MULTIPLE MICRONUTRIENT SUPPLEMENTS VERSUS IRON FOLIC ACID SUPPLEMENTATION ON PREGNANCY OUTCOMES IN NANDI COUNTY, KENYA

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Multiple Micronutrient Supplements Versus Iron Folic Acid Supplementation on Pregnancy Outcomes in Nandi County, Kenya

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DECLARATION

This thesis is my original work and has not been presented for a degree in any other university.

Signature…………………………………………………..Date………………………

Betsy Chebet Rono

This thesis has been submitted for examination with our approval as University Supervisors.

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DEDICATION

To my two fathers the late Pr Joseph K. Rono and Fredrick K. Cheriro who supported me greatly before their sudden deaths, their love and words of wisdom gave me the momentum to reach this far. To my dear loving husband and children; Jeerox, Jayrix & Jofrex who wish me excellence each glorious morning and to all those who, selflessly, dedicate their energies towards addressing, epidemiological issues towards better health in our continent, I dedicate this work. I hope this is a milestone, towards achieving Sustainable Developing Goal Number Three in Sub Saharan Africa.

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ABBREVIATIONS AND ACRONYMS

ANC	Antenatal Clinic
CHW	Community Health Worker
GOK	Government of Kenya
HIV	Human Immunodeficiency Virus
IFA	Iron folic acid supplementation
IUGR	Intra Uterine Growth Retardation
KDHS	Kenya Demographic and Health Survey
KNBS	Kenya National Bureau of Statisitics
LBW	Low Birth Weight
MDG	Millennium Development Goals
MM	Multiple Micronutrients
MNP	Multiple micronutreits powders
MMR	Maternal Mortality Rate
MNH	Maternal and Newborn Health
MOH	Ministry of Health
NGO	Non Governmental Organization
PHC	Primary Health Care
PPH	Post Partum Hemorrhage

RDA	Recommended Daily Allowance
RH	Reproductive Health
SDG	Sustainable Development Goals
SGA	Small for Gestational Age
TBA	Traditional birth attendant
UN	United Nations
USD	United States Dollar
WHO	World Health Organization

OPERATIONAL DEFINITION OF TERMS

Apgar score	Clinical classification of newborn at birth
Government	The exercise of authority; control; direction; regulation by Ministry of Health
Infant	A child up to one year old
Labor	Onset for birth pains
Micronutrients	Advised nutrients necessary for one's health promotion
Neonate	A newborn up to 28 days of life
Pregnancy outcome	Weight gain, anemia, labor, birth of baby, postpartum blood loss, lochia loss, breastmilk availability
Pica	Unusual oral craving during pregnancy; for laundry Starch, dirt, red clay among others
Pregnancy	Period from conception to delivery which is 36-40 Weeks
Pueperium	Period after delivery up to 42 days or 6 weeks
Skilled	Employment of expertise during ANC/delivery
Supplements	Use of processed vitamins to substitute food requirements
Unskilled	Employment of traditional ANC/delivery options

ABSTRACT

According to World Health Organization use of more than two micronutrients is beneficial to pregnant women. However, anemia prevalence, labor duration, neonatal Apgar score, blood loss and lochia loss, have not been studied in relation to multiple micronutrient use. The study supplemented maternal micronutrients to influence anemia, pregnancy weight gain, labor and birth duration, blood loss, lochia loss and infant development in Kenya. The study using convenience sampling, defined sub-populations at risk of nutritional deficiencies and provided opportunities, for early intervention through use of multiple micronutrients on pregnancy outcomes. The study objective was to determine the effect of multiple micronutrient supplements and Iron Folic acid supplementation on maternal infant health outcomes. This was through a Cluster Randomized Controlled study. The treatment arm was administered with a daily multiple micronutrients while the control arm took the standard care; iron folic acid. A semi structured questionnaire and focus group discussion were applied to collect data on effect of prenatal multiple micronutrients among the pregnant women. The study demonstrated that the difference in means of: hemoglobin levels was 12.1 (11.6, 12.4) in MM group and 11.3 (9.7, 11.8) p=0.038, duration of labor was; 8.0 (6.0,20.0) hours for the MMs and 20.0 (15.0,30.0) for IFA p=0.023. Average birthweight in kilograms at birth; 3.3 (3.2,4.1) for MM and 3.2 (3.0,3.5) kgs for IFA (p=0.024). Blood and lochia loss: light (MM) 79%; (IFA) light-21%, p=0.001; heavy (MM) 10.5%, (IFA) 48.2% p=0.001 Breastmilk was available within thirty minutes in 85.7% of MM group and 20% of IFA group p=0.001. Third trimester weight gain mean was 67.89 kilograms (SD: 8.5) for MM and 62.7 kilograms (SD: 6.4) for IFA p=0.032. There was significance in subjects effects for labor duration in hours p=0.006, blood loss p=0.001 and lochia loss p, 0.025. Roy's Largest Root was equivalent to Hotellings' Trace; therefore, the effect observed was associated with; labor duration p=0.003, blood loss p=0.001 and lochia loss p=0.001. Contrast results demonstrated that there was a significant effect difference observed in the model in the dependent variables; labor duration p=0.003, blood loss p=0.001 and lochia loss p=0.001. Since the significance levels for the dependent variables were less than 0.05, the study concluded that the difference observed was not due to chance variation, therefore, contrast concludes that the multiple micronutrients reduces labor duration during pregnancy, postpartum hemorrhage, lochia loss amount and duration. The study recommends a policy change from iron folic acid use to multiple micronutrients to promote reduced; labor duration, postpartum hemorrhage, lochia loss amount and duration.

CHAPTER ONE

INTRODUCTION

1.1 Background

Based on current evidence, World Health Organization (WHO) approved use of multiple micronutrients during pregnancy to reduce micronutrient deficiency (WHO, ANC 2020). Globally, micronutrient deficiency influence maternal and infant health outcomes. Micronutrients deficiency is a modifiable risk factor of public health importance that poses a health risk to an otherwise thriving pregnancy (Zerfu, *et al* 2018;Oh, *et al* 2020). Micronutrient deficiency is common among women of reproductive age (WRA) regardless of their economic backgrounds (Taha, *et al* 2016; Keats, *et al* 2022). Micronutrient deficiency may have serious consequences on pregnancy and newborns due to increased metabolic demands associated with physiological and hormonal changes. Among the newborns, 15 out of 1000 have preventable birth defects (Zatollah, *et al* 2014). Infants approximately 20 million i.e. 6-30% are born with a low birth weight (LBW) globally. A third of the LBW are small for gestational age (SGA) especially in settings of maternal undernutrition (Smith, *et al* 2019). Among the infants, 3.6 million die during the neonatal period. Two-thirds of these deaths occur in developing countries. More than a third of these deaths are thought to be attributable to maternal and child health undernutrition (Zerfu, *et al* 2018).

Maternal and infant malnutrition is a modifiable risk factor that can be integrated into existing Kenya Ministry of Health efforts, to prevent adverse birth outcomes among pregnant women of low-income populations. Multiple micronutrient (MM) supplements have been reported to be beneficial to mothers, neonates, and infants (Keats, *et al* 2019). Public health strategies are feasible in promoting maternal neonatal health outcomes noting that; a worthy outcome is the critical expectation in every pregnancy (Oh, *et al* 2020).

Micronutrient supplementation is an epidemiological prophylactic approach that contributes to a decline in maternal and infant morbidities (Bourassa, *et al* 2019).

Magnesium and Vitamin A supplementation has been reported to prevent preeclampsia and premature birth occurrence (Oh, *et al* 2020). Magnesium and Vitamin A can be sourced by eating spinach, potatoes, almonds and cashew nuts. MM reduces the proportion of anemia <11g/dl of hemoglobin and decreases the proportion of low iron stores (Keats, *et al* 2019).

A successful maternal infant outcome is the critical probability out of every pregnancy irrespective of their economic status (Oh, *et al* 2020). The study sought to determine the effect of multiple micronutrient versus iron folic acid supplementation on pregnancy and infant health.

1.2 Statement of the Problem

Globally, micronutrient deficiency deprives the woman of nutrients and accounts for; low birth weight (LBW) 8-55%, preterm birth 7-28%, small for gestational age (SGA) 22-71%, stillbirth 3%, infant mortality 0.6-6.7% and maternal mortality 0.2-0.7% (Oh, *et al* 2020). In Sub Saharan Africa, nearly half of all underfive deaths are associated with undernourishment. Effects of nutrients deficiency can only be experienced late in life, accompanied by long-term complications during pregnancy, postnatal and infants' life (Masiyiwa, 2015; Tuan, 2017). Many adult disorders could be linked to pregnancy period: an exemplar, deaths from heart disease and attacks are more common in men who had a low LBW; a child's brain if not fed with enough nutrients, suffers irreversible cognitive challenges (Masiyiwa, 2015, Tuan, 2017). Addressing nutritional deficiency is a marathon that needs consistency in achieving worthy health outcomes (WHO, 2020).

Currently the Kenyan maternal mortality ratio (MMR) is 362/100,000 live births according to the Kenya Demographic Health Survey (KDHS 2014, World Bank, 2020, Kimuthia, *et al* 2019). Maternal mortality and infant mortality rate (IMR) are escalated by postpartum hemorrhage (PPH) due to prolonged labor and poor maternal nutrition during pregnancy and lactation. Maternal deaths related to PPH remains at 34% in Kenya (Kinuthia, *et al* 2019) and 34,000 deaths in low and middle income countries (LMIC) according to (Ramanathan, *et al* 2018). Globaly, PPH occurs in 5% of all live births (Althabe, *et al* 2020). Postpartum hemorrhage is a physiological response to nutritional defieicency (Mclean, *et al* 2019).

During the antenatal clinic (ANC) visits, women are advised to eat a balanced diet to promote a healthy pregnancy. This has not been feasible under conditions of poverty. Past studies have reported that diets of these women are low in energy, protein and specific micronutrients which include, iron, zinc and Vitamin A. Nutrient deficiencies are detrimental to fetal growth and development contributing to the prevalence of low birth weight (LBW) of less than 2500g at birth and small for gestational age (SGA) persist (Douglas, *et al* 2014).

The Kenya government has made commitments to eliminate preventable maternal and neonatal deaths (WHO 2020; KDHS 2008-09,2014): Though iron folic acid (IFA) supplementation has been in place for decades among the pregnant women (NRHS 2009-2015), it only addresses iron deficiency anemia and neural tube defects in the fetus. Women with low iron stores shown by ferritin levels < 15ɥg/l or Hgb level < 11g/dl on diet alone cannot restore deficient iron levels to normal within an acceptable timeframe (Huda, *et al* 2020; Liu, *et al* 2020). Globally, the target is to reduce anemia by 50% in women of reproductive age WRA from 29% (2012) to 15% (2025) with an Annual Average Rate of Reduction (AARR) of 5.2%. (Heidkamp *et al* 2017).

Mothers and neonates are therefore predisposed to temporary and permanent disability due to nutritional deficiency complications (Abraha, *et al* 2019). World Health Organization advises that enhancing nutrition of WRA and under-five children prevents development of cardiovascular, renal and metabolic diseases. No clear directive has been issued by WHO on use of multiple micronutrients during pregnancy except during emergencies (UNICEF, 2014;WHO, 2020). Micronutrient strategies to strengthen interventions to improve maternal- neonatal nutrition are only practiced on prescription and not mass distribution (WHO, 2014). Over the counter price in Kenya for a month dose of the fifteen (15) multiple micronutrients are sold at approximately thirty six (36) United States dollar (USD) currency sampled from assorted pharmacies in Kenya's Eldoret town. A negligible number of women afford the MM (Oh, *et al* 2020; Zerfu, *et al* 2013).

1.3 Justification

According to WHO, more studies to determine micronutrients benefits during pregnancy (WHO 2016). Supplementation programs with micronutrients are beneficial and feasible to populations where the magnitude and severity of nutritional deficiencies are a major public health problem (Bourassa, *et al* 2019, Zatollah, *et al* 2014). Infants and women of reproductive age (WRA) in developing countries are recognized to be at risk of multiple micronutrient deficiencies (Salam, *et al* 2014); iron, folic acid, iodine, zinc, vitamins A&D, riboflavin, B6 and B12 (Zatollah, *et al* 2014). According to a study in Iran, evidence for the impact of MM is still inadequate and there is a need for further studies before a switch from IFA is implemented (Zatollah, *et al* 2014).

According to a past study, there is insufficient evidence to recommend routine prenatal MM to women in developing countries. It is further noted that few studies have examined the effects of micronutrient supplementation on long-term child health outcomes; morbidity, mortality, breastfeeding, growth and cognitive development. It has been proven that pregnant women are susceptible to nutritional insufficiency due to increased physiological requirements of micronutrients (Bourassa, *et al* 2019).

Previous studies on micronutrients have only concentrated their focus on newborns' birth weight, head circumference leaving maternal infant outcomes unaddressed. MM use has not been tested fully to assess the effects on maternal neonatal health ((Oh, *et al* 2020).

There is need for more studies to evaluate the use of MM versus IFA and their effect on PPH, labor duration and lactation in reducing maternal neonatal morbidity and mortality (Bloem, et al 2015, WHO, 2016, WHO, 2020). There is need therefore for further studies with different combination and doses of micronutrients supplements particularly in areas with a high prevalence rate of malnutrition (Bourassa, *et al* 2019).

The study attempted to address the gaps identified in previous studies towards a reduction of undernutrition and subsequent deaths in Nandi County being the sixth highest with stunting in Kenya, which is a developing countries by adapting the MM intervention.

1.4 Objectives

1.4.1 Broad Objective

The braod objective was:

To determine the effect of multiple micronutrients supplements and iron folic acid supplementation on pregnancy outcomes

1.4.2 Specific Objectives

1. To determine the effect of MM and IFA supplementation on prevalence of anemia during pregnancy;
2. To assess the effect of MM and IFA supplementation on pregnancy weight gain;
3. To determine variations on labor and birth duration among the MM and IFA groups
4. To determine the effect of MM and IFA supplementation on maternal postpartum blood and lochia loss
5. To assess the effect of MM and IFA supplementation on breast milk availability
6. To determine the perceptions of women on their health and use of MM versus IFA supplementation during pregnancy

1.5 Hypothesis

Null: There is no difference between use of multiple micronutrient and iron folic acid supplementation on pregnancy outcomes

CHAPTER TWO

LITERATURE REVIEW

2.1 Micronutrients and pregnancy

Micronutrient deficiency is common among women of reproductive age (WRA) regardless of their economic backgrounds. Three point six million infants, die during the neonatal period and two thirds of these deaths occur in developing countries. More than a third of these deaths are attributable to maternal and child health undernutrition (Bourassa, *et al* 2019). Low iron status during pregnancy is associated with child cardiovascular morbidity (Siekmans, *et al* 2017).

Globally, 42% of maternal deaths occuring during the intrapartum period are associated with over one million neonatal deaths and close to a million birth asphyxia. According to World Bank, maternal mortality ratio (MMR) in Kenya, remains high and currently 362/100,000 live births (World Bank 2020). Public health interventions are needed to reduce it to 70/100000 live births to attain Sustainable Development Goal (SDG) number three by 2030 (WHO 2017). The United Nations (UN) has asserted that no woman or infant should die of pregnancy related causes; however, the progress in reducing MMR and IMR remains a monumental task. (Alkema, *et al* 2016, UN report 2014, Yucosey *et al* 2014).

Maternal deaths are associated with: premature labor, prolonged labor; postpartum hemorrhage (PPH), low hemoglobin levels, pernicious anemia, preeclampsia, eclampsia, puerperal and neonatal sepsis (Temesgen W G 2017; West, *et al* 2014).

2.2 Micronutrients versus Anemia

According to past studies, anemia is common among women from developing countries and related to iron and folate deficiency (Bailey, *et al* 2015; Tincalp, *et al* 2020). Iron deficiency can be prevented through supplementation to prevent onward complications to their children in the future (Zerfu, *et al* 2018). Low iron is associated with poor nutrition regardless of economic background (Dika, *et al* 2018; Taha, *et al* 2016; Rukoni, *et al* 2015; Breymann, *et al* 2017; Auerbach, *et al* 2018).

Iron supplements is likely to increase hemoglobin concentration during pregnancy (Maghsoudlou, *et al* 2016).

According to the WHO classification of anemia; hemoglobin level <11.0g/dl among the pregnant women is anemia (Miao, *et al* 2015) and has a higher risk of preterm birth, low birth weight and small for gestational weight. Low hemoglobin in the third trimester has a higher risk of low birth weight (Tincalp, *et al* 2020).

Anemia affects 38% of pregnant women globally (WHO 2016). Anemia prevalence in Africa is 44.6%: Ghana is 56%; and Uganda 32.5% (WHO 2020). According to the World Health Organization, anemia prevalence is high and an unacceptable public Health concern (Kamau, *et al* 2018). Women practicing pica are 1.23 times more likely to be anemic compared to those who didn't (Intiful, *et al* 2016).

Pica status is a preliminary clinical indicator for micronutrient deficiency (Miao, *et al* 2015). Nutrition and mineral deficiency precipitate pica behavior which can either be; geophagia, pagophagia or amylophagia. Nutritional advice and prescriptions for multivitamins are given but prescribed multivitamins are never obtained leading to continued pica behavior (Quinn, *et al* 2020).

The causal relationship between pica and micronutrients remains unclear needing further studies. This then necessitates investigation into the strength of association which has been inconsistent. Iron and zinc supplementation has been associated with cessation of pica. Pica is common regardless of sex, race, culture, social position or residence (Ezzedin, *et al* 2016).

Despite all the studies, pica etiology remains unclear with a prevalence of between 0.02-74% in Iran and 46% among the pregnant adolescents in the USA. The relationship between pica and iron status biomarkers is unknown though it has been in observance for greater than 2000 years according to Hippocrates in 400BC (Lumish 2014). Pica practice is common in developing countries: Pica prevalence in Ghana is 9.1%; in Pemba Tanzania for amylophagia -36.3%; geophagia and any pica- 40.1%. Amylophagia has been observed to be associated with low hemoglobin concentration and iron deficiency anemia (Young, *et al* 2010).

2.3 Micronutrients versus breast milk feeding and breastmilk substitution

Globally, breastfeeding duration and exclusivity fall below the World Health Organization (WHO) recommended level, calling for interventions to benefit both infant and maternal health (WHO 2013; Zerfu, *et al* 2013). According to WHO exclusive breastfeeding is recommended to infants till six months of age to achieve optimum growth (Khanal 2016, Haroon 2013). In Sub Saharan Africa, Ethiopia is leading on exclusive breastfeeding with a prevalence of 70.5% and an awareness of 92.4% (Sonko, *et al* 2015). Currently in Kenya, only 38% of the women practice exclusive breastfeeding and hope to achieve 50% by 2025; with an expected annual rate of reduction (AARR) of 2.11%. Successful breastfeeding requires sufficient nutrients to sustain to six months (Zerfu, *et al* 2013).

In Brazil, maternal education is associated with a high prevalence of exclusive breastfeeding. However, locally antenatal education has not been proven to significantly increase exclusive breastfeeding (Boccolini, *et al* 2015). This calls for randomized controlled studies with adequate power to evaluate the effectiveness of breastfeeding interventions (Lumbiganon, *et al* 2011). Face to face support in enhancing exclusive breastfeeding up to 6 months has been demonstrated to have better success rates. Women have tried expressing their breast milk to enhance exclusive breastfeeding but instead resulted in a shorter breastfeeding period (Jiang, *et al* 2015).

According to past studies, exclusive breastfeeding of the infant is related to a reduced risk of overweight gain or obesity later in the first year (Hornel, *et al* 2013). In Ghana, despite a 99% awareness of exclusive breastfeeding, only 10.3% of the women practice exclusive breastfeeding coupled with shorter maternity leave days (Dun-Deny, *et al* 2016). According to past studies in Saudi Arabia, exclusive breastfeeding for the first six months is only practiced by 31.4% of the women. Working women are less likely to practice exclusive breastfeeding which remains a challenge (Alzaheb, *et al* 2017).

Kenyan neonatal mortality rate (NMR) remains at 20/1000 (2018) while the underfive mortality rate (U5MR) was 41/1000 (2018) per live births. According to

WHO, they target an under-five mortality rate reduction to 25/1000 by 2030 and NMR to 12/1000 with a 30% reduction in LBW by 2030 (Hategeka *et al* 2019). Child mortality is high in populations living below poverty at 46% and non exclusively breastfed infants (World Bank 2018, KDHS 2014). Nutrient deficiency related congenital lesions has a prevalence of 2.4/1000 births in Africa (Liu *et al* 2019).

2.4 Micronutrients versus labor and birth duration

There has been no study to establish the effect of multiple micronutrients on the reduction of labor duration and Apgar score at birth. According to past studies, glucose supplementation in intravenous fluids has been reported to reduce labor duration (Pre, *et al* 2017, Sharma, *et al* 2012). However, other studies negate the fact that there is a difference in labor length based on dextrose addition to intravenous fluids (Fong, *et al* 2017). Increasing the intravenous volume did not affect labor length (Garmi, *et al* 2017). Other women have tried water aerobics during labor but it had no impact on reducing the labor duration (Baciuk, *et al* 2008). Prolonged labor was also associated with adverse maternal outcomes: uterine atony; and third or fourth-degree perineal tear; with an 8.7% increase in odds for each extra hour in labor. There is an increased risk of neonatal admission to an intensive care unit with a prolonged second stage, with an odds ratio of 1.4 (Rouse, *et al* 2009). A prolonged second stage of labor of more than or equal to four hours in nulliparous women is the accepted upper limit (Leveno, *et al* 2014), but has no significance in influencing maternal neonatal morbidity outcomes, and reduces the incidence of expedited delivery cesarean or vaginal operation (Gimovsky, *et al* 2016).

Prolonged labor of more than twelve hours, had no difference between the intravenous groups (Kavitha, *et al* 2012); but is associated with an increased risk of a low five minute Apgar score (Altman, *et al* 2015). Children with Apgar scores of less than ten (<10) at five minutes are more vulnerable to emotional challenges with a risk of developmental vulnerability at five years (Razas, *et al* 2016, Li, *et al* 2013). Apgar score at five minutes, predicts the infant and under-five morbidity and mortality (Dalili, *et al* 2016, Jeganathan, *et al* 2017, Temesgen, *et al* 2017, Park, *et al*

2018). MM use reduces the risk of neonatal morbidity and mortality (Haider, *et al* 2011).

2.5 Micronutrients and maternal postnatal blood and lochia loss

Globally, blood loss prevalence is 18% after birth (Edmonds, *et al* 2010). In France, the prevalence of severe postpartum hemorrhage dropped to 0.6% following vaginal deliveries (Dupont, *et al* 2014). Incidence of PPH was 9.0% in Uganda (Ononge, *et al* 2016). In Japan, 63.3% lost less than 500mls, 12.9% lost 500-800m and only 4% had more than 1000mls blood loss at birth (Eto, *et al* 2017). Postpartum hemorrhage is the leading cause of maternal mortalities especially in low resource settings where Kenya is included (Prata, *et al* 2014; Pacagnella, *et al* 2013; Gallos, *et al* 2018). Lochia loss is an important indicator of delayed postpartum hemorrhage and needs attention (Fletcher, *et al* 2012).

Blood loss during delivery is underestimated and quantifying mechanisms have been outlined to approximate the amounts lost as a result of delivery (Ramirez, *et al* 2015). There have been incidences of under evaluation of blood loss by 21-28% by the medical staff (Jones, *et al* 2015). Gravimetric measurement of blood is assumed to be directly associated with a fall in postpartum hemoglobin (Lilley, *et al* 2014). Severe acute PPH has been classified as blood loss of more than one thousand milliliters (Edmonds, et al 2010), but another classification is blood loss of more than fifteen hundred mililitres at birth (Lilley, *et al* 2014).

Several factors have been associated with PPH incidence: there is a tendency of increase in blood loss with increases in neonatal birth weight; duration of delivery; primigravida (Eto, *et al* 2017); anemia before delivery; labor induction, long duration of labor (Hofmeyr, *et al* 2013). There has been no attention being given to micronutrients and its associated importance in preventing postpartum hemorrhage. This study tried to establish the relationship between the use of multiple micronutrients during pregnancy and blood loss at birth.

2.6 Pregnancy and postnatal health

During pregnancy, pregnant women are given health talks while seeking ANC services at the maternal child health clinics. Seventy three percent of the women acknowledge receipt of information on importance of taking iron, folic acid and calcium. Forty six percent of the women had a one to one teaching session. Eighty eight (88%) percent use iron and folic acid while only 25.4% used calcium (KNBS 2020).

Despite expecting a good outcome out of a pregnancy there are possible risks of complications: Preeclampsia is experienced by 3% of the pregnant population; PPH and poor maternal effort are possibly experienced during the second stage, out of which 10% develop hypertensive disorders among all pregnancies. Globally 41.8% of all pregnancies have anemia with iron deficiency leading to a risk of birth asphyxia, LBW, preterm delivery and poor Apgar score (Zatollah, *et al* 2014).

Six to thirty (6-30) % of all births results in a LBW of which a third are small for gestational age (SGA) in settings of maternal undernutrition contributing to intrauterine growth retardation (IUGR). Preterms have organ immaturity unlike SGAs leading to a risk of stillbirths and perinatal/neonatal mortality due to perinatal asphyxia, meconium aspiration, and hypoglycemia. (Yucesoy, *et al* 2014).

Pre-eclampsia is a possible risk to all pregnant women after twenty weeks of gestation and affects 8% of all pregnant women in developing countries. The result is a slow intrauterine fetal growth. Spontaneous abortion is related to low pre-pregnancy weight and leg cramps arising out of low magnesium in the body. The solution is to take a multivitamin-mineral supplement daily during pregnancy till pueperium; magnesium supplements 350mg daily (Zatollah, *et al* 2014).

There is a recommendation by UNICEF on use of a fifteen multiple micronutrients powders (MNPs) to provide diet supplementation among children over six months old (UNICEF 2015). The MNPs will support a global goal of a forty percent reduction in children stunting and a thirty percent reduction in low birth weight alongside a fifty percent increase in exclusive breastfeeding within the first six months of infant life (WHO 2020).

Zinc in pregnancy aids the mother in labor. There is minimal literature on MM and labor duration and outcomes (Yucesoy, *et al* 2014). Prolonged labor predisposes a mother to postpartum hemorrhage (Nyflot *et al* 2017).

2.6.1 Infant health

Considering that of all births, 6-30% results in a LBW of which a third are SGA in settings of maternal undernutrition contributing to IUGR (West, *et al* 2014). Low birth weight and congenital malformations are associated with selenium, zinc, magnesium and Vitamins A, E, B12 and Folic acid deficiencies (Hammouda, *et al* 2013, Marsal, *et al* 1987).

Lack of sufficient breast milk contributes to early infant weaning which increases the risk of infant mortality. There is a lower risk of folate deficiency or depletion at one-month postpartum for those using MM (Zerfu, *et al* 2013). MM contributes to a significant 18% reduction of early infant mortality by reducing the risk of LBW. This gives a long-term outcome of greater infant survival (Salam, *et al* 2014). Impaired fetal growth due to the maternal diet may predispose an infant to heart disease during adulthood. Current research findings shows that there is a relationship between maternal nutrition during pregnancy and disease in adulthood. It has further been proven that deaths from heart diseases are more common in men who had a LBW. Among the newborns, 15 out of 1000 are born with congenital malformations which can be prevented by use of MM (Zatollah, *et al* 2014).

2.6.2 Breastfeeding

Exclusive breastfeeding is important to all newborns. WHO recommends mothers worldwide to exclusively breastfeed their infants for the first six months to achieve optimal growth, development, and health. According to the SDGs, during the World Health Assembly (WHA71), a resolution was issued in 2018 that set a target for 50% exclusive breastfeeding by 2025 (WHO 2018). But this has not been feasible.

Exclusive breastfeeding practice remains at 43% in East Asia Pacific and only 20% in West and Central Africa. UNICEF reports that 1 in 5 babies gets exclusively breastfed upto six months of age. According to WHO and UNICEF, increasing global breastfeeding rates could save upto 800,000 underfive children (Marinelli, et al 2019). The recommendation by WHO is the initiation of breastfeeding within the first one hour of neonate life, to promote exclusive breastfeeding (WHO, 2018; Belachew, A 2019; Smith *et al* 2017; Tewabe, T, 2016; Alzaheb, R A 2017; Alebel *et al* 2017).

Mother's milk contains key nutritional supplements for the newborns. Lipase and amylase promote intestinal health. Omega 3 is important for brain development. Oligosaccharides are prebiotic and protect against intestinal infection. Immunoglobulins protect against infections. Lactoferrins and lysozymes kill pathogens, bacteria, viruses and fungi in the intestines. These are absent in Cow's milk and other foods that substitute breastmilk (Zatollah, *et al* 2014).

2.7 Multiple Micronutrients and pregnancy

Multiple micronutrients during pregnancy is a public health concern and should be upheld as the preventive arm in improving pregnancy outcomes. MM is a combination of multiple micronutrients with additive and synergistic benefit on maternal and child outcomes (Zatollah, *et al* 2014). Micronutrients despite its small amounts, prepare the maternal body for labor, parturition and later demands of lactation. A careful balance is necessary for providing immune surveillance to protect women from infection and maintain maternal health (Hiten, *et al* 2011).

Micronutrients are absolute requirements and only required in very small quantities daily for a healthy pregnancy and good outcomes. Insufficient intake of some nutrients may occur in all countries regardless of the socio-economic situations or diet patterns adopted in these communities. Women do not portray nutritional symptoms but because of increased nutritional needs, food dislikes, morning sickness, and pica for certain foods, is an indication for need of supplementation (Douglas, *et al* 2014).

In previous studies, it has been observed that women with low ferritin levels < 15umg or Hb level < 11g/dl on diet alone cannot restore deficient levels to normal during the pregnancy period. Iron deficiencies are associated with neural tube defects. There is need for Iron supplementation (George 2015). WHO and UNICEF recommend RDA of 15 vitamins and minerals as MM which includes iron (Zatollah, *et al* 2014). MM is a combination of fifteen (15) micronutrients as the daily recommended dose.

A daily supplement of 200ug of iodine during pregnancy and breastfeeding is effective in preventing mental retardation and other lifelong detrimental consequences to a child arising out of maternal iodine deficiency. Reduced intake of Vitamin E, D, and zinc during pregnancy is associated with increased wheezing in children. Zinc prevents intrauterine growth retardation, congenital malformation, low birth weight, and preterm birth. Vitamin A prevents adverse maternal, fetal and neonatal outcomes by improving hemoglobin concentration without which is related to perinatal mortality. Folate is important in the prevention of neural tube defects (Ibid 2014). Calcium supplementation is associated with the prevention of preeclampsia and improves the infant birth weight (Buppasin, *et al* 2011) by halving the risk and occurrence of the composite outcomes i.e. death, serious morbidity (Quinn, *et al* 2020). Vitamin B Complex maintains normal homocysteine levels, Selenium, Copper, Zinc and manganese superoxide dismutases protect the placenta from undue harm leading to the prevention of preeclampsia (West, *et al* 2014).

2.7.1 Multiple micronutrients deficiency

Proper nutrition prior and during pregnancy optimizes maternal neonatal outcomes. The deficiency of trace elements during pregnancy is related to mortality and morbidity of both mother and baby. Reduced intake of micronutrients in pregnancy predisposes women to nutritional deficiency. A pregnant woman's diet is deficient of macro and micronutrients and leads to detrimental effects on the mother and affects the newborn baby. These effects may be short term but in most cases poses a lifelong effect (Keats, *et al* 2022). MM deficiency is associated with; spontaneous abortion, fetal malformation, placental abruption, increased maternal morbidity and LBW babies. About 16% of all live births are LBW and 90% of them are born within the low-income countries (Quinn, *et al* 2020).

MM has been reported to influence the immune system and facilitates a reduction in maternal, placental and fetal inflammation from infection. It further reduces pathological stress, improves maternal placental function, reduces the risk of hypertensive disease, hormonal balance, epigenetic programming that could improve nutrient utilization, embryo-fetal growth and development (Oh, *et al* 2020) MM and the following trace elements are necessary during pregnancy: selenium, copper, zinc, and manganese (George, 2015).

2.7.2 Effects of MM deficiency

2.7.2.1 Selenium deficiency and preeclampsia

The common effects of MM deficiency are fetal growth retardation and preeclampsia etc. Preeclampsia affects 3% of all pregnancies and is the leading cause of maternal mortality and morbidity globally. Preeclampsia contributes to 60,000 maternal deaths yearly (Mistry, *et al* 2011). Table 2.1 illustrates MM deficiencies in pregnancy outcomes on mother and infant (George 2015).

Table 2.1: MM deficiency and related consequences

MM Deficiency	Effects of its deficiency	
	Mother	**Baby**
1. Zinc	Preterm delivery, preeclampsia	Intrauterine growth retardation, Low birth weight Congenital malformation Increased wheezing in childhood Sporadic miscarriage
2. Vitamin A	Anemia, Increased chances of Perinatal mortality	Stillbirth Congenital malformation
3. Iron	Anemia	Neural tube defect
4. Folate – Folic Acid	-	Neural tube defect Congenital malformation
5. Iodine	-	Mental retardation
6. Vitamin E	-	Congenital malformation
7. Vitamin D 8. Calcium	- Preeclampsia Death, Serious morbidity	- Low birth weight
9. Niacin	-	-
10. Magnesium	Preeclampsia	Congenital malformation
11. Vitamin B Complex	Homocysteinaemia	-
12. Vitamin B12	-	Congenital malformation
13. Selenium	- Preeclampsia	Sporadic miscarriage Congenital malformation
14. Copper	- Preeclampsia	Sporadic miscarriage, Low birth weight
15. Manganese Superoxide Dismutase	- Preeclampsia	Sporadic miscarriage

MM deficiency leads to IUGR contributing to increased perinatal mortality and morbidity. Premature deliveries at 33-36 weeks and early pregnancy loss have been associated with reduced selenium amniotic fluid concentration. These women may benefit from the optimization of selenium status which is important in antioxidant defense and maybe a potential factor in women at risk of preeclampsia. Selenium supplementation in pregnancy leads to reduced thyroid inflammatory activity and the incidence of thyroid and counter balances the postpartum immunological rebound. This has been reported in Selenium trials with lower rates of preeclampsia and or pregnancy-induced hypertension in supplemented groups (George 2015).

2.7.2.2 Copper deficiency

Severe copper deficiency can lead to reproductive failure and early embryonic death. Copper is positively correlated with neonatal weight and may have interactive connections in the human placenta (Yucesoy, *et al* 2005).

2.7.2.3 Zinc deficiency

Zinc in pregnancy assists fetal brain development and aids mother during labor. It has been noted that a pregnant woman in 3rd trimester needs zinc twice as much than a non-pregnant woman. Zinc concentrations decline as the pregnancy progresses i.e. 1st trimester 71.3ug/l and 12.9 ug/l in the third trimester. A nutrition analysis has revealed that in pregnant women the daily diet intakes include not more than 50% of the daily requirement of zinc (Yucesoy, *et al* 2005). Late alteration in Zinc homeostasis may have devastating effects on pregnancy outcomes e.g. prolonged labor, fetal growth restrictions and embryonic or fetal death. Pregnant women with zinc supplements had a greater birth weight, head circumference compared to controls. Zinc deficiency is associated with preeclampsia (Yucesoy, *et al* 2005).

2.7.2.4 Manganese

Manganese was reported to be low in women with growth restrictions compared to healthy controls. Manganese is important in maintaining fetal growth. There has been low manganese in preeclamptic mothers (George 2015).

2.7.2.5 Vitamin C and E

Deficiency of Vitamin C and E leads to increased risk of fetal loss or perinatal death, pre-labor and rupture of membranes. Low micronutrients pose a health risk to a successful pregnancy (George 2015).

2.8 Conceptual Framework

The key variables guiding the study are outlined in figure 2.1.

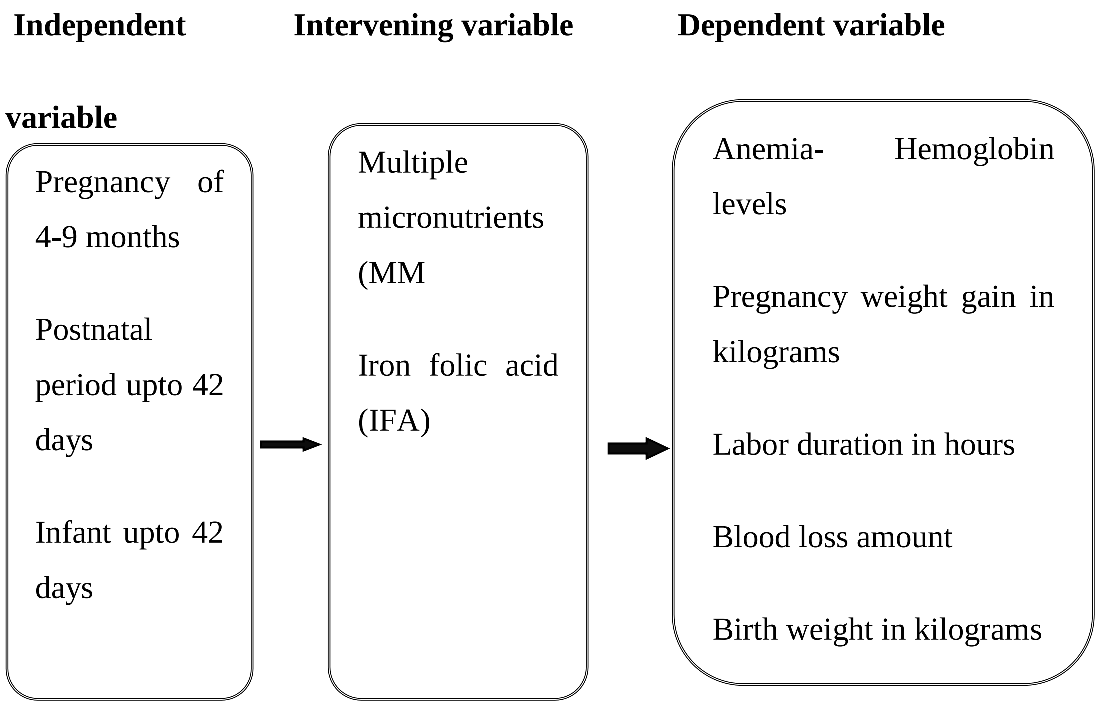

Figure 2.1: Conceptual framework

CHAPTER THREE

METHODOLOGY

3.1 Study design

A cluster randomized controlled study was adopted (King *et al* 2021). The clusters, in this study the tea estates, were randomized to either receive multiple micronutrients or the iron folic acid.

3.2 Study site

Based on the stunting report, Rift valley is the third highest region with stunting. Nandi County, the sixth county overall with stunting was therefore selected using non probabilistic technique's convenience sampling over the regions with marked stunting. Nandi County was conveniently selected to overcome time limitation by opting for ease of access versus West Pokot and Kitui (Taherdoost H, 2016).

Overall stunting rate in Kenya is 26%. Stunting is an indicator of malnutrition, based on the Kenya Demograhic Health Survey (KDHS 2014); the leading counties reported to have stunting; West Pokot 46%, Kitui 46%, Kilifi 39%, Mandera 36%, Bomet 36% and Nandi 30%. However, the stunting report by regions in descending order are; Coast 30.8%, Eastern 30.1%, Rift valley 29.8%, Western 25.2%, North Eastern 24.7%, Nyanza 22.7%, Central 18.4% and Nairobi 17.2% (KNBS 2014).

The study was carried out in Eastern Produce Kenya Ltd (EPK) and Nandi Tea Company within Nandi County (*Appendix 4B*) being the largest tea companies in Nandi County. They are situated approximately 350kms North West of Nairobi, Kenya's capital. Each Tea company is divided into tea estates and each estate is further subdivided into residential villages. Each village has an average of 48 two roomed houses. Each house has an open kitchen inside and accomodates two families with an average of 5 family members. Each estate has a dispensary offering Primary care services to all their workers.

Nandi Tea Company has three estates; Taito, Mokong and Kapsumbeiywo. EPK owns ten estates: Sokot, Chemomi, Kepchomo, Kipkoimet, Kamarya, Sitoi, Savani, Siret, Kibwari and Tinderet. EPK has a total of 103 villages with over 5000 houses. The Kapsumbeiywo, Kipkoimet, Kipkeibon, Kibwari, Savani, Sitoi, Chemoni, and Kepchomo estates were included in the the study after randomization. All women due for delivery from the Estates were referred to Nandi Hills County Hospitals in respect to their choice i.e. Nandi Hills County Hospital, Kaptumo Sub-County Hospital, St. Franscisca Hospital Kapsabet and Kapsabet County Referral Hospital.

3.3 Study populations

i. Criteria for inclusion of subjects

- Women who were pregnant
- Women with more than three months (16 weeks) pregnancy. They were followed up on enrollment to 42 days (postpartum) post-delivery
- Women who consented to the study

ii. Criteria for exclusion of subjects

- Women who did not to consent to the study and those with mental challenges.

3.4 Sample size determination

The following formula was employed to determine the sample size for the treatment and control groups:

$$n = \frac{2SD^2\,(Z\beta + Z\alpha/2)^2}{(Difference)^2}$$

(Fleiss, J, L, 1981)

Where

- n = sample size in each group (assumes equal-sized groups)
- SD = Standard deviation of the outcome variable
- Z_α = Represents the desired level of statistical significance i.e. 1.96

- Z_β = Represents the desired power i.e. 0.84 for 80%
- Difference = Effect size, the difference in means

To determine the sample in each group

- SD = 0.4
- Z_α = 1.96
- Z_β = 0.84 for 80%
- Difference in mean birth weights = 3.3 kgs-3.1kgs = 0.2 kgs (Zatollah, *et al* 2014)

The key variables in the proposed study were: labor and delivery (2nd stage) duration. Since no study had handled this variables, therefore using the study by (Zatollah, *et al* 2014 as a reference, birth weight was adopted as a key variable in calculating the sample size (Zatollah, *et al* 2014)

Therefore;

$$n = \frac{2(0.4)^2(0.84 + 1.96)^2}{0.2^2}$$

n=2.5088/0.04 = 63 minimum sample size

n= 63 + 6.3 (10%)= 69.3

10% was added to take care of loss to follow up (Serdar, *et al* 2021).

n= therefore a minimum of seventy (70) study participants were adopted in each group, inclusive of an additional 10% of the minimum sample size.

3.4.1 Sampling procedure and randomization

Based on the Kenya Demograhic Health Survey (KDHS 2014); the leading counties reported to have stunting; West Pokot 46%, Kitui 46%, Kilifi 39%, Mandera 36%, Bomet 36% and Nandi 30%. However, the stunting report by regions in descending order are; Coast 30.8%, Eastern 30.1%, Rift valley 29.8%, Western 25.2%, North Eastern 24.7%, Nyanza 22.7%, Central 18.4% and Nairobi 17.2% (KNBS 2014).

Using the non probabilistic technique, convenience sampling was applied in selecting the Nandi County due to time limitation as the study site for ease of access despite it being the sixth overall counting with stunting (Taherdoost 2016).

Thereafter, probability sampling technique, was employed using stratified random sampling method. Four tea estates were grouped together into stratas and adopted as clusters. Cluster one: Chemomi, Sitoi, Kibwari, Savani; Cluster two: Kepchomo, Kipkeibon, Kipkoimet, Kapsumbeiywo, Cluster three: Kibabet, Nandi, Mokong and Taito. The Estates grouped as stratas were thereafter, subjected to randomization. The outcome was then the study clusters.

The three clusters of four (stratas) estates each were all placed in an opaque envelope and the nurse incharge, at the Nandi Tea Doctors Scheme Association Head office was requested to pick blindly and place each cluster randomly against a paper written either control, neutral or intervention respectively. The clusters placed against control and intervention were adopted into the study.

Cluster random sampling method was lastly employed in the study to sample all the study participants in the village. All pregnant women in each cluster who met the study inclusion criteria were included in the study.

The women in the intervention cluster were given multiple micronutrient (MM) supplements and the women in the control cluster were given Iron Folic Acid (IFA) supplements respectively. The study undertook to establish the difference in pregnancy outcomes after use of multiple micronutrients versus the usual standard care of IFA among pregnant women in Nandi County. The vitamins were administered to the women in the intervention and control blocks and followed up to observe their impact on pregnancy, delivery, postnatal and infant health upto forty two days post-delivery.

In figure 3.1, the neutral block was not included in the study group. Pregnant women with a gestation of 16 weeks or more were eligible to be enrolled in the study. They were identified by Field Educators based on their residential clusters. Pregnancy medical records were also verified at the Dispensary using their maternal child health cards and Clinic registers between Monday to Friday. Thereafter a visit was conducted by the researcher to the cluster villages. MM was administered to the women in the intervention cluster and IFA for the control cluster within their respective homes. The MM or IFA was taken daily up to six weeks (42 days) post-delivery.

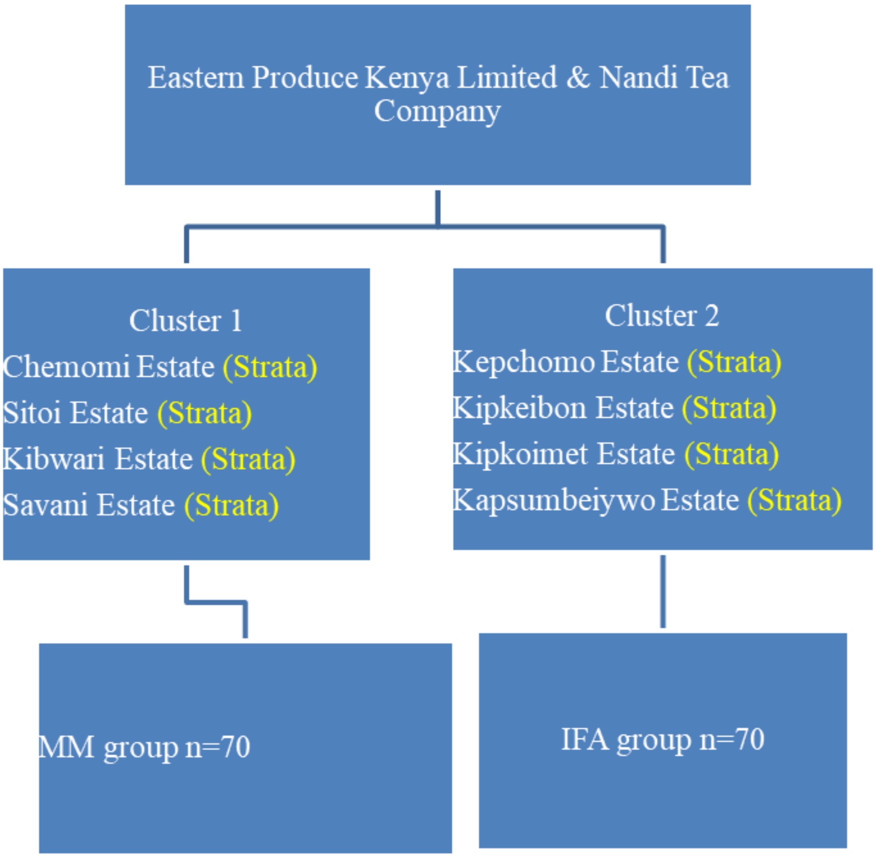

Figure 3.1: Randomization clusters

3.5 Data Collection

i. . Baseline data was collected on enrollment for treatment and control group at the initiation of the study to include; ANC profile, pica behavior, weight, height, BP and current complaints being experienced i.e. weakness, dizziness, etc. The client's delivery file was analyzed to abstract data. The data collected on delivery included: duration of labor and the second stage and puerperium. The baby's Apgar score, sex and weight were also recorded. Data was collected from all the study participants at 6 weeks (42 days) postnatally to assess; infant outcome i.e. weight, head circumference, milestones, breastfeeding patterns.

ii. The treatment group was administered with a daily capsule containing multiple micronutrients from 16 weeks of pregnancy to 6 weeks (42 days) post-delivery (*Table 3.1*), within a heavy meal. The control group was given the standard iron folic acid (IFA) from pregnancy to 6 weeks (42 days) post-delivery.

Table 3.1: Multiple micronutrient supplements factsheet per capsule

Vitamin	Vitamin name	Daily values	Percent of daily values
1. Vitamin A	Retinyl palmitate	2675 IU	33%
2. Vitamin C	Calcium ascorbate	55mg	92%
3. Vitamin D	Cholecalciferol	200IU	50%
4. Vitamin E	Di-alpha tocopheryl acetate	22.5IU	75%
5. Vitamin B1	Thiamin hydrochloride	1.4mg	82%
6. Vitamin B2	Riboflavin	1.4mg	70%
7. Vitamin B6	Pyridoxine Hydrochloride	1.9mg	76%
8. Vitamin B12	Cyanocobalamin	2.6mcg	33%
9. Niacin	Niacinomide	18mcg	90%
10. Folic Acid	Folic acid	600mg	75%
11. Iron	Iron sulfate	27mg	150%
12. Iodine	Potassium Iodide	250mcg	167%
13. Zinc	Zinc Oxide	10mg	67%
14. Selenium	Sodium Selenite	0.30mcg	Not established
15. Copper	Copper Oxide	1.15mg	58%

iii. There were both quantitative and qualitative data in this study. Quantitative data was collected using a structured interviewer administered questionnaire. (Appendix 1B) Qualitative data was collected during the focus group discussions using an interview guide. (Appendix 1D). Twelve women were enrolled in each of the two focus groups based on MM or IFA (Table 3.2).

The main purpose of the focus group was to bring a deeper understanding on the use of MM and IFA that may have been missed out in the questionnaire. The interview was tape-recorded and later transcribed. Thematic evaluation (Thomas et al 2008) was employed to bring out key themes surrounding pregnancy and MM. Data analysis was conducted for the continuous variables; weight, height and BP. Ordinal data analyzed for categorical variables during 2nd (4-6 months gestation) and 3rd trimester. Data was collected at four points during pregnancy, labor, delivery and at 42 days (6 weeks) postnatally.

Table 3.2: Study participants (pregnant women) enrolled

Month	Treatment group-MM		Control – IFA	
	Proposed	Actual	Proposed	Actual
July 2017	15	20	15	25
August 2017	15	15	15	15
September 2017	15	16	15	15
October 2017	15	15	15	10
November 2017	15	4	15	10
Total	**75**	**70**	**75**	**70**

iv. Pilot study was undertaken for data verification and validation in the field (Thabane et al 2017). A pilot study was carried out on 10% of the sample size to verify the data collection questionnaire at the Kaptumo Health center (currently Sub-County Hospital). Five percent of the interviewees were re-interviewed to ascertain the data validity before forwarding the data for cleaning and entry. SPSS version 25 was used for data analysis.

3.6 Study measures

The study was guided by the following measures:

i. Birth weight was measured in grams and weight of:< =2500g is low birth weight and 2500g-4000g is normal birth weight. Baby's weight was measured at birth and later at six weeks manually using a weighing scale. A baby was expected to gain 150 to 210g weekly, height by 2.5cm monthly and head circumference by 1.5cm monthly for the first 6 months.

ii. Hemoglobin levels 12-16 g/dl range was considered to be normal. Below or above the range was considered abnormal. Hb level was measured using a procured Hemocue machine: on enrollment, in the third trimester and at 42 days postpartum. A peripheral blood film was collected using a needle prick on the index finger.

iii. Pregnancy weight gain was measured in kilograms: on enrollment and in the second and third trimester.

iv. Labor duration was assessed from the onset of labor pains with dilatation of the cervix to the delivery of the baby (second stage of labor) placenta (third stage of labor).

v. Breast milk feeding was assessed based on exclusive breast milk or inclusive of other food substitution i.e. early weaning. The date of early weaning in days was considered and recorded including the reasons for early weaning.

vi. Postpartum blood and lochia loss amount and duration was measured during delivery and puerperium period against the standard guideline measures of low, mild or heavy. (Anger, *et al* 2019, Diaz, *et al* 2018)

3.7 Data analysis

Data analysis followed three key steps. First testing and control of confounding in maternal neonatal outcomes through bivariate analysis. Adjusted odds ratios were calculated amongst the outcome variables to control for confounding in the study using the Cochran and Mantel Haenzel formula (Cochran W G 1954 & Mantel *et al* 1959).

The potential confounding factors in the study were: age, education level versus the labor duration, blood loss during delivery, lochia loss duration, breastmilk availability versus substitution. The data was stratified against two levels of confounding factors.

The data was stratified into dichotomous outcome variables and risk factors. Age and education level stratified analysis was carried out against the outcomes of interest. A series of two by two tables showing the dichotomous outcomes were created and crude odds ratios were calculated. Thereafter, the age and education level stratification tables were created before calculating the weighted average which is the adjusted odds ratios across the data strata showing the levels of confounders.

The Cochran-Mantel-Haenzel estimate using a standard contingency table was applied in calculating the adjusted odds ratio and confounding effect in the outcomes of interest: labor duration, blood loss during delivery, lochia loss duration, breastmilk availability and substitution versus the age and education level stratification.

The Cochran-Mantel-Haenzel estimate formula was applied.

$$\hat{O}R_{CMH} = \frac{\sum \frac{a_i d_i}{n_i}}{\sum \frac{b_i c_i}{n_i}}$$

(Cochran et al 1954, Mantel et al 1959)

Data was stratified using age and education levels. Age stratified analysis was conducted by having those below twenty-five years in a stratum and above twenty-five years in a different stratum. Data analysis was conducted based on their risk factor versus the outcome variable respectively.

Education level were based on one having either primary education or secondary education as the highest level. Primary education level analysis was analyzed based on its stratums as well as the secondary education respectively.

Secondly, bivariate analysis was conducted between multiple micronutrients and iron-folic acid on hemoglobin levels, pregnancy weight gain, labor and birth duration, postpartum blood and lochia loss, breastmilk availability and women's perceptions on their health.

Finally independent t-test was conducted between the multiple micronutrients and iron-folic acid groups respectively to compare the means for any significance concluding with measuring of effect and testing of the null hypothesis.

Descriptive statistics was undertaken on the demographic data; age, occupation, marital status, education level, and antenatal visits frequency. Bivariate analysis was also applied to establish the association between multiple micronutrients on hemoglobin, pregnancy weight gain, hemoglobin levels, labor and birth duration,post partum blood and lochia loss. Results were presented using Person Chi square test, Wilcoxon sign test and Ancova test. Data was analyzed and presented in tables and graphs.

Inferential statistics were applied to quantitative variables to answer objective one by establishing the effect of MM and IFA on prevalence of anemia during pregnancy.

Data analyses to answer objective two, three, four and five were conducted to establish variations on the outcome variables; pregnancy weight gain, labor and birth duration, postpartum blood and lochia loss and breastfeeding availability among the MM and IFA groups. Multivariate analysis was also conducted to establish the association between multiple micronutrients and outcome variables. Adjusting for any possible confounding variables was conducted using age and education level stratification.

Inferential statistics were applied by calculating the Levene's test of equal variance assumption through the independent t-test to establish whether the difference in outcome variable means being observed was by chance alone or as a result of the manipulation by multiple micronutrients or iron folic acid.

Hypothesis testing was conducted using general linear modelling and effect size measurements were conducted using the four significant test established during the general linear modelling: Pillai’s Trace, Wilks’ Lambda, Hotelling’s Trace, Roy’s Largest Root and confirmed using Partial Eta squared. Significance level was $p=0.05$.

All analyses was conducted using SPSS version 25 (IBM, 2017). A significance level of less than $p<0.05$, was considered to be significant and concluded that the difference observed was due to the manipulation of the treatment arm; multiple micronutrients in the study.

Data analysis to answer objective six on perceptions of women on their health and use of multivitamins were conducted by employing the qualitative data collected during the focus group discussions. One focus group was conducted in the control and intervention clusters respectively. The data was collected using handwritten notes and a voice recorder. After which, the information in the voice recorder was transcribed and compared with the handwritten notes from the two focus groups to ensure no detail was omitted. Thematic analysis was conducted to derive common themes in using multiple micronutrients versus iron-folic acid between the groups (Thomas *et al* 2008).

3.7.1 Data Storage

The filled case report forms are locked in a metal cabinet pre and post data analysis.

3.8 Result dissemination

The study results have been disseminated through two publications: based on two objectives and study results in a local and international peer-reviewed journal; World Journal of Public Health and Central African Journal of Public Health. The results have been disseminated in the scientific conferences both locally: the 11th JKUAT Scientific Conference in November 2017 and internationally: Bethesda, Maryland USA, NIH grant conference in May 2017.

3.9 Ethical considerations

The study was implemented after ethical approval number: 0001618, was granted from the Moi University/MTRH Institutional Research and Ethics Committee (IREC), Eldoret and approval of the study topic by the Board of Postgraduate Studies of Jomo Kenyatta University of Agriculture and Technology (JKUAT). Permission to implement the study within the Tea Estates was sought from the Chief Executive Officer of the entire Eastern Produce Tea Estates, then the Doctor in charge of the

Nandi Hills Doctors Scheme Association. Eastern Produce Tea Estates is housed within the Nandi County in Kenya. The study carried no more than minimal risks. The possible side effects experienced in earlier studies include GIT irritation when taken without food. Pain due to needle prick when evaluating the hemoglobin levels. Autonomy was applied to ensure each pregnant woman, had an equal chance of being recruited to the treatment or control group. Informed consent by study participants was used to ensure voluntary enrollment into the study. The study participants' consent was recorded in this form. *(Appendix 1A, 1B, 1C, 1D*).

CHAPTER FOUR

RESULTS

4.1 Sociodemographic characterisitics of the women

One hundred and forty participants were enrolled in the study. The average age was 25.7 (SD: 6.0) years with a minimum and a maximum of 15.0 and 38.0 years respectively.

Table 4.1: Socio Demographic Characteristics of women, Nandi County, Kenya (2018)

Variable	N	Mean (SD) or n (%)
Age (Years), Mean (SD)	140	25.7 (6.0)
Range (Min. – Max.)		15.0 – 38.0
Gestational age (Weeks), Mean (SD)	140	23.8 (8.0)
Range (Min. – Max.)		16.0 – 42.0
Reported sickness during pregnancy, n (%)		
No	140	99 (70.6)
Yes		41 (29.4)
Number of children, n (%)		
0		21 (15.0)
1 – 2	140	80 (57.1)
> 2		39 (27.9)
Level of education, n (%)		
Primary		88 (63.0)
Secondary	140	47 (33.3)
Tertiary		5 (3.7)
Marital status, n (%)		
Single		23 (16.7)
Married	140	117 (83.3)
Occupation, n (%)		
Not employed		47 (33.6)
Self employed	140	6 (4.2)
Employed		87 (62.2)
Tea plucker		75 (53.7)
Kilograms of tea plucked, Mean (SD)	75	27.6 (11.6)
Range (Min. – Max.)		10.0 – 60.0
Hours worked plucking tea, Mean (SD)	75	8.5 (0.8)
Range (Min. – Max.)		7.0 – 10.0

The mean gestational age at the time of enrollment was 23.8 (SD: 8.0) weeks with a minimum and a maximum of 16.0 and 40.0 weeks respectively. Forty-one participants, 29.4%, reported sicknesses during the pregnancy.Forty-three percent of the participants were nulliparous, and 15.0% reported that they had no children.Sixty-three percent of the participants had primary level of education and 3.7% had tertiary level of education.Eighty-three percent of the participants were married.The sample constituted 53.9% tea plucking women who worked for an average of 8.5 (SD: 0.8) hours per day plucking an average of 27.6 (SD: 11.6) kilograms of green tea leaves with a range of 10.0 to 60.0 kilograms.

4.2 Women clinical findings and presentation

The weight gained during pregnancy, hemoglobin levels during pregnancy, blood pressure levels, syphyllis test and complaints presented by the pregnant woman shall guide the clinical findings and presentation. Table 4.2 further illustrates these findings.

Table 4.2: Women's Clinical Characteristics, Nandi County, Kenya(2018)

Variable	N	Mean (SD) or Median (IQR) or n (%)
Weight in the second trimester (Kg), Median (IQR)	140	60.0 (56.0, 65.0)
Range (Min. – Max.)		41.0 – 80.0
Weight in third trimester (Kg), Median (IQR)	140	63.1 (60.0, 68.0)
Range (Min. – Max.)		47.0 – 90.0
HB levels in second trimester (g/dL), Median (IQR)	140	11.2 (10.7, 11.8)
Range (Min. – Max.)		7.4 – 15.2
Anemic during the second trimester, n (%)		
No	140	82 (58.6)
Yes		58 (41.4)
HB in third trimester (g/dL), Median (IQR)	140	11.6 (10.8, 12.2)
Range (Min. – Max.)		8.9 – 14.0
Anemic during the third trimester, n (%)		
No	140	102 (72.9)
Yes		38 (27.1)
Syphilis test, n (%)		
Reactive	140	11 (8.0)
Non-reactive		129 (92.0)
Blood pressure levels, n (%)		
Low <90/60mmhg		5 (3.9)
Normal <120/80mmhg	140	121 (86.3)
High 120-129/80mmhg		14 (9.8)
Complaints on enrollment n (%)		
None		9 (6.4)
Nausea		27 (19.6)
Vomiting	140	25 (17.9)
Dizziness		67 (47.6)
Fatigue		3 (2.1)
Other		9 (6.4)

NB: IQR – interquartile range, HB – hemoglobin levels

The median weight for the participants during the second trimester was 60.0 (IQR: 56.0, 65.0) kilograms with a range of 41.0 to 80.0 kilograms. During the third trimester the participants had added weight to a median of 63.1 (IQR: 60.0, 68.0) kilograms with the lowest being 47.0 kilograms and the highest being 90.0 kilograms.The median hemoglobin (HB) levels during the second trimester was 11.2 (IQR: 10.7, 11.8) g/dL with the lowest and the highest Hgb being 7.4 g/dL and 15.2 g/dL respectively. During this period, 41.4% of the participants were anemic. During the third trimester the HB levels had improved to a median of 11.6 (IQR: 10.8, 12.2) g/dL with the minimum and the maximum of 8.9 g/dL and 14.0 g/dL. During the third trimester, 27.1% of the participants were anemic.One fifth of the participants reported complaints of nausea, 19.6% reported about vomiting, and 47.6% reported experiencing dizziness.

Table 4.3: Pica and food preference among pregnant women

Variable	N	n (%)
Pica, n (%)		
No		34 (24.1)
Yes	140	106 (75.9)
Preference for pica, n (%)		
Stones		103 (73.5)
Charcoal	140	20 (14.3)
Gas smelling		3 (2.4)
Others		14 (9.8)
Food preference, n (%)		
All (Carbohydrates, Proteins, Vitamins)		8 (5.8)
Carbohydrates		30 (21.4)
Carbohydrates & proteins		16 (11.4)
Carbohydrates & vegetables		3 (2.1)
Carbohydrates & fruits	140	3 (2.1)
Proteins		16 (11.4)
Fruits		40 (28.5)
Vegetables		11 (7.9)
Vegetables and fruits		5 (3.6)
Carbonated drinks		8 (5.8)
Complaints during pregnancy, n (%)		
None		105(75.0)
Fatigue		3 (2.1)
GBM		14 (10.0)
Heartburn	140	6 (4.3)
Hypertension		3 (2.1)
Malaise		3 (2.1)
Mood swings		3 (2.1)
Pain in the right thigh		3 (2.1)

Three quarters of the participants reported pica, (75.9%). Of this number, 73.5%, 14.3%, 2.4% and 9.8% preferred stones, charcoal, gas and others respectively.Up to 37.0%, 22.8%, 11.5%, 32.1% of the participants had preference for carbohydrates, proteins, vegetables, and fruits respectively. There were 8 (5.8%) who had preference for a soft drink (soda). Only 5.8% of the participants were eating all the foods.

During pregnancy, 35 (25.0%) of the participants reported pregnancy related complaints.

4.3 Antenatal visits

The month at which every pregnant woman initiatied the antenatal visits was recorded including the frequency of these visits and the place where the services were sought to determine whether this was skilled or unskilled. Table 4.4 further elaborates these findings.

Table 4.4: Antenatal Characteristics

Variable	N	n (%)
Gestational age at first antenatal care clinic, n (%)		
3 Months		27 (19.3)
4 months		47 (33.6)
5 Months	140	37 (26.4)
6 Months		16 (11.4)
7 Months		8 (5.7)
8 Months		5 (3.6)
Number of ANC visits, n (%)		
Once		5 (3.6)
Twice	140	24 (17.1)
Thrice		50 (35.7)
Quadruple		61 (43.6)
Place of ANC, n (%)		
Dispensary		113 (80.7)
Health Centre	140	19 (13.6)
Hospital		8 (5.7)

Up to 19.3% of the participants started visiting antenatal care clinic at the first trimester and by the second trimester 90.7% had made at least a visit to the ANC clinic. Among the participants who attended ANC, 79.3% made at least three antenatal care clinic visits with 80.7% attending clinic visits in the dispensaries.

4.4 Women delivery outcomes

Place of onset of labor, delivery place, presence of a companion during delivery and postpartum hemorrhage amounts are key delivery measures. Table 4.5 illustrates these findings.

Table 4.5: Delivery Characteristics

Variable	N	Median (IQR) or n (%)
Place of onset of labor, n (%)		
Home		107 (76.9)
Work place	140	27 (19.2)
Market		3 (1.9)
Dispensary/Health Centre		3 (1.9)
Duration of labor (Hours), Median (IQR)	140	8.0 (6.0, 16.0)
Range (Min. – Max.)		2.0 – 48.0
Duration of second stage of labor (Minutes), Median (IQR)	140	15.0 (10.0, 30.0)
Range (Min. – Max.)		1.0 – 180.0
Place of delivery, n (%)		
Home with help		3 (1.9)
Home alone		3 (1.9)
Home with TBA	140	13 (9.3)
On the way to TBA		3 (1.9)
Hospital		118 (85.2)
Presence of companion, n (%)		
No		10 (7.4)
Yes	140	130 (92.6)
Postpartum blood loss, n (%)		
Light		61 (43.5)
Mild	140	33 (23.9)
Heavy		46 (32.6)

Note- TBA- Traditional Birth Attendant

For 76.9% of the participants' onset of labor began at home with labor median duration of 8.0 (IQR: 6.0, 16.0) hours. Shortest labor was 2 hours. Median second stage of labor was a duration of 15.0 (IQR: 10.0, 30.0) minutes.Eighty-five percent of the participants delivered at the hospital, 13.1% delivered at home; three in the presence of a helper; another three on their own, and 13 (9.3%) with the help of a traditional birth attendant. Three women delivered on their way to the traditional birth attendant. One hundred and thirty (92.6%) of the participants had a companion in the delivery room. Heavy blood loss was reported for 32.6% of the participants who delivered.

4.5 Infant outcomes

The key infant outcome measures are: presence of congenital malformations, Apgar score at birth, infant gender, and baby outcome after forty two days post delivery. Table 4.6 further illustrates the infant outcome findings.

Table 4.6: Infant outcomes

Variable	**N**	**Median (IQR) or n (%)**
Birth outcome at birth		
Alive	140	140 (100.0)
Presence of congenital malformation, n(%)		
No		140 (100.0)
Yes	140	0 (0.0)
Apgar score at 1 minute, n (%)		
Abnormal (<4)		56 (40.0)
Near normal (4-6)	140	12 (8.9)
Normal (>6)		72 (51.1)
Apgar score at 5 minutes, n (%)		
Near normal (4-6)		53 (37.8)
Normal (>6)	140	87 (62.2)
Apgar score at 10 minutes, n (%)		
Normal (>6)	140	140 (100.0)
Birthweight (kilograms), Median (IQR)	140	3.2 (3.0, 3.6)
Range (Min. – Max.)		2.2 – 6.6
Baby's sex, n (%)		
Female	140	80 (56.9)
Male		60 (43.1)
Breastfeeding done, n (%)		
No	140	26 (18.5)
Yes		114 (81.5)
Breast milk availability (Minutes), n (%)		
≤ 10		5 (3.8)
11 – 20		16(11.3)
21 – 30	140	50 (35.9)
31 – 40		11 (7.6)
41 – 50		5 (3.8)
> 51		53 (37.7)
Breast milk amount, n (%)		
Sufficient	140	109 (78.0)
Insufficient		31 (22.0)
Breast milk substitution, n (%)		
No		126 (89.8)
Yes	140	14(10.2)
Baby outcome at 42 days, n (%)		

Alive	140	137 (98.1)
Died		3 (1.9)
Baby milestones at 42 days, n (%)		
Follows objects		4 (2.9)
Grasping		25 (17.7)
Head control		4 (2.9)
Neck control and support	140	8 (5.8)
Sitting		4 (2.9)
Social smile		95 (67.7)

All the children were alive at birth without any malformation. Based on Apgar score at 1 minute 51.1% of the children were normal, based on the 5 minutes Apgar score 62.2% of the children were normal. Assessment of the children at 10 minutes revealed that all the children were normal based on the Apgar scale.

The median birth weight was 3.2 (IQR: 3.0, 3.6) kilograms with the lowest and the highest being 2.2 and 6.6 kilograms respectively.Forty-three percent of the children born were boys. Up to 81.5% of the children were breastfed and the availability of breastmilk was most frequent between 11 and 30 minutes at (47.2%). Breast milk was available for 37.7% of the children after 50 minutes.

Breast milk was insufficient for 22.0% of the children and 10.2% of the children had milk substitution. At 42 days, 1 (1.9%) of the children had died. The babies' milestones at 42 days indicate that 17.7% of the children could grasp items when given to them, and 67.7% expressed a social smile.

4.6 Maternal postpartum outcomes

Maternal clinical presentations post delivery is a key indicator on her health, including postpartum blood and lochia loss. These will determine the woman's overall postnatal health either to be stable or not. Table 4.7 gives more details.

Table 4.7: Maternal postpartum health outcomes

Variable	N	Median (IQR) or n (%)
Mother's condition after delivery, n (%)		
Normal/Good		105 (75.5)
Near normal	140	24 (17.0)
Abnormal/Bad		11 (7.6)
Lochia loss amount, n (%)		
Light		71 (50.9)
Mild	140	37 (26.4)
Heavy		32 (22.6)
Lochia loss duration, n (%)		
1 – 2 weeks		17 (12.2)
3 – 4 weeks		69 (49.0)
5 – 6 weeks	140	23 (16.3)
> 6 weeks		31 (22.5)
Mother's HB after delivery, n (%)		
Low		3 (2.0)
Normal	140	123 (88.0)
High		14(10.0)
Mother's overall postnatal health, n (%)		
Stable		122 (87.2)
Unstable	140	18 (12.8)
Any complain, n (%)		
Bleeding		32 (23.1)
General body weakness		11 (7.7)
Headache	140	75 (53.9)
Headache/Backache		11 (7.7)
Weakness/Pale		11 (7.7)
Days to resumption of tea plucking, Median (IQR)	75	46.5 (30.0, 90.0)
Range (Min. – Max.)		6.0 – 270.0
Days to resumption of house chores, Median (IQR)	140	37.0 (26.0, 39.0)
Range (Min. – Max.)		15.0 – 42.0

Assessment of the mother after delivery showed that 75.5% of them were in good condition.Forty-nine percent of the mothers had mild to heavy lochia loss, and 38.8% of the mothers had lochia loss that lasted beyond a month.The mothers' HB was normal for 88.0% but low for 2.0%. Up to 87.2% of the mothers were reported to be stable. Of those who reported complaints, 23.1% reported bleeding and 53.9% reported headache. General body weakness, and weakness or pale skin were each reported by 7.7% of the mothers.It took a median of 46.5 (IQR: 30.0, 90.0) days for mothers to resume tea plucking with an extreme minimum of 6.0 days and a maximum of 270.0 days. Mothers also took a median duration of 37.0 (IQR: 26.0, 39.0) days to resume the house chores.

4.7 Women and infant sociodemographic findings per treatment group

Table 4.8 compares the socio-demographic characteristics of the participants who were enrolled in the multiple micronutrient supplement groups to those who were enrolled in the iron folic acid supplement group. The key measures are: age, marital status, parity, education level and occupation.

Table 4.8: Comparison of socio-demographic characteristics by the treatment groups

		Groups		
		MM (n=70)	IF (n=70)	
Variable	**N**	**Mean (SD) or n (%)**	**Mean (SD) or n (%)**	**P-value**
Age (Years), Mean (SD)	140	24.6 (6.1)	26.3 (6.0)	0.335[t]
Gestational age (Weeks), Mean (SD)	140	25.5 (8.0)	21.8 (7.9)	0.160[t]
Reported sickness during pregnancy, n (%)				
No	140	42 (60.0%)	55 (79.0%)	
Yes		28 (40.0%)	15 (21.0%)	0.229[c]
Parity, n (%)				
0		26 (36.8%)	35 (50.0%)	
1	140	22 (31.6%)	0 (0.0%)	0.033[c]
> 1		22 (31.6%)	35 (50.0%)	
Number of children, n (%)				
0		9 (13.3%)	11 (16.0%)	
1 – 2	140	47 (66.7%)	36 (52.0%)	0.642[c]
> 2		15 (21.0%)	23 (32.0%)	
Level of education, n (%)				
Primary		51 (72.7%)	39 (56.2%)	
Secondary/ Tertiary	140	19 (27.3%)	31 (43.8%)	0.218[c]
Marital status, n (%)				
Single		10 (13.6%)	13 (18.8%)	
Married	140	60 (86.4%)	57 (81.2%)	0.620[c]
Occupation, n (%)				
Tea plucker	140	40 (57.1%)	35 (51.6%)	
Others		30 (42.9%)	34 (48.4%)	0.695[c]
Kilograms of tea plucked, Mean (SD)	75	31.7 (14.0)	24.5 (8.6)	0.106[t]
Hours worked plucking tea, Mean (SD)	75	8.1 (0.7)	8.8 (0.9)	0.026[t]

[c] Pearson's Chi Square test, [t] Independent samples t-test, P-value-significance level

The average age of the participants who were enrolled in the MM supplement group was 24.6 (SD: 6.1) years compared to 26.3 (SD: 6.0) years among the IFA supplement group. However, there was no sufficient evidence from the data to show a difference between the two groups (p = 0.335). The average gestational age of the participants who were enrolled in the multiple micronutrient supplement group was 25.5 (SD: 8.0) weeks while the average gestational age among the participants who were enrolled in the iron folic acid supplement group was 21.8 (SD: 7.9) weeks. There was however, no sufficient evidence from the data to show a difference between the two groups (p = 0.160).

The proportion of participants who reported sickness during the pregnancy was 40.0% among the participants in the multiple micronutrient supplement group and 21.0% among the participants who were enrolled in the iron folic acid supplement group. The difference was however not statistically significant, p = 0.229.

The proportion of participants who reported to be nulliparous, uniparous and multiparous in the multiple micronutrient supplement group were 36.8%, 31.6%, and 31.6% respectively while in the iron folic supplement group the proportion of participants who reported they were nulliparous, uniparous and multiparous were 50.0%, 0.0%, and 50.0% respectively. The test for association showed that parity was not balanced across the two groups (p = 0.033).

Similarly, the data show that the proportion of participants without a child, with 1-2 children and with more than two children were 13.3%, 66.7%, and 21.0% respectively while in the iron folic supplement group the proportion of participants without a child, with 1-2 children and with more than two children were 16.0%, 52.0%, and 32.0% respectively. There was no evidence of a difference in the distribution of the number of children of the participants across the two groups (p = 0.642).

Compared to participants who enrolled in the multiple micronutrient supplement group, a lower proportion of those who enrolled in the iron folic acid supplement group had secondary or higher level of education, 27.3% vs. 43.8%. However, the difference was not statistically significant (p=0.218).

The proportion of married participants were similar in the two groups, 86.4% vs. 81.2%, p = 0.620.

The proportion of participants who had their occupation as tea plucking was 57.1% among those who were enrolled in the multiple micronutrient supplement group and

51.6% among those who were enrolled in the iron folic supplement group. The difference between the two groups was however, not statistically significant, p = 0.695.

The tea average kilograms the participants were plucking, was similar for the two groups, 31.7 (SD: 14.0) vs. 24.5 (SD: 8.6) kilograms, p = 0.106. However, there was evidence from the data that the participants who were enrolled in the iron folic supplement group worked for a longer duration compared to those who were enrolled in the multiple micronutrient supplement group, 8.8 (SD: 0.9) vs. 8.1 (0.7) hours, p = 0.026.

4.8 Women's clinical findings and presentations per treatment groups.

In Table 4.9, the clinical characteristics including weight, hemoglobin (HB), VDRL test results, and blood pressure status were compared between the participants who were enrolled in the multiple micronutrient supplement groups to those who were enrolled to the iron folic acid supplement group.

The findings show no evidence of a difference in the mean weight of the participants during the second trimester among those enrolled to the multiple micronutrient supplement group compared to those who were enrolled to the iron folic acid supplement group, 62.8 (SD: 9.1) vs. 59.4 (SD: 5.5) kilograms, p = 0.104.

The weight gained by the participants enrolled in the multiple micronutrient supplement group during the third trimester was significantly higher than that gained by the participants enrolled in the iron folic acid supplement group, 67.8 (SD: 8.5) vs. 62.7 (SD: 6.4), p = 0.032. Table 4.9 compares clinical characteristics between the two groups

The median hemoglobin levels during the second trimester were similar for the two groups of participants, 11.2 (IQR: 10.8, 12.1) vs. 11.2 (IQR: 10.4, 11.8) g/dl, p = 0.758. Also, the proportion of anemic participants in the multiple micronutrient supplement group was similar to that of the participants enrolled in the iron folic acid supplement group, 43.8% vs. 40.0%, p = 0.812. The median hemoglobin levels during the third trimester among the participants who were enrolled in the multiple micronutrient supplement group was 12.1 (IQR: 11.6, 12.4) g/dL. This was significantly higher than the median posted by the participants enrolled in the iron folic supplement, median: 11.3 (IQR: 9.7, 11.8) g/dl, p = 0.038.

Table 4.9: Comparison of clinical characteristics by the treatment groups

Variable	N	Groups: MM (n=70) Mean (SD)/Median (IQR) or (%)	IF (n=70) Mean (SD)/Median (IQR) or (%)	P-value
Weight in the second trimester (Kg), Median (IQR)	140	62.8 (9.1)	59.4 (5.5)	0.104^{t}
Weight in third trimester (Kg), Median (IQR)	140	67.8 (8.5)	62.7 (6.4)	0.032^{t}
HB levels in second trimester (g/dl), Median (IQR)	140	11.2 (10.8, 12.1)	11.2 (10.4, 11.8)	0.758^{w}
Anemic during second trimester, n (%)				
No	140	39 (56.2%)	42 (60.0%)	
Yes		31 (43.8%)	28 (40.0%)	0.812^{c}
HB in third trimester (g/dl), Median (IQR)	140	12.1 (11.6, 12.4)	11.3 (9.7, 11.8)	0.038^{w}
Anemic during third trimester, n (%)				
No	140	60 (85.7%)	46 (65.2%)	
Yes		10 (14.3%)	24 (34.8%)	0.173^{c}
Syphilis test, n (%)				
Reactive	140	0 (0.0%)	10 (13.8%)	
Non-reactive		70 (100.0%)	60 (86.2%)	0.129^{f}
Blood pressure levels, n (%)				
Low		3 (5.0%)	2 (3.2%)	
Normal	140	64 (90.0%)	59 (83.9%)	0.823^{f}
High		3 (5.0%)	9 (12.9%)	
Complaints, n (%)				
None		3 (4.6%)	5 (6.9%)	
Nausea		10 (13.6%)	16 (24.1%)	
Vomiting	140	13 (18.2%)	12 (17.2%)	0.854^{f}
Dizziness		38 (54.6%)	31 (44.8%)	
Fatigue		0 (0.0%)	3 (3.5%)	
Other		6 (9.1%)	3 (3.5%)	

^{c} Pearson's Chi Square test, ^{t} Independent samples t-test ^{w} Wilcoxon sign test ^{f}Fishers exact test

Further, the proportion of anemic participants during the third trimester among those enrolled in the multiple micronutrient supplement group was lower than that reported for the participants enrolled in the iron folic acid supplement group, 14.3% vs. 34.8%, but not statistically significantly different, p = 0.173.

None of the participants enrolled in the multiple micronutrient supplement group was diagnosed of syphilis compared to 13.8% among those enrolled in the iron folic supplement group. The difference was however, statistically not significant, p = 0.129

There was no evidence from the data to demonstrate a difference in the distribution of participants by blood pressure levels across the two groups, p = 0.823.

Similarly, there was no evidence from the data to link complaints to a particular enrollment group, p = 0.854.

In Table 4.10, the clinical characteristics including pica, medical complaints, food preference and issues arising during pregnancy were compared between the participants who were enrolled in the multiple micronutrient supplement groups to those who were enrolled to the iron folic acid supplement group.

Table 4.10: Comparison of pica and food preference by treatment groups

Variable	N	Groups MM (n=70) n (%)	IF (n=70) n (%)	Pvalue
Pica after two weeks, n (%)				
No		60 (13.6)	22 (31.2)	
Yes	140	10 (86.4)	48 (68.8)	0.137[c]
Preference for pica, n (%)				
Stones		59 (84.2)	44 (63.6)	
Charcoal	140	11 (15.8)	10 (13.6)	0.166[f]
Gas		0 (0.0)	3 (4.6)	
Others		0 (0.0)	13 (18.2)	
Food preference, n (%)				
All(Carbohydrates, Proteins, Vitamins)		6 (9.1)	1 (3.3)	
Carbohydrates		6 (9.1)	21 (30.0)	
Carbohydrates & proteins		13 (18.2)	5 (6.7)	
Carbohydrates & vegetables		0 (0.0)	2 (3.3)	
Carbohydrates & fruits	140	3 (4.6)	0 (0.0)	0.060[f]
Proteins		3 (4.6)	12 (16.7)	
Fruits		26 (36.4)	16 (23.3)	
Vegetables		3 (4.6)	7 (10.0)	
Vegetables and fruits		0 (0.0)	5 (6.7)	
Soda		10 (13.6)	2 (3.3)	
Complaints during enrollment , n (%)				
None		46 (66.7)	56 (80.8)	
Fatigue		0 (0.0)	3 (3.9)	
GBM		8 (11.1)	5 (7.7)	
Heartburn	140	4 (5.6)	3 (3.9)	0.571[f]
Hypertension		0 (0.0)	3 (3.9)	
Malaise		4 (5.6)	0 (0.0)	
Mood swings		4 (5.6)	0 (0.0)	
Pain in the right thigh		4 (5.6)	0 (0.0)	

[c] Pearson's Chi Square test, [f] Ancova f-test

Among the participants who had pica and enrolled in the multiple micronutrient supplement group 84.2% had preference for stones while 63.6% had preference for stones among those enrolled in the iron folic supplement group. Those who had preference for charcoal were 15.8% in the multiple micronutrient group and 13.6% among those who were enrolled to the iron folic acid supplement group. There was no evidence though to show varied distribution of participants by their pica preference to micronutrient supplementation group (p = 0.166).

The findings show that the proportion of participants who had pica were similar among those who were enrolled in the multiple micronutrient supplement group compared to those who were enrolled in the iron folic supplement group, 86.4% vs. 68.8%, p = 0.137.

There was no difference in pica experience between the treatment and control arm at study enrollment. However, after at least two weeks of being administered and using multiple micronutrients and Iron folic acid respectively: the MM group had no pica at 13.6% and IFA at 31.2% correspondingly.

This is also consistent with the focus group discussions within the groups:

A woman said, "Since I became pregnant, I have been eating stones and have to carry them in my pocket,s because when I am not doing some work I throw some in my mouth to keep the urge down". Control group.

But a woman in the MM – intervention group said: *"I had tendencies to eat soil and stones when I became pregnant: but after taking the vitamins for only about two weeks; I didn't have the urge to eat them again, I forgot that I used to eat them!"* Intervention (MM) group

The food preference as well as reported issues on enrollment arising during the pregnancy were not significantly differently distributed between the two groups, p = 0 0.060, and 0.571 respectively.

4.9 Antenatal visits per treatment groups

Table 4.11 shows the comparison of the ANC characteristics by treatment groups and is guided by the following measures: duration in months at the initiation of antenatal clinic visits, frequency of the ANC visits and the place of attendance.

Table 4.11: Antenatal care clinic visit characteristics by the treatment groups

Variable	n	Groups MM (n=70) n (%)	 IF (n=70) n (%)	P-value
Gestational age at first antenatal care clinic, n (%)				
3 Months		13 (18.1)	14(19.4)	
4 months		26 (36.4)	23 (32.3)	
5 Months	140	16 (22.7)	20 (29.0)	0.951[f]
6 Months		6 (9.1)	9 (12.9)	
7 Months		6 (9.1)	2 (3.2)	
8 Months		3 (4.6)	2 (3.2)	
Number of ANC visits, n (%)				
Once		3 (4.6)	2 (3.2)	
Twice	140	6 (9.1)	16 (22.6)	0.013[f]
Thrice		13 (18.2)	34 (48.4)	
Quadruple		48 (68.2)	18 (25.8)	
Place of ANC, n (%)				
Dispensary	140	70 (100.0)	47 (67.7)	
Health Center		0 (0.0)	16 (22.6)	0.006[f]
Hospital		0 (0.0)	7 (9.7)	

[f] Ancova f-test

The distribution of the participants by the gestational age at first antenatal care clinic were not significantly different between the two groups, p = 0.951. However, the data show that the participants in the iron folic acid supplement group were more likely to have attended ANC once twice or thrice compared to those in the multiple micronutrient group who attended four times, p = 0.013. Further, the place of ANC attendance was more likely to have been dispensary for the participants who were enrolled in the multiple micronutrient group compared to those in the iron folic acid supplement group, p = 0.006.

4.10 Labor and delivery outcomes by treatment groups

Table 4.12 gives comparison of the labor and delivery characteristics findings, by place of onset of labor, labor duration and postpartum hemorrhage amounts.

Table 4.12: Comparison of labor & delivery characteristics by treatment groups

Variable	n	Groups MM (n=70) Median (IQR) or (%)	 IF (n=70) Median (IQR) or (%)	P-value
Place of onset of labor, n (%)				
Home		48 (68.2%)	58 (83.3%)	
Work place	140	16 (22.7%)	12 (16.7%)	0.279[f]
Market		3 (4.6%)	0 (0.0%)	
Dispensary/Health		3 (4.6%)	0 (0.0%)	
Duration of labor (Hours), Median (IQR)	140	8.0 (6.0, 8.0)	12.0 (8.0, 21.0)	0.005[w]
Duration of second stage of labor (Minutes), Median (IQR)	140	11.0 (6.0, 20.0)	20.0 (15.0, 30.0)	0.023[w]
Birth attendant present (%)				
Home with help		3 (4.6%)	0 (0.0%)	
Home alone		0 (0.0%)	2 (3.1%)	
Home with TBA	140	3 (4.6%)	9 (12.5%)	0.454[f]
On the way to TBA		0 (0.0%)	2 (3.1%)	
Hospital		64 (90.9%)	57 (81.3%)	
Presence of companion, n (%)				
No		60 (86.4%)	68 (96.9%)	
Yes	140	10 (13.6%)	2 (3.1%)	0.293[f]
Postpartum blood loss, n (%)				
Light		56 (79.0%)	13 (18.5%)	
Mild	140	7 (10.5%)	23 (33.3%)	<0.0001[f]
Heavy		7 (10.5%)	34 (48.2%)	

[f]Ancova f test, [w]Wilcoxon sign test

A higher proportion of participants who were enrolled in the iron folic acid supplement group had onset of labor at home compared to 68.2% among those who were enrolled in the multiple micronutrient supplement group. There was, however, no sufficient evidence from the data to demonstrate different distributions in the place of labor onset by the two treatment groups (p = 0.279).

The median duration of labor among the participants who were enrolled in the multiple micronutrient supplement groups was significantly lower than that of the participants who were enrolled in the iron folic acid supplement group, 8.0 (IQR: 6.0, 8.0) vs. 12.0 (IQR: 8.0, 21.0), p = 0.005.

Similarly, the median duration of second stage of labor for the participants who were enrolled in the multiple micronutrient supplement groups was significantly shorter than that reported for those enrolled in the iron folic acid supplement group, 11.0 (IQR: 6.0, 20.0), vs.20.0 (IQR: 15.0, 30.0) p = 0.023.

This is further supported by one of the women in the focus group who said *"When I felt the pains in my stomach, I knew the baby was about to come, but it took a day to get the baby out!" (Control group).* Another woman also said *"I delivered at home because I was young and didn't know what to do and went to hide in my grandmother's house and took care of me. It took a long time for the baby to get out. I was in so much pain and my grandmother kept checking me down there and telling me to wait until the pain was so much. She then told me to push the baby out, but by that time I was so weak to push. I kept trying and when the baby came out, I bled alot and fainted. I don't know what happened after that. (Control group)*

A woman in the treatment group said *"From the time pains started, it took me two hours to deliver, I didn't even get to Nandi Hills Hospital, I was assisted by the sister in the Dispensary. (Intervention group).*

The presence of a birth attendant at the time of delivery and the presence of a companion at the time of delivery were not significantly different between the two groups, p = 0.454 and 0.293 respectively.

There was evidence from the data to show that the participants who were enrolled in the iron folic acid supplement group were more likely to have mild (33.3%) to heavy (48.2%) blood loss compared to those who were enrolled in the multiple micronutrient supplement group; mild (79.0%) and heavy (10.5%), p < 0.0001. This is further confirmed by one of the women in the focus group who said*: "I used to bleed so much after delivering in the last times, but after taking the vitamins, during* *this delivery, I only bled very little". (Intervention group) one of the women in the control group had a different experience and said: "When I got my baby, immediately I bled a lot and was weak even to stand up. Mother in law supported me to bed and I am still weak to do even small housework". (Control group)*

4.11 Infant outcomes by treatment groups

Table 4.13 presents the comparison of the infant outcomes by treatment groups. The measures are guided by Apgar score and outcome at forty two days post delivery of the infant.

Table 4.13: Comparison of the infant outcomes by the treatment groups

Variable	n	Groups: MM (n=70) Median(IQR) or n (%)	Groups: IF (n=70) Median (IQR) or n (%)	P-value
Apgar score 1 minute, n				
Abnormal (<4)		38 (54.6%)	18 (26.1%)	
Near normal (4-6)	140	0 (0.0%)	12 (17.4%)	0.037^{f}
Normal (>6)		32 (45.4%)	40 (56.5%)	
Apgar score 5 minutes, n (%)				
Near normal (4-6)		35 (50.0%)	18 (26.1%)	
Normal (>6)	140	35 (50.0%)	52 (73.9%)	0.098^{c}
Birthweight (kilograms), Median (IQR)	140	3.3 (3.2, 4.1)	3.2 (3.0, 3.5)	0.024^{w}
Baby's sex, n (%)				
Female	140	29 (40.9%)	31 (44.8%)	
Male		41 (59.1%)	39 (55.2%)	0.780^{c}
Breastfeeding done, n (%)				
No	140	0 (0.0%)	22 (31.2%)	
Yes		70 (100.0%)	48 (68.8%)	0.003^{f}
Breast milk availability (Minutes), n (%)				
≤ 10		7 (9.5%)	0 (0.0%)	
11 – 20		13 (19.1%)	4 (6.3%)	
21 – 30	140	40 (57.1%)	16 (21.9%)	0.001^{f}
31 – 40		3 (4.8%)	7 (9.4%)	
41 – 50		0 (0.0%)	4 (6.3%)	
> 50		7 (9.5%)	39 (56.3%)	
Breast milk amount, n (%)				
Sufficient	140	70 (100.0%)	43 (60.7%)	
Insufficient		0 (0.0%)	27 (39.2%)	0.001^{f}
Breast milk substitution, n (%)				
No		70 (100.0%)	57 (81.5%)	
Yes	140	0 (0.0%)	13 (18.5%)	0.056^{f}
Baby outcome at 42 days, n (%)				
Alive	140	70 (100.0%)	68 (96.7%)	
Died		0 (0.0%)	2 (3.3%)	>0.999^{f}
Baby milestones at 42 days, n (%)				
Follows objects		4 (5.7%)	0 (0.0%)	
Grasping		21 (29.4%)	4 (5.9%)	
Head control		4 (5.7%)	0 (0.0%)	0.181^{f}
Neck control	140	4 (5.7%)	0 (0.0%)	
Neck support		4 (5.7%)	0 (0.0%)	
Social smile		49 (70.6%)	45 (64.7%)	

^{c} Pearson's Chi Square test, ^{w}Wilcoxon sign test, ^{f} Ancova f-test

The participants enrolled in the iron folic acid supplement group were more likely to have infants with near normal to normal Apgar score at 1 minute compared to participants enrolled in the multiple micronutrient supplement group, p = 0.037.

There was however, no evidence of a difference in the distribution of the infants between the two groups based on Apgar score at 5 minutes (p = 0.098).

The participants enrolled in the multiple micronutrient group were more likely to have children with higher median birthweight compared to those who were enrolled in the iron folic acid supplement group; 3.3 (IQR: 3.2, 4.1) vs. 3.2 (IQR: 3.0, 3.5) kilograms, p =0.024.

The distribution of the infants by gender were similar in the two groups, p = 0.780.

There was evidence from the data that the proportion of the children who experienced exclusive breastfeeding done was higher among the participants enrolled in the multiple micronutrient supplement group compared to those who were enrolled in the iron folic acid supplement group, 100.0% vs. 68.8%, p = 0.003.

The data further demonstrate that the availability of breast milk was rare for the infants who were born to mothers enrolled in the iron folic acid supplement group compared to those enrolled in the multiple micronutrient supplement group, p = 0.001.

The data also show that all (100%) the infants who were born of mothers who were enrolled in the multiple micronutrient supplement group had sufficient breast milk compared to 60.7% among the mothers who were enrolled in the iron folic acid supplement group, p = 0.001.

None of the infants born of mothers who were enrolled in the multiple micronutrient supplement group had breast milk substitution compared to 18.5% of the infants born of mothers enrolled in the iron folic acid supplement group. The difference was however not statistically significant, p = 0.056.

Infant mortality rate among the infants of the mothers enrolled in the iron folic acid supplement group was 3.3% while the infant mortality rate among the infants of the mothers enrolled in the multiple micronutrient supplement group was 0.0%. There was no sufficient evidence though to demonstrate a difference, p > 0.999.

The baby's milestones at the age of 42 days were compared between the two groups and it was established that 5.9% of the babies in the multiple micronutrient supplement group and 0.0% of the babies in the iron folic acid supplement group could follow objects, 29.4% in the multiple micronutrient supplement group and 5.9% in the iron folic acid supplement group could grasp objects. The children in the multiple micronutrient supplement group achieved head control at 5.9% compared to none in the iron folic acid supplement group. Similarly, the children in the multiple micronutrient supplement group achieved neck control 5.9% compared to none in the iron folic acid supplement group. A higher proportion of the children in the multiple micronutrient supplement group at 70.6% could exhibit a social smile compared to 64.7% of the children in the iron folic acid supplement group. The variance in the distribution of the children by their milestones at 42 days was however not statistically significant ($p = 0.181$).

4.11 Maternal postnatal blood loss by treatment groups

Maternal postnatal blood loss outcomes were analyzed and compared against each treatment group. The key variables considered were: maternal health status perception and lochia loss post delivery whether it was normal or abnormal. The women were expected to verbalize their feelings on how they health status is post delivery. Lochia loss was also assessed whether it was light, mild or heavy and the duration it took including other clinical complaints a woman may present with.

Table 4.14 presents comparison of the maternal outcomes by each treatment groups. The findings are guided by lochia loss amounts and duration and mothers overall health presentation.

Table 4.14: Maternal outcomes by the treatment groups

Variable	n	Groups MM (n=70) Median (IQR) or n (%)	IF (n=70) Median (IQR) or n (%)	P-value
Mother's perception on postnatal condition, n (%)				
Normal/Good		64 (90.9%)	45 (64.5%)	
Near normal	140	6 (9.1%)	16 (22.6%)	0.091[f]
Abnormal/Bad		0 (0.0%)	9 (12.9%)	
Lochia loss amount, n (%)				
Light		57 (81.8%)	20 (29.0%)	
Mild	140	13 (18.2%)	23 (32.3%)	<0.001[c]
Heavy		0 (0.0%)	27 (38.7%)	
Lochia loss duration, n (%)				
1 – 2 weeks		7 (10.0%)	10 (13.8%)	
3 – 4 weeks		53 (75.0%)	22 (31.0%)	0.013[f]
5 – 6 weeks	140	7 (10.0%)	14 (20.7%)	
> 6 weeks		3 (4.5%)	24 (34.5%)	
Mother's HB level postdelivery, n (%)				
Low		3 (4.8%)	0 (0.0%)	
Normal	140	67 (95.2%)	58 (82.8%)	0.036[f]
High		0 (0.0%)	12 (17.2%)	
Mother's overall health, n (%)				
Stable		70 (100.0%)	53 (76.0%)	
Unstable	140	0 (0.0%)	17 (24.0%)	0.023[f]
Any complain, n (%)				
Bleeding		35 (50.0%)	13 (18.2%)	
General body weakness		0 (0.0%)	6 (9.1%)	>0.999[f]
Headache	140	35 (50.0%)	39 (54.6%)	
Headache/Backache		0 (0.0%)	6 (9.1%)	
Weakness/Pale		0 (0.0%)	6 (9.1%)	
Days to resumption of tea plucking, Median (IQR)	26	46.5 (21.0, 90.0)	50.0 (30.0, 105.0)	0.641[w]
Days to resumption of house chores, Median (IQR)	64	38.0 (30.0 38.5)	26.0 (16.0, 40.0)	0.639[w]

[c] Pearson's Chi Square test, [w]Wilcoxon sign test, [f] Ancova f-test

Up to 90.9% of the participants enrolled in the multiple micronutrient supplement group perceived their health to be good or in a normal condition postnataly compared to 64.5% among those who were enrolled in the iron folic acid supplement group. There were 9.1% and 0.0% of the participants in the multiple micronutrient supplement group reported a near normal and abnormal/bad condition respectively compared to 22.6% and 12.9% respectively among the participants enrolled in the iron folic acid supplement group. The test for association did not reveal any evidence of such association between mothers' condition after delivery and the group they were enrolled in, p = 0.091.

The participants enrolled in the iron folic acid supplement group were more likely to lose mild (32.3%) to heavy (38.7%) lochia compared to 18.2% and 0.0% among the participants who were enrolled in the multiple micronutrient supplement group, p <0.0001. Further, the data show that the participants enrolled in the iron folic acid supplement group were more likely to lose the lochia for more than four weeks compared to those who were enrolled in the multiple micronutrient supplement group, p = 0.013.

Among the participants who were enrolled in the iron folic acid supplement group 82.8% had normal HB and 17.2% had higher HB after delivery levels compared to 95.2% and 0.0% respectively among the participants who were enrolled in the multiple micronutrient supplement group. The test for association show evidence of difference in the distribution of participants by the level of HB after delivery across the two groups, p = 0.036.

The data show that a significantly higher proportion of the participants enrolled in the multiple micronutrient group were stable compared the participants who were enrolled in the iron folic acid supplement group, 100.0% vs. 76.0%, p 0.023.

There was no evidence of association between the clinical complains reported by the participants and the treatment group, p > 0.999.

The median duration to resumption of tea plucking among the participants enrolled in the multiple micronutrient supplement group was 46.5 (IQR: 21.0, 90.0) days while the median duration to resumption of tea plucking among the participants enrolled in the iron folic acid supplement group was 50.0 (IQR: 30.0, 105.0) days.

The difference between the two groups was however not statistically significant, p = 0.641.

Similarly, the median duration to resumption of household chores among the participants enrolled in the multiple micronutrient supplement group was 37.5 (IQR: 30.0, 38.5) days while the median duration to resumption of household chores among the participants enrolled in the iron folic acid supplement group was 26.0 (IQR: 16.0, 40.0) days. However, the difference between the two groups was not statistically significant, p = 0.639.

4.12 Effect size and hypothesis testing using General linear model

The study dependent variables were:

- Weight gain during pregnancy
- Hemoglobin levels during pregnancy
- Labor duration
- Neonates' birth weight
- Postpartum blood and lochia loss
- Breastmilk availability

However, in testing the hypothesis and effect size; weight gain and hemoglobin levels during pregnancy, labor duration, neonates' birth weight and postpartum blood and lochia loss was applied. Table 4.15 shows the descriptive statistics.

Table 4.15: Comparison of group means and standard deviations

Dependent variable	Enrolled	Mean	Std. Deviation	n
Weight gain in third trimester	MM	5.84	6.61874	70
	IFA	5.53	12.79394	70
	Total	6.32	10.73661	140
Change in hemoglobin levels	MM	1.25	3.02903	70
	IFA	0.61	2.57932	70
	Total	0.85	2.73281	140
Labor duration in hours	MM	8.85	3.02341	70
	IFA	20.90	14.65573	70
	Total	16.29	12.99541	140
Birth weight in kilograms	MM	3.92	1.15963	70
	IFA	3.28	0.58874	70
	Total	3.52	0.89275	140
Blood loss	MM	0.27	0.64667	70
	IFA	1.40	0.73679	70
	Total	0.92	0.89098	140
Lochia loss	MM	1.27	0.64667	70
	IFA	2.00	0.84515	70
	Total	1.69	0.83758	140

There is a difference in group means and standard deviations observed in table 4.15. Table 4.16 tests equality of covariance matrices using Box’s M.

Table 4.16: Test of Equality of covariances

Box's M	F	df1	df2	Sig
43.496	3.699	138	3.004	0.001

The Box’s M F test statistics was (3.699, p=0.001) and demonstrates that the null hypothesis is not accepted because the observed covariance matrices of the dependent variables are not equal across groups because the significance level is less than 0.05. The assumptions are therefore not met. Table 4.17 furthers tests for homogeinity using Levene’s Test of Equality.

Table 4.17: Levene's Test of Equality of Error Variances

Dependent variable	F	df1	df2	Sig.
Weight gain	0.412	1	138	0.525
Change in HB levels	0.215	1	138	0.646
Labor duration in hours	11.762	1	138	0.002
Birth weight	6.879	1	138	0.013
Blood loss	1.658	1	138	0.210
Lochia loss	1.389	1	138	0.250

The test statistics for labor duration (F,11.76; p=0.002) and birthweight (F,6.879; p=0.013) demonstrates that the null hypothesis observed covariance matrices of the dependent variables are not equal across groups because the significance level is less than 0.05 in weight gain and change in hemoglobin. The assumptions in the model are therefore met.

The test statistics for weight gain (F, 0.412; p=0.525), change in hemoglobin levels (F 0.215; p=0.646, blood loss (F,1.658; p=0.210) and lochia loss (F,1.389; p=0.250) demonstrates that the null hypothesis observed covariance matrices of the dependent variables are equal across groups because the significance level is greater than 0.05 in weight gain, change in hemoglobin, blood loss and lochia loss. The assumptions in the model are therefore met. Table 4.18 tests between subjects effects.

Table 4.18: Test of between subjects effects

Source	Dependent Variable	df	Mean Square	F	Sig.	Partial Eta Squared
Intercept	Weight gain	1	1245.714	10.492	0.003	0.247
	Change in Hemoglobin levels	1	27.764	3.654	0.065	0.102
	Labor duration in hours	1	7106.969	51.622	0.001	0.617
	Birth weight	1	415.821	576.80	0.001	0.947
	Blood loss	1	17.757	36.171	0.001	0.601
	Lochia loss	1	3.357	5.680	0.001	0.827
Supplements	Weight gain	1	4.679	0.039	0.844	0.001
	Change in Hemoglobin levels	1	3.294	0.433	0.515	0.013
	Labor duration hours	1	1167.557	8.481	0.006	0.210
	Birth weight	1	3.232	4.483	0.042	0.123
	Blood loss	1	8.064	16.427	0.001	0.406
	Lochia loss	1	3.357	5.680	0.025	0.191

There was significance in the between subjects effects for labor duration in hours only p=0.006,birthweight p=0.042, blood loss p=0.001 and lochia loss p=0.025 while the effects in weight gain p=0.844 and hemoglobin levels p=0.515 were not significant.

4.12.1 Measuring effect size and null hypothesis testing

Table 4.19 test the null hypothesis to establish whether it can be rejected or accepted using the four significant tests and partial eta squared against the dependent variables; labor duration, blood loss, lochia loss hemoglobin levels and birth weight.

Table 4.19: Hypothesis testing and effect size

	Effect	Value	F	Hypothesis df	Sig.	Partial Eta Squared
Intercept	Pillai's Trace	0.992	4.145	4	0.001	0.992
	Wilks' Lambda	0.008	4.145	4	0.001	0.992
	Hotelling's Trace	131.89	4.145	4	0.001	0.992
	Roy's Largest Root	131.89	4.145	4	0.001	0.992
Supplements	Pillai's Trace	0.611	4.937	4	0.002	0.611
	Wilks' Lambda	0.389	4.937	4	0.002	0.611
	Hotelling's Trace	1.571	4.937	4	0.002	0.611
	Roy's Largest Root	1.571	4.937	4	0.002	0.611

The test statistics calculations were based on exact statistics. General linear modelling multivariate analysis was applied in the four tests of significance; Pillai's trace, Wilks' Lambda, Hotelling's Trace and Roy's Largest root.

Pillai's Trace was 0.611(p=0.002) with a Partial Eta Squared of 0.611, showing there was effect variation in the model. The study concludes that the results are not due to chance but manipulation by multiple micronutrients.

Wilks' Lambda was 0.389 (p=002) with a Partial Eta Squared of 0.611, showing there was effect variation in the model. The study concludes that the results are not due to chance but manipulation by multiple micronutrients.

Hotellings' Trace was 1.571 (p=002) with a Partial Eta Squared of 0.611, showing there was effect variation in the model. The study concludes that the results are not due to chance but manipulation by multiple micronutrients.

Roy's Largest Root was 1.571 (p=002) with a Partial Eta Squared of 0.611, showing there was effect variation in the model. The study concludes that the results are not due to chance but manipulation by multiple micronutrients.

Since Roy's Largest Root is equal to Hotellings' Trace, it demonstrates that the effect observed is associated with the dependent variables; labor duration (p=0.003), blood loss (p=0.001) and lochia loss (p=0.001) indicated in the contrast table.

Table 4.20 tests for contrast to demonstrate the effect in the model.

Table 4.20: Contrast testing of the dependent variables

Simple contrast		**Dependent variable**					
		Weight gain	**Hemog-lobin level**	**Labor duration**	**Blood loss**	**Birth weight**	**Lochia loss**
Level 2 (IFA) vs. Level 1 (MM)	Contrast Estimate	-2.776	0.119	12.910	1.240	-0.674	1.104
	Hypothesized Value	0	0	0	0	0	0
	Difference (Estimate - Hypothesized)	-2.776	0.119	12.910	1.240	-0.674	1.104
	Std. Error	2.942	0.622	3.890	0.247	0.333	0.250
	Sig.	0.353	0.850	0.003	0.001	0.052	0.001
	95% CI Lower Bound	-8.801	-1.156	4.942	0.735	-1.356	0.592
	Upper Bound	3.249	1.394	20.877	1.745	.007	1.616

The contrast results demonstrate a non-significant effect difference in the model observed in the dependent variables; weight gain (p,0.353), hemoglobin level (0.850) and birth weight (0.052) dependent variables. Since the significance levels for the dependent variables were greater than 0.05, the study concludes that the difference observed is due to chance variation.

The contrast results demonstrate that there was a significant effect difference observed in the model in the dependent variables; labor duration (p,0.003), blood loss amount (0.001) and lochia loss amounts (0.001) dependent variables. Since the significance levels for the dependent variables were less than 0.05, the study concludes that the difference observed is not due to chance variation.

The contrast concludes that the multiple micronutrients reduces labor duration during pregnancy, postpartum hemorrhage and lochia loss amount and duration. The model therefore suggests that multiple micronutrients should be used by pregnant women in place of iron folic acid.

4.12.2 Profile plots

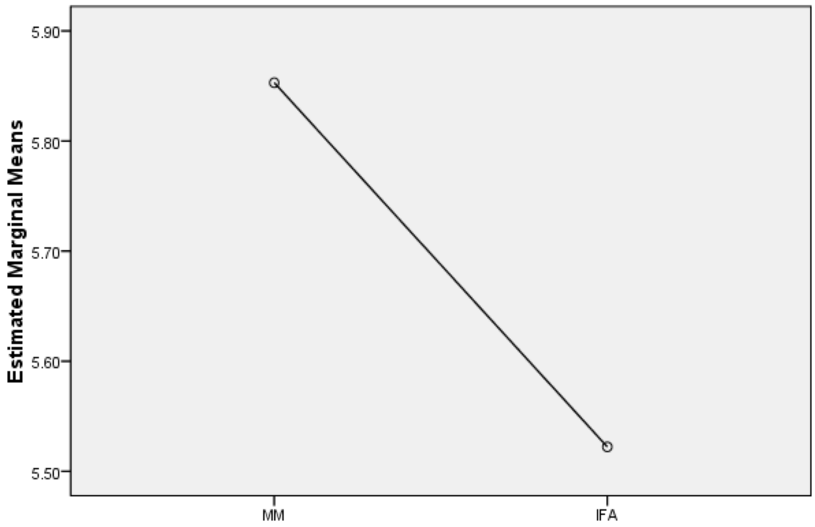

Figure 4.1: Pregnancy weight gain versus MM and IFA groups

The MM group had a higher mean weight gain compared to IFA group.

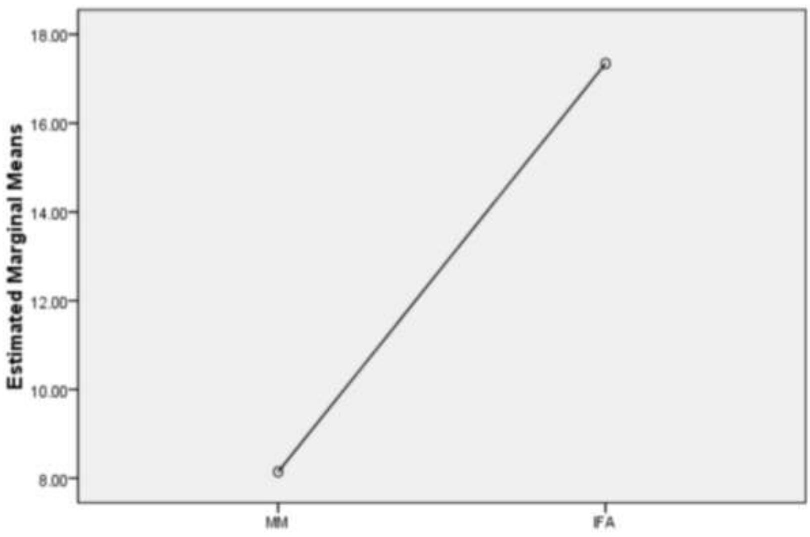

Figure 4.2: Labor duration versus MM and IFA groups

The IFA group had a higher mean labor duration compared to MM group.

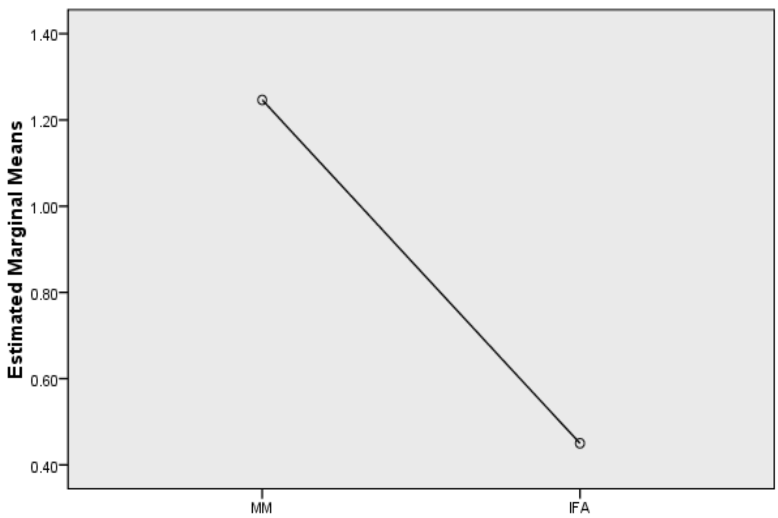

Figure 4.3: Hemoglobin levels versus MM and IFA groups

The MM group had a higher mean change in hemoglobin levels compared to IFA group.

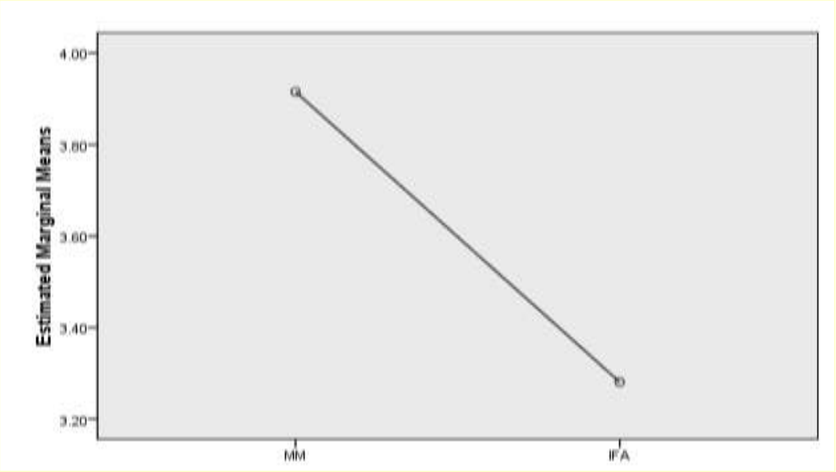

Figure 4.4: Birthweight versus MM and IFA groups

The babies born to MM group had a higher mean birthweight compared to IFA group.

4.13 Adjusting for confounding factors

4.13.1 Age stratification

i. Parity versus labor duration

Table 4.21: Parity versus labor duration

	Age < 25 years			**Age > 25 years**			**ODDs ratio**
	Labor duration in hours						
	< 12 hours	**>12 hours**	**Total**	**< 12 hours**	**>12 hours**	**Total**	
Parity < 1	28	16	44	18	4	22	Crude Odds ratio = 0.64
Parity > 1	32	4	36	26	12	38	Adjusted Odds ratio = 0.63
Total	**60**	**20**	**80**	**44**	**26**	**60**	

There was confounding between parity and labor duration stratified by age, confirmed by a crude Odds ratio of 0.64 and adjusted Odds ratio of 0.63 which are closely equal.

ii.Labor duration versus blood loss during delivery

Table 4.22: Labor duration versus blood loss during delivery

	Age < 25 years			**Age >25 years**			**ODDs ratio**
	Blood loss during delivery						
	Light	**Mild-Heavy**	**Total**	**Light**	**Mild-Heavy**	**Total**	
Labor duration <12 hours	35	14	49	16	28	44	Crude Odds ratio = 5.7
Labor duration >12 hours	6	25	31	3	13	16	Adjusted Odds ration = 6.2
Total	**41**	**39**	**80**	**19**	**41**	**60**	

There was no confounding confirmed by a crude Odds ratio of 5.7 and an adjusted ratio of 6.2.

iii. Labor duration versus lochia loss duration

Table 4.23: Labor duration versus lochia loss duration

	Age < 25 years			**Age >25 years**			**ODDs ratio**
	Lochia loss duration						
	<4 weeks	**>4 weeks**	**Total**	**<4 weeks**	**>4 weeks**	**Total**	
Labor duration <12 hours	47	6	53	27	19	46	Crude Odds ration =6.9
Labor duration >12 hours	9	18	27	3	11	14	Adjusted Odds ration =9.6
Total	**56**	**24**	**80**	**30**	**30**	**60**	

There was no confounding confirmed by a crude Odds ratio of 6.9 and an adjusted ratio of 9.6.

iv. Labor duration versus lochia loss amount

Table 4.24: Labor duration versus lochia loss amount

	Age < 25 years			**Age >25 years**			**Odds ratio**
	Lochia loss amount						
	Light	**Mild-heavy**	**Total**	**Light**	**Mild-heavy**	**Total**	
Labor duration <12 hours	38	11	49	23	24	47	Crude Odds ratio =5.1
Labor duration >12 hours	8	23	31	3	10	13	Adjusted Odds ratio = 6.4
Total	**46**	**34**	**80**	**26**	**34**	**60**	

There was no confounding confirmed by a crude Odds ratio of 5.1 and an adjusted ratio of 6.4.

v. Breastmilk availability versus breastmilk substitution

Table 4.25: Breast milk availability versus breastmilk substitution

Breastmilk substitution	**Age < 25 years**			**Age >25 years**			Odds ratio
	Breastmilk availability						
	< 30 minutes	**>30 minutes**	**Total**	**<30 minutes**	**>30 minutes**	**Total**	
No	41	26	67	26	24	50	Crude Odds ratio=3.1
Yes	5	8	13	3	7	10	Adjusted Odds ratio= 2.8
Total	**46**	**34**	**80**	**29**	**31**	**60**	

There was confounding confirmed by a crude Odds ratio of 3.1 and an adjusted ratio of 2.8.

4.13.2 Education level stratification

vi. Breastmilk substitution and availability

Table 4.26: Education level versus breastmilk availability

Breastmilk substitution	Primary			Secondary			ODDs ratio
	Breast milk availability						
	< 30 minutes	>30 minutes	Total	< 30 minutes	>30 minutes	Total	
No	52	6	58	18	3	21	Crude odds ratio = 2.5
Yes	26	6	32	20	9	29	Adjusted odds ratio = 2.3
Total	**78**	**12**	**90**	**38**	**12**	**50**	

There was confounding confirmed by a crude Odds ratio of 2.5 and an adjusted ratio of 2.3.

vii. Lochia loss amount versus lochia duration

Table 4.27: Lochia loss amount versus lochia loss duration

Lochia duration	Secondary education level			Primary education level			ODDs ratio
	Lochia loss amount						
	Light	Mild-heavy	Total	Light	Mild-heavy	Total	
< 4 weeks	17	11	28	39	17	56	Crude Odds ration =5.5
>4 weeks	6	16	22	9	25	34	Adjusted Odds ration = 5.9
Total	23	27	50	48	42	90	

There was no confounding confirmed by a crude Odds ratio of 5.5 and an adjusted ratio of 5.9. This is because education is not a logical cause for lochia loss but biological plausibility which was not factored in adjusting for confounding in lochia loss amount and duration.

Viii. Summarised adjusted versus crude odds ratio on outcome variables

Table 4.28: Adjusted versus crude odds ratio

Stratum	Variable	Crude odds ratio	Adjusted strata odds ratio	Remark
Age < 25 years	Parity versus labor duration	0.64	0.63	There was confounding
	Labor duration versus blood loss amount	5.7	6.2	No confounding
Age > 25 years	Labor duration versus lochia loss duration	6.9	9.6	No confounding
	Labor duration versus lochia loss amount	5.1	6.4	No confounding
	Breast milk availability versus breastmilk substitution	3.1	2.8	There was confounding
Primary education level Secondary education level	Breastmilk substitution and breastmilk availability	2.5	2.3	There was confounding
	Lochia loss amount versus lochia loss duration	5.5	5.9	No confounding

There was confounding on the parity versus labor duration and breastmilk availability versus breastmilk substitution outcome variable. There was no confounding experienced among the blood loss amount, lochia loss amount and duration outcome variables. Therefore, age was controlled in interpretation of parity, labor duration, breastmilk availability and its substitution. The higher the age and parity, the shorter the labor duration and breastmilk availability establishement related to past birth experience. Breastmilk substitution time is also advanced to six months.

CHAPTER FIVE

DISCUSSION

5.1 Discussion summary

5.1.1 Socio-demographics

The fertility rate was 2.03 and is below the national fertility rate of 3.9 in 2014 down from 4.6 in 2008-09 (KDHS 2008-09). The education attainment experience in this setting was 47% for the secondary level. This is higher than the national average which currently is placed at 43%. Primary education level was at 88% which is higher than the national level average of 25% (KDHS 2014). Therefore, the Tea Estate community have attained primary education more than secondary education.

5.1.2 Effect of MM and IFA supplementation on anemia prevalence

The average hemoglobin level experienced in this setting was 11.6g/dl which is above the World Health Organization recommended non-anemic hemoglobin level of 11.0g/dl. Hemoglobin level above 11.0g/dl is encouraged to prevent adverse neonatal outcomes: prevent risk for preterm; low birth weight (Sukrat, *et al* 2013).

The average anemia prevalence was 41.5% with MM group having a prevalence of 43.8% and IFA arm having a prevalence of 40% respectively. This is higher that the regional anemia prevalence at 27.1% and global anemia prevalence of 32.8% (WHO 2014 & Sukrat, *et al* 2013). The anemia prevalence is lower than the WHO cut off among the pregnant women which is 41.8%. Africa has a prevalence of 44%. Ghana has anemia prevalence of 56%. Uganda has anemia prevalence of 32.5% (Ononge, *et al* 2014, Intiful, *et al* 2016). Pica is believed to be a clinical indicator of micronutrient deficiency. The pica experience and practice among the pregnant women was diverse: pica for stone and clay i.e. geophagia was at 73.5%, charcoal at 14.3%. This is consistent with meta-analysis conducted which demonstrated a prevalence of between 11.0% -76.5%. This is further consistent with a study done in Iran which gave a range of 0.02% to 74% (Ezzedin, *et al* 2016). Pica is experienced more among the pregnant adolescents in the USA at 46% with pagophagia (pica for ice) at 37% (Lumish, *et al* 2014). Pica experience for geophagia (pica for soil) in Tanzania is at 5.2% and amylophagia (pica for raw starch) at 36.3% and other pica practices at 40% (Young, *et al* 2010). Ghana pica practice prevalence is at 9.1% (Young, *et al* 2010). Therefore, MM improved hemoglobin levels more that IFA supplementation.

5.1.3 Effect of MM and IFA supplementation on pregnancy weight gain

The women during pregnancy gained an average weight of 5.69kgs during the entire pregnancy, which is below the Institute of Medicine (IOM) guidelines of between 11.5-16.0 kgs as the recommended total pregnancy weight gain (Hutcheon, *et al* 2014, Daley, *et al* 2016, Yang, *et al* 2015, Drehmer, *et al* 2013, Phelan, *et al* 2011, Lipsky, *et al* 2016, Rauh, *et al* 2015, Gernard, *et al* 2012).

The increase in pregnancy weight gain during third trimester was higher for the MM group at 5.85 kgs than IFA at 5.52 kgs but not significant $p = 0.914$, correspondingly. This was lower than the weight gain recommendations by the Institute of Medicine (IOM). The Institute of Medicine (IOM) guidelines recommends a weight gain of 11.3-18.4kgs among women with a body mass index of 18.5-24.9 kgs/m^2 (Hutcheon 2014). An average increase in pregnancy weight gain of 11.5-16.0kgs during the entire pregnancy is recommended by IOM and other studies (Daley 2016, Drehmer 2013, Phelan 2011). Therefore, MM increases weight gain during pregnancy.

5.1.4 Effect of MM and IFA supplementation on birth weight and breast milk feeding

The increase in birth weight observed in the study is equated to the use of multiple micronutrients use among pregnant women in the study and is consistent with past studies (Batool, *et al* 2011). The study demonstrated an increase in birth weight which is consistent with other studies (Haider, *et al* 2011).

The difference observed in breast milk, availability and substitution in the study is associated with the multiple micronutrient use among pregnant women. Variations in breast milk nutrient content have been reported to be related to micronutrient dietary intake. Past studies have shown that zinc, copper, and iron have no correlation between breast milk concentration and dietary intake (Abe, *et al* 2016).

Exclusive breast milk feeding established in the study was 89.8% within the first forty-two days of infant life was above the national overall observed; 61% in 2014 (UNICEF, 2015, KDHS, 2014). The exclusive prevalence observed in the study is higher than what was observed in a study in urban slums in Nairobi which was 2% (Mutua, *et al* 2016).

The study also established that among newborns more than a third; 85.7% were breastfed in the first thirty minutes following delivery and is not consistent with the urban slum study which observed that only 37% were breastfed and 40% given breast milk substitution for the first three days (Mutua, *et al* 2016). Therefore, MM increased birthweight and enhanced establishment of breastmilk immediately after birth. MM increased breastmilk feeding by increasing its amount which thus reduced the chance of its substitution.

5.1.5 Effect of MM and IFA supplementation on labor duration

Use of multiple micronutrients during pregnancy reduced labor duration compared to IFA. Previous studies only compared use of oral fluids; glucose and lactated ringer's solution with minimal success on labor duration reduction. (Kavitha, *et al* 2012, Garmi, *et al* 2017).

The women using multiple micronutrients experienced shorter labor duration than those using IFA. There has been no study comparing the effect of multiple micronutrients on labor duration; previous studies applied the use of 5% dextrose to shorten and augment labor successfully (Sharma, *et al* 2012, Pare, *et al* 2017, Fong, *et al* 2017). There was no effect on labor duration when ringer's lactate intravenous solution was given to women in labor (Kavitha,*et al* 2012, Garmi, *et al* 2017). Other studies compared use of exercise; which reduced the chance of assisted delivery (Davenport et al 2018). Some studies observed that use of epidural analgesia increased labor duration while patient controlled analgesia reduced labor duration (Naito *et al* 2019, Thorbirmson *et al* 2020). Labor onset is determined at the rapture of membranes (Cohen *et al* 2018). The standard in labor duration is pegged on cervical dilatation benchmark of one centimeter(1cm/hr) per hour (Oladapo *et al* 2018, Abalos *et al* 2018, Oladapo *et al* 2018). Therefore, MM use reduces labor duration during during delivery.

5.1.6 Effect of MM and IFA supplementation on blood and lochia loss during puerperium

Women who took multiple micronutrients during pregnancy experienced minimal blood loss. Previous studies have only tried to reduce anemia before delivery to prevent hemorrhage development. There has been no application of MM as a strategy to prevent heavy blood loss (Hofmeyr, *et al* 2013).

The women who received MM experienced light lochia loss for a maximum of three-four weeks compared with IFA group who experienced heavy lochia loss. This is less than other previous studies conducted among women with no bleeding disorders. They experienced lochia loss for a median of 31 days(10-62 days) and those with bleeding disorder had a median of 39 days with range of 21-58 days (Chi, *et al* 2010). Therefore, MM use during pregnancy reduced blood loss amount during delivery and postpartum lochia loss amount and its duration.

5.1.7 Effect of MM and IFA supplementation on infant milestones achievements- neck control and social smile

The study established that: babies whose mothers' used MM compard to IFA could follow objects, had head and neck control, could grasp objects and exhibited a social smile by 42 days post delivery. Past studies are consistent that malnutrition and iron deficiency leads to a delay in milestone achievements (Lozoff, *et al* 2014, Shelvin *et al* 2018, Moraleda *et al* 2018, Lancet, WHO, UNICEF, World Bank 2016). Use of MM compared to IFA is not consistent with other studies that found out that milestone achievements are associated with child's physical and neuroactivity, parental behavior and social interaction (Filatova *et al* 2018, Klin *et al* 2015, Mireault *et al* 2015, Schultz *et al* 2018, Flensborg *et al* 2019, White-Traut *et al* 2013, Brouwer *et al* 2019). Therefore, MM use promotes early achievement of infant milestones evidenced by infant neck control and social smile by forty two days of life.

5.1.8 Women's health perception while using MM and IFA supplementation

Up to 90.9% of the participants enrolled in the multiple micronutrient supplement group perceived their health to be good or in normal condition postnataly compared to 64.5% among those who were enrolled in the iron folic acid supplement group. There was a 9.1% and 0.0% of the participants in the multiple micronutrient supplement group who reported a near normal and abnormal/bad condition respectively compared to a 22.6% and 12.9% respectively among the participants enrolled in the iron folic acid supplement group. No past study has compared womens health perception with other supplements. Therefore, MM improves womens' health perception.

5.2 Strengths and limitations of the MM and IFA supplementation study

The study benefited from the administrative clusters within the Tea Estates which made it efficient in the randomization of the study area to either the intervention or control clusters. The study experienced time limitations and in the design adopted and applied in implementation. The study would have achieved better results if the double-blind randomized design would have been adopted. However, this was limited to time in view of academic requirements; needed to repackage and import the multiple vitamins and combine the iron-folic acid to one capsule same as one earlier IFA by the Ministry of Health.

5.3 Conclusion

Based on the results discussed in the previous chapter, the study demonstrated that the observed maternal, neonatal and infant outcomes cannot be equated to chance but the manipulation by the multiple micronutrients. The following conclusions are drawn.

- **Multiple micronutrients supplementation reduces anemia prevalence.**

Use of multiple micronutrients increases hemoglobin levels among pregnant women.

- **Multiple micronutrients increases newborn birth weight.**

The participants enrolled in the multiple micronutrient group had a higher median birthweight compared to those who were enrolled in the iron folic acid supplement group.

- **Multiple micronutrients enhances immediate initiation of reastfeeding and breast milk availability.**

Availability of breast milk post delivery was rare for infants born to mothers enrolled in the iron folic acid supplement group compared to those enrolled in the multiple micronutrient supplement group.

- **Multiple micronutrients promotes decrease in postpartum hemorrhage, lochia loss amount and duration.**

Most of the participants enrolled in the in the multiple micronutrient supplement group, had mild and few experienced heavy blood loss during delivery. The iron folic acid supplement group experienced heavy and few mild blood loss during delivery. Participants enrolled in the multiple micronutrient supplement group had mild and moderate lochia loss while the iron folic acid supplement group had; mild, moderate and heavy lochia loss. The participants enrolled in the iron folic acid supplement group experienced lochia loss for more than four weeks than those enrolled in the multiple micronutrient supplement group.

- **Multiple micronutrients shortens labor and prevents prolonged labor.**

The median duration of labor among the participants in the multiple micronutrient supplement groups was lower than those enrolled in the iron folic acid supplement group. Median duration of second stage of labor for the participants in the multiple micronutrient supplement groups was shorter than those enrolled in the iron folic acid supplement group.

- **The women believed their health was better with use of multiple micronutrients compared to iron folic acid.**

Participants enrolled in the multiple micronutrient supplement group perceived their health to be good or in normal condition postnataly compared to those were enrolled in the iron folic acid supplement group.

5.3 Recommendations

Arising from the results and the conclusions made in this study, the following recommendations are made:

- A comprehensive evidence-based WHO policy on multiple micronutrients accessibility and distribution, should be formulated to guide intake during pregnancy, to enhance iron and folic acid to a fifteen micronutrients composition. World Health Organization has already approved the use of a in fifteen micronutrients to promote pregnancy health and for children, but, there is no direct policy to promote and task the governments and Ministries of Health to uphold intake of multiple micronutrients; among the pregnant women and infants. There is need to support its accessibility to pregnant women from the second trimester and infants for maximum benefits.
- The successful introduction of policies related to multiple micronutrients during antenatal care, should be adopted into Ministry of health national programmes to include well-planned and health care management participatory consensus-driven processes of multiple micronutrients adaptation and implementation. These processes shall include the development or revision of national guidelines and protocols based on this recommendation.
- The MoH should create an enabling environment for the use of multiple micronutrients recommendation, including changes in the behavior of health care practitioners to enable the use of MM as per the evidence-based practice.

- These recommendations should be adapted into locally-appropriate documents and tools that are able to meet the specific needs of each county health service in Kenya. Modifications to the recommendation, where necessary, should be justified in an explicit and transparent manner by the Ministry of Health.
- There is need for further studies to support the significant beneficial outcomes of multiple micronutreints identified during this study; increase in birth weight, prevention of postpartum hemorrhage, postpartum health promotion and reduction of labor duration.
- There is need for further studies to determine the significance of micronutrients use in promoting the hemoglobin levels during pregnancy and other unknown benefits of multiple micronutrients identified in the study: breastmilk availability and exclusive breastmilk feeding upto six months of an infant life.

5.4 The Philosophy of the study

Based and owed to the study findings and conclusion: there is therefore introduction of new knowledge, that the use multiple micronutrients:

- reduces labor duration and maintains the standard labor duration of 1cm per hour during childbirth by preventing prolonged labor.
- increases birthweight by decreasing the chance of babies with a birthweight of < 2500 grams
- reduces postpartum hemorrhage to only the light or mild blood loss during delivery and lochia loss within the pueperium period
- Therefore promotion of use of multiple micronutrients than iron folic acid among the pregnant women, shall reduce maternal-infant morbidity and mortality in Kenya.

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APPENDICES

Appendix I: Questionnaire Consent form

Consent information statement for pregnant women in Nandi County

I anticipate each questionnaire interview will take about 15 minutes to complete per visit. You may complete the form on your own or I can sit with you and complete the questionnaire as we go through it. When complete, your anonymous questionnaire will be inserted in an envelope and stored in a locked box to protect your identity. I will be interviewing at least 3 people at each Eastern Produce and Nandi Tea Estates daily. My data collection should be complete at the end of December 2017 and it will take me until March 2018 to compile my report.

The purpose of the study is to introduce you to Multivitamins for pregnant and breastfeeding mothers you shall be required to swallow ONLY once every day immediately after taking food strictly and not tea. You shall be required to start taking the vitamins ONLY after being pregnant for six months till your baby shall be given the first immunization at 6 weeks after birth. You may continue taking the vitamins until the baby is 6 months old.

I hope to learn how the vitamins will help you to be healthy while you are pregnant and also have a healthy baby till one year. I would like to know other benefits you see while using the vitamins plus all matters related to the child's and your health. This will enable me to know the goodness of these vitamins. I hope to learn how to reach the vitamins to many pregnant women so that they can have good health and also strong babies.

I do not anticipate asking you questions that will be difficult to answer, but some may cause you to think about pregnancy conditions that are not good and may cause you to be sad.

You may refuse to take the vitamins and may withdraw from the study at any time without penalty. When you complete the questionnaire and return it to me, you are conveying your consent to participate without giving me your name.

You may be concerned; giving a negative report about the vitamins is not wrong and has no risk. I have attempted to ensure that you give accurate answers by the following ways: 1) The questionnaire is anonymous; your name is not attached to your responses; 2) If the research assistants read the questions to you and record your spoken answers, this will be done in a private setting where no one can overhear your responses.

If you have any questions, please do not hesitate to ask me: Betsy C. Rono at

0722 345 954

You may also call the Jomo Kenyatta University of Agriculture Science and Technology, School of Public Health to verify the approval of the study or ask for the Director, Institute of Tropical Medicine and Infectious Diseases (ITROMID) or my supervisors Prof. Yeri Kombe on 0718 279 964 and or Prof Makokha on 0713817436.

Please remove this page and keep it for your records.

I **accept/do not accept** to be part of the study. (**Cancel/circle what isn't needed)**

Study participant's Signature: ……………………………….

Date: …………………………………………………………

Betsy C. Rono

Printed name of researcher obtaining consent

Signature: ……………………………….

Date: ………………………………………

Appendix II: Questionnaire

MULTIPLE MICRONUTRIENTS VERSUS IRON FOLIC ACID SUPPLEMENTATION ON MATERNAL AND INFANT OUTCOMES IN NANDI COUNTY.

Section I: Enrollment

Are you pregnant? No ………………………. Yes …...…………………………..

When was your last menstrual period (LMP)? ……………………………………………………………..

If not 16 weeks, expected date of enrollment ………………………………………

Gestation of pregnancy ………...**If >16 weeks (4 months), enroll into the study.** Date of enrollment into study (**<u>1st visit)</u>** ……………………………………………

Expected Date of delivery **(2nd visit)** ……………………………………......

Date of birth………………………………………………………………………

Date of day 42 (6 weeks) (**<u>3rd visit)</u>** ………………………………………………..

Section II: **General information**

Current occupation……………… Average tea plucked daily in Kgs…..…………. Husband's occupation……………………Husband's Education level ..…………, Specify age in years …………..…, Woman's Parity (Fertility rate)………….. (No. Of children) and ages ……, ……., ……., ………, …….., ….. Gravida ..…..……………………………

Section III: Background Information

Instructions to Interviewee: This section provides the background details of the respondents.

#	Questions	Enter or circle your answers.	Answer chosen
1.	County Name		
2.	Tea estate Name		
3.	Dispensary Name		
4.	Village residence Name		
5.	Current Occupation		
6.	If Tea Plucker, specify average daily kgs	…………….	
7.	Plucking duration in hours		
8.	Education level	1=primary 2= secondary 3= college 4 = university	
9.	Birth year	**19** ☐☐ (yy)	
10.	Marital status	1=Single 2=Married 3=Divorced 4=Widowed 5=Separated	
11.	Husband's Occupation		
12.	Husband's Education level		

Section IVA: PREGNANY HEALTH BASELINE DATA TO BE COLLECTED ON ENROLLMENT

Evaluate based on current pregnancy and delivery. Researcher to circle/write the response.

Questions	Enter or circle your answers.	Answer chosen
1.Parity	……..	
2.Gravida	……..	
3.Age of children		
4.VDRL	1. Reactive 2. Non -Reactive	
5.Current complaints	1. Nausea 2. Vomiting 3. Dizziness 4. Other specify……….	
6.Urinalysis	1. NAD 2.	
7.Pica	1. Stones 2. Charcoal 3.Others Specify ……….	

Section IVB: PREGNANCY HEALTH PROGRESSIVE DATA TO BE COLLECTED ON ENROLLMENT, SECOND AND THIRD TRIMESTER AND ON DAY FORTY TWO (42)

Researcher to write the response in each space as per the specified time. Add more paper whre necessary.

Health guide	On Enrollment	2nd Trimester	3rd Trimester	Day 42	Remarks
1.Health status describe in words……					
2.Known sicknesses , explain …..					
3.Blood pressure					
4.Pica					
5.Preffered foods					
6.Appetite, explain					
7.Weight in kgs					
8.Height in cm					
9.BMI- Pre-pregnancy					
10.Hgb level in g/dl					
11.Work i.e. Tea plucked kgs					
12.Work in hours					
13.Day work stop/resumed					
14.Neonatal bwt					
14.Neonatal head circumference					

Section III: DATA ON DELIVERY

#	Questions	Enter or circle your answers.	Answer chosen
1	First ANC visit	1 = 3 months 2 =4 months 3 =5 months 4 =6 months 5 =7 months 6 =8 months 7 =9 months	
2	ANC attended	1 = once 2 = twice 3 = thrice 4 = four times 5= not attended while pregnant	
3	Where attended ANC – Tick All that apply	1 = Dispensary 2= Health Centre 3. Kapsabet County Hospital 4= Nandi Hills County Hospital 5. Kaptumo Sub- County home alone 6= TBA's home 7 = other specify…………………………	
4.	Labor onset	1 = home 2 = at work e.g. digging, fetching water, cooking etc, 3 = at the market 4 = in relatives home 5 = health centre/Dispensary 6 = hospital 7 = other specify-----------	
5.	Labor duration in hours	☐☐☐☐	
6.	Duration of second stage, specify	………………………………………………	
7.	Delivered	1 = Dispensary 2= Health Centre 3. Kapsabet County Hospital 4= Nandi Hills County Hospital 5. Kaptumo Sub- County home alone 6= TBA's home 7 = other specify…………………………	
8.	Presence of birth companion, specify who?	………………………	
9.	Approximate blood loss	…………………………………………	
10.	Neonatal outcome	Apgar score at:- 0 mins …… 5mins …..10 mins ……. Nature of birth:- live ………… stillbirth ……………… Weight …………….. Head circumference ……………….. Gender – male …….. female ………… Congenital malformations, if any specify ……	
11.	Was baby breastfed immediately, specify in hours	…………………………………………………… ………………………………	

12.	How soon was breast milk available, specify in hours	…………………………………………………… ………………………………	
13.	General health condition of mother on discharge, specify	…………………………………………………… …………………………………………………… ……………………………………………………………………… ……………………………………………………………………… ……………………………………………………	

Section VI: DATA AT 42 DAYS (6 WEEKS) POST DELIVERY

Tick the appropriate answer based on mother and baby's condition at 42 days postnatal

Questions	Enter or circle your answers.	Answer chosen
1.Lochia loss amount – no.of pads daily		
2.Lochia loss duration		
3.Mother's weight		
4.Mother's BP		
5.Breast milk amount	1. Sufficient for baby 2. Not sufficient for baby	
6.Breast milk substitution day	Specify day………………………	
7.Specify food baby fed with……..	Specify ………………….. ……………………………	
8.Neonatal outcome	1. Alive ………. 2. ……… Weight …………	
9. Milestones at 42 days	1. Social smile 2. Neck Control 3. Hand grip 4. Others specify	
10.Mother's health Specify day and complaint ………	……..	
11.Mother's return to work time. Specify in days …	……..	
12.Tea in kgs plucked daily after delivery	……..	

Appendix III: Consent form for Focus Group Discussion

I am asking you to participate in a study about pregnant women and those who have delivered in Nandi County. This consent form should give you the information you need to decide whether to be in the study. I welcome your questions about the purpose of the research, what I would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When I have answered all your questions, you can decide if you want to be in the study. This process is called "informed consent." I will give you a copy of this form for your records.

Purpose of the study

The purpose of the study is to learn the importance of vitamins during pregnancy, delivery and aftert delivery period. The benefits of vitamins, (if any) you shall tell me will help the government to give many pregnant women these vitamins. This will enable me to tell them that the vitamins are useful. I hope to learn what the Ministry of Health and the Hospitals will do to improve your (mother and baby) health.

Study procedures

FOCUS GROUPS: There will be a focus group of 8-12 pregnant women. The focus groups will take a maximum of 90 minutes, depending on the number of people. I would like to write down the discussions so they can be transcribed. No names will be attached to the focus groups, and the tapes will be destroyed as soon as they are transcribed, or within three months, whichever comes first.

Risks, stress, or discomfort

I do not anticipate that the questions will be difficult to answer, but some may cause you to think about pregnancy conditions that are distressing and may cause emotional discomfort. You may refuse to answer any question at any time, leave the focus group at any time, and may withdraw from the study at any time without penalty.

Confidentiality

No findings in this study will be linked to individual respondents. I will ask participants to respect each other's confidentiality, but I cannot ensure this. Data will be handled by data entry clerks. You may also call the Center for Public Health Research, Jomo Kenyatta University of Agriculture of Science and Technology, School of Public Health for any clarification or my supervisors Prof. Yeri Kombe on 0718 279 964 and or Prof Makokha on 0713 817 436

Please remove this page and keep it for your records.

I **accept/do not accept** to be part of the study. (**Cancel/circle what isn't needed)**

Study participant's Signature: ……………………………….

Date: …………………………………………………………

Betsy C. Rono

Printed name of researcher obtaining consent

Signature: ……………………………….

Date: ………………………………………

Appendix IV: Interview Guide

IMPACT OF MULTIPLE MICRONUTRIENTS VERSUS IRON FOLIC ACID SUPPLEMENTS ON PREGNANCY, DELIVERY AND POST DELIVERY UPTO 42 DAYS IN NANDI.

A. Introduction

The facilitator shall provide an overview of the goals of the discussion and introductions are made.

B. Rapport Building Stage

Easily answered questions on pregnancy, delivery and post delivery health shall be asked to encourage participants to begin talking and sharing.

i. Did you take soil, stones, charcoal or urge to eat some specific foods you rarely eat? Which ones? How often?
ii. Were you given some drugs from the hospital? Which ones? Did you take iron and folic acid you given from the hospital?
iii. How many times have you used these drugs/vitamins? Why?
iv. Did you like them? Why? Why not?

C. In-depth Discussion

These will focus on the main questions in the topic guide, encouraging conversation that reveals participants feelings and thoughts. e.g.

1. Pregnancy, delivery and postnatal period
    a. How was your pregnancy experience?
    b. Did you take any vitamins? Which ones?
    c. Was there difference in your pregnancy after taking the vitamins?
    d. How was your labor expereince?
    e. How was your delivery process?
    f. Did your baby cry immediately?
    g. How long did it take for you to breastfeed your baby after delivery?
    h. How are you doing you and your baby several days after delivery?
    i. What suggestions do you have to on taking vitamins?

D. Closure

Then summarize the impressions or conclusions gathered and participants clarify, confirm or elaborate on the information.

Appendix V: Ethical Approval 2017

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2015/162
Approval Number: 00061618

12th May, 2017

Ms. Betsy Rono,
Jomo Kenyatta University of Agriculture & Technology,
P.O. Box 62000-00200,
NAIROBI-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
12 MAY 2017
APPROVED
P. O. Box 4606-30100 ELDORET

Dear Ms. Rono,

RE: CONTINUING APPROVAL

The Institutional Research and Ethics Committee has reviewed your request for continuing approval to your study titled:-

"Impact of Multiple Micronutrients Versus Iron Folic Acid Supplementation on Pregnancy Outcomes in Nandi County, Kenya".

Your proposal has been granted a Continuing Approval with effect from 12th May, 2017. You are therefore permitted to continue with your study.

Note that this approval is for 1 year; it will thus expire on 11th May, 2018. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc:	CEO	-	MTRH	Dean	-	SOD
	Principal	-	CHS	Dean	-	SPH
	Dean	-	SOM	Dean	-	SON

Appendix VI: Ethical Approval 2016

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

12th May, 2016

Reference: IREC/2015/162
Approval Number: 0001618

Ms. Betsy Rono,
Jomo Kenyatta University of Agriculture & Technology,
P.O. Box 62000-00200,
NAIROBI-KENYA.

12 MAY 2016

Dear Ms. Rono,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Impact of Multiple Micronutrients Versus Iron Folic Acid Supplementation on Pregnancy Outcomes in Nandi County, Kenya."

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1618*** on 12th May, 2016. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 11th May, 2017. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc	CEO	-	MTRH	Dean	-	SOP	Dean	-	SOM
	Principal	-	CHS	Dean	-	SON	Dean	-	SOD

Appendix VII: Publications

Central African Journal of Public Health
2018; 4(4): 95-101
http://www.sciencepublishinggroup.com/j/cajph
doi: 10.11648/j.cajph.20180404.11
ISSN: 2575-5773 (Print); ISSN: 2575-5781 (Online)

SciencePG
Science Publishing Group

Multiple Micronutrients Versus Iron Folic Acid on Pica and Hemoglobin Levels Among Pregnant Women in Kenya

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[2]Center for Public Health Research, Kenya Medical Research Institute, Nairobi, Kenya
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doi: 10.11648/j.cajph.20180404.11

Received: July 6, 2018; **Accepted**: July 25, 2018; **Published**: August 27, 2018

Abstract: Pica is an indicator of low micronutrients in a pregnant woman's health. Low micronutrients pose a great risk to an otherwise healthy pregnancy. A healthy pregnancy, results in a healthy mother and baby; the critical probability in every pregnancy. The aim of the study was to introduce multiple micronutrients to promote maternal nutrition and influence development in pregnancy health outcomes. Sub-populations at risk of nutritional deficiencies and provided opportunities for early intervention to support the known benefit of multiple micronutrients on pregnancy outcomes i.e. up to six weeks (42 days) post delivery. The variations on pregnancy health, pica and hemoglobin levels among the Multiple Micronutrients (MMs) and Iron Folic Acid (IFA) groups. This was a block randomized controlled study. The intervention arm received MMs while the control received the usual care of IFA. A structured questionnaire with open and closed ended questions was used. Focus group discussions were conducted using a semi-structured guide to collect the qualitative data on the effects of prenatal multiple micronutrients among the pregnant women. The study assumed equal variances based on the Levene's test of >0.10 (f, 0.196, p=0.661). The difference in inter trimester weight gain means was 5.85 kgs for MMs and 5.52 kgs for IFA (t, 0.109, p=0.914), duration to resumption of household work was 7 days for MMs and 14 days for the IFA groups. The hemoglobin level increased by; 1.25 g/dl for MMs, and 0.45 g/dl for the IFA (t, 0.897, p= 0.376). Pica for stones was experienced among 55.6% of pregnant women; however there was no pica within 14 days among MMs enrollment, but persisted in the IFA group. The study demonstrated no significance in the importance of multiple micronutrients in increasing hemoglobin level (P,0.376), reduction of pica craving during pregnancy (P,0.176) and resumption of household duties (P,0.067) post delivery compared to those on Iron Folic Acid.

Keywords: Nutrients Deficiencies, Pregnancy Outcomes, Weight Gain, Return to Work

1. Introduction

According to past studies, pica status is a preliminary clinical indicator for micronutrient deficiency. [1] Nutrition and mineral deficiency precipitates pica behavior which can either be: geoghagia, pagophagia or amylophagia. Nutritional advice and prescriptions for multivitamins are given but never obtained leading to continued pica behavior. [1]

The causal relationship between pica and micronutrients remains unclear needing further studies. This then necessitates investigation into the strength of association which has been inconsistent. Iron and zinc supplementation has been associated with cessation of pica. Pica is common regardless of sex, race, culture, social position or residence. [2]

Despite all the studies, pica etiology remains unclear with a prevalence of between 0.02-74% in Iran and 46% among the pregnant adolescents in the USA. The relationship between pica and iron status biomarkers is unknown though it has been in observance since > 2000 years according to Hippocrates in 400BCE. [3] Pica practice is common in developing countries. Pica prevalence in Ghana is 9.1%, in Pemba, Tanzania for amylophagia -36.3%, geophagia and any pica- 40.1%. Amylophagia has been observed to be associated with low hemoglobin concentration and iron deficiency anemia. [4]

Women practicing pica have a 1.23 times more likely to be anemic compared to those who didn't. Anemia affects 38% of pregnant women globally. [5] Anemia prevalence in Africa is 44.6%: Ghana is 56%; and Uganda 32.5%. [5] According to World Health Organization, anemia prevalence is high and unacceptable public Health concern. [6]

According to WHO classification of anemia; hemoglobin level <11.0g/dl among the pregnant women is anemia, [1] and has a higher risk of preterm birth, low birth weight and small for gestational weight. Low hemoglobin in third trimester has a higher risk of low birth weight. [7, 8]

According to past studies, anemia is common among women from developing countries and related to iron deficiency and low intake. Iron deficiency can be prevented through supplementation to prevent onward complications to their children in future. [9]

2. Method

2.1. Ethical Considerations

The study was implemented after ethical consideration and approval was sought from the Moi University/Moi Teaching and Referral Hospital Institutional Research and Ethics Committee (IREC) and approval of the study topic by the Board of Postgraduate Studies of Jomo Kenyatta University of Agriculture and Technology (JKUAT). Permission to implement the study within the Tea Estates was sought from the Chief Executive Officer of the entire Eastern Produce Tea Estates, then the Doctor in charge of the Nandi Hills Doctors Scheme Association. Eastern Produce Tea Estates is housed within the Nandi County in Kenya.

2.2. Study Design

This sub-study was part of a block randomized controlled study. The Tea Estates administrative blocks were adopted and randomized to either the treatment or control arms. All pregnant women within the treatment and control arm blocks, meeting the inclusion criteria, were enrolled in the community until the sample size was achieved.

2.3. Study Participants

Participants were enrolled from the fourth month of pregnancy and followed up till forty two days post delivery. Community entry was done by seeking permission from the estate manager, clinical officer and village headman. The village field educator escorted the researcher to the respective homes with pregnant women for study enrollment. Study participants from the treatment arm were administered with a fifteen micronutrients capsule daily with meals, while the control arm continued with the usual standard care of taking Iron folic acid.

2.4. Study Implementation

Enrollment was conducted within the village homes of the women. Thereafter, bimonthly visits were done to the homes within the first month; thereafter next visits were conducted, during the third trimester, a week within delivery and at forty two days post delivery. Data was collected on pregnancy health i.e. age, parity, level of education, gestation, hemoglobin level, occupation, sickness and pica cravings.

2.5. Statistical Analysis

Data analysis followed four key steps: first the study sought to identify any possible relations between confounding factors and short term maternal neonatal outcomes in bivariate analysis; secondly, bivariate analysis was conducted between multiple micronutrients and iron folic acid on pica practice frequency and duration; thirdly bivariate analysis was conducted between multiple micronutrients and iron folic acid on hemoglobin levels; finally independent t test was conducted between the multiple micronutrients and iron folic acid groups respectively to compare the means for any significance.

Qualitative data was collected during the focus group discussions: one was conducted in the control and intervention clusters respectively. The data was collected using hand written notes and a voice recorder. Thereafter, the information in the voice recorder was transcribed and checked word per word to ensure no information was left out. The hand written notes from the two focus groups was compared with the transcribed information to ensure no detail was omitted. Thematic analysis was conducted to derive common themes in using multiple micronutrients versus iron folic acid between the groups. Qualitative variables derived from the questionnaires were expressed as percentages.

Descriptive and inferential statistics was applied to quantitative variables. Descriptive statistics was undertaken on the demographic data i.e. age, occupation, marital status, education level and antenatal visits frequency. Data was analyzed and presented in tables and graphs.

Inferential statistics was applied by calculating the Levene's test of equal variance assumption and through the independent t-test to establish whether the difference in means being observed is by chance alone or as a result of the multiple micronutrients or Iron folic acid on the pica and hemoglobin's variable tests.

Bivariate analysis was applied to establish the association between multiple micronutrients; pica and hemoglobin. Multivariate analysis was also conducted to establish association between multiple micronutrients; pica and hemoglobin while adjusting for any possible confounding variables. All statistical analysis results with $P < 0.05$ were considered significant. All analyses were done using SPSS version 16.

3. Results

Sixty study participants: out of one hundred and twenty five pregnant women; met the inclusion criteria and were included in the study. The main reasons for ineligibility were that their pregnancy was less than four months, had twin pregnancy or had less than two weeks to expected delivery date; in compliance to the specified eligibility criteria.

Maternal mean age was twenty five (25.65) years; with the youngest woman being fifteen years (15) and eldest during the pregnancy experience was thirty eight (38) years correspondingly with a standard deviation of +/- 6.01 years. Seventy five percent (45) of the women were married with only 25% (15) single *(See table 2)*.

Average parity was 1.24 children with majority of the women being pregnant for the first time with a parity of 0.00 at 46% and highest having a parity of 6.00 with a standard deviation of +/- 1.48. Average number of children per woman was 2.03 with the least having no children and highest having at most six (6) children *(See table 1)*.

The pregnant women had varied education levels: primary 61.7% (37), secondary 35% (21) and only 3.3% (2) had tertiary education. Thirty nine out of sixty women were working: 58.3% (35) were tea pluckers; 6.7% (4) factory workers; 30% (18) were housewives; 3.3% (2) were students in primary and secondary schools respectively; and 1.7% (1) was a teacher correspondingly. The pregnant women who were tea pluckers were able to pluck and average of 24.9kilograms daily; with the least having no plucking at all and the highest having sixty kilograms of tea plucked daily with a standard deviation of +/- 13.75 kilograms daily. They were able to work for an average of 7.9 hour s daily not working at all and the highest working for ten hours daily with a standard deviation of +/- 2.26 hours. Adolescent pregnancies were experienced at 18.3% (11) but the eldest women being between 35-39 years at 10% (6). Majority of the women were between 20-24 years at 31.7% (19) correspondingly *(See table 2)*.

Pica for stones was 73.3% (44), charcoal 15.0% (9), gas 1.7% (1) and other products- starch aroma 10% (6). However, there was preference for assorted kinds of food i.e. carbohydrates, proteins, fruits and vegetables: most preferred fruits at 31.7% (19); carbohydrates at 16.7% (10); least preferred was other vegetables (kales, pumpkin) at 3.3% (2) and milk at 3.3% (2) correspondingly. There was no difference in pica experience between the treatment and control arm at study enrollment (P=0.217). However, after at least two weeks of being administered and using multiple micronutrients and Iron folic acid respectively: the MMs group had pica at 6% (2) and IFA at 90% (27) correspondingly.

This is also consistent with the focus group discussions with the groups:

A woman said "Since I became pregnant, I have been eating stones and have to carry them in my bag because when I am not doing some work I throw some in my mouth to keep the urge down". Woman # 5 in Control group.

Table 1. *Showing Women's Demographics Ref: Betty original 12018.*

Mother characteristics	Specific characteristic		Study cohort	Percentage %
	Mean	25.65		
	Median	25		
Age in years	95% CI Age range - Minimum	15	60	100
	-Maximum	38		
	Std. deviation	+/- 6.01		
	Mean	1.24		
	Median	1.00		
Parity	95% CI Age range - Minimum	0.00	60	100
	Maximum	6.00		
	Std. deviation	+/- 1.48		
	Mean	2.03		
	Median	2.00		
No. of children	95% CI Age range - Minimum	0.00	60	100
	Maximum	6.00		
	Mean	24.9		
	Median	25.00		
No. tea kilos plucked in kgs	95% CI Age range - Minimum	0.00	30	58
	Maximum	60.00		
	Std. deviation	+/- 13.75		
	Mean	7.9		
	Median	8.0		
Hours worked in hours	95% CI Age range - Minimum	0.00	39	65
	Maximum	10.00		
	Std. deviation	+/- 2.26		
Hemoglobin levels -	Mean	11.39	60	100
	Median	11.20		
	95% CI Age range - Minimum	7.40		
	Maximum	15.20		
	Std. deviation	+/- 1.46		

But a woman in the MMS – intervention group said "I had tendencies to eat soil and stones when I became pregnant: but after taking the vitamins for two weeks; I didn't have the urge to eat them again, I forgot that I used to eat them!" Woman #3 in the intervention (MMs) group

Table 2. Demographic characteristics' frequencies in MMs versus IFAs groups.

Characteristic	Frequency MMs	Percentage %	Frequency IFAs	Percentage %
Parity- 0	11	36.7	16	55.6
1	9	30.0	0	0
2	4	13.3	12	38.8
3	0	0	2	5.6
4	2	6.7	0	0
5	2	6.7	0	0
6	2	6.7	0	0
Total	30	100%	30	100%
Occupation – Business	3	10	1	3.3
Factory worker	3	10	2	6.7
Housewife	7	23.4	11	36.7
Tea plucker	15	50	15	50
Students	1	3.3	1	3.3
Teacher	1	3.3	0	0
Total	30	100%	30	100%
Level of education -Primary	20	61	17	56.7
Secondary	9	35	12	40.0
Tertiary	1	3.3	1	3.3
Total	30	100%	30	100%
Marital status – Married	21	83.3	24	80.0
Single	9	16.7	6	20.0
Total	30	100%	30	100%
Maternal age - 15-19 years	8	27.8	3	10
20-24 years	10	33.3	9	30
25-29 years	7	23.3	7	23.3
30-34 years	2	6.7	8	26.7
35-39 years	3	10	3	10
Total	30	100%	30	100%
Foods preferred – Fruits-mangoes, pineapples, avocado, guava	12	40	7	23.3
Carbohydrates – ugali, chapatti, porridge, potatoes, Chips	3	10	7	23.3
Carbohydrates and beans	5	16.7	4	13.3
Milk	1	3.3	1	3.3
Proteins - Fish, liver, meat (matumbo)	0	0	4	13.3
Indigenous vegetables-"sderema", spider flower, black night shade	1	3.3	5	16.7
Other vegetables –kales, pumkins	2	6.7	0	0
Snacks- soda, biscuits	4	13.3	1	3.3
- None preferred- eats all	2	6.7	1	3.3
Total	30	100%	30	100%
Pica after two weeks – yes	2	6	27	90
No	28	94	3	10
Total	30	100%	30	

Ref: Betsy original 2 2018

Average anemia prevalence as per the WHO classification i.e. hemoglobin < 11.0g/dl was 41.5% among the pregnant women with MMs group having an average of 43.75% and IFA group at 40% respectively.

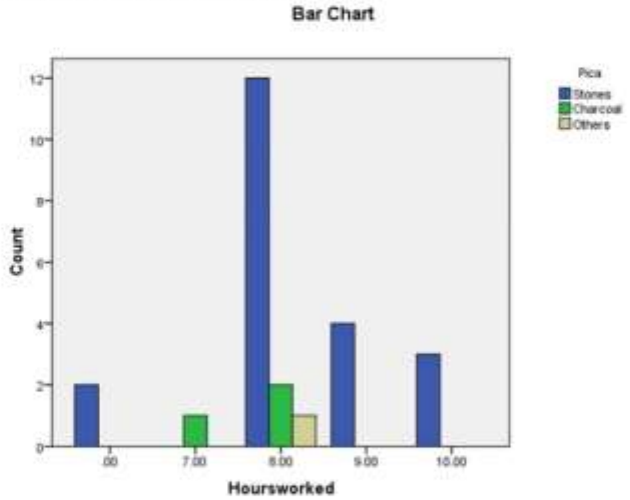
Most women experience dizziness at 48% followed by nausea at 20% and vomiting at 18%; though about 6% raised no complaint during their pregnancy experience. There was no association observed between sickness and pica practice; those sick at 8.3% (<5), but those not sick practiced pica at 25% (15). There was no significant difference in sickness and pica experience between the treatment and control arms with a Chi-square significance at ($p=0.217$). There was difference observed between length of work duration and pica practice ($p=0.000$); longer working hours was associated with a higher number of women practicing pica, *(See Figure 1 and Table 5 below)*. A minimal number of women were applied to test this variable; the association of work and pica practice versus those who regularly worked for longer hours only.

Table 3. The t test for pica and hemoglobin levels at 58 degrees of freedom.

	Levene's Test for Equality of Variances		t-test of equality of means					
Variables	**F**	**Sig.**	**t**	**df**	**Sig. 2-tailed**	**Mean Difference**	**95% Confidence Interval of the Difference**	
							Lower	**Upper**
Pica	2.096	0.000	-2.150	58	0.037	-0.615	-1.192	-0.038
HB levels in 2nd	2.079	0.157	0.051	58	0.960	0.024	-0.932	0.980
Change in HB levels	0.196	0.661	0.897	58	0.376	0.796	-1.005	2.5978
Weight added in 3rd	0.308	0.582	0.109	58	0.914	0.331	-5.806	6.467
Weight in 2nd trimester	0.045	0.832	1.770	58	0.083	5.284	-0.712	1.128

Ref Betsy Original 3 2018

There was a non- significant difference of 0.796 g/dl increase in the hemoglobin levels of the MMs versus IFA with a (t, 0.897, p=0.376.). However, there was a significant difference on pica practice among the two groups with a (t = -2.150 at 58 df, p= 0.037). *(See table 3 above)*. The pregnant women (n=60) both groups i.e. MMs and IFAs; on enrollment, experienced varied complaints: Dizziness at 47%, nausea at 20%, vomiting at 18%, fatigue at 2% and 5% had no complaints experienced.



Ref Betsy original 4 2018

Figure 1. *Association between hours worked and pica types among the women.*

Table 4. Test Statistics showing hemoglobin levels and pica.

			Enrolled	**HB levels in 2nd**	**Change in HB levels**	**Pica**
Chi-Square			1.852[a]	11.585[b]	13.158[c]	51.976[d]
Df			58	58	58	58
Asymp. Sig.			.174	.996	.983	.000
Monte Carlo Sig.	Sig.		.223[e]	.998[e]	.988[e]	.000[e]
	95% Confidence Interval	Lower Bound	.213	.997	.985	.000
		Upper Bound	.234	.999	.991	.000

Ref Betsy Original 5 2018

a. 0 cells (.0%) have expected frequencies less than 5.

b. 28 cells (100.0%) have expected frequencies less than 5. The minimum expected cell frequency is 1.5.

c. 27 cells (100.0%) have expected frequencies less than 5. The minimum expected cell frequency is 1.4.

There was a significant association between pica and hemoglobin levels. Women with minimal pica practice had no anemia, p, 0.000 *(See table 4 above)*. Use of multiple micronutrients reduced the urge of pica practice.

Table 5. *Association between hours worked versus pica.*

			Hours worked	Pica
Chi-Square			26.000[a]	29.120[b]
df			58	58
Asymp. Sig.			.000	.000
Monte Carlo Sig.	Sig.		.000[c]	.000[c]
	95% Confidence Interval	Lower Bound	.000	.000
		Upper Bound	.049	.049

a. 28 cells (100.0%) have expected frequencies less than 5. The minimum expected cell frequency is 5.0.
b. 0 cells (.0%) have expected frequencies less than 5. The minimum expected cell frequency is 8.3.
c. Based on 60 sampled

4. Discussion

Fertility rate was 2.03 which is below the national fertility rate of 3.9 in 2014 down from 4.6 in 2008 & 2009. [10], [11] The education attainment experience in this setting was at 38% for secondary level. This is below the national average which currently is placed at 43%. Primary education level was at 37% which is higher than the national level average of 25%. [11]

The average hemoglobin level experienced in this setting was 11.39g/dl which is above the World health Organization recommended non-anemic hemoglobin level of 11.0g/dl. Hemoglobin level above 11.0g/dl is encouraged during pregnancy; to prevent adverse neonatal outcomes; prevent risk for preterm; low birth weight. Anemia prevalence among the pregnant is 57.1%. [7], [12]

The anemia prevalence was 41.5% with the MMs arm having a prevalence of 43.75% versus the IFA arm having a prevalence of 40% respectively. The anemia prevalence is below the WHO recommended level; but consistent with the global anemia among the pregnant women which is 41.8%; and also in the African region which has a prevalence of 44%. Ghana has anemia prevalence of 56%. Uganda has anemia prevalence of 32.5%. [5], [13] Pica is believed to be a clinical indicator of micronutrient deficiency. The pica experience and practice among the pregnant women was diverse; pica for stone and clay i.e. geophagia was at 73.3%, charcoal at 15%. This is consistent with meta-analysis conducted which demonstrated a prevalence of between 11.0% -76.5%. [1] This is further consistent with a study done in Iran which gave a range of 0.02% to 74%. [2] Pica experience is experienced more among the pregnant adolescents in the USA at 46% with pagophagia (pica for ice) at 37%. [3] Pica experience for geophagia (pica for soil) in Tanzania is at 5.2% and amylophagia (pica for raw starch) at 36.3% and other pica practices at 40%. [4] Ghana pica practice prevalence is at 9.1%. [5]

The study benefited from the administrative blocks within the Tea Estates which made it efficient in randomization of the study area to either the intervention or control blocks. The study experienced limitations in the design adopted in its implementation. The study would have achieved better results if the double blind randomized design would have been adopted. However, this was limited to finances required to repackage and import the multiple vitamins and combine the iron folic acid to one capsule same as Iron Folic Acid one tablet implemented earlier by the Ministry of Health.

5. Conclusion

Multiple micronutrients supplementation has a non significant effect on hemoglobin level increase but a significant effect on pica practice reduction and control. World Health Organization approved use of a fifteen micronutrients to promote pregnancy health: but there is no direct policy to promote and task the governments and Ministries of Health to enhance intake among the pregnant women. There is need for a WHO policy on multiple micronutrients use among the pregnant women with a focus on community initiatives. The Ministry of Health has only managed to implement the Iron and Folic Acid tablets being a two micronutrients supplement. However, the women are still experiencing poor pregnancy health outcomes. Use of the fifteen micronutrient capsule has proven efficient and easy to take supported by marked improvement in pica practice and hemoglobin levels improvement.

There is need to replace the current Iron Folic Acid package with the fifteen multiple micronutrients given to women during pregnancy to prevent pica for stones(soil and clay) eating which has promoted anemia by encouraging helminthes and other worms infestation.

There is need for more studies to support other benefits of multiple micronutrients i.e. pica practice suppression and hemoglobin levels increase; other than the focus on birth weight increase.

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Multiple Micronutrients Versus Iron Folic Acid on Neonatal Breastfeeding Intervals and Period in Kenya

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Abstract: Exclusive breastfeeding within the first six months of life, provides sufficient infant nutrients, but remains a challenge for the postnatal women. Maternal pregnancy nutrient deficiency has long-term infant complications: heart disease; heart attacks; deaths; and irreversible cognitive challenges. Half of under five morbidity and mortality are associated with under nourishment. The study introduced multiple micronutrients to promote maternal nutrition to try and influence sustained exclusive breastfeeding to support neonatal and infant health. The study defined sub-populations at risk of nutritional deficiencies and provided opportunities for early intervention to support the known benefit of multiple micronutrients on breastfeeding outcomes up to six weeks (42 days) post delivery. The study determined variations on breastfeeding intervals and period among the Multiple Micronutrients (MMs) and Iron Folic Acid (IFA) groups. This was a Block Randomized Controlled study; treatment arm was administered with MMs while the control arm continued with the usual standard care of IFA. A structured Questionnaire with open and closed ended questions was employed to answer the research questions. Focus group discussions were conducted to collect qualitative data on impact of prenatal multiple micronutrients among the infants. The study demonstrated a significant difference in breast milk amounts and substitution between the treatment and control arm and assumed non-equal variances with a Levene's test <0.10 ($f=7.379$, $p=0.009$); breast feeding was initiated immediately at 100% for MMs and 68.8% for IFA; breast milk was available within 30 minutes post delivery in 86.3% of MMs and 25% for IFA (t, -4.8 $p=0.000$); breast milk amount was sufficient at 100% for MMs and 60.7% for IFA (-3.697, $p=0.001$); and no breast milk substitution was effected at 100% for the MMs, while breast milk was substituted in 18.5% of the IFAs within 42 days post delivery (t,-2.190, $p=0.033$). The study demonstrated significant benefits in micronutrient supplementation to promote infant health compared to the Iron folic acid use by enhancing exclusive breastfeeding practice.

Keywords: Substitution, Infant Health, Nutrient Supplementation

1. Introduction

Breastfeeding duration and exclusivity in Kenya, falls below the World Health Organization (WHO) recommended level, calling for interventions to benefit both infant and maternal health. [1] WHO recommends exclusive breastfeeding with exception to medicine and vitamin syrup, to infants till six months of age to achieve optimum growth. [2, 3] In Sub Saharan Africa, Ethiopia is the leading on exclusive breastfeeding with a prevalence of 70.5% with an awareness level of 92.4%. [4]

In Brazil, maternal education is associated with a high prevalence of exclusive breast feeding; however, locally antenatal education has not been proven to significantly increase exclusive breastfeeding. [5] This calls for randomized controlled studies with adequate power to evaluate effectiveness of breastfeeding interventions. [6] Face to face support in enhancing exclusive breastfeeding up to 6 months has been demonstrated to have better success rates. [7] Women have tried expressing their breast milk to enhance exclusive breastfeeding but instead resulted in a shorter period. [8]

According to past studies, exclusive breastfeeding of the infant is related to a reduced risk of overweight gain or obesity later in the first year. [9] In Ghana, despite a 99% awareness on exclusive breastfeeding, only 10.3% of the women practice exclusive breastfeeding coupled with shorter maternity leave days. [10] According to past studies in Saudi Arabia, exclusive breastfeeding for the first six months is only practiced by 31.4% of the women. Working women are less likely to practice exclusive breastfeeding, remaining a challenge. [11]

The study undertook to establish the difference in breastfeeding intervals and period outcomes in use of multiple micronutrients versus the usual standard care of Iron folic acid supplementation among the pregnant women in the Nandi County. The multiple micronutrients was the treatment arm administered to the women in the intervention blocks and followed up to observe their impact on breastfeeding of the newborn children up to forty days post delivery.

2. Method

2.1. Ethical Review

Permission to conduct the study was sought through the Institutional and Ethical Review Committee (IREC), Moi University/Moi Teaching and Referral Hospital, Kenya. Approval was given vide FAN: IREC 1618. Thereafter approval of the study topic by the Board of Postgraduate Studies of Jomo Kenyatta University of Agriculture and Technology (JKUAT) was also granted after meeting all the University requirements. The study was then implemented officially after a written permission to implement the study within the Tea Estates was received from the Chief Executive Officer of the entire Eastern Produce Tea Estates, then the Doctor in charge of the Nandi Hills Doctors Scheme Association. Nandi County houses the Eastern Produce Tea Estates in Kenya.

2.2. Study Design

This was a sub-study of a block randomized controlled study. The Estates are organized into administrative blocks with an average area of about five kilometers wide with expansive tea estates. The estates are further divided into 4-5 villages of about 90-120 homes that houses the tea pluckers with their families. Each tea plucker is given a one roomed house used as a bedroom, living room and kitchen for the family and divided into rooms using large pieces of line hooked into the wall. The estates were adopted as blocks and randomized to either the treatment or control arms. All pregnant women within the treatment and control arm blocks, meeting the inclusion criteria, were enrolled within their villages and homes in the community, until the sample size was achieved. Twelve color coded cards were used to randomize the Estates into blocks i.e. 4 orange, 4 white and 4 green based on the Estates proximity and location. Each Estate was labeled as 'A' 'B' 'C' 'D'; 'E' 'F' 'G' H; and 'I' 'J' 'K''F' respectively. The twelve cards were placed in an opaque envelope and mixed thoroughly, then the Security guard In Charge at the Nandi Tea Doctors Scheme, was asked to pick a card at random blindly and place each card placed against each block (Estate) consecutively, till all the (three blocks) 12 cards were over from the envelop. The Estates with orange color were the intervention and green the control blocks correspondingly. Women pregnant within these Estates were enrolled into the control and intervention blocks respectively. The intervention blocks were administered with MMS and the control administered with the usual care and given IFAS correspondingly till the sample size was achieved.

2.3. Study Participants

Community entry was done by seeking permission from the estate manager, clinical officer and village headman. The village field educator escorted the researchers to the respective homes with pregnant women for study enrollment. Study participants from the treatment arm were administered with a fifteen micronutrients capsule daily with meals, while the control arm continued with the usual standard care of taking Iron folic acid. Pregnant women with a gestation of 16 weeks or more were eligible to be enrolled into the study. They were identified by the Field Educators using simple random sampling, between Monday and Friday. Thereafter, a visit was made to the villages, MMS for the intervention or IFAS for the control, was administered in their respective homes. Participants were enrolled from the fourth month of pregnancy and followed up till forty two days post delivery.

2.4. Study Implementation

A visit to the women's homes on enrollment was conducted by the Researchers and Field educators. A follow up visit was conducted to the homes within the first month; thereafter next visits were conducted, during the first month of the third trimester, a week within delivery and at forty two days post delivery. Data was collected during these visits; on pregnancy and neonatal health; breastfeeding duration and time for substitution of breast milk.

2.5. Statistical Analysis

The data analysis was initiated by calculating frequencies of the demographic data; women's parity, occupation, level of education, marital status, and neonates' gender at birth. Case summaries and reports were generated for the birth outcomes and breastfeeding. Thereafter, the same variables were subjected to inferential statistics by calculating the difference in means and the significance tests. Equal variances of the variables were not assumed in all the calculations; the Levene's tests had a significance level less than < 0.10. Data was presented in tables and graphs. Inferential statistics was applied by calculating the independent t-test to establish whether the difference in means being observed was by chance alone or manipulation by the multiple micronutrients or Iron folic acid on the breastfeeding intervals and substitutions' variables.

Descriptive and inferential statistics was applied to quantitative variables. Descriptive statistics was undertaken on the demographic data i.e. age, occupation, marital status, education level and delivery data.

The study also had qualitative data which was mainly collected during the focus group discussions: the control and intervention clusters respectively. Hand written notes were carried out and applied in the data analysis. A voice recorder was also applied as a back up and to capture information missed out through the handwritten notes. The information in the voice recorder was transcribed and checked word per word to ensure no information was left out. Then the hand written notes from the two focus groups was compared with the transcribed information to ensure no detail was omitted. Thematic analysis was conducted to derive common themes in using multiple micronutrients versus iron folic acid between the groups. Qualitative variables derived from the questionnaires were expressed as percentages.

The outcome variables were the breast milk availability, amount and substitution and whether the baby was breast fed immediately after birth. A significance level of less that p = <0.05, was considered to be significant and concluded that the difference observed was due to the manipulation of the treatment arm i.e. multiple micronutrients in the study. All analyses were done using SPSS version 16.

3. Results

A total of sixty study participants met the inclusion criteria and were enrolled.

Most women had a parity of two at 38.8% (23) and zero parity at 32% (19). Most of the participants were tea pluckers at 58.3% (35) followed by 25% (15) who are housewives. The highest education level achieved by the women was tertiary at 3.3% (2) and secondary at 61% (37) *(See table 1 below.)*

***Table 1.** Showing frequency distribution of mother's and baby's characteristics.*

Characteristic	Frequency	Percentage %
Parity- 0	19	32
1	9	15
2	14	23
3	4	6
4	4	6
5	5	9
6	5	9
Occupation – Business	2	3.3
Factory worker	4	5
Housewife	15	25
Tea plucker	35	58.3
Students	2	5
Teacher	2	3.3
Level of education - Primary	37	61
Secondary	21	35
Tertiary	2	3.3
Marital status – Married	50	83.3
Single	10	16.7
Newborn Gender - Male	34	56.7
- Female	26	43.3

Ref. Betsy original 1 2018

Among the newborns; 56.7% (34) were males and 43.3% were females. There was a difference in the mean birth weights between the groups: MMs group had a mean birth weight of 3.819 kilograms versus the IFA group with 3.237 kilograms. The mean birth weight difference between the groups was 0.582 kilograms (t, 2.41, p, 0.023). All the neonates were born alive at 100%, but at forty two days after birth, one child died in the IFA group *(See table 2 below).*

Seventy five percent of the children at forty two days had achieved a social smile and neck control in the MMs group compared to only 40% (12) with a social smile and 6.7% (2) with neck control in the IFA group (*See table 3*).

The infants at forty two days had increased their birth weight by an average of 1.49kgs for the MMs group compared to 1.55kgs in the IFA group.

***Table 2.** Birth outcomes t-test statistics.*

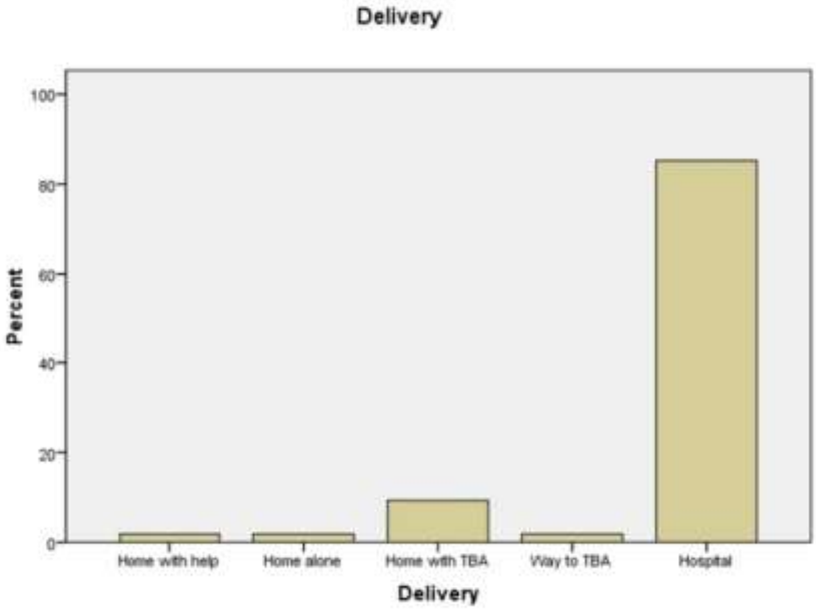
Variables	Levene's Test for Equality of Variances		t-test for Equality of Means				95% Confidence Interval of the Difference	
	F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Lower	Upper
Birth weight	8.7	0.005	2.41	58	0.023	0.582	0.088	1.077
Breast milk availability	6.1	0.018	-4.60	58	0.000	-1.855	-2.667	-1.043
Breastfeeding done	74.3	0.000	-2.72	58	0.009	-0.269	-4.684	-6.999
Breast milk Amount	3.5	0.000	-3.55	58	0.001	-0.385	-6.031	-1.66
Breast milk Substitution	32.9	0.000	-2.19	58	0.034	-0.192	-3.690	-1.53

Ref. Betsy original 2 2018

Breast milk was available within thirty minutes among 54.5% (16) of the MMs group compared to only 23.3% (7) in the IFA group. More than 60% (18) of the IFA group took over fifty minutes to breast milk availability.

Breast milk amount was sufficient for the neonates born to women in the MMs group compared to 60% (18) in the IFA group.

Breastfeeding was initiated immediately among 100% of the MMs group compared to 68% (21) of the IFA group. Breast milk substitution was not practiced among the MMs group compared to 18.5% of IFA group.



Ref Betsy original 4 2018

Figure 1. *Showing Place of delivery n=60.*

Despite the referral system in place within the Tea Estates: eighty five percent of the total women had a skilled delivery but a total of about fifteen percent had unskilled delivery; either at home alone, with the traditional birth attendant (TBA) on her way to the TBA *(See figure 1 above)*.

There was a significant difference in birth weight with a (t, 2.41 p=0.023). Therefore the noted difference in birth weight of 0.582 kilograms cannot be equated to chance alone but the multiple micronutrients introduced to the treatment arm.

Breast milk availability within thirty minutes had a significant difference between the groups with a (t, -4.60, p=0.000). Breast feeding therefore, was therefore initiated immediately giving a significant difference between the groups with a (t, -2.72, p=0.001). Breast milk sufficiency had a significant difference observed with a (t,-3.55, p=0.001). There was a significant difference in breast milk substitution between the groups with a (t, -219, p=0.034).

Table 3. *Frequency, means and standard deviation of neonatal outcomes.*

Variable	Measure	Supplements taken			
		MMs n=30	**Percent**	**IFAs n= 30**	**Percent**
1. Birth weight in kgs	Mean	3.819	Not applicable	3.237	Not applicable
	Median	3.300		3.200	
	Min	2.60		2.200	
	Std. Dev	+/- 1.01		+/- 0.545	
2. Birth outcome at birth	Alive	30	100%	30	100%
	Dead	0		0	
3. Birth outcome at 42 days	Alive	30	100%	29	96.7%
	Dead	0	0%	1	3.3%
4. Congenital malformation	None		None		
5. Baby milestones at 42 days	Social smile	22	75%	12	40%
	Neck control	22	75%	2	6.7%
	Grasping	7	24%	1	3.3%
	None of above	0	0	15	50%
6. Increase in birth weight in kgs	Mean	1.49		1.55	
	Median	1.55		1.50	
	Min	-1.00		-1.30	
	Maximum	3.10		5.20	
	Std. Dev	+/- 1.33		+/- 1.37	
7. Breast milk availability post delivery in minutes	Within 10	3	9.1	0	0.0
	11-20	7	22.8	1	3.3
	21-30	16	54.5	6	20.0

Variable	Measure	Supplements taken			
		MMs n=30	Percent	IFAs n= 30	Percent
	31-40	1	4.5	3	10.0
	41-50	0	0.0	2	6.7
	Over 50	3	9.1	18	60.0
8. Breast milk amount	Sufficient	30	100	18	60.7
	Not sufficient	0	0	12	39.3
9. Breast feeding done immediately	Yes	30	100	21	68.8
	No	0	0	9	31.2
10 Breast milk substitution	No	30	100	24	81.5
	Yes	0	0	6	18.5

Ref: Betsy original 4 2018

4. Discussion

The increase in birth weight observed in the study is equated to the use of multiple micronutrients use among the pregnant women in the study and is consistent with past studies. [12]

The difference observed in breast milk, availability and substitution in the study, is associated with the multiple micronutrient use among the pregnant women. Variations in breast milk nutrient content have been reported to be related to micronutrients dietary intake. Past studies have proven that zinc, copper and iron have been established to have no correlation between breast milk concentration and dietary intake. [11]

The exclusive breast milk prevalence established in the study was 81.5% within the first forty two days of infant live which was above the national overall observed; 61% in 2014. [13, 14] The exclusive prevalence observed in the study is higher than what was observed in a study in urban slums in Kenya which was 2%. [15]

The study also established that newborns more than a third; 36.7% were breastfed in the first thirty minutes following delivery and not consistent with the urban slum study that observed that 37% were not breastfed and 40% given breast milk substitution for the first three days. [15]

5. Conclusion

The study demonstrated that, the observed neonatal and infant outcomes cannot be equated to chance but the manipulation by the multiple micronutrients in the study supported by their significant outcomes. There was significant improvement noted on the neonatal and infant cognitive, neurological and physiological growth.

Use of multiple micronutrients contributed to the significant increase in newborn birth weight, infant birth weight increase, which is almost equivalent to the observed birth weight increase, in the Iron folic acid group substituting breast milk with other foods and water. The breast milk was sufficient for the infant; there was no breast milk substitution by the women in the group using multiple micronutrients up to forty two days. Use of multiple micronutrients enhanced immediate initiation of breastfeeding within thirty minutes of neonatal birth and breast milk availability enhanced exclusive breastfeeding within the first forty days of the infant life.

There has been a series of global, regional and national campaigns on exclusive breastfeeding to support the known benefits; sustainability has been improving slowly; use of multiple micronutrients will enhance uptake of exclusive breastfeeding practice for the infants, evidenced by sufficient breast milk experienced by the women up to forty two days post delivery.

There was no neonatal or infant mortality experienced: Multiple micronutrient use contributed towards reduction of neonatal and infant mortality. There is need for more support in promoting use of multiples micronutrients among the pregnant women to prevent maternal, neonatal and infant mortality, globally and especially in the LMICs where the study was carried out. More studies are needed to support and demonstrate the key role undertaken by the fifteen multiple micronutrients. There is need for a comprehensive WHO policy on multiple micronutrients intake during pregnancy, to replace the iron and folic acid.

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Appendix VII: A Sketch map of Kenya, not drawn to scale

Geographical: Eastern produce and Nandi Tea Estates are in Nandi County.

Appendix VIII: Tea Estates Map (Google maps 2020)