EFFECTS OF TIMED PHONE CALL SURVEILLANCE VERSUS ROUTINE CARE ON POSTPARTUM CARE, IDENTIFICATION OF RISK FACTORS AND ADVERSE MATERNAL AND NEONATAL OUTCOMES AT KENYATTA NATIONAL HOSPITAL, A RANDOMIZED CONTROLLED TRIAL

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A research dissertation, submitted to the University of Nairobi, Department of Obstetrics and Gynecology in partial fulfilment of the requirements, for the award of a degree in Masters of Medicine in Obstetrics and Gynecology.

2021

DECLARATION

This dissertation is my original work and has not been presented elsewhere. This research project is my original work and has not been presented for academic award in any other university. References to work done by others have been clearly indicated.

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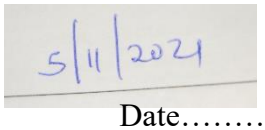

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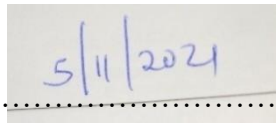

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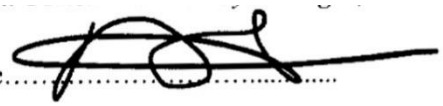

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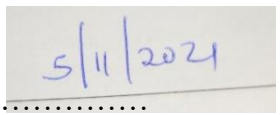

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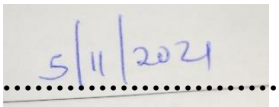

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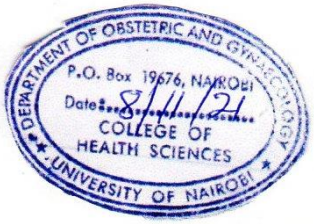
This is to certify that this thesis is the original work of **Dr.Liyayi Brain Nicharius**, an MMed student **H58/87627/2016** in the Department of Obstetrics and Gynecology, College of Health Sciences, University of Nairobi, under the guidance and supervision of Dr. Bosire Alex Nyakundi, Dr. Alfred Osoti and Dr. Rosa Chamwey. This thesis has not been presented in any other university for award of a degree.



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Finally, I would like to thank all the mothers who agreed to take part in this study with their babies.

May God bless you all.

DEDICATION

To my dear parents Nicholas Machafu and FelistasKhabayi for their support and guidance throughout my education and for ensuring I got the best quality of education. To my wife EvalyneChagina for her love, patience, support and prayers.

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

CONSORT= Consolidated Standards of Reporting Trials

CS= Caesarean section

DSMB= Data and Safety Monitoring Board

ERC=Ethical Review Committee

HIV= Human Immunodeficiency Virus

KDHS=Kenya Demographic health Survey

KNH= Kenyatta National Hospital

mHealth= Mobile Health

MMED= Master in Medicine

ODK=Open Data Kit application

PI= Principal Investigator

PNC= Postnatal care

RA= Research Assistant

RCT= Randomized Controlled Trial

SPSS= Statistical Package for the Social Sciences

SSA= Sub-Saharan Africa

SVD= Spontaneous Vaginal Delivery

UoN= University of Nairobi

WHO= World Health Organization

OPERATIONAL DEFINITIONS OF TERMS

Adverse Maternal outcomes: Selected outcomes such as: death, mastitis. surgical site infection, endometritis, secondary PPH, preeclampsia, postpartum visits, rehospitalization admission and surgery

mHealth: The delivery of health services via mobile communications

Adverse Neonatal outcomes: Selected adverse baby outcomes up to 6 weeks: jaundice, cord infection, outpatient visits,readmissionand death

Postnatal Care (PNC): Care provided by skilled healthcare professionals to postpartum mothers to ensure thewell-being of the mother and the baby

Postpartum: The period between one hour of placental expulsion and six weeks after birth

Routine PNC: Involves discharging patients to the nearest health facility for follow-up unless in special circumstances which require continued follow up at KNH

Timed Phone calls: Phone calls made at specific intervals during the postpartum period at 72 hours, 10-14 days, and 6 weeks as guided by the WHO guidelines.

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ABSTRACT

Study title: Effect of timed phone call surveillance versus routine care on postpartum care, selected adverse maternal and neonatal outcomes at KNH, a randomized controlled trial.

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Background: Postnatal care (PNC) can lower newborn and or maternal morbidity and deaths by increasing recognition and management of postnatal complications that may affect the baby and the mother. In Kenya, only 51% receive good PNC in 48 hours after delivery while 57 % go for a postnatal checkup at 6 weeks postpartum. It is estimated that 10-27% of newborn deaths would be averted by adequate utilization of PNC. Mobile phone based postpartum interventions have improved day 3 PNC attendance from 45% to 81% in South Africa. They can therefore be scaled in the postpartum period to increase quality of PNC through recognition of danger signs and reminders for PNC visits.

Objective: To determine the effect of timed phone call-based PNC compared to routine PNC on PNC attendance and selected adverse maternal and neonatal outcomes at 72 hours, 10-14days, and 6 weeks after delivery.

Methodology: This was an open label randomized controlled trial where eligible postnatal women at KNH were randomly assigned to either an intervention, a timed phone call(n=70) or control, routine of care(n=71). The nature of intervention was impossible to blind. The intervention group received a phone call at 72 hours,10-14 days and 6 weeks postpartum. The routine care group received a phone call only at 6 weeks postpartum. During enrollment and each call, participants underwent interviewer administered questionnaire using a checklist. The primary outcomes were PNC attendance and identification of risk factors for adverse maternal and neonatal outcomes while the secondary outcomes were adverse maternal and neonatal outcomes.

Study Population: Women who delivered at KNH and were within first 3 days postpartum.

Study setting: KNH labor and postnatal wards.

Analysis plan: Data was collected via ODK collect application, cleaned and analyzed using Stata®14. Categorical data were summarized as frequencies and proportions and compared between the two groups using Chi-square test or Fishers exact test. Continuous data were summarized as means and standard deviations or median and interquartile range and compared between the two groups using independent student t test or Mann Whitney u test. Relative Risk (RR)were also calculated. P value <0.05 was considered statistically significant.All analysis was intention to treat.

Results: Between October and December 2019, 161 postnatal women were screened and 141 enrolled. The baseline characteristics were similar. The mobile phone call increased PNC attendance at 72 hours (5.7% vs 4.2%, RR=1.35[(95%CI 0.31 5.82) p=0.684].and at 10-14 days (69% vs 44%, RR=1.57[(95%CI 1.15 2.14) p=0.003]) compared to routine PNC. Women in the phone call group were more likely to identify risk factors for adverse outcomes compared to the routine care group (36.6% vs 8.6%, RR=4.56, P<0.001). Adverse maternal and neonatal outcomes were more likely to be recorded in the phone call group compared to the routine care group (20%vs 8.5%, RR=2.37, p=0.049). The study did not involve any medical intervention therefore no reported risk to the participants.

Conclusion: Compared to routine care, phone calls for PNC follow up improved the 2-week clinic attendance and resulted in more risk factor identification for adverse maternal and neonatal outcomes among women who delivered at KNH and were randomized into this study.

Recommendations: Mobile Phone call interventions are recommended for use in the postpartum period to improve 10-14-day postnatal retention. They can as well be used to improve risk factor identification for adverse maternal and neonatal outcomes.

Trial registration:PACTR202005876065918
Funding: Self-funded

CHAPTER 1. INTRODUCTION

1.1 Background

Postnatal Care (PNC) is defined as the care provided by skilled healthcare professionals to postnatal women to ensure the best health conditions for mothers and their babies. It involves health education, health promotion, risk identification, prevention and management of pregnancy related diseases(1).

PNC reduces maternal and neonatal morbidity and mortality both indirectly by identifying postnatal women at increased risk of developing complications post-delivery and directly by detecting and treating such complications. Attendance of PNC provides an opportunity for care providers to prevent and manage conditions such as HIV which are part of the indirect causes of maternal mortality and morbidity contributing approximately 25% of maternal death and near misses.Those that do not receive care during this critical period have a higher risk of disability, death, and or missed opportunities for the promotion of health behavior.(2)

Despite knowledge of PNC services, they remain neglected and with the poorest coverage(3). PNC services are out of reach for many newborns and women with less than 50% receiving this vital service within 48 hours of a birth. Those that deliver at home have only a 13% chance of receiving PNC within 48 hours of a normal or caesarian birth (1).In Kenya, only 51% receive good PNCin 48 hours after birth and 57 % go for a postnatal checkup at 6 weeks postpartum(4). The proportions are even lower in other low and middle income countries such as Rwanda and Congo recording 43% and 35 % respectively(2).

The postnatal period therefore is an appropriate time for providing interventions for enhancing the health of both mothers and their newborns. It would help reduce the suffering and death of mothers and their children by increasing recognition and management of postnatal complications that may affect the baby and the mother. Estimates show that with adequate utilization of PNC by mothers and newborns of up to 90 percent coverage, 10-27 percent of newborn deaths would be averted (5).

WHO recommends at least four postnatal visits, which are timed as: at least 24hours after birth, 48-72 hours after a birth, 7-14 days after delivery, and about six weeks after delivery, with specific activities being conducted at each visit.(2)Thisevidence-based PNC package is

among many practical steps that have been taken worldwide by different health organizations and countries in building and reinforcing continuity of care after child birth. Many countries have adopted some sort of PNC policy, though many countries still lack national guidelines for implementation. Moreover, more human resource and funding isneeded. InsubSaharanAfrica, most countries have adopted the above-mentioned WHO model or modifications of the same. In Kenya for instance, the Ministry of health has designed a register for 3 targeted visits: within 48 hours; within one to two weeks and the last after 6 weeks.

Even with the above targeted visits, PNC coverage remains low(KDHS 2014). This has resulted in approachesforchampioning maternal and neonatal care beyond formal health systemsto improve the continuum of care. Such approaches entail linking up of services from the facility, home and at the community level. They include: skilled providers visiting the home to provide care; community health worker (CHW) visiting the mother and baby; combination of both facility-based care and home/community-based care. With the proper support, this strategyhas been found to have success though with challenges in implementation. For instance, in underfunded health systems, challenges in human resource and training for CHW as well as supervision and management become a hindrance to implementation. This is especially in setups where skilled birth attendance is low.

The delivery of healthcare services via mobile communications (mHealth) and integrating information and communication technologies (ICT) with health (eHealth) has emerged as a potential approach of addressing different health needs. According to WHO, mHealth refers to a public health and or medical practice integrated with personal digital assistant (PDAs), mobile phones, and other wireless/ mobile devices. As per the United Nations Foundation, mobile technology represents a high reach, cost-efficient method for making healthcare more accessible, affordable and effective across the developing world.(6).

Globally there has been rapid growth of use of mobile phone technology with wireless subscribers standing at over 5 billion worldwide (international telecommunication union). Most of this are from middle- and low-incomecountries.According to the latest communication Authority of Kenya statistics 2018, Mobile phone penetration currently stands at over 95% with Kenya leading in internet traffic in 2018 due to its increased smartphone penetration rate(over 41 million mobile subscriptions)(7).

Mobile technology therefore has the potential of creating high impact in PNC.On its own capacity and combined with the different approaches of improving postpartum care, it can be scaled to influence maternal and newborn care hence reducing adverse maternal and neonatal outcomes in the developing world. This can be achieved by positively influencing postnatal mothers to attend all the recommended clinics through clinic reminders; early identification of risk factors for adverse maternal and neonatal outcomes and health promotion and prevention. This as a result can reducedelays, that is, the delay in deciding to seek care and delay in receiving adequate treatment.

KNH is a level 6 referral hospital that receives patients referred from all over the country and therefore conducts a large volume of deliveries. PNC for most patients involves counselling at discharge and referral to the hospital nearest to them. A few of the patients who had high-risk pregnancies or deliveries are advised to seek care at KNH postnatal. The institution mainly follows the national guidelines for PNC, which are adopted, from WHO guidelines for patients who choose to continue with follow up at KNH.The large volume of patients and down referral creates gaps in proper patient counselling, postnatal follow up and smooth continuum of care after delivery which influences maternal and newborn outcomes.

It is in this context that this study was designed; A mobile phone call was to augment the normal PNC services thus reduce the delays in seeking care by use of simple easy to use evidence-based checklists and guidelines as clinic reminders and for risk factor identification. It also would ensure equity in service offered since the same checklist was used for everyone despite differences in gender, race, ethnicity, or socioeconomic status.

CHAPTER 2. LITERATURE REVIEW

2.1 Introduction

PNC reduces maternal and neonatal morbidity and mortality both indirectly by identifying postnatal women at increased risk of developing complications post-delivery and directly by detecting and treating such complications.OurmHealthintervention focused on client education and behavior change communication and data collection and reporting. MHealth interventions have a role to improve PNC as demonstrated in the studies below.

2.2 mHealth Interventions in Antenatal and Postnatal care

The studies below assessed the role of mHealth (Phone calls and SMS messaging (in antenatal and postnatal care.

2.2.1 Worldwide

A systematic review to evaluate the impact of mHealth interventions on maternal health in low income countries was done in 2016.Peer reviewed papers published between January 2000 and July 2015 were identified from web-based databases. 370 papers were found andassessment of 57 full text studies and 19 papers reviewed (8).All the papers addressed different mHealth strategies. For the papers that addressed use of mHealth for appointment reminding, a 20% increase in PNC attendance was reported compared to the control group. The review highlighted the potential for using mHealth to improve maternal health. Ithowever recommended rigorous testing before allocating resources.

To determine the efficacy of mHealth in improving access to and use of antenatal care (ANC),immunizations, andPNC (PNC), a review of 10 studies in low and middle countries was conducted by Jessica et al in 2015.PNC attendance, childhood immunizations and more than 4 antenatal visits increased by 50%,10% and 10% respectively compared to the control for patients that received text message appointment reminders. The ability of such telephone based interventions to improve the immunization rate of children, PNC attendance, and antenatal care attendance was therefore demonstrated (9).

A Cochrane review conducted in 2013, assessed the effect of telephone support for parturientandduring the first six weeks of the postpartum versus routine care (no telephone support). Five electronic databases were searched for randomized control trials(RCTs) which evaluated the administration of routine care and telephone support postpartum between 1982 and 2012(10).27 RCTs involving 12256 women were included with one study being fromahigh resource area. According to this review, two studies indicated that telephone

support might have a positive effect on the satisfaction of women with both antenatal and PNC. However, even with such good results outcomes were inconclusive.

An RCT conducted in Ecuador assessed the relationship between infant and maternal health and access to a phone-based education program during the postpartum.In the intervention and control groups, a retention of 73.5% (n=75) and 78.9%(n=60)was reported respectively(11).With the above intervention, there were significant changes in improved clinic newborn checkup (72%-intervention vs 53%-control) and exclusive breastfeeding at three months (86.7%-intervention vs 66.7%-control). The study therefore concluded that mobile phone based postpartum intervention are good for follow up care.

In 2017, a systematic review toevaluate the role of mHealthin postnatal and antenatal care in low-to-middle-income countries was conducted.A search was done in three electronic databases (international) between the year 2000 and 2016 and the effect of mHealth solutions o preventive healthcare services (maternal) explored. The relevant studies (14) were categorized into client education, vital event/registry tracking, client education, data collection/reporting, and electronic health records(12) and the commonest application of mHealthservices found to be in behavior change communication and in education of clients. A correlation between access to mHealth interventions and an improvement in postnatal and antenatal services was also evident, especially by intervention targeting behavior change of parturient and of mothers during the postpartum period.However, whether other categories of mHealth applications offer the same benefits isa matter of speculation.

2.2.2 Africa

In Ethiopia, a non-randomized controlled study was conducted to evaluate the effect of locally curated mHealth Interventions on the utilization of care services during the delivery and the postpartum period in health centers. Ten (10) healthcare centers serving around 250000 people were recruited. The intervention group health workers received reminders for scheduled visits from an android device during the antenatal period, during delivery, and during PNC. They also received educational messages on the common complaints and danger signs to look out for during pregnancy. Overall, more women in the interventional group compared to the control group(41.2 versus 21.1%) attended PNC(13).The study concluded that MHealth use can improve utilization of postnatal health services by influencing the behavior of both clients (pregnant women) and health workers.

A review off the Rwanda rapidSMSprogram (mHealth program) on monthly interrupted time series data from 2012-206 of public hospitals public hospitals. The study evaluated how Rapid SMS influences four indicators deliveries, antenatal care attendance, malnutrition screening, and post-natal care utilization in public hospitals and found that supporting Rapid SMS systems with training, provision of equipment, and supervision can increase utilization of child health and maternal services in public hospitals. However, when used alone, rapids SMSdoes not offer additional benefits compared to standard protocols of service provision (14).

An RCT was conducted inSouth Africa in 2009/2010 to determine whether mobile phone technology have an influence on PNCattendance. A total of 415 women were randomized into three groups: phone call, SMS reminder and standard of care groups. It was noted that phone call/SMS reminder significantly increased rates of patient attendance at the 3-day appointment from 45% in controls to 72% and 81% in the phone call and SMS reminders groups respectively[$p<0.001$]. It concluded that mobile technology can be used for appointment reminders and health education and awareness (15).

2.2.3 Kenya

An evaluation research study was conducted in Western Kenya to determine the effect of a mobile health care system in hospital attendance (antenatal and postnatal). RAs interviewed 20 community health workers (CHWs) on the adherence of women to PNC and ANC in their health institutions. All CHWs indicated that the APAS is essential for tracking vital events compared to old paper-based tracking systems. Moreover, to odds of attending more ANCs was significantly higher among women who were enrolled in the APAS system. Moreover, a significant relationship between ASPA enrollment and the likelihood of attendance of the six recommended postpartum follow ups was also reported. Finally, the MTCT rate of women enrolled in the program at 9 months follow up and at 18 months follow-up (0%) was significantly lower than that of non-registered women (9%), and the global rate as well (30%) (16).

An RCT was conducted in the Nyanza region of Kenya to ascertain whether texting women during the postpartum period can improve hospital attendance and therefore lower the risk of MTCT of HIV and testing of infants for HIV(17).The target population were HIV-positive

pregnant Kenyan women (18+ years old) who either received atext messages (195) aimed at lowering PMTCT of HIV or that usual care (193). Eight messages were sent before delivery and six postpartum and the outcomes (HIV testing of infants by week 8 and clinic attendance) compared between study groups.Attendance of postpartum clinics was higher among women in the SMS group (19.5%) than in the control group (11.8%). A difference in HIV testing was also reported between the two groups, with the prevalence being higher in the SMS group (92%) compared to the control group (85.1%).

Another RCTinKiambu County Kenya evaluated the effect of health worker administered checklists on the knowledge and health seeking behavior of women. A total of 109 women were randomized into 3 groups: Community health care worker visit checklist, phone call administered checklist and standard of care. Follow up surveys were scheduled ten days and 9 weeks later and outcomes on postnatal knowledge of family planning, feeding, and nutrition; care seeking behavior; and self-reporting of health problems evaluated.It was noted that in the mobile phone and home visits study arms, mothers responded promptly to postnatal problems. Mobile phones and checklists also prompted timely care seeking even though a small sample size and setting of the study were limitations (18).

An RCT in NakuruPGHevaluated the efficacy of the usage of mobile phone on patient retention in PNC. Mother-infant pairs (180 in total) were enrolled in the study. Primary outcome accessed were rates of postnatal clinic attendance at 48hours, 2 weeks and 6 weeks. Secondary objective was to determine impact on breastfeeding, identify neonatal danger signs and outcome of the infant at 6 weeks across study groups. There were significant higher retention rates at all points of observation. The 48-hour attendance for control, text and phone call were 39%, 64% and 75% (p=0.005 text versus control and p=0.0001 phone versus control). The 2-week attendance was as well higher with the intervention but statistically different only in the phone call arm=0.047. The 6 weeks attendance rates were 72.9,90 and 88.9% in the control, text arm and phone call respectively. There was a 33% and 38% increase in identification of danger signs in text and phone call arms respectively(19).The study concluded that both phone calls and text messages can be important strategy in improving postnatal clinic attendance and improving knowledge on neonatal danger signs.

CHAPTER 3. CONCEPTUAL FRAMEWORK

3.1 Conceptual Framework Narrative

The postnatal period remains an important and delicate time in the lives of mothers and their newborns due to associated mortality and morbidity. The well-being of most mothers and their babies should be generally good with PNC attendance. However, there is an interplay of several risk factors i.e. sociodemographic factors (age, parity, level of education,occupation,religion,) immediate postpartum care and counselling and comorbidities such as (hypertension, renal disease, cardiac disease, HIV); which if dealt with in good time would most likely give good maternal and neonatal outcomes.

The movement from comorbidities or sociodemographic factors involved equitable assignment of participants to the intervention by randomization. To ensure randomization, baseline characteristics were compared to establish balance of these characteristics. Through randomization we hoped to study the effect of mobile phones on PNC.

3.2 Conceptual Framework Flowchart

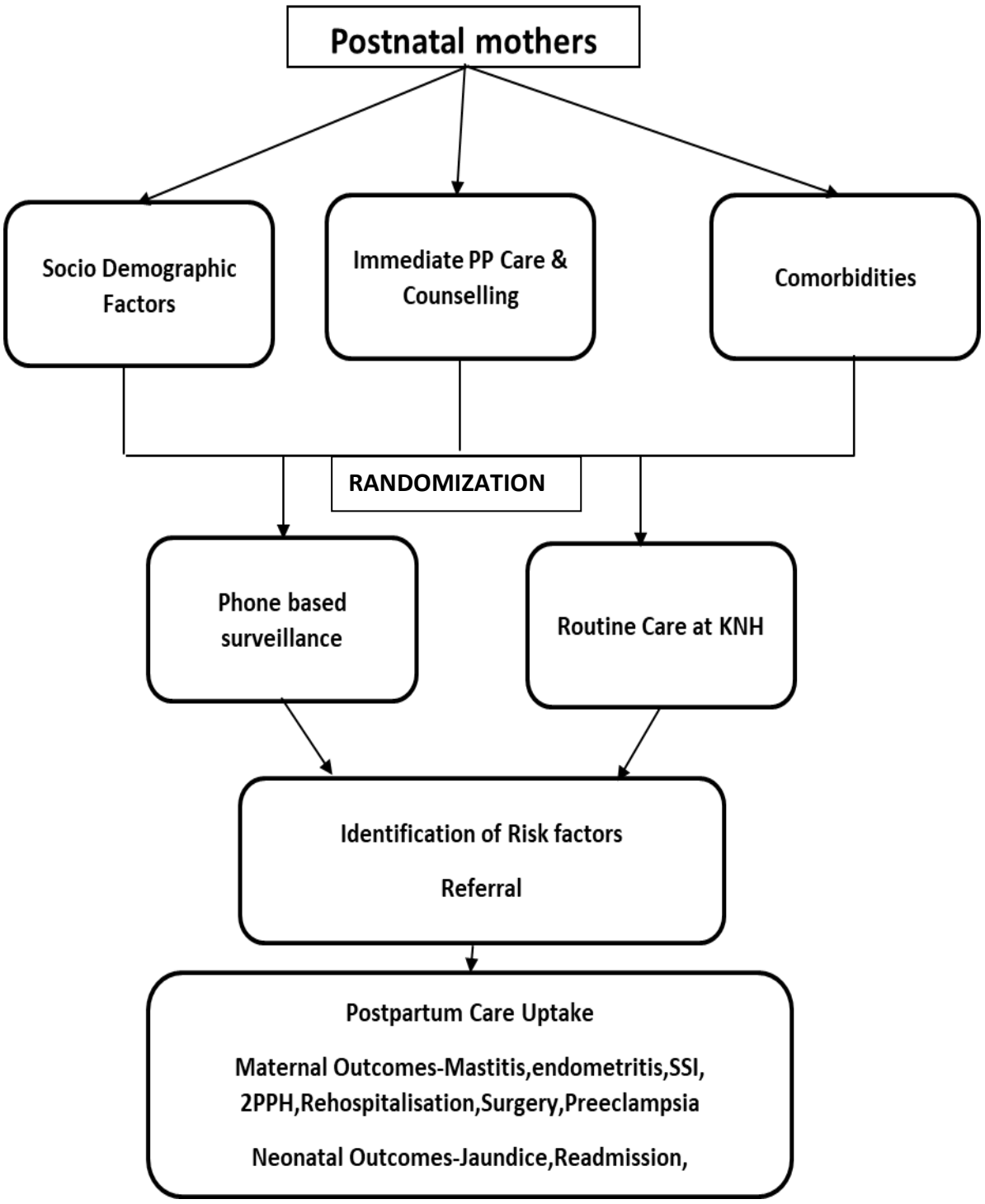

Figure 1. Conceptual framework flowchart

CHAPTER 4. JUSTIFICATION

In Kenya, the Ministry of health has adopted the WHO guidelines for PNC and designed a register for three targeted visits: within 48 hours; within one to two weeks and the last after 6 weeks. This interventionincludes health promotion, preventive care, screening and timely treatment of complications.Despite the availability of suchevidence-based protocols for PNC, there still exists a gap in its accessibility and uptake in low- and middle-income countries: 37 and 57 percent of women receive a postnatal visit within 2 days and 42 days of birthrespectively(2). The gap has been attributed to:

- Poor counselling of mothers at discharge on the necessity of PNC.
- Women not feeling sick and therefore not seeing a need for PNC
- Low level of education
- Distance and means to attend postnatal clinic.

The gaps are more pronounced in referral hospitals like KNH who despite priding in providing quality healthcare are overwhelmed by numbers. This results in down referral of patients to lower cadre hospitals after delivery for PNC. As such, the follow up of such patients and the quality of care received cannot be guaranteed as there is loss to follow up.

Mobile phones use has been found to be effective in health care promotion(20).Their use in the postpartum period may increase PNC attendance, improve mother'sknowledge and early detection of danger signs. This may thenlowermaternal mortality and morbidity.

There has been no other study that looked at the effect of PNC on PNC attendance andadverse maternal and neonatal outcomes. This study sought thereforeto inform on the phone call as an additional intervention of reinforcing uptake of postnatal services and therefore improving maternal and newborn health.

CHAPTER 5. STUDY OBJECTIVES

5.1 Research Question

What is the effect of phone call-based surveillance at 72 hours, 10-14days and 6 weeks after delivery compared to routine care on PNC attendance with identification of risk factors and selected adverse maternal and neonatal outcomes at KNH?

5.2 Objectives

5.2.1 Broad Objective

To determine the effect of phone call-based surveillance at 72 hours, 10-14days and 6 weeks after delivery compared to routine care on PNC attendance, identification of risk factorsandselected adverse maternal and neonatal outcomes atKNH.

5.2.2 Specific Objectives

Among mothers who deliver at KNH and are randomized to phone calls group versus routine care group, to compare;

1. The proportion of postpartum mothers who attend PNC at 72 hours,10-14 days and 6 weeks postpartum.
2. The proportion of postpartum mothers whose risk factors for adverse maternal & neonatal outcomes are identified during the first 6 weeks postpartum.
3. The proportion of postpartum mothers with selected adverse maternal & neonatal outcomes during the first 6 postpartum weeks.

CHAPTER 6. METHODOLOGY

6.1 Study Design

This was a parallel open label randomized control trial of timed phone call surveillance versus routine care PNC in a ratio of 1:1.

6.2 Study Setting

This study was carried out at the KNH post-natal wards (ward GFA, GFB, 1A). KNH is the largest public referral and teaching hospital to the University of Nairobi and Kenya Medical Training College.

The hospital receives patientsfrom Nairobi and its environs as well as referrals from all other hospitals in Kenya. The bed capacity is 1800 and is located 2km south west of the Nairobi central business district.It has an average of 1000 deliveries per month. These deliveries occur amongst mothers of varying socioeconomic status.

Being a national referral hospital, most patients receive immediate after delivery care, are counselled at discharge and referred to the hospital nearest to them for postnatal care. This is due to the large volume of patients that deliver at KNH as well as most patients preferring follow up to a place nearer them.

Patients who had high risk pregnancies, high risk deliveries or were on follow up antenatally at KNH are advised to return to KNH. For such patients the institution mainly follows the national guidelines for PNC which are adopted from WHO guidelines (3 targeted visits: within 48 hours; within one to two weeks and the last after 6 weeks).The clinic takes place every Friday at clinic number 18 and is run by a team of nurses, registrars and consultants.An average of 100-150 patients are seen every Friday. They are triaged on arrival, uncomplicated vaginal deliveries are seen by the postnatal nurses while patients with comorbidities, those who had complicated deliveries and post caesarean deliveries are reviewed by registrars and consultants.

6.3 Study Population

These were postnatal women within 3 days of delivery and ready for discharge.

6.3.1 Inclusion Criteria:

These women were included if;

- Theydeliveredat KNH
- They provided Informed Consent
- They had access and ability to use personal or family mobile phones
- They were within 3 days of delivery at the time of enrollment.
- They were ready for discharge/discharged

6.3.2 Exclusion Criteria:

These women were excluded if;

- They were too sick to consent/declined to participate.
- They delivered preterm babies.
- They had prolonged hospitalization. (>72 hours after delivery)
- They were planning to leave the country after delivery
- They were unable to give at least 2 phone contacts

6.4 Study Groups

6.4.1 Intervention

Postnatal care provided with additional phone call surveillance. It involved use of the phone call to remind patients of PNC attendance. Patients were also reminded about danger signs through the use of checklists adopted from the WHO PNC guidelines. This allowed for flagging of risk factors for adverse maternal and neonatal outcomes thus allowing patients to be advised to seek care.

6.4.2 Control

Postnatal care provided as a routine at KNH based on the ministry of health guidelines. It involved clinic visits at 2 weeks and 6 weeks after discharge. Since KNH is a referral facility

most patients are however advised to seek care at their previous clinics or the nearest clinic to them.

6.5 Sample Size Determination

The main outcome of this study was the proportion of PNC attendance as compared to routine care. Prior studies estimated that the proportion of PNC is 54% (Kemunto et al). We postulated that offering timed phone calls in the postpartum; we would increase this proportion to 80%, a difference of 26% that is clinically meaningful. Therefore, for us to detect a 26% difference in proportion between the intervention group and routinecaregroup we estimated using the sample size formula

$$n = \frac{2\left(z_{1-\alpha_2}\sqrt{2\bar{p}(1-\bar{p})} + z_{1-\beta}\sqrt{p_c(1-p_c)+p_a(1-p_a)}\right)^2}{(p_c - p_a)^2}$$ [Allan Donner; Stat. Medicine(1984)](21)that

We would need to study a total of 102 in total (51 per group) to achieve a 80% power to detect the stated difference of 26% at a two-sided alpha=0.05 level of significance. Where We defined p_c=54% and p_a=80% to be the proportions of routine care and intervention group respectively and $\bar{p} = (p_C + p_a)/2$ ($Z_{0.25}$ =1.960, and $Z_{0.8}$ =0.842).

We added a 20% loss to follow up rate and therefore recruited {100/100-20x 102} =64 per arm and 128 in total.

Estimated sample sizes for a two-sample proportions test
Pearson's chi-square test: Ho: p2 = p1 versus Ha: p2≠p1

Study parameters:

- Alpha: 0.0500
- Power: 0.8000
- Delta: 0.2600 (difference)
- p1: 0.5400
- p2: 0.8000

Estimated sample sizes:

- N = 102

- N per group = 51

Assume 20% loss to follow up for each64/64=128. A total sample size of 128was needed.

6.6 Study Procedures

6.6.1 Patient recruitment

TheRAswere trained by the PI on the use of data tools. Potential study participants who had delivered in the labor and postnatal wards were identified and chosen if they met the eligibility criteria (inclusion and exclusion).Recruitment and enrollment werecarried out by the RA or PI who were all part of the study team.

6.6.2 Sampling

Stratified random sampling was used to select patients for the study. Therefore, all patients delivering at KNH during the study period were recruited as long as they met the eligibility criteria and provided informed consent.

6.6.3 Consent

Once identified, the PIorRA briefed the patients on the purpose and method of the study and attained verbal consent. Thereafter, consent was given in written form, on a pre-designed consent form. The consent form provided described the purpose of the study, the study procedure to be followed, and the potential benefits and risks of participating in the study. Any pertinent questions regarding the study from the parent/guardian were answered at this point. This process was free from coercion and was explicitly voluntary.

Those who accepted to take part in the study were asked to sign the consent form, which was counter-signed by the PI. Records were kept regarding reasons for non-participation of eligible participants. The PI or RA would then countersign the consent form. A copy of the signed consent form was given to the participant. All consenting patients who met the eligible criteria were immediately randomized into the two groups.

6.6.4 Randomization

A list with the allocations was made using computer generated block randomization. To ensure unpredictability of the allocation sequence, sequence numbers were sealed in

sequentially numbered opaque brown envelopes.Randomizationwas done by the RAs in the postnatal wards at the time of discharge.

6.6.5 Blinding

The nature of intervention made it impossible to blind the study participants.

6.6.6 Intervention group

In addition to the routine postnatal care in the postnatal wards (postnatal education, breastfeeding education and danger signs awareness) ,upon discharge, the intervention group received follow up phone calls at 72 hours, 10-14days, and 6 weeks postpartum. A checklist wasadministered at each of the 3 intervals and data collected on PNC attendance and danger signs identification.When danger signs were identified, patients were asked to go to a nearby hospital for care. In cases where participants could not be reached after 3 phone calls, attempts were made to reach the other given phone numbers within 24 hours before being labelled as a failed contact. Data on adverse maternal and neonatal outcomes was collected at 6 weeks through a phone call interview by the RA.

6.6.7 Control Group

The control group received the routine care at KNH by the nurses in the postnatal wards which included postnatal and breastfeeding education and danger signs awareness.The normal routine care was to discharge uncomplicated delivered patients and refer them to nearest health facilities for PNC.A few would come back to KNH after delivery for PNC follow-up.Theywere then interviewed at 6 weeks post-delivery by the RA and data on adverse maternal and neonatal outcomes collected.

6.6.8 Data collection

Data was collected by RA at enrollment & 6 weeks for the control group and enrollment,72 hours, 10-14 days and 6 weeks for the intervention group. This was done using a questionnaire as detailed in appendix I that was uploaded in ODKapplication and thus uploaded in KNH server where it was password protected for PI access for data monitoring.

Sociodemographic data was collected upon recruiting the participants into the study.Postnatal checklist adopted from WHO was be administered at 72 hours, 10-14 days and at 6 weeks for

the intervention group. Data on clinic attendance was obtained during that time as well as danger signs and marked on the postnatal checklist as per the WHO recommendations.

Attendance was assessed as any clinic or hospital visit before the timelines of the call. Data was collected on any admissions resulting from the phone call as a result of any identified danger sign. Data on adverse maternal and neonatal outcomes was collected via a phone call interview for both groups at 6 weeks

6.7 Data Variables

Table 1. Data variables

Objective	Exposure Variables	Outcome Variables	Data Sources
Post-natal clinic attendance	Phone call vs. standard of care	Attendance of clinic at by 72 hours, at 10-14 days and at 6 weeks	Phone call interviews
Identified risk factors for adverse maternal/neonatal outcomes	Phone call group routine care	**Maternal risk factors** Infection: Fever, Foul smelling discharge, wound discharge, abdominal pain, body weakness, Breast pain/enlargement/cracked nipples Secondary PPH Difficult breastfeeding, no milk DVT/PE: Immobility, leg swelling and pain Psychosis: Stress, lack of support, easily crying Birth injuries: Difficulty passing urine/retention, pain in the legs Anemia: headache, palpitations, body weakness Preeclampsia: LOC, headache, epigastric tenderness, Blurring of vision **Newborn Risk factors** Irritability Fever Yellowness of eyes, palms Difficulty breathing Difficulty breastfeeding Not passed urine/meconium Umbilicus red/swollen/discharging pus Skin infection-pustules convulsions	Phone call interviews
Adverse Maternal/Neonatal outcomes	Phone call Routine care	**Adverse Maternal outcomes:** Death, Sepsis-Mastitis, SSI, Endometritis Secondary PPH preeclampsia	Phone call Interviews

		Postpartum visits, Rehospitalization Surgery other **Adverse Neonatal outcomes:** Jaundice, Cord infection. No of outpatient visits, Readmission Death	

6.8 Data Management and Analysis

6.8.1 Data Management

Data was entered into the ODK collect mobileapplicationwhich was password protected to limit access and for privacy. The PI constantly revieweddata for errors and omissions by downloading some of the data from the server by the use of password as the study progressed.

6.8.2 Data Analysis

Data was cleaned and analyzed by the use of Stata®14. Baseline characteristics of the participants (sociodemographic data) in the two groups were compared. Similarities in the 2 groups were revealed by comparing baseline characteristics using student's T test and Chi square tests for continuous and categorical variables respectively.The effect of phone calls on PNC attendance was measured by comparing frequencies and proportions ofPNCattendanceat 72 hours, 10-14 days and 6 weeks.General Linear model was used to get relative risk to compare the identified risk factors for adverse maternal and newborn outcomes as well as adverse maternal and neonatal outcomes between the two groups. All statistical tests were done at 95% confidence level and 5% level of significance ($p<0.05$). Presentationwas done in form of charts, graphs, andtables. All the analysis was intention to treat.

6.9 Ethical Considerations

6.9.1 Ethical Review

Authorization was obtained to conduct the study fromKNH (KNH)/University of Nairobi (UoN) Ethics Research Committee (KNH-UoN ERC) before the start of the study to collect

data. Data that was collected was stored safely in a private secured server to ensure privacy and confidentiality.

Participants in this study did not receive reimbursement or compensation for this study. All costs were covered by the PI and no participant incurred any cost to themselves.

This protocol and the template informed consent form found in the appendix, and any subsequent modifications to this form, were reviewed and approved by the KNH/University of Nairobi Ethics Research Committee (KNH-UoN ERC) prior to initiation of the study, with respect to scientific content and compliance with applicable research and human subjects' regulations.

Safety and progress reports were to be submitted to the KNH-UoN ERC, after study completion or in the case of study termination or occurrences of any adverse events. The reports included the total participants enrolled in the study, the number of participants that completed the study, all changes in the research activity and all other problems that were not anticipated that involved risks to human subjects or others.

A Data and Safety Monitoring Board (DSMB) had been constituted and all open DSMB reports were to be provided to the KNH-UoN ERC. Refer to Appendix: Data and Safety Monitoring Plan; this contains the DSMB charter with the members, responsibilities and monitoring procedures.

The trial was registered by the Pan African trial Registry under the identification number:PACTR202005876065918.

6.9.2 Informed consent

We obtained a written informed consent from participants or from the parents/guardians of underage mothers who lack the capacity to provide consent.Adequate explanation and counseling weredone before attaining consent. Participant's partnerswere informed about the study. Participant requests for the partner's presence or advice before consentingwere granted if the partner was within the hospital at the time of the request. The partnerwould then append their signature as a witness as provided for in the consent form. However, the participant's approval was considered as approval from the partner, unless otherwise specified.

The informed consent form described the purpose of the study, the procedures to be carried out and the risks and benefits in accordance with applicable regulations. The consent form was translated into Swahili for ease of understanding.

Literate participants appended their signatures at the provided space in the consent form. Non-literate participants documented their approval by marking the form using their thumbprint, in the presence of a literate third-party witness. Any other local ERC requirements for obtaining informed consent from non-literate persons were followed. Participants or their parents/ guardians were provided a copy of their informed consent forms and this fact was documented in the participant's record.

No personal identifiers were employed for participants. A unique study identification number was assigned to each participant for purposes of identification. This identification number linked them to a log with their personal details. This information was stored in a password protected data base that was only accessible to the PI.

6.9.3 Risks

Risks were anticipated and addressed accordingly. We ensured the participants privacy and confidentiality was maintained at all times. However, it was possible that others knew of the participant's involvement in the study, we believe there was no stigma related to this and hence no harm.

6.9.4 Benefits

The participants benefited from the study by receiving a phone callfollow-upon top of their normal scheduled postnatal follow up. The results from this study may benefit other patients in the future.

6.9.5 Confidentiality

All the information collected were handled with Belmont's principles of confidentiality (Beneficence, Justice and Respect for persons,). Each participant was allocated a unique study number for confidentiality. The coded number identified all reports, data collected and other administrative forms. All the information on the participants and the study as a whole was stored and secured at the study site and stored in lockable file cabinets. We also

securedall electronic databases with password to prevent any unauthorized entry. The study's information of the participantswasnotsharedwithout the permission (written) of participants, except for monitoring by the DMSB, or KNH-UoN-ERC.

6.9.6 Study Discontinuation

The study's goal was to achieve ≥ 95% participant retention. We made every reasonable effort to retain any enrolled study participant until completion of the study. Participants were at will to withdraw from the study if they were unwilling or unable to comply with the required study procedures. In order to protect participants' safety, the PIcould withdraw study participants from the study.A final evaluation was completed for the study participants who withdrew from the study before completion. The reasons for the withdrawal were recorded in the participants'records.Finally,the study could have been discontinued at any time by the KNH-UoN-ERC.

6.9.7 Training

The research team involved undertook Good Clinical Practice (GCP) training and certification. Once the study had been approved, it was registered with the clinical trial registry and clinicaltrial.gov.Consolidated standards of reporting trials (CONSORT) were used to facilitate complete and transparent reporting of the trial (22).

Training of RAs took place over the duration of 5 days; initially they observed the process of obtaining informed consent and filling of the checklist. Thereafter they worked under supervision until the PIwas satisfied. The PI constantly reviewed the checklists for completion.RAsunderwentsensitization and training prior to commencement of the study via clinical teachings.

6.10 Study Strength

The study is a Randomized Controlled Trial therefore offers higher level of evidence.

6.11 Study Limitations

The study results were mainly subjective to what the patients reported with no room for objective assessment of patients.It was not blinded and therefore could be prone to observer

bias. This was reduced by randomization and blinding of outcome assessment.There may be loss to follow up though effort will be made to ensure study retention of participants.

6.12 Dissemination of Research Findings

All participants in our study were given a report of the findings for review and for their feedback.Moreover, after completion of the study,results are to be disseminated by three methods:

- Writing of a report that will be sent to the Department of Obstetrics and Gynaecology.
- Publishing papers in specialist and general, national and international journals.
- Presentation of papers at both national and international conferences.

CHAPTER 7. RESULTS

7.1 Characteristics of enrolled patients

A total of 161 postnatal mothers were screened for the study during the data collection period from October 2019 to November 2019 at KNH. These patients were all postnatal mothers in the postnatal wards. A final number of 141 participants (88% of those screened) were enrolled into the study and randomly assigned into either the control or intervention group, 70 in the intervention arm and 71 in the control arm (Figure 1).

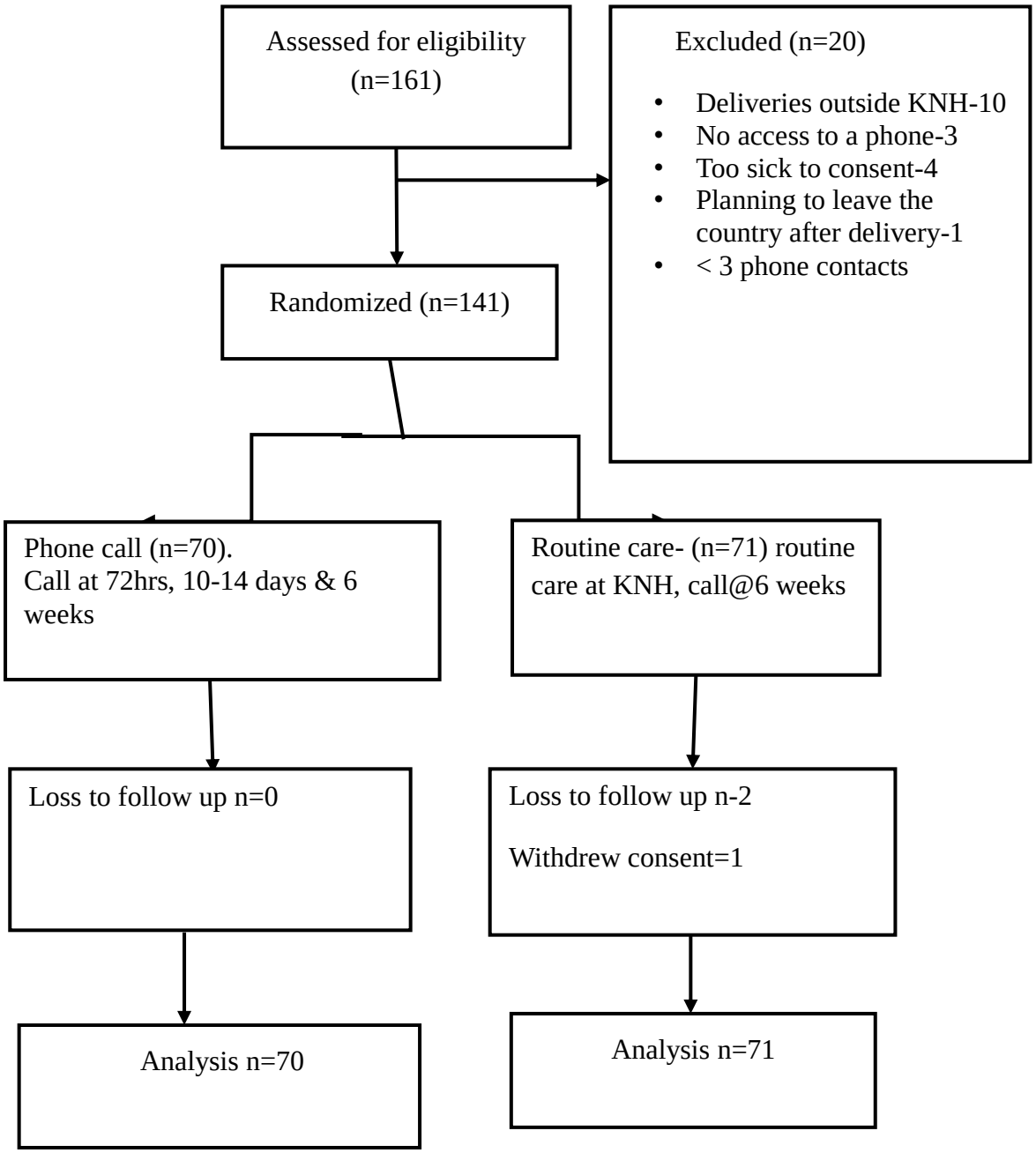

Figure 2. Study flow chart showing the characteristics of enrolled participants

7.2 Socio-demographic Characteristics

The characteristics of the 141 participants in the study are displayed in table 1 below. Randomization was successful in the two arms. The maternal characteristics measured for the two arms were found to be similar.At enrollment postnatal mothers in the two arms were comparable in terms of age, marital status, county of residence, education level and occupation. Majority of the mothers reside in Nairobi county, inthe phone call arm 67.1% and in the routine care arm 77.1%. More than 80% of the mothers had attained a minimum of secondary education in both groups. Majority of the mothers were married with 84.3% in the phone call group and 78.9% in the routine care group.

Table 2.Maternal sociodemographic and clinical characteristics

Characteristic	Category	Phone call PNCn (%)	Routine PNCn (%)	P
Age	<25	27 (38.6)	27 (38.0)	
	26-34	36 (51.4)	37 (52.1)	
	35-44	7 (10.0)	7(9.9)	
Marital status	Married	59 (84.3)	56(78.9)	0.690
	Single	11 (15.7)	15 (21.1)	
Residence(county)	Nairobi	47(67.1)	47(77.1)	
	Other	23(32.9)	14(22.9)	1.58
Education level	Primary	9(12.9)	19(26.8)	
	Secondary	34(48.6)	32(45.1)	4.67
	Tertiary	27(38.5)	20(28.1)	
Occupation	Employed	36(51.4)	28(39.4)	
	Not employed	34(48.6)	43 (60.6)	2.04
Parity	Primipara	28(40.0)	25(35.2)	0.557
	Multipara	42(60.0)	46(64.8)	
Mode of delivery	C-section	36(51.4)	30(42.3)	1.19
	SVD	34(48.6)	41(57.7)	
Facility attended	Dispensary	1 (1.4)	3(4.2)	
	Health Centre	36(51.4)	31(43.7)	0.648
	Private Clinic	16(22.9)	19(26.8)	
	Hospital	17(24.3)	18(25.3)	
Number of ANC visits	<4 visits	20(28.6%)	15(21.1%)	1.05
	>=4 visits	50(71.4%)	56(78.9%)	

7.3 Postnatal Clinic Attendance

Table 3.Postnatal clinic attendance compared between the Phone call PNC and the Routine PNC

Clinic Attendance	Phone call PNC n (%)	Routine PNC n (%)	Phone call PNC vs Routine PNC (RR)	95% Confidence Interval	P Value
PNC attendance at 72 hours post discharge	4(5.7)	3(4.2)	RR (1.35)	(0.31 5.82)	0.684
PNC attendance at 10-14days post discharge	48(68.6)	31(43.7)	RR (1.57)	(1.15 2.14)	0.003
PNC attendance at 6 weeks post discharge	70(100)	71(100)	-	-	-

As in the table 3 above,at72 hours after discharge, mothers were more likely to attend PNC (n=4, 5.7%) in the phone call arm compared to those in the routine care arm(n=3,4.2%). The attendance was 1.4 times more in the phone call arm compared to the routine care arm.(RR=1.35, p=0.684).

At 10-14 days post discharge, there was more clinic attendance in the phone call arm (n=48 ,68.6%) compared to the routine care arm (n=31,43.7%).The proportion of mothers attending clinic in the phone call arm was 1.57 times more than the routine care arm (RR=1.57[95%CI 1.15 2.14]p=0.003).

At 6 weeks, 70 out of 70 mothers in the phone call arm and 71 out of 71 showed up for the 6-week clinic visit. There was no difference noted among the two arms for this visit.

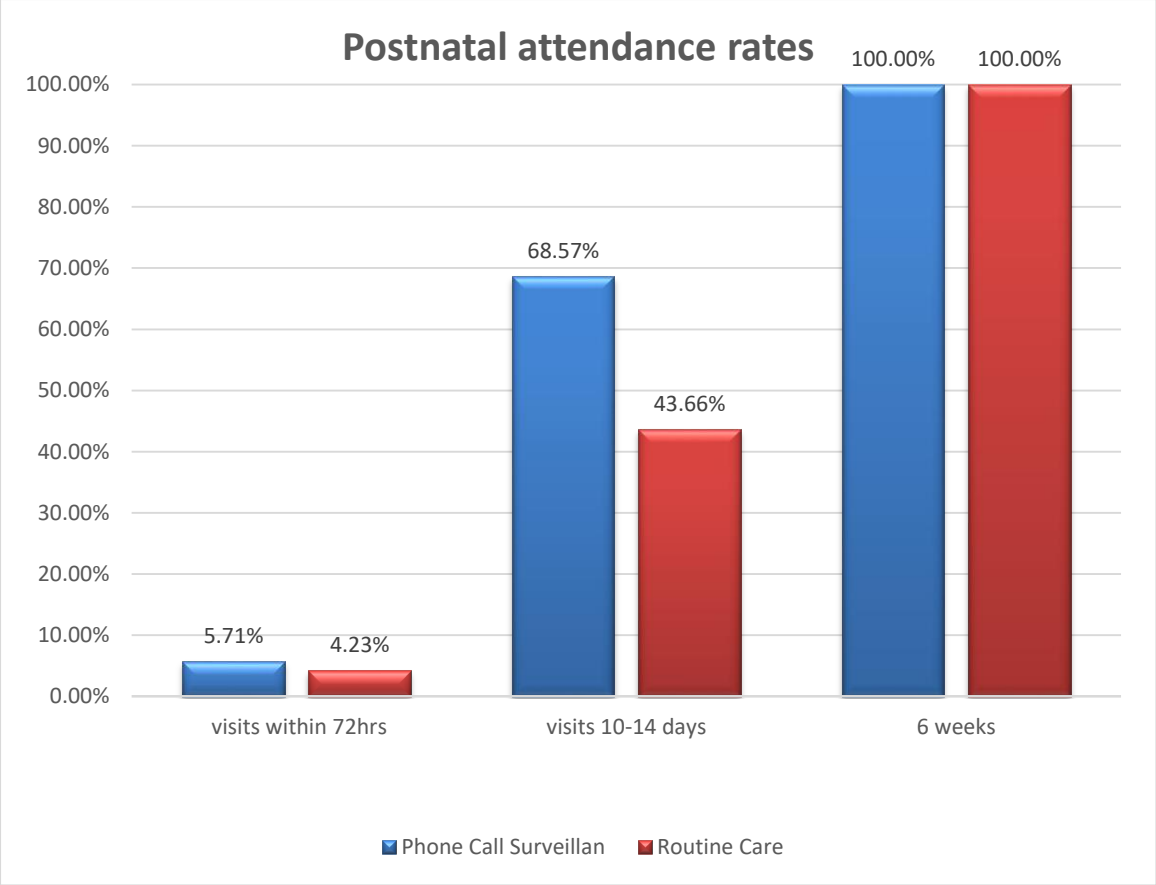

Figure 3. Postnatal attendance ratescompared between the Phone call PNC and the Routine PNC

7.4 Risk Factors Identification

A sum of the risk factors for adverse maternal outcomes was used to compare the ability to recognize danger signs between the two arms. Overall risk factors identified for the phone call arm were(n=27,38.58%) compared to (n=6, 8.45 %) for the routine care arm. T test was done to compare the overall risk factor identification. Mothers in the phone call arm were found to be 4.6 times more likely to identify risk factors for adverse outcomes compared routine care arm and the difference was noted to be statistically significant(RR=4.56, P=<0.001).

Table 4. Risk factorscompared between the Phone call PNC and the Routine PNC

Risk factor identified	Phone call PNC	Routine Care PNC
Fever	1	0
Foul Smelling vaginal discharge	7	3
Abdominal pain	4	1
Wound discharge	5	2
Breast Engorgement and Pain	2	0
Cracked nipples	1	0
Increasing Vaginal bleeding	2	0
Inadequate Milk	1	0
Severe headache	1	0
Epigastric pain	2	0
Blurring of vision	1	0
TOTAL	27(38.58%)	6(8.45%)
RR=4.56, P Value=<0.001		

7.5 Adverse Maternal and Neonatal Outcomes

7.5.1 Adverse Maternal Outcomes

As shown in table 4 below, at 6 weeks,adversematernal outcomes were more likely to be reported in the phone call arm (n=14, 20%) than in the routine care arm (n=6, 8.45%).Theproportion of adverse outcomes reported were therefore 2.4 times higher in the phone call arm (RR=2.37, p=0.049) compared to the routine care arm.

Table 5.Adverse Maternaloutcomescompared between the Phone call PNC and the Routine PNC

Adverse Maternal Outcome	Phone call Arm n=70	Routine Care Arm n=71	P
Mastitis	2(2.90)	0(0.00)	-
SSI	4(5.80)	2(2.82)	0.40
Endometritis	2(2.90)	2(2.82)	0.64
Secondary PPH	2(2.90)	0(0.00)	-
Preeclampsia	1(1.45)	1(1.41)	0.72
Unscheduled Postpartum visits	1(1.45)	1(1.41)	0.135
Re-hospitalization	2(2.90)	0(0.00)	-
TOTAL	14(20%)	6(8.45%)	0.049
RR=2.37, P Value=0.049			

7.5.2 Adverse Neonatal Outcomes

A highernumber of adverse neonatal outcomes were reported in the phone call arm (n=14,20%) compared to the routine care arm (n=7, 9.85%). However, this difference was not statistically significant(RR=2.03, p=0.09). Notably, there were 2 neonatal mortalities in the routine care group with an incidence of 2.81% and none in the phone call arm. The mortalities happened at day 7 and day 10 respectively and were attributed to sudden infant death and Pneumonia. It was the opinion of the research team that this were preventable deaths given the delays noted in seeking care especially for the latter case.

Table 6.Adverse Neonatal outcomescompared between the Phone call PNC and the Routine PNC

Adverse Neonatal Outcomes	Phone call Arm n (%)	Routine Care Arm n (%)	P
Jaundice	4(5.80)	2(2.82)	0.4
Cord infection	2(2.90)	0(0.00)	-
Unscheduled postpartum visits	7(10.14)	1(1.41)	0.5
Readmission	1(1.45)	2(2.82)	0.5
Death	0(0.0)	2(2.82)	-
TOTAL	**14(20%)**	**7(9.85%)**	**0.09**
RR=2.03, P Value=0.09			

CHAPTER 8. DISCUSSION, CONCLUSION AND RECOMMENDATIONS

8.1 DISCUSSION

In this randomized controlled trial,the phone call intervention was demonstrated to have a positive effect on postnatal care at KNH.In the assessment of postnatal care attendance rates, we found that the phone call intervention was effective in improving postnatal clinic attendance rates by 25% for the 2-weekPNC.This is in keeping with Munira et al 2016 who found that the 2-week postnatal clinic attendance was increased by 24%.(19). Similarities could be attributed to similar study setups as they were both conducted in referral hospitals whose postnatal care is strained by large number of patients and lack of proper follow up strategies. Most maternal and neonatal deaths (66%)occur within the first 2 weeks of life(23). An improved clinic attendance is a significant finding since it would help in health education, health promotion, risk identification, prevention and management of pregnancy related diseases thus alleviate such adverse maternal and neonatal outcomes.

We did not find a difference in PNC attendance at 72 hours post discharge between the 2 groups (5.71% vs 4.23%). This could be explained by the nonexistence of a planned 72-hour clinic for patients after discharge at KNH. Our intervention arm was also not reminded of this visit prior to receiving a call at 72 hours. This was different from Mokaya et al 2015 South Africa who noted an increase in attendance of up to 27%(72.3 vs 45.3) at 72 hours post discharge (15).The above difference was attributed to difference in methodology; as opposed to our study, Mokaya et al called patients prior to the 72 hour visit to remind them of clinic attendance.

At 6 weeks all the mothers attended PNC. This could be explained by the compulsory baby immunization that happens at 6 weeks in our setup and the need for contraception that prompts most mothers to attend clinic. This was different from Munira et al 2016Nakuru who noted a 15.6% increase (88.5 vs 72.9) in clinic attendance at 6 weeks. The difference could be explained by their largely rural catchment area and lower level of education compared to our study setup.

Knowledge on risk factors for adverse maternal and neonatal outcomes by mothers or care providers is a key component and predictor of adverse outcomes. In this study we found a significant improvement in risk factor identification between the two arms of study. Mothers

were 4.7 times more likely to identify risk factors for adverse maternal and neonatal outcomes in the phone call arm compared to the routine care arm. This was similar to Butt et al who noted an increase in danger signs recognition and knowledge from 35% to 98% post intervention and McConnel et al 2015Kiambu who also noted an increased risk factor identification from 67% to 78%.(24)(18). Our study mainly focused on the risk factor identification when prompted which was different from the above two studies that looked at both the mother's knowledge and risk factor identification and thus the difference in the proportions.

At 6 weeks mothers had a phone interview to establish the adverse maternal outcomes. The study demonstrated a higher number of patients with reported selected adverse maternal outcomes in the intervention arm as compared to the routine care arm (20% vs 8.45%). This could be explained by higher risk factor identification noted in the intervention arm thus resulting in improved heath seeking behavior. They were therefore most likely to report adverse maternal outcomes from their frequent hospital visits compared with the routine care arm. We could not find a study that studied the phone call intervention effect on adverse maternal outcomes to make comparisons.

There was also reported higher adverse neonatal outcomes in the phone call intervention arm compared to routine care arm (20% vs 9.85%). We interpreted this as a result of improved health seeking behavior from the phone call intervention. However, 2 neonatal mortalities were reported in the routine care group. Munira et al noted 3 infants died in the control arm and I from the phone call arm though the difference in mortality was not statistically significant.(p=0.360)(19). The difference in adverse neonatal outcomes from this study for both intervention and control arms of the study was not statistically significant (p=0.09). They however could not be fully assessed since this study was not powered for the assessment of such outcomes.

The main strength of this study was that it was an RCT thus provides high level evidence and that it made an attempt to study effect of phone call on adverse maternal outcomes. Randomization was successful and therefore the observed effect can be attributed to the intervention.

The study was limited as it depended on subjective self-reporting of information by participants which could have been inaccurate. The risk factors reported depended on the patient's assessment and therefore there was no objective way of determining the same.

8.2 Conclusion

Compared to the routine postnatal care at KNH, Mobile phone calls for PNC improved the PNC attendance at day 10-14 post discharge and also improved the recognition of risk factors for adverse maternal and neonatal outcomes.

8.3 Recommendations

Based on these findings, Mobile phone call interventions are recommended for use in the postpartum period to improve 10-14-day postnatal retention. They can as well be used to improve risk factor identification for adverse maternal and neonatal outcomes. This would result in early care seeking thus reduce the first delay of seeking care.We believe this result justifies the need for larger multi center studies to further assess Mobile phone calls and other mHealth platforms in improving postnatal care.

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CHAPTER 10. APPENDICES

AppendixI: Questionnaire/Follow up Checklist

1.AT ENROLLMENT

- Initials
- Age
- Parity
- Level of education
- Marital Status
- Occupation
- Telephone numbers:
    1.
    2.
    3.
    4.
    5.

- Where is your Residence?:
- Describe your Household?
    - Bedsitter/self-contained/
    - Shared bathroom/own bathroom
    - Shared toilet/own toilet

ANC HISTORY

- What Facility did you Attend?
- What was the number of visits made?
- What was the ANC profile? BG, HB, VDRL, HIV, HEPB, RBS
- Was there any pregnancy complication: Preeclampsia, DM, anemia, HIV, Hep B, Malaria, DVT,others?

DELIVERY

- What was the Mode of delivery: C-section/ SVD?
  If C-section, Indication:
- What was the Birth weight and Apgar score?
- Was Baby admitted to NBU?
- Were there any delivery complications?
    - PPH
    - Perineal tear
    - Surgical complications
- Were you referred to KNH? If so from which hospital

72 HOUR CHECKLIST

Have you attended clinic yet since discharge? Yes □ No □

Have you experienced any of the following symptoms (Yes/No)?

Maternal Checklist

1.	Fever?		Yes	□	No	□
2.	Foul smelling PV discharge?	Yes	□	No	□	
3.	Abdominal Pain?	Yes	□	No	□	
4.	Wound discharge?	Yes	□	No	□	
5.	Breast pain/engorgement?	Yes	□	No	□	
6.	Cracked Nipples ?		Yes	□	No	□
7.	Generalized body weakness?		Yes	□	No	□
8.	Increased Per vaginal Bleeding?	Yes	□	No	□	
9.	Difficult breastfeeding?		Yes	□	No	□
10.	Inadequate milk ?		Yes	□	No	□
11.	Lower limb swelling &Pain?		Yes	□	No	□
12.	Immobility?		Yes	□	No	□
13.	Stress?		Yes	□	No	□
14.	No social support?	Yes	□	No	□	
15.	Easily crying?		Yes	□	No	□
16.	Difficulty passing Urine ?		Yes	□	No	□
17.	Hip joint Pain/Pain in the limbs?	Yes	□	No	□	
18.	Severe Headache?	Yes	□	No	□	
19.	Palpitations?		Yes	□	No	□
20.	Epigastric tenderness?		Yes	□	No	□
21.	Blurring of vision ?		Yes	□	No	□

Neonatal Checklist

1.	Irritability?	Yes	□	No	□
2.	Fever?	Yes	□	No	□
3.	Yellowness of eyes, palms?	Yes	□	No	□
4.	Difficulty breathing?	Yes	□	No	□
5.	Difficulty breastfeeding?	Yes	□	No	□
6.	Not passed urine/meconium?	Yes	□	No	□
7.	Umbilicus red/swollen/discharging pus?	Yes	□	No	□
8.	Skin Infection?	Yes	□	No	□
9.	Convulsions?	Yes	□	No	□

Have you been advised to go to hospital for review?

Mother	Yes	□	No	□	
Baby		Yes	□	No	□

10 -14 DAY CHECKLISTS

Maternal Checklist

22. Fever?		Yes	□	No	□
23. Foul smelling PV discharge?		Yes	□	No	□
24. Abdominal Pain?	Yes	□	No	□	
25. Wound discharge?	Yes	□	No	□	
26. Breast pain/engorgement?	Yes	□	No	□	
27. Cracked Nipples ?		Yes	□	No	□
28. Generalized body weakness?		Yes	□	No	□
29. Increased Per vaginal Bleeding?	Yes	□	No	□	
30. Difficult breastfeeding?		Yes	□	No	□
31. Inadequate milk ?		Yes	□	No	□
32. Lower limb swelling &Pain?		Yes	□	No	□
33. Immobility?		Yes	□	No	□
34. Stress?		Yes	□	No	□
35. No social support?	Yes	□	No	□	
36. Easily crying?		Yes	□	No	□
37. Difficulty passing Urine ?		Yes	□	No	□
38. Hip joint Pain/Pain in the limbs?	Yes	□	No	□	
39. Severe Headache?	Yes	□	No	□	
40. Palpitations?		Yes	□	No	□
41. Epigastric tenderness?		Yes	□	No	□
42. Blurring of vision ?		Yes	□	No	□

Neonatal Checklist

10. Irritability?	Yes	□	No	□
11. Fever?	Yes	□	No	□
12. Yellowness of eyes, palms?	Yes	□	No	□
13. Difficulty breathing?	Yes	□	No	□
14. Difficulty breastfeeding?	Yes	□	No	□
15. Not passed urine/meconium?	Yes	□	No	□
16. Umbilicus red/swollen/discharging pus?	Yes	□	No	□
17. Skin Infection?	Yes	□	No	□
18. Convulsions?	Yes	□	No	□

Have you been advised to go to hospital for review?

Mother	Yes	□	No	□
Baby	Yes	□	No	□

19. Any hospital visits due to previous recognized danger sign? Yes □ No □
20. What was the diagnosis at hospital?

6 WEEKS CHECKLIST (Routine Care)

- Number of postnatal visits/ a) Due to mother
  b) Due to baby
  c) Due to scheduled clinic Visit
  d)Due to an identified Danger sign?
  e) Did the Phone call play a role in your Visit? (phone call)
- Were any of the following observed during the last 6 weeks and if Yes what did you do about it?

Maternal Checklist

43. Fever?		Yes	□	No	□
44. Foul smelling PV discharge?		Yes	□	No	□
45. Abdominal Pain?	Yes	□	No	□	
46. Wound discharge?	Yes	□	No	□	
47. Breast pain/engorgement?	Yes	□	No	□	
48. Cracked Nipples ?		Yes	□	No	□
49. Generalized body weakness?		Yes	□	No	□
50. Increased Per vaginal Bleeding?	Yes	□	No	□	
51. Difficult breastfeeding?		Yes	□	No	□
52. Inadequate milk ?		Yes	□	No	□
53. Lower limb swelling &Pain?		Yes	□	No	□
54. Immobility?		Yes	□	No	□
55. Stress?		Yes	□	No	□
56. No social support?	Yes	□	No	□	
57. Easily crying?		Yes	□	No	□
58. Difficulty passing Urine ?		Yes	□	No	□
59. Hip joint Pain/Pain in the limbs?	Yes	□	No	□	
60. Severe Headache?	Yes	□	No	□	
61. Palpitations?		Yes	□	No	□
62. Epigastric tenderness?		Yes	□	No	□
63. Blurring of vision ?		Yes	□	No	□

Neonatal Checklist

21. Irritability?	Yes	□	No	□
22. Fever?	Yes	□	No	□
23. Yellowness of eyes, palms?	Yes	□	No	□
24. Difficulty breathing?	Yes	□	No	□
25. Difficulty breastfeeding?	Yes	□	No	□
26. Not passed urine/meconium?	Yes	□	No	□
27. Umbilicus red/swollen/discharging pus?	Yes	□	No	□

28. Skin Infection? Yes □ No □
29. Convulsions? Yes □ No □

Have you been advised to go to hospital for review?

Mother Yes □ No □
Baby Yes □ No □

Reported complications/ Diagnosis at admission during postpartum (For Both groups)

1. Death, Yes □ No □
2. Mastitis, Yes □ No □
3. Surgical site infection Yes □ No □
4. Endometritis Yes □ No □
5. Depression, Yes □ No □
6. Secondary PPH Yes □ No □
7. Preeclampsia Yes □ No □
8. Postpartum visits, Yes □ No □
9. Rehospitalization Yes □ No □
10. ICU admission Yes □ No □
11. Surgery related to delivery Yes □ No □
12. Other Yes □ No □
    Specify:

Adverse Neonatal outcomes:

- Jaundice, Yes □ No □
- Cord infection. Yes □ No □
- No of outpatient visits, Yes □ No □
- Readmission Yes □ No □
- Death, Yes □ No □
- Other
- Baby examined?

AppendixII: Case Log

EFFECTS OF TIMED PHONE CALL SURVEILLANCE VERSUS ROUTINE CARE ON POSTPARTUM CARE, IDENTIFICATION OF RISK FACTORS AND ADVERSE MATERNAL AND NEONATAL OUTCOMES AT KENYATTA NATIONAL HOSPITAL, A RANDOMIZED CONTROLLED TRIAL

Date	Name	Enrolment Id Number	1st Tel No	2ndTell No	Date Of 1st Call	Date Of 2nd Call	Date Of 3rd Call

AppendixIII: Consent in English

Date (date/month/year): _____

STUDY TITLE:EFFECTS OF TIMED PHONE CALL SURVEILLANCE VERSUS ROUTINE CARE ON POSTPARTUM CARE, IDENTIFICATION OF RISK FACTORS AND ADVERSE MATERNAL AND NEONATAL OUTCOMES AT KENYATTA NATIONAL HOSPITAL, A RANDOMIZED CONTROLLED TRIAL

Principal Investigator:
Dr. Liyayi Brian Nicharius (MBChB)
Department of Obstetrics and Gynaecology, University of Nairobi.
Telephone Number: 0726579329

Investigator's Statement:

We are requesting you to kindly participate in this research study. The purpose of this consent form is to provide you with the information you will need to help you decide whether to participate in the study. This process is called 'Informed Consent'. Please read this consent information carefully and ask any questions or seek clarification on any matter concerning the study with which you are uncertain. You are free to ask any questions about the study. The investigator will be available to answer any questions that arise during the study and afterwards.

Introduction:

PNC is the care provided by skilled healthcare professionals to both mothers and babies up to 6 weeks post-delivery. This ensures early detection and management of any complications that may arise during that time as well as offer advice and counsel mothers on how to care for themselves and the newborns.

Due to the referral nature of our hospital, we are unable to follow up on all patients and we therefore refer them to the nearest hospital for care. In this study, we are additionally following up our patients with a phone callin order to assess any differences in adverse maternal and neonatal outcomes.

Benefits:

As a participant you will benefit from the study by receiving a phone call during the postpartum period. You will benefit by receiving health education and advice during this period as well as inform on your well-being. Your participation in the study may benefit others in future from the information we find in this study.

Risks:

There is a risk of leak of information but we will maintain privacy and confidentiality by using unique identifiers and secure storage of collected data.

Voluntariness:

The study will be fully voluntary. There will be no financial rewards to you for participating in the study. One is free to participate or withdraw from the study at any point. Refusal to participate will not compromise you or your child's care in any way.

Confidentiality:

All the information obtained from you will be held in strict confidentiality. Any information that may identify you or your child will not be published or discussed with any unauthorised persons. No specific information regarding you, your child or your family will be released to any person without your written permission. Your research number will be used in place of your names. All the electronic health records will be stored in secure KNH servers that will only be accessible with the PI's authorization.

Sharing of results

Study staff will protect your personal information closely so no one will be able to connect your responses and any other information that identifies you. Federal or state laws may require us to show information to university or government officials (or sponsors), who are responsible for monitoring the safety of this study. Directly identifying information (e.g. names, addresses) will be safeguarded and maintained under controlled conditions. You will not be identified in any publication from this study.

Study Procedures

The RA will approach you and inform you of this study and request for your participation. You will be allowed to ask as many questions as possible before consenting for participation Once informed consent is provided, the clinician will open a sealed, numbered, opaque envelope containing the allocation. You will either be allocated to be called after 6 weeks after delivery or to the intervention group where you will be called at 72 hours, 10 days and 6 weeks.

The RA will call you at thetimelinesindicated in your allocation postnatally to ask you a series of questions concerning your postnatal health. You are still required to continue with your postnatal follow up as advised at the hospital. The follow up is not meant to substitute it.

Problems or Questions:

If you ever have any questions about the study or about the use of the results you can contact

the PI, Dr.Liyayi Brian by calling 0726-579329. If you have any questions on your rights as a research participant you can contact the KNH Ethics and Research Committee (KNH- ESRC) by calling 2726300 Ext. 44355.

Consent Form: Participant's Statement:

I _____having received adequate information regarding the study research, risks, benefits hereby AGREE / DISAGREE (Cross out as appropriate) to participate in the study with my child. I understand that our participation is fully voluntary and that I am free to withdraw at any time. I have been given adequate opportunity to ask questions and seek clarification on the study and these have been addressed satisfactorily.

Parent's name: _____ Signature/thumb print: _____

Date _____

Witness name: _____ Signature/thumbprint: _____

Date: _____

I _____ declare that I have adequately explained to the above participant, the study procedure, risks and benefits and given him /her time to ask questions and seek clarification regarding the study. I have answered all the questions raised to the best of my ability.

Interviewer's name and Signature: _____ Date: _____

Appendix IV: Fomu Ya Ridhaa

Tarehe (siku/mwezi/mwaka): _____

STUDY TITLE:EFFECTS OF TIMED PHONE CALL SURVEILLANCE VERSUS ROUTINE CARE ON POSTPARTUM CARE, IDENTIFICATION OF RISK FACTORS AND ADVERSE MATERNAL AND NEONATAL OUTCOMES AT KENYATTA NATIONAL HOSPITAL, A RANDOMIZED CONTROLLED TRIAL

Mtafiti Mkuu:

Dkt. Liyayi Brian Nicharius (MBChB)

Idara ya Uzazi na Afya ya kina mama, Chuo kikuu cha Nairobi.

Nambari ya simu: 0726579329

Taarifa ya mtafiti:Tunakuomba kushiriki kwenye utafiti huu. Lengo la fomu hii ya idhini ni kukupa habari utakayohitaji ili ikusaidie kuamua ikiwa utashiriki kwenye utafiti. Utaratibu huu unaitwa 'Idhini ya kujulishwa'. Tafadhali soma ujumbe wa idhini hii kwa uangalifu na uulize maswali yoyote au ufafanuzi kwa mambo yoyote yanayohusisha utafiti ambayo hauna uhakika nayo. Uko huru kuuliza ma swali yoyote kuhusu utafiti. Mtafiti atakuweko kujibu maswali yatakayotokea wakati wa utafiti na baadaye.

Utangulizi:

Huduma za baada ya kijifungua za akina mama ni huduma zinazotolewa na wataalamu wenye ujuzi wa afya kwa wanawake ili kuhakikisha hali nzuri ya afya kwa mama na mtoto baada ya kujifungua. Hii inatekelezwa kwa kutambua na kutibu matatizo ya baada ya kujifungua na pia kuwaelimisha akina mama kuhusu afya yao na ya watoto wachanga
Kwa kuwa hospitali ya KNH ni ya rufaa, Kufuatilia wagonjwa baada ya kujifungua una ugumu na kwa hivyo tunawashauri kuenda kwa hospitali ya karibu na nyumbani. Utafiti huu unaongezea kutumia simu kuangazia afya ya akina mama baada ya kujifungua.

Faida:

Kama mshiriki utafaidika kutokana na utafiti kwa kupigiwa simu kwa kipindi hiki baada ya kujifungua.Utafaidika kwa kupokea elimu na ushauri wa afya kwa kipindi hiki. Ushiriki wako kwa utafiti huu utawafaidi wagonjwa wengine kwa wakati ujao kulingana na matokeo tutakayopata.

Hatari:

Kuna uwezekano wa kuvuja kwa habari utakayotupa lakini tutahakikisha kuwa usiri wako utahifadhiwa wakati wote kwa kutumia nambari za siri za utambulizi na kuhifadhi salama.

Kujitolea:

Utafiti utakua wa kujitolea. Hakuta kuwa na malipo ya kifedha kwa kushiriki kwenye utafiti huu. Mtu ako huru kushiriki au kujiondoa kwenye uta fiti kwa wakati wowote. Kukataa kushiriki hakutaathiri malezi yako au ya mwanao hata.

Usiri:

Habari yoyote itakayotolewa kwako itawekwa kwa usiri wa hali ya juu. Habari yoyote ya kukutambulisha wewe au mwanao haitachapishwa au kujadiliwa na watu wasiona kibali. Hakuna habari maalum kukuhusu, kuhusu mwanao au mtu wa familia yako itapeanwa kwa mtu mwingine bila ruhusa yako iliyoandikwa. Nambari yako ya utafiti itatumika badala ya jina lako. Rekodi zote zitahifadhiwa katika seva za salama za KNH ambazo zitaweza kupatikana tu na idhini ya mtafiti mkuu.

Kujulisha wengine matokeo

Wafanyakazi wa utafiti watalinda habari sana habari yako ya kibinafsi ilimtu yeyote asije akajua akaunganisha majibu yako na habari inayoweza kukutambulisha. Sheria za serikali zatuhitaji kuonyesha habari kwa wawakilikilishi wa serikali (wafadhili) au chuo kikuu ambao wana jukumu la kufuatilia usalama wa utafiti huu. Habari inayotambulisha moja kwa moja (majina, anwani) zitalindwa na kuwekwa katika hali salama. Hautatambulishwa na chapisho lolote kutoka na utafiti huu.

Tutakachofanya

Idhini ya ruhusa itakapotolewa, daktari atafungua bahasha iliofungwa, iliyonanambari, bahasha isioonyesha kilicho ndani iliyo na mgao wa matibabu. Itaonyesha kama utawekwa kwa kikundi cha kupigiwa simu baada ya wiki sita ama utawekwa kwa kikundi cha pili cha kupigiwa simu baada ya masaa 72, siku 10 na wiki 6.

Shida au Maswali: Ikiwa una maswali kuhusu utafiti au matumizi ya majibu waweza asiliana na mtafiti, Dkt. Liyayi Brian kwa kupiga 0726-579329. Ikiwa una maswali kuhusu haki yako kam mshiriki waweza wasiliana na kamati ya madili na tafiti ya hospitali kuu ya (KNH-ESRC) kwakupiga 2726300 Ext. 44355.

Fomu ya Idhini: Taarifaya Mshiriki:

Mimi_____Nimepewa habari ya kutosha kuhusiana na utafiti , hatari, faida, NINAKUBALI/SIKUBALI (weka alama inavyostahili). Kushiriki kwenye utafiti na mwanangu. Ninaelewa kwamba kushiriki kwangu ni kwa kujitolea na niko huru kujiondoa wakati wowote. Nimepewa nafasi ya kutosha ya kuuliza ma swali na kuuliza ufafanuzi wa utafiti na nimeelezewa haya nikatosheka.

Jina la mzazi: _____ Sahihi/alamayakidole:_____

Tarehe _____

Jina la mshahidi: _____ Sahihi/alamayakidole:

_____

Tarehe: _____

Mimi_____Natangaza yakwamba nimemwelezea mshiriki aliye hapo juu yakutosha, taratibu za utafiti, hatari na faida na nimempa wakati wakuuliza naswali nakuuliza ufafanuzi kuhusu utafiti. Nimejibu maswali yake yote kwa uwezo wangu wote.

Jina la anayeuliza ma swali na sahihi: _____Tarehe: _____

Appendix V: Data Monitoring and Safety Plan

STUDY TITLE: EFFECTS OF TIMED PHONE CALL SURVEILLANCE VERSUS ROUTINE CARE ON POSTPARTUM CARE, IDENTIFICATION OF RISK FACTORS AND ADVERSE MATERNAL AND NEONATAL OUTCOMES AT KENYATTA NATIONAL HOSPITAL, A RANDOMIZED CONTROLLED TRIAL

PI: Dr Liyayi Brian Nicharius

MEMBERS

1. **Prof. Dalton Wamalwa-Paediatrician**
2. **Wycliffe Ayieko-Statistician**
3.

BRIEF STUDY OVERVIEW

Objective: To determine the effect of phone call-based surveillance at 72 hours, 10-14days and 6 weeks after delivery compared to routine care on PNC attendance, selected adverse maternal and neonatal outcomes at KNH.

Methodology: It was an open label randomized controlled trial. Where postnatal mothers who met the eligibility criteria will be randomized to either the phone call group or the routine care group.The primary outcome wasPNC attendance. The secondary outcomes were: risk factor identification; adverse maternal and neonatal outcomes.

DSMB OVERSIGHT RESPONSIBILITIES

Oversight of the trial was provided by the DSMB. Meetings were to take place to monitor safety of patients and signals of efficacy, futility or harm. The DSMB members had a first virtual meeting before study commenced. A second meeting was to be constituted in case of any adverse event and a final meeting on conclusion of the study. In the case that unacceptable safety concerns/results occur, the board would recommend termination of the study.

Potential risks to the participants included loss of data and breach of privacy and confidentiality. The safety of the participant was paramount.

MONITORING PROCEDURES

Dr.Liyayi ensured that informed consent was obtained prior to performing any research procedures, that all subjects met eligibility criteria, and that the study was conducted according to the ERC-approved research plan.

Study data was accessible for the DSMB statistician to review in case of adverse events, or at completion of study. The PI reviewed study conduct every alternate day that is acquisition of consent, any dropouts, and completeness of questionnaire. The PI reviewed AEs individually real-time and in aggregate on a daily basis.

The PI ensured all protocol deviations, AEs, and SAE were reported to the ERC, DSMB and KNH administration according to the applicable regulatory requirements.

DATA ANALYSIS PLANS

The study statistician was blinded and data monitoring was continuous, he reported the results to the DSMB at the completion of the study or if there were any significant SAES. This would result in no interim analysis.

PLAN FOR DATA MANAGEMENT

Compliance of regulatory documents and study data accuracy and completeness was maintained through an internal study team quality assurance process.

Confidentiality throughout the trial was maintained by assigning a code to each participant, for purposes of identification. The key, linking the patient to the identifying code was stored separately from the research data, in a password-protected database. This was only accessible to the PI.

The Electronic Health Records was transmitted from the mobile phone to the KNH/Uonservers that was secure. All the data related to the patient was stored in the central server. No data was saved in the clinician's mobile devices. Only the system administrators had access to the web application dashboard.