EFFICACY OF ELECTRONIC MOBILE PHONE APPLICATION COMPARED WITH MOTHER AND CHILD HEALTH BOOKLET IN IMPROVING QUALITY OF ANTENATAL CARE FROM FIRST VISIT THROUGH THIRD TRIMESTER 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 Gynaecology in partial fulfilment of the requirements, for the award of a degree in Master of Medicine in Obstetrics and Gynaecology.

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DECLARATION

This research work and dissertation is my original work and to the best of my knowledge it contains no materials previously published or written by another person. It has not been submitted for award of a degree in any other university. References to work done by others have been clearly indicated.

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DEDICATION

This thesis is dedicated to my parents, Prof. Mohamed Badamana and Mrs. Aisha Naji for their unconditional support, prayers, and love. To mybrother Luqman, for always being there to encourage me and remind me to believe in myself. And finally, to my siblings, Maryam and Malik for their continued advice and support, for always looking out for me and providing me a second home with their boys Yusuf and Ammar.

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

ANC= Antenatal Care

API= Application Programming Interface

ART= Antiretroviral Therapy

ARV= Anti-Retroviral

BP= Blood Pressure

CHW= Community Health Worker

CI= Confidence Interval

CME= Continuing Medical Education

CONSORT= Consolidated Standards of Reporting Trials

CS= Caesarean Section

DM= Diabetes Mellitus

DSMB= Data and Safety Monitoring Board

EMR= Electronic Medical Records

ERC=Ethicsand Research committee

FANC= Focused Antenatal Care

FHG= Full Haemogram

GCP= Good Clinical Practice

GCT= Glucose Challenge Test

GSM= Global System for Mobile

Hb= Haemoglobin

HIV= Human Immunodeficiency Virus HTTPs=

Hypertext Transfer Protocol Secure ICT= Information

and Communication Technology IPTp= Intermittent

Preventive Treatment in Pregnancy

ITU= International Telecommunication Union

JASA= Junior Aspirin

KDHS= Kenya Demographic and Health

Survey KNH= Kenyatta National Hospital

LFTs= Liver Function Tests

LTFU= Lost to Follow Up

MCH= Mother and Child Health

MHealth= Mobile Health

MTCT= Mother to Child Transmission

OGTT= Oral Glucose Tolerance Test

OR= Odds Ratio

PCR= Polymerase Chain Reaction

PI= Principal Investigator

PMTCT= Prevention of Mother to Child Transmission

PNC= Postnatal Care

PPH = Postpartum haemorrhage

QoC= Quality of Care

RA= Research Assistant

RBS= Random Blood Sugar

RCT= Randomized controlled trial

SD= Standard Deviation

SDG= Sustainable development goal

SMS= Short Message Service

SPSS= Statistical Package for the Social

Sciences SSA= Sub-Saharan Africa

STD= Sexually Transmitted Disease

SVD= Spontaneous Vaginal Delivery

TB= Tuberculosis

TCA= To Come Again

TOLAC= Trial of Labour after Caesarean

Section UNFPA= United Nations Population

Fund UNICEF= United Nations Children‟s Fund

UoN= University of Nairobi UTI= Urinary Tract

Infection

UTI= Urinary Tract Infection

VBAC= Vaginal Birth After Caesarean Section

VDRL= Venereal Disease Research Laboratory

test WHO= World Health Organization XML=

Extensible Markup Language

OPERATIONAL DEFINITION OF TERMS

Antenatal care: care provided by skilled healthcare professionals to pregnant women and adolescent girls in order to ensure the best health conditions for both mother and baby during pregnancy

Quality of care: The degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge

eHealth: The use of information and communication technologies (ICT) for health. It encompasses health services and information delivered or enhanced through the internet and related technologies

mHealth: This is a medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices

Trimester: Any of the three month periods pregnancy is divided into. The first trimester encompasses the first 13 weeks of pregnancy, second trimester from week 14 to week 26 of pregnancy and third trimester lasts from 27 weeks to delivery.

Complete records of ANC: This is defined as records where all observations that needed to be made during a clinical encounter are present. The completeness was measured considering if a patient‟s record contained all desired types of data as per the MCH Booklet.

LIST OF TABLES AND FIGURES

EFFICACY OF ELECTRONIC MOBILE PHONE APPLICATION COMPARED WITH MOTHER AND CHILD HEALTH BOOKLET IN IMPROVING QUALITY OF ANTENATAL CARE FROM FIRST VISIT THROUGH THIRD TRIMESTER AT KNH, A RANDOMIZED CONTROLLED TRIAL

ABSTRACT

Background: Antenatal care (ANC) directly reduces maternal and perinatal morbidity and mortality through detection and treatment of complications during pregnancy as well as indirectly through identification of women at risk of developing labour and delivery complications. It also provides an opportunity to prevent, detect and manage comorbidities such as HIV and Malaria, which as part of indirect causes, contribute to 25% of maternal deaths and near misses.In regions which have the highest maternal mortality rates, such as sub-Saharan Africa, fewer pregnant women received ≥ 4 ANC visits (52%), and in Kenya, 58% of them had ≥ 4 ANC visits (KDHS 2014). The mother and child booklet was developed by the Ministry of Health and launched in 2010 to provide health workers and mothers practical guidance on maternal and child health. However, the fill in rate has been found to be inadequate in previous studies.

In low resource settings, a mobile phone solution may increase the access to higher quality and standardized ANC for pregnant women especially in more remote areas.Limited studies on mobile phone application to enhance quality of ANC in SSA have demonstrated the feasibility and potentialof mobile health applicationfor completing and standardizing ANC visits according to WHO guidelines. The use of mobile phone application versus standard of care, MBB for enhancing quality of ANC in Kenya has not been studied.

Objective: To determine the efficacy of an electronic mobile phone application in improving quality of antenatal care from first visit to third trimester as compared to the Mother and Child Health booklet at Kenyatta National Hospital.

Methodology: An open labelrandomized controlled trial, in which eligible pregnant women at gestation less than 28 weeks, were either randomized to antenatal mobile phone or to the Mother and Child Health Booklet based care at first visit and followed until 28 weeks. All subsequent visits were conducted as per the randomization arm. The primary outcomes were complete antenatal care records and birth and emergency care plan. The secondary outcomes were identificationof risk factors for adverse pregnancy outcomes, subsequent ANC visit rates and average duration of each visit. The qualitative data which was the health worker experience was collected using technology acceptance model questionnaires with a Likert scale.

Study setting: Kenyatta National Hospital Antenatal Care Clinic

Data collection tool: Electronic mobile phone application, Mother and Child Health Booklet, and interviewer administered questionnaires were used.

Analysis plan: Data was collected using the mobile phone application for the mobile phone armand questionnaires for MCH Booklet arm.The data was downloaded from the KNH serverand analyzed by the use of SPSS® version 21. Categorical data was analyzed and presented as frequencies and proportions and compared using chi square test, while continuous data was summarized and presented as means and standard deviations or median and interquartile range and compared using independent student t test. Risk estimates were obtained and p value <0.05 considered statistically significant. All analyses were intention to treat.The qualitative data used to assess health worker

experience was collected using technology acceptance model questionnaires with a Likert scale. The data was then analyzed by frequencies of their responses.
Results: Between 3rd June 2019 and 6th November 2019, 215 women were screened and 101 enrolled. The baseline characteristics were found to be similar. The mobile phone application had more complete records for Hepatitis B screening, physical examination and education and counselling, birth and emergency plans compared to the Mother and Child Booklet (p=<0.001). Women in the mobile phone application arm were more likely to be screened for previous hypertensive disorder, hepatitis B and anomaly scan. Compared to the Mother and Child Booklet, the mobile phone application had significantly longer average duration at first visit (22.9min vs 12.1min) and at subsequent visits (13.6min vs 7.4min) (p=<0.001). The health worker experience was positive overall with all three intending to continue to use it if available.
Conclusion: Compared to the standard MCH booklet, mobile phone application for ANC improved the quality of ANC by increasing completeness of records,increasing the duration of ANC visits and was highly acceptable to health care providers. **Key words:** mobile phone, antenatal care, booklet

CHAPTER 1: INTRODUCTION/BACKGROUND

Antenatal care (ANC) can be defined as the care providedto pregnant women and adolescent girls by skilled healthcare professionals so as to ensure the best health conditions during pregnancy for both the mother and baby. The components of ANC include identification of risk factors; prevention and management of pregnancy-related or concurrent diseases; as well as health promotion andeducation(1).

Antenatal care (ANC) directly reduces maternal and perinatal morbidity and mortality through detection and treatment of complications during pregnancy as well as indirectly through identification of women at risk of developing labour and delivery complications. It also provides an opportunity to prevent, detect and manage comorbidities such as HIV and Malaria, which as part of indirect causes, contribute to 25% of maternal deaths and near misses(1).

WHO defines eHealth as the use of information and communication technologies (ICT) for health. It is an upcoming field in the intersection of public health, medical informaticsand business. It refers to health information and services enhanced or delivered through the internet and other related technologies.

According to WHO Global Observatory for e-health (GOe), mHealth is a sub-segment of eHealth where mobile devices, such as mobile phones, patient monitoring devices and other wireless devices are used to support medical and public health practice. As per the United Nations Foundation, mobile technology is a higher reach and cost-efficient method that can be used to make healthcare more accessible, effective and affordable in the developing world (2).

MHealth technologies have the potential to create a high impact in obstetric care. They canencourage women to attend and register for early antenatal care, attend all recommended visits, as well as deliver in a health facility thus positivelyinfluencing pregnant womento engage with the health system. They can also assist to reduce the delays resulting in increased maternal mortality in low resource settings, that is, the delay in deciding to seek care, delay in reaching care in time and delay in receiving adequate treatment.

Electronic health recordsas part of eHealth, can be defined as records containing all personal health information of an individual, that are entered and then accessed by healthcare providers electronically and extend beyond acute inpatient situations including outpatient care settings. They have been shown to improve quality of care by improving the accuracy and quality of data recorded as well as improving accessibility of the records by different healthcare practitioners.(3)

A birth plan or emergency preparedness plan includes identifying several elements such as preferred place of birth and birth attendant, the most accessible health facility, preparing for expenses related to pregnancy and delivery, as well as transport for the birth or in case of emergency.(4) It is a WHO recommendation that all pregnant women should have a written birth and emergency plan that should be discussed and reviewed at every antenatal assessment.

Risk factor identification is also a critical component of antenatal care. It allows for timely evidence-based interventions related to screening and early treatment as well as health promotion and preventive measures. This has been shown to reduce pregnancy and birth complications, as well as reducing stillbirths and perinatal mortality, and ensuring integrated care throughout pregnancy(1).

Clinic attendance rates directly impact quality of care received.The 2016 WHO Antenatal Care guidelines recommend at least eight contacts in order to provide a more positive pregnancy experience and to reduce perinatal deaths(1) This recommendation was informed by evidence suggesting increased perinatal deaths in the previous 4-visit ANC model, evidence supporting improved safety with increased frequency of maternal and fetal assessment as well as indicating that increased contact between pregnant women and healthcare workers is more likely to lead to a positive pregnancy experience.

As per UNICEF global databases 2016, although 86 per cent of women attendANC at least once, only three in five women (62 per cent) receive four antenatal visits. In areas such as sub-Saharan Africa where there are higher maternal mortality rates, only 52 per cent of women received a minimum of four antenatal visits.In Kenya, 58

per cent of pregnant women had four or more antenatal care visits as per KDHS 2014(5).

It is in this context that we developed an antenatal electronic mobile phone model for use in antenatal care clinics, to assess for improvement in quality of antenatal care. The WHO definition of quality of care is “the extent to which health care services provided to individuals and patient populations improve desired health outcomes. In order to achieve this, health care must be safe, effective, timely, efficient, equitable and people-centered.”

The mobile application was likely to increase safety as electronic health records are specific to each patient, with all the results/data complete per patient, hence reducing medical errors. It is also effective as the services provided are based on checklists that were formed in line with scientific and evidence-based guidelines. It is timely by reducing delays in healthcare service provision due to the simplified checklist format. It is efficient in delivering health care in a manner that maximizes the use of resources, for example lab tests are less likely to be repeated due to results getting lost. It is also equitable in delivering health care of the same quality regardless of personal characteristics, since the same mobile application is used for all patients.

LITERATURE REVIEW

Introduction and Epidemiology

Antenatal care (ANC) directly reduces maternal and perinatal morbidity and mortality through detection and treatment of complications during pregnancy as well as indirectly through identification of women at risk of developing labour and delivery complications(1).

MHealth applications can be broadly classified into five groups: behavior change communication and client education, registries and tracking of vital events, data reporting and collection, electronic health records and provider to provider communication. Our intervention focused on data collection and reporting, and electronic health records. This is demonstrated as per our first objective of assessment of completeness of health records and risk factor identification. We also assessed the clinic attendance rates as influenced by the SMS appointment reminders hence assessing client education and behavior change communication. mHealth interventions have great potential to improve the quality of antenatal care as demonstrated in the studies highlighted in this section.

MHealth interventions

In a systematic reviewby *Feroz A. et al,*the role played by mHealth applications in low and middle income countriesto improve both antenatal and postnatal care was assessedby searching three international electronic databases in 201, from January 1st 2000 to January 25th 2016(6). The 14 final studies were categorized in to five mHealth applications:behavior change communication and client education, registries and tracking of vital events, data reporting and collection, electronic health records and provider to provider communication. The most common use of mHealth was for client education and behavior change communication, in the form of voice reminders and SMS [n= 9,65%]. While most of the studies showed the effectiveness of mHealth interventions in improving antenatal care and postnatal care services, there is little evidence on other types of mHealth applicationsespecially those assessing completeness of health records as does our study.

Electronic Health Records

These studies assessed the electronic health records obtained with the use of mHealth interventions. In assessing the quality of antenatal care provided by our mobile application we assessed the completeness of records as a primary objective as did the studies listed below.

In 2015, one of the most recent mobile phone application based studies, the PANDA (Pregnancy and Newborn Diagnostic Assessment) mHealth pilot study in Madagascar assessedthe feasibility and usability of an mHealth system to provide quality antenatal care, in line with the WHO recommendations(7). 100 women were invited to participate in the pilot study (PANDA) from January to March 2015. The telemedicine system was based on mobile technology incorporating the recommendations by WHO.The average duration of ANC visits was 29.6min. Healthcare providers were able to collect 100% of medical and personal data variables with no data lost. There were no major technical problems encountered. The alert function was generated in 17 visits (17%) in order to highlight abnormal results that required an intervention, that is, therapy or referral to another hospital. Participants, both providers and patients,acceptability of the mobile system was at 100%. This telemedicine system was most similar to our study, as we assessed the completeness of records, duration of visit and health worker experience as well.

A pre-post study in Northern Nigeria was conducted by McNabb M. et al to assess the effect of the CommCare mobile phone application on the quality of antenatal care services provided by cadres of a lower level (8). The application guided the community health workers both in the registering of new clients as well as followingup patients on their subsequent visits. The quality score improved from 13.3 at baseline to 17.2 at end line ($P < 0.0001$) out of 25 as a result of the introduction of the CommCare system. There were improvements noted in counseling, provision of technical services, as well as the quality of health education.

In Western Kenya, Mushamiri et al conducted an evaluation study looking at antenatal and postnatal attendance as influenced by a mobile health

system(9).Following theregistration of 800 pregnant women in to mobile health system (ANC/PMTCT Adherence System-APAS), 20 CHWswere interviewed in order to assess the adherence to the clinics.They allreported that,compared to the paper-based system, APAS helped them to track vital events more efficiently. The women registered in APAS were more likely to go for more visits than those not registered. The women who were registered had atransmission rate of 0% at 9 months and 18 months while those not registered had an MTCT rate of 9% at 18 months.

Haskew et al conducted a study in Kenya in 2015 to assess for reduction in gaps in HIV treatment in rural Kenya with the implementation of electronic medical records that were cloud-based (10). This study was conducted in a HIV outpatient setting located in Western Kenya. It assessed a novel system with cloud-based electronic medical records and evaluated its impact on reduction of gaps in the continuum of HIV treatment such aseligibility of patients for ART and missing data. There were significant improvements reported in clinical care provision and data quality upon implementation of the novel EMR system. This helped to ensure early treatment for those who were eligible. Pre-implementation, 1,346 patients had not yet started ART, yet they were eligible, as compared to 270 patients post-implementation.

Birth and Emergency Preparedness

Limenih et al conducted a cross-sectional study in Farta district, Ethiopia, to assessreadiness planning, birth preparednessand other associated factors. 676 mothers were recruited from 1st October to December, 2016. As per the study,34% of the women were found to havepracticed birth preparedness and implemented aplan for complication readiness(12).

Mutiso et al conducted a descriptive cross-sectional study in order to evaluate birth preparedness and complication readiness among pregnant women in Kenyatta National Hospital. Between May and August 2006, 394 women were recruited. Of these women, over 60% were found to have been counselled by health care workers on birth preparedness. Those aware of their expected date of delivery were 87.3%,

84.3% had set aside transport funds to hospital when they go intolabour while 62.9% emergency funds. Majority of them did not have a clear plan for an obstetric emergency should one arise. Th respondents level of education was found to positively influence birth preparedness.(11)

Clinic Attendance Rates

In 2010, Kaewkungwal J et alevaluated the application of mobile phone system to improve ANC for pregnant women in Thai-Myanmar border area (12). In this study, the system consisted of a module that contained a web-based and mobile technology system. It was utilized to generate ANC clinic dates in which CHW could identify, cross-check, as well as update the mother‟s status at the household location during a home visit or at the healthcare facility. 58.68% were to come on-time after the intervention compared to 43.79% women before the intervention ($p < 0.01$). The odds of having an on-time visit were increased by by 2.97 (1.60-5.54) following appointment messages. Therefore, the module assisted to develop better procedures of data collection and reporting resulting in enhanced ANC (12).

Lund et al conducted a clustered randomized control trial in Zanzibar in 2014 to evaluate the association between a mobile phone intervention and antenatal care clinic attendance.(13) The results showed that there were two times higher odds of receiving more than four antenatal care visitswhen using the intervention(OR, 2.39; CL, 1.03-5.55). There was also improved timing and quality of antenatal care services among the women in the intervention arm, although this was not found to be statistically significant. For example, the number of pregnant women receiving two doses of tetanus vaccination was higher (72% vs 56%) and IPTp (65% vs 52%) as compared to the control arm.

A randomized control trial in Njoro division in Kenya by Fedha et al in 2014 assessed the impact of mobile phones on maternal health service provision (14).Text message reminders and health education messages for the mothers were sent to their mobile phones after which antenatal clinic attendance rates were evaluated. Of the women receiving the messages, 4% had less than 4 antenatal

clinic visits compared to 18.6% of those who had not received the messages (P = 0.002).

Quality of Care

Kanyangarara M. et al conducted a study that used evidence from nationally representative health facility assessments to assess the quality of antenatal care service provision in health facilitieslocated across sub–Saharan Africa(15).In the 20 health facility assessments, a total of 10,534 health facilities were surveyed. Of these, 8742 were included in the analysis as they reported offering antenatal services. There was a range of 24.8% to 75.8% in attendance of at least 4 antenatal clinic visits.There were marked gaps reported for all interventions, particularly syphilis screening and treatment and hypertensive disease management.

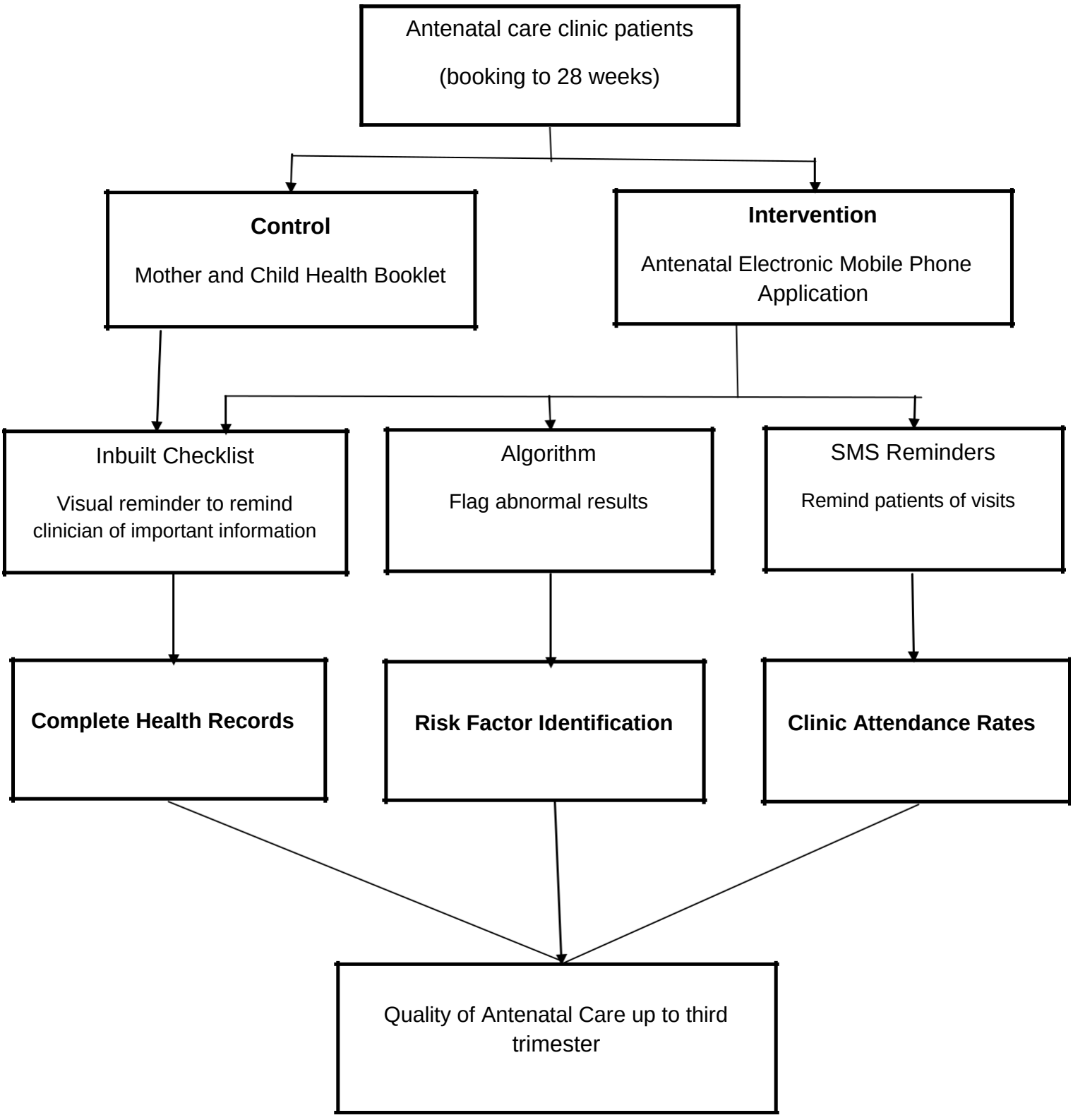
Do M et al assessed the quality of antenatal care as well as client satisfaction in Namibia and Kenyain 2017(16). The data used was obtained from Service Provision Assessment (SPA) surveys of health facilities that were nationally representativein Namibia and Kenya. A common problem encountered was long waiting time that was found to be worse in hospitals and health centers as compared to smaller facilities and clinics. This was associated with lower client satisfaction. The study also indicated that the health care provider's technical preparedness may not have been sufficient to ensure client satisfaction and provide high quality services (16).

Mudany M A et al evaluated the Mother & Child Health Booklet that was developed tofacilitate timely management and follow up of patients by helping to relate the mothers' obstetrical history to the infants' healthcare providers(17).The booklet was evaluated in a 1-year pilot in Nyanza province in 2007-2008, and the number of HIV DNA tests done on infants was noted to increase from 9,966 to 13,379 (34%). Subsequently, in 2009, the booklet was distributed nationwide. Between 2007 and 2012, the number of HIV DNA infant tests rose from 27 000 to 60 000, which accounts for approximately 60% of HIV-exposed infants in Kenya.

The utilization of the Mother-Child Health Booklet by health care service providers was assessed in 2015 at Mbagathi District Hospitalby Opondo et al.(23). The results

showed that most sections of the booklet were not adequately filled in; 12.8% had filled in delivery records, 3.7% developmental milestones, 9.3% postnatal examination, 9.6% counseling on infant feeding, and 0.6% of identification of HIV exposed section was filled. There was a strong association between level of education of the providers and utilization aOR 3.65(95%CI 1.49-8.94 p = 0.005) and a previous history of child loss aOR 0.34(95% CI 0.16-0.87 p = 0.03). Heavy work load and a lack of training were found to be the barriers to utilization by healthcare providers.

CONCEPTUAL FRAMEWORK



CONCEPTUAL FRAMEWORK NARRATIVE

The Mother and Child Health Booklet, distributed by the Ministry of Health in 2009 has been adopted in Kenyatta National Hospital and other antenatal care facilities. It provides visual reminders to the clinician and patients, in the form of advice on danger signs, and important information about pregnancy. It also contains checklists to enable the clinician to fill mandatory information. In so doing it has helped to standardize antenatal care across different facilities.

The Antenatal Electronic Phone Application has been developed based on this booklet, and contains similar checklists that incorporate the WHO recommendations for ANC. It however has the ability to flag abnormal results so as to alert the clinician to take action and sends SMS reminders to patients to remind them of the next visit which is likely to improve clinic attendance rates.

The study compared the quality of antenatal care which was assessed using completeness of health records, birth and emergency care plan, risk factor prediction and clinic attendance rates.The health worker experience and duration of each visit was also evaluated.

JUSTIFICATION

Antenatal care has been shown to reduce complications from pregnancy and delivery as well as reducing perinatal deaths and stillbirths as it ensures integrated delivery of antenatal care throughout pregnancy. It is critical as it enables timely and appropriate evidence-based interventionssuch as health promotion, preventive measures, as well as screening and early treatment.

Despite the availability of the standardized Mother and Child Health Booklet distributed by the Ministry of Health in 2009, and the adaptation of this booklet in Kenyatta National Hospital (KNH) and other ANC facilities, there have still been some gaps in the provision of antenatal care in KNH. This may be due to:

- Missing laboratory test results and long turnover time for results to get to files
- Lack of recognition of risk factors during ANC visits
- Lack of attention given to counselling and development of a birth and emergency plan
- Advice on danger signs not being given to each patient at every visit
- Inconsistency in prescription of preventive supplementation
- Patients arriving late or missing clinic visits
- Unavailability or loss of the ANC booklet

This study sought to bridge that gap by the development of an electronic mobile phone antenatal care application that recorded patient information, flagged results that were out of the normal range, and included a section on counselling and advice as well as a birth and emergency plan. There were also SMS alerts sent to the patients with appointment reminders to ensure they did not miss their visits.

Currently, there is limited data on mHealth interventions being used to store electronic health records as well as send appointment reminders in antenatal care in low and middle income settings, especially those involving electronic health records as opposed to client education. This was therefore a good opportunity to assess the efficacy of an application providing electronic health records as well as sending SMS reminders to patients.

While there have been studies assessing the Mother and Child Health Booklet in Kenya, there are none assessing a mobile application alternative, therefore a comparison of the two would be beneficial in assessment of quality of antenatal care.

STUDY OBJECTIVES

Research Question

What is the efficacy of an electronic mobile phone application compared to the Mother and Child Health booklet in improving quality of antenatal care from first visit through third trimester, at Kenyatta National Hospital?

Broad Objective

To determine the efficacy of using an electronic mobile phone applicationcompared to the Mother and Child Health booklet in improving quality of antenatal care from first visit to third trimester in KNH

Primary Objectives

Among antenatal patients at KNH who receive electronic mobile phone versus the Mother and Child Health booklet based care from the first visit to third trimester of pregnancy, to compare:

1. The proportion with complete antenatal care records and birth and emergency care plan
2. The proportion among whom risk factors for adverse pregnancy outcomes are identified
3. The number of subsequent ANC visits

Secondary Objective

To describe healthworker experiences in using the mobile phone antenatal care application.

Null Hypothesis:

There is no difference in the quality of antenatal care among women who received electronic mobile phone based care versus the Mother and Child Health Booklet Care from the first visit to the third trimester at Kenyatta National Hospital

CHAPTER 2: RESEARCH METHODOLOGY

STUDY DESIGN

This was a parallel, efficacy, open-label, randomized controlled trial of an antenatal electronic mobile phone Application versus standard of care, Mother and Child Health Booklet in a ratio of 1:1.

INTERVENTION

Antenatal care provided with an electronic mobile phone application used by the clinician to record patient information. It contained an inbuilt checklist based on the Mother and Child Health Booklet, as well as the latest WHO ANC guidelines. It also flagged results that were out of the normal range, and included a section on counselling and advice as well as a birth and emergency plan. There were SMS alerts sent to the patients with appointment reminders to ensure they did not miss their visits.

CONTROL

Antenatal care provided with the Mother and Child Health Booklet developed by the Ministry of Health and launched in 2010. It is the current standard of care in KNH, and contains visual reminders on the parameters to be assessed.

STUDY SETTING

This study was carried out at the Kenyatta National Hospital (KNH) Antenatal clinic (clinic 18). KNH is the largest referral and teaching public hospital servingboth the University of Nairobi and Kenya Medical Training College.

The hospital receives nationwide hospital referralsas well as patients from Nairobi and its environs. It is located 2km south west of the Nairobi central business district.

Antenatal Clinic Booking took place every Monday morning in Clinic 18 and was run by a team of registrars and a consultant. This is when there was first contact with new patients and the relevant investigations ordered as the patient was booked for clinic on a date dependent on the urgency of their condition.

Antenatal Care Clinic took place every Tuesday, Wednesday and Thursday at Clinic 18. This clinic was run by a team of registrars and consultants. There was also a laboratory within the clinic where some tests such as the routine antenatal profile tests were done.

The standard of care was the use of the Mother and Child Health Booklet contained in the files of the patients, with the patients given a copy to carry home. The files were stored in the KNH records department. For the intervention arm, the electronic medical records were stored in the secure KNH servers.

STUDY PERIOD

This study wascarried out at Kenyatta National hospital from June 2019 to November 2019.

STUDY POPULATION

Pregnant women presenting for antenatal care in Kenyatta National Hospital who were at gestation less than 28 weeks.

Inclusion Criteria:

1. Pregnant women attending clinic for the first time in KNH
2. Pregnant women who wereless than 28 weeks‟ gestation
3. Women who provided informed consent to participate in the study

Exclusion Criteria:

1. Women with lack of access to a mobile phone that could receive SMS reminders prior to clinic visits
2. Women without results of ultrasound or pregnancy diagnostic test to confirm pregnancy

SAMPLE SIZE

Sample size calculation for comparison between two groups

(–)

= Desired sample size

_ = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

= 1.282 (From Z table) at 90% power

= Difference in proportion of events (complete health records) in two groups

Pooled prevalence = (Prevalence in group **+** Prevalence in group **) /** 2

Assume 10% missing records or LTFU for each 48/48=
96 Therefore, a total sample size of 96 was required.

Sample size calculation guided by the primary objective assessing completeness of health records, where the completeness in the control group is assumed to be 60% while that in the intervention group is assumed to be 90%.

In one previous study, 100% of variables were collected. However, it did not report on their completeness.(18). In this other study, the difference between the electronic medical records (EMR) were 40% more complete than paper based system. It used archived data. (19)

We therefore assumed 30% difference as we will be collecting data at the same time and 30% difference is clinically meaningful.

STUDY PROCEDURES

Patient recruitment

A clinical officer at the antenatal clinic recruited potential study participants. Those who met the eligibility criteria (inclusion and exclusion) were identified and chosen for the study. Women were enrolled at their first antenatal visit, provided they were less than 28 weeks‟ gestation and met the eligibility criteria. Recruitment and enrolment was carried out by the research assistants, attending nurse or principal investigator who were all part of the study team.

Sampling

Consecutive sampling, of all eligible patients attending antenatal clinic in KNH during the study period were recruited who provided informed consent until required sample size was achieved

Consent

Once identified, the principal investigator or research assistant informed the patients on the purpose and method of the study and attained verbal consent. Thereafter, a pre-designed consent form was used to provide written consent. This consent form described the objective of the study, the study procedures, as well as the potential benefits and risks involved with participation in the study. The patient was provided with answers to any pertinent questions concerning the study.

This process was voluntary and explicitly free from coercion.

Those who agreed to participate in the study wererequested to sign the consent form, after which the investigator counter-signed it. Reasons for non-participation of eligible women were recorded. The participant was given a copy of the signed consent form.

All consenting patients who met the eligible criteria were immediately randomized into the two different groups.

Randomization

The statistician did simple randomization into the two arms using a computer-generated list. The study enrollment numbers from 1-102 were entered into Microsoft Excel and a random number generator was used to determine which of the two arms they are assigned to. The randomization instructions were given to the investigator and research assistants in sequentially numbered, identical, sealed, opaque envelopes containing an unpredictable allocation code, so as to ensure allocation concealment.

Randomization wascarried out by the research assistants located in the triage area of Clinic 18. This was done after the patients had opened files and had vital signs taken, waiting to see the doctor.

Blinding

The nature of the intervention made it impossible to blind the study participants and the clinicians providing antenatal care. However, for the control group, the clinicians seeing mothers using the standard of care, mother and child health booklet, were not aware of their status as study participants in order to accurately represent the standard of care. Outcome assessors were however blinded.

Intervention groups

The intervention group went through the triage area just as the control group did, where the nurses located at the triage station took vital signs. These included blood pressure, heart rate, weight and height. They were then seen by the clinician (registrar), using the mobile phone based antenatal care model. Each registrar had a secure username and password to enable them to access the application.All the data collected during the clinic visit, that is, the history and physical exam findings were entered into the mobile application.

The application contained an inbuilt checklist to remind the clinician of mandatory information. It also flagged abnormal results to remind the clinician to take action. At the end of the visit, the data was backed into the Kenyatta National Hospital server to ensure confidentiality. The duration of the visit was automatically recorded by the

application. A research assistant then proceeded to transcribe the records from the mobile phone application to the patient‟s file to ensure that there was no disruption in the Kenyatta National Hospital records. The patient‟s contact information was recorded to enable her to receive an SMS reminder prior to the next clinic visit.

The control group received care using the standard Mother and Child Health Booklet currently in use at Kenyatta National Hospital. They had their vital signs taken at the triage area and then proceeded to see one of the registrars running the clinic. The history and examination findings were recorded in the booklet attached in the patient‟s file. The duration of the visit was recorded by the research assistant.

Data collection

Mother and Child Health Booklet

Obstetric and medical data wasobtained from maternal health care records in the Mother and Child Health Booklet in the patients file. Data collected included medical and surgical history, previous obstetric history, physical examination findings, education and counselling information, present pregnancy information and laboratory test results. This data was collected by the research assistants or principal investigator.

Mobile phone application

This was an android based application which was implemented using Native Java, XML and SQLite. The application was primarily used by the clinicians to collect data. The data sent from the application forms was sent using the RESTful APIs and Volley Libraries which was the integration between the main server and the android application. The application also enabled the clinicians to view simpler reports including the appointments, patient profiles, background information and all the services the patient had received since their first visit.

Procedures to ensure differences are only due to mHealth vs MCH Booklet

- The m health platform was fully based on the MCH Booklet. This ensured similarity in care.
- All residents were briefed about the study during the CME/Proposal presentation which also ensured similarity in quality of care.
- During first ANC visits-eligible participants were randomly assigned to residents at the same level of training by year of training. Ensured bias was eliminated and residents were not being informed before they report to the clinic if they would see study patients.
- Those assigned to the mobile phone were briefed and trained on how to effectively fill the form prior to recruitment of their first participants. This ensured the interventions were solely due to the Application of care rather than quality of training before data collection.
- Those assigned to the MCH Booklet did not receive any additional training as this is the standard of care. However, a research assistant documented time of care from initial contact to exit.
- During subsequent visits those who had used the mobile phone did not use the book anymore but continued with mobile phone to eliminate any potential bias introduced by carrying along the information they had during past training and use of mobile platform.
- During subsequent visits, those who had used the book were briefed on the mobile phone if they were now randomly assigned to the mobile arm. This is because the mobile device would be pre-populated with a summary of baseline medical data and alerts essential for follow-up. MCH Booklet is unlikely to alter subsequent care. Otherwise they continued with the book. However once on the mobile arm, they stayed there and did not cross-over.

DATA VARIABLES

TABLE 1

Objective	Independent Exposure	Dependent Outcome	Data Source
Data completeness	Mobile phone application Mother and Child Health booklet	Complete antenatal profile, Tetanus toxoid received, Fundal height corresponding with dates, Weight, Blood Pressure, Urinalysis, Early ultrasound, Anomaly scan DM screening, Hepatitis B screening, Danger signs, Breastfeeding advice	BP measurement at PNC Mobile application data Patient files

Birth and emergency plan	Mobile phone application Mother and Child Health booklet	SVD Elective CS TOLAC	Mobile application data Patient files

TABLE 2

Objective	Independent Exposure	Dependent Outcome	Data Source
Risk factor prediction	Mobile phone application Mother and Child Health booklet	Previous CS, Previous hypertensive disorder in pregnancy, Rhesus negative mother, HIV positive mother, Anemia, Hepatitis B screening, Multiple pregnancy, JASA initiation, UTI treatment	Mobile application data Patient files

TABLE 3

Objective	Independent Exposure	Dependent Outcome	Data Source
Clinic attendance rates	Mobile phone application Mother & Child Health Booklet	Number of visits	Patients files Mobile application data

TABLE 4

Objective	Independent Exposure	Dependent Outcome	Data Source
Health worker experience	Mobile phone application, Mother & Child Health booklet	Duration of visit, Ease of use, Challenges, Perception	Questionnaire

DATA COLLECTION, MANAGEMENT AND ANALYSIS

DATA COLLECTION

After obtaining formal permission from KNH administration and ethical clearance, (Protocol no. P648/09/2018) the study was registered with the Pan African Clinical Trial registry (PACTR202001700173081). The eligible participants signed an informed consent form. Respective data collection was done in the antenatal care clinic (Clinic 18).

For the intervention group, data was collected by the clinicians and entered into the mobile phone application. Mobile phones for this purpose were provided by the principal investigator.The data was also transcribed into the patients‟ files by a research assistant after each visit so as to ensure continuity of health records at the hospital.

The mHealth system had the following operations:

1. Filled in the antenatal admission, examinations, tests, treatments and counselling data using the mobile application.
2. Flagged specific data metrics that were out of the normal standards and were considered as risk factors of the antenatal care.
3. Sent clinical visits SMS alerts to the patients.
4. Generated all antenatal services reports including the flag reports.
5. Sent notifications to the clinical officers and the administrators when flagged conditions were met.
6. Got detailed reports from the web application dashboard.
7. All the data related to the patient was stored in the central server. No data was saved in the clinicians‟ mobile devices.

The general system architecture was as seen in Figure 2 below:

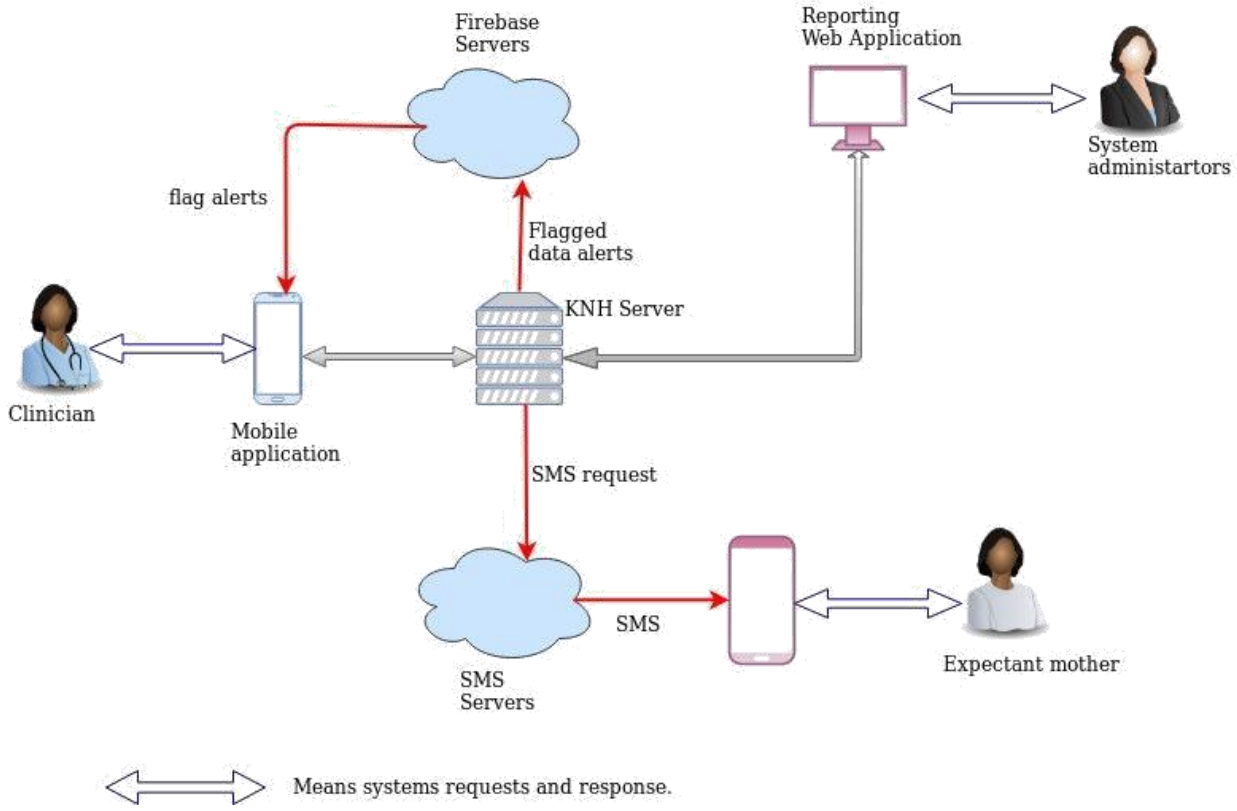


Figure 2: Phone model general system architecture

The principal investigator and fellow clinicians (registrars)carried out the data collection using the mobile application and Mother and Child Health Booklet in the two arms.

For the intervention group, there were four components of the electronic system; the mobile application, web application, external servers and main system server which was the KNH server.

The mobile application was an android based application which is implemented using Native Java, XML and SQLite. The application was primarily used by the clinicians to collect data. The data sent from the application forms was sent using the RESTful APIs and Volley Libraries which was the integration between the main server and the android application. The application also enabled the clinicians to view simpler reports including the appointments, patient profiles, background information and all the services the patient had received since admission.

The web application provided comprehensive reports about all the patients, the services they have been offered, the flagged metrics and clinical officers management module. It allowed data to be exported in pdf and excel formats.

The external servers were used to send SMS to the expectant mothers and send mobile notifications to the antenatal clinicians.

The main system server contained the main system and the database. This was hosted in the KNH servers to ensure security and confidentiality of the patient data. The connection between the web application and the main server was made using the HTTPS protocol to ensure end-to-end encryption of the data communication. The android application was using the Django Restful API to communicate to the server.

For the control group, the data was collected by clinicians and filled in the Mother and Child Health Booklet. A structured survey questionnaire was then used by a research assistant to gather obstetrical and medical details, from the patient files.

Training of research assistants took place over the duration of one week; initially they observed the process of obtaining informed consent and filling of the questionnaires. Thereafter they worked under supervision until the principal investigator was satisfied. The principal investigator constantly reviewed the questionnaires and filled forms from the web server. The intervention was carried out by registrars who were trained by demonstrations by the principal investigator.

DATA ANALYSIS

Data was collected using the mobile phone application for the mobile phone arm and questionnaires for MCH Booklet arm. The data was downloaded from the KNH server and analysed by the use of SPSS® version 21. Categorical data was analysed and presented as frequencies and proportions and compared using chi square test, while continuous data was summarized and presented as means and standard deviations or median and interquartile range and compared using independent student t test. Risk estimates were obtained and p value <0.05

considered statistically significant. All analyses were intention to treat.

The qualitative data used to assess health worker experience was collected using technology acceptance model questionnaires with a Likert scale. The data was then analysed by frequencies of their responses and reported.

The completeness of health records, risk factor identification and clinic attendance rates in the two groups were presented in tables and charts and analysed using frequencies and proportions.The health worker experience evaluated using the Likert Scale in the technology acceptance model questionnaire (Appendix IV) was presented and analysed using frequencies and proportions. All statistical tests were performed at 5% level of significance (p value<0.05), and odds ratios and corresponding 95% confidence intervals were reported for regressions analyses.

ETHICAL CONSIDERATIONS

Ethical Review

Authorization was obtained from KNH administration to collect data using an alternative method, the mobile phone application (mHealth system). The data from the mobile phone was stored in the secure KNH servers, to ensure privacy and confidentiality was observed at all times. All this data collected from the patients in the intervention arm was also transcribed into the patients‟ files so as to ensure continuity of records and enable the hospital to access the records.

The patients received SMS appointment alerts at no cost to themselves, all the costs were covered by the principal investigator. The patients therefore received no reimbursement or compensation during this study.

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

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 enrolled study participants, the number of participants that completed the study, any changes in the research activity, as well as all other unanticipated problems involving 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 V: Data and Safety Monitoring Plan; this contains the DSMB charter with the members, responsibilities and monitoring procedures.

Informed consent

We obtained a written informed consent from participants or from the parents/guardians of participants who could not consent for themselves. Adequate explanation and counseling was done before attaining consent. Participant‟s

partners were informed about the study. Participant requests for the partner‟s presence or advice before consenting was granted if the partner was within the hospital at the time of the request. The partner would then append their signature as a witness as provided for in the consent form. However, the participant‟s approval was considered as tacit approval from the partner, unless otherwise specified.

The informed consent form described the study purpose, the study procedures to be carried out and the risks and benefits as per 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 in the presence of a third-party witness who is literate by using their thumbprint to mark the form.The local ERC requirements for obtaining informed consent from non-literate persons were followed. Participants were provided with a copy of their informed consent forms and this was documented in the participant‟s record.

There were no personal identifiersemployed 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 principal investigator.

Risks

Risks were anticipated and addressed accordingly. We ensured the participants privacy and confidentiality was maintained at all times. However, it is 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.

Benefits

The participants benefited by receiving close monitoring throughout the study period. They benefited by receiving SMS alerts to remind them of upcoming visits at no extra cost to themselves. The information learnt from this study may benefit others in the future.

Confidentiality

Belmont‟s principles of confidentiality (Respect for persons, Beneficence and Justice) were employed when handling collected information. To maintain confidentiality, a unique study identification number was allocated to each participant. 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 file cabinets that were locked and only accessible by study staff. All databases were secured with password-protected access systems. The study information of the participants was not released without the written permission of the participant, except for monitoring by the DMSB, or KNH-UoN-ERC.

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 principal investigator could 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.

Training

The research team involved undertook Good Clinical Practice (GCP) training and certification. Once the study had been approved, registration was done 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(21).

Training of research assistants took place over the duration of one week; initially they observed the process of obtaining informed consent and filling of the

questionnaires. Thereafter they worked under supervision until the principal investigator was satisfied. The principal investigator constantly reviewed the questionnaires for completion. Research assistants and midwives underwent sensitization and training prior to commencement of the study via video tutorials and clinical teachings.

STUDY LIMITATIONS

The patients were only being followed up to the beginning of the third trimester, therefore maternal and neonatal outcomes were not assessed. There is room for further studies assessing outcomes in the postpartum period.

We did not provide the patients with an interface where they could carry their basic antenatal information with them as we did not have the resources to print the records within the clinic.

The cost effectiveness of the mobile phone application was not being evaluated.

The study setting was also a tertiary institution where more experienced doctors are seeing patients, as opposed to the peripheral facilities where lower cadre health workers would see patients. It cannot therefore assess as well the impact of the application when used by less experienced healthcare workers.

DISSEMINATION OF RESEARCH FINDINGS

The participants in the research wereall given a report of the findings, and they were encouraged to give feedback on them.
Dissemination of the results will also take place by the following methods:

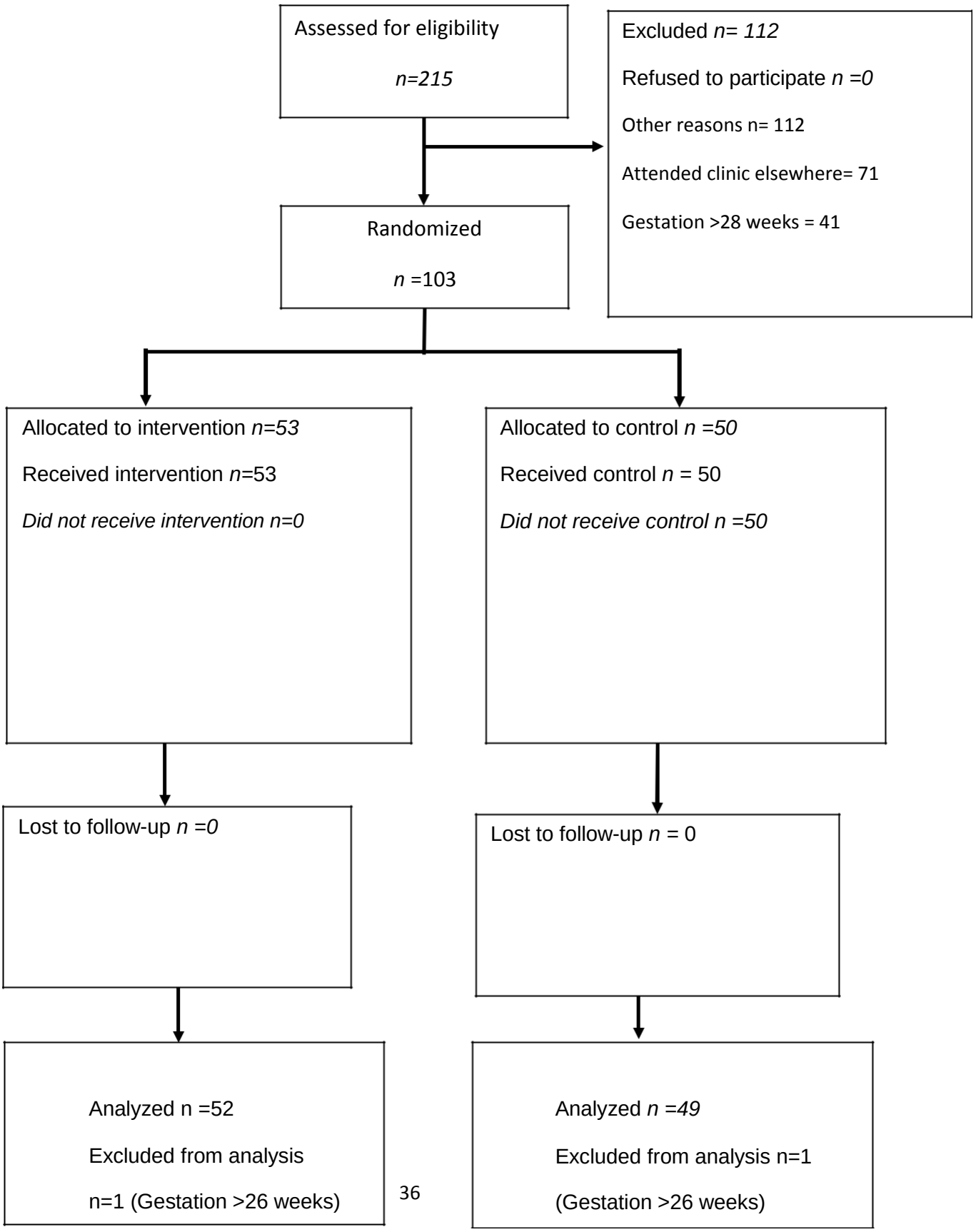
- Preparation of a report to be sent to the obstetrics and gynaecology department.
- Publishing of papers in general and specialist, national and international journals.
- Presentation of papers at conferences, both national and international.

CHAPTER 3: RESULTS

Characteristics of enrolled patients

During the study period, a total of 215 patients were screened from June 2019 till November 2019 at Kenyatta National Hospital. These patients were attending antenatal clinic. A final number of 102 subjects (47% of those screened) were enrolled into the study and then randomly assigned to either the intervention or control group, 52 in intervention arm and 49 in control arm.

STUDY FLOWCHART



Participants' Characteristics

This section describes the sociodemographic and clinical characteristics of the participants who were recruited for the study from the antenatal care clinic at the Kenyatta National Hospital. The baseline characteristics of the women in each group were found to be similar.

Table 1: Maternal sociodemographic and clinical characteristics

Characteristic	Category	Phone Model n (%)	MCH Booklet n (%)	P value
Age	<25	4 (7.7)	11 (22.4)	Ref
	25-34	33 (63.5)	28 (57.1)	0.057
	35-44	15 (28.8)	10 (20.4)	0.041
Marital status	Married	43 (82.7)	39 (79.6)	0.690
	Single	9 (17.3)	10 (20.4)	
Education level	Primary level	9 (17.3)	7 (14.9)	Ref
	Secondary level	22 (42.3)	15 (31.9)	0.828
	University level	21 (40.4)	25 (53.2)	0.465
Occupation	Employed	15 (28.8)	9 (19.6)	Ref
	Self-employed	25 (48.1)	28 (60.9)	0.212
	Housewife	10 (19.2)	3 (6.5)	0.371
	Student	2 (3.8)	6 (13.0)	0.066
Parity	0	9 (17.3)	9 (18.8)	Ref
	1	20 (38.5)	22 (45.8)	0.866
	2	18 (34.6)	12 (25.0)	0.499
	≥3	5 (9.6)	5 (10.4)	1.000
Gestational age at first visit	<20 weeks	32 (65.3)	39(81.2)	0.076
	21-26 weeks	17 (34.7)	9 (18.8)	

The distribution of mother‟s age, marital status, educational level, employment status was similar between the two groups as seen in Table 1. Majority of the mothers first attended ANC at a gestation of 13-20 weeks.

Primary Outcomes

Completeness of Health Records

This section presents the completeness of health records, with a summary of the completeness of the antenatal profile, and then the completeness of the other sections following. This was assessed after the last visit we recorded at the beginning of the third trimester from the files of the patients in the control arm and the electronic medical records for the intervention arm.

Table 2: Complete Records- Antenatal Profile Section

Lab Test	Phone Model (n=52)	MCH Booklet (n=49)	p-value
Hemoglobin	52 (100)	49 (100)	-
Blood Group	52 (100)	49 (100)	-
Rhesus	52 (100)	49 (100)	-
VDRL	52 (100)	49 (100)	-
HIV client	52 (100)	44 (89.8)	0.019
HIV partner	52 (100)	2 (4.1)	<0.001
Urinalysis	52 (100)	47 (95.9)	0.142
RBS	52 (100)	47 (95.9)	0.142
OGTT/GCT	52 (100)	0 (0.0)	-
Hepatitis B	52 (100)	0 (0.0)	-

The completeness of the records in the antenatal profile is depicted in Table 2 above. The phone model was at 100% because it was mandatory to fill and was either listed as done, with result or not done.

The hemoglobin, blood group, rhesus and VDRL sections were 100% done in both arms as seen in Table 3 below. The HIV status of the client, urinalysis and RBS were both done at >85% with no statistical difference between the two groups. The HIV partner, OGTT/GCT and Hepatitis B screening were poorly carried out in both arms but still higher in the phone model than the MCH Booklet.

Table 3: Complete Antenatal Profile – Tests Done

Lab Test	Phone Model (n=52)	MCH Booklet (n=49)	p-value
Hemoglobin	52 (100)	49 (100)	-
Blood Group	52 (100)	49 (100)	-
Rhesus	52 (100)	49 (100)	-
VDRL	52 (100)	49 (100)	-
HIV client	45 (86.5)	44 (89.8)	0.924
HIV partner	8 (15.1)	2 (4.1)	0.095
Urinalysis	49 (94.2)	47 (95.9)	1.000
RBS	43 (82.7)	47 (95.9)	0.061
OGTT/GCT	5 (9.4)	0 (0.0)	0.057
Hepatitis B	13 (24.5)	0 (0.0)	<0.001

The completeness of the other sections of the antenatal care booklet and phone model is summarized in the table below.

Table 4: Completeness of Health Records

Section	Phone Model (% filled) n=52	MCH Booklet (% filled) n=49	P-value
Maternal profile	**99.7**	**93.1**	0.879
Medical and surgical history	**93.2**	**89.1**	0.863
Previous pregnancy	**89.5**	**81.1**	0.732
Physical Exam	**100**	**22.5**	<0.001
Education and Counselling	**100**	**38.3**	0.006
Present pregnancy	**94.7**	**56.8**	0.089

The filled percentage of the maternal profile, medical and surgical history, previous pregnancy and present pregnancy did not exhibit a statistical difference even though they were all slightly more filled in the intervention arm. The physical exam section was 100% filled in the phone model and 22.5% filled in the MCH booklet with a p-value of <0.001, while education and counselling was 100% filled in the phone model and 38.3% filled in the MCH booklet with a p-value of 0.006.

The completeness in the section of an established birth and emergency plan is demonstrated below.

Table 5: Birth and Emergency Plan

	Phone Model (% filled) n=52	MCH Booklet (% filled) n=49	P value
Birth plan established	51 (98.1)	15 (30.6)	<0.001
Emergency care plan established	51 (98.1)	11 (22.4)	<0.001

The birth plan was established in 98.1% of the patients in the phone model arm, as opposed to 30.6% in the MCH Booklet while the emergency plan was established in 98.1% of patients in the phone model and 22.4% in the MCH Booklet. These differences were both found to be statistically significant at p-value of <0.001.

Risk Factor Identification

This section presents the results on risk factor identification in the two groups.

Table 6: Risk factor Identification

Risk factor	Phone Model (n=52)	MCH Booklet (n=49)	P value
Previous CS	19	16	0.689
Previous hypertensive disorder in pregnancy	6	4	0.581
Blood grouping (Rh –ve)	1	2	0.517
HIV positive	4	2	0.447
HB test (anemia)	1	2	0.517
Diabetes in pregnancy	1	0	-
Hepatitis B positive	0	0	-
Family history of twinning	1	0	-
Anomaly on scan	0	0	-
Urinalysis with UTI	10	8	0.705
UTI treatment	10	8	0.705

The risk factors were identified as in Table 6 above. There was no statistical difference in the two groups as far as risk factor identification was concerned.

Table 7: Risk factor Screening

Risk factor	Phone Model (n=52)	MCH Booklet (n=49)	P value
Previous CS	51 (98.1)	46 (93.9)	0.353
Previous hypertensive disorder in pregnancy	51 (98.1)	31 (63.3)	<0.001
Blood grouping	52 (100)	49 (100)	-
HIV screening	47 (90.4)	45 (91.4)	1.000
HB test (anemia)	52 (100)	49 (100)	-
Diabetes screening	43 (82.7)	47 (95.7)	0.033
Hepatitis B screening	13 (24.5)	0 (0)	-
Family history of twinning	8 (16)	8 (16)	0.903
Anomaly scan	31 (59.6)	6 (12.5)	<0.001
Urinalysis	50 (96.2)	47 (95.9)	1.000
UTI treatment	51 (98.1)	48 (98)	1.000

The risk factor screeningwas assessed by checking whether the tests were done in the two groups by the time of completion of the study when the participants were beginning their third trimester. The results are depicted in Table 7 above.

The risk factors were screened at similar rates in the two groups, except for the Hepatitis B screening, anomaly scan and previous hypertensive disorder in pregnancy which were better filled in the phone model. In the intervention arm, 13 patients were screened for Hepatitis B which comes to 24.5%, while none were screened in the control arm. This was statistically different with a p-value of <0.001. The anomaly scan was done in 31 patients in the intervention arm (59.6%) as opposed to 6 patients in the control arm (12.5%). This was a statistically significant difference with a p-value of <0.001. Previous hypertensive disorder was enquired about in 98.1% in the phone

model as opposed to 63.3% in the control arm. The Random Blood Sugar test was better covered in the control arm than the intervention arm.

Clinic Attendance Rates

This section presents the results on the clinic attendance rates after analysis of gestation at first visit and number of visits. All patients were found to have their last visit at 28 weeks +/- 2 weeks. Table 7 below presents the average gestation at first visit.

Table 8: Average gestation at first visit

Variable	Phone Model mean (sd)	MCH Booklet mean (sd)	P value
Gestation at first visit	19.4 (3.5)	16.9 (6.3)	0.004

Table 9: Number of visits

	Phone Model Mean (sd)	MCH Booklet Mean (sd)	P value
No. of visits	3.1 (1.1)	3.0 (0.4)	0.404

The average number of visits in both arms was 3 visits with no statistical difference between the two groups as shown in Table 8.

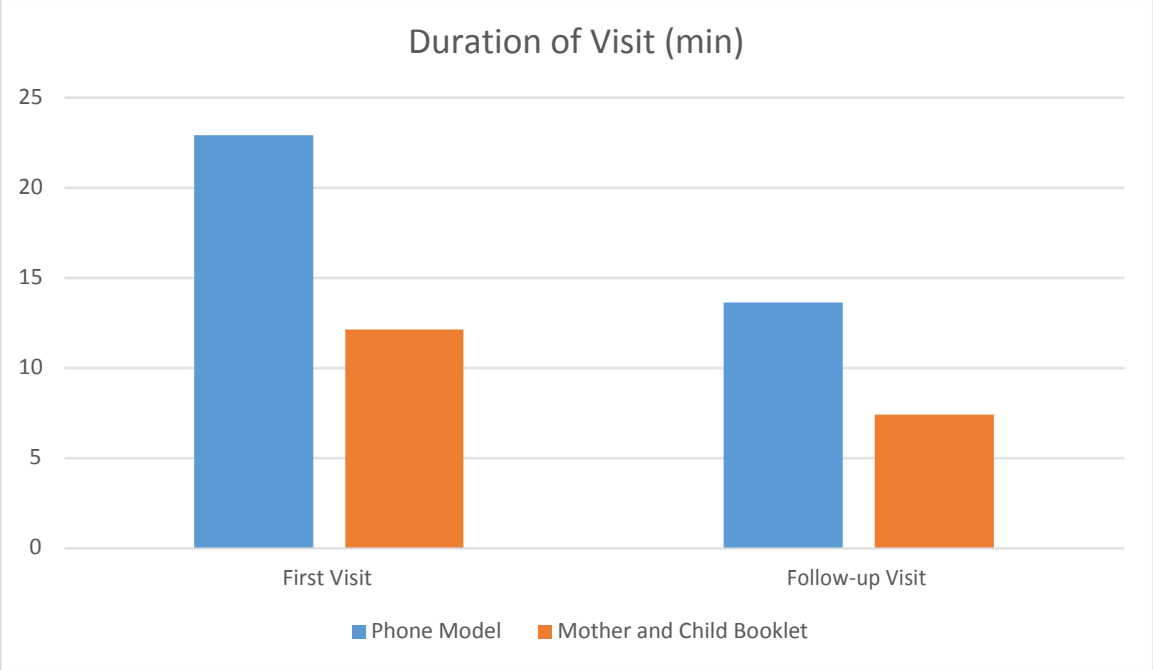
Duration of Visit

This section presents the average duration of visits of the two groups. This is divided into the average duration of first visit and average duration of follow up visits for each of the two arms.

Table 10: Average Duration of Visit

	Group	N	Mean (min)	Standard Deviation	P value
First Visit	Phone Model MCH Booklet	52 49	**23.2** **12.2**	7.6 5.4	<0.001
Follow up visit	Phone Model MCH Booklet	52 49	**13.7** **7.5**	6.7 2.2	<0.001

Figure 4: Duration of Visit



The average duration of first visit was 23.2min in the group using the phone model and 12.2min in the group using the MCH Booklet. For the follow up visit, the average in the intervention group was 13.7min and the control group was 7.5min.

Secondary Outcome

Health Worker Experience

This was assessed by the three doctors who used the application using the Likert scale as per the questionnaire attached in Appendix IV. The questionnaire was based on the technology acceptance model where they were asked to rate the following parameters on a scale of 1 to 6, with 1 being strongly disagree and 6 being strongly agree.

Perceived Usefulness: The three doctors felt that the application improved the quality of their work, improved their productivity, and made it easier to do their job as well as enhancing their effectiveness. However, they all agreed that the application did not enable them to accomplish tasks more quickly.

Perceived Ease of Use: The doctors felt that their interaction with the application had been clear and understandable, and that they rarely made errors when using it. However, while two felt it was easy to use and that learning to operate it was easy, the other one felt that they sometimes became confused and got frustrated when using it.

Perceived Behavioral Control: The doctors agreed they had the ability and knowledge to use the application and were able to confidently use it. They also reported they had control over the application but they felt they did not have the resources to use it.

Subjective Norm: All three doctors agreed that people who influence their behavior thought they should use the mobile phone application.

Voluntary: They all agreed that the use of the application was voluntary, and that although it may be helpful, using the electronic phone application was not compulsory in their jobs.

Behavioral Intention: They all agreed that they intended to continue using the electronic phone application to perform their job if it was available.

DISCUSSION

In this randomized trial comparing the efficacy of an antenatal mobile application to the MCH booklet at the Kenyatta National Hospital in Kenya, we demonstrated that the mHealth intervention improved the quality of antenatal care.

In the assessment of the completeness of the health records, we found that the system allowed for a more comprehensive approach with the patient, with prompts for sections of health education and counselling. The antenatal profile, physical examination and education and counselling sections were 100% filled, which was significantly more complete in the intervention arm than the control arm.This is in keeping with the PANDA mHealth study that found health records to be 100% filled and McNabb et al who found improvements related to health counseling and quality of health education in using a mobile application for ANC.(7)(8)

This study also demonstrated a marked increase in the number of patients with a birth and emergency plan established, with a majority of clients in the control arm not having an established birth and emergency plan.This is in keeping with Mutiso et al who found that a large proportion of clients attending antenatal clinic in Kenyatta National Hospital were not prepared for obstetric emergencies.(11)Limenih et al in Ethiopia found that the women with a birth and emergency plan to be 34% which was similar to our control group which had 30.6% with a birth plan. (21)

The risk factor identification in the two groups was similar, but there was improvement in risk factor screening using the application in regards to previous hypertensive disorder in pregnancy, hepatitis B screening, and anomaly scan. Risk factor identification is an important goal of antenatal care in improving maternal and neonatal outcomes.

There was however no increase in clinic attendance rates with an average of 3 visits overall. This differs from Lund et al who found that mobile phones improved clinic attendance rates. Kaewkungwal et al found that appointment messages increased odds of visit on-time by 2.97(13)(12).This could be partially attributed to the fact that there was an initial hitch in the sending of the appointment reminders as the patients were given different dates by the records officer than the date given by the doctor because of

the large numbers of patients, to avoid overbooking the patients. This was rectified by asking the patients to return to the doctor if they were given a different appointment date.

The length of the ANC visits using the application was almost twice that of the control arm at 23.2min for the first visit and 12.2min for follow up visits as opposed to the control arm where duration was 13.7min and 7.5min. The durations were found to be longer in the first few weeks which could be attributed to the fact that it is a new technology and we could only train the doctors using the application for a limited time, about a week before data collection began.

The first visit was found to last longer than the follow up visit. This may be because the first visit involves collecting a comprehensive patient history (including patient information,medical and obstetrichistories) as well as providing education and counselling. Even so, theaverage duration of our first ANC visits (23.2min) is lower than the WHO recommended durationfor a first ANC visit (30-40min).(22) It was also lower than the findings by Benski AC, et al who got an average duration of 29.6min.(7)

The health worker experience in using the application was overall positive, with all intending to continue using the application as they reported it improved the quality of their work and enhanced their effectiveness. This is consistent with the PANDA study that showed high acceptability among health workers, as well as with previous studies that have reported good acceptability of mHealth interventions by patients in different African countries.(7)(13)

The main strength of our study is that it is the first RCT of its kind to assess impact of mHealth intervention on antenatal care in such a setting hence it is well applicable to similar high patient burden settings. It is Level I evidence and can be built on to improve quality of antenatal care in other facilities by use of mHealth interventions.

The system was able to reliably collect all the patient information and store it in the servers with confidentiality maintained. In case of technical difficulties, the application allowed immediate identification of transmission problems with generated alerts stating

that the data could not be saved. This allowed for manual data entry to ensure that no data was lost. No major technical problems were encountered.

Our study was limited in that we were unable to follow up the patients for a longer period of time and assess the maternal and neonatal outcomes. We also did not provide the patients with a simple interface containing their basic antenatal information which was a limitation. Furthermore, the study setting was a tertiary institution, hence we cannot assess the impact of the application when used by less experienced healthcare workers.

Over the whole period of the study, the antenatal care system proved an effective way to collect patient data and to create clinical files for each patientwith confidentiality maintained and an overall improvement in quality of antenatal care.

CONCLUSION

Compared to the standard MCH booklet, mobile phone application for ANC improved the quality of ANC by increasing completeness of records, was highly acceptable to health care providers, but increased the duration of ANC visits.

RECOMMENDATIONS

Based on these findings, mHealth interventions are recommended for use in antenatal clinic to improve efficacy in the provision of antenatal care.

It is vital to inform policymakers both at a facility and national level on the importance of mHealth interventions as an achievable way to transition into a digital system using electronic medical records.

We believe the results of this trial justify the need for larger multi-center studies to further evaluate the potential benefits of mHealth interventions in improving antenatal care in different settings.

TIMELINES

2018					2019		
	April-July	August	September-January	February-May	June-November	November-December	December
Proposal Development							
Proposal Presentation							
Ethics Committee Review							
ICT Dept Server Setup							
Data Collection							
Data Analysis							
Results Presentation							
Submission to Department							

BUDGET

Components	Unit of Measure	Duration/ Number	Unit Cost (Kshs)	Total Cost (Kshs)
Personnel				
Research Assistant – Clinical Officers	1	40	1500	60,000
Statistician				30,000
ICT Programmer	1	12	1500	70,000
Registrars	3	16	3000	144,000
Printing				
Consent Form	1 copy	8 pages	10	80
Screening Tool	1	1	10	10
Questionnaires	1 copy	7 pages	10	70
Interview Guide				
Final Report - Colour	6	20	20	2400
Final Report – B/W	1	100	10	1000
Photocopying				
Consent Form	110	4 pages	3	1320
Assent Form	110	1 page	3	330
Questionnaires	55	7 pages	3	1155
Interview Guide				
Final Report	5	100	3	1,500
Final Report Binding	6	1	500	3,000
Pens		10	30	300
Other costs				
Mobile phones		2	15,000	30,000
Airtime	48	8	2	768
ERC Fees				2,000
Notebooks	5	1	50	250
Poster Printing	1	1	2,500.00	2,500.00
Training	5	1	500	2,500
Total				**Ksh 353,183**

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APPENDICES

APPENDIX I: CONSENT

Date (date/month/year):_____

Study Title:EFFICACY OF ELECTRONIC MOBILE PHONE APPLICATION COMPARED WITH MOTHER AND CHILD HEALTH BOOKLET IN IMPROVING QUALITY OF ANTENATAL CARE FROM FIRST VISIT THROUGH THIRD TRIMESTER AT KNH, A RANDOMIZED CONTROLLED TRIAL

Principal Investigator:

Dr. Sumayya Mohamed Badamana (MBChB)

Department of Obstetrics and Gynaecology, University of Nairobi.

Telephone Number: 0727-746693

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:

Antenatal careis the care provided by skilled healthcare professionals to pregnant women and adolescent girls in order to ensure the best health conditions for both mother and baby during pregnancy. This is done through detection and treatment of pregnancy related complications and through identification of women at increased risk of developing complications during labor and delivery.

At KNH, we use the Ministry of Health recommended Mother and Child Health Booklet, that is attached in each file, to fill in records. In this study, we have developed a mobile application based on this booklet, and in line with the international recommendations for antenatal care. It will be used by the clinician to fill in records and to send youan SMS appointment reminder prior to your next clinic visit.

Benefits:

As a participant you will benefit from the study by receiving close monitoring. You will benefit by receiving health education and advice during your pregnancy, as well as SMS reminders prior to your next appointment. You will be able to access the principal investigator at any time during the study period. Your participation in the study may benefit others in future from the information we find in this study.

Risks:

We will ensure that your privacy and confidentiality is maintained at all times. If you are attended to using the mobile application, all the records will be copied onto your file after the visit to ensure that no data is lost in case of technical difficulties.

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 principal

investigator‟s authorization.

Access of health records

You may apply for access to your own records, or may authorise third parties such as lawyers, employers, or insurance companies to do so on your behalf. The Principal Investigator can be contacted if access to health records is required.

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

Once informed consent is provided, the clinician will open a sealed, numbered, opaque envelope containing the allocation. You will either be allocated to be seen by the doctors using the usual Mother and Child Health Booklet, or to be seen by the doctor using the electronic mobile phone Application.If you are allocated to the intervention group, you will be seen by a doctor who will have a secure username and password to access your records on the application. All the data collected during the clinic visit, will be entered into the mobile application and stored in KNH server. After each visit, the information will be transferred into your file as well. You will receive an SMS reminder prior to your next appointment.

Problems or Questions:

If you ever have any questions about the study or about the use of the results you can contact the principal investigator, Dr. Sumayya Badamana by calling 0722-746693. If you have any questions on your rights as a research participant, you can

contact the Kenyatta National Hospital 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:

_____ _____

Problems or Questions:

If you ever have any questions about the study or about the use of the results you can contact the principal investigator, Dr. Sumayya Badamana by calling 0727-746693. If you have any questions on your rights as a research participant, you can contact the Kenyatta National Hospital Ethics and Research Committee (KNH- ERC)

by calling 2726300 Ext.44355.

APPENDIX II: CONSENT FORM IN KISWAHILI

FOMU YA RIDHAA

Tarehe (siku/mwezi/mwaka): _____

Study Title: EFFICACY OF ELECTRONIC MOBILE PHONE APPLICATION COMPARED WITH MOTHER AND CHILD HEALTH BOOKLET IN IMPROVING QUALITY OF ANTENATAL CARE FROM FIRST VISIT THROUGH THIRD TRIMESTER AT KNH, A RANDOMIZED CONTROLLED TRIAL

Mtafiti Mkuu:

Dkt. Sumayya Badamana (MBChB)

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

Nambari ya simu: 0727-746693

Taarifa ya mtafiti:

Tunakuomba kushiriki kwenyeutafiti huu. Lengo la fomu hii ya idhini ni kukupa habari utakayohitaji iliikusaidie kuamua ikiwa utashiriki kwenye utafiti. Utaratibu huu unaitwa „Idhini ya kujulishwa". Tafadhali soma ujumbe wa idhini hii kwa uangalifu na uulize maswali yoyote au ufafanuzikwa 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 ya ujauzito ni huduma inayotolewa na wataalamu wenye ujuzi wa afya kwa wanawake wajawazito na wasichana ili kuhakikisha hali nzuri ya afya kwa mama na mtoto wakati wa ujauzito. Hii inatekelezwa kwa kutambua na kutibu matatizo ya ujauzito na kupitia utambuzi wa wanawake walio katika hatari kubwa ya kuendeleza matatizo wakati wa kujifungua.

Hapa KNH, tunatumia kitabu cha Afya ya Mama na Mtoto kilichopendekezwa na Wizara ya Afya. Kitabu hiki huwa kimewekwa kwenye kila faili, ili kujaza rekodi. Katika utafiti huu, tumetengeneza programu ya simu inayolingana na kijitabu hiki, na kulingana na mapendekezo ulimwenguni ya huduma za ujauzito. Hii programu itatumiwa na daktari kujaza rekodi zako na itakutumia ujumbe kwa njia ya SMS kabla ya kukukumbusha tarehe ya kliniki ijayo.

Faida:

Kama mshiriki utafaidika kutokana na utafiti kwa kupata malezi ya kufwatiliwa kwa karibu.Utafaidika kwa kupokea elimu na ushauri wa afya wakati wa ujauzito, pamoja na kukumbushwa kwa njia ya SMS kabla ya tarehe ya kliniki ijayo.Utaweza kumfikia mtafiti mkuu wakati wowote kwa wakati wa utafiti. Kushiriki kwako kwenye utafiti kwaweza wafaidi wengine wakati wa usoni kutokana na habari tutakoyopata kwenye utafiti huu.

Hatari:

Tutahakikisha kuwa usiri wako utahifadhiwa wakati wote. Ikiwa utahudumiwa kwa kutumia programu ya simu, rekodi zote zitaandikwa kwenye faili yako kuhakikisha kuwa hazitapotea iwapo kuna shida yoyote ya kiteknolojia..

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.

Kupata rekodi za kimatibabu

Unaweza kuomba ku weza kufikia rekodi zako au kuruhusu watu wengine kama vile mawakili, waajiri au kampuni za fidia kufunya hivyo kwa niaba yako. Mtafiti mkuu anaweza fikiwa ikiwa rekodi zako zahitaji kufikiwa.

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 utahudumiwa na daktari kutumia Kitabu cha Afya cha Mama na Mtoto kama kawaida, au kuhudumiwa na daktari atakayetumia programu ya simu.

Daktari atakaye kuhudumia kutumia programu ya simu atakuwa na nenosiri ili kufikia rekodi zako kwenye programu. Rekodi zote zitaingia kwenye programu ya simu na kuhifadhiwa kwenye seva ya KNH. Baada ya kila kliniki, rekodi zitahamishiwa kwenye faili yako pia. Utapata kumbukumbu ya SMS kabla ya cliniki yako ijayo.

Utaweza kukutana na mtafiti mkuu wakati wowote unapofuatiliwa.

Shida au Maswali:

Ikiwa una maswali kuhusu utafiti au matumizi ya majibu waweza asiliana na mtafiti, Dkt. Sumayya Badamana kwa kupiga 0727-746693. Ikiwa una maswali kuhusu haki

yako kam mshiriki waweza wasiliana na kamati ya madili na tafiti ya hospitali kuu ya (KNH- ERC) 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:

_____

Shida au Maswali:

Ikiwa una maswali kuhusu utafiti au matumizi ya majibu waweza asiliana na mtafiti, Dkt. Sumayya Badamana kwa kupiga 0727-746693. Ikiwa una maswali kuhusu haki yako kam mshiriki waweza wasiliana na kamati ya madili na tafiti ya hospitali kuu ya (KNH- ERC) kwakupiga2726300 Ext. 44355.

APPENDIX III: INCLUSION AND EXCLUSION SCREENING ENROLMENT FORM

Study Title:EFFICACY OF ELECTRONIC MOBILE PHONE APPLICATION COMPARED WITH MOTHER AND CHILD HEALTH BOOKLET IN IMPROVING QUALITY OF ANTENATAL CARE FROM FIRST VISIT THROUGH THIRD TRIMESTER AT KNH, A RANDOMIZED CONTROLLED TRIAL

Date: (date/month/year):_____

Enrolment identification number: _____

Inclusion Criteria: Answers MUST be 'yes' for these questions.

Pregnant women attending clinic for the first time in KNH

Pregnant women who are less than 28 weeks‟ gestation

Women who provide informed consent to participate in the study

Exclusion criteria: *If any answer is 'Yes' exclude from enrolment*

Pregnant women who have already attended antenatal care clinic in other facilities and have the Mother and Child Health Booklet

Women who cannot access mobile phone consistently Unconfirmed

pregnancy by ultrasound or pregnancy diagnostic test

APPENDIX IV: DATA COLLECTION TOOLS

Study Title: EFFICACY OF ELECTRONIC MOBILE PHONE APPLICATION COMPARED WITH MOTHER AND CHILD HEALTH BOOKLET IN IMPROVING QUALITY OF ANTENATAL CARE FROM FIRST VISIT THROUGH THIRD TRIMESTER AT KNH, A RANDOMIZED CONTROLLED TRIAL

QUESTIONNAIRE 1: HEALTH RECORDS

SECTION I: DATA COMPLETENESS

To be filled from Mother and Child Health Booklet in Patient's File

Indicate all times using the 24-hour clock, and dates in this format date/month/year.

DATE_____

Enrolment identification number: _____

Date of Signed Informed Consent: ____/_____/_____

Part 1: Maternal Profile

Records Filled (Yes/No)

Name	Yes □	No □
Age	Yes □	No □
Gravida	Yes □	No □
Parity	Yes □	No □
LMP	Yes □	No □
EDD	Yes □	No □

Marital status	Yes	□	No	□
Education	Yes	□	No	□
Occupation	Yes	□	No	□
Residence	Yes	□	No	□
Telephone	Yes	□	No	□
Next of kin	Yes	□	No	□
Next of kin Address	Yes	□	No	□

Part 2: Medical and Surgical History

Records Filled (Yes/No)

Surgical operation	Yes	□	No	□
Blood transfusion	Yes	□	No	□
Family history	Yes	□	No	□
Twins	Yes	□	No	□
Tuberculosis	Yes	□	No	□
Diabetes	Yes	□	No	□
Hypertension	Yes	□	No	□

Part 3: Previous Pregnancy

Records Filled (Yes/No)

Pregnancy order	Yes	□	No	□
Year	Yes	□	No	□
Place of Delivery	Yes	□	No	□
Maturity	Yes	□	No	□
Duration of labor	Yes	□	No	□
Type of Delivery	Yes	□	No	□
Reason	Yes	□	No	□

Weight	Yes	□	No	□
Sex	Yes	□	No	□
Outcome	Yes	□	No	□
Pregnancy complications	Yes	□	No	□

Part 4: Physical Examination (1st Visit)

Records Filled (Yes/No)

General	Yes	□	No	□
CVS	Yes	□	No	□
RS	Yes	□	No	□
CNS	Yes	□	No	□
Breasts	Yes	□	No	□
Abdomen	Yes	□	No	□
Vaginal exam	Yes	□	No	□
Discharge	Yes	□	No	□

Part 5: Weight for Date Chart

Records Filled	Yes	□	No	□

Part 6: Education and Counselling

Records Filled (Yes/No)

Individual counselling and testing	Yes	□	No	□
Partner to clinic	Yes	□	No	□
Sharing results with partner	Yes	□	No	□
Partner Counselling and testing	Yes	□	No	□
Anti-retroviral therapy	Yes	□	No	□
Infant feeding	Yes	□	No	□
Self-Care	Yes	□	No	□
Hygiene	Yes	□	No	□
Maternal Nutrition	Yes	□	No	□

STDs	Yes	□	No	□
Danger Signs	Yes	□	No	□
Labor	Yes	□	No	□
Mode of delivery	Yes	□	No	□
Baby Care	Yes	□	No	□
Family planning	Yes	□	No	□

Part 7: Birth and Emergency Preparedness

Records Filled (Yes/No)

Preferred site of delivery	Yes	□	No	□
Method of transport	Yes	□	No	□
Preferred mode of delivery	Yes	□	No	□

Part 8: Present Pregnancy

Records Filled (Yes/No)

Parameter	**1st visit**		**2nd visit**		**3rd Visit**		**4th Visit**	**5th Visit**		
Records Filled	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
Date										
Weight										
Height										
BMI										
Urinalysis										
BP										
Hb										
Pallor										
Maturity										
Fundal Height										
Tenderness										
Presentation										
Lie										
Descent										
Contractions										

Fetal Heart Rate										
Edema										
Ultrasound										
Other investigations										
Comments										
Plan										
TCA Date										

Part 9: Mother at Risk

Records Filled (Yes/No)

Referral Yes □ No □

Reason for referral Yes □ No □

Part 10: PMTCT Services

Records Filled (Yes/No)

Pretest Counselling

Individual Yes □ No □

Couple Yes □ No □

Posttest Counselling

Individual Yes □ No □

Couple Yes □ No □

HIV status:

Client Yes □ No □

Partner Yes □ No □

Other lab tests:

CD4 client Yes □ No □

Viral load Yes □ No □

FHG Yes □ No □

LFTs Yes □ No □

Part 11: Laboratory Tests

Records Filled (Yes/No)

Hb	Yes	□	No	□
Blood group	Yes	□	No	□
Rhesus	Yes	□	No	□
VDRL	Yes	□	No	□
HIV client	Yes	□	No	□
HIV partner	Yes	□	No	□
Urinalysis	Yes	□	No	□
RBS	Yes	□	No	□
OGTT/GCT	Yes	□	No	□
Hepatitis B screening	Yes	□	No	□

Part 12: Treatment

Records Filled (Yes/No)

HIV positive

ARV mother	Yes	□	No	□
ARV baby	Yes	□	No	□
STD Drugs	Yes	□	No	□
O/S prophylaxis	Yes	□	No	□

Supplements:

Iron supplementation	Yes	□	No	□
Folate supplementation	Yes	□	No	□
Combined multivitamins	Yes	□	No	□
Progesterone supplements	Yes	□	No	□
Calcium supplementation	Yes	□	No	□

TB Drugs	Yes	□	No	□

Malaria

IPT 1	Yes	□	No	□
IPT 2	Yes	□	No	□
IPT 3	Yes	□	No	□
Junior Aspirin (JASA)	Yes	□	No	□
Heparin	Yes	□	No	□
Warfarin	Yes	□	No	□

Part 13: Immunization and Other Services

Records Filled (Yes/No)

Tetanus Toxoid Immunization	Yes	□	No	□
Provision of ITNs	Yes	□	No	□
Nutritional Counselling	Yes	□	No	□
TB screening	Yes	□	No	□
Cervical cancer screening	Yes	□	No	□

SECTION II: RISK FACTOR IDENTIFICATION

Previous CS	Yes	□	No	□
Previous hypertensive disorder in pregnancy	Yes	□	No	□
Blood Grouping	Yes	□	No	□
HIV screening	Yes	□	No	□
Hb test (anemia)	Yes	□	No	□
Diabetes screening	Yes	□	No	□
Hepatitis B screening	Yes	□	No	□
Family history of twinning	Yes	□	No	□
Anomaly scan	Yes	□	No	□
Urinalysis	Yes	□	No	□
UTI treatment	Yes	□	No	□

Study Title: EFFICACY OF ELECTRONIC MOBILE PHONE APPLICATION COMPARED WITH MOTHER AND CHILD HEALTH BOOKLET IN IMPROVING QUALITY OF ANTENATAL CARE FROM FIRST VISIT THROUGH THIRD TRIMESTER AT KNH, A RANDOMIZED CONTROLLED TRIAL

QUESTIONNAIRE 2: TECHNOLOGY ACCEPTANCE MODEL QUESTIONNAIRE

Please place an "X" in the appropriate box to rate the following items using a scale of 1-6:

1= Strongly Disagree 2= Disagree 3= Slightly Disagree 4= Slightly Agree 5= Agree 6=Strongly Agree

Perceived Usefulness (PU)	1	2	3	4	5	6	N/A
The electronic phone Application enables me to accomplish tasks more quickly.							
The electronic phone model has improved the quality of my work.							
The electronic phone application makes it easier to do my job.							
The electronic phone application has improved my productivity.							
The electronic phone application gives me greater control over my job.							
The electronic phone application enhances my effectiveness on the job.							
Perceived Ease of Use (PEU)							
My interaction with the electronic phone application has been clear and understandable.							
Overall, the electronic phone application is easy to use.							
Learning to operate the electronic phone application was easy for me.							

I rarely become confused when I use the electronic phone application.							
I rarely make errors when using the electronic phone application.							
I am rarely frustrated when using the electronic phone application.							
Perceived Behavioral Control (PBC)							
I am able to confidently use the electronic phone application.							
I have the knowledge to use the electronic phone application.							
I have the resources to use the electronic phone application.							
I have the ability to use the electronic phone application.							
I have control over using the electronic phone application.							
Subjective Norm (SN)							
People who influence my behavior think I should use the electronic phone application.							
People who are important to me think I should use the electronic phone application.							
My immediate supervisor thinks I should use the electronic phone application.							
My close friends think I should use the electronic phone application.							
My peers think I should use the electronic phone application.							
People whose opinions I value prefer that I use the electronic phone application in my work.							
Voluntary (V)							
My use of the electronic phone application is voluntary.							
My supervisor requires me to use the electronic phone application.							
Although it might be helpful, using the electronic phone application is not compulsory in my job.							
Behavioral Intention (BI)							
I intend to continue using the							

electronic phone application to perform my job if it is available.							
I intend to frequently use the electronic phone application to perform my job if it is available.							

APPENDIX V: DATA AND MONITORING SAFETY PLAN

Study Title: **EFFICACY OF ELECTRONIC MOBILE PHONE APPLICATION COMPARED WITH MOTHER AND CHILD HEALTH BOOKLET IN IMPROVING QUALITY OF ANTENATAL CARE FROM FIRST VISIT THROUGH THIRD TRIMESTER AT KNH, A RANDOMIZED CONTROLLED TRIAL**

Principal Investigator: Dr Sumayya Mohamed Badamana

MEMBERS

Prof. James Kiarie – Coordinator for WHO Human Reproduction Team, Obstetrician and Gynecologist, Associate Professor Obstetrics and Gynecology, Affiliate Associate Professor Global Health

Dr. George Gwako - Obstetrician and Gynecologist, Lecturer, Epidemiologist.

Mr. Francis Njiri - Statistician

BRIEF STUDY OVERVIEW

Objective: To determine the efficacy of using an electronic mobile phone antenatal care application in improving quality of care from first visit to third trimester as compared to the Mother and Child Health booklet in Kenyatta National Hospital.

Methodology: This will be an open labelrandomized controlled trial, in which pregnant women with gestation less than 28 weeks who meet the selection criteria, will be randomized to either antenatal mobile phone based care or the Mother and Child Health Booklet based care. The primary outcomes will be complete antenatal care records and birth and emergency care plan. The secondary outcomes will be risk factor prediction for adverse pregnancy outcomes, clinic attendance rates and duration of visit.

DSMB OVERSIGHT RESPONSIBILITIES

Oversight of the trial is provided by the DSMB. Meetings will take place to monitor on safety of patients and signals of efficacy, futility or harm. The DSMB members will have a first virtual meeting before study is commenced. A second meeting will 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 can recommend termination of the study.

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

MONITORING PROCEDURES

Dr. Sumayya will ensure that informed consent is obtained prior to performing any research procedures, that all subjects meet eligibility criteria, and that the study is conducted according to the ERC-approved research plan.

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

The PI will ensure all protocol deviations, AEs, and SAEs are reported to the ERC, DSMB and KNH administration according to the applicable regulatory requirements.

DATA ANALYSIS PLANS

The study statistician will be blinded and data monitoring will be continuous, he will alert report the results to the DSMB at the completion of the study or if there are significant SAES. There will be no interim analysis.

PLAN FOR DATA MANAGEMENT

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

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

The Electronic Health Records will be transmitted from the mobile phone to the KNH servers that will be secure. All the data related to the patient will be stored in the central server. No data will be saved in the clinician‟s mobile devices. Only the system administrators will have access to the web application dashboard.

APPENDIX VI: LINK LOG

Study Title:EFFICACY OF ELECTRONIC MOBILE PHONE APPLICATION COMPARED WITH MOTHER AND CHILD HEALTH BOOKLET IN IMPROVING QUALITY OF ANTENATAL CARE FROM FIRST VISIT THROUGH THIRD TRIMESTER AT KNH, A RANDOMIZED CONTROLLED TRIAL

DATE	NAME	ENROLMENT IDENTIFICATION NUMBER	TELEPHONE NUMBER