EFFICACY OF AN IRON FORTIFIED INFANT CEREAL ON THE NUTRITIONAL STATUS OF CHILDREN AGED 6-18 MONTHS IN THE LA NKWANTANANG MUNICIPALITY OF THE GREATER ACCRA REGION

BY
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JULY, 2017
DECLARATION

I, Akwaa Harrison Obed do hereby declare that all the information in this thesis except the cited references, was produced by me through research under the supervision of Prof. Matilda Steiner-Asiedu and Dr Frederick Vuvor, in the Nutrition and Food Science Department, University of Ghana.

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ABSTRACT

Background: The nutritional status of mothers before conception and nutrition of the child during the first 1000 days of life starting from conception is a critical determinant of their future well-being. Iron deficiency Anaemia is still an issue of concern in Ghana. It increases mortality rate and impairs development of the grey matter infrastructure. The study sought to assess the efficacy of an iron fortified complementary food on the nutritional status of children 6-18 months of age in some peri-urban communities in the La-Nkwantanang Municipality of the Greater Accra Region.

Methods: The study design was a double blinded randomised controlled trial where one group received the iron fortified infant cereal and the other usual infant cereal. The four communities were assigned randomly to receive either of the foods. The duration of the study was 8 months; 6 months feeding period and 2 months post intervention (no feeding). Background characteristics, dietary, anthropometric and biochemical data were collected at baseline and repeated subsequent 2 months, 4 months, 6 months and at 8 months with the exception of background information. Worm infestation and malaria status was assessed at baseline and endline to account for them as potential confounders. Measurement of weight was done with a SALTER hanging scale, height was assessed with a SECA infantometer and MUAC was measured using an inextensible MUAC tapes. Haemoglobin concentration (Hb) was determined with a digital HemoCue photometer using a finger prick blood sample from the children. With the help of a 24-hour recall, dietary intake of the consumed foods from the various food groups was assessed. Stool samples were collected to assess for the presence of helminths through the microscopic smear test. Assessment of malaria was done using the RDR procedure while the microscopic technique was also done as a confirmatory test. Data collected were used to measure dietary diversity score, height, weight MUAC, HAZ, WAZ, WHZ, and
Hb; a proxy for anaemia status, per each point of data collection. Changes both between and within the indicators of the 2 groups at baseline and endline were compared by means of paired and independent sample t-test and Pearson Chi-square for continuous and categorical variables respectively.

**Results:** It was found that the iron fortified complementary food significantly increased the mean haemoglobin concentrations from baseline to endline. The control group recorded a mean change in haemoglobin of 1.16±0.21 while the intervention group recorded a higher mean change of 1.98±0.19 at a P value of <0.01. Comparison of the mean changes between the two groups revealed a significant change in their mean Hb concentrations of 0.68±0.30 g/dL at a P value of 0.02. There was a decline in anaemia prevalence for both groups thus (84.1% to 42.8% vs. 89.1% to 62.8%) in the intervention and control groups respectively. The impact on anaemia prevalence was relatively high by -20 percentage point difference. There was no improvement in linear growth (thus mean change of length in control group was 6.24 ± 0.28 cm vs. 5.62 ± 0.27 cm, p=0.21 in the intervention group) or weight gain (thus mean change of weight in control group was 1.03 ± 0.24 kg vs. 1.31 ± 0.2 kg, p=0.41 in the intervention group).

**Conclusion:** The iron fortified infant cereal improved the haemoglobin concentrations and reduced the prevalence of anaemia among the study participants. Thus, the iron fortified infant cereal has the potential to alleviate iron deficiency anaemia which is an issue of public health concern in Ghana and most developing countries.
DEDICATION

I dedicate this work to my Mother Hannah Akuba Harrison, my beloved Benedicta Aziavor and my lovely daughter Hannah Akuba Oyemam Harrison for their sacrifices, love and support through my graduate studies.
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# TABLE OF CONTENT

<table>
<thead>
<tr>
<th>CONTENT</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>DECLARATION</td>
<td>i</td>
</tr>
<tr>
<td>ABSTRACT</td>
<td>ii</td>
</tr>
<tr>
<td>DEDICATION</td>
<td>iv</td>
</tr>
<tr>
<td>ACKNOWLEDGEMENT</td>
<td>v</td>
</tr>
<tr>
<td>TABLE OF CONTENT</td>
<td>vi</td>
</tr>
<tr>
<td>LIST OF TABLES</td>
<td>x</td>
</tr>
<tr>
<td>LIST OF FIGURES</td>
<td>xi</td>
</tr>
<tr>
<td>LIST OF ACRONYMS</td>
<td>xii</td>
</tr>
</tbody>
</table>

## CHAPTER ONE ................................................................. 1

1.0 INTRODUCTION ..................................................................... 1

  1.1 Background Information .................................................. 1
  1.2 Rationale ........................................................................ 2
  1.3 Objectives of Study ...................................................... 4
    1.3.1 Main Objective: ...................................................... 4
    1.3.2 Specific Objectives: ............................................... 4

## CHAPTER TWO ........................................................................ 5

2.0 LITERATURE REVIEW .......................................................... 5

  2.1 Infant and Young Child Feeding ...................................... 5
  2.2 Appropriate Complementary Feeding ................................ 8
  2.3 Trends in the Nutritional Status of Children: Globally, Africa and in Ghana ...... 10
  2.4. Physiology and Importance of Iron in Nutrition and Health 12
    2.4.1 Bioavailability and Absorption of Iron ....................... 13
    2.4.2 Enhancers and Inhibitors of Iron Absorption ............... 13
    2.4.3 Implications of Inadequate Supply of Iron ................ 14
    2.4.4 Complementary Feeding and Iron ............................. 15
  2.5 Anaemia ........................................................................ 15
    2.5.1 Classification of Anaemia ........................................ 16
    2.5.2 Types and Causes of Anaemia in Children .................. 18
      2.5.2.1 Iron Deficiency Anaemia ................................... 18
3.3.3 Biochemical.................................................................39
3.3.3.1 Haemoglobin (Hb) Concentration.................................39
3.3.3.2 Worm Infestation and Parasitemia..................................39
3.3.4 Clinical Signs ..................................................................40
3.3.5 Dietary Assessment ..........................................................40
3.4 Data Analyses ....................................................................40

CHAPTER FOUR..............................................................................42
4.0 RESULTS ..............................................................................42
4.1 Background Characteristics ....................................................42
4.2 Anthropometric Indices of Participants .....................................44
4.2.1 Baseline Anthropometric Indices of Study Participants ..........44
4.2.2 Changes in Anthropometric Indices with Time and According to Study Groups .................................................................................................................................46
4.3 Dietary Data ..........................................................................49
4.3.1 Usual Food Groups Consumed by Infants at Baseline and Endline ....49
4.3.2: Dietary Diversity Score of Infants ...................................50
4.3.3: Breastfeeding Rate at Baseline ......................................52
4.4 Hematological Data ................................................................53
4.4.1 Changes in Haemoglobin Concentration Overtime ..........53
4.5 Changes in nutritional status indicators over the study period by study groups....58

CHAPTER FIVE..............................................................................61
5.0 DISCUSSION ........................................................................61
5.1 Preamble .............................................................................61
5.2 Effect of the iron fortified complementary food on haemoglobin levels and anaemia .................................................................62
5.3 Effect of iron fortified complementary food on growth ............64
5.4 Limitations of Study...............................................................65

CHAPTER SIX .............................................................................66
6.0 CONCLUSIONS AND RECOMMENDATIONS ............................66
6.1 Conclusions .......................................................................66
6.2 Recommendations ................................................................67
LIST OF TABLES

Table 2.1 Anaemia amongst infants below the ages of 5 in some selected countries...... 25
Table 4.1: Background characteristics of study participants at baseline .................... 42
Table 4.2: Socio-demographic characteristics of caregivers.................................. 43
Table 4.3 Baseline anthropometric indices of participants by study group .................. 45
Table 4.3 Continued: Baseline anthropometric indices of participants by study group ... 46
Table 4.4: Usual food groups consumed by infants at baseline ................................ 50
Table 4.5: Usual food Groups consumed by infants at endline ............................... 50
Table 4.6: Breastfeeding rate at baseline by groups ............................................. 52
Table 4.7: Breastfeeding rate at endline by groups............................................. 52
Table 4.8: Changes in haemoglobin concentrations from baseline to month 6 by gender and age...................................................................................................................... 55
Table 4.9: Changes in haemoglobin concentrations from baseline to month 8 by gender and age...................................................................................................................... 57
Table 4.10 Changes in nutritional status indicators over the study period by study groups59
LIST OF FIGURES

Figure 2.1: Conceptual framework of the proximal factors affecting linear growth during the period of complementary feeding .................................................................33
Figure 4.1: MUAC profiles of study participants over time ........................................47
Figure 4.2: Height profiles of study participants over time ........................................48
Figure 4.3: Weight profiles of study participants over time .........................................49
Figure 4.5: Trends in haemoglobin concentration from baseline to month 6 ..............53
Figure 4.6: Changes in haemoglobin levels within and between groups from months 0 - 6 ..54
Figure 4.7: Trends in haemoglobin concentration from baseline to month 8 ...............56
Figure 4.8: Prevalence of anaemia at baseline and endline by study groups ...............58
Figure 4.9: Prevalence of malaria at baseline and endline by study groups ...............60
## LIST OF ACRONYMS

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDD</td>
<td>Centre for Disease Control</td>
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<td>CI</td>
<td>Confidence Interval</td>
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<td>DHS</td>
<td>Demographic Health Survey</td>
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<td>FAO</td>
<td>Food and Agriculture Organization</td>
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<td>CG</td>
<td>Control Group</td>
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<tr>
<td>IG</td>
<td>Intervention Group</td>
</tr>
<tr>
<td>GSS</td>
<td>Ghana Statistical Service</td>
</tr>
<tr>
<td>HAZ</td>
<td>Height for Age Z-Score</td>
</tr>
<tr>
<td>Hb</td>
<td>Haemoglobin</td>
</tr>
<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
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<tr>
<td>IYCF</td>
<td>Infants Young Child Feeding</td>
</tr>
<tr>
<td>MICS</td>
<td>Multiple Indicator Cluster Survey</td>
</tr>
<tr>
<td>MUAC</td>
<td>Mid-Upper Arm Circumference</td>
</tr>
<tr>
<td>RDT</td>
<td>Rapid Diagnostics Test</td>
</tr>
<tr>
<td>SD</td>
<td>Standard Deviations</td>
</tr>
<tr>
<td>SE</td>
<td>Standard Errors</td>
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<tr>
<td>UNICEF</td>
<td>United Nations International Children’s Emergency Fund</td>
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<td>Weight for Age Z-Score</td>
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<td>WFP</td>
<td>World Food Programme</td>
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<tr>
<td>WHO</td>
<td>World Health Organizations</td>
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<tr>
<td>WHZ</td>
<td>Weight for Height Z-Score</td>
</tr>
</tbody>
</table>
CHAPTER ONE

1.0 INTRODUCTION

1.1 Background Information

The first 1,000 days of a child’s life, that is, the period from the time of conception to the child’s second birthday is when nutrition can make the difference between a successful future and one that is plagued with poor health and growth failure. Also, this period “window of opportunity” indirectly shapes the future of families, communities and prosperity of the global world (WFP and CDC, 2005). Adequate nutrition is critical in the development and growth of children especially from birth to their second birthday (Rao et al., 2011). Malnutrition during this crucial period could make children suffer irreversible cognitive damage affecting their health, quality of life and economic well-being in the future (Dewey and Adu-Afarwuah, 2008). The negative effects of insufficient nourishment may carry on to adulthood resulting in a vicious cycle of growth failure that may continue for generations (Rao et al., 2011).

Although the detrimental effects of poor nutrition on a child’s health are preventable, infant malnutrition still remains a challenge globally, especially in developing countries. Globally, malnutrition accounts for about 50% of all child deaths, while deaths from other causes claims the lives of about 3.1 million every year. Almost 200 million children are chronically malnourished and suffer from severe, often irreversible, cognitive and physical damage (WFP and CDC, 2005). The recent Multiple Indicator Cluster Survey (MICS) in Ghana reveals that 13% of children below the age of 5 years are underweight, 23% are stunted and 6% are wasted (Ghana Statistical Survey, 2011). According to the Ghana Statistical Service (2011), the nutrition situation of children in Greater Accra Region alone is alarming. Stunting plaques 13.7% of children below 5 years, 8.3% are underweight and 5.4% are wasted (Ghana Statistical Survey, 2011).
The Infant and Young Child Feeding (IYCF) global strategy as well as the WHO recommends that mothers initiate breastfeeding very early thus within the first 30 minutes to one hour, and exclusive breastfeeding for the first six months of life to attain optimum growth, health and development. Thereafter, in order to meet their changing nutritional needs, infants should be fed timely with nutritionally adequate meals which are of good dietary quality and safe complementary foods alongside breast feeding for at least 18 to 24 months (WHO, 2002). This is an important measure because at this life stage, the child’s nutritional needs are rapidly changing and the breast milk is no longer able to meet these needs (energy, protein and micronutrient (especially iron) (Dewey, 2002). Even when complementary feeding is done, the poor knowledge concerning its timeliness, safety and adequacy with associated poor practices and beliefs undermines the impact on the child’s nutrition.

1.2 Rationale

The relationships between early childhood nutrition, childhood morbidity and mortality are well documented (Dewey and Adu-Afarwuah, 2008). Poverty, lack of knowledge in nutrition, poor child feeding practices and infectious diseases are the reasons why adequate nutrition is not met in developing countries and this leads to increased morbidity and mortality. Inappropriate practices such as delayed or early introduction of complementary foods, low energy and nutrient deficiencies of foods offered, feeding thin consistency diets or gruels in small amounts and food restrictions due to cultural beliefs are common (Gyampoh et al., 2014). However, studies on prevalence and knowledge about complementary feeding in the sub region are sparse (Gyampoh et al., 2014). It is therefore not surprising that in spite of the improvement in the country’s economy and interventions to improve the poor nutrition situation, malnutrition remains a challenge in Ghana. The recent National Demographic Health Survey revealed that, among Ghanaian children under age 5 years, 19 % stunted, 5 % are wasted, and 11 % are
underweight. About 3% of children are overweight. The prevalence of anaemia had declined to 57%. Anaemia is a major concern for children because it increases the risk of mortality, impairs cognitive development and stunts growth. Causes of anaemia includes worm infestation, nutritional deficiencies, chronic infections and some genetic conditions like sickle cell. After 6 months, the iron stores of infants gotten from their mothers would have been exhausted and as such require another iron supply from their diet. The prevalence of child anaemia in children under 5 years has greatly reduced from 78% in 2008 to 57% in 2014 (Ghana Statistical Service, Ghana Health Service(GHS), & ICF Macro 2009; Ghana Statistical Service, 2015). However, the current anaemia situation in under 5s is still above the WHO cutoff (40%) for a severe public health problem (Benoist et.al, 2008). All these can be blamed on poor maternal nutrition prior to and during pregnancy and particularly poor nutrition during the first two years of a child’s life.

Dewey and Adu-Afarwuah (2008), evaluated 10 efficacy trials of complementary feeding interventions and reported an improvement on linear growth only in Sudan, Senegal and Ghana all in Africa. They asserted that growth faltering appears to be more prominent at after birth than before delivery and hence may be more responsive to change by adopting nutritional interventions after birth in the form of appropriate complementary foods. Also, Dewey and Adu-Afarwuah (2008) stated that a food-based all-inclusive approach may be more effective and sustainable, than programmes that targets specific nutrient deficiencies. Considering the potency of adequate, timely, safe and properly fed complementary foods in addressing the poor infants and young child nutrition situation, this study sought to evaluate the efficacy of an iron fortified infant cereal, on improving the nutritional status of children between 6 to 18 months.
1.3 Objectives of Study

1.3.1 Main Objective:

The main objective of the study was to assess the efficacy of a model iron fortified infant cereal on the nutritional status of children aged 6 completed months to 18 months in some communities of the La Nkwantanang District of the Greater Accra Region.

1.3.2 Specific Objectives:

1. To assess the efficacy of the iron fortified infant cereal on haemoglobin levels
2. To assess the efficacy of the iron fortified infant cereal on growth
3. To determine the dietary diversity score among the study participants.
4. To determine the malaria status of the study children
5. To determine worm infestation among the children
6. To assess the breastfeeding rate among the children
CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Infant and Young Child Feeding

Adequate nutrition is critical in the development and growth of children especially from birth to their second birthday (Rao et al., 2011). Malnutrition during this crucial period could make children suffer irreversible cognitive damage affecting their health, quality of life and economic well-being in the future (Dewey and Adu-Afarwuah, 2008). The negative effects of insufficient nourishment may carry on to adulthood resulting in a vicious cycle of growth failure that may continue for generations (Rao et al., 2011).

The Infant and Young Child Feeding (IYCF) global strategy as well as the WHO recommends that mothers initiate breastfeeding very early thus within the first 30 minutes to one hour, and exclusive breastfeeding for the first six months of life to attain optimum growth, health and development. Ideally, human milk is the preferred food for infants below the age of 2 years due to its ability to meet the nutritional requirements of infants. It contains a good amount of protein for rapid growth during that stage, non-protein for hormones and is also rich in fatty acids needed for brain development, a good source of energy and also helps to minimise the risk of infections (Dewey, 2001). According to Dewey (2001), the composition changes as time goes on after birth.

At about 6 months, certain nutrients especially micronutrients such as zinc and iron are not passed through the breast milk in the amounts needed to meet the nutritional requirements of the child (Dewey, 2013). Thus, complementary foods are required. WHO (2010), provided an information on how frequently complementary foods should be consumed; 2-3 times a day for infants between 6-8 months, 3-4 times a day for infants from 9-11 months and the same for
infants from 12-24 months, additional snacks should be given all together with breastfeeding till 24 months. However, the issue is not only with the frequency of consumption and the quantity of food given. When infants have access to quality, nutrient rich foods, diverse diets, adequate maternal care and infant practices, as well as healthy living environments and access to adequate health care, they are more likely to have normal nutritional status (UNICEF, 2013).

Infants below five are susceptible to defects from under nutrition, however the most crucial part of life to meet the nutritional requirements of a child for optimum maturity according to the 2013 UNICEF documentation on improving the nutritional status of children, is within the first 1000 days. The count starts from conception till the child’s second birthday (Biesalski and Black, 2016). The first 1000 days is crucial because during this period the child has the highest demands of nutrition to support rapid growth and development of the brain and the body. Also, the child is fragile and its means of survival depends entirely on the mother during gestation and upon care and social interactions provided by the caregivers after birth.

Mothers in developing countries usually fail to give their children a healthy start to life. In such countries, the meals given to the children as complementary foods are predominantly cereals and grains (Dewey, 2013). The food from these groups are in large quantities and provide energy with little or no addition from the other food groups needed to provide the infants wholly with the nutrients for maximum growth. According to UNICEF, the most occurring nutrient deficiencies in infants are deficiency in iron, vitamin A, iodine, folate, vitamin D, calcium, zinc and vitamin B_{12}. Iron deficiency anaemia is the most common nutritional deficiency and is also the commonest form of nutritional anaemia (UNICEF, 2011).
When children begin their lives as malnourished, it creates defects that are difficult to correct. In addition, the poor nutritional status of a child is not only attributed to the meals they are given. Elder and Ransom (2003), explains that poor nutritional status and health of a mother before conception and after delivery can negatively affect the nutritional status of the child. A child whose mother’s nutrition is inadequate is likely to have health complications and cognitive impairments all through their lives with a higher risk of death (Elder and Ransom, 2003).

The nutritional status of interest in infants are assessed mainly by anthropometry, particularly: height and weight, which are classified into the indices; stunting (low-height-for-age), wasting (low-weight-for-height) and underweight (low-weight-for-age). Based on these indices, children who fall below -2SD of the mean for the referenced population are considered to have moderate cases of any of the indices and below -3SD are severe. These cases of malnutrition have been found to be associated with anaemia (Kuziga, et al., 2017).

Stunting occurs when the right type of nutrients and foods in terms of quality and quantity are not given to the children especially during the gestation period and within their first two years of life and it is almost impossible to correct afterwards (UNICEF, 2012). It often results in poor cognitive functions and poor performance in school. It gives an idea about the nutritional status of the child in the past.

The 2015 Global Nutrition Profile revealed that worldwide, 24%, 8% and 6% of children under 5 were affected by stunting, wasting and overweight respectively. In Ghana, one-third of the child deaths have malnutrition mainly under nutrition as an underlying cause. Based on the 2014 Ghana Statistical Service, 19% of Ghanaian children were stunted, 8% wasted, about 11%
underweight and 3% were overweight across the country but predominantly in these Northern sectors (Ghana Nutritional Profile, 2014). There has been an improvement over the years about the nutritional status of infants in Ghana, however, the rate of improvement is different across the regions. According to the Ghana Nutrition Profile (2014), burdens of under nutrition continue to exist in the three Northern Regions in Ghana.

Stunting is risk factor for anaemia amongst infants from 6-59 months as compared to the other nutritional status indicators (SPRING, 2016). Another study also carried in other countries showed a similar result where stunting, as compared to the other nutritional status was associated with anaemia (Kuziga et al., 2017). Like the situation worldwide, deficiencies in the micronutrients: iron, vitamin A, iodine, folate, vitamin D, calcium, zinc and vitamin B_{12} occurs in Ghana with deficiency in iron being the most prevalent.

2.2 Appropriate Complementary Feeding

According to (WHO, 2002) appropriate complementary feeding is; timely, adequate, safe, and it ensures that a child is properly fed. Being timely means that complementary foods are to be introduced at 6 completed months when an infant’s energy and nutrient needs increase beyond that which can be provided solely by breast milk (WHO, 2002). This is usually when the infant is six months old. (Agedew et al, 2014) explains that this time is at the end of the six months of life and not at the beginning of the sixth month. Knowing exactly when to start complementary feeding is important. USDA (2009) explains that, introduction of complementary foods at the appropriate age promotes development of speech through jaw and muscle development. According to Agedew et al (2014) and USDA (2009), introducing complementary foods before the recommended age can displace breast milk because it prevents the infant from consuming sufficient amounts of breast milk. This will increase the risk of
getting infections like diarrhoea as a result of decreased intake of protective factors present in breast milk. The displacement occurs because the complementary food prevents the child from consuming adequate amounts of breast milk. This, in turn, promotes decrease in weight of the child and eventually causes malnutrition. Late introduction of complementary foods may increase risk of nutrient deficiencies and rejection of foods. The latter usually arises because the child becomes used to being suckled, involved in bottle or breastfeeding which is easier and hence tend to face difficulties with developing abilities to eat on their own (USDA, 2009).

For adequacy, the complementary food must contain nutrients in amounts that meet the child’s nutritional needs (WHO, 2002). Thus, in addition to breast milk, the food must be dense in nutrients; protein, energy and micronutrients so as to meet a child’s nutritional needs. The small size of the stomach is another factor that should be considered when feeding children to meet their energy and other nutrient needs. The food should not be too much but rather energy dense for a small quantity fed and also packed with the right proportions of all other nutrients needed.

For a complementary food to be safe, it must be cooked under strict hygienic conditions in order to reduce the child’s is exposure to food-borne infections. Again, the food must be stored under hygienic conditions to prevent contamination. It also involves the use of clean spoons, hands and utensils during feeding. It, however, prohibits the use of teats and bottles (WHO, 2002). USDA( 2009) explains that teats and bottles are prohibited because they teach a child how to eat complementary foods wrongly. They also increase risk of a child choking on food because the nipples of teat are usually widened in order to suit complementary foods. When this happens, food in the bottle flows rapidly into the mouth of the child and may cause choking.
Lastly, properly feeding children of complementary feeding age means that food should be given based on the child’s cues of hunger and satiety. Thus, a child should only be fed when he/she shows signs of hunger and feeding must cease when he/she show signs of being satisfied (WHO, 2002). Proper feeding also involves the use of appropriate meal frequencies. Dewey (2002) explains that appropriate meal frequencies are important because extreme displacement of breast milk will occur if meal frequencies are greater than required. Meal frequencies increase with increasing age of the child. The following guidelines on meal frequencies are therefore given; 2-3 for 6-8 months old children, 3-4 meals for 9-11 and 12-24 months old children with addition of a snack such as a piece of fruit for the latter (Dewey, 2002).

2.3 Trends in the Nutritional Status of Children: Globally, Africa and in Ghana

A report on global nutrition recorded 159 million (23.8%) children being stunted in the year 2014, 50 million (7.5%) wasted and 41 million (6.1%) being overweight out of 667 million children under age five worldwide (Haddad, 2016). In Pakistan, 45% of children below 5 years of age are stunted, 30% underweight and 11% wasted. The rates of these three indicators were obtained only from children with preceding birth interval less than 24 months and their mothers’ nutritional status measured, with their BMI (National Institute of Population Studies [NIPS] [Pakistan] and ICF International, 2013). Currently, 24% of children under five in the whole of Latin America and Caribbean region are stunted due to poor nutrition. Their poor nutrition is as a result of frequent disasters that occur in these regions. Approximately 43% and 24% of children under five are in a state of chronic malnutrition in Guatemala and Haiti respectively (UNICEF, 2011). India has the largest number of children under five who are moderately or severely stunted and they account for 38% of the global burden. India again records the highest number of children who are moderately and severely wasted (Tiwari et al., 2016).
Of all children under five years in Africa, 58 million children were stunted as at 2015, 13.9 million wasted and 10.3 million overweight according to the Africa Nutrition Scorecard 2015. According to the 2013 Nigeria DHS, 37% of children under five are stunted, 18% are wasted and 29% are underweight (National Population Commission [Nigeria] and ICF International, 2014). There has been an improvement in the proportion of stunted children from 41% as at 2008 to 37% in 2013. Also in Kenya, currently 26% of children under five are stunted, 11% underweight and 4% wasted. Wasting is highest in children between 6-8 and 9-11 months and this may be because this is the period where complementary food is introduced and it may vary in terms of quantity and dietary quality. However, the trend in nutritional status from 1998 to 2014 shows an overall improvement; 38% to 26% for stunting, 7% to 4% for wasting and 18% to 11% for underweight prevalence (Kenya National Bureau of Statistics and ICF International, 2015).

The 2014 Ghana DHS also reported nutritional status of children below five years according to their age groups. It was reported that amongst all children under five years, those between the ages of 24-35 months are more stunted with a percentage of 28.2% while those between 6-8 months are less stunted with a percentage of 5.9%. For only breastfeeding children, those between the ages of 18-23 months are more stunted with a percentage of 21.9% while those between ages 6-8 months remain the less stunting group as above. Of all children under five years, males are more stunted with a percentage of 20.4% and females 17% (Ghana Statistical Service, 2015).

The prevalence of wasting among male children under five years is 4.3% while that of females is 5.1% (Ghana Statistical Service, 2015). It was also recorded that among children under five years, high prevalence is seen in those between the ages of 9-11 months with a percentage of
10.6% and least in children between the ages of 36-47 months with a percentage of 1.4%. The proportion of children who were stunted has improved; from 35% in 2003 to 19% in 2014. That of wasted children reduced from 8% to 9% between 2003 and 2008 and further to the current 5% in 2014. The proportion of underweight children has also seen a remarkable improvement as it is currently 11% compared to 18% in 2003. Between 2003 and 2008, the level of overweight among children under five years was fluctuating between 4% and 5%. However, its level has decreased to 3% currently (Ghana Statistical Service, 2015).

2.4. Physiology and Importance of Iron in Nutrition and Health

Iron is a very important nutrient for blood production in humans. Approximately, 70% iron in the body is found in the red blood cells and in myoglobin which are the cells of muscles. Haemoglobin is vital for transferring oxygen in the blood from the lungs to the tissues whilst Myoglobin functions by accepting, storing, transporting and releasing oxygen (Milman, 2011). An estimated 6% of body iron forms part of certain proteins which are necessary for energy metabolism and respiration and involved in the synthesis of collagen and some neurotransmitters as a component of enzymes. Another important function of iron is its need for proper immune function. It is approximated that in a well-nourished individual, the body contains 3-4 g of iron (Milman, 2011).

Iron absorption in the healthy individual is controlled by four major factors and these are physiological need of iron, iron bioavailability in dietary intake, dietary iron intake and adaptation (Mahan and Escott-Stump, 2008). Iron deficiency is mainly the result of insufficient dietary iron intake. Dietary iron is made of the heme and non-heme iron. The heme iron has a characteristically good bioavailability with favourable absorption gastrointestinally and is present in animal food products like poultry, meat and fish. Non-heme iron which has its origin
in plant food products, however, has a poor bioavailability with decreased absorption. Non-heme iron is present in vegetables, cereals, whole grains and legumes and its absorption requires the presence of vitamin C (Milman, 2011).

About a quarter of the iron in the body is stored as ferritin, found in cells. Women have only about 300 mg (which is enough for about 6 months) whereas an adult male on the average has about 1,000 mg of stored iron (which is enough for about 3 years). When there is a low intake of iron for a long time, the iron stores can become depleted; leading to low haemoglobin levels and ultimately results in iron deficiency anaemia. Infants are born with iron stores enough to last about the first 6 months of life. These stores of iron are dependent on the maternal intake of iron during pregnancy (Griffin & Abrams, 2001).

2.4.1 Bioavailability and Absorption of Iron

Two forms of iron exist in food: these are non-heme and heme. The heme iron is absorbed more readily by the body, and rich food sources includes animal products like red meats (from goat, cow etc.), poultry, and fish. The non-heme form is found in plant foods such as green leafy vegetables and legumes as well as fortified foods such as grains, infant formulas, and cereals. Most of dietary iron is consumed in the non-heme form and is less readily absorbed (Mahan and Escott-Stump, 2008).

2.4.2 Enhancers and Inhibitors of Iron Absorption

The extent and amount of iron absorbed from food is dependent on its constituents/components thus the quantity of enhancers or inhibitors present in that food. According to Mahan and Escott-Stump (2008), some of the components of food that enhance iron absorption includes the water-soluble vitamin C (ascorbate). As a strong reducing agent, vitamin C helps reduce
iron (III) to iron (II) which is more readily available. It also counteracts the effect of other inhibitors. Unfortunately, people are usually ignorant of the importance of this fact and may disregard the food sources of vitamin C as being food hence do not add it as an important part of a meal. Other factors that enhance vitamin C absorption includes germination and fermentation of cereals and legumes. Usually, heme sources like red meat promotes the absorption of iron from other less bioavailable food sources.

The inhibiting factors of iron absorption includes phytates which can be found in beverages like tea and coffee hence these should not be consumed with a meal or shortly after a meal. The same is known for calcium which is rich in food sources like milk and milk products including cheese, yoghurt etc. (Mahan and Escott-Stump, 2008). This calls dietary improvements and the adoption of dietary diversity

2.4.3 Implications of Inadequate Supply of Iron

Deficiency of iron supply to the bone marrow leads to impairment in haemoglobin synthesis and a decline in the circulating red blood cells. This subsequently leads to iron deficiency anaemia (IDA) with a low haemoglobin concentration. Anaemia is typically microcytic with a low mean red blood cell volume and hypochromic with low haemoglobin concentration in the red blood cells, referred to as low mean corpuscular haemoglobin and low mean corpuscular haemoglobin concentration. The contribution of iron deficiency to the overall burden of anaemia is approximately 50%. This proportion may, however, vary according to different population groups influenced by the unique demographic variables (WHO, 2015).

Iron deficiency anaemia is also commonly caused through blood loss. This loss of blood may be as a result respiratory tract bleeding. Other conditions of iron deficiency anaemia include
continual blood loss from the gastrointestinal tract due to infections, intestinal parasites and inflammatory bowel disease. Women in their reproductive years who experience heavy blood losses during their menstrual periods are at risk of developing IDA. Recurrent uterine bleeding associated with some gynaecological diseases increase the risk of IDA (Milman, 2011). Although iron deficiency is endemic, certain diseases cause iron overload, (where the storage capacity of ferritin is exceeded). The excess iron forms a precipitate around the ferritin particles and causes them to aggregate. These iron-rich aggregates are called hemosiderin. IDA characteristically can be treated with iron, either by the oral route or intravenously (Milman, 2011).

2.4.4 Complementary Feeding and Iron

Poor feeding practices and nutrition during the complementary feeding period can result in an increased risk of growth failure and nutritional deficiencies of which iron is prime and may have long term negative effects on overall growth, health and cognitive development (Fleischer et al., 2000). According to Mahan and Escott-Stump, (2008), the iron required in complementary foods based on age are; 6.8mg/d for 6-8 and 9-11-month-old children and, 3.8 mg/d for children aged 12-23 months. These needs can only be met through consumption of iron rich foods such as liver, fish, beef and egg (which however has a questionable iron bioavailability). Only about 30% of dietary iron is absorbed.

2.5 Anaemia

Anaemia occurs when the number and size of red blood cells, as well as the haemoglobin (oxygen-carrying capacity) concentrations of the red blood cells, falls below a specific level thus it is not enough to meet the body’s physiological needs of the individual (WHO and Chang, 2011; Elder and Ransom, 2003). Haemoglobin is an essential protein in the red blood cells
which help to transport oxygen from the lungs to other tissues through the blood stream body. The oxygen is needed in the body specially to enhance mental capacity and physical ability (Wardlaw, 2003). The red blood cells usually wear out after a period of about 120 days. Thus, the body needs constant replacement of the cells for normal functions. Mahan and Escott-Stump (2008) state that anaemia is usually as a result of imbalances between red blood cell production and blood loss except in cases of abnormal blood loss. The normal functioning of the bone marrow helps to maintain the balance of the red blood cells. Hence any process that interferes with the production of red blood cells can cause anaemia.

The onset of anaemia for any individual is characterised by the reduction in the general well-being of the individual, tiredness, lethargy and decreased work performance weakness, pale skin, shortness of breath and physical capacity (Horton and Ross, 2003). The child of an anaemic pregnant woman is likely to be faced with intrauterine growth restrictions, low birth weight, being anaemic at birth, poor cognitive development (all with different implications) and to a greater extent, perinatal mortality (Haggaz et al., 2010 and Lone et al., 2004).

### 2.5.1 Classification of Anaemia

Several methods can be used to classify the types of anaemia. The common classifications are based on pathophysiology and morphological changes. The morphological classification is based on the size or the volume of the red blood cells as well as the colour of the red cells due the haemoglobin concentrations (Sarojini et al. 2011) and they are:

Hypochromic microcytic anaemia: the red blood cells are pale in colour (hypochromic) due to reduced haemoglobin concentration and have small mean corpuscular volume (microcytic) (Brennand et al., 2005). Examples of the types of anaemia that fall within this category are iron
deficiency anaemia which is caused by deficiency in iron, thalassemia caused by deficiency in the synthesis of globin which is a component of the red blood cells (Mahan and Escott-Stump, 2008).

Normochromic macrocytic anaemia: the red blood cells have a normal level of haemoglobin and colour but the mean corpuscular volume is large (Brennand et al., 2005). Examples include pernicious anaemia and megaloblastic anaemia.

Normochromic normocytic anaemia: in this case, the colour and size of the red blood cells are normal however there is imbalance between the formation and the decomposition of the red blood cells (Wick et al., 2003). In this case, the types of anaemia are due to factors that lead to blood loss in many ways such as severe accidents and child delivery, factors that lead to hemolysis such as infestations from parasites like hookworms and Plasmodium like and also factors that lead to decrease in the erythropoietin production like renal and liver disease (Mahan and Escott-Stump, 2008).

The pathophysiological classification is based on the cause of the anaemia and is related to the alterations of physiological processes due to the onset of diseases and any factors that lead to the metabolic and regulatory changes of the red blood cells. The causes are divided into two broad aspects: Defective production of the red blood cells or impairment in the production of the red blood cells and factors that increase the rate of blood loss either by bleeding or premature destruction (hemolysis). Despite the morphological classifications, all the types of anaemia have either one or both aspects stated above as a cause of the type of anaemia.
2.5.2 Types and Causes of Anaemia in Children

At birth, an amount of iron is stored in the liver of a baby which is enough for building the blood of the infant till about four months according to Wardlaw, (2003). Thus, anaemia in infants during their early months; before four months of life may be due inadequate prenatal stores of iron caused by low intake of iron rich foods by the mother during pregnancy, premature birth or multiple birth. A child may have good stores of iron at birth but the iron gets depleted as they develop, and anaemia can set in.

Globally, anaemia in infants as they mature is caused mainly by deficiencies in nutrients linked to erythropoiesis like iron, vitamin A, vitamin B\textsubscript{12} and folate, with deficiency in iron being the most prevalent cause of anaemia. These deficiencies set in when monotonous diets lacking these nutrients are continually fed to the infants or when the infants are given diets which consist of milk as a major portion for an extended period of their early lives (Wardlaw, 2003). Anaemia as a result of malaria and worm infestations have also for a long period of time been recognised amongst children especially those in developing countries (Jonker et al., 2012; Jamison et al., 2006). Other underlying factors can further increase the susceptibility of infants to anaemia.

2.5.2.1 Iron Deficiency Anaemia

Iron is a necessary mineral required by humans. About 70\% of the iron in the body is found in the red blood cell. It is a component of the haemoglobin responsible for transferring oxygen in the blood from the lungs to the tissues which helps to sustain life. It also forms part of enzymes that are used for many processes such as the production of energy to work in order to enable the body carry out its functions (Wardlaw, 2003).
Iron can be obtained from diet. However, dietary iron is in two forms one is heme iron which has a high bioavailability, it is not hindered by dietary constituents and found mainly in animal based foods such as poultry, red meat and fish. Thus, for obtaining maximum iron from foods, these animal based foods must be consumed more. The second is non-heme iron, found in both animal sources and plant sources such as green leafy vegetables and absorption is affected by components of the food being consumed such as phytates in foods like legumes and grains, tannic acid in tea and coffee, oxalates and fibre in foods. Vitamin C, however, enhances the absorption of non-heme iron in the food (Mahan and Escott-Stump, 2008).

Iron deficiency is the most prevalent cause of anaemia amongst infants all over the world. In developing countries such as Ghana, deficiency in iron is as a result of poor dietary intake of iron rich foods primarily due to low economic status. There is also decrease in the absorption of dietary iron due to high prevalence of infections or intestinal blood loss usually as a result of helminths infestations (WHO, 2008). Mothers also consume less food rich in iron or consume foods that inhibit the absorption of iron the diets (Elder and Ransom, 2003). This then leads to less stores of iron for the mother and consequently for the child.

Generally, when the supply of iron to the bone marrow is deficient it leads to impairment in haemoglobin synthesis and a decline in the circulating red blood cells. This hence is the cause of anaemia due to iron deficiency (Wardlaw, 2003). However, this occurs in three stages: initially, the iron stores for the production of the red blood cells are depleted but the rate of synthesis of the red blood cells is quite normal, later the iron stores are so low that enough is not transported for the synthesis and finally the cells which are small in size and deficient in haemoglobin replace the old, worn out cells. This leads to anaemia which is associated with low haemoglobin synthesis (hypochromic) and low transport of iron (Berdanier et al., 2008).
2.5.2.2 Megaloblastic Anaemia

In the 19th century, another form of anaemia was discovered to be associated with large red blood cells than the normal size. The cells were identified to have different precursors called megaloblasts and this led to the establishment of megaloblastic anaemia associated with this characteristic but found to be as a result of deficiency in folic acid or vitamin B\textsubscript{12} (Kraemer and Zimmermann, 2007).

Folate and vitamin B\textsubscript{12} are required for creating new blood cells. During deficiencies of these vitamins, DNA synthesis and division of the red blood cells is impaired. The inability of the cells to divide give rise to the large cells called the macrocytic cells (Brennand et al., 2005). Folate is considered greatly in treating anaemia, as it is the leading cause of vitamin deficiency anaemia although unlike iron, the extent to which folate deficiency contributes to anaemia has not yet been thoroughly investigated. According to Kraemer and Zimmerman (2007), deficiency in infants is associated with prolonged poor nutrition or dietary deficiency of folate of the child and faulty absorption accompanied with increased needs of the child.

Foods rich in folate includes organ meat, Brussels sprout and fresh green vegetables. Folate, however, has limited stores in the body, it is quickly depleted within about 2 to 4 months if not continually obtained from diets and it is easily lost during harvesting, storage, and distribution and cooking. Thus, water used in preparation of foods containing folate is advised to be consumed. (Crowley, 2007).

2.5.2.3 Pernicious Anaemia

It is caused by deficiency in Vitamin B\textsubscript{12} by decrease in the red blood cells as a result of the neutralisation of the intrinsic factor needed to absorb Vitamin B\textsubscript{12} for the formation of the red
blood cells. With deficiency in Vitamin B₁₂, megaloblastic anaemia is also observed. The daily requirements for Vitamin B₁₂ is low in the body hence body stores are generally high thus deficiencies of Vitamin B₁₂ are not usually common. However, deficiencies in infants are usually seen within the first year of life as a result low storage during gestation, being breastfed by mothers who are already deficient in Vitamin B₁₂ or have low intakes of rich food source or are generally vegans (Kraemer and Zimmermann, 2007). Breast feeding children whose mothers do not obtain early diagnosis of Vitamin B₁₂ deficiencies are also at risk of pernicious anaemia as high in takes of folate according to can mask the deficiency of Vitamin B₁₂. Pernicious anaemia is also characterised by megaloblastic anaemia as well as degeneration of the spinal cord. Liver, salmon, red meat and most animal source foods are rich in Vitamin B₁₂.

2.5.3 Vitamin A Deficiency in Relation to Anaemia

Some surveys have shown a relationship between vitamin A and anaemia. Other studies have also shown how improving the vitamin A status have improved the haemoglobin levels (Semba and Bloem, 2002). According to Kraemer and Zimmermann (2007), deficiencies in Vitamin A can affect the production of red blood cells. This can arise from defects in absorption, release or transport of iron to the bone marrow; all of which are functions of Vitamin A. Good food sources as suggested by (Pencharz and Ball, 2004) are fruits, green leafy vegetables and liver of animals.

2.5.4 Helminths Infestations and Anaemia

Infestation by helminths (worms) is also prevalent in the tropical regions where surveys have shown that its prevalence is due to poor sanitation and poverty. At any location, personal hygiene practices like washing of hands and practices such as disposal of human waste and refuse if not done appropriately can also cause helminths infestations. Soil transmitted
helminths especially hookworms are the group that cause the infestation most in humans within these regions (Kumar et al., 2014; Dickson et al., 2000). These helminths have also been associated with anaemia especially in the regions where they are most prevalent. The worms rely on a host to continue their life cycle. In their host, the hookworms they feed on the blood by creating holes in the intestinal walls which leads to blood loss (Kumar et al., 2014). It also leads to the loss of haemoglobin in the urine and faeces and a consequent high demand for iron. When dietary intake of iron is not enough to meets the needs of the individuals, it leads to iron deficiency and anaemia.

In treating helminths infections, the degree of treatments depends on the intensity of the infection (Bennett and Guyatt, 2000). However, prevention of infections can occur if there is good environmental sanitation (proper disposal of human waste), availability of safe drinking water and good personal hygiene practices of both the young and elderly.

2.5.5 Malaria and Anaemia

According to Mohandas and An (2009), malaria is the most serious parasitic disease caused by mosquitoes that affects humans. About 500 million people are affected with malaria with about 1 million people, usually infants and young children dying as a result. It is caused by five species of the Plasmodium genus with P. falciparum being the cause of majority of the disease in Africa. These parasites thrive well in areas containing water such as swamps, ponds, paddles, lagoons and marshy areas as well as exposed containers that can hold water (DeSilva and Marshall, 2012). All of which are characteristics of poor sanitation which is found mostly in developing countries, hence the prevalence in these areas.
In 2015, it was estimated by WHO that about 429,000 deaths occurred due to malaria, with about 92% occurring in Africa. Children are vulnerable to malaria due to lowered immunity (Mohandas and An, 2009). According to WHO (2015), the rate of infant death by malaria has reduced since 2000, however death of children still occurs especially in sub-Saharan Africa. Aside the availability of water for development of the eggs of the mosquitoes, the female Anopheles mosquitoes thrive well within temperatures of about 25°C and 30°C, making tropical regions a suitable place for the survival of the mosquitoes (WHO 2015). In areas where malaria is prevalent, anaemia has been shown to be present as well, especially amongst children in their first 3 years of life.

Mohandas and An (2009) explains that the manner of development of anaemia by malaria parasites is not fully known, however, all the phases during the cycle of the parasite interacts with the red blood cells in a way. The red blood cell production either gets depleted in the bone marrow or the cells get destructed leading to anaemia (WHO, 2015; Menendez et al., 2000). In addition, aside the direct link between the parasites and the red blood cells, the inflammatory nature of the disease prevents the recycling of iron from the liver (Nweneka et al., 2009) and this may decrease the amount of iron needed for erythropoiesis causing low blood levels as worn out red blood cells will not be adequately replaced.

2.6 Anaemia Situation amongst Children

Anaemia is a wide spread public health problem that usually affects pregnant women and children especially in developing countries (Jonker et al., 2012). According to the 2011 Global Prevalence of Anaemia report by WHO (2015), all countries that provided data have either of the classifications of anaemia present. In 2008, WHO provided an estimate of the prevalence of anaemia in Africa to be 64.6%. A prevalence of above 40% is a public health concern which
is severe and must be addressed. Anaemia amongst children in developing countries is primarily due to insufficient dietary iron as well as other factors such as poor health of pregnant women, early weaning, insufficient safe drinking water, inadequate hygiene and sanitary conditions, poor nutrition of the child (WHO, 2008).

All these factors are usually associated with poverty. Thus, even in the developed countries, children in families that are poor may also have a higher risk of being anaemic as such characteristics may be dominant. The socio-economic status of a household can also affect the prevalence of anaemia. Households of members with higher levels of education and high-income occupations are more likely to provide a better life for their children so as to reduce the factors stated earlier which are likely to cause anaemia in infants (Simbauranga et al., 2015). Previous studies carried out also revealed that anaemia is common in infant males than females (Chaparro, 2008).

In Ghana, prevalence is highest amongst children below the age of 2 years and Ewusie et al., 2014, Ghana Statistical Service, 2004, 2009 and 2015 reported prevalence rates of 85.1%, 81.23%, 83.15% and 77.45% respectively. Even though there has been a decrease over the years from 85.1% in 2003 to 66% in 2014 according to the Ghana Statistical Service, anaemia is still considered as a public health problem in Ghana, as rates above 40% according to the WHO cutoffs are considered as such.

Table 2.1 shows the prevalence of anaemia in some selected countries, explaining that although some of these countries such as Norway and USA are developed, there is still some prevalence of anaemia.
Table 2.1 Anaemia amongst infants below the ages of 5 in some selected countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Percentage Hb &lt;11g/dL</th>
<th>Level of public health significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>59</td>
<td>Severe</td>
</tr>
<tr>
<td>Norway</td>
<td>14</td>
<td>Mild</td>
</tr>
<tr>
<td>Oman</td>
<td>41</td>
<td>Severe</td>
</tr>
<tr>
<td>Ghana</td>
<td>76</td>
<td>Severe</td>
</tr>
<tr>
<td>USA</td>
<td>6</td>
<td>Mild</td>
</tr>
<tr>
<td>South Africa</td>
<td>27</td>
<td>Moderate</td>
</tr>
<tr>
<td>Brazil</td>
<td>24</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

Source: WHO (2015)

2.7 Challenges and Strategies to Overcome Anaemia Prevalence

2.7.1 Challenges of Anaemia Prevalence

There are some reasons why anaemia is still a worldwide problem. The prevalence of anaemia has mainly been attributed to iron deficiency thus the slow pace in its reduction. The haemoglobin levels are mainly used to screen for anaemia for a large population and this underestimates its prevalence. Using the haemoglobin levels alone overlooks the role of other causes like deficiencies in the other nutrient and also malaria which is widespread in Africa especially, and even accounts for more cases of the prevalence of anaemia than the nutritional causes (WHO and FAO, 2006).

The reluctant nature of government officials in countries to invest in improving diets and social disproportions is also one of the reasons why anaemia is still a global problem. In addition, the health systems available to the poor and less privileged who are usually the population amongst which anaemia prevalence is higher are of low standards making them unreachable to good health care (UNICEF, 2012) systems, thus aggravating infestations and illness which contribute to anaemia. Also, the inaccessibility to good health care systems makes the various interventions like the provision of iron and folic acid supplements, antenatal health talks unavailable to the less privileged.
Anaemia, as stated, is prevalent in developing countries and within these countries, areas with high levels of poverty often have the highest prevalence. Usually, the diets of these poor people are low in quality than quantity. This is because the diets composed mainly of carbohydrates which are usually available and provides them with the needed energy at a lower cost. The bioavailability of the nutrient components is so low and further lessened as the intake is coupled with phytates or high amounts of fibre (Elder and Ransom, 2003).

Just like the global situation, the Ghana Demographic Health Survey 2014, does not explicitly give data on the risk factors of anaemia but some few studies have shown a relationship between anaemia and helminths infestations, malaria and fever amongst infants. Some activities have been put in place to overcome anaemia in many countries however a lot of these countries have not coordinated strategies to combat the prevalence in their countries. In Ghana, routine deworming of children has been instituted. However, the coverage for deworming have not improved over the years from 2008 to 2014. There has only been a 4% decrease with the current prevalence of 38% worm infestations (Ghana Statistical Service, 2015).

Also, data on the intake of micronutrient deficiencies in Ghana are so scanty that there is not much to show the relationship between information about their dietary intake and anaemia (SPRING, 2016). Findings from the 2016 Analysis of Anaemia in Ghana has shown that the factors that cause anaemia other than iron deficiency has not been addressed much thus, anaemia remains a problem in Ghana (SPRING, 2016).
2.7.2 Strategies to Overcome Anaemia Prevalence amongst Infants in Ghana

Taking into consideration the trends of the prevalence of anaemia especially in the developing countries, it cannot be certain that anaemia can be curtailed in the next decades if careful strategies are not put in place (Stoltzfus et al., 2004). Balarajan et al., (2011), states that in controlling anaemia, dietary diversity should be encouraged to improve the intake of micronutrients, prevention and treatment of malaria and helminths and an overall reduction in the burden of infections and diseases should also be considered. Kraemer and Zimmerman (2007), states that nutritional anaemia should be seen as a reflection of purchasing power and hence to undergo a nutritional intervention, there must be strategies to assuage poverty. In addition to dietary diversity as a means of improving micronutrient intake, there should also be micronutrient supplementation which should be easily accessible especially by the poor and those in need of them.

Ghana has also adopted the fortification of foods like vegetable oils and wheat flour. Almost all of the oils sold on the market these days are fortified. However, most people in rural areas and remote areas do not purchase these oils and hence do not benefit from this fortification. The wheat flour fortification has not yielded much outcome as general consumption in Ghana is low. Attention on fortification and bio fortification should be given to the staple foods which are consumed most by infants such as maize and rice in Ghana during cultivation. The processing of such foods should be centralised and subsidised so that the target population can have access to them.

In general, to implement some of the strategies stated above. There should be figures showing the prevalence of anaemia caused by other factors rather than only iron deficiency so as to channel the resources available even if little to the right places. In addition, education should
be given to all groups of people to increase sensitization on the causes, prevalence and effects of anaemia and ways to reduce anaemia prevalence so that strategies and interventions can be useful.

2.8 Assessment of Nutritional Status

2.8.1 Anthropometric Methods

Duggan, (2010) describes anthropometry as a useful tool for monitoring growth and nutritional assessment which has been used for a long time as a diagnostic tool for grading malnutrition. He further describes it as a deceptively simple tool for nutritional assessment of individuals because of its objectivity and relatively low technology required in its usage. Anthropometric measurements are most widely used indicators for nutritional status in a community. It can be used to determine prevalence of malnutrition in a surveyed population (WFP & CDC, 2005). It is also used to assess growth and development, especially in young children.

Anthropometry involves taking body measurements such as weight, height and comparing them to the WHO growth standards. These body measures are used to formulate indicators that give some information on the nutritional status of the child. There are three main indicators used in assessing nutritional status of children by anthropometry they are height-for-age, weight-for-height and weight -for-age.

2.8.1.1. Anthropometric Indices

Height -for-age: It measures linear growth. Faltering in linear growth is detected as low height for age and is referred to as stunting. Stunting is a reflection of chronic malnutrition which results from prolonged inadequate nutrient intake (GSS, 2011). Stunting is the greatest problem of the three indicators and can also result in underweight. 31% of children in low and middle-
income countries are stunted (Prentice et al., 2008). Even in Ghana, stunting has been the greatest problem, 28% of the children under five are stunted (Ghana Statistical Service (GSS), Ghana Health Service (GHS), & ICF Macro, 2009).

Weight-for-height: This measures the child’s weight versus their height. Low weight for height is referred to as wasting. This is a measure of acute malnutrition that is recent nutrition deficiency (Prentice et al., 2008). This indicator shows significant changes associated with the availability of food or disease prevalence (GSS, 2011).

Weight-for-age: This assess the weight of the child for his age and is a measure of acute and chronic malnutrition (Prentice et al., 2008). Low weight-for-age is referred to as underweight (GSS, 2011).

2.8.2 Biochemical Methods

Biochemical assessment is used in assessment of the nutrients in the body. It involves collection of laboratory samples to assess nutritional status. Samples such as blood and urine are taken from the individual. These tests are done to assess the level of biological markers in the body. These markers are used to determine levels of nutrients the body contains (Maqbool et al., 2008).

2.8.3 Clinical Assessment

Signs of malnutrition may be seen on the body of the individual. These signs can be seen by close observation of experts. Maqbool et al., (2008), elaborates on clinical assessment; it involves the close examination of ones’ physical body such as skin, hair and teeth. This is done to find evidence of specific nutritional deficiencies. Clinical assessment serves as a valuable aid in detecting nutritional deficiency since it requires little expertise.
Signs of malnutrition may be seen on the body of the individual. These signs can be seen by close observation of experts. (Maqbool et al., 2008) elaborates on clinical assessment; it involves the close examination of ones’ physical body such as skin, hair and teeth. This is done to find evidence of specific nutritional deficiencies. Clinical assessment serves as a valuable aid in detecting nutritional deficiency since it requires little expertise.

2.8.4 Dietary Methods

This involves a measure of dietary intake and one’s feeding ability. It can be used to measure both nutrient and food intake. Dietary assessment involves different methods. It includes individual dietary assessments, food frequency questionnaires, household survey methods and simple food list. It is an essential component of nutritional assessment because it provides information about the amount, and quality of food consumed and also eating patterns and behaviours of the family (Maqbool et al., 2008). In nutritional assessments of children, it also gives an idea of the child’s intake over a specified time period. It is most at time used as a reflection of the child’s diet.

2.8.5 Environmental Methods

In the assessment of nutritional status, it is very important to consider the nature of environment in which the individuals reside. This is crucial because it impacts directory on nutrition and health status of the individual. Some useful things that are considered in assessing the environment bothers on sanitation and hygiene. Some of these things include the nature of the refuse disposal site, toilet facility that is available in the household, source of drinking water for cooking and drinking, availability and use of mosquito nets, nature of the drainage systems, hand washing facilities and practices amongst others.
2.9 Review of Efficacy Trials

Several studies conducted here in Africa and around the World, that focused on the efficacy or effectiveness of an intervention on the nutritional status of children were reviewed. These studies varied in the nature of the intervention given. Some of the interventions explored was the use of nutrition education, food alone, fortification and increase in the energy density of complementary food using modified technology (Dewey & Adu-Afarwuah, 2008). A number of different outcomes were examined and it included: growth, morbidity, child development, micronutrient intake, iron status, vitamin A status, and zinc status. This review will, however, focus on those interventions that used fortified complementary foods as the approach with growth and iron status as the outcome since that fits well into the scope of this current study.

Considering growth as an outcome, 6 efficacy trials explored the effect of fortified complementary foods on growth with the same amount of energy provided in both comparison groups thus control and intervention groups. Of these studies, 3 employed home fortification using micro nutrients supplements. 2 out of this 3 studies involved children between 6-12 months of age were conducted in Ghana and South Africa respectively (Adu-Afarwuah et al., 2007 & Smuts et al., 2005) and the third involved children between 6-18 months of age from Cambodia (Giovannini et al., 2006). The remaining 3 other studies employed fortification at a central point during processing. 2 of these studies used legume/cereal mixes (Faber et al., 2005 & Larstey et al., 1999) and the other used a milk based formulation (Dhingra et al., 2004) were conducted in South Afric, Ghana and India respectively. However, compared to the first 3 studies in these latter studies, the control groups received unfortified products.

With regards to weight gain, only 1 out of the 6 studies showed significant improvement in growth, thus the one that used a milk based fortified product in India (Dhingra et al., 2004). At
the end of the 12 months of supplementation, the children in the intervention group significantly gained more weight (by 0.21 kg, 95% CI 0.12, 0.31 kg) and greater WLZ (mean difference 0.16Z, 95% CI 0.03, 0.30Z) and WAZ (by 0.24Z, 95% CI 0.11, 0.36Z) as compared to the control group.

Similarly, for linear growth, it was only in the India study that recorded significant effect of the fortification (Dhingra et al., 2004). At the end of the study, the children in the intervention group recorded greater length gain of (8.6 ± 1.14 vs. 8.10 ± 1.37 cm, P < 0.05) and LAZ (by 0.19Z, 95% CI 0.12, 0.26) compared with the control group.

Considering iron as an outcome Dewey & Adu-Afarwuah (2008) reviewed several efficacy trials and found that the overall average effect across seven of the studies was an increase of 0.6 g/dL change in Hb and -17 percentage points difference in the prevalence of anaemia. In Ghana, Lartey et al., (1999) found a relatively small impact on anaemia thus reduction by -4 percentage points difference in anaemia prevalence which was attributable to the other possible causes of anaemia such as malaria and worm infestation.

According to Dewey & Adu-Afarwuah (2008), several proximal factors affects linear growth during complementary feeding period. These interlinked proximal factors are quantity, quality of complementary foods, morbidity and breast milk intake. The quantity of complementary foods given impacts positively on the linear growth, however, the relationship between the quantities of food received and linear growth is modified by the dietary quality of the food in terms of its nutrients density as well as by the intake of breastmilk. Intake of complementary foods reduces breast milk consumption and thereby increases linear growth. There is an inverse relationship between morbidity and linear growth. In the sense that, a higher rate of morbidity
decreases linear growth. However, sustained breast milk intake also improves on morbidity because of the immunoglobulins in it. The inter linkages between these proximal factors are depicted in Fig 2.2.

Source: (Dewey & Adu-Afarwuah, 2008)

**Figure 2.1:** Conceptual framework of the proximal factors affecting linear growth during the period of complementary feeding
CHAPTER THREE

3.0 METHODOLOGY

3.1 Research Design and Study Area

3.1.1 Research Design

The study was a double blinded randomised controlled trial. It involved 6 month feeding period which was followed with post intervention evaluation at the 8th month. The post evaluation was to give indication of what happens if the feeding is stopped. This was to see the actual effect on the test group who received the food. The study was in two phases involving an initial cross-sectional evaluation where pre-tested semi-structured questionnaire was used to assess information concerning the mothers/caregivers knowledge and complementary feeding practices. The second phase of the study was a randomised controlled field trial. Under the second phase, the study communities were randomly assigned to receive either the test food or the control. The control group did not receive the test products but were rather fed with a placebo (the usual infant cereal) and the intervention group these received iron fortified infant cereal. The foods were coded as A and B so both the investigators and the subjects were blinded and it was randomly assigned by simple balloting such that each group received either of the 2 foods. After preliminary analysis, the code was broken and it was known that those who received food A were the control group and those in group B received the intervention. The second phase of the study was to help assess the efficacy of the test product on the nutritional status of the children who were enrolled in the test group. To assess the change in nutritional status, anthropometric, biochemical and clinical measures were taken at baseline, during feeding and after the period of feeding. Thus, there was a baseline (pre-intervention) evaluation on all variables of interest followed with time series of data collection (2 months interval that is; 2nd month, 4th month and 6th month during intervention and 8th-month post intervention evaluation).
3.1.2 Study Area
This study was carried out in the La Nkantanang Madina Municipal District found in Greater Accra Region, Ghana. It was formed in the year 2012 and is one of the sixteen Metropolitan, District Assemblies and Municipalities within the Greater Accra Region. It was created from the then Ga East Municipality and covers a total of about 70887 km$^2$ of land. The study area is generally urban (84%). The communities involved were Ayi Mensah, Danfa, Kweiman, Adoteiman and Ottinibi. There are about 259668 people living in the municipality (National Population and Housing Census, 2010).

3.2 Study Population, Sampling and Sample Size Calculation

3.2.1 Study Population
The study participants were healthy children between the ages 6-18 completed months who resided in Ayimensa, Danfa, Kweiman, Adoteiman and Otinibi. Details of the trial such as purpose, duration, procedures, potential benefits and risks was explained to the mothers/caregivers in a language of their choice and in terms they best understood.

3.2.2 Sampling
The Greater Accra region has 16 administrative regions. Out of these 16 regions, 1 was selected randomly through balloting and it was the La Nkwantanang Municipal District. The district was found to have 15 peri-urban communities. The names of these 15 communities were written on paper and concealed in a box. The box was shaken to ensure thorough mix up and then one-third (5 out of 15) of these communities were randomly selected to give a representation of the peri-urban communities. A census was carried out in these 5 communities and the area was thus demarcated into 2 groups to prevent contamination. This 2 groups were
randomly assigned to receive either of the 2 foods (test food or control food). All investigators and caregivers were blinded with respect to the food type.

3.2.3 Sample Size Calculation

Assuming an alpha level of 0.05, confidence interval of 95% and power of 90% from most field trials involving humans and assuming mean Hb level of 9.4g/dL, SD of 1.6g/dL and estimating an increase of 1.0 g/dL after 6 months intervention from a previous study by Lima et. al. (2006), the sample size was 54 in each group. This was rounded up to 100 for each group to account for 86% attrition rate. The total sample size was then 200 for both groups. This was determined as stated by Charan & Biswas (2013).

Sample size (n) = \( \frac{2SD^2}{\alpha^2} \cdot f(\frac{\alpha}{\beta}) \)

Where;

- n= sample size per each group
- \( f(\frac{\alpha}{\beta}) \)= z statistics which is 10.5 for 90% power at significance level of 5%
- d= effect size at a P-value of 0.05 with 95% confidence and
- SD= Standard deviation or variability

\[ n = \frac{2 \cdot 1.6^2 \cdot [10.5]}{1^2} \]

n = 53.76

86 % Attrition Rate=86%*53.76= 46.24

Final sample size = 53.76 + 46.24 = 100 per each group

3.2.4 Inclusion and Exclusion Criteria

Children between the ages of 6-18 completed months were enrolled as study participants. Eligible participants were not sick (self-reported) or on any sort of medication due to recent
ailment and were not allergic to wheat based foods. Subjects were also permanent residents of the study area and were willing to participate after the study protocol had been explained to the mothers/caregivers.

3.2.5 Ethical Considerations:

Ethical approval was sought from the Institutional Review Board (IRB) of The Noguchi Memorial Institute for Medical Research, University of Ghana, Legon (Approval Number: NMIMR-IRB CPN 031/15-16). Written informed consent was sought from the mothers/caregivers of all the recruited participants. The communities for the study were also sensitised through the chiefs and community elders from whom prior permission had been sought and details of the study explained to.

3.2.6 Recruitment of Participants

All participants in the study were volunteers whose mothers/caregivers agreed to be part of the study. Participants in this study were recruited over a period of one month through house to house visits. The study protocol was fully explained to the mothers/caregivers of the children and written informed consent was sought.

3.2.7 Intervention (feeding)

The children in the control group were given a placebo (the usual cereal complementary food) to complement other family foods and breast milk that are already given to the child. Those in the intervention group, on the other hand, were fed with the test product for a period of 24 weeks (thus 6 months). Since this was a double blinded randomized case control study, both the investigators and the study participants did not know which of the 2 groups they were assigned until the end of the study when preliminary analysis was run and the code was broken.
to reveal that those in Group A received the placebo and Group B received the intervention food. Since the chosen communities are closed ones (thus the settlements were not dispersed), the food was taken to them in their homes. The subjects received weekly rations of the food as this gave us the opportunity to interact and know how the feeding was going. Also, weekly follow up calls was made to monitor the feeding process. Each child between 6-8 months received 50g daily rations which contained 210 Kcal of energy. Those children between 9-11 months received about 75g daily rations which also gave them 320 Kcal of energy and all children between 12-18 months received 100g daily rations which contained 420 Kcal of energy per day. This calculations were done based on the complementary feeding requirements outlined by Dewey and Brown (2003).

3.3 Data Collection and Instruments

3.3.1 Socio-demographics

Information on participants’ socio-demographic features was collected using a pretested questionnaire. Information on age, household size, level of education, occupation, was obtained for the children and mothers/caregivers pairs.

3.3.2 Anthropometric Measurements

The weights of the children were taken using the SALTER hanging weighing scale and their recumbent length (height) recorded with an infantometer. The Mid-Upper-Arm Circumference (MUAC) was measured with non-extensible MUAC tapes. Measurements was done in duplicates and recorded as mean and standard deviations.
3.3.3 Biochemical

3.3.3.1 Haemoglobin (Hb) Concentration

Haemoglobin concentration was measured using the digital HemoCue Photometer system. This system is made up of a disposable micro cuvette coated with a dried reagent that functions as the blood collection device and a photometer run by a battery. A drop of capillary blood was drawn from a child’s heel or fingertip and is drawn into the micro cuvette. The blood in the micro cuvette is analysed using the photometer, which displays the concentration of haemoglobin in grammes per deci litters.

3.3.3.2 Worm Infestation and Parasitemia

Baseline and end line worm infestation test and confirmatory microscopic malaria test were done at the Immunology Department of Noguchi Memorial Research Institute to identify worm infestation and malaria so as to monitor their effect on the haemoglobin data. The stool samples were collected into clean, dry plastic jars with screw-cap lids, well labelled with respective ID, and they were sent to the lab. These samples were arranged on a clean laboratory bench prior to analysis. 85% Normal saline was prepared and filtered clean. Equal volume of saline was added to stool sample and mixed well with wooden applicator. 20 microns of emulsified stool was pipetted onto a clean slide and covered immediately with cover slip. Observations of the wet stool preparation were then made under the microscope starting from x10 and further at x40 for confirmation of unusual substance or parasite form.

Assessment of malaria status was done using the RDT test and the microscopy technique was done in addition as a confirmatory procedure. For the microscopic examination, a small drop of well-mixed blood was placed near the frosted end of a clean glass slide. A thick film with multiple layers of cells was prepared. A small drop of well-mixed blood was placed near the
thick film. With a second slide as a spreader, the blood was streaked in a thin film over the slide to obtain an even monolayer of smear. The slide was allowed to air-dry, fixed and it was then stained to facilitate microscopic examination of cells.

3.3.4 Clinical Signs

Clinical signs were examined at the following areas; gum, teeth, tongue, mouth, lips, hair, skin, nails, and eyes. The observations made were compared to standard charts to see if there were any abnormal signs in the children.

3.3.5 Dietary Assessment

Information on child’s usual dietary intake including the diversity and frequency were assessed using questionnaires. The dietary diversity part of the questionnaire focused on a list of foods from all the food groups and other vitamin A rich cereals or complementary foods that were consumed in the last 24 hours prior to the interview. A dietary diversity score was used to classify the degree of diversity of food intake. Foods eaten from \( \leq 3 \) of the food groups was classified as a low dietary diversified diet, foods eaten from 4 food groups was classified as medium dietary diversity and foods from > 4 food groups was classified as highly diversified diet (Swindale & Ohri-Vachaspati, 2004). The dietary data was beneficial in estimating the dietary diversity score. The feeding frequency questions helped to know how often the children were fed.

3.4 Data Analyses

The data were entered into the Statistical Package for Social Sciences (SPSS) version 21.0 and this tool was used for analyses. Microsoft Excel version 2010 was used for plotting graphs and for illustrating trends in the outcome variables over the study period. Descriptive Statistics was
used to compute frequencies, means and standard deviations. With the dietary diversity scores, foods eaten from <4 food groups were classified as a low dietary diversity and foods consumed from 4 or >4 was classified as a medium or high diversified diet respectively. The presence of anaemia was stated with reference to an Hb level of <11g/dL. Magnitude of treatment effect for anaemia prevalence was calculated using Percentage Points (PP) Difference (thus % for intervention group-% for control group). WHO Anthro software was used to calculate the z-scores of the infants to determine their nutritional status which was classified as stunting, wasting and underweight. Statistical analysis included baseline data comparisons between groups, differences in anthropometric measures, biochemical and clinical variables by using Analysis of Covariance (ANCOVA). Since this is an intervention study, the mean changes between the months specified for data collection was used in the ANCOVA for children in the treatment and control groups who completed the study controlling for potential confounders as child’s age, socioeconomic background of caregivers, worm infestation, malaria and foods eaten during the period. Pearson’s chi-square test (for the percentages) and t-tests (for the continuous variables) was used to determine whether changes from baseline and end-line were statistically significant. Baseline and end-line comparisons within groups was conducted using paired t-test. Changes in variables was calculated for both treatment and control groups and comparisons between the mean changes in the intervention group with that in the control group was made using independent sample t-test.
CHAPTER FOUR

4.0 RESULTS

4.1 Background Characteristics

The background socio-demographic features of the children and their caregivers involved in this study are shown in Table 4.1 and Table 4.2 respectively. The results presented in these tables reveal that the child-mother pairs enrolled both the intervention and control groups were similar in all characteristics of interest assessed. Thus, there was no significant difference in the background characteristics of the study participants in both groups at baseline. Table 4.1 shows that the mean age of the children was 12 ± 4 months and 13 ± 4 months in control and intervention groups respectively. Majority of the children were delivered at a public hospital thus 77.2% and 84.1% in control and intervention groups respectively. Also in the control group, more than half (57.4%) of the children were boys whilst in the intervention group, girls were the most (thus 52.3%).

Table 4.1: Background characteristics of study participants at baseline

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>CG (n=101)</th>
<th>IG (n=107)</th>
<th>Total (N=208)</th>
<th>P-value¹</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
</tr>
<tr>
<td><strong>Children</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (months) [M±SD]²</td>
<td>12 ± 4</td>
<td>13 ± 4</td>
<td>13 ± 4</td>
<td>0.26</td>
</tr>
<tr>
<td>6-8</td>
<td>28(28.0)</td>
<td>15(14.6)</td>
<td>43(21.2)</td>
<td>0.05</td>
</tr>
<tr>
<td>9-11</td>
<td>24(24.0)</td>
<td>23(22.3)</td>
<td>47(23.2)</td>
<td></td>
</tr>
<tr>
<td>12-15</td>
<td>22(22.0)</td>
<td>37(35.9)</td>
<td>59(29.1)</td>
<td></td>
</tr>
<tr>
<td>16-18</td>
<td>26(26.0)</td>
<td>28(27.2)</td>
<td>54(26.6)</td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>58(57.4)</td>
<td>48(44.9)</td>
<td>106(51)</td>
<td>0.07</td>
</tr>
<tr>
<td>Female</td>
<td>43(42.6)</td>
<td>57(52.3)</td>
<td>98(49)</td>
<td></td>
</tr>
<tr>
<td><strong>Place of delivery</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public hospital</td>
<td>78(77.2)</td>
<td>90(84.1)</td>
<td>168(80.8)</td>
<td>0.40</td>
</tr>
<tr>
<td>Private hospital</td>
<td>14(13.9)</td>
<td>9(8.4)</td>
<td>23(11.1)</td>
<td></td>
</tr>
<tr>
<td>Home</td>
<td>9(8.9)</td>
<td>8(7.5)</td>
<td>17(8.2)</td>
<td></td>
</tr>
</tbody>
</table>

Significance based on independent T-test for continuous variables and chi-square for categorical variables; ¹n (%); ²Mean± standard deviation. P-value significant at <0.05. CG: Control Group, IG: Intervention Group
Table 4.2 also shows that most (thus 72.3% in control and 62.3% in intervention) of the caregivers in both groups lived in joint (extended) family systems. Also about half (46.5% in control and 43.9% in intervention) of the caregivers in both groups engaged in Petty trading and also had more than 2 children (thus 48.5% in control and 40.6% in intervention). There was, however, a difference in their level of education as majority (51.0%) of the respondents in the control group had attended secondary/vocational school as compared to 38.3% in the intervention group. However more mothers in the intervention group had tertiary education compared to the control mothers (thus 11.3% vs. 2.0%).

Table 4.2: Socio-demographic characteristics of caregivers

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>CG (n=101)</th>
<th>IG (n=107)</th>
<th>Total (N=208)</th>
<th>P-value¹</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mother</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age(years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;19</td>
<td>3(3)</td>
<td>4(3.7)</td>
<td>7(3.4)</td>
<td>0.58</td>
</tr>
<tr>
<td>20-24</td>
<td>11(10.9)</td>
<td>19(17.8)</td>
<td>30(14.4)</td>
<td></td>
</tr>
<tr>
<td>25-29</td>
<td>36(35.6)</td>
<td>33(30.8)</td>
<td>69(33.2)</td>
<td></td>
</tr>
<tr>
<td>30-34</td>
<td>29(28.7)</td>
<td>33(30.8)</td>
<td>62(29.8)</td>
<td></td>
</tr>
<tr>
<td>≥ 35</td>
<td>22(21.8)</td>
<td>18(16.8)</td>
<td>40(19.2)</td>
<td></td>
</tr>
<tr>
<td><strong>Number of Children</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>0(0.0)</td>
<td>1(0.9)</td>
<td>1(0.5)</td>
<td>0.52</td>
</tr>
<tr>
<td>One</td>
<td>18(18.6)</td>
<td>25(23.6)</td>
<td>43(21.2)</td>
<td></td>
</tr>
<tr>
<td>Two</td>
<td>32(33.0)</td>
<td>37(34.9)</td>
<td>69(34.0)</td>
<td></td>
</tr>
<tr>
<td>More than 2</td>
<td>47(48.5)</td>
<td>43(40.6)</td>
<td>90(44.3)</td>
<td></td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Employed</td>
<td>16(15.8)</td>
<td>17(15.9)</td>
<td>33(15.9)</td>
<td>0.99</td>
</tr>
<tr>
<td>Part-time Labour</td>
<td>5(5.0)</td>
<td>4(3.7)</td>
<td>9(4.3)</td>
<td>0.67</td>
</tr>
<tr>
<td>Full Time Salary</td>
<td>3(3.0)</td>
<td>11(10.3)</td>
<td>14(6.7)</td>
<td>0.05</td>
</tr>
<tr>
<td>Selling goods</td>
<td>47(46.5)</td>
<td>47(43.9)</td>
<td>95(45.2)</td>
<td>0.59</td>
</tr>
<tr>
<td>Student</td>
<td>2(2.0)</td>
<td>0(0.0)</td>
<td>2(0.0)</td>
<td>0.14</td>
</tr>
<tr>
<td>Artisan</td>
<td>30(29.7)</td>
<td>28(26.2)</td>
<td>58(27.9)</td>
<td>0.57</td>
</tr>
<tr>
<td><strong>Family System</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nuclear</td>
<td>73(72.3)</td>
<td>67(62.3)</td>
<td>140(67.3)</td>
<td>0.14</td>
</tr>
<tr>
<td>Joint</td>
<td>28(27.7)</td>
<td>40(37.4)</td>
<td>68(32.7)</td>
<td></td>
</tr>
<tr>
<td><strong>Educational Status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>8(8.0)</td>
<td>11(10.3)</td>
<td>19(9.2)</td>
<td>0.04</td>
</tr>
<tr>
<td>Primary</td>
<td>24(24.0)</td>
<td>22(20.6)</td>
<td>46(22.2)</td>
<td></td>
</tr>
<tr>
<td>Middle/JHS/JHS</td>
<td>15(15.0)</td>
<td>21(19.6)</td>
<td>36(17.4)</td>
<td></td>
</tr>
<tr>
<td>Secondary/Vocational</td>
<td>51(51.0)</td>
<td>41(38.3)</td>
<td>92(44.4)</td>
<td></td>
</tr>
<tr>
<td>Tertiary</td>
<td>2(2.0)</td>
<td>12(11.2)</td>
<td>14(6.8)</td>
<td></td>
</tr>
</tbody>
</table>

Significance based on chi-square for categorical variables; ¹n (%); P-value significant at <0.05. CG: Control Group, IG: Intervention Group


4.2 Anthropometric Indices of Participants

4.2.1 Baseline Anthropometric Indices of Study Participants

The baseline anthropometric indices before initiation of the 6-month feeding are recorded in Table 4.3. There was no statistically significant difference in the mean weight of the males in the control which was (9.01±1.50) kg and that of the intervention group which was (8.65±1.61) kg at a P value of 0.23. The same was seen for the weight of the females in both groups which were no different from each other thus (9.20±1.39) kg and (8.63±1.31) kg at a P-value of 0.05.

The results for height also revealed no difference between the two comparison groups and for both sexes (Thus 74.55±5.55cm; 73.09±5.37cm at P-value of 0.17 for males in control and intervention groups respectively and also 75.66±4.51cm; 73.82±5.96cm at a P-value of 0.09 for females in control and intervention respectively. The mean Mid Upper Arm Circumference (MUAC) measured for both comparison groups were also normal and statistically similar at the beginning of the study. Males in the control recorded a MUAC measure of 14.66±1.32cm and that of the intervention was 14.42±1.26cm at a P-Value of 0.19. For stunting, the control group recorded 5.0% and intervention was10.5% at a P-value of 0.14. Wasting was 4% in the control and 12.1% in the intervention at a P-Value of 0.09. Underweight was 5% and 12.4% at a P-value of 0.06 in control and intervention respectively. Finally, overweight which is an emerging situation in children was also observed in both groups but the difference was not statistically significant. Control group had 3% of the children being overweight whilst intervention had 3.7% at a P-value of 0.09. All in all, table 3 illustrated that the baseline anthropometric parameters of both groups were fairly similar, however, specific categories were different.
Table 4.3 Baseline anthropometric indices of participants by study group

<table>
<thead>
<tr>
<th>Variables</th>
<th>N</th>
<th>CG (N=101)</th>
<th>IG (N=107)</th>
<th>Total (N=208)</th>
<th>p-value¹</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>M ± SD</td>
<td>M ± SD</td>
<td>M ± SD</td>
<td></td>
</tr>
<tr>
<td>Weight/kg (Males)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All (months)</td>
<td>58</td>
<td>9.01±1.50</td>
<td>8.65±1.61</td>
<td>8.83±1.55</td>
<td>0.23</td>
</tr>
<tr>
<td>6-8</td>
<td>17</td>
<td>8.95±1.15</td>
<td>8.26±0.72</td>
<td>8.61±0.94</td>
<td>0.23</td>
</tr>
<tr>
<td>9-11</td>
<td>12</td>
<td>8.56±1.88</td>
<td>8.34±1.78</td>
<td>8.45±1.83</td>
<td>0.78</td>
</tr>
<tr>
<td>12-15</td>
<td>11</td>
<td>9.05±1.55</td>
<td>8.98±1.63</td>
<td>9.02±1.59</td>
<td>0.91</td>
</tr>
<tr>
<td>16-18</td>
<td>18</td>
<td>9.36±1.51</td>
<td>8.57±1.74</td>
<td>8.96±1.62</td>
<td>0.21</td>
</tr>
<tr>
<td>Weight/kg (Females)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All (months)</td>
<td>43</td>
<td>9.20±1.39</td>
<td>8.63±1.31</td>
<td>8.92±1.35</td>
<td>0.05</td>
</tr>
<tr>
<td>6-8</td>
<td>11</td>
<td>9.21±1.38</td>
<td>8.30±1.18</td>
<td>8.75±1.28</td>
<td>0.10</td>
</tr>
<tr>
<td>9-11</td>
<td>12</td>
<td>8.73±1.16</td>
<td>8.28±0.97</td>
<td>8.48±1.06</td>
<td>0.32</td>
</tr>
<tr>
<td>12-15</td>
<td>11</td>
<td>9.68±1.38</td>
<td>8.37±1.06</td>
<td>9.02±1.22</td>
<td>*0.01</td>
</tr>
<tr>
<td>16-18</td>
<td>9</td>
<td>9.23±1.67</td>
<td>9.39±1.58</td>
<td>9.31±1.62</td>
<td>*0.02</td>
</tr>
<tr>
<td>Height/cm (Males)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All (months)</td>
<td>58</td>
<td>74.55±5.55</td>
<td>73.09±5.37</td>
<td>73.82±5.46</td>
<td>0.17</td>
</tr>
<tr>
<td>6-8</td>
<td>17</td>
<td>74.42±4.65</td>
<td>68.8±2.52</td>
<td>71.61±3.58</td>
<td>*0.02</td>
</tr>
<tr>
<td>9-11</td>
<td>12</td>
<td>73.77±6.21</td>
<td>72.59±5.20</td>
<td>73.18±5.70</td>
<td>0.62</td>
</tr>
<tr>
<td>12-15</td>
<td>11</td>
<td>75.64±5.41</td>
<td>74.73±5.04</td>
<td>75.18±5.22</td>
<td>0.64</td>
</tr>
<tr>
<td>16-18</td>
<td>18</td>
<td>74.54±6.28</td>
<td>72.61±6.30</td>
<td>73.57±6.29</td>
<td>0.43</td>
</tr>
<tr>
<td>Height/cm (Females)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All (months)</td>
<td>43</td>
<td>75.66±4.51</td>
<td>73.82±5.96</td>
<td>74.74±5.23</td>
<td>0.09</td>
</tr>
<tr>
<td>6-8</td>
<td>11</td>
<td>75.46±3.55</td>
<td>73.75±5.48</td>
<td>74.40±4.51</td>
<td>0.38</td>
</tr>
<tr>
<td>9-11</td>
<td>12</td>
<td>75.22±5.73</td>
<td>70.63±4.51</td>
<td>72.92±5.12</td>
<td>*0.04</td>
</tr>
<tr>
<td>12-15</td>
<td>11</td>
<td>76.54±4.11</td>
<td>73.05±3.62</td>
<td>74.95±3.86</td>
<td>*0.03</td>
</tr>
<tr>
<td>16-18</td>
<td>9</td>
<td>75.40±4.83</td>
<td>76.90±7.79</td>
<td>76.15±6.31</td>
<td>0.61</td>
</tr>
<tr>
<td>MUAC/cm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All (months)</td>
<td>101</td>
<td>14.66±1.32</td>
<td>14.42±1.26</td>
<td>14.54±1.95</td>
<td>0.19</td>
</tr>
<tr>
<td>6-8</td>
<td>28</td>
<td>14.27±1.48</td>
<td>14.47±1.19</td>
<td>14.37±1.33</td>
<td>0.64</td>
</tr>
<tr>
<td>9-11</td>
<td>24</td>
<td>14.65±1.13</td>
<td>14.07±1.01</td>
<td>14.36±1.07</td>
<td>0.07</td>
</tr>
<tr>
<td>12-15</td>
<td>22</td>
<td>14.85±1.51</td>
<td>14.59±1.38</td>
<td>14.72±1.44</td>
<td>0.52</td>
</tr>
<tr>
<td>16-18</td>
<td>27</td>
<td>14.90±1.11</td>
<td>14.46±1.35</td>
<td>14.68±1.23</td>
<td>0.12</td>
</tr>
</tbody>
</table>

¹Significance based on independent T-test; M±SD indicates mean ± standard deviation; *p≤0.05. CG: Control Group, IG: Intervention Group
Table 4.3 Continued: Baseline anthropometric indices of participants by study group

<table>
<thead>
<tr>
<th>Variables</th>
<th>CG (N=101)</th>
<th>IG (N=107)</th>
<th>Total (N=208)</th>
<th>p-value¹</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n(%)</td>
<td>n(%)</td>
<td>n(%)</td>
<td></td>
</tr>
<tr>
<td>HAZ (stunting)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All (months)</td>
<td>5(5.0)</td>
<td>11(10.5)</td>
<td>16(7.8)</td>
<td>0.14</td>
</tr>
<tr>
<td>6-8</td>
<td>1(3.6)</td>
<td>1(5.6)</td>
<td>2(4.3)</td>
<td>0.74</td>
</tr>
<tr>
<td>9-11</td>
<td>0(0.0)</td>
<td>3(12.5)</td>
<td>3(6.2)</td>
<td>0.07</td>
</tr>
<tr>
<td>12-15</td>
<td>3(13.6)</td>
<td>4(11.4)</td>
<td>7(12.3)</td>
<td>0.81</td>
</tr>
<tr>
<td>16-18</td>
<td>1(3.7)</td>
<td>3(10.7)</td>
<td>4(7.3)</td>
<td>0.32</td>
</tr>
<tr>
<td>WAZ (Underweight)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All (months)</td>
<td>5(5.0)</td>
<td>13(12.4)</td>
<td>18(8.7)</td>
<td>0.06</td>
</tr>
<tr>
<td>6-8</td>
<td>0(0.0)</td>
<td>3(16.7)</td>
<td>3(6.5)</td>
<td>*0.03</td>
</tr>
<tr>
<td>9-11</td>
<td>2(8.3)</td>
<td>1(4.2)</td>
<td>3(6.2)</td>
<td>0.55</td>
</tr>
<tr>
<td>12-15</td>
<td>3(13.6)</td>
<td>5(14.3)</td>
<td>8(14.0)</td>
<td>0.95</td>
</tr>
<tr>
<td>16-18</td>
<td>0(0.0)</td>
<td>4(14.3)</td>
<td>4(7.3)</td>
<td>*0.04</td>
</tr>
<tr>
<td>WHZ (Wasting)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All (months)</td>
<td>4(4)</td>
<td>13(12.1)</td>
<td>17(8.2)</td>
<td>0.09</td>
</tr>
<tr>
<td>6-8</td>
<td>0(0.0)</td>
<td>2(11.1)</td>
<td>2(4.3)</td>
<td>0.15</td>
</tr>
<tr>
<td>9-11</td>
<td>2(8.3)</td>
<td>3(12.5)</td>
<td>5(10.4)</td>
<td>0.52</td>
</tr>
<tr>
<td>12-15</td>
<td>2(9.1)</td>
<td>2(5.4)</td>
<td>4(6.8)</td>
<td>0.59</td>
</tr>
<tr>
<td>16-18</td>
<td>0(0.0)</td>
<td>6(21.4)</td>
<td>6(10.9)</td>
<td>*0.03</td>
</tr>
<tr>
<td>WHZ (Overweight)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All (months)</td>
<td>3(3)</td>
<td>4(3.7)</td>
<td>7(3.4)</td>
<td>0.09</td>
</tr>
<tr>
<td>6-8</td>
<td>1(3.6)</td>
<td>0(0.0)</td>
<td>1(2.2)</td>
<td>0.15</td>
</tr>
<tr>
<td>9-11</td>
<td>0(0.0)</td>
<td>1(4.2)</td>
<td>1(2.1)</td>
<td>0.52</td>
</tr>
<tr>
<td>12-15</td>
<td>0(0.0)</td>
<td>0(0.0)</td>
<td>0(0.0)</td>
<td>0.59</td>
</tr>
<tr>
<td>16-18</td>
<td>2(7.4)</td>
<td>3(10.7)</td>
<td>5(9.1)</td>
<td>*0.03</td>
</tr>
</tbody>
</table>

Significance based on chi-square for categorical variables; n(%) . P-value significant at <0.05. CG: Control Group, IG: Intervention Group

### 4.2.2 Changes in Anthropometric Indices with Time and According to Study Groups

Figure 4.1 displays the Mid Upper Arm Circumference (MUAC) Profiles of the study participants according to comparison groups. It revealed that the control group had a sharp increase in MUAC by month 2 through month 4 and continued with a steady rise onwards to month 8 whereas intervention exhibited a steady rise in MUAC from baseline to month 6 but a fall after the intervention was withdrawn.
Figure 4.1: MUAC profiles of study participants over time

Figure 4.2 illustrates the changes in height of the children enrolled in the study over a period of 8 months. It can be seen that both control and intervention groups had a rise in their heights over the time of the 6 months intervention. However, the control group overtook the intervention group when the feeding was withdrawn.
The changes in weight of children in both comparison groups are depicted in Figure 4.3. The control group exhibited a gentle rise in weight at each time point and even after the intervention was withdrawn by month 8. The intervention group, however, recorded a steeper rise in weight. Compared to the trend seen in the control, intervention children recorded a slightly lesser weight gain during the 2 months post intervention period when feeding was ceased.
4.3 Dietary Data

4.3.1 Usual Food Groups Consumed by Infants at Baseline and Endline

The 24-hour dietary recall conducted at baseline revealed that both groups exhibited similar dietary diversity in most of the food groups listed with the exception of consumed Vitamin A rich fruits and vegetables; other fruits and the widely consumed Grains, roots and tubers (Table 4.4); For Grains, roots and tubers, 83.2% of the children in the control group consumed it as compared to 92.5% of the children in the intervention at a P-value of 0.04. 1 in every 10 children in the control as compared to 1 in every 4 children in the intervention consumed Vitamin A rich fruits and vegetables at a P-value of <0.01. Also for other fruits, 17.8% of the children in the control as compared to 31.1% of children in the intervention was fed with these and the difference was significant at a P-value of 0.03.
Table 4.5 shows the usual food groups consumed by the study participants at the end of the 6 months of feeding. It was evident that both groups were fairly similar with regards to their dietary intakes from the different food groups with the exception of other vegetables consumed which was significantly different.

Table 4.4: Usual food groups consumed by infants at baseline

<table>
<thead>
<tr>
<th>Food Groups</th>
<th>CG (N=101)</th>
<th>IG (N=107)</th>
<th>Total (N=208)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n(%)</td>
<td>n(%)</td>
<td>n(%)</td>
<td></td>
</tr>
<tr>
<td><strong>Legumes and nuts</strong></td>
<td>18(17.8)</td>
<td>24(22.6)</td>
<td>42(20.3)</td>
<td>0.39</td>
</tr>
<tr>
<td><strong>Grains, roots &amp; tubers</strong></td>
<td>84(83.2)</td>
<td>98(92.5)</td>
<td>182(87.9)</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Vitamin A rich fruits</strong></td>
<td>10(9.9)</td>
<td>28(26.4)</td>
<td>38(18.4)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>&amp; vegetables</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Other fruits</strong></td>
<td>18(17.8)</td>
<td>33(31.1)</td>
<td>51(24.6)</td>
<td>0.03</td>
</tr>
<tr>
<td><strong>Other vegetables</strong></td>
<td>30(29.7)</td>
<td>38(35.8)</td>
<td>68(32.9)</td>
<td>0.35</td>
</tr>
<tr>
<td><strong>Dairy products</strong></td>
<td>31(30.7)</td>
<td>33(31.1)</td>
<td>64(30.9)</td>
<td>0.95</td>
</tr>
<tr>
<td><strong>Flesh foods</strong></td>
<td>43(42.6)</td>
<td>57(53.8)</td>
<td>100(48.2)</td>
<td>0.12</td>
</tr>
<tr>
<td><strong>Eggs</strong></td>
<td>11(10.9)</td>
<td>22(20.8)</td>
<td>33(15.9)</td>
<td>0.05</td>
</tr>
<tr>
<td><strong>Fats and oils</strong></td>
<td>51(50.5)</td>
<td>63(59.4)</td>
<td>114(55.1)</td>
<td>0.20</td>
</tr>
</tbody>
</table>

Significance based on chi-square for categorical variables; *n(%). P-value significant at <0.05. CG: Control Group, IG: Intervention Group

Table 4.5: Usual food Groups consumed by infants at endline

<table>
<thead>
<tr>
<th>Food Groups</th>
<th>CG (N=101)</th>
<th>IG (N=107)</th>
<th>Total (N=208)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n(%)</td>
<td>n(%)</td>
<td>n(%)</td>
<td></td>
</tr>
<tr>
<td><strong>Grains, roots &amp; tubers</strong></td>
<td>71(94.7)</td>
<td>81(97.6)</td>
<td>152(96.2)</td>
<td>0.34</td>
</tr>
<tr>
<td><strong>Legumes and nuts</strong></td>
<td>27(35.5)</td>
<td>30(36.1)</td>
<td>57(35.8)</td>
<td>0.94</td>
</tr>
<tr>
<td><strong>Vitamin A rich fruits</strong></td>
<td>27(35.1)</td>
<td>39(47.0)</td>
<td>66(41.2)</td>
<td>0.13</td>
</tr>
<tr>
<td>&amp; vegetables</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Other fruits</strong></td>
<td>28(36.4)</td>
<td>34(41.0)</td>
<td>62(38.8)</td>
<td>0.55</td>
</tr>
<tr>
<td><strong>Other vegetables</strong></td>
<td>9(11.7)</td>
<td>37(44.6)</td>
<td>46(28.8)</td>
<td>&lt;0.00</td>
</tr>
<tr>
<td><strong>Dairy products</strong></td>
<td>33(42.9)</td>
<td>41(49.4)</td>
<td>74(46.2)</td>
<td>0.41</td>
</tr>
<tr>
<td><strong>Flesh foods</strong></td>
<td>68(88.3)</td>
<td>64(77.1)</td>
<td>132(82.5)</td>
<td>0.06</td>
</tr>
<tr>
<td><strong>Eggs</strong></td>
<td>22(28.6)</td>
<td>23(27.7)</td>
<td>45(28.1)</td>
<td>0.90</td>
</tr>
<tr>
<td><strong>Fats and oils</strong></td>
<td>60(77.9)</td>
<td>67(80.7)</td>
<td>127(79.4)</td>
<td>0.66</td>
</tr>
</tbody>
</table>

Significance based on chi-square for categorical variables; *n(%). P-value significant at <0.05. CG: Control Group, IG: Intervention Group
4.3.2: Dietary Diversity Score of Infants

The dietary diversity score of the study participants over the study period are illustrated in figure 4.4. The results revealed that 83.2% of the children in the control group had low dietary diversity as compared to about half (59.4%) of the children in the intervention at $P= <0.01$ during baseline. This trend was expected to improve as the children transitioned into eating complementary foods and family foods by 6 months’ time. However less than half (thus 25.3% in the control and 42.2% in the intervention at $P=0.08$) of the children in both groups exhibited high dietary diversity that is eating foods from more than 4 of the 9 selected food groups or items. By month 8 when feeding was withdrawn, participants in the intervention were catching up with about 65.1% exhibiting high dietary diversity but not much improvement was seen in the control which reported 15.5% thus implicating a challenge with complementary feeding.

Figure 4.4: Distribution of dietary diversity score of infants in both Groups over time
4.3.3: Breastfeeding Rate at Baseline

The breastfeeding rate at baseline is reported in table 4.6 for both groups. Considering proportions in the control group, children between the ages of 6-8 months consumed the most (27.7%) breast milk followed by those between the ages of 16-18 months (26.7%). In the intervention group however, children between the ages of 12-15 months followed by those between 16-18 months consumed the most. The overall breastfeeding rates for both groups were nonetheless fairly similar thus 92.0% in the control group and 89.6% in the intervention at a P-value of 0.55. After 6 months their breastfeeding rate had declined to 57.1% in the control and 41.0% in the intervention group as the older children transitioned from eating complementary foods to family foods (See Table 4.7).

Table 4.6: Breastfeeding rate at baseline by groups

<table>
<thead>
<tr>
<th>Age categories (months)</th>
<th>CG (N=101)</th>
<th>IG (N=107)</th>
<th>Total (N=208)</th>
<th>p-value¹</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n(%)</td>
<td>n(%)</td>
<td>n(%)</td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>92(92.0)</td>
<td>95(89.6)</td>
<td>187(90.8)</td>
<td>0.55</td>
</tr>
<tr>
<td>6-8</td>
<td>28(27.7)</td>
<td>18(16.8)</td>
<td>46(22.1)</td>
<td>0.17</td>
</tr>
<tr>
<td>9-11</td>
<td>24(23.8)</td>
<td>24(22.4)</td>
<td>48(23.1)</td>
<td>0.32</td>
</tr>
<tr>
<td>12-15</td>
<td>22(21.8)</td>
<td>37(34.6)</td>
<td>59(28.4)</td>
<td>0.89</td>
</tr>
<tr>
<td>16-18</td>
<td>27(26.7)</td>
<td>28(26.2)</td>
<td>55(26.4)</td>
<td>0.42</td>
</tr>
</tbody>
</table>

Significance based on chi-square for categorical variables; ¹n(%). P-value significant at <0.05.

Table 4.7: Breastfeeding rate at endline by groups

<table>
<thead>
<tr>
<th>Age categories (months)</th>
<th>CG (N=101)</th>
<th>IG (N=107)</th>
<th>Total (N=208)</th>
<th>p-value¹</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n(%)</td>
<td>n(%)</td>
<td>n(%)</td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>44 (57.1)</td>
<td>34 (41.0)</td>
<td>82 (51.2)</td>
<td>0.04</td>
</tr>
<tr>
<td>6-8</td>
<td>19 (43.2)</td>
<td>9 (26.5)</td>
<td>28 (35.9)</td>
<td>0.02</td>
</tr>
<tr>
<td>9-11</td>
<td>12 (27.3)</td>
<td>15 (44.1)</td>
<td>27 (34.6)</td>
<td>0.76</td>
</tr>
<tr>
<td>12-15</td>
<td>6 (13.6)</td>
<td>9 (26.5)</td>
<td>15 (19.2)</td>
<td>0.88</td>
</tr>
<tr>
<td>16-18</td>
<td>7 (15.9)</td>
<td>1 (2.9)</td>
<td>8 (10.3)</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Significance based on chi-square for categorical variables; ¹n(%). P-value significant at <0.05.
4.4 Hematological Data

4.4.1 Changes in Haemoglobin Concentration Overtime

The results from the month 6 data collected reveals very significant changes in the haemoglobin (Hb) concentrations of the participants with higher changes occurring in those in the intervention group (Intervention Mean change in Hb was 1.90±1.81, P value = <0.01 and Control was 1.22±1.83, P value = <0.01).

There was no interference from the potential confounders being malaria status, worm infestation and usual diet of the children with the treatment foods received as none of the study participants were infested with worms both at baseline and endline and also the prevalence of malaria was rather too low to refute the validity of the haemoglobin data collected. Correlational analysis conducted between the outcome variable Hb and the potential confounders were not significant.

![Figure 4.5: Trends in haemoglobin concentration from baseline to month 6](image-url)
The efficacy of the iron fortified complementary food on the haemoglobin levels of the study participants are reported in Figure 4.6. It revealed significant changes in the mean haemoglobin concentrations from baseline to endline for both within each of the groups and between the groups. Control Group recorded a mean change in haemoglobin of 1.22±0.22 at a P value of <0.01 while Intervention Group recorded an even higher mean change of 1.90±0.20 at a P value of <0.01. Comparison of the mean changes between the two groups revealed a significant change in their mean Hb concentrations of 0.68±0.30 g/dL at a P value of 0.02.

Figure 4.6: Changes in haemoglobin levels within and between groups from months 0 - 6
Table 4.8: Changes in haemoglobin concentrations from baseline to month 6 by gender and age

<table>
<thead>
<tr>
<th>Age groups (months)</th>
<th>Haemoglobin concentration (g/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BL (N=70) M±SD</td>
</tr>
<tr>
<td><strong>Males</strong></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>9.35±1.62</td>
</tr>
<tr>
<td>6-8</td>
<td>9.65±1.34</td>
</tr>
<tr>
<td>9-11</td>
<td>8.66±1.75</td>
</tr>
<tr>
<td>12-15</td>
<td>9.57±1.83</td>
</tr>
<tr>
<td>16-18</td>
<td>9.43±1.62</td>
</tr>
<tr>
<td><strong>Females</strong></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>9.26±1.31</td>
</tr>
<tr>
<td>6-8</td>
<td>8.62±1.22</td>
</tr>
<tr>
<td>9-11</td>
<td>9.90±0.62</td>
</tr>
<tr>
<td>12-15</td>
<td>9.28±1.59</td>
</tr>
<tr>
<td>16-18</td>
<td>10.4</td>
</tr>
<tr>
<td><strong>Both Sexes</strong></td>
<td>9.32±1.50</td>
</tr>
</tbody>
</table>

*Change is significant at P-Value < 0.05; BL= Baseline, M6= Month 6, SD= Standard Deviation, M= Mean, N= Total number of subjects per group, CG: Control Group, IG: Intervention Group*
The results from the post intervention data reveals a decline in Hb for both control and intervention group when compared to the month 6 data and this is illustrated in the trend analysis in figure 4.7. However, the intervention group (10.35±1.24 g/dL) still recorded a higher mean haemoglobin (Hb) concentration than control group (10.88±1.18 g/dL). Also, a comparison of the mean Hb concentration for baseline and month 8 revealed significant improvements for both groups however the magnitude of change was again higher in intervention group (1.68±1.72 g/dL at P-value of <0.01) while control group had a lower change of (0.89±1.87 g/dL at P-value of <0.01).

Also, figure 4.8 compares the prevalence of anaemia at baseline and endline between the 2 Groups. It was evident that by endline, anaemia prevalence had declined from (84.1% to 42.8% vs. 89.1% to 62.8%) in the intervention and control groups respectively. The impact on anaemia prevalence was relatively high by -20 percentage point difference.

Figure 4.7: Trends in haemoglobin concentration from baseline to month 8
Table 4.9: Changes in haemoglobin concentrations from baseline to month 8 by gender and age

<table>
<thead>
<tr>
<th>Age groups (months)</th>
<th>Haemoglobin concentration (g/dL)</th>
<th>CG</th>
<th>IG</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BL (N=76) M±SD</td>
<td>M8 (N=76) M±SD</td>
<td>Change M±SD</td>
</tr>
<tr>
<td>Males</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>9.46±1.64</td>
<td>10.39±1.29</td>
<td>0.94±2.04</td>
</tr>
<tr>
<td>6-8</td>
<td>9.67±1.18</td>
<td>10.73±1.20</td>
<td>1.04±1.33</td>
</tr>
<tr>
<td>9-11</td>
<td>8.80±1.72</td>
<td>10.32±1.31</td>
<td>1.52±1.98</td>
</tr>
<tr>
<td>12-15</td>
<td>9.50±1.94</td>
<td>10.31±1.54</td>
<td>0.81±2.36</td>
</tr>
<tr>
<td>16-18</td>
<td>9.65±1.80</td>
<td>10.17±1.28</td>
<td>0.52±2.50</td>
</tr>
<tr>
<td>Females</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All</td>
<td>9.46±1.23</td>
<td>10.27±1.17</td>
<td>0.81±1.56</td>
</tr>
<tr>
<td>6-8</td>
<td>8.61±1.30</td>
<td>10.64±0.96</td>
<td>2.03±1.50</td>
</tr>
<tr>
<td>9-11</td>
<td>10.04±0.53</td>
<td>10.18±1.55</td>
<td>0.14±1.09</td>
</tr>
<tr>
<td>12-15</td>
<td>9.57±1.39</td>
<td>10.07±0.92</td>
<td>0.50±1.61</td>
</tr>
<tr>
<td>16-18</td>
<td>9.87±1.10</td>
<td>10.13±1.63</td>
<td>0.27±1.40</td>
</tr>
<tr>
<td>Both Sexes</td>
<td>9.46±1.49</td>
<td>10.35±1.24</td>
<td>0.89±1.87</td>
</tr>
</tbody>
</table>

Change is significant at P-Value < 0.05. Note: BL= Baseline, M8= Month 8, SD= Standard Deviation, M= Mean, N= Total number of subjects per group, CG: Control Group, IG: Intervention Group
4.5 Changes in nutritional status indicators over the study period by study groups

The changes in nutritional status indicators from months 0 to month 6 were compared for both groups when potential confounders were adjusted or not and these are depicted in Table 4.10. The results revealed these covariates were not correlated to the nutritional status indicators. Only haemoglobin levels of the participants had increased significantly in both comparison groups by the end of the study thus higher changes occurred in those in the intervention group than those in control group (Intervention mean change in Hb was 1.97±0.19 and Control was 1.16±0.21, P value = <0.01). Contrary to this there was no significant change in linear growth and weight gain.
Table 4.10 Changes in nutritional status indicators over the study period by study groups

<table>
<thead>
<tr>
<th>Indicators</th>
<th>Adjusted</th>
<th></th>
<th></th>
<th>Unadjusted</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CG Mean ±SE</td>
<td>IG Mean ±SE</td>
<td>P-value</td>
<td>CG Mean± SE</td>
<td>IG Mean± SE</td>
<td>P-value</td>
</tr>
<tr>
<td>Hb/ g/dL</td>
<td>1.16±0.21</td>
<td>1.97±0.19</td>
<td>&lt;0.01</td>
<td>1.22±0.22</td>
<td>1.90±0.20</td>
<td>0.02</td>
</tr>
<tr>
<td>WHZ</td>
<td>-0.18±0.19</td>
<td>0.06±0.19</td>
<td>0.38</td>
<td>-0.21±0.18</td>
<td>0.11±0.17</td>
<td>0.21</td>
</tr>
<tr>
<td>HAZ</td>
<td>2.47±0.27</td>
<td>2.54±0.27</td>
<td>0.84</td>
<td>2.28±0.26</td>
<td>2.30±0.25</td>
<td>0.95</td>
</tr>
<tr>
<td>WAZ</td>
<td>0.99±0.19</td>
<td>1.13±0.20</td>
<td>0.61</td>
<td>0.87±0.19</td>
<td>1.06±0.19</td>
<td>0.48</td>
</tr>
<tr>
<td>Weight /kg</td>
<td>1.03±0.24</td>
<td>1.31±0.24</td>
<td>0.41</td>
<td>0.87±0.23</td>
<td>1.20±0.22</td>
<td>0.30</td>
</tr>
<tr>
<td>Height /cm</td>
<td>6.24±0.28</td>
<td>5.62±0.27</td>
<td>0.21</td>
<td>6.11±0.27</td>
<td>5.55±0.26</td>
<td>0.14</td>
</tr>
</tbody>
</table>

Change is significant at P-Value < 0.05 using ANCOVA. Adjusted for malaria status, worm infestation, dietary diversity score and mothers education. CG: Control Group, IG: Intervention Group

4.6 Trends in malaria prevalence and worm infestation over time

Figure 4.9 shows the prevalence of malaria at baseline and endline of the study. Malaria were very minimal, thus at baseline 2.97% (3 children ) in the control group had malaria while no one in the intervention group had malaria. At endline, only 3.85% in the control group had malaria with just 1.19% in the intervention group. There was no worm infestation recorded at both baseline and endline.
Figure 4.9: Prevalence of malaria at baseline and endline by study groups
CHAPTER FIVE

5.0 DISCUSSION

5.1 Preamble

Several approaches have been adopted with regards to complementary feeding. These are nutrition education/ counselling, central fortification or home fortification, food supplementation, and the application of food processing technologies to enhance the dietary quality or increase in energy density of complementary foods. Also, the outcomes of these programmes and interventions vary among different studies (Dewey and Adu-Afarwuah 2008). This study adopted food fortification as an approach and assessed haemoglobin concentration and measured growth as the outcomes. This was necessary because of the current state of the nutritional situation of children between 6-24 months of age in Ghana and also necessitated by the second goal of the Sustainable Development Goals (SDGs) that seek to eliminate hunger and all forms of malnutrition.

The study started with 107 participants in the intervention group and 101 in the control group. 21.5% attrition was observed in the intervention group and 24.8% attrition in the control, however, this level of attrition was not a problem because an attrition rate of about 86% was accounted for in the study design and sample size estimation since drop out is anticipated in all longitudinal studies. Some of the caregivers of these drop outs relocated from the study area a few months into the study or were posted to other areas by their jobs while a few others voluntarily quit due to unexplained personal reasons and preferences. The comparison groups were similar in all characteristics at baseline with the exception of the caregiver’s educational level. This was accounted for in further analysis alongside other potential confounders like worm infestation, malaria status and dietary intake. This suggests the comparison groups were homogenous to a large extent.
5.2 Effect of the iron fortified infant cereal on haemoglobin levels and anaemia

The results of the study showed that the iron fortified infant cereal significantly increased the mean haemoglobin concentrations from baseline to endline. Even though at baseline the control group had a higher mean haemoglobin concentration than that of the intervention group (thus 9.35±1.62 g/dL in control group vs. 8.80±1.85 g/dL in the intervention group), the trend analysis in figure 4.5 and Table 4.8 reveals that the intervention group overtook their counterparts in the control group by month 4 and sustained a sharper and higher rise to endline but both groups depicted a decline in Hb during the post intervention period when feeding was withdrawn for 2 months. At endline, the control group recorded a mean change in haemoglobin of (1.16±0.21) g/dL while the intervention group recorded a higher mean change of (1.98±0.19) g/dL at a P value of <0.01 as seen in Table 4.10. Also, comparison of the mean changes between the two groups revealed a significant change in their mean Hb concentrations of 0.68±0.30 g/dL at a P value of 0.02. These results were consistent with reports from literature and other reviews of efficacy trials which reveals that changes in Haemoglobin as a biomarker for iron status takes 4-6 weeks and even more for others (Dewey and Adu-Afarwuah 2008; Upfal 2007; Wallach 2015). This significant improvement in haemoglobin concentration was not surprising because the iron fortified in the food was in bioavailable state thus iron (II) and literature reveals that intake of foods with that form of iron is readily absorbed and helps replenish iron stores in term of ferritin levels, transferrin saturation and haemoglobin or red blood cell count (Mahan and Escott-Stump, 2008). Similar reports of increase in haemoglobin concentration have been recorded in other efficacy trials here in Africa and around the world (Adu-Afarwuah et al., 2007; Giovannini et al., 2006; Faber et al., 2005; Smuts et al., 2005; Dhingra et al., 2004; and Lartey et al., 1999).
With regards to iron deficiency anaemia, there was a reduction in the prevalence of anaemia in both comparison groups thus (84.1% to 42.8% vs. 89.1% to 62.8%) in the intervention and control groups respectively as shown in figure 4.8. The impact on anaemia prevalence was relatively high by -20 percentage point difference. This improvement on the prevalence of anaemia is expected as there was a rise in the haemoglobin concentration. Dewey & Adu-Afarwuah (2008) reviewed several efficacy trials and found that the overall average effect across seven of the studies was an increase of 0.6 g/dL change in Hb and -17 percentage point’s difference in the prevalence of anaemia. In Ghana, Larney et al., (1999) found a relatively small impact on anaemia thus reduction by -4 percentage points difference in anaemia prevalence which was attributable to the other possible causes of anaemia such as malaria and worm infestation. However, in this study, the situation was different as there was no worm infestation recorded both at baseline and endline and those children tested malaria were rather very minimal thus at baseline 2.97% (3 children ) in the control group had malaria while no one in the intervention group had malaria. At endline, only 3.85% in the control group had malaria with just 1.19% in the intervention group (Figure 4.9). This low prevalence of malaria could be as a result of the high usage of insecticide treated nets in the study area. As part of the national strategies to reduce malaria, the government of Ghana with the help of the Ghana Health Services had distributed free insecticide treated nets to every household and the children were routinely dewormed as part of their child welfare clinic visits. It is not a surprise then that the magnitude of effect in the reduction of anaemia prevalence was high in this study. Another issue of concern was with the poor dietary diversity which was exhibited by the children as illustrated in figure 4.4 and which may explain the decline in Hb levels in both groups during post intervention and may thus implicate that the caregivers had a challenge with knowledge appropriate complementary foods to be given and the need to eat from variety of all the available food groups.
5.3 Effect of iron fortified infant cereal on growth

There was no significant improvement in linear growth (thus mean change of length in control group was $6.24 \pm 0.28$ cm vs. $5.62 \pm 0.27$ cm, $p=0.21$ in the intervention group) or weight gain (thus mean change of weight in control group was $1.03 \pm 0.24$ kg vs. $1.31 \pm 0.2$ kg, $p=0.41$ in the intervention group; Table 4.10). This may be as a result of the short duration of the intervention as growth as an outcome usually requires time to manifest. Our study only fed the children for only 6 months so it is not very surprising that no significant linear growth and weight gains were observed. Only a few efficacy studies observed significant improvement in growth. An example is an efficacy study that fed children with a milk based fortified product in India (Dhingra et al., 2004). At the end of the 12 months of supplementation, the children in the intervention group significantly gained more weight (by 0.21 kg, 95% CI 0.12, 0.31 kg) and greater WLZ (mean difference 0.16Z, 95% CI 0.03, 0.30Z) and WAZ (by 0.24Z, 95% CI 0.11, 0.36Z) as compared to the control group. Similarly, for linear growth, the children in the intervention group recorded greater length gain of $(8.6 \pm 1.14$ vs. $8.10 \pm 1.37$ cm, $P < 0.05$) and LAZ (by 0.19Z, 95% CI 0.12, 0.26) compared with the control group (Dhingra et al., 2004). However, this is reasonable as the study lasted for a long duration of 12 months which in this study was rather very short. Several studies in Ghana and other part of Africa recorded no significant change in growth because of their short duration (Adu-Afarwuah et al., 2007; Giovannini et al., 2006; Faber et al., 2005; Smuts et al., 2005 and Lartey et al., 1999). Dewey and Adu-Afarwuah 2008 explained that child growth may not be a very sensitive indicator of benefit even though it is the most commonly measured outcome. They further explained that there are constraints that limits the degree to which interventions after birth can impact a child’s growth. This is because the intergenerational cycle of growth faltering and intra-uterine growth restriction may require several years to break the vicious cycle (Dewey and Adu-Afarwuah, 2008).
5.4 Limitations of Study

The findings of this study were presented with the following limitations:

1. The use of self-reported 24-hour dietary recall may lead to over or under estimating the usual food intakes.

2. The duration of the intervention study was relatively short (6 months) and this might limit the impact of the intervention.

3. Haemoglobin levels in the human body is affected by several factors like the concentration of micronutrients (e.g. vitamins A, B\textsubscript{12}, iron and folate). Thus, a further biochemical analysis assessing the concentrations of these nutrients in the body would help in better validating the haemoglobin concentrations of participants.
CHAPTER SIX

6.0 CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

Based on the findings of this present study the following conclusions may be drawn;

1. The iron fortified infant cereal significantly increased the mean haemoglobin concentrations from baseline to endline. The control group recorded a mean change in haemoglobin of 1.16±0.21 while the intervention group recorded a higher mean change of 1.98±0.19 (P <0.01). Comparison of the mean changes between the two groups revealed a significant change in their mean Hb concentrations of 0.68±0.30 g/dL (P = 0.02).

2. There was a reduction in the prevalence of anaemia among both intervention and control groups; 84.1% to 42.8% and 89.1% to 62.8% respectively. The magnitude of effect of the iron fortified infant cereal on anaemia prevalence was -20 percentage point difference indicating that the intervention had a high impact on anaemia reduction.

3. There was no significant improvement in linear growth or weight gain due to the short duration of the study.

4. It was found that none of the study participants had worm infestation and the prevalence of malaria was very negligible.

5. Though the study participants exhibited an expected breastfeeding rate, observations made from the dietary diversity scores revealed that there was a challenge with complementary feeding.

6. In this study, the potential confounders such as malaria, worm infestation etc. pointed out by literature did not correlate with the haemoglobin levels because they were almost negligible in this study group.
6.2 Recommendations

Observations and findings from this study have implications for further research and policy.

1. The researchers recommend that further studies be carried out over a longer period of time.

2. Also since haemoglobin concentration is affected by several other factors beyond malaria and worm infestation, assessment of other relevant micronutrients like Vitamin A, Vitamin B, and folate will help in validating the results of the improved haemoglobin concentrations.

3. The future packaging of the iron fortified infant cereal should be done taking into consideration the difference in energy requirements from complementary foods across the age categories from 6 months to 24 months.
REFERENCES


APPENDICES

Appendix I: Map of study area-La-Nkwantanang Municipality
Appendix II: Study questionnaire

QUESTIONNAIRE ON INFANT FEEDING KNOWLEDGE AND PRACTICES

SECTION A: PARENTS SOCIO-DEMOGRAPHIC STATUS

1. Date of interview…………………………

2. Serial number…………

3. What is the age of the mother?

4. What type of family system is the mother engaged in?
   A. Nuclear [ ]    B. Joint [ ]

5. What is the mother’s educational status?
   A. Primary school [ ]    B. Middle school [ ]    C. Secondary/Vocational school [ ]
   D. Tertiary [ ]    E. None [ ]

6. What type of work does the mother do?
   A. Not employed    B. Retired    C. Part time wage lab
   D. Full-time salary,   E. Selling goods   F. Casual labour
   G. Farming (subsistence)    H. Farming (commercial)   I. Full-time student
   J. Artisan    K. Driver    L. Other (specify) ……………………………

7. How many children do you have?
   One [ ]    Two [ ]    More than two [ ]

SECTION B: CHILD’S DEMOGRAPHY

8. Name of child……………………………………………………………………………………

9. Serial number………………

10. Age of the child (in completed months)…………………………………………………

11. Sex of child
   A. Male [ ]    B. Female [ ]

12. Where did you deliver this child?
   A. Primary health centre [ ]    B. Private hospital [ ]    C. Public hospital [ ]
   D. Home [ ]

SECTION C: KNOWLEDGE OF MOTHERS ON COMPLEMENTARY FEEDING

13. In your own opinion which age do you think it is appropriate to start complementary
14. How many times do you think a baby under 1 year should be fed?
A. Once [ ]   B. Twice [ ]   C. Thrice [ ]   D. 4-5 times [ ]
E. 6-10 times [ ]   F. > 10 times [ ]   G. As often as child requests

15. Which food groups would you recommend to be used for complementary feeding per day?

<table>
<thead>
<tr>
<th>Food groups</th>
<th>Tick where applicable (could be more than one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grains, roots and tubers</td>
<td></td>
</tr>
<tr>
<td>Legumes and nuts</td>
<td></td>
</tr>
<tr>
<td>Dairy product (milk, yoghurt, cheese)</td>
<td></td>
</tr>
<tr>
<td>Vegetables</td>
<td></td>
</tr>
<tr>
<td>Fruits</td>
<td></td>
</tr>
<tr>
<td>Meat/fish/Egg</td>
<td></td>
</tr>
<tr>
<td>A small amount of butter/oil</td>
<td></td>
</tr>
</tbody>
</table>

16. Are there some foods you think should not be given to children who are on complementary feeding? .................................................................

17. What is your reason for Q17?
...........................................................................................................................................
...........................................................................................................................................
...........................................................................................................................................
SECTION C: BREASTFEEDING AND COMPLEMENTARY FEEDING PRACTICES

18. Did you ever breastfeed (CHILD)?
   A. Yes        B. No

19. How long after birth did you first put (NAME) to the breast?
   A. Within the first one hour     B. after an hour     C. after 1 day     D. after 1 week     E. after 1 month

20. During the first three days after delivery, did you give (NAME) the liquid that came from your breasts?
   A. Yes        B. No

21. During the first three days after delivery, did you give (NAME) anything else to eat or drink before feeding him/her breast milk?
   A. Yes        B. No

22. If yes what did you give (NAME)? (Please circle all that apply)
   A. Milk        B. Plain water   C. Water with sugar/salt   D. Fruit juice
   E. Tea/Porridge   F. Honey   G. Infant formula   H. Other (Please specify)..........................

23. Are you currently breastfeeding (NAME)?
   A. Yes        B. No

24. How long do you intend to breastfeed (NAME)?
   A. 1 year     B. 2 years       C. > 2 years     D. Other (please specify)..........

25. At which month, did you start complementary feeding with (NAME)?
   A. < 6 months   B. At 6 months     C. > 6 months

26. If mother did not start at the 6th month, what was the reason for the delay?
   A. Did not know exactly when to start
   B. Mother feel that the breast milk is enough for the child
   C. Advice from family elders not to give food before one year
   D. Mother feel child may not be able to digest food
   E. Mother did not try as child had no teeth

27. Did (NAME) drink any of the following liquids yesterday during the day or at night? (please circle all that apply)
   A. Breast milk   B. Plain water   C. Infant formula   D. Any other Milk   E. Fruit juice
   F. Coffee or tea   G. Any other liquids   H. Liquid traditional medicine

28. Did (NAME) drink anything from a bottle with a nipple yesterday during the day or at night?
   A. Yes        B. No

29. Did (NAME) eat any of the following foods yesterday during the day or at night? (Please circle all that apply)
   A. Foods made from grain, roots or tubers (rice, banku, Koko, yam, cassava, potato)
   B. Legumes and nuts (beans, Groundnuts/peanuts, or any other nuts)
   C. Dairy products (milk, Cheese or yoghurt)
   D. Flesh foods (Beef, pork, lamb, goat, rabbit, Chicken, Duck, Fresh or dried fish or shellfish, Crabs, snails, Organ meats (liver, kidney))
E. Eggs
D. Vitamin A rich fruits and Dark green leafy vegetables (ayoyo, ademe, kontomre)
F. Other Fruits (orange, ripe mango, pawpaw, water melon)
G. Other Vegetables (Carrots, cabbage, garden eggs)
H. Food made with oil, fat, or butter, red palm oil, palm nut pulp/sauce

30. How many times did (NAME) eat solid/semi-solids, or soft foods yesterday during the day and at night?
   A. Once [ ]    B. Twice [ ]    C. Thrice [ ]    D. 4-5times [ ]
   E. 6-10times [ ]    F. > 10 times [ ]

31. May I see the salt that is used for cooking? ......................
   A. Iodized salt [ ]    B. Ordinary salt [ ]

32. Did (NAME) receive a vitamin A dose... in last 6 months?
   A. Yes    B. No

ANTHROPOMETRIC AND BIOCHEMICAL DATA

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Code</th>
<th>Readings</th>
</tr>
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</tr>
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<td></td>
<td></td>
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<td>2.__________________m</td>
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<td>Mid Upper Arm Circumference</td>
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<td></td>
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<td>2.__________________cm</td>
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<td>Haemoglobin level</td>
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THANK YOU
Appendix III: Consent forms

CONSENT FORM

Title: *Efficacy of a complementary food on the nutritional status of children between 7-24 months of age*

Principal Investigator: Prof. Matilda Steiner-Asiedu

Address: Department of Nutrition and Food Science, Box LG 134, University of Ghana, Legon

Email: tillysteiner@gmail.com

**General Information about Research**

The purpose of this study is to quantify the effect of a complementary food on the nutritional status of Children between ages 7 to 24 months of age in a 6-month intervention study in the Ga East District of the Greater Accra Region. If you agree to participate in this research study, you will be asked some few questions about your knowledge on complementary feeding and some associated practices. Your child’s food intake and also his/her haemoglobin level, weight, length and mid upper arm circumference (MUAC) measurements will be taken at 0, 2, 4 and 6 months. We will contact you 2 months after the intervention to repeat these measurement so as to see how your child is doing after the 6 months intervention period.

**Possible Risks and Discomforts**

There are no known risks associated with your participation in this study. The inconvenience you may experience is the time you would have to dedicate to complete the questionnaires.
Possible Benefits

Information gathered from this study will help inform educational campaigns and policies on infant feeding in your community and the Nation at large. Also, your child’s nutritional status will be improved.

Confidentiality

Any information obtained from you will be kept strictly confidential. Your consent form will be kept separate from the data and the data will not be available to anyone other than the researchers. The information obtained may be used in presentations and/or research papers; however, your name will never be used. You should also know that the Ethics Committee of the Noguchi Memorial Research Institute may inspect study records as part of its auditing program, but these reviews will only focus on the researchers and not on participant responses or involvement. The Internal Review Board (IRB) for the Noguchi Memorial Research Institute is a group of people who reviews research studies to make sure they are safe for participants.

Compensation

You will receive one medium sized bucket at the end of this study as a token of appreciation for your participation.

Additional Cost

Your participation in this study will be at no cost to you.
Voluntary Participation and Right to Leave the Research

Your participation in this study is not compulsory. You are free to stop at any point in time if you so wish. You will not be penalised for withdrawing.

Contacts for Additional Information

We will be happy to answer any questions you may have about this study. If you have further questions or concerns related to your participation in this study, or if you have a research-related problem, you may contact the Principal Investigator of the study at the University of Ghana-Legon, Prof. Matilda Steiner-Asiedu by telephone at 0541260704 or by email at tillysteiner@gmail.com).

Your rights as a Participant

This research has been reviewed and approved by the Institutional Review Board of Noguchi Memorial Institute for Medical Research (NMIMR-IRB). If you have any questions about your rights as a research participant you can contact the IRB Office between the hours of 8am-5pm through the landline 0302916438 or email addresses: nirb@noguchi.mimcom.org
VOLUNTEER AGREEMENT

The above document describing the benefits, risks and procedures for the research title *(Efficacy of a complementary food on the nutritional status of children between 7-24 months of age)* has been read and explained to me. I have been given an opportunity to have any questions about the research answered to my satisfaction. I agree to participate as a volunteer.

_____________________________  ______________________________
Date  Name and signature or mark of volunteer

If volunteers cannot read the form themselves, a witness must sign here:

I was present while the benefits, risks and procedures were read to the volunteer. All questions were answered and the volunteer has agreed to take part in the research.

_____________________________  ______________________________
Date  Name and signature of witness

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above individual.

_____________________________  ______________________________
Date  Name Signature of Person Who Obtained Consent
Appendix IV: Malaria prevalence among study participants from baseline to endline

Baseline

- Control: 2.97
- Intervention: 1.19

Endline

- Control: 3.85
- Intervention: 1.19

Study duration
## Appendix V: Sample confirmatory results for worm infestation and malaria

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Appendix VII: Sample ethical approval letter

NOGUCHI MEMORIAL INSTITUTE FOR MEDICAL RESEARCH
Established 1979
A Constituent of the College of Health Sciences
University of Ghana

INSTITUTIONAL REVIEW BOARD

Phone: +233-302-916438 (Direct)
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Fax: +233-302-502182/13202
E-mail: nirb@noguchi.ug.edu.gh
Telex No: 2556 UGL GH

My Ref. No: DF:22
Your Ref. No:

4th January, 2017

ETHICAL CLEARANCE

FEDERALWIDE ASSURANCE FWA 00001824
NMIMR-IRB CPN 031/15-16 revd. 2017
IRB 00001276
IORG 0000908

On 4th January, 2017, the Noguchi Memorial Institute for Medical Research (NMIMR) Institutional Review Board (IRB) at a full board meeting conducted continuing review and renewed your protocol titled:

TITLE OF PROTOCOL: The efficacy of complementary food on nutritional status of children between 7 to 24 months of age in a 6 month intervention study in the Ga East District of the Greater Accra Region

PRINCIPAL INVESTIGATOR: Prof. Matilda Steiner Asiedu

Please note that a final review report must be submitted to the Board at the completion of the study. Your research records may be audited at any time during or after the implementation.

Any modification of this research project must be submitted to the IRB for review and approval prior to implementation.

Please report all serious adverse events related to this study to NMIMR-IRB within seven days verbally and fourteen days in writing.

This certificate is valid till 3rd January, 2018. You are to submit annual reports for continuing review.

Signature of Chair: 

Mrs. Chris Dadzie
(NMIMR – IRB, Chair)