EFFICACY OF PHONE BASED COUNSELLING IN SUPPORTING PRIMI-PAROUS WOMEN TO EXCLUSIVELY BREASTFEED.

A DISSERTATION PRESENTED IN PART FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF THE MASTER’S DEGREE IN PAEDIATRICS AND CHILD HEALTH, UNIVERSITY OF NAIROBI

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DECLARATION

I declare this is my original work and it has not been presented in any other university for a degree award.
ACKNOWLEDGEMENT
I would like to sincerely thank my supervisors, Prof. Rachel Musoke, Prof. Ruth Nduati, Dr. Dalton Wamalwa and Christine Mwangi for the guidance and patience during the study period. My gratitude also goes to Jedida Ndinda and her team from KEMRI who worked tirelessly in collection of saliva samples from mother-baby pairs, and Peter Mwaura MSc (Biometrics) for statistical support.
DEDICATION
I dedicate this work, first and foremost to the Almighty God, for the strength throughout this period, my parents, Stephen Waweru Kihara and Lucy Nduta kihara, my sisters, Loice Njoki, Martha Nyaguthii and Teresia Wangari for their support and prayers
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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>BFHI</td>
<td>Baby Friendly Hospital Initiative</td>
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<td>EBF</td>
<td>Exclusive Breastfeeding</td>
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<td>IF</td>
<td>Infant Feeding</td>
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<td>KDHS</td>
<td>Kenya Demographic and Health Survey</td>
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<tr>
<td>KEMRI</td>
<td>Kenya Medical Research Institute</td>
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<td>KNH</td>
<td>Kenyatta National Hospital</td>
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<tr>
<td>MCH</td>
<td>Maternal Child Health Clinic</td>
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<tr>
<td>MDG</td>
<td>Millennium Development Goal</td>
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<tr>
<td>UNICEF</td>
<td>United Nations International Children’s Emergency Fund</td>
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<td>WHO</td>
<td>World Health Organization</td>
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ABSTRACT

**Background:** Although Exclusive breastfeeding has been shown to have great health benefits to both mother and child, current rates of exclusive breastfeeding have remained low especially in the developing countries. Frequent contact with an infant feeding counselor has been the most effective method of increasing exclusive breastfeeding in populations that traditionally breastfeed. Health systems in resource constrained settings where the public health and individual benefits of exclusive breastfeeding are highest do not have the resources to maintain a cadre of health workers who visit all mothers of new born babies to support infant feeding. This study evaluated phone based counseling as a strategy of supporting the primiparous mothers to breastfeed their infants exclusively. A recognized problem in assessing the effect of lactation counseling is that the effect is based on mothers’ self-reported behavior, and it is a concern that mothers in the intervention group may over report rates of exclusive breastfeeding. This study was designed to measure breast-milk and nonbreast-milk water intakes by using the dose-given-to-the-mother (dose-to-mother) deuterium dilution technique and to validate reported exclusive breastfeeding in a subgroup of mother-infant pair.

**Objective:** To assess the efficacy of phonebased breastfeeding support among primiparous women at Kenyatta National Hospital. In a subset of the women, to evaluate the accuracy of self report by mothers on their infant feeding practices by use of deuterium dilution technique.

**Design:** Randomized controlled study.

**Methods:** Subjects were drawn from Kenyatta National Hospital labour Ward and randomly assigned to receive either phone based breastfeeding support or standard health care messages. The group in the intervention arm received phone calls weekly in the first month and fortnightly in the second and the third month. Data on infant feeding practices was collected by use of the standard WHO questionnaire at scheduled MCH visits (6wks, 10wks and 14wks).

In a subsample of 20 mothers infant pairs(mean infant age six weeks) who reported exclusive breastfeeding by self report, intakes of breastmilk and non breastmilk were measured to assess the validity of self report in reporting exclusive breastfeeding.

**Results:** A total of 180 mother-baby pairs were enrolled into the study, 91 in the
intervention arm and 89 controls. At 6 weeks 51(56%) of the 91 women randomized to the intervention showed up for the interview compared to 52 (58%) of 89 in the control arm (p=0.881). A further 20 (22%) women in the intervention arm and 18 (20%) in control arm were interviewed over the phone. Overall at 6 weeks there was interview data for 78% of the women in both the intervention and control arm. At 10 weeks 42 (46%) of 91 in intervention arm and 44 (49%) of 89 in control arm were seen at 10 weeks.(p=0.659). A further 15 (16%) women in the intervention arm and 17 (19%) in the control arm were interviewed over the phone. Therefore interview data at 10 weeks was available for 62% of the women in the intervention arm and 68% in the control arm of the study. At 14 weeks 37(40%) of the 91 women in the intervention arm and 40(45%) of the 89 in the control group were seen at 14 weeks (P=0.561).

Overall, high exclusive breastfeeding rates were achieved in the intervention arm. Exclusive breastfeeding rates were 93% at 6, 90% at 10 and 87% at 14 weeks postpartum and 72%,58% and 45% in the same time periods for the control babies. The exclusive breastfeeding rates were significantly higher in the phone based counselling group at all three points of evaluation (p value <0.05).

Self reporting of exclusive breastfeeding was an inaccurate method of obtaining information on exclusive breastfeeding rates with the gold standard test using deuterated water giving a positive predictive value of 20%.

**Conclusion:** Phone based counselling by a paediatric SHO resulted in > 90% EBF rates up to 14 weeks, and significantly reduced child mortality.

**Recommendations:**

A repeat study to determine the efficacy of counselling by other health cadres in supporting the mothers to breastfeed their infants exclusively should be done. The hospital should consider designating a paediatrician or well trained paediatric Clinical officer to do phone based counselling of mothers of newborns in the first six weeks of life to improve breastfeeding and health seeking behaviour.

A larger study should be done focussing mainly on the cost implication and feasibility of use of phone call in supporting breastfeeding mothers at a national level.
LITERATURE REVIEW

The fourth millennium goal (MDG-4) commits the international community to reducing mortality among the under five years by two-thirds between 1990 and 2015\(^1\). Globally, breastfeeding is now recognized as central to achievement of the millennium development goals. Breastfeeding saves lives and exclusive breastfeeding for the first 6 months, protects infants against common childhood diseases such as diarrhea and acute respiratory infections\(^2\). Further, breastfeeding has important long-term health benefits that include reduced risks of obesity, allergies, heart disease, diabetes, breast and ovarian cancer in women, and facilitates child spacing\(^2\). Recent data indicates that exclusive breastfeeding is the most effective preventive intervention for ensuring child survival and it is estimated that universal coverage (99% uptake by all mothers of young children) would result in 13% reduction of all under-five deaths\(^3\) as shown in figure 1.
The WHO and UNICEF recommendations on breastfeeding are as follows:

1. Initiation of breastfeeding within the 1st hour after birth.

2. Exclusive breastfeeding for the first six months of life.

3. And continued breastfeeding for two years of life or more together with safe, nutritionally adequate, age appropriate and responsive complementary feeding starting after the 6th month. Despite the known and proven benefits, the prevalence of exclusive breast-feeding in many parts of the world is disconcertingly low. According to the WHO data bank on breastfeeding in 2000, only 35% of infants between 0-4 months were exclusively breastfed. In sub-Saharan Africa, only 33% of children under the age of three months were exclusively breast-fed. The potential impact of optimal breastfeeding practices is especially important in developing nations, but non-breastfed children in industrialized countries are also at greater risk.
of dying. A study of post-neonatal mortality in the United States found a 25% increase in mortality among non-breastfed infants\textsuperscript{6}. In the UK Millennium Cohort Survey, six months of exclusive breast feeding was associated with a 53% decrease in hospital admissions for diarrhoea and a 27% decrease in respiratory tract infections\textsuperscript{6}. Figure 2, shows the percentage of children less than six months on exclusive breastfeeding world wide as at 2000-2006.

Figure 2: Percentage of children <six months old exclusively breastfed (2000-2006)\textsuperscript{5}
KENYAN SITUATION

Infant and Young child feeding practices have been deteriorating over the past two decades in Kenya. Exclusive breastfeeding rates at six months are dismally low and declined from 3.5% in 1998 to 2.7% in 2003 as shown in table 1. This is despite the fact that Kenya is a signatory to all the global conventions with a commitment to do everything possible to promote, protect and support optimal infant and young child feeding practices.

Situation of breastfeeding and complementary feeding practices in Kenya

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<tr>
<td>Initiation of breastfeeding</td>
<td>58%</td>
<td>52%</td>
<td>58%</td>
</tr>
<tr>
<td>( % of babies’ breastfed within one hour of birth)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exclusive breastfeeding</td>
<td>3.5%</td>
<td>2.6%</td>
<td>3.6%</td>
</tr>
<tr>
<td>( % of babies 6 months of age exclusively breastfed in the last 24 hours)</td>
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<tr>
<td>Duration of breastfeeding</td>
<td>21 months</td>
<td>20 months</td>
<td>21 months</td>
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<tr>
<td>(median duration in months of breastfeeding of children under three years of age)</td>
<td></td>
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<tr>
<td>Bottle-feeding</td>
<td>17.7%</td>
<td>27.6%</td>
<td>16.9%</td>
</tr>
<tr>
<td>( % of breastfed babies 0–&lt;12 months of age fed from bottles in the last 24 hours)</td>
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Regional studies have had results that are consistent with the findings of the demographic health surveys. Studies on Infant feeding (IF) conducted in Kibera, Kitui, and Muranga districts showed dismal rates of exclusive breastfeeding with over two thirds of infants surveyed introduced to other feeds by 2 – 3 months of age. A
study conducted in Karatina and Homa bay district to evaluate infant feeding practices showed, poor knowledge of appropriate breastfeeding practices with seventy five percent of the women in Karatina and eighty nine percent in Homa Bay believing that water should be given to babies in addition to breast milk. In addition, mothers thought that other complementary foods should be provided in addition to breast milk in the first month of life\textsuperscript{12}.

**FACTORS AFFECTING BREASTFEEDING**

Successful breastfeeding results from the interplay of a complex series of physiological and behavioral interactions between a mother and her infant. Maternal choice is influenced by the breastfeeding information the woman receives, as well as by the physical and social support provided to her. Breastfeeding should be promoted as the natural way of feeding among the general public. Parents usually make decisions on infant feeding shortly before or early in pregnancy. The choice, however, can be influenced by attitudes established long before a pregnancy is even contemplated. It is therefore, important to represent breastfeeding to the general public as the natural way to feed infants, and create an environment where breastfeeding becomes the normal, easy and preferred choice for the vast majority of parents.
It is important that boys and men should also receive infant feeding information because, as potential future fathers, they will have an important supportive role to play in the decision to breastfeed and in the success of breastfeeding. Breastfeeding is affected by several factors as demonstrated in figure 3.

**Figure 3: Model of breastfeeding behaviour. Source: HPN/HPP/PAHO**
TYPES OF INTERVENTIONS TO PROMOTE EXCLUSIVE BREASTFEEDING

Breastfeeding support is the extra support given to mothers to educate and motivate them to exclusive breastfeed especially in the early months of the infant’s life.

The support can be categorized into hospital based strategies and community based strategies delivered by professionals and volunteers

HOSPITAL BASED INTERVENTIONS

Breastfeeding Education

Health education specifically dedicated to breastfeeding and regular contacts with competent health workers, lactation consultants and/or peer counselors, is an effective way to promote the initiation and to extend the duration of breastfeeding, especially when continued after childbirth\(^\text{13}\). For mothers to succeed in breastfeeding, they need accurate information during pregnancy and support at the time of birth for early initiation. Breastfeeding education provides correct information in simple language and provides solutions to mothers’ fears like ‘not enough milk’, and breast problems like sore nipples, mastitis and engorgement.

A systematic review and meta analysis of the U.S preventive task force on effectiveness of interventions to promote breastfeeding showed that, of all interventions, educational programs had the greatest effect of any single intervention on both initiation (difference 0.23; 95% confidence interval [CI], 0.12–0.34) and short-term duration (difference 0.39; 95% CI, 0.27–0.50). Support programs conducted by either telephone or personal contact, or both increased short-term (difference 0.11; 95% CI, 0.03–0.19) and long-term duration (difference 0.08; 95% CI, 0.02–0.16). When education was combined with support programmes, larger increases
in initiation (from difference of 0.06; 95% CI, -0.02-0.15 to difference 0.21; 95% CI, 0.07-0.35), short-term duration (from difference 0.11; 95% CI, 0.30-0.19 to difference 0.37; 95% CI, 0.17-0.58)\textsuperscript{14}.

There is a direct relationship between the outcome of exclusive breastfeeding rates and the number of times the information on EBF is relayed. In a randomized control study done in Peri-urban Mexico on efficacy of home based peer counseling, there were two intervention groups with different counseling frequencies. Six visits and three visits were compared with a control group that had no intervention. At 3 months post partum, exclusive breastfeeding was practiced by 67% of the mothers in the six visit group, 50% of the mothers in the three visits group and 12% of the mothers in the control mothers (intervention group v/s control p<0.001 six visits v/s three visits p=0.0214\textsuperscript{15}.

**Baby Friendly Hospital Initiative**

The Ten Steps for Successful Breastfeeding of the Baby Friendly Hospital Initiative has proven to be effective. In particular, rooming-in which allows breastfeeding on demand, results in ample milk production and helps establish adequate lactation, thus overcoming the often perceived problem of lack or insufficiency of breast milk. In the Republic of Belarus, a trial on promotion of Breastfeeding Intervention (PROBIT) done. Sites were randomly assigned to receive an experimental intervention (n = 16) modeled on the Baby-Friendly Hospital Initiative of the World Health Organization and United Nations Children’s Fund, which emphasizes health care worker assistance with initiating and maintaining breastfeeding and lactation and postnatal breastfeeding support, or to a control intervention (n = 15) of continuing usual infant feeding.
practices and policies. Infants from the intervention sites were significantly more likely than control infants to be breastfed to any degree at 12 months (19.7% vs 11.4%; adjusted odds ratio [OR], 0.47; 95% confidence interval [CI], 0.32-0.69), and were more likely to be exclusively breastfed at 3 months (43.3% vs 6.4%; \( P < .001 \)) and at 6 months (7.9% vs 0.6%; \( P = .01 \))\(^{16} \).

**Community focused strategies**

Step 10 of the BFHI stresses on community support. Support programs involve telephone or in-person clinic, hospital, or home visits by lactation consultants, nurse or peer counsellor\(^{17} \). Recent Canadian data indicate that 22% of new mothers aged 15–49 years breast-feed for less than 3 months, this premature discontinuation was more as a result of difficulty with breast-feeding, including lack of information and support, than of women's choice\(^{18} \). A national survey in Singapore in 2001 found that only 21% of mothers were breast feeding at six months, with less than 5% of mothers exclusively breast feeding, despite the fact that nearly 90% of the mothers surveyed indicated that breast feeding was the best form of infant nutrition and 95% said they had attempted to breastfeed\(^{19} \). It is evident that many mothers are unable to establish and maintain breast feeding successfully, despite wanting to do so. While antenatal education and counseling is helpful, 68% of mothers said that early problems with breast feeding was the main reason they stopped nursing before two months postpartum\(^{20} \). Other barriers were lack of knowledge about breast feeding and lack of support from health professionals\(^{20} \). Women value being shown how to breast feed rather than being told how to\(^{21} \).
In Dhaka, Bangladesh, 95% of mothers have home deliveries and therefore hospital based strategies for breastfeeding promotion cannot reach mothers. Mothers were randomized into intervention and control arm. In the intervention group, 15 home-based counseling visits were scheduled, with two visits in the last trimester, three early postpartum (within 48 hrs, on day 5, between days 10 and 14), and fortnightly thereafter until the infant was 5 months old. Peer counselors were local mothers who had received 10 days' training. 363 women were enrolled into each group. Peer counseling significantly improved breastfeeding practices. For the primary outcome, the prevalence of exclusive breastfeeding at 5 months was 202/228 (70%) for the intervention group and 17/285 (6%) for the control group (difference=64%; 95% CI 57%-71%, p>0.0001).

A recognized problem in assessing the effect of lactation counseling is that the effect is based on mothers' self-reported behavior, and it is a concern that mothers in the intervention group may over report rates of exclusive breastfeeding. Whereas methods such as unannounced observations of mother-child interactions, monitoring of infant weight gain, and monitoring of the duration of lactational amenorrhea can help validate reports, no gold standard method of validation is available. In a recent study from Brazil, Albernaz et al used a stable-isotope dosing method to show that lactation counseling increases breastfeeding duration but does not increase breast milk intakes in infants assessed at 4 mo of age. Because this stable-isotope method also estimates the intake of non-milk fluids, it could potentially be used to validate mothers' reports of infant feeding practices. This study was designed to measure breast-milk and nonbreast-milk water intakes by using the dose-given-to-the-mother
(dose-to-mother) deuterium dilution technique and to validate reported exclusive breastfeeding in a subgroup of mother-infant pairs.

The conventional method for measuring breast milk intake entails weighing the baby before and after each feeding\textsuperscript{24}. This is time-consuming, inaccurate and it interferes with the mother’s normal activities. It can also not be used when the baby sleeps with the mother and is fed on demand many times during the night. A more practical and accurate method is to measure milk intake by isotope dilution using deuterium labelled water (\( \text{H}_2\text{O} \)) as described by coward et al(1982)\textsuperscript{25}.

Deuterium labelled water is administered by mouth to the mother, it enters the baby via breast milk and mixes with all the water in the baby’s body. The rate of deuterium appearance in the baby measured in saliva collections is proportional to breast milk intake. The main advantages of using deuterium include: it gives integrated measurement of infants milk intake over 10-14 days, it improves accuracy and its practical for measurements in the field.
Breast milk intake by the baby is determined as described by Coward et al (1982) based on the two-compartment analysis as shown in Figure 4

![Two compartment model analysis](image)

**Figure 4: Two compartment model analysis**

\( F \) indicates water flow. Subscript \( m \) refers to mother, \( o \) to outside and \( b \) to baby. \( V \) is the total body. The combination of subscripts indicates the direction of fluxes (for example, \( F_{mo} \) indicates the flow to the mother from outside).

**STUDY JUSTIFICATION AND UTILITY**

Although, exclusive breastfeeding is now globally recognized as the most effective preventative intervention for ensuring child survival, the practice is rare among Kenyan mothers. Exclusive breastfeeding rates at six months are dismally low and declined from 3.5% in 1998 to 2.7% in 2003. In the recently released 2008-2009 KDHS, the exclusive breast feeding rate at six months was 3.6\(^{10}\). The impact of early initiation of breastfeeding on infant mortality and its economic advantages are well known, yet little attention has been paid by health-care practitioners and policy-makers to this simple preventive strategy, except for annual campaigns that aim to highlight its importance, such as the World Breastfeeding Week\(^{26}\). Phone based counseling has been shown to improve rates of exclusive breastfeeding in other countries as evidenced by a study that was done in Toronto to show the effect of peer
support on breast feeding duration among primi-parous women. The control group had the conventional care while the intervention group had conventional care plus telephone based support initiated 48hrs after hospital discharge by a woman who had experience with breastfeeding. Significantly more mothers in the peer support group than in the control group continued to breast-feed at 3 months post partum (81.1% v. 66.9%, \( p = 0.01 \)) and did so exclusively (56.8% v. 40.3%, \( p = 0.01 \)). Breast-feeding rates at 4, 8 and 12 weeks post partum were 92.4%, 84.8% and 81.1% respectively among the mothers in the peer support group, as compared with 83.9%, 75.0% and 66.9% among those in the control group (\( p \leq 0.05 \) for all time periods.

Currently, mobile phones are relatively affordable to many Kenyans due to importation of mobile phones from China and calling rates have been lowered due to the competition in the communication market. Therefore, the cost of making phone calls is relatively affordable.

To support mothers on proper feeding practices, there are such national programs as Malezi lBora, community health workers and health workers at health facilities. But no studies have been done in Kenya to determine the impact of these initiatives.

Current health care systems in Africa, Kenya included, are not able to employ health or community health workers to follow up women frequently as required.

The study determined the impact of counseling through phone calls on the rates of exclusive breastfeeding. This intervention is less labour intensive and relatively cheap
OBJECTIVES

Primary objective
To determine the efficacy of phone calls as a means of promoting and supporting primi-parous mothers to exclusively breast feed.

Secondary objective
To validate use of self report as a means of obtaining infant feeding practices by use of deuterium dilution technique

METHODOLOGY

Study design
This was a randomized controlled trial.

Study Site
The study was carried out in Kenyatta National Hospital, labour wards, post natal wards and MCH clinic. Kenyatta National Hospital is a certified Baby Friendly Hospital and has a busy maternity ward with an average of 650 spontaneous vertex deliveries (SVD) per month. It is a University teaching Hospital and draws its clients from people of both low and high social economic status.

Study Population
Primi-parous women who delivered at Kenyatta National Hospital.
Study period

The study period lasted 14 weeks as shown in figure 4 (from the time of delivery to the reception of the last pentavalent vaccine)

Recruitment and inclusion criteria

The study involved 3 stages of screening of participants. All medical records of primiparous women admitted into the labour ward were reviewed. List of names of primiparous women were selected if they met the following criteria:

Stage 1

1) Absence of any medical condition e.g. HIV/AIDS, pre-eclampsia, diabetes or using illegal drugs
2) Gestational age of 37 weeks or more.
3) More than 18yrs of age.

Women, who met the inclusion criteria for participation based on the medical records review, subsequently were approached by a recruiter and the study introduced to them.

Stage 2

A screening interview was carried out by the interviewer to ascertain eligibility at this stage. To qualify for participation at this 2nd stage, the mothers had to satisfy the following criteria:

1. Considering to breastfeed her newborn
2. Only takes one bus to come for maternal child health clinic for immunizations
3. Willing to stay in the study area for at least 3 months after delivery.
4. Available and willing to be contacted by phone

5. Willing to come for immunization at Kenyatta Maternal Child Health clinic (MCH)

6. Willing to participate in the study

Stage 3

The 3rd stage of screening occurred during post partum hospitalization to ascertain if both mother and her infant were still qualified for the study. The mother had to be free of any known medical condition that would prevent her from successful breastfeeding.

For the newborn to be included he/she had to be;

1) Born at term >37wks

2) Birth weight>2.5kg

3) With no neonatal medical complication requiring treatment in the neonatal unit.

4) Delivered through spontaneous vertex delivery

5) Apgar scores at 1 and 5 minutes equal to or more than six.

Women who met the inclusion criteria and agreed to participate in the study signed a written consent and responded to a baseline interview to provide data on demographic, socioeconomic and biomedical factors.

Randomization was done at this stage into either intervention group or control group

Exclusion criteria

1. Mothers who declined to participate in the study.

2. Mothers who were multi-parous
Summary of the recruitment process is as shown in figure 5 below.

Primi mothers coming to deliver at KNH labour wards

1st screening procedure (220 mothers)
2nd screening procedure (200 mothers)
3rd screening procedure postnatally (180 mothers)

Eligible  Not eligible  Excluded
Informed consent

Yes  No
Recruited, baseline Questionnaire
Health breastfeeding education

Randomization

Control arm  Intervention arm

Figure 5: Summary of the Recruitment Process
Randomization process

Participants were randomly assigned to two arms.

A table of random numbers with even and odd numbers was computer generated by a statistician. The numbers were sealed in individual consecutive envelopes and were assigned to the participants as they were being enrolled.

Both groups received standard breastfeeding education. The breastfeeding education topics included the following:

1) Definition of exclusive breastfeeding.
2) Early initiation of breastfeeding.
3) Importance of colostrum.
4) Breastfeeding on demand.
5) Benefits of exclusive breastfeeding for the infants and their mothers.
6) Breastfeeding techniques (positioning and attachment).
7) Dangers of pre-lacteal feeds.
8) Adequacy of breast milk for six months.
9) Dangers of breast milk substitutes.

The health talks were provided every day during the post-partum hospitalization by the principal investigator or by the designated assistants. A video on correct positioning and attachment was shown to all mothers and they were given brochures from the ministry of health on infant feeding to carry home. The intervention group was informed that they will subsequently be called while at home as a form of extra support.

Intervention group

Upon discharge, women randomized to telephone counseling, were offered breastfeeding support by use of phone calls. This was done weekly in the first month and fortnightly in the second and third month. During the phone calls, the mothers were reminded the issues discussed during breastfeeding education and were allowed to ask questions and discuss any challenges they were experiencing during the breastfeeding period.
Control procedure

Women in the control arm, were only called to be reminded to come for the immunization visits at 6wks, 10wks, and at 14 wks and no extra information was offered to them regarding infant feeding.

Evaluation of breastfeeding practice.

The evaluation of breastfeeding practice among the mothers in the two groups was done by interviewing the mothers using the standard WHO tool for assessing infant feeding practices. The interviews were conducted at 6 weeks, 10 weeks and at 14 weeks. These are times when children attend their immunization clinics.

SAMPLE SIZE CALCULATION

From the study done in Toronto, Canada where peer counselors were used to support primi mother to exclusively breastfeed by use of phone calls, 56% of women in the interventional group were found to exclusively breastfeed at 3 months and 40% in the control group\(^2\), we adopted these figures for the sample size calculation.

The sample size formula for comparing equal proportions was used.

\[
N = \left( z^2 + \beta^2 \right) \left( p_1 (1-p_1) + p_2 (1-p_2) \right) / (p_1 - p_2)^2
\]

Where \( z^2 \) represented the critical value for a normal distribution for 95% confidence (=1.96),

\[ \beta^2 \] is the critical value for a normal distribution at 80% power (=0.84).

\( p_1 \) is the proportion of participants in the intervention arm expected to exclusively breastfeed

\( p_2 \) is the proportion of participants in the control arm expected to exclusively breastfeed.

\( N \) is the sample size
Assuming that 56% of study participants on intervention arm will adhere to exclusive breastfeeding compared to 40% of participants in control, at 95% confidence and 80% power, we needed to enroll 87 study participants in each arm.
DATA COLLECTION

CLINICAL METHODS
Confidential questionnaire were completed by all the participants after recruitment. The pre-intervention questionnaire assessed demographic characteristics, socioeconomic status, pregnancy intention, intended breastfeeding and the planned exclusive breastfeeding duration. The follow-up questionnaire assessed infant feeding practices and breastfeeding challenges encountered. During follow-up, participants in the intervention group were offered phone based breastfeeding support weekly during the first month and fortnightly during the second and third month. During the postnatal visits at the MCH Clinic, (at 6weeks, 10weeks and 14 weeks), the mothers were interviewed on their infant feeding practices by a blinded interviewer, using the standard WHO tool.

LABORATORY METHODS
In a sub sample of 20 mothers who had themselves reported that they were exclusively breastfeeding, intakes of both breast milk and nonbreast-milk water were estimated 6 weeks after delivery by using the dose-to-mother deuterium dilution technique as described by coward (1984). This is based on water turnover rates in both mother and baby.

Pre-dose saliva samples were collected from the mother-baby pair to measure baseline deuterium concentration before dosing the mother with deuterium. A dose of thirty grams (30 g) of deuterium oxide (99.8% purity) was orally administered to the mother. This was followed by a weighed 200g of tap water to rinse down the whole dose, after which saliva samples were collected. Subject dosing with deuterium and
sample collection was done at Kenyatta MCH clinic. Saliva samples were collected by means of a ball of sterile cotton wool rotated in the mouth until soaked with saliva, and squeezed through a syringe into a sterile polypropylene vial. Post-dose saliva samples from both the mother and infant was collected on days 1, 2, 3, 4, 13 and 14 into 5ml sterile polypropylene tubes. Samples were transported in cool boxes (0 to -3°C) to the laboratory in KEMRI and stored at -20°C until analysis.

MEASURES OF OUTCOME

The primary outcomes of this trial were self reported duration of exclusive breastfeeding using 24-hour recall (for the past 24hrs did your baby receive any other food except breast milk?), and “ever given” recall (did the infant receive any other food than breast milk since birth) as per the standard WHO tool for assessing breastfeeding practices. The data was collected at 6 weeks, 10 weeks, and 12 weeks during the postnatal visits at the KNH MCH. The secondary outcome was to verify the validity of data obtained by self report on infant feeding practices: Intakes of breast milk and nonbreast-milk measured by use of dose given to the mother deuterium dilution technique.

WHO DEFINITIONS

Exclusive Breastfeeding: The infant receives only breast milk from his/her mother or a wet nurse and no other liquids or solids with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines.28
**Predominant breastfeeding:** The infant’s predominant source of nourishment has been breast milk, however the infant may also have received water and water based drinks, fruit juices, ORS, drops or syrups.\(^{28}\)

**Mixed-milk feeding:** The child consumes breast milk and any other non-human milk, such as commercial or home-prepared infant formula, cow’s milk, fermented milk, evaporated milk, other animal milk. The child may also consume any of the liquids allowed under predominant breast-feeding but no solid foods or food-based fluids.\(^{28}\)

**Complementary feeding:** the child consumes breast milk and any semi-solid or solid food or food-based liquid other than fruit juice or sugar water (e.g., thin cereal-based gruel). The child may also consume any liquid or non-human milk.\(^{28}\)

**DATA HANDLING AND MANAGEMENT**

Participants’ files were stored in a locked cabinet by the investigator during data collection and in a lock cabinet in the statistician’s office during data entry. None of the participant files had information that could directly identify the participant; rather the participants’ files bore serial numbers instead of names. Data was entered into a password protected Microsoft Access database and once entry was completed, the principal investigator compared the contents of the database with the hard copy files of the participants to identify any data entry errors.
STATISTICAL ANALYSIS

The study data was analyzed using the Statistical Package for Social Scientists (SPSS), USA Version 17.0. Other statistical analysis software like S-Plus and Stata were be used for better graphical presentation of the results. Categorical variables were compared using the chi-squared tests for nominal variables whereas continuous variables were compared using t-tests for comparing means. Independent correlates of exclusive breastfeeding were identified using logistic regression. The proportion that died in the intervention group was calculated as total number of children in the intervention group who died divided by the total number of children randomized into the intervention arm of the study. Similarly the proportion that died in the control group (CIo) was calculated as the total number of deaths in the control group divided by total number of children in the control group. The incidence density of the deaths of the children in the intervention arm (IDe) and in the controls (IDO) was then calculated as total number of deaths divided by the total time of observation in weeks and expressed as death per child-weeks of follow-up. The relative risk of death in the intervention arm was calculated as Ie/Io. The protective factor of phone based counseling was calculated as (Ie - Io)/Ie.
ETHICAL CONSIDERATIONS

During the study the following ethical issues were considered:

1. The nature of the study was explained to the personnel at MCH clinic and labour ward.

2. Informed consent was sought from the mothers before being included in the study. No name of the participant was written. The study subjects were coded with numbers. No mother was victimised for declining to participate in the study.

3. The study protocol was presented at the department of paediatrics and child health as well as the KNH ethical and research committee for approval.

4. Deuterium being a stable isotope is safe to both the mother and the infant.

STUDY LIMITATIONS

1. The study period lasted only 3 months and therefore the effect of breastfeeding support was not assessed at 6 months as is recommended by the WHO.

2. Loss to follow up
RESULTS

Characteristics of the enrolled women

Table 1, shows the socio-demographic characteristics of the enrolled mothers. The intervention group and controls were comparable in terms of age, marital status, level of education, average income per month and employment status with none of the differences between the two groups achieving statistical significance at $p \leq 0.05$. Therefore, the randomization process was quite successful.

Table 1: Baseline data for the study population.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Intervention arm N=91</th>
<th>Control arm N=89</th>
<th>P-value</th>
<th>Odds ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10-18</td>
<td>3 (4.3%)</td>
<td>5 (5.6%)</td>
<td>0.99</td>
<td>-</td>
</tr>
<tr>
<td>19-25</td>
<td>57 (61.9%)</td>
<td>58 (65.1%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>26-35</td>
<td>31 (33.6%)</td>
<td>26 (29.2%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>72 (79.1%)</td>
<td>66 (74.1%)</td>
<td>0.43</td>
<td>1.32(0.62-2.8)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertiary</td>
<td>45 (49.4%)</td>
<td>35 (39%)</td>
<td>0.176</td>
<td>-</td>
</tr>
<tr>
<td>Secondary</td>
<td>38 (41.7%)</td>
<td>40 (44.9%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary &amp; below</td>
<td>13 (14.1%)</td>
<td>20 (22.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 3,000</td>
<td>21(23%)</td>
<td>21(23.5%)</td>
<td>0.179</td>
<td>-</td>
</tr>
<tr>
<td>3,000-5,000</td>
<td>22(24.1%)</td>
<td>26 (28.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5,001-10,000</td>
<td>26(28.5%)</td>
<td>25 (27.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10,001-15,000</td>
<td>9(9.8%)</td>
<td>6 (6.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;15,000</td>
<td>13(14.2%)</td>
<td>11 (12.1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>43(47.5%)</td>
<td>40</td>
<td>0.75</td>
<td>1.1(0.59-2.06)</td>
</tr>
</tbody>
</table>
Figure 6: Flow chart showing progression of subjects in the study.

Key

FTF: Face to Face interview

PBI: Phone based interview
FOLLOW-UP OF THE STUDY PARTICIPANTS

Figure 6, above summarizes the progression of the study participants at different time points.

At 6 weeks, 51 (56%) of the 91 women randomized to the intervention showed up for the interview compared to 52 (58%) of 89 in the control arm (p=0.881). A further 20 (22%) women in the intervention arm and 18 (20%) in control arm were interviewed over the phone. Overall, at 6 weeks, there was interview data for 78% of the women in both the intervention and control arm.

At 10 weeks, 42 (46%) of the 91 women in intervention arm, and 44 (49%) of the 89 women in control arm were seen at 10 weeks. (p=0.659). A further 15 (16%) women in the intervention arm and 17 (19%) of the 89 women in the control arm were interviewed over the phone. Therefore, interview data at 10 weeks was available for 62% of the women in the intervention arm and 68% in the control arm of the study.

At 14 weeks, 37 (40%) of the 91 women in the intervention arm and 40 (45%) of the 89 in the control group were seen at 14 weeks (P=0.561). Other 13 (14%) of the 91 women in the intervention arm and 14 (15%) of the 89 women in the control arm were interviewed over the phone. Overall interview data was collected from 54% of the 91 women in the intervention group and 60% of the 89 women in the control group. Thus the drop-out rates in the two arms of the study were comparable.

Causes of drop out from the study

20 of the 39 infants who did not reach the 6 week visit were reported to have died. An additional 5 infants died in the period 6-10 weeks. 15 of the infants died in the...
first week and 5 in the period 8 – 28 days. No infant was reported to have died after 10 weeks of life. Overall, 14 (10%) of the 180 women whose infants were presumably alive, did not come for the 6 week visit and were unreachable on the phone contact they had provided. At 10 weeks, 23(16%) women were lost to follow-up and at 14 weeks, 14(11%) women were lost to follow up.

Table 2, shows that the women who dropped out of the study and the ones left in the study by the end of 14 weeks were comparable p value being insignificant

Table 2: Comparison of baseline characteristics of the mothers who dropped out of the study and the ones left in the study by the end of 14 weeks.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>In the study at 14 weeks n=104</th>
<th>Dropped out by 14 weeks n=76</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10-18</td>
<td>5 4.4%</td>
<td>4 5.3%</td>
<td>0.770</td>
</tr>
<tr>
<td>19-25</td>
<td>66 63.9%</td>
<td>47 61.8%</td>
<td></td>
</tr>
<tr>
<td>26-35</td>
<td>33 31.7%</td>
<td>25 32.9%</td>
<td></td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>80 76.7%</td>
<td>54 71.1%</td>
<td>0.560</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tertiary</td>
<td>46 44.4%</td>
<td>30 39.5%</td>
<td>0.192</td>
</tr>
<tr>
<td>Secondary</td>
<td>45 43.3%</td>
<td>37 48.7%</td>
<td></td>
</tr>
<tr>
<td>Primary &amp; below</td>
<td>19 18.3%</td>
<td>14 18.3%</td>
<td></td>
</tr>
<tr>
<td><strong>Income</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 3,000</td>
<td>24 23.3%</td>
<td>16 21.1%</td>
<td>0.841</td>
</tr>
<tr>
<td>3,000-5,000</td>
<td>28 26.7%</td>
<td>21 27.6%</td>
<td></td>
</tr>
<tr>
<td>5,001-10,000</td>
<td>29 28.3%</td>
<td>25 32.9%</td>
<td></td>
</tr>
<tr>
<td>10,001-15,000</td>
<td>9 8.3%</td>
<td>6 8.3%</td>
<td></td>
</tr>
<tr>
<td>&gt;15,000</td>
<td>14 13.3%</td>
<td>9 11.8%</td>
<td></td>
</tr>
<tr>
<td><strong>Employment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>48 46.1%</td>
<td>39 51.3%</td>
<td>0.093</td>
</tr>
</tbody>
</table>
**Breastfeeding practice**

Table 3: Visit at 6 weeks

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Intervention group N= 71</th>
<th>Control group N = 70</th>
<th>P value</th>
<th>Odds ratio (CI 95%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breastfeeding initiation Days Hours</td>
<td>2 69</td>
<td>2 68</td>
<td>1.00</td>
<td>0.99(0.1-10.14)</td>
</tr>
<tr>
<td>Pre lacteal feeds given</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2 69</td>
<td>27 53</td>
<td>0.000</td>
<td>0.06(0.01-0.26)</td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

At the 6 weeks visit, mothers were interviewed regarding infant feeding practice since birth of the child. Significantly, fewer mothers in the intervention arm reported to have given pre lacteal feeds i.e.2 (2.8%) of 71 mothers in the intervention arm and 27(38.5%) of 70 babies in the control arm reported to have given pre lacteal (p=<0.001) as shown in table 3.

**Introduction of complementary feeds (other milks and solids)**

As shown in table 4, at 6 weeks, 25 mothers reported that they had introduced complementary feeds, 7 % in the intervention arm and 28.5% in the control arm (p = <0.05). At 10weeks, 29 mothers had introduced complementary feeds 5% in the intervention arm and 42.6% in the control group (p=<0.05). At 14weeks, 35 mothers had started complementary feeding, 10% in the intervention arm and 55% in the control group (p=0.001).
Table 4: Pattern of introduction of complementary feeding

<table>
<thead>
<tr>
<th>Age at assessment for introduction of complementary feeds</th>
<th>Intervention group N= 71</th>
<th>Control group N = 70</th>
<th>P value</th>
<th>Odds ratio (CI 95%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 weeks</td>
<td>5/71(7.0%)</td>
<td>20/70(28%)</td>
<td>0.005</td>
<td>0.19(0.06-058)</td>
</tr>
<tr>
<td>10 weeks</td>
<td>3/57 (5.3%)</td>
<td>26/61(42%)</td>
<td>0.000</td>
<td>0.07(0.02-0.29)</td>
</tr>
<tr>
<td>14 weeks</td>
<td>5/50 (10%)</td>
<td>30/54 (55%)</td>
<td>0.001</td>
<td>0.2(0.1-0.5)</td>
</tr>
</tbody>
</table>

Impact of the phone based counseling on child deaths

Determination of the impact of the phone based counseling on child deaths was restricted to the women with known outcomes, 71 in the intervention arm and 70 in the control arm of the study. Table 5 below presents data on death outcomes.

Table 5: Mortality rates in the two groups

<table>
<thead>
<tr>
<th>Timing of deaths</th>
<th>Intervention arm N=71</th>
<th>Control arm N=70</th>
<th>Total deaths N=141</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before 6wks</td>
<td>5(7%)</td>
<td>15(21.4%)</td>
<td>20 (14%)</td>
</tr>
<tr>
<td>After 6 wks</td>
<td>0(0.0%)</td>
<td>5(7.1%)</td>
<td>5 (3.5%)</td>
</tr>
<tr>
<td>Total deaths</td>
<td>5 (7%)</td>
<td>20 (28.6%)</td>
<td>25 (17.7%)</td>
</tr>
</tbody>
</table>
Overall, 25 (17.7%) of 141 infants with available outcome data were reported to have died. Twenty (80%) of the 25 infant deaths occurred within the first 6 weeks of life, 15 in the first week and 5 before 6 weeks.

Another 5 children died in the period between 6 and 10 week of life. The largest contributor to the mortality of these children was found to be delay in seeking health care and inability of the mothers to identify danger signs in their sick children. The mothers of the children, who sought care, did so in the small private clinics which most are ran probably by unqualified staff.

There was a lower mortality rate in the phone based counseling arm of the study. A total of 5 (7%) of the 71 children in the intervention of arm and in whom outcome information was available at 6 weeks point of observation had died compared to 15 (21%) of 70 children in the control arm of the study giving a relative risk of RR 0.33 (95% CI 0.13-0.86, p=0.01). By the end of 10 weeks, there were an additional 5 deaths in the control arm of the study and none after that until 14 weeks of follow-up. Therefore, the mortality rate was 5 (7%) of 71 infants in the intervention arm, 20 (28%) among the 70 infants in the control arm as shown in table 5 above. The risk of death by 10 weeks among children in the intervention arm was RR=0.25 [(0.1, 0.62) p < 0.001].

**Breastfeeding problems**

Overall, women in the intervention arm reported fewer problems compared to those receiving facility based counseling 10(14.0%) versus 28 (40.0%) p=<0.05 at 6 weeks. Similar observations were made at 10 weeks and 14 weeks with 6(8.4%) women in the intervention arm reporting breastfeeding problems compared to 20 (28.5%) of the women in the control arm p = (<0.05) as demonstrated in figure 7 below. The most
commonly reported breastfeeding problems were; pain during breastfeeding, cracked/sore nipples and breast engorgement.

Figure 7: Comparison of the Breastfeeding problems between the two arms
SECONDARY OBJECTIVE:

**Breast milk output as determined by deuterium dilution technique.**

Saliva levels of D2 were determined using Fourier Transform Infrared Spectrometry (FTIR) and based on equations developed by Coward et al. Intake of human milk and water from sources other than human milk was determined. Babies with < 25 g/day of water from other sources were classified as exclusively breastfed.

Only 4 of the 20 women who reported exclusive breastfeeding were truly exclusively breastfeeding as determined by the deuterium dilution technique. The proportion of women who truly exclusively breastfed was $\frac{4}{20}=0.2(20\%)$ (Table 6).

Mean volume of breast milk in the women who reported exclusive breastfeeding was 647.3 g/day compared to 586.7 g/day in those classified as not exclusively breastfeeding ($p=0.530$). The mean volume of non-human milk intake was 56.3 g/day in the 4 women classified as exclusive breastfeeding compared to 209 g/day in the non-exclusive breast feeders ($p=0.003$).
Table 6: Breast Milk intake per day.

<table>
<thead>
<tr>
<th>Code</th>
<th>Milk intake (g/day)</th>
<th>Non oral Milk intake (g/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>657</td>
<td>-157</td>
</tr>
<tr>
<td>2</td>
<td>677</td>
<td>342</td>
</tr>
<tr>
<td>3</td>
<td>553</td>
<td>382</td>
</tr>
<tr>
<td>4</td>
<td>596</td>
<td>51</td>
</tr>
<tr>
<td>5</td>
<td>810</td>
<td>66</td>
</tr>
<tr>
<td>6</td>
<td>553</td>
<td>137</td>
</tr>
<tr>
<td>7</td>
<td>498</td>
<td>428</td>
</tr>
<tr>
<td>8</td>
<td>457</td>
<td>158</td>
</tr>
<tr>
<td>9</td>
<td>498</td>
<td>94</td>
</tr>
<tr>
<td>10</td>
<td>572</td>
<td>168</td>
</tr>
<tr>
<td>11</td>
<td>184</td>
<td>559</td>
</tr>
<tr>
<td>12</td>
<td>534</td>
<td>4</td>
</tr>
<tr>
<td>13</td>
<td>576</td>
<td>-75</td>
</tr>
<tr>
<td>14</td>
<td>809</td>
<td>216</td>
</tr>
<tr>
<td>15</td>
<td>832</td>
<td>3</td>
</tr>
<tr>
<td>16</td>
<td>856</td>
<td>86</td>
</tr>
<tr>
<td>17</td>
<td>802</td>
<td>169</td>
</tr>
<tr>
<td>18</td>
<td>625</td>
<td>122</td>
</tr>
<tr>
<td>19</td>
<td>442</td>
<td>243</td>
</tr>
<tr>
<td>20</td>
<td>455</td>
<td>123</td>
</tr>
</tbody>
</table>
DISCUSSION
In this study, we found the exclusive breastfeeding rates at 6, 10 and 14 weeks postpartum in the intervention arm significantly more than in the control arm. The rates were 93%, 90%, and 87% respectively as compared with 72%, 58% and 45% among the control group (p value <0.05 for all time period.) These results were comparable with a study done in Toronto Canada to show the effect of peer support on breast feeding duration among primiparous women. In that study, the control group had the conventional care while the intervention group had conventional care plus telephone based support, initiated 48hrs after hospital discharge from a woman who had experience with breastfeeding. Significantly more mothers in the peer support group than in the control group continued to breast-feed at 3 months post partum (81.1% v. 66.9%, p = 0.01) and did so exclusively (56.8% v. 40.3%, p = 0.01).

Breast-feeding rates at 4, 8 and 12 weeks post partum were 92.4%, 84.8% and 81.1% respectively among the mothers in the peer support group, as compared with 83.9%, 75.0% and 66.9% among those in the control group (p ≤0.05) for all time periods.

The intervention worked because by calling the mothers, the message that exclusive breastfeeding is adequate for the baby was reinforced and made clear. Therefore, the mothers felt confident, more so, because the message was relayed by a health care worker.

The mothers were able to call in with their questions and concerns and prompt answers provided to them, reassured them especially when they were not sure on the correct step to take regarding the challenges they were facing.

Some of the most frequently questions asked by the mothers were:
1) Is my breast milk alone adequate for the baby?

2) Should I give the baby some water, if the baby does not open bowels frequently?

3) Maternal nutrition during lactational period.

4) Appropriate contraception during lactational period.

5) Management of colic in the infant.

6) Danger signs to look for in a sick infant and action to take.

Another key finding in our study is the significant reduction in mortality in the intervention group, the cumulative incidence of death in the intervention arm was found to be 7% compared to 21% in the control arm, this translates to relative risk of 0.266.ie more than 70% reduction in mortality in the intervention arm. Majority of the deaths occurred before six weeks of life.

The largest contributor to the mortality of these children was found to be delay in seeking health care and inability of the mothers to identify danger signs in their sick children due to inexperience by virtue of these mothers being primi parous. The mothers of the children, who sought care, did so in the small private clinics which most probably are ran by unqualified staff.

We cannot conclude reduced mortality in the intervention arm was purely attributable to improved breastfeeding rates .The mothers received additional information on actions to take when the child was unwell. This resulted to early seeking of health care and early identification of danger signs.

The total cost of calling the 91 mothers in the intervention arm for the study period was ksh10,000.ie cost of weekly calls in the first one month, and biweekly in the second and the third month. We cannot compare the increase in cost of phone call
versus the losses due to death which translates to waste of maternity costs, funeral costs, human suffering and increased risk of postpartum depression.

Self reports of exclusive breastfeeding was inaccurate method of obtaining information on exclusive breastfeeding rates with the gold standard test using deuterated water giving a positive predictive value of 20%.

The use of stable-isotope techniques to quantify breast milk intake has several important advantages over previously used methods, such as test weighing and feeding frequency assessment, but the key benefit is that isotopic methods do not interfere with normal routines and behaviors and are not a burden to participating mothers. In addition, measurement of breast milk intake can be performed in the absence of direct supervision of the research team, which encourages normal feeding behaviors. The measurement of breast milk intake by isotopic methods has been compared with test weighing methods in numerous studies, such as the study by Butte et al 24 and a good correlation was observed.

**STRENGTHS OF THE STUDY**

There was successful randomization since the mothers were comparable at baseline.

**WEAKNESS OF THE STUDY.**

There was 30% loss to follow-up but loss is not differential therefore there is still data integrity and the women who were lost were comparable to those left in the study.
CONCLUSION
Phone based counseling by a paediatric senior housing officer, resulted in > 90% EBF rates out to 14 weeks, and significantly reduced child mortality.

Self report is an inaccurate method of obtaining information on exclusive breastfeeding.

RECOMMENDATIONS.
- Repeat study with other health cadres to determine whether it will be as effective in increasing exclusive breastfeeding rates and reducing infant mortality.

- The hospital to consider designating a paediatrician or well trained paediatric Clinical officer to do phone based counselling of mothers of newborns in the first 6 weeks of life to improve breastfeeding and health seeking behaviour.

- A larger study should be done focussing mainly on the cost implication and feasibility of use of phone call in supporting breastfeeding mothers at a national level.
REFERENCES


8. GOK (2008). National Strategy on Infant and Young Child Feeding


26. WHO World Breastfeeding Week over the years. Available at: [http://www.worldbreastfeedingweek.net/](http://www.worldbreastfeedingweek.net/)

Appendix 1 PARENT INFORMATION SHEET

Mother-Infant Pair No………

PARENT INFORMATION SHEET

My name is Dr.Kihara from the University of Nairobi; Department of Pediatrics and Child Health. I am conducting a study to evaluate a method of promoting exclusive breastfeeding among primi-parous women.

You are being asked to participate in the study because both you and your baby meet the inclusion criteria

Benefits of participating:

1. The results of the study will help us get important information that may help in formulating policy at national level on promotion of exclusive breastfeeding.

2. The study will also assess breast milk output and therefore prove to you and other breastfeeding women that breast milk is adequate for their infants.

This will require that I administer to you a questionnaire at the beginning of the study and during the MCH visits (6weeks, 10weeks and 14 week) on infant feeding practices.

I will also require to take samples of saliva from you and your baby after dosing you with a stable isotope which is safe to you and your baby to establish your breast milk output.

Your participation in the study is voluntary and you are free to withdraw from the study even after recruitment without consequences.

All information will be kept confidential and all the laboratory results will be explained to you comprehensively.

Our contacts
Principal Investigator: Dr. Kihara. Tel No 0721494021

Supervisors: Prof. Musoke, Prof. Nduati, Dr. Wamalwa and Mrs. Christine Mwangi

University of Nairobi

Department of Pediatrics and Child Health.
APPENDIX 2: CONSENT FORM

Mother- Infant Pair  No--------

CONSENT FORM

I, Mr./Mrs./Ms -----------------------------------------------, the parent

Of (child’s name) -----------------------------------------------.

agree to the above and give consent for me and my child to be included in this study

As explained to me by-----------------------------------------------

I understand the purpose of the study and conditions of participation.

Sign----------------------------------------- Date-----------------------------------------

Witness Sign-------------------------------- Date-----------------------------------------
Appendix 3: IDHINI YA MZAZI WA MTOTO (Kiswahili)

Mother Infant Pair   No--------

IDHINI YA MZAZI WA MTOTO (Kiswahili)

Mimi------------------------------------------------------------------------------------------------ni m,zazi

wa--------------------------------------------------------------------------------------------------Nimekubali

kushiriki katika utafiti huu kama nilivyo elezewa na Daktari

-----------------------------------------     Tarehe------------------------------------

Sahihi ---------------------------------------------     Tarehe ------------------------------------

Shahidi ------------------------------------------       Tarehe ----------------------------------
Appendix 4: PRE INTERVENTION QUESTIONNAIRE

1. Code number of the mother-infant pair

2. Age of the mother

- 10yrs-18yrs
- 19yrs-25yrs
- 26yrs-35yrs
- 35yrs-45yrs

3. Date of birth of the baby

4. Marital status

- Married
- Single
- Divorced
- Separated
- Widowed

5. Residence

6. How many rooms?

- One
- Two
- Three
7. Amount of house rent per month in Kenya shillings

Less than 3 thousand

3-5 thousand

5-10 thousand

10-15 thousand

Above 15 thousand

8. Do you have electricity Yes

9. Flooring material

Earthen

Cement

Wood

10. Level of education

Tertiary

Secondary complete

Secondary incomplete

Primary complete

Primary incomplete

None
11. Employment status? 
   Employed [ ] Not employed [ ]

12. If employed
   Professional /technical [ ]
   Skilled manual [ ]
   Unskilled manual [ ]
   Domestic services [ ]
   Agriculture [ ]
   Small scale business [ ]

13. Did you attend ANC during pregnancy? Yes [ ]
    No [ ]

14. What is your source of information on breastfeeding?
   You mother in law [ ]
   Media [ ]
   Medical staff [ ]
   Friends [ ]
Appendix 5: Infant feeding practices questionnaire

Before the interview, all participants must sign an informed consent form.

Questionnaire completed by (name):

Questionnaire completed on (Day/Month/Year):

0.5 Maternal age (in years): .............................................................

(Unknown = 99)

A. FEEDING HISTORY

1. Breast-feeding Initiation and Frequency

- Breast-feeding initiation (first visit only)   6wks

1.0 Did you ever breast-feed your infant? 1 = yes, 2 = no .............

(if no, end of the questionnaire)

2.0 How soon after delivery was your infant first put to the breast?

Days    |___|___|

Hours   |___|___|

Minutes |___|___|
3.0 Did you give the first milk that comes from your breast to your infant?  [___]

1 = yes, 2 = no

4.0 Did your infant receive anything to eat/drink before your milk came in (breasts full of milk)?

1 = yes, 2 = no, 9 = don’t know (if no, go to question 5)
4.1 What did he receive? If item quoted yes, specify (if applicable), give reason(s) and who recommended giving it to infant

<table>
<thead>
<tr>
<th>Given</th>
<th>Reason 1</th>
<th>Reason 2</th>
<th>Who recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 = yes</td>
<td>2 = no</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*(If no, go to next item)*

01. Plain water | ___ | ___ | ___ | ___ |
02. Sugar or glucose water | ___ | ___ | ___ | ___ |
03. Honey       | ___ | ___ | ___ | ___ |
04. Herbal preparation | ___ | ___ | ___ | ___ |
05. Non-human milk | ___ | ___ | ___ | ___ |
06. Semi-solid food | ___ | ___ | ___ | ___ |
07. Vitamins, mineral drops | ___ | ___ | ___ | ___ |
08. Liquid medicine | ___ | ___ | ___ | ___ |
09. Other       | ___ | ___ | ___ | ___ |
10. Other       | ___ | ___ | ___ | ___ |

**Codes Reasons**

- 01. Child was crying
- 02. Child was hungry
- 03. Child was thirsty
- 04. Child had colic/gas/abdominal pain
- 05. Child had diarrhoea
- 06. Child was not well
- 07. Child refused to breast-feed
- 08. Mother was tired
- 09. Mother had breasts problems
- 10. Mother was sick
- 11. Mother had no milk
- 12. Mother died
14. Traditional belief

90. Other reason

99. No reasons offered

**Codes who recommended**

1. Infant’s mother herself
2. Husband
3. Infant’s grand-mother
4. Health worker
5. Somebody else
6. Don’t know
At any time after leaving the hospital, have you or anyone else given your infant anything to eat or drink other than your breast milk?

1 = yes, 2 = no, 9 = don’t know

5.1 What was given to the infant? If item quoted yes, specify (if applicable).

Indicate the number of days it has been given; give reason(s) and who recommended giving it to infant

<table>
<thead>
<tr>
<th>Given</th>
<th>How many days</th>
<th>Reason 1</th>
<th>Reason 2</th>
<th>Who recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>01. Plain water</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>02. Sugar or glucose water</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>03. Honey</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>04. Herbal preparation</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>05. Non-human milk</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>06. Semi-solid food</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>07. Vitamins, mineral drops</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>08. Liquid medicine</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>09. Other</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Other</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(If no, go to next item)
<table>
<thead>
<tr>
<th>Codes</th>
<th>Reasons</th>
<th>Codes who recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>01.</td>
<td>Child was crying</td>
<td>1. Infant’s mother herself</td>
</tr>
<tr>
<td>02.</td>
<td>Child was hungry</td>
<td>2. Husband</td>
</tr>
<tr>
<td>03.</td>
<td>Child was thirsty</td>
<td>3. Infant’s grand-mother</td>
</tr>
<tr>
<td>04.</td>
<td>Child had colic/gas/abdominal pain</td>
<td>4. Health worker</td>
</tr>
<tr>
<td>05.</td>
<td>Child had diarrhea</td>
<td>5. Somebody else</td>
</tr>
<tr>
<td>06.</td>
<td>Child was not growing well</td>
<td>6. Don’t know</td>
</tr>
<tr>
<td>07.</td>
<td>Child was not well</td>
<td></td>
</tr>
<tr>
<td>08.</td>
<td>Child refused to breast-feed</td>
<td></td>
</tr>
<tr>
<td>09.</td>
<td>Mother was tired</td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Mother was sick</td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>Mother had breasts problems</td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>Mother had no milk</td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>Mother died</td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td>Traditional belief</td>
<td></td>
</tr>
<tr>
<td>90.</td>
<td>Other reason</td>
<td></td>
</tr>
<tr>
<td>99.</td>
<td>No reasons offered</td>
<td></td>
</tr>
</tbody>
</table>

• Breast-feeding Frequency (all visits):

6.0 Are you breast-feeding your infant now? 1 = yes, 2 = no .......................................... [___] [___]

7.0 How many times did you breast-feed (put infant to the breast) yesterday during the daylight hours? Code ‘99’: can’t specify [___] [___] [___]

8.0 Was the infant breast-fed on demand during the daylight hours? ……….[___] [___]

8.1 Was the infant breast-fed on demand during night-time hours? ……….[___] [___]

1 = yes, 2 = no

9.0 How many times did you breast-feed yesterday during the night-time? Code ‘99’: can’t specify [___] [___] [___]

2. CEASSATION OF BREAST-FEEDING (all visits)

10.0 Have you stopped breast-feeding every day and night your infant? ……….[___]

1 = yes, 2 = no

11.0 How old was your infant when you stopped breast-feeding him every day and night? (Code 00’ days for never breast-feed, and code 99’ days for don’t know)

<table>
<thead>
<tr>
<th>Months</th>
<th>[<em><strong>] [</strong></em>]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weeks</td>
<td>[<em><strong>] [</strong></em>]</td>
</tr>
<tr>
<td>Days</td>
<td>[<em><strong>] [</strong></em>]</td>
</tr>
</tbody>
</table>

12.0 If known, specify date (day/month/year): …………… [___] [___] [___] [___] [___] [___] [___]
13.0 Why did you stop breast-feeding your infant? 1 = yes, 2 = no

<table>
<thead>
<tr>
<th>Code</th>
<th>Reason</th>
<th>Mark</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>infant old enough</td>
<td>[ ]</td>
</tr>
<tr>
<td>02</td>
<td>infant no longer wanted to breast-feed</td>
<td>[ ]</td>
</tr>
<tr>
<td>03</td>
<td>infant did not want to eat solid foods</td>
<td>[ ]</td>
</tr>
<tr>
<td>04</td>
<td>pregnancy</td>
<td>[ ]</td>
</tr>
<tr>
<td>05</td>
<td>fear of transmitting HIV</td>
<td>[ ]</td>
</tr>
<tr>
<td>06</td>
<td>advised by health provider</td>
<td>[ ]</td>
</tr>
<tr>
<td></td>
<td>if yes, specify who: [ ]</td>
<td></td>
</tr>
<tr>
<td>07</td>
<td>advised by husband/partner</td>
<td>[ ]</td>
</tr>
<tr>
<td>08</td>
<td>advised by other person</td>
<td>[ ]</td>
</tr>
<tr>
<td></td>
<td>if yes, specify who: [ ]</td>
<td></td>
</tr>
<tr>
<td>09</td>
<td>separation from infant due to work</td>
<td>[ ]</td>
</tr>
<tr>
<td>10</td>
<td>separation from infant for other reasons</td>
<td>[ ]</td>
</tr>
<tr>
<td></td>
<td>if yes, specify: [ ]</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>mother too sick to breast-feed</td>
<td>[ ]</td>
</tr>
<tr>
<td></td>
<td>if yes, specify: [ ]</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>infant too sick to breast-feed</td>
<td>[ ]</td>
</tr>
<tr>
<td></td>
<td>if yes, specify: [ ]</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>infant not growing well</td>
<td>[ ]</td>
</tr>
<tr>
<td>14</td>
<td>other reason</td>
<td>[ ]</td>
</tr>
<tr>
<td></td>
<td>if yes, specify: [ ]</td>
<td></td>
</tr>
</tbody>
</table>

**B. BREAST-FEEDING RELATED PROBLEMS (ALL VISITS)**
22.0 Have you experienced any problems breast-feeding your infant? .........  |___|

1 = yes, 2 = no (if no, go to 23.0)

22.1 What problems have you experienced?

<table>
<thead>
<tr>
<th>Event occurred?</th>
<th>Infant’s aged when occurred?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1=yes, 2 = no</td>
<td></td>
</tr>
</tbody>
</table>

(if no, go to next item)

01 breasts engorged ..........................

02 pain during feeding ........................

03 infant does not want to nurse.............

04 infant nurses too often....................

05 infant not able to suckle..................

06 not enough milk.............................

07 cracked nipples, sore nipples ..............

08 breast or areola abscesses/oozing sore....

09 mastitis or breast inflammation ............

10 nipple exudate/rash/itching ...............  

12 mother sick .................................

if yes, specify:  ................................

13 other ........................................

if yes, specify:  ................................
Appendix 6: SALIVA COLLECTION SHEET

Mother -infant pair……………………

<table>
<thead>
<tr>
<th>Days</th>
<th>Specimen Collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 0 baseline</td>
<td>Yes</td>
</tr>
<tr>
<td>Day 1</td>
<td>Yes</td>
</tr>
<tr>
<td>Day 2</td>
<td>Yes</td>
</tr>
<tr>
<td>Day 3</td>
<td>Yes</td>
</tr>
<tr>
<td>Day 4</td>
<td>Yes</td>
</tr>
<tr>
<td>Day 13</td>
<td>Yes</td>
</tr>
<tr>
<td>Day 14</td>
<td>Yes</td>
</tr>
</tbody>
</table>