweight and none of the infants was wasted. Anaemia was nearly universal (84.3%), with the mean haemoglobin concentration of 98.7±10. 9 g/L. Mothers reported to have introduced their infants to fluids and foods other than breast milk at the mean age of 4.9±1.3 months (median [25th, 75th percentiles]: 5 [4, 6] months). Frequency of feeding meals was 1.7±1.1 times per day. At the time baseline data was being collected, it was the post-harvest, dry period; and subsequently, end of trial data was collected when it was a harvest, dry period.

4.4.2 Baseline characteristics of study households and parents

Households participating in the trial had an average of five persons, were primarily male-headed, owned a house and land for cultivation, had a latrine and consumed an average of two meals per day (**Table 4.2**). Water for domestic use originated from protected deep wells or springs connected to village taps (74%), rivers (16.8%) and unprotected shallow wells (9.2%). Walking was the main (>90%) means of transport to health facilities. More than half of fathers and mothers had formal education, however more mothers (30-35%) than fathers (<10%) were not able to read (**Table 4.2**). Slightly more than one-third of mothers in intervention and control villages (35.9% and 38.7%) could state the benefits of breast milk. Majority of mothers were able to state correctly the danger signs of childhood illness, 96.2% in intervention and 96.8% in control villages. Imbalances in ownership of some household assets and amenities were found between intervention and control groups (house [0.0322], roof [0.0321], walls [0.0385], motorcycle [0.0320]) and between households lost to follow-up and those remaining (i.e. roof [0.0505]). Because the construction of wealth index incorporated them in the classification of socio-economic status, wealth index was included as covariate in the final models.

4.4.3 Infant characteristics at baseline

All eligible infants in each village were recruited. A total of 370 infants (184 intervention, 186 control) were recruited at baseline (**Figure 4**). Baseline characteristics of infants by study groups are presented in **Table 4.2**. There was a balance in baseline characteristics between intervention and control infants. At the end of trial, 118 (64.1%) and 128 (68.8%) infants were present for assessment in intervention and control group, respectively. There were no significant differences in infant characteristics between those lost to follow-up and those remaining. All infants had received vaccinations scheduled according to their ages except four in control group whose status could not be verified due to absence of child's health clinic cards. Rate of timely introduction or consumption of solid, semi-solid and soft complementary foods was 88.6% and 87.1% in intervention and control group. Practices related to feeding infants during illness were similar between groups, whereby mothers who would feed less food than usual were 69.9% and 66.13% in the intervention and control group, respectively. Prevalence of stunting in intervention and control groups was 18.6% and 15.2%, respectively.

Table 4.2 Baseline characteristics of infants, parents and households in rural Mpwapwa District by study groups and loss to follow-up

Characteristics	Intervention N=184	Control N=186	Lost to follow-up N=79[1]
	n(%) or mean ± SD	*n(%) or mean ± SD*	*n(%) or mean ± SD*
Household			
Household size	5.15 ± 1.99[2]	5.56 ± 1.89	5.70 ± 2.14
Household head, male	156 (84.8)[2]	162 (87.1)	67 (84.8)
Wealth index			
Poorest (1st quintile)	28 (15.2)	46 (24.7)	18 (22.8)
Poorer	39 (21.2)	35 (18.8)	19 (24.0)
Middle	41 (22.3)	33 (17.7)	13 (16.5)
Rich	35 (19.0)	39 (21.0)	14 (17.2)
Richest (5th quintile)	41 (22.3)	33 (17.7)	15 (19.0)
Have latrine	162 (88.0)	165 (88.7)	66 (83.5)
Have mosquito bednet	131 (71.2)	122 (65.6)	55 (69.6)
Meal frequency	2.47 ± 0.52	2.44 ± 0.49	2.51 ± 0.50
Dietary diversity score	5.12 ± 1.05	5.20 ± 1.34	5.77 ± 1.48
Fathers			
Age (yrs)	31.6 ± 9.75	32.5 ± 8.92	33.3 ± 0.90
Education level			
Primary school or higher	115 (67.6)	125 (74.0)	56 (80.0)
Occupation, farming and/or livestock	128 (75.3)	134 (79.3)	44 (62.9)
Mothers			
Age (yrs)	26.2 ± 7.35	26.4 ± 7.07	26.6 ± 7.20
Marital status, married[3]	162 (88.0)	165 (88.7)	64 (83.6)
Education level			
Primary school or higher	105 (57.1)	113 (60.8)	49 (62.0)
Occupation, farming and/or livestock	155 (84.2)	165 (88.7)	63 (79.7)
Reading ability			
Read clearly	70 (38.0)	81 (43.5)	36 (45.6)
Read poorly (*unclear, hesitated*)	48 (26.1)	40 (21.5)	14 (17.7)
Could not read	64 (34.8)	61 (32.8)	28 (35.4)
Place of delivery			
Home	50 (27.2)	53 (28.5)	26 (32.9)
Health facility	134 (72.8)	133 (71.5)	53 (67.1)
Child			
Age (mo)	6.45 ± 0.26	6.37 ± 0.24	6.36 ± 0.28
Sex			
Male	84 (45.6)	94 (50.5)	40 (50.6)
Female	100 (54.4)	92 (49.5)	39 (49.4)
Birth weight (g)	3226.35 ± 535.48	3349.35 ± 515.93	3296.81 ± 518.82
Low (<2500 g)	9 (6.4)	1 (0.8)	1 (2.0)
Normal	131 (93.6)	122 (99.2)	50 (98.0)
Weight (kg)	7.61 ± 1.01	7.68 ± 1.03	7.68 ± 1.16
Length (cm)	64.82 ± 2.64	65.24 ± 2.40	65.37 ± 2.22
Prevalence of stunting (LAZ <-2)	34 (18.6)	28 (15.2)	15 (19.2)
Prevalence of wasting (WLZ<-2)	0 (0)	0 (0)	0 (0)
Prevalence of underweight (WAZ<-2)	7 (3.8)	10 (5.4)	6 (7.7)
Nutritional status, Z-scores			
LAZ	-1.11 ± 1.17	-0.92 ± 1.12	-1.02 ± 1.08
WLZ	0.70 ± 1.00	0.63 ± 1.05	0.53 ± 1.02
WAZ	-0.22 ± 1.12	-0.15 ± 1.16	-0.29 ± 1.18
Age introduced complementary foods	5.09 ± 1.20	4.84 ± 1.46	4.72 ± 1.49

[1]Recruited at baseline but lost to follow-up thereafter. [2]mean ± SD, number (percentage), all such values. [3]Comprised monogamous and polygamous.

4.4.4 Change in feeding practices: meal frequency and dietary diversity

All infants were breastfeeding at the end of the trial except one in control village whose mother had died and one in intervention village whose mother had stopped due to health reasons. **Table 4.3** presents results of infant feeding practices before and after intervention by study group. Infants reported to have not consumed any food a day before the survey (20 in intervention, 21 in control) were excluded in analysis of nutrients intake due to lack of food intake data. Feeding practices were similar between the study groups at baseline. Comparison of the study groups at the end of trial showed that intervention infants had a significantly higher meal frequency and dietary diversity. The mean change in feeding frequency between intervention and control group was similar (1.63±1.25 vs. 1.27±1.39, p=0.051), whereas the mean change in dietary diversity in was significantly higher in intervention than control group (2.03±1.1 vs. 1.50±1.3, p=0.005). Mean absolute increases in meal frequency and dietary diversity for intervention and control group over the trial period are illustrated in **Figures 5a** and **5b (Appendix 4.3)**, respectively. Proportion of infants who received semi-solid or soft foods the minimum number of times was similar in both groups at the end of the trial (p=0.982). A significantly higher proportion of infants in the intervention group compared to control group consumed meals made from 4 or more food groups (71.8% vs. 45.3%, p=0.002). Comparison of study groups in the consumption of individual food groups at the end of the trial showed no significant differences in the proportion of infants who consumed grains, roots and tubers, legumes, nuts and oilseeds, milk and milk products, and eggs **(Table 4.3)**. A significantly higher proportion of intervention than control infants consumed flesh and organ meats (p=0.006), vitamin-A rich vegetables and fruits (p=0.006) and other vegetables and fruits (p=0.001) at the end of the trial.

Unadjusted effects showed that meal frequency was 0.36 times higher (95% CI: 0.02, 0.69, p=0.035) for infants in intervention group. Dietary diversity of intervention infants was 0.53 higher (95% CI: 0.21, 0.85, p=0.001) than that of control infants. After adjustment for baseline feeding variables, infant's characteristics (age, sex, morbidity), wealth index, household dietary variables (meal frequency or diversity) and mother education (or father occupation), the intervention effect on feeding practices showed that infants from intervention group had a significant mean increase in meal frequency (β = 0.29, 95% CI: 0.0, 0.5, p=0.018) and dietary diversity (β = 0.40, 95% CI: 0.1, 0.7, p=0.007) than infants in control group **(Table 4.3)**. Infants in intervention group were more likely to meet the minimum dietary diversity and acceptable diet criteria as compared to control infants. Intervention infants were more likely to consume milk, meats or organ meats, vitamin-A rich vegetables and fruits and other vegetables and fruits than control; however a significant effect was shown only in the consumption vitamin-A rich vegetables and fruits and other vegetables and fruits.

Table 4.3 Comparison of infant feeding practices before and after intervention by study group in Mpwapwa District

Feeding practices	Baseline (December 2014)		End (June 2015)		Adjusted effect[5]	
	Intervention n=164	Control n=165	Intervention n=117	Control n=128	β [95% CI]	p
Mean feeding frequency	1.95 ± 0.92[1]	1.93 ± 0.97	3.29 ± 1.05[1]*	2.89 ± 1.05	0.29 [0.0, 0.5]	0.018
Meal frequency[2]						
Once/day	63 (38.4)	65 (39.4)	2 (1.7)	7 (5.5)		
Twice or more/day	101 (61.6)	100 (60.6)	115 (98.3)	121 (94.5)	0.97 [0.1, 8.3]	0.982
Mean dietary diversity	1.90 ± 0.84	1.93 ± 0.89	3.89 ± 1.01**	3.26 ± 1.08	0.40 [0.1, 0.7]	0.007
Dietary diversity[3]						
1-3	155 (94.5)	155 (93.9)	33 (28.2)	70 (54.7)		
4 or more	9 (5.5)	10 (6.1)	84 (71.8)**	58 (45.3)	2.92 [1.5, 5.7]	0.002
Consumption of meals from 7 food groups						
Grains, roots and tubers	162 (98.2)	163 (98.2)	115 (97.5)	128 (100)	-	-
Legumes, nuts, oilseeds	103 (62.4)	97 (58.4)	101 (85.6)	111 (86.7)	0.71 [0.3, 1.9]	0.654
Milk and milk products	11 (6.7)	25 (15.1)	17 (14.4)	10 (7.8)	1.32 [0.6, 2.7]	0.450
Flesh and organ meats	6 (3.6)	10 (6.0)	38 (32.2)**	18 (14.1)	2.16 [0.9, 4.9]	0.062
Eggs	1 (0.6)	2 (1.2)	3 (2.5)	6 (4.7)	0.38 [0.1, 1.2]	0.110
Vitamin-A rich vegetables and fruits	13 (7.9)	11 (6.6)	82 (69.5)**	66 (51.6)	1.93 [1.3, 2.9]	0.001
Other vegetables, fruits	16 (9.7)	12 (7.2)	101 (85.6)**	79 (61.7)	2.60 [1.5, 4.6]	0.001
Minimum acceptable diet[4]						
Do not meet criterion	155 (95.1)	155 (93.9)	33 (28.2)	70 (54.7)		
Meet the criterion	8 (4.9)	10 (6.1)	84 (71.8)**	58 (45.3)	2.92 [1.5, 5.7]	0.002

Data based on one 24-hour food recall at each assessment period. Infants who did not consume any food 24 hours before the survey were excluded. No differences were found at baseline. [1]mean ± SD, number (percentage), all such values. [1]*Differences between groups at end of trial adjusted for clustering. *p<0.05, **p<0.01. [2]WHO indicator: minimum meal frequency (2 times/day at 6-8 months-old, 3 times/day at 9-23 months-old). [3]WHO indicator: minimum dietary diversity (consuming 4 or more food groups). [4]WHO indicator: minimum acceptable diet (receiving the minimum meal frequency and minimum dietary diversity previous day). [5]Multilevel linear and logistic regression adjusted for clustering and covariates (baseline values, age, sex, morbidity, wealth index, household dietary diversity, mother education, father occupation), β is mean difference (continuous variable) or odds ratio (binary variable comparing intervention and control proportions at end of intervention); 95% Confidence Interval of the change/difference, p-value for final model.

4.4.5 Consumption pattern of specific nutrient-dense foods

Extent of consumption of selected foods promoted during the intervention was further investigated from a 7-day food frequency data and compared between the study groups (**Table 4.4**). The pattern of consumption of legumes, groundnuts and oilseeds, avocado, orange or any citrus, mango, baobab fruit pulp and juice from fresh fruit was similar between the study groups. The odds of consuming eggs, beef, pork or goat, fish, sardines, any leafy vegetables, pumpkin or carrot and ripe banana more than twice per day as compared to fewer frequencies was significantly greater in intervention than control group. Although many infants had never consumed liver, kidney or papaya, the odds of consuming these foods once per week or more was significantly greater in intervention than control group.

Table 4.4 Distribution of infants according to a 7-days consumption pattern of selected foods at the end of the intervention in Mpwapwa District[1]

Food item	Intervention *(n=118)*			Control *(n=128)*			Unadjusted effect[2]		
	never	1/wk	≥2/wk	never	1/wk	≥2/wk	OR	95% CI	p
undiluted cow's milk	44.9	12.7	42.4	62.5	12.5	25.0	2.02	0.97, 4.23	0.061
legumes e.g. beans, pigeon peas, cowpeas	8.5	25.4	66.1	14.8	25.0	60.2	1.44	0.92, 2.28	0.115
groundnuts, oilseeds	5.1	2.5	92.4	9.4	7.8	82.8	1.24	0.71, 2.15	0.453
eggs	46.6	22.9	30.5	71.1	15.6	13.3	2.83	1.70, 4.71	0.000
beef, pork or goat	24.6	25.4	50.0	45.3	28.9	25.8	2.82	1.66, 4.79	0.000
chicken or duck	69.5	21.2	9.3	77.3	17.2	5.5	1.52	0.32, 3.22	0.051
liver or kidney	88.1	6.8	5.1	95.3	2.3	2.3	2.72	1.02, 7.20	0.044
fish	26.3	28.8	44.9	39.8	31.3	28.9	1.99	1.05, 3.76	0.035
sardines	35.6	28.8	35.6	51.6	23.4	25.0	1.78	1.06, 3.00	0.030
any leafy vegetables	3.4	3.4	93.2	9.4	8.6	82.0	1.69	1.17, 2.44	0.005
pumpkin or carrot	49.1	22.9	28.0	74.2	12.5	13.3	2.79	1.63, 4.76	0.000
avocado	94.9	4.2	0.9	96.1	2.3	1.6	1.30	0.35, 4.92	0.696
ripe banana	16.1	22.9	61.0	45.3	25.0	29.7	3.80	2.21, 6.53	0.000
papaya	80.5	11.0	8.5	89.8	8.6	1.6	2.23	1.01, 4.93	0.048
orange or any citrus	51.7	23.7	24.6	64.1	17.9	17.9	1.66	0.83, 3.28	0.149
mango	95.8	3.4	0.8	93.7	5.5	0.8	0.67	0.21, 2.08	0.484
baobab fruit pulp	9.3	5.9	84.8	18.0	7.0	75.0	1.17	0.51, 2.68	0.703
juice from fresh fruit	85.6	2.5	11.9	91.4	4.7	3.9	1.88	0.90, 3.90	0.092

[1]Based on the number of times the food was consumed 7 days before the survey. [2]Ordered logistic regression adjusted for clustering without covariates; OR – odds ratio, 95% CI – 95% confidence interval and p-value for the model. Bonferroni correction for multiple testing will set a new p-value threshold for significance at 0.003.

4.4.6 Change in infants' nutrients intake

Infant's nutrients intakes at baseline and end of trial are presented in **Table 4.5**. Nutrient intakes at baseline were similar between groups. Baseline intakes were probably not adequate for energy, iron, zinc and vitamin A when the median intakes are compared to the dietary recommendations for energy (202 kcal), iron (9.3 mg), zinc (4.1 mg) and vitamin A (63 µgRE) (26, 63, 65). Median nutrients intakes increased in both groups during the intervention. At the end of intervention, nutrient intakes were significantly higher in intervention compared with the control group, except for protein intake. Overall intervention effect showed that infants in intervention group consumed more energy (43.8 kcal, 95% CI: 7.3, 80.4, p=0.019), fat (2.7g, 95% CI: 0.2, 5.2, p=0.033), vitamin A (41.1 µgRE, 95% CI: 17.9, 64.4, p=0.001) and vitamin C (2.1mg, 95% CI: 0.1, 4.0, p=0.036) in comparison to infants in control group. No effect was observed for iron, zinc calcium and protein intake.

Table 4.5 Median energy and nutrients intake by study group during the intervention in Mpwapwa District

Nutrients	Baseline		End		Unadjusted effect[2]		Adjusted effect[3]		
	Intervention *n=164*	Control *n=165*	Intervention *n=117*	Control *n=128*	β [95% CI]	p	β [95% CI]	p	ICC
Energy (kcal/d)	109 (72, 166)[1]	107 (76,168)	626 (456, 653)[1]**	518 (417, 597)	72.1[25.5, 118.7]	0.002	43.8[7.3, 80.4]	0.019	0.000
Energy (kJ/d)	459 (305, 696)	451 (319, 706)	2619 (1912, 2735)**	2171 (1744, 2501)	301.7[106.8, 496.6]	0.002	183.4[30.5, 336.4]	0.019	0.000
Protein (g/d)	2.9 (2.0, 4.7)	2.9 (2.0, 5.2)	17.3 (8.6, 21.4)	14.9 (10.1, 20.4)	0.9[-1.2, 3.0]	0.395	-1.6[-3.3, 0.12]	0.070	0.000
Protein, % energy	11.5 (9.9, 13.3)	11.6 (9.1, 13.5)	12.1 (9.1, 14.3)	11.6 (9.6, 14.2)	-0.12[-1.7, 1.5]	0.880	-	-	-
Fat (g/d)	1.9 (0.8, 4.4)	2.4 (0.9, 6.6)	18.4 (11.5, 26.2)**	13.9 (7.4, 19.8)	5.4[2.4, 8.3]	0.000	2.7[0.2, 5.2]	0.033	0.000
Fat, % energy	15.4 (8.7, 37.3)	21.0 (8.9, 38.9)	27.4 (20.0, 37.8)**	23.4 (15.1, 32.5)	8.05[1.6, 14.5]	0.014	-	-	-
Carbohydrate (g/d)	19.2 (13.9, 26.8)	17.8 (13, 25.5)	111.3 (88.8, 129.9)***	89.0 (68.6, 110.5)	15.5[4.9, 26.1]	0.004	3.4[-3.3, 10.1]	0.318	0.001
Calcium (mg/d)	11.5 (8.5, 18.9)	11.6 (8.1, 19.6)	95.1 (70.0, 192.0)***	61.5 (42.1, 108.4)	44.7[5.0, 84.5]	0.028	24.7[-11.9, 61.3]	0.187	0.007
Iron (mg/d)	0.8 (0.5, 1.3)	0.8 (0.4, 1.2)	5.7 (3.7, 7.9)*	4.4 (2.8, 6.3)	0.9[-0.3, 2.0]	0.143	-0.2[-1.3, 0.9]	0.765	0.000
Zinc (mg/d)	0.6 (0.4, 0.8)	0.6 (0.4, 0.9)	3.9 (2.7, 5.4)**	3.0 (2.2, 4.1)	0.8[0.4, 1.3]	0.000	0.2[-0.1, 0.54]	0.277	0.000
Vitamin A (µgRE/d)	3.0 (0, 28.2)	2.8 (0, 23.3)	145.7 (98.7, 232.2)***	86.0 (17.4, 149.2)	54.6[32.2, 77.0]	0.000	41.1[17.9, 64.4]	0.001	0.000
Vitamin C (mg/d)	0 (0, 0)	0 (0, 0)	10.3 (5.5, 16.0)**	7.2 (1.2, 11.9)	3.3[0.9, 5.7]	0.007	2.1[0.1, 4.0]	0.036	0.000

Data based on one 24-hour food recall at each assessment period. Infants who did not consume any food 24 hours before the survey were excluded. No imbalances were found between groups at baseline. [1]Median (25th, 75th percentiles), all such values [1]*Medians significantly different between intervention and control group at end of trial using Mann-Whitney U test (or Wilcoxon Rank Sum): *p<0.05, **p<0.01, ***p<0.001 [2]Multilevel mixed-effects linear regression model unadjusted for energy and covariates; β is difference in change; 95% Confidence Interval of the change, p-value for crude model. [3]Multilevel mixed-effects linear regression model adjusted for clustering, baseline value, energy, age, sex, morbidity, meal frequency and dietary diversity; β is difference in change for full model; 95% Confidence Interval of the change; p-value for final model; Intra-class correlation coefficient (ICC). Bonferroni correction for multiple testing will set a new p-value threshold for significance at 0.004

4.4.7 Morbidity, anaemia and healthcare-seeking practices

Infant morbidity pattern within 2 weeks before the survey, as reported by mothers during baseline and end of intervention, are presented in **Figure 6a** and **Figure 6b**. Acute respiratory infection (ARI) was the single most common illness among the infants at baseline and end of trial. A high proportion of infants had suffered from multiple symptoms of diarrhoea, fever and ARI.

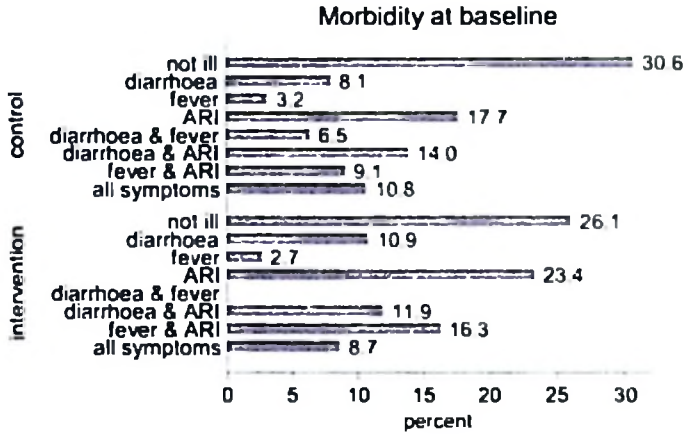

Figure 6a. Illness symptoms (%) among 370 infants at baseline by study group in Mpwapwa District. Prevalence of morbidity without combining symptoms: Control group (n=186): diarrhoea 39.2%, fever 29.6%, ARI 51.6%, others 15.6%; Intervention group (n=184): diarrhoea 31.5%, fever 27.7%, ARI 60.3%, others 14.1%. Other diseases: malaria, skin and eye disease, vomiting, measles

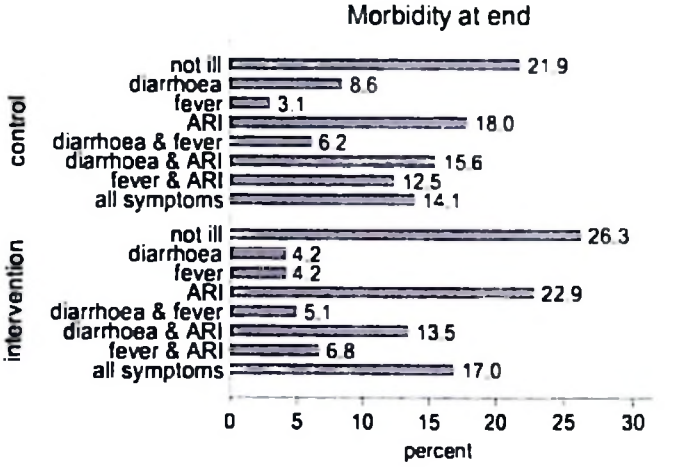

Figure 6b. Illness symptoms (%) among 246 infants at end of trial by study group in Mpwapwa District. Prevalence of morbidity without combining symptoms: Control group (n=128): diarrhoea 44.5%, fever 35.9%, ARI 60.2%, others 22.7%; Intervention group (n=118): diarrhoea 39.8%, fever 33.1%, ARI 60.2%, others 17.0%. Other diseases: malaria, skin and eye disease, vomiting, measles.

No significant associations were found between study group and type of illness at baseline (diarrhoea, p=0.124; fever, p=0.694; ARI, p=0.119) or end of trial (diarrhoea, p=0.603; fever, p=0.634; ARI, p=0.998). Baseline data (*all infants, n=370*) showed that a decision to send an infant to a health facility for treatment during her/his last episode of illness was done by both mothers and fathers (68.1%), mothers (18.7%), grandparents (6.2%) and fathers (3.2%). Few infants (n=14, 3.8%) were not sent to a health facility, either because they had never been sick since they were born or their parents/mothers were less concerned. Health care for the sick infants was sought on the day the symptoms appeared (19.4%), the following day (53.1%), the second day (20.3%), and three or more days later (7.1%). No differences were found between the study groups regarding persons who made a decision to seek health care (p=0.823) or when care was sought (p=0.188). At the end of trial, health care was sought on the day the symptoms appeared (21.9%), the following day (53.7%), the second day (17.1%) and three or more days later (7.3%). No significant difference was found between the study groups (p=0.631).

There were no differences at baseline between the study groups in the proportion of sick infants whose families sought treatment for ARI (p=0.332), diarrhoea (p=0.374) and fever (p=0.954). Similarly, no differences between the study groups were found at the end of trial in the proportion of sick infants whose families sought treatment for ARI (p=0.299), diarrhoea (p=0.393) and fever (p=0.844). Majority of sick infants received health care at government facilities at the end of trial (intervention: 86-88%, control: 64-71%); and no differences were found between the study groups for each of the three illness symptoms (ARI, p=0.335; diarrhoea, p=0.401; fever, p=0.517). Reasons for not seeking health care were mainly the high cost of medical care and a perception that the illness was not serious. Very few mothers reported that the health facility was far from home or medications were not available at the facility (intervention n=7; control n=12). There were no differences in the proportion of infants who had slept under mosquito bednet the night before the survey between groups at baseline (intervention: 53.8%, control: 48.4%, p=0.555) and the end of trial (intervention: 71.2%, control: 63.3%, p=0.361).

Mean haemoglobin concentration (g/L) was similar between groups at the end of intervention (intervention 93.23±13.52, control: 89.67±14.93, p=0.381). Haemoglobin values remained low after the trial in both groups, with a lower magnitude of decrease in intervention than control group (mean change from baseline: -5.8 vs. -8.1 g/L, p=0.43). Anaemia was highly prevalent in the study area; with the baseline levels reaching 84.7% (n=150/177) and 83.9% (n=151/180) in intervention and control group, respectively. Anaemia levels remained high after the intervention (intervention: 87.3%, 103/118; control: 93.0% 119/128). No association was found between anaemia and study group, child sex, presence of individual illness symptoms (e.g. ARI) or a combination of symptoms.

4.4.8 Change in infant growth outcomes

Infant growth indicators at baseline and end of intervention, and their mean changes between the two periods are presented in **Table 4.6**. Unadjusted analyses comparing mean changes between

baseline and end of trial for each study group showed that intervention infants experienced a higher gain in weight than control (1.04 vs. 0.85 kg, p=0.041) and length than control (5.05 vs. 4.15 cm, p=0.004). Mean absolute gains in length and weight for intervention and control group over the trial period are illustrated in **Figures 5c** and **5e (Appendix 4.4)**, respectively. Mean LAZ, WLZ and WAZ declined after the trial in both study groups; however the decline in LAZ and WAZ was lower in intervention than control group (LAZ: -0.68 vs. -1.04, p=0.004; WAZ: -0.35 vs. -0.54, p=0.056). No differences were found in WLZ change between the groups. Mean absolute changes in LAZ, WAZ and WLZ for intervention and control group between the two trial periods are illustrated in **Figures 5d, 5f** and **5g (Appendix 4.4)**, respectively. Crude models showed a significant difference in weight (p=0.010), length (p=0.001), LAZ (p<0.001) and WAZ (p=0.017) in favour of intervention infants (**Table 4.6**). After adjustment for covariates (infant characteristics [e.g. baseline LAZ, sex, meals, morbidity], maternal age, household diet and wealth), the intervention effect remained significant only in length (0.47cm, 95% CI: 0.01, 0.92, p=0.043) and LAZ (0.20 Z-score, 95% CI: 0.29, 0.38, p=0.022). The intervention had no differential effects on changes in weight, WLZ and WAZ. Prevalence of stunting and underweight increased in both groups during the intervention (**Table 4.6**). There was no significant difference between the groups in the proportion of stunting and underweight after the intervention.

4.4.9 Other associations with outcome variables in the adjusted models

Household meal frequency and dietary diversity at the end of trial were positively associated with change in child's meal frequency (0.41, 95% CI: 0.13, 0.70, p=0.004) and dietary diversity (0.25, 95% CI: 0.15, 0.36, p<0.001), respectively. Mean household dietary diversity at the end of trial was positively associated with change in LAZ (0.1 Z-score, 95% CI: 0.03, 0.15, p=0.003) and length (0.23 cm, 95% CI: 0.08, 0.38, p=0.002). In bivariate analyses, household dietary diversity was found to be significantly higher in intervention than control group (6.3±1.26 vs. 5.7±1.27, p=0.03). High morbidity burden (having a combination of three illnesses) at the end of trial was negatively associated with change in WLZ (-0.36 Z-score, 95% CI: -0.63, -0.09, p=0.009), WAZ (-0.33 Z-score, 95% CI: -0.55, -0.11, p=0.004) and weight (-0.31 kg, 95% CI: -0.55, -0.06, p=0.013).

Table 4.6 Infant growth outcomes at baseline and end of intervention, and their changes by study group

Characteristic	Intervention[1]	Control[2]	Differences at individual level		Unadjusted effects[5]		Adjusted effects[7]			
			ΔI (SD)[4]	ΔC (SD)[4]	β[6]	p-value	β	95% CI	p-value	ICC
Weight (kg)										
Baseline	7.61 ± 1.01[3]	7.68 ± 1.03								
After 6 mo	8.65 ± 1.05	8.60 ± 1.08	1.04 (0.62)	0.85 (0.54)	0.19	0.010	0.11	[-0.08, 0.29]	0.266	0.04
Length (cm)										
Baseline	64.82 ± 2.64	65.24 ± 2.40								
After 6 mo	69.80 ± 2.58	69.56 ± 2.51	5.05 (1.81)	4.15 (1.76)	0.88	0.001	0.47	[0.01, 0.92]	0.043	0.03
Length-for-age Z-scores (LAZ)										
Baseline	-1.11 ± 1.17	-0.92 ± 1.12								
After 6 mo	-1.81 ± 1.05	-1.92 ± 1.02	-0.68 (0.70)	-1.04 (0.67)	0.36	0.000	0.20	[0.29, 0.38]	0.022	0.02
Weight-for-length Z-scores (WLZ)										
Baseline	0.70 ± 1.00	0.63 ± 1.05								
After 6 mo	0.49 ± 1.06	0.48 ± 0.98	-0.25 (0.82)	-0.20 (0.67)	-0.03	0.780	-0.03	[-0.25, 0.19]	0.810	0.06
Weight-for-age Z-scores (WAZ)										
Baseline	-0.22 ± 1.12	-0.15 ± 1.16								
After 6 mo	-0.55 ± 1.11	-0.63 ± 1.07	-0.35 (0.64)	-0.54 (0.53)	0.19	0.017	0.14	[-0.00, 0.28]	0.054	0.01
Prevalence stunting (LAZ<-2)										
Baseline	34 (18.6)	28 (15.2)								
After 6 mo	54 (45.8)	57 (44.5)	27.2%	29.3%	1.05	0.846	0.92	[0.45, 1.89]	0.829	0.00
Prevalence underweight (WAZ<-2)										
Baseline	7 (3.8)	10 (5.4)								
After 6 mo	10 (8.5)	14 (10.9)	4.7%	5.5%	0.75	0.516	0.41	[0.04, 4.03]	0.443	0.38
Prevalence wasting (WLZ<-2)										
Baseline	0 (0)	0 (0)								
After 6 mo	2 (1.7)	0 (0)	1.7%	0%	-	-	-	-	-	-

[1]Number measured: 183 at baseline, 118 at end of trial. [2]Number measured: 184 at baseline, 128 at end of trial. [3]mean ± standard deviation SD, number (percentage), all such values. [4]Mean difference before and after trial in the intervention group (ΔI) and control group (ΔC), and SD standard deviation adjusted for clustering. [5]Multilevel mixed linear and logistic regression models adjusted for clustering, study group as the only predictor. [6]β is mean difference (continuous variable) or odds ratio (binary variable comparing intervention and control proportions at end of trial) [7]Multilevel mixed models adjusted for clustering and covariates (baseline value, age, sex, meal frequency, morbidity, mother's age, wealth index, household dietary diversity). Odds ratio for wasting (WLZ<-2) not modelled due to lack of observations in one category (no wasted child in control group).

4.5 Discussion

This cluster-randomised trial evaluated the effectiveness of a nutrition education package on feeding practices, nutrient intakes and growth of 6-12 months infants in rural Tanzania. The package resulted in a significant effect in feeding frequency and dietary diversity, increased consumption of some foods (flesh meats, vitamin A-rich and other vegetables and fruits), and energy and fat intakes. There was no evidence of intervention effect on change in iron and zinc intakes. The package resulted in significant changes in length and LAZ. There was no evidence of intervention effect on weight, WLZ and WAZ. Prevalence of stunting and underweight increased during the trial.

Effect of intervention on feeding practices

The package promoted continued breastfeeding on demand, during the day and night throughout 2 years of age or beyond in line with international recommendations (26). It was encouraging to observe high rates of breastfeeding during the intervention; however the breastfeeding rates were similar in both study groups. This similarity could be explained by the fact that it is a common practice in the study area to breastfeed young infants and mothers consider it as an important source of nourishment. High rates of breastfeeding throughout the second half of infancy were also reported in a nutrition education intervention in China, with lack of difference between intervention and control groups (153). Length of duration at each breastfeed and frequency of breastfeeding per day could have distinguished the two groups, but these were not assessed in this study.

The trial found a significant difference in meal frequency, both before and after adjustment for child and household variables. The mean difference in meal frequency of less than once per day between the study groups is regarded modest when considering that the education package promoted increased, age-specific frequency in meals and snacks consumption in intervention group. This is also reflected in the proportion of infants who were able to meet the minimum number of meals per day; the odds were similar between groups. A modest difference of 0.5 times/day in meal frequency between intervention and control group was also found in infants aged 9 and 18 months participating in a nutrition education trial in India (82). Potential explanation for modest effect in this study could be that mothers generally increase meal frequency as children got older, and this happened in both study groups where meal frequency increased between baseline and end of trial. Inadequate time for child care including feeding could have hindered mothers in intervention group from increasing meal consumption. Mothers identified fewer feeding opportunities when they described their daily schedules during the education sessions. As more feeding opportunities were discussed, it is possible that some mothers could not implement the proposals. The observed meal frequency of 3.3 times/day achieved by intervention infants meets the minimum number of meals recommended by the WHO, whereby infants aged 9-23 months need to eat 3-4 times/day plus nutritious snacks 1-2

times/day (26). When compared with other nutrition education interventions, the meal frequency of 3.3 times/day was lower than 4.17 times/day reported in China (153) and 5 times/day reported in Kenya (201).

Effect of intervention on dietary diversity

The education package was associated with significant increase in mean dietary diversity. This led to a higher proportion of intervention infants than control consuming a more varied diet and able to achieve the minimum dietary diversity. Common meals consumed by infants in both study groups included porridge made from cereals (maize, sorghum, pearl millet) and groundnuts with or without milk or sugar, soft stiff porridge with legume-, vegetable- or meat-based sauce and milk. Eggs, organ meats and fruits were consumed occasionally. To enhance nutrient adequacy, a key message of the education package in addition to increase meal frequency described earlier, was to increase food variety by including meals containing foods from cereals, legumes, animal source foods, vegetables, fruit and oil. This resulted in significantly more infants in intervention than control group consuming meats, organ meats, vitamin-A rich vegetables and fruits and other vegetables and fruits at the end of trial. The observation that higher proportion of intervention children were able to achieve a minimum dietary diversity or consumed a more varied diet has been reported in previous nutrition education studies (81, 82, 153, 201, 202). Proportion of children who consumed food from four or more food groups was lower than 87.3% reported in the Kenya study (201). Significant differences were observed only in the consumption of flesh meats, vitamin A-rich and other vegetables and fruits, while the Kenyan study (201) reported differences in all food groups except grains, roots and tubers, and eggs. In China, significant differences were observed in all foods except bread, rice and noodles (153).

The observation that consumption of grains and legumes food groups was similar between study groups could be attributed to the fact that these foods, particularly cereal flour and groundnuts, are the main ingredients in most of the infant meals. The observation that consumption of milk increased in the intervention group but the difference was not significant at the end of trial can be explained by the differences in intake between the study groups being not large enough. Another reason is reduced availability and high cost of milk at the end of trial. End of trial data was collected during the harvest-dry period, where animal pastures had began to dry up and milk was scarce and expensive. Lack of effect on egg consumption can be explained by low consumption driven by economic and maternal habitual feeding choices driven by cultural reasons. During the first education session mothers explained that eggs were generally for sale and that they were not used to prepare egg-containing meals. After explaining the nutritional benefits, participating in the egg-containing recipe preparation and observing their children's consumption, many appreciated and agreed to try the promoted recipes and other feeding recommendations. The same was done for flesh meats and green leafy vegetables because these foods were commonly withheld until when infants grow teeth for adequate chewing and are able to swallow without choking.

It is important to note that the dietary diversity described earlier was based on a one-day food recall. Among the key messages of the intervention were to offer meals made from a variety of nutrient-dense foods. Thus, to assess a short-term food consumption pattern, additional information from a 7-day food frequency was collected. The consumption pattern showed that some foods were consumed more frequently than others, by more infants in intervention than control groups. These included eggs, beef, pork or goat, fish, sardines, any leafy vegetables, pumpkin or carrot and ripe banana. Ripe bananas and baobab fruit pulp were more readily available during the intervention than other fruits (e.g. avocado, orange, mango). Lack of effect on consumption of these fruits is attributed to unavailability due to seasonal fluctuations and low household economic status. Mothers gave reasons for not giving fruits more regularly, and these included inadequate household income to purchase the foods which become relatively expensive when out of season. Household dietary patterns could also explain the low consumption observed among the infants. In this study, household meal frequency and dietary diversity at the end of the trial significantly accounted for much of the influence of intervention on infants' meal frequency and dietary diversity. Home food environment and maternal dietary diversity have been documented to determine child's dietary consumption (128, 131, 203, 204).

Effect of intervention on dietary intake

Results of this study have demonstrated a higher median intake in energy, fat, vitamins A and C among intervention than control infants. The effect of the intervention on energy intake was small (+43.8 kcal/day) compared to +65 kcal/day reported from a nutrition education study in Bangladesh which promoted consumption of energy- and protein-rich foods through cooking demonstrations (78). Relatively higher dietary diversity in intervention than control infants has also shown that intervention infants were more likely than control to have consumed animal-source foods, vegetables and fruits rich in Vitamin A and other vegetables and fruits. This, together with relatively higher meal frequency, could have contributed to improved intakes in energy, fat, and vitamins A and C. As expected, energy and fat intakes were significantly influenced by meal frequency at the end of the trial. This observation suggest that if infants had increased daily frequency of meals, relatively higher improvements in energy and other nutrients could have been achieved. Despite the increase in energy intake, infants with a high morbidity burden (i.e. three illnesses) in both study groups had a significant reduction in energy intake compared with infants who were not ill. On sick days, sick children are known to consume 20-30% less energy from complementary foods. Limitations of high morbidity on energy intakes and potential success of nutrition education interventions have previously been documented (78, 205, 206). This mainly occurs as a result of increased metabolic cost, loss of appetite and withholding food during illness. Lack of intervention effect on intakes of iron, zinc and other nutrients could be explained by morbidity and inadequate consumption of iron- and zinc-rich foods. A high proportion of study infants had multiple illness symptoms, both at baseline and end of trial. Poor appetite (as a result of morbidity or insufficient micronutrient intake to improve immunity) and presence and severity

of infections reduce nutrient intake and metabolism (11, 207, 208). Although consumption of foods rich in bioavailable iron and zinc (i.e. flesh and organ meats) were significantly higher in the intervention than control group, the intakes were probably not high enough to contribute to significant effects. The intakes also appeared to be lower than the recommended nutrients intakes (65). Intakes of iron and zinc from complementary foods were also documented to be below the recommended intakes in the Peru intervention study (81). Unfortified complementary foods that are predominantly plant-based have been reported to provide insufficient iron and zinc to meet the recommended nutrient intakes during the age of 6-24 months (26, 59, 63). Inclusion of animal-source foods (ASF) can meet the gap, however the amounts that can feasibly be consumed by infants at 6-12 months may be insufficient to meet the gaps in iron and zinc (63). Furthermore, the lowest income groups may not be able to afford the cost of ASF (26).

Although the intervention demonstrated significant effects in some of the outcomes, study infants were still overwhelmed with high morbidity and anaemia. This observation is a reflection of health problems facing infants in the country. Prevalence of ARI and diarrhoea were high among children below the age of one year in the 2010 TDHS; likewise for the prevalence of anaemia (22). Healthcare-seeking practices during the trial were encouraging as the majority of households sought health care for their sick infants and the majority of sick infants were reported to have received health care from government facilities. Use of mosquito bednets as a disease preventive measure at the end of trial was encouraging as many infants were reported to have slept under a bednet the night before the survey. Although the study did not investigate the prevalence of malaria to ascertain its relation with anaemia, previous health reports in the district have shown that malaria, anaemia and pneumonia were the main health problems and leading causes of deaths among children below the age of five years (114). Anaemia caused by iron deficiency cannot be ruled out as the dietary iron intake appeared to be lower than the recommendation. Together with high morbidity and increased iron requirements at 6-11 months which was not matched by high dietary intakes, study infants were more likely to have remained anaemic during the trial.

Effect of intervention on growth

The magnitude of the difference in weight, length, LAZ and WAZ between the groups was significant, in favour of intervention group before adjustment for covariates. Possible explanations include optimal feeding and health recommendations promoted by the nutrition education package (e.g. continued breastfeeding, modest improvement in meal frequency and diversity, energy and fat intake). After adjustment for covariates, the nutrition education package was associated with modest improvement in length (0.47 cm) and LAZ (0.20 SD units) alone. This was also the case of a nutrition education in India where intervention effects were observed on length and not on weight gain (82). The authors identified breastfeeding practices, better hygiene practices and consumption of milk or milk-based porridge as the possible reasons for better linear

growth. In this study, emphasis on continued breastfeeding and overall improvement in meal diversity and dietary intake might have been essential. This, together with other factors (e.g. recurrent morbidity) could have resulted in relatively small or lack of effects in the improvement in linear growth and weight.

Similar nutrition education interventions without food or micronutrient supplementation have reported improvements in growth of young children below the age of 2 years in China (153), India (82), Peru (81) and Kenya (201). The intervention effect of 0.11 kg on weight in this study was higher than 0.04 kg found in India, lower than 0.22 kg reported in China and lower than the pooled estimate of 0.30 kg reported in a review of nutrition education interventions (77). The length gain of 0.47 cm in our study was higher than 0.32 cm found in India, lower than 0.66 cm found among the Chinese infants, and comparable to the pooled estimate of 0.49 cm reported in the review (77). In the Peru study, assessments on weight and length gains were done at 18 months, making our study infants younger by six months. Nevertheless, the intervention effects on weight and length were 0.20 kg and 0.71 cm, respectively. The intervention effects on attained LAZ and WAZ at 12 months were similar to those found in the India study (Odds ratio: LAZ 0.92, WAZ 1.17). The decline in LAZ during the intervention has also been reported among the Kenyan children. The contrast between findings of this study and others may be a reflection of differences in the characteristics of children (i.e. initial nutritional status, diets, morbidity), intervention (i.e. intensity, duration) and home environment (i.e. economic, demographic, dietary).

Intervention effects observed in this study suggest that the nutrition education package may be an effective strategy to improve growth of infants as compared to current health education. Infants in this study were initially stunted, mildly or moderately anaemic, ill with one or more diseases and their diets most likely to have been inadequate in energy and micronutrients. Much higher effects than what was currently observed were expected, as higher deficits have been associated with larger intervention responses (75). The observed positive effects were most likely too small to have a physiologic significance, sufficient enough to reduce growth faltering. The finding that mean length and LAZ increased but the proportion of stunting did not decrease in the intervention group can be explained by inadequate nutrients intake, morbidity and household factors; which are common in general population. This observation resulted in lack of shift in growth pattern from a typical trend observed in a population without intervention. The linear growth trend of infants in this study was similar to the population trend describing the nutritional status of Tanzanian children (22). Prevalence of stunting in this study increased to about 45% at 11-12 months-old; whereas the national levels showed an increase from 20.6% (at 6-8 months) to 43.2% (at 12-17 months). Energy and nutrients intake at baseline were most likely to have been inadequate for most of the children and the intervention effect on mean change could have been too small to have significant effect on growth. Much of the influence of intervention on length and

LAZ gains was accounted for by household dietary diversity at the end of the trial. This indicates the importance of household dietary consumption in influencing child nutrition.

Influence of morbidity on growth was most apparent on change in weight, WLZ and WAZ. Much of the influence of intervention on weight, WLZ and WAZ gains was accounted for by morbidity and household meal frequency at the end of the trial. Weight and WAZ had positive intervention effects; however after adjustment for covariates the effect was no longer significant. Lack of effects can be explained by high burden of diseases coupled with suboptimal feeding during illness. Proportion of infants who received usual amounts or more fluids or meals during illness was low at baseline. Although feeding during illness and recovery were addressed by the education package through responsive feeding styles and many mothers reported to have tried the practice (i.e. encourage your child to drink and eat more frequently during illness and give extra food after illness), feeding during illness remained low after the trial. In addition to knowledge and skills, feeding during and after illness require adequate time and patience (186). It is challenging for caregivers to continue feeding sick children during illness because of frequent rejection or consumption of very small quantities of food. It is possible that mothers' time, patience and ability to practise the skills consistently were constrained by high workload particularly from agricultural activities and cultural beliefs about withholding food during illness.

Although nutrition education interventions have been documented to have small to modest effects (60), the 6-months duration for this intervention could have been relatively short to allow sufficient assessment of the outcomes. A longer intervention period may allow for the investigation of consumption patterns and child growth in the context of community and household dynamics. These include seasonal variation in food availability, child care practices as influenced by agricultural activities and sustainability of behaviour change. On the other hand, the package could benefit from other elements such as medical treatment which have a direct influence on child growth.

4.6 Limitations

In interpreting the findings of this study, it is important to keep in mind on the limitations of the intervention. First, compliance with the intervention was lower than expected. This could have reduced the ability to detect group differences at the end of the trial. As was observed in **Figure 4**, reasons were not related to the intervention but rather customary of household responsibilities. Most mothers were involved in farming and others had family obligations. Second, it was not possible to double blind VHW and study participants from village allocation. Care was taken to mask data collection team of the village allocation and the team was not part of trial implementers or residents in any of the villages. Data collection was standardised and the interviews were structured through regular training of interviewers, supervision, random assignment of interviewers and calibration of instruments. Third, the study relied on self-reporting

and retrospective recall to assess maternal adoption of recommended practices without including supportive objective outcomes. This is prone to recall bias and socially desirable answers, which could have overestimated some outcomes, particularly those related to feeding practices. To reduce bias, precautions were taken to standardise and structure data collection methods and interviews. It was expected that potential recall lapses will be reduced and expected to be similar between the study groups. To improve recall and enhance reliability of the self-reports, the recall period was designed to be relatively short (past 1 day, past 1 week, past 2 weeks). Future research could consider use of biomarkers (e.g. soluble transferring receptor test for iron, plasma zinc) to assess extent of change in dietary practices and intakes.

4.7 Conclusion

The nutrition education package is feasible in rural Tanzania, can be implemented with high coverage, and is relevant for fostering infant feeding and health behaviours. The results add to evidence that group nutrition education with cooking demonstrations and regular home visits can improve feeding practices, dietary intake and growth as compared to routine health education. In addition to nutrition education package, favourable home food environment influenced better infant feeding practices. Observations that the intervention resulted in modest effects or lacked effects were explained by irregular consumption of a more varied diet, inadequate consumption of nutrient-dense foods, high morbidity, limited time for meal preparation and feeding, mothers' habitual and cultural feeding choices and inadequate household income. Results of this trial recommends that future interventions investigate the extent to which maternal farm work influence limited time for meal preparation and feeding since high maternal workload has been associated with inadequate child care in cross-sectional studies. Future interventions need to consider incorporation of other elements that have a direct or indirect impact on infants and young child nutrition. These include ensuring treatment of sick infants, initiation of income generation schemes and education for positive socio-cultural norms and beliefs.

Chapter 5. Process evaluation of a nutrition education package to improve feeding practices, nutrients intake and growth of infants and young children in rural Tanzania

This chapter has been submitted as:
Kulwa KBM, Verstraeten R, Mamiro PS, Kolsteren PW. Process evaluation of a nutrition education package to improve feeding practices, nutrients intake and growth of infants and young children in rural Tanzania.

5.1 Summary

Objective: A nutrition education package designed to improve feeding practices, dietary adequacy and growth among infants aged 6-7 months was delivered in rural villages and evaluated in a cluster-randomised controlled trial. The package was implemented for six months in rural Mpwapwa district, Tanzania. Core components of the package included 1) a 3-months interval group education and counselling with infant mothers, 2) two training sessions for village health workers (VHW) to support mothers and family members during monthly home visits, and 3) supportive supervision of the trained VHW. This chapter evaluate the implementation and process evaluation of the package, and identify challenges to package effectiveness.

Methods: Implementation and process data were collected from structured questionnaires, VHW pre- and post-training tests, structured observations (VHW performance, conduct of routine health education) and review of activity logs. Fidelity, recruitment, reach, dose and contextual factors were reported.

Results: The education package was delivered as planned. Fidelity, dose and exposure were high for each component. The package was well received with good dose and majority of mothers and VHW were satisfied with the various package components. VHW knowledge on nutrition and health of infants and young children increased significantly during the first (+ 5.7-point, $p<0.001$) and second (+ 4.1-point, $p=0.003$) training sessions. Observations showed a significant improvement in VHW skills performance scores ($p<0.001$). Between midtrial and end of trial, there was high proportion of mothers who read or someone else read the information booklet provided during the session (82.6% and 82.21%), tried any of the cooked/promoted recipes at home (89.8% and 94.6%) and tried all the recommended practices (37.7% and 66.1%). Majority of mothers ranked education-counselling (78.8%) and cooking demonstrations (82.2%) as their first or second choice; and information booklet (75.4%) and home visits (85.6%) as their third or fourth choice. Barriers to adopt some of the recommended practices included high maternal workload, habitual feeding choices influenced by cultural beliefs, and inadequate household income.

Conclusion: The process evaluation demonstrated that the education package can feasibly be implemented in a rural area. VHW knowledge, skills and confidence for supporting mothers during home visits were improved. Findings showed that nutrition education with cooking demonstrations and regular home visits can improve feeding practices, dietary intake of macronutrients and infant growth. Provided that multidisciplinary strategies address challenges faced by rural households, the education package has the potential to contribute to greater improvements in infant and young child nutrition.

Trial registration: ClinicalTrials.gov Identifier: NCT02249754

Keywords: nutrition education, process evaluation, village health worker, complementary feeding, infant and young child, Tanzania, supervision

5.2 Introduction

Nutrition interventions are increasingly becoming complex; often adopting a variety of strategies and components, engaging multiple audiences, expecting performance of multiple behaviours and outcomes; all in an attempt to achieve a significant impact on nutrition. The importance of understanding and assessing implementation and processes of interventions and outcomes have been emphasised in literature (95, 99, 209). Assessment of processes provides valuable insight into why an intervention fails or has unexpected consequences, or why a successful intervention works and how it can be optimised. It plays a key role in monitoring and ensuring successful implementation (179). It is also used to assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in outcomes (210-212). Process evaluation planning, methods and indicators have been well outlined by various researchers (93, 97, 99). Commonly used indicators include extent and quality of intervention implementation (i.e. fidelity, recruitment, reach, dose delivered), exposure of target audience to the intervention (i.e. exposure, dose received) and the setting surrounding the intervention (i.e. contextual factors, facilitators, barriers, limitations).

A recently finalised nutrition education intervention to improve feeding practices, diets and growth of infants aged 6-12 months in rural Tanzania demonstrated mixed results, with modest effects in some outcomes and lack of effects in others. The intervention compared routine health education given at health facilities and a nutrition education package which had the following components: 1) education and counselling of mothers, 2) training of village health workers (VHW) to counsel mothers and family members during monthly home visits, and 3) supportive supervision of the trained village health workers (176). The intervention effects on meal frequency, dietary diversity, energy and fat intakes were positive and significant. No effects were observed for iron and zinc intakes. The intervention resulted in significant higher mean change in length and length-for-age Z-scores in intervention than control group. No differential effects were observed in mean changes in weight, weight-for-length and weight-for-age Z-scores. Because the intervention was context specific and used multiple components to increase impact on behavioural actions, evidence-based process evaluation is vital for providing insights into the extent of implementation and explaining the effects of the nutrition education package.

With increasing coverage and need to inform programme policy, facilitate scaling up and sustainability of infant and young child feeding (IYCF) interventions, there is limited knowledge on mechanisms underlying the achievements of these interventions. Increasingly, process evaluations are being conducted within the framework of various interventions, such as those that aimed to improve infants and young child nutrition (92, 93, 213-215) as well as neonatal and infant health (216-218). These provided insights into the nature of the processes and key factors (e.g. organisational, characteristics of intervention, delivery strategy) expected to explain intervention effectiveness.

This chapter evaluate the implementation and process evaluation of the package in rural Tanzania. The process evaluation reports whether the package was implemented as planned (i.e. fidelity), evaluates extent to which the package reached intended mothers (i.e. reach, recruitment, dose delivered), determines the degree to which the mothers were exposed to intervention (i.e. exposure, dose received), and describes the rural setting (i.e. contextual factors, facilitators, barriers) into which the package was implemented. Challenges to package effectiveness are also identified.

5.3 Methods

5.3.1 Study setting, design and ethical considerations

The study was conducted in rural Mpwapwa district, Dodoma region, central Tanzania. The region is predominantly semi-arid. The district is characterised by a long dry season (May to mid-November) and a short single wet season (November to March) (114). Detailed information on study setting, trial design and ethical considerations are given in Chapter 4 (**section 4.3.1**). The study was conducted according to the Declaration of Helsinki research guidelines involving human subjects/patients, and approved by the Tanzania's National Institute of Medical Research (NIMR/HQ/R.8a/Vol.IX/943), Institute of Tropical Medicine (ITM/IRB/AB/ac/879/13, Belgium) and University of Antwerp (B300201317997, Belgium). The trial was registered with ClinicalTrials.gov, number NCT02249754, https://clinicaltrials.gov/show/NCT02249754.

5.3.2 The nutrition education package

As described in Chapter 4 (**section 4.3.3**), the nutrition education package was composed of three components: 1) education and counselling of mothers, 2) training of village health workers (VHW) to counsel mothers and family members during monthly home visits, and 3) supportive supervision of the trained village health workers. The education content for mother and training content for VHW was centred on infant feeding healthcare-seeking practices, hygiene and sanitation. Detailed description of the education package, sessions, topics and recommended practices are presented in Chapter 3 (**section 3.3.5**). Recipes promoted during the intervention are described in Chapter 4 (**section 4.3.3**) and **Appendix 3.4**.

5.3.3 Framework for the analysis and reporting of process evaluation results

The nutrition education package protocol pre-defined the process evaluation measures and indicators and the evaluation was carried out in parallel with the main trial (176). A guide for the conduct of process evaluation (99) and a systematic approach outlined by Saunders and colleagues (97) was used to design the evaluation and analysis of results. The plan included the following evaluation elements: fidelity, reach, recruitment, dose delivered, exposure, dose received and contextual factors (e.g. facilitators, barriers, limitations). These elements were used across the primary groups targeted by the package (VHW, mothers). Detailed process evaluation methods, indicators, data collection and timing are presented in **Table 5.1**.

Table 5.1 Process evaluation framework for the nutrition education package delivered in rural Mpwapwa District, Tanzania, 2014-2015

Process indicator	Evaluation measure	Data sources, instruments	Timing[1]
Training VHW			
Fidelity	% of VHW trained	Registration forms Attendance records	beginning and end
	% of taught modules (and topics) to VHW	Activity logs	beginning and end
	% of VHW with training resources	Activity logs	periodic
Dose received	VHWs' level of knowledge and skills gained during training	Pre- and post-training test scores	beginning and end
Dose received (satisfaction)	Perception on training: % felt prepared to use counselling resources % felt training enhanced knowledge, skills % confident to apply knowledge, skills	Daily evaluation forms Final evaluation forms	beginning and end
Education and counselling mothers			
Recruitment Reach	Number of recruited infants. Number lost to follow-up and reasons	Activity logs	baseline, midtrial and end[2]
Fidelity	Number of education and counselling sessions (and topics) held with mothers	Activity logs	baseline, midtrial and end
Dose delivered	% of mothers attending each education session	Attendance records	baseline, midtrial and end
Dose delivered	% of mothers with information booklets	Attendance records	baseline, midtrial and end
Dose received	% of mothers who could spontaneously recall key practices learned in education sessions	Structured interviews	midtrial and end
Dose received	% of mothers who tried any of the cooked/promoted recipes at home % of mothers who tried the recommended practices	Structured interviews	midtrial and end
Dose received	Observation of mothers' attentiveness, interest/keen (e.g. asked/answered questions, give examples) during sessions	Un-structured observations	baseline, midtrial and end
Dose received	Amount of meal consumed by infants at cooking demonstration sessions	Un-structured observations	baseline, midtrial and end
Dose received (satisfaction)	% of mothers with positive attitude toward intervention usefulness and preference of intervention	Structured interviews	end of trial
Reach Fidelity	% health facility staff sensitised % sessions/meetings where health facility staff were present	Activity logs	baseline, midtrial and end
Home visits			
Fidelity	Number of home visits conducted by VHW	VHW workbooks	monthly: 6 times
Dose received (satisfaction)	% of mothers satisfied with VHW services	Structured interviews	midtrial and end
Supervision of VHW			
Fidelity	% of supervisory visits held	Activity logs	periodic
Fidelity, Dose delivered	% VHW able to use counselling skills during home visits (interpersonal skills, use of reading resources, problem-solving)	Structured observation checklist Performance scores	periodic
Dose delivered	% of VHW with completely and appropriately filled-in workbooks	VHW workbooks	periodic
Intervention context			
Context	Observation of health facility staff conducting routine health education	Structured observations	once per village[3]
Context (facilitators,	% VHW with positive perception of intervention delivery	Structured interviews, Field notes	after two and four months of

barriers)	VHW's description of barriers/challenges, facilitators/strengths, suggestions for delivery of intervention's components		trial[2]

[1]Timing: beginning=November 2014; baseline=December 2014; periodic=twice in January 2015, twice in February 2015, once in April, once in June 2015, after two and four months of trial=January & June 2015; midtrial=March 2015; end=July 2015; monthly=January, February until June 2015; once=date varied depended on village's growth monitoring schedule. [2]Information collected in both intervention and control villages

5.3.4 Data collection

Structured interviews with VHW. A pre-tested structured questionnaire was used to document characteristics of VHW in both control and intervention villages at baseline. An additional questionnaire, administered in intervention villages alone, was used to collect information on VHW's opinions about the intervention (i.e. implementation, home visits, its reception by mothers/families, barriers, facilitators). Information on the presence of any ongoing intervention/programme, actions or events within the villages was collected in all villages.

Structured interviews with mothers. Maternal recall of key issues learnt from previous education sessions, extent to which recommendations were practiced and perception on usefulness of the package elements (education-counselling, cooking demonstrations, information booklet, home visits) were collected using pre-tested structured questionnaires comprised of a mixture of close- and open-ended questions. From the list of 11 recommendations promoted during the education sessions, mothers were asked, item by item, whether they had tried the recommendation since the previous education session. Mothers ranked the elements according to their perceived usefulness, from 1st (as most preferred) to 4th (as least preferred) choice.

Review of records. Activity logs and forms were used to document number of recruited and existing infants-mothers pairs, modules and sessions delivered, supervisory visits made, training resources distributed and presence of health facility staff during education of mothers and village characteristics.

Evaluation of VHW training. The Kirkpatrick's four-level training evaluation model guided the design of training evaluation (219). Two standardised training tests with multiple and open-ended short questions on child feeding and health were administered to VHW. A correct answer was given a score of 1 and 0 for a wrong answer. None of the questions was weighted. A total score of 30 points could be achieved in the first pre/post-training tests in November 2014, and 46 points in the second pre/post-training tests in July 2015. VHW in control villages received the first pre-training test to ascertain knowledge levels comparability to VHW in intervention villages. No further testing was given thereafter.

Structured observations of VHW performance. VHW performance during counselling sessions with mothers was documented using a structured observation checklist adopted from a guideline for

counselling supervision of infant and young child nutrition programmes (175, 220). The checklist (**Appendix 5.1**) contained 13 skills that a VHW needed to perform during counselling. The skills demonstrate adequate use of interpersonal skills, use of counselling resources, promotion of problem-solving and discussion of practical solutions. A score of 2 was given if the skill was sufficiently performed, 1 if performed inadequately and 0 if not performed, giving a maximum score of 26. All VHW knew that they will be visited regularly for a home visit observation and that they will receive constructive feedback. However, they were not aware that their performances will be scored and days in which the scores will be made. To quickly assess whether VHW had learnt what they required to know and identify skills needing urgent improvement, performance scores of the first observation were taken. The second performance assessment was taken during the fourth supervisory visit after previous DHMT experience with VHW training indicated that VHW may require two to three supervisory visits to improve on skills. The VHW performance scores and reviews of their workbooks assessed on first and fourth supervisory visits are herein designated as the first and second observation, respectively.

Review of VHW workbooks. Records related to home visits (e.g. encountered feeding and health problems, practices discussed and adopted, barriers/challenges) were documented by VHW in their workbooks, and these were reviewed during the supervisory visits. Records were checked for comprehensiveness and feedback for improvement discussed with individual VHW.

Structured observations of routine health education sessions at health facilities. A structured observation checklist was designed to document how routine health education sessions were conducted in intervention and control villages. The checklist documented session duration, audience, attendance, topics covered and use of guidelines or job aids (**Appendix 5.2**).The list was validated with the district reproductive and child health staff and contained relevant actions expected to take place at the facility during a health education session. The observations were conducted in a representative sample of nine villages.

5.3.5 Data analysis

Data forms were reviewed in the field for accuracy, consistency, and completeness. Quantitative data were entered in EpiData version 3.1, checked for consistency using range checks and original forms, and exported to Stata/IC release 12.1 (StataCorp, College Station, Texas) for analysis. Data were expressed in number (and proportion), median (and interquartile range) or median (and minimum, maximum values) and mean (and standard deviation); accounting for cluster design using the survey *'svy'* command in Stata. Comparisons between study groups were done with cluster adjustment using the survey 'svy: mean' or user-written 'clttest' (for continuous variables) and 'clchi2' (for categorical variables) commands in Stata. McNemar test was used to assess associations of binary matched-pairs proportions (midtrial vs. end of trial outcomes). Wilcoxon signed rank sum test (non-normal unmatched data) was used to test the equality of medians

generated by maternal perception (usefulness, ranking) of package elements. A 2-sided p-value <0.05 was considered significant. For qualitative analyses, frequent or major themes inherent in the responses were identified from the interviews and structured observations, and direct quotations were presented.

5.4 Results

5.4.1 Implementation fidelity

All package elements (group education-counselling, cooking demonstrations, education-training resources, home visits, training of VHW, supervision of trained VHW) were delivered in all villages as outlined in the original protocol (176). A minor adjustment was made to the sensitisation meetings which were initially designed as a standalone component. Sensitisation meetings were incorporated in other components to ensure adequate reach and realistic delivery. Sensitisation meetings with family members were incorporated in home visits as it was possible to have an audience with family members at home rather than in a separate meeting. Sensitisation meetings with health staff were incorporated in education sessions with mothers because they could be present when the sessions were delivered in the villages. Delivery of the intervention and assessments are summarised in the intervention timeline presented in Figure 7.

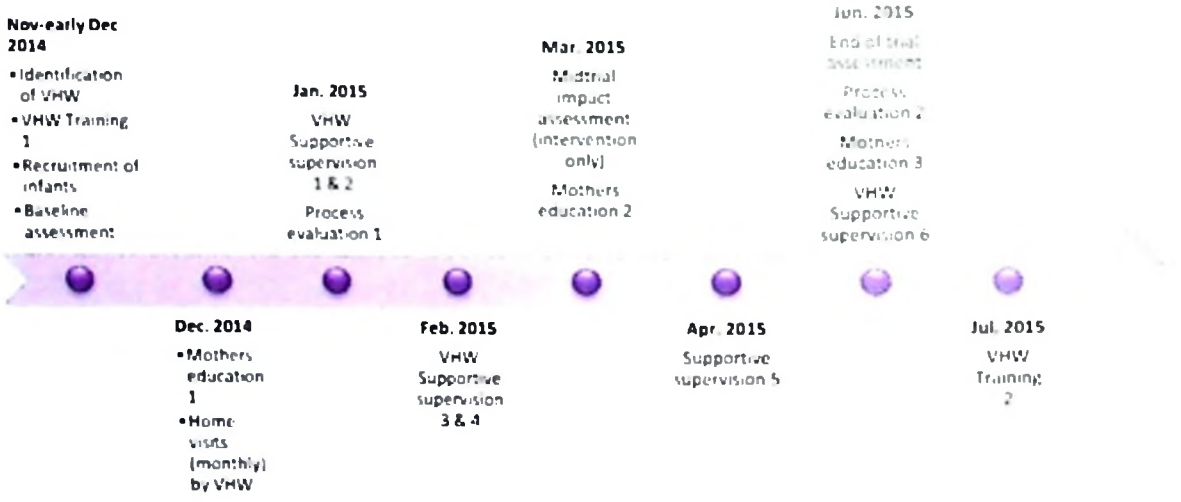

Figure 7. Intervention timeline: November 2014 – July 2015

5.4.2 Main effects of the intervention

Overall, the nutrition education package resulted in better feeding practices, dietary intake and growth outcomes than the routine health education. However, findings demonstrated modest intervention effects on some outcomes and lack of effects in others (Chapter 4, **section 4.4**). The effects on meal frequency, dietary diversity, energy and fat intakes were positive and significant. No effects were observed for iron and zinc intakes. The intervention resulted in significant higher mean change in length and length-for-age Z-scores in intervention than control group. No

differential effects were observed in mean changes in weight, weight-for-length and weight-for-age Z-scores.

5.4.3 Recruitment and reach

The trial recruited all eligible infants found in the villages. A total of 370 infants were recruited at baseline; 186 from control and 184 from intervention villages. The education package reached 184 mothers during the first session (at baseline), 138 during the second session and 118 in the third and last session. Infants who completed trial were 128 (68.8%) in control villages and 118 (64.1%) in intervention villages. There were no significant differences in infant characteristics between those lost to follow-up and those remaining (**section 4.4.3**). Reasons for not attending education sessions were unrelated to the nature of intervention. Majority of mothers missed the sessions because of farming activities during the day or had temporarily migrated to their farms. Other reasons were related to family obligations (e.g. mother travelling with child, caring for a sick family member), child ill and family moving away from the village. It is important to note that the sessions coincided with the pre-harvest and early harvest periods. These periods are characterised by high peak and heavy agricultural workload. Reasons for not attending assessments for mothers in control villages were similar to those in intervention villages; except for two child deaths and four fathers who declined to participate to avoid missing out on farming.

The package also reached 8 out of 16 health facility staff (50%) who participated during the three education sessions with mothers. However, their participation was not fully as expected. They were observed to frequently attend to outpatients.

Characteristics of participating VHW, 22 in control and 18 in intervention villages, are presented in **Table 5.2**. Overall mean age was 42.5 years and almost all VHW had completed primary school. Most of the VHW characteristics were comparable between study groups. However, significantly more VHW in control villages had lived in the villages longer than their intervention counterparts and they had previously received training on breastfeeding. Slightly more VHW in control than intervention villages felt their voluntary role was usually conflicting with household responsibilities, but this difference was not significant. Majority of VHW assisted health facility staff to weigh children during growth monitoring and organise mothers on immunisation days. Other services performed by VHW included community education on health-nutrition during pregnancy, lactation and infancy, sensitisation and education on family planning and safe motherhood, general health education, home-based care for people living with HIV, environmental sanitation and home hygiene.

Table 5.2 Demographic characteristics of recruited VHWs in intervention and control villages in Mpwapwa District, Tanzania

Characteristics	Intervention N=18	Control N=22	p-value[2]
Age (years)	42.3 ± 7.4[1]	43.3 ± 8.3	0.621
Sex			
Male	8 (44.4)	10 (45.4)	0.949
Female	10 (55.6)	12 (54.6)	
Duration of stay in the village	33.9 ± 10.6	42.2 ± 8.6	0.013
Duration worked as volunteer VHW	14.1 ± 5.0	13.3 ± 6.9	0.672
Household size	5.6 ± 2.0	5.9 ± 1.3	0.606
Education level			
Not completed primary school	1 (5.6)	1 (4.6)	0.713
Completed primary school or higher	17 (94.4)	21 (95.4)	
Occupation			
Farming alone	10 (55.5)	14 (63.6)	0.789
Farming and/or livestock	8 (44.4)	7 (31.8)	
Self-employed with skill	0 (0)	1 (4.6)	
VHW role conflicts with household responsibilities	6 (33.3)	15 (68.2)	0.086
Previous involvement in NGOs or programmes activities	14 (77.8)	22 (100.0)	0.153
Previous short training on infant feeding	13 (72.2)	18 (81.8)	0.554
Previous short training on breastfeeding	9 (50.0)	18 (81.8)	0.043
Previous short training on counselling	9 (50.0)	14 (63.6)	0.385
Family approve role of VHW	17 (94.4)	22 (100.0)	0.432
VHW involvement in current research may affect income/earning	2 (11.1)	2 (9.1)	0.832
Main service offered: assisting health staff at health facility	14 (77.8)	20 (90.9)	0.322

[1]mean ± SD, number (percentage), all such values. [2]p-value for compared means (independent t-test) and proportions (Chi-square test) adjusted for clustering.

5.4.4 Training of village health workers: delivery, fidelity and dose

A total 18 VHW received the first training and the same VHW successfully completed the second training. With no attrition, this makes a 100% training retention. All three training modules and their respective topics were delivered during the scheduled sessions. Topics with a greater use of group activities, demonstrations and role plays, however, took longer time than expected. From the planned 6-hours per day, delivery of training took up to 7 hours and 10 minutes per day. This extra time was repeatedly stated as the least liked aspect of training. Typical comments from the evaluation forms were: *Topics are longer than allocated time* (VHW1), *Time table is not adhered* (VHW2) and *Training time should be increased* (VHW3).

Results of a test carried out to ascertain VHW knowledge level before the intervention showed no significant difference between VHW in intervention and control villages in knowledge scores (8.1±3.6 vs. 10.5±4.3, p=0.137). **Table 5.3** presents VHW training evaluation results during the first and second training periods. There was a significant increase in knowledge scores from pre-test to post-test during the first training (+ 5.7-points, p<0.001). In this first training, very few VHW (n=3,

16.7%) obtained a pre-test score equal or higher than 50% as compared to 13 (72.2%) who obtained a post-test score of 50% or higher. A significant increase in knowledge scores from pre-test to post-test was found during the second training (+ 4.1-points, p=0.003). Proportion of VHW who obtained pre-test and post-test scores of 50% or higher during the second training was 88.9% and 100%, respectively. Assessment of individual questions showed that majority of VHW gave correct answers on breastfeeding, child illness and communication channels questions, both during the first and second training. Most of the questions on principles of complementary feeding and adoption of new behaviours were left unanswered or their answers were incorrect during the pre-test of the first training; however an improvement was observed during the post-test of the second training. Having previously attended short training on breastfeeding, complementary feeding or counselling had no influence on knowledge change scores.

Results showed further a positive reaction toward the training and the training materials. Proportion of VHW who felt prepared to use the counselling resources (cards, workbooks) was high in both periods (**Table 5.3**). Overall, training enhanced VHW knowledge, skills and confidence. Proportion of VHW who reported that the training enhanced their knowledge, skills, and that they felt confident to apply what they had gained was high. None of the VHW reported to feel unprepared or unconfident.

Table 5.3 Evaluation of VHW training during the first and second training periods in Mpwapwa District, Tanzania

Attribute of training	First training (Nov. 2014)	Second training (Jul. 2015)	p-value[1]
	n(%) or mean ± SD		
Training (n=18)			
Knowledge			
Pre-training score	10.5 ± 4.3[2]	30.0 ± 6.8[3]	
Post-training score	16.3 ± 5.4	34.2 ± 6.1	
p-value[4]	p<0.001	p=0.003	
Felt prepared to use counselling cards			
Very prepared	12 (66.7)	15 (83.3)	0.179
Prepared	6 (33.3)	3 (16.7)	
Felt prepared to use workbook			
Very prepared	15 (83.3)	13 (72.2)	0.414
Prepared	3 (16.7)	5 (27.8)	
Training enhanced knowledge			
Enhanced strongly	11 (61.1)	16 (88.9)	0.058
Enhanced slightly	7 (38.9)	2 (11.1)	
Training enhanced skills			
Enhanced strongly	12 (66.7)	15 (83.3)	0.179
Enhanced slightly	6 (33.3)	3 (16.7)	
Confidence to apply knowledge, skills			
Very confident	5 (27.8)	11 (61.1)	0.008
Confident	13 (72.2)	7 (38.9)	

[1]p-value for matched-data using McNemar test for proportions. [2]Maximum score: 30 points during First training. [3]Maximum score: 46 points during Second training. [4]p-value comparing test scores within First or Second training.

5.4.5 Education and counselling of mothers: fidelity and dose

All three education and cooking demonstration sessions were held with mothers as planned. Mothers were generally attentive and showed interest in the discussions by asking and responding to questions and giving examples. Each mother brought her booklet to the education sessions and it was a frequently-referred resource for key issues or points of emphasis. All infants consumed the meals prepared during the cooking demonstrations, with the exception of few who were sleepy or sleeping during the feeding period. Proportion of mothers who were able to spontaneously recall issues taught or learned from the first session decreased from 89.8% (115/128) at midtrial to 79.3% (73/92) at the end of trial. Majority of mothers had read or had someone else read the booklet to them, 82.6% at midtrial and 82.2% at end of trial. Majority of mothers reported to have tried one or more of the cooked/promoted recipes at home, 89.8% (115/128) after the first session and 94.6% (87/92) after the second session. Among those who tried the recipes, 93.0% (at midtrial) and 83.9% (at the end) of mothers reported that the recipes were easy to prepare. It was generally observed during the education and cooking sessions that some mothers were not aware of the many food combinations that can make nutritious meals. They mentioned that what and how they prepare meals and feed their infants were influenced by previous experiences with older children.

There was a significant increase in the proportion of mothers who tried all the recommended practices between the education sessions ($p<0.05$); 37.7% (52/138) after first session (i.e. baseline-midtrial period) to 66.1% (78/118) after second session (i.e. midtrial-end period). **Table 5.4** shows the distribution of mothers in intervention villages according to extent of practice of key recommendations. Majority of mothers were able to try one or more of the recommended practices. There were no differences in the proportion of mothers who tried recommendations on feeding frequencies or feeding a child during and after illness after the first and second education sessions. Giving undiluted cow's milk at least 3 times per week was the least practiced recommendation, however, a significant increase in the proportion of mothers who tried was observed after the second education session. Mothers reported that giving undiluted cow's milk, providing animal-source foods and preparing thick, mashed and semi-solid meals made from at least one food from the five food groups were the most difficult recommendations to implement. Lack of money to purchase some of the foods and unavailability of some foods due to seasonal variations were the most frequently cited reasons for failure to implement some of the recommendations. Other reasons included lack of adequate time for food preparations due to farm work and perceived child's dislikes of some foods.

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There was a significant increase in the proportion of mothers who tried all the recommended practices between the education sessions ($p<0.05$); 37.7% (52/138) after first session (i.e. baseline-midtrial period) to 66.1% (78/118) after second session (i.e. midtrial-end period). **Table 5.4** shows the distribution of mothers in intervention villages according to extent of practice of key recommendations. Majority of mothers were able to try one or more of the recommended practices. There were no differences in the proportion of mothers who tried recommendations on feeding frequencies or feeding a child during and after illness after the first and second education sessions. Giving undiluted cow's milk at least 3 times per week was the least practiced recommendation, however, a significant increase in the proportion of mothers who tried was observed after the second education session. Mothers reported that giving undiluted cow's milk, providing animal-source foods and preparing thick, mashed and semi-solid meals made from at least one food from the five food groups were the most difficult recommendations to implement. Lack of money to purchase some of the foods and unavailability of some foods due to seasonal variations were the most frequently cited reasons for failure to implement some of the recommendations. Other reasons included lack of adequate time for food preparations due to farm work and perceived child's dislikes of some foods.

Table 5.4 Proportion of mothers in intervention villages who tried key recommendations after first and second education-counselling-cooking sessions in Mpwapwa District, Tanzania

Feeding and health recommendations tried	After 1st education session[1] (n=138)	After 2nd education session[2] (n=118)	p-value[3]
1. Continue to breastfeed on demand, day and night	138 (100)[4]	118 (100)	-
2. Give thick porridge from combined cereals (e.g. maize, sorghum, pearl millet), groundnuts/oilseeds, egg or milk, dried jute mallow leaves	124 (89.9)	115 (97.5)	0.004
3. Prepare soft, thick, mashed and semi-solid meals made from at least one food from the five food groups[5]	102 (73.9)	100 (84.7)	0.002
4. Give undiluted cow's milk at least 3 times per week	76 (55.1)	93 (78.8)	0.0001
5. Cook, mash, and add legumes (e.g. beans, pigeon peas, bambara groundnuts, cowpeas) to child's meals	126 (91.3)	118 (100.0)	0.008
6. Animal source foods (e.g. eggs, beef, pork, chicken, liver, fish, sardines) at least 3 times per week	105 (76.1)	115 (97.5)	p<0.001
7. Leafy vegetables and other vegetables (e.g. pumpkin)	124 (89.9)	118 (100.0)	0.002
8. Fruit (e.g. papaya, ripe banana, mango, orange) after a meal	121 (87.7)	112 (94.9)	0.012
9. Feed 2-3 times/day at 6-8 months. Feed 3-4 times/day at 9-11 mo. Feed 3-4 times/day at 12-23 mo. Give snacks 1-2 times/day (e.g. piece of potato, fruit) between meals	131 (94.9)	112 (91.5)	0.257
10. Encourage to drink and eat more frequently during illness and extra food after illness	123 (89.1)	108 (91.5)	0.133
11. Wash your hands and child hands with soap before feeding children	118 (85.5)	114 (96.6)	0.004

[1]Assessed at midtrial. [2]Assessed at the end of trial. [3]p-value for matched proportions by McNemar test. [4]Number (proportion). [5]Five food groups: cereals, tubers, roots; legumes and animal-source foods; vegetables, fruits; fats and sugar.

Maternal satisfaction with the four elements of education package (i.e. education-counselling sessions, cooking demonstrations, booklet, home visits) was generally good. Their perception on usefulness of education-counselling sessions, cooking demonstrations, booklet and home visits after the trial was 100%, 100%, 95.8% and 100%, respectively. When mothers were asked to rank the four elements, majority of the mothers gave first or second choice education-counselling (78.8%) and cooking demonstrations (82.2%). On the other hand, majority of mothers gave third or fourth choice information booklet (75.4%) and home visits (85.6%). Detailed distribution of their choices is presented in **Figure 8**. This ranking pattern was similar across villages, indicating that cooking demonstration was the mostly preferred element, followed by education-counselling sessions, booklet and home visits.

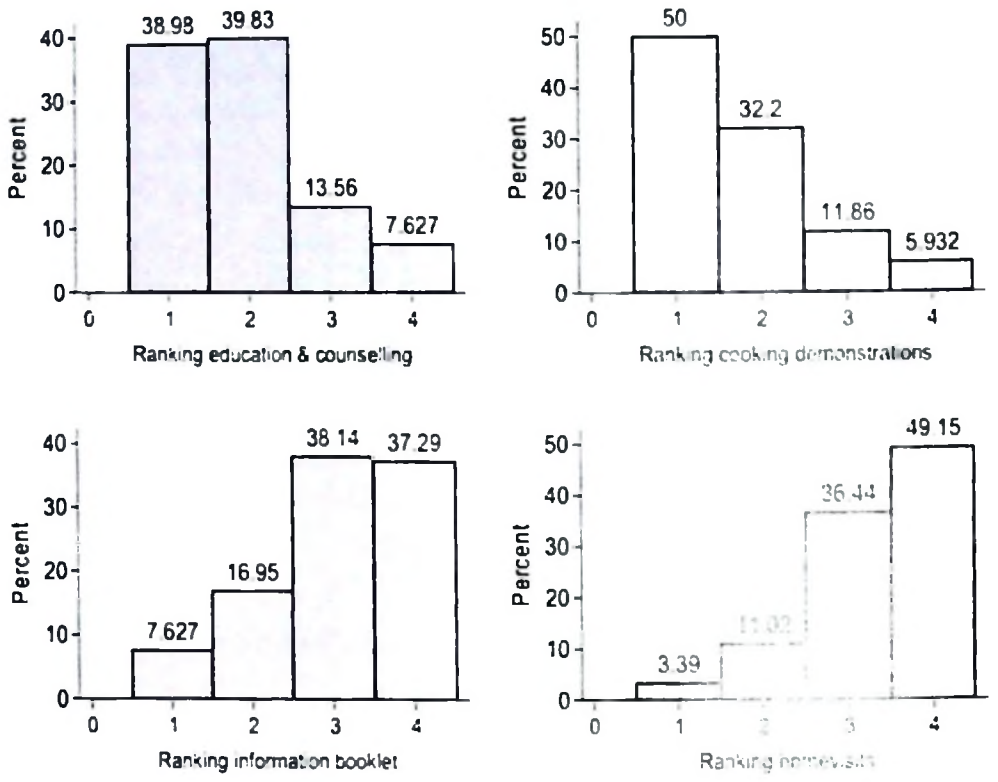


Figure 8. Distribution of mothers' perceived usefulness of the education package elements after intervention in Mpwapwa District, Tanzania. Ranking: 1=first choice, 2=second choice, 3=third choice, 4=fourth choice.

5.4.6 Home visits: fidelity and dose

A high proportion of mothers expressed their satisfaction with the home visits made by VHW; 89.1% (123/138) during midtrial assessment and 93.3% (110/118) at the end of trial. Few mothers reported to have not received a home visit, 10.9% (15/138) during midtrial and 11.0% (13/118) at the end of trial. Similarly, few mothers were not satisfied with the VHW visits, 10.9% (15/138) during midtrial and 6.8% (8/118) at the end of trial. Mothers who were not satisfied with VHW services reported receiving fewer home visits; and in cases where VHW visited, they were not counselled, they were just informed of a forthcoming outcome assessment or given a general health message. Mothers mentioned further that VHW would tell them to read the booklet or to follow instructions found in the booklet. Proportion of mothers who received these types of messages or instructions decreased from 15.9% (22/138) during midtrial to 7.6% (9/118) at the end of trial (p=0.057). Common comments from mothers regarding the home visits were: *I was not asked much about how I feed my child* (Mother 1), *I was not counselled on how I should continue feeding my child* (Mother 2) and *The VHW came to tell me of the date for next measurements* (Mother 3).

Close examination of VHW workbooks and discussions revealed that some VHW were not spending adequate time with the mothers, or making unscheduled visits which found the mother unprepared and unsettled. Some mothers had migrated temporarily to their farms during the peak agricultural season, resulting in one or two missed visits. Because their return dates were unknown and VHW were making repeated checks, impromptu meetings ensued if the mother was found at home. In these situations, a hurried discussion happened, resulting in lost counselling opportunity and inadequate information sharing/exchange. This was the case for mothers who were told to read the booklet or follow booklet instructions, reminded of education or assessment dates or given general child health messages. Further examination of structured observation notes found that it was common, especially during midtrial, for VHW to fail to discuss with the mother a plan for the follow-up visit (i.e. agreement on next appointment). Skipping this important counselling skill could have resulted in unscheduled and missed visits.

5.4.7 Supportive supervision of VHW: fidelity and dose

The VHW were supervised as planned, every 2 weeks in the first 2 months and at 2-months intervals thereafter. A total of six supervisory visits were made (**Table 5.1, Figure 7**). Structured observations showed a significant improvement in VHW mean performance scores (first observation: 13.9±2.5 [range: 9-19]; second observation: 19.8±1.9 [range: 16-23], p<0.001). A significant increase in mean performance score was found among VHW who had previously attended a short training on counselling as compared to those who had not attended a similar training (+7.2-point vs. +4.5-point, p=0.013). Examination of individual skills showed that some skills were quite challenging to the VHW. Skills which majority of VHW did not perform during the first observation included the use of information contained in counselling resources (88.9%), discussions of next meeting when closing the conversation (61.1%) and offering appropriate referrals for other services such as health advice (50%). The VHW were commonly observed to rely on their summarised notes or memory instead of referring to the printed documents. During supervision, these and other skills were re-examined and emphasised. During the second observation, all VHW were able to perform all skills. However, some skills were not adequately performed as required. These included promoting problem-solving, negotiating (asking current practices, praising, helping to select feasible options), discussing practical solutions that mothers could try and encouraging mothers to participate in discussions. Additional support was given to improve skills performance.

Proportion of VHW whose workbooks were comprehensive with clear descriptions according to guidelines was 22.2% (4/18) at the first observation. The records contained clearly described infant feeding and health problems, appropriate recommendations and challenges faced by the household, records of sick infants and follow-ups and proper use of the event calendar. Common comments given by VHW regarding their workbooks included: *This exercise is very new to me. I was used to writing short reports* (VHW 1), *The workbook contains a lot of issues to report* (VHW

2), *I could not differentiate well the two terms, problems and challenges* (VHW 3) and *I had to use a pencil first to write down my records until after the feedback* (VHW 4). The comprehensiveness of the workbooks improved during the second observation: 72.2% (13/18), 100% (18/18) and 88.9% (16/18) of VHW workbooks contained clearly described problems-recommendations-challenges, records of sick infants and scheduled appointments, respectively. This improvement was described by VHW as: *The way I see it, reporting in workbook is simple if you were serious (meaning: paid attention) to the topics taught during training* (VHW 1) and *The calendar part is very useful; it helped me to organise multiple schedules, the home visits and my own activities* (VHW 2). Comment from a VHW whose workbook needed more improvement was *I think I need more time* (VHW 3).

5.4.8 Delivery of routine health education in control and intervention villages

Routine health education took place during the growth monitoring and promotion (GMP) sessions, which involved weighing children below the age of five years. Outpatient clinic, immunisations, antenatal clinic, drug dispensing and family planning were taking place in parallel with the GMP on different locations of the health facility. Health facility staff were generally very busy, moving from one service to another. VHW were present to assist with the weighing. Large numbers of mothers and their children were in attendance, with some coming for weighing alone and others for multiple services. There was a great variation in the way the sessions were delivered, ranging from absence of sessions, brief announcements or talks to a full session. In one village, a VHW delivered a session. Sessions were conducted before or after weighing. All mothers in attendance received the same message; however, others missed the talks because of arriving late or in-between sessions. The sessions lasted between 5 and 15 minutes. The topics of focus were general and lacked consistency. Use of nutrition job aids was almost non-existent. Commonly emphasised messages were continued weighing until child reaches five years, household contribution to community health fund insurance, giving birth at a health facility, preventive measures of diseases, exclusive breastfeeding, immunisations and feeding balanced meals. The messages were relatively similar across villages where full education sessions were given; however lack of detailed elaboration on balanced meals, differentiating or prioritising vulnerable groups (e.g. lactating women and children below the age of two years) was observed. In villages where brief announcements or talks were given, mothers of infants who had failed to gain or lost weight were told to improve feeding. Common comments were expressed as: *Why has the child lost weight? You should feed your child well* (Health staff 1) and *Your child has not gained weight, the third month now. It is important to feed your child balanced diet* (Health staff 2).

Although out of scope of the present study, a great variation was observed in the way children were weighed and types of weighing scales used. There was limited use of standard anthropometric procedures and the scales had low precision, uncalibrated or were too old to serve the purpose. There is an immediate need to address these important aspects of GMP.

5.4.9 Barriers

The study identified a number of barriers to intervention effectiveness, and these are described here. First, the study area is semi-arid, characterised by a short single wet season and a long dry season. Rainfall is variable (i.e. timing, amount, frequency), affecting crop and livestock productivity. These eventually contribute to inadequate harvests, seasonal food fluctuations, limited amount of food for home consumption and sale, inadequate income and low household purchasing power. This affected the ability of most families from implementing some of the recommended practices (e.g. purchase of some foods, feeding a variety of foods, purchase of medications for sick infants). For example, mothers explained that they were able to afford milk because it was a raining season where animals produce a lot of milk and the milk is readily available. But after rains, pastures begin to dry up, milk would be scarce and expensive, thus they will not be able to give milk to their infants. Second, heavy involvement in agricultural activities stopped some mothers from participating in the sessions. This resulted in low or irregular attendance rates or complete withdrawal from the intervention. Low and varied attendance could have reduced the consistency of education messages and effectiveness of other package elements. Increased demand on farm labour has a negative implication on childcare practices by reducing time available for food preparations, feeding and healthcare-seeking. Third, maternal habitual feeding choices and perceived infant's food preferences were a barrier to feeding some of the promoted foods. Mothers believed that certain foods need to be given after teething for adequate chewing and swallowing. The most affected foods were flesh and organ meats, legumes such as beans and cowpeas, eggs and leafy vegetables. Different ways of preparing these foods (e.g. mashing, pounding and boiling meats, milling and mixing dried flours) were practiced during the cooking demonstrations and mothers' expressed intentions to try the recipes were encouraging. It was evident during the session discussions that mothers would generally stop feeding a particular food if the child refuses at the first instance. Responsive feeding practices were emphasised to improve maternal feeding styles and overcome this barrier. Another barrier was the difficulty in assembling all mothers at the agreed time to begin a session. As a result, sessions tended to start and end relatively later than planned.

5.4.10 Facilitating factors

All VHW had positive attitude towards the intervention delivery. Training was relevant to what was expected of VHW, and the fact that it was conducted in their district, enabled them to relate to their environment. This was expressed by two VHW: *Training has been very useful to us and the community we live in. It has helped us to implement the intervention activities* (VHW 1), Practical exercises and feedback, *and provision of appropriate working tools (e.g. counselling cards, manual) have been my greatest motivation factors* (VHW 2), and *Feeding challenges in my village are similar to those we found in the village where we had field practice* (VHW 3). Mothers' willingness to participate in the intervention and eagerness to learn were the significant factors that facilitated delivery of the intervention. Home visits provided a chance to know the family situation

and counsel accordingly and gave mothers the freedom to express themselves and hold discussions freely.

5.4.11 Intervention cost

The cost of developing the nutrition education package totalled 25,117 United States dollars (USD). This included USD 4,865 for illustrations and drawings, USD 11,830 for materials development, translations and review, and USD 8,422 for layout design and printing. The cost of delivering the package and conducting the intervention trial in 9 intervention and 9 control villages totalled USD 61,116. This included USD 49,566 for VHW training and monthly incentives, transport, equipment (e.g. food weighing scales), supplies (e.g. cooking utensils, blood lancets) and operating expenses (e.g. data collection forms, food items, communication); and USD 11,550 for human resource (drivers, data collectors, research team, supervisors of VHW). If the package is to be delivered in control villages, additional costs will mainly be due to printing extra copies of existing education resources and data collection forms, training new VHW and monthly incentives, transport, supplies, operating expenses and human resources.

5.5 Discussion

The process evaluation of the nutrition education package in rural villages has shown rigour in implementation, good recruitment and reach. The package components and elements (training VHW, education, counselling and cooking demonstration with mothers, home visits, supervision of VHW) were homogenously implemented across the intervention villages as planned. Fidelity, dose delivered and exposure were high for each intervention component. The intervention was well received with good dose and was well accepted by VHW, mothers and their families. Recruitment was high at the beginning of intervention, whereby all eligible infants were recruited. However, extent of reach decreased at the end of trial. The loss-to-follow-up was primarily related to maternal responsibilities. Low compliance has also been a limitation in other community-based nutrition interventions involving rural mothers and households (153, 221, 222).

Training VHW resulted in improved knowledge, skills and attitudes; and appropriate use of their acquired information and skills during home visits. The training evaluation was consistent with previous community health workers training evaluation on knowledge, skills performance and perceptions (223-225). The supportive supervision carried out in this study significantly improved VHW skills performance and record keeping; and the assessments were well received. The supervision is in line with previous researchers who emphasised supportive supervision for improvement of health workers performance and motivation (226-231). The study contributed evidence for supervision of volunteer health workers which was needed to improve health services in resource-limited settings (232, 233).

Education, counselling and cooking demonstration sessions improved and reinforced maternal nutritional knowledge and enhanced adoption of recommended practices and promoted recipes. Similar to this study, previous nutrition education interventions that were able to improve complementary feeding practices and other outcomes such as growth had used culturally-appropriate key educational messages, cooking demonstrations, printed materials (e.g. recipe booklets, leaflets, feeding guides, counselling cards) and a variety communication approaches (60, 75). This intervention has shown that monthly home visits were feasible and acceptable by majority of mothers. Coverage of home visits by VHW was high, albeit few mothers reported fewer visits and inadequate time spent during the visits. Interventions which used home visits as a strategy have shown to be effective in improving complementary feeding (60, 220, 234), pregnancy outcomes and newborn care (158, 235, 236) and rehabilitation of malnourished children (237). Compared to the routine health education, nutrition education package showed a greater fidelity and dose in message delivery and regular support. The routine health education sessions at the facilities were characterised by general information, hurried and often-inconsistent messages, irregular sessions of short duration and lack of educational materials. Unsystematic education sessions as was observed in routine health education have previously been reported in African settings (220, 238).

Overall, findings of the process evaluation suggest that education-counselling, cooking demonstrations and information booklets improved maternal positive attitude and sense of ease and ability to practice the recommendations. There were no indications of perceived pressure from others not to adopt the recommendations because optimal feeding and health practices are generally communicated by health workers. Home visits reinforced maternal knowledge, contributed to improved attitude, self-efficacy and family influences. VHW received regular support to improve their delivery skills. Contrary to the expectation that the package will improve feeding and health care practices and ultimately improve growth; dietary practices did not translate into significant improvements in some of the growth indices, whereas in others, the effects were modest. Prevalence of stunting, underweight and anaemia increased during the intervention and infants experienced relatively high morbidity.

The reasons why the education package did not have or had modest effects could be explained by irregular consumption of a more varied diet, inadequate consumption of nutrient-dense foods, high morbidity, limited time for meal preparation and feeding, habitual feeding choices influenced by culture, inadequate home food environment and inadequate household income.

Although intervention infants had significantly higher dietary diversity than control infants, the varied diets were probably not regular or adequate enough to have a significant physiological impact on weight, WAZ and WLZ. Modest effects were however observed in length and LAZ. Giving meals from a variety of foods was expressed by mothers as one of the most difficult

recommendations to implement. Inadequate consumption of nutrient-dense foods such as animal-source foods (ASF), particularly flesh meats, eggs and milk could have contributed to lack of effects on iron and zinc intakes. This was demonstrated at the end of trial where less than one-third of the study infants consumed ASF, and that mothers found giving ASF as a difficult recommendation to implement. Previous observation and intervention studies in developing countries have shown that diets containing few animal products, fruits and vegetables did not provided adequate amounts of minerals and vitamins (239, 240); and that inclusion of milk and ASF improved growth (241-243). In addition, a review of feeding interventions involving infants and young children have shown that emphasis on and increased consumption of ASF led to increased intakes of micronutrients and significant impact on weight and length gain (60). Some of the nutrition education interventions had reported improved intakes in iron and zinc (81, 156, 244); however others reported no improvement as the intakes were lower than the recommendations (202). Overall, it can be concluded that intervention infants did not receive adequate amounts of ASF regularly. In addition to insufficient intakes, high morbidity experienced by the study infants reduced the impact of diets on growth, particularly weight, WAZ and WLZ where morbidity had a negative significant effect on these indices.

Throughout the trial period mothers were greatly engaged in agricultural activities, resulting in some missing the education sessions and home visits or dropping out. In this situation, child care practices such as meal preparations, patience to feed, healthcare-seeking and attention are most likely to be affected due to limited time. And this was the case with some of the mothers in the study who reported to have lacked adequate time to prepare infant meals and feed responsively. High maternal farm workload has previously been documented to limit the time mothers can have on child care (50, 146). This study also noted some degree of maternal habit and cultural belief on withholding certain foods to young infants. Although the intervention addressed these issues during the education sessions and home visits, the intervention duration was probably not long enough to observe behavioural change and maintenance.

Household meal frequency and dietary diversity at the end of the trial significantly influenced infants' meal frequency and dietary diversity. This indicated that what was available at home largely determined what the infant received. Home food environment has been documented to determine child's dietary consumption (131, 204). Lack of money to purchase some of the foods as evidenced by mothers during the trial was also a limitation to food accessibility at home. Financial constraints and lack of resources for family income generation have also been reported in rural settings (48). In this study, inadequate household income appeared to be aggravated by low agricultural productivity, poor marketing and transport infrastructure for agricultural produce and seasonal fluctuations in food supply.

Cost of delivering the package is an important aspect when considering scaling up. In this study, total costs of delivering the education package were presented to inform resource allocation. It was not possible in this study to collect costs related to routine health education for comparison with the education package. Future research on cost-effectiveness of the package delivered in varied rural contexts is needed to inform policy decision.

Results of this trial have highlighted the need to reconsider the education approach offered at health facilities in the country. Because of persistent higher levels of undernutrition the existing approach need to be reviewed and improved. The delivery and content should be audience-specific with monitoring of infants at increased risk of growth faltering to alleviate further deterioration. Improvement in health services as well as access will reduce high rates of child morbidity observed in young children. A multidisciplinary approach is needed in resource-limited areas like the one studied. Strategies are needed to 1) increase household income; 2) promote positive habitual preferences and cultural beliefs; 3) improve maternal-child care; 4) improve food production using optimal dry land farming practices; and 5) improve marketing and transport infrastructure to enhance food distribution. For resource-poor households and those constrained by seasonal food insecurities, food or conditional cash transfers may be required in addition to nutrition education.

5.6 Limitations

This study had some limitations. First, the use of self-reporting in assessing maternal recall of key recommendations learnt in education sessions could be prone to recall bias and socially desirable answers. Similarly, use of self-reporting measures to assess maternal adoption of recommended practices without support of other objective measures could have overestimated the outcomes. To improve recall and enhance reliability of the self-reports, the recall period was designed to be relatively short (past 1 day, past 1 week, past 2 weeks). Future research could consider use of biomarkers to complement self-reports and assess extent of change in dietary practices and intakes. Second, the trial experienced higher loss to follow-up than anticipated which could have introduced selection bias and affected intervention conclusions. In addition to having few differences between participating and lost to follow-up households, confounding which could arise was minimised by incorporating the household characteristics in a wealth index and adjusting for wealth index by regression modelling. Third, outcomes of structured observations during home visits could have been influenced by the presence of the observer (i.e. VHW supervisor). This is commonly described as reactivity, a common phenomenon in behavioural interventions (93, 245, 246). Assessment of VHW performance could not be conducted without their knowledge, however efforts to minimise reactivity were taken; and these included not informing VHW that the observations were scored and days in which the scores were made. And to the mothers who participated in the counselling session, it was generally told that the teacher would like to know how their babies were progressing. Fourth, the lack of midtrial assessment in control villages does

not permit the differentiation and comparison of feeding practices and other experiences occurring in the intervention villages. However, end of trial comparison is made on the major complementary feeding indicators. The midtrial was especially designed to investigate, at an early stage, whether the nutrition education package was being delivered as planned and identify corrective measures if required, and begin to build evidence of short-term nutrition changes.

5.7 Conclusion

In conclusion, results of the process evaluation showed that the nutrition education package was delivered as planned and well received by VHW, mothers and their families. The package was effective in improving knowledge, skills and confidence of community-based VHW, thus built local capacity to sustain behaviour change. Results add to the evidence that nutrition education incorporating cooking demonstrations and regular home visits can improve feeding practices, dietary intake of macronutrients and infant growth. Differential effects reported in this study suggest that household income, culture and maternal workload influenced the intervention outcomes; and these need to be addressed in future. Components that address health services strengthening may enhance the effectiveness of the package by reducing morbidity and improve delivery of nutrition education. A slightly longer training period for VHW, from the current three to five days, will be beneficial for enhancing adequate skills performance. Future research is needed to evaluate the impact of the package in other rural areas in the country where varied contexts may provide conclusive understanding of the effects and generalisability beyond one context. Overall, other multi-sectoral strategies are needed to increase household income, improve maternal-child care, promote positive cultural beliefs, enhance productivity from dry land farming and improve marketing and transport infrastructure.

Chapter 6. General discussion and perspectives

Research presented in this thesis focused on feeding practices, diets and growth during the complementary feeding period among infants below the age of one year in a rural district in central Tanzania. Cross-sectional studies characterised dietary and growth patterns of infants and young children. Intervention Mapping and Theory of Planned Behaviour frameworks guided the development of a nutrition education package for improving feeding practices, dietary adequacy and growth. The education package was evaluated using a cluster-randomised controlled trial and results of package effects on child outcomes and process evaluation were presented. In this chapter, discussion of main findings, research drawbacks and considerations for improvement are discussed. Further, future perspectives for the nutrition education package and recommendations for future research are presented.

6.1 Main findings

Nutrition situation of infants in rural areas

Results of the cross-sectional studies have shown the magnitude of poor nutrition, inadequate feeding practices and low dietary intakes in young infants in rural Tanzania and the importance of addressing the nutrition situation. Stunting was a major form of undernutrition among the rural infants. Feeding practices were characterised by low feeding frequency (i.e. fewer number of meals per day), small meal portion sizes and limited dietary variety. Nutrient content of sampled complementary porridge and meals were generally low due to over-dilution of porridge and consumption of broths and soups without the fleshy portions of foods. Relatively high amounts of water were used in porridge preparation, resulting in watery consistency and reduced overall energy and nutrients content. In the case of meals, infants had mostly broths, soups or stews made from beans, beef, vegetables, sardines or fish because mothers withheld the fleshy parts of the foods until when infants grew sufficient number of teeth for chewing. These practices contributed to infants not meeting their recommended nutritional requirements. A repeated study of the same cohort of infants showed that inadequate feeding practices and high prevalence of stunting persisted into the infants' second year of life. Inadequate feeding practices, dietary adequacy and growth observed among the infants could have been contributed by infant morbidity, limited household food availability and accessibility, aggravated by seasonal food variation, lack of nutritional knowledge and negative cultural beliefs. A considerable number of infants were not receiving health care or were receiving it from non-formal sources. With less than one-third of households (30.7%) reporting to produce food crops sufficient to meet family needs between harvest seasons and few households having food in storage during the post-harvest (21.3%) than the harvest season (72.5%), it was more likely that infant diets were vulnerable to seasonal food fluctuations. Lack of nutritional knowledge, most likely determined by cultural beliefs, was evidenced by limited maternal feeding choices, leading to inadequate feeding practices.

Use of nutrient content tables and missing values

Investigation of the nutrient composition of locally prepared complementary meals is necessary, not only for the development of reliable food composition data, but also for assessment of aetiology and prevention of multiple nutritional deficiencies in rural Tanzania. Two sets of food composition tables exist in Tanzania, namely *Tanzania Food Composition Tables* (134) and *The Composition of Foods commonly eaten in East Africa* (247). Many of the values in these tables represent raw foods; however many foods are eaten as composite dishes, after processing and/or preparation in a variety of ways that may influence the final nutrient levels. In view of the limited data on composition of cooked foods for young children, this research study analysed and contributed nutrient composition of locally prepared complementary meals to the Tanzania Food Composition Tables (FCT). The analysed results presented in **Chapter 2** enabled the assessment of the nutritional quality of complementary meals and guided the planning of nutritious meals and messages for infants and young children. The Tanzania food composition tables were used instead of analyses reported in **Chapter 2** to make nutrient intakes in this study more comparable to others conducted in the country. It is expected that in future, the nutritional values will be incorporated in the national data and used to assess dietary intakes for young children in different parts of the country.

For the assessment of dietary intake, and to make nutrients intakes in this study comparable to others conducted in the country, the Tanzania Food Composition Tables (134) were used as the primary source of food composition information. This was based on the assumption that national FCT provides the most comprehensive reference of foods indigenous to the country and most accurate data on nutrient content of locally available foods (248). The Tanzania FCT missed nutrients values for some food items (boiled sweet potato, kale, dried cowpea leaves, raw and dried jute mallow leaves, wholemeal maize flour). Nutrient values for these foods were supplemented from other FCTs, namely the WorldFood System, NutriSurvey, and East Africa Food Composition (247, 249, 250). Translation of food intakes into nutrients uses food composition tables (FCT), and the choice of FCT can have an impact on the nutrients intake (248). Despite the observation that national and international databases provided the nutrient values of foods closely related to those found in Mpwapwa, differing analytical methods and non-analytical estimations (e.g. use of nutrient retention factors after meal preparation) could have introduced errors in nutrient intake estimates. A mismatch between meals actually consumed and foods/meals with available nutrient information could have occurred due to differing ingredients in local dishes (248). To minimise potential errors, systematic procedure for food substitution was followed (251, 252).

Effect of nutrition education package on primary and secondary outcomes

Effectiveness of the education package was assessed by examining the impact on evidence-based outcome measures reflecting change in feeding practices, dietary intakes and growth (60, 74), as

well as processes explaining the intervention effects. The primary outcome LAZ is an index of linear growth. It results from chronic or recurrent malnutrition and it responds more slowly to interventions. The trial included other growth-related measures, weight and WLZ, as secondary outcomes. In contrast to LAZ, weight and WLZ result from acute conditions (i.e. insufficient food intake and/or a high incidence of infectious diseases) and intervention effects can be observed within a relatively short period. These outcomes, together with length and WAZ, are well established physical growth indicators used globally to assess and compare effects of educational or supplementation interventions and track progress in child malnutrition (14, 60, 71, 73). Since nutrition education promoted optimal feeding behaviours for improving dietary intakes, feeding behaviours and nutrients intake were included as secondary outcomes. Feeding-related measures included meal frequency, dietary diversity, and intakes of energy, fat, iron and zinc. These dietary outcomes are common indicators in infant and young child feeding (26, 74, 186). All the outcomes were assessed at two time points, baseline and end, thus permitting evaluation of magnitude of change in intervention effect.

Although the feeding and growth indicators were appropriate outcome measures for this education intervention, conclusion on intervention effect are expected to vary depending on the nature of the indicator used and intervention duration. As nutrition education affects growth through improved eating behaviours and increased nutrients intake, ideally one could have selected eating behaviours and nutrients intake as primary outcomes rather than growth indicators because they are more directly influenced by nutrition education before growth can be attained. For this study, both dietary and growth outcomes were included, with dietary outcomes as measures of intermediate objectives on intervention and LAZ as the ultimate indicator of improved nutrition. Although it is practical to expect an effect on growth indicators within 6 months, a combination of several factors needs to be in place to enhance the effects and distinguish them during assessment. Previous nutrition education interventions highlight the possibility that interventions of longer duration may permit detection in larger change in LAZ or other growth indicators (81, 82, 253). These interventions were conducted for more than 12 months in Peru, India and China, and reported significant gains in length, weight or both. The trial period of 6 months could have been insufficient to detect larger change in LAZ due to the fact that LAZ responds slowly to interventions. It is however important to recognise that several factors which usually differ among the interventions could have contributed to the improvement in the growth indicators. In this study, modest effect or lack of it could be explained by small sample, leading to lack of adequate power to detect larger effects. While the sample for final analysis in this study contained 118 to 128 infants, the previously mentioned interventions (Peru, India, China) had samples ranging from 195 to 435 infants. Other factors limiting the effects of intervention on growth and feeding indicators are further discussed in **section 6.3**.

Public health impact of the nutrition education package

Considering the magnitude of undernutrition in rural Tanzania, the nutrition education package can contribute to improved feeding practices, dietary intake and growth, particularly in settings where feeding practices are inadequate and poor diets are widespread. Results of the trial showed significant improvement in length, LAZ, meal frequency, dietary diversity and intakes in energy and fat as a result of nutrition education package. Lack of effect was demonstrated in weight, WLZ and WAZ. Although the intervention results showed modest effects or lack of improvements in some outcomes, they are promising because most of the changes in primary and secondary outcomes were in favour of the nutrition education package.

Although the education package demonstrated better outcomes than the routine health education, new evidence on long-term effects of the package needs to be evaluated. The package could also be strengthened by inclusion of other components and/or elements that address barriers such as those identified by the study. For example, strengthening health services and improvement in access and utilisation of services will contribute to reduction in high rates of child morbidity in rural areas.

Generalisability of findings: setting and infant characteristics

The research described in this thesis (**Chapters 2 and 4**) included children below the age of one year who are at increased risk of undernutrition. Chronic undernutrition and inadequate diets have consistently been reported among young children in rural areas (22, 23). A nutrition education package to improve their nutrition was conducted in one of the three regions in the country with the highest prevalence of undernutrition. Villages typical of other rural villages in the country were randomly assigned to either nutrition education package or routine health education. Village selection process cautiously considered the possibility of contamination bias if the nutrition education package was to be delivered within the same villages with on-going nutrition projects. Thus, to enhance the conclusion that the intervention effects are a result of the education package rather than an on-going project, villages with active nutrition projects were excluded (**Figure 4**). Village randomisation was the natural choice for trial design because the intervention aimed to improve practices at the household level and encourage collective participation at the community level and modify behaviours in groups of individuals (254). The study recruited all eligible infants and methods of recruitment were the same for all villages. It can thus be concluded that the study setting, design and targeted children were representative of children under the age of one year in the country and that the findings can be generalised to rural areas where infants are at increased risk of undernutrition. Lack of information from similar education interventions in the country limits comparison of this study to a wider context. It is possible that barriers to intervention effectiveness identified in this study could vary within the country due to variations in socio-cultural, economic and climatic conditions. Delivery of the

education package in rural areas of varying context may enhance understanding of its wider effectiveness.

A pictorial presentation of the study area context and intervention activities is shown in **Appendix 6** to broaden understanding of intervention barriers, challenges, facilitating factors. Basic services such as health services and water were available in the study area. Factors such as inadequate rains, rainfall variability and inadequate farming practices could have contributed to limited crop productivity and inadequate harvests. Farms located close to the rivers and river beds were irrigated, thus increasing the possibility of harvesting adequate food for consumption and growing a variety of foods (e.g. vegetables) for both consumption and sale. Households were particularly vulnerable during the dry season (May to mid-November) where water for domestic use became unreliable or in short supply, leading to longer time spent on fetching water and use of unsafe water sources (e.g. unprotected hand-dug shallow wells). Grazing land and water for animals became scarce as well, resulting in low animal productivity (e.g. low milk supply, low animal price at the market due to poor nutrition condition).

6.2 Perspectives on the development and process evaluation of the nutrition education package

6.2.1 Development of the nutrition education package

The intervention described in this thesis is the first in Tanzania to have used Intervention Mapping as a planning model and Theory of Planned Behaviour as a theoretical framework to guide the design and evaluation of a nutrition education package. The experience showed that Intervention Mapping (159, 162, 163) and Theory of Planned Behaviour (160, 166, 168-170) are useful frameworks for systematic identification of intervention objectives, understanding and linking of behaviour objectives, intervention strategies and components. Based on data from the 2009-2010 studies, it was acknowledged that mothers needed practical knowledge, skills, motivation and regular support to improve feeding and health behaviours, and ultimately to improve infant growth (**Appendix 3.1**). The frameworks identified practical nutritional knowledge, skills and attitudes at the household level as the main focus of the intervention (**Appendix 3.2**). Multiple and interrelated education and communication methodologies and individual counselling were included to enhance practical knowledge and encourage a positive attitude and self-efficacy. Cooking demonstrations were important for increasing practical knowledge and skills on selection and preparation of nutritious meals. Training and supervision of VHW to conduct monthly home visits were important for motivating, supporting and maintaining mothers' behaviour change. Sensitisation of family members was important for supporting mothers' intentions, self-efficacy and social influences on behaviour change. Sensitisation of health facility staff aimed to reinforce mothers' feeding and health care practices specifically when they attend the well-baby or sick-child clinics.

Mechanisms of how behavioural determinants (attitudes, subjective norms, self-efficacy) influenced final behaviour (i.e. feeding practices) were beyond the scope of the study due to limited capacity, time and resources to develop assessment tools and test their validity, and the anticipated extra burden to respondents. It is however acknowledged that studying behavioural determinants could have identified and quantified amount of change in outcomes explained by the determinants (169, 255-257). Findings of this research demonstrated that the theoretical framework allowed the systematic development of a nutrition education package which is culturally appropriate for Tanzania context and able to meet immediate needs of mothers and support groups such as the VHW.

6.2.2 Process evaluation of the nutrition education package

Process evaluation showed that the package can feasibly be implemented in a rural area, and that fidelity and dose were high for each component. The package was well received and accepted by VHW and mothers. The package led to increased adoption of recommended practices and recipes for nutrient-dense meals. Compared to the routine health education delivered at the health facilities, the nutrition education package showed greater fidelity and dose in information-message delivery and regular support. The nutrition education sessions were characterised by age-specific, simple and easy to follow information and messages, active participation, promotion of problem-solving, practical solutions for mothers' concerns and learn-by-doing cooking demonstrations. These were offered in a low intensity (3-month intervals) contacts coupled with high intensity (monthly) home visits. On the other hand, the health education sessions at the facilities were characterised by general information, hurried and often-inconsistent messages, irregular sessions of short duration and lack of educational resources.

These findings demonstrate the initial premise that mothers lacked adequate nutritional knowledge and skills, and that the nutrition education package provided mothers with the necessary information and motivation to increase knowledge and skills on feeding practices. These practices, together with household food environment led to improved diets and growth. The findings also confirm accuracy of the initial hypothesis that nutrition education package will improve feeding practices, dietary adequacy and growth as compared to the routine health education given at health facilities.

The process evaluation showed that recruitment was high at the beginning of intervention; however extent of reach decreased at the end of trial mostly due to maternal responsibilities. Women and mothers in rural areas bear the burden of responsibility for several productive tasks such as farming, domestic labour, herding animals, care giving (healthy and sick members), food preparation and child bearing (258). Studies conducted in rural areas in many countries including Tanzania, have shown that rural women spend much time in agricultural, market and home production activities and children are fed less often during the peak labour seasons (50, 259-261).

The consequences include mothers using less time in food preparation, child care and feeding children they bring with them to the farms, and lack time to prepare special foods for young children resulting in eating whatever is cooked for the whole family. A study in Bolivian Andes showed that through lack of time and family support, agricultural burden affects maternal self-efficacy as mothers are left with a despondent outlook, lack motivation and confidence in their ability to adopt new practices (258).

As women contribute to household food and income, attempts to improve child nutrition should balance between agriculture and child care. Providing or improving access to farming resources (e.g. land, labour-saving technologies [e.g. draught animals save time tilling land], services [e.g. inputs, credit, marketing]), education and support networks to enhance better time-use efficiency have previously been emphasised (262). Efforts to further guide time use decisions toward child care include transformation of culturally embedded attitudes towards women to create enabling environment for sharing responsibilities to free up mothers' time and family involvement by making child nutrition relevant and linking child outcomes to family goals (e.g. raising a healthy family child healthy growth contributes to future labour and family income). These efforts will contribute to improved time to access and utilise health services such as nutrition education. The intensity of nutrition education and duration per session offered by the package was adequate since many mothers were able to attend all the three sessions. The three sessions were advantageous because the content was age-specific according to feeding recommendations (i.e. 6-8, 9-11, 12-23 months) and timed to coincide with child's age at 6, 9 and 12 months. Delivery strategies used for the education package reached and supported the intended audience; however barriers to intervention effects have demonstrated that mobilisation of supporting audience is required for improvement of household food environment, cultural beliefs and village development. These include family members (e.g. fathers, mothers-in law, grandmothers), community leaders, district experts and community organisations. To improve compliance and maintain cooperation, efforts need to purposively develop good rapport, establish during the planning stages with all community stakeholders the significance of the activities, provide personalised feedback and use community-oriented social networks.

6.3 Drawbacks to intervention findings and considerations for improvement

Consideration of issues that may influence generalisability of findings to other settings is as important as acknowledging design issues and study population characteristics for conclusive evidence on a cause-effect relation (254, 263). The intervention described in this thesis faced methodological shortcomings that could have influenced the overall effect of the nutrition education package. High infant morbidity and environmental factors contributed to moderate or lack of intervention effects.

6.3.1 Methodological issues

Sample size

The intervention trial originally planned to enrol 297 infants in each study group, an average of 33 infants per village. However, due to smaller numbers of infants who had reached the complementary feeding period, the study was able to enrolled fewer numbers than planned. In addition, limited funding which was available for a period of only six months could not permit progressive enrolment of additional infants. Differing population dynamics such as birth rates limited the recruitment of a large number of infants. Smaller sample size could have reduced the statistical power to detect changes in some of the intervention outcomes. Future research requires replication with a relatively larger sample to draw definite conclusions on intervention effects.

Loss to follow-up (attrition)

As earlier reported, the intervention trial experienced higher loss to follow-up in both study groups than anticipated. Although the trial coincided with peak agricultural activities, some mothers were able to participate. It is unfortunate that others were unable to attend because it was expected before the intervention that attendance would be less affected by forthcoming agricultural activities. Because consent to participate in the study was given earlier, reasons for not returning to subsequent sessions or assessments were understood to have not been related to the intervention and outcome of the study. Family responsibilities were reported to be the main reasons for not showing up. To improve compliance, future research should consider local contexts, discuss better times to hold intervention sessions and emphasise the benefits of the intervention to participants so that their commitment is enhanced. To reduce risk of selection bias, all absent infant-mother pairs were equally followed up. Few differences were found in household characteristics (i.e. ownership of land, house, house roof material) between participants and those lost to follow-up. Confounding which could arise from the effects of these variables was minimised by incorporating them in the wealth index and adjusting for wealth index by regression modelling (264). Other confounders which could have influenced the interpretation of outcomes (e.g. infant morbidity, mother's age and education, father's occupation) were considered prior to the intervention (45, 60, 81, 127), collected during trial and adjusted for in the models.

Duration and season of intervention

The nutrition education package was delivered within a six-month period and the duration was adequate to evaluate short-term effects. Assessment of whether short-term behaviour change is maintained over a longer period and how other factors (e.g. agriculture-food seasonal variations, income fluctuations) influence the intervention effect would have been possible if the package was delivered longer than six months. This is important because the trial began during the end of postharvest season, through the pre-harvest period, and ended during the harvest season. Food

stocks could have been declining for some of the households during the end of the postharvest season through the pre-harvest period, and begin to improve with the beginning of harvest season. As foods become more available and accessible during harvest and households make adjustments between seasons (e.g. consumption patterns, time for child care, money for health care), it is not known whether an additional intervention period and season would have permitted observation of different intervention effects. The present trial would have contributed additional insights on how seasonal variations influence intervention effects. Future research should take seasonality and assessment of household food security into account in the study design as well as increase duration of intervention to permit evaluation of long-term effects and maintenance of dietary-related behaviours.

Dietary assessment methods

An interactive 24-hour food recall method was used in this research (**Chapters 2 and 4**) to estimate food and nutrient intakes of infants largely because the method has a relatively small respondent burden and respondents are less likely to alter their eating behaviour (118, 265-268). Although the method has been validated and tested for reproducibility for use with rural populations in developing countries (118, 269), the method is prone to recall bias and social desirability (or undesirability), resulting in under-reporting or over-reporting of intakes (270). The method overestimates energy and nutrient intakes in children below the age of two years when compared to weighed food records (269, 271). It is therefore possible that nutrient intake overestimations occurred in this study. To enhance recall and facilitate estimation of portion size, standardised data collection procedures (e.g. using open-ended questions to probe on details of meals-food ingredients, avoidance of leading questions) were used in conjunction with household measures from mother's own home, actual weights of duplicate portions if food ingredients were available, and visual aids of fresh foods (e.g. tomatoes, onions) provided by the study. In addition to conducting 24-hour food recalls, a 7-day qualitative food frequency questionnaire (FFQ) was used (**Chapter 4**) to investigate usual intakes of selected nutrient-dense foods eaten alone and in mixed dishes (178). Because of the 7-day recall period, it is possible that the FFQ data was affected by inadequate maternal memory and social desirability (or undesirability), leading to over-reporting or under-reporting of intakes.

6.3.2 High morbidity

Illness recognition and prompt healthcare-seeking by mothers, referral and follow-up of sick infants by VHW during home visits were essential elements of the education package for promotion of appropriate healthcare-seeking and improvement of infant health. Appropriate healthcare-seeking means that the need to take the child for treatment outside the home is recognised, that care is not delayed, and that the child is taken to an appropriate health facility for treatment (186). Despite the expectation that healthcare-seeking and management of illnesses would have improved infant health, prevalence of morbidity and anaemia remained high during

the trial. Medical costs appeared to be higher for some families. The package did not address medical treatment *per se* because it was generally supposed that government health services were equitably accessible to all children below the age of five years. Nevertheless, occasional lack of medications at health facilities (which meant purchase from private providers) and inability or unwillingness to pay for a cost-sharing health care scheme, community health insurance fund (CHF), were some of the factors which influenced healthcare-seeking, and possibly could have affected adherence to treatment. The CHF is a voluntary pre-payment scheme which enables a household to pay premium at the primary health facilities when they have funds rather than at the time of illness. Households not willing to join the CHF scheme pay a user fee when they visit a health facility for any chargeable service (272). These factors could have influenced persistent morbidity observed in this study; however their actual mechanisms need to be evaluated. Strengthening health services and improvement in access and utilisation of services need to be addressed in future for reduction in high rates of child morbidity in rural areas.

6.3.3 Environmental factors

In **Chapters 4** and **5**, factors that contributed to moderate or lack of intervention effects were elucidated. These included high morbidity, limited time for meal preparation and feeding due to high maternal workload, inadequate household income and mothers' habitual and cultural feeding choices. In addition to the observation that irregular consumption of a more varied diet and inadequate consumption of nutrient-dense foods affected individual infants directly, environmental factors operating at the household and community levels had indirect effects on the outcomes. High maternal workload, cultural beliefs on feeding choices and inadequate household income were described in **Chapter 5** as the common barriers to adoption of the recommended practices. These findings demonstrate that environmental factors such as socio-cultural factors and household economic conditions played a significant role in decreasing the overall intervention effects.

Socio-cultural factors

Socio-cultural influences might be related to the way community norms determine maternal and child care practices and beliefs on food preferences. In this population, mothers' contribution to household economy appeared to be so crucial that it modified their activity patterns and limiting their time for adequate child feeding. It is strongly believed that existing cultural beliefs reinforced maternal habitual feeding choices, which in turn lead to limited food choices or withholding of certain foods. Cultural barriers to infant feeding are not uncommon in developing countries where foods such as flesh meats, legumes and leafy vegetables are generally offered after infant teething. Despite the cultural barrier, it was encouraging that a considerable number of mothers adopted the recommended practices. This suggests that the education package was able to address some commonly-known cultural beliefs. It is however not known whether the package can maintain behaviour change in the long-run since this study was conducted for only six months.

Household dietary consumption

Household food environment, specifically meal frequency and dietary diversity, had a significant positive influence on infants' diet. This finding demonstrates that better or favourable household dietary consumption was an important determinant for improving infants' diets and nutrition. Availability of more diverse foods and high meal frequency in the home provided the opportunity to increase infants' meal diversity and frequency. This observation is similar to studies on home food environment in developed countries where home availability of fruits, vegetables and other less-nutritious foods were significantly and directly associated with children's intake of corresponding foods and drinks (131, 273, 274). In low-economic settings, home food availability and accessibility are largely influenced by crop production systems and diversity, household food security, socio-economic status and food prices (129, 258, 275-277). It is clear that future educational interventions that seek to improve infant and young child nutrition must comprehensively consider and integrate context-specific home food environments. The assumption is that tailoring nutrition education content to foster positive motivation and values regarding healthy eating for all family members will create a favourable environment for households to modify overall food choices, dietary patterns and habits (85). As family eating behaviours are improved and more nutritious foods become available and accessible in the home, diets of infants and young children are more likely to improve (277).

Household economic conditions

Households in the study villages are largely small holder farmers, experiencing bumper harvests in some years and scarcity in others. Inadequate household purchasing power, a frequently mentioned barrier to access to promoted foods, may be a reflection of inadequate crop harvests for sale and limited off-farm opportunities to generate extra income for the household. Although it can be argued that what is not cultivated can easily be purchased, poor transport infrastructure within the district limits food distribution, raises food costs, creates irregularity in food availability and may limit on types of foods that can be available to the households. In most cases, many households may not be able to afford the cost of those foods. This was a common case for fruits and legumes; where although in season and readily available at markets located at the district headquarter, the foods were not available in district villages. On the other hand, lack of agri-food markets limit households from selling surplus produce at a profitable price. Villages have market days once per months, however these were largely observed to sell non-food products such as clothes and kitchen utensils. As these aspects influenced what was available in the community, they also impacted on what was available for infant consumption. It is generally observed in many nutrition education interventions in developing countries that the economic environment of households is not a straightforward matter to intervene (204). Price of food, income, time, household structure and educational level are some of the complex economic factors influencing dietary practices (85). Although in-depth investigation of these factors could have provided useful insights, this research only focused on ability of households to access foods. It is however possible

to improve household economy through promotion of co-operatives and group entrepreneurial ventures, establishment of financial services for loans and improvement in other sectors which boost agricultural productivity and sale of produce.

6.4 Future perspectives for the nutrition education package

The strength of this study is that it used formative research to assess nutritional problems and needs (278, 279), planning model and theory-based guidelines to develop a culturally-appropriate package, cluster-randomised controlled trial design to evaluate the effectiveness of the package, intention-to-treat and multilevel approaches to analyse findings (171, 196, 280-283). The nutrition education package is in line with the 2011-2016 National Nutrition Strategy (NNS) goal stating that: "all Tanzanians attain adequate nutritional status, which is an essential requirement for a healthy and productive nation" (108). The education package has addressed infant and young child feeding and dietary improvement, which are among the priority areas in the NNS. In the frame of the NNS objective "Increase access to nutrition services at community and facility level" the intervention delivered a package of nutrition services that can be integrated in health services and provided multiple contacts (community and health facility) for nutrition services. In the frame of the NNS objective "Strengthen the quality of nutrition services" the package contributed to the technical resources and tools which can be used in nutrition services. Findings generated in this research suggest that the nutrition education package is a potential evidence-based strategy more likely to receive attention in the current policy environment.

Future perspectives for the nutrition education package reported here are generally related to the dissemination of research findings and replication of the package in other rural villages, taking into account the identified drawbacks.

Dissemination of research findings

Dissemination strategy will take the following format:

- sharing research findings as a form of feedback from the field with stakeholders from various sectors (e.g. agriculture-livestock, marketing, community development) in the targeted district and region, as well as relevant institutions
    - to enhance extensive discussion of underlying problem and possible solutions
    - to refine the education package further
- enhancing availability and access of research findings, including education and training resources
    - make brief synopsis for policymakers and other non-academic and academic audiences
    - disseminate to target audiences and stay engaged
- engagement with key policymakers, networking and active participation in fora related to infant and young child nutrition and health

Review of the nutrition education package

Review of the package will take the form of:

- strengthening package components (e.g. increase the duration of VHW training)
- integrating socio-cultural norms and beliefs in each package component
- designing a new component that address household- and community-related issues
    - promotion of co-operatives and group entrepreneurial ventures to improve household incomes
    - sensitisation of community leaders to foster positive socio-cultural norms

Replication: evaluation research

Design of the research would need to generate critical in-depth information (outcomes, process, cost) necessary for rapid scale up. This may include assessing:

- mechanisms underlying access and utilisation of health services, both at the household and health facility levels
- socio-cultural norms and beliefs, and how they impact on behavioural determinants (intention, attitudes, subjective norms, self-efficacy) and final behaviours
- household food security situation
- in-depth evaluation of routine health education. If a nutrition education package is proposed to be delivered by health facility staff in the future, background information on their nutritional knowledge, competency and curricular needs to be evaluated

Personal reflection on the research process

Since bias remains a naturally occurring human characteristic, positionality allows for a narrative placement for researcher objectivity and subjectivity. Through recognition of our biases, we presume to gain insights into how we might approach a research setting, members of particular groups, and how we might seek to engage with participants (284). Prior to conducting research detailed in this thesis, I worked as a lecturer and researcher in the fields of human nutrition and consumer sciences at a university in Tanzania for most of my working life. My experience in research with diverse groups in rural areas and interaction with various stakeholders helped me to learn about the different livelihoods and associated challenges. This led to my interest in conducting research on infants and young children to learn more about the ways that can improve their nutrition and health, and eventually impact on improved school performance.

As a researcher I have an internal belief system that certain intervention approaches will work or produce positive results in a certain context. Having knowledge about the context and evidence at hand, I embarked in the designing of an intervention approach using the best combination of strategies to enhance chances of success. It is logical that after designing the intervention I participated in its implementation. The double role of designing and implementing the intervention could have subjected me to bias, particularly if my involvement was too much to

influence results. Less involvement in certain research activities and letting other people not directly involved in research participate in other activities may reduce researcher subjectivity. In this research, I participated in the design, development of educational resources and data collection tools, collection of data and data analysis. To restrict my involvement, other people assisted in various activities **(see Acknowledgement and section 1.7)**. For example, a statistician not related to research randomised the villages; village health workers, sub-village leaders and health facility staff identified eligible infants; I conducted education/training with others; data collection was done by individuals not part of implementing team and were not residents in any of the villages, I conducted data analysis with another individual, etc. In many of these activities I had to remain in the supervisory capacity, to ensure the intervention is implemented as planned.

6.5 Suggestions for future research

The nutrition education package needs to be replicated and implemented in varied rural contexts in order to strengthen understanding of its effects and demonstrate generalisability beyond one context. This will provide comprehensive information that will guide decision for implementation of effective and sustainable interventions at scale.

Research findings showed that many infants were already undernourished at the age of six months when the period of complementary feeding commenced. This implies that a series of insults were at play either during the pre-natal period or soon after birth and continued throughout the first six months of life. For this reason and to enhance better outcomes during the first two years of life, it will be of utmost interest to consider strategies which improve birth outcomes and infant nutrition during the first six months. Exclusive breastfeeding and good health are important goals to ensure optimal nutritional status during the first six months of life. Understanding factors which influence optimal practices (e.g. culture, knowledge, education, gender, livelihoods), developing and testing effective communication strategies and messages, and dissemination to target audiences (pregnant women, breastfeeding mothers, fathers, mothers-in-laws, traditional birth attendants) will contribute to significant improvements in infant nutrition. Reaffirming the significance of breast milk and breastfeeding to health workers and other community support groups is vital to the success of interventions during infancy.

Relatively high morbidity and anaemia were found in the study area despite the availability of health services and mothers' reported use of the services. Reasons for the larger prevalence must be investigated. The extent to which health cost-sharing, availability of medications, household access to medications and healthcare-seeking practices impact on child morbidity need to be studied. This is important because morbidity had a negative effect on overall nutrition of infants in the present study. Investigation of biomarkers of inflammation, malaria and deficiencies of micronutrients such as iron will shed light as to the causes of anaemia and guide decision on prevention and control.

Cost of delivering interventions or programmes is an important aspect to consider when scaling up. Cost evaluations may range from total cost, cost of enumerated programme activities, to more sophisticated cost-effectiveness analyses that consider programme impact (285, 286). Data required for cost evaluations include population covered by intervention, child malnutrition cases before and after intervention, intervention costs organised by activities (e.g. training, production of education resources, household visits) and overhead costs (e.g. personnel, telephone, administration, electricity, vehicle fuel). In addition to the intervention costs, families may incur financial costs for participating in interventions, therefore documenting participants cost (e.g. travel to attend the service, consultation fees) is important. The full intervention cost can be calculated per child reached or per case of moderate or severe malnutrition prevented.

Nutrition education interventions conducted in developing countries rarely report cost-impact studies. Cost-effectiveness report from only one study has been reported, and this was a health facility-based nutrition education intervention counducted in Peru (287). The study reported full intervention cost of USD 15.37 per child reached, cost per case of moderate to severe stunting prevented of USD 138.50, and additional cost to households of USD 0.19 per child reached. The intervention reported in this thesis reported total cost for developing educational resources and delivering the education package to inform resource allocation. Future studies on cost-effectiveness and cost-benefit analyses of interventions are needed to inform policy decision. Specifically, cost data for both nutrition education package and routine health education should be collected and compared. Other options for investing financial resources on nutrition of young children need to be explored. Questions for reflection include whether it is cost-effective to channel more investments to children below the age of two years (considered to be at high-risk of undernutrition) than older children (e.g. maximum vs. normal package), mothers or families of the young children receive a social protection package (e.g. cash transfers) during the period of economic constraints in addition to the normal package.

Routine health education at health facilities has existed for quite a while in the country, conducted by health personnel of differing levels (e.g. public health nurses, health officers, medical attendants). Curricular of health personnel need to be in line with new strategies, guidelines and interventions targeting nutrition of young children, especially during the window of opportunity (i.e. the first 1000 days – pregnancy to 2 years). Except for the observation that educational resources were noticeably absent in health facilities located in villages, this study did not establish competency of health personnel responsible for delivering nutrition services. With national data showing high prevalence of undernutrition in rural areas consistently over the years, a comprehensive review of routine health education framework is recommended. New recommendations will guide policy on effective delivery of nutrition services for improvement of health and nutrition in infants and young children.

As was previously observed that intervention effects were constrained by environmental and macro-level factors operating at the household, community or higher levels, joint strategies and diversity of actions are needed across sectors, levels, and actors to address child undernutrition. With the existence of a national nutrition policy, national nutrition steering committee (comprising key government ministries, development partners, private and civil society organisations), national-level multi-sectoral technical working group on nutrition and recruitment of nutrition officers at the district level, Tanzania government is committed to addressing the multi-factorial nature of undernutrition. In addition to improving nutrition and health services, future government initiatives should focus on the macro-level environmental factors which have a considerable effect on what people eat (288). These include policies with a direct and indirect role on nutrition, agriculture-livestock productivity, food distribution and marketing systems, water and energy supply, transport infrastructure, education and community development initiatives and economic price structures for household incomes (289, 290). Instead of focusing on providing information to educate individuals and enabling choice by offering limited participation in unintegrated programmes (291), the approach should shift to structural causes and interventions supported by government laws and regulations (290, 291). Examples of interventions addressing broader structural causes of child undernutrition include public water chlorination to reduce exposure to water-borne illnesses, integration of dry land irrigation with access to inputs, credit and output markets, and social protection policies for vulnerable groups (289, 290). A well-planned and robust investments and favourable political environment will help to overcome challenges (e.g. shortage of skilled personnel, inadequate administrative and technical capacity for coordination and monitoring) of improving population health and nutrition.

6.6 Overall conclusion

This PhD research has shown that inadequate feeding practices, meals of low nutrients content, high morbidity and poor growth are significant health problems in rural Tanzania. Intervention Mapping and Theory of Planned Behaviour are useful frameworks for identification, application and linking behavioural objectives to intervention objectives, strategies and components. Findings add to the evidence that practical nutrition education incorporating cooking demonstrations and regular home visits can improve feeding practices, dietary intake of macronutrients and infant growth. The package can feasibly be implemented in rural areas with good fidelity and dose. The package was well received and accepted by VHW and mothers. Compared to the routine health education delivered at health facilities, the nutrition education package showed greater fidelity and dose in message delivery, practical problem-solving and regular support. For practical and policy implications, cost-effectiveness data are needed to guide decision for implementation of the nutrition education package at scale. Barriers to intervention effects include high morbidity, high maternal workload, inadequate household income and mothers' habitual and cultural feeding choices. The findings suggest that nutrition education package was not adequate enough for mothers to modify multiple behaviours. For larger impacts in infant feeding, nutrients intake and

growth, the nutrition education package or other education initiatives need to be supported with improvements in other sectors (e.g. health, agriculture, marketing, education, roads, energy). Evidence-based, multi-sectoral, integrated packages are needed to provide a more holistic approach to solving the multiple causes of undernutrition in rural areas.

Appendices

Appendix 2.1 Study questionnaire used in the cross-sectional study

Interviewer: Introduce yourself and where you come from. Explain research objectives. Thank the interviewee for his/her time.

Name of interviewer _____ Date of interview (dd/mm/yyyy) ___/___/___

Household ID Number _____

A. Background information

1. Ward 1.Mazae 2.Lumuma
2. Village 1.Kisokwe 2.Gulwe 3.Chiseyu 4.Pwaga 5.Kitati 6.Munguwi
3. First name of mother (respondent) _____ Second name _____
4. Age of mother _____(yrs)
5. First name of father (household head _____ Second name _____
6. Age of father _____(yrs)
7. Household is headed by 1. male 2. female
8. Household composition

	Below 2 yrs	2-4.9 yrs	5-14 yrs	15-19 yrs	20-64 yrs	≥ 65 yrs	Total
Number							

9. What type of fuel does your household mainly use for cooking? 1.wood 2.charcoal 3.kerosene 4.cow-dung 5.solar 6.others: specify _____

Household dietary patterns

10. During this period, how many times per day do you usually cook family meals? _____
11. Please describe the household's habitual eating pattern during this period

Eating frequency per day[1]	Meal occasion[2]	Main dish	Regular relish[3]

[1] *Frequency: 1=once 2=twice 3=three times 4=four times* [2] *Meal occasion: 1=breakfast 2=snack 3=lunch 4=supper.* [3] *Relish: 1= legume-based 2= fish-based 3= sardines-based 4=meat-based 5=vegetable-based 6=groundnut-based 7=yoghurt-based 8=others: write on the table*

12. Are the food crops that you cultivate usually sufficient to meet family consumption needs from one harvest season to the next? 1.Yes 2.No

Mother characteristics

13. How many children do you have now? _____
14. Marital status 1.single 2.married/monogamous 3.married/polygamous 4.widowed S.separated/divorced
15. For how many years have you attended school? _____
16. Which level of education did you attain? 1.None 2.Primary-incomplete 3. Primary-complete 4.Adult education 5.Secondary-completed 6.Advanced secondary-completed 7.Certificate/Diploma for any skill 8.University-level
17. Where did you deliver this child? 1. District government hospital 2. Government health centre or dispensary 3.Missionary health centre or dispensary 4.Private health centre or dispensary 5.Home 6.Others: specify _____

Infant characteristics: *If children were born twins, record information about the older twin then continue with the younger twin in a different questionnaire. Request the mother to show you her child's clinic card. Use it to verify questions 19, 20, 23, 25, 26.*

18. First name of child _____ Second name _____
19. Date of birth (dd/mm/yyyy)___/___/_____
20. Verification of date of birth 1.clinic card 2.mother recall 3.others: specify _____
21. Age (months) _____
22. Sex 1.male 2.female

23. Birth weight _____ kg
24. Birth order 1. First born 2.Second born 3. Third born 4.Fourth born 5.Fifth born 6.Others: specify ___
25. Did you take your child to growth monitoring during the last scheduled visit? 1.Yes 2.No 8=child has just been born
26. Has the child been immunized-for-age ***(check the indicated vaccination dates)*** 1.Yes 2.No 9.clinic card not present

Infant breastfeeding and complementary feeding practices

27. How long after birth did you put the child to the breast? 1.within 1 hr 2. one to 24 hrs 3.after 24 hrs
28. Are you still breastfeeding this child? 1.Yes 2.No
29. How do you breastfeed your infant? 1.on demand by the child 2.according to schedule 3.according to mother's inclination
30. Do you sleep with your child during the night? 1.Yes 2.No
31. What fluids and foods did your child consume yesterday during the day and at night? (ORS, vitamin and mineral syrups or medicines may be given) ***(indicate one choice only)***
    1. Breast milk alone
    2. Breast milk, plain water
    3. Breast milk, water-based drinks (herbals, ritual fluid, teas), or fruit juices
    4. Breast milk, non-human milk (e.g. animal milk, infant formula)
    5. Breast milk, non-human milk (e.g. animal milk, infant formula), soft, semi-solid, or solid foods
    6. Breast milk, soft, semi-solid, or solid foods
    7. Soft, semi-solid, or solid foods alone
32. Since birth, have you ever given your child fluid or food other than breast milk? 1.Yes 2.No

Note: If mother answers 'Yes' to question 32, continue with questions 33-39. If mother answers 'No' in question 32, do not ask questions 34-39, and that will be the end of the interview.

33. What fluid or food other than breast milk did you give your infant as the first food? Specify the ingredients used in preparation. At what age did you give your baby the first fluid or food? Why did you give your child such fluid or food? How do you feed these fluids & foods?

Type fluid/food	Ingredients	Age (mo.)	Reason (giving fluid/food)	How fluid/food is fed

34. How many times yesterday did you feed your child fluids and foods other than breast milk? ___

Anthropometry

35. Infant anthropometric and biochemical measurements

Weight (kg)			Length (cm)		
W1	W2	Average	L1	L2	Average

Infant food intake: 24-hour recall

36. Was the child ill yesterday? 1.Yes 2.No
37. Is the child taking any nutritional supplements? 1.Yes 2.No
38. Was yesterday a usual day or was it a festivity/celebration day where you ate special foods? 1.usual 2.festivity

If the child was given fluids, foods or snacks yesterday, continue with question 39. If the child received breast milk only, do not ask question 39.

39. Please tell me what your child ate and drank yesterday from the time he/she woke up to the time when he/she went to sleep. Probe for:
    i. Time (e.g. 0800, etc) and meal occasion (e.g. breakfast, snack, etc)
    ii. Type of meal (e.g. bean stew, porridge, etc) or fluid (e.g. orange juice, soda, etc)
    iii. Ingredients used to prepare the meal or added to already-prepared meal (e.g. refined maize flour, sugar, sour milk, etc)
    iv. Amount (in household measure) of ingredients used to prepare the meal/fluid or added to meal/fluid

v. Amount (in household measure) of total meal/fluid prepared, served to child, consumed and left uneaten

Time	Meal occasion	Type of Meal	Ingred. used	Amount of ingred.	Stand. measure	Total vol. of meal	Stand. measure	Amount served	Amount left-over	Amount consumed

Appendix 2.2 Description of ingredients and methods of preparing different types of porridge

Porridge ingredients and mixing ratio [in grams or ml]	Preparation[a] and cooking methods
Whole maize, white (*Zea mays*)	
Whole maize flour, Sugar, Water (44:5:265)	Flour added to cold water, mixed thoroughly and brought to boil while stirring constantly. Porridge left to simmer (5 mins.) with occasional stirring then sugar added to taste.
Whole maize flour, Groundnuts, Salt, Water(32:11.5:0.5:195)	Flour and ground/pounded groundnuts added to cold water, mixed thoroughly. Mixture brought to boil while stirring constantly, left to simmer (5 mins.) then salt added to taste.
Whole maize flour, Groundnuts, Salt, Sugar, Water (40:6:1:10:360)	Flour and ground/pounded groundnuts added to cold water, mixed thoroughly. Mixture brought to boil while stirring constantly and left to simmer (5 mins.), salt and sugar added to taste.
Whole maize flour, Baobab fruit pulp, Water (63:26:400)	Flour added to cold water, mixed thoroughly and brought to boil while stirring constantly. Porridge left to simmer (5 mins.), baobab fruit pulp added to taste while stirring, then removed from heat.
Whole maize flour, Baobab fruit pulp, Sugar, Water (54:23:10:300)	Flour added to cold water, mixed thoroughly and brought to boil while stirring constantly. Porridge left to simmer (5 mins.), baobab fruit pulp added to taste while stirring, then sugar added to taste.
Whole maize flour, Sunflower cooking oil, Salt, Water (18:5:0.25:170)	Flour added to cold water, mixed thoroughly and brought to boil while stirring constantly. Sunflower oil added and mixture left to simmer (5 mins.) then salt added to taste.
Composite flour (Whole maize flour, Finger millet flour, Sardines, Groundnuts), Water	Cleaned maize grains (500g), finger millet grains (400g), groundnuts (300g) and dried de-headed sardines (300g) mixed and locally milled. 75g of composite flour added to 255ml cold water, mixed thoroughly, brought to boil while stirring constantly, left to simmer for 7 mins.
Whole maize flour, Cow's milk, Salt, Water (45:100:1.5:150)	Flour added to cold water, mixed thoroughly and brought to boil while stirring constantly. Cow's milk added, mixture left to simmer (5 mins.), salt added to taste
Dehulled maize, white (*Zea mays*)	
Dehulled maize flour, Salt, Water (47:0.4:300)	Flour added to cold water, mixed thoroughly, brought to boil while stirring constantly. Porridge left to simmer (3 mins.), salt added to taste.
Dehulled maize flour, Groundnuts, Sugar, Water (32:11:10:200)	Flour and ground/pounded groundnuts added to cold water, mixed thoroughly. Mixture brought to boil while stirring constantly and left to simmer (3 mins.) then sugar added to taste.
Dehulled maize flour, Cow's milk, Salt, Water (65:155:0.5:100)	Flour added to cold water, mixed thoroughly and brought to boil while stirring constantly. Cow's milk was added, mixture left to simmer (3 mins.) then salt added to taste.
Dehulled and soaked maize, white (*Zea mays*)	
Dehulled and soaked maize flour, Salt, Water (24:1.5:200)	Flour added to cold water, mixed thoroughly and brought to boil while stirring constantly. Porridge left to simmer (2 mins.), salt added to taste.
Dehulled and soaked maize flour, Groundnuts, Salt, Water (32:15:0.5:270)	Flour and ground/pounded groundnuts added to cold water, mixed thoroughly. Mixture brought to boil while stirring constantly, left to simmer (2 mins.), then salt added to taste.
Dehulled and soaked maize flour, Baobab fruit pulp, Sugar, Water (55:16:9:340)	Flour added to cold water, mixed thoroughly and brought to boil while stirring constantly. Porridge left to simmer (2 mins.), baobab fruit pulp added to taste while stirring, then sugar added to taste.
Dehulled and soaked maize flour, Cow's milk, Sugar, Water (50:40:10:230)	Flour added to cold water, mixed thoroughly and brought to boil while stirring constantly. Cow's milk added, mixture left to simmer (2 mins.) then sugar added to taste.

Sorghum, white (*Sorghum bicolour* (L.) Moench)	
Whole sorghum flour, Salt, Water (105:1.25:550)	Flour added to cold water, mixed thoroughly and brought to boil while stirring constantly. Porridge left to simmer (4 mins.) then salt added to taste.
Whole sorghum flour, Groundnuts, Salt, Water (80:50:1.25:375)	Flour and ground/pounded groundnuts added to cold water, mixed thoroughly, brought to boil while stirring constantly, simmers (4 mins.), then salt added to taste.
Pearl millet (*Pennisetum glaucum*)	
Whole pearl millet flour, Salt, Water (85:2:570)	Flour added to cold water, mixed thoroughly and brought to boil while stirring constantly. Porridge left to simmer (4 mins.), salt added to taste.
Whole pearl millet flour, Groundnuts, Salt, Water (41:29:0.5:200)	Flour and ground/pounded groundnuts added to cold water, mixed thoroughly. Mixture brought to boil while stirring constantly, left to simmer (4 mins.) then salt added to taste.
Finger millet, red (*Eleusine coracana*)	
Whole finger millet flour, Sugar, Water(180:15:870)	Flour added to cold water, mixed thoroughly, brought to boil while stirring constantly. Porridge left to simmer (4 mins.) with occasional stirring then sugar added to taste.
Fresh cow's milk, Water, Sugar	Milk is boiled, sieved, cream removed, water added (milk:water ratio of 1:0.5) then sugar added to taste.

[a] Flour preparation: whole (winnow, sort, mill); dehulled (winnow, sort, dehull, mill); dehulled and soaked (winnow, sort, dehull, wash, soak overnight 12-14 hours in cold water [grain to water 1:4], wash, drain, sun-dry, mill)

Appendix 2.3 Description and methods for preparation of staple and accompanied relish

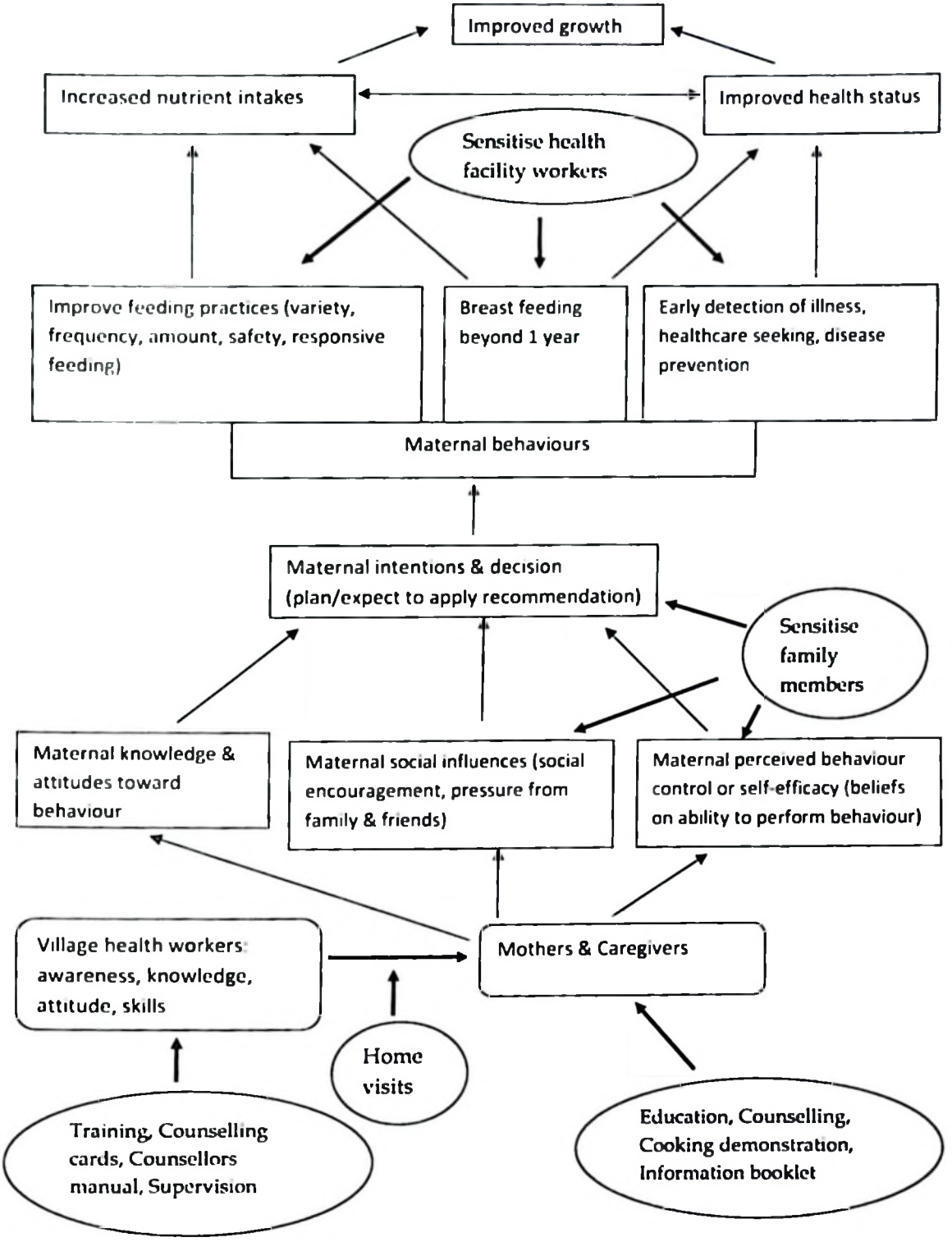
Staple and relish ingredients	Preparation and cooking methods
Staple	
Whole maize stiff[a] porridge	Flour mixed thoroughly with cold water (flour:water range from 1:3 to 1:5). Mixture brought to boil, simmers with frequent stirring to make thick porridge. Flour added gradually with constant turning to form thick paste of desired softness then addition of flour stopped. Constant turning of paste and occasional addition of little boiled hot water continued for 4-5 minutes (2-3 minutes for dehulled or soaked flour) to ensure thorough mixing, gelatinisation and cooking. Paste covered and left to cook for 3-4 minutes (2-3 minutes for dehulled or soaked flour).
Dehulled maize stiff porridge	Same as above
Dehulled and soaked maize stiff porridge	Same as above
Whole sorghum stiff porridge	Same as above
White rice cooked	Sunflower oil and salt added into boiling water, stirred, rice added (rice:water of 1:3) and left to cook until soft and water has dried or evaporated.
Relish	
Beef, Tomatoes, Onions, Sunflower oil, Salt	500g beef (lean+fat) de-boned, chopped in small pieces, washed and boiled with regular addition of water until soft. 110g chopped onions stir-fried in 50g oil, 220g sliced tomatoes added, stirred until soft, water added to make sauce, salt added to taste. Boiled beef added in mixture and left to cook (5-10 mins).
Fish (dried), Tomatoes, Onions, Sunflower oil, Salt	150g dried fish soaked in warm water for 20 mins, washed drained. 52g chopped onions stir-fried in 55g oil, 300g sliced tomatoes added, stirred until soft, water added to make sauce, salt added to taste. Pieces of fish added in mixture and left to cook (12-15 mins) until soft.
Sardines (dried), Tomatoes, Onions, Sunflower oil, Salt	150g sardines sorted, de-headed, soaked in hot water for 15 mins, washed and drained. 52g chopped onions stir-fried in 40g oil, 240g sliced tomatoes added and stirred until soft. Sardines added, mixed, water added to make soup, salt added to taste and left to cook (10-15 mins) until soft.
Fermented cow's milk[b]	Unboiled cow's milk sieved, kept in a local gourd, covered, kept in a warm kitchen corner and left to ferment for 2-3 days. When ready, it was stirred with a wooden stick to a desired consistency.
Beans (*Phaseolus vulgaris* L.), Tomatoes, Onions, Sunflower oil, Salt	500g winnowed, sorted, washed, drained and boiled with regular addition of water until soft. 32g chopped onions stir-fried in 15g oil, 90g sliced tomatoes added and stirred until soft. Boiled beans added, mixed, water added to make soup, salt added to taste, and left to cook (7-10 mins).
Beans (*Phaseolus vulgaris* L.), Onions, Sunflower oil, Salt	500g winnowed, sorted, washed, drained, and boiled with regular addition of water until soft. 77g chopped onions stir-fried in 5g oil until soft, boiled beans added, mixed, water added to make soup, salt added to taste and left to cook (7-10 mins).
Chinese cabbage (*Brassica rapa* L. var. chinensis), Tomatoes, Onions, Sunflower oil, Salt	Fresh leaves de-ribbed, washed and finely chopped. 80g chopped onions were stir-fried in 68g oil, 240g sliced tomatoes added and stirred until soft (little water added occasionally). 450g chopped leaves were added, mixed, salt added to taste, and left to cook (10-15 mins.) until soft.
Sweet potato leaves (*Ipomea batatas* L.), Tomatoes, Onions,	Fresh leaves had the small upper section destalked and thin outer skin peeled off. Leaves were washed, drained and cut. 85g chopped

Sunflower oil, Salt	onions, 240g sliced tomatoes, 7g oil, and 400g cut leaves were put in a pot. Salt added to taste, pot covered and put on fire. Mixture was left to boil (5-7 mins.) with occasional stirring and little addition of water if needed until soft.
Fresh cowpea leaves (*Vigna unguiculata* L.), Tomatoes, Onions, Sunflower oil, Salt	Fresh leaves destalked, washed, cut. 240g cut leaves added into boiling water, left to boil (30-45 mins.) while covered until soft. 105g chopped onions stir-fried in 35g oil, 186g sliced tomatoes added and stirred until soft (little water added occasionally). Boiled leaves were added, mixed, salt added to taste, and left to cook (5-10 mins).
Dried cowpea leaves (*Vigna unguiculata* L.), Tomatoes, Onions, Sunflower oil, Salt	120g dried leaves soaked in water (15 mins.), washed, drained. 85g chopped onions and 135g sliced tomatoes were stir-fried in 21g oil until soft. Soaked leaves were added, salt added to taste, and left to cook (15-20 mins.) with occasional stirring to avoid sticking
Pumpkin leaves (*Curcubita maxima* Duchesne), Tomatoes, Onions, Sunflower oil, Salt	Fresh leaves had the outer skin peeled, a small upper section destalked, washed, chopped finely (620g), and boiled (15-20 mins.) while covered until soft. 83g chopped onions were stir-fried in 90g oil, 152g sliced tomatoes added and stirred until soft (little water added if needed). Boiled leaves were added, mixed, salt added to taste, and left to cook (5-10 mins).
Dried jute mallow leaves (*Corchorus olitorius* L.), Ground nuts, Salt	Dried leaves pounded, sieved to remove inedible stalks. Groundnuts pounded to obtain soft flour. 340g pounded leaves and 35g groundnut flour mixed with cold water to make a smooth liquid mixture. Mixture brought to boil with stirring to make a paste, salt added to taste, and left to boil (7-10 mins) stirring occasionally to avoid sticking.
Dried jute mallow leaves (*Corchorus olitorius* L.), Salt	Dried leaves pounded, sieved to remove inedible stalks. 320g pounded leaves mixed with cold water to make a smooth liquid mixture. Mixture brought to boil with occasional stirring to make a paste, salt added to taste, and left to boil (7-10 mins) with occasional stirring to avoid sticking.
Kale leaves (*Brassica oleracea* L. var. acephala), Tomatoes, Onions, Sunflower oil, Salt	Fresh leaves de-ribbed, washed, finely chopped. 29g chopped onions were stir-fried in 95g oil, 200g sliced tomatoes added and stirred until soft (little water added occasionally). 540g chopped leaves were added, mixed, salt added to taste, and left to cook (10-15 mins.) while covered until soft.

[a]Thick porridge paste locally called *ugali*

[b]Spontaneously fermented. Consumed alone or with ugali or rice

Appendix 3.1 Conceptual framework illustrating intervention components and targeted behaviours leading to improvement of child growth



Appendix 3.2 Matrix of intervention and behavioural objectives

Intervention objectives (IO) and behavioural objectives (BO)	Performance objectives (target behaviours)	Determinants
IO 1. To improve feeding practices		**Personal:** KS.1. Describes how child feeding practices and child health principles impacts on child growth and overall health KS.2. Demonstrate how to provide nutritious meals and feed her child responsively AT.1. Believes that appropriate feeding and health practices is important to ensure optimal growth and is achievable AT.2. Expresses positive attitude towards nutritional benefits of adopting optimal child nutrition practices AT.3. Believes in obtaining support from family members PBC.1. Express confidence in understanding optimal feeding practices PBC.2. Express confidence in recognising the need for appropriate treatment of illnesses PBC.3. Express confidence in own ability to try the recommended practices **External:** SN.1. Perceives family, friends, peers, and community are expecting them to practice recommended behaviours SN.2. Recognise that mothers with children of similar age in the village are also putting into practice the recommended behaviours SN.3. Receives support/reinforcement from nutrition counsellors and health facility staff
BO 1.1. Increase awareness & knowledge on feeding	Continue to breastfeed as often as the child wants throughout the first and second years	
	Introduce other fluids and foods to your child at 6 months	
	Gradually increase meal consistency, variety, amount as child gets older	
BO 1.2. Increase knowledge on benefits of different varieties of foods	Identify & group locally available foods for making typical meals	
	Select nutrient-dense foods	
	Prepare nutritious meals	
BO 1.3. Increase feeding during child illness & recovery	Encourage your child to eat with patience and love	
	Offer more frequently fluids, soft, varied, and appetizing foods/meals during illness & recovery	
	Increase frequency of breastfeeding during illness & recovery	
BO 1.4. Handle foods and meals in hygienic way and prepare safe meals	Wash hands before handling food & during meal preparation	
	Wash hands after using the toilet or cleaning a child	
	Keep your home & compound clean	
BO 1.5. Increase utilisation of health services during illness	Identify danger signs of childhood illnesses	
	Seek health care promptly at health facilities	
BO 1.6. Adhere to medical treatment	Comply to treatment & advice	
	Protect children from communicable diseases	
IO 2. To improve dietary adequacy		
BO 2.1. Increase diversity in diets	Add legumes in each meal	
	Feed eggs, beef, pork, chicken, liver, fish, or sardines at least 3 times per week	
	Add vegetables in each meal	
	Give a fruit at least once per day	
BO 2.2. Increase frequency	Increase number of meals per day	
	Increase number of snacks per day	
BO 2.3. Increase nutrient density	Prepare thick porridge made from a combination of foods	
	Add milk to porridge	
	Increase amount & consistency	
BO 2.4. Maintain breastfeeding	Continue to breastfeed as often as the child wants throughout the first and second years	
	Breastfeed first before giving other meals	
IO 3. To improve growth		
BO 3.1. Reduce stunting	Perform optimal feeding practices	
BO 3.2. Reduce underweight		
BO 3.3. Reduce prevalence of acute respiratory illnesses and diarrhoea	Ensure prompt and appropriate treatment during illness	

KS=Knowledge and Skills; AT=Attitude; PBC=Perceived behavioural control; SN=Subjective norms

Appendix 3.3 Education and training resources

Cover pages of education and training resources: Information booklet for mothers and families (top), VHW manual (bottom left) and Counselling cards (bottom right)

Appendix 3.4 Promoted recipes and meal preparation

Session 1: children aged 6 months

1A Sorghum porridge enriched with pearl millet flour, cow's milk, dried-ground-sieved jute mallow leaves, pounded groundnuts, sugar
1B Mashed potatoes and beef (with pumpkin + pumpkin leaves + tomatoes + cooking oil + salt).
1C Mashed fruit (papaya, ripe banana or avocado)
1D Potatoes mashed with milk

Session 2: children aged 9 months

2A Sorghum porridge enriched with finger millet flour, egg, dried-ground-sieved jute mallow leaves, cooking oil, sugar
2B Mashed sweet potatoes and beans (with carrots + cowpea leaves + tomatoes + groundnuts + salt)
1C Mashed fruit (papaya, ripe banana or avocado)
2C Sweet potatoes mashed with avocado

Session 3: children aged 12 months

3A Stiff porridge made from maize (or sorghum) flour
3B Sardines stew (with tomatoes + onions + pumpkin + salt) and cowpea leaves with groundnuts
3C Freshly-squeezed orange juice
3D Undiluted cow's milk

NOTE: If a certain food is not in season, an alternative food from the same food group can be selected for replacement (e.g. pumpkin fruit for carrots, cowpea leaves for pumpkin leaves). The food groups include: 1) Cereals, roots and tubers; 2) Legumes and animal-source foods; 3) Vegetables; 4) Fruits; 5) Fat and sugar.

Cooking steps

Recipe	Cooking steps
1A	Mix whole sorghum and whole pearl millet flour (1:1). Add ground/pounded groundnuts and dried jute mallow leaves, mix thoroughly. The flour will first be mixed with cold water, then later with milk when the mixture starts to boil. Add cold water to flour (1:1) and mix thoroughly. Bring mixture to boil while stirring and let it simmer for 5 mins. Add milk (1:2) with constant stirring, checking the consistency. Let it simmer for 1 min. Add sugar to taste.
2A	Mix whole sorghum and whole finger millet flour (1:1). Add dried jute mallow leaves and mix thoroughly. Add cold water to flour and mix thoroughly (1:3). Beat an egg and set it aside. Bring mixture to boil while stirring. Let the mixture simmer for 5 mins. With vigorous stirring, add the beaten egg and continue to stir as the porridge simmers for 1 min. Add sugar to taste.
1B	Boil deboned beef (or chicken) with regular addition of water. When adding the last water, pour in pumpkin and pieces of potatoes, and chopped pumpkin leaves. Boil them together until the items are soft. Add chopped tomatoes and cooking oil, and stir to mix them thoroughly. As the mixture simmers, mash until soft with a wooden stick. Add salt sparingly to taste.
1C	Wash the fruits with clean boiled water. Peel and cut into small pieces. Mash and serve
1D	Boil pieces of potatoes until soft. In low heat, mash with a wooden stick, adding boiled milk to make a soft thick paste.
2B	Boil beans in water and half way before they are soft, add pieces of sweet potatoes. Later, add pieces of carrots, cowpea leaves, chopped tomatoes, and pounded groundnuts. Mix them well, let them boil until tender, and then mash until soft with a wooden stick. Add salt sparingly to taste
2C	Boil sweet potatoes until soft; add salt sparingly to taste, and mash. Peel washed avocado, cut into small pieces, and mash. Mix the mashed items
3A	Mix flour thoroughly with cold water (1:4). Bring the mixture to boil with frequent stirring to make a thick porridge. Let the porridge simmer for 1 mins. then add flour gradually with constant turning until the mixture form a paste of desired softness. Continue turning the paste with occasional addition of boiled hot water for 3-4 minutes to ensure thorough flour-water mixing and gelatinisation. Cover and leave to cook for 2-3 minutes.
3B	Boil deboned sardines and pumpkin pieces. Just before tender, add cowpea leaves, chopped tomatoes and onions, continue boiling until tender. Add groundnuts and little water, mixing and mashing the ingredients with a wooden stick to make a thick stew. Let it simmer for 2 mins and add

	salt sparingly to taste.
3C	Wash oranges with clean boiled water. Peel, cut into 2 pieces and squeeze the juice on a clean cup. Serve
3D	Boil cow's milk, cool, and serve in a clean cup or keep for use in porridge preparation

Appendix 4.1 Baseline questionnaire used in the intervention trial

Interviewer: Introductions. Explain research objectives. Thank the interviewee for his/her time.

1. Ward: _____ Village: _____
2. Date of interview (day/month/year): ____/____/____
3. Season of data collection: 1. pre-harvest, rain 2. harvest, dry 3. post-harvest, dry
4. Household/Child ID Number _____

Household characteristics

5. Household is headed by 1. male 2. female
6. Household composition

	Below 2 yrs	2 - 4.11 yrs	5 - 14 yrs	15 - 19 yrs	20 - 64 yrs	≥ 65 yrs	Total
Number							

7. **Housing construction**
   Type of roof: 1. iron sheet 2.soil & grass/thatch 3.palm/bamboo 4. Others: specify _____
   Type of walls: 1. grass 2. mud&poles 3. unbaked bricks 4. baked bricks 5.cement/stones 6. Others: specify_____
   Type of floor: 1. earth/sand 2. cement/stones/concrete 3. palm/bamboo 4. Others: specify _____
8. How many rooms does your household have? _____ Number of rooms used for sleeping _____
9. Main type of fuel used by household for cooking 1. wood 2. charcoal 3. others: specify _____
10. Main source of drinking water for household. 1. spring source with village communal tap outside house 2. protected deep well 3. unprotected shallow well 4. river 5. rain water 6. Others: specify _
11. Does your household have a toilet? 1. Yes 2. No, use neighbour's 3. No, use farm or bush
12. Please indicate whether your household own or have access to any of the following assets

Asset	1.yes 0.no	Asset	1.yes 0.no
Land for farming		Motorcycle	
Livestock (cows, poultry, etc)		Radio	
Draft animals		Television	
Hand plough		Mobile phone	
Donkeys for carrying luggage		Sewing machine	
House you live in		Furniture (chairs, table, stool)	
Bicycle		Generator	

13. Mother, which of the following family issues do you participate in making decisions?

Issue	1. participate 0. dont participate
Use of household income or resourcese.g. chicken, etc	
Purchase of food items	
Seeking of health care	

14. During this period, how many times per day does your family eat? ___
15. Please tell me what your family ate and drank yesterday from the time you woke up to the time when you went to sleep. Fill in **column 1** all the meals and drinks consumed, including their ingredients. **Categorise** the meals/drinks into food groups identified in column 2 then fill in the respective food groups in column 3, by writing 1 if consumed meal contained that food group and 0 if consumed meal did not contain that food group.

Type of food/meal/drink consumed	Food group	1. yes 0. no
	Cereals e.g. maize, sorghum, finger millet, pearl millet, rice, wheat	
	Vitamin A-rich (red/yellow/orange) vegetables and tubers e.g. pumpkin, carrots, orange-fleshed sweet potatoes	
	Other roots and tubers e.g. cassava, round potatoes, white sweet potatoes, yams, green bananas	
	Green leafy vegetables	
	Other vegetables [e.g. okra, sweet pepper, egg plant, onion]	
	Vitamin A-rich (red/yellow/orange) fruits e.g. mangoes,	

	papaya	
	Other fruits	
	Organ meats e.g. liver, kidney, blood-based foods	
	Flesh meats e.g. beef, goat, pork, lamb, chicken or duck	
	Eggs	
	Fish, sardines, or other river/sea foods	
	Legumes [e.g. beans, peas, cowpeas, pigeon peas, green grams, chickpeas, soya bean], nuts and oilseeds [e.g. ground nuts, sunflower, sesame, pumpkin seeds]	
	Animal milk, milk products	
	Oil, fat, ghee or butter used for cooking or added to food	
	Sugars, honey or sugary products e.g. sodas, sweets, teas	

Parents information

16. Father's name _____. Age _____ (yrs)
17. Mother's name _____. Age _____ (yrs)
18. Marital status 1. Married-monogamous 2. Married-polygamous 3. Separated/divorced 4. Single 5. Widowed
19. Father, which level of education did you attain? 1. Didn't attend school 2. Didn't complete primary 3. Adult education 4. Completed primary 5. Completed secondary 6. Completed advanced-level secondary 7.Certificate/Diploma for any skill (teaching, carpentry, etc)
20. Mother, which level of education did you attain? 1. Didn't attend school 2. Didn't complete primary 3. Adult education 4. Completed primary 5. Completed secondary 6. Completed advanced-level secondary 7.Certificate/Diploma for any skill (teaching, carpentry, etc)

This research expects in the near future to distribute to the families various reading resources on infant feeding and health. Use of these resources will depend on parents' abilities to read and understand. Therefore, we are requesting to assess your reading abilities.

21. Request father to read this sentence. Listen clearly: **When your child completes 6 months, he/she continues to grow and his/her nutritional needs increases.** Assessment of his reading: 1. Read clearly 2. Read poorly (*unclear, hesitated*) 3. Could not read 4. Refused to read 5. Father absent
22. Request mother to read this sentence. Listen clearly: **In order to prepare child's meals of adequate nutritional quality, you need to know different types of foods, their grouping and skills on how to combine the foods.** Assessment of her reading: 1. Read clearly 2. Read poorly (*unclear, hesitated*) 3. Could not read 4. Refused to read
23. Father occupation: 1. Farming 2. Farming & livestock production 3. Farming & personal business 4. Business/petty trading 5. Skilled work e.g. carpentry 6. Casual labour 7. Formal employment8. Other: specify _____
24. Mother occupation: 1. Farming 2. Farming & livestock production 3. Farming & personal business 4. Business/petty trading 5. Skilled work e.g. carpentry 6. Casual labour 7. Formal employment8. Other: specify _____

Infant characteristics

If child has a twin, record information about the older twin then the younger twin in a different questionnaire. Request mother to show you her child's clinic card, and use it to verify some questions

25. Child's name _____ ***(similar to what is written in the clinic card)***
26. Date of birth (dd/mm/yyyy) ____/____/_____ ***(copy from clinic card)***
27. Verification of date of birth 1. clinic card 2. mother recall 3.others: specify _____
28. Child's sex: 1. Male 2. Female
29. Birth weight _____ (gram) ***(copy from clinic card)***
30. Birth order 1. First born 2. Second 3. Third 4. Fourth 5. Others: specify ___
31. Was the child born alone (i.e. singleton) or has a twin? 1. singleton 2. twin
32. Where did you deliver this child? 1. Home 2. District government hospital 3. Government health centre or dispensary 4. Missionary health centre or dispensary 5.Others: specify _____

33. Has the child been immunised-for-age 1. Yes 2. No ***(check the indicated vaccination dates)***
34. Did you attend health education session during the last growth monitoring visit? 1. Yes 2. No *(didn't go, was late)* 3. Session not given
35. If yes, what did the health worker/nurse teach or emphasized?
    1. types of foods to give infants 1. yes 2. no
    2. amount and frequency of meals per day 1. yes 2. no
    3. importance of continued breastfeeding 1. yes 2. no
    4. safe preparation and storage of foods/meals 1. yes 2. no
    88. I didn't hear, I was late
    99. I don't remember

Breastfeeding and complementary feeding practices

36. Did your child breastfeed yesterday? 1. Yes 2. No
37. At what age did you first give your baby first fluids or foods other than breast milk? ____ (months)
38. What fluids and foods did your child consume yesterday? (ORS, vitamin and mineral syrups or medicines may be given) ***(indicate one choice only)***
    1. Breast milk alone2. Breast milk, water, other liquids (e.g. tea, herbals, ritual fluid, juice)
    3. Breast milk, non-human milk (e.g. animal milk, infant formula) 4. Breast milk, porridge
    5. Breast milk, porridge, non-human milk 6. Breast milk, porridge, semi-solid or solid foods
    7. Did not eat anything
39. How many times yesterday did you feed your child porridge, semi- or solid-foods or fluids other than breast milk?

Porridge	Semi- or solid-foods	Fluids or snacks

40. The last time your child was ill, how much food did you give him/her to eat? 1. less than usual 2. about the same amount 3. more than usual 4. nothing

Child morbidity and healthcare-seeking behaviour

41. Would you kindly tell me which signs of illness would indicate that your child is very sick and in need of urgent attention or treatment?

Sign of illness	1.correct 0.wrong	Sign of illness	1.correct 0.wrong
1.		3.	
2.		99. I dont know any sign	99

42. Has the child had three or more liquid or semi-liquid stools (i.e. diarrhoea) within 24 hours at any time in the past 2 weeks? 1.Yes 2.No
43. When the child had diarrhoea, was there blood in the stool? 1.Yes 2.No
44. Did you seek treatment for the diarrhoea? 1.Yes 2.No
45. Where did you seek advice or treatment? 1. Government health facility 2. Religious/missionary health facility 3. Pharmacy or Drug store 4. Local shop 5. Local herbs/traditional healer 6. Others: specify

    _____

46. Has the child been ill with a body temperature above normal (i.e. fever) at any time in the past 2 weeks? 1.Yes 2.No
47. Did you seek treatment for the fever? 1.Yes 2.No
48. Where did you seek advice or treatment? 1. Government health facility 2. Religious/missionary health facility 3. Pharmacy or Drug store 4. Local shop 5. Local herbs/traditional healer 6. Others: specify

    _____

49. Has the child been ill with a respiratory problem at any time in the past 2 weeks? 1.Yes 2.No
50. When the child had a respiratory problem, did he/she have difficulty breathing, breathe faster than usual with short, rapid breaths or breathe with severe noise or wheezing? 1.Yes 2.No
51. Did you seek treatment for the respiratory problem? 1.Yes 2.No

52. Where did you seek advice or treatment? 1. Government health facility 2. Religious/missionary health facility 3. Pharmacy or Drug store 4. Local shop 5. Local herbs/traditional healer 6. Others: specify _____
53. When your child fell ill, and she or he was taken to a health facility, who decided that the child should seek such treatment? 1. Father 2. Mother 3. Father and mother 4. Grandparents 5. Relative/guardian 6. I did not send child to health facility
54. When did you seek health care the last time your child was sick? 1. On the day the child showed signs of illness 2. The following day 3. Two days later 4. Three or more days later
55. If you did not seek advice or treatment for any illness (diarrhoea, fever, respiratory), what was the reason? 1. Health facility too far from home 2. Costs are too high 3. Most medications are not available 4. Expected illness to disappear (child just got well) 5. Others: specify _____
56. Did the child suffer any other illness apart from the ones mentioned above (diarrhoea, fever, respiratory) within the past 2 weeks? 1. Yes 2. No
57. If yes, mention the illnesses (mention one) 1. malaria 2. skin disease 3. eye disease 4. vomiting 5. Measles 6 .Other: specify _____
58. Does your household have any mosquito nets that can be used during sleeping? 1.Yes 2.No
59. Did your baby sleep under the mosquito net last night? 1.Yes 2.No

Anthropometry and haemoglobin:

60. Fill in child's weight, length and haemoglobin concentration after measurements are taken

Weight (kg)	Length (cm)	Haemoglobin conc. (g/l)

24-hour dietary recall

61. Is the child taking any nutritional supplements (e.g. iron, vitamin A)? 1. Yes 2. No
62. ***If child received breast milk only (Qn. Number 39), do not ask this question.*** Please tell me what your child ate and drank yesterday from the time he/she woke up to the time when he/she went to sleep. *First, fill-in information in **Table A**. Then transfer information found in column 3 and 4 of Table A to column 1 of **Table B***

Table B. Fill in column 1 all the meals and drinks consumed, including their ingredients. Categorise the meals/drinks into food groups identified in column 2 then fill in the respective food groups in column 3, by writing 1 if consumed meal contained that food group and 0 if consumed meal did not contain that food group.

Type of foods/fluids consumed	Food group	1.Yes 0.No
	Cereals, roots and tubers	
	Legumes (e.g. beans, cowpeas, pigeon peas), nuts and oilseeds (e.g. groundnuts, sunflower, sesame)	
	Animal milk and milk products e.g. yoghurt	
	Flesh and organ meats (e.g. beef, fish, goat, pork, lamb, chicken, duck, liver/kidney, fish, sardines	
	Eggs	
	Vitamin-A rich vegetables (e.g. green-leafy, pumpkin, carrots) and fruits (red/yellow/orange e.g. mango, papaya)	
	Other fruits and vegetables (e.g. ripe bananas, baobab fruit pulp, tomatoes, onion)	
	Fats and oils	

Table A. Ask:

i. Time (e.g. 0800, etc) and meal occasion (e.g. breakfast, snack, etc)
ii. Type of meal (e.g. bean stew, porridge, etc) or fluid (e.g. milk, orange juice, soda, etc)
iii. Ingredients used to prepare meal or added to already-prepared meal (e.g. refined maize flour, sugar, etc)
iv. Amount (household measure) of ingredients to prepare the meal/fluid or added to meal/fluid

v. Amount (household measure) of total meal/fluid prepared, served to child, left uneaten and consumed

Time	Meal occasion	Type of Meal	Ingred. used	Amount of ingred.	Stand measure	Total vol. of meal	Stand. measure	Amount served	Amount left-over	Amount consumed

Appendix 4.2 End of trial questionnaires

Appendix 4.2a End of trial questionnaire: Intervention group

Interviewer: Introductions. Explain objectives of assessment. Thank the interviewee for his/her time.

Name of interviewer _____ Household/Child ID Number _____

Ward: _____ Village: _____

Date of interview (day/month/year): _____/_____/_____

Season of data collection: 1. pre-harvest, rain 2. harvest, dry 3. post-harvest, dry

1. During this period, how many times per day does your family eat? ___
2. Please tell me what your family ate and drank yesterday from the time you woke up to the time when you went to sleep. Fill in **column 1** meals/drinks consumed, including the ingredients. Categorise meals/drinks into food groups identified in column 2 then fill in respective food groups in column 3, by writing 1 if consumed meal contained that food group and 0 if consumed meal did not contain the food group.

Type of food/meal/drink consumed	Food group	1. yes 0. no
	Cereals e.g. maize, sorghum, finger millet, pearl millet, rice, wheat	
	Vitamin A-rich (red/yellow/orange) vegetables and tubers e.g. pumpkin, carrots, orange-fleshed sweet potatoes	
	Other roots and tubers e.g. cassava, round potatoes, white sweet potatoes, yams, green bananas	
	Green leafy vegetables	
	Other vegetables [e.g. okra, sweet pepper, egg plant, onion]	
	Vitamin A-rich (red/yellow/orange) fruits e.g. mangoes, papaya	
	Other fruits	
	Organ meats e.g. liver, kidney, blood-based foods	
	Flesh meats e.g. beef, goat, pork, lamb, chicken or duck	
	Eggs	
	Fish, sardines, or other river/sea foods	
	Legumes [e.g. beans, peas, cowpeas, pigeon peas, green grams, chickpeas, soya bean], nuts and oilseeds [e.g. ground nuts, sunflower, sesame, pumpkin seeds]	
	Animal milk, milk products	
	Oil, fat, ghee or butter used for cooking or added to food	
	Sugars, honey or sugary products e.g. sodas, sweets, teas	

3. Did you attend health education session during the last growth monitoring visit? 1. Yes 2. No *(didn't go, was late)* 3. Session not given
4. If yes, mention one issue that the health worker/nurse taught or emphasized?

_____ 99. I don't remember

5. Has the child been immunised-for-age 1. Yes 2. No ***(check the indicated vaccination dates)***
6. Did you breastfeed your child yesterday? 1. Yes 2. No
7. How many times yesterday did you feed your child porridge, semi- or solid-foods or fluids other than breast milk?

Porridge	Semi- or solid-foods	Fluids or snacks

8. **Food frequency:** How many times during the past 7 days (*remind mother of days: from ... to ...*) have you fed your child the following foods or meals made from these foods? (Insert a tick (V) where appropriate)

Food item	Frequency						
	never	once per week	2-4 times per week	5-6 times per week	every day	2-3 times per day	≥ 4 times per day
undiluted cow's milk							
beans, pigeon peas, cowpeas							

groundnuts, oilseeds							
eggs							
meats (beef, pork, goat)							
chicken or duck							
liver, kidney, other offals							
fish							
sardines							
any leafy vegetables							
pumpkin fruit or carrot							
avocado							
ripe banana							
papaya							
orange or any citrus fruit							
mango							
baobab fruit pulp							
juice from fresh fruit							

Maternal recall and practice of recommendations

9. Name 3 most important issues you learned from the previous education lesson
   0. I did not attend 99. I do not remember

10. Have you tried at home any of the promoted recipes? 1. Have tried 2. Have tried a little 3. Have not tried
11. If you tried, how difficult or easy were the recipe preparations? 1. Very difficult 2. Somewhat difficult 3. Neutral 4. Somewhat easy 5. Very easy
12. Do you have a booklet given to you during the education lessons? 1. Yes 2. No
13. Have you read the booklet? 1. Yes 2. Someone read to me 3. No
14. If you read of someone else read the booklet to you, please recall messages found in the information booklet which are relevant for your child's age? 99. I do not remember

15. Did you receive a home visit by a nutrition counsellor last month or this month? 1. Yes 2. No
16. What nutrition advice or messages did you receive from the counsellor during their last home visit? 99. I do not remember

17. How would you rate your extent of satisfaction with counsellors' services? 1. Very satisfied 2. Somewhat satisfied 3. Not satisfied
18. What benefit have you gained from counsellors' services? (*mention one only*)

    _____

19. If you are not satisfied, please tell me why? (*mention one reason only*)

    _____

20. Would you kindly tell me which signs of illness would indicate that your child is very sick and in need of urgent attention or treatment?

Sign of illness	1.correct 0.wrong	Sign of illness	1.correct 0.wrong
1.		3.	
2.		99. I dont know any sign	99

21. When your child is ill, how much food did you give him/her to eat? 1. less than usual 2. about the same amount 3. more than usual 4. Nothing

22. Please let me know if you have practised any of the following recommendations since the last education session:

Recommended practices	1.Yes 0.No
Continue to breastfeed your child on demand, during the day and night	
Prepare a thick porridge from a combination of cereal flours (maize, sorghum, pearl millet), groundnuts or ground oilseeds, egg or milk, dried vegetable flour (jute mallow leaves)	
Start with soft and thick meals then continue with mashed and semi-solid meals. Meals should be made from at least one food item from the five food groups	
Offer undiluted cow's milk to your child at least 3 times per week	
Cook, mash, and add ingredients from legumes (e.g. beans, pigeon peas, bambara groundnuts, cowpeas) in each meal	
Cook, mash and feed animal source foods (e.g. eggs, beef, pork, chicken, liver, fish, sardines) at least 3 times per week	
Cook, mash and feed leafy vegetables and other vegetables (e.g. pumpkin)	
Offer your child a fruit (e.g. papaya, ripe banana, mango, orange) after a meal	
Feed your child 2-3 times per day at 6-8 months (3-4 times at 9-11 mo.; 3-4 times at 12-23 mo.). Include snacks 1-2 times per day (e.g. piece of potato/cassava, fruit) between meals	
Encourage your child to drink and eat more frequently during illness, and provide extra food after illness to facilitate quick recovery	
Wash your hands and child hands with soap before feeding children	

23. If mother has failed to implement any of the above-mentioned recommendations:

a. What prevented the mother from implementing the recommendations? (*mention only one obstacle*)

_____

b. Which recommendations mentioned earlier was the most difficulty? (*write one recommendation only*)

_____

24. What aspects of the intervention did you find most useful to you? Please rank the listed intervention components according to their usefulness to you, starting with number 1 as the most useful

	Intervention component/element	(1. Useful 2. Not useful)	Rank
1	Education and counselling lessons		
2	Cooking demonstrations		
3	Information booklet		
4	Home visits by nutrition counsellors		

25. In general, what is your opinion on intervention activities you participated in, are you satisfied or not satisfied? 1. Satisfied 2. Not satisfied

Child morbidity and healthcare-seeking behaviour

26. Has the child had three or more liquid or semi-liquid stools (i.e. diarrhoea) within 24 hours at any time in the past 2 weeks? 1.Yes 2.No
27. Did you seek treatment for the diarrhoea? 1.Yes 2.No
28. Where did you seek advice or treatment? 1. Government health facility 2. Religious/missionary health facility 3. Pharmacy or Drug store 4. Local shop 5. Local herbs/traditional healer 6. Others: specify

_____

29. Has the child been ill with a body temperature above normal (i.e. fever) at any time in the past 2 weeks? 1.Yes 2.No
30. Did you seek treatment for the fever? 1.Yes 2.No
31. Where did you seek advice or treatment? 1. Government health facility 2. Religious/missionary health facility 3. Pharmacy or Drug store 4. Local shop 5. Local herbs/traditional healer 6. Others: specify

_____

32. Has the child been ill with a respiratory problem at any time in the past 2 weeks? 1.Yes 2.No
33. When the child had a respiratory problem, did he/she have difficulty breathing, breathe faster than usual with short, rapid breaths or breathe with severe noise or wheezing? 1.Yes 2.No
34. Did you seek treatment for the respiratory problem? 1.Yes 2.No
35. Where did you seek advice or treatment? 1. Government health facility 2. Religious/missionary health facility 3. Pharmacy or Drug store 4. Local shop 5. Local herbs/traditional healer 6. Others: specify

_____

36. When did you seek health care the last time your child was sick? 1. On the day the child showed signs of illness 2. The following day 3. Two days later 4. Three or more days later
37. If you did not seek advice or treatment for any illness (diarrhoea, fever, respiratory), what was the reason? 1. Health facility too far from home 2. Costs are too high 3. Most medications are not available 4. Expected illness to disappear (child just got well) 5. Others: specify _____
38. Did the child suffer any other illness apart from the ones mentioned above (diarrhoea, fever, respiratory) within the past 2 weeks? 1. Yes 2. No
39. If yes, mention the illnesses (mention one) 1. malaria 2. skin disease 3. eye disease 4. vomiting 5. Measles 6 . Other: specify _____
40. Did your baby sleep under the mosquito net last night? 1.Yes 2.No

Anthropometry and haemoglobin:

41. Fill in child's weight, length and haemoglobin concentration after measurements are taken

Weight (kg)	Length (cm)	Haemoglobin conc. (g/l)

24-hour dietary recall

42. Is the child taking any nutritional supplements (e.g. iron, vitamin A)? 1. Yes 2. No
43. Please tell me what your child ate and drank yesterday from the time he/she woke up to the time when he/she went to sleep.
    *First, fill-in information in **Table A**. Then transfer information found in column 3 and 4 of Table A to column 1 of **Table B**.*
    Table B. Fill in column 1 all the meals and drinks consumed, including their ingredients. Categorise the meals/drinks into food groups identified in column 2 then fill in the respective food groups in column 3, by writing 1 if consumed meal contained that food group and 0 if consumed meal did not contain that food group.

Type of foods/fluids consumed	Food group	1.Yes 0.No
	Cereals, roots and tubers	
	Legumes (e.g. beans, cowpeas, pigeon peas), nuts and oilseeds (e.g. groundnuts, sunflower, sesame)	
	Animal milk and milk products e.g. yoghurt	
	Flesh and organ meats (e.g. beef, fish, goat, pork, lamb, chicken, duck, liver/kidney, fish, sardines	
	Eggs	
	Vitamin-A rich vegetables (e.g. green-leafy, pumpkin, carrots) and fruits (red/yellow/orange e.g. mango, papaya)	
	Other fruits and vegetables (e.g. ripe bananas, baobab fruit pulp, tomatoes, onion)	
	Fats and oils	

Table A. Ask:

i. Time (e.g. 0800, etc) and meal occasion (e.g. breakfast, snack, etc)
ii. Type of meal (e.g. bean stew, porridge, etc) or fluid (e.g. milk, orange juice, soda, etc)
iii. Ingredients used to prepare meal or added to already-prepared meal (e.g. refined maize flour, sugar, etc)
iv. Amount (household measure) of ingredients to prepare the meal/fluid or added to meal/fluid
v. Amount (household measure) of total meal/fluid prepared, served to child, left uneaten and consumed

Time	Meal occasion	Type of Meal	Ingred. used	Amount of ingred.	Stand. measure	Total vol. of meal	Stand. measure	Amount served	Amount left-over	Amount consumed

Appendix 4.2b End of trial questionnaire: Control group

Interviewer: Introductions. Explain objectives of assessment. Thank the interviewee for his/her time.

Name of interviewer _____ Household/Child ID Number _____

Ward: _____ Village: _____

Date of interview (day/month/year): _____/_____/_____

Season of data collection: 1. pre-harvest, rain 2. harvest, dry 3. post-harvest, dry

1. During this period, how many times per day does your family eat? ___
2. Please tell me what your family ate and drank yesterday from the time you woke up to the time when you went to sleep. Fill in **column 1** meals/drinks consumed, including the ingredients. Categorise meals/drinks into food groups identified in column 2 then fill in respective food groups in column 3, by writing 1 if consumed meal contained that food group and 0 if consumed meal did not contain the food group.

Type of food/meal/drink consumed	Food group	1. yes 0. no
	Cereals e.g. maize, sorghum, finger millet, pearl millet, rice, wheat	
	Vitamin A-rich (red/yellow/orange) vegetables and tubers e.g. pumpkin, carrots, orange-fleshed sweet potatoes	
	Other roots and tubers e.g. cassava, round potatoes, white sweet potatoes, yams, green bananas	
	Green leafy vegetables	
	Other vegetables [e.g. okra, sweet pepper, egg plant, onion]	
	Vitamin A-rich (red/yellow/orange) fruits e.g. mangoes, papaya	
	Other fruits	
	Organ meats e.g. liver, kidney, blood-based foods	
	Flesh meats e.g. beef, goat, pork, lamb, chicken or duck	
	Eggs	
	Fish, sardines, or other river/sea foods	
	Legumes [e.g. beans, peas, cowpeas, pigeon peas, green grams, chickpeas, soya bean], nuts and oilseeds [e.g. ground nuts, sunflower, sesame, pumpkin seeds]	
	Animal milk, milk products	
	Oil, fat, ghee or butter used for cooking or added to food	
	Sugars, honey or sugary products e.g. sodas, sweets, teas	

3. Did you attend health education session during the last growth monitoring visit? 1. Yes 2. No *(didn't go, was late)* 3. Session not given
4. If yes, mention one issue that the health worker/nurse taught or emphasized?

_____ 99. I don't remember

5. Has the child been immunised-for-age 1. Yes 2. No ***(check the indicated vaccination dates)***
6. Did you breastfeed your child yesterday? 1. Yes 2. No
7. How many times yesterday did you feed your child porridge, semi- or solid-foods or fluids other than breast milk?

Porridge	Semi- or solid-foods	Fluids or snacks

8. **Food frequency:** How many times during the past 7 days (*remind mother of days: from ... to ...*) have you fed your child the following foods or meals made from these foods? (Insert a tick (√) where appropriate)

Food item	Frequency						
	never	once per week	2-4 times per week	5-6 times per week	every day	2-3 times per day	≥ 4 times per day
undiluted cow's milk							
beans, pigeon peas, cowpeas							

groundnuts, oilseeds							
eggs							
meats (beef, pork, goat)							
chicken or duck							
liver, kidney, other offals							
fish							
sardines							
any leafy vegetables							
pumpkin fruit or carrot							
avocado							
ripe banana							
papaya							
orange or any citrus fruit							
mango							
baobab fruit pulp							
juice from fresh fruit							

9. Would you kindly tell me which signs of illness would indicate that your child is very sick and in need of urgent attention or treatment?

Sign of illness	1 correct 0.wrong	Sign of illness	1 correct 0.wrong
1.		3.	
2.		99. I dont know any sign	99

Child morbidity and healthcare-seeking behaviour

10. Has the child had three or more liquid or semi-liquid stools (i.e. diarrhoea) within 24 hours at any time in the past 2 weeks? 1.Yes 2.No
11. Did you seek treatment for the diarrhoea? 1.Yes 2.No
12. Where did you seek advice or treatment? 1. Government health facility 2. Religious/missionary health facility 3. Pharmacy or Drug store 4. Local shop 5. Local herbs/traditional healer 6. Others: specify _____
13. Has the child been ill with a body temperature above normal (i.e. fever) at any time in the past 2 weeks? 1.Yes 2.No
14. Did you seek treatment for the fever? 1.Yes 2.No
15. Where did you seek advice or treatment? 1. Government health facility 2. Religious/missionary health facility 3. Pharmacy or Drug store 4. Local shop 5. Local herbs/traditional healer 6. Others: specify _____
16. Has the child been ill with a respiratory problem at any time in the past 2 weeks? 1.Yes 2.No
17. When the child had a respiratory problem, did he/she have difficulty breathing, breathe faster than usual with short, rapid breaths or breathe with severe noise or wheezing? 1.Yes 2.No
18. Did you seek treatment for the respiratory problem? 1.Yes 2.No
19. Where did you seek advice or treatment? 1. Government health facility 2. Religious/missionary health facility 3. Pharmacy or Drug store 4. Local shop 5. Local herbs/traditional healer 6. Others: specify _____
20. When did you seek health care the last time your child was sick? 1. On the day the child showed signs of illness 2. The following day 3. Two days later 4. Three or more days later
21. If you did not seek advice or treatment for any illness (diarrhoea, fever, respiratory), what was the reason? 1. Health facility too far from home 2. Costs are too high 3. Most medications are not available 4. Expected illness to disappear (child just got well) 5. Others: specify _____
22. Did the child suffer any other illness apart from the ones mentioned above (diarrhoea, fever, respiratory) within the past 2 weeks? 1. Yes 2. No
23. If yes, mention the illnesses (mention one) 1. malaria 2. skin disease 3. eye disease 4. vomiting 5. Measles 6 . Other: specify _____
24. Did your baby sleep under the mosquito net last night? 1.Yes 2.No

Anthropometry and haemoglobin:

25. Fill in child's weight, length and haemoglobin concentration after measurements are taken

Weight (kg)	Length (cm)	Haemoglobin conc. (g/l)

24-hour dietary recall

26. Is the child taking any nutritional supplements (e.g. iron, vitamin A)? 1. Yes 2. No
27. Please tell me what your child ate and drank yesterday from the time he/she woke up to the time when he/she went to sleep.

*First, fill-in information in **Table A**. Then transfer information found in column 3 and 4 of Table A to column 1 of **Table B**.*

Table B. Fill in column 1 all the meals and drinks consumed, including their ingredients. Categorise the meals/drinks into food groups identified in column 2 then fill in the respective food groups in column 3, by writing 1 if consumed meal contained that food group and 0 if consumed meal did not contain that food group.

Type of foods/fluids consumed	Food group	1.Yes 0.No
	Cereals, roots and tubers	
	Legumes (e.g. beans, cowpeas, pigeon peas), nuts and oilseeds (e.g. groundnuts, sunflower, sesame)	
	Animal milk and milk products e.g. yoghurt	
	Flesh and organ meats (e.g. beef, fish, goat, pork, lamb, chicken, duck, liver/kidney, fish, sardines	
	Eggs	
	Vitamin-A rich vegetables (e.g. green-leafy, pumpkin, carrots) and fruits (red/yellow/orange e.g. mango, papaya)	
	Other fruits and vegetables (e.g. ripe bananas, baobab fruit pulp, tomatoes, onion)	
	Fats and oils	

Table A. Ask:

i. Time (e.g. 0800, etc) and meal occasion (e.g. breakfast, snack, etc)
ii. Type of meal (e.g. bean stew, porridge, etc) or fluid (e.g. milk, orange juice, soda, etc)
iii. Ingredients used to prepare meal or added to already-prepared meal (e.g. refined maize flour, sugar, etc)
iv. Amount (household measure) of ingredients to prepare the meal/fluid or added to meal/fluid
v. Amount (household measure) of total meal/fluid prepared, served to child, left uneaten and consumed

Time	Meal occasion	Type of Meal	Ingred. used	Amount of ingred.	Stand. measure	Total vol. of meal	Stand. measure	Amount served	Amount left-over	Amount consumed

Appendix 4.3 Mean changes in feeding practices outcomes by study group and over time

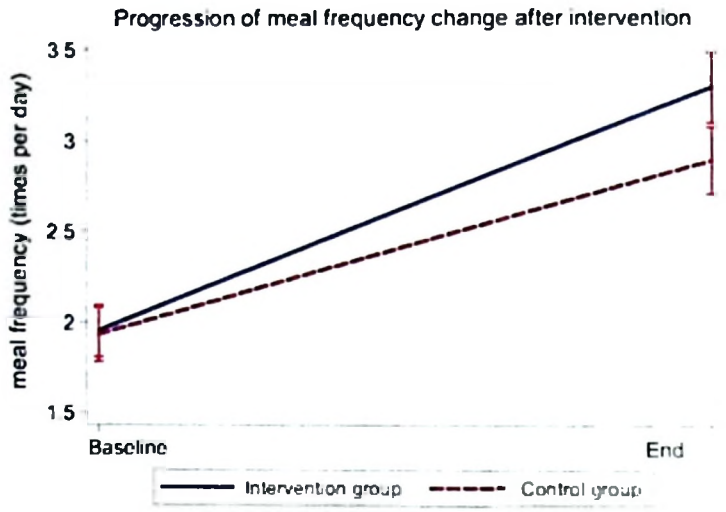


Figure 5a. Progression of meal frequency change after intervention (p=0.051)

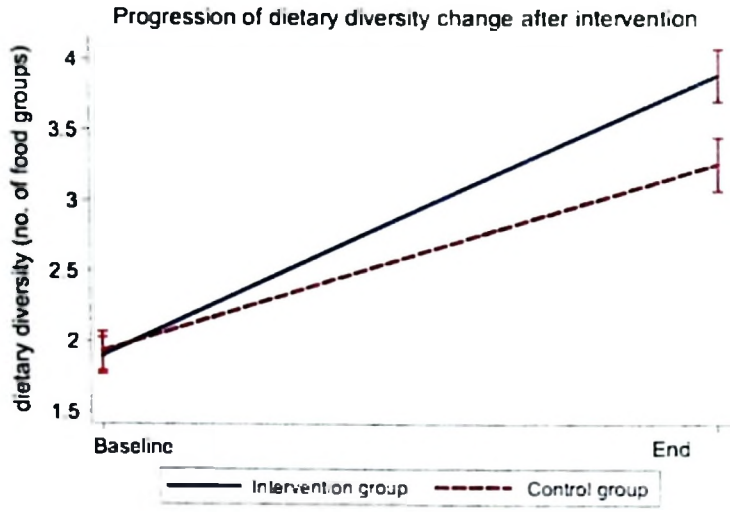


Figure 5b. Progression of dietary diversity change after intervention (p=0.005)

Appendix 4.4 Mean changes in growth outcomes by study group and over time

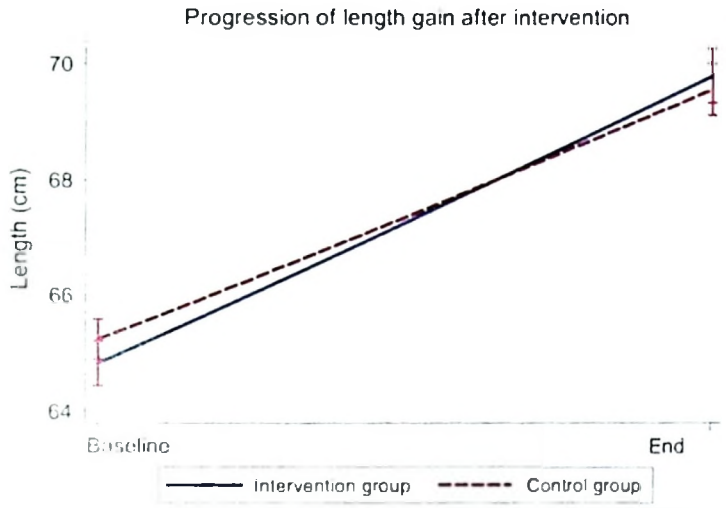


Figure 5c. Progression of length gain after intervention (p=0.0038)

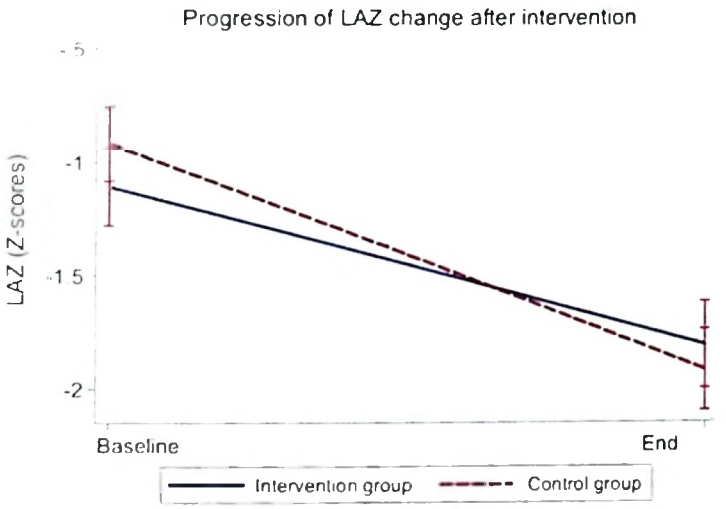


Figure 5d. Progression of LAZ change after intervention (p=0.0037)

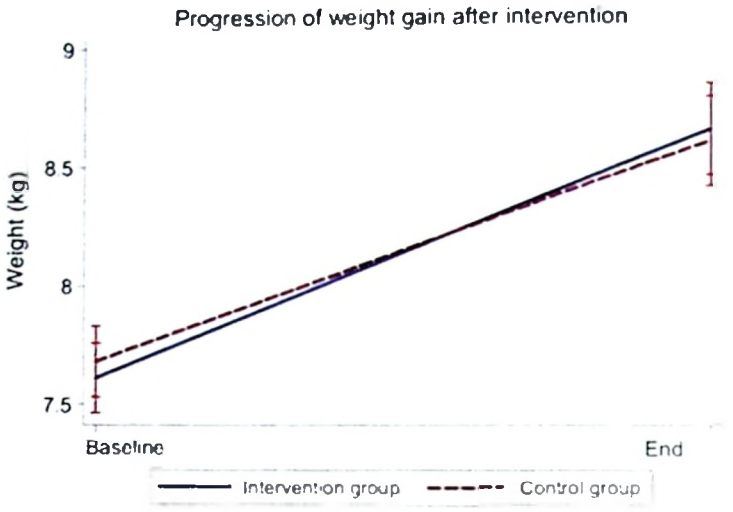


Figure 5e. Progression of weight gain after intervention (p=0.0416)

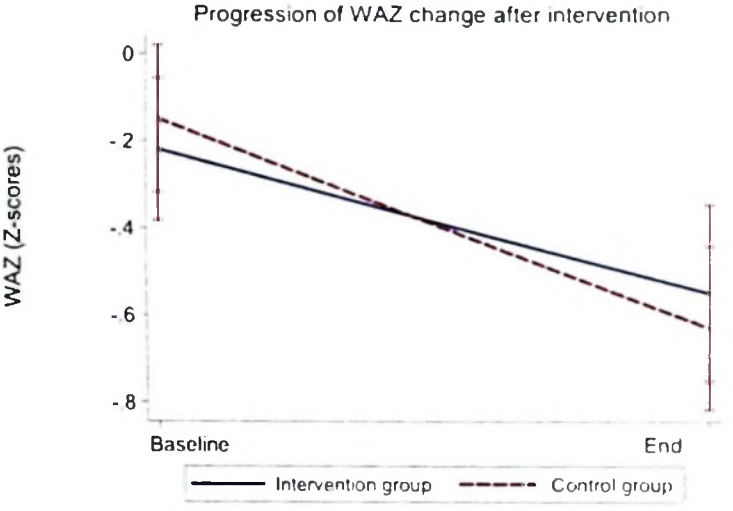


Figure 5f. Progression of WAZ change after intervention (p=0.0557)

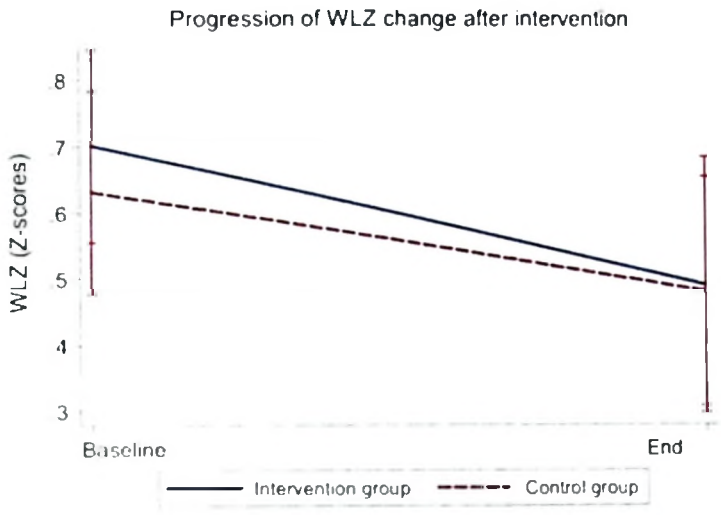


Figure 5g. Progression of WLZ change after intervention (p=0.7408)

Appendix 5.1 Structured observation of VHW skills during home visits

Did the VHW practice the following skills?
Codes for assessment: Yes, sufficient (= 2); Yes, limited (= 1); None at all (= 0).

Skills to observe	Yes, sufficient	Yes, limited	None at all	Comments
Introduces self and puts mother at ease				
Speaks slowly (unhurriedly) and clearly				
Uses verbal and non-verbal cues (eye contact, head nodding, facial)				
Shows respect and interest, listens and looks attentively				
Negotiates (asks current feeding & health practices, gives praise for what is done well, understands challenges, recommends & helps select options, asks if willing to try)				
Maintains open, honest, nonjudgmental atmosphere				
Encourages participation (e.g., do not interrupt, pay attention to questions/comments, encourage more information)				
Uses information contained in counselling card or manual effectively to convey information e.g. discussion not lecture				
Provides accurate information				
Promote problem-solving				
Discusses practical solutions/actions that mother can try				
Follow-up: discusses date for next meeting and encourages to try recommended practice(s)				
Offers referrals appropriately for other services				
TOTAL SCORE: 0 - 26				

Appendix 5.2 Structured observation of routine health education sessions

How was the routine health education delivered in intervention and control villages?

Village: _____ Date: _____

Name of health facility: _____

Ownership of health facility 1. Government 2. Faith-based 3. Private

Type of facility 1. health centre 2.dispensary

Type of services offered at the facility:

1. Out-patient 2. Growth monitoring & promotion 3. Immunisation 4. Family planning

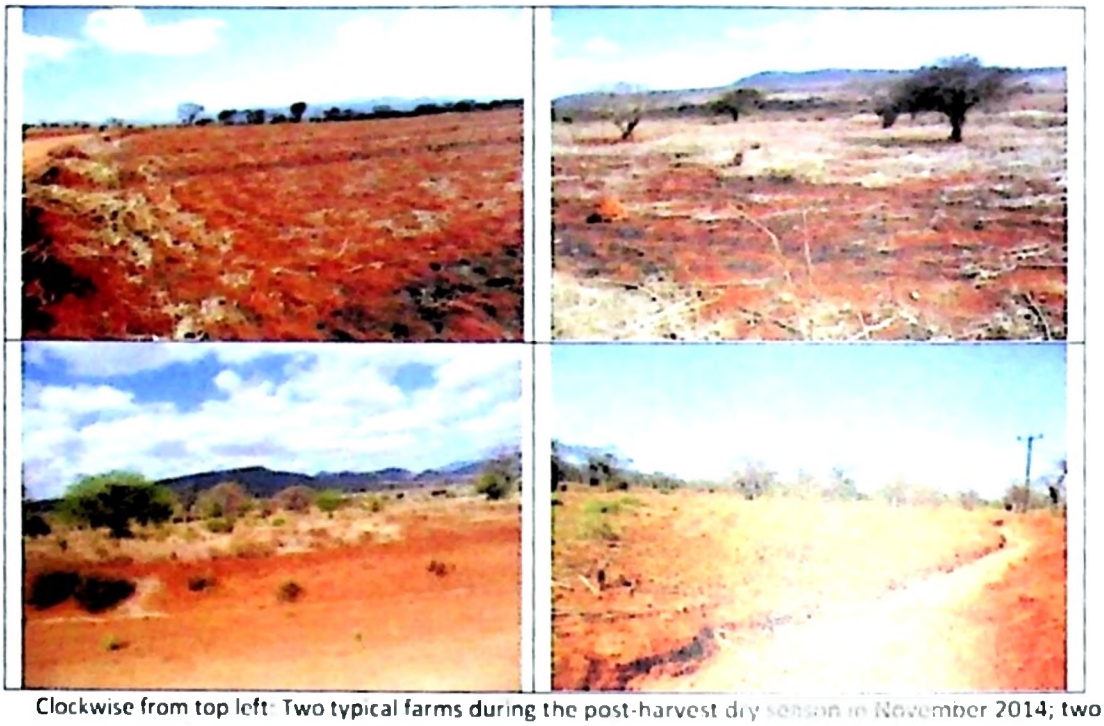
5. Antenatal 6. Delivery & Immediate Postpartum 7. _____

8. _____ 9. _____ 10. _____

Number of health workers (staff): ____

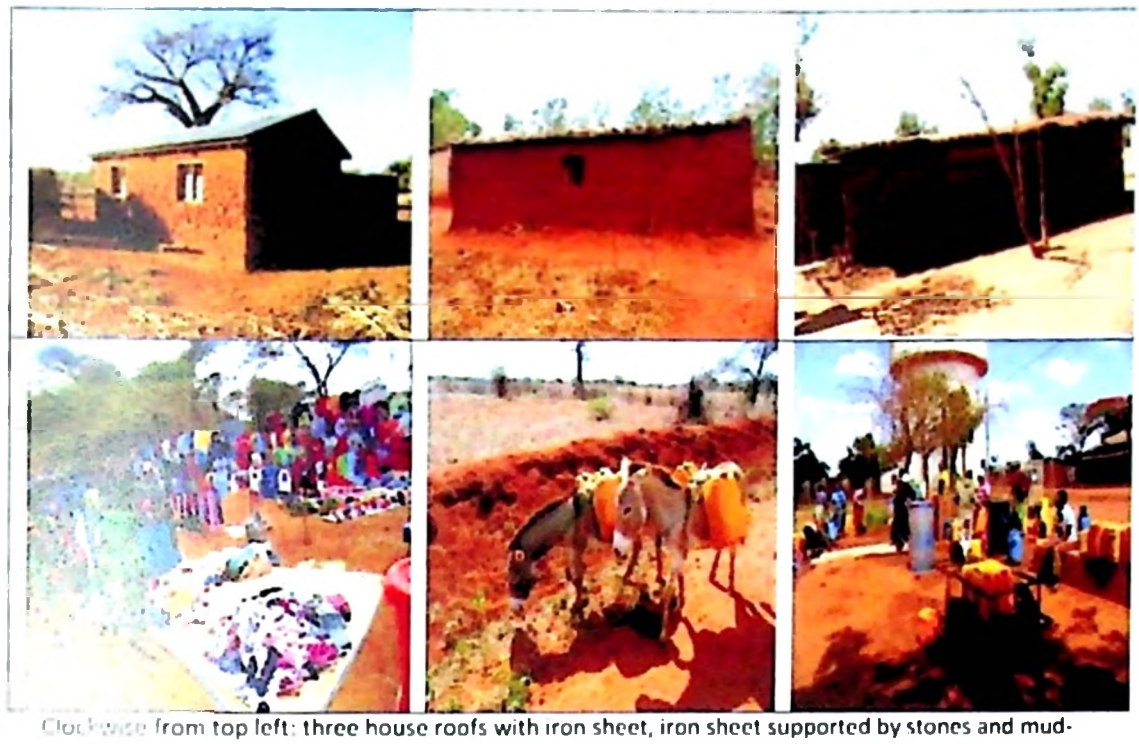
Variables/actions to observe	Comments
When is the session held: before/after growth monitoring, immunisation	
Type of audience present (mixed or separated: mothers of young vs. older infants, toddlers, sick children)	
Sitting arrangement/comfortability	
Topic of the day	
Time session started	
Number of mothers present as session started	
If guideline/manual/brochure is used for reference	
If education topic was adequately introduced to mothers	
Aspects of the topic covered	
If teaching aids were used, if practical/realistic examples were given	
If any motivation/inspiration was given	
Were the mothers attentive or showed interest (e g. asked or answered questions, give examples)	
Any distractions (e.g background noise, educator stop/leave/return, etc), type of distraction	
If questions were allowed, if time was allocated for, time for individual counselling	
Recommendations given/emphasised	
Number of mothers present at end of session	
Time session ended	
Existence of plan of topics for education	
If guideline/manual/booklet/leaflet is used for preparation. List	

Appendix 6 Photographs from the field (November 2014 - June 2015)

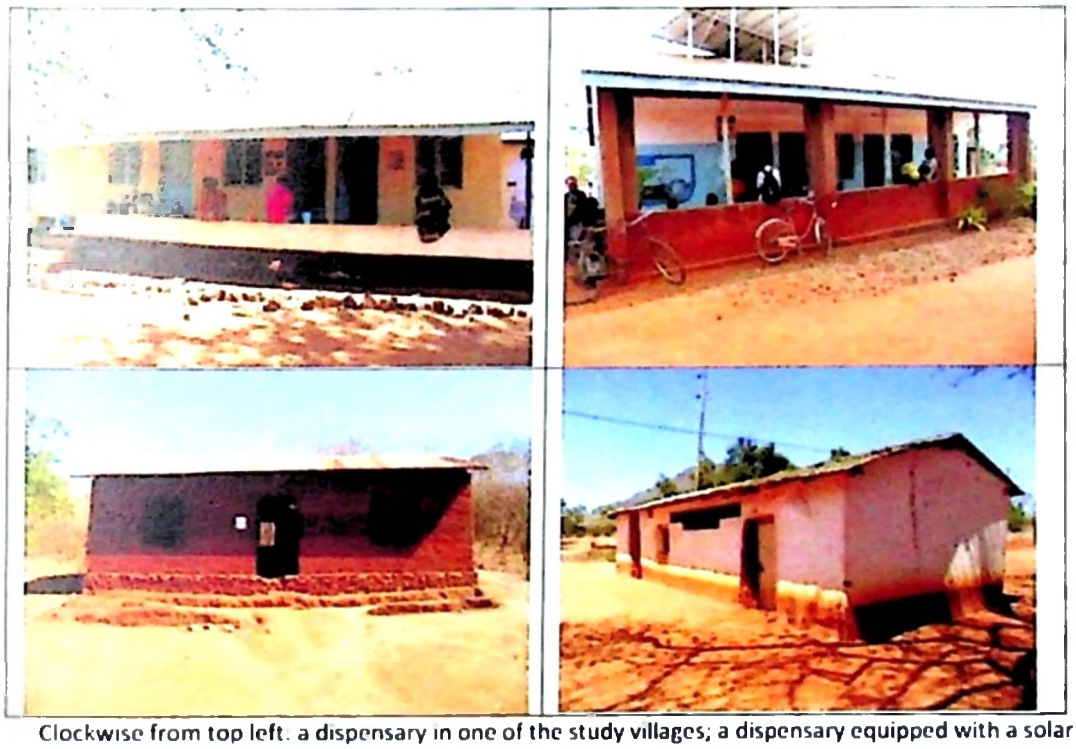


Clockwise from top left: Two typical farms during the post-harvest dry season in November 2014; two landscapes during the same period.

Clockwise from top left: a dry river bed; a dry river bed where vegetables are cultivated during the dry season; a wet river bed useful for both man and animals; animals brought to the watering point.



Clockwise from top left: three house roofs with iron sheet, iron sheet supported by stones and mud-thatched; women at the village water point, donkeys carry water to the homesteads, a village market day



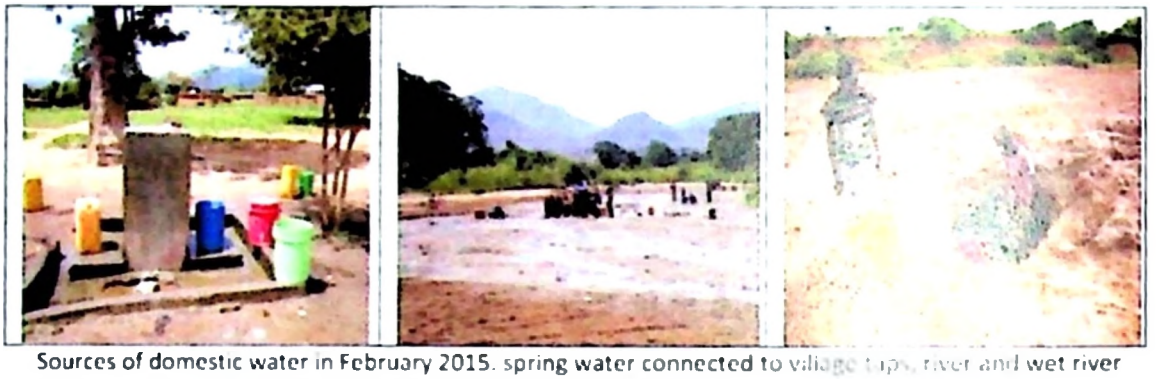
Clockwise from top left: a dispensary in one of the study villages; a dispensary equipped with a solar system; two village administrative offices in villages lacking a health facility, where GMP and health education sessions are held within their vicinity.

Farmers' fields located in three different study villages during the rainy season in March 2015: two normal farms and an irrigated farm plot close to the river (far right).

Sources of domestic water in February 2015: spring water connected to village taps, river and wet river bed, unprotected hand-dug shallow well located on dry river bed.

Mothers at a routine GMP session, mothers lining up for a routine GMP session, a VHW giving a health education talk (far right).

Farmers' fields located in three different study villages during the rainy season in March 2015: two normal farms and an irrigated farm plot close to the river (far right).



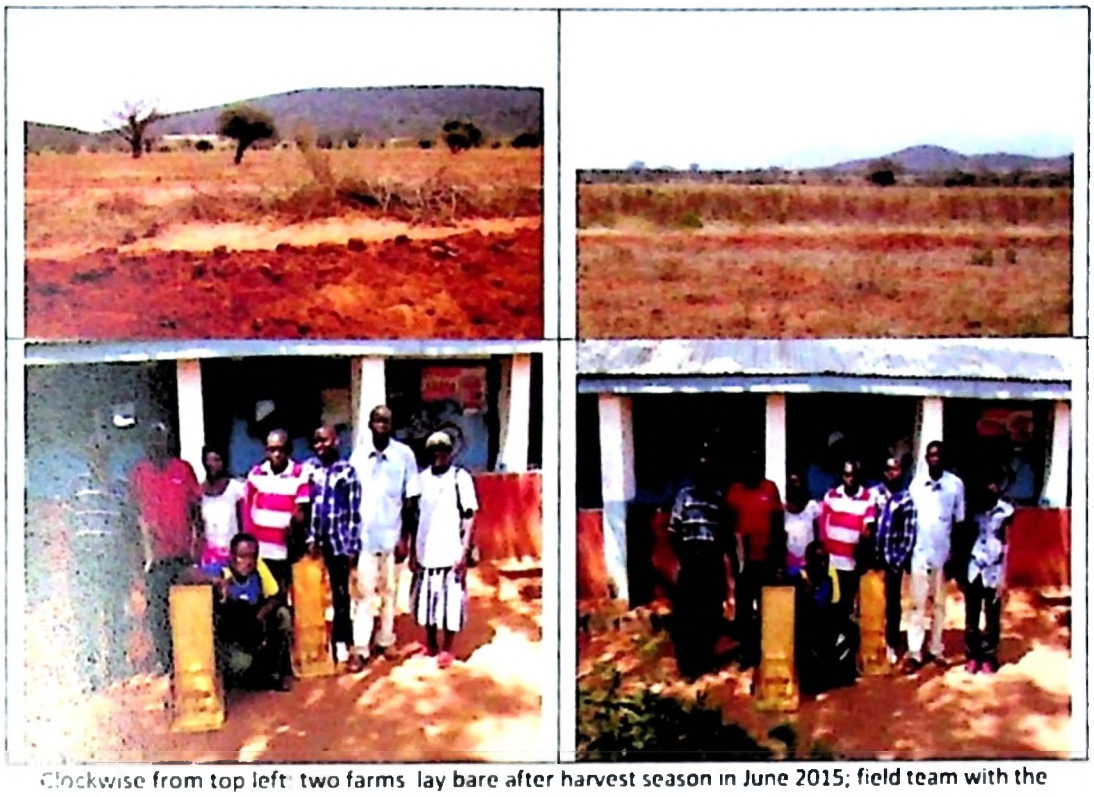
Sources of domestic water in February 2015: spring water connected to village taps, river and wet river bed, unprotected hand-dug shallow well located on dry river bed.

Mothers at a routine GMP session, mothers lining up for a routine GMP session, a VHW giving a health education talk (far right)

Clockwise from top left: VHW from intervention villages and two trainers (3rd left, 1st and 3rd right) during the first training session in November 2014; a group education session; mothers following a session, mothers posing after a session.

Clockwise from top left: mothers preparing leafy vegetables; mothers peeling potatoes, boiling milk; cooking a meal; cooked cereal-legume-dried vegetable porridge blend

Clockwise from top left: serving meals; mothers feeding their infants after a cooking demonstration.



Clockwise from top left: two farms lay bare after harvest season in June 2015; field team with the principal researcher (far right), two VHW of one of the 18 villages (second and third left), laboratory technologist (far left), data collection team (fourth to sixth left and forefront); the same field team with a graduate nutrition student (far right).

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About the author

Kissa Buponelo Martin Kulwa (Morogoro, 20 March 1972) completed high school at Weruweru Secondary School (Kilimanjaro) in 1991. In 1995 she obtained BSc. Home Economics and Human Nutrition from the Sokoine University of Agriculture (Tanzania). After graduation, she worked as a secondary school teacher before joining a postgraduate programme in 1997 at the University of Nairobi (Kenya). She graduated in 2001 with MSc. Applied Human Nutrition. In December 2001, she joined the Sokoine University of Agriculture as an Assistant lecturer and has continued working as a Lecturer and currently as a Senior lecturer in the Department of Food Technology, Nutrition and Consumer Sciences. In November 2008, she joined the Department of Food Safety and Food Quality of Ghent University (Belgium) as a doctoral student under the supervision of Prof. Patrick Kolsteren. During this period, she carried out research studies with infants and young children in rural Tanzania, developed a nutrition education package to improve diets and nutritional status of the children, and oversaw its implementation and evaluation. As a result of this research project, she has two scientific publications and two manuscripts under consideration in international peer-reviewed journals. She has also attended training on a number of research-related transferable skills offered by the Doctoral Schools of Ghent University and London School of Hygiene and Tropical Medicine (UK).

Publications

Publications in peer-reviewed journals

- **Kulwa KBM**, Mamiro PS, Kimanya ME, Mziray R, Kolsteren PW. 2015. Feeding practices and nutrient content of complementary meals in rural central Tanzania: implications for dietary adequacy and nutritional status. *BMC Pediatrics* 15:171.
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Submitted publications

- **Kulwa KBM**, Mamiro PS, Kolsteren PW. Effectiveness of the nutrition education package on feeding practices, nutrients intake and growth of infants and young children in rural Tanzania: results of a cluster randomised trial.
- **Kulwa KBM**, Verstraeten R, Mamiro PS, Kolsteren PW. Process evaluation of a nutrition education package to improve feeding practices, nutrients intake and growth of infants and young children in rural Tanzania.

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- **Kulwa K**, Kolsteren P, Mamiro P. 2014. Poor nutrition and health persist across seasons among infants and young children in rural Tanzania. 2nd International Conference on Nutrition and Growth, Barcelona, Spain January 30 - February 1, 2014. Book of Abstracts.
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Completed doctoral training activities

- Leadership Foundation. November 2015. Ghent University.
- Fostering Responsible Conduct of Research. October 2015. Ghent University.
- Clinical Trials. September 2011. London School of Hygiene and Tropical Medicine, University of London.
- Systematic Reviews of Health Research. September, 2011. London School of Hygiene and Tropical Medicine, University of London.
- Project Management. October, 2010. Ghent University.
- Personal Effectiveness. October, 2010. Ghent University.
- Advanced Academic English: Conference Skills. October, 2010. Ghent University.
- Introductory Statistics. October, 2010. Ghent University.