FACTORS ASSOCIATED WITH EXCLUSIVE BREASTFEEDING INTERRUPTION AND LINEAR GROWTH IN A COMPREHENSIVE SUPPORT SETTING IN HOMA BAY COUNTY, KENYA

BY

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A Research Thesis Submitted in Partial Fulfillment of the Requirements for the Award of a Degree of Master of Science in Epidemiology and Biostatistics of Jaramogi Oginga Odinga University of Science and Technology

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DECLARATION

This thesis is my original work and has not been presented for an award of a degree or diploma in any other university or institution.

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H153/P/2510/2021

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ABBREVIATIONS

BF	Breastfeeding
BPS	Board of Post Graduate Studies
BW	Birth weight
CGHR	Centre for Global Health Research
COVID	Corona Virus Disease
CRF	Case report form
EBF	Exclusive Breastfeeding
EED	Environmental Enteric Dysfunction
ERC	Ethics Regulatory Committee
GHO	Global Health Observatory
HAZ	Height-for-age z-score
JOOUST	Jaramogi Oginga Odinga University of Science and Technology
KEMRI	Kenya Medical Research Institute
KDHS	Kenya Demographic Health Survey
KPPB	Kenya Pharmacy and Poisons Board
LAZ	Length-for-age z-score
ΔLAZ	Change length-for-age z-score
LMICs	Low-income and Middle-income countries
LSTM	Liverpool School of Tropical Medicine
MIYCN KAP	Maternal, Infant and Young Children Nutrition Knowledge Attitude and Practices
MUAC	Mid Upper Arm Circumference
NACOSTI	National Commission for Science and Technology
REC	Research Ethics Committee
SERU	Scientific Ethics Review Unit
SD	Standard Deviation

STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
UNICEF	United Nation Children's Fund
WASH	Water Sanitation and Hygiene practices
WLZ	Weight-for-length z-score
WHO	World Health Organization
WHZ	Weight-for-height z-score

DEFINITION OF TERMS

Environmental enteric dysfunction Abnormal gut structure and function characterized by villous atrophy, chronic inflammation and a "leaky" mucosa affecting the small intestines, is often subclinical and may manifest by growth failure.

Exclusive breastfeeding Child only receives breast milk from birth up to 6 months of age without other liquids or solids, not even water, except oral rehydration solution or drops/syrups of vitamins, minerals, or medicines.

Growth faltering Used to describe the deviation of a child's weight or height from the expected centile line from child growth chart.

Linear growth This is the increase in a person's height or length over time.

Linear growth change This will be defined as change will be defined as the change in mean length-for-age z-score (ΔLAZ) from enrolment to 12 months.

Early interruption of breastfeeding Defined as child receiving anything other than breast milk within 3 months after successful initiation of breastfeeding.

Prebiotic A non-digestible food ingredient that beneficially affects the host by selectively stimulating the growth and/or activity of one or a limited number of bacteria in the colon.

Late interruption of breastfeeding Defined as child receiving anything other than breast milk between 3-6 months after successful initiation of breastfeeding.

Probiotic	A preparation of or a product containing viable, defined microorganisms in sufficient numbers, which alter the microflora (by implantation or colonization) in a compartment of the host and by that exert beneficial health effects in this host.
Rooming-in	Placing mother and baby in the same room next to each other for 24 hours per day, soon after leaving the delivery room until hospital discharge.
Synbiotic	Combination of prebiotic and synbiotic.
Under nutrition	This will signify insufficient intake of energy and nutrients to meet an individual's needs to maintain good health, identified by low weight- for- age.

ABSTRACT

Exclusive breastfeeding (EBF) is defined as feeding babies with only breast milk and not any other foods or liquids, except for medications or vitamin and mineral supplements before the age of 6 months. In a setting with intensive support for breastfeeding and child health practices, we documented level and reasons for EBF interruption, evaluated factors associated with interruption of EBF and compared linear growth outcomes in the EBF interruption categories. We conducted a retrospective longitudinal cohort study of a random sample of 366 out of 600 infants enrolled in a trial in Homa Bay County, western Kenya (PROSYNK). The trial assessed whether dietary supplementation of newborns with pro/synbiotics improved gut health and reduced systemic inflammation. Socio-demographic and anthropometric data were obtained from cleaned trial data. When and why interruption of EBF occurred were abstracted from participant's home visit records. Chi-square and Fisher's exact tests used to compare categorical variables. Bivariate and multivariate analysis used to investigate further associations. Changes of SD for LAZ over time in the EBF interrupted categories were graphically illustrated. EBF was interrupted in 165/366 (45.1%) infants. Perception that breast milk was not enough was the major reason for interruption (83; 50.3%). Reasons for EBF interruption differed according to timing, early interruption was mostly due to school resumption (48%, 23/48) while late interruption was mostly due to perception that breastmilk was not enough (53%, 62/117) p=0.002. Interrupted EBF was associated with mothers who were younger (p=0.01), single (p<0.01) and with fewer children (p<0.04). Linear growth of infants with early interruption fluctuated greatly over time. EBF was uncommon despite comprehensive support. Support for breastfeeding to younger mothers, especially those who are unmarried and still attending school, needs to be prioritized. This study holds significance, highlights specific groups of lactating mothers who need special focus for breastfeeding programing.

CHAPTER ONE: INTRODUCTION

1.1. Background

Breastfeeding a critically important intervention for the prevention of childhood mortality and morbidity, improving a child's neuromotor development (Khan *et al*., 2015; Sankar et al 2015; Choi *et al.,* 2018; Grace *et al*., 2017; Tumwine *et al*., 2018). WHO advocates for initiation of breastfeeding within 1 hour of life, exclusive breastfeeding (EBF) for the first six months of life coupled with appropriate introduction of complementary foods when a child attains six months of age (WHO 2014). EBF, defined as feeding babies with only breast milk and not any other foods or liquids including infant formula or water, except for medications or vitamin and mineral supplements before the age of 6 months. In a systematic review, EBF up to 6 months versus EBF for 3-4 months followed by mixed breastfeeding. Results showed better outcomes in EBF for up to 6 months; lowered the risk of gastrointestinal infection for the baby, resulted in more rapid maternal weight loss after birth, and delayed the return of menstrual periods (Kramer & Kakuma 2012). In view of these benefits, there is a call for collaborative efforts by healthcare workers, lactating mothers, and their support systems to support initiation and maintenance EBF for at least 6 months (UNICEF, 2018).

It is difficult to map variation in breastfeeding practice over time in LMICs due to lack of data (Bhattacharjee *et al*., 2021). It is expected that variation between settings would occur due to differences in socio-demographic characteristics, cultural and religious factors. In Kenya, the average duration for EBF is approximately 4.3 months and EBF was prevalent at 61% at 6 months. Furthermore, contrary to the WHO recommendation, only 60% had breastfeeding initiated within one hour (KDHS 2016). The low rates of EBF in Kenya points to inadequate support, encouragement, and guidance to lactating mothers (Talbert *et al*., 2020). Although interventions demonstrated to improve EBF include counselling, video demonstrations and psycho-education integrated into routine care in the pre and post-natal periods (Olufunlayo *et al.* 2019), it is important to understand the factors influencing breastfeeding practices to provide appropriate support. The care continuum for a child is not limited to proper breastfeeding and appropriate complementary feeding but also the context surrounding his or her growth and development (Engebretsen *et al.*, 2008). Factors such as maternal age and level of schooling, income, marital status, number of children, mode of

delivery, smoking and maternal HIV status, have been associated with EBF interruption (Cohen *et al*., 2018; Santana *et al*., 2018). However, how these factors influence EBF in settings with appropriate support for initiation and maintenance is not well studied. An understanding of factors that could be associated with interruption of exclusive breastfeeding after successful initiation will help feed into breastfeeding programs to achieve optimal breastfeeding benefits.

In settings where stunting is prevalent breastfeeding would greatly reduce its burden (Sirajuddin *et al*., 2020). Globally in 2020, according to World Health Organization (WHO) Global Health Observatory (GHO) data 85 million children under 5 years of age were underweight (WAZ <-2 SD from median for WHO Child Growth Standards), with majority living in Africa and Asia. The same report by WHO recorded that undernutrition in low- and middle-income countries (LMICs) is approaching 40% for children under five years of age. In Western Kenya a survey conducted between 2014 and 2015 of 858 under-fives in 10 villages (1800 households) reported mean (SD) WHZ score was − 0.12 (± 1.1) with 4.8% children wasted and a mean (SD) HAZ score was − 1.2 (± 1.2) with 23.5% stunted (Mosites *et al.*, 2016). It would therefore be of great use to understand how interruption of exclusive breastfeeding categorised as either early (interruption occurring with 3 months) and late (interruption occurring between 3 to 6 months) impacts on a child's linear growth. Linear growth faltering, defined as deviation of a child's height from the expected centile line from child growth chart will facilitate understanding of the growth outcomes. Growth faltering is particularly important since it is a precursor to stunting. In addition, growth faltering is a marker of vulnerability to childhood infection, decreased vaccine efficacy and lifelong morbidity (Crane & Berkley, 2017). Tackling child malnutrition is key to achieving the third Sustainable Development Goal of good health and wellbeing for all, breastfeeding is central in achieving optimal growth and development of the child.

Utilizing data from a randomised, open label clinical trial assessing whether supplementation of newborns recruited within the first 3 days of life in western Kenya with pro/synbiotics prevented environmental enteric dysfunction (EED) and reduced systemic inflammation compared with non-supplemented controls (PROSYNK; Otiti *et al*., 2022). The PROSYNK trial enrolled 600 participants in the ratio of 1:1:1:1 across the three

intervention arms and control group. The trial collected data on anthropometric indices of participants at enrolment (within 3 days of life), 6 weeks, 3 months, and 12 months. The anthropometric data is deemed to be reliable since its collected in clinical setting by trained staff, weekly calibrated measurement tools and an average of two repeat measurements were used (Casadei & Kiel, 2022). All mothers participating in the trial were provided with information on the benefits of breastfeeding and healthy practices during home visits by peer mothers (trained mother to mother peers) which occurred daily for the first 10 days and then weekly to age 6 months. The use of peer mothers has been shown to improve post-discharge survival and growth of low birth weight infants (Dickinson *et al*., 2023). We set out to describe the timing of interruption to EBF, determine the reasons behind interruption and evaluate associations with socio-demographic factors. We also evaluated linear growth according to EBF interruption.

1.2. Statement of the Problem

Childhood undernutrition remains rampant in many resources limited settings. Stunting an indicator of chronic malnutrition is prevalent in more than one-quarter of children under the age of five in Kenya (KDHS 2016). According to UNICEF (2018) 'breastfeeding babies for the first two years would save the lives of more than 820,000 children under the age of five annually'. WHO advocates for initiation of breastfeeding within 1 hour of life, exclusive breastfeeding for the first six months of life coupled with appropriate introduction of complementary foods when a child attains six months of age (WHO 2014). In Kenya, the Kenya demographic and health survey report (KDHS) records only 60% had breastfeeding initiated within one hour. Exclusive breastfeeding was only prevalent at 61% and less than 20% received appropriate complementary foods after attaining 6 months (KDHS 2016). In Homa Bay county, counselling for initiation and maintenance of EBF may not be fully afforded to lactating mothers. Only 77% of women age 15–49 with a live birth received a post-natal check within 2 days of delivery, which is lower than the national average of 83% (KDHS 2022). Maternal, Infant and Young Children Nutrition Knowledge Attitude and Practices (MIYCN KAP) baseline survey report of Homa Bay county show higher knowledge (79.3%) and positive attitude towards EBF (81.0%) but practice stands at 38.4% (MIYCN Assessments Reports – Nutrition Portal, n.d.).

Despite evidence generated in previous studies on benefits exclusive breastfeeding and existence of a framework for implementation of support for breastfeeding uptake is still low. Evaluation of a comprehensive support setting for initiation and maintenance of breastfeeding would provide insights on factors that facilitate longer breastfeeding duration and act as a benchmark for up scaling.

1.3. Objectives

1.3.1. Broad Objective

To evaluate factors of exclusive breastfeeding interruption in a comprehensive support setting and linear growth at one year among children in Homa Bay County.

1.3.4 Specific Objectives

i. To document the level of exclusive breastfeeding in a setting with comprehensive support for EBF.

ii. To identify the reason for EBF interruption in a setting with comprehensive support for EBF.

iii. To evaluate factors associated with interruption of EBF in a setting with comprehensive support.

iv. To compare linear growth outcomes in the EBF interruption categories.

1.4. Research Questions

i. What is the level of exclusive breastfeeding in a setting with comprehensive support for EBF?

ii. What are the reasons for EBF interruption in a setting with comprehensive support for EBF?

iii. What are the factors associated with interruption of EBF in a setting with comprehensive support?

iv. How does linear growth outcomes compare in the EBF interruption categories?

1.5. Research Hypothesis

Longer durations of exclusive breastfeeding would be associated with increasing favorable predictors of EBF in a setting with comprehensive support.

1.6. Study Justification

Breastfeeding is a low-cost intervention that has been demonstrated to have numerous benefits including reducing risk of morbidity and mortality. Understanding how comprehensive support settings for initiation and maintenance of EBF perform and why even with support to initiate and maintain EBF interruption of EBF still occurred. This will provide insights on additional considerations that should be undertaken by breastfeeding programs giving priority to target groups of lactating mothers to increase uptake of EBF.

1.7. Study Significance

This research aims to establish the level of EBF in a comprehensive support setting. This study will also identify the reasons for interruption of EBF, contribute valuable insights into the complex interaction of predictors of longer EBF and compare linear growth in the breastfeeding interruption categories. Ultimately, the study's significance lies in its potential to characterize EBF in a resource limited setting with educational support to improve self-efficacy of lactating mothers.

1.8. Scope of the Study

This study documented reasons and level of exclusive breastfeeding interruption, evaluated socio-demographic factors for exclusive breastfeeding interruption and compared linear growth in the breastfeeding categories. This study was a retrospective longitudinal cohort study design. Reasons for exclusive breastfeeding interruption were abstracted from participants' files, merged with baseline socio-demographic characteristics and anthropometric data from the PROSYNK trial.

The sample consisted of 366 infants randomly selected from a cohort of 600 participant from the PROSYNK trial. Participants in the PROSYNK trial were neonates enrolled within 3 days of birth, singleton birth, birth weight ≥2000g, had taken at least one breast feed well,

living within the catchment area of the hospital, and an informed consent secured from the mother. Participants who were excluded from the trial were; multiple births, infants aged more than 4 days, suspicion, or presence of acute illness, those with congenital abnormalities, reported contraindication of probiotics, mother unlikely to stay in study area for the duration of the study and concerns over safety of participation in the trial. Data analysis included: Presentation of frequencies for distributions, Chi-square test for differential distribution, regression analyses and graphical presentation of change in standard deviation for LAZ over time to was used to illustrate growth faltering in the breastfeeding categories.

1.9. Study Limitation

The predictors for breastfeeding interruption are not exhaustive, the ones considered in this study partly explain the observed relationship of predictors and of longer breastfeeding. Risk factors such as maternal health, maternal level of education, and family socio-economic status impact on a child's growth outcomes. The infant supplement study did not include these covariates at 12 months. The scope of this study does not also include WASH practices and child health which have been demonstrated to also influence infant health outcomes, these were not included due to time constraint. This study also did not focus on duration of interruption of exclusive breastfeeding and re-initiation of breastfeeding.

The study sample size was relatively small which affected the precision i.e. wide confidence interval for the reported odds ratio. Additionally, the study was conducted in a single center, potentially limiting the generalizability to other settings or populations of lactating mothers. These factors should be considered when considering the broader impact and applicability of the results.

With standardized support by peer mothers who had lived experience of taking care of low-birth-weight infants and appropriate training on childcare, the hope was that these efforts controlled for of this study through communication of healthy practices and timely referral of identified ill mother-infant dyad. The infant supplement study also provided standard of care at no cost to study participants. Since the study utilizes secondary data i.e. a retrospective longitudinal cohort design. Internal validity is maintained since data is from a

randomized controlled trial and proposes further studies with thorough evaluation of predictors of interrupted breastfeeding and use of larger sample size from diverse populations to facilitate external validity.

1.10. Study Assumption

The major assumption of this study is that nutritional supplements do not improve the growth of children.

CHAPTER TWO: LITERATURE REVIEW

2.1. Introduction

Breastfeeding is a natural act that delivers antibodies vital for protection against illnesses, provides nourishment and energy during childhood (Choi *et al.,* 2018; Grace *et al*., 2017). Breastfeeding advocacy following established benefits to both mother and baby has been gaining momentum over the years. The integration of best practices on breastfeeding from research in a constantly changing world in settings where communities are at different levels of growth and development is challenging. An environment supportive of breastfeeding is not only alive to it benefits but also recognizes barriers to access and factors that drive its uptake (Tumwine *et al*., 2018).

WHO endeavours to create an enabling environment for increasing rates of breastfeeding by 50% by the year 2025 (UNICEF, 2018). In the ten-step approach of successful breastfeeding WHO/UNICEF underscores that hospitals should have a written breastfeeding policy, competent staff to teach breastfeeding techniques, support initiation of breastfeeding within 1 hour of birth amongst others. Kenya ascribes to treaties that uphold exclusive breastfeeding for six months and also regulates marketing and distribution of breast milk substitutes (The Breast Milk Substitutes Regulations Act, 2021). With the deliberate efforts to create legal and policy frameworks, the country has seen improved rates of breastfeeding from 32% in 2008 to 60% in 2022 (KDHS 2022). Coupled with this increase in breastfeeding rates, there has been reducing child mortality which can be attributed either directly or indirectly to breastfeeding as a practice.

The link between child mortality and breastfeeding has previously been identified form foundational research work published in *The Lancet* dating back in 2003 (G. Jones et al., 2003). The researchers noted that effective breastfeeding could help save up to 13% of under five deaths. Additionally, specific evidence on concentration of breastfeeding on a specific age group (Exclusive breastfeeding for 6 months) and comparison of longer versus shorter durations on breastfeeding on childhood illnesses has also been generated. In a systematic review synthesizing evidence for effects of optimal breastfeeding on infection related mortality in infants aged 0-23 month showed that mortality was higher in non-

breastfed infants compared to predominantly and partially breastfeed infants (Sankar et al., 2015). However, the settings for benefits of breastfeeding were pragmatic. Gaining understanding of how a comprehensive support setting providing support for initiation and maintenance of EBF performs is important for breastfeeding programs development. This literature review therefore seeks to understand the predictors of longer breastfeeding duration, levels and reasons for breastfeeding interruption and finally, growth and breastfeeding.

2.2. Predictors of longer breastfeeding duration

Timely initiation of breastfeeding as described by WHO is the placing of the newborn baby to the breast within one hour of birth. Support during attendance of antenatal clinic and institution where a mother delivers were found to influence initiation (Gemeda *et al*., 2022). Successful initiation also depends on a nursing mother's knowledge of the potential benefits of breastfeeding, this was found to be lacking in most women (Cardoso *et al*., 2017).

In resource limited settings maternity units are characterized with high number of pregnant women presenting for delivery coupled with a high number seeking care for pregnancy related complications (Chadwick et al., 2014). Healthcare workers in such setting don't have enough time to demonstrate and even support new mothers to initiate breastfeeding in the first hour of life. There is a direct association of a post-natal check within 2 days of delivery and breastfeeding rates, in Homa Bay county where few mothers with a live birth receive a post-natal check within 2 days of delivery records lower than national rates of breastfeeding (KDHS 2022). In an interview study (Blixt *et al*., 2019) reported that lactating mothers require individualized sensitive support on breastfeeding. Postpartum is the period immediately preceding delivery, it is characterized with physical, emotional, and social changes. The period requires motivated as well as experienced healthcare workers who can identify cues for attention for mother and baby dyads (UNICEF, 2018).

Many studies have explored factors that are associated with breastfeeding maintenance; including, a couple of systematic reviews that have given in-depth perspective to these factors (Cohen *et al*., 2018; Santana *et al*., 2018). The factors for increased maintenance of breastfeeding are summarized as; older maternal age, maternal high level of schooling for

high income and low level of schooling for low-income countries, lower family income, married mother, previous experience of breastfeeding (more children), vaginal delivery, and non-smoking. Further, Alzaheb, 2017 found that in addition to factors above and particularly influencing initiation were rooming-in and prelacteal feeding. Even though these factors were identified in settings with varied maternal experiences. It would be particularly important to have a glimpse on how these factors play out in a resource limited setting with instituted educational support on breastfeeding and communication of healthy practices to lactating mothers.

2.3. Levels of EBF and reasons for interruption of EBF

Breastfeeding is therefore a low-cost intervention in the prevention of childhood mortality and morbidity (Roberts *et al*., 2013). Breastfeeding babies save a country from valuable foreign exchange that would otherwise have been used on milk importation. With the existing body of knowledge on benefits of breastfeeding it beats logic why up take is low, this points to low support, encouragement, and guidance to lactating mothers to accept and maintain the potential lifesaving intervention. Some of the interventions that have been demonstrated to improve exclusive breastfeeding include; prenatal breastfeeding counselling at health facility and at home, postnatal breastfeeding counselling at health facility and at home, video demonstrations of breastfeeding, psycho-education integrated into routine care in pre and post-natal period, telephone call pre and post-natal period. Olufunlayo *et al.* (2019) in a systematic review of interventions to improve breastfeeding found out that all interventions except telephone calls improved exclusive breastfeeding.

It is difficult to map breastfeeding inequalities over time in LMICs due to diverse populations, difference in developmental stages and lack of data (Bhattacharjee *et al*., 2021). In Kenya, according to KDH (2016), the average duration for excusive breastfeeding is approximately 4.3 months and continued for an average of 21 months. Further in the Kenya demographic and health survey report; contrary to WHO recommendation of breastfeeding initiation within the first hour of life, only 60% had breastfeeding initiated within one hour in Kenya. Exclusive breastfeeding was only prevalent at 61% and less than 20% received appropriate complementary foods after attaining 6 months. It is expected that the national level would vary from region to region due to differences in socio-demographic

characteristics, cultural, religious, clinical settings among others. In Homa Bay county despite high knowledge and attitude levels, only 4 in 10 children were exclusively breastfed for 6 months (MIYCN Assessments Reports – Nutrition Portal, n.d.).

In a systematic review of barriers and facilitators of EBF in sub-Saharan Africa countries (Ejie *et al*., 2021), the authors noted that most lactating mothers gave up the practice due to the perception that breastmilk was not enough to meet the growing child's nutritional needs. This mindset is expected to be widespread and particularly amongst mothers resuming school and work following delivery. In a study by Muelbert & Giugliani (2018), they found out that interruption of breastfeeding occurs commonly in adolescents since the current support structures do not meet their unique needs.

2.4. Growth and Breastfeeding

Child nutrition is important for growth and development, if properly given in the early years of life. It provides optimal physical, mental, and cognitive growth. Suboptimal nutrition specifically, can lead to impaired growth, immune and metabolic dysfunction, increased risk of infection, altered development of the nervous system and other abnormalities (WHO, 2014). There is increased risk of infection and death as severity of undernutrition increases (Kirolos *et al*., 2021). Undernutrition broadly encompasses protein energy malnutrition, specific micronutrient deficiencies as well as descriptive names such as kwashiorkor and marasmus. Stunting, or low height-for-age is an indicator of inadequate growth environment to which children have been exposed and also a pointer to general population wellbeing (Perumal et al., 2018).

Globally in 2020, according to World Health Organization (WHO) Global Health Observatory (GHO) data 85 million children under 5 years of age were underweight (WAZ <-2 SD from median for WHO Child Growth Standards), with majority living in Africa and Asia. The same report by WHO recorded that undernutrition in low- and middle-income countries (LMICs) is approaching 40% for children under five years of age. In Kenya, the government recognizes the need for the nation to become food secure in a bid to tackle malnutrition. The National Food and Nutrition Security Policy 2011, underpins the importance of ensuring maternal, newborn and all other ages nutritional needs are met for

healthier populations (National Food and Nutrition Security Policy, n.d.). In Western Kenya a survey conducted between 2014 and 2015 of 858 under-fives in 10 villages (1800 households) reported mean (SD) WHZ score was − 0.12 (± 1.1) with 4.8% children wasted and a mean (SD) HAZ score was − 1.2 (± 1.2) with 23.5% stunted (Mosites *et al*., 2016). Many factors are associated with a child's growth. In a conceptual hierarchal framework study of determinants of growth (Engebretsen *et al*., 2008), demonstrated community deprivation and low knowledge on appropriate feeding practices were leading causes of growth impairment. Majority of the population in Homa Bay county live in deprivation, almost half of the county residents live below the poverty line at 48.4%. The county has a score of 0.46 against a national average of 0.56 on the Human Development Index (HDI). The score combines indicators such as life expectancy, education attainment and income. It is therefore expected that with the prevalent poverty, the malnutrition will also be rampant in such settings.

To be able to quantify that a child's growth is deviating from expected, use of WHO growth standards from longitudinal studies is appropriate. It is therefore expected that a healthy child's growth will be within growth centiles (WHO 2006). The choice of a clinical indicator to be used in the assessment of nutritional status depends on the aim of a study. In clinical settings, qualitative and quantitative measures of nutritional status can be used such as; body composition, clinical signs of deficiency, physical function, biochemical compounds, metabolic processes or dietary intake. For community studies, body size is an easy to measure sensitive indicator for nutritional status (Casadei & Kiel, 2022).

Anthropometric data from a clinical trial with rigorous processes in collection, completeness, and accuracy. The infant supplement study where data was sought provided opportunity for meaningful assessment of linear growth. Breastfeeding interruption was categorized as occurring early (within 3 months) and late (occurring between 3-6 months) provided groups for comparison in change of LAZ over time. Since selection for participation for the trial only ensured inclusion of healthy neonates as assessed by the study clinician, with a birth weight ≥2000g and enrolled within 3 days of life. These considerations limits baseline variability as would affect final results as demonstrated in a

study assessing linear growth and relative weight gain during early life (de Beer *et al.*, 2015).

This study evaluated linear growth changes in the interrupted breastfeeding categories from baseline measurement (taken within 3 days of life), 6 weeks, 3 months, 6 months, and 12 months. Mean length-for-age z-score from WHO 2006 reference population to calculate the average of two repeated length (cm) per child per time point. Further, stunting (low length-for-age) will be categorized using Waterlow classification of undernutrition using Z score; 2.0 to -0.99 will be categorized as normal, -1.0 to -1.99 will be categorized as mild, -2.0 to –2.99 will be categorized as moderate and < -3.0 categorized as severe. Proportion of children in these categories will be compared across breastfeeding interruption categories (Ezzat *et al.*, 2022).

The WHO/UNICEF Global Strategy for Infant and Young Child Feeding (IYCF) outlines community-based breastfeeding practice as a key component of a comprehensive program for breastfeeding (A. D. Jones *et al.*, 2014). Utilizing data from the infant supplement study where staff provides personalized support by; providing information on breastfeeding, ensuring initiation of breastfeeding within one hour and regularly encouraging mothers to continue breastfeeding during scheduled supplement administration visits. The communication of healthy practices is done by a team of peer mothers with lived experience of low birth weight childcare from a previous study in the host community (Unsworth *et al.*, 2021). The educational support is expected to improve self-efficacy enabling lactating mothers to initiate and maintain EBF for recommended 6 months.

The literature review provides overview of predictors of longer breastfeeding durations, the level and reasons of breastfeeding interruption as well as considerations for linear growth evaluation. Despite of the existing body of research, notable gaps on experiences from a comprehensive support setting is insufficient for breastfeeding programming. Results from this research work are from a trial setting with rigorous controls and mimics what a well-functioning breastfeeding program offering personalized support mothers to initiate and maintain breastfeeding. Therefore, an understanding how comprehensive support settings

for initiation and maintenance of EBF perform and why even with support to initiate and maintain EBF interruption of EBF still occurred.

2.5. Theoretical Framework

This research work was partly grounded in practical implications and partly Bandura's Social Cognitive theory. Grounded in the practical implications of the policy requiring initiation of breastfeeding within one hour and exclusive breastfeeding for 6 months. This study provided insights why exclusive breastfeeding interruption occurred even with support to initiate and maintain exclusive breastfeeding for 6 months among participants enrolled in an infant supplement trial with robust follow up. Further, the study compared and provided evidence that longer breastfeeding durations had better linear growth outcomes.

A mother's postpartum experience is coupled with great physical and psychological stresses. Albert Bandura's Social Cognitive Theory (SCT) provided a valuable theoretical framework for exploring the complex personal, environmental, and behavioral factors influencing lactating mothers' choice to initiate and maintain breastfeeding for 6 months (The Social Cognitive Theory, n.d.). In this study all three SCT determinants were touched: personal - Lactating mother's in this comprehensive support setting were afforded support for initiation including opportunity to observe fellow lactating mother to improve their self-efficacy, behavioral – using mother with lived experience of taking care of low birth weight babies (peer mother) daily home visits for 10 days and thereafter weekly home visit up to six months were conducted to reinforce breastfeeding skills, environmental – during the visits the peer mothers stayed on to observe a breastfeeding session. Ultimately, in this comprehensive support setting it was expected that breastfeeding rate would be improve from baseline utilizing the educational support.

In this study we aimed to investigate "Factors associated with exclusive breastfeeding interruption and linear growth in a comprehensive setting". We investigated how a setting with support for initiation and maintenance of exclusive breastfeeding reinforced uptake of the lifesaving intervention and whether there were differences in linear growth among infants who had early versus late interruption of breastfeeding. In the relationship of a comprehensive support setting and whether interruption of breastfeeding would occur, number of previous antenatal clinics attended was a moderating variable since prior

knowledge of the practice may increase its uptake and no knowledge or little knowledge as would be expected in younger women would lead to lower uptake.

Variables identified to be related to both dependent and independent variables from literature review are maternal age, marital status, parity, mode of delivery, residence, maternal HIV status, reported smoking, socio-economic status, and level of education. Due to changing population dynamics, the study monitored factors hindering breastfeeding uptake to ascertain those that were associated with longer breastfeeding durations. A lactating mother's ability to master the skill of breastfeeding determined how long they were able to breastfeed their babies, this therefore mediated the relationship between comprehensive support setting and breastfeeding interruption.

2.6. Conceptual Framework

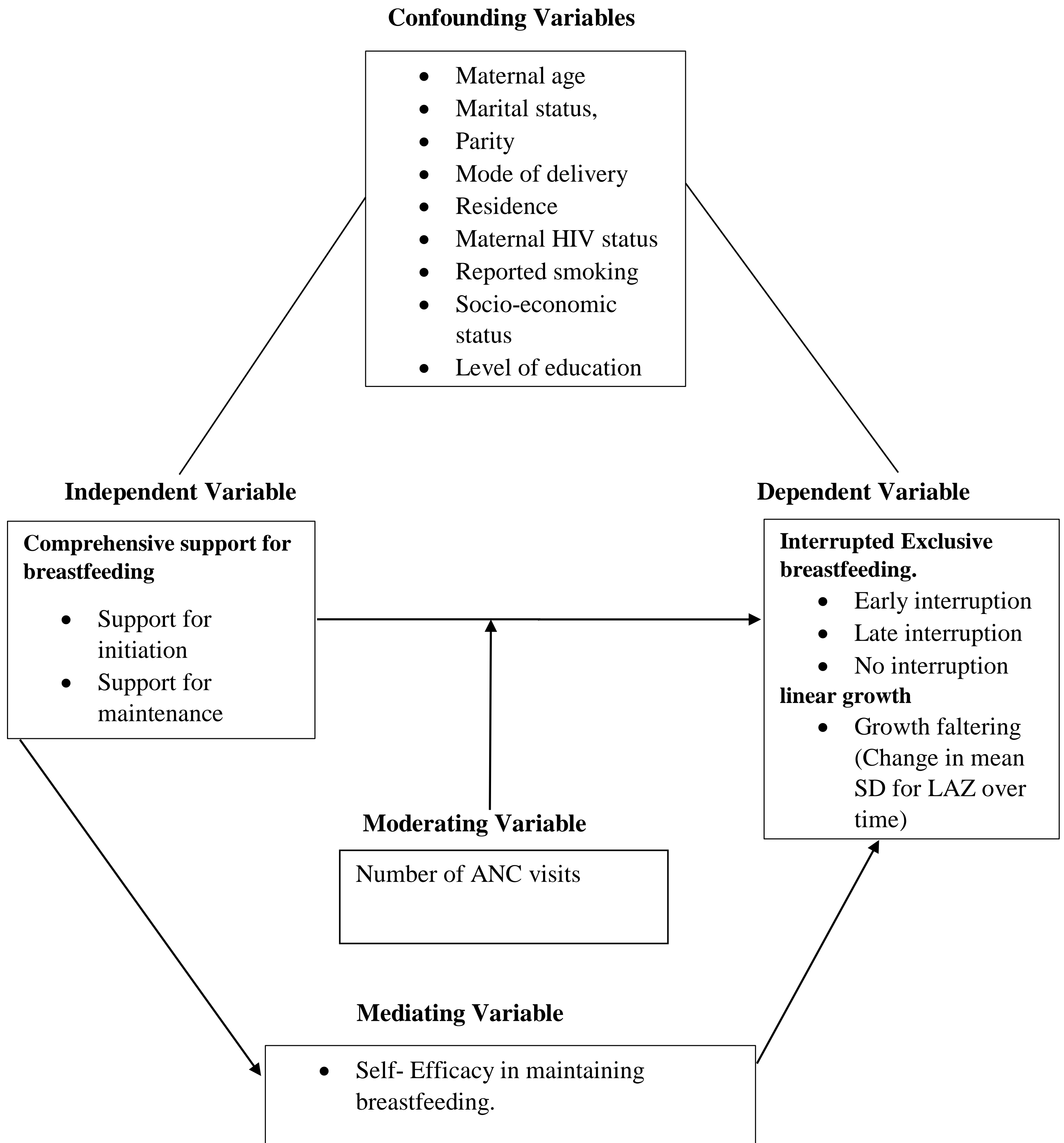


Figure 2.1: *Conceptual framework* **(Source: Micah, 2024)**

CHAPTER THREE: METHODOLOGY

3.1. Study Setting

The study was conducted in Homa-Bay County which is one of the 47 counties in Kenya. Homa Bay town serves as the administrative and commercial centre of Homa Bay County. The recruitment site the PROSYNK study was Homa Bay County Teaching and Referral Hospital (HCTRH) which is in Homa Bay town. The town is located on the eastern shore of Lake Victoria, the largest freshwater lake in Africa and on the western side of Kenya.

The main economic activity is subsistence farming, fishing, and small-scale trading. The county has a population of 1,131,950 (KNBS 2019) and covers an area of 3,154.7km^2. The population density is 359 people per square kilometre. Has approximately 262,036 households with an average of 4.3 members per household. The county has 8 sub-counties with 206 health facilities (Homa Bay County 2022). With a score of 0.46 on the Human Development Index (HDI), this means that the county ranks below average in most socio-economic indicators. The population is rapidly growing, fertility rate of 5.2 children per woman higher than national average of 4.6 children per woman (KNBS 2019).

Most of the county's populations live in deprivation and malnutrition is prevalent (KDHS 2022). Breastfeeding as a low-cost intervention which has several benefit to both mother and baby perhaps if the rates were to be increased, this would go a long way in improving health outcomes giving every baby a fair start to life.

3.2. Study Design

This study employed a retrospective longitudinal cohort study design utilizing data from the infant supplement trial. The infant supplement trial was a 4- arm, open label, individually randomized, controlled, phase-2, study of a probiotic and two synbiotics (PROSYNK). The aim of the trial was to assess whether dietary supplementation of newborns in rural Kenya with pro-synbiotics improved gut health and reduced systemic inflammation. The trial involved 600 participants (150 per study arm) the allocation was in the ratio of 1:1:1:1 in the three intervention arms and the control arm.

At baseline, immediately after delivery (within 3 days of life) staff consented mothers of potential participants, randomized participants into the four study arms, stratified by HIV exposure status. Careful screening was done to ensure only those who met inclusion criteria

as follows were recruited; singleton newborn, birthweight (BW) or current weight (if BW not known) ≥2000g, well infant who is breastfed and has taken at least one breast feed well, within the catchment area and informed consent secured from the mother/carer. Socio-demographics (predictors of breastfeeding) and anthropometric data were collected at enrolment, 6 weeks, 3 months, and 12 months. These participants were visited daily for the first 10 days of life and thereafter weekly until they were 6 months old for supplement administration.

During home visits, communication of healthy practices including support for maintenance of exclusive breastfeeding was performed. If complementary feeding was introduced at any point during the six months of close monitoring, interrupted breastfeeding was said to have occurred and this was recorded in the participant's visit home notes.

This breastfeeding interruption evaluation study utilized data collected from the PROSYNK trial and abstracted additional information on breastfeeding interruption and reasons for interruption from participants' home visit records.

3.3. Target Population

The county residents resided mainly in rural areas, but those closest to the recruiting hospital live in urban and peri-urban areas. The recruitment site for the infant supplement study was Homa-Bay County Teaching and Referral Hospital, which boosts of an average of 300 deliveries per month and with this a recruitment target of 600 participants was met within one year. The referral facility receives clients from the 8 sub-counties and from neighboring counties. Recruitment was conducted between October 2020 to January 2022.

3.4. Study Population

Participant in this breastfeeding interruption evaluation study were a random sample of 366 from the 600 participants recruited in the PROSYNK trial.

3.5. Eligibility Criteria

Participants in this breastfeeding evaluation study represented 68% of participants with complete follow-up data up to 12 months from the 600 participants in the original PROSYNK sample.

3.6 Sample Size Determination

To be able to achieve objectives of this study, a single population proportion calculation was chosen since the outcome of interest was categorical (Cochran's sample size formula). The following assumptions were made: The proportion exclusively breastfed for the first six months of life in Kenya was 61% (KDHS, 2016), q was the proportion in the target population not having the particular characteristics, Z which was set at 95% confidence level, which is equal to 1.96 (Z value of alpha = 0.05) or 5% level of significance (α =0.05) and a 5% margin of error (d =0.05).

Sample size (n)= Z^2pq/d^2

n= (1.96^2) (0.61) (0.39)/0.05^2 =366.

3.7. Sampling Procedure

Simple random sampling was used to select participant included in the breastfeeding evaluation study. Participants who had completed month 12 follow-up with anthropometric data for all scheduled visits, duration and reasons for breastfeeding interruption charted formed the sampling frame. Simple random sampling using STATA 16.1 code was employed to select the sample of 366 participants. Consideration was made to ensure that the number was equally distributed in all four arms of the PROSYNK study i.e. in the ratio of 1:1:1:1 (aiming at 91 in each study arm).

3.8 Data Collection

3.8.1 Data Collection Tools

The PROSYNK trial collected, of interest to this breastfeeding interruption evaluation study; socio-demographic (maternal age, marital status, parity, mode of delivery, residence, maternal HIV status and reported smoking), feeding and growth and on 600 infants from birth to age 12 months compiled from a combination of questionnaires and review of medical records.

Exclusive breastfeeding interruption, defined as when complementary feeding was introduced. This information was ascertained during home visits and recorded on participant home visit charts together with the reason for interruption. A standard abstraction form hosted in CommCare was used to manually abstract when interruption occurred and reasons for exclusive breastfeeding interruption (see appendix 1).

3.8.2 Procedures

The PROSYNK trial used Case Report Forms (CRFs) questionnaires in paper format designed using Teleform and machine readable. Teleform is a forms processing application for capturing and verifying handwritten data from paper. Trained study staff used Scansnap ix500 scanners to scan the paper forms into portable document format (PDFs). The staff performed verification of scanned documents before they were saved to a password protected dropbox for business folder (cloud file storage), accessed via a site laptop. The CRF was used to collect socio-demographic (predictors of breastfeeding) at enrollment and during scheduled visits as described previously.

Anthropometric measurement obtained from the PROSYNK trial was length which was used to evaluate change in standard deviation (SD) for length for age z-score (LAZ) overtime. Length was measured for each child in recumbent position using a length board with a fixed and sliding foot piece. Length of enrolled participants was also recorded in CRFs collected at enrolment and during scheduled visits.

Information on when breastfeeding interruption occurred and reasons for breastfeeding interruption were abstracted from participants home visit notes filed in participants' files. The information was abstracted using standard abstraction forms (DAFs) hosted in CommCare (software for field data capture). The data was later exported in excel tables for cleaning.

Clean datasets of predictors of breastfeeding, length and LAZ were merged with cleaned abstracted data in readiness for analysis.

3.9.Reliability and Validity

3.9.1. Reliability

Data obtained from the PROSYNK trial was deemed reliable since it had all the hallmarks ensuring integrity and credibility such as; standardized protocol was used, personnel were trained with appropriate certification such as Good Clinical Practice (GCP), randomization was employed to ensure equal distribution of confounders, source documents were verified, data management plan was followed and finally there were rigorous quality control measures instituted maintaining rigorous oversight (by regulatory authority and ethics committee) to ensure data quality.

Reliability of abstracted data from the participants' files was ensured through; defining clear instructions on how to use the data abstraction form, we pilot tested the data abstraction tool with a few abstractors using files that were not sampled for the breastfeeding interruption study, all abstractors were trained, frequent consistency checks were performed, and feedback loops incorporated to address issues raised during the data abstraction process. Additionally, inter-rater reliability was performed, the principal investigator sampled 10% of each abstractor's files for re-abstraction. Assignment of interrupted breastfeeding was assessed for the possibility of agreement. A Cohen's Kappa of above 0.65 was maintained for all files evaluated.

3.9.2. Validity

At collection of length measurements for the infant supplement study, measurements were measured two times and repeated a third time if the two measurements differed by 0.7 cm. An average of the two measurements was used in the calculation of LAZ. For other data points collected using CRFs and information contained in the home visit notes, manual quality checks were performed together with monthly data querying to ensure accuracy.

For the abstracted data content validity ensure at initial training and during feedback loops where clarifications of data points was done. The form was reviewed by supervisors to ensure that all relevant variables were covered.

The laptops and tablets used for data abstraction and analysis were encrypted, required a login password and were kept in a lockable cabinet together with other study documents out of reach by non-study staff.

3.10. Data Analysis

Cleaned dataset obtained from the infant supplement study were merged with abstracted dataset. Demographic analysis to understand the study population was done. This presented data related to various demographic variables, including age, gender of the participants, parity, marital status, residence, mode of delivery, HIV exposure status and infant characteristic i.e. intervention arm of the participant from the PROSYNK trial.

The level of exclusive breastfeeding in this study setting with comprehensive support was ascertained by tabulation in STATA 16.1 after labelling the breastfeeding interruption

categories as; early interruption, late interruption and exclusively breastfed. This was also graphically presented by sex of child.

The reasons for EBF interruption in this setting with comprehensive support for EBF were broadly categorized based on the responses abstracted from participants' home visit notes (e.g. interruption due to resumption of school, interruption due to resumption of work, maternal illness, child illness, mother's perception that breast milk is not enough to meet child's nutritional needs, child's sudden refusal to breastfeed, etc.). These were summarized according to absolute frequencies and percentages of subjects in each category level. Differential distribution was assessed using Chi-square test and Fisher's exact test where cell frequencies were <5.

Factors/predictors associated with interruption of EBF in this setting with comprehensive support for initiation and maintenance of EBF were evaluated. Association of predictors (baseline socio-demographic factors) for both mother and infant were evaluated with early and late interruption of EBF by Chi-square or Fisher's exact tests since variables were categorical. Further, Binary logistic regression was used to generate unadjusted odds ratios for factors with significant differential distribution at $\alpha < 0.05$. Additionally, multivariable logistic regression was used to generate adjusted odds ratios and 95% confidence intervals for variables with significant differential distribution and longer duration of breastfeeding. Lastly, confounders in the relationship between longer duration of breastfeeding and predictors of breastfeeding interruption were assessed.

Growth outcomes were evaluated at different time points up to 12 months using calculated Z scores from WHO Anthro Survey Analyzer with WHO 2006 child growth standards. Proportions of growth outcomes such those who were underweight, wasted and stunted were presented at 6 week, 3 months, 6 months and 12 months. Graphical presentation of change in standard deviation for LAZ over time to was used to illustrate growth faltering in the breastfeeding categories.

3.11 Ethical Considerations

In this retrospective longitudinal cohort study data was sought from the PROSYNK trial. Trial participants had consented for additional research on data and samples collected during the initial study. Accessing medical records which are sensitive information is an ethical

concern. The trial participants' files only had a unique study number and abstractors were unable to link the information to trial subjects. Additional safeguards for data security were put in place included using tablets and laptops that were password protected for data abstraction and keeping study documents in lockable cabinets. Selection of participants included in this study was by simple random sampling eliminating bias. The findings of this study together with the finding of the main trial will be disseminated to stakeholders and scientific community.

The infant supplement study protocol, informed consent documents were reviewed and approved by Regulatory and Ethics Committee (REC) at Kenya Medical Research Institute (KEMRI) (ref; KEMRI/SERU/CGHR/320/3917), Kenyan Pharmacy and Poisons Board (KPPB) and Liverpool School of Tropical Medicine (LSTM-sponsor) (ref; 19-048). Authority to use the infant supplement study data was granted in a letter dated 16th February 2023 by the sponsor (see appendix II). Authority to conduct research was granted by Jaramogi Oginga Odinga University of Science and Technology (JOOUST) board of post graduate studies and ethical review board (ref; ERC 35/12/23-15/07) in letters dated 2nd November 2022 and 10th January 2023 respectively (see appendix III and IV). Research permit was obtained from National Commission of Science and Technology (NACOSTI) (ref; 586326 see appendix V).

CHAPTER FOUR: RESULTS

4.1. Participants' records flow and descriptive analysis of baseline characteristics

A total of 534 (89%) of the 600 participants recruited in the PROSYNK study had complete follow up data up to 12 months. 366 participants were randomly selected to be included in this study (Figure. 4.1) which was the calculated sample size. The sample was 68.5% of the total study cohort. Using this proportion, we distributed the number with complete follow up in the study arms.

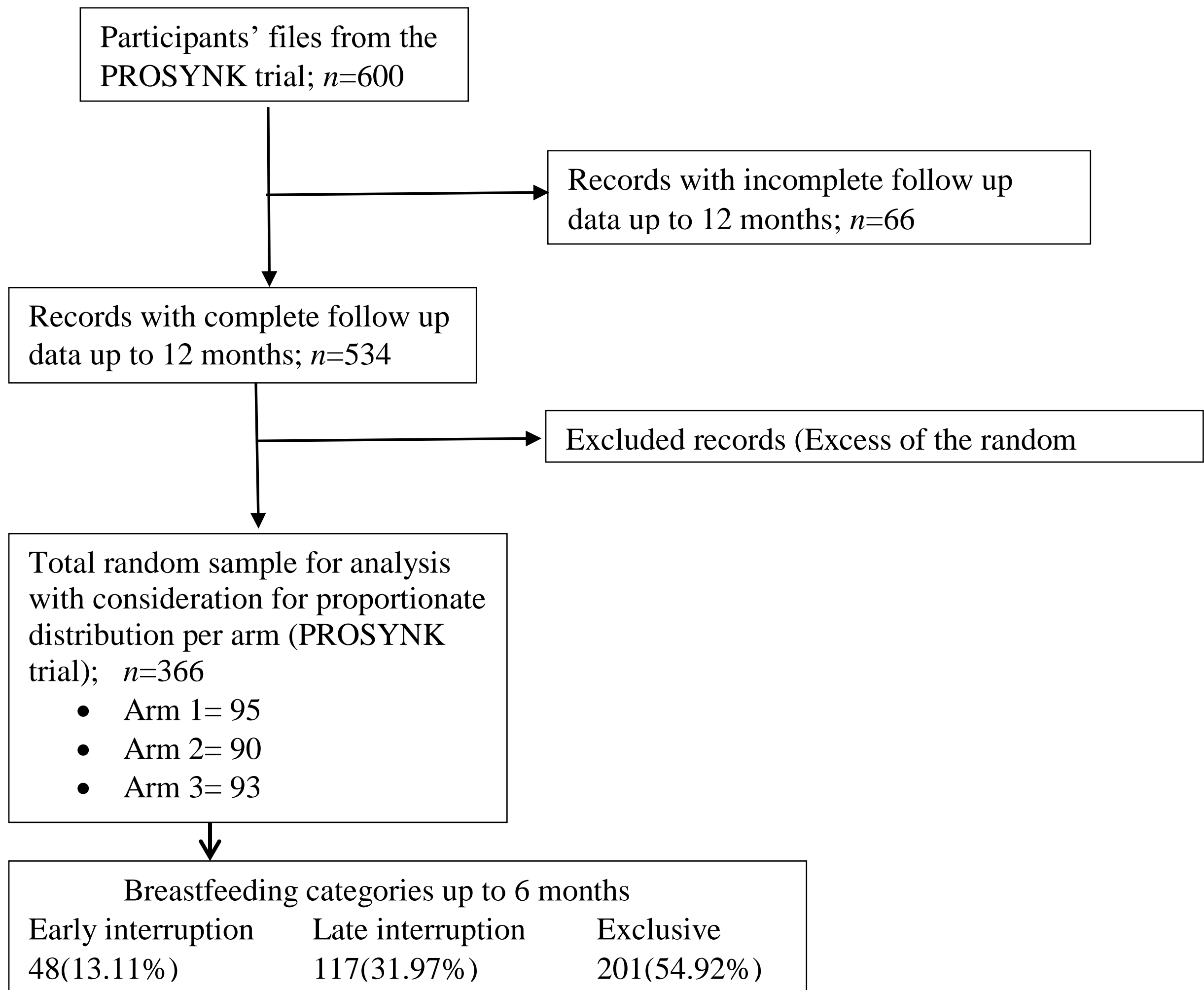


Figure 4.1: *STROBE * Flow diagram for participants*

* STROBE: strengthening the reporting of observational studies in epidemiology (Vandenbroucke *et al*., 2007).

Table 4.1. *Descriptive analysis of baseline characteristics/predictors in the EBF interruption categories*

Characteristic	Overall (N=366) n (%)	EBF (N=201) n (%)	Interrupted EBF (N=165) n (%)	Early interruption of EBF (N=48) n (%)	Late interruption of EBF (N=117) n (%)
Maternal age					
<15	10 (2.7)	2 (1.0)	8 (4.8)	6 (12.5)	2 (1.7)
15-24	166 (45.4)	80 (39.8)	86 (52.1)	27 (56.2)	59 (50.4)
25-35	171 (46.7)	108 (53.7)	63 (38.2)	12 (25.0)	51 (43.6)
>35	19 (5.2)	11 (5.5)	8 (4.8)	3 (6.2)	5 (4.3)
Number of children					
1	99 (27.0)	31 (15.4)	68 (41.2)	27 (56.2)	41 (35.0)
2	79 (21.6)	52 (25.9)	27 (16.4)	6 (12.5)	21 (17.9)
≥3	188 (51.4)	118 (58.7)	70 (42.4)	15 (31.2)	55 (47.0)
Marital status					
Single	71 (19.4)	16 (8.0)	55 (33.3)	28 (58.3)	27 (23.1)
Married	288 (78.7)	181 (90.0)	107 (64.8)	20 (41.7)	87 (74.4)
Separated/divorced	5 (1.4)	3 (1.5)	2 (1.2)	0 (0.0)	2 (1.7)
Widowed	2 (0.5)	1 (0.5)	1 (0.6)	0 (0.0)	1 (0.9)
Residence					
Rural	237 (64.8)	129 (64.2)	108 (65.5)	33 (68.8)	75 (64.1)
Peri-urban	104 (28.4)	57 (28.4)	47 (28.5)	12 (25.0)	35 (29.9)
Urban	25 (6.8)	15(7.4)	10(6)	3 (6.2)	7 (6.0)
Mode of delivery					
Spontaneous vaginal	351 (95.9)	193 (96.0)	158 (95.8)	46 (95.8)	112 (95.7)
Cesarean Section	15 (4.1)	8 (4.0)	7 (4.2)	2 (4.2)	5 (4.3)
Sex					
Male	167 (45.6)	90 (44.8)	77 (46.7)	18 (37.5)	59 (50.4)
Female	199 (54.4)	111 (55.2)	88 (53.3)	30 (62.5)	58 (49.6)
HIV Exposure					
Exposed	63 (17.2)	38 (18.9)	25 (15.2)	8 (16.7)	17 (14.5)
Non-Exposed	303 (82.8)	163 (81.1)	140 (84.8)	40 (83.3)	100 (85.5)
Study arm per PROSYNK trial					
Arm 1	95 (26.0)	57 (28.4)	38 (23.0)	11 (22.9)	27 (23.1)
Arm 2	90 (24.6)	47 (23.4)	43 (26.1)	13 (27.1)	30 (25.6)
Arm 3	93 (25.4)	45 (22.4)	48 (29.1)	11 (22.9)	37 (31.6)
Control	88 (24.0)	52 (25.9)	36 (21.8)	13 (27.1)	23 (19.7)

Note. N is the total in each category, n is the number of characteristics in the category and (%) is the proportion of the characteristics in the category.

The descriptive table above (Table 4.1) provides an overview of maternal and infant baseline characteristics/predictors of breastfeeding interruption and distribution in the EBF interruption categories. Overall, majority of mothers were married, resided in rural areas, and they had a spontaneous vaginal delivery. Additionally, majority of mothers who interrupted EBF were younger and those who interrupted breastfeeding early (within 3 months) had only one child. In the sample, there were 199 (54.4%) female and 167 male (45.6%) infants, whereas those HIV exposed were 63 (17%) and non-exposed were 303 (83%). The proportion of infants exposed was similar to that of the whole PROSYNK study cohort.

4.2. Level of EBF interruption

Interruption of exclusive breastfeeding, defined as introduction of other feeds to infants before the age of 6 months, occurred among 45.08% (95% CI:0.40-0.50) of infants (Figure 4.2). Among those infants who had interrupted breastfeeding, majority of them 70.91% (95% CI:0.63-0.78) were breastfed for longer, while less than one third of infants 29.09%, (95% CI: 0.22-0.37) interruption occurred early. Proportion of male and female infants in the interrupted EBF categories appeared not to be different from the total proportion (Figure 4.2).

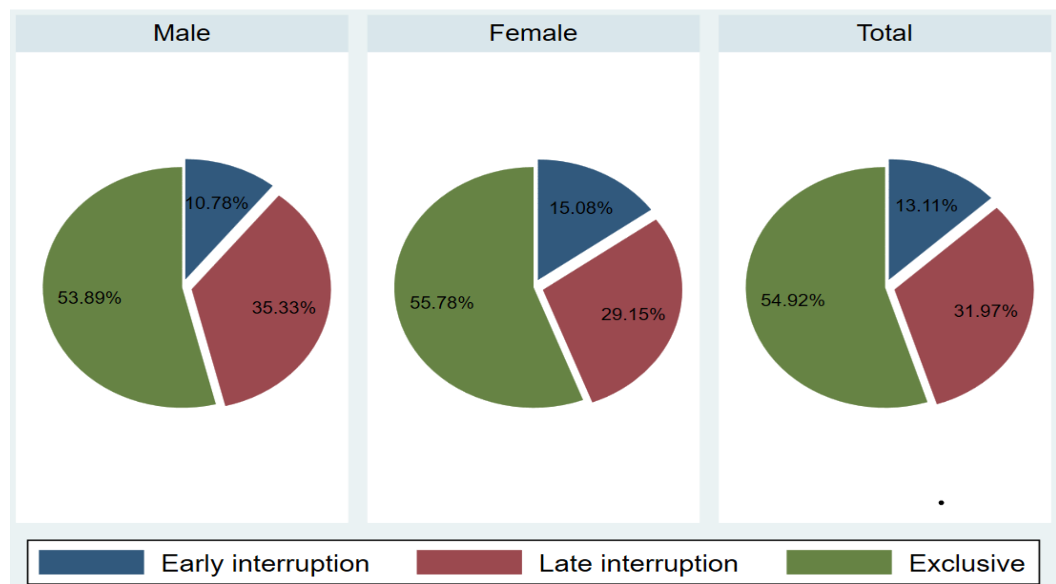


Figure 4.2: *Exclusive breastfeeding interruption by sex of child*

4.3. Reasons for EBF interruption

The reasons for interruption of exclusive breastfeeding were as follows: The common reason reported accounting to half 50.3%(83/165) of mothers who interrupted breastfeeding and introduced complimentary feeds was due to the feeling that breast milk was not enough to meet child's nutritional needs, School resumption was the second most common reason given by mothers (26.1%, 43/165), while resumption of work was reported as the third common reason for interruption accounting for (11.5%, 19/165) mothers. Maternal illness (~5%, 8/165) and perceived child's sudden refusal to breastfeed (~4%, 6/165) were less common reasons reported by mothers. 4/165 (2.4%) of the reasons for breastfeeding interruption were missing in the participant's files. Reasons for EBF interruption differed according to the timing of EBF interruption. Those who had early interruption were mostly due to school resumption (48%, 23/48), while those who had late interruption were mostly due to perception of breastmilk was not enough to meet growing baby's feeding needs (53%, 62/117). The chi-square statistic for differential distribution of reasons of EBF interruption in the EBF interruption categories was 20.6 with 6 degrees of freedom. The p-value was 0.002 indicating significant differential distribution in the interrupted EBF categories (Table 4.2).

Table 4.2. *Reasons for EBF interruption.*

Reasons	Total interruption N=165 n (%)	Early interruption N=48 n (%)	Late interruption N=117 n (%)
Perception that breast milk is not enough to meet baby's feeding needs	83 (50.3)	21 (43.8)	62 (52.9)
School resumption	43 (26.0)	23 (47.9)	20 (17.1)
Resumption of work/livelihood	19 (11.5)	3 (6.3)	16 (13.7)
Maternal illness	8 (4.9)	1 (2.1)	7 (6.0)
Child's sudden refusal to breastfeed	6 (3.6)	0 (0.0)	6 (5.1)
Child illness i.e. malnutrition requiring therapeutic feeds	2 (1.2)	0 (0.0)	2 (1.2)
Other	4 (2.4)	0 (0.0)	4 (3.4)

Note. N is the total in each category, n is the number of characteristics in the category and (%) is the proportion of the characteristics in the category.

4.4. Predictors of EBF interruption.

Maternal age at enrolment was not normally distributed, the overall median age was 25 years, the youngest mother was 12 years and the oldest was 43 years. Factor/baseline characteristic that were associated with EBF interruption were also associated with duration of EBF. They included maternal age, marital status and number of children as shown in Table 4.3a below.

Table 4.3a. *Maternal socio-demographic/predictors of EBF interruption, baseline characteristics and Chi-Square test for association of EBF interruption.*

Note. N is the total in each category, n is the number of characteristics in the category and (%) is the proportion of the characteristic in the category.

Variable	Overall (N=366) n (%)	EBF (N=201) n (%)	Interrupted EBF (N=165) n (%)	*p* - value; EBF vs. interrupted EBF	Early interruption of EBF (N=48) n (%)	Late interruption of EBF (N=117) n (%)	*p* - value; early vs. late interruption of EBF
Maternal age							
• <15	10 (2.7)	2 (1.0)	8 (4.8)	0.01*	6 (12.5)	2 (1.7)	0.01*
• 15-24	166 (45.4)	80 (39.8)	86 (52.1)		27 (56.2)	59 (50.4)	
• 25-35	171 (46.7)	108 (53.7)	63 (38.2)		12 (25.0)	51 (43.6)	
• >35	19 (5.2)	11 (5.5)	8 (4.8)		3 (6.2)	5 (4.3)	
Number of children							
• 1	99 (27.0)	31 (15.4)	68 (41.2)	<0.01*	27 (56.2)	41 (35.0)	0.04*
• 2	79 (21.6)	52 (25.9)	27 (16.4)		6 (12.5)	21 (17.9)	
• ≥3	188 (51.4)	118 (58.7)	70 (42.4)		15 (31.2)	55 (47.0)	
Marital status							
• Single	71 (19.4)	16 (8.0)	55 (33.3)	<0.01*	28 (58.3)	27 (23.1)	<0.01*
• Married	288 (78.7)	181 (90.0)	107 (64.8)		20 (41.7)	87 (74.4)	
• Separated/divorced	5 (1.4)	3 (1.5)	2 (1.2)		0 (0.0)	2 (1.7)	
• Widowed	2 (0.5)	1 (0.5)	1 (0.6)		0 (0.0)	1 (0.9)	
Residence							
• Rural	237 (64.8)	129 (64.2)	108 (65.5)	0.87	33 (68.8)	75 (64.1)	0.81
• Peri-urban	104 (28.4)	57 (28.4)	47 (28.5)		12 (25.0)	35 (29.9)	
• Urban	25 (6.8)	15(7.4)	10(6)		3 (6.2)	7 (6.0)	
Mode of delivery							
• Spontaneous vaginal	351 (95.9)	193 (96.0)	158 (95.8)	0.90	46 (95.8)	112 (95.7)	1.00
• Cesarean Section	15 (4.1)	8 (4.0)	7 (4.2)		2 (4.2)	5 (4.3)	

*$p<.05$.

The infant baseline and socio-demographic characteristics evaluated, none was significantly associated with breastfeeding interruption (Table 4.3b).

Table 4.3b. *Infant socio-demographic/predictors of EBF interruption, baseline characteristics and Chi-Square test for association of EBF interruption.*

Variable	Overall (n=366) n (%)	Not interrupted (n=201) n (%)	Interrupted (n=165) n (%)	*p*-value; not interrupted vs. interrupted	Early interruption (n=48) n (%)	Late interruption (n=117) n (%)	*p*-value; early vs. late interruption
Sex							
• Male	167 (45.6)	90 (44.8)	77 (46.7)	0.72	18 (37.5)	59 (50.4)	0.13
• Female	199 (54.4)	111 (55.2)	88 (53.3)		30 (62.5)	58 (49.6)	
HIV Exposure							
• Exposed	63 (17.2)	38 (18.9)	25 (15.2)	0.34	8 (16.7)	17 (14.5)	0.73
• Non-Exposed	303 (82.8)	163 (81.1)	140 (84.8)		40 (83.3)	100 (85.5)	
Study arm per PROSYNK trial							
• Arm 1	95 (26.0)	57 (28.4)	38 (23.0)	0.32	11 (22.9)	27 (23.1)	0.62
• Arm 2	90 (24.6)	47 (23.4)	43 (26.1)		13 (27.1)	30 (25.6)	
• Arm 3	93 (25.4)	45 (22.4)	48 (29.1)		11 (22.9)	37 (31.6)	
• Control	88 (24.0)	52 (25.9)	36 (21.8)		13 (27.1)	23 (19.7)	

Note. N is the total in each category, n is the number of characteristics in the category and (%) is the proportion of the characteristics in the category. *$p<.05$.

Using the enter method, factors meeting priori differential distribution by Chi square cut off 0.05 were included in a multivariable logistic regression model assessing for factors associated with longer breastfeeding duration. Based on the likelihood ratio test, the model containing all predictors was significant relative to null model [LR $X^2(4) = 16.6$, P=0.002]. In the univariate analyses, advancing maternal age (OR=1.1), higher number of children (OR=2.4) and being in a union (OR=4.1) were significantly associated with longer breastfeeding durations. Holding other factors constant, the odds of breastfeeding for longer was 4.7 (95% CI:1.1, 14) times for women in a union as compared to women in non-unions (Table 4.4c).

Table 4.3c. *Odds ratios (crude and adjusted) for predictors of longer breastfeeding duration.*

Independent variables	Late interruption n=117(%) median maternal age	Crude Odds Ratio (95%CI)	P-value	Adjusted Odds Ratio (95%CI)	P-value
Parity					
1	41(60%)	[Ref]			
2	21(78%)	2.3(0.82-6.45)	0.112	1.32(0.41-4.20)	0.643
3 and above	55(79%)	2.4(1.14-5.11)	0.021*	0.7(0.17-2.60)	0.551
Marital status[a]					
Non-union	30(52%)	[Ref]			
Union	87(81%)	4.1(2.0-8.2)	<0.001*	4.7(1.6-13.9)	0.005*
Mother's age at enrolment (yrs.) median (range)	24 (12-43)	1.1(1.0-1.13)	0.014*	1.0(0.93-1.11)	0.753

Note. Late interruption as the response variable. CI = confidence interval. Ref= Reference category.
[a] Due to few numbers in the separated/divorced and widowed categories, these were merged with mothers who were single. *p<.05

4.5. Summary growth indicators and linear growth

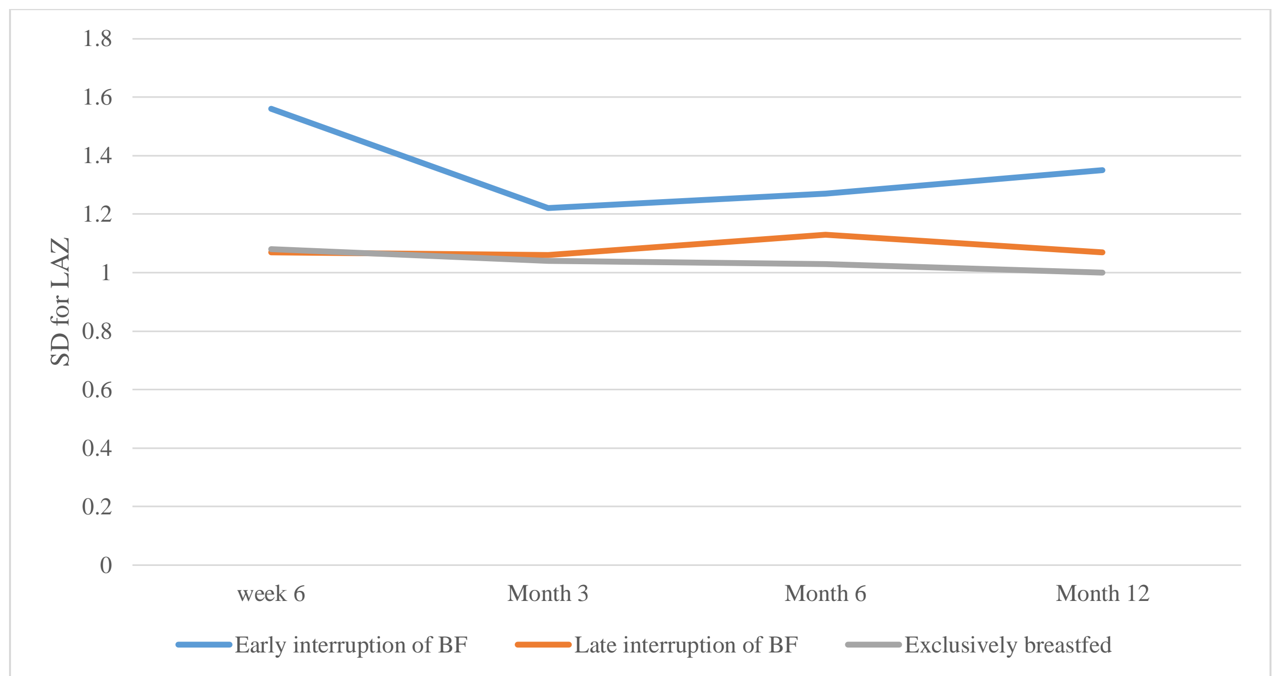
The prevalence of underweight, wasting and stunting is high at six weeks, relatively lower at three and six weeks but rises at twelve months (Table 4.5). The overall prevalence of stunting was 9% at 12 months whereas, in the EBF interruption categories stunting prevalence was 15% (95% CI:0.06, 0.28) and 4% (95% CI:0.01, 0.10) in the early and late EBF interruption respectively at 12 months.

Table 4.4: *Summary growth indicators by visit for the sampled participants.*

			Underweight		Stunting		Wasting				
visit	**avHeight**	**avWeight**	**%**	**95% CI**	**%**	**95 % CI**	**%**	**95% CI**	**avWAZ**	**avWHZ**	**avLAZ**
6 weeks	54.2	4.42	4.1	(2.3,6.7)	6.3	(4.0,9.3)	4.1	(2.3,6.7)	-0.169	0.099	-1.123
3 months	59.81	6.1	1.9	(0.7,3.9)	4.1	(2.3,6.7)	1.9	(0.8,3.9)	0.126	0.41	-0.141
6 months	65.44	7.55	2.1	(0.9,4.2)	6	(3.8,9.0)	2.2	(0.9,4.3)	0.521	0.369	-0.252
12 months	72.8	9	5.1	(3.2,8.0)	9	(6.3,12.4)	5.2	(3.2,8.0)	-0.224	0.09	-0.582

Note. av=Average. CI = Confidence Interval. WAZ=Weight for Age Z-score. LAZ=Length for Age Z-score. WHZ=Weight for Height Z-score.

Comparing linear growth of infants over a period of twelve months, Figure 4.3 depicts stable and low variability in changes of SD for LAZ over time for infants who interruption of breastfeeding occurred late and those exclusively breastfed. The linear growth of infants where interruption of breastfeeding occurred early, their linear growth fluctuates greatly over time.



Note. SD for LAZ=mean Standard Deviation for Length for Age Z-score.

Figure 4.3: *Line graph of SD for LAZ at different time points within one year*

CHAPTER FIVE: DISCUSSION

Previous chapters of this study present thorough examination of predictors for longer durations EBF in a setting with comprehensive support for initiation and maintenance. Additionally, the study documents the level of EBF in a comprehensive support setting for EBF, why interruption of EBF occurred and compares mean SD for LAZ over time in the EBF categories. The results section presented statistical association of predictors of EBF interruption and further evaluated combined effect of favorable predictors of EBF on longer breastfeeding duration. This section attempts to interpret the results, put the finding into context, and disentangle the confirmed hypothesis to highlight its significance to help inform breastfeeding programing, policy drafter and implementers.

5.1. Level of EBF Interruption

There was improved level of EBF with comprehensive support for initiation and maintenance, higher than the reported baseline rate of 38.4% in Homa Bay county (MIYCN Assessments Reports – Nutrition Portal, n.d.). The level of exclusive breastfeeding was at 55% in this comprehensive EBF support setting compared to national average of 60% (KDHS, 2022). Both levels are well above the WHO target of 50% by the year 2025 (UNICEF, 2018). The finding is consistent with a systematic review of 24 trials on educational programs for breastfeeding self-efficacy which showed breastfeeding educational interventions improved breastfeeding rates (Chipojola *et al*., 2020). Therefore, consistent and sufficient support for initiation and maintenance of EBF emerged as a powerful programmatic approach for breastfeeding programming. Pragmatically, application of consistent and sufficient support for initiation and maintenance of EBF in the Kenyan context would mean designing a breastfeeding evaluation tool for implementation by health promoters to be incorporated in their routine household visits.

5.2. Reasons for EBF Interruption

Overall, the most common reason for EBF interruption was due to the mother's feeling that breast milk was not enough to meet child's nutritional needs accounting for half 50.3% (83/165) of the reported reasons for interrupting breastfeeding. Reasons for EBF interruption differed according to the timing of EBF interruption. Those who had early interruption were mostly due to school resumption (48%, 23/48), while those who had late

interruption were mostly due to perception of breastmilk being insufficient to meet the growing baby's feeding needs (53%, 62/117). Consistent with findings from a systematic review of barriers and facilitators of EBF in sub-Saharan Africa countries (Ejie *et al*., 2021), EBF interruption is mostly due to lactating mothers' feeling that breastmilk is insufficient to meet the growing child's nutritional needs. Homa Bay county where there exists high knowledge and attitude on breastfeeding with low uptake of the lifesaving intervention (MIYCN Assessments Reports – Nutrition Portal, n.d.). Efforts should be directed towards sufficient and consistent support to lactating mothers, compassionately encouraging them to sustain the act throughout the recommended period of 6 months for EBF. Coupled with effective breastfeeding support infrastructure at workplaces, these should address needs of older women who interrupt breastfeeding post resumption of work (Breastfeeding-Room-Guide. Pdf, n.d.).

Mothers who were younger (median age 18 years) were more likely to interrupt breastfeeding early due to resumption of school. Congruent with other studies, interruption of breastfeeding occurs commonly in adolescents since the current support structures do not meet their unique needs (Muelbert & Giugliani, 2018). In Kenya, according to Kenya Demographic and Health Survey (KDHS) 2022 there was a decline in teenage pregnancy rates from 18% in 2014 to 15% in 2022. The household survey report also highlighted that poverty and lack of education were drivers to high number of teen pregnancies. Homa Bay county where the Human Development Index (HDI) is 0.46, poverty is rampant and teenage pregnancy is high (KNSB 2019) and is expected to remain high. Consequently, the county and national governments should make considerable investment to ensure public health facilities are adolescent and youth friendly where support for breastfeeding is afforded to younger mothers.

5.3. Predictors of EBF Interruption

Factors that were associated with EBF interruption were younger maternal age (including mothers who were still in school), not being in a union, and smaller families (perhaps with less previous experience of breastfeeding). Similarly, these factors were also associated with longer duration of exclusive breastfeeding. Consistent with previous findings, the practice of breastfeeding is influenced by several factors such as antenatal care practice, religious,

cultural practices and most commonly socio-demographic factors (Cohen *et al*., 2018; Santana *et al*., 2018). Further, the unique and complex relationship of these factors were explored and being in a union was the only factor associated with longer breastfeeding duration in the final model containing the above favorable predictors of longer EBF duration. However, this relationship appears spurious since the older a woman is, the more likely she is married and will have more children. Therefore, closer examination of more predictors of breastfeeding is warranted for complete understanding of how the factors interrelate. This observation withstanding, being in a union in economic terms could have meant that mothers were provided with enough to eat, were well taken care of and coupled with cultural connotation that spouses needed to be close post-delivery to provide emotional support (Ejie *et al.*, 2021) could have led to longer durations of EBF. Furthermore, breastfeeding requires collaborative efforts by healthcare workers, lactating mothers, and their support systems to be able to mitigate against negative influences for the practice (UNICEF, 2018).

5.4. Growth and EBF Interruption

The overall prevalence of stunting in the study sample was 9% (95% CI: 6-12) at 12 months against a national prevalence of 18% at 5 years (KDHS 2022), in the EBF interruption categories stunting prevalence was 15% (95% CI: 6-28) and 4% (95% CI: 1-10) in the late and early EBF interruption respectively at 12 months. Stunting prevalence was also increasing over time in the population, a rise from 4.1% at 3 months to 9% at 12 months. Stunting is a indicator of chronic malnutrition which is a result of accumulation multiple factors including poor maternal nutrition, low access to good healthcare, poor socio-economic factors, inadequate dietary diversity and poor sanitation (Vaivada *et al.*, 2020). The low prevalence of stunting in the study sample could have been due to overall benefits of close monitoring afforded to trial participants or a demonstration that breastfeeding is an effective intervention to tackle stunting.

There was higher mean SD for LAZ amongst infants with early interruption and this greatly changed over time. The SD for LAZ within the category of infants with early EBF interruption shows that an individual child's LAZ greatly varied over the period of infancy. This denotes that early breastfeeding interruption leads to growth faltering. Growth faltering

refers to a state where a child's growth rate is slower than expected for their age, leading to failure to attain the height or weight normally typical for their age group. Growth faltering established early on is a vulnerability maker for stunting and other adverse infant outcomes (Crane & Berkley, 2017). Similarly, this explained why stunting was more prevalent amongst infants who had EBF interrupted early. Moreover, lower mean SD for LAZ and low change over time in mean SD for LAZ amongst infants who were exclusively breastfed and those who were exclusively breastfed for longer provides evidence to support EBF for 6 months.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

This study reports: a higher than baseline level of EBF in the comprehensive support setting, late interruption of EBF was because mothers felt breastmilk was not enough for their children's nutritional needs, early interruption was because of school resumption. Interrupted EBF was associated with mothers who were younger, single and with fewer children. Finally, the study documents high variability of mean SD for LAZ over time for infants with early interruption of EBF and was coupled with high proportion of stunting in this category compared to overall study sample proportion at 12 months.

The findings confirms that consistent and sufficient support for initiation and maintenance of EBF serve to increase EBF rates. Surprisingly, even with the robustness of support the rates were still lower than the national rates. As a child grows older, mothers become more concerned of whether breastmilk alone is enough for the child and hence the reason for late interruption of EBF. Majority of younger mothers were school going and interruption was because of resumption of studies. Meanwhile, being a young mother, single and with fewer number of children emerged as predictors of EBF interruption. Notably, the combined effect of the predictors was not fully understood since the older a mother is the more likely she is married and could be having many children. Linear growth as depicted by mean SD for LAZ for children in the EBF category was stable over time and serves to reinforce benefits of EBF and an intervention against stunting.

6.2. Recommendations

These research findings require a call for collaborative effort by healthcare workers, lactating mothers, and their support systems to support initiation (within 1 hour) and maintain exclusive breastfeeding for at least 6 months. The collaborative scope should be expanded to include policy drafters (both in national and county governments) and implementers of breastfeeding programs outside health care sector.

1. Consistent and sufficient support for EBF by healthcare providers in health facilities and in the community. WHO/UNICEF Ten steps for successful breastfeeding need to be implemented in all settings as from antenatal visits in Mother Child Health clinics (MCH) through the peripartum period for initiation in hospital delivery units and post-partum period for maintenance of breastfeeding in MCH clinics as mothers bring their babies for vaccination and in community settings through delivery of community health package.
2. Educational support to expectant mothers and lactating mothers should be revamped in health facilities by healthcare workers and in the community by health promoters to demystify the perception that breast milk is not enough to meet the growing child's nutritional needs.
3. Greater support for younger mothers, especially those who are unmarried and still attending school needs to be prioritized through provision of health services in youth friendly centers.
4. Promoting and supporting appropriate breastfeeding practices is an essential strategy to prevent growth faltering which is a precursor of stunting. In addition to educational support provided to lactating mother on importance of EBF, perhaps implementation of interventions aimed at addressing stunting such as nutritional supplementation and improvement in water and sanitation would greatly benefit this community.

6.3 Suggestion for Further Research

This study only looked at quantitative data, incorporation qualitative methods would give more perspective on EBF interruption. The phenomenon of combined effect of factors for EBF interruption was not fully explored due to the limited number of variables available in this retrospective longitudinal cohort study. Complete and thorough evaluation of predictors with consideration for re-initiation following interruption of exclusive breastfeeding should be evaluated in comprehensive educational support settings utilizing a prospective longitudinal cohort study design to provide background information of what the level of breastfeeding would look like in a well-functioning breastfeeding program for up scaling.

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APPENDICES

APPENDIX I: DATA ABSTRACTION FORM

BREASTFEEDING SUB-STUDY 1083365826

1.	**Subject ID**	P S K - _ _ _ _ _
2.	**Study Arm**	○ Labinic synbiotic (Arm1) ○ Lab4b synbiotic (Arm2) ○ Probiotic (Arm3) ○ Control (Arm4)
3.	**Date of enrolment**	_ _ / _ _ _ / 2 0 _ _
4.	**HIV exposure status**	○ Exposed ○ Non-Exposed
5.	**Date of Week 6 FUP**	_ _ / _ _ _ / 2 0 _ _
6.	**Date of Month 3 FUP**	_ _ / _ _ _ / 2 0 _ _
7.	**Date of Month 6 FUP**	_ _ / _ _ _ / 2 0 _ _
8.	**Date of Month 12 FUP**	_ _ / _ _ _ / 2 0 _ _
9.	**Complementary feeding before 6 months**	○ Yes ○ No *if No, Skip to 13*
10.	**What age did the child first receive anything other than breastmilk?**	_ _ Month _ _ Weeks _ _ Days
11.	**Reasons for complementary feeding before 6 months**	○ Disruption due to school resumption ○ Desruption due to resumption of work/livelihood ○ Maternal illness ○ Child illness i.e malnutrition requiring therapeutic feeds ○ Maternal death ○ Mother and child separation due to social circumstances i.e disagreement between parents ○ Mother perception that breast milk is not enough to meet baby's nitritional requirements ○ Child's sudden refusal to breastfeed ○ Other
12.	**If other, specify**	
13.	**Completed by:**	_ _ _

APPENDIX II: APPROVAL TO USE PROSYNK DATA

Professor Stephen Allen
Liverpool School of Tropical Medicine
Pembroke Place
Liverpool
L3 5QA

Thursday, 16 February 2023

Dear Professor Allen,

Re. Research Protocol (19-048) Gut Power: Protecting the early life gut microbiome to prevent malnutrition.

Thank you for your correspondence of 8 February 2023 providing the LSTM Research Ethics Committee and LSTM Research Governance Manager with details of a request for approval to provide access to data from your study for secondary analyses.

The Committee note that Micah June, who is the Study Coordinator, is currently undertaking an MSc in Epidemiology and Biostatistics at the Jaramogi Oginnga Odinga University of Science and Technology, Bondo, Siaya County, Kenya. His study project, "Evaluation of sociodemographic factors associated with breastfeeding and linear growth of infants in Homa Bay county", has received in-country approval from the University.

This request has now been reviewed, noted and accepted on the behalf of the Committee and the LSTM, as study Sponsor. Please continue to adhere to the conditions of approval and to update us of any further changes to the study that may arise.

Yours sincerely,

Professor Graham Devereux
Chair
LSTM Research Ethics Committee

Yours sincerely,

Ms Denise Watson
Research Governance & Integrity Manager
LSTM Research Governance and Ethics Office

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APPENDIX III: BOARD OF POSTGRADUATE STUDIES APPROVAL

JARAMOGI OGINGA ODINGA UNIVERSITY OF SCIENCE & TECHNOLOGY

BOARD OF POSTGRADUATE STUDIES

Office of the Director

Tel. 057-2501804 — P.O. BOX 210 - 40601,
Email: bps@jooust.ac.ke — **BONDO**

Our Ref: H153/P/2510/21 — **Date:** 2nd November 2022

TO WHOM IT MAY CONCERN

RE: MICAH JUNE JUNE - H153/P/2510/21

The above-mentioned person is a bonafide postgraduate student of Jaramogi Oginga Odinga University of Science and Technology in the School of Health Sciences, pursuing Master of Science in Epidemiology and Biostatistics. He has been authorized by the University to undertake research on the topic: ***"Evaluation of Sociodemographic Factors Associated with Breastfeeding and Linear Growth of Infants in Homabay County".***

Any assistance accorded him shall be appreciated.

Thank you.

Prof. Dennis Ochuodho
DIRECTOR, BOARD OF POSTGRADUATE STUDIES

APPENDIX IV: JOOUST ERC APPROVAL

JARAMOGI OGINGA ODINGA
UNIVERSITY OF SCIENCE AND TECHNOLOGY

DIVISION OF RESEARCH, INNOVATION AND OUTREACH
JOOUST-ETHICS REVIEW OFFICE

Tel. 057-2501804
Email: erc@jooust.ac.ke
Website: www.jooust.ac.ke

P.O. BOX 210 - 40601
BONDO

OUR REF: JOOUST/DVC-RIO/ERC/E4

10th January, 2023

Micah June
SHS
JOOUST

Dear Ms. June,

RE: APPROVAL TO CONDUCT RESEARCH TITLED "EVALUATION OF SOCIODEMOGRAHIC FACTORS ASSOCIATED WITH BREASTFEEDING AND LINEAR GROWTH OF INFANTS IN HOMABAY COUNTY"

This is to inform you that JOOUST ERC has reviewed and approved your above research proposal. Your application approval number is **ERC 35/12/23-15/07.** The approval period is from 10th January, 2023– 09th January, 2024.

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 JOOUST IERC.
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 NACOSTI IERC within 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks of affected safety or welfare of study participants and others or affect the integrity of the research must be reported to NACOSTI IERC 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 JOOUST IERC.

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

Yours sincerely,

for
Prof. Francis Anga'wa
Chairman, JOOUST ERC

Copy to: Deputy Vice-Chancellor, RIO   Director, BPS   DEAN, SHS

APPENDIX V: NACOSTI APPROVAL

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **586326**

Date of Issue: **23/February/2023**

RESEARCH LICENSE

This is to Certify that Mr.. Micah June June of Jaramogi Oginga Odinga 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 Homabay on the topic: EVALUATION OF SOCIODEMOGRAPHIC FACTORS ASSOCIATED WITH BREASTFEEDING AND LINEAR GROWTH OF INFANTS IN HOMA BAY COUNTY. for the period ending : 23/February/2024.

License No: **NACOSTI/P/23/23371**

586326

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION