EFFECT OF CRICKET ENRICHED PORRIDGE AND NUTRITION EDUCATION ON GROWTH AND GUT HEALTH OF INFANTS AND YOUNG CHILDREN IN ALEGO USONGA, SIAYA COUNTY

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A Thesis Submitted to the School of Public Health, Biomedical Sciences and Technology in Partial Fulfillment for the Requirements of the Award of Doctor of Philosophy in Public Health Nutrition Degree of Masinde Muliro University of Science and Technology.

October 2025

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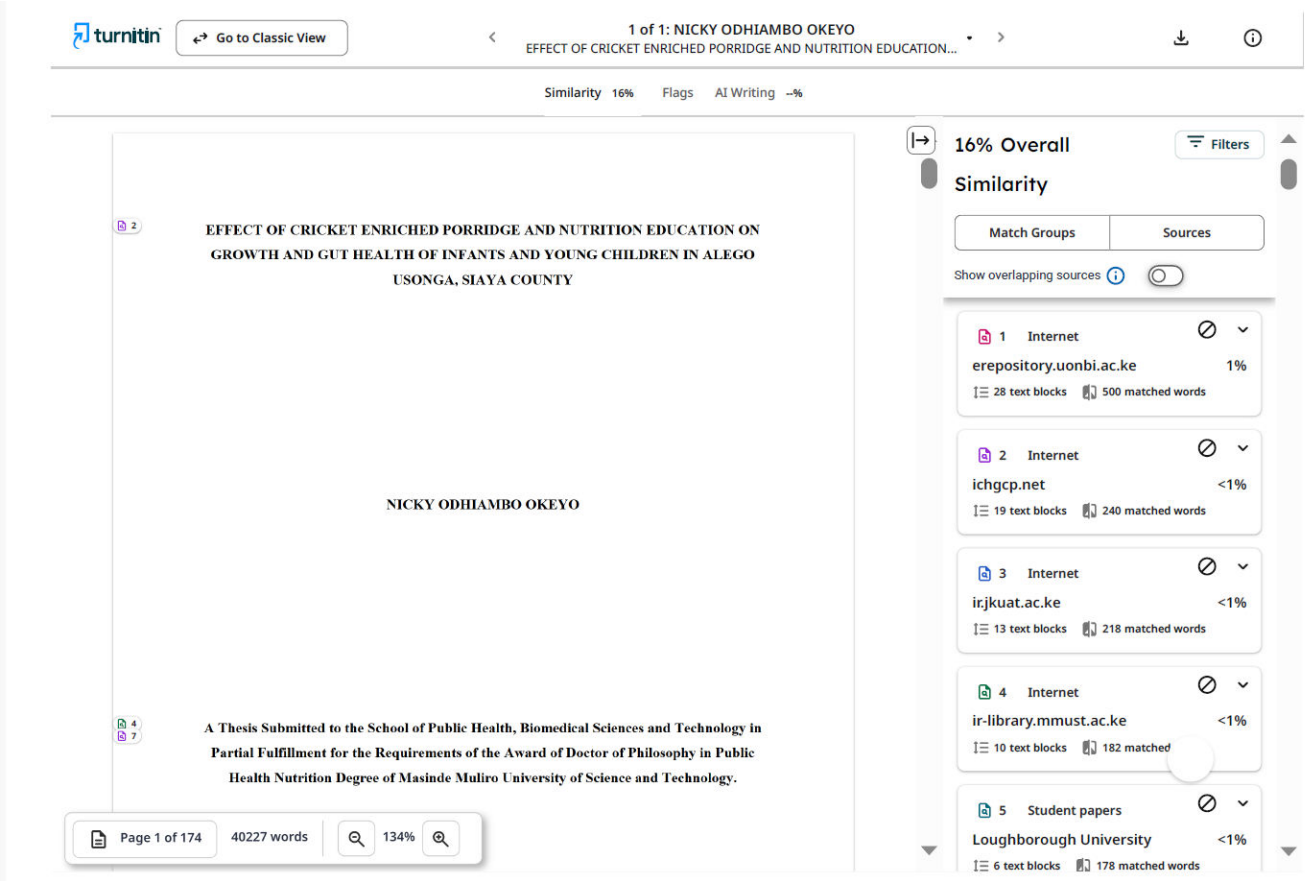

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DEDICATION

This thesis is dedicated to my father's family whose support has seen me through it. To my wife Gertrude, daughter, Lisa, and sons Eli and Elon, the Lord is my source of strength and you, my inspiration.

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ABSTRACT

Globally about 45% of all deaths in children is attributed to undernutrition. Children who survive severe undernutrition suffer long-term growth retardation. There is a growing interest in insects for alleviation of malnutrition due to their energy density, protein quality, vitamins and mineral contents. Insects can potentially replace dairy and flesh in complementary foods (CFs) in food insecure settings. In this study, infants 6 months old were exposed to daily serving of insect-based CF for 8 months, with their mothers exposed to nutrition education were evaluated for linear growth as primary outcome. Secondary outcomes included skinfolds and dietary diversity. The study was an experimental randomized controlled trial with 4 study arms. It enrolled 284 mother-infant dyads, randomly assigned to the study arms at Rwambwa Sub-County Hospital. Each dyad was assigned to a combination of the two treatments: Cricket treatment (+/-CR), and Nutrition Education treatment (+/-ED). The study CFs were provided monthly as take-home rations adjusted for age, while +NE sessions were monthly personalized audio-visual sessions with both education messages and reminder sent to the mother's mobile phones. Monthly, infant anthropometric, feeding practices and child health data were collected using structured questionnaires. Gut health at baseline was tested in a random sample of 40 infants using ^{13}C-Sucrose breath test. Both study CFs had high acceptability rate of 98.3% and 99.2% for +CR and -CR respectively. The researcher observed a significant (Z=-0.28 (p=0.03)) height-for-age z-score (HAZ) effect between -CR and +CR with no significant change in height on either cricket or education treatment. Signifying a relatively similar growth rate in terms of absolute height. Nutrition education to mothers significantly improved the weight-for-height (WHZ), irrespective of CFs consumed by a magnitude of 0.45 WHZ-score. Those suffering more than 3 episodes of illness were significantly (p=0.03) associated with at least a four times likelihood of suffering acute malnutrition as noted by low middle upper arm circumference (MUAC). Girls were significantly (p=0.01) 1.98 times likely to be malnourished by MUAC compared to boys at end-line. The mean cumulative % ^{13}C-sucrose dose recovered in a breath at 90 min from stunted infants was lower compared to the non-stunted. It is supposed that high breastfeeding rates combined with the small difference in nutrients composition, limited detection of difference in absolute linear growth and stunting effect. Concluding, this similarity in growth rate in all study arms suggest the potential of insects in providing healthy protein comparative to the super cereal. The study recommends, uptake of safe, deliciously prepared cricket porridge to enhance diet diversity, with a call for research on gut health for more insight on their contribution to human growth.

Key words: infants, insects, crickets, complementary feeding, linear growth, gut health

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LIST OF ABBREVIATIONS AND ACRONYMS

AAP	American Academy of Pediatrics
ANOVA	Analysis of Variance
ASFs	Animal Source Foods
BAZ	BMI for Age Z Score
BMI	Body Mass Index
+CR	Porridge with cricket
-CR	Porridge without cricket
COVID-19	Corona Virus Disease
CPDR-90	Cumulative % ^{13}C-sucrose dose recovered in a breath at 90 min
CSB+	Corn-Soy Blend Plus
^{13}C	Thirteen Carbon Atom
^{13}C-SBT	^{13}C-Sucrose Breath Test
DGA	Dietary Guidelines for America
DDS	Dietary Diversity Scores
DMS	Dutch State Mines
+ED	Nutrition Education given
-ED	No Nutrition Education given
EED	Environmental enteric dysfunction
ELISA	Enzyme-Linked Immunosorbent Assay
FAO	Food and Agriculture Organization of the United Nations
FTIR	Fourier Transform Infrared Spectrometry
HAZ	Height for Age Z Score
Hb	Hemoglobin

HiCN	Hemiglobincyanide
ICSH	International Council for Standardization in Haematology
IgE	Immunoglobulin E
JKUAT	Jomo Kenyatta University of Agriculture and Technology
KEBS	Kenya Bureau of Standards
Kg	Kilogram
KSh	Kenya Shillings
LMICs	Low and Middle Income Countries
MMUST	Masinde Muliro University of Science and Technology
MOH	Ministry of Health
MUAC	Mid-Upper Arm Circumference
MUACZ	MUAC Z scores
NACOSTI	National Commission for Science, Technology and Innovation
NCHS	National Center for Health Statistics
SMS	Short Message System
SRS	Simple Random Sampling
UNICEF	The United Nations Children's Education Fund
U5	Under-Fives
WAZ	Weight for Age Z Score
WHO	World Health Organization

OPERATIONAL DEFINITION OF TERM

Accrual rates: Follow-up visit attendance and flour picking rate of the expected participants over time

Acheta domesticus are crickets that are also referred to as house Crickets. They are typically gray or brownish in color, grows up to 16–21 mm in length, have long hind wings when they become adult, which they sometimes shed off

Bottle feeding is defined in this study as any form of feeding where the child feeds from a bottle or cup with a teat/nipple that is sucked irrespective of the liquid food provided which could as well be expressed breast milk

Cohen's d: Cohen's d magnitude is expressed in a number of standard deviations that separate the two groups. Thus, a d of 0.5 can be understood as one group being located 0.5 standard deviations away from the other group

Complementary feeding is defined as the feeding which occurs during the period when foods or liquids are provided along with continued breastfeeding to meet the additional nutrition needs for the child. Usually this happens when the child is between 6 months to 2 years of age

cPDR90: The cumulative percent of the ^{13}C-sucrose dose recovered in a breath at 90 min after dosing with the ^{13}C-sucrose isotope solution

Crickets are orthopteran insects with cylindrical shaped bodies, round head and long antennae. There hind legs are enlarged adapted for jumping

Cricket Enriched Porridge: Cricket enriched porridge is porridge made from 20% cricket flour combined with 35% maize, 45% millet and vitamin premix added

Cross-reactivity: Cross-reactivity is defined as when IgE antibodies originally raised against one allergen bind to another structurally-related allergen. Cross-reactivity occurs frequently between allergens from taxonomically related species due to the existence of pan-allergens

Design Effect: Ratio of variance (Estimate) of complex sampling and variance (Estimate) of Simple random sampling (SRS). {mathematically defined as: [Design Effect= (variance (Estimate) of complex sampling) / (variance (Estimate) of SRS)]}

Dysbiosis: This is a microbial imbalance in the body, leading to an impaired microbiota, which is a commonly reported condition in the gastrointestinal tract, due to small intestinal bacterial or fungal overgrowth

Effect Size: The difference of the means between the lowest group and the highest group over the common standard deviation is a measure of effect size. $[(x_1-x_2)/sd]$

Enrolment: This is the inclusion of the study participant into the food intervention program having attained the age of 6months when a child is introduced to complementary food

Environmental Enteric Dysfunction in this study, refers to as an impairment of the structure and function of the small intestine, characterized by increased permeability, reduced absorptive capacity, and inflammation irrespective of the cause

Gut Heath in this study refers to the gut permeability which measure how leaky the gut is and is measured by ^{13}C-sucrose dose recovered in a breath at 90 min after dosing with ^{13}C-sucrose solution

Human microbiome: This refers to the collective genomes of the microorganisms in a human body

Pathogens: Pathogen is anything that causes a disease thus used to describe an infectious agent

Food allergy: Food allergy is defined as an adverse health effect arising from a specific immune response that occurs reproducibly after exposure to a given food

Persistence: Persistence in this study refers to the continued or prolonged use of the study food over the study period

Power of a test: Power of a test is the probability of detecting a true underlying difference given that it exists. That is the long term probability of rejecting false null hypothesis, given the effect size in the population, the chosen significance level and number of participants tested (Bahçecitapar et al., 2016; Brysbaert, 2019)

Main effect: This is the effect of one independent variable on the dependent variable—averaging across the levels of the other independent variable. Implying, there is one main effect to consider for each independent variable in the study

Infants: A baby who is aged 0 to 12 months is referred to as an infant

Interaction: There is an interaction effect (or just "interaction") when the effect of one independent variable depends on the level of another

Recruitment: Recruitment is the first entry step entailing the action of inviting the study participant to be involved in the study based on the recruitment criteria and does not necessarily imply receiving the intervention food especially those whose age are below 6 Months of age

Simple effects: Simple effects are a way of breaking down the interaction to figure out precisely what is going on. An interaction simply informs us that the effects of at least one independent variable depend on the level of another independent variable. Whenever an

interaction is detected, researchers need to conduct additional analyses to determine where that interaction is coming from

Stunting: Stunting is an impaired growth defined as, low height for age and classified as more than 2 standard deviations below the median value of the NCHS/WHO International Growth Reference for length- or height-for-age. It is therefore an impaired growth indicator. In this document growth and stunting may be used to define impaired growth interchangeably in context

Young child: Any baby older than one year and yet still younger than five years of age is referred to as a young child

CHAPTER ONE

INTRODUCTION

1.1 Background Information of the Study

According to UNICEF, the quality of diet consumed by a child before age 2 years should be the best than any time in their life (UNICEF, 2020a). At six month of age, the infant's food requirements out-grow breast milk and complementing becomes necessary. During these early days of rapid growth and microbiome build up, a child requires adequate quantity and quality of protein in addition to other essential nutrients. Malnutrition is a complex health state that is not only caused by nutrient deprivation, but is influenced by a myriad of factors including: individual factors, socio-economic factors, demographic factors, food production system, food supply chain, environment factors as well as political situations (Bartelt et al., 2019). As a health-related condition, malnutrition in childhood can have an adverse vicious cycle, with malnutrition causing disease and vice versa. Children who survive severe undernutrition suffer long-term stunting and neurodevelopmental deficits that can be felt across generations. These consequences holds the children back from reaching their physical and cognitive potential, as such addressing nutrition gap requires diverse approaches (Evang et al., 2020).

Stunting which can begin in utero, is the most serious nutrition related risk factor. It can lead to common childhood growth faltering, morbidity and mortality especially if not addressed within the first 1000 days of life when it can effectively be corrected with nutritious foods breast milk inclusive (Tao & Li, 2018). As any intervention against stunting after the first 1000 days simply offer growth catch up opportunity (Hossain et al., 2017; Parikh et al., 2021; Prentice et al., 2013). Introducing a variety of food during early life effectively supports the buildup of the child's microbiome and adaptation to the varied taste. In addition to cereals, animal source foods (ASFs) are hailed and recommended as best source of required macro and micro nutrients including essential amino acids for infant and children aged 6 -23 months (Dewey, 2003). However, with the onset of climate change, global warming and increase in human population, there exist pressure on the mainstream ASFs. Insect as food on the other hand, is gaining acceptance as alternative source of protein and micro nutrients with low carbon foot print (De Gier & Verhoeckx, 2018; Imathiu, 2020; Tao & Li, 2018; Van Huis et al., 2021).

Globally there is concerted efforts to mass produce insects by following safe farming and food processing protocols for safe and nutritious harvest (Alemu et al., 2023). Though such properly farmed and processed Insects have actually been shown to be safe for human consumption, only few research on human consumption have been conducted (Adegboye, 2022; FAO, 2021). And those conducted are largely in traditional insect consuming regions such as: Sub-Saharan Africa, India, Indonesia, Southeast Asia, and Latin America (FAO, 2013; Kipkoech et al., 2023; Krongdang et al., 2023; Matandirotya et al., 2022; Omuse et al., 2024; Sabri et al., 2023; Siddiqui et al., 2023). These studies, mainly consider the use of edible insects for older children or adults, and rarely for infants. Even in communities where edible insects is most common such as Indonesia and India, the community knowledge and practices in infant is not well documented for effective integration into infant nutrition (Sabri et al., 2023). Similar trend is also observed in Africa where mothers, school going children and adults have been the target groups (Adegboye, 2022). With the ever-growing interest in the consumption of edible insects there is a growing interest of edible insects in even regions that were not traditionally consuming such as Eastern Europe and central Asia (Omuse et al., 2024).

According to Kinyuru *et.al*. (2015) and Payne & Itterbeeck, (2017), edible insects have currently attracted research due to their potential in reducing poverty, alleviating hunger, improving nutrition and saving the environment. Kinyuru *et.al*. (2015) reports that insects are cold blooded, have a fast growth, have high feed to meat conversion efficiency with low green gas emission making them more ecofriendly and easier to rear than other domestic animals. Research has shown that insects are rich in protein, dietary fibre, beneficial fatty acids, a good source of micronutrients and medicinal elements. Comparatively to, termite (*Macrotermes nigeriensis*), grasshopper (*Melanoplus foedus*) and moth caterpillar (*Cirina forda*), field cricket (*Gryllus assimilis*) were found to have a higher protein quality and better digestibility (FAO, 2021) which makes crickets one of the promising insects for human nutrition (Magara et al., 2021)

Crickets generally are leaping insects in the order of orthopteran. House cricket (*Acheta domesticus*) in particular has more or less protein content at between 62.41-71.09 g/100g dry weight compared to 71.04±0.01 g/100g in *Gryllus assimilis* also referred to as field cricket. House crickets are already popularly accepted as food in both developed and developing countries and a preferred species for large scale production globally (Magara et al., 2021). Besides the nutritional value, crickets have also been recommended for healthy gut and

reduction of systemic inflammation at a daily dosage of 25g of cricket powder/day (Adegboye, 2022; Stull et al., 2018). With the evidence of Insect-enriched complementary foods being considered safe and acceptable, there is a growing research interest on their effect on the nutritional status in children is growing (Adegboye, 2022). Crickets can therefore form a more cost-effective source of essential nutrient if added to the home-based unfortified plant based complementary food commonly served in Kenya.

Kenya has established a robust regulatory framework to ensure the safety and quality of insect-based products in recognition of the global acceptance of insects as viable sources of food and feed. The country has developed four key national standards through the Kenya Bureau of Standards (KEBS) to regulate the harvesting, domestication and processing of insects as well as the specification of insect products: 1) **KS 2921:2020** - Production and handling of insects for food and feed - Code of practice, 2) **KS 2711:2017** - Dried insect products for compounding animal feeds – Specification 3) **KS 2922-1:2020** - Edible insects specification Part 1: Edible insects' products and 4) **KS 2922-2:2020** - Edible insects specification Part 2: Products containing edible insects. These standards provide a formal structure for harvesting, rearing, processing, and commercialization of insect-based products, thereby enhancing consumer safety and market acceptability (Kinyuru & Ndung'u, 2022).

The critical knowledge required for the uptake and sustained use of cricket enriched food and other healthy nutrition practices can be achieved through nutritional education that is targeting early life. The nutrition education should adopt various strategies to promote healthy food choices, supportive environment and nutritional behaviors that promote health and wellness for both the caregiver and the infants as they grow up (Dattilo & Saavedra, 2020).

1.2 Statement of the Problem

Globally, stunting declined from 33.1% in 2000 to 22.0% in 2020, however about 41% of the world stunted children under 5 year old live in Africa, 32.6% in Eastern Africa. The stunting rate of 19.4% (UNICEF et al., 2021) in Kenya is still unacceptably high, and requires a sound and efficient nutrition intervention. Different proteins sources provide different essential nutrients required for optimal child growth, leading to the recommendation for early introduction of diverse ASFs during complementary feeding. In spite of this recommendation, production of large animals requires large volume of water and emits green gases which have

been linked to global warming and negative environmental impacts. Red meat and dairy products are also associated with non-communicable diseases including cancer and child obesity (Alisson-Silva et al., 2016). This has led to the call for studies on the effects of other rich protein sources with lower health risks (Tang, 2018). Cricket consumption has been shown to improve gut health and reduce systemic inflammation with research interest to understand their nutritional effect and the underlying mechanisms (Stull et al., 2018). A review of literature by Adegboye, (2022), on the potential use of edible insects in complementary foods for children, positively confirms safety and acceptability of insect enriched complementary food. This review included three studies on nutritional effect from which it established mixed finding on nutritional effect of edible insect consumption. Most of the current research have however targeted older children or adults and rarely infants (Aboge et al., 2021, 2024; Adegboye, 2022; Kipkoech et al., 2023; Konyole et al., 2023). Hence the conclusion there are limited nutritional studies on efficacy of consuming insect-enriched (one of which was crickets) foods with recommendation for more studies to establish effect of insect enriched food on child nutritional status (Adegboye, 2022; Boit et al., 2024). This current study therefore sought to fill the gap by improving food diversity by inclusion of crickets as readily available source of protein and essential minerals, with the aim to determine the effect of cricket enriched porridge on reducing stunting and improving growth of infant and young children.

1.3 Objectives of the study

1.3.1 Broad objective

To determine the effects of complementing with edible cricket enriched porridge in combination with nutrition education on linear growth and gut health of infants and young children from 6-14months in Alego Usonga Sub-County, Siaya County.

1.3.2 Specific objectives

i. To assess study food acceptability and estimate the adherence to taking cricket enriched porridge after its first introduction as a complementary food by infants and young children in Alego Usonga Sub-County
ii. To establish the effects of cricket enriched porridge consumption on the linear growth of infant and young children over the 8 months study observation period in Alego Usonga Sub-County

iii. To determine the effects of nutrition education on the linear growth of infant and young children over the 8 months study observation period in Alego Usonga Sub-County
iv. To establish the effect of baseline gut status on infant growth status at the end of the study period in Alego Usonga Sub-County
v. To evaluate the combined intervention effects of cricket enriched porridge consumption and nutrition education on child's linear growth over the 8 months study observation period in Alego Usonga Sub-County

1.4 Hypotheses

In this study, it is hypothesized that the intervention would lead to improved feeding practices, dietary intakes, and growth of children. This hypothesis is on the assumption that, feeding young ones on cricket enriched porridge increases animal-based protein intake and that there is no important interaction between the two interventions on the primary outcomes, specifically the study tested the null hypotheses:

Ho: Providing nutrition education to caregivers of infants and cricket enriched porridge to the infants for a period of eight months increases linear growth rate among the children than any single intervention

1.5 Significance of the study

Insects generally and crickets in particular not only provide us with a delicious and nutritious food, but provides the world with an opportunity to reduce global warming while assuring household of food security. By focusing on cricket enriched porridge and nutrition education in reducing protein and micronutrient deficiency, the study provided an opportunity to understand the effect of cricket enriched porridge on a child's health and growth. The finding of this research provides information on product acceptability and the nutritional benefit of in cooperating crickets in complementary feed. It forms a basis for promoting healthy nutritional diet and contribute knowledge to the body of entomophagy. The knowledge generated by the study is beneficial in the review of existing policies on insect as food.

1.6 Justification of the Study

The African continent accounts for over a third of the cases of malnutrition in the world. Protein deficiency, iodine deficiency, vitamin A deficiency, vitamin B12 deficiency and Iron deficiency are the macro and micronutrient deficiencies of concern in sub-saharan Africa (Willett et al., 2019). Protein deficiency and vitamin B12 which is almost exclusively available from animal-source foods are of particular concerns in African rural households' where most children are fed on cereal or tuber-based porridge.

Meat, pork, milk, and eggs are viewed as expensive and the myth that eggs make children dumb or stammer reduces the chances of preparing these products to supplement child nutrition. Additionally whole grain, seeds, legumes, vegetables and fruits are highly recommended with moderate consumption of sea food, poultry and a reduction on red and processed meat for optimal growth, reduced infection and good child development (Van Huis et al., 2021; Willett et al., 2019) Globally, insect food has been identified as a possible alternative to red meat, and a source of highly digestible dietary proteins with sufficient amino acid composition, containing high vitamin and mineral (FAO, 2013).

A literature review on the potential use of edible insects in complementary foods for children, besides establishing safety and acceptability, only found two studies on the efficacy of insect enriched food indicating no nutritional effect. One of the two reviewed studies was conducted amongst community habitually consuming high protein diet hence the conclusion, there are limited nutritional studies on efficacy of consuming insect-enriched foods leading to the recommendation for more studies to establish effect of insect enriched food on child nutritional status (Adegboye, 2022; Arnesen et al., 2022; Stull et al., 2018; Tang, 2018).

Research has also shown that single nutrition interventions are less effective for reducing malnutrition and stunting in particular, with a combination of nutrition-specific and nutrition-sensitive interventions considered potentially to be yielding better outcome (Hossain et al., 2017). In spite of recognizing impact of stunting, there is limited evaluation on integrated nutrition interventions for the reduction of stunting amongst infants and young children (Elisaria et al., 2021). This situation justified the need to conduct an integrated nutrition intervention involving insect enriched complementary food and maternal nutritional education. This study assessed the potential effect of introducing cricket enriched porridge with nutrition

education emphasizing recommendation on protein and overall nutrient adequacy for optimum child growth.

1.7 Scope of the study

This study was conducted to determine the effect of cricket enriched porridge nutrition intervention and nutrition education on children aged 6-14 months in western Kenya, Siaya County. The study targeted eligible children of the parents who visited the health facility for any health care service during the study recruitment period. The study collected data on the child feeding behavior, anthropometric response, and the general child health during the study period. The methods and strategies used were individual centric with flour distribution and care services offered at the facility premise.

1.7.1 Limitations of the Study

The experiment involved children with rapid growth and weight gain which is unlike the adult with minimal weight and height gain hence the findings cannot be generalized to the entire human population. Second the nutrition intervention was limited to healthy children and so, the result can not address the needs of children who are sick especially those with diarrhea and severe anemia given that the area is malaria endemic with high malaria incidence which is a risk factor for anemia. The study documented the history of the foods the infants was feed on based on the caregiver's report which is potentially limited to the caregiver's ability to recall or can be biased to selective memory. In addition, the data collected was limited to the precision level of the measuring instrument which results in some level of measuring bias.

1.7.2 Delimitations of the Study

Though child malnutrition is a wide nutrition problem covering various topical issues this study focused on protein deficiency with interest on stunting in the context of mal-absorption disorder mediated by poor gut health. The study focused on insect protein as a source of animal protein for better growth and health. And although Kenya has multiple cultural communities with diverse food culture the study was delimited to the western Kenya communities with history of insects' food as part of their traditional diet.

1.8 Theoretical model

This study was based on UNICEF conceptual framework on the causes of child malnutrition and two theoretical models; 1) The theory of child surviving and thriving and 2) Constructivism learning theory.

UNICEF's conceptual framework of malnutrition argues that the child's nutritional status is determined by more than just food, health and care that a child receives. The theory of child surviving and thriving is adapted from the revision of the UNICEF's conceptual framework of malnutrition by recognizing that besides improving diet and reducing diseases, children require a more comprehensive, multi-sectorial system of services and opportunities. It emphasizes the significance of nurturing care and protection in supporting a child to grow and achieve their full potential. This combined model emphasizes that children require attention to health, nutrition, learning, responsive caregiving, and safe secure environment (Black et al., 2020).

Constructivism theory emphasizes, the learner's construction of new knowledge is based on the new information and past experience with both being at the core in determining the beneficial knowledge to retain. The study was therefore based on social constructivism, which is a collaborative form of learning based on interaction, discussion and knowledge sharing among learners using real life case-based approach which is often more appropriate for adult learners. This theory holds that an individual's knowledge acquisition is substantially based on their past experiences, social context (based on interactions between personal characteristics), behavioral patterns and environmental factors. In this model the influence of the significant knowledgeable persons in the child's environment are believed to have great impact on the nutritional behavior of the child (Dattilo & Saavedra, 2020; Gillespie, 1981).

In summary from the two theories and the UNICEF framework, a child's nutrition status is determined by more than food, nutrition, feeding practices, health, responsive caregiving, child protection and proactive learning environment the study fed the child at home and monitored the child's health at every visit. It therefore recognizes the contribution of the infants parent/caregiver that is largely influence by the nutritional and health knowledge. Emphasizing the need to address all the interrelated components of a child's welfare and nutritional needs as

summarized in Figure 1.1. This conceptual frame work summarizes the background factor that are often moderated by proximate factors which includes transitionary states and habitual practices that determines a child's health and nutritional status

1.9 Conceptual Framework

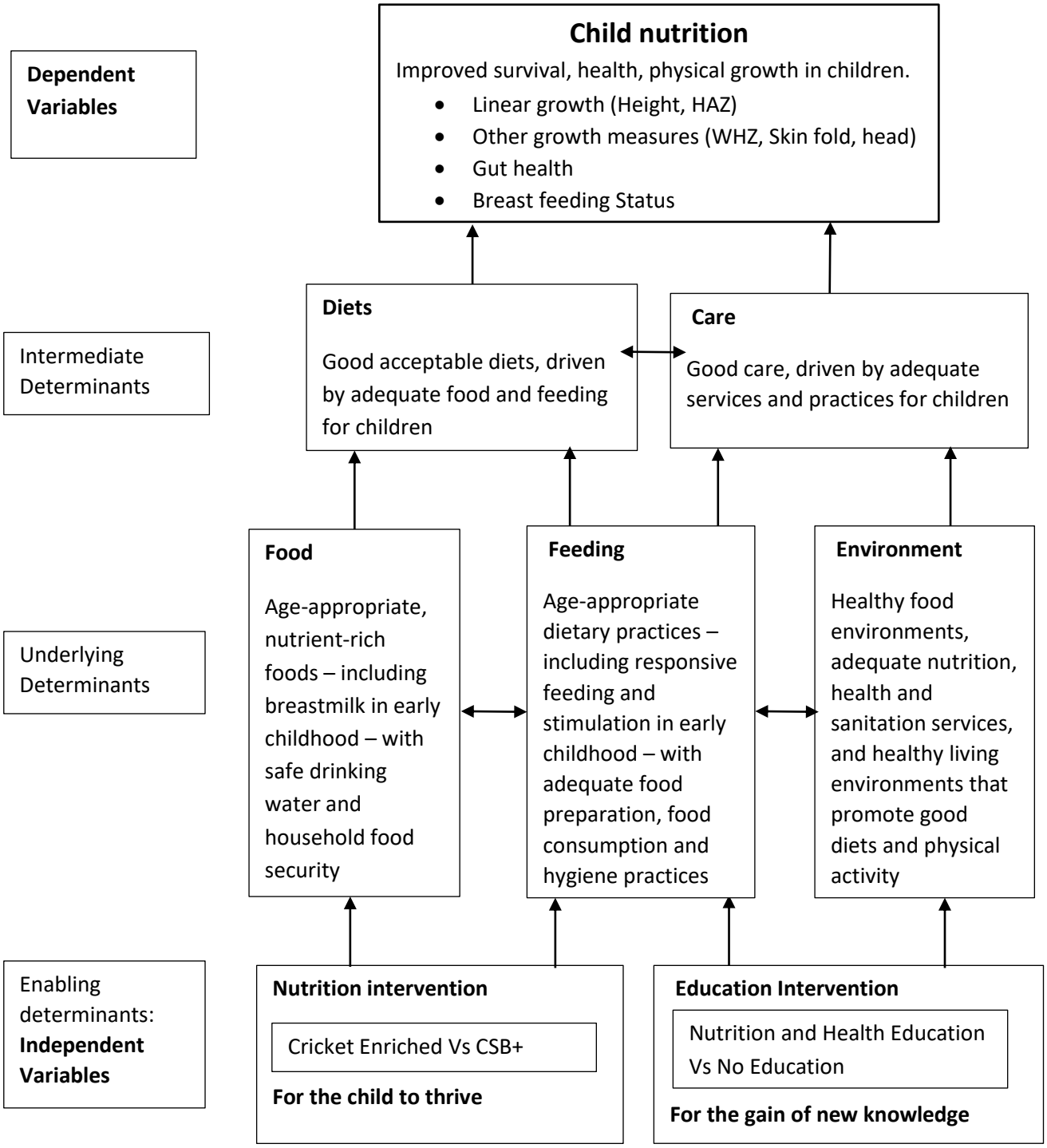

Figure 1.1 The conceptual framework for the prevention of malnutrition

Adapted from the "UNICEF Conceptual Framework on the Determinants of Maternal and Child Nutrition, 2020. A framework for the prevention of malnutrition in all its forms" (UNICEF, 2020b)

CHAPTER TWO

LITERATURE REVIEW

2.0 Introduction

This chapter reviews the work done by other researchers on malnutrition situation, relationship between malnutrition and the introduction of complementary feed, food acceptability in the light of insect food, contribution of nutrition education in the alleviation of malnutrition and describes the significance of integrated nutritional interventions. It further explores the contribution of nutrition related factors such as child morbidity, gut microbiome and household determinants of malnutrition as observed by various researchers.

2.1 Malnutrition Situation

The nutritional status of a child defines the child's health status and vice versa with both over-nutrition and undernutrition being the undesired health status often termed as malnutrition. Commonly, malnutrition is associated with multiple causes and disease conditions (Akombi et al., 2017; Masuku-Maseko & Owaga, 2012). Undernutrition in particular is a condition due to energy and/or micronutrient deficiency which can manifest as stunting, underweight and wasting. Unfortunately, malnutrition of any form can predispose a child to child morbidity, language impairment, poor cognitive and/or motor development and at worst result in child mortality (Akombi et al., 2017; Eaton et al., 2019). A child requires, adequate supply of protein and micronutrients such as Iron, Vitamin A, Zinc and Iodine in addition to other macronutrients for optimal growth, reduced infection and good development (Masuku-Maseko & Owaga, 2012).

Untreated early childhood malnutrition can be life threatening, as it leads to increased susceptibility to childhood infections and potentially deprive the child from living to full potential (Tam et al., 2020; Tao & Li, 2018; WHO, 2018). In 2018, more than 820 million people globally were undernourished. As at 2018 among children who are under five years old an estimate of, 149.2M (21.9%) were stunted, 45.4M (6.7%) were wasted while 38.9 million (5.7%) were overweight (UNICEF, 2019; WHO, 2018). Of the stunted children, about 33% resided in East and Southern Africa. Generally, between 2000 and 2020, the number of children with stunting declined in all regions except for Africa and Oceania. Asia dropped from 135.9M

to 79M, Latin America and the Caribbean 10.2M to 5.8M, Europe 2.4M to 1.8M while Oceania increased from 0.4M to 0.6M and Africa increased from 54.4M to 61.4M (UNICEF, 2019). Globally though stunting has declined steadily globally since 2000, a faster progress is needed if we are to achieve the 2030 UNICEF target of zero hunger with projected global stunting at 12.1% (UNICEF et al., 2021).

To achieve this great expected reversal, Africa must be part of the focus. Africa records high number of malnutrition cases and accounted for slightly over a third of the world's malnutrition cases in 2009 (WHO, 2010) . By 2021 41% of the worlds stunted children were living in Africa (UNICEF et al., 2021). According to African regional strategy report of 2005-2015, in sub-Saharan Africa an estimated 200M people were chronically malnourished, with malnutrition clearly being widespread in children younger than 10 years of age. The report estimates that, of the malnourished children in Africa, about 36 million children leaving in sub-Saharan Africa were undernourished. The report further qualifies, iodine deficiency disorders, Vitamin A deficiency and iron deficiency as micronutrient deficiencies of concern in sub-Saharan Africa (African Union, 2015). As at 2010 East and West Africa regions reported some of the highest prevalence of malnutrition. Specifically, East Africa accounted for about 39.4% of the stunted cases, 24.9% of the underweight and 10.3% of the wasted children aged below 5 years of age worldwide, making it a heavy burden zone on the global map (WHO, 2010).Currently the stunting rate in Eastern Africa is 36.2%, which is equivalent to approximately 22.1M of the Under 5 year old children being stunted (UNICEF et al., 2021).

In Kenya, similar to the global trend stunting has been on the decline: 40% in 1993 down to 18% in 2022 (KNBS & ICF, 2023). These rates are still way above the 2030 UNICEF target of 12.1% stunting rate. Stunting affects 20% of the urban and 30% of rural children under five years of age while wasting affect 7% and 13% of children in both urban and rural areas respectively (Evang et al., 2020). As at 2022 the rural-urban pattern remained the same for stunting though with a reduction in rates; 20% and 12% being stunted rural and urban areas respectively (KNBS & ICF, 2023). This clearly demonstrates that the rural population are at a higher risk than the urban population with regards to malnutrition. According to the Second Siaya County Integrated Development Plan 2018-2022, (Siaya County Government, 2018) in Siaya county wasting (4.7%) and underweight (7.8%) are classified as normal based on WHO classification however stunting (24.7%) level is high. In 2022 wasting increased by 1% (from 4% to 5%) while stunting dropped to 19% in Siaya. In spite of this drop Siaya still remains the

county with highest stunting rate in the lake region (Kisumu 9%, Homabay 13%, Migori 15%) and is 1% higher than the national rate (KNBS & ICF, 2023).

Stunting is largely related to the health of the child and how the child is feed. Breastfeeding is the primary food for a child in the first six months of life. According to the Kenya Demographic Health survey 2014, the county has low exclusive breast-feeding practice at 65.5% compared to the national target of 80% (KNBS & ICF, 2015). Worse still in 2022 country's breastfeeding rate dropped from 61% to 60% (KNBS & ICF, 2023). Similarly the country has low coverage of dewormed children at 26.6% for children aged 12-59months compared to the national average of 29.3% (KNBS & ICF, 2015). This therefore exposes the need that Siaya County requires concerted efforts to improve nutrition indicators in the lake region.

2.2 Introduction of Complementary Feed to Infants

Complementary feed should be introduced after the first six months of exclusive breastfeeding, when the infant's nutrition need supersedes what is available in breast milk. Stunting though may begin in the uterus is often accelerated at the introduction of complementary feeding. The limited diversity of complementary foods which more often than not is heavily cereals, coupled with early cessation of breast feeding adversely affect infant and young child's growth (Adepoju & Ajayi, 2020). Importantly ASFs have been hailed and recommended by WHO for daily consumption as the best source of high-quality nutrient-rich food. The ASF is considered to be rich in macro nutrient, micro nutrients and required essential amino acids for infant aged 6 -23 months (Adesogan, 2020; Dewey, 2003). Leading to UNICEF's recommendation; ASFs (such as e ggs, meat, poultry, fish and dairy) should be introduced early as some of the first food due to their nutritive value (UNICEF, 2020a)).

Positive growth effect of ASFs has further corroborated with evidence of higher decline in stunting amongst countries with increased per capita meat consumption. As such the recommendation to have meat be introduced starting at or approximately 6 months is currently consistently supported by Dietary Guidelines for America (DGA), the American Academy of Pediatrics(AAP), the National Academy of Medicine and World Health Organization (Hawthorne et al., 2022). And to achieve better health, whole grain, seeds, legumes, vegetables and fruits are highly recommended with moderate consumption of sea food, poultry and a

reduction on red and processed meat consumption (Van Huis et al., 2021; Willett et al., 2019). This follows the association of red meat with diseases such as cancer of the colon, hence the need if its consumption in moderation.

2.3 Food Acceptability

The acceptance of a food is not straight forward behavior, but a complex act dependent on many interacting individual and food related factors (Huey et al., 2024). Food acceptability relates directly to the interaction a person has with the food including sensory attributes of the food such as taste, texture, appearance and aroma. This is then crowned by the good feel effect a person gets on consumption of the food (Maina, 2018). The introduction of new food may also cause challenges to the person consuming it. These challenges are largely shaped by the persons' cultural perspective and belief, exposure and environment. In Africa, Asia, Latin America and Oceania edible insects are considered delicacy where as in the western societies they are considered a disgust and rejected as food (Ambele et al., 2025).

A persons' body may react especially to some protein, with introduction of a new food due to allergic effect. Food allergy is an adverse immune response to protein containing food (Imathiu, 2020). Food allergy is characterized by a very wide spectrum of clinical manifestations more often occurring in children (8%) where it is a transitory character than adults (3-10%). Most of the reactions observed, have been caused by various common foods including milk, egg, peanut, tree nuts, fish, soy, wheat or crustaceans (Radlovic et al., 2016; Ribeiro et al., 2021). These allergic reactions can range from mild localized reaction to more severe systemic clinical presentation such as anaphylactic shock, which is a life-threatening reaction often within seconds or minutes after exposure to the allergic food.

In spite global acceptance that, with edible insects, the community could benefit from insects' potential in reducing poverty, alleviating hunger, improving nutrition and saving the environment, there is concern of insect food safety and allergic reactions. Insects just like some animal and plant-based food may carry exogenous and endogenous risk factors to human health (Belluco et al., 2015; Imathiu, 2020). Though food allergy has been reported for other insects such as mealworm, silkworm, sago worms, caterpillars (mopane caterpillar), grasshopper,

locust, bee, cicada, bruchus lentis, clanis bilineata, female dactylopius coccus insects and silkworm cockroaches cross reactivity, little is documented on crickets allergy and/or cross-reactivity (Belluco et al., 2015; De Gier & Verhoeckx, 2018; Imathiu, 2020).

With the limited available information on the allergenicity of edible insects and some evidence of cross-reactivity, there is need for more studies on insect food allergy (Belluco et al., 2015; Marchi, 2021). This possibility of allergic reaction, calls for close monitoring of persons being when introduced to insect-based diet to identify potential signs and actual allergic reactions.

2.3.1 Insect as Source of Quality Food

Currently, during complementary feeding, the consumption of animal products including eggs which are rich in protein, essential fat and micro nutrients such as iron, zinc, choline, vitamin A, vitamin B12, Omega-3, and Omega-6 is promoted (Eaton et al., 2019; Masuku-Maseko & Owaga, 2012). In as much as cohort studies have shown that animal protein (especially dairy protein) are associated with obesity in old age, the lack of Randomized Control Trial (RCT) showing the same precludes stronger grading on this findings (Arnesen et al., 2022; Hawthorne et al., 2022; Kittisakmontri et al., 2022). Secondly, systematic reviews on animal protein intake indicate evidence of strong positive association of animal proteins with growth than plant protein (Adegboye, 2022; Arnesen et al., 2022; Magara et al., 2021). Whereas, one systematic review noted that even with a RCT on high protein intake in infants, there was no significant effect on both weight and growth (Faber et al., 2022), yet another RCT study in Ecuador, found that an egg a day to children 6-9months reduced stunting by 47% and caused no allergies, confirming mixed findings commonly reported in literature (Magara et al., 2021; Tang, 2018).

In spite of the associated nutritional benefit, animal-based proteins, particularly meat has also been associated with increased prevalence of non-communicable diseases including cancer. Secondly, due to global warming effects, the fact that animals production requires more water and emits large amount of greenhouse gases, there has been consistent demand for alternative and efficient food and nutrition sources (Van Huis et al., 2021; Willett et al., 2019). Further, evidence clearly shows that insect nutritional composition is highly diverse comparatively to meat because of their many species. And with improving levels of acceptability, this could be effective in tackling undernutrition(Payne et al., 2016).

Globally edible insects has remained a delicacy and source of good nutrition in many cultures with controversial estimate of approximately two billion people consuming insects (De Gier & Verhoeckx, 2018; Imathiu, 2020; van Huis et al., 2022). Insect food are energy dense, good source of proteins with sufficient amino acid composition and micronutrients with many edible insects being confirmed to have iron and zinc levels sufficient enough when compared to the current animal source (Tao & Li, 2018; Van Huis et al., 2021). The insect protein is highly digestible and identified as possible alternative for animal source dietary proteins (FAO, 2013). The high content of zinc and iron in crickets is of particular interest to nutritionist in alleviating deficiencies in popular traditional Complementary feeding food (Eaton et al., 2019) . Additionally consumption of cricket supports the growth of probiotic bacterium, *Bifidobacterium animalis* which is associated with good gut health and reduction of systemic inflammation (Stull et al., 2018). This probiotic property has resulted in crickets being recommended for healthy gut and reduction of systemic inflammation with a daily dosage of 25g of cricket powder/day (Adegboye, 2022)

Insects are generally either consumed whole or as added ingredients to various food products to increase acceptability and boost targeted nutrient need (Tao & Li, 2018). Adding insect to flour or adding insect powder to drinks and familiar foods such as cookies, chips and burgers is some of the new promising innovative food technologies that are currently being adopted (Melgar-Lalanne et al., 2019) . A study by Adepoju and Ajayi (2020) has shown that winged termite insect enriched complementary porridge which is high in both nutrient and energy content has a high acceptances rate with no side effects documented.

In Kenya there is a mixed reaction in the acceptance of crickets as food with some accepting while others getting disgusted with it. It has also been observed that enrichment of flour with cricket flour can potentially alter food sensory attribute (Aboge et al., 2021). However, for those who accept crickets as food, often appreciates its tenderness and promotes its consumption for both adults and children. Aboge and Konyole (2021) have demonstrated that porridge enriched with crickets is acceptable amongst the general population. A recent review by Adegboye (2022) found insect-enriched complementary food to be safe and acceptable and recommended more studies on their effect on the nutritional status in children.

2.4 **Nutrition Education**

Nutrition education is an interactive training engagement between a nutritionist and a client. The target of this engagement is to change nutrition related practices or behavior to that which promote health and wellness at individual level (Dattilo & Saavedra, 2020). According to Mochoni and Kimiywe in their study "Effect of Nutrition Education Videos on Mothers' Knowledge, and Practices on Complementary Feeding of Children 6-23 Months In Nairobi City County, Kenya", suggest that the high level of stunting can be attributed to poor maternal knowledge and practices on optimal complementary feeding (Mochoni & Kimiywe, 2020). This is supported by Gobel et al., (2020) who argues that, parents nutrition knowledge makes positive contribution to a child's nutrition and eating habits. Previous studies have shown varied stunting results in populations that are food secure compared to population that are food insecure, with limited studies conducted on stunting comparison in food secure population with and with no nutrition education provided (Bhutta et al., 2013). It is however important to note that focused nutrition education can make a difference in the nutrition outcomes.

In children, nutrition education to caregivers improves the child's dietary habits and behavior development, particularly by reducing unhealthy eating behaviors and promoting healthy foods (Hassani, 2020; Hu et al., 2009). This is largely because caregivers' nutrition knowledge determines how they plan, shop and prepare a child's meal. This knowledge level is therefore a determinant of the feeding habit the child acquires and potentially improves the child's dietary diversity scores (DDSs) (Effendy et al., 2020). Through nutrition education parental knowledge, attitudes and behaviors can positively be impacted (Hu et al., 2009). Studies have shown that nutrition education interventions can improve nutrition awareness, dietary practice and anthropometric measurements in target population (Antwi et al., 2020; Roseman et al., 2020). Signifying the role of parental nutritional knowledge, attitudes and behaviors on the development of their children's eating behaviors.

2.5 Integrated Nutrition Targeted Interventions

An integrated approach focusing on the child (stimulation and nutrition), the caregiver (knowledge and psychosocial health) and the caregiver-child relationship (knowledge and responsive care skills for feeding, play and communication) is more effective and sustainable

than an approach that considers the child with no attention to the family context (Hurley et al., 2016). Li et al., (2024) while implementing a combined nutrition and psychosocial stimulation interventions (CNPSI) confirmed it was more beneficial in combined form than stand-alone supplemental nutrition interventions. They confirmed the combined intervention had better growth environment and lower risk of developmental delay than single intervention for children 7-33months in a clustered randomize trial.

2.6 Other Nutrition Related Factors of interest

2.6.1 Child Morbidity

Malnutrition and disease are quite interrelated. Malnutrition predisposes a child to disease through low body immunity while disease causes appetite loss which in turn increases nutritional requirement leading to malnutrition (Masuku-Maseko & Owaga, 2012). This vicious cycle has led to the universally accepted recommendation of infant feeding with prolonged breast-feeding up to 2 years, as a way to reduce under five morbidity and mortality (Al-Jawaldeh et al., 2018). Low breast milk in take in breast-feeding babies may therefore explain the morbidity experienced by young children. It is estimated that one in ten deaths among under 5 year old in LMICs occur in malnourished children due to increased risk of infectious diseases (Headey et al., 2020).

However, the breast-feeding status reported in majority of the papers is mothers self-report which is often not precise (Slater et al., 2019). With validity question asked on self-reported breastfeeding and advances in technology, the use of stable isotope (such as deuterium) in measuring breast milk intake is currently gaining traction (IAEA, 2010; Slater et al., 2019). Deuterium is a non-radioactive isotope used to measure breastmilk intake in body water such as urine, plasma or saliva based on isotope ratio mass spectrometry(IRMS) or Fourier transform infrared spectrometry(FTIR) (IAEA, 2010).

Environmental Enteric Dysfunction (EED) is another condition that is associated with deficient linear and ponderal growth biomarkers in children (Singh et al., 2021; Tickell, 2019). This EED condition lacks a universally accepted case definition with no universally accepted diagnostic tests or set of diagnostic criteria. However, the current geographical distribution of EED suggests, the syndrome is most prevalent in areas of poor access to improved water and

sanitation with potential fecal matter contamination (Singh et al., 2021; Tickell, 2019). Given the current limited level of understanding, its believed EED could be a heterogeneous condition, resulting from a convergence of dynamic microbial and nutritional factors which may either be episodic or persistent, and resulting in disruptions of intestinal surface area (Bartelt et al., 2019; Marie, 2018). It is thus referred to as an impairment of the structure and function of the small intestine, characterized by increased permeability, reduced absorptive capacity, and inflammation (Singh et al., 2021).

Children identified with associated EED pathogens exhibits an increased enteric inflammation and decreased linear growth, even in the absence of diarrhea. This can be attributed to the fact that EED substantially damages intestinal structure. It causes shortened and blunted villi and crypt hyperplasia, leading to loss of absorptive intestinal surface area. The end result is increased malabsorption of nutrients. Nutrient malabsorption is the most critical driver of weight loss and wasting, causing impaired growth in children than systemic inflammation caused by EED (Bartelt et al., 2019; Tickell, 2019). In addition the damaged intestinal structure is also associated with enteric microbiome dysbiosis which increases the invasion by the associated EED pathogens (Tickell, 2019). This inspires the interest to understand gut microbiome status in the context of nutrition intervention.

2.6.2 **Human Microbiome**

Human microbiome refers to the collective genomes of the microorganisms in a human body. The gut microbiome existing in the human gastrointestinal tract and influences many areas in a person's health from innate immunity to appetite and energy metabolism (Valdes et al., 2018). In particular the good gut bacteria improve immune system, ferments dietary fibers to short chain fatty acids and produces essential nutrients such as vitamin K and B vitamins. These beneficial bacteria also keep at bay both harmful organisms hence limiting gut dysbiosis (Pallister & Spector, 2016). Importantly there is also some evidence that the gut microbiota might be the mediator between protein quality and growth trajectories(Stull et al., 2018; Tang, 2018).

Healthy diets help in shaping the gut microbial community which promotes nutrient processing increasing the nutrient and energetic value of that diet. With a diverse variety of food in a persons' diet one is able modify their gut health through food(Salas Garcia et al., 2018). For example, at infancy breast milk provides bioactive molecules which modulate the composition

and functioning of an infant's gut microbiota. This confirms the value of continued breast feeding during complementary feeding. Plant based diet with minimally processed high-fibre diet can potentially reverse negative effects of excess meat based diet on the gut microbiome(Pallister & Spector, 2016). Cricket consumption have also been shown to improve gut health and reduce systemic inflammation (Stull et al., 2018).

Research has also shown that there exists a relationship in how hosts and specific microbes adapt and how these microbial interactions shape host intestinal function, deal with inflammation, metabolism, and affects physical growth (Bartelt et al., 2019). Dysbiosis due to small intestinal bacterial or fungal overgrowth is a microbial imbalance commonly reported in children if their diet is in-appropriate and/or with frequent antibiotic use (Pallister & Spector, 2016; Underwood et al., 2020; Vangay et al., 2015). Gut dysbiosis is implicated in various diseases (Underwood et al., 2020), such as obesity, type 2 diabetes, cancer, mental health issues, coeliac disease, asthma, allergies and inflammatory bowel disease. In later life of a person, early childhood malnutrition such as stunting has also been associated with overweight and chronic diseases such as diabetes, cardiovascular disease, cancer as well as mental illness (Wali et al., 2020). On the other hand obesity raises ones risk of severe illness from other illnesses and in particular, covid-19 largely seen in adults (Coombes, 2020).

2.7 **Household Determinants of Malnutrition**

A child's nutritional status can significantly vary with regards to a number of household related factors including but not limited to; residence of the household, household economics wellbeing, mothers education level, household drinking water, distribution of food within the household, prioritization of nutritious diets for children, decision making in food purchase, gender preference in feeding children, caregivers' ability to provide appropriate feeding and the care to their young child as impacted by the level of stress and/or emotional status of the caregiver (Khan & Das, 2020; Masuku-Maseko & Owaga, 2012; UNICEF, 2020a).

The level of household social support and protection also increases the households ability to access food and improves nutrition knowledge of the caregivers. Birth spacing, child's age, child immunization status, mothers culinary skills, level of men's participation in child feeding, level of men's participation in care and level of women empowerment are other factors

associated with a child's malnutrition status (Al-Jawaldeh et al., 2018; Lestari, 2019; UNICEF, 2020a). Other external shocks such as the COVID-19 pandemic, is predicted to increase the world's malnutrition status by disruption of household food availability and accessibility. The lockdown measures, combined with mobility disruption and food distribution system disruption was estimated to potentially increase the prevalence of moderate or severe wasting among children under five years(U5) by 14.3% (Headey et al., 2020).

2.8 **Research Gaps**

With the growing human population and the complexity of global warming there is a high demand for sustainable approach to healthily feed the world's population. This concern is especially high for the most vulnerable groups like children. An estimated one in ten deaths among under 5 years old in LMICs occur in malnourished children. With an increased risk of infectious diseases observed in protein deficient stunted children. Although according to literature, edible insects are shown to improve food diversity, proven to be cost effective, is environmentally friendly and highly nutritious for the general population (Aboge et al., 2021). However, little is known on the effect of using cricket enriched porridge as a complementary feed. Particularly the effect of insect based protein on infant and young child growth is not well documented (Adegboye, 2022). The available research on protein and growth which are largely based on formula feeds show mixed conclusions (Tang, 2018). As a functional food the contribution of crickets to gut health is likewise not well understood(Stull et al., 2018). This study aimed at filling the gap of food diversity by inclusion of crickets while assessing the impact of providing cricket enriched porridge intervention alongside nutrition education among infants in Kenya.

CHAPTER THREE

RESEARCH METHODOLOGY

3.0 Introduction

This chapter describes the research design adopted for this study. It describes the study area, target population, design and sampling methods, calculates the expected sample size and describe both data processing and statistical analysis. Ethical consideration is also described.

3.1 Study Area

The study was conducted in Siaya County, of Western Kenya. Siaya County lies between latitude 0° 26' to 0° 18' north and longitude 33° 58' east and 34° 33' west. Siaya County borders Busia County to the North West, Vihiga and Kakamega counties to the North East, Kisumu County to the South East and Homa Bay County across the Winam Gulf to the South. Siaya county as at 2022 had a projected population of 1,114,735 persons of whom 162,585 was estimated to be under five years of age. Of the under five years, 37,361 (18,826 Males) were under 1 year of age. Alego Usonga Sub-County is the most populous with an estimated total of 233,552 persons (Siaya County Government, 2018).

3.2 Study Design

This is a blinded randomized control trial (RCT) conceptualized as a public health intervention program. The study was based on factorial experimental design. Factorial designs are best used where the effects of more than one treatment are under investigation and treatment interaction is less likely. Presence of extensive or slight interaction may lead to biased estimates of the treatment effects or may be under powered to detect interaction respectively (Byth & Gebskil, 2004). A 2x2 (two factors of two levels each) randomized factorial study design was conducted to assess the main treatment effects and combined treatment effects of nutritional education and cricket enriched porridge consumption on the growth of children attending postnatal program in the selected health facility. The first factor was nutrition intervention with two levels; given versus not given while the second factor was educational intervention also with two levels; provided versus not provided resulting into four study arms. The first treatment, nutrition intervention was double blinded with both research assistants and the research participants being blinded from knowing what product the participants were assigned to. For

the nutrition education it was not possible to achieve double blind as the participants in nutrition education knew they were receiving nutrition education as well as the specific research assistants implementing the nutrition education. In spite of this, the team of research assistants taking anthropometric measures were completely blinded from knowing the education arm the participant was assigned to. Two sub studies were conducted, the first was to determine baseline gut health status of the enrolled infants. And the second to determine the level of breast milk by a master student attached to the main research. The sub-studies were based on lab analysis and were conducted on sub samples of the primary study. Finally at the end of the trial a qualitative evaluation of the two porridges acceptability and experiences of the participants was conducted.

3.2.1 Research Intervention

The intervention consisted of two components (Nutrition and Education component) implemented singly or jointly in a factorial design where cricket treatment was denoted as +CR vs -CR and education treatment denoted as +ED vs -ED. The study consisted of four study arms consisting of infants receiving: cricket treatment with education treatment (+CR & +ED), cricket treatment with no education treatment (+CR & -ED), no cricket treatment with education treatment (-CR & +ED), and no cricket treatment with no education treatment (-CR & -ED) which served as control (see **Table 3.1** and **Appendix V**). Time to time implementation of all study intervention activities and timeline is summarized in **Appendix IV**

Table 3.1 Table of Treatment Allocation

		Receive Cricket Enriched flour	
		Yes	No
Receive Nutrition Education	Yes	+CR & +ED	-CR & +ED
	No	+CR & -ED	-CR & -ED

3.2.2 Study Control

The study adopted a positive control group using an existing nutritional intervention with known effect, so as to meet ethical practice and be able to determine the effect of the new intervention response from the experimental group. The study adopted a positive control and double blinded approach with the control group receiving standard known flour, where both the caregiver and person administering the food were blinded from the content of the flour.

3.2.3 Nutrition Component

The nutrition component was aimed at meeting the child's nutritional needs. The intervention CF was an enriched nutritive porridge that is high in protein, mineral and vitamins and the standard Corn-Soy Blend plus (CSB+) was considered as the control (**Table 3.2**). The enriched porridge flour was developed by Jomo Kenyatta University of Science and Technology (JKUAT) and certified by the Kenya Bureau of Standards (KEBS) for infant and young child feeding. Children aged 6 months were registered into the program, and received daily age-appropriate recommended ration (**Table 3.3**) of enriched porridge daily for a period of eight months meeting the recommended minimum of six months for nutrition intervention(Shi et al., 2023). The porridge was prepared using a standard recipe of one part flour to four parts water then boiled to simmer (Aboge et al., 2021). It was then cooled to approximately 40^0C fit enough for babies' consumption, before serving. The parents/guardians of the infant were trained on how to prepare the porridge and participated on practical demonstration of preparation and initial serving as detailed in **Table 3.4**. They were also educated on the benefits of deworming the child three monthly as from their first birth date and encouraged to do so regularly for good child health and growth.

3.2.4 Flour Production

The raw material included: soya beans, dehulled maize, roasted millet, sunflower seed oil and soya bean oil. These were sourced from the local shops while vitamin and mineral premix (IS 723 FBF-V10) was sourced from Dutch State Mines (DSM) Nutritional Products South Africa (Pty) Ltd. (Johannesburg, South Africa). Cricket powder was sourced from InsectiPro Ltd, Nairobi, Kenya.

The porridge flours were processed by co-extrusion using a locally fabricated twin-screw extruder at Jkuates Enterprises Ltd (Nairobi, Kenya). The extrudates were then ground into fine flour that could be reconstituted into porridge. Ingredients of Cricket Enriched Porridge (+CR) were blended using an automated mixer, preconditioned by mixing 2 liters of water with 50 kg of raw materials and extruded. Feed moisture and barrel temperature were adjusted from 15–16% and 128°C to 142°C for Zone I, and 105°C to 114°C for Zone II, respectively. The main motor and feeder speeds were between 29.66 to 30.25 rpm and 09.00 to 11.82 rpm respectively. The resulting extrudates were milled and sieved through a 0.45 mm sieve size and flavoured

using a caramel essence at the rate of 50g/100Kg with vitamin/mineral premix added. The flour was packaged in 500 g plastic containers and transported to the study site in Siaya. The porridge was prepared using a simple standard recipe shown in **Table 3.4.**

Table 3.2 Composition and Nutrition Contents of Study Foods

Cricket enriched (+CR)		Control (-CR)	
Composition per 100 g			
Dehulled maize (g)	30.0	Soya beans dried (g)	24.0
Roasted millet (g)	40.0	Maize dry (g)	64.3
Vitamin/ Minerals premix[ɻ] (g)	0.2	Vitamin/ Minerals (g)	0.2
Crickets/Gryllus (g)	24.0	Sugar (g)	7.5
Sunflower seed oil (g)	5.8	Soya bean oil (g)	4.0
Nutrition contents per 100 g			
Energy (kcal)	430.0		409.9
Protein (g)	14.4		16.0
Fat (g)	7.7		9.0
Carbohydrate (g)	75.8		60.9
Fibre (g)	2.6		2.9
Ash(g)	2.1		4.2
Iron (mg)	6.2		6.5
Zinc (mg)	4.4		5.0
Iodine (µg)	0.0		2.3
Calcium (mg)	166.9		362.0
Manganese (mg)	21.2		-
Phosphorus (mg/100g)	462.8		280.0

ɻ V premix (FBF-V-13) was source from Dutch State Mines South Africa;
+CR cricket enriched porridge; -CR Control porridge

Source: Kiiru et al., 2024

Table 3.3 Daily Complementary Food Requirement Ratios

Age group	Age in Months		
	6-8	**9-11**	**12-24**
Total Energy Requirement (kcal)	641	711	868
Breast Milk Energy Contribution (%)	69	Slightly above 50	33
Daily Complementary Rations (kcal)	200	300	550
Cricket Enriched Porridge Flour (g) $	29	44	80
CSB+ Flour (g)$	31	47	86

$ 60% of required Energy level

Table 3.4 Method of Porridge Preparation

1. Take $1\frac{1}{2}$ heap table spoon of the flour into a clean cooking sufuria (≈29-33g)
2. Add one cup (250ml) of cold water
3. Stir the mixture till you get a smooth paste without flour lumps
4. Heat the mixture to boil, while stirring, keep stirring until it thickens and starts boiling or else lumps will be formed
5. Allow the porridge to simmer under low heat for 2-3minutes
6. Sweeten if need be and cool to the right temperature for your child's serving

3.2.5 Education Component

Education component was adopted from the UNICEF Nutrition Strategy 2020-2030 (UNICEF, 2020b) and was aimed at giving the caregivers a total of one hour twenty minutes standardized education session, conducted by a trained nutritionist followed by bi-weekly SMS reminders on good child nutrition. The nutrition education component had the following content: a) Nutritional value of food b) Designing a healthy baby diet c) Advice on dietary adaptation to address the most common child hood nutritional problems (Arija et al., 2012) d) Identification and response to the child's cues and support for the child's socio-emotional and cognitive development (Hurley et al., 2016). The education intervention was targeted to increase the consumption of fruits/vegetables and whole grains while highlighting the importance of healthy snacks, deworming and nutritional hygiene.

The education intervention was performed using two modes namely 1) face-to-face and 2) Short Text Messages (SMS). The face-to-face session consisted of education lessons with lecture method using pictures, video as media, and discussion sessions to enhance participants' understanding of the nutritional concepts and practices. Whereas the SMS system used was an automated bulk SMS system sending scheduled specific massage to the mothers based on next visit and study arm she belonged to. **Appendix VIII** show the training plan used in the study clearly detailing main nutrition information and lifestyle behavior, promoted in the study. **Appendix IX** specify the educational information and mode of teaching while **Appendix X** outlines the specific nutritional text messages sent to the mothers.

3.2.6 Treatment Interaction

It was assumed that the effect of cricket treatment might not be influenced by the presence of nutritional education treatment. If the assumption is false and interaction exists, the interaction can either be antagonistic/negative or synergistic/positive and depending on the magnitude of interaction. With interaction it is desired that we use appropriate sample size in the sub groups to ensure adequate power to detect potential interaction effects (Byth & Gebskil, 2004). Using the factorial design, all possible combinations of treatment groups was built and assessed so as to directly compare all their responses (**Table 3.1**).

3.3 Study Population

The study population were the infants aged 6+ months at enrollment who are ready for complementary feeding. They were enrolled into the intervention program and followed for eight months (child age 14+months) if born at Rwambwa sub county hospital or the caregivers sought postnatal health services at Rwambwa sub county hospital in Alego Usonga Sub-County, Siaya County, Kenya (see **Appendix III**).

3.3.1 Inclusion Criteria

The children recruited in the study, were those who's mothers attended Post Natal Care (PNC) services at the facility of recruitment, aged 6 months at the time of enrolment, with a hemoglobin (Hb) of ≥7 g/dl (not severely anemic) and having a normal nutrition status defined by MUAC>11.5cm. The mother-infant dyads were able and willing to take porridge and not allergic to any ingredients in the porridge as determined by mothers' willingness and child's medical history. The parent/caregiver accepted to participate by signing the consent form and committing to follow the prescribed study procedure.

3.3.2 Exclusion Criteria

Children found to be in need of prescribed therapeutic food or any other medical attention requiring consistent medical observation for at least one week at screening were excluded. Children strictly fed on formula feed with no breast feeding were also excluded. Others excluded were those with any underlying health conditions such as obvious chronic diseases requiring regular clinical medication. The children in need of medical attention were referred for medical attention and supported to navigate the hospitals health system at Rwambwa Sub-County hospital. Those in need of further treatment were additionally support to get referral note for further medication at Siaya County Referral Hospital.

3.4 Study Variables

3.4.1 Study Outcomes

The primary outcome measure of the study is linear growth measured by height or length, for age. This was measured repeatedly over time and analyzed comparing study arm stunting status at baseline and end term. Secondary outcomes for the study are dietary intake and gut health status measured using breath at baseline.

3.4.2 Dependent Variables

i. Child growth (Height, HAZ)
ii. Gut health status (Healthy Gut Vs Not Healthy Gut)

3.4.3 Independent Variables

i. Treatment (study food and nutrition education)
ii. Household hygiene practices
iii. Perception of caregivers on child feeding behavior
iv. Household Food security situation
v. Child food diversity and nutrition
vi. Caregiver's child feeding practices
vii. Caregivers' child food training and learning options
viii. Breastmilk intake status
ix. Child security and protection

3.5 Sampling Design

3.5.1 Sampling Strategy

Siaya County and in particular Alego Usonga Sub-County was purposively selected as study county and sub-county, respectively based on three reasons. First, the high rate of under nutrition (more than 1 in 7 under weight) and more than 1 in 10 (11 per cent) are severely stunted in Siaya as documented in the county reports (Kenya National Bureau of Statistics, 2013)with the desire to reduce stunting from 20.7% in 2019 to 16% in 2027 (Siaya County Government, 2023). Second, proximity to the KEMRI cold storage facility at Siaya for easy

handling of human samples. Lastly the fact that there was no other county led complementary nutritional program running in Alego usonga sub-county at the time as per the county nutritional office. The children were stratified based on age and sex to ensure equal representation by age and sex. The children were enrolled systematically using systematic random sampling strategy with respect to arrival and recruitment time at Rwamba Sub-County hospital. Based on the stratification and systematic random assignment scheme (independently generated at Copenhagen University), infants were randomly assigned to the four study groups. In the case of twins, the first child was randomized and the second assigned to the same group. The mothers who complete the main study were randomly selected and invited for a qualitative evaluation of study food acceptability and cnsumption.

3.5.2 Sample Size Determination

Different study design requires different methods of sample size calculation with emphasis that sample size depend mainly on i) level of significance, ii) power of the study, iii) expected effect size and the iv) standard deviation in the population. In complex designs using statistical software is handy. Using R statistical software under the assumption of no loss to follow-up, full compliance to study procedures and homogeneity of treatment effect, we performed sample size calculation for 2 x 2 factorial design analyzed by analysis of variance using F statistics for the purpose of testing existence of difference between the groups. This calculation was based on number of groups in the experiment, acceptable level of significance, desired effect size and power of the test. We used baseline population standard deviation of 2.9cm from a nutrition study that enrolled children at 6 month to determine the expected minimal difference to be detected based on selected effect size.

The effect size was estimated based on Cohen's argument of effect size. Cohen made a distinction between three types of effect sizes: d = .2 for a small effect size, d = .5 for a medium effect size, and d = .8 for a large effect size. Based on this categorization, we used effect size of d = .2 as a reasonable estimate of a useful effect size and calculated the required numbers of participants based on this size (Goulet-Pelletier & Cousineau, 2018). Funder & Ozer (2019) confirms that any effect size of between d=0.2 and d=0.3 is more important for practical use whereas very small effects ($d<0.2$) have negligible practical significance while larger effect ($d>0.4$) is grossly over estimated and may not be detected even with large samples.

The sample size calculation for this study was then based on the following parameters:

1. Number of groups: = 4
2. Effect size =0.2 sd
3. Significance level =0.05
4. Power of test= 80%

The sample size was calculated using the following R statistical script:

#1) We are interested in determining if there is a difference in childs weight/height between 4 different intervention program [(i) Control (ii) Education (iii) Food (iv) Food+education] using small effect size (0.2sd) and 4 groups of comparison

pwr.anova.test(k =4, f=0.2, sig.level=0.05 , power=0.80)

A previous study in the same region established that the average height child 6 months of age was 65.4cm with a standard deviation of 2.9cm (Konyole et al., 2019). Implying to detect a 2.9 sd or greater difference between any of the four groups at 5% significance and power of 80% based on the require 70 clients per group (as shown in **Table 3.5**) we are able to pick a height difference of 0.69cm [$\Delta = \frac{4\sigma}{\sqrt{n}} = \frac{4*2.9}{\sqrt{280}} = 0.69$].

Table 3.5 Treatment Groups and Sample Size Distribution

Group	Treatment		Sample size
	Nutrition Education	Improved diet	
1	No	No	n1= 70
2	Yes	No	n2= 70
3	No	Yes	n3=70
4	Yes	Yes	n4= 70
Total	-	-	n=280

Based on available financial resources a random sub sample of 40 children equally proportion in the four study arms were invited from the 280 children for breath sampling to establish gut health. A second random subsample of 61 mother-infant dyad not participating in breath test was selected and proportionately allocated to two study arms (Group 1 and Group 4; Table 3.4) for breast milk intake test by a master student attached to the study.

3.6 Data Collection

Data was collected using structured questionnaires covering maternal characteristics, household characteristics, child nutrition, feeding practices and laboratory samples details. Some of the data collected over the study implementation period included: Anthropometric measurements (length, height, weight, MUAC, Skin folds, BMI) using weight scale, length mat, stadiometer, and measuring tape; Blood sample hemoglobin test results data; sample details for testing level of breast milk intake using emerging technology using stable isotope (deuterium) to determine valid breast milk intake; Breath sample details used to determine gut integrity as assessed using ^{13}C Sucrose breath test.

3.6.1 Data Collection Procedures

Data was collected using an electronic data capture system developed on open data kit (ODK) platform and data stored in password protected computers. Based on this system all patients were assigned unique identifiers for identification at every visit. Data for all study participants was collected and stored into the electronic system during each visit and linked by the infant's enrolment number during the whole intervention implementation period.

3.7 Study Intervention Implementation

3.7.1 Participant Recruitment

Clients were recruited at the health facility during the date of their clinic visit or on the targeted enrollment date advertised to mother by community health care workers serving in their community. Children who were 4-5months old at the onset of the intervention were enlisted and followed up for enrolment when they were age eligible. Those 6 months and eligible were directly enrolled into the food program while those younger were enlisted and called in when they turned 6 months though phone numbers documented at first contacts.

3.7.2 Randomization and Blinding

A computerized stratified randomization technique was used to assign enrolled infants and mothers into the four study arms. The infants were stratified by sex and assigned to a study arm using 8 blocks, in a ratio of 1:1:1:1. The blocks were generated by a third party using sealedenvelope.com and a coded version confidentially assigned in trust to the study administrator, solely responsible for field randomization and study food dispensing. The study block code was kept at the University of Copenhagen by staff who was not involved in the study, for custody to the end of primary data analysis. The randomization assignment was based on the randomization scheme that was based on sex and sequential order of the participants arriving at the facility during enrolment. Blinding was obtained by assigning all randomization lists to a study administrator who distributed the study foods in similar containers distinguished only by food label code with no disclosure of who received what food product to the study team. All the field assistants who were taking measurements of the children were blinded on what food product the mother received to avoid unconscious bias in measurement. Blinding was not possible with nutrition education treatment for the study implementation team. Data analyst and investigators were also blinded from the treatment detail until the main analysis was concluded

3.7.3 Nutrition Treatment Implementation

The infants were assigned and remained in their assigned intervention groups (see **Appendices V & VI**) for the entire period of the study. The mother was trained on how to prepare and serve the porridge using a standard developed recipe (See **Table 3.4**). At every study visit a one-month sufficient supply of the study flour was issued to the mother as per the study implementation protocol in **Figure 3.1**. During the time of feeding, the mother was asked to observe the baby's eating cues and feeding habits. On the subsequent monthly visit, the mother was asked to rate the overall level of study food acceptance as perceived from general feeding behavior of the child. The mother also was asked to give her views on the quality and taste of the study porridges consumed. Monitoring the adherence to consuming the study food was based on mother-reported responses, and assessment of returned empty food packs during next pick.

3.7.4 Nutrition Education Implementation

Nutrition education was implemented at individual level for six sessions using audio visual training materials as per the study implementation protocol in **Figure 3.1**. The room where the training happened was isolated quiet and equipped with the training materials including wall chart and computer for video display.

3.7.5 Gut Health Sub-Studies

Gut health was implemented as a sub-study with 40 randomly selected infants. This sample size was selected based on cost and is comparative to samples from other studies such as Ritz et al., (2004) examined 9 volunteers; Schillinger et al., (2022) examined 24 Adults with the challenges of attempting large sample explained by Shivakumar et al., 2024. As a secondary objective carbohydrate digestion and absorption (intestinal sucrase activity), was assessed at baseline using 13Carbon-Sucrose Breath Test (13C-SBT) (Shivakumar et al., 2024). To the selected participants a 15 ml solution containing a single dose 0.4μg/kg body weight, dissolved in water, was administered orally. Serialized breath samples were collected using a direct tube to nose or mouth method using a unidirectional labco evacuated breath sample exetainers. The mouth choice was used if the child had common cold. To collect the sample, the infant was made comfortable and easy through play, then the unidirectional breath exetainers placed directly on infants' nostril or close to mouth for approximately 5-7 seconds and immediately caped tightly. Evidence of trapped alveolar air was indicated by fogging of the exetainer.

The infant was fasted for one hour before baseline sample was collected. After ingestion the child was again fasted for a second hour during which the child was permitted to take water if thirsty. Next samples were collected in different time interval for additional 11 samples labelled T2 to T12. The time interval between T2 to T7 was each 15min, Time interval between T7 and T12 was 30min each. At 2.5 hours after dosing the mother was permitted to breastfeed the child (Shivakumar et al., 2024) and sample collection continued to the last sample. The collected breath samples were stored at room temperature before shipment for analysis in Lusaka Zambia. The breath samples were analysed for change of the concentration of $^{13}CO_2$ over the twelve sampling points using a Thermo Scientific DeltaRay Connect Isotope Ratio Infrared

Spectrometer in the Tropical Gastroenterology & Nutrition group (TROPGAN) laboratory and normalized against a Reference standard CO_2.

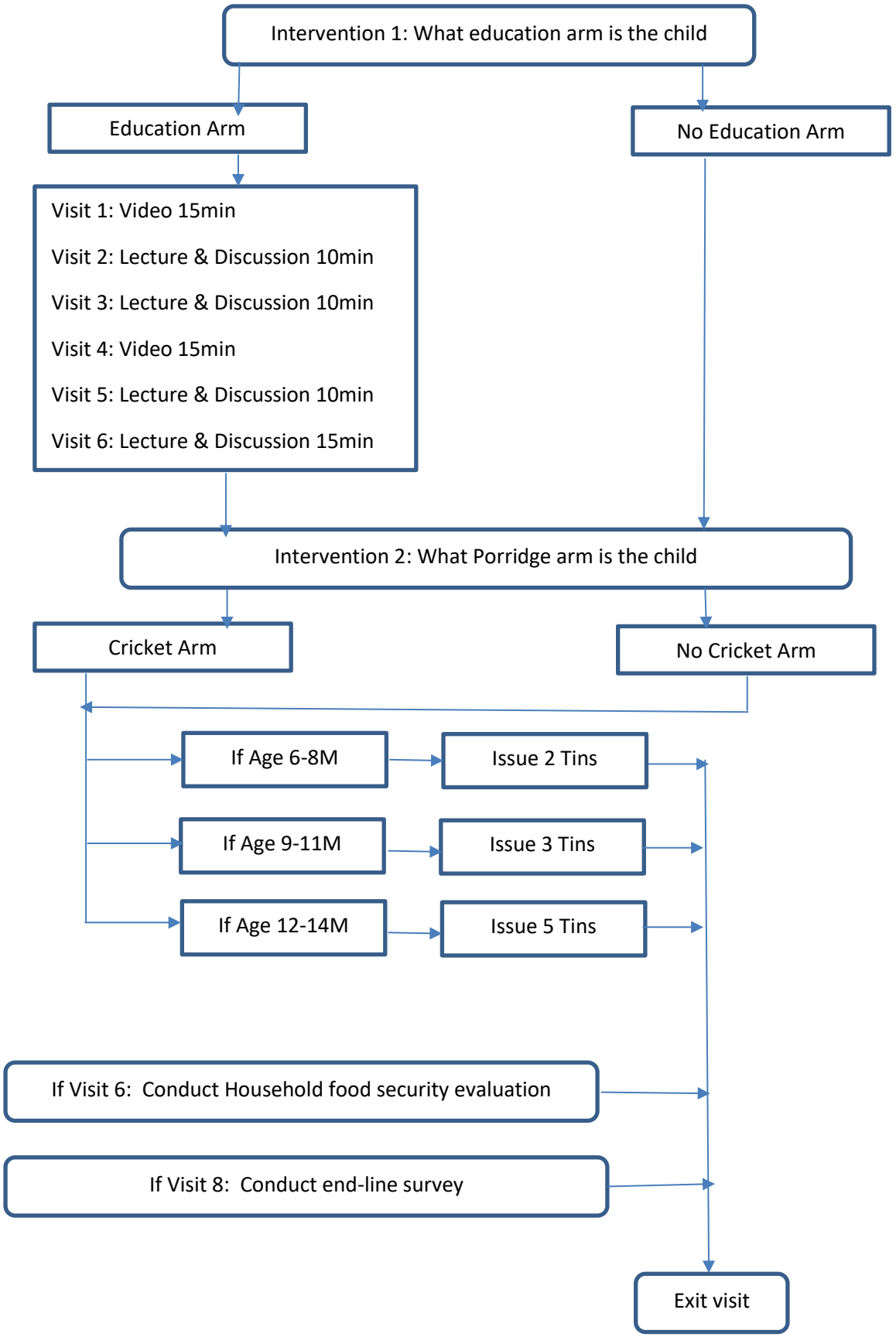

Figure 3.1 Intervention implementation Protocol

3.7.6 Health Monitoring Method

Qualified clinicians from the health facility helped to monitor the children for any allergic reactions during study. The caregivers were notified to check out for any allergic reactions and report immediately to the research team with assurance that the child will be treated at the health facility. The mothers were informed that in case of any allergic reaction, the study team will refer and accompany any sick child to the facility. Besides handing the caregiver and child to the attending physician at the health facility they were assured of treatment follow-up for the allergic reaction. The study met the direct medical outpatient cost to the tune of KSH 300 per illness episode during the study period. At enrolment the parents and caregivers were asked to provide their preferred phone number for communication and nutritional education. To ensure we minimize loss to follow-up and missing data, staff were trained on both quality program implementation procedures and data documentation procedures. During the implementation period the accrual rates was monitored to ensure a drop of more than 5% is tracked, explained and remedial action taken with proper documentation. Using the participant's phone contact any loss to follow-up was traced with a phone call or SMS and reminded to return to program on an appropriate time within program time lines.

3.8 Measurements Taking

3.8.1 Anthropometric Measurements (weight and height)

Anthropometric measurements of mothers and infants were collected at baseline and repeated for infants at monthly re-visit (see **Appendix VII**), using the WHO standard procedures. Infant length and head circumference were measured using Seca 210 infant length measure mat and measuring tape calibrated to an accuracy of 5mm and 1mm respectively. Both mother and infant's weight were measured using Kern 572-30 digital scale made in Germany to an accuracy of 0.1 kg with the infants' weight determined by the mother-baby weight difference. Skinfolds was measured in millimeters using stainless steel Harpenden skinfold callipers. Mothers' height was measured using adult ShorrBoard® ICA Measuring Board at an accuracy level of 0.1cm. Childs mid-upper arm circumference (MUAC), was measured using a MUAC tape. Anthropometric indices weight for age (WAZ), height for age (HAZ), and BMI were computed using WHO Anthropometric software programmed in stata codes based on the 2006

WHO growth standard reference. Additional clinic and child records were abstracted from the mother child booklet.

Questionnaires on household characteristics, family size, feeding practices and child health were built on KoboCollect App based on the attached data collection Questionnaires (See **Appendix I - Appendix II F**). Data manager working at the study site downloaded and reviewed study data weekly. Using Stata study specific data management codes, the data manager checked and cleaned all identified data inconsistencies. This was done in confirmation with field data staff who provided clarity on required change, while correcting all obvious data cleaning and edits required. Both data and Stata do files were stored in a password protected computer. Data was back up weekly using external hard drive securely stored in a lockable cabinet drawer.

3.8.2 Dietary Diversity Measurement

Child diet was assessed using Food frequency questionnaires administered monthly. The parent/caregivers of the participant were asked what food the child ate inclusive of study porridge and the number of times they ate the said food in the family within one week. All food and beverage consumed were recorded, and grouped into different categories as; plant protein, animal protein, cereals, or fruits for ease of analysis.

3.8.3 Nutrition Education Measurement

Nutrition education was measured at two levels, first, using a binary scale indicating if the caregiver received nutrition education or did not and at the second level the intensity of the participation in nutrition education was measured.

3.8.4 Laboratory Analysis

3.8.4.1 Breast Milk Intake Sample Analysis

Saliva samples from the infant was used to evaluate the amount of breast milk consumed based on IAEA 2010 breast test protocol. This was based on deuterium oxide dose to the mother technique which involves giving the mother a drink of deuterium labelled water and following the disappearance of the deuterium from the mother and its appearance in the baby as a result

of its consumption in breast milk. Saliva sample results was analyzed using FTIR instrument (Model 4500t manufactured in USA by Agilent Technologies) and results used to confirm baseline breast milk intake.

3.8.4.2 Breath Sample Analysis

The ^{13}C-sucrose breath test (13C-SBT) was used to evaluate intestinal sucrose digestion/metabolism through sucrase activity revealing gut integrity. The experiment was performed on a randomly assigned sub population of infants across the four main study arms. To the selected participants a 15 ml solution containing a single dose 0.4μg/kg body weight, dissolved in water, was administered orally. Serialized breath samples were collected using a direct tube to nose or mouth method using a unidirectional labco evacuated breath sample exetainers. The mouth choice was used if the child had common cold. To collect the sample, the infant was made comfortable and easy through playing, then the unidirectional breath exetainers placed directly on infants' nostril or close to mouth for approximately 5-7 seconds and immediately caped tightly. Evidence of trapped alveolar air was indicated by fogging of the exetainer.

The breath samples were stored at room temperature before shipment for analysis in Lusaka Zambia. The breath samples were analyzed for change of the concentration of $^{13}CO_2$ over the twelve sampling points. The breath samples were analyzed using a Thermo Scientific DeltaRay Connect Isotope Ratio Infrared Spectrometer manufactured by Thermo Fisher Scientific Inc. This equipment enables continuous measurement of isotope ratios and concentrations of CO_2. The measurements were normalized against a Reference standard CO_2 at the Tropical Gastroenterology & Nutrition group (TROPGAN) laboratory.

3.8.4.3 Hemoglobin Analysis

Hemoglobin level used for study inclusion was analyzed from blood collected from a finger prick at baseline. The tip of the third finger was cleaned with 70% ethanol and wiped with dry cotton wool before pricking. Finger prick needles used were child-friendly and blood for hemoglobin test collected following the World Health Organization standard operating procedures. Rapid analysis of hemoglobin will be done using a DiaSpect Tm hand-held hemoglobin analyzer machine (see **Appendix XII**) with a measuring range of 0-25.5 g/dL, an accuracy precision of CV < 1%, and a sample volume of <10 µL. The device is Calibrated

according to the hemiglobincyanide (HiCN) reference method according to International Council for Standardization in Haematology(ICSH) (*DiaSpect TM Technical Specifications - Hemoglobin*, n.d.).

3.9 Data Collection Instruments

The baseline questionnaire was used in determining the child and household baseline information. A Routine visit Questionnaire was used for monitoring the study food complementation, routine child health, growth status as well as implementation of nutritional education. Food frequency questionnaire was used for collecting infant habitual dietary intake. Once the main study ended, a study evaluation was conducted between January 15, 2024 and January 18, 2024 using open ended qualitative interview questions. The evaluation FGD was conducted for each study arm separately making up four FGDs, with the socio demographic characteristics of the FGD participants also collected (see **Appendix XIV**).

3.10 Reliability

Reliability points to the stability of findings and is mainly concerned with the degree to which any measuring tool controls for random error. A reliable instrument affirms the faith one can have in the data obtained. Most of the questions used were adapted from standard questionnaires. The tools were pre-tested at Bondo Sub County hospital to ensure the questions were sound and yield stable responses. The recruited enumerators comprised of those who were able to communicate with ease in the local language and fluent in English for an effective common understanding on the questions and how to administer them.

3.11 Validity

Validity concerns what an instrument measures, and how well it does so, hence represents the truthfulness of the desired findings. To achieve content validity, the research tool was reviewed and adjusted to adequately contain set of items that covers the research question. The contextual concepts were considered ensuring that the different nutrition elements, skills and behaviors were adequately and effectively measured for content validity. The proposed study was reviewed by MMUST subject matter expert to ensure the right content is covered before

approval for implementation. For face validity the research questions were adapted from previously used and tested nutrition questions. This was done to ascertain that the questions used assessed the intended construct under study. The questionnaires were reviewed by the study team to ensure feasibility, readability, consistency of style, correct formatting, and the clarity of the language used before and during field training.

Face validity was assessed during pilot study by testing the proposed survey tools in a different site (Bondo sub-county hospital) from the proposed study sites. At the pilot site the questionnaires were administered to 15 mothers who were then invited to a discussion section to take their feedback on the ease of comprehension and completion of the questionnaire. The final instrument was revised accordingly based on the pilot field feedback. Both construct and criterion validity were achieved through the adoption of already existing related data collection instruments. To ensure all measures were collected correctly and accurately, research assistants were trained and well calibrated instruments used. The standard nutrition growth measure cut offs were adopted to classify growth measure.

3.12 Quality Assurance

Research assistants were trained on research procedures (including food preparation, the importance of children's adherence to their allocated group, data collection, and data entry), study goals and research ethics. Research assistants adhered to all the required quality procedures including: i) before taking any reading the weighing machine was initialized to zero (recalibrated) ii) the reading was carefully taken by a trained research assistant supported by trained nutritionist, and iii) three readings were independently taken by the research assistant to minimize reading error.

Pre-testing of all the instruments was done at location not participating in the main study to determine viability of the tool in terms of content, ask ability and answerability of the proposed question. After the pre testing exercise, a feedback meeting was conducted by the pre-testing team. Then its deliberations were used to review the final questionnaire. During pre-test research assistants practically understood the study data collection standard operating procedures.

3.12.1 Pilot Study

The use of cricket-based porridge for infant Complementary feeding was piloted in an alternative site (Bondo sub-county hospital) before the implementation of the main study to determine food acceptability level and get feedback from the public with regard to the proposed nutrition education and study implementation procedures. From this pilot the two porridges were accepted well with the children served approximately 91.9±34.1g porridge by weight and consumed on average 84.0±27.7g and 99.0±37.9g of the cricket enriched porridge and CSB+ porridge respectively. The caregivers gave their approval of the cricket enriched porridge and liked the CSB more: "*The baby loves white porridge than the brown porridge*" another said "*Very nutritious. Smells like biscuits* [Cricket enriched]" with the other emphasizing "*Just sweet but has no aroma as the brown one*"

3.13 Data Analysis

Qualitative interviews were transcribed analyzed using narrative analysis methods providing quotes in both the local verbatim and translated quotes (Younas et al., 2022). The messages were translated in context and not the direct translation of the said statement. Narrative method was used to understand participants personal stories with a focus to depict the overall common story. Quantitative questionnaire data was keyed into an electronic database system daily as the field data collection proceeded. Missing data that could be imputed based on existing data was updated and rate of missing data in variables of interest and loss to follow-up statistic reported. To illustrate the geographical coverage of the population the participants were mapped by approximate child locational distribution in space (See **Appendix III**).

All analyses were performed using both STATA® version 13 and R statistical software. Using Q-Q plot (See **Appendix XIII**), normality of the data per treatment was confirmed then data analyzed to show the proportion of respondents by selected background characteristics with regard to anthropometric outcomes. Descriptive statistics was used to describe population distribution across the study arms at baseline. Calculated Length/height for age z-score (HAZ) to assess linear growth. Length gained per child from baseline to end-line was a key effect estimate used to answer the question "how does cricket enriched porridge and provision of nutrition education influence a child's growth?". The overall paired anthropometric differences

between baseline and end-line measurements were calculated. Since the distribution of all the treatment arms was normally distributed, the statistical technique in the ANOVA family was used to determine which specific groups differed from each other. This was done by conducting both intentions to treat and per-protocol analysis base on mixed linear model. Mixed linear model was selected as it allows one to simultaneously measure multiple random effects (eg subject, treatment and visits effects). It can handle unbalanced design and able to cope with missing data commonly experienced in cohort studies through partial data pooling. This model also allowed us to compare individual child to self at baseline while allowing for the simultaneous comparison of multiple data variables.

Data was modelled as a two-level repeated measure with level 1 being the repeated visits and level 2 representing the individual children. Linear mixed models were fitted with the baseline value of the outcome variable, included as part of the dependent variable (Xue et al., 2010). The analysis of covariance (ANCOVA) type of models included three-way interactions between time and the two treatments: Nutrition education and CF porridge type. The models were a priori adjusted for sex as fixed effects, and participant ID as random effects to account for differences between individual infants in the study while estimating the effect of the two intervention treatments. No ANCOVA post hoc test was conducted since there was no significant difference in the treatment groups.

Secondary to investigating the impacts of the intervention, a logistic regression analysis was conducted on some selected household, maternal and child characteristics as predictors of child growth for the entire study population. To illustrate the population geographical coverage the participants were mapped illustrating the child's locational distribution in space. Because all comparisons were made at alpha =0.05, only p-values less than 0.05 were reported as statistically significant (see T**able 3.6**). Finally, The FGD recorded audio were transcribed verbatim then analyzed using narrative analysis method. Narrative method was used to understand caregivers' personal stories with a focus to depict the overall common story the mothers were sharing. Mothers in the FGD expressed themselves in Swahili or Luo which is reported in the spoken verbatim and translated in context (Younas et al., 2022).

Table 3.6 Analysis Plan

Sno	Research Analytical Objective	Statistical Method
1	Study population Description and growth pattern	Data flow diagram, Count, mean, proportions, Chi test, Overall stunting rate,
2	To assess study food acceptability and estimate the adherence to taking cricket enriched porridge after its first introduction as a complementary food by infants and young children in Alego Usonga Sub-County	Count, Accrual rates, mean, proportions, and Narrative analysis using qualitative data
3	To establish the effects of cricket enriched porridge consumption on the linear growth of infant and young children over the 8 months study observation period in Alego Usonga Sub-County	ANOVA & F-statistics
4	To determine the effects of nutrition education on the linear growth of infant and young children over the 8 months study observation period in Alego Usonga Sub-County	ANOVA & F-statistics
5	To establish the effect of baseline gut status on infant growth status at the end of the study period in Alego Usonga Sub-County	Count, mean, proportions
6	To evaluate the combined intervention effects of cricket enriched porridge consumption and nutrition education on child's linear growth over the 8 months study observation period in Alego Usonga Sub-County	Determine existence of interaction, Q-Q plot test of normality, ANCOVA & F-statistics Logistic regression for further analysis

3.14 Logistical and Ethical Considerations

The ethical clearance for this research was obtained from Institutional Scientific Ethics Review Committee of the University of East Africa Baraton (UEAB/ISERC/23/12/2022) and research permit from National Commission for Science, Technology and Innovation (NACOSTI) (Ref No. 475925). This RCT is Registered at https://clinicaltrials.gov (ID number: NCT06002620), the study protocol and procedures were discussed with the local health authority for implementation clearance within Siaya County. The mothers of the infants gave written informed consent after either reading or being read for in the language of their choice and took home a copy of signed consent. All data were stored in password protected computers with personal identifiers striped off the analytical dataset. Study arms codes were keyed in as codes and only broken at end of analysis. Consent to export breath sample to Tropical Gastroenterology & Nutrition group (TROPGAN) laboratory, University of Zambia School of Medicine, Lusaka, Zambia for further analysis was sought from the caregivers with the permit to export the same obtained from the Kenya pharmacy and poisons board (UCR Number: 24KEP051423018N002088964). Permission to implement at Rwambwa sub-county hospital was done through signed letters of support from the Ministry of Health (MOH) office of the Director for Public Health Promotion and Disease Prevention following all due processes and obtaining research approvals (See **Appendix. XVI**)

The caregivers were given, information regarding the study, informed of the ingredients and the safety of the porridge offered to their children. They were also informed of sample shipment for further analysis before being enrolled into the study. Those who willingly accepted to participate, signed a written informed consent. All caregivers were assured that their consent to participate would be at will and can be withdrawn at any time during the study period if they or their child got dissatisfied with the study procedures and/or food offered. The information they provide to the study team was treated as confidential and their identity was never revealed to any unauthorized person in this study. No identifiable information is included in any study report including this thesis. All study participants identifiers were treated as confidential and the data was always password protected. Prior appointments messages were sent to study participants for all meeting sessions at least two weeks to the appointment date with a reminder message sent a day to the appointment date.

In summary this research was based on the following ethical principles: voluntarism, informed consent, privacy, confidentiality and beneficence. Voluntarism allowed the participants to withdraw at any time having joined willingly given the level of study information given at enrollment eliciting informed consent. All the study procedures were provided in a private space and data collected stored securely and accessible only to study permitted persons. All study participants benefited from the nutritional intervention irrespective of the study arm.

CHAPTER FOUR

RESULTS

4.0 Introduction

This chapter presents the study findings as per the study objectives. The chapter begins by describing characteristics of the study population and study follow-up attrition as per CONSORT guidelines. The finding of the first objective, acceptability of and adherence to study porridges are presented immediately after CONSORT diagram. The treatment effects as per objective 2 and 3 is presented followed by the findings from the gut health analysis then objective 5, which presents the combined treatment effect. The chapter concludes with further analysis to determine possible explanation to the non-significant growth detected.

4.1 Consort and Baseline Characteristics

A total of 303 mother-infant dyads were invited for screening. Of the 303 invited, 19 mother-infant dyads dropped off at screening; 3 parents declined participation, 8 did not meet the inclusion criteria and the remaining 8 were not reachable on phone contact provided, and at the same time never honored the screening appointment. This attrition resulted in a net total enrolment of 284(Male=149 Female=135) infants. The primary caregivers of all 284 infants were mothers of the index child. Within the enrolled were six pairs of twins and were randomized to the same group. A total of 244 children completed the end-line giving a retention rate of 85.9% that is above the 80% threshold for results validity in clinical trials (Fewtrell et al., 2008). Of the 1988 (284x7) potential monthly follow up visits, 1607 (80.8%) visits were honored. During the study period the study experienced a loss to follow up of 40 children. Twenty-two of whom relocated out of the study area. Thirteen could not be reached, three of opted out, while two died. By verbal autopsies conducted with the mother of the infant, there was no attributable link to the study product or procedures for the two deaths. Both deaths were deemed to be attributed to normal natural childhood mortality causes in area (See **Figure 4.1**).

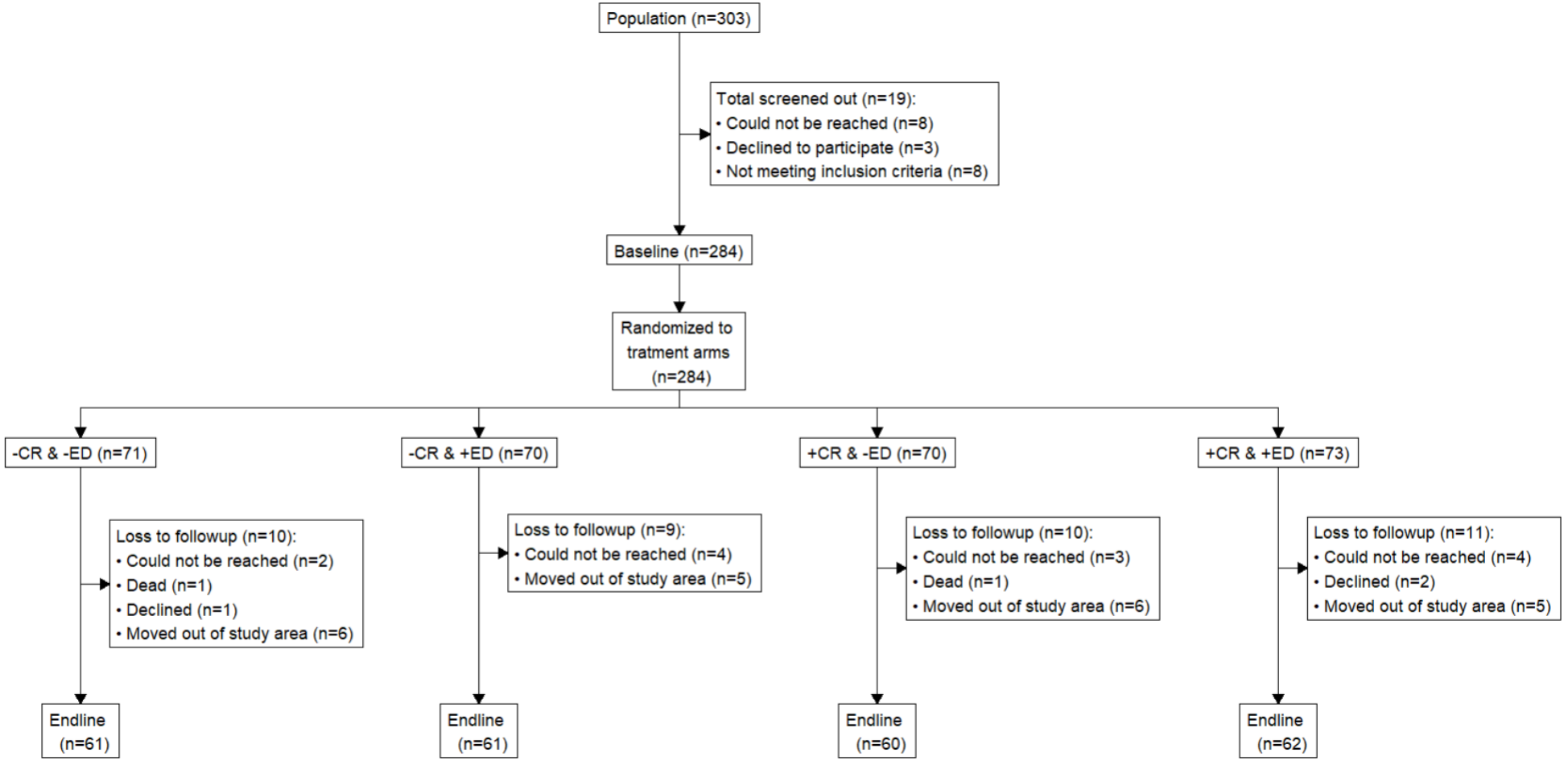

Figure 4.1 The Consolidated standard of reporting trial (Consort) flowchart summarized from recruitment to end-line.

+CR: cricket treatment; -CR: Control; +ED Education treatment offered; -ED No Education treatment offered; -CR & -ED: Control with No Education treatments offered

Baseline characteristics of mothers and infants are shown in **Tables 4.1**. Mothers were on average 26.5 years old with half (51.1%) of them having below secondary education qualification. A round half of the households reported severe food insecurity at the 6th month of study implementation. At enrolment infants were on average 6.3±0.5 months, weighing 7.6±1.1 kg and 65.7±3.1 cm in height. The infants' baseline growth status by HAZ averaged -0.63±1.32, with total 35 (12.4%) classified as stunted [HAZ<-2]. All infants were breastfeeding at baseline except 6 (2.1%). Approximately 40.9% (n=116) of the mothers reported practicing exclusive breastfeeding, based on the questions: "the child is currently breastfeeding, never took any fluid within the first two days after birth, never drank any milk except breast milk and has never eaten any additional food". The randomization to the four treatment arms resulted in similar distribution in terms of the age, Hb, birthweight, height and gender balance, while the prevalence of stunting at baseline randomly varied between arms, ranging from 12 children (17.1%) in arm [+CR & -ED] to 6 children (8.6%) in arm [+CR & +ED] the variation was a random selection. In general, the randomization result was satisfactorily well distributed across the treatment arms.

Table 4.1a Baseline Characteristics of Maternal Socio Economic and Child Feeding Practices[θ]

Randomized to intervention arms (n)		-CR & +ED (70)	-CR & -ED (73)	+CR & -ED (n=71)	+CR & +ED (70)	Total (284)
Socio-economics		**(n) mean±sd⏚**	**(n) mean±sd⏚**	**(n) mean±sd⏚**	**(n) mean±sd⏚**	**(n) mean±sd⏚**
Mothers age	Years	(70)25.3±6.1	(73)26.4±5.7	(71) 27.3±7.5	(70)27.1±7.4	(284)26.5±6.7
Mothers' education	Below secondary	(35) 50.7%	(39) 53.4%	(37) 52.1%	(33) 47.8%	(144) 51.1%
Household food insecurity [λ]	Severely food insecure	(32) 52.5%	(29) 49.2%	(27) 45.0%	(36) 57.1%	(124) 51.0%
Birth and feeding practices		**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Mode of child birth (284)	Natural	68 (97.1)	72 (98.6)	66 (93.0)	69 (98.6)	275(96.8)
Infants birth weight (273)	>2.5 kg	64(94.1)	62(88.6)	65 (94.2)	61 (92.4)	252 (92.3)
Who decides what child eat (269)	Baby's Mother	52 (76.5)	59 (85.5)	59 (88.1)	51 (78.5)	221 (82.2)
Is the child bottle fed (284)	Yes	19 (27.1)	24 (32.9)	22 (31.0)	15 (21.4)	80 (28.2)
Currently breastfeeding (283)	Yes	69 (98.6)	71 (97.3)	70 (98.6)	68 (97.1)	278 (98.2)
Exclusive breastfeeding (284)	Yes	26 (37.1)	27 (37.0)	30 (42.3)	33 (47.1)	116 (40.9)
Introduced fluids by 2nd day of life (284)	Yes	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)	4(1.4)
Other milk apart from breastmilk currently used? (254)	Yes	20 (32.8)	26 (38.8)	27 (45.8)	25 (37.3)	254(89.4)
Practices hand washing using running water with soap (284)	Yes	12 (17.1)	11 (15.1)	13 (18.3)	12 (17.1)	48(16.9)
Time started breastfeeding after birth (284)	<60 min	56 (80.0)	63 (86.3)	58 (81.7)	53 (75.7)	230(81.0)

θ - Data are number of respondents, mean ± SD and % for selected baseline characteristics of interest for child mother and household

⏚ - Units of measure for the characteristics of interest is mean±sd unless otherwise stated as (n)%

λ - Household food security was assessed during the sixth routine visit when the child was on average 1 year

+CR: cricket enriched porridge; -CR: Control porridge; +ED Nutrition Education offered; -ED No nutrition Education offered

Table 4.1b Baseline Characteristics of Infants Nutrition Status[θ]

Randomized to intervention arms (n)		-CR & +ED (70)	-CR & -ED (73)	+CR & -ED (n=71)	+CR & +ED (70)	Total (284)
Child nutritional status		**(n) mean±sd⍊**	**(n) mean±sd⍊**	**(n) mean±sd⍊**	**(n) mean±sd⍊**	**(n) mean±sd⍊**
Age	Months	(70) 6.4±0.6	(73) 6.3±0.5	(71) 6.3±0.5	(70) 6.2±0.4	(284) 6.3±0.5
Infant sex	Female	(34) 48.6%	(35) 47.9%	(35) 49.3	(31) 44.3%	(135) 47.5%
Baseline weight	Kg	(70) 7.5±1.01	(73) 7.6±1.1	(71) 7.7±1.3	(70) 7.5±1.0	(284) 7.6±1.1
Baseline height	Cm	(70) 65.7±2.9	(73) 65.7±3.2	(71) 65.7±3.7	(70) 65.8±2.4	(284) 65.7±3.1
HAZ	z-score	(70) -0.69±1.28	(73) -0.67±1.42	(71) -0.56±1.49	(70) -0.60±1.08	(284) -0.63±1.32
Stunted at baseline [§]	HAZ< -2	(8) 11.4%	(9) 12.3%	(12) 17.1%	(6) 8.6%	(35) 12.4%
WAZ	z-score	(70) -0.35±1.15	(73) -0.23±1.39	(71) -0.17±1.51	(70) -0.31±1.11	(284) -0.26±1.30
WHZ	z-score	(70) 0.21±1.09	(73) 0.37±1.05	(71) 0.46±1.18	(70) 0.17±1.13	(284) 0.30±1.11
Wasted at baseline [¢]	WHZ<-2	(2) 2.9%	(2) 2.7%	(1) 1.4%	(2) 2.9%	(7) 2.5%
Hb	g/dL	(63) 10.2±1.4	(66) 9.8±1.3	(62) 10.2±1.4	(68) 10.1±1.6	(259) 10.1±1.4
Birth weight	Kg	(68) 3.2±0.5	(70) 3.2±0.7	(69) 3.2±0.6	(66) 3.2±0.5	(273) 3.2±0.6
MUAC	Cm	(70) 13.4±1.1	(73) 13.4±1.3	(71) 13.5±1.4	(69) 13.4±1.1	(283) 13.4±1.2
Head circumference	Cm	(70) 42.8±1.4	(73) 43.0±1.3	(71) 42.5±2.0	(70) 42.6±1.5	(284) 42.7±1.6
Skinfold suprailliac	Mm	(70) 9.6±2.3	(73) 9.3±2.4	(71) 9.2±2.4	(70) 9.1±1.9	(284) 9.3±2.2
Skinfold abdominal	Mm	(70) 7.8±2.2	(73) 8.1±2.4	(71) 8.4±2.5	(70) 7.8±1.8	(284) 8.0±2.2
Skinfold triceps	Mm	(70) 9.0±1.8	(73) 9.2±1.8	(71) 9.0±1.8	(70) 8.6±1.9	(284) 9.0±1.8

θ - Data are number of respondents, mean ± SD and % for selected baseline characteristics of interest for child mother and household

⍊ - Units of measure for the characteristics of interest is mean±sd unless otherwise stated as (n)%

§ - Overall stunting rate and stunting per arm measured in (n) %;

¢ - Overall wasting rate and stunting per arm;

HAZ, height-for-age z-score; WHZ, weight-for-height z-score; Hb, Haemoglobin; MUAC, middle upper arm circumference; +CR: cricket enriched porridge; -CR: Control porridge; +ED Nutrition Education offered; -ED No nutrition Education offered

4.2 Acceptability of the Study Foods

4.2.1 Doubt, Anxiety the Feeding Start Challenges

Naturally on introduction to new food people have some level of doubt, averseness and reluctance but should the food have a good acceptable attributes and taste people quickly embrace it upon tasting. Some of the mothers were **averse with the porridge** at onset but with time, appreciated it, especially when they observed the level of acceptance indicated by how their child consumed the porridge. This was further promoted by the level of belief in how healthy the porridge was as demonstrated by the following quotes:

R7: … unga nasema ilikuwa mzuri sana waah kulingana na venye mtoto alikuwa anaikunywa uji naweza sema ilikuwa mzuri sana juu pia wakati nilikuwa namjaribu na ingine ya kawaida alikataa, which means hii yenu ilikuwa sawa aii ikafanya mtoto akakuwa healthy akakuwa strong. Naa , nilikuwa nai doubt mwanzo mwanzo but niliona kama inampeleka vizuri. Eee sijaona shida yoyote (***Following how the child consumed it the porridge was very good, cause when I introduced alternative porridge the child rejected, this study porridge made the child strong and healthy. At the onset I doubted it but it has done the child great without any challenge***) [FGD2; +CR Porridge; R7]

R4: ….. venye nilianza ya kwanza uji ilimsumbua lakini baadaye akashika mita. Sasa ilikuwa inampeleka vizuri tena alikuwa healthy sana (***at the start the child had a challenge but with time got used to the study porridge and is very healthy***) [FGD3; -CR Porridge; R4]

4.2.2 Introduction of New Food Experience

It was however observed that with introduction of new food or switch over to new alternative food, children may experience stomach discomfort resulting in diarrhea which clears off with repeated consumption of the new food or resumption on what they are used to. This is confirmed by the following quotes:

R4: …. to kamiye macha [alternative porridge] to aneno kodiewo koro immediately mane ochakomadho mano[study porridge] to aneno kaoonge gishida moro amora omadhe ma ka nyuka makoro ohero (***…..when I gave my child the alternative porridge the child would diarrhea but when on study porridge the child has no problem and takes it happily***) [FGD1; -CR Porridge; R4]

R5: ….mtoto alikuwa anakunywa vizuri na anaendelea vizuri na lakini na ikiisha tu hivi uanze kumpa hii ingine saa zingine nilikuwa naona anaanza kuharahara kidogo aki kunywa hii ingine lakini tena akianza kuendelea na hii ingine sikuwa nikiona aki hara hiyo ndiyo changamoto. Niliona wakati unga ilikuwa imeisha nikaanza hii ingine lakini vile alikuwa anakunywa hiyo sikuona hata akihara hata siku moja. …. Wakati huo unga

ulikuwa umeisha nilikuwa naanza kumpatia hii ingine hapo ndiyo nilikuwa na ugumu lakini tena nikija tena nichukuwe hii na kuendelea kupatia hapo tena mambo ilikuwa ikiendelea … kwa sababu alikuwa anaendelea kunywa tu kama kawaida. (***On the study porridge the child would do well and a change to alternative porridge meant force feeding and would be followed by diarrheal episodes which cleared with continuous use of the alternative but when returning to study porridge was happy feeding and no experience of diarrhea***) [FGD2; +CR Porridge; R5]

4.2.3 Level of Acceptability

During the main study we lost a total of 40 children for various reasons and retained 244 who consumed the study food to the last day in the study. The reasons given for loss to follow up were largely due to relocation with none due to rejection nor adverse allergic reaction from the study food. Gauged by how aggressive the child demanded the next bite, over time, the two-study porridges consistently gained acceptability. At first revisit an acceptability level of 79.7% and 80.3% was observed, which over the 8-month time rose to 98.3% and 99.2% for +CR and -CR respectively. Corresponding to dropping porridge rejection behavior from a high of 8.6% to a near 0% at the time of end line visit. All completely accepted the +CR study porridge except one who spat while eating the cricket-based porridge at end line visit (7^{th} revisit) yielding a rejection rate of 0.8% (**Figure 4.2**).

Table 4.2 shows assessment of porridge acceptability of all the children who completed the main study in a scale of one to seven times. The child signaled for more porridge aggressively at an overall mean score of 5.6±1.6 times. With the times signaled being 0.1 times higher for +CR (5.7±1.6) against -CR (5.6±1.6). All the dislike attributes tested rated on average with a score less than 1 time. When caregivers were asked to give their overall rating for the quality of the study porridge in a scale of 1-10 with 10 being the best porridge ever given to their infant, both porridges were rated equally (at mean±SD of 8.5 ±1.5 for +CR and mean±SD of 8.6 ±1.4 for -CR). And the care-givers in the study were willing to recommend the porridge to other mothers at a mean±SD of 8.5 ±1.4 for +CR and mean±SD of 8.5 ±1.5 for -CR. According to the caregivers, rejection of the study porridge alternatives was above 60% with more than 30% strongly disliking the alternative food offered at home. From child behavior approximately 6% of the infants completely rejected the alternative while over 50% consumed the alternative reluctantly when the study food was over.

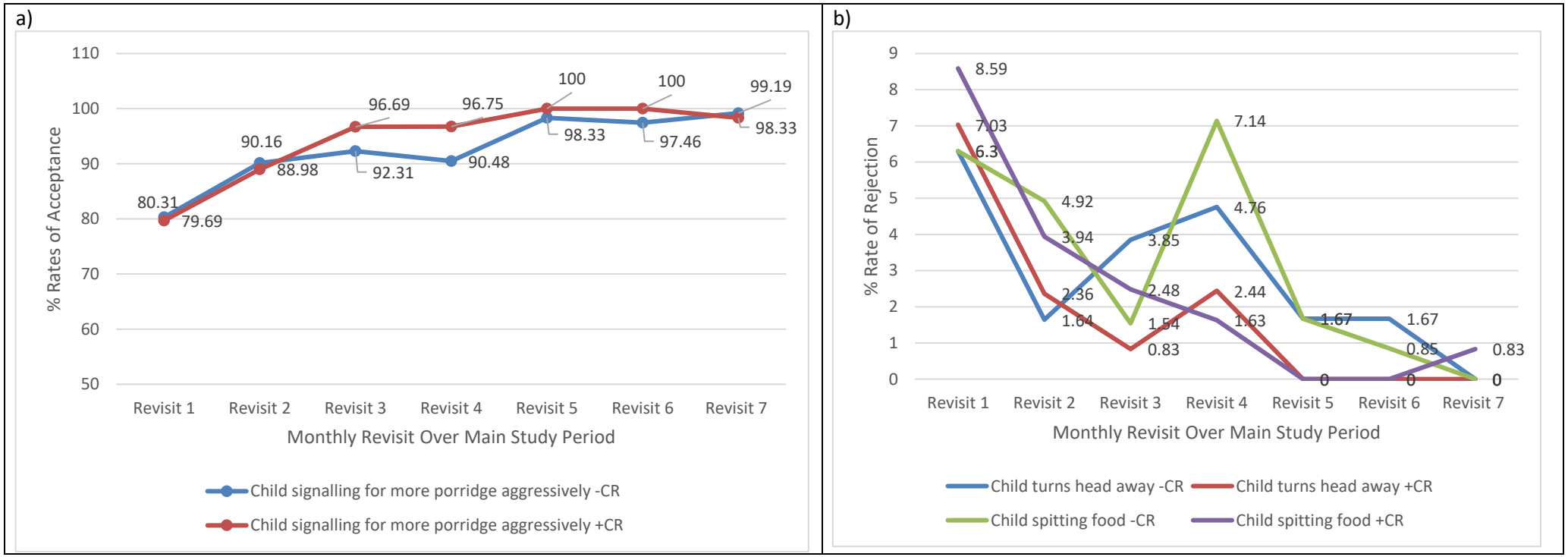

Figure 4.2 Trend of porridge acceptability and rejection behavior over the study period

Table 4.2 Child Observed and Care-givers Opinion on the Level of Acceptability of the Study Porridge

Observed child signals	Scale	+CR (mean±SD)	-CR (mean±SD)	Overall (mean±SD)	Chi	P-value
Child signaling for more aggressively		5.7±1.9	5.6±1.9	5.6±1.9		
Child accepts porridge passively		0.2±0.5	0.2±0.6	0.2±0.5		
Child turns head away		0.1±0.4	0.2±0.5	0.1±0.4		
Child spitting food		0.2±0.5	0.2±0.5	0.2±0.5		
Child crying, refusing to eat		0.01±0.1	0.03±0.2	0.02±0.1		
Child crying, but eats		0.1±0.3	0.1±0.4	0.1±0.3		
Child vomits		0.01±0.1	0.01±0.1	0.01±0.1		
Care-givers' study porridge rating in a scale of 1 to 10		8.5±1.5	8.6±1.4	8.6±1.6		
Care-givers' willingness to recommend the study porridge to others should it be sold		8.5±1.4	8.5±1.5	8.5±1.5		
		n (%)	n (%)	n (%)		
Proportion of care-givers rating the porridge above 8/10 (243)	Yes	97 (80.2)	101 (82.8)	198 (81.5)		
	No	24 (19.8)	21 (17.2)	45 (18.5)	0.28	0.60
	Total	**122 (100)**	**121 (100)**	**243 (100)**		
Observed child response to alternative food when study porridge flour is over (238)	Accepted highly	42 (35.6)	42 (35.0)	84 (35.3)		
	Accepted but reluctantly	70 (59.3)	69 (57.5)	139 (58.4)	0.59	0.74
	Rejected	6 (5.1)	9 (7.5)	15 (6.3)		
	Total	**118 (100)**	**120 (100)**	**238 (100)**		
Care-givers' rating level for child's like or dislike of the alternative food offered (240)	Like extremely	2 (1.7)	3 (2.5)	5 (2.1)		
	Like slightly	29 (24.6)	27 (22.1)	56 (23.3)		
	Neither like nor dislike	12 (10.2)	5 (4.1)	17 (7.1)	3.99	0.41
	Dislike slightly	36 (30.5)	41 (33.6)	77 (32.1)		
	Dislike extremely	39 (33.1)	46 (37.7)	85 (35.4)		
	Total	**118 (100)**	**122 (100)**	**240 (100)**		

+CR cricket enriched porridge; -CR control porridge; mean±SD mean and the associated standard deviations; proportion above 8/10 imply above 80% approval; p-values are chi square statistics, three infants had single vomit episodes while feeding (+CR, two infants at one at 2nd and another at 8th visits while +CR, one infant at 6th visit)

The similarity in the level of acceptance of the study porridge is seen in the none significant difference (p= 0.60) in proportional rating, indicating no significant difference between the two porridges. This level of rating indicates that, both study porridges were highly accepted by the mother-infant dyads a position that is qualified by the care-givers' verbatim comments. In the care-givers comments, they **appreciated the porridge for, its aroma, taste and how their child consume it when offered.** The aroma was strong enough that it set it apart from any other porridge making it easy for the child and mother to identify. Clearly the mothers' personal statements and the expression of the challenges they experienced when the child missed the porridge confirms porridges' acceptability:

R1: Wangu naye alipenda immediately kuliko famila yenye nilikuwa nampikia ……alikuwa anaichukuwa vizuri akiweka kwa mapua ana jua ni hiyo na anakunywa (***my child liked it at onset more than the previous porridge I bought from the shop and would identify it from the aroma and feed***) [FGD1; -CR Porridge; R1]

R7: … kulingana na venye mtoto alikuwa anakunywa uji naweza sema ilikuwa mzuri sana juu pia wakati nilikuwa namjaribu na ingine ya kawaida alikataa, which means hii yenu ilikuwa sawa (***From observation this porridge is very good the child took it very well and has since rejected the local alternative porridge***) [FGD2; +CR Porridge; R7]

R3: So ilinilazimu nimlazimishe cause alikuwa amezoea ile na hiyo …. na all over a sudden unabadilisha so ili azoe hii ilikuwa …challenge but so alikuwa amebase kwa maziwa lakini hii amezoea tu vizuri (***I am forced to force feed as the child liked the study food and over sudden had to return to local alternative porridge when study food was over so had to depend on milk as better alternative***) [FGD4; +CR Porridge; R3]

Some caregivers observed that the **flour was finely ground, satisfying, and provided adequate energy** to the child making the child comparatively strong and active:

R3: To mar ariyo ma ayudo kokonya ni wach kaka yande odhoth ahinya ne wach nyukacha ok ong'iyo go, sani ok ane ka odhoth ahinya yani sama ongiyo gi nyukani chalne gi chak mar thuno nikech nyukani yom mogoni yom. Koro sama oginene samomadho nyukani ok odhodh ahinya kaka yande odhoth makoro pache duto nie thuno. Koro aneno ka sama nende abedie ka tiyo tijena to komadho nyukani sama omadhonyuka cha koro thunono ok o depend e ahinya mano okonya kaka sani otek ojing onyalo ringo moingo kaka ne en ko madho nyuka moko ka ne hinye samatin iye kuot mato komadho to odhiaadhia mayom (***secondly upon introduction to the study flour the child reduced rate of breast feeding because this porridge is finely ground so am able to perform other tasks and the child is very energetic and more active than before when I used the other porridge which led to constipation***) [FGD1; -CR Porridge; R3]

R2: Agoyo erokamano gima mogoni otimona. Omiyo nyathina sani strong sani en ngat moro makata ka arango gi nyamingi maneonge e migawo mar mogoni en weak nyaka sani pod en weak. Lakini mogoni osekonyo na mihiani omiyo mihichani sani en strong (***I am grateful for what this porridge has done to me, it has made my child stronger than the older sibling who was not in this study and remains weak todate. This porridge has helped my child***) [FGD1; -CR Porridge; R2]

Some of the mothers **associated the study porridge to the health** of their children. They appreciated how well the children gained weight and height as observed in the clinic visits and observed that the alternative they provided when the study porridge was over midway resulted either to diarrhea or constipation as confirmed by the following quotes:

R5: Kwa mtoto ilisaidia, juu wakati nilianza feeding nilianza na hiyo porridge. Nikaona anaendelea nayo poa, alikuwa kilo kidogo but with time ali grow haraka haraka compaired to others, my previous kids. So akakuwa active then ugonjwa hakuwa nayo. Vile alikuwa nayo mwazno aki.. from 1 month to 6 months. Tulikuwa on and off to the hospital but immediately tulianza kuja hapa akanzakutumia hiyo uji ikamsaidia kabisa. (***To the child the porridge was helpful, I introduced the child to this porridge as first solids and observed the child grow fast beginning with low weight and rapidly gaining weight compared to my other previous kids, getting active and with no ailments as was in the earlier months before month 6 when I was on off hospital but when we started on this porridge the child benefitted***) [FGD1; -CR Porridge; R5]

R2: … hiyo unga ilikuwa mzuri kwa sababu huyu mtoto wangu anadhoofika kila saa alikuwa na magonjwa hakukuwa na afya nzuri, lakini niliona tofauti. (***My child was sickling but when I put the child on study porridge, I saw a difference so the flour is good***) [FGD2; +CR Porridge; R2]

R4: …. kwa upande wangu hii uji niliona na mpea mtoto akienda haja kubwa anaenda vizuri ikiisha nimpea yangu ya kusiaga tu akienda haja kubwa ni ngumu kidogo.(***when my chid was on study porridge defecation was ok but when study food was over and I give what we prepare at home the child gets constipated***) [FGD2; +CR Porridge; R4]

R3: … ber ma aneno e mogoni an mihichani ne achako ruwone nyuka moko ma wa ma wanyiewo eduka gi ne ayudo ni ok dhikode maber, iye moko iye korore ko dhi e cho ok odhi maber. (***What pleased me in the flour, my child started taking porridge made from flour bought in local shops which did not go well as the child was ever constipated***) [FGD1; -CR Porridge; R3]

A number of mothers observed that the study porridge **was more preferred** by the children than the alternatives porridge they bought from shop or processed at home:

R1: Wangu naye mwanzoni nilikuwa nampeanga ile famila sasa vile nilijaribu hii nikaona amekataa famila hadi saa hii sasa vile siku zake zilifika ali stopishiwa sasa siku hizi

hakunywangi uji ukimpea na anasukuma kikombe juu alikuwa amezoea ile … na unga alikuwa analamba hata ukichukuwa kidogo uweke kwa sahani analamba (***my child was taking porridge from the shop but when we introduced the study porridge the child rejected the porridge from shop todate even now that the study phase is over the child pushes off mug of the alternative porridge…the child would lick the study flour directly in its powder form***) [FGD1; -CR Porridge; R1]

R4: …. Maa mogo machielo, kane mogono oserumo to to naneno ka bet ne en gi pek emadho nikech noseng'iyo gi macha … kane migao oseketo ni koro an ne asebiro makawone mogik nomadho to kane orumo koro achako ketone mogo morono, omadh amadh nikech koro day one to newayware aywaya nimondo ne ongii gi nyukani maber nimar ne oseng'iyo gimorocha koro gi sani to omadho amadha kod chiemo mamokogo be ochamo (***my child had difficulty with the alternative porridge flour once the study period ended having gotten used to the study porridge. Currently though not as well as previous study porridge the child takes porridge and eats others foods too***) [FGD1; -CR Porridge; R4]

R1: Hii uji kulingana na vile ilikuwa mzuri …… na hiyo uji tumeona ilikuwa mzuri sana hata kushinda za duka (***this porridge was very good and much better than the one we get from the shops***) [FGD2; +CR Porridge; R1]

R2: …. uji umetupatia imeisha kama haijafika date yenye uliandikiwa sasa ilikuwa inaniletea changamoto cause unapata hataki za duka , ashazoea hii na hii pia imeisha saa ilikuwa inabaki tu namweka maziwa kwa sasa asikose kitu kama….pia si kosi eeh sasa ikifika ile ya kuchukuwa ile naendelea tu nayo lakini ya duka nayo ilishindikana mpaka wa leo hataki so nikaachana tu nayo (***The study porridge would run out before next appointment date and return to the old porridge was a challenge as the child dislike the flour bought at the shops because the child is used to study porridge***) [FGD3; -CR Porridge; R2]

4.2.4 Other Observation on Acceptability

Other observations made by mothers in the study was improvement of baby's appetite. One caregiver said that the - CR porridge also increased the child's appetite making the child eat other foods provided very well:

R2: …. ber nyukani seche mimiye mihiya cha en gi vitamin moro kanyo olero chuny mihiya gi chiemo koro aneno ka mihiyani omadho nyuka to kila gimoro ochamo kila gimoro ochamo to awachoni ee asenyuolo nyithindo to pok aneno mihiya ma dweche auchiel ama kanyalo chamo rabuon kaok iginene kaok ibondabonda maye to aneno kajowadgi chamo rabuon en bende okwanyo otimo angowa okete edhoge koro kaneosengiyo gi nyukano neomiye vitamin moro kanyo mar chiemo (***the good attribute of this porridge is when giving it to the child it has an appetizing ("vitamin") property enabling the child to eat all foods given. I have given birth but this child surprised me eating whole***

un-mashed sweet potatoes at 6 months along with other children, this porridge gave the child appetite) [FGD1; -CR Porridge; R2]

They also appreciated the porridge for the time required to prepare the porridge. The time was relatively shorter compared to the ordinary porridge The study flours were extruded making **cooking duration of the study porridge generally shorter** than that of the unextruded flour found in shops or at home and is confirmed by this quote:

R5 …. alafu kitu nilipenda as long as isikuwe abit hard kuiva kwake haikuwa ina chukuwa time. Kuna wakati hata mtoto akinisumbua usiku nilkuwa namwekea tu maji warm hivi naweka maji warm, naweka unga alafu anakunywa tu hivyo sikuona effect yoyote hakuhara alikuwa anipenda hivyo then nikona nilikuwa na…. ukipika inaiva haraka (***as long as the paste is not hard it cooks fast, there was a night when the child was hungry and I used warm water to make the porridge without cooking and the child comfortably took it without any side effects not even diarrhea…. When you cook, it takes a short time***) [FGD1; -CR Porridge; R5]

4.3 Effects of cricket enriched porridge on linear growth

The scatter plot (**Figure 4.3**) of height by age for the two level of porridge treatment is randomly distributed indicating no apparent difference in height for children consuming either porridge.

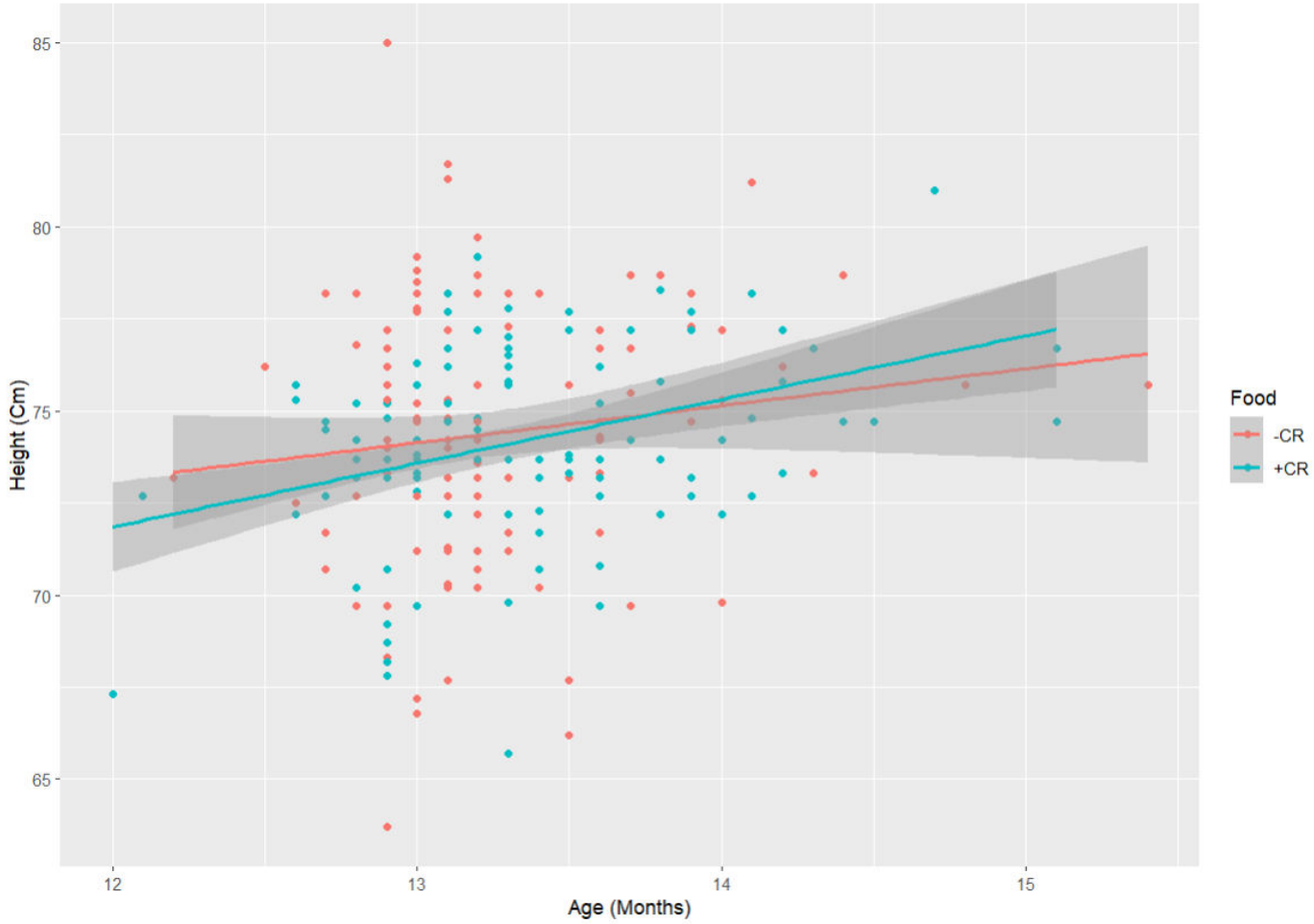

Figure 4.3 Participant's height against age by porridge type

Table 4.3 ANOVA Testing Slope Equality Between Porridge Types by Comparing a Full Model with Interaction to Reduced Model with no Interaction

Model 1		**Df**	**Ss**	**ms**	**F**	**p-value**
	Age	1	117.79	117.79	23.26	0.000
	Average baseline weight	1	977.31	977.31	192.99	0.000
	Gender	1	1.47	1.47	0.29	0.590
	Porridge Type	1	1.44	1.44	0.28	0.595
	Age*Average baseline weight	1	22.36	22.36	4.41	0.037
	Age*Gender	1	14.06	14.06	2.78	0.097
	Average baseline weight*Gender	1	0.29	0.29	0.06	0.812
	Age*Porridge Type	1	0.08	0.08	0.02	0.902
	Average baseline weight*Porridge Type	1	7.17	7.17	1.42	0.235
	Gender*Porridge Type	1	1.57	1.57	0.31	0.578
	Average baseline weight*Gender	1	6.51	6.51	1.28	0.258
	Average baseline weight*Porridge Type	1	0.69	0.69	0.14	0.712
	Age*Gender*Porridge Type	1	2.64	2.64	0.52	0.471
	Average baseline weight*Gender*Porridge Type	1	0.62	0.62	0.12	0.726
	Age*Average baseline weight*Gender*Porridge Type	1	0.04	0.04	0.01	0.925
	Residuals	228	1154.63	5.06		
Model 2	Age	1	117.79	117.79	23.25	0.000
	Average baseline weight	1	977.31	977.31	192.94	0.000
	Gender	1	1.47	1.47	0.29	0.59
	Porridge Type	1	1.44	1.44	0.28	0.59
	Residuals	239	1210.65	5.07		

Model 1 Vs 2	**Resid. Df**	**Resid. ss**	**Df**	**Ss**	**F**	**p-value**
Model 1	228	1154.63				
Model 2	239	1210.65	-11	-56.022	1.006	0.442

Model - statistical function; Df - degrees of freedom; ss – sum of squares; F - F statistics; ms – mean sum of squares; Resid. Df - Residual Degrees of freedom; Resid ss - Residual sum of squares

The hypothesis Ho: The slopes are equal for the two slopes between two different categories (two porridge types) along the covariates of interest was tested by fitting a full model with interaction and comparing to a reduced model with no interaction (**Table 4.3**). With p-value=0.44 there is no sufficient evidence to reject the null hypothesis. Hence conclude that the slopes are equal implying the two porridges did not result in a statistically significant different effect

Table 4.4 Potential Outcome Means Comparison of +CR Vs -CR Groups

		Coef.	**Std. Err.**	**Z**	**p-value**	**95% CI**
Potential Outcome Means	+CR	70.10	0.26	269.06	0.00	(69.59 70.61)
	-CR	69.97	0.24	287.92	0.00	(69.50 70.45)
Average treatment effect	+CR vs -CR	-0.13	0.19	-0.69	0.49	(-0.50 0.23)

+CR Cricket Enriched flour; -CR CSB+

Table 4.4 shows that the estimated potential outcome means for the two porridge was averagely 70 cm with similar confidence interval and none significant (p=0.49) treatment effect of -0.13. Indicating that those on -CR were 0.13cm shorter than those on cricket enriched porridge.

4.4 Effects of Nutrition Education on Stunting Status

The scatter plot **(Figure 4.4**) for the two level of Education treatment is randomly distributed potentially indicating no apparent difference in height for children on either nutrition education arm or no nutrition education arm

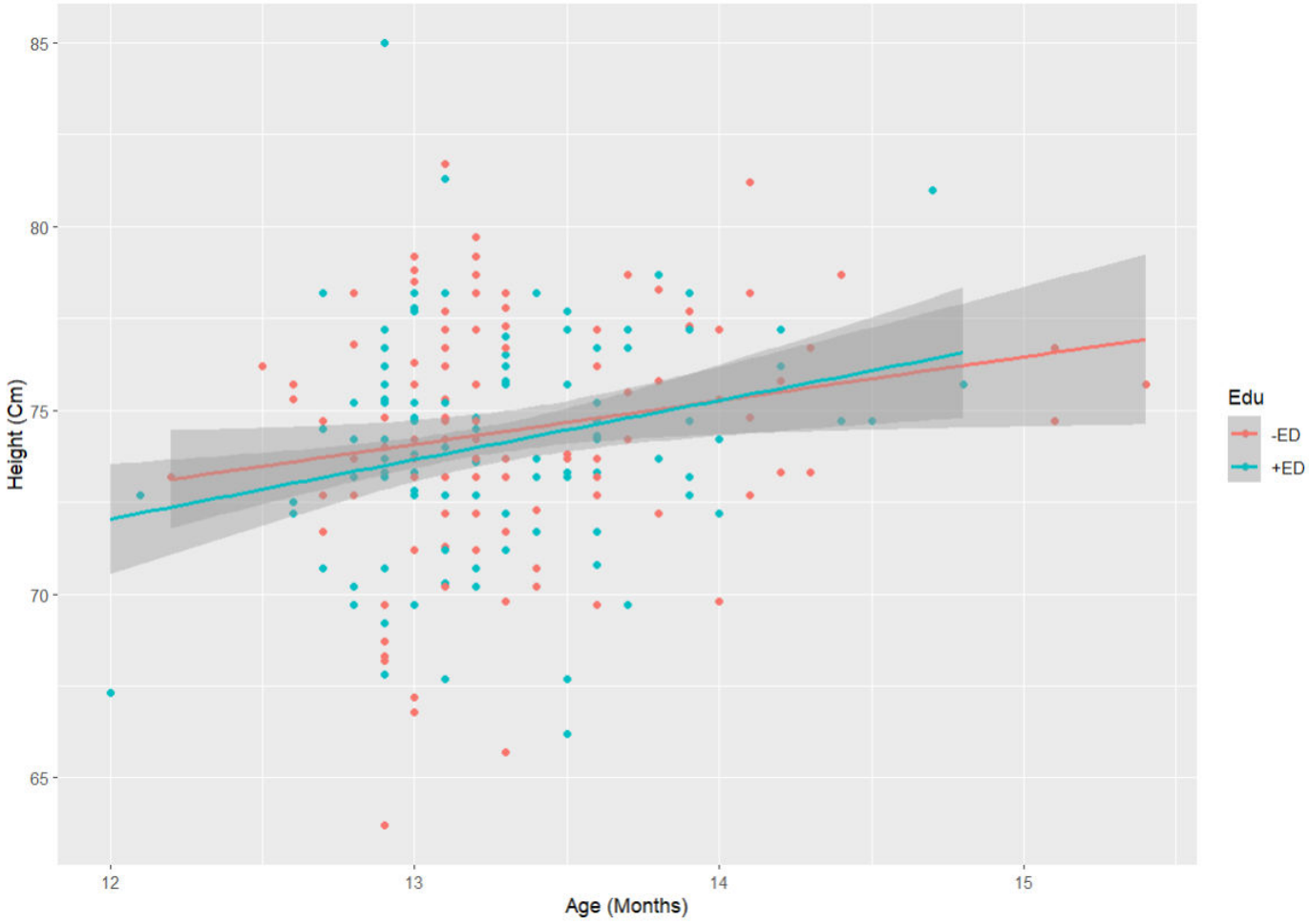

Figure 4.4 Participants height plotted against age by education treatment

Table 4.5 ANOVA Testing Slope Equality Between Education Treatment by Comparing a Full Model with interaction to Reduced Model with no Interaction

Model 1		Df	Ss	Ms	F	p-value
	Age	1	117.79	117.79	23.42	0.000
	Average baseline weight	1	977.31	977.31	194.32	0.000
	Gender	1	1.47	1.47	0.29	0.589
	Porridge type	1	0.45	0.45	0.09	0.766
	Age*Average baseline weight	1	23.19	23.19	4.61	0.033
	Age*Gender	1	12.72	12.72	2.53	0.113
	Average baseline weight*Gender	1	0.14	0.14	0.03	0.867
	Age*Porridge type	1	0.17	0.17	0.03	0.854
	Average baseline weight*Porridge type	1	0.86	0.86	0.17	0.680
	Gender*Porridge type	1	0.00	0.00	0.00	0.985
	Average baseline weight*Gender	1	8.40	8.40	1.67	0.197
	Average baseline weight*Porridge type	1	7.38	7.38	1.47	0.227
	Age*Gender*Porridge type	1	0.18	0.18	0.04	0.850
	Average baseline weight*Gender*Porridge type	1	3.37	3.37	0.67	0.414
	Age*Average baseline weight*Gender*Porridge type	1	8.51	8.51	1.69	0.195
	Residuals	228	1146.71	5.03		
Model 2	Age	1	117.79	117.79	23.23	0.000
	Average baseline weight	1	977.31	977.31	192.78	0.000
	Gender	1	1.47	1.47	0.29	0.590
	Porridge type	1	0.45	0.45	0.09	0.767
	Residuals	239	1211.64	5.07		

Model 1 Vs 2	Resid. Df	Resid.ss	Df	Ss	F	p-value
Model 1	228	1146.7				
Model 2	239	1211.6	-11	-64.928	1.17	0.306

Model - statistical function; Df - degrees of freedom; ss – sum of squares; F - F statistics; ms – mean sum of squares; Resid. Df - Residual Degrees of freedom; Resid ss - Residual sum of squares

In **Table 4.5** the two slopes between two different categories (Education vs no education groups) along the covariates of interest were equal was tested by fitting a full model with interaction and comparing to a reduced model with no interaction. This was to test the hypothesis Ho: The slopes are equal. With the p-value of 0.31, there is not a sufficient evidence to reject the null hypothesis hence conclude that the slopes are equal implying the education vs no-education treatment did not result in a statistically significant different effect.

Table 4.6 Potential Outcome Means Comparison of +ED Vs -ED Groups

		Coef.	Std. Err.	Z	p-value	95% CI	
Potential outcome means	-ED	69.92	0.26	273.49	0.00	(69.42	70.43)
	+ED	70.12	0.25	276.94	0.00	(69.63	70.62)
Average treatment effect	+ED vs -ED	0.20	0.19	1.05	0.30	(-1.77	0.58)

+ED Nutrition Education; -ED No Nutrition Education

Table 4.6 show the estimated potential outcome means for either nutrition education or no nutrition education group was averagely 70 cm with similar confidence interval and none significant (p=0.30) treatment effect of 0.20. Indicating that those on nutrition education were 0.20cm taller than those on the no nutrition education study arm.

4.5 Effect of Baseline Gut Health on Child End-Line Stunting Status

The overall gut health sub-study had a total of 40 participants with a sex ration of 1:1. Of the 40 participants enrolled in the breath test sub study four were lost to follow up with two migrating outside the study area, one was not reachable on the contact details provided while the last participant declined to continue with the study (See **Figure 4.5**). The average birth weight for the infants was 3.26kgs gaining weight over the study period to an average weight of 9.76kgs. To establish the effects on gut health over the 8 months study observation period we evaluated stunting status of the infants, against the baseline Cumulative Percentage of Dose Recovered at 90 minutes (cPDR90). On average the participants had an average cPDR90 of 22.00±7.43. The study participants started off (see **Table 4.7**) with a baseline stunting rate of (4/40) 10.0%. At the end of the study the stunting rate had increased to (6/36) 16.7%. Four of the infants who were stunted at baseline remained stunted to the end of the study, three of them had a cPDR90 of less than 18.0%. while one had a cPDR90 of 26.1%. At end line two additional infants regressed from normal health to being stunted the two had cPDR90 of 25.3% and 30.0%. The two infants who regressed from normal to stunted were on +CR while all the other four initially stunted were equally distributed across the four study arms. Comparing the average baseline cPDR90 by nutrition status at both baseline and end-line gives the indication that the two infants who regressed over the intervention period increased the average cPDR90 for the stunted while the cPDR90 for the non-stunted remaining fairly stable as seen in **Figure 4.6**. Generally, a higher cPDR90 in a ^{13}C-sucrose breath test (^{13}C-SBT) indicates a better small intestinal function, in terms of sucrase activity and is associated with higher absorption.

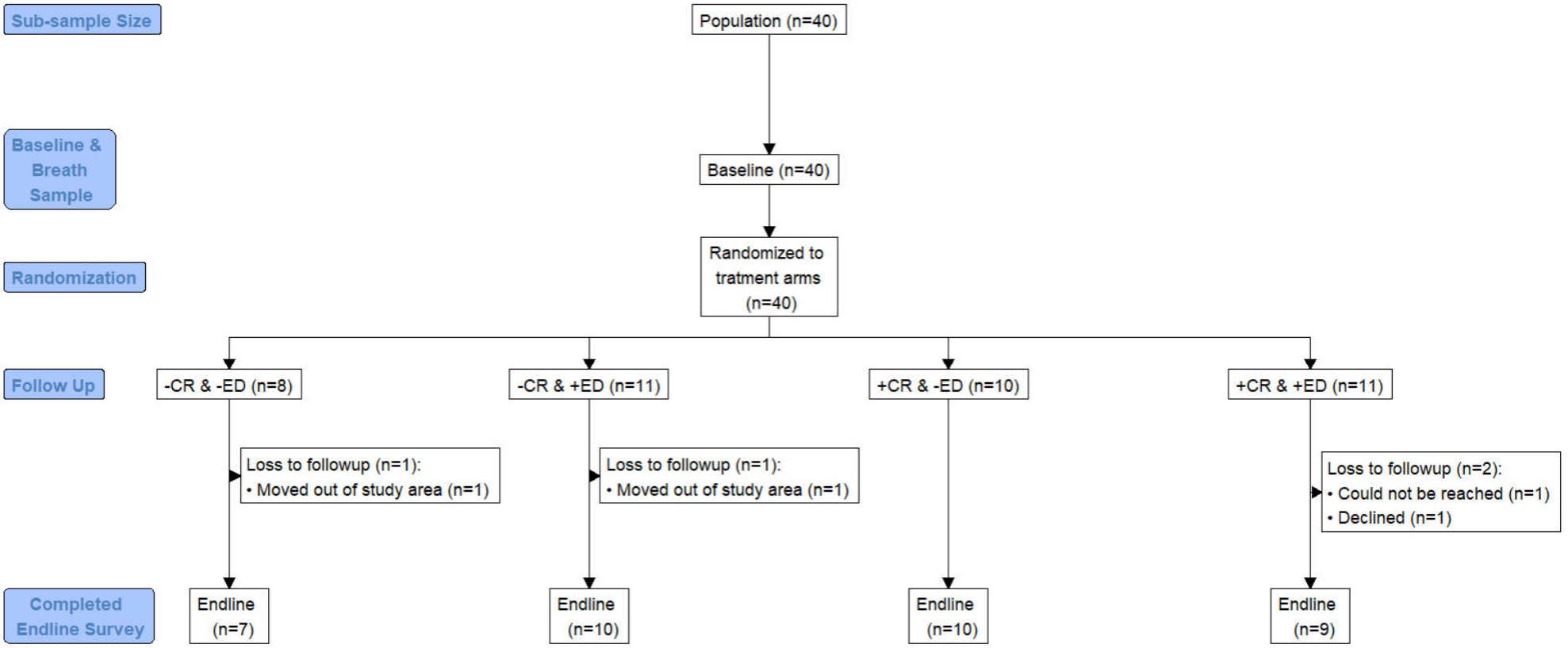

Figure 4.5 Flowchart summarized for breath sub-study from recruitment to end-line.

+CR: cricket treatment; -CR: Control; +ED Education treatment offered; -ED No Education treatment offered; -CR & -ED: Control with No Education treatments offered

Table 4.7 Summary Statistics for the Infants Participating in Gut Health Sub Study[θ]

Infants' Sex & Stunting rates		Units	-CR & +ED	-CR & -ED	+CR & -ED	+CR & -ED	Total
			n (%)	n (%)	n (%)	n (%)	n (%)
Baseline Child Gender	Male		6(60.0)	5(45.5)	2(25.0)	7(63.6)	20(50.0)
	Female		4(40.0)	6(54.5)	6(75.0)	4(36.4)	20(50.0)
End-line Child Gender	Male		6(60.0)	4(44.4)	1(14.3)	6(60.0)	17(47.2)
	Female		4(40.0)	5(55.6)	6(85.7)	4(40.0)	19(52.8)
Baseline stunting	Non-Stunted		9 (90.0)	10(90.9)	7(87.5)	9 (90.0)	36(90.0)
	Stunted		1(10.0)	1(9.1)	1(12.5)	1(10.0)	4(10.0)
End-line Stunting	Non-Stunted		9 (90.0)	8(88.9)	5(71.4)	8(80.0)	30(83.3)
	Stunted		1(10.0)	1(11.1)	2(28.6)	2(20.0)	6(16.7)
Baseline to End-line Stunted status Change[#]	Stunted to Stunted		1(10.0)	1(9.1)	1(12.5)	1(9.1)	4(10.0)
	Non-Stunted to Stunted		0(0.0)	0(0.0)	1(12.5)	1(9.1)	2(5.0)
	Non-Stunted to Non-Stunted		9(90.0)	8(72.7)	5(62.5)	8(72.7)	30(75.0)
	Non-Stunted to Missing		0(0.0)	2(18.2)	1(12.5)	1(9.1)	4(10.0)
Anthropometrics			**Mean±SD**	**Mean±SD**	**Mean±SD**	**Mean±SD**	**Mean±SD**
	Birth weight	(kg)	3.23±0.42	3.38±0.74	3.11±0.34	3.29±0.53	3.26±0.53
	Baseline weight	(kg)	7.80±0.88	7.49±0.56	7.58±1.57	7.96±1.08	7.72±1.02
	End-line weight	(kg)	9.87±1.02	9.47±0.81	9.57±1.85	10.05±1.54	9.76±1.30
	Baseline HAZ	(z-score)	-0.54±1.14	-0.60±0.98	-0.43±1.55	-0.27±1.43	-0.46±1.23
	Baseline HAZ	(z-score)	-0.56±1.13	-0.80±1.05	0.34±1.67	-0.04±1.72	-0.43±1.38
	Baseline age	(Months)	6.20±0.32	6.0±0.26	6.34±0.56	6.22±0.38	6.20±0.38
	End-line age	(Months)	13.15±0.40	13.14±0.30	13.37±0.55	13.12±0.36	13.20±0.39
	Baseline MUAC	(Cm)	13.60±1.08	13.15±0.70	12.86±1.90	13.53±1.15	13.31±1.21
	End-line MUAC	(Cm)	13.91±1.03	13.52±0.76	13.33±1.72	14.35±1.03	13.82±1.16
Gut Health[$]	cPDR90	(%)	20.28±4.40	23.77±8.32	22.27±9.58	21.59±7.61	22.00±7.43

θ - Baseline had 40 infants while end-line had 36

- two infants who were not stunted at baseline ended up stunted at end-line

$ - is the average cumulative % ^{13}C-sucrose dose recovered in a breath at 90 min per study arm

cPDR90, ^{13}C-sucrose dose recovered in a breath at 90 min; HAZ, height-for-age z-score; MUAC, middle upper arm circumference

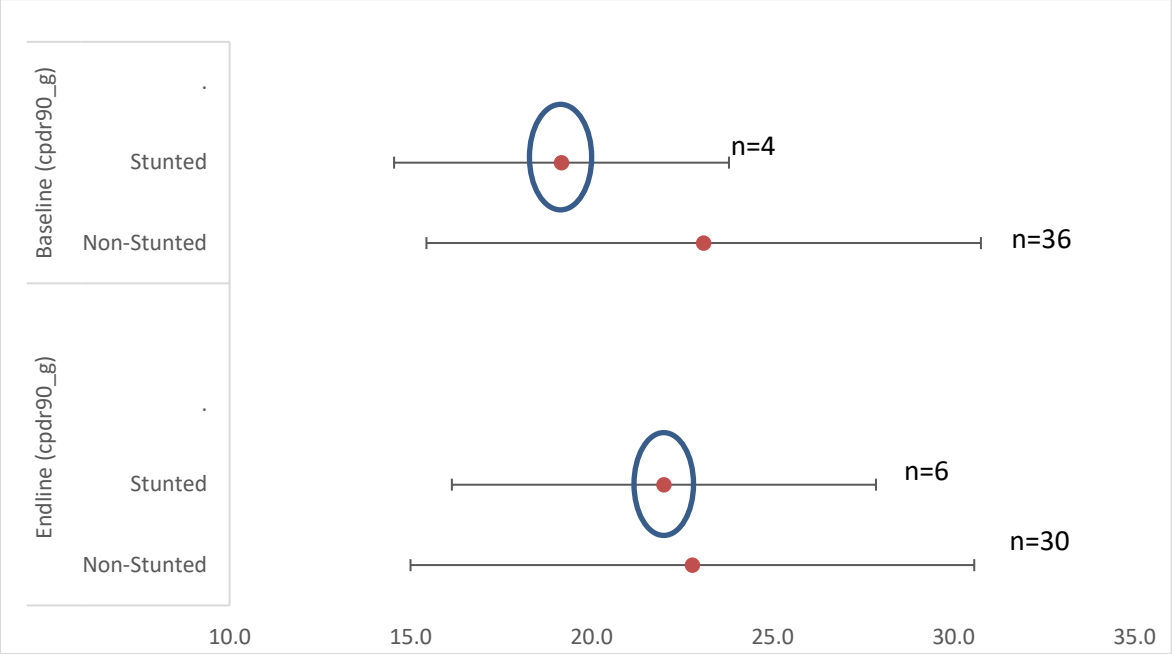

Figure 4.6 Comparison of baseline CPDR90 for participants by nutrition status

4.6 Combined Intervention Effects of Cricket Enriched Porridge and Nutrition Education on Linear Growth

Table 4.8 shows primary and secondary anthropometric measures at baseline, end-line, and the mean paired difference for participants with both baseline and end-line (n=244) completed. Over the intervention period, those with complete end-line measurements on average gained 8.5 cm in length, 1.9 kg body weight and 3.2 cm in head circumference. With a loss of on average 0.2cm, 1.0mm and 0.6 mm in MUAC, suprailliac and abdominal skin fold thicknesses, respectively.

Table 4.8 Change Baseline to End-line in Primary and Secondary Growth Measures over 8 Months Intervention[θ]

	Base-line [ɟ]		End-line [ɟ]		Paired Mean	
	n	mean±sd	n	mean±sd	Difference [λ] (95% CI)	
Primary outcomes						
Height (cm)	284	65.8±2.9	244	74.3±3.1	8.5	(8.2, 8.7)
HAZ (z-score)	284	-0.60±1.27	244	-0.86±1.19	- 0.3	(-0.4, -0.2)
Stunting [§]	284	(35) 12.4%	244	(39) 16.0%		3.6%
Secondary outcomes						
Weight (kg)	284	7.6 ±1.1	244	9.5±1.3	1.9	(1.8, 2.0)
WHZ (z-score)	284	0.31±1.11	244	0.30±1.04	-0.01	(-0.12, 0.11)
WAZ (z-score)	284	-0.21±1.26	244	-0.18±1.16	0.04	(-0.06, 0.13)
MUAC (cm)	283	13.4±1.2	241	13.5±1.0	-0.02	(-0.1, 0 .1)
Head circumference (cm)	284	42.8±1.5	241	45.9±1.4	3.2	(3.1, 3.3)
Suprailliac (mm)	284	9.4±2.2	241	8.4±2.0	-1.0	(-1.3, -0.7)
Abdominal (mm)	284	8.1±2.3	241	7.5±2.0	-0.6	(-0.9, -0.3)
Triceps (mm)	284	9.0±1.8	241	9.3±1.7	0.3	(0.1, 0.5)

θ - Data are number, mean ± SD, paired difference (end-line—baseline) with 95% CI and % as specified

ɟ - Baseline includes all who were registered while end-line only those who participated on end-line survey irrespective of any number of missed appointments in between

λ - Difference is individual measure gained as at end-line for infants with both baseline and end-line measurements (actual individual difference over time);

§ - Stunting (HAZ<-2) prevalence, number and percentage

HAZ, height-for-age z-score; WHZ, weight-for- height z-score; WAZ, weight-for-age z-score; MUAC, middle upper arm circumference

+CR: cricket enriched porridge; -CR: Control porridge; +ED Nutrition Education offered; -ED No nutrition Education offered

Table 4.9 Intention to Treat (ITT) Intervention Impacts: Treatment Interaction, Average Effects of Education Treatment and Cricket Treatment Adjusted for Sex and Baseline Value over 8 Months Trial Period[θ]

	Interaction, (P-value) [⏚]	Education Treatment (n=284)					Cricket Treatment (n=284)				
		-ED		+ED		Contrast [ɣ]	-CR		+CR		Contrast [ɣ]
		Effect Size [λ]	CI [§]	Effect Size [λ]	CI [§]	-ED vs +ED Contrast [¢] (P-value)	Effect Size [λ]	CI [§]	Effect Size [λ]	CI [§]	-CR vs +CR Contrast [¢] (P-value)
Primary Outcomes											
Height (cm)	0.08	7.68	(3.83, 11.52)	8.01	(4.17, 11.86)	0.34 (0.32)	7.49	(3.61, 11.36)	8.03	(4.17, 11.89)	0.54 (0.11)
HAZ (z-score)	0.74	0.08	(-0.11, 0.27)	0.25	(0.06, 0.45)	-0.18 (0.17)	0.03	(-0.36, -0.03)	0.31	(-0.39, -0.07)	-0.28 (0.03)
Secondary Outcomes											
Weight (kg)	0.75	-0.86	(-1.30, -0.43)	-0.93	(-1.36, -0.50)	-0.07 (0.55)	-1.00	(-1.38, -0.63)	-1.02	(-1.39, -0.65)	-0.02 (0.84)
WHZ (z-sore)	0.96	0.54	(0.29, 0.80)	0.09	(-0.16, -0.35)	-0.45 (0.01*)	0.45	(0.20, 0.71)	0.20	(-0.06, 0.45)	-0.26 (0.12)
WAZ (z-score)	0.56	-0.16	(-0.48, -0.37)	-0.27	(-0.30, -0.12)	-0.25 (0.06)	-0.05	(-0.15, -0.26)	0.03	(-0.18, -0.24)	-0.03 (0.84)
MUAC (cm)	0.49	4.46	(3.69, 5.22)	4.30	(3.53, 5.06)	-0.16 (0.27)	4.28	(3.51, 5.05)	4.45	(3.69, 5.21)	0.17 (0.24)
Head circumference (cm)	0.25	8.92	(6.38, 11.46)	8.90	(6.37, 11.44)	-0.02 (0.94)	8.71	(6.17, 11.26)	8.89	(6.33, 11.45)	0.17 (0.41)
Suprailliac (mm)	0.22	5.62	(4.83, 6.41)	5.64	(4.84, 6.44)	0.02 (0.95)	5.57	(4.77, 6.36)	5.65	(4.85, 6.45)	0.08 (0.81)
Abdominal (mm)	0.06	4.79	(3.99, 5.59)	4.61	(3.82, 5.39)	-0.19 (0.62)	4.29	(3.48, 5.10)	5.25	(4.45, 6.04)	0.95 (0.01*)
Triceps (mm)	0.18	4.45	(3.67, 5.23)	4.21	(3.45, 4.96)	-0.24 (0.38)	4.35	(3.59, 5.11)	4.35	(3.58, 5.12)	-0.003 (0.99)

θ - Data are p value for interaction between Education treatment, Cricket treatment and age in months, main effect of each intervention with 95% CI based on linear-mixed effect model with random slope and intercept adjusted for sex, and baseline, with time parameter being the infants age so accounting for all infants in the study;

⏚ - coefficient and p-Value of the interaction term Education *Cricket Flour*Infant age monthly;

λ - marginal effect size over the study period;

§ - Confidence interval of the effect size;

¢ - Contrast of the margins as observed with comparative p value for treatment levels of Education and Cricket treatments;

ɣ - We used pwcompare command to calculates all pairwise differences and contrast of the margins after mixed effect model, eg pairwise differences of the height for Education treatment yields contrast of 0.34 and a none significant difference at 5% alpha level (p-values >0.05) signifying no significant difference in Education treatment level;

* Significant at alpha=0.05;

HAZ, height-for-age z-score; WHZ, weight-for- height z-score; WAZ, weight-for-age z-score; MUAC, middle upper arm circumference

+CR: cricket enriched porridge; -CR: Control porridge; +ED Nutrition Education offered; -ED No nutrition Education offered

For the primary outcome, results of intention-to-treat (ITT) analysis in **Table 4.9** show there were no significant interaction between the ED and CR treatments. There was a significant effect on the cricket treatment for the primary outcomes of linear growth by HAZ (with a contrast Z=-0.28 [p=0.03]) and no significant effect (p>0.05) of education or cricket treatment on primary outcomes of linear growth by total height. The overall estimated height gain adjusted for sex and baseline value, ranged from 7.49 to 8.03cm: Participants in +CR arm gained a height of 8.03cm (95% CI [4.17, 11.89]) and HAZ of -0.31 Z-score against -CR height of 7.49cm (95%CI [3.61, 11.36]) and HAZ of 0.03 Z-score. Participants in -ED arm gained 7.68cm (95% CI [3.83, 11.52]) against participants in +ED who gained 8.01cm (95%CI [4.17, 11.86]). The absolute height gained by participants in +CR (8.03cm) arm was greatest followed by +ED (8.01cm) arm with -CR arm having the least gain of 7.49 cm. Comparatively those on education intervention against those not on education intervention, resulted in a 0.34 cm (contrasts) increase in height.

For the secondary outcomes, we observed a significant difference on WHZ of -0.45 (p=0.01) in Z-score between infants whose mothers did not receive nutrition education and those who did (-ED vs +ED). This difference was irrespective of the cricket treatment (-CR or +CR) that the child was in. A significant difference of 0.95mm (p=0.01) abdominal skinfold was observed between those who received -CR vs +CR. Comparing +ED against -ED, resulted in an increase of 0.02 mm in suprailliac skin fold, while comparing -CR vs +CR resulted in an increase of 0.08 mm in suprailliac skin fold.

Table 4.10 Per Protocol Intervention Impact: Treatment Interaction, Average Effects of Education Treatment and Cricket Treatment Adjusted for Sex and Baseline Value over 8 Months Trial Period[θ]

		Education Treatment (n=244)		Cricket Treatment (n=244)	
	Interaction[⸸],	+ED vs -ED (Base) (n=121 vs n=123)		-CR vs +CR (Base) (n=122 vs n=122)	
	P-values	β (P-value[λ])	(95% CI) [§]	β (P-value[λ])	(95% CI) [§]
Primary Outcomes					
Height (cm)	0.27	-0.12 (0.87)	(-1.60, 1.35)	-0.18 (0.82)	(-1.70, 1.34)
HAZ	0.26	-0.09 (0.39)	(-0.28, 0.11)	0.06 (0.52)	(-0.26, 0.13)
Secondary Outcomes					
Weight (kg)	0.73	-0.07 (0.50)	(-0.25, 0.12)	0.05 (0.63)	(-0.14, 0.23)
WHZ	0.89	-0.22 (0.10)	(-0.48, 0.12)	0.10 (0.36)	(-0.16, 0.23)
WAZ	0.94	-0.19 (0.13)	(-0.43, 0.06)	0.07 (0.55)	(-0.17, 0.32)
MUAC (cm)	0.49	-0.04 (0.72)	(-0.17, 0.25)	-0.09 (0.42)	(-0.12, 0.30)
Head Circumference (cm)	0.32	-0.10 (0.49)	(-0.39, 0.18)	0.07 (0.64)	(-0.35, 0.22)
Suprailliac (mm)	0.31	-0.14 (0.55)	(-0.60, 0.32)	-0.02 (0.94)	(-0.48, 0.44)
Abdominal (mm)	0.07	0.45 (0.09)	(-0.07, 0.97)	0.13 (0.62)	(-0.38, 0.65)
Triceps (mm)	0.42	0.21 (0.33)	(-0.21, 0.62)	0.09 (0.68)	(-0.33, 0.50)

θ - Data are p value for interaction between education treatment, cricket treatment and visit, and main effect Beta of each intervention with 95% CI and p value based on linear-mixed effect models adjusted for sex, and baseline y values;

⸸ - Interaction between education treatment, nutrition and Visits;

λ - P-value for the contrast at the last visit(visit7);

§ - CI, confidence interval;

* - Significant at alpha=0.05

HAZ, height-for-age z-score; MUAC, middle upper arm circumference;

+CR: cricket enriched porridge; -CR: Control porridge; +ED Nutrition Education offered; -ED No nutrition Education offered

Per protocol analysis in **Table 4.10** show results of linear mixed-effect models with random intercept, random slope and visits (baseline visit coded 0 and end-line visit coded 7) used as time scale parameter for the analyses. This analysis includes infants who remained in the study to the end having both baseline and end-line visits. The analyses showed no significant effects of either education treatment or cricket treatment on the primary outcomes of linear growth. Growth in +ED compared to -ED was associated with a 0.12cm (95% CI [-1.60,1.35]; p=0.87) increase in height and -0.09 (95% CI [−0.28, 0.11]; p = 0.39) increase in height for age z-score. The -CR compared to +CR was associated with -0.18 (95% CI [−0.71, 0.32]; p = 0.82) cm increase in height and 0.06 (95% CI [−0.26, 0.13]; p = 0.52) increase in height for age z-score.

Similar to the ITT analysis comparing weight in +ED to -ED was associated with an improved Z-score difference of -0.22 WHZ (95% CI [−0.48, 0.12]; p = 0.10). Comparing Education and cricket treatment to their respective bases, MUAC and Suprailliac values were smaller than the base values though not statistically significant. For treatment +ED vs -ED, the MUAC had a corresponding estimate of -0.04 (95% CI [−0.17, 0.25]; p = 0.72) cm indicating those receiving +ED gained 0.04mm compared to those receiving -ED. Comparing -CR vs +CR, the MUAC had a corresponding estimate of -0.09 (95% CI [−0.12, 0.30]; p = 0.42) cm indicating a loss of 0.09mm among those receiving -CR compared to those receiving +CR.

4.7 Level of Breast Milk Intake by Infants in the Study

In a sub study to find out if the complementary foods replaced breastmilk intake, a total of 65 mother-infant dyads were recruited for breast milk (BM) intake measurements, of which 4 were excluded due to lack of breastfeeding, decline of participation or unreachability. Of the remaining 61 mother-infant dyads, 3 missed more than one follow-up visit and were excluded from the final analysis. A total of 812 saliva samples from 58 mother-infant dyads, 30 in the control arm and 28 in the full intervention arm, were analyzed. Finally, 4 dyads with outlier results based on a sensitivity analysis were removed, reducing the final sample size to 54 participants for statistical analysis. The mean milk intake of the analyzed study population (n=54; 27 in each arm), with an average age of 7-month-old (6.92 ± 0.6) was 783±211 g/day. This sub-study showed no significant difference in breast milk intake between the two study intervention arms (-CR & -ED Vs +CR & +ED) studied (Wille, 2023).

4.8 Further Analysis of Growth Factors

To explore underlaying causes, which may explain or shadow the impacts of the intervention on nutritional status, we performed a secondary analysis of risks of undernutrition irrespective of the intervention allocation. Using MUAC cut off >135mm

to classify the nutrition status and HAZ cut-off -2 z-score to classify stunting status. The resulting odd ratios (OR) are tabulated in **Table 4.11**. Notable, girls were significantly (p=0.01) 1.98 times at higher risk of malnutrition by MUAC compared to boys. Those who consumed ASFs more than twice in the week prior to end-line survey tended (p=0.12, CI 0.26-1.16) to less likely (OR=0.55) be stunted than those who consumed it less than three times per week.

The 66 children who were reported to be bottle fed before six months of age had almost twice the risk (OR 1.95, p=0.09, CI 0.89-4.27) of being stunted than those who were not. Cumulative number of disease episodes significantly increased the risk of undernutrition by MUAC. Compared to those who had no disease episode over the study period, those having 1 to 2 episodes were significantly (p=0.07) 3.29 times likely to be malnourished. Those with 3 or 4 episodes were significantly (p=0.03) 4.30 times likely while those with 5+ episodes being significantly (p=0.01) 5.85 times likely to suffer undernutrition indicated by low MUAC. Of the 44 infants who had either vomiting or diarrhea illness symptom, 10 experienced vomiting, 14 suffered diarrhea while 20 experienced both diarrhea and vomiting in the study period. A vomiting infant was significantly 4.50 times likely to be stunted. Those with diarrhea were 1.91 times likely stunted. Infants with both diarrhea and vomiting incidence had 0.89 times likelihood of being at risk of stunting and were 1.06 times likely to experience malnutrition than those with neither diarrhea nor vomiting episode by MUAC measurement.

Table 4.11 Secondary Analysis: Risk of Undernutrition, Logistic Regression of MUAC and HAZ Binary Nutrition Outcome on Some Household, Maternal and Child Characteristic of Study Participants with End-Line Survey Completed(n=244)[θ]

		MUAC [ɬ]				HAZ [λ]			
Characteristics		**OR**	**P>z**	**(95%**	**CI)**	**OR**	**P>z**	**(95%**	**CI)**
Household food security status (HFIA)[§]	Severely food insecure access (218)	Ref				Ref			
	Secure to moderately food secure access (26)	0.87	0.76	(0.36,	2.11)	0.58	0.47	(0.13,	2.57)
Sex	Male (127)	Ref				Ref			
	Female (117)	1.98	0.01*	(1.15,	3.41)	0.77	0.50	(0.36,	1.63)
Family size	<6 (163)	Ref				Ref			
	6 + (81)	1.27	0.42	(0.71,	2.26)	0.67	0.34	(0.29,	1.54)
Maternal education level	< Secondary (124)	Ref				Ref			
	Secondary + (119)	0.81	0.47	(0.47,	1.42)	0.53	0.11	(0.24,	1.15)
Food frequency (Child fed on solid foods more than 3 times a day for:)	6+ Months (196)	Ref				Ref			
	Less than 6 Months (48)	1.59	0.22	(0.76,	3.34)	1.27	0.63	(0.48,	3.33)
Animal source protein (Consuming meat more than twice a week prior to last study visit) [¢]	No (113)	Ref				Ref			
	Yes (131)	0.78	0.37	(0.45,	1.35)	0.55	0.12	(0.26,	1.16)
Dietary diversity (at least 4 Visit with ≥4 food groups consumed)	<4+ Visits with 4+ Food Groups (122)	Ref				Ref			
	4+ Visits with 4+ Food Groups (122)	1.15	0.63	(0.64,	2.08)	1.11	0.81	(0.48,	2.55)
The child was ever bottle fed [ɣ]	No (178)	Ref				Ref			
	Yes (66)	1.29	0.41	(0.70,	2.38)	1.95	0.09[#]	(0.89,	4.27)
Number of months the child fell ill during study period [ς]	0 Episode (14)	Ref				Ref			
	1-2 Episode (70)	3.29	0.07[#]	(0.89,	12.10)	2.25	0.47	(0.24,	20.71)
	3-4 Episodes (113)	4.30	0.03*	(1.21,	15.37)	2.30	0.45	(0.27,	19.89)
	5+ Episodes (47)	5.85	0.01*	(1.46,	23.41)	2.62	0.41	(0.27,	25.36)
Symptoms of Diarrhoea or Vomiting [¥]	None (200)	Ref				Ref			
	Vomiting (10)	0.46	0.26	(0.12,	1.81)	4.50	0.05*	(1.02,	19.77)
	Diarrhoea (14)	0.64	0.46	(0.19,	2.09)	1.91	0.36	(0.48,	7.52)
	Diarrhoea and Vomiting (20)	1.06	0.90	(0.39,	2.91)	0.89	0.87	(0.23,	3.48)

θ - Data are odds ratio, 95% CI and p value from logistic regression analysis with the outcome being nutrition status measured by MUAC coded as 0 for those with normal nutrition status [per WHO cut off of >135mm (coded green)] and 1 otherwise while **HAZ** coded as either 1=stunted (Z score < -2) or 0=otherwise.;

ɬ - By MUAC 45.1% of infants were normal falling on the green band with MUAC cut off >135mm;

λ - The proportion who were stunted at end-line were 16.0%; § - Household food security was measured as per HFIA; ¢ - Animal source food was fish and meat, excluding egg and milk;

ɣ - Bottle feeding was any child who suckled a bottle teat over between birth and baseline of study;ς - Illness episode was presence of any illness incidence prior to the current visit;

¥ - Diarrhoea and vomiting in this context were reported as symptoms of an incidence of illness with a total of 44 infants presenting with symptoms of vomiting, diarrhoea or both vomiting and diarrhoea over the study period;

Significant at alpha=0.1; * Significant at alpha=0.05; HAZ, height-for-age z-score; MUAC, middle upper arm circumference

CHAPTER FIVE

DISCUSSION

5.0 Introduction

This chapter discuss the study findings and comparing these finding to the findings of other scholars. It discusses the findings as per the study objectives and expands on the interpretation of the study findings in relation to the socio economic and cultural context of the study area.

5.1 Flour Acceptability

The mother's acceptance of the study food and the child's liking of the porridge was key to the overall acceptance of the study food. The surrounding where the porridge was consumed was critical to the acceptance of new food. The perception and comments of the people in the surrounding as well as experience following the first taste was critical in the sustained uptake. Achieving the taste which meets or exceed expectation is a fundamental driver of acceptability (Liem & Russell, 2019; Van Huis & Rumpold, 2023; Wendin & Nyberg, 2021). In this study the expected health benefit, porridge taste, perceived diet diversity and the cooking training offered at onset, were the inspiration to the first and sustained uptake of the study porridge.

The similarity in the level of acceptance of the study porridges is confirmed by the none significant difference($p>0.05$) in proportional rating. The none-significance p-values in the acceptance of the two porridges indicate the two porridges were not different from each other in proportional acceptance rating. Both porridges were highly accepted such that when the porridge was over the children reluctantly consumed the available alternative. The high level of willingness to consume and recommend the study porridge is reflected by their frustration when the children rejected what was currently in the market alongside what the parents could locally prepare at home. There were no reported allergic reaction nor rejection of the study porridges for any other reason. It could probably be concluded that the porridge received full acceptance with a strong (80%) level of acceptability rating.

This findings is different from Aboge et al., (2024) who observed a reduction in acceptability with addition of crickets flour among mothers and caregivers. The high acceptance rate could be attributed to the age at which this new food was introduced, porridge quality and perceived benefit of the porridge by the mothers. Given a mothers diet is varied, breastfed infants upon entering complementary stage in life are equipped with a set of predispositions facilitating acceptance of foods with varied tastes; sweet, salty, sour or bitter (De Cosmi et al., 2017). This predisposition continues with introduction complementary foods with different taste, flavor and texture. The predisposition shapes a child's food preferences based on repeated experience of the new food in a positive reassuring context (Birch & Fisher, 1998). For the infants in the study, the mothers were the critical enablers for repeated exposure to cricket enriched porridge. The repeated exposure to food (Liem & Russell, 2019) of between eight to ten tastes, increased the infant's familiarity to the food and increased their willingness to consume it (Spill et al., 2019).

The repeated exposure to study food with promotion of a variety of other foods through nutrition education intervention during complementation must have modulated their acceptance of the study food. This is consistent with the findings of (Bouhlal et al., 2014) who argues that exposure to a variety of foods, during complementary feeding, modulates acceptance of the new food in the first year of life better than if introduced later. This emphasizes the significance of timing, sensory aspects coupled with the roles of nutrition education, chef and society stance in the acceptance of insect food.

5.2 Effects of the Study Interventions

The study experienced a loss to follow up of 40 infants which was 16.5% attrition rate which is within the acceptable rate of less than 20% (Fewtrell et al., 2008). Fewtrell recommends that a loss to follow up below 5% is of little concern while that above 20% possess a validity threat but supports the cut-off of 80% to be as the separator between high

and low evidence in evidence medicine. Amico (2009) recommended that for best-evidence interventions required retention rate above 69%.

5.2.1 Effect of the Nutrition and Education Intervention on Linear Growth

We observed a significant difference in growth status measured by HAZ and did not detect a significant difference in linear growth assessed by change in total height of infants across the study arms. Using mixed model analysis based on all the data points, the infants did not differ in linear growth irrespective of the combination of food or education treatment they were in for both ITT (all 284 infants) and per protocol analysis with 244 infants. Other studies targeting stunting in children 6 months and older on insect protein diet have previously reported no significant reduction in stunting (Bauserman et al., 2015; Konyole et al., 2019; Menasria et al., 2018). Across intervention arm the infants in our study grew on average 8.5 cm – slightly more than 1 cm per month - in total height, and HAZ decreased slightly by 0.30 over the 8 months, while the prevalence of stunting increased slightly from 12.4% to 16.0% in our study. This current study observed a considerably lower prevalence rate than other previous studies using edible insects in infant feeding.

In a study in Cambodia by Menasria et al., the stunting prevalence increased from 20.7% to 42.3% in a cluster-randomized controlled community trial providing 3 groups of children age 6 to 23 months daily with 41g cricket enriched powder with nutrition, 16g moringa powder with nutrition education and, the third group received nutrition education alone (Menasria et al., 2018). Another study in Democratic Republic of Congo provided caterpillar cereal supplemented complementary food to children age 6-18 months, observing stunting prevalence increase dramatically from 35% to 69% at age 18 months (Bauserman et al., 2015). An individually randomized study by Konyole et al., observed stunting increased from 13% to 32%, for infants randomized to different daily complementary foods after enrolment at 6 months and followed to 15 months in a similar geographical region of Kenya (Konyole et al., 2019). Stunting increased in all groups of which one treatment group including a product with edible termites. In an individually

randomized study in Cambodia, infants enrolled at the age of 6 months continued with growth faltering after being randomized to daily supplement with different complementary food products, of which one unfortified product contained a small proportion of edible tarantula (Skau et al., 2019). The individually randomized studies in Kenya and Cambodia both included intervention groups receiving standard fortified humanitarian corn-soy blends (CSBs), including milk-based CSB++, which also failed to prevent stunting. A study in Uganda enrolling only already stunted children at a mean age of 30 month found supplementing with energy-dense lipid-based supplements reversed stunting and induced catch-up growth, in contrast to an un-supplemented control group (Mbabazi et al., 2023). In this study the target population was already stunted children 12 to 59 months old. The children were randomized to 4 formulations of lipid-based nutrient supplement with milk protein or soy protein isolate and whey permeate or maltodextrin (100 g/day for 12 weeks) or no supplementation. The analysis was based on ITT using linear mixed-effects models adjusted for age, sex, season, and site.

The successful reversal of stunting in already stunted children indicates nutrition programs providing high-quality food supplements is relevant in treatment of stunting, while the prevention of stunting in the general population is more complex and calls for multi-sectorial approaches (Leroy & Frongillo, 2019). These findings suggest that stunting is a manifestation of complex biological response to compromised past and present living conditions. Supporting the critical transition with fortified nutritionally optimal supplements though beneficial(Taneja et al., 2022), alone is insufficient to prevent stunting. These findings further mirror the conclusion by (Shi et al., 2023), confirming nutrition interventions with short intervention time may not show obvious effect. In their study Shi et al. referred to period below 6 months as short while our study yields comparable finding with 8 months follow up period. Similar argument on duration of intervention and non-significant change in HAZ with nutrition studies was also advanced by Elisaria et al.,(2021). This is further validated by Palmer et al., (2025) who observed that high-quality protein with or without presumptive treatment for enteric pathogens, did not improve linear growth between 6 months and 1 year.

We observed a significant difference HAZ between -CR and +CR in spite of insignificant change in absolute height depicting similar observation as Lundeen et al., (2014) who observed HAZ score increased despite increasing height deficits among children in developing countries. The comparable linear growth effect of providing animal protein in the form of cricket enriched porridge in combination with nutrition education, compared to plant-based control with no nutrition education could also be attributed to other causes. First, though the supplement was provided in the early phase of introducing complementary foods, the infants in the study were well breastfed at baseline and throughout the 8 months intervention, with 231 (95.1%) being breastfed to some extent at end-line. Since the early phase of complementary feeding is the most critical time for onset of undernutrition, continued breastfeeding is beneficial and was promoted in the nutrition education sessions. A sub-study on 58 of the enrolled mother-infant dyads in this study, assessing breastmilk intake by deuterium dose to the mother method for the award of a master degree, established the mean breast milk intake as 783±211 g/day for infants with average age of 6.9 ± 0.6 months (Wille, 2023). This overall breastfeeding intensity likely masks any potential effects of providing food supplements.

Second, in families with other young siblings, possible food sharing could not be controlled for fully. Our secondary analysis (Table 6) did not indicate family size to be a risk factor for malnutrition, but food sharing could be an unaccounted factor within families, independent of the household size. Third, the household food security was severe in half of the household limiting the efficacy of the study food. This food situation level is similar to the findings of Oloo et al., (2021), who observed that 36.6% households reported just surviving and 37.7% were insecure in Ugunja, Siaya County. Food insecurity is a major concern affecting ability to access sufficient and adequate quality food.

5.2.2 Effect of Nutrition Education on Weight

Those who received education were comparatively better at WHZ-score than those who did not. Comparatively, from ITT analysis those on +ED against those on -ED, resulted in a -0.45 WHZ decrease. This weight gain in +ED group may be attributed to changed child food and feeding practices following exposure to educational intervention coupled with

adequate breastfeeding practices leading to higher energy available for tissue deposition (Mennella et al., 2018; Dharod et al., 2023). This finding agrees with another study that showed a positive protein dose response rate in weight with greater effect seen with ASFs (Kittisakmontri et al., 2022). Improved food diversity among children 6-23 months following nutrition education was also observed by Adugna et al., (2024) in a community-based cluster randomized trial in Ethiopia. Similarly, weight gain following improved dietary behaviour have been observed in either the pregnant mother, child or both in other studies (Beressa et al., 2024; Hadi et al., 2023; Jahan et al., 2014), clearly demonstrating mothers ability to translate nutrition education content to practice hence increasing nutrient intake.

5.2.3 Effect of Study Intervention on Skin Fold

The body composition of infants, change progressively from birth throughout infancy as they grow and mature. In this study, the suprailliac and abdominal skin folds dropped within standard trends band of skinfolds for this ages (WHO, n.d.). In the ITT analysis, those who received nutrition education had positive effect size though not significant on suprailliac in comparison to those without. Implying comparatively those on education intervention against those not, experienced a 0.02 mm increase in suprailliac. The triceps decreased by between 0.24 to 0.003mm (Table 4) remaining within the normal rate at 14 months. The observed triceps increment is similar in trend to observation by Reddy and Rao while studying growth pattern in India indicting consistent accumulation of muscle and fat in children aged between 6 months and 14 months (Reddy & Papa Rao, 2000) . The 1mm higher abdominal fold observed in the ITT analysis for those receiving +CR than those on -CR could be attributed to rapid increase of the diameter of fat cells for those on +CR associated with the bodies response to accommodate surplus energy (Boulton et al., 1978).

5.2.4 Effect of Health and Socio-Demographic Factors on Child Nutrition

The growth and nutritional faltering observed with episodes of illness is similar to the observation of Bourdon et al., (2024) who found that poor growth and underweight persist after acute illness having followed children aged 2 to 23 months for 180 days to monitor growth during recovery from acute illness in Africa and South Asia. The diarrhea and vomiting episodes we report may not have met the WHO definition as we queried symptom following a reported illness hence, interpret the findings with caution of possible diarrheal risk over reporting. The low numbers of infants who reported vomiting too limits the conclusions.

Disease episodes of whatever nature is detrimental, the more the episodes the worse the nutrition situation. Post-primary education (Secondary+, OR=0.81), male gender (Female, OR=1.98) This finding on gender is contrary to the findings of stunting, underweight and wasting that indicates that boys are more likely to be malnourished than girls based on DHS data (Okutse & Athiany, 2025). However such finding is not strange as was also observed by Ndiku et al., who observed that boys significantly had higher energy intake with girls being more stunted , underweight and wasted in rural eastern Kenya region (Ndiku et al., 2011). Cumulative food diversity (4+ visits with 4+ Food Groups, OR=1.15) were protective against malnutrition. Indicating that those with below secondary education, Female and those consuming four food groups for less than four of the seven study visits had a higher likelihood of being at risk of malnutrition. A higher stunting likelihood was observed amongst those with below secondary education and females (OR=0.77) infants were less likely to be stunted than male infants. Similar associated factors are outline by Mkhize and Sibanda (Mkhize & Sibanda, 2020) in their review of factors associated child nutrition.

5.2.5 Early Introduction of Bottle Feeding

Bottle feeding is routinely discouraged in Kenya based on challenges of sanitation and ease of contamination when left exposed. However some mothers still continue using it in the early months of the child's life a practice similar to the finding of Terefe et al., (2024). This

could be due to the fact that, suckling bottles mimic breastfeeding which encouraging its adoption in some compelling situations such as work or other maternal engagement that forces mother to separate from their children for a while. It is therefore critical to acknowledge that while breastfeeding is the global priority, bottle feeding is still a prevalent practice. Although our analysis reveals a non-significant(at alpha 0.05) risk of bottle feeding to malnutrition (OR: 1.29) and stunting (OR: 1.95), the challenges of cleaning, handling and storage of feeding bottles should be emphasized to reduce inappropriate bottle feeding practices (Kotowski et al., 2020).

5.3 Difference in Breast Milk Intake

The no significant difference in breastmilk intake between the interventions study arms, indicates that breast milk intake in this community is generally high. However strict evaluation of the study population revealed a 40.9% exclusive breast feeding against the national sustained breastfeeding of 60% based on maternal response. This isotope confirmed high breast milk intake could be the a predictor of the increased exclusive breast feeding rates (60%) that Kenya has attained which is above the 2025 global target of 50% (WHO | Regional Office for Africa, 2025)

5.4 Association of Baseline Gut Health and Overall linear Growth

From the study findings we do not have sufficient information to conclude the effect of cricket on gut health with the 10% loss to follow-up and regression of only two clients in the cricket enriched porridge. Generally, the findings show that lower cPDR90 is a keen to stunting and that even those who have higher cPDR90 of above 20% are also not immune to stunting. This finding are in agreement with the conclusion that result of breath test can grossly identify gut dysfunction (Brouwer et al., 2024). The clear difference in the cPDR90 means for stunted children at baseline and a similar pattern at end-line, points to observation that intestinal sucrose digestion/metabolism disorder may vary among children presenting with enteric which is associated with stunting (Tooley et al., 2010). This finding adds to the to the possible use of isotope C13 as a noninvasive method for the determination

of a person's gut integrity which not only save the patient risk but will reduce diagnostic time.

5.5 Limitation of the Study

The study design was limited by lack of an un-supplemented feeding group, which would have added to understanding the effect of providing a complementary food supplement, irrespective of the composition. The ethics of enrolling children without providing a supplement limited the study design in this respect. Bottle feeding was defined by at least an instance of suckling a bottle with teat without accessing frequency per day, duration bottle fed or circumstances leading to bottle feeding.

CHAPTER SIX

SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

6.0 Introduction

This chapter give the conclusion drawn from the study and recommend actions for each of the objectives studied while suggesting areas of further research based on the overall research implementation experience and final analyzed findings of the study.

6.1 Summary

To respond to the study research questions the investigator implemented an integrated nutrition study with eight month follow up for each child enrolled at six months of age. The study was a 2x2 factorial randomized controlled trial: Cricket treatment (+/-CR), Nutrition Education treatment (+/-ED). Mother-infant dyads were randomly assigned to 4 study arms at Rwambwa Sub-County Hospital. For each participating child the study intervention was implemented as per the randomly assigned study arm for the entire period. The children were exposed to daily serving of either insect-based complementary porridge or one with no crickets added with their mothers either exposed to nutrition education or not.

Study CF products were provided monthly as take-home rations adjusted for age. The +NE sessions were monthly personalized audio-visual sessions with education messages and reminder sent to mother's mobile phones. Immediately after enrollment of mother-infant dyad, baseline survey was conducted to determine the base statistics of the infants and to confirm the success level of the randomization process. The individual child's anthropometric measures, health and feeding habits were monitored monthly over the study period and documented using structured questionnaires.

Two additional sub-studies were conducted within this study; the first was a study with 40 infants to determine the general gut integrity of the children at enrollment using ^{13}C-Sucrose breath test and the next had 65 infants used to determine the breastmilk intake

level during complementary feeding using deuterium dose to the mother method. From the two sub studies it was established that the ^{13}C-sucrose dose recovered in a breath at 90 min (cPDR90) varied among the children presenting with stunting compared to the non-stunted with those stunted having lower average mean outcome compared non-stunted indicating higher cumulative % ^{13}C-sucrose dose recovered in a breath at 90 min for the non-stunted. This higher dose is associated with lower inhibition of sucrase-isomaltase enzyme and better break down of sucrose. While the breastfeeding status of the infants remained high (783±211 g/day) with the introduction of complementary feeding.

The study enrolled 284 eligible mother-infant dyads registering high acceptability rate of 98.3% and 99.2% for +CR and -CR respectively. Evaluating the stated hypothesis on growth, there was no significant linear growth effect in consuming cricket or participating in education treatment as measured by infants' total height. The significant positive change in HAZ for +CR against -CR, showed the contribution of including crickets in a fortified complementary porridge, compared to porridge fortified with plant-based protein. Absolute height gain, similar in children consuming the two porridges irrespective the education arm indicates competitive nature of crickets fortified complementary porridge when compared to super cereal. This resulted in the rejection of all the study hypothesis implying providing both cricket enriched porridge and nutrition education did not register a higher linear growth outcome than those on education or food supplement alone.

The findings of this study led to the secondary analysis which determine that at the end of study girls were significantly ($p=0.01$) 1.98 times likely to be malnourished by MUAC compared to boys at end-line, +ED was significantly associated with higher weight-for-height z score (WHZ) by a magnitude of 0.45 WHZ-score, those suffering above 3 episodes of illness were significantly ($p=0.03$) associated with at least a four times likelihood of suffering acute malnutrition measured as low MUAC. Nutrition education to mothers improved the WHZ, irrespective of CF consumed. We suppose that high breastfeeding rates combined with the small difference in nutrients composition, limited detection of difference absolute linear growth and stunting effect. Concluding, the similarity in growth rate in all study arms. The comparative growth outcome observed with cricket enriched

flour suggest the potential of insects in providing healthy protein for growth of infants' comparative to the super cereal.

6.2 Conclusions

These findings of this study have contributed to the literature of infant feeding and the use of crickets in child complementary food with key conclusions being made on the study objectives on acceptability, intervention treatment effects and contribution of gut health.

6.2.1 Conclusion on Porridge Acceptability

From the nutritional exposure and the various level of training the participants received during the intervention period, the participants level of nutrition knowledge improved. This knowledge gained, enhanced participants acceptability of the study product as a result of their expected health benefit from the products. This is clearly explained by the constructivism learning theory that argues that the acquired new knowledge is largely influenced by the past knowledge, experience and modified by the new knowledge on the basis of the newly gained or expected benefit. The promotion of initial initiation of the study food at six months followed by none allergic reaction inspired hope and confidence in the food. The acceptable taste was achieved by the skilled food production technologies and good cooking practices as provided in the cooking protocol supporting the concept of interdisciplinary contribution to nutritional outcome. The desire to achieve optimal growth of the infants as supported by the theory of child surviving and thriving was supported by early gradual introduction with repeated consumption of a well prepared, served, tasty insect-based food that enhanced by the culinary experience leading to high acceptability and preferences of new insect-based foods.

6.2.2 Conclusion on Treatment effects

It was observed that children consuming the two study porridges grew at similar rate irrespective of their mother receiving or not receiving nutrition education. This similarity in growth rate in all study arms suggest the potential of insects in providing healthy protein for growth of infants' comparative to the super cereal. We suppose that high breastfeeding

rates, a small difference in nutrients composition for both plant and animal base food sources, may have limited our ability to detect the difference in effect on both the absolute linear growth and stunting. Childhood disease episodes of whatever nature is detrimental, and the more the worse it affects the nutrition situation of the child. However post-primary education and cumulative food diversity had a protective contribution to growth. This leads to the conclusion that cricket enriched product though provides essential nutrition requirements, a combined multisectoral, comprehensive approach to addressing stunting is required, with interventions addressing nutrition knowledge and medical care for childhood illnesses being one key component for change. This strengthen the argument advanced by UNICEF's conceptual framework of malnutrition, which argues that the child's nutritional status is determined by more than just food, health and care that a child receives. With the children growing well under the special food but grossly affected by episodes of diseases a situation that the significance of nurturing care and protection a child requires in supporting them grow and achieve their full potential.

6.2.3 Conclusion on Gut Health

The baseline gut health measured by cPDR90 imply the stunted infants were not able to break down sucrose as well as the non-stunted hence remained stunted despite food intake from study food, leading to the conclusion that, the gut health of the infants is one of the primary determinants of the infants' nutritional status.

6.3 Recommendations

6.3.1 Recommendation for Study Porridge Acceptability

Based on the level of acceptability we recommend the introduction of insect-based diet at earlier age with junior school providing an opportunity for porridge enriched with insect protein. Secondly the insect-based food should be properly produced, prepared and served without obvious sight of insects in the food to increase their quality of taste and acceptability. Leading to the recommendation that the food and hospitality industry could play the critical role in promoting the acceptability of insect diets through professional culinary art enhancing food organoleptic properties.

6.3.2 Recommendation for Edible Cricket Enriched Porridge

Because of the high acceptability level and the fact that we saw similar growth rate as was in those consuming super food during the early growth period, there is need for further research on nutritional benefits other than growth for +CR porridge. Especially on the need to understand long-term effects of cricket porridge beyond the follow up period, the study recommends a follow-up study for this cohort of children at older age (for example at 5years) to track growth changes, and other long term health benefits conferred by the early introduction of cricket enriched food. A gain, in order to determine if +CR performed more or less equivalently to -CR, a non-inferiority study is recommended if to confirm +CR is non-inferior or equivalent to -CR. With validation studies on other plant-based proteins such as peas and peanuts to be able to adequately rank the contribution of insect protein in diets. The study further recommends a review of the effects of diarrhea and vomiting episodes measured as per WHO standards on malnutrition under a food-based intervention.

6.3.3 Recommendation for Nutrition Education

Nutrition education remains a solid approach to emphasizing and promoting good nutrition practices and should be targeted to some of the existing negative practices such as force feeding with emphasis on timely introduction of solid food with continued sustained breastfeeding practices. It is recommended that nutrition education should be consistent and designed with age-appropriate messages. The education component should cover introduction of new food, introduction of finger foods, consumption of ASF, covering how to identify and deal with allergies during the entire period of the child's care from conception.

6.3.4 Recommendation for Gut Health

Similar to other studies, this study indicates that gut health studies hold part of the answers to understanding human growth. It is therefore recommended that, to clearly depict its contribution in science, gut health studies should be well designed with adequate sample size, specific age group, repeated gut health assessment over time (including clear baseline and end-line time points), specific linear growth parameters (including HAZ and stunting status), other nutrition parameters eg wasting as well as child developmental milestones.

6.3.5. Policy Recommendation

This study has demonstrated three clear policy issues which are: 1) Breastmilk intake within the community understudy is reasonably high and more effort should then be directed in it sustenance for the good of the child. 2) Edible cricket resulted in comparable nutritional outcome making them a good product for protein enrichment in infant complementary food, the researcher therefore recommends the inclusion of edible crickets in infant complementary food as healthy protein source with essential micronutrients. 3)

The research finally support the global recommendation for the adoption of carbon 13 sucrose isotope as a non-inversive safe method for the assessment of gut integrity

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APPENDICES

APPENDIX I: Study Information and Consent Form

EFFECT OF CRICKET ENRICHED PORRIDGE AND NUTRITION EDUCATION ON GUT HEALTH AND NUTRITION STATUS OF INFANT AND YOUNG CHILDREN

Invitation to participate:
I am being invited to participate in the nutrition study because I have a young child aged 6 months who is ready for complementary food and I visit _____ health facility for my postnatal child care program.

Study by who:
This research study is being conducted by Mr Nicky Okeyo a Student of nutrition science at Masinde Muliro University of Science and Technology (MMUST).

Study Purpose:
Insects have been consumed traditionally by our fore fathers. Cricket in particular is an old traditional food that not only provides us with a delicious and nutritious food, but provides the world with an opportunity to reduce global warming while assuring household of food security. The purpose of this study is to evaluate cricket enriched porridge consumption with nutritional education on child growth rate. In this study we want to evaluate how this enriched porridge enhances growth in the young infant and children.

Study procedure:
In this study all eligible children will be fed on nutritionally rich porridge over the study period. To determine eligibility child will be finger pricked for small blood. If selected into the study you will be randomly be assigned to three groups namely general group, second being breath and stool sample group and the third group will be mother-child dyad saliva sample group. implying if eligible, at the start of the study each participant will randomly be selected for the stool and breath samples, or randomly selected as a pair of mother and

child for saliva samples while the rest no additional sample will be collected. The caregivers will be invited to a two hour in person training in addition to SMS messaging.

Confidentiality:
The data collected in the study will be handled as confidential and stored in password protected computer systems.

Risk:
Just like any other food children may react or be allergic to new food. In this case I am require to observe my child seek medical assistance and report any form of reaction to both the field study team and the study principal investigator through phone number 0721 864 474 for immediate medical attention and treatment follow up of the child

Benefit:
My participation in this study will give me an opportunity to reflect on the current child feeding practices for children under two years of age. The information I share may help the investigator identify strategies for improving child feeding practices, while the participation of my child will contribute to understanding the contribution of enriched porridge for child growth and wellbeing.

Participation:
I am being asked to consent to responding to the research questions, supporting collection of lab samples and feeding my child on enriched porridge. I agree to participate I will be expected to bring my child to the health facility for breath and blood test as well as provide the required stool sample. I will also participate in the education program both in person and via text message.

Voluntary Participation:
I am under no obligation to participate and if I choose to participate, I may withdraw from the study at any point and/or refuse to answer any questions.

Contact and Complaint desk:

I am at liberty to talk to the researcher(s) about any questions, concerns or complaints I have about this study. You can contact the principal investigator through this phone number 0721 86 44 74. If you wish to voice any problem or concerns I am at liberty to contact the University Institutional Ethics Review committee on postal address P.O Box 190-50100, Kakamega

Consent:

I _____have read and understood to my satisfaction the information regarding my participation in this research study and agree to participate.

Participant's Name _____

Participant's Signature_____ Date_____

Left Hand Thump print

If can't sign

Witness's Name _____

Witness's Signature_____Date_____

Name of Research assistant obtaining consent _____

Research Assistant's Signature_____ Date_____

APPENDIX II: Data Collection Tools

APPENDIX II A: Screening & Recruitment Tool

Masinde Muliro University of Science and Technology

Study topic: Effect of Cricket Enriched Porridge and Nutrition education on Gut Health and Nutrition Status of Infant and Young Children in Siaya County, Kenya

Quantitative Survey Data Tool

2022

SECTION 0: Identification Page

HEALTH FACILITY NAME……

ENUMERATOR NAME……..

SUPERVISOR NAME…….

INTERVIEW DATE…….

1a: DEMOGRAPHIC AND SCREENING INFORMATION

DEM 1	Date of Assessment		
DEM 2	Health Facility		
DEM 3	Name of Mother /Caregiver		
DEM 4	Age of **main** caregiver		
DEM 5	Sex of **main** caregiver		
DEM 6	What is the relationship of **main** caregiver to the infant (name):	1=Mother	
		2=Father	
		3=Sister/Bother	
		4=Grandmother	
		5=Other Specify	
DEM 7	Does the caregiver have a mother child booklet, Clinic or growth monitoring Card?	Yes □ No □	
DEM 8	If No, Does [name] have a birth notification card	Yes □ No □	
DEM 9	Name of the Infant (As documented in health or notification card)		
DEM 10	Documented sex of the infant	Male □ Female □	
DEM 11	Date of birth		
DEM 12	Infants' birth order		
DEM 13	Is the infant (name) a twin?	Yes □ No □	
DEM 14	If Yes Name of the twin sibling		
DEM 15	Sex of the twin sibling	Male □ Female □	

DEM 16	Is the infant (name) currently breastfeeding?	Yes □ No □	
DEM 17	If No, at what age did the infant (name) stop breastfeeding?		
DEM 18	Do you use any kind of milk apart from breastmilk?	Yes □ No □	
DEM 19	If yes indicate type of milk used?		
DEM 20	Apart from breast milk, does the child (name) eat any other food?	Yes □ No □	
DEM 21	If yes, what was the first food introduced?		
DEM 22	If yes which complementary foods does the child currenly consume? (Enumerator asks about each of the following and select all that apply)	Porridge from whole **maize** flour	Yes □ No □
		Porridge from whole **sorghum** flour	Yes □ No □
		Porridge from whole **millet** flour	Yes □ No □
		Porridge from whole mixture of flour (**millet, maize and cassava**)	Yes □ No □
		Porridge from whole mixture of flour including legumes or oil seeds (**millet, maize and cassava + beans or groundnut**)	Yes □ No □
		Porridge from whole mixture of flour including legumes or oil seeds and omena (**millet, maize and cassava + beans or groundnut+ Omena**)	Yes □ No □
		Normal family food	Yes □ No □
		Others porridge specify_____	
DEM 23	When you prepare porridge at home, how long do you normally cook the current porridge?	_____ min.	
DEM 24	Is there any type of commercial food you use for child feeding?	Yes □ No □	

Allergies

DEM 25	Do **you** have any food allergies?	Yes □ No □
DEM 26	Please list any foods you dislike or will not eat or allergic to:	

DEM 27	Does your **child** have any food allergies?	Yes □ No □
DEM 28	Please list any foods your **child** dislike or will not eat or allergic to:	

SECTION1b: HEALTH INFORMATION

Anthropometric Measure

		Reading 1	Reading 2	Reading 3	Average
ANTH1	Weight (kg)				
ANTH2	Length(cm)				
ANTH2	MUAC(cm)				

Laboratory Assessment

LAB 1	Hemoglobin level in grams per deciliter (g/dL)*	___ ___ g/dL

***To be measured on site USING HEMOCUE MACHINE**

General Health

GH1	Has child been ill in the last one week?	1=Yes 2=No 8=Don't know	
GH2	If [Child Name] was ill, what were the symptoms like	Fever	Yes □ No □
		Runny nose or cold	Yes □ No □
		Cough	Yes □ No □
		Diarrhea	Yes □ No □
		Vomiting	Yes □ No □
		Fits	Yes □ No □
		Stomachache	Yes □ No □
		Skin rashes	Yes □ No □
		Difficulty breathing	Yes □ No □
		Other? Specify ---------- ----------	

SECTION 1b: CONTACT INFORMATION

CI 1	Nearest landmark (e.g. school, market, church etc)	
CI 2	CHW covering the area	
CI 3	Mother (caregiver) telephone contact(Primary Contact)	
CI 4	Secondary telephone contact (neighbour's etc)	

For official Use

DCRS 1	Decision to recruit into study	1=Yes Recruite 2=No Inelligible Remarks……..…… …….……

APPENDIX II B: Household Quantitative Data Collection Tool (Baseline and End-line)

Masinde Muliro University of Science and Technology

Study topic: Effect of Cricket Enriched Porridge and Nutrition education on Gut Health and Nutrition Status of Infant and Young Children in Siaya County, Kenya

Quantitative Survey Data Tool

2022

SECTION 0: Identification Page

LOCATION NAME…….

SUB-LOCATION NAME……

VILLAGE-NAME……

ENUMERATOR NAME……..

SUPERVISOR NAME…….

INTERVIEW DATE…….

SECTION 1a: HOUSEHOLD DEMOGRAPHIC INFORMATION

101 Code of each H/H member *(*namba mar jo ot*)*	**102** Name of H/H member eating regularly here for last **3** Months *(*nying jo ot mosebedo ka chiemo e odni kuom dweche adek mokalo)	**103** DoB **Or** Age in Completed years *(ne onyuoli kar ang'oo kata* **Ija** igni adi*)* For under 1 year enter number of months followed by "M"	**104** Sex 1.Male 2.Female	**105** Relationship to H/H *(*Kit wat moriwo u kod wuon ot) 1. Head 2. Spouse 3. Child by Birth 4. Grand child 5. Other children by relation 6. House help 7. Others specify	**106** Education*(***okang** mar somo*)* 1. None 2 Primary 3. Secondary and above 4. Still in school 5. <6 years	**107** Marital Status*(***kit** kend mari) 1. Married (monogamy) 2. Married, polygamy 3. Widow (er) 4. Separated 5. Single 6. Others (specify)

Respondent Code |__|__| Caregiver code |__|__| How many people live in your household? _____

SECTION 1b: HOUSEHOLD SOCIAL AND ECONOMIC INFORMATION

Now we would wish to know your (Caregiver's) household's social and economic information

	Question	Answer	
HSE 1	What is your social group Membership(s)? (In jabura/memba mar kidieny koso group mane)	None	Yes □ No □
		Mothers group	Yes □ No □
		Church/religious	Yes □ No □
		Social Club	Yes □ No □
		Under age(Under 16 yrs)	Yes □ No □
		Youth	Yes □ No □
		Business/Chama	Yes □ No □
		Women /men	Yes □ No □
		Others Specify	
HSE 2	What is your common household religious Affiliation ***(Ilemo e kanisa mane)***	0=None	
		1=Catholic	
		2=SDA	
		3=Indigenous Church	
		4=Muslim	
		5=Anglican	
		6=Others Specify	
HSE 3	Main source of household income***(Yore mag yuto)***	0=None	Yes □ No □
		1=Farming	Yes □ No □
		2=Self Employed	Yes □ No □
		3=Salaried	Yes □ No □
		4=Remittances	Yes □ No □
		5=Not applicable	Yes □ No □
		6=Others Specify	
HSE 4	Employement status of the household head?	1=Government employee	
		2=Private employed	
		3=Self employed	
		4=Casual labourer	
		5=Un-employed	
HSE 5	Type of housing (Main house) the family live in (***Observation***)	1= Permanent	
		2= Semi-permanent	
		3= All temporary	
HSE 6	How many bed rooms does the main house have(excluding kitchen, toilet, bathroom and store)?	1=One	
		2=Two	
		3=Three +	
HSE 7	How long have this household lived in your current place of residence?		YY |__|__| Mm |__|__| DD |__|__|
HSE 8	What type of **tenure** do you have on your current place of residence?	1=Owned	
		2=rented	
		3=Others Specify	

SECTION 2: DOMESTIC HYGIENE AND WATER SOURCE

We would like to know about the your household practices and water source. Please indicate the response that matches current practice or options

DHW1	What is your main water source? ***(Pi uumbo kanye?)***	1=Roof-catchments	
		2= Ground and Natural sources(spring, stream, rivers, lakes)	
		3=Borehole	
		4=Piped water	
		5=Water vendor	
		6=Other Specify	
DHW2	How long does it take you to walk to your main water source?	1=Less than 5Mins	
		2=5Min-15min	
		3=More 15min	
DHW3	What do you do to make your drinking water safe *(Ang'o ma utimo ne pi mondo obed maber mar modho)*?	0=None	
		1=Boil	
		2=Add chemical(Chlorine)	
		3=Seiving	
		4=Others Specify	
DHW4	What do you do to make your baby's drinking water safe *(Ang'o ma utimo ne pi nyathi mondo obed maber mar modho)*?	0=None	
		1=Boil	
		2=Add chemical(Chlorine)	
		3=Seiving	
		4=Others Specify	
DHW5	When do you wash your hands? (Ilogo ga saa mane) (Enter all responses mentioned)	1=After meals	Yes □ No □
		2=Before meals	Yes □ No □
		3=After handling babies stools	Yes □ No □
		4=Before preparing food	Yes □ No □
		5=Before feeding baby	Yes □ No □
		6=After toilet	Yes □ No □
		8=Others Specify	
DHW6	How do you wash your hands? ***(Ilogo nade)***	1= Using water in a basin	
		2= Using water in a basin with soap	
		3= Using running water	
		4= Using running water with soap	
		5= Others (Specify)	
DHW7	Does your family share latrine /toilet with other families	Yes □ No □	

Maternal and child info

MCI 1	At the time of delivering [name], who conducted delivery ***(Kane ipek kod ich [name] ng'ama ne ocholi?)***	1=Self/family member	
		2=TBA	
		3=Trained Health Personnel	
		5= Others (Specify)	
MCI 2	Mode of delivery	1= Natural	
		2= Through ceacerian section	
MCI 3	Mothers anthropometric	Height	|__|__|.|__|__|
		Weight	|__|__|.|__|__|

Child Feeding Practices

CFP 1	How long after birth did you first put [NAME] to the breast?	1=Less than one hour	
		2=Between 1 and 23 hours	
		3=More than 24 hours	
		8=Don't know	
CFP 2	Are you currently breastfeeding this child ***(Pod idhodho nyathini)?***	1=Yes	
		2=No	
CFP 3	If Yes, each time you breastfeed, do you feed from one breast or both?	1=One breast 2=Both sides	
CFP 4	If Not currently breastfeeding for how long did you breastfeed (NAME)? ***(Ka ok idhodho nyathini, ne idhodhe kuom ndalo maromo nade)?*** IF LESS THAN ONE MONTH, RECORD "00" MONTHS.		YY |__|__| Mm |__|__| NA |__|

Factor	**Label**	**Item**	**Scale**
			1 = never, 2 = rarely, 3 = sometimes, 4 = often/most of time, 5 = always
Perceived Responsibility	PERP1	How often are you responsible for feeding the child	1 2 3 4 5
	PERP2	How often are you responsible for deciding what your child's portion sizes are?	1 2 3 4 5
	PERP3	How often are you responsible for deciding if your child has eaten the right kind of foods?	1 2 3 4 5
Feeding on demand	DEM1	I feed my baby whenever he wants	1 2 3 4 5
	DEM2	I feed my baby at set times	1 2 3 4 5
	DEM3	I decide when it is time for my baby to have a feed	1 2 3 4 5
	DEM4	I let my baby decide when he would like to have a feed	1 2 3 4 5
	DEM5	My child has a set mealtime routine	1 2 3 4 5
Using food to calm	FC1	I feed my baby to settle him, even if he is not hungry	1 2 3 4 5
	FC2	I offer my baby a feed when he is unsettled or crying	1 2 3 4 5
	FC3	I offer my baby a feed when he is hurt	1 2 3 4 5
	FC4	When my baby gets unsettled or is crying, feeding him is one of the first things I do	1 2 3 4 5
	FC5	I feed my baby to make sure that he does not get unsettled or cry	1 2 3 4 5
	FC6	I use food to distract my child or keep him/her busy	1 2 3 4 5

Factor	Label	Item	Scale				
			1 = never, 2 = rarely, 3 = sometimes, 4 = often/most of time, 5 = always				
Persuasive feeding	PERS1	I feed my baby extra milk, just to make sure he gets enough	1	2	3	4	5
	PERS2	If my baby indicates s/he is not hungry, I try to get him to feed anyway	1	2	3	4	5
	PERS3	I feed my baby extra milk so he sleeps longer	1	2	3	4	5
	PERS4	I say or do something to show my disapproval of my child for not eating	1	2	3	4	5
	PERS5	I praise my child after each bit to encourage finishing the food	1	2	3	4	5
	PERS6	When my child refuses food they usually eat, I encourage her/him to eat it	1	2	3	4	5
	PERS7	I play games to make sure my child eats enough	1	2	3	4	5
Parent-led feeding	PARENT1	When deciding how much to feed my baby, I rely on how hungry my child is	1	2	3	4	5
	PARENT2	I feed my baby for a set time	1	2	3	4	5
	PARENT3	I carefully control how much my baby feeds	1	2	3	4	5
	PARENT4	I follow a rule about how much my baby should feed	1	2	3	4	5
	PARENT5	I let my baby decide how much he feeds	1	2	3	4	5
	PARENT6	I decide how much my baby feeds	1	2	3	4	5

Factor	Label	Item	Scale				
			1 = never, 2 = rarely, 3 = sometimes, 4 = often/most of time, 5 = always				
Using (non-) food rewards	REW1	I offer foods to my child as a reward for good behavior.	1	2	3	4	5
	REW2	I offer my child their favorite foods in exchange for good behavior.	1	2	3	4	5
	REW3	I promise my child something other than food if they eat (for example: “If the child eat you kiss the child in appreciation”).	1	2	3	4	5
	REW4	When my child refuses food they usually eat, I encourage eating by offering a non-food reward (for example: favorite toy or sticker).	1	2	3	4	5
	REW5	I encourage my child to eat something by using food as a reward (for example: “If you finish your vegetables, you get banana”).	1	2	3	4	5
	REW6	I make my child finish the main course before having a dessert.	1	2	3	4	5

APPENDIX II C: Child Repeat Nutrient Diversity Tool

Date		Facility Name	
Child Name		Study ID	

CND 1	Did the child consumed the nutritious food given by the project today?	Yes □ No □ If No date last consumed and reason why __/__/___ : ……..

CND 2	On average how many minutes does it usually take to feed your baby/child?	1= <6Min 2= 6-14Min 3=15-30Min 4= 30+ Min	

Dietary Diversity Score

QNo	Food group	Examples	Response	In over the last seven days, how many days has your child/ren eaten the food?
1	CEREALS: Has your child/ren eaten cereals, roots and tubers in the last seven days?	corn/maize, rice, wheat, sorghum, millet or any other grains or foods made from these (e.g. bread, noodles, porridge or other grain products) + *insert local foods e.g. ugali, nshima, porridge or pastes or other locally available grains* white/orange potatoes, white yams, white cassava, or other foods made from roots	YES=1 NO=0	1 2 3 4 5 6 7
2	VITAMIN A RICH FRUITS & VEGETABLES Has your child/ren eaten fruits and vegetables in the last seven days?	dark green/leafy vegetables, including wild ones + *locally available vitamin A rich leaves such as amaranth, cassava leaves, kale, spinach etc.* ripe mangoes, cantaloupe, apricots (fresh or dried), ripe papaya, dried peaches + *other locally available vitamin A rich fruits* pumpkin, carrots, squash, or sweet potatoes that are orange inside + *other locally available vitamin A rich vegetables (e.g. red sweet pepper)* other vegetables (e.g. tomato, onion, eggplant), including wild vegetables other fruits, including wild fruits	YES=1 NO=0	1 2 3 4 5 6 7
3	EGGS Over the last seven days, did your child/ren eat eggs?	chicken, duck, guinea fowl or any other egg	YES=1 NO=0	1 2 3 4 5 6 7

QNo	Food group	Examples	Response	In over the last seven days, how many days has your child/ren eaten the food?
4	MEATS Has your child/ren eaten meat products (meat, poultry, offal, and fish) in the last seven days?	liver, kidney, heart or other organ meats or blood-based foods beef, pork, lamb, goat, rabbit, wild game, chicken, duck, or other birds fresh or dried fish or shellfish	YES=1 NO=0	1 2 3 4 5 6 7
5	LEGUMES, NUTS AND SEEDS Has your child/ren eaten pulses, legumes and nuts in the last seven days?	beans, peas, lentils, nuts, seeds or foods made from these	YES=1 NO=0	1 2 3 4 5 6 7
6	MILK AND MILK PRODUCTS Has your child/ren eaten milk and dairy products in the last seven days?	milk, cheese, yogurt or other milk products	YES=1 NO=0	1 2 3 4 5 6 7
7	OILS AND FATS	oil, fats or butter added to food or used for cooking	YES=1 NO=0	1 2 3 4 5 6 7
8	SWEETS	sugar, honey, sweetened soda, sweetened juice or sugary foods such as chocolates, candies, cookies and cakes	YES=1 NO=0	1 2 3 4 5 6 7
9	SPICES, CONDIMENTS, BEVERAGES	spices (black pepper, salt), condiments (soy sauce, hot sauce), coffee, tea, alcoholic beverages or *local examples*	YES=1 NO=0	1 2 3 4 5 6 7
10	In your opinion how would you describe feeding time with your baby? (select one that best describe feeding time)	1= Always pleasant 2= Usually pleasant 3= Sometimes pleasant 4= Never pleasant		

APPENDIX II D: Child Repeat Visit Health Questionnaire

Date		Facility Name	
Child Name		Study ID	

	Question	Answer	
CHQ 1	Has child been ill in the last one week?	1=Yes 2=No 8=Don't know	
CHQ 2	If [Child Name] was ill, what were the symptoms like	Fever	Yes □ No □
		Cough	Yes □ No □
		Diarrhea	Yes □ No □
		Vomiting	Yes □ No □
		Fits	Yes □ No □
		Stomachache	Yes □ No □
		Skin rashes	Yes □ No □
		Difficulty breathing	Yes □ No □
		Other? Specify ---------- ----------	
CHQ 3	If [Child Name] was ill, do you know the name of the illness?	1=Yes 2=No 8=Don't know	
CHQ 4	If know illness what was the illness?		
CHQ 5	Did you do anything to treat the illness?	Yes □ No □	
CHQ 6	If Yes what did you do?	Bought medicines from shop	Yes □ No □
		Went to traditional healer	Yes □ No □
		Went to a small private health facility	Yes □ No □
		Went to a small private health facility	Yes □ No □
		Went to public health facility	Yes □ No □
		Was admitted for care	Yes □ No □
		Other? Specify ---------- ----------	
CHQ 7	If No Qn 1, did the [Child Name] experience an episode of diarrhea and fever in the **last two weeks**	Yes □ No □	

APPENDIX II E: Mother Child Sensory & Acceptability Tool

Section A: Mothers Sensory

Date		Facility Name	
Child Name		Study ID	

		Dislike a lot	**Dislike a little**	**Neither like nor dislike**	**like little**	**Like a lot**
						
SAT 1	Appearance (colour and look)					
SAT 2	Aroma (smell/odour/fragrance)					
SAT 3	Taste/flavor/chemical sensation					
SAT 4	Sweetness					
SAT 5	Texture/mouth-feel/ Consistency					

Comments……..

……

……

SAT 6. Having tasted the food circle the option that best represent you feeling	
	1=I would eat this every opportunity that I have
	2=I would eat this very often
	3=I like this and would eat it now and then
	4=I would eat this if available but would not go out of my way
	5=I don't like this but would eat it on occasion
	6=I would hardly ever eat this
	7=I would eat this only if forced to

SAT 7	In your own opinion how well would you child take this porridge?	1. Extremely Well 2. Slightly Well 3. Neither Well nor Poorly 4. Slightly poorly 5. Extremely Poorly	
SAT 8	How much porridge did the child consume during this feeding?	Amount served (ml) = A	____ml
		Amount spilt (ml) = B	____ml
		Amount left (ml) = C	____ml
		Amount eaten = A- (B+C) {B+C} ≤ A	____ml

Section B: Child acceptability test (Feeding observation)

Provide porridge in graduated cup to the parent / guardian together with a plastic spoon.
Ask the mother to feed the CHILD with porridge and take notes.
Ask the mother to give the PORRIDGE to the child.

	Has [Child Name] been introduced to other feeds besides breast milk?	Yes □ No □					
	Use scale (1-5) as on the side document your observations on:	1. Dislike extremely 2. Dislike slightly 3. Neither like nor dislike 4. Like slightly 5. Like extremely					
		1	2	3	4	5	Score
CAT 1	Child's facial expressions as the child see the food						
CAT 2	Child's facial expressions as the child receives the food for the first time						
CAT 3	Child's facial expressions as the child receives the food on second offer						
CAT 4	Child's facial expressions as the child receives the food on subsequent offers						
CAT 4	Observe and record child's behavior during subsequent offers of porridge (Tick all applicable)	Child signaling for more aggressively				Yes □ No □	
		Child accepts porridge passively				Yes □ No □	
		Child turns head away				Yes □ No □	
		Child spitting food				Yes □ No □	
		Child smiling while eating				Yes □ No □	
		Child crying, refusing to eat				Yes □ No □	
		Child crying, but eats				Yes □ No □	
		Child vomits				Yes □ No □	
		Any other observations on the child's reaction to the food				Yes □ No □	
		Other observations on the child's reaction to the food? Specify ---------- ----------					
CAT 5	Write down any other comment made by the mother / caregiver or the child that are not captured above	…… ……					
CAT 6	In your opinion how would you describe feeding time with your baby? (select one that best describe feeding time)	1= Always pleasant					
		2= Usually pleasant					
		3= Sometimes pleasant					
		4= Never pleasant					

APPENDIX II F: Lab Sample Management Tool

Date		Facility Name	
Child's Name		Study ID	

Blood Sample Assessment

LAB 2	Hemoglobin level in grams per deciliter (g/dL)*	_____g/dL

***To be measured on site USING HEMOCUE MACHINE**

Stool Sample Assessment Form

LAB 3	Time collected		
LAB 4	Time Received at facility		
LAB 5	Time put in ice cold cooler box		
LAB 6	Time stored in freezer		
LAB 7	Sample reference ID		
LAB 8	Sample quality	Size	1. < size of a thumbnail 2. >= size of a thumbnail
		Stool Type	3. Formed 4. Semi-formed 5. Liquid
		Container Tightly closed	Yes □ No □

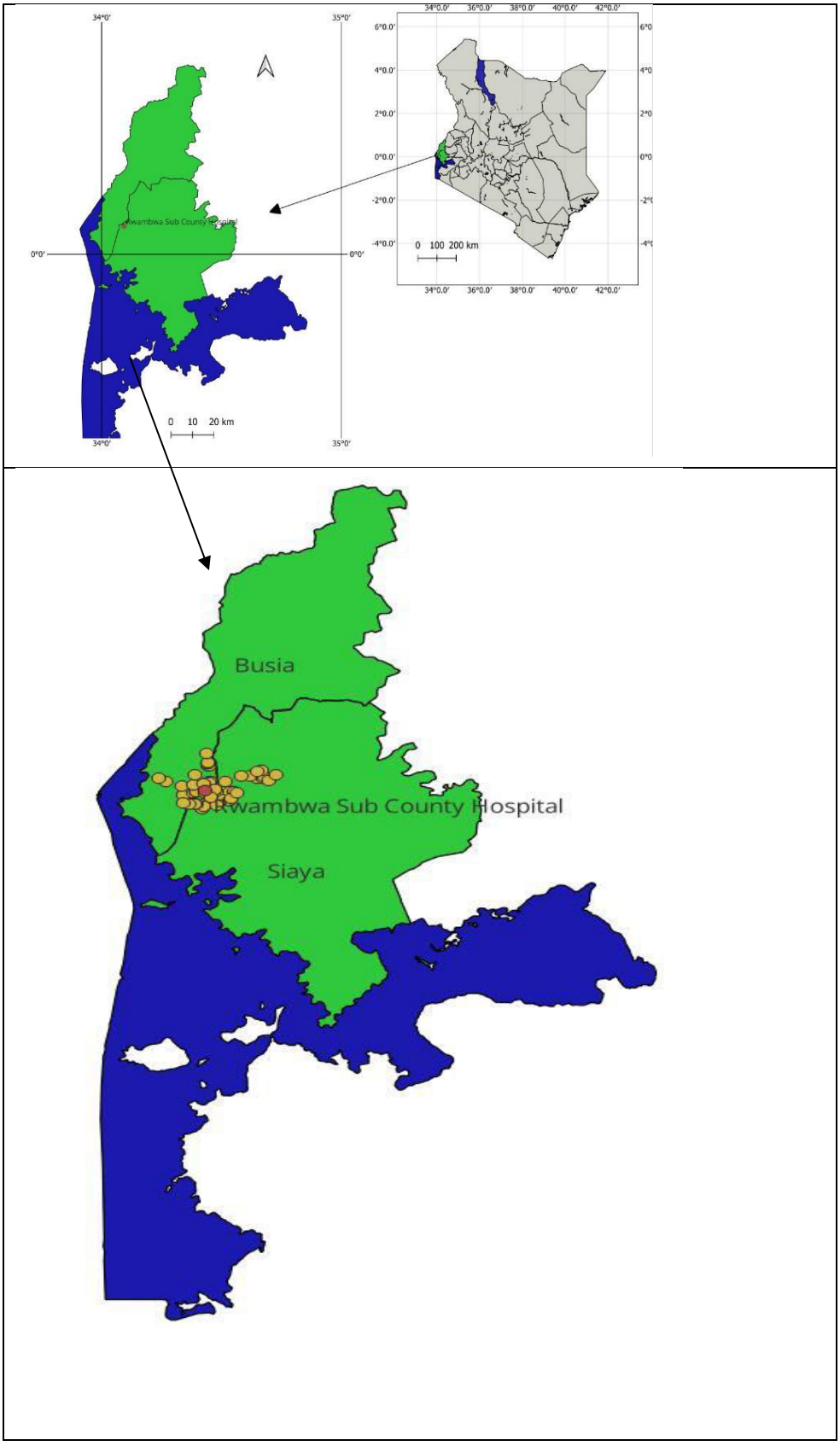
Breath Sample Assessment Form

LAB 9	Time collected	
LAB 10	Time Received at facility	
LAB 11	Time put in ice cold cooler box	
LAB 12	Time stored in freezer	
LAB 13	Sample reference ID	
LAB 14	Colour of the of sample tube	

Saliva sample Form

LAB 15	Time collected	
LAB 16	Time Received at facility	
LAB 17	Time put in ice cold cooler box	
LAB 18	Time stored in freezer	
LAB 19	Sample reference ID	
LAB 20	Number of samples collected	

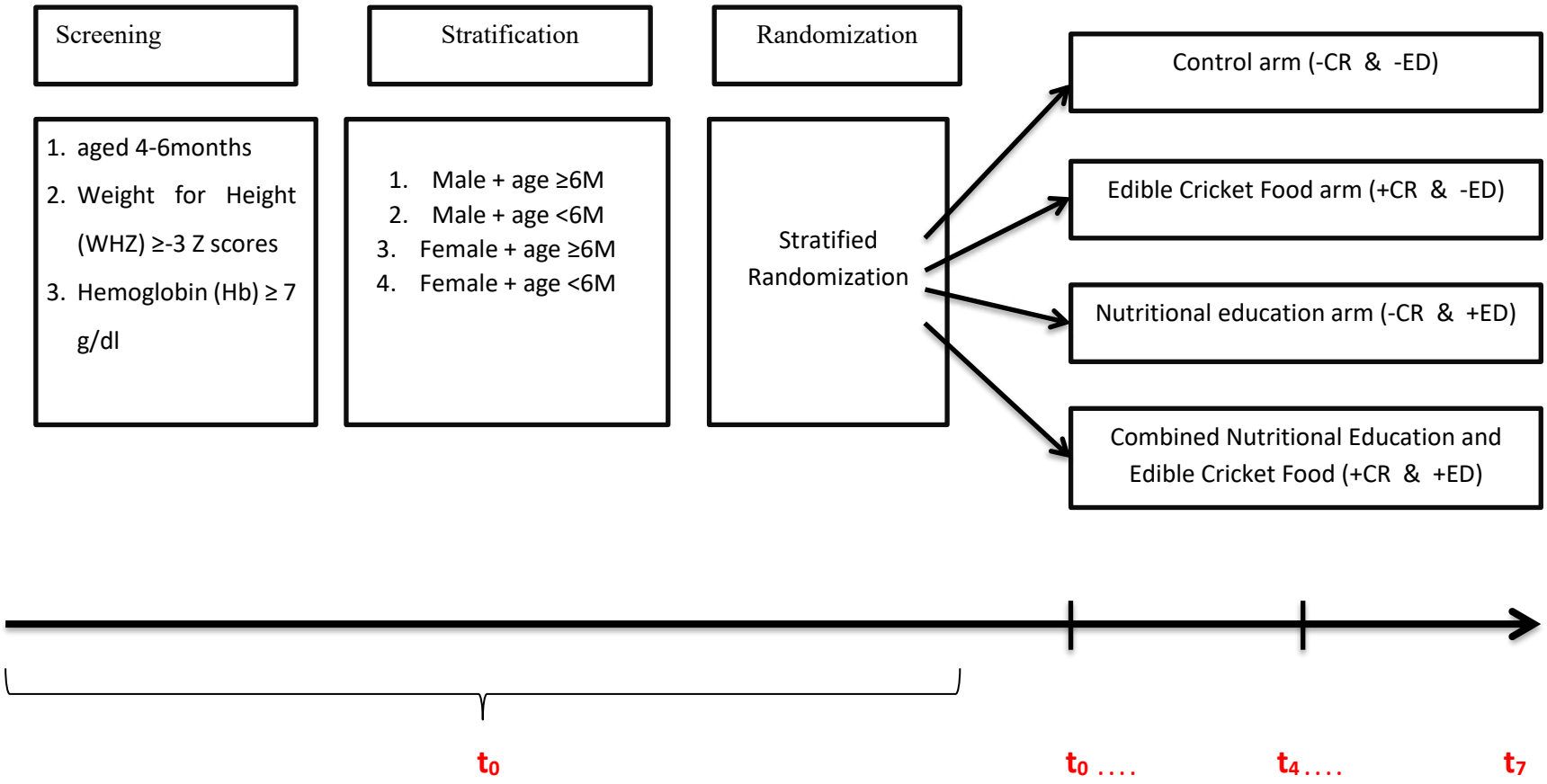
APPENDIX III: Study Area Map



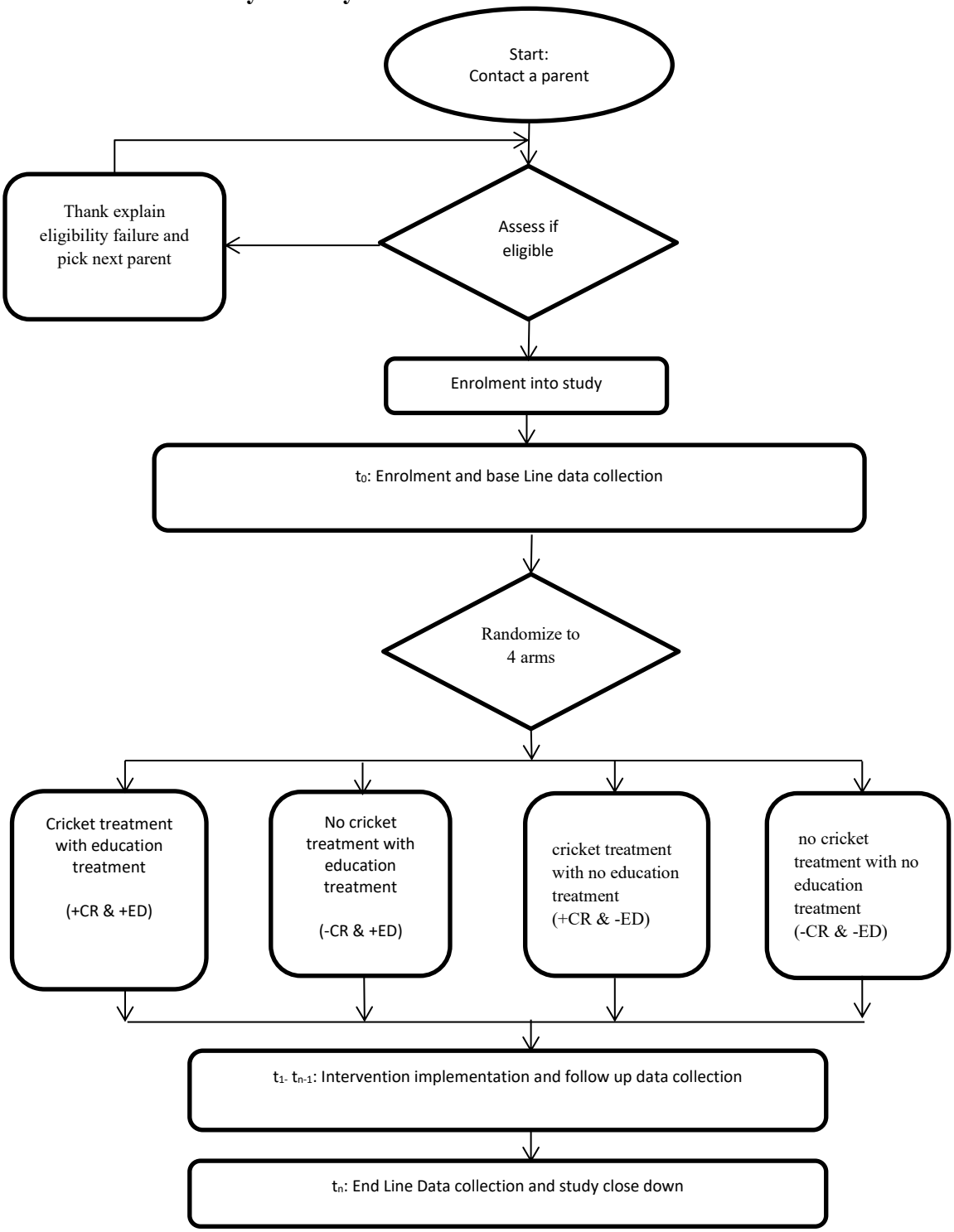
APPENDIX IV: Study Activity Time Chart

Activity	Time line (Months)							
	0	1	2	3	4	5	6	7
Screening and Recruitment	*							
Randomization	*							
Complementary feeding	*	*	*	*	*	*	*	*
Routine Visits/supervision	*	*	*	*	*	*	*	*
Clinical examination	*	*	*	*	*	*	*	*
Anthropometry	*	*	*	*	*	*	*	*
Dietary diversity	*	*	*	*	*	*	*	*
Nutritional education	*	*	*	*	*	*	*	*
Nutritional Education Assessment	*							*
Blood sampling (Hb)	*							
Breast milk intake sampling	*							
Breath test	*							
Stool	*							*

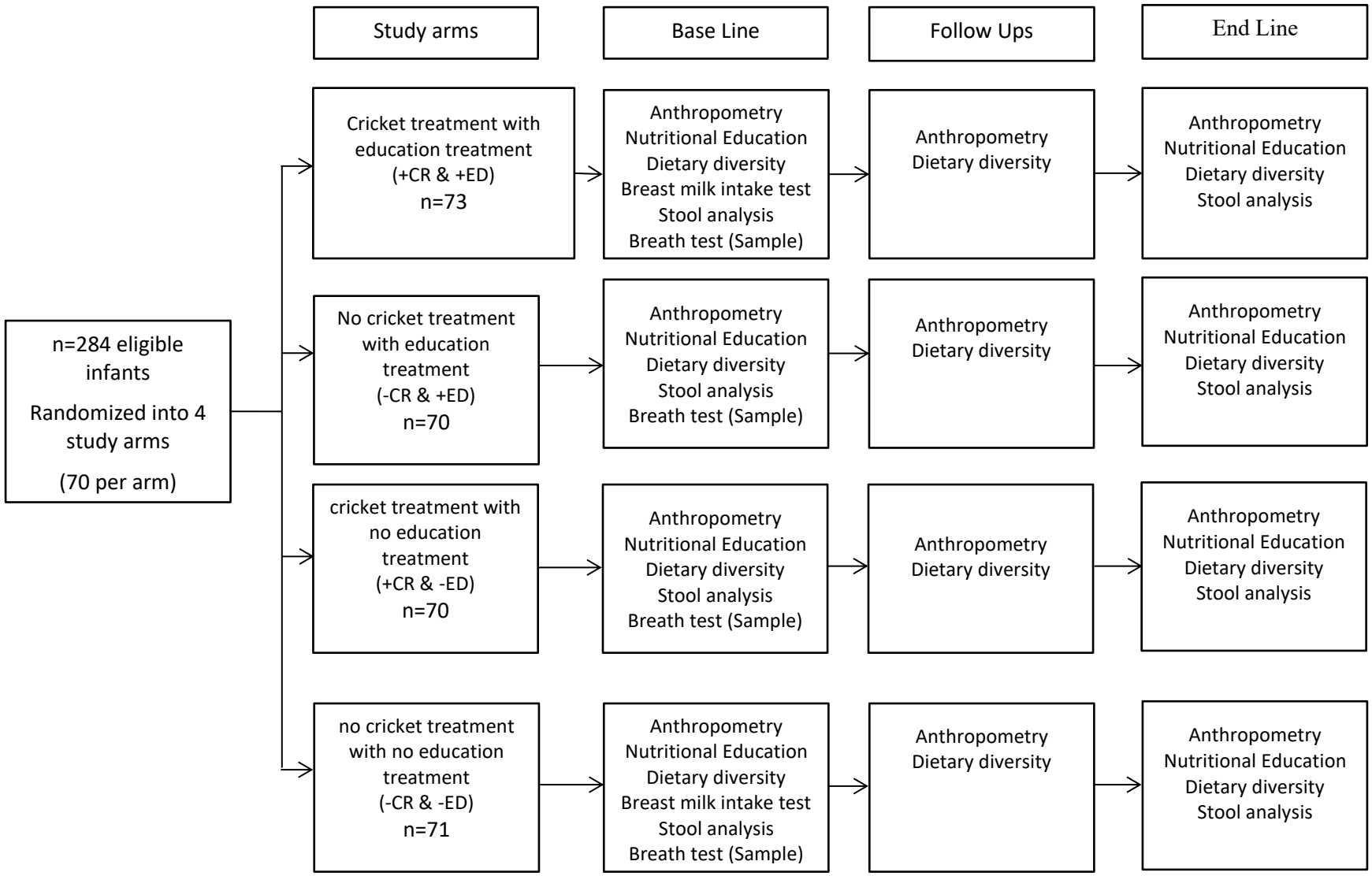
APPENDIX V: Study Design: Recruitment, Randomization and Intervention



APPENDIX VI: Study Activity Flow Chart



APPENDIX VII: Study Intervention Chart



APPENDIX VIII: Nutrition Education Training Plan

Sessions	Topic	Specific Messages
1	• Hygiene & Disease control	• Practice good hygiene and do not bottle feed • Wash yours and child's hands before meals.
2	• Responsive feeding & child satiety	• Practice responsive feeding - Do not force feed - Be patient when feeding your child • Continue breastfeeding until the child is at least 2 years old • Continue to feed the child during illness
3	• Meal diversity • Texture	• Feed a soft, consistent, thick porridge • Amount of food • Variety of food
4	• Frequency of feeding	• Frequency of feeding • For breastfed child: - At 6 months, start with twice daily and gradually increase the frequency following the increase of child's age. - From 9 months, give your child the main meals 3 times daily and healthy snacks 1 or 2 times daily. • For non-breastfed child: - Give your child main meals 3 times and healthy snack 1 or 2 times.

APPENDIX IX: Nutrition Education Content

Session/ Duration	Topic & detailed content coverage	Teaching method/ Learning Task	Timing & Resources
Session 1 15Min	Welcome the mother (Start loudly and confidently, with a welcoming smile, since it is Session 1). Share study background and randomization to remind the care-giver it's a random assignment. Introduce nutrition education concept and watch Video 1. At the end discuss video 1's content with emphasis on responsive feeding	Discussion and Video watching	**Visit 1** Video 1
Session 2 10Min	Welcome the mother and recap Video 1 Using the wall charts answer the following: Why nutrition? How should I feed my child? How often I should feed my child? Do an introduction to food diversity and value of animal source proteins	Discussion, Recall and chart aided teaching	**Visit 2** Wall charts Involve the mother in the learning process
Session 3 10Min	1. General discussion covering lessons learnt in sessions 1&2 2. Promotion of breastfeeding up to 2 years of age 3. Breast milk production and how to boost it	Discussion and Recall: Discussion of lesson learnt-BF (Breast milk production)	**Visit 3** Involve the mother in the learning process
Session 4 15Min	Welcome the mother and quick recap Video 1, Session 2 and 3 then watch video 2. At the end discuss 2nd video with emphasis on 1. Child food texture and feeding frequency 2. Introduction of varied foods 3. General hygiene and baby hygiene	Discussion and Video watching	**Visit 4** Video 2
Session 5 10Min	1. General discussion covering lessons learnt in sessions 1, 2&4 2. Promotion of breastfeeding up to 2years of age 3. Breast milk production and how to boost it 4. Continue to feed the child during illness increasing the feeding frequency in small quantities	Discussion and Recall: Discussion on lesson learnt	**Visit 5** Involve the mother in the learning process
Session 6 10-15Min	1. Discussion of the SMS received with emphasis on lessons learnt in sessions 1, 2&4 2. Promotion of breastfeeding up to 2years of age	Discussion and Recall: Letting the mother voice	**Visit 6** Involve the mother in the learning process

APPENDIX X: Nutrition Education Messages

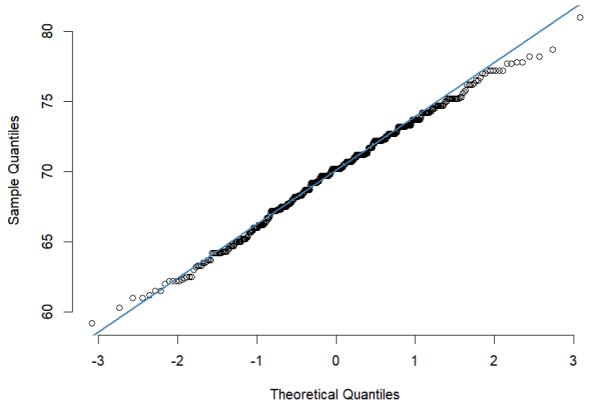
Main Theme	Message	SMS Category
Preparation for complementary	*Mum complementing before 4months of age is not recommended as a baby's digestive tract and immune system have not fully matured.*	General
Preparation for complementary	*Mum delaying complementary food beyond 6 months is also not recommended as it may increase risk of nutritional deficiencies and feeding problems.*	General
Increasing breast milk production	*To enhance your milk production, eat plenty of green leafy vegetable (Murenda), plenty of water and some whole grains and seeds.*	General
Health Care Monitoring	*Visit child welfare clinics for child growth monitoring and immunization service up to the age 5 years for good health*	General
One day reminder Appointment Call	*Your next child (**clientid**) porridge flour visit date is on (**date**)*	General
Responsive feeding	*Mother, please always follow the child's hunger cues while feeding.*	Nutrition Education SMS
Child stimulation and relationship building	*Feeding is crucial to developing a healthy relationship between you and your child. Your close physical contacts during feeding facilitate good eating practices healthy social and emotional development.*	Nutrition Education SMS
Continued breastfeeding	*Always give your baby the first food after breastfeeding or between breastfeeding and adopt appropriate infant feeding practices.*	Nutrition Education SMS
Introduction of new foods	*When complementing, only introduce 1 new food at a time and monitor for signs of food allergy for over 3-4days before introducing another new food. Start by giving baby 2-3 table spoons twice a day as you continue breastfeeding.*	Nutrition Education SMS

APPENDIX XI: Returned Used Flour Containers

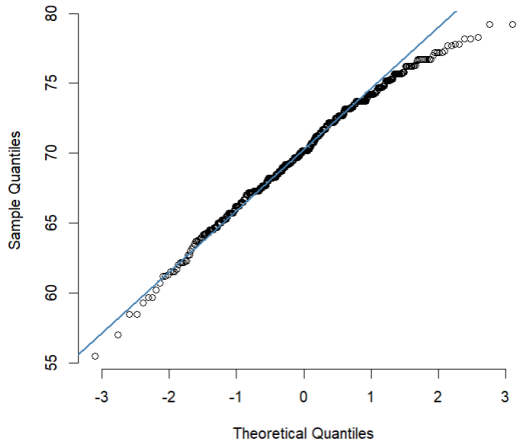
APPENDIX XII: DiaSpect TM Haemoglobinometer

APPENDIX XIII: Q-Q Plots Test for Normality

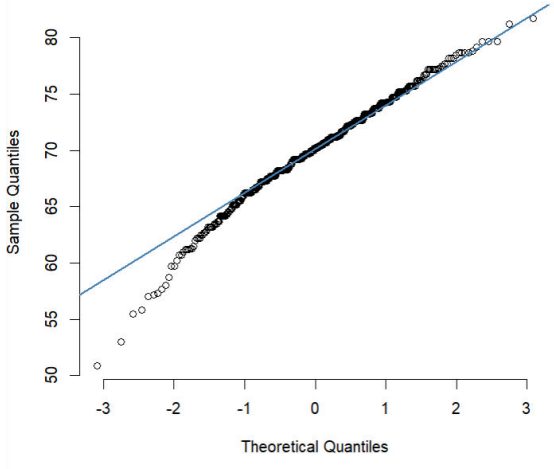
Q-Q Plot for Arm A



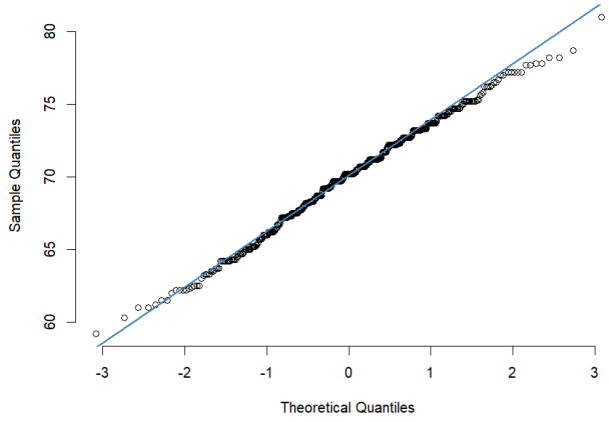
Q-Q Plot for Arm B



Q-Q Plot for Arm C



Q-Q Plot for Arm D



APPENDIX XIV: Distribution of Socio-Demographic Characteristics of Focus Group Discussions Participants by Treatment Allocations

Socio Demographic Characteristics		-CR/+ED	-CR/-ED	+CR/-ED	+CR/+ED	Total		
		n (%)	n (%)	n (%)	n (%)	n (%)	Chi	P-value
Level of Household Food Insecurity Access	Food secure	0 (0.0)	0 (0.0)	1 (100)	0 (0.0)	1 (100)		
	Mildly food insecure access	1 (100)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100)	6.46	0.69
	Moderately food insecure access	2 (15.4)	4 (30.8)	4 (30.8)	3 (23.1)	13 (100)		
	Severely food insecure access	4 (33.3)	2 (16.7)	4 (33.3)	2 (16.7)	12 (100)		
Household Size	<5 Members	4 (50.0)	2 (25.0)	1 (12.5)	1 (12.5)	8 (100)		
	5-9 Members	3 (15.0)	4 (20.0)	8 (40.0)	5 (25.0)	20 (100)	8.04	0.24
	> 9 Members	0 (0.0)	1 (100)	0 (0.0)	0 (0.0)	1 (100)		
Type of housing (Main house) the family live in	Permanent	1 (25.0)	1 (25.0)	1 (25.0)	1 (25.0)	4 (100)		
	Semi-permanent	6 (28.6)	5 (23.8)	6 (28.6)	4 (19.1)	21 (100)	1.79	0.94
	All temporary	0 (0.0)	1 (25.0)	2 (50.0)	1 (25.0)	4 (100)		
Mother Education level	Primary and below	4 (22.2)	5 (27.8)	5 (27.8)	4 (22.2)	18 (100)	0.55	0.91
	Secondary	3 (27.3)	2 (18.2)	4 (36.4)	2 (18.2)	11 (100)		
Household religious grouping	Indigenous churches	1 (11.1)	2 (22.2)	4 (44.4)	2 (22.2)	9 (100)		
	Catholic	0 (0.0)	1 (25.0)	2 (50.0)	1 (25.0)	4 (100)	4.64	0.591
	Protestant	6 (37.5)	4 (25.0)	3 (18.8)	3 (18.8)	16 (100)		
Main Household's source of income	None/Remittance	2 (33.3)	3 (50.0)	1 (16.7)	0 (0.0)	6 (100)		
	Farming	2 (18.2)	2 (18.2)	6 (54.6)	1 (9.1)	11 (100)	13.2	0.15
	Self Employed/Owns business	3 (33.3)	2 (22.2)	1 (11.1)	3 (33.3)	9 (100)		
	Salaried	0 (0.0)	0 (0.0)	1 (33.3)	2 (66.7)	3 (100)		

+CR: cricket enriched porridge; -CR: Control porridge; +ED Nutrition Education offered; -ED No nutrition Education offered

APPENDIX XVI: Research Clearance and Study Approvals

OFFICE OF THE CHAIRPERSON
INSTITUTIONAL SCIENTIFIC ETHICS REVIEW COMMITTEE
UNIVERSITY OF EASTERN AFRICA, BARATON
P.O. BOX 2500-30100, Eldoret, Kenya, East Africa

B2320122022 December 20, 2022

TO: Nicky Odhiambo Okeyo
Department of Community Health Nutrition
Masinde Muliro Unkjversity of Science and Technolo

Dear Nicky,

RE: Effects of Cricket Enriched Porridge and Nutrition Education on Stunting and Gut Health of Infants and Young Children

This is to inform you that the Institutional Scientific Ethics Review Committee (ISERC) of the University of Eastern Africa Baraton has reviewed and approved your above research proposal. Your application approval number is UEAB/ISERC/23/12/2022. The approval period is 20th December, 2022 – 20th December, 2023.
This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by the Institutional Scientific Ethics Review Committee (ISERC) of the University of Eastern Africa Baraton.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to the Institutional Scientific Ethics Review Committee (ISERC) of the University of Eastern Africa Baraton within 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to the Institutional Scientific Ethics Review Committee (ISERC) of the University of Eastern Africa Baraton within 72 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to the Institutional Scientific Ethics Review Committee (ISERC) of the University of Eastern Africa Baraton.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://oris.nacosti.go.ke and also obtain other clearances needed.

Sincerely yours,

Prof. Jackie K. Obey, PhD
Chairperson, Institutional Scientific Ethics Review Committee

University of Eastern Africa, Baraton
20 DEC 2022
P. O. Box 2500-30100, ELDORET
Research Ethics Committee

A SEVENTH-DAY ADVENTIST INSTITUTION OF H IGHER LEARNING
CHARTERED 1991

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **475925**

Date of Issue: **24/January/2023**

RESEARCH LICENSE

This is to Certify that Mr.. nicky Odhiambo okeyo of Masinde Muliro University of Science and Technology, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Siaya on the topic: EFFECT OF CRICKET ENRICHED PORRIDGE AND NUTRITION EDUCATION ON STUNTING AND GUT HEALTH OF INFANTS AND YOUNG CHILDREN for the period ending : 24/January/2024.

License No: **NACOSTI/P/23/23107**

475925

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

See overleaf for conditions

Kenya Bureau of Standards
Standards for Quality life
KEBS Centre, Popo Road
P.O. Box 54974, 00200 Nairobi
Tel.: +254 (0) 20 6005490, 6005506
Fax: +254 (0) 20 6009660
E-Mail:info@kebs.org
Website: www.kebs.org

Laboratory Test Report

REPORT UID: 20230303091534-V1
KEBS Sample Ref. No: BS202306836
Date : 3 March, 2023

1. Description of Sample: COMPOSITE FLOUR
2. Sample Submitted by: JOHN NDUNGU KINYURU
3. Customer Contact: JOHN
4. Customers Ref No: KEBS/HQ/TEST/PRIVATE
5. Customer's Address: KENYA
6. Lab Ref: KEBS/TES/MIC-NAR/M/23
7. Date of Receipt: 23 February, 2023
8. Date Analysis Started: 24 February, 2023
9. Sample Submission Form No: 298347

10. Additional Information provided by the customer:
UJI PRO;PRODUCT CODE 333:BNO 180223 DOM18/02/2023

11. Acceptance criteria-title and number of specification against which it is tested:
KS EAS 782: 2019 KENYA STANDARD Composite flour - Specification

12. Parameters tested and Method(s) of test: as listed in the report below:

LABORATORY TEST REPORT

No.	Parameters		Results	Requirements	Test Method No.	LOD
1.	E.coli	cfu/g	<10	100Max	TES/MIC/TM/17	
2.	Salmonella	/25g	Not Detected	Shall be Absent	TES/MIC/TM/08	
3.	Staphylococcus aureus	cfu/g	<10	100Max	TES/MIC/TM/09	
4.	Total Viable Count	cfu/g	69000	100000Max	EAS 782*	10.0
5.	Yeast and Moulds	cfu/g	40	10000Max	TES/MIC/TM/11	

* Not SANAS Accredited.
Result(s) Marked "Not SANAS Accredited" in this report is not included in the SANAS Schedule of Accreditation for this laboratory

COMMENTS/REMARKS:
The sample performed as shown

Clarkson Agembo - Manager, Microbiology Laboratory
FOR: MANAGING DIRECTOR

3 March, 2023
Date of Issue

Kenya Bureau of Standards
Standards for Quality life
KEBS Centre, Popo Road
P.O. Box 54974, 00200 Nairobi
Tel.: +254 (0) 20 6005490, 6005506
Fax: +254 (0) 20 6009660
E-Mail:info@kebs.org
Website: www.kebs.org

Laboratory Test Report

REPORT UID: 20230303091508-V1
KEBS Sample Ref. No: BS202306837
Date : 3 March, 2023

1. Description of Sample: COMPOSITE FLOUR

2. Sample Submitted by: JOHN NDUNGU KINYURU

3. Customer Contact: JOHN
4. Customers Ref No: KEBS/HQ/TEST/PRIVATE

5. Customer's Address: KENYA

6. Lab Ref: KEBS/TES/MIC-NAR/M/23

7. Date of Receipt: 23 February, 2023
8. Date Analysis Started: 24 February, 2023
9. Sample Submission Form No: 298347

10. Additional Information provided by the customer:
UJI PRO PRODUCT CODE 544:BNO160223;DOM16/02/2023

11. Acceptance criteria-title and number of specification against which it is tested:
KS EAS 782: 2019 KENYA STANDARD Composite flour - Specification

12. Parameters tested and Method(s) of test: as listed in the report below:

LABORATORY TEST REPORT

No.	Parameters		Results	Requirements	Test Method No.	LOD
1.	E.coli	cfu/g	<10	100Max	TES/MIC/TM/17	
2.	Salmonella	/25g	Not Detected	Shall be Absent	TES/MIC/TM/08	
3.	Staphylococcus aureus	cfu/g	<10	100Max	TES/MIC/TM/09	
4.	Total Viable Count	cfu/g	1730	100000Max	EAS 782*	10.0
5.	Yeast and Moulds	cfu/g	190	10000Max	TES/MIC/TM/11	

* Not SANAS Accredited.
Result(s) Marked "Not SANAS Accredited" in this report is not included in the SANAS Schedule of Accreditation for this laboratory

COMMENTS/REMARKS:
The sample performed as shown

arkson Agembo - Manager, Microbiology Laboratory

R: MANAGING DIRECTOR

3 March, 2023
Date of Issue

REPUBLIC OF KENYA

COUNTY GOVERNMENT OF SIAYA

Department of Health

Correspondence should be addressed to:
The County Government of Siaya
Email: siayachd@gmail.com
In reply please quote:

County Health Headquarters
Adjacent to JCC Church
P.O. Box 597 – 40600
SIAYA

REF: CGS/CHD/RESEARCH/VOL.V(59)

6th February, 2023

The Medical Superintendents
Bondo SCH, Rwambwa SCH, Siaya County Referral Hospital

CLEARANCE TO CONDUCT YOUR PhD RESEARCH ON EFFECT OF CRICKET ENRICHED PORRIDGE AND NUTRITION EDUCATION ON STUNTING AND GUT HEALTH OF INFANTS AND YOUNG CHILDREN

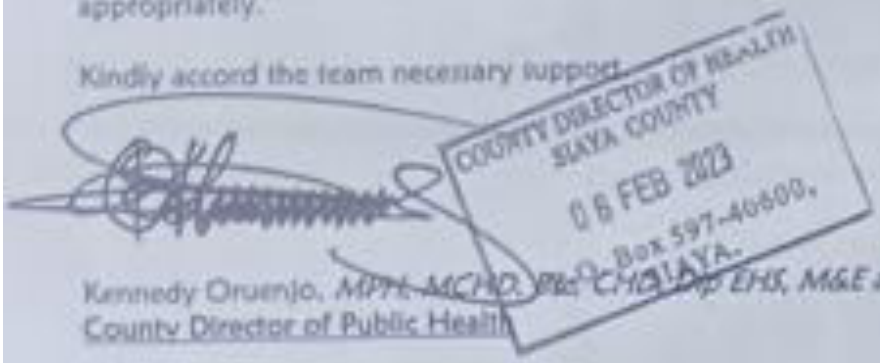
Mr. Nicky Odhiambo Okeyo of Masinde Muliro University of Science and Technology (MMUST), have been licensed to conduct the above referenced research in our County (Alego Usonga Sub-County: Rwambwa & County Referral) as per provision of the National Commission for Science, Technology and Innovation (NACOSTI) and Institutional Scientific Ethics Review Committee University of East Africa, Baraton (UEAB), vide License No: NACOSTI/P/23/23107 and Ref No B2320122022 respectively.

The specific objectives being:

1. To estimate how long the infants and young children adheres to taking cricket enriched porridge after its first introduction among the enrolled infant and young children in Alego Usonga Sub-County.
2. To establish the effects of cricket enriched porridge consumption on infant and young child's gut health and stunting status over the 8 months study observation period in Alego Usonga Sub-County.
3. To determine the effects of nutrition education on infant and young child's gut health and stunting status over the 8 months study observation period in Alego Usonga Sub-County.
4. To evaluate the combined effects of cricket enriched porridge consumption and nutrition education on child gut health and stunting status over the 8 months study observation period in Alego Usonga Sub-County.

This is to notify you that the research has been approved by the office of the undersigned. It is expected that the results will be disseminated to stakeholders appropriately.

Kindly accord the team necessary support.



Kennedy Oruenjo, MPH, MCHO, PBC, CHO, ... EHS, M&E and HCF
County Director of Public Health

Copy to:

- The CECM – Health
- The Chief Officer of Health
- The County Director of Medical Services
- Mr. Nicky Odhiambo Okeyo
  Masinde Muliro University of Technology

COUNTY GOVERNMENT BUSIA
County Director of Health
Health & Sanitation Department
P.O. BOX 1040 – 50400
BUSIA, KENYA

CG/BSA/H/1/56/V.III/87

Date: 13th April 2023

TO WHOM IT MAY CONCERN

RE: APPROVAL TO CONDUCT RESEARCH IN BUSIA COUNTY

This is to confirm that Nicky Odhiambo Okeyo who is a Phd student at Masinde Muliro University of Science and Technology (MMUST) has been approved to conduct a study entitled: **"Effect of cricket enriched porridge and nutrition education on stunting and gut health of infants and young children"**.

The Research approval documents are attached for your perusal.

Kindly accord the research team any necessary co-operation.

Yours Faithfully,

COUNTY DIRECTOR OF HEALTH

DR. Melsa Lutomia
County Director of Health.....
Department of Health and Sanitation
BUSIA COUNTY,

C.C. C.E.C.M. – Department of Health and Sanitation

Chief Officer – Department of Health and Sanitation

REPUBLIC OF KENYA PHARMACY AND POISONS BOARD

EXPORT PERMIT

Document	321J - EXPORT PERMIT
Document Type	2 - Permit
Application Reference No : 2024CPPB321J0002725215	Version No : 1
Master Approval No	
Master Approval Version No	
UCR Number	24KEP051423018N002088964

Application Status

Approval Status :Approved - Pending cargo release | Application Date :2024-04-04 15:34:48.35 | Amended Date :

Expiry Date :2025-04-05 13:20:47.311 | Approval Date :05/04/2024 13:20:58

Applicant Details

Name :SILETO PHARMACEUTICALS LIMITED

PIN :P051423018N	Application Code :SII
Address :48694 00100	Country :KENYA
Contact Person :ROSE JEMATYA	Email : rkotut@gmail.com

Consignee Details

Name :Dr. Ellen Besa

PIN :P000000000N	OGA Ref No :
Physical Address :LUSAKA	Physical Country :REPUBLIC OF ZAMBIA
Postal Address :	Postal Country :
Telephone :260966694341	Fax :260966694341
Email :ellen@tropgan.net	Sector of Activity :
Warehouse Code :	Warehouse Location :

Importer Details

Name :Dr. Ellen Besa

PIN :P000000000N	OGA Ref No :
Physical Address :LUSAKA	Physical Country :REPUBLIC OF ZAMBIA
Postal Address :	Postal Country :
Telephone :260966694341	Fax :260966694341
Email :ellen@tropgan.net	Sector of Activity :
Warehouse Code :	Warehouse Location :

MINISTRY OF HEALTH
OFFICE OF THE DIRECTOR GENERAL

Telephone: (020) 2717077
Fax: (020) 2713234
Email: dghealth2019@gmail.com

AFYA HOUSE
CATHEDRAL ROAD
P. O. Box 30016 – 00100
NAIROBI

When replying please quote
REF: MOH/DNLS /DGH/003 /54/ VOL.II

19th February, 2024

Dr. Silvenus O. Konyole (RNut,PhD)
Principal Investigator
Masinde Muliro University of Science & Technology
P O Box 190 – 50100
KAKAMEGA

RE: AUTHORITY TO SHIP BIOLOGICAL SAMPLES

The Ministry of Health is in receipt of a request from Masinde Muliro University of Science and Technology dated 20th November 2023. The letter requests for approval to shipment of 40 x 12 human breath samples to Lusaka Zambia for analysis of gut health. The applicants indicate that these samples were obtained from an approved study and the justification for this shipment is that the suitable equipment to conduct required tests are unavailable locally. The applicants further indicate that they have already executed Biological Materials Transfer Agreement with the recipient.

The purpose of this letter is to issue an approval to ship the indicated number of samples for further analysis. This approval is issued under the following caveats,

1. Ensure that all other permits required for shipment of these samples are obtained from relevant authorities.
2. That a data sharing agreement between the sender and the recipient is in place and that this agreement is in line with the Kenya Data Protection Act.

Dr. Patrick Amoth, EBS
Ag. DIRECTOR GENERAL