A pilot randomised controlled trial to explore Telephone Support Intervention as a means of supporting young mothers in the immediate postnatal period in western Kenya

A thesis submitted to the University of Manchester for the degree of Doctor of Philosophy in the Faculty of Biology, Medicine and Health

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DEDICATION

To all young mothers and mothers-to-be, whose efforts often go unnoticed and uncelebrated as they bring forth human offspring, and navigate through all the challenges in (young) motherhood while nurturing their young ones to full independence. Bravo!

And

To my late mother, Elizabeth Chebor, who passed on shortly after I had just completed my undergraduate studies; your constant encouragement and motivation, your unfailing love, and the spirit of working hard and determination that you instilled in all of us shall forever shine in our lives. Truly, you began it all!

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My special gratitude goes to Tom and Judith Sears (The Sears family), without whom I would not have had the opportunity to pursue my PhD studies, hence this Doctoral thesis! On behalf of my entire family and myself, I say thank you very much for the scholarship and for your financial support throughout my PhD programme. May God richly bless you.

I would not forget the critical role played by my colleagues who helped me as Research assistants. Thank you so much Anne and Sheila for your sacrifices and taking your time to deliver the intervention and following up the mothers with their concerns. Indeed, it has been a great experience sharing with you. To Vincent, Felix, Miheso, Winnie and Echesa, thank you so much. May your future be bright as you pursue your career goals and aspirations.

I also wish to convey my gratitude to Moi University for granting me study leave and to my colleagues at workplace for their moral support and well wishes in my studies.

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LIST OF ABBREVIATIONS

ARHAdolescent reproductive health
ASRHAdolescent sexual and reproductive health
ANCAntenatal care
APNAdvanced nurse practitioners
ARTAntiretroviral therapy
CASPCritical Appraisal Skills Programme
CATCritical appraisal tool
CPATCellular phone-enhanced planned activities training
EBFExclusive breastfeeding
EPDSEdinburgh postnatal depression scale
ERCEthics Research Committee
FAFramework analysis
FGDFocus group discussion
GoKGovernment of Kenya
HCDSHealth care delivery system
HIVHuman Immune-deficiency virus
H/FHealth facility
HCPsHealth care providers
IRECInstitutional Research and Ethics Committee
KCGHKakamega County General Hospital
KDHSKenya Demographic and Health Survey
KNBSKenya National Bureau of Statistics
LAMRNLugina Africa Midwives Research Network
LMICLow and middle-income countries
MAMeta-analysis
MCHMaternal and Child Health
MCIDMinimal clinically important difference
MICMaternal and Infant Care
MMRMixed-methods research
MRCMedical Research Council (UK)
MoHMinistry of Health
MoMSMinistry of Medical Services
MoPHSMinistry of Public Health and Sanitation
MSSSMaternal social support scale

MTRH......Moi Teaching and Referral Hospital

NCK.....Nursing Council of Kenya

PI.....Principal investigator

PIS.....Participant information sheet

PPD.....Postpartum depression

QDA.....Qualitative data analysis

RA.....Research assistant

RCT.....Randomised controlled trial

RMBH......Riley Mother and Baby Hospital

SES.....Self-esteem scale (maternal)

SMS.....Short message service

SNOSE......Sequentially Numbered Opaque and Sealed Envelopes

SPSS.....IBM Statistics

SSA.....Sub-Saharan Africa

TSI.....Telephone support intervention

UMREC.....University of Manchester Research Ethics Committee

UoM.....The University of Manchester

UNFPA......United Nations Population Fund

US(A).....United States of America

WHO......World Health Organization

DEFINITION OF TERMS/OPERATIONAL DEFINITIONS

Immediate postpartum/postnatal period: The immediate postpartum period refers to the period after birth (usually after the birth of the placenta) up to 48 hours after birth; postpartum period refers to the time following birth up to 42 days (6 weeks) after birth (in which maternal complications following birth are very critical); postnatal period refers to the period following birth and covers beyond the postpartum period (and thus it is inclusive of the postpartum period). In this study, and for practical reasons, the immediate postnatal period refers to the time following birth up to 10 weeks after birth, which corresponds to the second clinic appointment for the baby and immunisation. This period was considered reasonably adequate to evaluate the telephone support intervention in the pilot randomised controlled trial.

Telephone support intervention: This refers to any form of supportive information provided by means of telephone communication. In this study, it refers to specific information package (motivational health messages) specifically developed for young postnatal mothers (through Delphi technique), and provided through a telephone call and SMS over a defined period (up to 10 weeks) following birth.

Young mother: Young people (often referred to as youth) refer to persons aged 12-24 years, with the youth in the age-group 20-24 often referred to as young adults. A child refers to a person under the age of 18 years (also with regard to the setting of the present study). A young mother thus refers to a woman aged 12-24 years and has had childbirth. In this study, a young mother refers to a woman who has had a childbirth and aged between 12-19 years, which also includes the adolescents.

THE AUTHOR

The author pursued his undergraduate (BSc.N) in Nursing and Masters degree (MSc.N-Maternal and Neonatal Health) in Moi University School of Nursing, College of Health Sciences. Currently, he is a Lecturer in Moi University School of Nursing in the Department of Midwifery and Gender. Previously, the author worked as a Reproductive Health Associate (RHPA) in the School of Medicine, Department of Reproductive Health (2008-2012), during which time he was the coordinator of research and community extension services undertaken by the department.

His interest in research and in particular among young/teenage women stems from when he coordinated an HPV vaccination exercise (Gardasil access programme) targeting primary school girls in selected primary schools in Western Kenya. While providing information to the pupils and their teachers (prior to contacting their parents and subsequently recruiting them), the lack of reproductive health information among this age group (including their teachers) was apparently clear from their questions. The challenges of participant access and the long follow-up period also shaped the author's experience regarding research involving young people. During his Masters programme, the author also had the opportunity of working with the young/adolescents in a youth centre where similar challenges (lack of accurate reproductive health information and their enthusiasm for the same) were observed. Besides, having taken part as a research assistant in several other projects, including a clinical audit of pre-eclampsia in MTRH also built his interest in research. These experiences and his keen interest thereof in midwifery/reproductive health drew him to this research.

The author also previously served as an Assistant lecturer in Moi University (School of Nursing), and as a Clinical Instructor in the University of Eastern Africa-Baraton (Kenya) among other volunteer services.

ABSTRACT

Title: A pilot randomised controlled trial to explore telephone support intervention as a means of supporting young mothers in the immediate postnatal period in western Kenya.

Background: Globally, pregnancy among the young/adolescent women is a growing public health issue of concern. This group of women are often socially and economically disadvantaged due to their age and low status, including low level of education. Most young/adolescent women (and/or mothers) are less likely to attend the recommended antenatal and/or postnatal visits. Consequently, this puts them and their babies/infants at a considerable health risk. Evidence suggests that adolescent mothers have exhibited lower self-esteem and more depressive symptoms, including low breastfeeding and general self-efficacy compared to older mothers. Trials and systematic review evidence on telephone support intervention (TSI), however, suggest a promising opportunity to offer supportive maternity care.

Aim(s): To explore the feasibility of conducting a main trial comparing telephone support versus no support for young mothers in improving maternal physical, psychological and social wellbeing during the immediate postnatal period.

Methods: A pilot randomised-controlled trial of a telephone support intervention was conducted between October 2016 and August 2017 using a mixed-methods approach. A sample of 52 young mothers (12-19years) were recruited in two referral hospitals and randomised into intervention and usual care groups, with n=43 retained in the pilot trial and analysed. The usual care group received standard postnatal care while the intervention group received an additional telephone support (weekly SMS, and telephone call after every 3 weeks) for 10 weeks postpartum. Descriptive statistics were used to analyse data (mean, median, 95%CIs), including Chi-square test, Independent-samples t-test and Mann-Whitney U test.

Results: Mothers who received telephone-support appeared to have higher maternal self-esteem (median=25 vs 22, 95%CI for difference in median=0.001 to 4.00), with moderate effect-size=0.54; and less infant-related anxiety (median=1.50 vs 4.00, 95%CI for difference in median= -3.00 to 1.00) respectively; and were less likely to report: being ill (22.7% vs 71.4%, 95%CI=-0.68 to -0.19); experiencing difficulty in breastfeeding (9.1% vs 38.1%, 95%CI=-0.51 to -0.03); and initiating early-weaning (22.7% vs 52.4%, 95%CI=-0.53 to -0.009). The results should, however, be interpreted with caution as this small pilot was not powered for significance. Qualitative results highlighted five main themes: social support needs for young mothers; maternal role modelling in maternal role transition and attainment; social support systems available to young mothers after birth; the (perceived) role of TSI; and the feasibility and acceptability of TSI among young mothers and midwives. Overall, the results suggest that TSI is feasible and acceptable among young/teenage mothers and health care providers (midwives) in Kenya.

Discussion: Young/teenage mothers in LMICs settings such as Kenya still lack knowledge and maternal competence as they transit to motherhood. Thus, it is important to understand the social support needs for such a group of mothers so as to meaningfully and effectively meet their needs, including the social support systems available to them. Moreover, innovative/novel strategies such as TSI may provide opportunities for addressing the gaps in maternal and infant care practices in such settings.

Conclusions: This pilot trial suggests that it is possible to recruit young/teenage mothers in LMICs such as Kenya for main trials. TSI appears helpful and acceptable to both midwives (and other service providers) and young mothers.

CHAPTER ONE

INTRODUCTION

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CHAPTER ONE: INTRODUCTION

1.0. Introduction and organisation of the thesis

This chapter lays out the organisation of the thesis and provides background information to the study. Chapter one is organised in two parts: Part A provides background to the study and highlights the issues surrounding teenage/adolescent pregnancy. This section also highlights the potential role of innovative strategies such as the telephone support intervention (TSI) in health care, and particularly in maternity care as a means of supporting (young) mothers after birth; Part B provides contextual information about the study setting, including the geographic location, demographic profile, the system of governance, and the organisation of the health care delivery system.

Chapter two presents the literature review, highlighting mainly the review and critical appraisal strategies that informed the study. Specifically, the literature findings of two search strategies are presented: an initial literature search of the postnatal needs of young mothers (search 1) and a second search of studies on telephone support intervention (TSI) in postnatal care of (young) mothers (search 2). Evidence of systematic reviews on TSI is also highlighted.

Chapter three is organised in two parts: Part A provides an overview of the philosophical issues/paradigms in research, with a view of informing the present study. Following this, the philosophical stance of post-positivism appeared consistent with the objectives of the present study and was therefore adopted; Part B describes the methods used in addressing the research question (exploring the feasibility and acceptability of TSI among young mothers), including the research objectives, design, participant

recruitment and consenting procedures, data collection and analysis, and the ethical considerations that were observed during the study.

Chapter four presents the process/procedures used in developing the intervention (TSI) for the pilot trial. The Delphi process, which was considered suitable for this is described in detail and the results thereof, which formed the intervention package for the study are highlighted. Chapter five presents the quantitative results of the pilot trial. The results are mainly descriptive analyses presented in tables and charts as appropriate. Chapter six presents the qualitative results of the study. The steps of Framework analysis (FA) approach which was used in the analysis are described in detail, and how they were applied in the data analysis process until the themes were derived.

Chapter seven presents the discussion of the results of the pilot trial. The results are integrated in the discussion as necessary, in view of the existing literature. Being a pilot/feasibility trial, the findings are also discussed in view of informing a definitive trial, including the strengths and limitations of the study. Chapter eight presents the conclusions and recommendations drawn from the study. The original contribution of the study is discussed, with its implications for practice, policy, future research and midwifery education. At the end, a personal reflection of 'my PhD journey' is presented.

PART A: Study background

1.1. Introduction

This section provides background to the study. First, it highlights the issues surrounding teenage/adolescent pregnancy, including the risk factors and the outcomes associated with these pregnancies with much reference to Sub-Saharan Africa (SSA) in which the study setting (Kenya) is situated. Second, the role of innovative strategies in maternal and infant care (MIC) such as the telephone support intervention (TSI) as a means of

supporting young mothers during postnatal care and in improving their overall wellbeing and that of their infants is also highlighted.

1.2 Background information

Pregnancy among the adolescent and young mothers has become a public health issue of concern across the globe. According to the World Health Organization (WHO), adolescent births account for over ten percent (over 15 million) of all the annual births worldwide (WHO, 2006). It has been cited that adolescent pregnancies are high in SSA, with more than half of the adolescents reportedly having had a child (Hindin, 2014). For instance, it has been documented that the levels range from 23% in Rwanda to 69% in Niger (Hindin, 2014), while Were (2007) also highlighted that SSA has one of the highest rates of teenage pregnancies in the world. In addition, young people constitute the greatest population in SSA (Ashford, 2007). According to Population Reference Bureau (PRB), young people aged between 10-24 years constitute more than a third of the population in SSA (PRB, 2006). With the high fertility rate in the region and improvements in child survival, this statistic was even projected to increase over the years (Kabiru et al., 2013, Ashford, 2007). Thus, with such a high and rising young population it is expected that the prevalence of teenage/adolescent pregnancies will rise in these countries. Moreover, the World Health Organization (WHO, 2014) report indicates that 49 out of every 1000 births are among women aged 15-19 years, with higher rates being recorded in SSA.

Notably, early child bearing is not only a health problem for the mother and child but is also associated with considerable socio-economic and demographic implications (Gupta and Jain, 2008). Adolescent pregnancy has been associated with significant medical, emotional and societal consequences for the adolescent mother, her child and her family (Black et al. 2012). Similarly, Foulifack et al. (2014) reported that adolescent pregnancies are a growing public health problem in Cameroon, and that most of such cases were associated with referrals, with poor maternal and foetal outcomes compared to pregnancies among adult women. A great concern is the fact that in low-income settings, 20% to 60% of young women's pregnancies and births are unintended, most coming sooner than planned (Gupta and Jain, 2008). Therefore, it is important to note that many women of this age are at a higher risk of pregnancy, labour and childbirth complications. These challenges are also compounded by the fact that postnatal care remains one of the neglected areas in maternity care (WHO, 2014).

1.3 Factors influencing teenage/adolescent pregnancy

Teenage pregnancy constitutes a high-risk pregnancy with complications arising from a combination of physiological, anatomical and socioeconomic factors (Ezegwui et al. 2012). According to a study on transition into first sex among adolescents in slum and non-slum communities in in Nairobi, Kenya, early sexual debut predisposes adolescents to negative health and psychological outcomes (Kabiru et al., 2010). In this study, Kabiru et al. (2010) observed that transition to first sex is influenced by age, slum residence, perceived parental monitoring and peer behaviour and concluded that there was a need to pay more attention to very young adolescents and those growing up in resource-poor settings due to increased vulnerability to negative health outcomes.

Mahavarkar et al. (2008) also cited cultural practices, poor socioeconomic conditions, low literacy rate and lack of risk awareness as some of the drivers to teenage pregnancy in rural India. Moreover, inadequate antenatal care and weight gain during pregnancy have also been cited as some of the key factors contributing to adverse outcomes in teenage pregnancies (Kuo et al. 2010). According to Gross et al. (2012) who studied timing of antenatal care among pregnant women in Tanzania, many pregnant women in SSA, especially the adolescents, start antenatal care attendance late, thereby missing out on the full package of preventive and curative services offered. Thus, with limited attendance to antenatal care and access to skilled birth attendance many of them are easily predisposed to pregnancy and birth complications.

1.4 Teenage/adolescent pregnancy and outcomes

Early childbearing is associated with negative consequences (Lopoo, 2011). Notably, adolescent pregnancy has been associated with adverse outcomes, including prolonged labour, preterm labour, intra-uterine growth restriction, premature rupture of foetal membranes, anaemia, low birth weight, preterm and caesarean births, and higher rates of both gestational duration extremes and mortality (Ogelle et al. 2011, Fouelifack et al. 2014). In the Netherlands, it was reported that women aged between 13 and 19 years were one and a half times more likely to be at risk of preterm birth than women between 20 and 29 years (Buitendijk et al., 1993). Moreover, the risk of intrauterine death was reportedly four times as high for those aged 13-17 years and twice as high for age 18-19 compared with older women (Buitendijk et al., 1993).

In a multi-country survey in low-resource countries in Africa, Asia and Latin America, it was also found that adolescent pregnancy was associated with increased risks of preterm birth and low birth weight; with pregnancy among those aged ≤ 15 years having a greater risk of caesarean birth due to cephalopelvic disproportion (Ganchimeg et al. 2013). Ganchimeg et al. (2013) further noted that adolescent mothers were more likely to have fewer ANC visits, lower BMI's, short stature and lower levels of education. Adolescent mothers were also more likely to be single. This shows that besides pregnancy and childbirth risks, teenage mothers experience other social factors that may largely influence their overall wellbeing and parenting competence, as well as their access and utilisation of health services. Obstetric fistulas have also been cited as common among the young mothers. Limited access to skilled birth attendance, lack of

obstetric emergency care and delayed access to maternity centres often lead to prolonged and obstructed labour, resulting in fistula (Roka et al., 2013, Miller et al., 2005, WHO, 2006).

Evidence also reveals that cases of obstructed labour were high, especially among women below 19 years, since by the time they get pregnant, the pelvis is not yet fully developed to accommodate childbirth (Neilson et al. 2003). Scholl et al. (1994) also observed that in low-income settings, the incidence of premature deliveries, low birth weight, maternal anaemia and caesarean birth has been reported to be higher among young mothers. Optimal care during pregnancy and childbirth is therefore key in reducing the incidence of obstetric fistula. Additionally, immediate diagnosis and repair of third and fourth degree perineal tears following childbirth may significantly reduce fistula burden (Lozo et al. 2015).

1.5 Adolescent sexual and reproductive health research

With regard to research in adolescent sexuality and health, Hindin et al. (2013) in their article on setting research priorities in adolescent sexual and reproductive health in low and middle income countries reported that health researchers (who were also the study participants), singled out maternal health as one of the key priority areas in health care. The authors further suggested the need of scaling up existing and the development of innovative interventions in addressing adolescent health (Hindin et al., 2013). It is therefore evident that further research in maternal health is necessary so that salient issues surrounding reproductive health among the adolescents are better understood. Innovative strategies such as TSI may therefore prove beneficial as a means of addressing the inequities and disparities in maternal access to health care especially among young women.

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1.6 Telephone Support Intervention in health care

1.6.1 Telephone support outside maternity services

Mobile health technologies have been reported to improve health care service delivery processes such as in health care provider support interventions on diagnosis and management outcomes (Free et al. 2013a). The use of telephone services has been widely used as a supportive tool in the management of long-term illnesses, both in the developed and developing countries, notably as clinical appointment reminders, self-management and self-efficacy skills support tool to medication adherence (De Jongh et al., 2012; Car et al., 2012; Gurol-Urganci et al., 2013; Mbuagbaw et al., 2015; Vodopivec-Jamsek et al., 2012). Similarly, in their study on telehealthcare for chronic obstructive pulmonary disease, McLean et al. (2012) found that the use of a telephone intervention was associated with a reduction in the risk of emergencies and hospitalisation. It has also been suggested that mobile text-messaging may offer a convenient and cost-effective opportunity in preventive care (Vodopivec-Jamsek et al., 2012).

A systematic review assessing the effectiveness of mobile-health technology-based health behaviour change or disease management interventions for health service users found that text-messaging interventions increased adherence to ART and smoking cessation (Free et al. 2013b). Free et al. (2013b) also noted that although the evidence suggested potential benefit in some other areas, they observed that high quality and adequately powered trials of similar interventions were necessary to evaluate their effects on outcomes.

1.6.2 Telephone support in midwifery/maternal-newborn care

The advent of information and communication technology, such as telephone use, has had a huge and positive impact on health care, including maternity care. Studies have shown that telephone use has gained much currency today in the optimisation of maternity services (Lavender et al. 2013; Snaith et al. 2014; Deverill et al. 2010; Osman et al. 2010). While recognising the importance of the number of antenatal visits, Deverill et al. (2010) highlighted that women may accept fewer visits if the care was offered by midwives as well as if they received an enhanced service package such as telephone advice line. Lavender et al. (2013) also noted that telephone support may be quite useful in specific areas of maternity care, adding that its use was gaining wide acceptance in the health care system.

Telephone-based interventions such as telephone calls and text messaging have been found to improve maternal and infant health outcomes following birth, and thus provided avenues for ensuring optimal MIC (Lavender et al. 2013, Hannan, 2013). For instance, telephone call follow up to low-income first-time mothers was found to be a safe, easy to use and cost-effective means that improved mother-infant health outcomes (Hannan, 2013). Therefore, midwives need to explore the use of telephone intervention to enhance the package and quality of maternal health services, especially in low resource settings, since it transcends physical and economic access to health care services.

Additionally, telephone support has been proven useful during pregnancy and the postnatal period. For instance, studies have shown that telephone support may be used in specific areas of maternity care such as prevention of depression related to childbirth among women and as a means of breastfeeding support (Lavender et al., 2013, Dennis and Kingston, 2008, Sipsma et al. 2015, Tahir and Al-Sadat, 2013). Regarding preventive care, the use of a mobile phone messaging platform has been cited as one of the convenient and cost-effective measures that can be adopted to support desirable health behaviour for preventive health care (Vodopivec-Jamsek et al., 2012).

1.7 Potential areas of maternity care for innovative supportive interventions

The immediate postnatal period also marks the transition to parenting, which for many young mothers, who are also likely to be first-time mothers, may be a daunting task as they may have little knowledge and experience of maternal obligations, especially after birth. Osman et al. (2010) highlighted that first-time mothers also face additional challenge of adaptation as a mother, which may impact on their confidence, self-esteem and overall emotional wellbeing. In addition, primiparous women cited negative emotions, breastfeeding challenges and the need for emotional support as major concerns soon after birth (Shorey et al., 2015).

Postnatal depression has also been cited as one of the major maternal morbidities related to childbirth, with dire health consequences to the mothers and their families (Dennis et al., 2009). Regarding novel interventions such as telephone support, it was observed that a 24-hour telephone hotline and postpartum support film had a significant reduction of stress and an overall positive effect on maternal mental wellbeing (Osman et al. 2014). A similar randomised study on the impact of home visitation and telephone call intervention revealed that the intervention group was two and a half times less likely to manifest symptoms associated with postnatal depression at fifteen weeks postpartum compared to the control group (Surkan et al., 2012).

Studies have also revealed that adolescent mothers were less likely to breastfeed exclusively as recommended compared to older mothers (Leclair et al., 2015; Sipsma et al., 2015). In a retrospective population-based cohort study on breastfeeding among adolescents, Leclair et al. (2015) observed that factors such as age, ANC attendance, socio-economic status, mode of birth, substance use, including the intention to breastfeed influenced breastfeeding rates among Canadian adolescent mothers.

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Similarly, Osman et al. (2010) in their study on what first-time mothers worry about, argued that first-time mothers used the telephone hotline service more frequently during the first four weeks postpartum, asking questions ranging from breastfeeding, care of the newborn to the general care of the infant. This underscores the importance of supportive interventions in maternal and infant care especially among young mothers. It has also been observed that provider-initiated telephone support during early postpartum period increased breastfeeding duration among first-time mothers (Fu et al. 2014, Tahir and Al-Sadat, 2013). Moreover, to improve health outcomes the need for a multidisciplinary approach to address the risk factors facing young mothers, both during pregnancy and in the postnatal period has been suggested (Leclair et al. 2015).

More importantly, the immediate postnatal period is a very critical time for the childbearing family, especially young mothers who most often are likely to be first-time mothers since it marks the transition to motherhood. During this period, mothers experience numerous challenges that may significantly affect their physical, emotional and psychosocial wellbeing, including predisposition to postnatal depression (McKellar et al. 2006). A qualitative study on perceptions of primiparous women on postnatal psychoeducation programme revealed that women often experienced negative emotions and breastfeeding challenges, and cited the need for emotional support as a priority concern soon after birth (Shorey et al., 2015). Therefore, in the context of further research on novel interventions and/or educational programmes targeting pregnant women or postnatal mothers, it would be imperative to explore such interventions as TSI in such areas, particularly among young mothers.

Indeed, in the context of this study (setting) such health educational programmes (including antenatal and postnatal education) are provided to all women and/or mothers at the hospital wards before being discharged. In so doing, the educational content is

often broadcasted by the health care provider (usually the midwife, and sometimes nutritionists) to the group of women or mothers as applicable irrespective of their individual characteristics and/or special needs such as age, level of education and social status. In such circumstances, young mothers, who may often be shy sharing the same platform with 'their mothers' and coupled with the likelihood of having attended less ANC visits may be at a great disadvantage compared with adult mothers. Novel interventions such as TSI may therefore provide an opportunity for disseminating such educational programmes in a systematic and individualised manner to such group of vulnerable women and/or mothers. Moreover, developing and testing such interventions in LMICs such as Kenya through feasibility studies provides a better understanding of how best they can be implemented. For instance, such studies may be informative on how to prioritise and sequence the educational content.

As highlighted above, in spite of the challenges that surround young motherhood, it is evident that supportive strategies such as telephone support intervention have been considered as possible approaches that can be used to improve maternal health care services. However, many studies on telephone support intervention in postnatal care of mothers have been conducted in developed countries, with very few in low-income settings. Thus, this provides limited evidence of the feasibility and potential effectiveness of such interventions in low-income settings, such as Kenya.

Moreover, in spite of its use in various areas of maternity care, it was observed that the existing evidence of its effectiveness is still inconclusive but promising (Lavender et al. 2013). Therefore, this study sought to explore the feasibility and acceptability, and the potential effectiveness of telephone support intervention among young mothers in two main referral health facilities in a low-resource setting (in western Kenya) during the immediate postnatal period. A detailed description of the methodology and methods

used in the study is presented in Chapter 3. Understandably, as a pilot randomised controlled trial, it was thought that the findings would provide baseline data that may be informative for conducting a main trial. Indeed, it has been highlighted that pilot studies are of critical importance in providing vital data ranging from the systematic processes involved, to the scientific and statistical principles to be observed in a main trial (Thabane et al. 2010).

PART B: Contextual information about the study setting

This section provides contextual information about the study setting. An overview of the setting is presented; this includes the geographic location, demographic profile, the system of governance and the organisation of the health care delivery system. Moreover, since the study concerns young mothers who included teenage/adolescents, an overview of adolescent and sexual reproductive health (ASRH) in Kenya is presented to provide the contextual background of the reproductive health care services, including maternity care available to them. In addition, since the study involved the use of a mobile phone services (or technology), it is important to note that mobile phone access or penetration in Kenya was projected at 87% (covering approximately 38.5 million of the population) in the last quarter of 2016 (Communications Authority of Kenya, 2017), with urban centres mainly enjoying 4G connectivity while the rural areas being served with 3G networks. The main mobile service providers include Safaricom and Airtel-Kenya. Therefore, with the study centres being referral hospitals serving a wider catchment including rural areas, the network connectivity by participants was variable depending on the locality.

1.8 Overview of the study setting (Kenya)

1.8.1 Geographical location and climatic conditions

Kenya is located in the eastern part of the African continent, bordering Uganda to the West, South Sudan to the northwest, Ethiopia to the North, Somalia to the northeast and Tanzania to the South. To the South-East lies the Indian Ocean. It lies between latitudes 5 degrees north and 5 degrees south, and between longitudes 24 and 31 degrees east, and is transected by the equator to almost two equal halves. It covers a total area of approximately 582, 646 square kilometres. Kenya enjoys a tropical climate, with seven climatic zones and diverse physical features (Jakanyakwaka and Mukhovi, 2014). Figure 1.1 presents the geographical location of Kenya in the African continent.



Figure 1.1: Geographical location of Kenya

1.8.2 Demographic profile

The total population in Kenya is currently estimated at over 47 million (KNBS, 2017) (Figure 1.2), with the 2009 Kenya Population and Housing census enumeration figures at 38.6 million (Kenya 2009 Census Report). The next national census exercise is due next year.

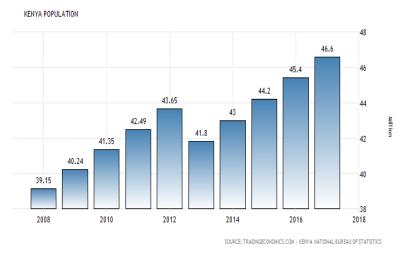


Figure 1.2: Population growth projections in Kenya

1.8.3 Culture, Religion and Socio-economic activities

Kenya boasts of over 43 ethnic communities with over 60 spoken languages which traditionally reflect a wide diversity in sociocultural and economic activities ranging mainly from pastoralism to crop farming depending on ecological zones that the communities reside in. However, there have been transcultural changes over time which has seen a major shift and transformation regarding the people's way of life. Despite the ethnic diversity, Kiswahili and English are the two main national languages. Majority of the population (about 80%) are Christians while the rest constitute Muslims, Hindus and other religions. Kenya's economy is predominantly agricultural, with concerted efforts towards industrialisation. The country also boasts of diverse tourist attraction sites, including Maasai Mara National Park and Game Reserve, Lake Nakuru National Park, the Great Rift Valley, Mt. Kenya and coastal beaches.

1.8.4 Governance and administrative structure

The country's governance structure is exercised at two levels: the national and the county governments (Constitution of Kenya, 2010). Administratively, the country is divided into 47 counties, headed by a jointly elected Governor and Deputy Governor, with a County assembly constituting of elected Members of County Assembly (MCAs).

The adoption of this system of governance was informed by the need to devolve power and resources, including health care services to local units (counties) so as to foster accountability to the people (Constitution of Kenya, 2010). The organisation of the Kenyan health care delivery system (HCDS) is described in the subsequent section (Section 1.8.6). The national government is headed by the Presidency (the President and the Deputy President, the executive arm of government), with a bicameral parliament (The National Assembly and the Senate) which forms the Legislative arm of the government. An Independent Judiciary constitutes the third arm of the government (Constitution of Kenya, 2010).

1.8.5 The organisation of the health care delivery system

The health function is a devolved function (Kenya Constitution, 2010), and thus health care delivery is basically run by the respective county governments. However, the national government is tasked with the role of health policy development and dissemination to the counties, as well as running the two national referral hospitals (Kenyatta National Hospital and Moi Teaching and Referral Hospital) both of which are Level-6 hospitals (Constitution of Kenya, 2010). The county governments therefore run all the other facilities (Levels 5 and below), including County referral hospitals (Level 5 referral hospitals), and sub-county hospitals, health centres and local dispensaries (Level 4, Level 3 and Level 2 respectively) within their respective counties. Accordingly, the referral system is based on the complexity level of the conditions or morbidities encountered at each level with the commensurate level of skilled staff and/or health specialities (seven in total) and a few newly upgraded facilities (county referral hospitals) following the devolved governance system. Level 6 hospitals form the top-most level of referral and comprise the two national referral hospitals.

The provision of health care is guided by the Kenya Health Policy Framework (KHPF) developed in 1994 which stipulates a collaborative approach in the provision of health care between the government and other agencies. Thus, health care services are provided by the government, non-governmental organisations (NGOs), faith-based organisations (FBOs), community-based organisations (CBOs) and the private-for-profit sector (KHPF, 1994). Subsequent to this policy, other health policies have been developed such as the National Health Sector Strategic Plans I & II (NHSSP I, 1999-2004 and NHSSP II, 2005-2010 respectively), including the first National Reproductive Health Policy (2007) and the National Reproductive Health Strategy 1997-2010. Similarly, Adolescent Reproductive Health and Development Policy (ARHD) (2003) and the National Adolescent Sexual and Reproductive Health Policy (2015) have been developed.

1.8.6 Maternal health services

Since this study concerns maternal health issues, particularly among young mothers it is imperative that an overview of maternal health care services (key maternal health indicators) in Kenya is presented. In general, it appears there is some improvement in maternal health indices in Kenya. According to the Kenya Demographic and Health Survey (KDHS), it was estimated that the maternal mortality ratio was 362 per 100,000 livebirths (KDHS, 2014) compared to the previous survey whose estimate was 414 per 100,000 livebirths (KDHS, 2008-09). Similarly, antenatal care attendance by a skilled provider; birth at a health facility; and skilled birth attendance increased to 96%, 61% and 62% respectively (KDHS, 2014) compared to 92%, 43% and 44% respectively reported in the KDHS 2008-09 survey. This improvement may partly be attributed to the introduction of free maternity care by the government in 2013. The use of contraception also showed an upward trend from 39% (KDHS 2008-09) to 53% (KDHS, 2014). Neonatal mortality also recorded a slight drop from 31 per 1000

livebirths in 2009 to 22 per 1000, and a similar trend in infant mortality from 52/1000 to 39/1000 livebirths in KDHS 2008-09 and in KDHS 2014 respectively.

Although these statistics show a positive trend regarding maternal health care (and infant/child care), it is important, however, to note that these figures still fall short of the expected Millennium Development Goals (MDGs) targets (by 2015) (currently Sustainable Development Goals, SDGs). Importantly, it is noteworthy that the maternal statistics also do not account for the disparities between different groups within the population such as based on age characteristics. Thus, in the context of policy formulation and development of health guidelines such as in maternal health care, it is possible that critical issues such as paying attention to the special needs of young women (and/or mothers) may be missed out.

1.8.7 Adolescent sexual and reproductive health services in Kenya

Although this study mainly concerned young women (who included teenage/adolescents) in the context of motherhood or rather as they transit to motherhood, it is important to understand some background information regarding the reproductive health services available to them prior to becoming a mother. This is in cognisance of the fact that access to such services before and/or during pregnancy may have a positive effect not only during pregnancy but also after birth. It is against this background that an overview of ASRH services in Kenya is presented.

Teenage pregnancies have been on a steady increase in Kenya owing to high fertility and early and unprotected sex among the adolescents and youth (KDHS 2008-09). According to the KDHS 2008-09 report, about 47% of women had had sexual intercourse before the age of 18 with western region (formerly Western province) leading with 69% (KDHS, 2008-09). Similarly, the subsequent KDHS report (KDHS, 2014) indicated that 18% of young women aged between 15 and 19 had already begun

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childbearing, 15% of whom were already mothers and an additional 3% were pregnant with their first child. Of this, 33% had not attended school, 55% had attained at least primary level of education, and 12% had attained a secondary level or above (KDHS, 2014). Hence, education level remains a significant factor in adolescent pregnancy and/or childbearing. Moreover, a previous study conducted on teenage experiences in rural Kenya highlighted that there is a high unmet reproductive health needs (Taffa et al. 2003). Coupled with cultural practices such as early marriages and female genital cutting, this predisposes the adolescent girls to numerous health risks including pregnancy. Moreover, most of these cases do occur among adolescents with low educational level.

However, of greater concern is the fact that in case of pregnancy, the young/adolescent women are subjected to the routine maternity care, oblivious of their special health needs as young women, especially regarding lack of knowledge on pregnancy, labour, birth and their obligations as mothers during postnatal period. Perhaps it is high time that health care systems, particularly in LMIC settings such as Kenya consider exploring the special needs of this group of women in the context of maternal and/or reproductive health care to optimise their service delivery and care package.

In a bid to address the issues related to the adolescent population in the country, Kenya developed her first Adolescent Reproductive Health and Development policy in 2003 (GoK, ARHDP, 2003) with a view of integrating adolescent health within the mainstream health care system, including establishing youth friendly services in the HCDS. Although there have been challenges in the implementation of the ARHDP as noted by an evaluation report (ARHD Policy Implementation Assessment, 2013), the initial policy provided framework for developing the current National Adolescent Sexual and Reproductive Health Policy (ASRHP), which aims at putting ASRH and

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rights issues into the country's mainstream health and development agenda (GoK, ASRHP, 2015).

1.9 Chapter summary

This chapter highlighted the background information regarding the study, mainly by highlighting key issues surrounding teenage pregnancy with specific regard to low resource settings in which the study setting falls within. The potential role of innovative strategies such as telephone support as a means of supplementing routine care practices, particularly in maternity care was also highlighted. Moreover, to enable a better understanding of the study context, relevant information about the setting was highlighted including the organisation of the health care delivery system, and maternal and adolescent reproductive health services.

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CHAPTER TWO

LITERATURE REVIEW

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CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter highlights the existing research evidence on the needs of young mothers and telephone support intervention (TSI) in maternity care, particularly during the postnatal period. First, an overview of the main types of (literature) reviews is presented (Section 2.2). In the review process, the evidence from systematic reviews on telephone support intervention in maternity care (pregnancy and childbirth) was initially sought so as to identifying the existing gap(s) in the literature regarding such interventions. Subsequently, two searches were performed; the first search was aimed at identifying the needs of young mothers during the postnatal period while the second search aimed at identifying studies on TSI in the context of young mothers during the postnatal period. A critical appraisal of the identified papers was performed and is described herein. Subsequently, the findings of the synthesis of the literature are presented in form of themes, and the conclusions thereof. The chapter therefore summarises the existing literature on support needs of young mothers and telephone use as a supportive tool in improving the overall health and wellbeing of women and their infants particularly during the immediate postnatal period. The initial literature review was conducted in December, 2015. Moreover, an update of the literature review was performed in 2018 (Jan-March) and the identified literature was incorporated in the discussion chapter.

2.2 Types of reviews

Broadly, literature reviews can be grouped into two: systematic and narrative reviews. Systematic review is a detailed and comprehensive search of literature with a preplanned strategy to identify all relevant studies, appraise and synthesise the data, with the aim of reducing bias (Feldstein, 2005, Uman, 2011). Hence, it demands a concise, structured and a replicable strategy. A structured narrative literature review is systematic but more pragmatic in approach, thus allowing for flexibility unlike systematic reviews. Owing to its flexibility, wider scope in terms of study design and comprehensive coverage of relevant literature, the structured literary review approach was deemed appropriate for this study. In view of the above objectives, two structured narrative reviews were performed (Section 2.4).

2.3 Systematic reviews evidence on TSI

An initial search in the Cochrane database was performed to identify systematic reviews on TSI. This search aimed at identifying the gaps in the literature regarding TSI with a view of informing the present study during the protocol development stage. Following this, four systematic reviews on telephone support were identified in this search (Lavender et al. 2013, Sipsma et al. 2015, Dennis and Kingston, 2008, and Shaw et al. 2006). The reviews included 27 RCTs; 6 studies (both randomised and non-randomised trials); 14 studies (published, unpublished and ongoing trials) and 22 trials (RCTs) respectively (Table 2.1). Of these, one review (Lavender et al. 2013) was of high quality owing to the methodological rigour employed and explicit assessment and reporting of biases in the included studies and the inclusion-exclusion criteria, while the other 3 reviews were of moderate quality (Sipsma et al. 2015, Dennis and Kingston, 2008, and Shaw et al. 2006). Two reviews specifically focussed on telephone-based support (Lavender et al. 2013, Dennis and Kingston, 2008), while the other two reviews focussed on a range of other supportive interventions postpartum (Sipsma et al. 2015, and Shaw et al. 2006) which included home visits, clinic and consultant visits, peer counselling, and school-based interventions. Three reviews assessed studies on pregnant or postnatal women during early postpartum (the first six weeks), with one (Sipsma et al. 2015) having specifically focussed on interventions aimed at improving breastfeeding among adolescent mothers (breastfeeding initiation, duration and exclusivity). Shaw et al. 2006 focussed on postpartum support and reviewed

interventions (RCTs) initiated immediately after birth up to one year postpartum. Moreover, two of the reviews (Lavender et al. 2013, and Dennis and Kingston, 2008) applied a wider scope of search strategies (databases). Generally, the reviews used standard tools for assessing quality of the included studies (Cochrane Risk of bias assessment tool) (Higgins, 2011), with only one review (Shaw et al. 2006) having used the Jadad scale (Jadad et al. 1996). The Critical Appraisal Skills Programme (Casper and Hogan, 2013) appraisal tool for systematic reviews (Appendix 2.1) was used in the quality appraisal of the included reviews. A summary of the systematic reviews on TSI is presented in Table 2.1. Overall, the reviews suggest that the existing evidence is not conclusive and thus recommended for further research and the development and evaluation of such supportive interventions.

A summary of the critical appraisal of the systematic reviews is presented in Appendix 2.2.

Author/	Objective	Study	Intervention	Data collection/	Data analysis	Summary of findings
Year		population		extraction	approach	
Lavender et	To assess the effects	Pregnant	All	Systematic search of	Dichotomous data	Review focused on one
al. 2013	of telephone support	women and	interventions	databases	– summary risk	specific intervention-
	during pregnancy and	postnatal	aimed at	[Cochrane Pregnancy and	ratio (RR) with	telephone support
	the first six weeks	women in the	supporting	Childbirth Group's Trials	95% confidence	postpartum.
	post birth, compared	first six	women by	Register]	intervals (CIs)	The evidence is
	with	weeks	using	Cochrane Central Register		inconclusive but
	routine care, on	postpartum	telephones	of	Continuous data-	suggests telephone
	maternal and infant			Controlled Trials	mean difference	support may be
	outcomes; and to			(CENTRAL)	(MD) or	beneficial in specific
	compare the effect of			MEDLINE	standardised	areas of maternity care
	different types			EMBASE	mean difference	e.g. breastfeeding
	of telephone support,			Handsearches of relevant	(SMD)	
	on maternal and			journals and conference		
	infant outcomes			proceedings		
				BioMed Central		
				27 RCTs included in the		
				review published up to Jan		
				2013		
				Setting: USA (13), Canada		
				(5), England (2), Australia		
				(2), Thailand (1), New		
				Zealand (1), Italy (1),		
				Zanzibar (1) & Scotland (1)		
		1	1		ı I	
Sipsma et al.	To review	Pregnant or	All articles	MEDLINE and PsycINFO	Dichotomous data	Only one intervention –
2015	interventions	postpartum	that evaluated		– summary risk	education and

Table 2.1: Summary of the systematic reviews on TSI

	designed to improve breastfeeding rates among adolescents to make recommendations for future research and practice	adolescents (mean/media n age <22 years)	interventions aiming to improve rates of breastfeeding initiation, duration, or exclusivity among adolescents. Interventions included: home visits; school-based programmes; telephone support.	6 studies included in the review between Jan 2000- March 2014 [Randomised and non- randomised] Setting: USA (5) and Netherlands (1)	ratio (RR) with 95% confidence intervals (CIs) Continuous data- mean difference (MD) or standardised mean difference (SMD)	counselling provided by lactation consultants improved breastfeeding duration and exclusivity. Other findings were mixed, with methodological limitations in some studies. Recommended the development and evaluation of more interventions, and tailored to adolescent mothers' needs.
Dennis CL & Kingston D. 2008	To assess the effects of telephone-based support on smoking, preterm birth, low birthweight, breastfeeding, and postpartum depression	Pregnant women and postnatal women in the first six weeks postpartum	All interventions aimed at supporting women by using telephones	Cochrane Pregnancy and Childbirth Group trials register (March 2006), Cochrane Central Register of Controlled Trials (March 2006), Medline (1966- 2006), EMBASE (1980- 2006), and CINAHL (1982- 2006). Secondary references were scanned and experts in the field were contacted.	Dichotomous data - summary relative risk with 95% confidence intervals (CIs) Continuous data- weighted mean difference was used	Proactive telephone support may be helpful in preventing smoking relapse; increasing breastfeeding duration and exclusivity; decreasing postpartum depressive symptomatology; and preventing low birthweight. Further research was recommended.

				14 trials included in the review (up to March 2006) Setting: USA (9), Canada (3), UK (1) &Australia (1)		
Shaw et al. 2006	To examine the published evidence of the effectiveness of postpartum support programs to improve maternal knowledge, attitudes, and skills related to parenting, maternal mental health, maternal quality of life, and maternal physical health	Pregnant women and postnatal women in the first six weeks postpartum	All interventions aimed at supporting women during postpartum period	MEDLINE, Cinahl, PsycINFO, and the Cochrane Library 22 studies included in this review (up to 2005) Setting: North America (12), Europe (5), Australia (5)	Data analysis procedures not described but the findings are presented	No sufficient evidence that universal postpartum support of any kind could improve parenting, maternal mental health, maternal quality of life or maternal physical wellbeing. Some evidence suggests that high risk groups may benefit from postpartum support.

2.4 The review process

Two structured narrative reviews were performed. The first review was aimed at identifying the postnatal needs of young mothers during the immediate postnatal period. This was thought to be necessary as it would identify thematic areas of the support needs and the gaps that still exist in addressing these needs as evidenced by the literature. This would further inform on the proposed interventional study. A second review was performed highlighting the evidence regarding the use of TSI in maternity care and its (potential) effectiveness. An understanding of the existing evidence on TSI would add more clarity to the proposed study as well as in informing the design of the proposed study. This would therefore provide a strong background of knowledge base to the proposed study, mainly by identifying gaps in the existing evidence on postnatal care of young mothers, as well as informing on practical decisions to be considered by the researcher.

2.4.1 Review 1

The first review was performed to identify the needs of young mothers (aged below 20 years) during the immediate postnatal period. The structured narrative review also allowed for articles discussing young mothers' experiences. This would provide an indepth understanding of maternal and infant care needs of young mothers, including their experiences.

2.4.2 Review 2

To critically assess the use of telephone as a supportive intervention in maternity care, a second structured literature search was performed. The structured narrative review allowed the search to be precise about the intervention (telephone support) and its potential effect (postnatal outcomes).

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2. 5 Search strategy/methods

In both reviews, the PICO (Population, Intervention (or Exposure), Comparison and Outcomes) approach (Davies, 2011) was adopted. The following electronic databases were searched; Medical Literature Analysis and Retrieval System Online (MEDLINE), Cumulative Index to Nursing and Allied Health Literature) (CINAHL) Plus, Excerpta Medica dataBASE (EMBASE), PUBMED (US National Library of Medicine), PsycINFO (American Psychological Association), Applied Social Sciences Index and Abstracts (ASSIA), and Maternal and Infant Care (for both search strategies). The Cochrane Library was included in the second search. In addition, since the study adopted a mixed-methods approach, and thus the need to include relevant qualitative and cross sectional studies as much as possible, some literature were searched manually and retrieved through Google. To enable inclusion of a wide range of articles as possible, the search was not limited to any specific period or setting. The summary of the two search strategies are presented in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) format (Moher et al. 2009).

2.6 Quality appraisal of the literature articles

Hawker's checklist (Hawker et al. 2002) was used to assess the quality of the studies that met the inclusion criteria in both search strategies. Hawker's checklist is a generic appraisal tool for disparate data, with a 4-point scoring scale ranging from very poor (score 1) to good (score 4) on a 9-item scoring scale. Therefore, the maximum scores range from 9 to 36. The tool explicitly outlines the criteria for assessing each of the nine items namely: abstract and title review; introduction and aims; methods and data; sampling; data analysis; ethics and bias; results; transferability and generalisability; and study implications/usefulness. The authors' explicit description of each of the nine thematic areas earns the maximum 4 points (rated good=4), the provision of most of the details but some missing, earns 3 points (rated fair=3), inadequate description earns 2

points (rated poor=2), while the lower extreme denotes lack of or inappropriate information and is scored 1 (rated very poor=1).

Besides being easy and convenient to use, the tool provides a means of assigning an overall score to determine the quality of a research as well as it can be used to appraise the quality of articles with diverse methodological designs, as well as it enables some form of consistency in appraising the selected studies (Hawker et al. 2002). Hence this tool was chosen to assess the quality of the included papers. For further information regarding the quality assessment tool, Hawker's checklist is provided in Appendix 2.3. However, it is important to mention that this tool (Hawker's quality appraisal checklist) has been thought to have some limitations. For instance, with its equal weightage of items studies may still achieve an overall high score despite having key methodological limitations yet in most cases, methodological issues are pertinent in determining the quality of research studies.

In their review of the development of critical appraisal tools (CATs), Crowe and Sheppard (2011) argued against the use of weighting scales in appraising the literature as they are prone to subjective bias in assigning the scores. The authors also noted with concern that several tools (including the Hawker's tool) were developed without performing any validation and reliability, which thus limits confidence on the use of the tools (Crowe and Sheppard, 2011). In summary, the authors suggested key considerations for researchers and/or reviewers in choosing a CAT: the need to understand the context of the review before choosing a CAT; ascertaining whether the CAT chosen was developed using the best evidence available; and the testing of reliability and validity of the CAT (Crowe and Sheppard, 2011). Despite these arguments, the critiquing of CATs provides an avenue for debate regarding future development of appropriate tools for appraising the evidence. For the purposes of this

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thesis, the summary of the literature search strategies, the results and quality appraisal are discussed below and will be presented narratively.

2.7 Search strategy 1: Needs of young mothers

2.7.1 Inclusion-exclusion criteria of the search1 strategy

The inclusion criteria for this search were:

- All relevant primary and review studies.
- All papers reporting at least one need for adolescent/teenage mothers during the postpartum period.
- All articles including adolescent age group or whose sample mean age lies within 12-19 years or not >19 years.
- Peer reviewed articles.

The exclusion criteria were:

• Articles whose sample characteristics reflect complex needs e.g. mothers who had caesarean birth, mental disorders, and infant admission to the special care unit or any special adverse condition during the postnatal period.

The following search terms were used in the search.

Parameter	Search terms
Population	Teen* mother*OR teen* parent* OR adolescen* mother*
	OR adolescen* parent* OR young wom?n OR teen* m?ms
Intervention/exposure	
Comparator/context	Postnatal OR postpartum
Outcome(s)	Needs OR concerns OR social support OR self-esteem OR emotional support OR self-concept OR psychological needs OR stress OR special needs OR health service needs

Table 2.2: Search strategy for review1

However, there was a slight variation on the search terms in the "outcomes" parameter across the databases since each database had different MeSH terms. Hence, the closest term related to the desired outcome of interest in the search was selected. This search was not limited to any specific context/setting.

2.7.2 Search strategy 1 results

In total, the search yielded 582 eligible papers, which were exported to the EndNote program. Duplicates (n=171) were then removed. A further 353 records were removed by abstract and title screening. These records were excluded mainly due to irrelevant subject area with regard to the objective of the study. The remaining articles (n=58) were subjected to full text review and 38 articles were excluded mainly because of the focus of the studies with respect to the study population (articles on adult mothers over 20 years), and irrelevant topical areas such as adolescent pregnancy, postpartum contraception, depression/mental disorders, and school based interventions).

The results of this search is represented in a PRISMA diagram (Figure 2.1).

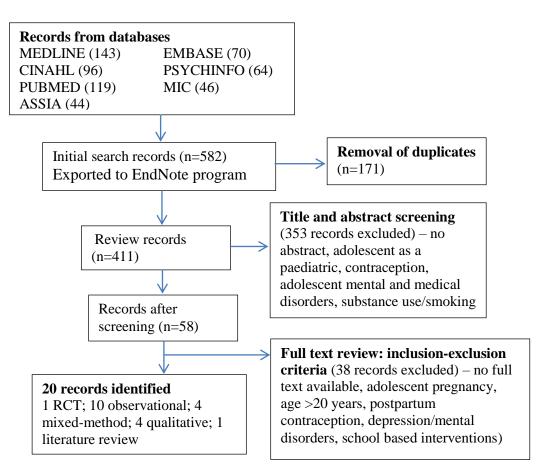


Figure 2.1: Studies included from the needs assessment search strategy

2.8 Summary and quality appraisal of search 1 literature

The aim of this review was to identify the needs of young mothers during the postnatal period. In total, 20 articles met the inclusion criteria. Of these, one study was a randomised controlled trial, 10 were observational studies, four were of mixed methods design, another four were qualitative, and one literature review. Most of these studies were from high income settings: mainly from the US (10) and the UK (3), with a single study each from Canada and Sweden. Only four studies were from low-income and middle-income settings: one study each from Uganda and Lesotho (low-income); and from Brazil and South Africa (middle-income). Overall, most of the studies were of moderate quality based on Hawker's quality assessment checklist, with the quality scores ranging from 24-30. Some of the studies scored low points due to poor methodological procedures and ethical/consenting procedures which were not

adequately described. In addition, several studies did not highlight the study limitations and how they addressed potential biases and confounders. The studies are described below according to their methodological designs.

2.8.1 Randomised controlled trial

The paper by Wambach et al. (2011) was generally of good quality, owing to its rigorous theory-based interventional design and analyses consistent with the outcome measures. In assessing the effect of an education and counselling intervention on breastfeeding initiation and duration among primiparous adolescent mothers (n=390), a 3-arm interventional study (experimental -n=128, and 2 control groups – usual caren=134, and attention control - n=128) was conducted, with the attention control group being used to control for unspecified effects of the intervention. The intervention comprised of prenatal, in-hospital, and postnatal education and support through 4 weeks postpartum, with an educational content from a Breastfeeding Educated and Supported Teen Club curriculum. Lactation-consultant hospital visit and peer counsellor telephone calls were also provided up to 4 weeks postpartum for the experimental group. Attention control participants also received similar intervention as experimental group but only differed on the amount of content and timing, and did not focus on breastfeeding. Both groups were however required to attend at least one class to continue participating in the study. The usual care group received standard prenatal and postnatal care at their respective clinics, with no limitations placed on the level or content of care. However, this study had high attrition rates, with a follow up sample of 77, 64, and 60 for experimental, usual care and attention control groups respectively at the time of hospital discharge. Together with the other reported limitations, the study results were of limited generalisability. Moreover, this was a non-blinded intervention, hence interventional biases were possible as participants were not blinded to the interventions. The study, however, generated useful information with clinical and research implications in the future. Overall, this study was of moderate quality (score=26).

2.8.2 Observational studies

Of the 10 studies, four were longitudinal in nature (Apostolakis-Kyrus, 2013, Sipsma et al. 2013, Angley et al. 2015, and Bailey et al. 2008), with two (Apostolakis-Kyrus, 2013 and Bailey et al. 2008)) also being comparative. In her retrospective populationbased study, Apostolakis-Kyrus (2013) compared factors influencing breastfeeding initiation among mothers ≤ 19 and those >19 years, while Bailey et al. (2008) compared psychological factors influencing breastfeeding duration among mothers aged 16-24 years and 25-40 years respectively. Of the remaining 6 studies, 3 others were also comparative (Wahn and Nissen, 2008, Atuyambe et al. 2008 and Yako, 2007). While Atuyambe et al. (2008) studied health seeking behaviour of primiparous adolescent mothers aged 13-19 in relation to adult mothers aged 20-29 years, Wahn and Nissen (2008) dwelt on socio-demographic characteristics and perception of health among mothers aged 15-19 and 25-29 years respectively. Yako (2007) on the other hand drew comparison between three adolescent groups in the 15-19 years age bracket (married, and unmarried adolescent mothers; and non-pregnant adolescent high school students) on perceived stress levels. The remaining three were general descriptive studies (Venkatesh et al. 2014, De Vito, 2007 and Howard, 1985).

Most of these studies were of moderate quality. The range of the quality scores was between 24 and 29. However, notable shortcomings in the studies included: inadequate description of consenting process, data collection procedures and data analysis, and the use of convenience sampling in participant selection. For instance, most of the studies exhibited at least one of the following shortcomings: omission/insufficient description of consenting process and other ethical considerations, considering the fact that the population under study included minors; inadequate sampling procedures including sampling by convenience; inadequate description of data collection procedures/process and tools, variable/outcome measures and data analyses applied, including omission. Additionally, with the cross-sectional design of some of the studies, some variables or outcome measures that need to be observed over time (which could be achieved through longitudinal study designs) also hinder the external validity of the results. However, longitudinal studies have to grapple with the risks of large attrition rates, which may limit the end-point sample sizes, thereby limiting generalisation of the results. With these shortcomings, the validity/credibility of results would be largely affected. Consequently, the transferability/generalisability of the results would be limited. Researchers therefore need to explicitly describe all study procedures to a reasonable minimum standard to enhance methodological rigour and applicability of the results.

2.8.3 Mixed-method studies

Overall, the four mixed-method studies (Monteiro et al. 2014, Tucker et al. 2011, Smith and Roberts, 2009, and Spear, 2006) were of moderate quality, with total quality scores ranging between 26 and 27. However, some studies had a few methodological issues. Although Monteiro et al. (2014) provided descriptive data (collected data from a national survey database), the study would have generated further useful information if inferential statistics were applied. However, perhaps the survey-nature of the source of data limited this. From the text, the qualitative component of the other three studies suggested that they were not well carried out, with only one study (Tucker et al. 2011) demonstrating rigour as the study was reportedly conducted with grounded theory principles and constant verification with research team.

2.8.4 Qualitative studies

Four studies (Nesbitt et al. 2012, Duggan and Adejumo, 2012, DeVito, 2010 and Cronin, 2003) were qualitative in nature, with three being specifically designed

qualitatively, while one (DeVito, 2010) was a secondary analysis of narrative comments from the author's previous study (DeVito, 2007). In general, the quality of the studies ranged from moderate to high (score range =25-30). Only one study (Nesbitt et al. 2012) was of high quality (score=30) owing to its methodologically rigorous principles hinged on the tenets of qualitative research, including sampling, data collection and analysis procedures.

The other three studies (Duggan and Adejumo, 2012, DeVito, 2010, and Cronin, 2003) were of moderate quality, most of which had fairly good description of sampling and analysis procedures. Overall, these studies generated rich data regarding young mothers' needs, perceptions and experiences of maternal care and parenting, and their expectations from the health care systems. For instance, the studies identified cross-cutting themes of lack of sufficient information, the conflicting advice from midwives/nurses, and the significant role of other support persons to the adolescent/young mothers.

2.8.5 Literature review article

The single review by Grassley (2010) identified 18 studies that were included in the review out of a search result of 51, searched between 2000-2009 from two databases (MEDLINE and CINAHL). Although the author stated the search terms, the inclusion-exclusion criteria of the search were not explicitly described. Moreover, it is not clear what search strategy was used, but seemingly a systematic approach was adopted. The author, however, presented a summary of the articles included in the review, which lends more credence to the quality of the review. However, the review was only limited to two databases, thus limiting the number of studies that would have potentially been identified and included in the review. In general, this review identified five thematic areas of support needs or forms of support (informational, instrumental, emotional, appraisal/esteem support and network support) for adolescent/young mothers; and

further proposed the need for health systems to consider integrating such aspects in the provision of care. This review had a moderate rating in quality (score=25).

2.9 Conclusion (search 1)

In conclusion, all the studies from this search were relevant to the subject area (needs for young mothers). As such, the studies highlighted key areas of adolescent/young mothers' needs, ranging from breastfeeding support to parenting. The summary of the quality scores of the included studies is presented in Table 2.3. Further information on the critical review of the individual studies and their quality assessment scores is presented in Appendix 2.4 and Appendix 2.5 respectively.

Author/Year	Study population	Sample size	Design	Score
	Randomised controlled			
Wambach et al.	Adolescent mothers	N=289	RCT	26
2011, USA	(Primiparous)	(Exp=128)	(prospective, non -	
	15-18 years	(C1=128)	blinded,	
		(C2=134)	3-group –	
			intervention and 2	
			controls)	
	Observational/cross-sec	tional studies		
Angley et al. 2015	Adolescent mothers	n=231 couples	Longitudinal study	29
Connecticut,	14-21 years	*		
USA	and their partners (>14			
	years)			
Apostolakis-Kyrus	Adolescent mothers	N=288,142	Retrospective	28
K. 2013	≤19 years	[≤19 years	population-based	
Ohio, USA	(Reference group >19	n=30,402;	cohort study	
	years)	>19 years		
		n=257,840]		
Atuyambe et al.	Adolescent (13-19	N=762	Cross sectional	27
2008	years) and adult (20-29	[442; 320]	design	
Uganda	years) mothers			
Bailey et al. 2008	Postnatal mothers	N=145	Longitudinal study	24
UK	(16-24 years) and		in 3 phases	
	(25-40 years)			
Howard S.J. and	First-time adolescent	N=66	Cross sectional	24
Sater, J. 1985	mothers		descriptive survey	
Southern	≤ 18 years			
California, USA				
DeVito 2007	Adolescent mothers	N=126	Cross sectional	28
New Jersey,	13-19 years		(Descriptive	
	•			1

<u>Table 2.3: Quality scores of included studies – search 1 (postnatal needs of young mothers)</u>

correlational)

USA

Sipsma et al. 2013	Adolescent couples	N=296	Longitudinal cohort	29
Connecticut, USA	(14-21 years)	N=290	study	29
Venkatesh et al.	Primiparous	N=106	Secondary	28
2014	adolescents	11-100	observational	20
USA			analysis of an RCT	
Wahn, E. H. and	Teenage mothers	N=97	Descriptive	25
Nissen, E. 2008	(15-19 years) and adult		comparative study	
Sweden	mothers		I	
	(25-29 years)			
Yako, E. 2007	Adolescents	N= 192	Cross sectional	24
Lesotho	(15-19 years)	[64 per group-	comparative and	
	•	married,	descriptive design	
		unmarried and	3 groups	
		non-pregnant		
		adolescents]		
	Mixed-methods studies			
Monteiro et al.	Adolescent mothers	(n=229)	Mixed methods,	26
2014	<19 years	Qual: semi-	cross sectional	20
Brazil		structured	study	
DIazii		interview(n=10)	2 phases	
Smith, D.M. and	Young parents	Quant: (n=47)	Mixed methods,	27
Roberts, R. 2009	<22years	Qual: 2 FGDs	cross sectional	21
UK (England)		(n=10; 5,5)	study	
Spear, H.J. 2006,	Adolescent mothers	N=53	Cross sectional	27
USA	14-19 years	11-55	descriptive survey	27
			Mixed method	
Tucker et al.	Adolescent mothers	Quant - n=389	Mixed methods	26
2011,North	≤ 17 years	Qual n=20	study	
Carolina, USA				
	Qualitative design artic	log		
Cronin, C. 2003	First-time mothers	N=13	Qualitative design	25
Ireland, UK	<20 years	19-13	Quantarive design	23
DeVito 2010	Adolescent mothers	N=126	Qualitative design	27
New Jersey,	<19 years	11-120	(Secondary analysis	21
USA	(1) years		of narrative	
CON			comments)	
Duggan, R. and	Adolescents	N=18	Qualitative design	26
Adejumo O. 2012	12-19 years		Camilian to doorgin	
South Africa				
Nesbitt et al. 2012	Adolescent mothers	N=16	Qualitative design	30
Canada	15-19years		(descriptive)	
	Literature review artic			
Grassley, J. S.	Adolescent mothers	18 articles	Literature review	25
2010		included in the	CINAHL	23
2010		review	MEDLINE	
			Databases	
	L	1	Datababbb	I

2.10 Search strategy 2: Interventional studies on telephone support in maternity care

2.10.1 Inclusion-exclusion criteria for search 2 strategy

Initially, the review sought to target studies with similar population characteristics (12-19 years) or with a mean age within this age bracket or the upper limit (mean age=19 years) but this was not feasible since only two papers recruited participants over 16 years. The inclusion-exclusion criteria thus had to be redefined. The inclusion criteria focused mainly on primary research studies but were not limited to any particular research design to allow for rich data from diverse methodological designs. In addition, the search was not limited to any particular time period.

The inclusion criteria for this search were:

- Telephone-based intervention during the postnatal (including the immediate postnatal) period.
- Papers reporting at least one mother/infant outcome of interest.
- English language or available translation.
- Peer reviewed articles.

The exclusion criteria were:

- Telephone based interventions for non-pregnant adolescents and outside maternity care.
- Telephone-based intervention for special or high risk postnatal mothers (caesarean birth, mental illness, and infant admission to the special care unit).
- Non-telephone based interventions for adolescents or adolescent mothers.
- Telephone-based RCT protocols (ongoing trials).

The following keywords, as presented in Table 2.4 were used to manage the search.

Table 2.4: Search strategy for review2

Parameter	Search terms
Population	Teen* mother*OR teen* parent* OR adolescen* mother* OR
	adolescen* parent* OR young wom?n OR teen* m?ms
Intervention	Telephone OR cellular phone OR mobile phone OR
	telemedicine OR short message service* OR SMS OR text
	messag* OR telephone hotline
Comparator	Usual care
Outcome(s)	Maternal health wellbeing OR maternal self-esteem OR maternal
	self-efficacy OR postpartum depression OR puerperal infection
	AND breastfeeding OR infant feeding OR infant wellbeing OR
	infant weight gain OR immuni?ation OR mother-infant relations
	OR newborn care OR infant care

2.10.2 Search strategy 2 results

Figure 2.2 outlines the summary of the search process. In total, the search yielded 322 eligible papers, which were exported to EndNote program upon which duplicates (n=67) were removed. Further screening by abstract and title removed 201 articles. Most of the studies were disqualified because of the contextual setting of the intervention (i.e. outside the postpartum period) and unrelated outcome(s) of interest. Thirty-seven records were further excluded by full-text review mainly due to context of the studies (specialised areas of care, telephone-based pMTCT intervention), including one article (Jang et al. 2008) that, although an abstract was available in English, full text was only available in Korean language. To enhance chances of inclusion, at least one outcome of interest was considered from either maternal or infant care domains since few studies had at least both maternal and infant outcomes reported in the same study. A total of 17 articles met the stipulated criteria and were subjected to complete process of critical appraisal using the Hawker's critical appraisal checklist (Hawker et al. 2002).

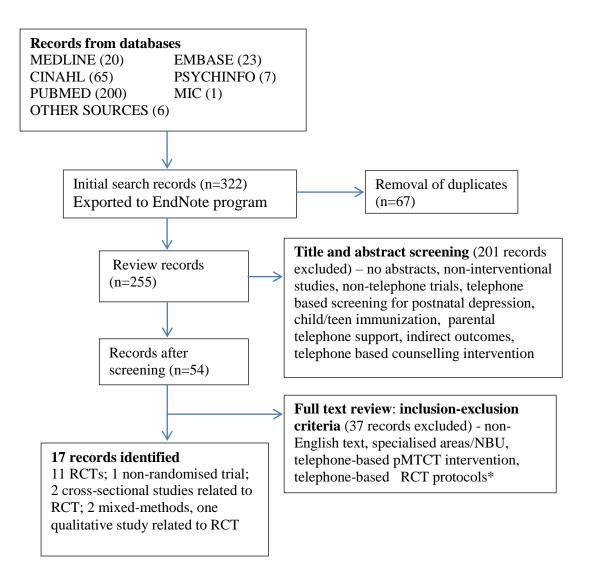


Figure 2.2: Studies included from the interventional search strategy

2. 11 Summary and quality appraisal of search 2 literature

In total, 17 articles met the inclusion criteria. Of these, 11 were randomised controlled trials, one was a non-concurrent comparison trial, two were cross-sectional studies related to RCTs, two were of mixed methods design, and one was a qualitative study related to an RCT. Most of the studies were also from high-income settings: US – (5 RCTs); Australia (2 – an RCT and a non-comparative trial); Canada (4 – two RCTS and two mixed-methods); middle income: Malaysia (an RCT); Lebanon (3 – an RCT and two cross-sectional); Singapore (qualitative); and low-income: Africa (Zimbabwe) – an RCT. In general, all the RCT studies were of moderate quality based on Hawker's quality assessment checklist, with a quality range score of 23-28. A summary of the

critical appraisal and the quality assessment scores of the included studies is presented in Appendix 2.6 and Appendix 2.7 respectively.

2.11.1 Randomised controlled trials

Although most of the RCTs were explicit in reporting the outcome measures of the studies and the analyses thereof, most lacked methodological rigour. As such, they scored relatively low in this respect. Overall, all the trials were of moderate quality with quality scores ranging from 23-28. For instance, three trials (Hannan, 2013, Bangure et al. 2015 and Pugh et al. 2002) did not adequately describe group assignment and blinding procedures. Since methodological procedures have key implications on RCTs, particularly on risks of biases, this may have increased the likelihood of bias and limitations in these studies. In addition, most of the trials used validated tools in data collection, with the exception of two studies (Bangure et al. 2015 and Pugh et al. 2002), which were not explicit on their data collection procedures and whether the tools used were piloted or validated.

One trial (Bunik et al. 2010) included a qualitative component, although the methodological rigour of the qualitative component was low. For instance, the data were collected using telephone interviews and thus other useful data related to the mothers' experiences and perceptions of the intervention may have been missed out. Notably, qualitative research is not only concerned on the data collection per se, but also about the process. This lends much credibility to the data as other aspects such as non-verbal cues are taken into account. This study also had unequal randomisation of groups (161 vs 180) suggesting differential attrition. Only one trial (Di Meglio et al. 2009) assessed the effect of breastfeeding support on breastfeeding outcomes among adolescent/young mothers, unlike most of the other studies which focussed on adult mothers. However, it is important to note that this study was conducted over a decade

ago from the time of publication and thus the results may have been overtaken by changes over time, especially on m-Health interventions.

2.11.2 Non-randomised trial (non-concurrent comparative trial)

The study by Gallegos et al. (2014) was intended to be a randomised controlled trial but due to overwhelming response by eligible participants, this was reportedly not feasible due to ethical issues. Before enrollment into the study, eligible participants were sensitised through the media and thus many turned up and were willing to participate in the intervention. As such it was considered unethical to assign a control group under the prevailing circumstances. The study was of moderate quality (score=27). Sampling, group assignment and data analysis procedures were not explicitly described. Together with the long time lapse between groups, many confounders may have been likely. However, besides the potential effect of TSI on breastfeeding, the study also assessed the potential effect of the intervention on perceived coping, with the results also suggesting positive outcomes (effective coping was reported among participants in the intervention group).

2.11.3 Mixed-methods studies

Two studies (Dennis, 2010, 2002) assessed maternal perceptions of peer telephone support and, maternal and peer volunteer perceptions of their experiences respectively while participating in an intervention. These studies were generally of good quality methodologically and in the reporting of outcomes, with good analytic procedures in both designs independently. The findings reveal both groups (the mothers and peer volunteers) being satisfied with the interventions. Both studies also highlight some of the challenges experienced during the interventions.

2.11.4 Cross-sectional studies

Both cross-sectional studies were conducted in Lebanon (a middle-income country). One study (Hamade et al. 2013) employed fairly appropriate measures and analyses of outcomes including sampling procedures. Overall the study was of moderate quality (quality score=28). The study assessed breastfeeding prevalence in Beirut and highlighted the independent factors that influenced exclusive breastfeeding such as age, mode of birth, employment status, income, infant health status, gestation age, intention to breastfeed and source of support.

The other study (Osman et al. 2010) was of poor quality due to poor methodological procedures and reporting. The study tested the feasibility of using telephone as an intervention in an RCT and the use of an algorithm to address parental concerns through a telephone hotline. The algorithms were designed based on the existing scientific evidence from medical journals and textbooks, and expert opinions to allow the midwife to respond to questions raised by the mothers in a consistent manner. Although the inclusion-exclusion criteria were adequately described, consenting, sampling, data collection and inaccurate analytical procedures adversely affected the quality of the study. For instance, despite stating the use of Chi-square and T-tests, it is not evident in the study how/where they were applied (no associations between the variables are described/reported), including stating the use of the T-test for qualitative data analysis. Overall, the paper had a score of 17. Despite the lack of methodological rigour, this study was included in the review since it contributes useful information on the topical areas of concern experienced by first-time mothers, and the appropriate timing of their dissemination with regard to the felt needs through the continuum of postnatal period.

2. 11.5 Qualitative studies

One study (Shorey et al. 2015) employed a qualitative approach to evaluate a postnatal psycho-education programme provided in a previous RCT. This study applied

appropriate qualitative research principles (testing and validation of research tools by experts, independent coding of themes and consensus discussion of emergent themes, and observation of ethical issues) which, besides enhancing rigour in the study, also contributed rich data pertaining the (processes in the) intervention. Overall, the study had a quality score of 29. Additionally, the findings highlight the expectations of postnatal mothers of the health care systems, including health professionals' attitudes.

2.12 Conclusion (search 2)

In conclusion, most of the studies included in this search were of moderate quality, with only one study (Osman et al. 2010) which was of poor quality due to its methodological shortcomings. None of the papers were of good quality. The summary of the quality scores is presented in Table 2.5.

Author/Year	Study population	Sample size	Design	Score
Randomised controlle				
Bunik et al. 2010	Primiparous	N=341	RCT	26
Denver, Colorado	low income women	[I=161]	(2-arm)	
USA	(Pred.Latina) - >18years	[C=180]		
Hannan, J. 2013	Primiparous mothers	N=139 [I-70; C-69]	RCT	25
South Florida (USA)	>18 years		(2-arm)	
Di Meglio et al. 2009,	Adolescents	N=78 [I-38; C-40]	RCT	26
USA	<20years		(2-arm)	
Pugh et al. 2010	Postpartum mothers	N=328	RCT	26
Maryland, USA	(Low income)	[I-168; C-160]	(2-arm)	
	[Pred. young- mean=23		, , ,	
	yrs]			
Pugh et al. 2002	Postpartum mothers	N=41 [I-?; C-?]	RCT	23
USA	Low income (mean =21yrs)	Numbers allocated to group unknown	(2-arm)	
Giallo et al. 2014	Postpartum mothers	N=202	RCT	26
Australia	>18 years	[I1-63; I2-67; C-72]	(3-arm)	
Dennis et al.2002	Primiparous women	N=252	RCT	27
Toronto, Canada	≥16 years	[I-126; C-126]	(2-arm)	
Dennis et al.2009	Postpartum women	N=701	RCT (2-	28
Ontario, Canada	(High risk of PND) -	[I-293; C-293]	arm)	
	>18yrs		multisite	
			study	
Tahir and Al-Sadat	Postpartum mothers	N=304	RCT	27
2013, Malaysia	>18 years	[I-152; C-152]	(2-arm)	

Table 2.5: Quality scores of included studies – search 2 (TSI)

Osman et al. 2014	All primiparous mothers	N=452	RCT	27
Beirut, Lebanon		[I1-127; I2 –121;	(4-arm)	
		I3 -101; C-103]		
Bangure et al. 2015	Woman or care giver	N=304	RCT	25
Zimbabwe	>18years	[I=152; C=152]	(2-arm)	
	ls (Non concurrent comparise	on trial)	-	
Gallegos et al. 2014	Postpartum mothers	N=234	A non-	27
Australia	>18 years	(I-120)	concurrent	
		(C-114)	comparative	
			trial (2-arm)	
Observational/cross-				
Dennis, C-L., 2010	Postnatal mothers	N=701	Cross-	28
Canada	>18 years	[n=293 per arm]	sectional	
			survey	
			[*RCT]	
Dennis, C-L., 2002	Primiparous breastfeeding	N=252	Cross-	26
Canada	mothers ≥16 years	[I-126; C-126] and	sectional	
		30 peer volunteers	survey	
			[*RCT]	
Hamade et al. 2013	All primiparous mothers	N=751	Longitudinal	28
Beirut, Lebanon			study	
			[*RCT]	
Osman et al. 2010	All primiparous mothers	N=353	Descriptive	17
Beirut, Lebanon			cross	
- 7			sectional	
	1			1
Qualitative studies				
Shorey et al. 2015	Postnatal mothers	N=18	Descriptive	29
Singapore			qualitative	
- 1			[*RCT]	

*Studies related to RCTs.

2.13 Synthesis of findings

The findings of the included studies in the two structured narrative reviews were synthesised using an integrative narrative approach. Key topical areas of support needs for young mothers were identified and the potential effect of supportive interventions in maternity care, including telephone support interventions were examined. The literature findings are presented under physical needs and wellbeing; informational needs; social support needs related to breastfeeding and psychological wellbeing, including postnatal depression; and maternal competence.

2.13.1 Physical needs/wellbeing

A number of the studies reported adolescent mothers being socio-economically disadvantaged (Wambach et al. 2011, Apostolakis-Kyrus, 2013, Angley et al. 2015, Wahn and Nissen, 2008), thereby being at a disadvantage in affording health care and in health decision-making. This may be attributed to a low level of education, which has an effect on employability and income status among such vulnerable populations.

In a longitudinal study comparing health-seeking behaviours between adolescent and adult mothers in Uganda, only about a half of the adolescent mothers had attained secondary level of education; adolescent mothers were one and a half times more likely to attend less than the four recommended ANC visits, and to delay initiating breastfeeding compared to adult mothers (Atuyambe et al. 2008). Consequently, this puts them and their babies/infants at a considerable health risk right from pregnancy to the postnatal period.

However, randomised controlled trials on telephone support have demonstrated improved health outcomes for both the mother and their infants (Hannan, 2013; Bangure et al. 2015; and Pugh, 2002). Infants reportedly had fewer sick visits and less use of medications in intervention groups (Hannan, 2013; Pugh, 2002). While assessing the effectiveness of short message service on immunisation coverage in Zimbabwe following a change of the immunisation programme, Bangure et al. (2015) found a significant uptake of immunisation at 6,10 and 14 weeks following birth, and reported that the intervention was widely acceptable and cost-effective. Interestingly, this was the only trial identified in this review that was conducted in Africa. Therefore, further interventional studies are necessary in such low-income settings in order to clearly demonstrate the effects of such novel interventions, particularly in maternity care.

2.13.2 Informational needs

Several studies highlighted the need for supportive health education among young mothers (Apostolakis-Kyrus, 2013, Duggan and Adejumo, 2012, Nesbitt et al. 2012; Smith and Roberts, 2009; Spear, 2006; Cronin 2003; Howard and Sater, 1985). More importantly, the significant effect of education on health care decision-making cannot be overstated. Possibly, the decision whether to attend antenatal and postnatal care (or any other medical appointment), including engaging in positive health practices or not may largely be influenced by an individual's level of education. It is instructing to note that adolescent mothers were more likely to attend fewer antenatal visits than the recommended, and to delay initiating breastfeeding compared to adult mothers (Atuyambe et al. 2008).

With low level of education and the reportedly low attendance to antenatal care among adolescent mothers (Apostolakis-Kyrus, 2013, Spear, 2006), it is not surprising that young mothers were at odds in terms of health information and decision-making. However, few of these studies explored in depth the interplay between extrinsic factors influencing knowledge acquisition among young mothers, other than the most obvious and likely reasons related to socio-demographics such as education level, age, and income. Such an inquiry would provide a deeper understanding of the issues surrounding young motherhood as far as their informational or health education needs are concerned.

In a cross-sectional study of 53 adolescent mothers, assessing breastfeeding experiences and behaviours of adolescent mothers, Spear (2006) noted that only two (3.8%) of the mothers had attended ANC classes, and that majority lacked information about breastfeeding. Similarly, it was reported that young mothers rarely attended postnatal classes (Smith and Roberts, 2009). With their limited attendance of antenatal and postnatal classes, most young mothers consequently lacked sufficient information that would have enhanced their decision-making and their skills and/or competence in motherhood. While investigating young parents' individual needs during the antenatal and postnatal period, Smith and Roberts (2009) cited age, gender and self-esteem as the most influential factors on young parents' attendance to support services, with self-esteem being significantly associated with ANC attendance.

In addition, in a qualitative study assessing the facilitating influences and barriers to initiation and duration of breastfeeding among adolescent mothers, Nesbitt et al. (2012) also identified the negative influence of informal groups such as peers and family members, who often may mis-advise mothers based on their own previous negative experiences with breastfeeding. Moreover, young/adolescent mothers reported having received conflicting advice from nurses/midwives (Nesbitt et al. 2012, Spear, 2006 and Cronin, 2003), which may also have contributed to their lack of information.

Young/adolescent mothers' lack of knowledge may therefore be attributed to a range of complex and multiple factors that need to be addressed. For instance, while providing supportive health education and practical skills on maternal and infant care, health care providers should explore the context in which the adolescent mothers operate or live in, and strive to provide consistent and evidence-based information to avoid conflicting communication which renders mothers confused. Health care systems also need to devise appropriate strategies of disseminating health information to young mothers that meet their individual needs. For example, regarding breastfeeding doctors and nurses/midwives need to give more information about how good it is to breastfeed and reinforce the benefits (Spear, 2006, pp.110).

Additionally, poor health-seeking practices and behaviours were reported among young/adolescent mothers (Atuyambe et al. 2008, Duggan and Adejumo, 2012). Health care system factors such as negative staff attitudes, non-friendly settings, and

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conflicting advice from nurses/midwives (Nesbitt et al. 2012; Spear, 2006; Cronin, 2003; Yako, 2007; Smith and Roberts, 2009) and stigma (Smith and Roberts, 2009; Atuyambe et al. 2008) have also been cited as factors hindering knowledge or information on health issues among young/adolescent mothers. These factors may be mediating a significant effect on behaviours and practices displayed by the young/adolescent mothers, including seeking health information. Several studies reported that young/adolescent mothers' perceived nurses/midwives as judgemental (Duggan and Adejumo, 2012, Smith and Roberts, 2009), while doctors were reportedly perceived as having no time for them (Smith and Roberts, 2009, Spear, 2006):

'My midwife was really old, she called me a baby..' (mother, age 20)...... '.... have a 10-minute slot and they're like "hurry up"...' (mother, age 19) (Smith and Roberts, 2009, pp.624).

Arguably, these may be potential systemic barriers to access and utilisation of health services by young/adolescent mothers, with the attendant consequence of limited or lack of knowledge or information regarding MIC practices, including reproductive health information. Interestingly, Howard and Sater (1985) identified the same issues related to lack of information over three decades ago.

2.13.3 Breastfeeding support

Breastfeeding remains one of the critical areas of support in maternity care, particularly for young mothers. In this review, this aspect was explored by several studies (Tucker et al. 2011; Sipsma et al. 2013; Monteiro et al. 2014; Apostolakis-Kyrus, 2013; Nesbitt et al. 2012; Yako, 2007; Hamade et al. 2013; Osman et al. 2010, Grassley, 2010; Atuyambe et al. 2008; Dennis, 2000), including nine trials (Bunik et al. 2010; Di Meglio et al. 2009; Dennis et al. 2002; Tahir and Al-Sadat, 2013; Pugh et al. 2010, 2002; Gallegos et al. 2014 and Wambach et al. 2011). Only two of these trials specifically studied the adolescent population (Wambach et al. 2011; Di Meglio et al. 2009). Young/adolescent mothers expressed difficulties in breastfeeding, citing pain,

engorgement, difficulty in latching and insufficient breastmilk as the main reasons inhibiting them from breastfeeding (Tucker et al. 2011; Monteiro et al. 2014; Yako, 2007), and to delay initiation of breastfeeding (Atuyambe et al. 2008).

In a longitudinal cohort study of adolescent mothers and their partners (n=289), the perception of breastfeeding difficulty was found to be a strong predictor of exclusive breastfeeding, with greater social support being associated with lower odds of breastfeeding (Sipsma et al. 2013). Similarly, a retrospective population-based study in the US, (Apostolakis-Kyrus, 2013) found that adolescent mothers were less likely to breastfeed, and even reported lower rates (24%) among the younger (less than 15 years) adolescent mothers compared to adult mothers. The author attributed this to low socio-economic status, limited social support and marital status (being single) among the adolescent mothers.

Social support from the health care system, family and peers was also found to be a key aspect in young motherhood. In a cross sectional study of adolescent mothers below 17 years, Tucker et al. (2011) noted that health care worker support, family support and having a family member who breastfed were positive influences to breastfeeding initiation. Similarly, in their explorative study examining the facilitating influences and barriers to initiating and continuing breastfeeding during postnatal period among adolescent mothers aged 15-19 years, Nesbitt et al. (2012) identified several factors influencing maternal decision to continue breastfeeding. These included; the impact of breastfeeding on intimate relationship, the availability of social support, physical demands of breastfeeding, and mother's perceived sense of comfort in breastfeeding (Nesbitt et al. 2012). Such issues, therefore, need to be accorded due consideration when addressing breastfeeding needs of young/adolescent mothers.

Moreover, it is noteworthy that the intention to breastfeed was significantly associated with breastfeeding initiation (Sipsma et al. 2013; Wambach et al. 2011). In a 3-arm prospective, randomised non-blinded trial on lactation counselling intervention, breastfeeding knowledge, prenatal intention to breastfeed, the timing of the breastfeeding decision (either before pregnancy, during the first trimester, during the second or the third trimester), and social and professional support were identified as significant predictors of breastfeeding initiation (Wambach et al. 2011). Similarly, in another trial on adolescent mothers, peer telephone support appeared to have an effect of prolonging 'exclusive breastfeeding' (Di Meglio et al. 2009). However, it is important to note that these trials had methodological limitations including attrition, self-reporting of data, and participation bias, and hence were not conclusive.

Furthermore, interventional studies on telephone support have largely targeted adult mothers (Bunik et al. 2010; Dennis et al. 2002; Tahir and Al-Sadat, 2013; Pugh et al. 2010, 2002; and Gallegos et al. 2014). These trials reportedly demonstrated a positive effect of telephone support on breastfeeding, but the evidence was not conclusive. An evaluation of maternal perceptions of peer telephone support on breastfeeding revealed that most of the mothers were satisfied with the intervention, stating that it helped them to achieve their breastfeeding goals (Dennis, 2000). The need for further interventional research is therefore imperative, particularly among young/adolescent mothers.

Although young/adolescent mothers cited the benefits of breastmilk on the health of their infants as a primary motivating factor to breastfeeding (Nesbitt et al. 2012, Monteiro et al. 2014), most of them never practised breastfeeding optimally (Monteiro et al. 2014). The adolescent mothers cited lack of knowledge about breastfeeding norms and practices, and incidences where conflicting information regarding breastfeeding was provided by nurses/midwives (Nesbitt at al. 2012), which may be considered as

additional barriers to effective breastfeeding. Negative breastfeeding experiences from peers were also discouraged adolescent mothers from breastfeeding (Tucker et al. 2011), yet much concerns about breastfeeding were commonly raised during the immediate postnatal period, especially by primiparous mothers (Osman et al. 2010).

Additionally, a review that included 18 studies examining the aspects of social support that adolescent mothers needed from nurses when initiating breastfeeding in early postpartum also highlighted the importance of postnatal support for (young) mothers (Grassley, 2010). Grassley (2010) identified five key areas of support; informational, instrumental, emotional, appraisal and network support, noting that such domains of support provide a framework for defining supportive healthcare provider behaviours. The author (Grassley, 2010) further noted that for nurses to provide appropriate and effective breastfeeding support to adolescent mothers, they needed to examine the adolescent mothers' attitudes about breastfeeding. The review concluded that nurses (and midwives) needed to integrate the five forms of support in their provision of care to enhance positive experiences in breastfeeding among the adolescent mothers. In view surrounding breastfeeding behaviours the issues and practices among of young/adolescent mothers, it is evident that salient issues that need to be addressed still exist, including the need for further research in order to provide evidence-based care to such vulnerable population groups.

2.13.4 Stress, postnatal depression and social support

Four trials (Osman et al. 2014; Giallo et al. 2014; Hannan, 2013, and Dennis et al. 2009) and five observational/cross sectional studies (Angley et al. 2015; Venkatesh et al. 2014, Yako, 2007; Wahn and Nissen, 2008, and Dennis, 2010) highlighted this aspect of maternal health and wellbeing. Although most young/adolescent mothers reported their families being supportive during pregnancy, those with postpartum depression

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(PPD) had significantly higher scores for total parenting stress, parental distress, parentchild dysfunction and a difficult child, with total parenting stress being a significant predictor of PPD (Venkatesh et al. 2014).

Unlike many cross sectional studies which measure variables at one point in time, this study (Venkatesh et al. 2014) attempted to measure and draw a causal relationship between parental stress and PPD using rigorous longitudinal analytic techniques. In addition, the study used a validated screening tool other than the reliance of self-reported measures of depression, which arguably enhances the validity of the results.. The study also reported that the previous trial (related to this study) had a protective effect against developing PPD but not on parental stress (Venkatesh et al. 2014). This study, therefore, highlighted the temporal association between parental stress and PPD.

Similarly, a longitudinal study of adolescent mothers and their partners (n=231 couples) explored the association between social support, family functioning and social capital on parenting competence, self-efficacy and satisfaction (Angley et al., 2015). In this study, Angley et al. (2015) found that Actor social support, Actor family functioning and partner family functioning were associated with decreased levels of depression, with lower levels of depression being significantly associated with greater parental satisfaction and self-efficacy.

In a descriptive comparative study in Sweden, teenage mothers had lower self-esteem and more depressive symptoms than adult mothers (Wahn and Nissen, 2008). Additionally, it was noted that most of the teenage mothers had experienced physical and psychological violence than the adult mothers before pregnancy (often perpetrated by friends and family other than the partner), and that they were more likely to have been exposed to difficult family situation and to have had school failure (Wahn and Nissen, 2008). The teenage mothers were also more likely to engage in risky behaviours than adult mothers. These manifestations clearly outline the social predicaments and vulnerability of young/adolescent mothers, who are at a greater psychosocial risk (which may predispose them to depression and risky behaviours). Consequently, such factors may negatively impact on young/adolescent mother's own health and wellbeing and that of their infants, including their coping mechanisms with parenthood.

While comparing perceived stress in general, stress due to pregnancy, and postpartum complications between married and unmarried first-time adolescent mothers, and non-pregnant adolescents, Yako (2007) also found that both groups of adolescent mothers had significantly higher levels of perceived stress compared to the non-pregnant adolescents. This finding is instructing since pregnancy and motherhood are by themselves potential stressors in life, yet it is commonly regarded as normal, thereby denying mothers an opportunity for a well-deserved social support.

However, in spite of the challenges associated with young motherhood, the evidence from the trials on telephone support intervention suggested a promising opportunity to offer supportive maternity care. The randomised controlled trials on TSI aimed at psychological wellbeing demonstrated a potentially positive effect on psychological outcomes, particularly in the prevention of stress and postnatal depression (Osman et al. 2014; Giallo et al. 2014; Hannan, 2013, and Dennis et al. 2009). In addition, mothers who received such interventions reported great satisfaction and they recommended its use (Dennis, 2010). With the promising results, however, it is important to note that most trials targeted adult mothers, and were conducted in high-income settings hence their effect among the young/adolescent mothers remains vague, especially in LMICs settings.

2.13.5 Parenting competence among young mothers

Parenting among the young/adolescent mothers was highlighted in four studies (Angley et al. 2015; Bailey et al. 2008; DeVito 2010, 2007). Adolescent mothers exhibited low breastfeeding self-efficacy, self-esteem and general self-efficacy compared to the older mothers (Angley et al. 2015). Conversely, parenting self-efficacy was strongly correlated with breastfeeding (Bailey et al. 2008). Angley et al. (2015) further argued that greater social support and higher family functioning were associated with higher parenting self-efficacy and satisfaction, with a greater partner family functioning being significantly associated with parenting satisfaction.

Similarly, DeVito (2007) noted that social support received by the adolescent mothers, especially from the maternal mother had influence on the adolescent mother's self-perception of parenting and observed that older adolescent mothers (18-19) had a more positive perception of parenting compared to the younger adolescent mothers. However, the study reported that there was no significant relationship between overall levels of social support and self-perception of parenting (DeVito, 2007). It is noteworthy that this study assessed some of the factors influencing self-perceptions of parenting among first-time adolescent mothers during early postpartum and compared the perceptions of three adolescent groups (below 14, 15-17, 18-19 years), and thus factored in the potential differences within the adolescent population. However, the exclusion of non-English speakers limits generalisability of the findings to other non-similar settings.

In addition, while exploring narrative comments (in an initial study (De Vito, 2007)) of the adolescent mothers' meaning and experience of parenting in early postpartum, DeVito (2010) found that the adolescent mothers were inadequately prepared for parenting. The study reported that adolescent mothers lacked knowledge on parenting and avoided the demands of their new role as a parent, while abdicating the

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responsibility for the care of their infant to their mother or grandmother (De Vito, 2010):

Thank God, I live with my mom. I don't know what to do when she [the baby] cries. I feel like crying when my mom picks her up..... Will I ever know what to do with a baby? [16 year old] (De Vito, 2010, pp.29).

I did not know what the [umbilical] cord was... . .it looked bad. . . . I did not know if I could touch it or wash the baby there either. . . . Then the nurse [at the postpartum clinic] told me about it and what to do. . .it freaked me out, but I got used to it and was glad when it fell [17- year-old mother at 4 weeks postpartum] (De Vito, 2010, pp.29).

2.14 Conclusions from synthesis of findings

It is therefore evident from the literature (both search strategies) that support needs for young/adolescent mothers have not been optimally met by the existing health care and social systems. In view of the fact that most of the studies in this review were from high-income countries like the USA, United Kingdom and Canada, and in middle-income settings in Asia, the situation may even be dire in low-income countries, particularly in Africa, including Kenya. Furthermore, it is evident that young mothers are more vulnerable, both socially and economically, owing to their age, low level of education and status in the society, yet most of the studies have targeted adult mothers. This limits the evidence base for informed decision-making in health care targeting young mothers.

Moreover, the fact that interventional studies (mainly RCTs) are critical in providing such evidence, it can be observed that only two RCTs in this review, both conducted in the US, represented the adolescent/young mothers (Wambach et al. 2011, Di Meglio et al. 2009). The only study conducted in Africa (Zimbabwe) (Bangure et al. 2015) focussed on the use of telephone support (text message reminders) on immunisation uptake following a change of the country's policy on immunisation. This study, however, targeted mothers or care-givers over 18 years who were sent text messages as

reminders for the new immunisation schedule. Therefore, other aspects of maternal support and their influence on maternal and infant outcomes have not been adequately explored in low-income settings.

These findings are further underscored by the four systematic reviews included in this review, which highlighted the critical areas of maternal care that are potentially viable for supportive interventions. The systematic reviews (Lavender et al. 2013, Sipsma et al. 2015, Dennis and Kingston, 2008; and Shaw et al. 2006) underscored the fact that supportive interventions, including TSI were potentially effective in improving maternal and infant outcomes. Overall, these reviews assessed diverse areas of maternity care, including breastfeeding, postnatal depression and the cost-effectiveness of such interventions. Notably, TSI has been mooted as one of the promising cost-effective interventions that can transcend geographical boundaries. As such, it is worth considering especially in low resource settings, where physical and economic access to health care may pose barriers to health care seeking and utilisation, especially for young mothers. It is against this background that a pilot study on telephone support intervention among young mothers (12-19 years) in Kenya was proposed to assess the feasibility and acceptability of such interventions in low-income settings. As observed earlier, with the limited evidence of interventional studies (mainly RCTs) in Africa, pilot trials would be critical identifying the potential effectiveness of such interventions, and possibly contribute useful information for future research.

2.15 Chapter summary

This chapter provided a detailed description of the literature search process performed during the conceptual stages of this pilot RCT. Indeed this review was very informative in developing the research protocol, particularly in informing the design of the study. Specifically, this review identified the gaps as far as the postnatal needs of young mothers are concerned. In addition, the second search highlighted the potential role of TSI in maternity care, possibly in meeting some of these needs. Thus at the conceptual stage of the study and with the recognition that the study sought to pilot test an intervention (TSI), it was therefore necessary that such needs were prioritised and thus this informed the use of the Delphi process (refer to Chapter 4) in the development of the intervention. Moreover, it became apparently clear that a mixed-methods approach would be more appropriate in answering the research question, whose objectives were further aided by the literature review. The lack of evidence on such novel interventions as TSI (and perhaps other similar health interventions) especially in LMICs (only one RCT was identified in this review from Africa), despite being thought to be cheap and cost-effective was also striking. The need for similar studies in low resource settings is therefore important, especially in consideration of advancing evidence-based healthcare in which such studies would contribute to the evidence pool of future systematic reviews. Indeed, it was interesting to note that the findings of the four systematic reviews in this review also highlighted the need for further supportive care to women.

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CHAPTER THREE

METHODOLOGY & METHODS

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CHAPTER THREE: METHODOLOGY AND METHODS

3.0 Introduction

This chapter is organised in two parts: Part A discusses the methodology used in the study. It describes the philosophical and paradigmatic stance taken by the researcher. However, to lay basis on the philosophical value of paradigms in research, a general overview of the paradigms is presented, with a focus on the post-positivist paradigm, which underpins this study. Part B describes the research methods employed in the study. The study area, the population, the design, the sample and sampling techniques, data collection methods, processing and analysis and presentation, and the ethical considerations in the study are described in detail. Additionally, the chapter highlights literature sources and methodological papers used to inform the design and methods used in this pilot randomised controlled trial (RCT).

PART A: METHODOLOGY

3.1 The research paradigms

Guba and Lincoln (1994, p.107) define 'paradigm' as "the nature of the world, the individual's place in it, and the range of possible relationships to the world and its parts". Denzin and Lincoln (2005) further state that a paradigm is based on faith, and there is no way to prove or disapprove whether it is true or not. Over the years, either a quantitative or a qualitative philosophical standing has mainly influenced research. Researchers often undertake research with some philosophical assumptions (Weaver and Olson, 2006). An understanding of the philosophical underpinning of research is therefore important, in order to avoid pitfalls in research (Creswell, 2003). This also facilitates an understanding of how the paradigmatic stance taken by a researcher influences the research process. Therefore, a researcher ought to clearly delineate the epistemological (theory of knowledge) and ontological (the study of being)

perspectives, and the theoretical underpinning of the research, all of which further inform the methodology (strategy of exploration/inquiry) (Dykes, 2004).

Similarly, paradigms have been described as 'philosophical worldviews' by Cresswell whose argument is premised on the view that a researcher holds a certain view about the world ('a general philosophical orientation') and that such philosophical orientations or beliefs are often shaped by discipline orientations, supervisor/mentor inclinations and the researcher's past research experiences (Cresswell, 2014 p.6). A researcher would therefore be influenced by such a philosophical orientation (or belief), thereby embracing a particular type of inquiry in a research (Cresswell, 2014). Similar to Dykes' perspective (Dykes, 2004), Cresswell (2014) also illustrates the interconnectedness of philosophical worldviews (paradigms), research designs and research methods terming it as a research framework (Figure 3.1).

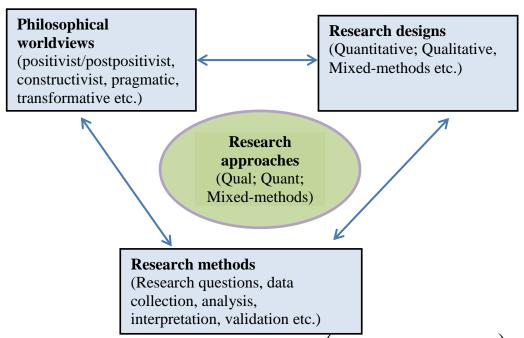


Figure 3.1: The components of a Research Framework (Source: Cresswell, 2014 p.5)

Sarantakos (1993) defines methodology as a model consisting of theoretical principles and a framework guiding the research process within a particular paradigm. Sarantakos (1993) further argues that the difference between quantitative and qualitative research methodologies emanates from particular philosophical positions (paradigms) with respect to the nature of knowledge and how such knowledge is discovered (Sarantakos, 1993). Furthermore, Silverman (2017) argues that methodology refers to the choices researchers make about the cases to study, the approaches to data collection, including the forms of data analysis while planning and conducting a study, which essentially define how the researcher will go about studying a phenomenon of interest. Traditionally, research has been defined within the two major methodologies, as either quantitative or qualitative, which follow positivists' and interpretivists' philosophical stances respectively. However, with research advancement, other philosophies emerged during the 20th century, including pragmatism, constructivism and participatory research (Creswell and Clark, 2007; Tashakkori and Teddlie, 1998).

3.1.1 Positivist and post-positivist paradigms

Quantitative methodology has generally been thought to follow the positivist/postpositivist paradigm, whose primary concern is not only to provide explanations about a phenomenon but also attempts to make predictions about the phenomenon. Through this, causal associations (cause-effect relationships) between variables are proposed. As such, positivists assert that the reality exists 'out there' and can be objectively measured through 'experimental research' to draw associations between variables (Hammersley and Atkinson, 2007). Moreover, positivists believe that the researcher and the 'researched' are independent entities (mutually-exclusive) (Guba and Lincoln, 1998). Thus, researchers assume they are more objective and neutral in the research process.

According to Tashakkori and Teddlie (1998, p.8), the difference between positivists and post-positivists fundamentally emanate from their beliefs on three principles regarding the nature of research inquiry: the value of an inquiry; the theoretical basis of facts; and the nature of reality. Whereas positivists view the reality through an 'objective and factual lens' and that the researcher and the researched are independent entities in

research, the post-positivists contend that research is influenced by the values of the investigator and by the theoretical framework (or hypotheses) adopted by the researcher, and that the reality is constructed (Tashakkori and Teddlie, 1998, p.8). Although both philosophies are principally quantitative, the view of the reality by the post-positivists as a co-construction process (between the researcher and the researched) is arguably borrowing a leaf from qualitative approaches. Therefore, this implies that post-positivists would essentially accommodate qualitative approaches in their inquiry about a phenomenon if the study necessitates a mixed-methods approach.

Further, post-positivists contend that absolute truth is not feasible in research as human subjectivity may also influence the research process (Schwandt, 2000). Unlike the positivists, post-positivists believe that reality cannot be contextualised as an independent entity but in a social and cultural context, and thus this reality can be discovered through interpretation rather than seeking prediction of causal associations between phenomena (Grix, 2004). This aforementioned argument therefore allows postpositivists not only to discover the reality through the objectivist stance but also through the 'interpretivist' view of a phenomenon. This places post-positivism in between the positivist and constructivist paradigms. Moreover, it is evident that post-positivism recognises the role of the 'researched' (participants) in contributing to the 'reality', thereby accommodating qualitative inquiry in understanding a phenomenon of interest. However, it is important to note that post-positivism is primarily objective in nature and thus seeks to understand phenomenon more so by exploring causal associations (such as through hypothesis testing), but in doing so it also recognises the social context in which the phenomenon under investigation and how such a context can influence the research.

3.1.2 Constructivist paradigm

Constructivists believe that knowledge is not discovered, but rather it is constructed through shared understanding, practices and beliefs (Schwandt, 2000, Creswell, 2014, Creswell and Clark, 2011). This school of thought also acknowledges that the reality exists but in multiple and diverse ways that cannot be purely measured objectively, but can only be explained through mental constructs that are developed socially and experientially (Guba and Lincoln, 1998). Social and experiential life shape people's ways of thinking and how they interpret social phenomena.

The proponents of constructivism therefore dispute the positivists and post-positivists' stance that although the reality cannot be perfectly understood, it can be objectively measured. Conversely, the understanding of phenomena is formed through participants' social interaction with others and their own historical experiences (Creswell and Clark, 2011). Consequently, constructivists' philosophy defies positivists' beliefs of objectivity and neutrality in research, arguably because meaning is socially constructed and interpreted through interactive processes. This philosophical worldview thus holds that the reality is co-constructed between the researcher and the 'researched' (participants) through their interactive processes and that researchers recognise that their own beliefs shape the interpretation of meanings of social phenomenon (Guba and Lincoln, 1998, Creswell, 2014). While seeking meanings of experiences and interactions, Creswell (2014) further argues that constructivists undertake to explore the complexity of multiple views about the reality, and that these meanings are negotiated socially and historically. This philosophy is therefore commonly associated with qualitative research.

3.1.3 Pragmatic paradigm

Following the seemingly endless debate of the 'paradigm wars', that is, the opposing views between the proponents of the thought that reality is only measurable through

objective and quantifiable means, and those who viewed the reality as a co-constructed entity between the researcher and the researched (Tashakkori and Teddlie, 1998), pragmatism emerged as a neutral and accommodative standpoint; it is thought that the emergence of the pragmatism paradigm 'neutralised' the wars (Creswell, 2003). Pragmatism has been widely regarded as the third paradigm (Creswell, 2003). This philosophy can be traced to the works of Charles Sanders Pierce, William James, Herbert Mead and John Deway; and later developed further by Abraham Kaplan and Richard Rorty (Johnson and Onwuegbuzie, 2004). Principally, it is based on inclusivity as opposed to the traditionally rigid views of 'either-or', and thus rejects the notion that research can take either the positivist or constructivist stance (incompatibility thesis) by embracing both viewpoints (compatibility thesis) (Tashakkori and Teddlie, 1998, p.23). Similarly, several other authors have also held the view that the two traditional methods can be jointly used in research (Teddlie and Tashakkori, 2010, Johnson and Onwuegbuzie, 2004).

The underpinning focus of pragmatism is the research outcome, other than the adherence of a method to a specific worldview (Creswell, 2003, Patton, 1990). As such, pragmatism does not subscribe to the adherence of any prescriptive beliefs of philosophy or reality, as either positivism (quantitative) or constructivism (qualitative) (Creswell, 2007, Morgan, 2007, Cherryholmes, 1992). Pragmatism offers flexibility in the research process, which facilitates free choice of the methods, design and procedures in research that best address the researcher's question. This flexibility permits the adoption of principles in either of the traditional paradigms (positivism and constructivism), provided it suits the research question. It is on this premise that several authors have emphasised the importance of a researcher understanding the research problem and then applying multiple approaches (mixed-methods) to address the problem (Tashakkori and Teddlie, 1998, Morgan, 2007 and Patton, 1990).

Pragmatism proposes a philosophy of using mixed-methods designs, which, allows for both inductive and deductive processes in understanding a phenomenon of interest. Johnson and Onwuegbuzie (2004) argue that pragmatic approach facilitates in-depth understanding of a research concept, which would have otherwise been missed if a single method were employed. Johnson and Onwuegbuzie (2004) further suggest that the approach adds rigour in research, thereby enhancing the validity and reliability of results as well as their generalisability. With such approaches, it can therefore provide a stronger evidence base for conclusion than if singular methods were used, through the convergent analysis and corroboration of findings. Moreover, a mixed-methods approach allows researchers to assume different world-views, to use multiple methods of data collection and analysis and to draw assumptions as necessary in the study.

3.1.4. Mixed-methods – When and How to mix

Mixed-methods research (MMR) has been defined as 'the type of research in which the researcher or team of researchers combines the elements of qualitative and quantitative research approaches (e.g. use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the purposes of breadth and depth of understanding and corroboration' (Johnson et al., 2007 p.123). Wisdom and Creswell also defined "mixed methods" as an emergent research methodology that involves the systematic integration, or "mixing," of quantitative and qualitative data within a single investigation or sustained program of inquiry (Wisdom and Creswell, 2013). The combination of both quantitative and qualitative methods has been considered more insightful in exploring and/or understanding the research problem(s) and question(s) than using either of the methods singularly (Creswell, 2012). In addition, it has been argued that such integration of methods provides a more 'complete and synergistic'

utilisation of data than when either of the methods is used independently (Wisdom and Creswell, 2013).

The mixed-methods approach can assume various dimensions depending on the 'mix approach' and the seemingly dominant method within the mix (Tashakkori and Teddlie, 1998). Sandelowski (2000) posits that mixed-method studies are not mixtures of paradigms of inquiry per se, but rather the choice of the techniques (mainly sampling, data collection and data analysis); and how and why they are combined should be consistent with the paradigmatic stance chosen. Primarily, this mix has been put forward under two main categories: the emergence of mixed-methods and the emergence of mixed-model studies (Tashakkori and Teddlie, 1998, p.15). This study adopted the emergence of mixed-methods category of equivalent status designs as espoused by Tashakkori and Teddlie (1998, p.15) (Table 3.1), which is equivalently denoted as 'convergent parallel mixed-methods design by Creswell (2014, p.15). The other mixed-methods designs described by Creswell include: explanatory sequential mixed-methods (quantitative precedes qualitative); exploratory sequential mixedmethods (qualitative precedes quantitative); transformative mixed-methods (may be convergent or sequential regarding social justice or power relations/marginalised groups); embedded mixed-methods (building on one another); and multiphase mixedmethods (concurrent or sequential, in program interventions or evaluations) (Creswell, 2014).

Creswell (2014, p.15) defines the convergent parallel mixed-methods as 'a form of mixed-methods design in which the researcher converges or merges the quantitative and qualitative data in order to provide a comprehensive analysis of the research problem'. In view of the different approaches within the MMR, a researcher can therefore choose a particular MMR design depending on the research question to be

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answered and the resources available (Creswell, 2014, Wisdom and Creswell, 2013). For instance, the convergent design involves the collection of data from both methods roughly at the same time and analysing them separately, and ultimately comparing them (Wisdom and Creswell, 2013). Similarly, explanatory sequential design involves an initial quantitative phase whose data directly informs the subsequent qualitative phase; and vice versa for the exploratory sequential design (Creswell, 2014, Wisdom and Creswell, 2013).

Importantly, the critical aspects underpinning the value of MMR have been highlighted, viz: complementarity (seeking to obtain mutual viewpoints about similar experiences or associations); completeness (ensuring total representation of experiences or associations); developmental (building questions from one method based on the prior implications of the other method or one method presenting hypotheses to be subsequently tested by the other); expansion (seeking to clarify or elaborate on the knowledge gained from a prior method); corroboration/confirmation (evaluating the trustworthiness of inferences gained from one method); compensation (providing for the weaknesses of one method using the other; and diversity (accommodating opposing viewpoints of the same experiences or associations (Venkatesh et al., 2013).

From inception of this study, both methods were considered as complementing each other since the main aim of the study was to explore the feasibility and acceptability of TSI among young mothers and HCPs (midwives/nurse-midwives). As such, the potential effect of the intervention on maternal and infant care could be evaluated quantitatively while at the same time exploring the acceptability of the intervention. Moreover, as a pilot RCT exploring feasibility of TSI among young mothers, it was thought that qualitative data would help in understanding and/or explaining the quantitative findings.

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Mixed-methods have also been thought to be ideal in assessing complex interventions (Wisdom and Creswell, 2013). In this context, based on the MRC definition of a complex intervention as an intervention with several interacting components (Craig et al. 2008), TSI could be regarded as one of those. Caruth (2013) also argues that MMR is valuable in research in that mixing the methods can complement each other, offer richer insights, and generate more questions of interest for future studies.

In addition, mixed-methods approach has been thought to offer several advantages; it enables comparison of quantitative and qualitative data, thereby providing understanding of any contradictions or convergence; it reflects participants' view point or rather gives voice to participants; it provides methodological flexibility (adaptable to many study designs); it enhances collaborative engagement in research (multidisciplinary team); and provides rich data owing to its integrative nature (Wisdom and Creswell). Nevertheless, it is also inherent with challenges such as being resource-intensive in terms of both research personnel and physical resources and its complex nature especially when used to evaluate complex interventions (Wisdom and Creswell, 2013, Creswell, 2012, Caruth, 2013). The summary of the mixed-methods approaches is presented in Table 3.1.

Category	Designs/approaches							
The emergence of mixed-	Equivalent status designs							
methods	Sequential (two-phase sequential studies)							
	QUAN/QUAL QUAL/QUAN							
	Parallel/simultaneous							
	QUAN + QUAL							
	Dominant-Less dominant designs							
	Sequential							
	QUAL/quan							
	QUAN/qual							
	Parallel/simultaneous							
	QUAL + quan							
	QUAN + qual							
	Designs with multilevel use of approaches							
The emergence of mixed-model	Single application within stage of study							
studies	Type of inquiry – QUAL or QUAN							
	Data collection/operations - QUAL or QUA							
	Analysis/inferences - QUAL or QUAN							
	Multiple applications within stage of study							
	Multiple applications within stage of study Type of inquiry – QUAL and/or QUAN							
	Data collection/operations - QUAL and/or							
	QUAN							
	Analysis/inferences - QUAL and/or QUAN							

Table 3.1: Main approaches in mixed-methods research

KEY: QUAL/qual=qualitative; QUAN/quan=quantitative (Source: Tashakkori and Teddlie, 1998, p.15)

3.2 Summary and justification of paradigmatic stance

Having considered the philosophical basis of the above paradigms, the paradigmatic stance of post-positivism appeared more suitable for this study. As noted earlier, while positivism is mainly quantitative as far as methodology is concerned (Denzin and Lincoln, 2005), post-positivism and pragmatism are accommodative of both methods of inquiry. Therefore, with the advent of mixed-methods research, both philosophies (post-positivism and pragmatism) have enabled better understanding of the complexities in health research. However, like positivism, post-positivism philosophy is also primarily

'objectivist', hence tends to lean more on the 'quantitative' paradigm, its flexibility notwithstanding. In addition, it has been highlighted that quantitative methods are usually suitable in investigating 'social facts' or the causes of phenomenon, while qualitative methods provide a better understanding of how such social phenomena come into being within the context of interactive processes with study participants (Silverman, 2017).

Following a comprehensive literature review (Chapter 2), it was evident that little is known about supportive interventions, including telephone support in terms of its feasibility and potential effectiveness, particularly among young mothers in LMIC settings. In addition, this literature review also involved the identification of postnatal needs of young mothers; it thus highlighted the social context of young motherhood, which could be better understood through qualitative inquiry. Therefore, to understand the complex world of young mothers' postnatal needs and the potential role of telephone support intervention, the adoption of a mixed-methods approach in the study was considered. Considering that the main focus of the study was to 'test' the potential role or less relate to 'hypothesis testing', hence would mainly be quantitative in nature. Conversely, the need to explore and understand other issues regarding the intervention such as its acceptability (among young mothers and midwives) necessitates qualitative inquiry. Hence, the aim and/or research question(s) of the pilot study appeared to be largely consistent with the philosophical tenets of post-positivism.

Creswell (2014) further argues that post-positivists 'hold a deterministic philosophy' in which "causes" are thought to determine "effects or outcomes". Researchers would therefore undertake to critically observe and measure the objective reality such as through experimental designs while seeking to assess causes that influence outcomes

(Creswell, 2014). Considering the fact that as a pilot trial this study sought to observe and compare outcomes between groups (intervention and control groups) following an intervention (TSI), such an objective would only be possible through experimental designs. Creswell (2014, p.13) argues that experimental research is used to test whether a specific treatment (or intervention) influences an outcome by comparing the groups with regard to the outcome(s) following the treatment. Bolyai-Sullivan and Bova (2014) also state that experimental designs are more appropriate for testing cause-effect relationships. These arguments were consistent with the main aim of the present study, which necessitated the adoption of an RCT with two groups. With these considerations, this study sought to explore the feasibility and acceptability of telephone support intervention among young mothers in low- and middle-income (LMIC) settings using an experimental design (a pilot RCT).

Although there is an ongoing debate regarding the definitions of feasibility and pilot studies particularly in the context of RCTs (Eldridge et al. 2016), it appeared the objectives of this study more or less related to the definition of a pilot study in that the design mimicked the aspects of a main trial but in a smaller scale. According to the National Institute for Health Research (NIHR, 2015) feasibility studies 'are pieces of research done before a main study with the aim of answering the question - Can this study be done?, while pilot studies are a smaller version (miniature) of main study aimed at testing whether the components of the main study can all work together'. Additionally, pilot studies focus on the processes of the main study and how they run such as recruitment, randomisation, treatment and follow-up assessments, and how they are all interconnected (NIHR, 2015). Since feasibility studies are concerned with identifying and/or estimating critical aspects needed in designing a main study (NIHR, 2015), pilot studies may therefore be regarded as a subset within feasibility study (Eldridge et al. 2016). With the ongoing debate on the topic, and the development of

conceptual framework for defining feasibility and pilot studies (Eldridge et al. 2016), there would be more clarity on the same in the future. Nevertheless, Eldridge et al. (2016) suggested feasibility as an umbrella term denoting all such studies.

Therefore, as a pilot study testing a novel intervention, and with particular consideration of the context of the study setting as a LMIC, it was imperative that feasibility and acceptability issues were explored and thus qualitative inquiry was also deemed necessary. Thus, it was important to explore both the breadth (quantitative) and the depth (qualitative) of this aspect of maternal health care.

As an interventional study, the study sought to observe and compare outcomes between intervention and control groups following an intervention (TSI) in which case the outcomes were primarily quantitative (refer to Section 3.9.1). However, to achieve an in-depth understanding of the study the mixed-methods approach was deemed appropriate. Moreover, mixed-methods are thought to be more appropriate for assessing feasibility studies (Thabane et al., 2010), including complex interventions (Wisdom and Creswell, 2013). Silverman (2017) also noted that quantitative data is useful in answering the 'why' questions while qualitative data suitably address the 'what' and 'how' questions. As such, pilot RCTs may therefore be used to determine the (potential) effectiveness of an intervention (quantitative) while interviews may provide data to assess the acceptability of such interventions (participants' qualitative accounts of the intervention).

Although pragmatism also embraces both methods of inquiry and the fact that it permits a higher degree of flexibility in the conduct of research, it was considered less appealing to the research question as such flexibility might have unduly influenced practical issues (feasibility findings) that this study sought to explore, which would have potentially created avenues for bias. For instance, permitting a researcher such a flexibility to choose 'what works' in answering the research question would potentially introduce the element of bias, which ordinarily becomes a limitation in the study especially in the context of (pilot) RCTs. Yet in such trials (and/or interventional studies) researchers are obliged to devise ways of reducing the risk of biases right from the conceptualisation of the study. Therefore, since post-positivism permits a real-world view of research, it appeared more suitable in answering the research question in this pilot RCT. This philosophy therefore informed this study. In view of the above, since the primary design of this pilot RCT was mainly quantitative the Dominant-Less dominant design of the mixed-methods research was adopted with a parallel/simultaneous approach to the conduct of the study i.e. [QUAN + qual] as highlighted in Table 3.1.

PART B: METHODS

3.3 Objectives

3.3.1 Broad objective

• To assess the feasibility of conducting a main trial comparing telephone versus no support for young mothers in improving maternal physical, psychological and social wellbeing during postnatal period.

3.3.2 Specific objectives

- 1. To develop a telephone-based intervention using the Delphi process and test it among young mothers during a pilot trial in western Kenya.
- To assess the availability of good quality data in the study setting to support a larger study.
- To assess the acceptability of the telephone support intervention among young women.
- 4. To assess midwives' perspectives on the use of telephone support intervention among young women.

- 5. To observe the differences between intervention and control group during postnatal period.
- 6. To determine an appropriate research design for a definitive study (primary outcome, sample size, design, data collection, analysis).

3.4 Study design

A mixed-methods approach was employed in this pilot RCT. The main aim of carrying out a pilot study is to determine the feasibility of main trials (Ross-McGill et al. 2000; Stevinson and Ernst, 2000). Therefore, since the study aimed at determining the feasibility and acceptability of conducting a main trial of the effectiveness of an intervention (TSI), an experimental design was deemed appropriate. Experimental research is used to test if a specific treatment (or intervention) influences an outcome by comparing the groups with regard to the outcome(s) following the treatment (Creswell, 2014 p.13). Thabane et al. (2010) also highlight that pilot studies provide an opportunity to assess feasibility of main trials and enhance their chances of success. As a pilot RCT, this study therefore sought to emulate a main trial in assessing the feasibility and acceptability of telephone support intervention among young mothers in the immediate postnatal period in LMIC settings. Moreover, the study sought to determine a primary outcome of interest and to inform the design of a definitive trial.

Being a pilot RCT, the study sought to explore the possibility of a causal association between groups with regard to specific maternal and infant health outcomes following TSI. Researchers who apply experimental designs often seek to identify and assess the causes that influence outcomes (Creswell, 2014). Thus, the study sought to measure and compare outcomes between the groups with the aim of assessing the differences in selected maternal and infant outcomes among young mothers during the postnatal period. The choice of the outcomes was informed by an in-depth and critical review of the literature, including systematic reviews, which identified the critical areas of postnatal needs of young mothers and the potential role of telephone support intervention in maternal and child health (Chapter 2). However, it is important to note that being a pilot, this study was not powered to test for statistical significance, and hence it compared the outcomes between the groups descriptively.

Additionally, to explore the acceptability and the potential effectiveness of such novel interventions, a qualitative evaluation was conducted at the end of the intervention. Individual interviews and focus group discussions (FGDs) were therefore conducted among the young mothers who took part in the trial. Similarly, considering that midwives play a critical role in meeting the health care needs of all women right from pregnancy through to birth and postnatal period, midwives were also thought to be instrumental in meeting young mothers' needs. As such, midwives were also considered critical in piloting and implementation of innovative interventions such as telephone support in maternity care. Thus, in-depth interviews among midwives were also conducted to explore their views/perceptions of telephone support intervention for young mothers during the immediate postnatal period. With their routine interaction with all women, the midwives were thought to be a critical group in meeting the needs of young mothers.

In executing the study, young mothers aged between 12-19 who were eligible for a telephone support intervention during the postnatal period were targeted. The eligible mothers were recruited and randomised into intervention and control groups during the first week postpartum (before discharge from maternity unit) at the respective study centres and followed up until the tenth week postpartum. During the intervention phase, the intervention group was administered a telephone-support intervention in the form of motivational health messages (SMS) on weekly basis and a follow up telephone call

after every three weeks together with the usual postnatal care, and compared to the nonintervention (Centers for Disease and Prevention) group who received the usual postnatal care.

The intervention was developed through the Delphi technique (Dalkey and Helmer, 1963), conducted among midwives in Kenya. The rationale for choosing the Delphi technique, and the Delphi process itself in this study is described in detail in Chapter 4. The tenth week provided an ideal opportunity to evaluate the intervention as it corresponded to the second booking for clinic appointment after birth at the Maternal and Child Health welfare clinic, which almost all mothers and their infants attend. Maternal and infant outcomes were therefore assessed at the 10th week postpartum in both groups for comparison. In summary, Figure 3.2 illustrates the design of the pilot randomised trial.

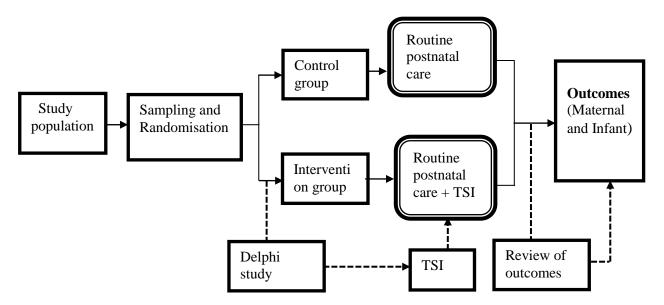


Figure 3.2: Diagrammatic representation of the study design

3.5 Study setting

The study was conducted in two public tertiary teaching hospitals in Western region in Kenya, namely, the Moi Teaching and Referral Hospital (MTRH) and in Kakamega County General Hospital (KCGH). MTRH is the second largest national referral hospital (Level-6 referral facility) in Kenya after Kenyatta National Hospital (KNH), while KCGH is a Level-5 referral facility in Kakamega County. MTRH is the main referral facility in Western region of the country. The facilities serve a catchment population of over 15 million.

3.6 Study and target population

The target population were women aged between 12-19 years presenting for postnatal care in Western Kenya. The study population were young mothers aged between 12-19 years, who presented at the Riley Mother and Baby hospital (RMBH) in MTRH and in the KCGH maternity unit for postnatal care.

3.6.1 Eligibility criteria

3.6.1.1 Inclusion criteria

- 1. All young postnatal mothers aged 12-19 years who gave birth to a singleton healthy baby at term at MTRH-RMBH and KCGH.
- 2. Those for whom consent was sought and/or those whose parents/guardians consented, and were willing to participate in the study.
- 3. Postnatal young mothers who owned a mobile phone and were able to use common mobile telephone operation services.
- 4. Ability to read telephone text either in English or Kiswahili to a basic level of understanding.
- 5. Qualified midwives and/or nurse-midwives with more than one year experience working in maternity setting in the respective study centres.

3.6.1.2 Exclusion criteria

 Young postnatal mothers who gave birth through caesarean, or who had multiple births and/or whose babies developed birth complications or had congenital anomalies. 2. Mothers who were known to have a limited capacity to consent e.g. those with recorded mental disability.

3.7 Sampling

Purposive sampling was used to select the study sites. The study centres were chosen because they are the main referral centres in the region (Level 6 and 5 health facilities respectively), and also provided easy accessibility to conduct the study. Being an RCT, and with the assumption that the target population would be presenting at the facilities at random, consecutive sampling was used to select the participants from the study population.

In determining the sample size for the study, the study adopted Kieser and Wassmer's (1996) estimate sample of 20-40 for pilot studies. Based on an assumption of 80% power for the main trial and 25% attrition rate (Whitehead et al. 2015), the study randomised 26 per group, aiming for 20 per group for analysis allowing for 20% attrition per group. Thus, a total of 52 participants were recruited for the study.

For qualitative data, participants were purposively selected from each arm of the study for individual interviews and group discussion. The sampling was based on the age group (12-19 years), a mother having had a normal childbirth, and her willingness to participate in the qualitative part of the study regardless of parity at the time of the study. In this case, the criteria for assessing normal birth was based on WHO definition of normal birth as that which is spontaneous in onset, low-risk at the start of labour and throughout labour and birth process, with the baby being born spontaneously in the vertex position at term (between 37 and 42 completed weeks of pregnancy), with an outcome of a healthy mother and baby (WHO, 1996). An in-depth interview schedule for young mothers (Appendix 3.2C) was used during the interviews. Midwives were also purposively selected, based on their experience (>1 year working at the maternity unit) at the selected study centres and interviewed using an in-depth interview schedule (Appendix 3.2D).

3.8 Recruitment and randomisation

3.8.1 Recruitment

Eligible participants were identified and recruited by a trained RA during the immediate postnatal period at the respective maternity units of the study centres after obtaining informed assent from the younger mothers (12-17 years) and consent from the older young mothers (18-19 years) respectively. Before assenting or consenting, the mothers were given a participant information sheet specific to the age group (see Appendices 3.3A and 3.3B). In addition, the parents/guardians of the younger age group (12-17) were fully informed of the aims of the study and all the procedures involved through an information sheet (Appendix 3.3C) prior to consenting and recruitment. For participants aged 18-19, consent was directly sought upon full explanation of the study (Appendix 3.3A). Written consent and assent forms were used for the respective groups as applicable (Appendices 3.4A, 3.4B and 3.4C).

3.8.2 Randomisation

Eligible participants who consented to participate in the study were randomised into control and intervention groups. Randomisation was stratified by age group and site, based on separate random allocation lists for participants aged 12-16 and those aged 17-19 for each site. The SNOSE (sequentially numbered, opaque and sealed envelopes) approach (Doig and Simpson, 2005) was used in allocation to a group, which was performed through a set of random allocation numbers generated by a computer, and carried out by someone independent of the intervention and data collection. It has been argued that the method used to assign interventions to participants in a trial design is a critical consideration, with random assignment often being the preferred method as it eliminates or reduces selection bias as well as enhancing blinding of treatments to

investigators, participants and evaluators (Moher et al. 2010). Opaque, sealed envelopes containing the random allocation numbers, opened by a trained Research Assistant (RA) during recruitment, were used to ensure concealment (Doig and Simpson, 2005), an approach which is appropriate for a low-income setting.

3.8.2.1 Control group

Study participants in the control group received the routine postnatal care interventions as prescribed by the Ministry of Health guidelines (MoH Kenya, 2010), including postnatal counselling before discharge. The package consists of maternal and infant care instructions on breastfeeding, nutrition and infant feeding, care of the newborn/infant, postnatal danger signs, immunisation and family planning, provided by the midwife prior to discharge. In addition, mothers were advised to make reference to the Mother-Child booklet (MoPHS and MoMS Kenya, 2010) which contains postnatal instructions on infant and maternal care, for further guidance.

3.8.2.2 Intervention group

Participants assigned to this group received the routine postnatal care interventions as outlined above for the control group plus a telephone support intervention in form of weekly text messaging and a telephone call once every three weeks postpartum until the tenth week. The support intervention was provided by a trained Research Assistant (RA) (intervention midwife) regularly at scheduled dates for each of the participants as agreed with the PI (Table 3.1). The participants were also given an option to call back for further informational support and/or clarification. The intervention midwife was asked to document such occasions (time/date of call and content domain of the information sought) in a field notebook provided by the PI. Further, the intervention midwife was asked to use his/her clinical acumen to make a proper assessment and referral during such occasions, of cases in need of medical attention for appropriate care and follow up. In summary, the TSI was scheduled as outlined in Table 3.1.

WEEK/	1	2	3	4	5	6	7	8	9	10
INTERVENTION										
SMS	* 🗸	~	~	~	~	~	~	~	~	~
Call	*		~			~			~	

Table 3.2: Schedule of the Interventional Support (TSI)

*Recruitment

3.8.3 Blinding

The midwife, who was trained and recruited to contact members of the intervention group as an intervention midwife (to offer telephone support) was blinded at the recruitment stage of the participants in either group. The recruiting RA only provided the intervention midwife with a list of the participants allocated to the intervention group and instructed to follow through with the TSI regularly as scheduled (Table 3.1). At the end of the intervention, a second RA was recruited and trained to collect outcome data from the two groups. Similarly, the RA was blinded of the participants' group allocation and was only required to administer the questionnaires.

3.9 Data collection

3.9.1 Quantitative data

Quantitative data were collected using validated and specifically designed tools measuring perceived sense of maternal wellbeing in terms of psychological (postnatal depression index), self-esteem and social support. The tools have been widely used in various clinical settings with a high degree of success in their effectiveness. In this study, the Maternity Social Support Scale (MSSS) was used (Webster et al., 2000) to assess maternal perceived social support, Rosenberg's Self-esteem Scale was used to assess maternal self-esteem (Rosenberg, 1965) and the Edinburg Postnatal Depression Scale (EPDS) was used to assess for postnatal depression (Cox et al., 1987). In addition, a screening questionnaire was used to assess breastfeeding and mother-infant bonding

(Brockington et al. 2001). An outcome-based questionnaire was also administered to assess for both maternal and infant health-related outcomes such as illness episodes/sepsis, contraception, self-medication [maternal]; and immunisation, breastfeeding, illness/sepsis, medication, and weight gain [infant].

The questionnaires were piloted prior to the main study at a different facility in the region (Uasin-Gishu district hospital), upon which a few adjustments were made. For instance, there was need to clarify the word 'conflict' to the mothers (question #4) in the MSSS, and thus the phrase '*any form of disagreement*' was added in brackets and the scale was subsequently tested and found to be better-understood by the mothers. The adjustments were discussed with the RAs and the supervisory team to ensure consensus in validity evaluation.

The questionnaires were interviewer-administered and the data were collected from both study groups at the end of the intervention period by the RA. Prior to the intervention, a structured questionnaire was used to collect baseline data (biodata) of all the participants who consented for the study. Secondary data (maternal health records) were also collected using a systematic data extraction form to ascertain the availability of quality data that may support main trial. The questionnaires were translated to the Swahili language (by a reputable Kiswahili teacher in one of the leading high schools in Kenya) to facilitate ease of understanding for participants whose language preference was Kiswahili and/or who did not understand English (Appendix 3.2A-Kiswahili version).

3.9.2 Qualitative data

Qualitative data from the mothers were collected through individual in-depth interviews and focus group discussions (FGDs) at the end of the study. Initially, the study aimed at conducting two FGDs (each consisting 5-8 participants) for the young mothers aged 1217 and 17-19 years respectively in each arm of the study to allow for consideration of the differences in age characteristics among the participants. However, this was not feasible as it was only possible to recruit seven mothers in the 12-17 age-bracket across both study centres. Thus, it was only possible to conduct nine individual interviews and three FGDs among the young mothers, each FGD comprising 5-6 participants. The interviews were conducted by the PI using an interview guide (Appendix 3.2C) to direct the questions. Similarly, one FGD and six individual interviews were conducted among the midwives using an interview guide (Appendix 3.2D) to assess their views regarding young motherhood and their perceptions of the telephone support intervention. The midwives were also asked to fill in a short demographics questionnaire (Appendix 3.2E) upon reading the respective participant information sheet (Appendix 3.3D) and consenting to participate (Appendix 3.4D). The interview sessions for both participant groups (young mothers and midwives) were audio-recorded, with field notes being taken concurrently to supplement the data recorded.

3.10 Data analysis and presentation

3.10.1 Quantitative data

Data were double-entered into IBM SPSS Statistics (version 23) for analysis. The data entry was cross-checked for correct entry by someone other than the PI, who was blinded to group allocation. The PI was unblinded to group allocation after analysis. The data were mainly analysed using appropriate descriptive statistics and the outcomes in the two arms of the study were compared descriptively. Recruitment rate, attrition rate and protocol adherence rate were estimated with 95% CIs. Effect sizes for differences in frequencies (percentages) or means between groups (Lancaster et al., 2004) were calculated and assessed to inform the main trial. Some statistical tests were performed to help inform the main trial too. The Pearson chi-square test was used to compare nominal variables, the Mann-Whitney U test to compare skewed numerical variables and independent-samples t-tests to compare non-skewed numerical variables. However, the test results were interpreted cautiously as the study was not powered to detect statistical significance. The data were presented in the form of tables, graphs, charts and a narrative report.

3.10.2 Qualitative data

Qualitative data were analysed using Framework analysis (Ritchie and Spencer, 1994). Framework analysis (FA) is a systematic and step-wise approach to qualitative data analysis, and has been used in various contexts of health care disciplines including midwifery (Swallow et al., 2011; Tierney et al., 2011; Furber and McGowan, 2011). In addition, FA offers a pragmatic approach for real-world research, suitable for health care policy and practice (Ward et al., 2013), as well as permitting for structured and flexible process of analysing data (Swallow et al., 2011). The steps in FA familiarisation with data, development of a theoretical framework/themes, indexing and charting, and summarising/interpretation of data - have been described in detail by several authors (Ward et al., 2013; Gale et al., 2013). Since this study sought to give a general interpretivist account of the study participants (young mothers) regarding a novel intervention such as TSI and midwives who are key stakeholders in midwifery, FA was thought to be more suitable compared to other qualitative analysis methods which are more grounded to particular philosophical paradigms. To provide a full account of their views and/or perceptions, verbatim narratives are presented where applicable in relation to the thematic framework developed from the data, to highlight on key findings or themes related to the mothers' and midwives' perceptions of the intervention.

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3.11 Reliability and validation of research instruments

The study used validated tools in data collection. For the research instruments developed to collect specific data (outcomes questionnaire and data extraction form), pilot-testing was performed prior to the main study at a County hospital to pre-test and evaluate the appropriateness of the tools in data collection (see details in section 3.9). Content validity of the questionnaires was evaluated by the supervisors (including clinical experts in Kenya) to determine if items were relevant to the content domain, understandable and captured all relevant content for the study population. Adjustments to the tools were then made as necessary.

Qualitative data were collected using semi-structured interviews. An interview guide was developed, guided by the objectives of the study (to test feasibility and acceptability of TSI) to direct and focus the questions. The wording and content of the interview guide was checked by the supervisory team, who are also more experienced researchers. This was in keeping with the suggestion that in designing an interview guide, besides asking questions that generate much information, researchers should also formulate questions that seek to effectively answer the research objectives (Gill et al. 2008). Being a novice researcher, semi-structured interviewing was appealing as it permits flexibility during interviews. Considering that the mothers were to be interviewed with their infants who may have to breastfeed in the process, the interviews were conducted in a room preferred by the participants within the study setting. This was to ensure that the interview environment would not negatively influence the interview process, and subsequently the quality of the data.

Further, the use of FA has been documented to enhance transparency in analysis and the results thereof, as well as provide a means of verification of the results by research team (Ward et al., 2013, Furber, 2010, Dixon-Woods, 2011, Furber et al., 2009). It has been

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argued that the use of verbatim quotes and keeping of an audit trail, as well as researcher reflexivity are key elements in enhancing rigour in qualitative research (Walsh and Barker, 2004). The researcher made an attempt to keep a reflective diary during the data collection process, including during the interviews and analysis of transcripts to enhance accurate interpretation of participants' accounts, besides working closely with the research team. Moreover, during transcription the researcher shared some of the transcripts with one of the RAs who assisted in taking field notes during interviews and with the supervisors. This was in a bid to ensure adequate verification of data, and also facilitated team-based analysis as the RA was able to enrich the data by giving contextual information captured in the field notes. This was also thought to minimise researcher bias. Periodic meetings were also held with the RAs and intervention midwives, as well as with the supervisors who provided much guidance during fieldwork to discuss and review progress of the research process.

3.12 Data quality assurance

To ensure that sound principles of data collection were adhered to, RAs were recruited and trained in January 2017. To be eligible as a RA (recruitment and post-intervention phases), one had to be a BSc.N graduate with at least one year working experience or doing internship. For intervention midwives (research midwife), one had to be a BSc.N holder and must have worked for at least one year in the postnatal unit. In summary, the RAs were trained on: an overview of the main types of designs (quant/qual); importance of research in healthcare; ethical principles in research; participant recruitment – consenting process; randomisation and blinding; and data collection and verification for completeness. Additionally, the RAs were sensitised on the use of a Distress Policy form (Appendix 3.5) during data collection, as this was a new aspect in conducting health research particularly in the context of the study setting. The training was conducted within two days (a half a day during both days) during off-peak hours. The

training schedule is presented in Appendix 3.8. The RAs were asked to ensure that the questionnaires were duly filled and to check for completeness and correct any shortcomings promptly. As noted in Section 3.10.1, double-entry of the quantitative data was also performed.

3.13 Ethical considerations

3.13.1 Ethical approval

Ethical approval from the relevant Research Ethics Committees, both at The University of Manchester (UMREC) and at Moi University-MTRH and KCGH (IREC), were sought before execution of the study as well as permission to conduct the study from the study centres (Appendices 3.6A, 3.6B and 3.6C). The study was also registered with Current Controlled Trials (Study ID. ISRCTN15017499). Consistent with the approval requirements, the participants were fully informed by the recruiting RAs of all the procedures involved in the study prior to seeking informed consent and were provided with participant information sheets (Appendices 3.3A, 3.3B, 3.3C and 3.3D).

3.13.2 Ethical principles

The principles of research ethics and governance were duly observed throughout the study. Since the study involved young mothers, including minors (those below 18 years) who could be regarded as potentially vulnerable, the study ensured that all participants were duly informed about the study before consenting and/or assenting as applicable. As noted above, separate participant information sheets (Appendices 3.3A and 3.3B), and consent and assent forms (Appendices 3.4A and 3.4B) were developed for young mothers aged 18-19 and 12-17 respectively. During the development of the PIS and consent/assent forms, the PI took into consideration the level of understanding of the participants and thus the forms were written with a reasonably ease of understanding. In

addition, for the younger mothers (12-17) the PIS were developed in a brochure form which was thought to be more 'friendly and appealing' to the group (Appendix 3.3B).

Moreover, separate PIS and consent forms for parent/guardian (Appendices 3.3D and 3.4D respectively) were developed which were concurrently administered with the assent forms for the minors. Thus, the parent/guardian-daughter pair was jointly involved in the consent and assent-seeking process in the study. Prior to recruitment, the eligible participants (including the parent/guardian) were also given an opportunity to seek any further clarification as necessary (from the recruiting RA) to ensure that the participants were duly informed about the study before consenting to take part. A written consent and assent form was then obtained from the participants as applicable.

Confidentiality of the data/information was observed at all times. The filled questionnaires were kept under key and lock in a cabinet and only retrieved for analysis by the researcher. Data entered onto computer were anonymised, with an internal study ID used to match the computer data with the questionnaires. Anonymity of participants was also guaranteed. No identifiers were used while handling the data (during analysis and presentation). To achieve this, participant IDs were used in the presentation of data. In addition, respect for the principles of individual rights was observed to safeguard the dignity of the participants at all times.

3.14 Chapter summary

This chapter presented the philosophical considerations that informed the design/approach undertaken in the study. Thus, the philosophical paradigms were discussed, highlighting their place in health research. The choice of the mixed-methods approach for the pilot trial was then justified, with the paradigmatic stance of the post-positivist research philosophy. Subsequently, the methods employed in the study were described in detail, including the description of the study setting, sampling, recruitment and randomisation procedures, data collection and analysis, and the ethical considerations in the study.

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CHAPTER FOUR

DEVELOPMENT OF THE

INTERVENTION – DELPHI

PROCESS

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CHAPTER 4: THE DEVELOPMENT OF THE INTERVENTION - DELPHI TECHNIQUE

4.1 Introduction

This chapter describes the process through which the proposed intervention (telephone support for young mothers) was developed prior to its execution in the main study. Specifically, it describes the Delphi process, which was thought to be more suitable for the topic at hand than other consensus methods. The rationale of choosing the Delphi technique over other consensus methods is highlighted herein. Specifically, the chapter highlights the design and methods used in the Delphi; the participant characteristics including the sample and recruitment process. The Delphi process is then described in detail with the output (results) and the dissemination plan for the intervention. At the end, the discussion of the Delphi results and the conclusions drawn thereof are presented, with a summary of the chapter.

4.2 Design and methods

The Delphi technique was selected to develop the TSI for young mothers during the immediate postnatal period. The Delphi technique has been defined as 'a method used to obtain the most reliable consensus of opinion of a group of experts by a series of intensive questionnaires interspersed with controlled feedback' (Dalkey and Helmer, 1963; p.458). However, it is important to note that other methods of consensus building also do exist, such as the nominal group technique (NGT) (Harvey and Holmes, 2012, Carney et al. 1996) and the consensus conference (Jones and Hunter, 1995). The NGT involves gathering participants for a discussion using a highly structured group approach with the aim of reaching at a high-level consensus (Keeney et al. 2010). Harvey and Holmes (2012) argue that NGT has been used to identify a problem(s); to develop solutions; to generate research questions; and in establishing priorities for

action, including gaining consensus on highly complex issues. Through an initial questioning by a moderator/researcher, the participants in NGT are asked to individually write their responses, which are then shared in a 'round-robin fashion' until a consensus is arrived at (Keeney et al. 2010). Similarly, consensus conference involves the invitation of a specific group or groups of individuals to a conference setting to deliberate and agree on a subject of importance (Keeney et al. 2010).

The Delphi technique has been widely used in health sciences research for various purposes, ranging from identification of priority areas of research to the development of research tools and health interventions (De Villiers et al. 2005, Antcliff et al. 2013, Maimbolwa et al. 2015, Murphy et al. 1998, Potter et al. 2004, Keeney et al. 2010). Through an iterative process of data collection, the Delphi technique aims at building a consensus on a topic at hand (Maimbolwa et al. 2015, Keeney et al. 2010, Hasson et al. 2000). The technique is generally thought to be friendly, cost-effective and familiar to midwives, and it can be used to reach participants over a wide geographical area (Maimbolwa et al. 2015). The method was thus deemed suitable for the current study since the participants were selected across three regional referral facilities in Kenya. This gave it a distinct advantage over the NGT and consensus conference, which require the participants to be in the same location. The Delphi method was therefore selected to achieve a convergence of opinion among midwives in Kenya on priority motivational health messages for young mothers during the immediate postnatal period (from birth to ten weeks postpartum).

4.2.1 Participants

An expert panel of midwives in Kenya was sought based on their professional expertise and experiences to enhance the content validity of the intervention being developed. Since the information being sought was practice-related, a written informed consent was not necessary. However, a verbal consent was sought: the purpose of the study was fully explained to the midwives and they were asked to voluntarily participate. In addition, due to the nature of the study, a formal ethical approval was deemed not necessary either. However, ethical principles in research were strictly adhered to, including consent, confidentiality and appropriate data handling and management. A short demographics questionnaire was used to collect the sociodemographic characteristics of the participants (midwives) who took part in the Delphi (Appendix 4.1).

4.2.2 Sample and recruitment

The participants were recruited between December 2016 and March 2017 from three main referral hospitals in Kenya, which included the two national referral hospitals (Kenyatta National Hospital and Moi Teaching and Referral Hospital) and one regional referral hospital (Kakamega County General Hospital). The facilities were chosen by convenience and it was thought they would provide a diverse sample of midwives regarding working experience, knowledge and skill mix. This was also thought to provide a good reflection of the setting of the main study which was based at two of the centres. A convenience sample of 30 midwives was therefore selected from the three facilities, equally distributed across the facilities. This sample also included 10 Lugina Africa Midwives Research Network (LAMRN) midwives in Kenya. LAMRN (http://lamrn.org/) [Online] is a research capacity-building initiative for midwives in low-income settings involving six countries in Africa, namely Kenya, Malawi, Zambia, Uganda, Zimbabwe and Tanzania, and is being spearheaded by LAMRN focal heads based in the University of Manchester (Midwifery). The overall goal of LAMRN is to build a network of midwives with enhanced capacity in research and priority setting, leadership skills, evidence-based practice knowledge and skills as well as developing a mentorship support system for the midwives (http://lamrn.org/) [Online].

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The recruitment was facilitated by a midwife appointed by the main researcher in each of the hospitals.

4.3 The Delphi process

4.3.1 Round 1

Round 1 of the Delphi usually involves brainstorming of opinions through a qualitative inquiry (Hasson et al. 2000). In this study, ten LAMRN midwives in Kenya were contacted during a LAMRN meeting held in September 2016 in Nairobi and invited to take part in the survey. This round involved an open-ended question asking the participants to list key issues/aspects of health educational support for young mothers aged 12-19 and their babies during the immediate postnatal period. To enhance specificity, the postnatal period was categorised into: week 1; weeks 2-6; and weeks 7-10 (Appendix 4.2). The midwives were asked to list as much as possible what they considered priority health educational issues, both for the mother (maternal care) and for the baby (newborn/infant care) across the three time-periods. The midwives were also asked to provide any other information they considered useful for this group of mothers and their babies/infants. The survey was conducted face to face and thus the feedback was immediate.

The responses were then organised and compiled in a list by the researcher. Following further discussion with my supervisors, the data were analysed, then compiled and sectioned appropriately to develop potential thematic areas for motivational health messages reflecting maternal care and newborn/infant care respectively. Based on clinical considerations, one item (high blood pressure/pre-eclampsia or eclampsia) was thought to be an important aspect and thus it was included in week 1 in the maternal care domain in spite of the fact that the midwives did not mention in Round 1 of the Delphi. Table 4.1 presents the list of items identified by the midwives in Round 1 which

were then organised accordingly to reflect maternal and infant care, and the respective time periods as highlighted above. In total, 68 items were listed in Round 1 (maternal care= 37; newborn/infant care= 31). These items constituted the Delphi 2 questionnaire (refer to Appendix 4.3).

Care domain	Week	List of key motivational messages (for Delphi 2)
A. Maternal care	Week 1	Infection prevention; Nutrition; Rest; Personal hygiene; Breast care; Psychosocial support; Pelvic floor/Kegel's exercises; *High blood pressure (Pre- eclampsia/Eclampsia); Bleeding/postpartum bleeding; Pain management; Partner/family involvement; pMTCT & STI screening and prevention; Family budget adjustments
	Weeks 2-6	Sleep; Nutrition Personal hygiene; Breast care; Psychosocial support; Mood changes; Pelvic floor/Kegel's exercises; Clinical appointment; Pain management; Family budget adjustments; Contraception/family planning; pMTCT & STI screening and prevention; Partner/family involvement
	Weeks 7-10	Pelvic floor/Kegel's exercises; Breast care; Psychosocial support; Rest; Nutrition; Personal hygiene; Bleeding Contraception/family planning; pMTCT & STI screening and prevention; Partner/family involvement; Family budget adjustments
B. Newborn/Infant care	Week 1	Breastfeeding; Immunisation; Warmth; Cord care; Bathing; Colic pain management; Sleep patterns; Signs of infection; pMTCT & STI screening and prevention; Bonding; Family budget adjustments; Partner/family involvement; Assessment of the baby – breathing/body
	Weeks 2-6	Immunisation; Breastfeeding; Infant feeding patterns; Warmth; Cord care; Skin care; Clinical appointment; Family budget adjustments; Partner/family involvement; pMTCT & STI screening and prevention
	Weeks 7-10	Immunisation; Breastfeeding; Infant care; Sleep patterns; Infection prevention/hygiene; Family budget adjustments; pMTCT & STI screening and prevention; Partner/family involvement

Table 4.1: List of items identified by midwives in Delphi Round 1 as priority health messages for developing the TSI

*Included based on clinical considerations

4.3.2 Round 2

Round 2 was sent to 30 midwives working in the postnatal unit in the three selected facilities (ten in each facility), including the ten LAMRN midwives who took part in Round 1. The midwives were asked to identify and prioritise key issues they considered to be of utmost priority for young/adolescent mothers at specific times during the immediate postnatal period. Specifically, the midwives were asked to choose and rank any 3 topical issues of motivational health messages from the list provided, for both young mothers (maternal care) and their babies/infants (newborn/infant care) at week 1; weeks 2-6; and weeks 7-10 after birth. Additionally, the midwives were asked to rank their choices between 1 and 3 based on what they considered to be of utmost priority (1=utmost priority). The participants were also given an option to comment on their choices, explaining their decision for prioritisation; and to suggest any additional information that they thought was important in the space provided. The midwives were asked to provide feedback within 3 weeks.

The results from Round 2 (n=30) were analysed based on the ranked order of the items. Initially, the frequency of each of the selected items (ranked 1; 2; 3) in each of the timeperiods (week1; weeks 2-6; and weeks 7-10) was identified. Subsequently, to determine which item was considered to be utmost priority the selected items were then ordered based on the frequency of the ranked order. An item ranked #1by the majority was considered to be of utmost priority. The same procedure was then applied to all the levels of the ranking order (1; 2; 3) until all the items were ranked in each of the timeperiods. In deciding on which items to retain, items chosen by \leq 4 of the participants starting from the lowest rank (#3) were removed, with the top 3 items being automatically retained for Round 3. Thus, a total of 21 items were removed (maternal-12; newborn/infant-9) from the original list of 68 items (maternal-37; newborn/infant-31), including items that were not chosen/ranked at all. However, for weeks 7-10 in maternal care, two items (bleeding and family budget adjustments) were retained despite each being having been ranked by <4 participants (n=2, 1-#1, 1-#2; and n=3, 1-#1, 2-#3 respectively). Therefore, having been ranked #1, both items were retained for Round 3. Eight new items were suggested (maternal care – 5; newborn/infant care – 3) which were added to the list accordingly. Following discussion with the supervisory team, the list was then compiled for the final round (Round 3). Table 4.2 presents the summary of the data analysis of the items analysed in Round 2, from which the Delphi 3 questionnaire (Appendix 4.4) was developed.

-	-	(A pilot RCT on te ate postnatal period i	-	-	· •		ention amo	ong young
Care domain	Week	Key motivational messages	Ranking and No. of responses (n)				Priority ranking	
			1		2	To tal	(for Delphi	
	_	(Delphi 2)	1	2	3	(n)	3)	Remarks
A. Maternal	Week							
care	wеек 1	Bleeding	11	7	1	19	1	Retained
		Infection						Retained
		prevention	11	3	6	20	2	
		High blood						Retained
		pressure (Pre- /Eclampsia)	4	1	1	6	3	
		Psychosocial	-	1	1	0	5	Retained
		support	2	1	3	6	4	notuniou
		Personal hygiene	1	8	1	10	5	Retained
		Breast care	1	4	3	8	6	Retained
		Nutrition	0	3	6	9	7	Retained
		Pain management	0	1	3	4	8	Dropped
		pMTCT & STI						Dropped
		screening and						
		prevention	0	1	0	1	9	
		Pelvic						Dropped
		floor/Kegel's	0	0	2	2	10	
		exercises Partner/family	0	0	2	2	10	Dropped
		involvement	0	0	2	2	10	Dropped
		Rest	0	0	1	1	10	Dropped
		Family budget	0	0	1	1	12	Dropped
		adjustments	0	0	0	0	N/A	
	Weeks 2-6	Nutrition	11	3	4	18	1	Retained
	-	Personal hygiene	6	5	2	13	2	Retained
		Breast care	5	6	1	12	3	Retained
		Clinical						Retained
		appointment	3	1	1	5	4	
		Contraception/fa mily planning	2	5	10	17	5	Retained
		pMTCT & STI	_		10			Retained
		screening and prevention	2	1	1	4	6	
		Mood changes	2 1	1	1 2	4	7	Retained
		Pelvic	1 0	1 2	2	4 5	8	Retained
			.24	2	5	5	0	retuined

Table 4.2: Summary analysis of Delphi 2 output

		floor/Kegel's						
		exercises						
		Psychosocial					_	Dropped
		support	0	2	1	3	9	
		Sleep	0	1	3	4	10	Dropped
		Pain management	0	1	0	1	11	Dropped
		Family budget						Dropped
		adjustments	0	1	0	1	11	
		Partner/family						Dropped
		involvement	0	0	2	2	13	
	Weeks	Contraception/fa						Retained
	7-10	mily planning	8	3	2	13	1	
		Pelvic						Retained
		floor/Kegel's						
		exercises	6	2	3	11	2	
		Psychosocial						Retained
		support	4	4	3	11	3	
		Personal hygiene	4	3	1	8	4	Retained
		Rest	2	5	4	11	5	Retained
		Nutrition	2	3	5	10	6	Retained
				-	-	-		Retained
		Breast care	1	4	4	9	7	
		pMTCT & STI						Retained
		screening and	1	1		~	0	
		prevention	1	1	3	5	8	D
		Bleeding	1	1	0	2	9	Retained
		Family budget						Retained
		adjustments	1	0	2	3	10	
		Partner/family						Retained
		involvement	0	3	4	7	11	
B.								Retained
Newborn/	Week	Breastfeeding						
Infant	1		14	11	3	28	1	
care		Warmth	12	7	2	21	2	Retained
		Cord care	2	9	12	23	3	Retained
		Bonding	2	0	1	3	4	Retained
		Assessment of the						Retained
		baby –						
		breathing/body	1	1	2	4	5	
		Immunisation	0	2	6	8	6	Retained
		Signs of infection	0	1	1	2	7	Retained
		Colic pain	0	1	1	2	,	Retained
		management	0	0	1	1	8	Retained
		Partner/family	0	0	1	1	0	Retained
		involvement	0	0	1	1	8	Retained
				0	0	1		Dropped
		Sleep patterns	0	-		-	N/A	
		Bathing	0	0	0	0	N/A	Dropped
		pMTCT & STI						Dropped
		screening and	0	0	0	0	N/A	

	prevention						
	Family budget						Dropped
	adjustments	0	0	0	0	N/A	
Weeks 2-6	Immunisation	18	5	5	28	1	Retained
	Breastfeeding	5	8	4	17	2	Retained
	Cord care	3	2	2	7	3	Retained
	Infant feeding patterns	2	5	4	11	4	Retained
	Clinical appointment	1	0	8	9	5	Retained
	Warmth	0	6	3	9	6	Retained
	pMTCT & STI screening and				-		Retained
	prevention	0	3	0	3	7	
	Skin care	0	0	2	2	8	Dropped
	Family budget adjustments	0	0	1	1	9	Dropped
	Partner/family involvement	0	0	0	0	N/A	Dropped
Weeks 7-10	Immunisation	11	6	1	18	1	Retained
	Breastfeeding	6	4	6	16	2	Retained
	Infant care	3	2	6	11	4	Retained
	Sleep patterns	1	5	3	9	5	Retained
	Infection prevention/hygien e	5	9	4	18	3	Retained
	Family budget adjustments	0	0	3	3	8	Retained
	pMTCT & STI screening and prevention	1	0	0	1	6	Retained
	Partner/family involvement	0	0	4	4	7	Dropped

NB: Retained items constituted Delphi 3 questionnaire with the additional items suggested in Round 2

4.3.3 Round 3

Round 3 was conducted in February 2017. The compiled list generated in Round 2 was sent to the same midwives who took part in Round 2. This was to ensure consistency in the Delphi study, as well as to give an opportunity for the midwives to critically reflect on their previous responses. Moreover, it was thought that by this time the midwives would have arrived at some consensus in their responses based on the homogenous nature of the topic, and thus they would have refined the priority areas of the educational intervention. The midwives were asked to select the priority items for the educational intervention in a similar way as Round 2, and requested to provide feedback within 3 weeks. Telephone reminders were made to 5 midwives who had not responded within the 3 weeks, one of whom did not respond.

Although a consensus level (commonly 70%) is often set beforehand, in this study this was not done since the main goal was to identify and rank any three priority areas of educational support for young mothers and their babies/infants during the immediate postnatal period. To help make the responses more specific, the researcher clearly defined the population group to the midwives (young mothers aged 12-19 years), and categorised the list of choices to be ranked to reflect the specific time-periods (Week1; weeks 2-6; and weeks 7-10) in which the intervention (messages) would be send. Table 4.3 presents the summary of the analysed items in Round 3.

		(A pilot RCT on tele te postnatal period in	weste	ern Ke	nya	nterve	ntion amor	ng young
Care domain	Week	Key motivational messages	Ranking and No. of responses (n)		Tot	Priority ranking		
		(Delphi 2)	1	2	3	al (n)	(final)	Remarks
A. Maternal care	Week 1	Bleeding (vaginal)	22	3	0	25	1	
		Infection prevention	6	9	8	23	2	Priority (3)
		Maternal danger signs	5	3	5	13	3	
		Monitoring of lochia changes	2	2	3	7	4	
		High blood pressure (Pre- /Eclampsia)	1	9	3	13	5	
		Personal hygiene	1	5	2	8	6	
		Breast care	0	4	8	12	7	
		Nutrition	0	2	8	10	8	
		Psychosocial support	0	1	1	2	9	
		Schooling/ education	0	0	1	1	10	
		Pre-conception care	0	0	0	0	N/A	
		Economic empowerment/IGA s	0	0	0	0	N/A	
	W/ 1 0	NT / '/'	10	0	7	25	1	
	Weeks 2- 6	Nutrition	10	8	7	25	1	
		Breast care	7	4	1	12	2	Priority (3)
		Maternal danger signs	6	2	2	10	3	
		Contraception/ family planning	4	5	1 1	20	4	
		Personal hygiene	4	4	3	11	5	
		Clinical appointment/follow up	2	11	5	18	6	
		pMTCT & STI screening & prevention	2	1	1	4	7	
		Pelvic floor/Kegel's	2	0	2	4	8	

Table 4.3: Summary analysis of Delphi 3 output

		exercises						
		Mood changes	1	0	0	1	9	
		Monitoring of	0	3	3	6	10	
		lochia changes	Ŭ	5	5	0	10	
		Pre-conception care	0	0	3	3	11	
		Schooling/educatio	0	0	0	0	N/A	
		n						
		Economic	0	0	0	0	N/A	
		empowerment/IGA						
		S	_					
	Weeks 7-	Contraception/	11	3	6	20	1	
	10	family planning						
		Nutrition	8	8	0	16	2	Priority (3)
		Psychosocial	4	3	5	12	3	(3)
		support				12		
		Breast care	4	0	0	4	4	
		Family budget	3	2	2	7	5	
		adjustments						
		Rest	2	3	1	6	6	
		Pelvic	1	10	7	18	7	
		floor/Kegel's						
		exercises	1	2	4	7	0	
		Personal hygiene				-	8	
		Pre-conception care	1	1	2	4	9	
		Bleeding	1	0	2	3	10	
		Monitoring of lochia changes	1	0	0	1	11	
		Schooling/educatio	0	3	0	3	12	
		n			Ŭ			
		pMTCT & STI	0	1	2	3	13	
		screening &						
		prevention	0					
		Maternal danger	0	1	0	1	14	
		signs Economic	0	0	6	6	15	
		empowerment/IGA	0	0	0	0	15	
		s						
		D	1.4		1	01	1	
B. Infant	Week 1	Breastfeeding	14	6	1	21	1	D:
0.0 #0		Warmth	10	14	4	28	2	Priority (3)
care		Assessment of the	8	3	2	13	3	(3)
		baby	0	5	2	15	5	
		Cord care	4	8	1	22	4	
					0			
		Bonding	2	2	3	7	5	
		Danger signs	0	1	8	9	6	
		(Baby/infant)						
		Signs of infection	0	1	8	9	6	
		Immunisation	0	1	1	2	8	

	Colic pain management	0	0	1	1	9	
	Partner/family involvement	0	0	0	0	N/A	
	Weaning	0	0	0	0	N/A	
	Birth registration	0	0	0	0	N/A	
Weeks 2- 6	Immunisation	15	9	4	28	1	
	Breastfeeding	13	7	2	22	2	Priority (3)
	Danger signs (Baby/infant)	4	2	9	15	3	
	Cord care	3	5	3	11	4	
	Clinical appointment/follow -up	1	5	6	12	5	
	Infant feeding patterns	0	5	5	10	6	
	pMTCT & STI screening & prevention	0	1	0	1	7	
	Birth registration	0	0	6	6	8	
	Warmth	0	0	1	1	9	
	Weaning	0	0	1	1	9	
XV 1 7	T.C. J.	10	11	0	20	4	
Weeks 7- 10	Infection prevention/hygiene	10	11	8	29	1	
	Breastfeeding	8	2	1	11	2	Priority (3)
	Infant care	7	9	5	21	3	
	Immunisation	7	7	0	14	4	
	Sleep patterns	1	7	5	13	5	
	Weaning	1	1	3	6	6	
	Danger signs (Baby/infant)	1	0	6	7	7	
	Birth registration	0	0	7	7	8	
	pMTCT & STI screening & prevention	0	0	1	1	9	

KEY: IGAs=Income generating activities

Following this, the top three items in each of the specified time-periods (week 1, weeks 2-6, and weeks 7-10) were identified for both maternal and newborn/infant care domains. Table 4.4 provides a summary of the prioritised items in this Delphi, from which the motivational health messages were developed.

Period	Thematic areas for the motivational health messages – (Prioritised)						
	Maternal care	Newborn/infant care					
Week 1	Bleeding (vaginal)	Breastfeeding					
	Infection prevention	Warmth					
	Maternal danger signs	Assessment of the baby					
Weeks 2-6	Nutrition	Immunisation					
	Breast care	Breastfeeding					
	Maternal danger signs	Newborn/infant danger signs					
Weeks 7-10	Family	Infection prevention					
	planning/contraception	Breastfeeding					
	Nutrition	Infant care					
	Psychological support						

Table 4.4: Summary of the priority items listed for developing the intervention

Importantly, although only the top three items were considered in the eventual development of the health messages (intervention package), it can be observed in Table 4.3 that in some instances there was an overlap in the prioritised items. For instance, in week 1 (maternal care) the two items ranked fourth and fifth (monitoring of lochia changes and high blood pressure/(pre)-eclampsia respectively)) in the Delphi 3 summary analysis are related to maternal danger signs (ranked third), including bleeding which was ranked first. Thus in one way or another, both items were considered in the drafting of the interventional package. Similarly, in week 1 (newborn/infant care), cord care (ranked fourth), and newborn/infant danger signs and signs of infection (both ranked sixth) are cardinal features in the assessment of the newborn/infant (ranked third) while bonding (ranked fourth) is mainly a factor in breastfeeding.

In addition, clinical appointment/follow-up (ranked fifth in weeks 2-6) in the newborn/infant care domain primarily concerns immunisation schedules (ranked first), including the overall assessment of the infant wellbeing in which infant danger sings (ranked third). With such overlap and/or inter-relatedness between items, the researcher also observed clinical considerations in the final drafting of the motivational health messages while ensuring that the prioritised items were adequately reflected in the interventional package. From the items in Table 4.2, motivational health messages that constituted the intervention package were developed (Table 4.7) and piloted among a similar group of mothers (refer to section 4.4.3). It is noteworthy that since this consensus was being sought from a homogenous group of experts (midwives), it was thought that with the existing group dynamics the midwives would reflect on their experience and practice and readily arrive at a consensus. A summary of the Delphi process is presented in Figure 4.1.

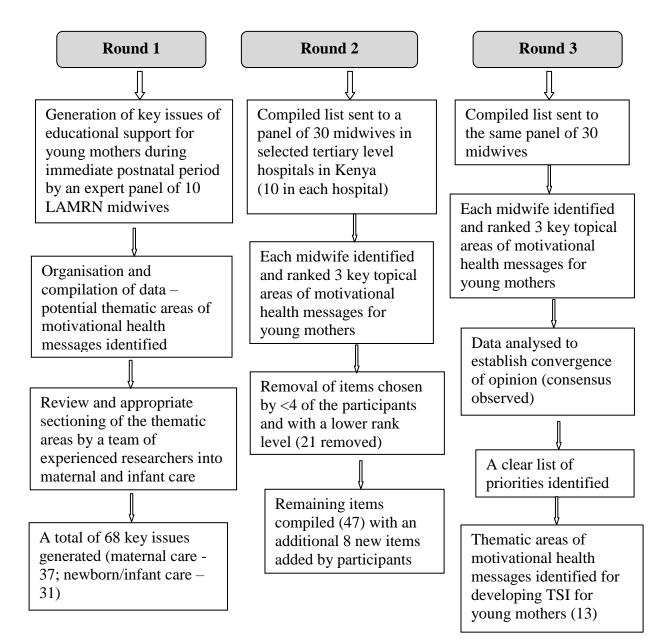


Figure 4.1: Diagrammatic representation of the Delphi process

4.4 Results

4.4.1 Response rate

Of the 30 midwives who took part in Round 2, 29 completed Round 3 thus giving a response rate of 96.7%.

4.4.2 Demographics/participant profiles

All the midwives were female, a half of whom (50%) were aged between 31 and 40 years, with a majority (93%) working as nursing officers. Over two-thirds (70%) of the

midwives had attained a diploma level of education, with only 2 (7%) having attained a certificate level, and none with a PhD. Most had a working experience of between 3-10 years and above, with a varying duration of working in the postnatal unit. Table 4.5 summarises the demographic characteristics of the midwives who took part in the Delphi.

Variable	Frequency (n)
Gender	
Female	30
Male	0
Age range (years)	
21-30	2
31-40	15
41-50	7
51-60	6
Professional qualification	
Enrolled nurse	2
Nursing officer	28
Highest academic qualification	
PhD	0
MScN	3
BScN	10
Diploma	21
Certificate	2
Working experience (years)	
1-2 years	2
3-10 years	15
11-20 years	6
>20years	7
Duration of working in postnatal unit	
<1 year	1
1-2years	6
2-5years	7
5-10years	5
10-20years	1
>20years	5

Table 4.5: Demographic characteristics of the participants (midwives)

4.4.3 Priority health messages for young mothers

Maternal and infant danger signs were identified as priority areas of educational support during the early weeks postpartum, with breastfeeding cutting across the entire period. Other aspects of care thought to be priority included infection prevention, nutrition, breast care and all aspects of infant care, including immunisation. A summary of the analysis of the priority health messages identified from the Delphi is presented in Table 4.6.

Domain of care	Postnatal period	Key motivational messages	Ranking (%) of res	Cumulati ve N (%)		
			1	2	3	
Maternal	Week 1	Vaginal bleeding	22 (76%)	3 (10%)	0 (0%)	25 (86%)
care		Infection prevention	6 (21%)	9 (31%)	8(28%)	23 (79%)
		Maternal danger	5 (17%)	3 (10%)	5(17%)	13 (45%)
		signs				
	Weeks	Nutrition	10 (34%)	8 (28%)	7(24%)	25 (86%)
	2-6	Breast care	7 (24%)	4 (14%)	1(3%)	12 (41%)
		Maternal danger	6 (21%)	2 (7%)	2(7%)	10 (34%)
		signs				
	Weeks	Contraception/	11 (38%)	3 (10%)	6 (21%)	20 (69%)
	7-10	family planning				
		Nutrition	8 (28%)	8 (28%)	0 (0%)	16 (55%)
		Psychological	4 (14%)	3 (10%)	5 (17%)	12 (41%)
		support				
Newborn/	Week 1	Breastfeeding	14 (48%)	6 (21%)	1 (3%)	21 (72%)
infant		Warmth	10 (34%)	14 (48%)	4 (14%)	28 (97%)
care		Assessment of the	8 (28%)	3 (10%)	2 (7%)	13 (45%)
		baby				
	Weeks	Immunisation	15 (52%)	9 (31%)	4 (14%)	28 (97%)
	2-6	Breastfeeding	13 (45%)	7 (24%)	2 (7%)	22 (76%)
		Infant danger signs	4 (14%)	2 (7%)	9 (31%)	15 (52%)
	Weeks	Infection prevention	10 (34%)	11 (38%)	8 (28%)	29 (100%)
	7-10	Breastfeeding	8 (28%)	2 (7%)	1 (3.45)	11 (38%)
		Infant care	7 (24%)	9 (31%)	5 (17%)	21 (72%)

Table 4.6: Summary analysis of the priority health messages for young mothers

4.4.4 Validity check and pilot testing of the interventional messages

The need to maintain and/or enhance rigour in Delphi research has been highlighted (Hasson and Keeney, 2011). Lincoln and Guba (1985) proposed a model of assessing

the quality and applicability of qualitative research findings based on established 'trustworthiness'. Morgan (2004) further argues that the establishment of this truth should primarily reflect the participants' perspectives, and the detailed description of the study process. In addition, Brod et al. (2009) notes that content validity is the assessment of whether items under investigation are comprehensive and adequately reflect the perspectives of the population of interest. While the overall rigour of a study is important, Morse et al. (2002) also argued that the application of verification strategies in the research process enables the researcher to correct both the direction of the analysis and the development of the study, thereby enhancing reliability and validity of the project.

Hasson and Keeney (2011) suggested a few approaches to achieving rigour in Delphi research such as using both qualitative and quantitative measurements and corroborating results for each individual in the Delphi with relevant evidence. The PI (and the research team) was aware of the significance of rigour in the Delphi process prior to the Delphi. To achieve this aim, the PI ensured that all the items listed in all Rounds of the Delphi were included in the subsequent Delphi accordingly following the analysis process and criteria. As such, any additional items that were suggested by the midwives (through the additional option to list any other important aspect/information they considered relevant) were included in the subsequent Round of the Delphi. This way, it was considered would ensure almost all aspects of the topical issue were exhausted hence the richness of the data. In addition, the PI consulted with the supervisory team regularly during the Delphi process.

Thus, following the Delphi output the thematic areas of the educational intervention (Table 4.2) were drafted into motivational health messages for the young mothers. To test the content and the technicality of implementing the proposed intervention, the

researcher shared the initial draft with the research midwives (intervention midwives) in both study centres as well as the supervisors. This served as a useful step in the Delphi in that it ensured prior testing and refining of the final output, including the incorporation of the practical views of the research midwives. The research midwives were asked to review the initial draft and to send their comments to the researcher, while ensuring that the core content of the messages was not lost. This process also served as member checking, and was repeated until a refined third draft was achieved. Notably, strategies such as peer debriefing, prolonged engagement and persistent observation, audit trails, negative cases, and member checks have been suggested to improve trustworthiness (Morse et al. 2002).

Subsequently, the content of the educational intervention was tested prospectively among 12 young mothers in a different health facility (Uasin Gishu District hospital), while making appropriate changes as necessary through regular consultation with the intervention nurses and supervisors. The aim was to ascertain the ease of understanding as well as to evaluate the content validity of the health messages. Following this, appropriate adjustments were made in the wording of the messages to make them more precise and simple. For instance, regarding danger signs the wording was phrased as a precise question asking: Is your baby having [list of neonatal danger signs]?, followed by appropriate action to take if they noted any of these signs. Similarly, for the mother the question was posed as: Are you experiencing [list of maternal danger signs]?, with the suggestion of an appropriate action to take. To ensure that the messages were motivational, words such as "*hello*"; "*how are you and the baby doing today*?"; "*please observe*…" etc. Table 4.7 presents the final draft of the health messages. <u>Table 4.7: Motivational health messages for young mothers (12-19 years)</u> <u>during early postnatal period (birth-10 weeks postpartum) - developed from a</u> <u>Delphi survey of midwives (in Kenya)</u>

Period	SMS draft
Week 1	Hello, hope you are well. Are you having heavy bleeding, hotness of body,
	headache, a bad smell from your vagina or are you feeling stressed? Please
	report to the Nurse/hospital immediately.
	Hello. Is the baby okay? Baby will be okay with breast milk alone and keep
	him warm always. Is the umbilicus red, with pus or has a bad smell? Is the
	baby having difficulty in breathing? If so, report immediately to the
	Nurse/hospital
Week 2	How are you and your baby? Take 1 small feed between meals, with plenty
	of vegetables, fluids and water, starch and proteins. Refer to your clinic
	book on P13. Attach baby well to the breasts and breastfeed on demand
Week 3	Hello, pls observe good attachment while breastfeeding to prevent
	development of cracked/sore nipples and pain during breastfeeding
Week 4	How are you today? Are you breastfeeding your baby well? Alternate
	breasts during feeding to prevent fullness. If your breasts are red, painful,
	swollen or cracked, pls report to the midwife or visit the hospital for
	assistance
Week 5	How are you and baby doing? Next week the baby will receive 2 nd
	immunisation. Remember to keep all clinic appointments.
Week 6	Hello. Have you noticed anything different with the baby like fever,
	irritability, vomiting, refusal to breastfeed or difficulty in breathing? Kindly
	seek medical attention from the Nurse/hospital
Week 7	Hello, Hope your clinic session went well. Have you started having your
	periods? They might be coming soon. Kindly visit the clinic to plan on
	future pregnancies/birth spacing and a suitable method for you
Week 8	Congratulations! Baby is about two months old. Feel free to ask and share
	your experiences with your partner, other elderly women/mothers, friends or
	the nurse. Do not allow yourself to be overwhelmed. Have fun and enjoy
	motherhood.
Week 9	Hello, how are you today? Always observe adequate nutrition as this is very
	important for you & your baby. Continue breastfeeding your baby for at
	least 6 months, if possible, without giving other foods.
Week 10	Hello, hope you are doing well. Always observe hygiene, exclusive
	breastfeeding, keep baby warm, observe all clinic appointments and
	immunisation schedules and sleep under insecticide treated mosquito nets.
	Remember your appointment for this week.

4.4.5 Dissemination of the intervention

Following consensus on the content and wording of the motivational health messages by the research team, further deliberations were made on how best the intervention would be implemented. To our understanding, we thought that the telephone support intervention would constitute the motivational health messages (Table 4.5) sent as a single weekly short text messages (SMSs) and an additional telephone call after every three weeks as described in the design of the study (Chapter 3). The telephone call was generally to inquire about the wellbeing of the mother and the baby/infant, and to provide additional support as necessary, including referral to the hospital in instances where the intervention midwife thought it was necessary. However, considering that the first week is the most critical both for the mother and the baby particularly regarding postnatal danger signs, two separate messages were sent for the mother and the baby. We thought this would help the mothers to specifically assess their own wellbeing and that of their baby independently and observe any of the danger signs listed in the messages.

The intervention nurse-midwives were trained as research assistants (research midwives), and they were working in the postnatal unit at the time of the study. Thus, they were better placed to provide this continuum of care, including responding to any issues raised by the young mothers. During the intervention phase, the researcher held regular contacts with the research midwives to evaluate the intervention process.

4.5 Discussion

The postnatal period is a transition time when physical, social and psychological adjustments need to be made by both the mother and her family (Shaw et al. 2006). The transition to motherhood marks a great change and experience for mothers and the

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childbearing family, most of whom feel inadequately prepared for it (McKellar et al. 2002, 2006). Specific information relating to self-care and baby care has been singled out as primary educational need for first-time mothers (McKellar, 2002).

Psychosocial support during the postpartum period have been thought to improve maternal knowledge, attitudes and skills in parenting and the overall maternal health wellbeing (Shaw et al. 2006). This period may even be more critical for teenage/adolescent mothers, who are more likely to be first-time mothers and may be inadequately prepared for motherhood. Therefore, health systems especially in low income settings need to provide additional and continuous postnatal support for such mothers, including devising innovative and cost-effective ways such as using the mobile telephone. Hannan (2013) noted that telephone call follow up to low income first-time mothers by nurse practitioners is a safe, easy to use and cost-effective means that improved mother-infant health outcomes.

Health care systems and midwives in particular, need to explore the use of such telephone interventions to enhance the package and quality of maternal health services, especially in low-income settings since it transcends physical and economic access to health care services. Moreover, the use of a mobile phone messaging platform has been cited as one of the convenient and cost-effective measures that can be adopted to support desirable health behaviour for preventive health care (Vodopivec-Jamsek et al. 2012). Evidence from systematic reviews on telephone support interventions also suggests that such interventions have proven useful and promising in specific areas of maternal and infant care such as breastfeeding and postnatal depression (Lavender et al., 2013; Sipsma et al. 2015, Dennis and Kinston, 2008; Shaw et al. 2006). With few trials on telephone support interventions having been conducted among women during postpartum period in low income settings such as Kenya, it was necessary to assess the

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feasibility of conducting a main trial on telephone support intervention among young mothers.

4.6 Conclusion

To a novice researcher, the Delphi technique has proven to be one of the useful and fairly easy and cost-effective method of developing consensus on an issue of interest among the other consensus development methods available. Premised on the thought that a collective opinion is more valid than an individual opinion (Keeney et al. 2010), this method provided the researcher with a first-hand experience of developing priority health messages for young mothers through consensus development among fellow midwives. The results of the Delphi were tested in a pilot randomised controlled trial on telephone support among young mothers in western Kenya. Chapters five and six presents the results of this pilot trial.

4.7 Chapter summary

This chapter higlighted the development of the intervention which involved three Rounds of the Delphi process. A detailed description of the procedures used in the Delphi process with appropriate illustrations as necessary, including the analysis of the data were presented systematically until the eventual intervention package was developed and piloted. To put the intervention package in context, the results of the Delphi were discussed in relation to the postnatal care of (young) mothers, specifically in the light of potential areas in which such an intervention (supportive postnatal health education and/or motivational health messages) may impact on MIC outcomes. Moreover, the approaches employed to enhance rigour (trusworthiness) of the Delphi results were highlighted.

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CHAPTER FIVE

QUANTITATIVE RESULTS

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CHAPTER 5: QUANTITATIVE RESULTS

5.0 Introduction

This chapter presents the quantitative results of the pilot trial. The initial section of the chapter describes the recruitment of the participants and provides an illustrative diagram of the participant flow and the baseline characteristics of the participants (sections 5.1-5.3). Subsequently, the descriptive statistics of the outcome measures of interest (postnatal depression, maternal social support, maternal self-esteem and postpartum bonding) are presented, including the inferences made from the data (section 5.4). In addition, self-reported outcome measures on selected aspects of maternal and infant outcomes are presented descriptively.

5.1 Recruitment

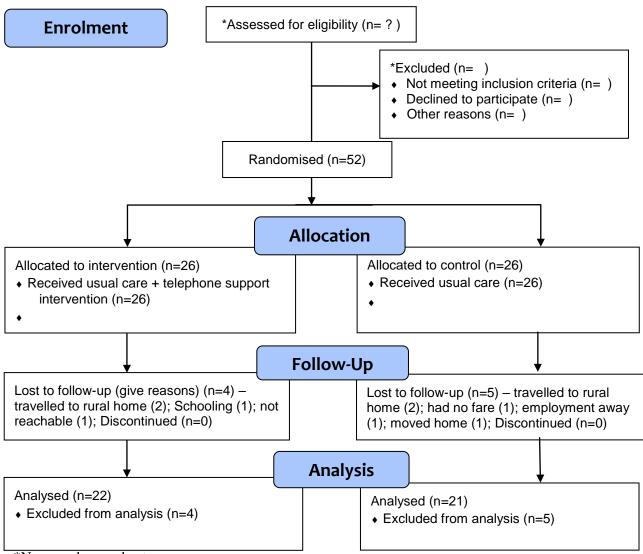
Eligible participants were recruited between 11th May and 7th July 2017 at the postnatal ward before being discharged in both study centres. Baseline data were collected once the participants had given consent. The participants were subsequently followed up for ten weeks postpartum, when outcome data were collected during their second clinical appointment for infant immunisation.

5.2 Participant flow and attrition

The participant flow is reported according to the CONSORT 2010 statement (Moher et al. 2010, Schulz et al. 2010). Moher and colleagues noted that trial reports need to be clear, complete and transparent to enhance the quality of reporting of RCTs and hence the reliability and validity of the trial results, including extracting data for systematic reviews (Moher et al. 2010). In this pilot trial, fifty-two young mothers were enrolled in the study, out of whom 43 completed the follow-up and were analysed (attrition rate=17.3%). There was no protocol violation in the study. Although there were incidences where eligible participants refused to take part in the study, no records were

kept in such cases, including for those who did not meet the inclusion criteria. There were also incidences where participants never returned the consent/assent form before leaving the hospital despite having agreed to take part.

These records would have been informative especially in the context of a pilot or feasibility study. However, this shortcoming has been acknowledged by the researcher. Figure 5.1 presents the participant flow in the pilot randomised trial.



*No records were kept

Figure 5.1: Participant flow in the pilot RCT on telephone support intervention

5. 3 Baseline data

There were no differences in characteristics at baseline between the two randomised groups (Table 5.1). Most of the participants were between 17-19 age bracket (83.7%),

and were single (69.8%) and either unemployed or schooling. Similarly, there were no baseline differences between the intervention and control groups regarding the mean birthweight (3211.2 and 3176.2 grams respectively) and the sex of the baby (53.5% female vs 46.5% male respectively) (Table 5.2).

		Intervention	Control	Total
		n(%)	n(%)	n(%)
Site	MTRH	11 (47.8)	11(55.0)	22(51.2)
	KCGH	11 (52.2)	9(45.0)	21(48.8)
Age group (years)	12-16	3 (13.6)	4(19.0)	7(16.3)
	17-19	19 (86.4)	17(81.0)	36(83.7)
Education level	Primary	10 (45.5)	7(33.3)	17(39.5)
	Secondary	11 (50.0)	14(66.7)	25(58.1)
	Tertiary	1 (4.5)	0(0.0)	1(2.3)
Marital status	Married	4 (18.2)	8(38.1)	12(27.9)
	Single	17 (77.3)	13(61.9)	30(69.8)
	Separated	1 (4.5)	0(0.0)	1(2.3)
Occupation	Self-employed	1 (4.5)	2(9.5)	3(7.0)
	Unemployed	11 (50.0)	12(57.1)	23(53.5)
	Student	10 (45.5)	7(33.3)	17(39.5)
Religion	Catholic	4 (18.2)	3(14.3)	7(16.3)
	Protestant	18 (81.8)	17(81.0)	35(81.4)
	Muslim	0 (0.0)	1(4.8)	1(2.3)
No. ANC visits	None	0 (0.0)	1 (4.8)	1(2.3)
	One	2 (9.1)	4 (19.0)	6(14.0)
	Two	2 (9.1)	0 (0.0)	2(4.7)
	Three	5 (22.7)	2 (9.5)	7(16.3)
	Four	11 (50.0)	9 (42.9)	20(46.5)
	>four	2 (9.1)	5 (23.8)	7(16.3)
Primary support pe	rson Parent	18 (81.8)	16 (76.2)	34(79.1)
	Partner	3 (13.6)	4 (19.0)	7(16.3)
	Friend	1 (4.5)	0 (0.0)	1(2.3)
	None	0 (0.0)	1 (4.8)	1(2.3)
Baby sex	Male	11(50.0)	9 (42.9)	20(46.5)
	Female	11 (50.0)	12 (57.1)	23(53.5)
Distance to clinic	<5km	11(50.0)	10 (47.6)	21(48.8)
	>5km	11 (50.0)	11 (52.4)	22(51.2)

Table 5.1: Socio-demographic characteristics of the enrolled participants by randomised group

KEY: MTRH – Moi Teaching and Referral Hospital; KCGH – Kakamega County General Hospital

Variable	Freq. n	Mean (SD)	Median	Min value	Max value	95% CI for mean
Birth-weight						
(grams)						
Intervention						
Control	22	3211.2 (507.4)	3263	2200	4500	2986.2 to 3436.1
	21	3176.2 (481.0)	3100	2100	4500	2957.2 to 3395.1

Table 5.2: Descriptive statistics for babies' birthweight by randomised group

5. 4 Post-intervention outcomes

5.4.1 Postnatal depression and maternity social support

Table 5.3 and Table 5.4 present the descriptive and group analysis summary statistics for EPDS and MSSS scores respectively. There was no difference between groups in means for both postnatal depression (EPDS) (intervention group mean 8.5, control group mean 8.6, p=0.916) and maternity social support (MSSS) (intervention group mean 22.9, control group mean 22.5, p=0.763). The effect sizes were small (Cohen's d=-0.03 and 0.09 for EPDS and MSSS) respectively.

<u>Table 5.3: Descriptive statistics for postnatal depression and maternity social</u> <u>support by randomised group</u>

	Freq.	Mean (SD)	Median	Min	Max	95% CI for
Variable	n			value	value	mean
Postnatal depression						
(EPDS)						
Intervention	22	8.5 (5.1)	8	1	17	6.2 to 10.8
Control	21	8.6 (4.9)	9	1	18	6.4 to 10.9
Maternity social						
support (MSSS)						
Intervention	22	22.9 (4.5)	22	12	30	20.9 to 24.9
Control	21	22.5 (3.8)	22	14	29	20.7 to 24.2

	Intervention	Control	Test	df	p-	95% CI for	Effect size
Variable			statistic		value	difference in	(Cohen's d)
	n	n	t			means	
Postnatal	22	21	- 0.107	41	0.91	-3.28 to 2.95	- 0.03
depression index					6		
(EPDS)							
Maternity social	22	21	0.304	41	0.76	-2.19 to 2.97	0.09
support (MSSS)					3		

<u>Table 5.4: Postnatal depression and maternity social support by randomised</u> <u>group</u>

5. 4.2 Maternal self-esteem and postpartum bonding

The summary of descriptive statistics and group analyses for both SES and PBI are presented in Table 5.4 and Table 5.5 respectively. Mothers in the intervention group appeared to have a very slightly higher self-esteem (mean=23.0, median=25) compared to the control group (mean=21.6, median=22). Mothers in the intervention group appeared to have a slightly lower infant-focussed anxiety (mean=2.6, median=1.5) than the control group (mean=3.7, median=4.0). There was no statistically significant difference between groups in means for maternal self-esteem (SES), (p=0.087) and postpartum bonding factors (PBI-1, PBI-2 and PBI-3, all p>0.05), but there was a moderate effect size for SES (Cohen's d=0.54).

	Freq.	Mean (SD)	Median	Min	Max	95% CI for
Variable	n			value	value	median
Maternal self-esteem						
(SES)						
Intervention	22	23.0 (4.5)	25	13	27	21 to 26
Control	21	21.6 (3.2)	22	16	27	20 to 24
PBI 1 -General						
Intervention	22	6.8 (5.3)	6	1	27	4 to 8
Control	21	6.7 (3.8)	7	1	14	4 to 10
PBI 2 -Rejection and						
pathological anger						
Intervention	22	3.0 (3.4)	2	0	9	0.001 to 5
Control	21	2.9 (2.8)	2	0	10	0.001 to 5
PBI 3 Infant-focussed						
anxiety						
Intervention	22	2.6 (2.5)	1.5	0	7	1 to 5
Control	21	3.7 (3.0)	4.0	0	10	0.001 to 6

<u>Table 5.5: Descriptive statistics for maternal self-esteem and postpartum</u> <u>bonding by randomised group</u>

KEY: PBI=Postpartum bonding instrument

Table 5.6: Maternal self-esteem and postpartum bonding indices by	
randomised group	

	Intervention n(%)	Control n(%)	Test statistic MW Z	p- value	95% CI for difference in medians	Effect size (Cohen's d)
Maternal self- esteem (SES)	22 (51.2)	21 (48.8)	- 1.709	0.087	0.001 to 4.00	0.54
Postpartum bonding – Factor 1 (PBI 1)	22 (51.2)	21 (48.8)	- 0.416	0.678	- 3.00 to 2.00	0.13
Postpartum bonding – Factor 2 (PBI 2)	22 (51.2)	21 (48.8)	- 0.250	0.803	-2.00 to 2.00	0.07
Postpartum bonding – Factor 3 (PBI 3)	22 (51.2)	21 (48.8)	- 0.911	0.362	-3.00 to 1.00	0.28

KEY: PBI=Postpartum bonding instrument

The potential effect of the intervention on maternal self-esteem can be illustrated by the following histograms (Figure 5.2). The histogram representing the intervention group (Group 1) was asymmetrical suggesting a non-Normal distribution (negative skewness) with a large peak at the right-hand side. Many of the participants receiving the intervention ended up with high maternal self-esteem. The histogram representing the

control group (Group 2) was symmetrical with bars of roughly the same height, suggesting a uniform distribution. Maternal self-esteem was not measured at baseline, but it is reasonable to assume that its distribution in the intervention group at baseline would be similar to that in the control group at follow-up. This suggests that the TSI clearly has the potential to improve maternal self-esteem. This should be confirmed with a larger study with maternal self-esteem measured at baseline and follow-up.

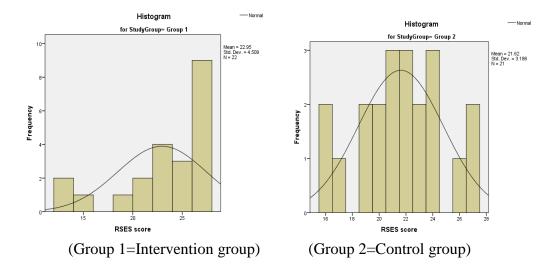


Figure 5.2: Histograms illustrating the potential effect of the intervention (TSI) on maternal self-esteem among young mothers

Histograms for infant-related anxiety in the intervention group (Group 1) and the control group (Group 2) were both asymmetrical with positive skewness (suggesting a non-Normal distribution) (Figure 5.3). Both histograms were bimodal, suggesting distinct groupings of participants with low and with medium anxiety in the two study groups at follow-up. However, none of the participants in the intervention group had high levels of anxiety after the intervention. Values on the scale score axis suggest that the intervention may have had a net effect of reducing infant-related anxiety among the young mothers. Again, this could be confirmed with a larger study with infant-related anxiety measured at baseline and follow-up.

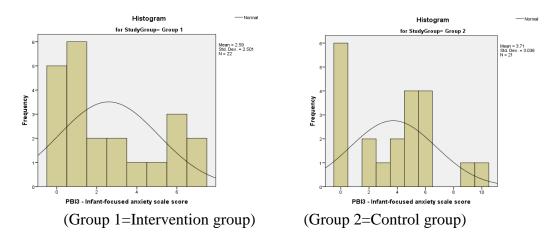


Figure 5.3: Histograms illustrating the potential effect of the intervention (TSI) on infant-related anxiety among young mothers

5.4.3 Maternal and infant health outcomes

Table 5.6 provides summary statistics for maternal and infant health outcomes in both randomised groups. Mothers in the control group were more likely to report having fallen ill (71.4% vs 22.7%), 95% CI for difference in percentages =18.9% to 68.1%); using medication after birth (57.1% vs 31.8% , 95% CI for difference in percentages=4.0% to 49.3%); having difficulty in breastfeeding (38.1% vs 9.1%, 95% CI for difference in percentages =3.5% to 51.0%); and introducing feeds to their infants, including water during in the early postpartum period (52.4% vs 22.7%, 95%CI for difference was observed between the groups regarding reported infant illness or medication use, vaccination, use/intention to use family planning method, and perception of infant getting enough breastmilk. Almost all mothers (n=42) had had their babies receive due vaccinations and perceived their babies were getting enough breastmilk at the time of the outcome evaluation, with all (n=43) having reported a weight gain among their infants.

Stem statement	Interventio n n(%)	Control n(%)	Chi- square (χ^2)	p-value	95%CI for difference in percentages (%)
Have you had any illness since giving birth?	5 (22.7)	15 (71.4)	10.24	0.001	18.9 to 68.1
Have you taken any (self) medication since giving birth?	7 (31.8)	12 (57.1)	2.79	0.095	-4.0 to 49.3
Has your baby fallen ill since you were discharged from hospital?	10 (45.5)	8 (38.1)	0.24	0.625	-33.8 to 20.7
Have you ever given any medication to your baby since giving birth?	10 (45.5)	10 (47.6)	0.02	0.887	-25.5 to 29.4
Have you fed your baby with other feeds? And water?	5 (22.7)	11 (52.4)	4.04	0.044	0.9 to 52.7
Are you using (or intend to use) any family planning method?	12 (54.5)	12 (57.1)	0.03	0.864	-25.1 to 29.7
Did you experience any difficulty in breastfeeding?	2 (9.1)	8 (38.1)	-	0.034*	3.5 to -51.0
Has your baby received due vaccinations since birth?	22 (100.0)	20 (95.2)	-	0.488*	-22.7 to 10.6
Is your baby getting enough breast milk?	22 (100.0)	20 (95.2)	-	0.488*	-22.7 to 10.6
Has your baby had any change in weight?	22(100.0)	21(100.0)	-	-	-15.5 to 14.9

Table 5.7: Maternal and infant health outcomes by randomised group

*p-value=Fisher's exact test

5.5 Chapter summary

In summary, this chapter presented the quantitative findings of the pilot RCT. It described the recruitment of participants into the study and the participant flow upon randomisation and group assignment. The findings of the outcomes of interest: postnatal depression (EPDS); maternal social support (MSSS); maternal self-esteem (RSES); and postpartum bonding (PBI), including maternal-infant outcomes of interest were presented descriptively with inferences as appropriate.

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CHAPTER SIX

QUALITATIVE RESULTS

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CHAPTER 6: QUALITATIVE RESULTS

6.0 Introduction

This chapter describes the analysis process of the qualitative data, specifically the Framework analysis (FA) method (Ritchie and Spencer, 1994). The chapter highlights the steps of FA and how they were applied in the data analysis process. It also provides specific examples of how the data were handled in each step, up and until the final themes (categories) were developed. The details of FA as a method of qualitative data analysis were described in Chapter three (Section 3.10.2).

This chapter begins with the sociodemographic characteristics of the participants who took part in the qualitative interviews. The themes and subthemes identified from the FA are then presented in detail. At the end, a summary of the chapter is presented.

6.1 Sociodemographic characteristics of participants

The participants in this study included young mothers (15-19 years) who were recruited soon after giving birth (before being discharged from the hospital), and midwives working in the respective study centres (refer to section 3.6.1 for eligibility criteria). Table 6.1 and Table 6.2 present the sociodemographic characteristics for the young mothers and midwives respectively, who took part in the qualitative interviews.

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		Primary	Christian	Unemployed	1+0	4
8	Single	Primary	Christian	Unemployed	1+0	4
.0	Married	Primary	Christian	Unemployed	1+0	4
5	Single	Primary	Christian	Student	1+0	2
7	Single	Secondary	Christian	Student	1+0	3
7	Single	Primary	Christian	Student	1+0	1
8	Married	Secondary	Christian	Unemployed	1+0	4
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9	Single	Secondary	Christian	Unemployed	1+0	3
8	Single	Secondary	Christian	Student	1+0	1
8	Single	Primary	Christian- catholic	Student	1+0	4
9	Single	Secondary	Christian	Unemployed	1+0	3
8	Single	Primary	Christian- catholic	Student	1+0	4
9	Married	Secondary	Christian	Unemployed	1+0	>4
9	Married	Secondary	Christian	Unemployed	1+0	4
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Table 6.1: Characteristics for young mothers

Participant ID	Gender	Age range (years)	Professional qualification	Working experience (years)	Highest academic qualification	Duration of working in ANC/PN unit (yrs)
MW M001	F	25-30	NO I	7	BSc.N	4
MW M002	F	36-40	NO I	9	BSc.N	3
MW K001	F	50-55	NO I	21	MSc.N	10
MW K002	F	31-35	NO III	7	Diploma	3
MW K003	М	25-30	NO III	8	Diploma	3
MW K004	F	31-35	NO III	5	Diploma	2
MW.fgd M001	F	36-40	NO III	13	Diploma	7
MW.fgd M002	F	36-40	NO I	8	BSc.N	4
MW.fgd M003	F	41-45	NO III	16	Diploma	9
MW.fgd M004	F	46-50	NO III	22	Diploma	12
MW.fgd M005	М	26-30	NO III	31/2	Diploma	2
MW.fgd M006	F	56-60	NO III	28	Diploma	11
MW.fgd M007	F	36-40	NO I	11	BSc.N	5
MW.fgd M008	F	56-60	NO III	23	Diploma	10

Table 6.2: Characteristics for midwife participants

6.2 The FA analytical framework

6.2.1 Familiarisation with data

Familiarisation is the initial step in FA, and involves repeated listening and/or reading of the audio recorded data or transcripts, including field notes respectively. Transcribed data were read through to identify emergent themes or concepts related to the identified framework. The framework was developed a priori (described in section 6.2.2 below). To make a general sense of the two participant-groups' views, this process was systematically carried out and performed separately for the midwives' and young mothers' interviews. Although much data were collected, including some that was less relevant to the research question, this step helped to narrow the focus of the identified

framework. Such data were therefore set aside. Moreover, being a novice researcher meant that this process helped the researcher to reflect on the skills of conducting a research interview, particularly on how to focus on the research question without necessarily inhibiting the generation of data from participants. The researcher found this aspect particularly challenging when interviewing such a group of young mothers (teenage mothers).

6.2.2 Identifying/developing the framework

Four thematic areas were identified a priori to guide the analysis plan: (i) midwives' perceptions of young mothers' needs for additional support after birth; (ii) young mothers' needs for additional support after birth; (iii) midwives' perception(s) of telephone support intervention (TSI); and (iv) young mothers' perception(s) of TSI. This framework was largely informed by the interview guide that was developed prior to conducting the study. As the study was a pilot RCT seeking to explore the feasibility and acceptability of a TSI, the interview guide largely focussed on young mothers' support needs after giving birth and the potential role of TSI in addressing such needs. Therefore, this informed the development of the thematic framework adopted in the study.

However, like in any other qualitative research process, the researcher was well aware of the need to have an open mind and maintain flexibility so as to review and/or refine the framework as necessary during the analysis process. In addition, although this framework was mainly based on two thematic areas (young mothers' support needs and TSI), the researcher (together with the supervisory team) were much aware of the need to explore the commonalities and variations of different participants' views – the perceived support needs (midwives) vs young mothers' needs; and their perceptions of TSI as service providers (midwives) and service-users (young mothers). It was thought

that this would provide a rich contextual data to draw upon when considering a future trial/study. In summary, Table 6.3 provides the thematic framework for the study, which constituted the main themes of the framework upon which the common themes identified from the iterative process of data analysis were aligned and indexed accordingly (forming the subthemes) as will be seen in the subsequent steps.

Participant group	Main themes [a priori themes]
Midwives	 Midwives' perceptions of young mothers' needs for additional support after birth Midwives' perception(s) of TSI Other emergent themes (new frames)
Young mothers	 4) Young mothers' needs for additional support after birth 5) Young mothers' perception(s) of TSI 6) Other emergent themes (new frames)

Table 6.3: Thematic framework for the study

TSI=Telephone support intervention

6.2.3 Indexing data

With the thematic framework in mind (Table 6.3), all the transcripts were read through again and data labels related to the main themes in the framework were extracted and aligned accordingly, while at the same time taking note of new labels or themes. At this point, the data labels which appeared to be similar in their content domain were grouped, and assigned a main label (subtheme). This process was performed repeatedly across all the transcripts. Throughout this iterative process, sensitivity to new data labels was observed by writing them down for further analysis so as to determine whether they could be considered as main themes (new frames), subthemes or otherwise. This was also to ensure that all the transcripts were analysed back and forth against the new data labels, notably where 'new frames' were identified. Moreover, to ensure that this aim was achieved, the researcher developed a 'working chart/table' where all transcripts can be analysed so as to identify the thematic areas, including new data (frames) that emerged. This process was very helpful as it ensured that all the contents of the

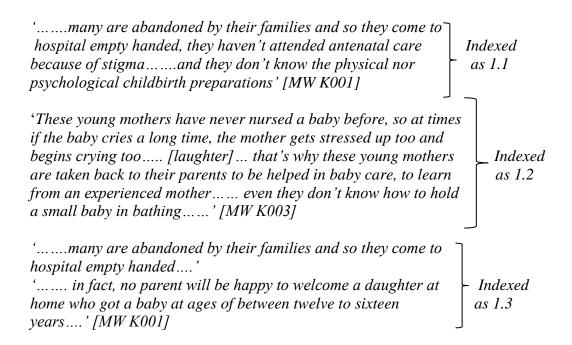
transcripts were analysed as well as taking note of the emergent themes prior to indexing. Moreover, it provided an easy means of tracking each transcript as well as comparing against the 'a priori' thematic framework, thus enhancing researcher sensitivity to new data and/or points of data convergence or divergence. Table 6.4 provides transcript extracts from individual interviews with two midwives that exemplify this process. The emergent themes derived from individual transcripts were then compared with the 'a priori themes' so as to ensure appropriate indexing was achieved.

Participant Interview transcript ID	Data extraction/participant raw data	Emergent themes
 MW K003 INT: so, to start us off, as a midwife, how can you describe your experience in helping young mothers during childbirth, and perhaps your perceptions about young motherhood? RES: it's a challenge in itself, because they are so inquisitive, they know nothing, that's why they ask so many questions, even during caring for their baby, hence they need someone reliable to help them, and since you helped them in delivery and even initiated breastfeeding, they end up taking your phone number, always sending text messages and phone calls INT: Secondly, what challenges do you think young adolescent mothers face during the immediate postnatal period? RES: These young mothers have never nursed a baby before, so at times if the baby cries a long time, the mother gets stressed up too and begins crying too [laughter] that's why these young mothers are taken back to their parents to be helped in baby care, to learn from an experienced mother, and in breastfeeding challenges include engorged breasts and even pain in the uterus contractions and even they don't know how to hold a small baby in bathing[laughter] INT: well, in your view as a midwife, do you think young mothers need additional support during childbirth or even in postnatal period? RES: Yes because, like one I have been following up, she needed someone to educate her INT: Could there be alternative ways of providing this additional support? 	It [experience with young mothers as a midwife] is a challenge in itself, because they are so inquisitive, they know nothing, that's why they ask so many questions, even during caring for their baby, hence they need someone reliable to help them, and since you helped them in delivery and even initiated breastfeeding, they end up taking your phone number, always sending text messages and phone calls These young mothers have never nursed a baby before, so at times if the baby cries a long time, the mother gets stressed up too and begins crying too [laughter] that's why these young mothers are taken back to their parents to be helped in baby care, to learn from an experienced mother even they don't know how to hold a small baby in bathing	*Lack of knowledge *Potential role of TSI as a means of support *Lack of motherhood experience/being first timers *Need emotional support? *Learning from experienced mothers *knowledge

MW K001	INT: Yeah, what about the young/adolescent mothers' preparation	many are abandoned by their families	*Stigma/rejection/lack
	for childbirth and motherhood?	and so they come to hospital empty handed,	of support
	RES: it's a challenge because they get unwanted pregnancies,	they haven't attended antenatal care because of	
	many are abandoned by their families and so they come to hospital	stigma, ended up as school dropouts because	*Lack of knowledge –
	empty handed, they haven't attended antenatal care because of	of low self-esteem, and they don't know the	not attended antenatal
	stigma, ended up as school dropouts because of low self-esteem,	physical nor psychological childbirth	care
	and they don't know the physical nor psychological childbirth	preparations	
	preparations		*Lack of motherhood
	INT: Yeah, so unfortunate these parents end up rejecting	They do not know how to breastfeed, the	experience/knowledge/p
	their children secondly, what challenges do you think	danger signs of a mother and baby also,	hysical needs
	adolescent mothers face during the immediate postnatal period?	puerperal sepsis, lack of sanitary pads, poor	-
	RES: They do not know how to breastfeed, the danger signs of a	hygiene, no soap, psychological torture, in	*Hostility/lack of
	mother and baby also, lack of sanitary pads, poor hygiene, no	fact, no parent will be happy to welcome a	support at home
	soap, psychological torture, in fact, no parent will be happy to	daughter at home who got a baby at ages of	
	welcome a daughter at home who got a baby at ages of between	between twelve to sixteen years	
	twelve to sixteen years [laughter]		
	INT: Yeah,meaning, we need to speak to parents also well,		
	in your view as a midwife, do you think young mothers need		
	additional support during childbirth or even in postnatal period?		

*Potential themes/thematic areas for indexing

As can be observed from the above extracts (Table 6.4), several issues were identified as potential themes: lack of knowledge; lack of motherhood experience or being firsttimers; stigma and/or rejection; hostility; and possibly the need for (emotional) support and/or learning from other experienced mothers, including the expressed need for telephone support (taking midwife's telephone number) by the young mothers. To illustrate the indexing process (refer to Table 6.5 for the full list of indexed items), the above interview extracts serve as examples.



Similarly, the mothers' responses were analysed and indexed in the same way, as

illustrated by the following excerpts:

'The telephone support was educative giving me knowledge on things I did not know, especially on hygiene, on danger signs and am so thankful to the sister [name withheld], because were it not for her, I would not know what to do, like, one time my baby had developed skin rashes with puss, so my mother advised me to apply ash on the baby, but when I asked the Nurse, she directed me to go to hospital.....[laughter]...' [YM.fgd₁ M001, 17 years] '..... My mother-in-law first helped me bathing my baby after I was discharged... I learnt from her and now I can comfortably clean and change my baby' [YM M002, 18 years] A metal set to go to hospital as the set to go to hospital as the set of the s Notably, during the indexing process new data labels were identified from the young mothers' interviews – the need to involve parents/guardians and spouses in TSI (indexed as a subtheme), and the use of alternative medicine/herbs during the postnatal period and/or in maternal and infant care (indexed as a new frame/main theme); and sex education (indexed as new frame/main theme) emerged as an important issue from the midwives' interviews. In general, Table 6.5 presents the summary of the main themes and subthemes after indexing that built the thematic framework of the study.

Ma	in themes	Subthemes	
1.	Midwives' perceptions of	1.1 Lack of knowledge/information	
	young mothers' needs for	1.1.1 Poor/lack of ANC attendance	
	additional support after birth	1.1.2 stigma as a hindrance to ANC attendance	
		1.1.3 Schooling as a hindrance to ANC	
		attendance	
		1.2 Lack of motherhood experience	
		1.3 Hostile home environment	
		1.3.1 Stigma	
		1.3.2 Lack of support	
2.	Midwives' perception(s) of	2.1 Perceived (potential) roles/benefits of TSI in	
	TSI	maternity care	
		2.2 Perceived TSI as feasible and acceptable	
		2.3 Perceived TSI as cheap/cost-effective and	
		time-efficient	
3.	Sex education for	3.1 The role of teachers/schools	
	adolescents/young people	3.2 The role of parents/guardians and the	
		community	
4	Variation of the second second second	4.1.1 set of here and the first superior	
4.	Young mothers' felt needs for additional support after birth	4.1 Lack of knowledge/information4.2 Lack of motherhood experience	
	additional support after offth	4.2 Lack of modelling	
		4.4 Social support systems for young mothers	
		after birth	
		4.5 Continued education/schooling as a concern	
		to young mothers	
5	Young mothers' perception(s) of	5.1 Perceived benefits of TSI in maternal role	
5.	TSI	attainment	
		5.2 Perceived TSI as cheap and cost-effective	
		5.3 Involving parents/guardians and spouses in	
		TSI	
6.	Use of alternative	6.1 Who provides alternative treatment/herbs	
	medicine/herbs during postnatal	6.2 Ailments (commonly) treated by traditional	
	period	herbs	

Table 6.5: Main themes and subthemes from the interview data

6.2.4 Charting, interpretation and summarising the data

These steps followed the indexing of the data in the thematic framework. The steps involved the analysis of the indexed data labels (themes and subthemes) against all the participant interviews. Therefore, the subthemes were charted as columns against the participants (cases) which formed the rows as denoted by the anonymised participant ID. Participant responses (verbatim quotes) relating to a particular subtheme were charted in the cells accordingly, from which the data were then summarised. Although these are two independent steps in FA, both were carried out concurrently using Microsoft Excel software. This allowed the researcher to constantly compare the participant verbatim statements with the summarised data so as to ensure that the original meaning of participant responses (transcripts) was not lost during the interpretation and summarising of the data. Moreover, this would facilitate an audit trail of the data.

To ensure that each indexed theme (Table 6.5) was comprehensively analysed, each theme (with the respective subthemes) were separately charted and analysed against all the transcripts (cases), while considering the relationships between themes. For instance, Theme 1 (midwives' perceptions of young mothers' needs for additional support after birth) was related to Theme 4 (young mothers' felt needs for additional support after birth) (Table 6.6 and Table 6.7 respectively). Similarly, midwives' perceptions of TSI (Theme 2) was related to young mothers' perceptions of the TSI (Theme 5) during the analysis, interpretation, and summarising of the data (Table 6.8 and Table 6.9). This approach was helpful in that the researcher was able to identify any convergence and/or divergence between the two participant groups across the themes at the earliest opportunity.

Thus, the summary of the thematic charts, interpretation and summary of data in the FA schema for midwives' and young mothers' interviews is presented accordingly (Tables 6.6 - 6.9).

1. Midwives'	. Midwives' perceptions of young mothers' needs for additional support after birth				
Participant ID	1.1 Lack of knowledge	1.2 Lack of motherhood experience	1.3 Hostile home environment		
MW K001	'many are abandoned by their families they haven't attended antenatal care and they don't know the physical nor psychological childbirth preparations		 'many are abandoned by their families and so they come to hospital empty handed' ' in fact, no parent will be happy to welcome a daughter at home who got a baby at ages of between twelve to sixteen years' 		
Summary data	Young mothers do not attend antenatal care because of stigma or being abandoned, so they lack adequate knowledge on childbirth		Young mothers face the dilemma of either being abandoned by their families or even being unwelcome after giving birth		
MW K003	'It is a challenge in itself, because they are so inquisitive, they know nothing, that's why they ask so many questions, even during caring for their baby, hence they need someone reliable to help them'	These young mothers have never nursed a baby before, so at times if the baby cries a long time, the mother gets stressed up too and begins crying too[laughter] that's why these young mothers are taken back to their parents to be helped in baby care, to learn from an experienced mother even they don't know how to hold a small baby in bathing			
Summary data	Midwives find it challenging while attending to young mothers and felt that they (young mothers) often need to be supported after birth because they lack knowledge and parenting skills	Young mothers lack prior experience in nursing their babies, and often get emotionally overwhelmed when the baby cries a lot. In such occasions, their parents become a very important source of support as they learn especially from an experienced mother			
MW M001	'most of them were not taken through the	'some had genuine concerns, but			

Table 6.6: Thematic chart for analysing midwives' interview data (Index: Theme 1)

Summary data	antenatal care process, so they did not know how to handle their babies[gesture] many did not attend antenatal care and neither were taught on birth preparedness and motherhood' Young mothers rarely attend antenatal care	others, just from their texts, you quickly realise that they are very green, asking petty questions because it is their first baby and first time experience, thinking that what their baby is facing is abnormal, yet it's very normal' Being a first-time mother is often	
	and thus miss vital lessons on birth preparedness that would enable them to effectively assume motherhood roles	characterised by lack of knowledge and parenting skills that renders them appear helpless as they transit to motherhood	
MW.fgd M001	'many adolescents leave school direct into the labour ward, they are busy with school, so they don't attend antenatal care, so if we get social workers they'll be of great importance'		
Summary data	Many young mothers especially the adolescents rarely attend antenatal care because they are schooling (during pregnancy), thus they only come to hospital when they are in labour		
MW.fgd M002			'In hospital, it is very friendly with all support from all health workers, but after discharge, home environment is hostile and with stigmatisation, this a major challenge to breastfeeding'
Summary data			Young mothers may find themselves in hostile environment characterised by stigma and lack of support as soon as they get discharged from the hospital

Table 6.7: Thematic chart for analysing young mothers' interview data (Index: Theme 4)

4. Young moth	ers' felt needs for addition	I. Young mothers' felt needs for additional support after birth				
Participant ID	4.1 Lack of knowledge	4.2 Lack of motherhood experience	4.3 Maternal role modelling	4.5 Social support systems for young mothers after birth	4.5 Continued education/schooling as a concern to young mothers	
YM.fgd ₁ M001 17 years	'The telephone support was educative giving me knowledge on things I did not know, especially on hygiene, on danger signs and am so thankful to the sister [name withheld], because were it not for her, I would not know what to do, like, one time, my baby had developed skin rashes with puss, so my mother advised me to apply ash on the baby, but when I asked the Nurse, she directed me to go to hospital'	'it was very tough at the beginning in bathing, washing and even changing the baby, because, the baby was too small to sit in a basin, you feel like she may fall' 'at the beginning, I had difficulties in breastfeeding, it was very painful, when I enquired from Sister [name withheld], she directed me on what to do, and later on I breastfed very well'	'It was hard to clean the baby when the umbilical cord had not dried, so my mother taught me how to do it'		<i>•yes,I still need support</i> in caring my baby just as my colleague has said, since I will be going back to school, so I need someone to help me'	
Summary data	Young mothers perceived the telephone support helped them to know and to seek accurate information in infant care	Young mothers experienced challenges in infant care such as difficulty in breastfeeding and bathing the baby	Maternal mother plays a key role in helping young mothers to assume motherhood responsibilities		Young mothers need continuous support in infant care since they may still be schooling	
YM M002 18 years			' my mother-in-law first helped me bathing my baby after I was discharged I learnt	'yes, I got support from relatives, neighboursthey helped me in caring my baby,		

~ ~ ~		from her and now I can comfortably clean and change my baby'	bathing, financially, baby care'	
Summary data	 	Young mothers learn parenting skills from family members particularly mother- in-law who serve as role-models until they attain confidence and independence in infant care responsibilities	Family support is very critical for young mothers particularly first-time mothers as they transit to motherhood	
YM.fgd ₃ M005 18 years	 			'I need support from my family members, to help me in baby care till I finish schooling'
	 			Family support to young mothers who are still schooling is very critical
YM.fgd ₁ M003 19 years	 		'As a young mother, I still need support at home, doing my home chores, even when am sick or at times when am tired, I need support'	
	 		Young mothers need continuous support after birth	

Table 6.8: Thematic chart for analysing midwives' interview data (perceptions about TSI)(Index: Theme 2)

2. Midwives' perceptions of telephone support intervention (TSI)Participant2.1 Perceived (potential)2.2 Perceived TSI as feasible and2.3 Perceived TSI as cheap/cos				
-	· •		2.3 Perceived TSI as cheap/cost-effective	
ID	roles/benefits of TSI in maternity	acceptable	and time-efficient	
	care			
MW K001	'Sending text messages and making phone calls as midwives to these young mothers will be very important, informing on cord care and some of the danger signs' 'I strongly suggest that we also do the same to in antenatal period'		'and even it will be cheaper economically and less time consuming, as in, wasting time and fare travelling from the village to hospital to seek assistanceand yet it can be sorted out using a two minutes phone call or a mere text message'	
	<i>`it will greatly reduce both maternal and neonatal deaths because they will know how to handle the danger signs'</i>			
Summary data	Midwives perceived the TSI as an important means of imparting knowledge on maternal and infant care to young mothers as well as help in reducing maternal and neonatal deaths; and thought the intervention could be initiated as early as during the antenatal period		Midwives perceived TSI to be cheap and cost- effective as it will save mothers traveling costs while seeking care for minor issues that can timely be addressed by a telephone means	
MW M002			'it will ease my work by helping me to plan well because you will be able to know and plan very well on who and who is coming on this day and date, even help in organizing for appointments with patients and even giving me good time management'	
Summary data			Midwives thought the TSI would be helpful in planning and organising their daily activities such as clinical appointments, thereby giving them a better time management	
MW M001		<i>'I will really appreciate having such a</i>	' the telephone support, having phone calls	

Summary data		follow-up system, and yes it's doable and feasible, because, its beneficial and I believe my fellow midwives will unanimously agree with it' Midwives thought the TSI would provide an effective follow up system for (young) mothers and perceived it to be feasible and readily acceptable among midwives	and short message services, this is cheaper and more economical than travelling all the way to hospital and back' Midwives thought the TSI would be cheaper and cost-effective means of meeting their health needs while at home other than travelling all the way to hospital
MW.fgd M001	'many times, you hear my colleagues say, "how is so and so, we took care of her, nursed her for three days and discharged her in a fairly stable condition" this is prove that we are interested to know the progress of our patients' Midwives perceived the TSI as one of the means of addressing the gap on providing continuity of care after hospital discharge	RES 1: ' as a midwife, I strongly concur with it because many times, you hear my colleagues say, "how is so and so, we took care of her, nursed her for three days and discharged her in a fairly stable condition" this is prove that we are interested to know the progress of our patients' Midwives are keen to know about the wellbeing of their clients (mothers) after discharge and thought that the TSI would provide them a better means of achieving	
MW.fgd M008	'In the recent past, it is we have had neonatal and maternal deaths because of ignorance, so, if telephone support is	this goal	
Summary data	implemented, it will help a great deal to curb these deaths' Midwives perceived that TSI may play a critical role in reducing maternal and neonatal deaths		

Table 6.9: Thematic chart for analysing young mothers' interview data (perceptions about TSI) (Index: Theme 5)

Participant ID	5.1 Perceived benefits of TSI in maternal role attainment	5.2 Perceived TSI as cheap/cost- effective	5.3 Involving parents/guardians and spouses in TSI
YM M001 19 years	'sister [name withheld] also send me sms and called me about my baby she told me about bathing and dressing the baby, taking care of the cord, keeping baby warm and attending clinic for immunisation'		
Summary data	The telephone support intervention seemed to have been helpful to young mothers, who reported having learnt infant care practices and being reminded on immunisation appointment		
YM.fgd ₁ M005 18 years	'Personally, I greatly benefited from the phone call and in fact I received several text messages from sister [name withheld] which were very educativein fact, it was cheaper[gesture] on my side, unlike travelling all the way from home to hospital to be directed, and travel back, it's very expensive'	'I received several text messages from sister [name withheld] which were very educativein fact, it was cheaper[gesture] on my side, unlike travelling all the way from home to hospital to be directed, and travel back, it's very expensive'	
Summary data	The TSI seemed to be beneficial in addressing the knowledge gap on maternal and infant care among young mothers	Young mothers felt it is very costly traveling to the hospital for routine care and perceived the TSI to be cheap and helpful	
YM.fgd ₁ M003 19 years			'As for me, I would recommend that you also take the phone numbers of our parents or spouses because they are the people who offer us support, it will also be good so that they know the kind of support we need from them'
Summary data			Young mothers expressed the need to involve their parents/guardians and

			spouses in supportive interventions such as TSI as they play a key role of providing direct/tangible support to them
YM.fgd ₂ K006 19 years		'I would really like the use of telephone support because some of us stay so far away from this hospital, so, it will be easier when we receive telephone support'	
Summary data		Young mothers perceived the TSI as an easy means of reaching them while at home especially when they reside far away from the hospital	
YM.fgd ₃ M004 17 years	'Yes, if health workers send us the text messages, we will benefit because it's important for follow-up of our babies and our health too'		
Summary data	Young mothers perceived TSI to be beneficial to them and their infants and expressed the need for such a follow up as TSI by health care providers		
YM M001 19 years	'aah, that will be good, it will help me learn more things to care my baby Text messages will be very good because I will be reminded on clinic day'		
Summary data	Young mothers perceived TSI as educative particularly on infant care and being reminded on clinic appointments, and welcomed the idea of using such an intervention in reaching them		

For the new frames that were identified (sex education for adolescents/young people; and the use of alternative medicine/herbs during postnatal period), both of which were indexed as Theme 3 and Theme 6 respectively (Table 6.5) the analysis was only performed to the level of sub-themes. This was mainly because these were 'newly emergent' issues in the data. Moreover, these issues could not have been explored further during the interviewing process as they were beyond the scope of the research question. Nevertheless, this underscores the value of qualitative inquiry in research which enabled the identification of such issues. As such, these issues may be subject to further inquiry/research in the future. However, it is important to note for instance, that the use of traditional herbs forms part of the complex world of social support system available to young mothers in settings such as where this study was conducted.

6.3 Themes

Following the FA framework as outlined above, the data were further reviewed and analysed to identify major thematic areas that summarise the entire data set. From the data summaries developed, five main thematic areas (categories) were identified: (i) social support needs for young mothers during the immediate postnatal period (perceived and felt needs); (ii) social support system available to young mothers during maternal role transition (family and community, healthcare system); (iii) maternal role-modelling in young mothers' maternal role transition and attainment; (iv) the (perceived) role of TSI in maternal and infant care/midwifery; and (v) the feasibility and acceptability of telephone support intervention in maternity care.

6.3.1 Theme 1: Social support needs for young mothers during the

immediate postnatal period

6.3.1.1 Sub-theme 1: Lack of knowledge/Informational needs

The midwives perceived young mothers to be lacking adequate knowledge on childbirth. This was mainly thought to be as a result of young mothers' poor or lack of attendance to antenatal care. As such, midwives thought these mothers were not sufficiently taken through the antenatal education, including birth preparedness and motherhood. The following excerpt clearly illustrates this viewpoint:

'....most of them were not taken through the antenatal care process, so they did not know how to handle their babies.....many did not attend antenatal care and neither were taught on birth preparedness and motherhood....' [MW M001]

Besides poor/lack of antenatal care attendance, some other factors that hinder young mothers' acquisition of such knowledge were identified such as stigma in the society, and the fact that most of them could be schooling (at this age) and thus would not have time to get to the clinic. These sentiments may be illustrated by some of the midwives' views, thus:

'.....many are abandoned by their families and so they come to hospital empty handed, they haven't attended antenatal care because of stigma.....and they don't know the physical nor psychological childbirth preparations' [MW K001]

Yet another midwife added:

`..... they [young mothers] are busy with school, so they don't attend antenatal care....' (MW K004)

Similarly, the young mothers themselves also expressed the need to be taught on various aspects of postnatal care such as postnatal danger signs, infant care as well as their general health wellbeing. This can be illustrated by the following young mothers' verbal accounts, one of whom clearly acknowledged being ignorant of the issues surrounding motherhood and expressed her views about the telephone support as:

'The telephone support was educative..... giving me knowledge on things I did not know, especially on hygiene, on danger signs.....' [YM.fgd₁ M001, 17 years]

Another young mother who also took part in the FGD cited the role of the telephone support as supportive in deciding between what is right and wrong, and added by saying:

'....the telephone support is educative, it helps us to know between right or wrong......' [YM.fgd1 M004, 19 years]

Evidently, this points to the fact that young mothers may be having a challenge accessing accurate information regarding motherhood (including reproductive health care). In such situations, young mothers may therefore rely on information from their peers or friends and the media. This may also be compounded by the lack of youth friendly services within the health care systems and the conservative nature of parents not being willing to discuss about sex education with their children.

6.3.1.2 Sub-theme 2: Lack of motherhood experience

Coupled with the notion that young mothers lacked adequate knowledge/information, midwives also perceived them to be lacking experience in assuming motherhood responsibilities, and that they therefore needed support to effectively transit to motherhood. The following midwife-excerpt illustrates this notion.

'These young mothers have never nursed a baby before, so at times if the baby cries a long time, the mother gets stressed up too and begins crying too..... that's why these young mothers are taken back to their parents to be helped in baby care, to learn from an experienced mother..... even they don't know how to hold a small baby in bathing.....' [MW K001]

In addition, it was also observed during recruitment into the study that most of the young mothers were first-time mothers. This lack of experience was displayed by the young mothers, some of whom expressed having some difficulty in carrying out some of the motherhood responsibilities like breastfeeding, bathing, and changing the baby. One of the young mothers' views clearly shows the dilemma young mothers face as they transit to motherhood and the seemingly 'overwhelming responsibilities' during motherhood who expressed it as:

'It was very tough at the beginning in bathing, washing and even changing the baby, because, the baby was too small to sit in a basin, you feel like she may fall..... It [motherhood] has come along with many responsibilities to me as a mother..... very many things now.....' (YM.fgd₃ M001, 19 years)

Notably, difficulty in breastfeeding during the initial days was singled out by a number of the mothers who were interviewed, ranging from having experienced pain to lack of enough breastmilk, with the result being to seek alternative means of feeding the baby, albeit that all mothers are encouraged to practice exclusive breastfeeding during this period. This dilemma was well illustrated by one of the mothers who said:

'Breastfeeding was very hard at the beginning... I had a lot of pain since milk was very little and it was very painful.....for the first three days, my baby fed on glucose and water but on the fourth day, I continued breastfeeding....' [YM. fgd₃ M005, 18 years]

6.3.2 Theme 2: Maternal role-modelling in young mothers' maternal role transition and attainment

The role played by significant others, particularly maternal mother or mother-in-law in providing support to young mothers as they transit to motherhood was evident, as many of the young mothers interviewed made reference to being supported, either physically, socially or emotionally by their own mother or mother-in-law. From the young mothers' point of view, this could be considered as one of the avenues of addressing the knowledge and motherhood experience gap exhibited by young mothers. In particular, most mothers highlighted the support they received in infant care responsibilities ranging from bathing and changing the baby to breastfeeding. A few excerpts are presented to illustrate this notion:

"…… my mother taught me how to bathe and change my baby and now I can do it myself….." [YM.fgd₃ M005, 18 years]

'..... my mother-in-law first helped me bathing my baby after I was discharged... I learnt from her and now I can comfortably clean and change my baby' [YM M002, 18 years] Importantly, some of the mothers highlighted the initial difficulty often experienced by the young and/or mostly first-time mothers in assuming motherhood responsibilities such as breastfeeding, cord care, including other infant care practices. Two of the mothers acknowledged the support they received from their mothers in breastfeeding and stated:

'Yes, I received support from my mother..... she even taught me on how to breastfeed my baby' [YM.fgd₃ M002, 19 years]

*`....on day one after discharge, I had no milk at all, so my mother encouraged me......' [YM.fgd*₂ K006, 19 years]

And yet another mother expressed the difficulty in handling the baby with an unhealed umbilicus, perhaps due to the lack of confidence and/or fear of 'hurting' the baby more. This mother stated:

'It was hard to clean the baby when the umbilical cord had not dried, so my mother taught me how to do it' [YM.fgd₃ M001, 19 years]

The above excerpts clearly illustrate the significant role of maternal mother and perhaps other family members in role modelling the young mothers as they transit to motherhood. As observed from these excerpts, it is evident that postnatal counselling alone provided by midwives and nurses may not be sufficient as it does not necessarily translate to tangible support that these mothers need. Thus, HCPs need to devise ways of involving these significant persons in the continuity of care for postnatal (young) mothers. Indeed, such groups are significant and form part of the social support system available to young mothers after birth, as highlighted in theme 3 below.

6.3.3 Theme **3**: Social support system available to young mothers

during maternal role transition

During data analysis, it became apparent that (young) mothers operate within a context of a social support system, be it supportive or otherwise. It was evident that while the healthcare system mainly provides psychosocial support, the family, and by extension the community plays an integral role in this context as it determines the actual level of support provided, including the tangible support received by these mothers. Midwives perceived that the home/community environment that young mothers revert to after discharge from the hospital might be challenging since they might face negative consequences, including stigma, rejection, hostility and lack of support. The following midwife-excerpts illustrate this dilemma that young mothers may find themselves in after leaving the hospital after birth:

'....the main challenge faced by these adolescents is actually their support system...., we don't have referral places for young mothers as soon as we discharge them home......' [MW.fgd M001]

Another midwife also highlighted some of the social challenges that the young mothers may encounter in the community soon after birth ranging from rejection to stigmatisation, and clearly captured this notion as:

`..... reception in the community back home is a challenge..... feeling of denial, rejection and dejection, stigmatisation.....' [MW K002]

Similarly, another midwife drew a sharp contrast between the supportive care provided to young mothers while in the hospital and what awaits them at home as soon as they are discharged. Also, it appeared parents may not be readily willing and/or prepared to welcome their daughters, and possibly accord them sufficient support after birth. The following midwives' excerpts clearly illustrate the contextual environment that young mothers may find themselves in after being discharged from the hospital, viz:

'In hospital, it is very friendly with all support from all health workers, but after discharge, home environment is hostile and with stigmatisation, this a major challenge to breastfeeding' [MW.fgd M002]

`....in fact, no parent will be happy to welcome a daughter at home who got a baby at ages of between twelve to sixteen years....' [MW K001]

Arguably, such environments may have serious effects on young mothers' transit to motherhood and assumption of motherhood responsibilities. However, despite these challenges, it appears young mothers have less of a choice as they still relied on their families for support, as well as the health care system. The need for continuous support can be elicited from the following young mothers' responses during an FGD, whereby one of them said:

'As a young mother, I still need support at home, doing my home chores, even when am sick or at times when am tired, I need support....' [YM.fgd1 M003, 19 years]

And yet another added:

'I need support from my family members, to help me in baby care till I finish schooling......' [YM.fgd₃ M005, 18 years]

Similarly, another young mother who took part in an individual interview acknowledged

having received support in the community, and said:

'yes, I got support from relatives, neighbours...they helped me in caring my baby, bathing, financially.....' [YM M009, 17 years]

Importantly, young mothers felt that health care workers should be kind and

compassionate while attending to them, as illustrated by the following young mother's

excerpt:

'I recommend you [healthcare workers] to continue supporting young mothers like us, let them not be harsh and abusive like another doctor who was so furious at my pregnancy..... they should be friendly and kind to help us as young mothers.....' [YM.fgd₃ M001, 19 years]

This notion clearly illustrates that although the health care system should ordinarily be one of the pillar support systems to all patients, including young mothers it can also be a source of negative support largely due to negative staff attitudes. Health workers must therefore strive to live to their call of duty, in particular discharge their mandate in line with the tenets of respectful maternity care.

Interestingly, it was also evident that within the support system, young mothers could receive unconventional forms of support such as the use of traditional herbs to treat common ailments that they experienced and their infants such as breast problems (engorged breasts) and colic pain. Although this finding was not anticipated, it was indexed as a 'new frame/theme' within the FA framework as it gave credence to the complex social support system that (young) mothers live in, which healthcare providers and researchers need to understand. The following excerpts illustrate this finding.

'....in the village, elders have traditional medicine and they give to children with stomach aches, but on inquiry from sister [name withheld], she counselled me to breastfeed exclusively....' [YM.fgd₃ M002, 19 years]

Indeed one of the young mothers who actually sought such an intervention (albeit unconventional) described it by saying:

'....It was some traditional herbs that she [grandmother] applied on my breast and after that she massaged it and the pain reduced....'

[YM.fgd₃ M003, 18 years]

6.3.4 Theme 4: Midwives' and young mothers' perceptions of telephone support intervention in maternal and infant care (MIC)/midwifery

6.3.4.1 Sub-theme 1: Perceived (potential) roles of TSI in MIC/midwifery

Midwives pointed out a few areas that they thought TSI would be useful in improving MIC/midwifery care, ranging from as a means of knowledge dissemination to young mothers to perceived direct effect on MIC/midwifery practice. In addition, it was

interesting to find that the TSI was perceived to improve effectiveness in work in terms of planning and time management, as well as job satisfaction among midwives which would thereby enhance service delivery. This perception was highlighted by one of the midwives' reflective observation, and who had this to say:

'Yes...... it [TSI] will ease my work by helping me to plan well because you will be able to know and plan very well on who and who is coming on this day and date, even help in organising for appointments with patients and even giving me good time management....'[MW M002]

In summary, Table 6.7 highlights four key areas that were perceived TSI would be useful in improving maternal and infant care, and presents the midwives' accounts of the perceived roles of TSI in MIC/midwifery.

2.1 Midwives' perceptions of the roles/benefits of TSI in MIC/midwifery	
•	Illustrative quotes
2.1.1 TSI as a	'It is [TSI] a good idea, because you will be passing forth knowledge,
means of	you know, you will be having one on one contact with them, so they
knowledge	will open up' [MW M002]
dissemination to	
young mothers	Sending text messages and making phone calls as midwives to these
	young mothers will be very important, informing on cord care and
	some of the danger signs'[MW K001]
2.1.2 TSI as a	'they needadditional support through telephone support especially for
means of bridging	those who can't travel to hospital' [MW M001]
the gap in	
healthcare access	' it will help solving many issues, especially to the ignorant people in the
	society, hence will not be a must for a young adolescent mother to travel to
	hospital' [MW K002]
	Sending text messages and making phone calls as midwives to these young
	mothers will be very importantin fact for those who are not educated in
	those remote villages need more health support than others' [MW
	K001]
2.1.3 TSI as a	'as a midwife, I strongly concur with it because many times, you hear my
means of providing	colleagues say, "how is so and so, we took care of her, nursed her for three
continuity of	days and discharged her in a fairly stable condition" this is prove that
care/follow up	we're interested to know the progress of our patients' [MW.fgd M001]
	'I strongly suggest that we also do the same to in antenatal period'
	[MW K001]
	' because honestly after handling, treating, nursing and discharging a
	patient, you will keep on asking questions, wanting to know the patients
	progress' [MW K003]
214 Dama 1	(I strength suggest that we shall be the summer to be sufficient of the set of the
2.1.4 Perceived effect/influence of	'I strongly suggest that we also do the same to in antenatal period' [MW K001]
TSI in	<i>(it [TSI] will greatly reduce both maternal and neonatal deaths because</i>
MIC/midwifery	they will know how to handle the danger signs '[MW K001]
	'In the recent past we have had neonatal and maternal deaths because of
	ignorance, so, if telephone support is implemented, it will help a great deal to
	curb these deaths' [MW.fgd M008]

Table 6.10: Perceived roles of TSI in MIC/midwifery (midwives)

Similarly, young mothers perceived TSI as beneficial particularly in helping them to (effectively) transit and assume motherhood responsibilities. Young mothers, particularly who received the TSI (intervention group) highlighted this perceived benefit from the

intervention, ranging from critical aspects such as breastfeeding support (where most mothers expressed having experienced difficulties/challenges as noted previously) to infant care practices such as bathing and changing the baby, including being reminded on their clinical appointments. The following excerpts present some of the views of young mothers regarding the TSI:

'....sister [name withheld] also send me sms and called me about my baby..... she told me about bathing and dressing the baby, taking care of the cord, keeping baby warm and attending clinic for immunisation...... Yes, they [sms+calls] helped me very much especially on how to breastfeed and reminded me on clinic day' [YM M002, 18 years]

'The telephone support and the text messages were of greater importance to me and my baby because I learnt many things.... it was my first time to give birth and my first experience on breastfeeding and I needed guidance....' [YM.fgd1 M001, 17 years]

Similar views were also expressed by the young mothers who received usual care (control group), largely expressing the view that the TSI would have helped them in some way, as illustrated by the following excerpts. Indeed, one of the mothers highlighted that she would have gained more knowledge on breastfeeding and infant care from the TSI and stated:

'Yes, I would have gained a lot because I would have been educated on breastfeeding and general guidance on baby care like especially on cord care' [YM.fgd₃ M001, 19 years]

And another expressed such a need (telephone support) from HCPs as a helpful means of

following them up and their babies by stating that:

'Yes, if health workers send us the text messages, we will benefit because it's important for follow-up of our babies and our health too.....' [YM.fgd₃ M004, 17 years]

Similarly, one other mother also stated:

'I will highly appreciate if you send me text messages, call and follow me up in postnatal care, reminding me on clinic days, breastfeeding.....' [YM.fgd₃ M002, 19 years]

On a practical note, the TSI was seemingly beneficial to the young mothers. This notion was also noted and highlighted by the intervention midwives. For instance, both research midwives reported and documented a few incidences in which they had to call back the mothers after receiving a 'please call me' message from them, and having to refer the mothers for appropriate care following their own illness and/or that of their infants, including possible assessment for abdominal ultrasound. The intervention midwives also noted and documented incidences where young mothers called or sent back text messages (mostly a 'please call me' messages), reporting having missed the vaccinations at the hospitals due the health workers strike at the time, upon which the intervention midwives sought alternative centres where they could get the vaccines and referred them accordingly.

6.3.4.2 Sub-theme 2: Perceived TSI as cheap/cost-effective

Midwives and young mothers also perceived telephone support to be cheaper, particularly as far as distance to the clinic is concerned. In addition, midwives felt that there are some aspects of care that could easily be addressed through telephone support, thereby helping mothers to save on fare as well as travel time to the clinic/hospital. One of the midwives' responses clearly illustrated this view, thus:

".....and even it will be cheaper economically and less time consuming, as in, wasting time and fare travelling from the village to hospital to seek assistance....and yet it can be sorted out using a two minutes phone call or a mere text message" [MW M001].

Most importantly, this midwife also served as an intervention midwife, and thus this notion could arguably be considered as a practical viewpoint on administering the telephone support intervention. It is important to note that during the interview, the intervention midwife was asked to give a reflective view of their experience during the study (administering the intervention) in relation to the routine practice. This way, it was

thought would minimise the chances of biased information by the midwife, having served as an intervention midwife.

Young mothers also seemed to be more appreciative of such an intervention as TSI and similarly shared this viewpoint, as illustrated by the following excerpts:

'.....I received several text messages from sister [name withheld] which were very educative.....in fact, it was cheaper[gesture] on my side, unlike travelling all the way from home to hospital to be directed, and travel back, it's very expensive......' [YM.fgd1 M005, 18 years]

'I would really like the use of telephone support because some of us stay so far away from this hospital, so, it will be easier when we receive telephone support.....' [YM.fgd₂ K006, 19 years]

'.....it is important to keep on reminding us on importance of exclusive breastfeeding and even cheaper for us than travelling to hospital' [YM.fgd₂ K003, 18 years]

From these excerpts, it can be observed that young mothers generally would prefer not to attend hospital for health care services. Thus it appears TSI was more appealing to them. Based on the literature review findings that highlighted that young mothers were less likely to attend antenatal and postnatal care (Chapter 2), it would not be surprising then as this finding attests to this.

Considering this convergence of views between midwives and young mothers, it appears therefore that cost implications remain a key factor for young mothers in seeking health care, and thus it may not be surprising that young mothers would rarely attend antenatal care as previously observed (in section 6.3.1). Most importantly, although the TSI was perceived to be cheap and cost-effective, and generally as beneficial to the young mothers, it should be noted that such an intervention does not substitute standard care practices but rather supplementing it. Hence, midwives should continually strive to reach out and attend to the needs of young mothers especially in LMICs regardless of the potential benefits of such novel interventions.

6.3.5 Theme 5: The feasibility and acceptability of telephone support intervention in maternity/midwifery care

As a pilot RCT, the main objective of this study was to explore the feasibility and acceptability of TSI among young mothers during the immediate postnatal period, and among midwives who are key service providers during this period. Considering the midwives' and young mothers' perceptions of TSI (potential roles of TSI in MIC/midwifery and the perceived cost-effectiveness of TSI) highlighted above (Theme 4), it generally appears that the intervention was well received among both participant groups. However, in an attempt to clearly expound on this primary objective of the study, it was also imperative to assess the feasibility and acceptability of TSI with a view to inform a future definitive trial. Generally, most midwives welcomed the idea of TSI and described it as 'a good idea or initiative', and thought that it would be quite acceptable among their fellow midwives observed that as midwives, they always wanted to know the progress of their clients/patients after discharge, as illustrated by the following excerpt:

".....as a midwife, I strongly concur with it [TSI] because many times, you hear my colleagues say, 'how is so and so, we took care of her, nursed her for three days and discharged her in a fairly stable condition'... this is prove that we are interested to know the progress of our patients" [MW.fgd M001]

Interestingly, similar thoughts were also shared by another midwife at the second study

centre, who stated:

"..... my personal experience as a midwife, I have really enjoyed on doing follow up, therefore, I know my fellow midwives will embrace and even other health workers, because, honestly after handling, treating, nursing and discharging a patient, you will keep on asking questions, wanting to know the patients" progress...." [MW K003] Arguably, this may imply that besides the fact that TSI was perceived as a valuable means of following up on clients/patients, midwives also felt it provided a good opportunity for them to achieve this goal. In addition, on a practical point of view, a few of the young mothers contacted the researcher (through the telephone contact provided in the participant information sheets) regarding the TSI. Interestingly, one of the mothers asked why she had not received any messages, besides inquiring about immunisation and clinic appointment. It was thus noted that the participant must have been in the control group; however, appropriate advice was provided, including clarifying on group assignment and referral to the hospital for the clinical appointment and infant immunisation. The second participant also inquired about breathing problems (blocked nostrils/running nose) and skin problems, and similarly she was advised including referral to the health facility. Importantly, it was encouraging that both mothers received their due care upon subsequent inquiry by the researcher about their wellbeing and that of their infants.

To further explore this study objective, midwives' perceptions of having such an intervention in their institutions, including their views whether it was feasible and acceptable among other health workers were sought. In addition, they were asked to suggest possible ways of implementing and/or improving such an intervention (TSI), including what they considered as possible challenges. The findings are presented under two subthemes: perceived facilitators, and perceived barriers to TSI, and thirdly, the practical aspects of conducting the pilot randomised controlled trial, including the challenges experienced during the pilot trial are also presented.

6.3.5.1 Sub-theme 1: Perceived facilitators for TSI

Most midwives thought their institutions had the capacity to implement such an intervention as TSI, largely because they felt they had many young mothers seeking care

at the facilities as well as the institutional capacity to implement such an intervention. The midwives mainly singled out the presence of existing programmes such as youth friendly centres (for adolescents) and maternal and child health programmes. Indeed, MTRH has established a youth centre for adolescents named *"RAFIKI CENTRE"* (opened in 2016). KCGH also had a maternal and child programme dubbed *"LINDA MAMA NA MTOTO"* (CARE FOR MOTHER and INFANT INITIATIVE) whereby first-time mothers are enrolled and provided with continuous follow-up up to two years, including some monetary incentive that would enable them to travel to the facility and meet some basic needs.

However, despite the general sense of acceptability and feasibility as noted above, the need for sensitisation among staff before such an intervention is implemented was suggested, including the need to involve other cadres of staff such as the nutritionists and community health workers. Most importantly, on a feasibility point of view this highlighted the importance of collaborative approach among health care providers as far as implementation of such an intervention as TSI, just like in many other projects and/or programmes. The following midwife excerpts illustrate this aspect:

'It is better to have a specific number for all clients as long as it will be for free services..... I think..... prior to implementation, then we should create awareness in every unit, so that everyone is part of this at different times' [MW K003]

'..... it will very important to incorporate the community health workers..... we can also fortify by additional financial support....., [laughter] that will not be bad, especially after assessing the financial status of these mothers by the help of Community Health Workers' [MW K001]

In addition, one of the midwives also suggested the need of having a telephone hotline for mothers, as well as incorporating it as part of the routine care as illustrated by the following excerpt: "..... work with a hospital hotline, so telephone is more practical, I strongly recommend telephone support in the hospital, then make it a policy, come up with a work plan, assigning a midwife every day for that responsibility' [MW M001]

Overall, based on these sentiments it appears that TSI is generally perceived to be feasible and acceptable within the healthcare system.

6.3.5.2 Sub-theme 2: Perceived barriers to TSI

Similarly, the midwives also pointed out some of the aspects that they perceived to be barriers to TSI implementation. Some of the key challenges highlighted included the notion that such an intervention is resource-intensive, both in terms of manpower and financial resources. As such, understaffing and financial challenges were mentioned as possible barriers. In addition, it was also thought some regions may have poor connectivity especially in the remote villages, including lack of phones by young mothers. The following excerpts highlight some of the midwives' perceived barriers to TSI:

'Number one challenge is man power, it's very key because, clients will always be more than the staff, secondly, sensitisation to the staff is equally important, some will agree and others refuse, however, it remains a good idea, the advantages outweighing the disadvantages' [MW M002]

'Many young adolescents' mothers do not have phones, you may call when some are in school, some parents may not want to receive the phone calls, and some may have sim cards, without cell phones....' [MW K002]

'.....but it may also be a challenge because of poor networked regions, in fact for those aren't educated in those remote villages, need more health support......' [MW K001]

`......financial challenges, getting airtime for calling every now and then is not easy.....' [MW.fgd M001]

Indeed, the researcher also agrees with the fact that such an intervention is resourceintensive, including in terms of time which really requires commitment on the part of personnel involved. It was therefore not surprising to get such a feedback from the midwives.

6.3.5.3 Sub-theme 3: Practical issues/challenges during the pilot RCT

Being a feasibility study, it was imperative to assess any practical challenges during the pilot trial. During recruitment, it was observed that there were a reasonably large number of mothers who were eligible for recruitment but who did not have personal mobile phones. As such they were excluded from the study for not meeting the inclusion criteria. Interestingly, this finding was also noted during the midwives' interviews as midwives also observed that many young mothers did not have mobile phones, while in some cases they may only have the sim card without a cell phone, as illustrated by the following excerpts:

'Many young adolescents mothers do not have phones, you may call when some are in school, some parents may not want them to receive the phone calls, and some may have sim cards, without cell phones.....' [MW K002]

'.....some did not have telephones.....and some were using the phone calls of their parents of whom when you would pass information, they would not faithfully transmit it to the recipients' [MW M001]

However, one of the midwives was of the opinion that despite young mothers lacking personal phones, they could use their parents' mobile phones at their convenient times. The midwife stated:

'Currently, at least everyone has a phone, if not the young mother then even the parents of the adolescent mother, so basically, we just enquire from the young mother, at what time it would be most appropriate time to call and when the phone is around' [MW M003]

Although this view was in contrast to the study's eligibility criteria, perhaps it is an issue worth consideration at least considering the context of the study as a feasibility trial; however, the merits and demerits are still debatable.

It is evident from these excerpts that the midwives acknowledged the use of parents' mobile telephone in reaching the young mothers, and seemingly the midwives did not

have a problem with it except for the personally held views/reservations about using parents' mobile telephone. Perhaps such reservations, also as initially held by the researcher, ought to be treated as perceptions as they may not necessarily reflect the reality in the contextual environment that young mothers operate in. As noted earlier (Theme 3), the family and the community form a critical part of the support system available to young mothers, be it supportive or otherwise and thus this ought not to be wished away.

Similarly, the intervention nurses reported that some of the young mothers could only be reached intermittently, meaning these mothers could not receive the entire information package as scheduled. However, in some incidences the young mothers could request the intervention midwives to resend the text messages that they thought they missed or to call back the young mothers, especially after the midwives had received a 'please call me' message suggesting the mothers were out of reach at the time they were called.

In addition, the intervention midwives also reported that some of the young mothers provided their parents' (mostly their mothers') telephone numbers in the course of the intervention period. Therefore, it was instructing that although the researcher held an initial view that parents may be a hindrance to the TSI dissemination, which thereby informed the inclusion criteria of 'ownership of a mobile phone by the eligible mothers', it appears this may not be necessarily the case. Indeed, the researcher held the view that since the study population comprised of young mothers, who were most likely to be teenage mothers, it would be prudent to directly contact them with the intervention, which also included sending text messages on 'controversial' topics such as family planning which may not be readily acceptable by parents/guardians. Perhaps therefore, similar studies in the future may have to consider involving parents/guardians and other

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significant persons who form the support system of young mothers in childbearing. In any case, the young mothers also raised similar sentiments during the interviews as illustrated by the following excerpt:

'.....I would recommend that you also take the phone numbers of our parents or spouses because they are the people who offer us support, it will also be good so that they know the kind of support we need from them.....' [YM.fgd1 M003, 19 years]

Furthermore, schooling may have also contributed to this finding since in such circumstances; young mothers would delegate their infant care responsibilities to their parents (mothers). As such, young mothers would provide their mothers' (or parent's) telephone numbers to the intervention midwives, besides the fact that students are not also permitted to carry mobile phones in school. This was also evident during data collection whereby one parent (mother) to one of the study participants brought the infant to the clinic since the daughter (study participant) was reportedly in school preparing for her exams.

Evidently, during data analysis schooling emerged as one of the main concerns for young mothers (Table 6.5, subtheme 4.5). Interestingly, the same concern also emerged from the midwives during the Delphi study (Round 1) conducted prior to the pilot randomised trial (Chapter 4), whereby the midwives who took part suggested continued education/schooling as an additional area of concern to young mothers. To illustrate this, the following young mothers' excerpts (who took part in an FGD) clearly demonstrate this need, which midwives and other health care providers ought to consider when attending to young mothers of this age group. One of them stated:

'I need support from my family members, to help me in baby care till I finish schooling......' [YM.fgd₃ M005, 18 years]

Another added:

'..... I still need support in caring my baby just as my colleague has said, since I will be going back to school, so I need someone to help me....' [YM.fgd₁ M001, 17 years]

As noted in Chapter 3, the pilot study had also planned to conduct two FGDs in each of the study centres so as to account for the differences in age characteristics among young mothers aged 12-16 and 17-19 years respectively. However, this was not feasible since a total of only seven mothers were recruited in the 12-16 years age group across both centres. Therefore, individual interviews were only possible in such circumstances. In view of a feasibility study, this finding was also informative for a similar study and setting in the future regarding recruitment of participants from such a study population. Such future trials therefore, may have to target recruiting teenage mothers over 14 years or more specifically the older age group (17-19 years) since none of the participants recruited in the study was less than 14 years.

Moreover, it was not also possible to constitute and conduct FGDs at the end of clinical appointment date since mothers came in at different times, as well as opting to come at different dates due to various reasons ranging from lack of fare to other personal reasons. Therefore, arrangements for the FGD sessions were made on an agreed date and time. In addition, future researchers may consider following up these mothers within the periurban facilities since some of the mothers reported having no fare to travel to the hospital, and the fact that some of them relocated to their rural homes.

6.5 Chapter summary

In summary, this chapter highlighted the qualitative findings of the pilot RCT, including the feasibility and acceptability of the TSI which was the primary objective of the pilot trial. Specifically, the chapter presented the demographic characteristics of the participants (midwives and young mothers) who took part in the interviews, and then the FA approach that was used in analysing the data is described in detail and systematically up to when and how the themes were derived from the data. Five main thematic areas were identified from the data: social support needs for young mothers during the immediate postnatal period; maternal role-modelling in young mothers' maternal role transition and attainment; social support system available to young mothers during maternal role transition; the (perceived) role of TSI in maternal and infant care/midwifery; and the feasibility and acceptability of telephone support intervention in maternity care. These themes were described in detail, highlighting both participant groups' (young mothers and midwives) views as well as the research team's fieldwork experience.

As observed in the findings, both midwives' and young mothers' views highlighted the lack of knowledge and motherhood experience among young mothers, as well as the need for maternal social support as critical issues during the postnatal period. Importantly, both participant groups perceived the TSI as beneficial in maternal and infant care (and/or midwifery), and that it is cheap and cost-effective. Overall, the findings suggest that TSI among young mothers is feasible and acceptable, despite the few challenges that were noted. However, these challenges may be regarded as informative particularly considering the fact that this was a pilot trial. A few suggestions that may inform a similar study in the future were therefore highlighted.

CHAPTER SEVEN

DISCUSSION

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CHAPTER 7: DISCUSSION

7.0 Introduction

This chapter presents the discussion of the findings in light of the main objective of the study which was to explore the feasibility of conducting a main trial comparing telephone versus no support for young mothers in improving maternal physical, psychological and social wellbeing soon after birth. The chapter highlights key findings in the pilot randomised trial, including practical issues noted from the pilot trial which may be used to inform a future definitive trial. It is, however, important to note that this pilot RCT was not powered to test for statistical significance, owing to the relatively small sample size involved.

This was an experimental study on a telephone support intervention (TSI) among young mothers following birth, and the potential effectiveness of the TSI in specific aspects of maternity/midwifery care such as postnatal depression, maternal social support, maternal self-esteem and postpartum bonding were explored using relevant and validated measurement tools (refer to Chapter 3). These constituted the quantitative data. Notably, one of the aims of this pilot trial was to identify a primary outcome of interest from such critical aspects of maternal/midwifery care. As such it was imperative to test the potential effectiveness of the TSI in such aspects of maternal/midwifery care.

In addition, to achieve a better understanding of the acceptability and feasibility of TSI, it was necessary that 'consumer' (young mothers) as well as 'service-provider' (midwives) views were sought through a qualitative inquiry (individual and FGDs in-depth interviews). This pilot RCT therefore employed a mixed-methods approach as described earlier in Chapter 3. The findings discussed herein are therefore drawn from both designs,

and are integrated as applicable, with relevant literature. Following this, conclusions and recommendations will be drawn from the pilot RCT and presented in the subsequent Chapter (Chapter 8), including the researcher's personal reflections throughout the 'PhD journey'.

From Chapter 3, the overall objective of the study was to assess the feasibility of conducting a main trial comparing telephone versus no support for young mothers in improving maternal physical, psychological and social wellbeing during postnatal period. The specific objectives were as follows:

- 1. To develop a telephone-based intervention using the Delphi process and to test it among young mothers during the pilot trial in western Kenya.
- 2. To assess the availability of good quality data in the study setting to support a larger study.
- 3. To assess the acceptability of the telephone support intervention among young women.
- 4. To assess midwives' perspectives on the use of telephone support intervention among young women.
- 5. To observe the differences between intervention and control group during postnatal period.
- 6. To determine an appropriate research design for a definitive study (primary outcome, sample size, design, data collection, analysis).

7.1 The intervention (TSI)

7.1.1 Development of the intervention

As noted previously, the intervention was developed through a Delphi process (described in Chapter 4) which proved to be an essential component in this pilot RCT. This process enabled the researcher to refine the intervention package (together with the intervention midwives and the supervisory team). Based on the UK Medical Research Council (MRC) definition of complex interventions (Craig et al. 2008), the TSI can be regarded as a complex intervention. The MRC has described complex interventions as those that contain several interacting components, with specific attributes that evaluators should consider such as the interacting components within the experimental and control interventions, target groups involved, outcomes of evaluation, flexibility of the intervention and dissemination issues (Craig et al. 2008). This framework therefore provides useful guidance for researchers undertaking interventional studies. Further, it has been recommended as a best practice to 'develop interventions systematically using the best available evidence and appropriate theory, and to test them in a phased manner including piloting before carrying out a definitive evaluation' (Craig et al. 2008). For this pilot RCT, the Delphi technique proved worthwhile in developing the TSI.

The critical role of consensus development in Delphi process has been explicitly documented, especially in the development of health interventions (Antcliff et al. 2013, Maimbolwa et al. 2015, De Villiers et al. 2005, Keeney et al. 2010). Cognisant of the iterative process involved in the Delphi process, the researcher tried to follow these steps with constant consultation to ensure the intervention was refined as much as possible. The involvement of the intervention midwives in testing the final intervention package was equally rewarding as it made it easy to identify key topical issues related to the content domain of the prioritised items, and to rephrase the wording to reflect the level of understanding of the study population as much as possible. This also underscored the importance of consensus building throughout the Delphi process (Hsu and Sandford, 2007). This aspect also helped the researcher to be more sensitive to the participants as

service-users. In view of a future trial and considering the rigorous process that was followed, the results of this Delphi may still be worth considering.

7.1.2 Dissemination of the intervention

The intervention package involved sending a weekly short text messages (SMS) and a telephone call after every 3 weeks up to 10 weeks after birth (intervention group), while young mothers in the control group received the usual care (refer to Chapter 3). However, regarding the dissemination of the intervention it was evident from the qualitative interviews that not all mothers in the intervention group received the entire intervention package as desired due to unforeseen challenges ranging from network connectivity issues (being out of reach) to lacking a phone in the course of the intervention. As such, the intervention was received intermittently in such circumstances. The participants, however, would still receive the intervention but at a later time than anticipated, and thus possibly not act on them at the desired time.

Moreover, the fact that mothers were given an explanation about the study and provided with the information sheets prior to recruitment and consenting (before discharge) may have allowed them to discuss about their grouping and possibly exchange their telephone contacts, and consequently share the information related to the TSI during follow up. While there was no evidence of this, if it happened, it might have had an influence on the results, leading to Type II errors, which constitute threats to validity of research results (Creswell, 2014 p.174).

A Type II error occurs when the null hypothesis is considered to be true when in reality it is false (Burns and Grove, 2005 p.449). In other words, there is a real difference between the groups in the population (the intervention is effective) but the data in the sample fail to detect this. However, in view of a pilot study these factors could not be avoided, yet at the inception of the study it was also necessary that the study could identify such factors in the context of TSI so as to inform a main trial. Several variables were therefore explored to assess the potential effectiveness of TSI (see section 7.4).

7.2 Feasibility findings

7.2.1 Ethical issues and access

Ethical principles governing research were observed during the study, particularly considering that the study population included young mothers who were minors (below 18 years). Ethical principles in research serve to protect the participant (Polit and Beck, 2006). The Institute of Medicine (2004) highlighted key ethical issues regarding research involving children/adolescents which included the need to ensure that research benefits the participants as well as prevents unnecessary burden upon them. Crane and Broome (2017) noted that 'children and adolescents are a vulnerable study population in the research context' with unique and varying needs. It has been suggested that researchers need to employ appropriate research methodologies/methods that recognise and/or support children/adolescents' intellectual and social abilities (Gibson and Twycross, 2008, Birbeck and Drummond, 2007).

Since the study participants included young mothers who were minors, it was necessary to observe these principles, including obtaining both parental consent and the young mother's assent (Crane and Broome, 2017) in such cases. Moreover, during data collection it was evident that parental (or guardian) involvement was still necessary throughout the research process since most young mothers still relied much on their parents/guardians. For instance, most young mothers had to seek the permission of their parents/guardians or ask the researcher to inform their parents about the appointment for data collection. This may also explain why some of the young mothers in the intervention

group provided their parents' telephone numbers. Thus parental involvement throughout the research process involving young mothers would therefore be an important consideration, especially in similar settings as the present study.

To ensure that participants were protected from any harm or discomfort during the study, a Distress Policy was developed prior to conducting the study (Appendix 3.5). Research assistants were trained and sensitised on the use of the Distress policy (refer to the training schedule in Appendix 3.8), which included appropriate assessment and referral of distressed participants to counselling services in the respective study centres. In such circumstances, the participant interests were paramount than the research. However, it is important to note that there were no such incidences in the study except for when participants (mainly in the intervention group) sought assistance from the intervention midwives. The use of the Distress policy is consistent with the ethical principles of beneficence and non-maleficence, that is, seeking to promote benefits and protect the participant from harm. It is noteworthy that the use of such a tool (Distress Policy) was relatively a new practice in the study setting, hence needs to be promoted to ensure research participants are adequately protected as they take part in research.

In addition, participants were provided with PIS forms prior to consenting and/or assenting and were recruited on voluntary basis into the study. Regarding research involving children (or minors), it has been suggested that researchers need to provide a detailed account of how informed consent/assent for children's active and voluntary participation in the research process will be negotiated (Lambert and Glacken, 2011). In this study, the participants were briefly informed about the research and were provided with respective PISs (including their parents/guardians as applicable) by the recruiting RA. The participants were given reasonably adequate time to read the PISs and they were

also free to seek clarifications or further information from the RA before consenting. This was too ensure that the participants make an independent decision regarding taking part in the study. Importantly, it has been highlighted that despite parents/guardians providing legal consent for their children, researchers need to obtain children's informed assent to promote a child-centred approach in research (Ford et al. 2007). Confidentiality of data and anonymity of participants were also observed. Data were kept in a key and lock cabinet and only retrieved for analysis by the PI. To ensure anonymity, participant IDs were used during data analysis and presentation.

7.2.2 Sample size and attrition

As stated earlier (Chapter 3), this pilot RCT adopted the Kieser and Wassmer (1996) estimate for a sample size of 20-40 for pilot studies, which is not based on powering to test for statistical significance. This is consistent with the sample size recommendations of Whitehead et al. (2015), who suggest that 20 per group is sufficient to estimate the sample size for a follow-up definitive trial when a conservatively low difference between the groups is assumed. Pilot studies are important in providing data for informing future trials, particularly in situations where no data is available from previous studies to inform the process including a sample size calculation for a definitive trial (Thabane et al. 2010). As a pilot RCT, this study mimicked the design of a definitive RCT to inform the sample size determination for that trial (Whitehead et al. 2015). The study randomised 26 per group, aiming at 20 per group for analysis allowing for 20% attrition per group. From the 52 participants recruited for the study, 43 were retained at the end of the study for analysis, 22 in the intervention group and 21 in the control group. The target of 20 per group for analysis was achieved.

However, the numbers of potential participants approached to take part at the two study sites were not recorded, so it was not possible to estimate a recruitment rate. A recruitment rate would have provided useful information to inform a definitive trial. Regarding attrition, the findings of this pilot study suggested a high attrition rate (overall attrition rate=17.3%) (15.4% vs 19.2% for intervention and control groups respectively) (refer to Fig. 5.1) compared to most RCTs in general. It was also interesting that the attrition was slightly but not significantly higher in the control group, suggesting that the more active engagement of the young mothers in the intervention group may have helped in retaining them. Therefore, in terms of outcome comparison post-intervention the remaining mothers may not have been completely comparable in terms of engagement. In view of a definitive trial, the high attrition rate and the differential group attrition would have to be considered, particularly in terms of whether and how the attrition rates could be reduced in a much larger study. Importantly, apart from the drop out, there were no protocol violations (participant(s) in one group crossing over to the other group during the trial)).

Moreover, other practical issues (challenges) may have also had an effect on the study regarding recruitment and/or retention and overall enrolment. During the study period, confounding factors such as health workers' strikes (which lasted almost the entire period of the study) and political campaigns (data collection coincided with the eve of electioneering) had an effect on the study. However, it may not be determined with certainty on which direction these factors may have influenced the recruitment rate, the retention rate and/or the overall enrolment rate, including outcomes of other variables. Although the follow-up period (the immediate postnatal period) in this study was relatively short, and which could as well be regarded as an 'active clinical period' for postnatal mothers, it was expected that the study participants (young mothers) would

actively engage with the health care system. Ideally, this would have minimised the attrition rate and enhanced the retention rate.

Thus, to allow for the adequate measurement of variables and to objectively assess for the possible effect of TSI, a definitive trial ought to recruit an adequate sample size that would permit external validity of the results. Such a study would therefore need to be powered to test for statistical significance (Thabane et al. 2010, Burns and Grove, 2005 p.451, Creswell and Creswell, 2018 p.151). Statistical power is defined as *'the probability that a statistical test will detect a significant difference that exists'* (Burns and Grove, 2005 p.451). To achieve this, important considerations in sample size determination such as the acceptable standard of error (β =0.20) and the level of significance (commonly used α =0.05) together with the available statistical indices of the selected outcome(s) of interest (Creswell and Creswell, 2018 p.152). These outcomes would be the primary outcomes chosen for the definitive trial, and sample size calculations for these will be presented in Section 7.6.

7.2.3 Recruitment and randomisation strategies

This pilot RCT initially aimed at recruiting young mothers aged 12-19 years. In case the ages of these young mothers affected the effectiveness of the outcome measures compared between the intervention and control groups, randomisation was stratified by age group (12-16 years v 17-19 years). There was no specific quota for the younger or older age group but young mothers in the two age groups were randomised independently to help guarantee that the intervention and control groups were balanced in terms of age group.

Further, to account for group dynamics, separate focus groups were planned for the two age groups. However, only seven mothers were recruited and enrolled in the study in the

12-16 age group across both study centres, with the youngest mother being aged 14. Following this, individual interviews were therefore conducted for the younger mothers. Arguably, this may imply that similar interventional studies in similar settings in the future may have to consider enrolling teenage mothers or specifically target the older age group (17-19). Alternatively, researchers may need to check the birth registers for ages of young mothers who gave birth within a given time period so as to determine the pool of potential participants that might be available for an RCT. This would provide a practical and meaningful approach of assessing and determining the specific age group for a definitive trial, including the projection of the trial time frame.

In addition, the SNOSE approach used in the randomisation and allocation concealment appeared to be quite effective. Practically, however, since this was the first time the researcher (including the RAs) used such an approach, more so having two sets of envelopes was a little confusing as to whether the recruitment was to be conducted on the basis of 'equal numbers' across the age groups. This prompted the researcher to seek clarification on how the approach works from the statistician (who helped in generating the list of the random numbers used in the pilot trial). Indeed, it was very instructing and exciting to understand that this 'challenge' was partly what the study sought to answer. Stratification by age group was not to help ensure equal numbers recruited from each age group across the study but to help ensure equal numbers from the younger age group in the intervention and control groups and equal numbers from the older age group in the intervention and control groups. It was therefore surprising that at the end the study only managed to recruit seven participants in one of the group sets (12-16 years).

In addition, one of the inclusion criteria for the eligible young mothers was ownership of a mobile phone. Although this was informed by the need to provide sufficient autonomy to the young mothers, especially as regards to decision-making on controversial issues such as family planning which may not be readily acceptable to their parents, it appeared young mothers still relied much on their parents and family for support. Notably, during recruitment most (79%) singled out their parents as the primary support persons following birth. This was also quite evident when a few of the young mothers who were enrolled in the intervention group could provide their parents' (mostly their mother's) telephone numbers to the intervention midwives for follow up. This finding parallels the study findings a recent study in Kenya among pregnant and adolescent new mothers, which reported that maternal mother was the primary source of social support for pregnant and parenting teens (Kumar et al. 2018).

The aim of the study by Kumar et al. (2018) was to explore the mental health challenges of pregnant adolescents and the experiences of adolescent new mothers, and the role of social support using grounded theory approach. Data were also reportedly collected from the adolescents' 'caregiving environment' (the adolescents' mothers, their partners, the community, and health care workers). Considering these aspects, the contextual set up of this study ('the care giving environment') seems to relate with one of the major themes identified in the pilot trial (Theme 3 – social support system available to young mothers). However, the methodological aspects in Kumar et al.'s study were not explicitly described (or probably not appropriately applied), particularly in the context of grounded theory principles such as concurrent and constant comparison in data analysis, theoretical sampling, coding of data or otherwise. The findings, however, lend credence to the significant role of social support for young mothers. According to WHO, non-supportive environments or settings often predisposed young mothers to depression and anxiety, thereby compromising their ability to care for their child (WHO, 2006).

Importantly, it was also apparent that schooling was a key concern for many of the young mothers, some of whom were students. Many local studies, however, have explored schooling or education in the wider context of adolescent/teenage pregnancy (Obare et al.2012, Beguy et al. 2013, Clark and Mathur, 2012, Were, 2007). These studies have explored the subject either as low level of education or lack thereof as a contributing factor to teenage/adolescent pregnancy (Obare et al.2012, Beguy et al. 2013) or dropping out of school as a direct consequence (Were, 2007) or both ways (Clark and Mathur, 2012). It is therefore not surprising that postnatal care of women remains one of the neglected areas of maternity care (WHO, 2014). Therefore, a deeper understanding of the social context and environment that young mothers operate in is critical for both healthcare providers and researchers. Future trials on young mothers may therefore need to consider finding a way of involving parents/guardians, either directly or indirectly as this may have a bearing in the success of such trials.

Moreover, in this pilot RCT, it was discovered during the qualitative interviews that the TSI was received intermittently by some of the young mothers enrolled in the intervention group. This was partly attributed to the young mother(s) 'lacking a phone' and/or network connectivity issues, including lack of battery power (due to lack of electricity at home to charge their phones) when the TSI messages were transmitted. However, in such circumstances (connectivity and battery power issues) the participants would still receive their messages albeit later than the expected time. In addition, to better assess the effect of the intervention (as in 'within-group analysis') it may be useful if definitive RCT would develop an 'interventional log frame' such that it would be possible to log in the intervention delivery time and whether it was delivered or not. In addition, such a log frame would enable recording of any relevant data/information related to the intervention such as whenever participants' seek further information or help from the

intervention midwife and/or the research team, including referral cases. Such a record may also complement and/or enrich the data collected from the main study. Besides, this would possibly provide a useful means of measuring the effect of the 'intervention dosage' within group, including engagement, besides the defined group comparisons.

The limited sample size (statistical significance) notwithstanding, such aspects may have also played part in the observable differences or lack thereof between the two groups as regards to the outcome variables, including possible sharing of information among participants between the groups. However, there was no evidence, either from the qualitative data or anecdotally to ascertain the possibility of contamination. In essence, there could be minimal or no difference between an individual who received little of the intervention package (TSI) and one who was in the control group (usual care). This could result in differences in outcome measures between the two groups being underestimated. Therefore, this study may not fully explain the differences between groups since confounding factors were not adequately controlled.

7.2.4 Data collection

Initially, baseline data were collected from the participants upon consent to participate. This included data on sociodemographic characteristics such as age, marital status, education level, occupation and parity, including their infants' birthweight. This baseline form was then serialised and filed according to the recruitment sequence provided in the envelopes (SNOSE) and attached with the main questionnaire for subsequent data collection at the end of the intervention phase. Files were provided for filing the questionnaires at the respective centres. To assess for the first specific objective (the availability of quality data in the study centres), the recruiting RA was asked to double check the files of the recruited participants using a separate data extraction form. The data

extraction form was nearly identical to the baseline data questionnaire and the RA was required to assess whether all the sociodemographic details of the mothers were accurately captured in the files, including the discharge summary notes and initial clinical appointments. On analysis, most of the files captured these details with only a handful missing items such as family planning counselling/education and/or initiation. Overall, it can be concluded that the clinical data that was available was sufficiently well captured.

The mixed-methods approach proved suitable for this pilot trial as the quantitative and qualitative methods complemented each other. Besides seeking to measure observable differences between groups following TSI, the study also sought to explore the acceptability of TSI through qualitative interviews. Salient issues regarding the intervention (young mothers' and midwives' perceptions, potential benefits, how it can be better implemented/improved and potential challenges) were better understood through the qualitative interviews.

The mixed-methods approach also made it possible to identify practical issues and challenges in the dissemination of the intervention such as the lack of phone among young mothers, and planning for and conducting the interviews especially the FGDs. This aspect underscores the value of mixed-methods in research. Venkatesh et al. (2013) highlighted the critical value of MMR, ranging from complementarity, corroboration to compensation between the methods in the 'mix'. Moreover, it has been suggested that researchers using MMR should carefully consider the choice of techniques to use as this has implications on critical aspects of research such as sampling, data collection and analysis (Sandelowski, 2000).

Initially, the study set out to conduct the FGDs concurrently after the questionnaire survey but this was not possible as mothers came in at different times and thus it was not

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possible to constitute the FGDs. The FGDs were therefore planned and conducted on an agreed date and time with the young mothers who were willing and consented to take part. This finding is important in view of a pilot RCT as it informs future interventional studies such as a definitive trial. Additionally, through the mixed-methods approach, critical components of maternity care such as maternal social support could be identified despite the challenges and/or limitations noted with the MSSS tool.

Arguably, this may clearly demonstrate the value of 'compensation and complementarity' in MMR as it was evident that social support emerged as a major theme in the qualitative data. Incidentally, this finding also generates important questions regarding tool development and validity that may be subject to future research. Mixing methods provides an in-depth understanding of phenomena that may raise more research questions for further inquiry (Caruth, 2013). Driscoll et al. (2007) also noted that MMR designs are suitable when exploring complex research questions since qualitative data enables an indepth understanding of (survey) responses, while the quantitative data provides a detailed assessment of patterns of responses. In view of the study as a pilot RCT, mixed-methods approach provided a valuable pragmatic sense to the research objectives.

As stated earlier, during piloting of the research instruments it was noted that one of the tools (the MSSS) (see Appendix 3.2A) presented challenges to the young mothers. Although a few corrections were made after the piloting (Chapter 3, section 3.9), the tool still appeared 'challenging' during the final data collection as some of the mothers left some questions blank. However since completeness of data had been emphasised during the RA training, the RAs asked the mothers to select the responses which were more close to their situation. Notably, four out of the six questions in the MSSS tool appeared to largely reflect mothers in some form of marital union. For instance, the four items sought

views ranging from the support they received from their husbands/partners to whether they experienced any form of conflict from their husband/partner.

Thus, it is important to note that most of the mothers in this study were single, and therefore this finding may be a probable explanation to the challenges experienced with the tool, besides sociocultural characteristics such as age (shyness). With these challenges related to research instrumentation, the possibility of Type II error was much likely as this would raise concern regarding precision in detecting (small) differences between groups, besides other factors (Burns and Grove, 2005 p.451). Perhaps therefore, a similar tool that reflects the setting and the study population in question (teenage mothers) need to be developed and validated.

7.3 Acceptability of the intervention

Midwives also described the TSI as 'a good idea/initiative'. This may imply that the pilot study provided an opportunity for the midwives to reflect upon their routine practice, and possibly think of how better they can reach and improve the care they provided to their clientele. This aspect was elicited in the midwives' FGD, where one of the midwives observed that as midwives, they always wanted to know the progress of their clients/patients after discharge. This finding was clearly illustrated by following excerpt:

".....as a midwife, I strongly concur with it [TSI] because many times, you hear my colleagues say, **'how is so and so, we took care of her, nursed her for three** days and discharged her in a fairly stable condition'... this is prove that we are interested to know the progress of our patients" [MW.fgd M001]

Further, from the analysis of midwives' interviews it was possible to draw the potential roles of TSI in maternity care (ranging from as a means of bridging the gap of healthcare access to, as a valuable means of knowledge dissemination and providing continuity of care to young mothers) (Table 6.7). The midwives also suggested that such an intervention (TSI) needed to be provided right from antenatal care period. Evidently, this

shows that the existing health care systems in such settings have not adequately explored the avenues of scaling up antenatal and postnatal education to (young) women and/or mothers but the need is acknowledged. These findings also reflect both the midwives young mothers' views that highlighted the lack of knowledge and motherhood experience, including other aspects of parenting skills and/or maternal competence among the young mothers. Notably, the need for supportive health education among young mothers has been widely acknowledged and over the years (Apostolakis-Kyrus, 2013; Nesbitt et al. 2012; Duggan and Adejumo, 2012; Smith and Roberts, 2009; Spear, 2006; Cronin 2003; Howard and Sater, 1985).

7.4 Outcomes

This section highlights issues related to the TSI such as the midwives' and young mothers' perceptions of the TSI, including potential effectiveness of TSI. As observed from the findings, it generally appeared that the TSI was feasible and acceptable. Both young mothers and midwives thought TSI had positive impact on maternal and infant wellbeing. Indeed, it is instructive to note that from both the midwives' and the young mothers' interviews, lack of knowledge and motherhood experience were identified to be critical areas of need for young mothers. This would ultimately have an impact on their overall health and wellbeing and those of their infants.

For instance, the lack of knowledge and motherhood experience could affect general infant care practices, including critical aspects such as breastfeeding in which most young mothers expressed having had difficulty with soon after birth. Yet studies have shown that adolescent mothers were less likely to attend prenatal care and to breastfeed (Apostolakis-Kyrus, 2013, Atuyambe et al. 2008, Spear, 2006). Similarly, Smith and Roberts (2009) also noted that young mothers rarely attend postnatal classes.

Consequently, with the limited attendance at prenatal and postnatal classes, many of them may lack sufficient information that might enhance their decision-making and skills to effectively transit to motherhood. Evidently, such areas as lack of knowledge, breastfeeding self-efficacy, and/or maternal or parenting competence would form important target areas for providing meaningful support to young mothers, including through novel interventions such as TSI.

7.4.1 Potential effectiveness of TSI

As stated earlier, this study was not powered to test for any significant associations due to its small sample size. This consideration was recognised when designing this trial. It has been argued that it is not sensible to use pilot studies to estimate treatment effects since the limited sample sizes may often present unrealistic or biased estimates (Thabane et al. 2010). However, to identify potential areas of the effectiveness of TSI and possibly identify a primary outcome(s) of interest, this study observed and measured differences between groups (control and intervention) following an intervention (TSI), and it reported such differences while considering this limitation. Caution was therefore drawn while interpreting the descriptive and inferential findings of this study.

Statistical significance notwithstanding, the study demonstrated areas where the TSI may have had a positive effect among young mothers. For instance, mothers in the intervention group appeared to have a very slightly higher self-esteem, and a slightly lower infant-focussed anxiety compared to the control group, with a moderate effect size for SES (Cohen's d=0.54) (Table 5.5 and Table 5.6). Smith and Roberts (2009) who conducted a mixed-methods among young parents aged below 22 found that self-esteem was significantly associated with antenatal care attendance. Smith and Roberts (2009) further cited age, gender and self-esteem as the most influential factors on young parents attending support services. This study (Smith and Roberts, 2009) therefore highlights the possible association of maternal self-esteem with antenatal care attendance although the observational nature of the study design may not permit drawing of cause-effect relationship.

However, it was interesting to note that the qualitative findings from this study appeared to suggest that young mothers were also less likely to attend ANC. This finding was also consistent with the findings of several other studies which also reported the reduced likelihood of young mothers attending ANC (Apostolakis-Kyrus, 2013, Atuyambe et al. 2008, Spear, 2006). Although most of these studies attributed this finding to factors commonly related to socio-demographics such as education level, age, and income, the current study observed that barriers such as stigma and lack of financial means (fare) to the hospital were possible factors contributing to young mothers' lack of ANC attendance. Perhaps then one of the questions that healthcare systems in LMICs settings like Kenya would need to address is to identify at what point and how, in the continuum of maternal and infant care, should such aspects as maternal self-esteem can be addressed among young mothers, including other aspects of care or areas of need as necessary. Indeed, the midwives highlighted the need for TSI to be initiated early enough (in the antenatal period) through to postnatal period as one of the ways of addressing the knowledge and parenting skills (motherhood experience) gap among young mothers. It is noteworthy that at present in Kenya such supportive care, including antenatal and postnatal health education is provided to all mothers in hospital settings without due consideration of age differences and/or characteristics. In such situations, and coupled with cultural norms young mothers may not be confident enough to express their needs, including their lack of knowledge and motherhood experience.

As observed in Table 5.7 (Chapter 5), mothers in the control group were more likely to report having fallen ill; using medication after birth; having difficulty in breastfeeding; and introducing feeds to their infants, including water and glucose during the early postpartum period compared to the intervention group. These findings are consistent with the findings in previous RCTs on telephone support which demonstrated improved health outcomes for both the mother and their infants (Hannan, 2013; Bangure et al. 2015; and Pugh, 2002), albeit that this was a small pilot RCT that was not powered to test for statistical differences. In these studies (Hannan, 2013; Pugh, 2002) infants in the intervention groups reportedly had fewer sick visits and less use of medications.

The only RCT from Africa that was identified in the literature (Bangure et al. 2015) which assessed the effectiveness of a short message service on immunisation coverage in Zimbabwe found a significant uptake of immunisation at 6,10 and 14 weeks following birth. Similarly, mothers who were retained in this pilot RCT had had all their infants immunised and their infants recorded a gain in weight by the end of the study (10 weeks postpartum). As stated earlier, the follow up window in this study was relatively short and covered one of the most critical periods after birth, and thus it was expected that mothers would still actively seek healthcare. Although one might have expected a difference between the groups, albeit very small, it is noteworthy that these findings depict positive outcomes for all mothers as should be the case in the provision of optimal care to mothers and their infants. Most importantly, in light of the overall objective of this study which was to assess the feasibility of TSI, the findings of this pilot RCT were consistent with the findings of Bangure et al. (2015) who also reported that the intervention (SMS) was widely acceptable and cost-effective.

Although the postpartum period conventionally covers up to six weeks, and remains one of the most critical yet neglected areas (WHO, 2014), this period may be quite challenging especially to young mothers who are often more likely to be first timers. For practical reasons, this period was extended to cover up to ten weeks in this pilot RCT to permit reasonable time to evenly disseminate the intervention package. Considering that the interventional package involved motivational health messages for both the mother and baby/infant following birth, it was thought that it may be quite impractical (and/or inappropriate) for both the mother-infant pair and the researcher to disseminate all the intervention package within a short course of time. Thus, it was considered that doing so would not have provided the mothers with sufficient time to internalise the information. On a practical point of view and recognising that this was a pilot RCT exploring the feasibility of a main trial, the extended follow up was seemingly appropriate and valuable. Thus, this aspect may remain an important consideration in the context of a main trial.

There were no observable differences between groups regarding postnatal depression (EPDS), maternal social support (MSSS) and some of the mother-infant bonding indices (PBI 1, 2 and 4) during the early postpartum period. However, this may not necessarily imply there were no differences between the groups, largely due to the smaller sample size and/or other possible confounders. For instance, the fact that the intervention package was received intermittently in some cases may also partly explain this observation since in reality such cases did not benefit from the whole package for the study to be able to objectively measure the differences between groups. In addition, with the challenges experienced in collecting data with the MSSS tool where 4/6 items reflected women in some kind of marital union (see Section 7.1.4), it may not be established with certainty whether the responses from unmarried young mothers sufficiently reflected the outcome

data. While reviewing the tool retrospectively (after data collection), the researcher noted that the tool was specially designed to assess maternal social support prenatally (Webster et al. 2000), an aspect that the researcher had not given a critical thought before.

However, the simplicity of the tool, and the fact that the study population were young mothers who were likely to have a low level of education informed the choice of this tool. Indeed, during data analysis the researcher also noted that the original study (Webster et al. 2000) that had used the MSSS tool opted to assign a zero score for the questions left blank by the respondents. This was in contrast to this pilot trial as the respondents were asked to choose responses that they closely related with. The analysis of such sets of data would therefore present different results.

Reflectively, this is an important finding in view of a pilot study as it may inform future researches assessing maternal support in the context of postnatal period as well as those targeting young mothers. For instance, in retrospect perhaps other similar tools such as the multidimensional scale of perceived social support (Zimmet et al. 1988) would have been more suitable. Interestingly, this aspect (social support system of young mothers) also emerged strongly as one of the themes in the qualitative interviews. The value of mixed-methods design as complementary research methods, therefore, cannot be overstated. Moreover, a recent qualitative study among adolescent mothers in Nairobi, Kenya, also highlighted that pregnant and parenting adolescents reportedly faced several challenges after birth, including lack of emotional support, stress, social stigma, and poor healthcare access (Kumar et al. 2018). Thus, the limitation of the tool notwithstanding, maternal social support remains an important aspect of maternity care worth clinical consideration.

The evidence from RCTs on TSIs targeting psychological wellbeing have also suggested a potentially positive effect on psychological outcomes, particularly in the prevention of stress and postnatal depression (Osman et al. 2014; Giallo et al. 2014; Hannan, 2013, and Dennis et al. 2009), with mothers who received such interventions reporting great satisfaction and recommending its use (Dennis, 2010). However, most of these trials have targeted adult mothers, and the effect of TSI arguably remains vague among the young/adolescent mothers. In addition, all these trials were conducted in high-income settings. This evidence partly informed this pilot RCT, which was then conducted among young mothers in LMICs (Kenya). Therefore, larger trials targeting young mothers would provide rich data that could favourably be compared to the existing trials on TSI.

7.5 Other considerations

Although this study did not intend to assess breastfeeding and parenting self-efficacy per se, it was established that young mothers experienced difficulty in breastfeeding particularly soon after birth. The mothers cited factors ranging from lack of breastmilk to pain and engorgement, sometimes resulting to some of them resorting to alternative forms of treatment (traditional medicine/herbs) for themselves and for their infants' illnesses. Lack of knowledge about breastfeeding norms and practices and conflicting information from nurses/midwives have been cited as additional barriers to effective breastfeeding among adolescent mothers (Nesbitt at al. 2012).

Surprisingly, although young/adolescent mothers acknowledged the benefits of breastmilk on the health of their infants as their primary motivating factor to breastfeeding (Nesbitt et al. 2012, Monteiro et al. 2014), most never practised breastfeeding optimally (Monteiro et al. 2014). In addition, adolescent mothers have exhibited low breastfeeding self-efficacy, self-esteem and general self-efficacy compared

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with older mothers (Angley et al. 2015), with parenting self-efficacy having been strongly correlated with breastfeeding (Bailey et al. 2008). A greater social support and higher family functioning were associated with higher parenting self-efficacy and satisfaction (Angley et al., 2015). Interestingly, social support system emerged as one of the key themes from the qualitative findings in this study (see Chapter 6). These arguments clearly posit young motherhood as a complex issue that can only be possibly understood through a multifactorial lens. Alternatively, future studies may seek to explore these factors independently with adequate control of the mediating factors.

Importantly, during data collection one infant (who was in the control group) was observed with signs of malnutrition and after this was pointed out to the midwives working at the clinic. A clinical reassessment of the case was performed and a further nutritional advice and close follow up was initiated. It was also instructive that early weaning had been initiated in this case as the mother (aged 15) was a candidate at the time preparing for her final exams in primary school, thus the infant was being taken care of by the maternal mother most of the time. This raises the concern of schooling as observed in the previous chapter (Chapter 6), as one of the key concerns in young motherhood that midwives (and other HCPs) need to consider while attending to young mothers. For instance, although due vaccinations had been administered, this case demonstrated the likely chances that HCPs may miss to judiciously carry out their mandate.

For example, as in previous studies involving young/adolescent mothers (Tucker et al. 2011; Monteiro et al. 2014; Yako, 2007), most mothers also reported difficulties in breastfeeding especially in early postpartum period, including pain, engorgement, and difficulty in latching and insufficient breastmilk. Delayed initiation of breastfeeding has

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also been reported (Atuyambe et al. 2008). Similarly, Apostolakis-Kyrus (2013) reported lower rates (24%) among the younger (less than 15 years) adolescent mothers compared to adult mothers, noting that adolescent mothers were generally less likely to as a result of low socio-economic status, limited social support and marital status (being single). Most of the mothers in this study were also single (70%), meaning the same factors could still be at play as far as their breastfeeding experiences and parenting competence is concerned.

Moreover, two trials that explored breastfeeding among adolescent mothers underscored the role of TSI in breastfeeding (Di Meglio et al. 2009, Wambach et al. 2010). Peer telephone support appeared to have an effect of prolonging 'exclusive breastfeeding' (Di Meglio et al. 2009). Similarly, in a randomised non-blinded trial on lactation counselling intervention, Wambach et al. (2010) cited breastfeeding knowledge, prenatal intention to breastfeed, the timing of the breastfeeding decision (before pregnancy, during the first trimester, during the second or the third trimester), and social and professional support as significant predictors of breastfeeding initiation. However, these trials were found to have methodological limitations including attrition, self-reporting of data, and participation bias, and thus may not be sufficiently provide conclusive evidence. This implies that breastfeeding support is still critical for young mothers, with the need to explore better approaches of addressing such support needs, including further trials on novel interventions such as TSI.

Also, running an interventional study is considerably an expensive venture. However, the role of interventional studies in social and health care cannot be overemphasised. Interventional studies demand a lot of resources, including time especially in the context of a multi-site study. Thus, such studies need to ensure that they employ a team of

researchers who not only are committed to it but also have interest in research. Institutions and governments alike need to realise the critical role of interventional studies so as to apportion proportionate resources to research for the overall health and social wellbeing of the population.

7.6 Sample size determination for a definitive trial

Following the findings of this study, and with clinical considerations by the researcher (who is also a midwife) and with the supervisory team, it appeared maternal social support and maternal self-esteem were critical aspects for the young mothers in LMICs such as Kenya as they transit to motherhood. Despite the notable challenges with the MSSS tool as previously highlighted, the social support system seemed one of the critical areas of need for young mothers in such settings. It also appeared the TSI had an effect of improving maternal self-esteem among young mothers in the study.

Moreover, the choice of these outcomes was in part informed by the characteristic attributes of the participants (young mothers) during the interviews whereby it appeared mothers who were in the intervention group were a 'little more expressive' compared with those in the control group. Thus, seemingly the intervention may have had an effect of enhancing maternal self-esteem, which in effect would influence their overall self-efficacy in maternal and infant care practices. In addition, the SES demonstrated a moderate effect size (0.54) for maternal self-esteem, while the other outcome variables (EPDS, PBI, MSSS) demonstrated small effect sizes (Kotrlik and Williams, 2003). However, it is important to note that this was a small pilot RCT and thus the difference between groups could not be adequately ascertained owing to the likelihood of Type II errors. The findings are, however, sufficient enough to inform a definitive trial. The choice of the primary outcome(s) was therefore not solely premised on the statistical

outcomes of these variables but also on due clinical considerations and the expertise of the supervisory team who are experienced researchers. Importantly, it has been argued that the selection of appropriate outcomes is critical when developing research protocols for clinical trials that compare the effects of interventions since such trials need to minimise bias as much as possible (Williamson et al., 2012).

Therefore, in view of a larger trial and with consideration of the two outcomes (MSSS and SES), the sample size may be determined based on the SES variable (the MSSS could not be used for the reasons highlighted earlier). Thus, the sample size was estimated using the online sample size calculator (http://powerandsamplesize.com/Calculators/Compare-2-Means/2-Sample-Equality), and considering a minimal clinically important difference (MCID) as 0.5SD (commonly recommended by statisticians when there is no guidance regarding clinical importance). With the standard deviation for the control group (SD=3.2), therefore 0.5SD=1.6, and with the power of 80% and 5% significance level, these values were in put in the calculator. With this as an example, the sample size required was then estimated to be 64. Thus a definitive trial powered to 80% with a significance level α =0.05 would require a sample size of approximately 64 participants per group. Therefore for a main trial, a sample of 128 participants would be randomised between two groups. It is thought that this sample would be sufficient to statistically detect any differences (statistical significance) between groups with regard to an intervention such as TSI.

Moreover, to allow consideration of a range of MCIDs (allowable differences) in determining the sample size for a definitive trial together with projected attrition rates, it was necessary that the sample sizes be determined factoring in all these assumptions and/or considerations. Devane et al. (2004) highlighted key considerations (referred them

as basic principles of sample size estimation) in determining the sample size for RCTs which included: the ethics of randomised trials, the null hypothesis, effect size, significance level and Type I error, and power and Type II error. The consideration of these factors in sample size estimations by health care researchers avoids the risk of misinterpreting findings or wrongful conclusions on the hypothesis tests due to inappropriate, unrepresentative and biased samples (Devane et al. 2004). The authors further argued that a sample that is too small may not detect a 'true' difference in outcomes hence fail to differentiate the effect of chance, and conversely a too large a sample size may be unethical in view of exposing more participants than necessary to a potentially less beneficial intervention (Devane et al. 2004). As such both situations may be unnecessarily costly in terms of resources, including ethical issues thereof (Devane et al. 2004, Kieser and Wassmer, 1996), hence there is need to meaningfully achieve a balance when determining sample size for interventional studies (or trials).

In addition, with the consideration of reducing Type I error (of falsely rejecting a true null hypothesis) while retaining a power of 80%, an attempt of determining the sample size by reducing the α -significance level to 1% was considered as suggested by Devane et al. (2004), including estimating the sample size with a 90% power for both α =5% and α =1%. This was thought to give a broader understanding of a future definitive trial regarding the sample size estimates. Thus, the sample size was estimated for the different combinations of α -significance and β -error (for power) with the assumption of following a t-test values (see Table 7.1 and Table 7.2).

Further, another approach to sample size determination in randomised clinical trials based on correlations has been suggested (Teerenstra et al. 2012, Borm et al. 2007). This approach has also been suggested for determining sample sizes for cluster randomised trials (Teerenstra et al. 2012). This approach has also been thought to be more suitable for continuous outcomes (such as SES in the present study), especially when the outcome under consideration can be collected at baseline in the trial and uses analysis of covariance (ANCOVA) (Teerenstra et al. 2012, Borm et al. 2007). Teerenstra et al. (2012) further highlighted that an analysis of covariance using both baseline and follow-up data (scores) of the outcome will increase the power of the trial. However, it is important to note that this approach was not used in the pilot RCT as the main aim was to assess for the feasibility and acceptability of TSI, including identifying a primary outcome of interest. As such, as explained earlier in Chapter three (Section 3.7) the pilot emulated a main trial with a conservative sample size estimate as recommended for pilot/feasibility trials (Kieser and Wassmer, 1996). Besides, as noted earlier the pilot study was not aimed at testing for statistical significance hence such an approach in sample size estimation was considered not to be necessary in the pilot trial.

With these considerations, including the likely consideration of collecting baseline data for the outcome variable (SES), and with the assumption of different combinations for correlations (r) i.e. 0.1, 0.3 and 0.5 as small, medium and large effect sizes for r respectively, the estimated sample sizes obtained from the above calculations (based on α -significance level=5% with 80% power and t-test assumption) were multiplied by the design effect (1-r²). As such, in situations where the correlation r is unknown, a moderate effect for r (r=0.3) may be plausible and conservative. This is also in consideration of the fact that the TSI demonstrated a moderate effect on SES. However, a definitive trial may consider collecting baseline data for the outcome of interest (SES) so as to objectively estimate the appropriate sample size based on an actual correlation factor to inform further studies. Table 7.1 and Table 7.2 presents a summary of sample size estimates per group for a definitive trial for different levels of statistical significance and power with ttest assumption; and the sample size estimates with potential attrition rates and correlations respectively.

MCID= 0.5SD	Cohen's d*	Sample size estimates per group							
		[α=5%; 1- β=80%]	[α=5%; 1-β=90%]	[α=1%; 1-β=80%]	[α=1%; 1-β=90%]				
1.2	0.38	112	150	167	212				
1.3	0.41	96	128	143	181				
1.4	0.44	84	110	123	156				
1.5	0.47	72	96	107	136				
1.6	0.50	64	86	94	120				
1.7	0.53	56	76	83	106				
1.8	0.56	50	68	74	95				

<u>Table 7.1: Sample size estimates for a definitive trial with different levels of statistical significance and power (with assumed t-test)</u>

*Assuming SD=3.2 (d=MCID/3.2

Table 7.2: Sample size estimates for a definitive trial showing impact of attrition and
correlation with baseline measurement for 5% significance and 80% power

MCID	Cohen's d*	Sample size estimate	Sample size estimates per group with projected attrition rates			Projected correlation with baseline measurement			Total sample size estimate per group*	
		[α=5%; 1-β=80%]	5%	10%	15%	20%	0.1	0.3	0.5	
1.2	0.38	112	118	124	129	135	111	102	84	<u>118</u>
1.3	0.41	96	101	106	111	115	96	<u>88</u>	72	<u>102</u>
1.4	0.44	84	89	93	97	101	84	<u>77</u>	63	<u>89</u>
1.5	0.47	72	76	80	83	87	72	<u>66</u>	54	<u>76</u>
1.6	0.50	64	68	71	74	77	64	<u>58</u>	48	<u>68</u>
1.7	0.53	56	59	62	65	68	56	<u>51</u>	42	<u>60</u>
1.8	0.56	50	53	55	58	60	50	<u>46</u>	38	<u>53</u>

*Assuming SD=3.2 (d=MCID/3.2)

**Based on α -significance level=5% with 80% power (assumed t-test), with a projected attrition rate of 5% and r=0.3.

7.7 Sample size estimates and practical considerations

In view of the above considerations, the sample size for a definitive trial was estimated based on a significance level of 5% (α =0.05) and 80% power (β =0.20), with a MCID estimate of 1.6. As observed earlier, the TSI appeared to have a moderate effect on SES (SD=3.2, hence 0.5SD=1.6). Following this, and with an assumed t-test the sample size was estimated to be 64 per group. Since attrition is a key aspect in studies with reasonably long follow up periods such as trials (or interventional studies) including longitudinal studies (Fewtrell et al. 2008), a projected attrition rate of 15% was considered in the sample size estimates in which the sample estimate scaled up to 74 per group. Moreover, with the possibility of collecting baseline data for SES (and possibly for other secondary outcomes) and the fact that SES is a continuous variable, a conservative correlation of 0.3 (r=0.3) was also considered. This was in consideration of the potential challenges in recruitment of large number of study participants and subsequent follow-up which may also increase the likelihood of high loss to follow up (attrition) due to extended periods. Thus applying this correlation factor in the sample estimation yielded a sample estimate of 68 per group (Table 7.2). A total sample of 136 study participants would therefore be recruited and randomised between two groups.

In addition, the recruitment of participants in the pilot RCT took about three months. Thus, for a definitive trial this period may even be longer considering the relatively large sample size. Recruitment for a definitive trial may therefore take up to one year, including ethical clearance, trial registration and other study logistics. Moreover, a definitive trial would need to devise ways of minimising attrition so as to enhance retention of reasonable sample size at the end of the trial. Attrition is a critical aspect in research especially in long term RCTs (and cohort studies) since it has direct implication on the statistical power, bias and generalisability of the study findings, with attrition rates more than 20% posing serious threats to validity (Fewtrell et al. 2008). Considering the differential attrition in this pilot RCT, perhaps one of the strategies of achieving this is by developing a participant-tracking sheet to periodically follow up participants particularly after the initial clinical appointment (at 6 weeks). Although the intervention involves telephone support, perhaps there would be need to remind all participants by telephone about their last appointment with the study (the study end point). To avoid any possible contamination or dilution of the intervention, such a follow up telephone reminder should be carried out by a person totally independent of the study. A protocol for a definitive trial is presented in Section 7.9 below.

7.8 Strengths and limitations of the study

The strengths and limitations of this study were assessed against the objectives of the study, and more so in consideration that this was a pilot study seeking to explore the feasibility of conducting a main trial on TSI among young mothers in a LMIC setting. While this pilot RCT was not powered to test for statistical differences between groups regarding TSI, this was a design feature and not a limitation of the study. The findings focus on informing a definitive trial by highlighting some of the methodological and practical considerations that future trials and/or interventional studies targeting young mothers may need to consider. As an inevitable consequence of the small sample size, test results and confidence intervals for differences between the groups were interpreted cautiously.

7.8.1 Strengths

To the researcher's knowledge, this is the only (pilot) RCT and among the few interventional studies targeting young (adolescent/teenage) mothers conducted in Kenya.

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Notably, the literature search also identified only one similar study - a short message service on immunisation coverage in Zimbabwe by Bangure et al. (2015) in Africa. Thus, being a smaller pilot RCT exploring the feasibility of conducting a definitive trial on novel interventions such as TSI in LMICs was a positive step towards future interventional studies. The lessons learnt from this study may offer researchers insight on conducting interventional studies in such settings, including providing them with confidence that such studies are doable.

It is worth mentioning that the researcher (whose personal reflections about the study are highlighted at the end of the next Chapter) was not even certain initially if such a study was possible, but the desire to try new things and the supervisory guidance from a team of experienced researchers propelled him to. Systematic reviews on TSI (Lavender et al. 2013, Dennis and Kingston, 2008, and Shaw et al. 2006) have highlighted the potential role of telephone support in improving maternal and infant care, but most of the trials which formed the evidence base of these reviews commonly involved adult mothers. Therefore this study forms the base of TSI trials among young mothers in the future.

From the onset, this study had intended to account for the age differences and social dynamics between younger mothers (12-16) and those aged 17-19 years across the two study centres. Therefore randomisation was stratified by site and age group. At the end, only seven mothers were recruited in the 12-16 age group, with the youngest having been 14 years. In terms of feasibility, this finding is informative for a main trial as this implies that such trials (or similar interventional studies) may have to specifically target the older age group. Moreover, conducting the study in two centres provided a better means of assessing for feasibility as the findings, including qualitative data could be compared for consistency or otherwise.

The development of the intervention involved a rigorous and iterative process using the Delphi technique which proved to be quite valuable in refining the intervention. The constant involvement of the panel of midwives throughout the process, including piloting of the intervention by the intervention midwives before the final adoption of the tool. Moreover, the supervisory team had a wide experience in the Delphi process and thus provided a valuable expert guidance which formed part of the consensus building process. Therefore the Delphi output in this pilot RCT is worth consideration in future interventional studies.

As a feasibility study, the findings of this study regarding the MSSS tool are a strength in that they inform a future study. Apparently, the need for developing and validating a similar tool that reflects the study population (young mothers) in LMICs settings was elicited. Such a study need to be specifically designed as a tool development and validation, independent of assessing interventions so as to critically assess the factors surrounding young motherhood.

In addition, the SNOSE approach used in randomisation appeared to have been effective and appropriate in this study. Blinding was also reasonably achieved, arguably to the satisfaction of the researcher since the RAs (during recruitment and outcome evaluation), and the intervention midwives were independently recruited and trained at different times in the study. This approach ensured that specific training on respective roles and role assignment was performed as reasonably as possible. Lastly, the statistical analyses performed in this pilot trial were deliberated on beforehand during protocol development of the pilot and adhered to. Although there was no intention of pooling the pilot data with a main trial data, in which case this consideration would be vital in minimising the potential bias of testing multiple issues, including performing opportunistic actions by researchers (Thabane et al. 2010), this action proved helpful in this study as all the analyses were performed as planned. It could therefore be argued that the study actually measured what it was set to. This was made possible by the initial consultation with a statistician while developing the protocol of this study.

7.8.2 Limitations

Although there was no evidence of this from the qualitative interviews or focus groups, it is possible that there was sharing of information between mothers across study groups. Participants were provided with information sheets and the study was explained to them during recruitment, and they were given some time to consider consenting to participate. The intervention was delivered by phone, and this may have enabled possible sharing of contacts, and consequently information related to the TSI. Moreover, considering that the mothers may have been residing within the localities of the study settings and the fact that being an African setting where people live in communal settings, it was also possible that the mothers may have interacted through social gatherings like churches and ceremonies. Incidentally, two mothers in the control group contacted the researcher regarding concerns related to infant care, with one further asking why she did not receive the intervention. Such potential contamination may have an implication on the observed findings in reducing observed differences between the study groups. A future trial may therefore consider using cluster randomised approach to minimise potential incidences of contamination, including possible protocol violation.

Not keeping a record of the number of young mothers who were approached to take part in the study sites was a limitation. The number assessed for eligibility is part of the CONSORT flow diagram (see Figure 5.1), which should also report the number not meeting the inclusion criteria and the number who declined to participate. These would have provided useful information to inform the conduct of a definitive trial. The overall attrition rate was relatively high and it was slightly higher in the control group. In a definitive trial, steps would be taken to minimise attrition, such as the suggestion of participant tracking in Section 7.6.

Lastly, with the challenges noted with the MSSS tool and the researcher's reflexive account of the same in retrospect, it is possible that the study may not have captured an outcome data that sufficiently reflect the study population regarding this variable. The findings on maternal social support need to be interpreted with caution.

7.9 Protocol for a definitive trial

Study title: A randomised controlled trial on TSI among teenage mothers (17-19 years) comparing telephone support versus no support during the immediate postnatal period in LMICs setting (Kenya): a study protocol

7.9.1 Background

The evidence from literature suggests that young mothers were less likely to attend antenatal and/or postnatal clinic, consequently putting them and their babies/infants at a considerable health risk. Few trials have, however, been conducted among teenage/adolescent mothers on supportive interventions such as TSI during postnatal period, especially in LMICs settings such as in Sub-Saharan Africa, including Kenya. A pilot trial on TSI among young mothers in Kenya, however, demonstrated that it was feasible to recruit such a group of mothers for a definitive trial and that the TSI was acceptable by both young mothers and health care providers. The pilot trial also identified maternal self-esteem as one of the key outcomes in which TSI may be beneficial to young mothers. Further, previous evidence suggests that adolescent mothers have exhibited lower selfesteem and more depressive symptoms, including low breastfeeding and general selfefficacy compared to older mothers. Trials and systematic reviews evidence on telephone support intervention (TSI), however, suggest a promising opportunity to offer supportive maternity care. In addition, critical aspects during postnatal period such as maternal social support and postpartum bonding remain important particularly among this group of mothers as they may often exhibit lack of motherhood experience and knowledge on MIC. The postpartum bonding questionnaire has been used to screen for mother–infant relationship disorders and its severity (Klier, 2006). Such trials may also consider assessing maternal satisfaction and perception of TSI as well as exploring their parents' perception of such interventions since it was evident from the pilot trial that parents/family was a critical component of social support system available to young/teenage mothers in LMICs settings as Kenya.

7.9.2 Study aims

The main aim of this trial is to assess the effectiveness of TSI among teenage mothers (17-19) through a trial comparing telephone support vs no support on maternal self-esteem during the immediate postnatal period in Kenya.

7.9.3 Study outcomes

7.9.3.1 Primary outcome

To observe differences between intervention and control groups following TSI during postnatal period on maternal self-esteem.

7.9.3.2 Secondary outcomes

1. To assess maternal satisfaction of the telephone support intervention during postnatal period.

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- 2. To assess and compare the potential influence or relationship between maternal self-esteem and selected maternal/infant outcomes following birth (breastfeeding self-efficacy, postpartum bonding, maternal social support).
- To assess the teenage mothers' perceptions regarding breastfeeding and their breastfeeding self-efficacy.
- 4. To assess parents' perceptions of TSI for teenage mothers during the postnatal period.

7.9.4 Eligibility criteria

7.9.4.1 Inclusion criteria

- 1. All postnatal mothers aged 17-19 years who gave birth to a singleton healthy baby at term at MTRH and KCGH.
- 2. Postnatal mothers who are willing to consent (18-19 years) or assent (17 years) to participate in the study, and whose parents/guardians are willing to consent their participation (for the 17-year old).
- 3. All postnatal young mothers who own or have access to a mobile phone and are able to use common mobile telephone operation services (SMS and call services).
- 4. Parents/guardians of teenage mothers who took part in the study, and who are willing to voluntarily take part in interviews regarding the TSI.

7.9.4.2 Exclusion criteria

- Postnatal teenage mothers who gave birth through caesarean, or who had multiple births and/or whose babies developed birth complications or had congenital anomalies.
- 2. Mothers who were known to have a limited capacity to consent e.g. those with recorded mental disability.

7.9.5 Design

This will be an RCT targeting teenage mothers (17-19 years) soon after birth. The study will employ a mixed-methods approach in data collection. The study will assess and compare maternal outcomes (SES) and maternal satisfaction following TSI, including parents' perceptions of the TSI. This design was informed by a similar pilot RCT (which explored the feasibility of a main trial in the same setting) and found that it was feasible to recruit young mothers for such a trial and that TSI was acceptable among both young mothers and health care providers.

7.9.6 Sampling and sample size determination

Purposive sampling will be used to select the study sites. Eligible participants will be selected through consecutive sampling (since they will be presenting at the facilities at random) and then randomised into control group (receiving usual care) and intervention group (receiving usual care and telephone support) during the first ten weeks after birth. The allocation to a group will be done through a set of random numbers developed by the Principal Investigator (PI) using an online randomisation program. Following the findings of a pilot RCT on TSI in the same setting, it was noted that TSI had a moderate effect (effect size=0.54) on maternal SES with a mean SD of 3.2 for the control group. Based on these findings and with an assumed 0.5SD as a possible minimal clinical important difference (MCID), and a projected attrition rate of 15%, the sample size required with a significance level of 5% and 80% power to detect a statistical difference between groups was estimated to be 74 per group. Thus, a total of 148 research participants will be recruited for the trial.

For qualitative data, participants will be purposively selected from either arm of the study for individual interviews and/or group discussion. Parents/guardians will also be

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purposively selected for individual interviews. The qualitative interviews will be conducted using an in-depth interview schedule.

7.9.7 Recruitment and randomisation

7.9.7.1 Recruitment

Eligible participants will be recruited during the immediate postnatal period (before being discharged) at the respective maternity units of the study centres. An informed consent and assent as applicable will be obtained prior to recruitment. The eligible participants will be fully informed of the study procedures through participant information sheets as applicable, and given sufficient time to read them (up to 48 hours) before consenting and/or assenting. Parents/guardians (for participants aged 17 years) will also be provided with respective PIS and consent forms. A written consent and assent forms will be used as applicable.

7.9.7.2 Randomisation

Eligible participants who consent or assent to participate in the study will then be randomised into control and intervention groups by the researcher using a list of random numbers generated by a computer program. The SNOSE (sequentially numbered, opaque and sealed envelopes) approach (Doig and Simpson, 2005) will be used in sample allocation to a group by the PI or someone independent of the intervention and data collection. The opaque, sealed envelopes containing the random allocation numbers will be opened by a trained Research Assistant (recruiting RA) during recruitment to ensure concealment (Doig and Simpson, 2005). The SNOSE approach was also used during the initial pilot trial and proved to be effective in randomisation and group allocation, as well as cost-effective.

a) Control group

Study participants in the control group will receive the usual postnatal care interventions as prescribed by the Ministry of Health guidelines (MoH, Kenya) including postnatal counselling before discharge. In addition, postnatal mothers are provided with maternal and infant care instructions on breastfeeding, nutrition and infant feeding, care of the newborn/infant, postnatal danger signs, immunisation and family planning by the midwife prior to discharge. Mothers are also advised to refer to their Mother-Child booklet (MoPHS and MoMS Kenya, 2010) which was provided during their antenatal care, which also contains postnatal instructions on infant and maternal care.

b) Intervention group

Participants in the intervention group will receive the usual postnatal care interventions as outlined above (control group) plus a telephone support intervention in form of weekly text messaging and telephone call once every two weeks after birth until the tenth week. The support intervention will be provided by a trained RA (midwife) regularly at scheduled dates for each of the participants as agreed with the PI. The participants will also be given an option to call back for further informational support and/or clarification. Whenever a study participant calls back or otherwise seeking further supportive information, the RA shall document such occasions (time/date of call and content domain of the information sought) in a field notebook provided by the PI.

7.9.8 Blinding and allocation concealment

The midwife who will be trained and recruited as a RA to contact the intervention group (offer telephone support) shall be blinded at the recruitment stage of the participants in either group. The intervention midwife shall only be provided with a list of the participants allocated to the intervention group by the recruiting RA and instructed to follow through with the TSI regularly as scheduled.

At the end of the intervention, the PI shall recruit and train a second RA to collect outcome data from the two groups. The RA shall be blinded of the participants' group allocation and shall only be required to administer the questionnaires. The PI shall also be blinded to group allocation.

7.9.9 Data collection

Quantitative data will be collected using validated tools. For the primary outcome (maternal self-esteem), the Rosenberg's Self-esteem Scale (Rosenberg, 1965) will be used. This will also involve the collection of data on the primary outcome at baseline to provide for adequate assessment and comparison of the effect of TSI on the primary outcome. For the secondary outcomes such as maternal satisfaction (about the TSI), maternal social support and breastfeeding self-efficacy, an appropriate assessment tool will be selected after a review of the existing tools, particularly with the consideration of the study population as young/teenage mothers. In addition, a screening questionnaire will be used to assess breastfeeding and mother-infant bonding aspects (Brockington et al. 2001). The questionnaires will be interviewer-administered and data will be collected from both study groups at the end of the intervention by a trained RA. Prior to the intervention, the socio-demographic data of all the participants who consented for the study will be collected using a structured questionnaire will be used to collect.

Qualitative data from the mothers will be collected through individual in-depth interviews and/or group discussion (FGDs) whenever possible, which will be conducted at the end of the study. Similarly, parents'/guardians' views and/or perceptions regarding the TSI will be sought through individual interviews. The interviews will be conducted using a semistructured interview guide. Both verbal and written consent will be sought prior to conducting the interviews.

7.9.10 Data analysis

Data will be double-entered into IBM SPSS Statistics (version 23) for analysis. The data entry will be cross-checked for correct entry by someone other than the PI to ensure adequate blinding in the trial. The PI will be unblinded to group allocation after analysis. The data will mainly be analysed using appropriate descriptive statistics and inferential statistics comparing the outcomes in the two arms of the study. Recruitment rate, attrition rate and protocol adherence rate will be estimated with 95% CIs. The Mann-Whitney U test will be used to compare skewed numerical variables and independent-samples t-tests to compare non-skewed numerical variables. In addition, analysis of covariance will be performed for the primary outcome comparing the baseline scores and the end-trial scores. Regression models may be used as appropriate. The data will be presented in the form of tables, graphs, charts and a narrative summary of the statistics.

Qualitative data will be analysed using Framework analysis (Ritchie and Spencer, 1994), which involves a systematic approach to qualitative data analysis - familiarisation with data, development of theoretical framework/themes, indexing and charting, and summarising/interpretation of data. Data from both the mothers and parents/guardians will be subjected to the FA. Verbatim narratives will be presented where applicable in relation to the thematic framework derived from the data to highlight key findings or themes as necessary.

7.9.11 Data management

The filled questionnaires will be kept under key and lock in a cabinet and only retrieved for analysis by the researcher. Data entered onto computer will be anonymised, with an internal study ID used to match the computer data with the questionnaires.

7.9.12 Ethical considerations

The principles of Research ethics and governance will be duly observed throughout the study. Ethical approval from the relevant Research Ethics Committees will be sought prior to commencing the study, as well as permission to conduct the study from the respective study centres. The study will also be duly registered with Current Controlled Trials.

Written and verbal informed consent to participate in the study will be sought from the eligible participants. The participants will be fully informed by the PI and RAs of all the procedures involved in the study prior to seeking informed consent. The participants will be provided with PISs accordingly before consenting or assenting as applicable. Confidentiality of the data/information will be observed at all times. The filled questionnaires will be kept under key and lock in a cabinet and only retrieved for analysis by the researcher. Data entered onto computer will be anonymised, with an internal study ID used to match the computer data with the questionnaires. Respect for the principles of individual rights, anonymity and privacy will be observed to safeguard the dignity of the participants. During data collection and/or interviews, the researcher(s) will always assess for any form of distress experienced by the participant(s) reported or otherwise, and use a Distress policy developed for the study to ensure the participants receive appropriate attention. In such cases, this may include appropriate referral for medical attention, including counselling services. This is in consistence with the observation of ethical principle of beneficence.

7.10 Chapter summary

This chapter highlighted and discussed the key findings of the pilot RCT. Notably, the development and dissemination of the intervention; the key methodological and/or

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practical issues that were noted during the study such as access and recruitment, randomisation strategies, and data collection were highlighted with a view of evaluating how best they worked or not during the pilot trial (feasibility findings). An understanding of these issues provides useful considerations that would inform similar interventional studies in similar settings in the future, including full trials. Moreover, the perceptions of midwives and young mothers regarding TSI (the acceptability of the intervention) were highlighted, including the potential areas of maternal and infant care where TSI was seemingly effective (the potential effectiveness of TSI).

Other considerations that emerged from the study such as breastfeeding among young mothers are also highlighted. These issues were discussed in relation with existing and relevant literature. Importantly and consistent with the primary aims of the study as a pilot RCT, the study also identified potential areas in maternal and infant care where novel interventions such as TSI may be useful. The study therefore identified primary outcome(s) of interest, and a sample size for a definitive trial was determined. A protocol for a definitive trial was therefore developed based on the pilot findings. Lastly but not least, the strengths and limitations of the study were also discussed, largely based on the practical issues and to lesser extent the potential role of TSI as one of the means of addressing the concerns of young motherhood.

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CHAPTER EIGHT

CONCLUSIONS &

RECOMMENDATIONS

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CHAPTER 8: CONCLUSIONS AND RECOMMENDATIONS

8.0 Introduction

This chapter presents the conclusions and the recommendations drawn from the study. Specifically, it highlights the original contributions to knowledge drawn from the study and the possible implications the study findings may have with respect to clinical practice (especially midwifery), research and policy. At the end, the researcher presents his personal account of experiences throughout the PhD journey, notably his academic and research growth over the period of study.

8.1 Original contribution to the body of knowledge

The findings of this study suggest that TSI is feasible and acceptable among young (or teenage) mothers. This pilot RCT has demonstrated that it is possible to recruit young/teenage mothers for a definitive trial and assessed a protocol on which a definitive trial could be based. Through the mixed-methods approach used in the design of the study, the study was able to unearth complex issues in young motherhood such as maternal role modelling and the social support environment/system that young mothers, who are often likely to be first-time mothers, find themselves in especially in the context of low resource settings. Health care providers need to understand such issues when attending to the needs of this group of mothers, more so in relation to the issues surrounding transition to motherhood such as parenting skills (maternal competence and self-efficacy) and social support (Entsieh and Hallström, 2016, McKellar et al. 2002).

In addition, this study also identified young mothers to be lacking adequate information (mainly due to limited attendance to ANC and the barriers to ANC attendance thereof); and motherhood experience (mainly due to being first-timers). The healthcare system should therefore recognise the unique place of young/teenage women in the continuum of care by identifying their unique needs while recognising their social dynamics at the same time. The development and implementation of the TSI (through the Delphi process) is an original contribution considering the study setting as a LMIC, and particularly in light of how research can be used to transform health care. The intervention package itself (the Delphi output) highlighted the priority areas of maternal and infant care practices worth considering in clinical practice. Moreover, the involvement of midwives in the study provided an opportunity for them to reflect on their routine practice and think how better they can reach out to their clients/patients after hospital discharge.

As a feasibility study, the limitations identified with the MSSS tool are informative, especially considering the study population (young mothers) and the study setting. This provides basis for the need to develop and validate a similar tool that reflects the study population in such settings. This study also noted the critical role of parents/guardians in the context of research involving young mothers (or perhaps young people in general), not only as gate keepers but also as active players in the social support system for the young mothers. This finding has a critical implication in interventional studies such as TSI, since researchers may have to find a way of involving the parents/guardians while at the same time strive to maintain the autonomy of the research participant (young mother). This is even very critical in the context of reproductive health issues which are often sensitive in view of power balance between parent and daughter/son relationship.

Like previous studies that have cited difficulties in breastfeeding among young/adolescent mothers (Tucker et al. 2011; Monteiro et al. 2014; Yako, 2007), this study also found breastfeeding as a key challenge for young mothers after birth. However, it is important to note that although this was not an intended primary outcome at the design of this pilot

RCT, the mixed method approach proved useful in identifying this aspect. This implies that breastfeeding remains a critical area of need, especially for young mothers regardless of setting. It therefore remains a universal challenge that needs further exploration and supportive care.

Moreover, with the FA approach used in qualitative data analysis, the 'new frames' or thematic areas (sex education for young/adolescents and the use of traditional medicine/herbs during postnatal period) may be regarded as original contributions from the present study. Such issues, however, need further inquiry to enable a deeper understanding of their implications in MIC. For instance, these issues could be explored in the context of the social support system available to young mothers and/or the adolescents since as observed earlier, the role of the family and the community is critical as far as postnatal support to (young) mothers is concerned.

8.2 Study implications

8.2.1 Implications for practice

Through a structured narrative review of the literature, this study has highlighted the needs of young mothers during the postnatal period. Evidently, postnatal period is one of the neglected areas in maternal care (WHO, 2014), yet very challenging particularly to young mothers who often may be lacking adequate knowledge and motherhood experience to effectively transition to motherhood. Healthcare providers, including midwives, who play a critical role in the care of the childbearing family need to deeply understand the social support system for young mothers, especially in LMICs such as Kenya. By doing so, a collaborative approach to the care of young mothers can be achieved through and with the family and the community at large. This may imply the need for healthcare systems in such settings to develop educational programmes not only

targeting the women (young mothers) (as it is in the current system), but also the family and the community where these women (young mothers) hail from.

For instance, this study identified that the social support system available to young mothers includes the presence of traditional herbalists who provide traditional medicine to (young) mothers and their infants, which may hitherto be harmful to their health or prevent them from seeking appropriate care. Recognising these factors and finding a balance of how to work with the community systems would therefore be helpful if HCPs engage meaningfully with the community. In addition, an understanding of barriers to effective care such as stigma, which was perceived as one of the factors preventing young mothers from attending antenatal care, thereby missing out on antenatal care and education would help HCPs to devise better strategies for reaching out and providing health education to young mothers. Such strategies may include TSI, which was also perceived to be cheap and cost-effective by both midwives and young mothers. Notably, this study provided the midwives with an opportunity to reflect on their routine practice and think about how they could provide continuum of care to mothers following birth. This was evident from their responses/perceptions of the TSI.

8.2.2. Implications for future research

As this was a pilot RCT seeking to explore the feasibility and acceptability of TSI among young mothers during the postnatal period, this study has demonstrated that it is feasible to recruit young mothers (teenage) for a definitive trial. However, for a definitive trial, key methodological considerations such as the need to power the study to measure for statistical significance would be necessary. This would permit adequate sample size that would enhance sufficient statistical measurement of selected outcome measure(s), and possibly the external validity (generalisability) of the results. This study also found that parents played a key role not only in the support system of young mothers, but also in access and follow up. Since access to such a population group (which included minors) presents ethical issues and considerations (Crane and Broome, 2017), similar trials in similar settings in the future may need to consider finding a way of actively involving their parents, not only during access and recruitment but also throughout the research process to enhance the chances of success in the trial. Moreover, most of the young mothers relied on their parents for fare to the hospital. This was particularly evident during data collection in that most of the young mothers had to seek the permission of their parents or asked the researcher to inform their parents about the appointment. Apparently, obtaining consent (assent and parental consent) during recruitment is not enough as an interventional study is all about continuous engagement.

Moreover, since lack of phones was noted as a key challenge during recruitment as well as in the delivery of the entire package of the TSI, similar trials in the future may consider providing mobile phones to young mothers who are willing to consent and take part to enhance the recruitment rates and the provision of optimal TSI. In addition, due to the challenges raised by the midwives and young mothers such as lack of fare to the hospital (whenever they were identified for referral by intervention midwives and during data collection), such a definitive trial may have to consider following up participants within the primary level (peri-urban) facilities in the setting as an alternative option. These facilities are within a proximal reach to mothers seeking maternal and infant care services. This is also in cognisance of the fact that one of the study centres (MTRH) seeks to decongest the referral facility by empowering these peri-urban facilities through staff training and capacity building. Since this was a pilot RCT, the researcher has attempted to apply the findings to inform a definitive trial and thus a protocol for a full trial has been developed (see Section 7.1).

Lastly, through the Framework Analysis (FA) approach (Chapter 6), this study identified other aspects surrounding young mothers such as sex education and the use of herbal medicine in maternal and infant care practices. These aspects were identified as new frames (Table 6.4) following the analysis of qualitative data. It is unlikely that these issues would have been identified if other approaches of qualitative data analysis (QDA) such as thematic analysis would have been used as they may have appeared 'irrelevant' to the aims of the study. For instance, it is possible that such issues could emerge and be interpreted as less dominant themes, yet in FA approach they could be interpreted as new facets or 'frames' in the data that need further exploration. Therefore, the flexibility provided by FA permitted the accommodation of such issues, which provides avenue for further research. For instance, although sex education has been incorporated into the school curricula in the Kenyan context, perhaps there is need to explore the approaches in which such information is disseminated to the adolescents/young people. This may also include reviewing the implementation of youth-friendly services in hospitals as well as evaluating their effectiveness/impact in preventing teenage pregnancy which has been on the rise in Kenya. Going by the findings of this pilot study it was evident that young/adolescent mothers lacked sufficient information related to sexuality and reproductive health. Further qualitative inquiry or otherwise would thus provide a better understanding of such issues. In addition, this study found that many young mothers expressed difficulty in breastfeeding at the beginning following birth, thus future studies may as well try to assess breastfeeding self-efficacy using relevant tools.

8.2.3 Implications for policy

This study underpins the importance of synergistic approach between universities/teaching hospitals and the Ministry of Health in healthcare research. Although the findings of this pilot RCT are not geared towards informing policy, it is important to note that this is one of the few known (pilot) RCTs in Kenya targeting young mothers with innovative interventions such as TSI. Over the years, maternal and infant health has been a major concern across the globe, particularly in LMICs such as in sub-Saharan Africa where maternal and infant mortality and morbidity is still high (WHO, 2014).

While such countries still depend more on the recommendations from health organisations like the WHO, they should also strive to invest in health care research especially in interventional studies such as RCTs which contribute to the pool of evidence in systematic reviews and evidence-based health care (Centre for Reviews and Dissemination (CRD), 2009)). Based on the literature search in this study, only one RCT relevant to the study was identified (Bangure et al. 2015) from sub-Saharan Africa. Since systematic reviews (with meta-analysis) may account for the differences in trials in different settings, the contribution of RCTs from settings such as LMICs to the evidence pool would be very critical, particularly considering that these settings bear the greatest burden of maternal morbidity and mortality globally. In essence, systematic reviews and meta-analyses have been thought as a key element of evidence-based healthcare (Khan et al. 2003; Boaz et al. 2002) since reviewers examine all the available (research) evidence, summarise the findings, and give feedback to the end-users regarding their confidence in the findings (Berkman et al. 2013). Policy makers therefore, especially in LMICs settings (or countries) such as Kenya need to understand such implications to better understand a 'return-in investment' regarding health care research so that they can objectively and meaningfully drive the research agenda, and ultimately develop policies that are consistent with their settings.

8.2.4 Implications for midwifery education

This study also highlights the need for midwifery educators and/or institutions to critically examine the scope of their training curricular regarding maternal and infant care. In particular, the training of midwives (or nurse-midwives) should consider the unique differences (including health care needs) of service users such as young and/or adolescent mothers so that their graduands become better placed to assess and identify such differences and provide a client-centered care. In addition, nursing/midwifery regulatory organs such as the Nursing Council of Kenya (NCK) should take lead and develop and/or review existing care and/or policy guidelines that reflect the evidence from research and meet the current dynamics in health care. Perhaps one of the ways of achieving this is for the NCK to consider working collaboratively (or strengthen such collaborations) with teaching institutions in developing such care guidelines and policies. This would enable the adaptation of these guidelines in clinical practice, including in the nursing/midwifery education.

8.3 Conclusion

This pilot RCT explored the feasibility and acceptability of TSI among young mothers aged 12-19 in a LMIC setting (Kenya). The study findings suggest that it is feasible to recruit young mothers for a similar definitive trial in future, largely with the consideration of an older age group of young mothers (17-19). The study explored the perceptions of both the young mothers and midwives using a mixed-methods approach regarding TSI during the immediate postnatal period, including its potential effectiveness in MIC. The findings suggest that TSI appears to have an effect in enhancing maternal self-esteem and

reducing infant-related anxiety among young mothers, as well as improving their overall wellbeing. The study therefore identified a primary outcome of interest (maternal self-esteem) in which the piloted intervention had a moderate effect.

The study also highlights the social support environment available to young mothers in the study setting and the role of family support in helping young mothers to assume motherhood responsibilities. Midwives also highlighted the potential areas in which the TSI could provide a meaningful supportive care in MIC ranging from as a means of providing follow-up or continuity of care to scheduling clinical appointments and reminders. The study's contribution to knowledge and implications for practice, policy, midwifery education and research were also highlighted, including the design of a possible definitive trial.

8.4 Personal reflections

This study gave me a rich real world research experience, especially learning what can be regarded as the 'nuts and bolts' of conducting an interventional study such as an RCT which I had not imagined I could do. As a novice researcher, reflecting on how to design an experimental study, the development of an intervention, ethical issues in research, and the field practicalities, I realise how all these steps have immensely contributed to my growth and experience in research. Learning the role of keeping a reflective diary in research, the skills of conducting qualitative interviews, and the approaches to qualitative data analysis (QDA) such as FA was very rewarding. Framework analysis approach in QDA really gave sense in my world view to the commonly (sometimes loosely) used terms like 'immersion into the data' as one has to contend with (re)reading of data transcripts against the 'developed framework', while sometimes checking for 'new frames' which is no mean task! Indeed, I would not be able to confidently state this were

it not for the superb supervision and guidance from my supervisors Prof. Tina Lavender, Dr. Rebecca Smyth and Dr. Malcolm Campbell who have really seen me through this journey of academic and career growth.

Moreover, this study provided me with the opportunity to have a first-hand experience with young mothers especially over a relatively longer span of time (study duration). This helped me to realise how different you may perceive and/or understand issues related to your field as a professional (a midwife) when you interact with your clients on a 'one-off time' and when you do the same over a continuous period of time. In deed during my interviews with fellow midwives, I was struck by their desire to know what happens to their clients after discharge from the hospital, something I had not initially given a critical thought, not until when I was collecting my data. Conducting interviews among the midwives and young mothers really helped me to understand the two groups' world views about young motherhood. For one, I got to understand that as midwives (and/or healthcare providers in general) we reasonably know the problems/challenges facing our clients, but perhaps our main challenge remains lack of adequate understanding of how to address them. In my view, this challenge may be more of 'perceived difficulties' other than real, which if the right attitude and good will is put into action better outcomes can be realised.

Indeed, I would not forget the critical knowledge that the course modules have imparted in me, albeit that they are really quite demanding in terms of time and thought process. More so, learning about the Critical Appraisal and Evidence Synthesis of literature (which I think grasping it at the earliest opportunity as possible as a PhD student would be helpful), and the different 'worlds' of qualitative research really provided new dimensions of knowledge to me. I would not forget to mention the Statistics module by Malcolm, which I may loosely put it as 'Stats made easy by MC' though I certainly know it is not as easy as I say or think. It was really rewarding having learnt a bit of Statistics that enabled me run all my quantitative analyses and tried to make sense of the data output. I had never developed so much interest in learning and understanding Statistics until I had this module, including what to make of quantitative results reported in literature articles, and the likely tendency of underreporting or not reporting certain data by authors.

Lastly, as part of the PhD journey, I will always remember the moments I would sit in the PGR study hub writing my thesis only to realise at the close of the day that I only managed to write 'a half a paragraph' for fear to say a few lines. Although it was literally distressing, not until when a fellow PhD colleague laments 'but you have been thinking all that time' that you realise that you have been actually doing something! This made me to realise that doing PhD is all but about reflective thinking and writing. In deed I would not forget to mention one of the moments during my preparation for departure to Manchester (safe for a few visa hitches) when I had the opportunity to hear from a family friend who had attended my farewell at home. Having had the opportunity to study her PhD in the UK, and keenly following her speech I remember her stating that, '*It (PhD) is a lone journey, you will plan your own time and work yourself…* 'words that really have had meaning in this journey as I can also remember the occasional moments when my supervisors would say '*It is your research…* '! All said and done, I am glad to say my PhD experience at UoM has been wonderful and exciting, and yes, it is a '*Lone Journey But You'll Never Walk Alone* '!

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APPENDICES

Appendix 2.1: Critical appraisal tool for systematic reviews (CASP appraisal tool-Systematic reviews checklist)

Critical Appraisal Skills Programme
(A) Are the results of the review valid?
Screening Questions
 1. Did the review address a clearly focused question? Yes Can't tell No HINT: An issue can be 'focused' In terms of The population studied The intervention given The outcome considered
 2. Did the authors look for the right type of papers? Yes Can't tell No HINT: 'The best sort of studies' would Address the reviews question Have an appropriate study design (usually RCTs for papers evaluating interventions)
Is it worth continuing?
Detailed questions
 3. Do you think all the important, relevant Yes Can't tell No studies were included? HINT: Look for Which bibliographic databases were used Follow up from reference lists Personal contact with experts Search for unpublished as well as published studies Search for non-English language studies
4. Did the review's authors do enough to assess □Yes □Can't tell □No the quality of the included studies?
HINT: The authors need to consider the rigour of the studies they have identified. Lack of rigour may affect the studies' results. ("All that glisters is not gold" Merchant of Venice – Act II Scene 7)
 5. If the results of the review have been combined, □Yes □Can't tell □No was it reasonable to do so? HINT: Consider whether The results were similar from study to study The results of all the included studies are clearly displayed The results of the different studies are similar The reasons for any variations in results are discussed
(B) What are the results?

6. What are the overall results of the review?

HINT: Consider

- If you are clear about the review's 'bottom line' results
- What these are (numerically if appropriate)
- How were the results expressed (NNT, odds ratio etc)

7. How precise are the results?

HINT: Look at the confidence intervals, if given

(C) Will the results help locally?

8. Can the results be applied to the local population? □Yes □Can't tell □No

HINT: Consider whether

- The patients covered by the review could be
- sufficiently different to your population to cause concern
- Your local setting is likely to differ much from that of the review

9. Were all important outcomes considered? Yes Can't tell No

HINT: Consider whether

• Is there other information you would like to have seen

10. Are the benefits worth the harms and costs? Yes Can't tell No

HINT: Consider

• Even if this is not addressed by the review, what do you think?

©Critical Appraisal Skills Programme (Casper and Hogan) Systematic Review Checklist 31.05.13

			CASP	-System		view c	hecklis	t items			
Author(s)/Year	Clearly focussed question?	Right type of papers?	Relevant studies included?	Quality of papers assessed?	Combination of results reasonable?	Overall results?	Precision of results?	Results applicable to local population?	Important outcomes considered?	Benefits worth harms/costs?	Remarks/comments
Lavender et al. 2013	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Can't tell	Yes	Yes	Comprehensive search of databases and analyses Used Cochrane's tool for quality assessment Statistical analyses described in detail and justified
Sipsma et al. 2015	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Used Cochrane's tool for quality assessment Limited databases searched
Dennis CL & Kingston D. 2008	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Used Cochrane's tool for quality assessment Statistical analyses described and justified Excluded studies listed
Shaw et al. 2006	Yes	Yes	Yes	Yes	Yes	Yes	Can't tell	No	Yes	Can't tell	Used Jadad scale in quality appraisal Analyses not sufficiently described

Appendix 2.2: Critical appraisal of the systematic reviews papers

Appendix 2.3: Hawker's quality appraisal tool (checklist)

	Hawker's ch	lecklist items
1)	Abstract and Tit	tle:
	Good	Structured abstract with full information and clear title.
	Fair	Abstract with most of the information and clear title.
	Poor	Inadequate abstract.
	Very Poor	No abstract.
2)	Introduction and	d Aims:
	Good	Full but concise background to discussion/study containing up-to-date literature review and highlighting gaps in knowledge. Clear statement of aim AND objectives including research questions.
	Fair	Some background and literature review. Research questions outlined.
	Poor	Some background but no aim/ objectives/questions, OR Aims/ objectives but inadequate background.
	Very Poor	No mention of aims/objectives. No background or literature review.
3)	Methods and da	ta:
	Good	Method is appropriate and described clearly (e.g. questionnaires included).
		Clear details of the data collection and recording.
	Fair	Method appropriate, description could be better. Data described.
	Poor	Questionable whether method is appropriate. Method described inadequately
	Very Poor	No mention of method, AND/OR Method inappropriate, AND/OR
		No details of data.
4)	Sampling:	
	Good	Details (age/ race/ gender/ context) of who was studied and how they were recruited. Why this group was targeted. The sample size was justified for the study.
		Response rates shown and explained.

	Fair	Sample size justified. Most information given, but few descriptive details.
	Poor	Sampling mentioned but few descriptive details.
	Very Poor	No details of sample.
	very roor	No details of sample.
5)	Data Analysis:	
	Good	Clear description of how analysis was done. Qualitative studies: Description of
		how themes derived/ respondent validation or triangulation. Quantitative studies:
		Reasons for tests selected hypothesis driven/ numbers add up/ statistical
		significance discussed.
	Fair	Qualitative: Descriptive discussion of analysis.
		Quantitative.
	Poor	Minimal details about analysis.
	Very Poor	No discussion of analysis.
6)	Ethics and bias:	
	Good	Ethics: here necessary issues or confidentiality, sensitivity, and consent were addressed. Bias: Researcher was reflexive and/or aware of own bias.
	Fair	Lip service was paid to above (i.e., these issues were acknowledged).
	Poor	Brief mention of issues.
	Very Poor	No mention of issues.
7)	Results:	
	Good	Findings explicit, easy to understand, and in logical progression.
		Tables, if present, are explained in text. Results relate directly to aims.
		Sufficient data are presented to support findings.
	Fair	Findings mentioned but more explanation could be given.
		Data presented relate directly to results.
	Poor	Findings presented haphazardly, not explained, and do not progress logically from results
	Very Poor	Findings not mentioned or do not relate to aims.

8) Transferability /	Generalisability:
Good	Context and setting of the study is described sufficiently to allow comparison with other contexts and settings, plus high score in Question 4 (sampling)
Fair	Some context and setting described, but more needed to replicate or compare the study with the others, PLUS fair score or higher in Question 4.
Poor	Minimal description of context/setting.
Very Poor	No description of context/setting.
9) Implications and	d usefulness:
Good	Contributes something new and/ or different in terms of understanding /insight or perspective. Suggests ideas for further research. Suggests implications for policy and/ or practice.
Fair	Two of the above (state what is missing in comments).
Poor	Only one of the above.
Very Poor	None of the above.

NB: [Scoring criteria: Good=4; Fair=3; Poor=2; Very Poor=1] (Source: Hawker et al. 2002)

Author/ Year	Objective	Study population	Design	Data collection	Data analysis	Key findings	Appraisal of findings	Score
Wambach et al. 2010 USA	To determine if an education and counseling intervention provided by a lactation consultant– peer counselor team increased breastfeeding initiation and duration up to 6 months postpartum among adolescent mothers	Adolescent mothers - Primiparous 15-18 years	Prospective, non - blinded, 3-group – intervention & 2 controls N=289	Questionnair es - validated BAPT KBS BKQ	SAS v9.1.3 software Descriptive ITT analyses ANOVA Chi- square/Fisher's exact tests Kruskal-Wallis tests	Breastfeeding knowledge, prenatal intention to breastfeed, the timing of breastfeeding decision, and social and professional support were key factors predicting breastfeeding initiation (all p<0.05). Breastfeeding duration was significantly longer among those in the experimental group compared to control groups ($p < .001$)	The study employed rigorous theory-based design in implementing the intervention, with appropriate analytical measures, which reasonably adjusted for confounders Results suggest that supportive interventions aimed at promoting breastfeeding initiation and duration by adolescent mothers are potentially viable and feasible	26
Apostolaki s-Kyrus K. 2013 Ohio, USA	To identify the most influential factors on breastfeeding initiation in adolescent mothers	Adolescent mothers ≤19 years (Reference group >19 years)	Retrospective population- based cohort study	Data collection tool(s) and procedures not clearly described	Stata software; descriptive statistics - (frequencies, means); bivariate and multivariate logistic regression; chi- square tests;	All mothers with preterm births were less likely to breastfeed. Adolescent mothers were 57% less likely to breastfeed; with 44% vs 65% among the adolescents and	The stratification of the study group accounted for the differences within the adolescent group thus providing deeper understanding of salient issues e.g. breastfeeding rates were lowest (27.5%) among the younger (<15	28

Appendix 2.4: Critical appraisal of articles on young mothers' postnatal needs (Search 1 literature)

Angley et al. 2015 Connecticu t, USA	To identify the association between social support, family functioning and social capital on parenting competence, self-efficacy & satisfaction	Adolescent mothers 14- 21 years and their partners (>14 years) (n=231 couples)	Longitudinal study	Structured interviews (computer assisted self interviews - CASI)	unpaired Student t-test SPSS v18 software; Paired t-tests (continuous variables) & McNemar tests (categorical variables) and Actor-Partner Independent model analyses	adult mothers breastfeeding initiation rates, even lowest (27.5%) among <15 years adolescents Contributing factors to low breastfeeding rates among adolescent mothers included - single status; lack of medical cover and social support and socioeconomic factors Greater social support was associated with higher parenting self- efficacy and satisfaction. Higher family functioning was associated with greater parenting satisfaction; a greater partner family functioning was significantly associated with parenting satisfaction (p=0.026).	years) adolescents, compared to the older mothers (65%). The study therefore, identifies key aspects of support areas (educational and socioeconomic) that need to be addressed in adolescent pregnancy and childbirth Study attempted to measure and draw a causal relationship between parental stress and PPD using rigorous longitudinal analytic techniques The study reports that the previous trial (related to this study) had a protective effect against developing PPD but not on parental stress. Therefore, this study provides useful information regarding the temporal association between parental stress and PPD.	29
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Venkatesh et al. 2014 USA	To evaluate the relationship between	Primiparous adolescents	Secondary observational analysis of an	Questionnair es Parenting	Stata v10 and SASv9.2 software	Actor social support, Actor family functioning and partner family functioning was associated with decreased levels of depression. Lower levels of depression were significantly associated with greater parental satisfaction and self- efficacy Adolescent mothers with PPD had significantly higher	Study attempted to measure and draw a causal relationship	28
	parental stress and postpartum depression among primiparous adolescents	(median=16 years)	RCT (n=106)	Stress Index KID-SCID (DSM-IV Childhood diagnoses)	Generalised estimating equations (GEE) Sensitivity analyses	scores for total parenting stress, parental distress, parent-child dysfunction and a difficult child. Parental stress did not differ in relation to infant sex. Following sensitivity	between parental stress and PPD using rigorous longitudinal analytic techniques, unlike many cross sectional studies which measure both variables at one point in time. The study reports that the previous trial (related to this study) had a protective effect against developing PPD but not	

						analyses, total parenting stress remained a significant predictor of PPD.	on parental stress. Therefore, this study provides useful information regarding the temporal association between parental stress and PPD.	
Tucker et al. 2011 North Carolina, USA	To investigate breastfeeding practices, barriers and facilitators among adolescents mothers	Adolescent mothers ≤17 years	Mixed methods study	Quant: Self- administered questionnaire s & telephone interviews (n=389) Qual: Semi- structured interviews (n=22)	SAS 9.1.3 & SUDAAN 9 software Descriptives - Frequencies and Chi-square NViVo8	52.1% of the adolescent mothers reported having ever breastfed; 28.4% reported breastfeeding for over 4 weeks; only 16.9% having done so exclusively Health care worker support, family support and having a family member who breastfed were cited as positive influences to breastfeeding initiation, while negative breastfeeding experiences from peers discouraged teen mothers from breastfeeding. Teen mothers cited fear of pain, schooling, insufficient breast milk, difficulty in latching and personal dislike of the	Most participants interviewed (17/22) initiated breastfeeding but half had stopped breastfeeding within the first month The study highlighted the barriers/challenges experienced by teenage mothers during breastfeeding; and the role of social support as a means of helping them to overcome such challenges The study theory based (Theory of Planned Behaviour) and the mixed-methods approach, with a reasonably large sample size in the study enriched the data/rigour	26

						practice as barriers to breastfeeding		
Monteiro et al. 2014 Brazil	To characterise breastfeeding practices among adolescents and to identify their breastfeeding needs	Adolescent mothers <19 years	Mixed methods, cross sectional study 2 phases	Quant: survey data from the Second National Survey of Breastfeedin g Prevalence (NSBP) (n=229) Qual: semi- structure interview (n=10)	Quant: SPSS v10 Qual: Thematic content analysis	75% of the adolescent mothers were breastfeeding their infants at the time of the survey. Of the 144 mothers with infants <180 days, 84% were still breastfeeding (19% exclusively, 74% predominately, 49% complementary feeds & 23% had weaned). Most mothers recognised that breastfeeding is beneficial to their infants, but never practised it optimally as required. The mothers cited breastfeeding difficulties (pain, engorgement, insufficient breastfieed) as factors which prompted them to give alternative	The qualitative arm of the study highlights the needs of adolescent mothers (supportive needs) and demonstrates that knowledge of the importance of breastfeeding alone is not sufficient to promote breastfeeding among adolescent mothers. This implies that multifaceted approaches are required in order to attain such goals. The quantitative study is generally descriptive (prevalence rates) and thus causal association cannot be determined. Group differences among the adolescent mothers cannot be elicited from the study.	26

						feeds		
De Vito 2007 New Jersey, USA	To investigate factors that may contribute to self- perceptions of parenting on adolescent mothers during 4-6 weeks postpartum	Adolescent mothers 13-19 years	Cross sectional (Descriptive correlational) N=126	Questionnair es Demographic form NSSQ WPL-R Tools tested for reliability	Descriptives Pearson Product Moment analysis & ANOVA	Most of the adolescent mothers (97%) were single; 68% were still living with their families and 3% living with their husbands. Social support received by the adolescent mothers had influence on self- perception of parenting. The late adolescent mothers (18-19) had more positive perception of parenting compared to the younger adolescent mothers. There was no significant relationship between the overall levels of social support and self-perception of parenting	This study demonstrates that age is a key factor influencing self- perceptions of parenting among adolescent mothers. This argument can reasonably be extended to other attributes such as self- efficacy and competence. Most adolescent mothers in this study were still living with their families (only 3% living with their husbands), thus it would be more informative to ascertain adolescent mothers' self-perceptions of social support in the context of couple relationships using a larger sample or longitudinal study	28
De Vito 2010 New Jersey, USA	To explore first time adolescent mothers' meaning and	Adolescent mothers <19 years	Qual. design (Secondary analysis of narrative comments)	Computer aided content analysis Expert opinions to	Content analysis	Three thematic areas were highlighted: <u>1)</u> <u>Being caught</u> <u>between two worlds;</u> <u>2) Feeling alone and</u>	Findings demonstrate adolescent mothers' unpreparedness in transiting to parenting role and the self-conflict	27

	experience of parenting 4-6 weeks postpartum			validate themes		desperate); 3) If Iknew then what Iknow nowSocial supportreceived by theadolescent mothershad influence on self-perception ofparenting	between former self (with freedom) and current status as a mother The study provides insights into what adolescent mothers make up of their transition into motherhood.	
Wahn, E. H. & Nissen, E. 2008 Sweden	To describe and compare teenage mothers giving birth in a hospital with adult mothers on sociodemograp hic characteristics, perception of health and social support	Teenage mothers (15-19 years) and adult mothers (25-29 years)	Descriptive comparative study N=97	Validated tools used MSSS SES EPDS	SPSS v13 Descriptive statistics – freq., means. Chi-square, Fisher's exact tests	73% of the teenage mothers compared to 14% of adult mothers reported pregnancy not being planned Only 17% of the teenage mothers had used contraceptives. The first antenatal booking (ANC) was between 5-36 weeks among the teenage mothers compared to 6-16 weeks for the adult mothers; 66% of the teenage mothers having their first ANC visit less than 12 weeks compared to 89% of the adult mothers (p<0.001). Teenage mothers	This study demonstrates that teenage mothers are more vulnerable socially and economically, hence more prone to physical and psychological abuse. The study also highlights that the teenage mothers were at a greater psychosocial risk (which may predisposes them to depression), and were more inclined to risky behaviours than adult mothers, which puts them at greater odds in their own health wellbeing and that of their infants as well as coping with parenthood. Thus, there is need to devise specially designed interventions/measures to	25

						smoked more often than adult mothers (56% vs 24%, OR 4.1, CI 2.1-8.1); were more often involved in binge drinking than the adult group (68% vs 37%, OR 3.7, CI 1.9-7.1) Teenage mothers had lower self-esteem than adult mothers (68% vs 83% reported high self-esteem, OR 2.3, CI 1.1-4.8); had more depressive symptoms (mean EPDS score of 8 vs 6, p=0.021) with 32% vs 16% scoring \geq 10 on the EPDS (OR 2.4, CI 1.1-5.0)	meet their unique needs.	
Bailey et al. 2008 UK	To discover psychosocial factors influencing breastfeeding duration at different age groups of mothers	Postnatal mothers (16-24 years) and (25-40 years)	Longitudinal study in 3 phases N=145	Validated tools used S/demograph ics BAS SES GSES BSES-SF PES BSS	Analytic methods not described	There was low breastfeeding self- efficacy, self-esteem and general self- efficacy among young mothers compared to the older mothers. Parenting self-efficacy (PES & BSES) was	This study highlights the psychological factors that influence the duration of breastfeeding (general self-efficacy and breastfeeding self- efficacy) and the important role of level of education, which are even more critical among young mothers. Young mothers' attitudes,	24

						strongly correlated with breastfeeding.	self-esteem, general self- efficacy and postnatal self-efficacy were lower than in older mothers. This implies that they were more likely not to effectively breastfeed and for longer duration as expected.	
Atuyambe et al. 2008 Uganda	To compare the health seeking practices of first-time adolescent and adult mothers during pregnancy and early motherhood	Adolescent (13-19 years) and adult (20-29 years) mothers	Cross sectional design N=762 [442; 320]	Structured questionnaire with a few open-ended questions	Stata v8 and Epi data OR, CIs	Adolescent mothers were 1.5 times more likely to attend less than 4 ANC visits compared to the adult mothers (OR=1.52, CI 1.12-2.07). Adolescent mothers were more likely to delay initiating breastfeeding (OR=1.48, CI 1.00- 2.17); were less likely to seek subsequent immunisation doses (2 nd and 3 rd doses) compared to adult mothers; and were more likely to experience violence by parents and being sent away from school/home,	This study highlights the dilemma faced by the adolescents following pregnancy, notably the stigma from the community and violence from parents, yet at this period, a pregnant woman requires adequate support to go through pregnancy and childbirth successfully. With the underlying barriers such as low level of education, socio-economic hardships and inadequate physical and psychological preparation for childbirth/parenting, many adolescent mothers would therefore be ill-	27

						rejection by partner, and stigmatisation in the community.	prepared for maternal-role transition. Consequently, this poses a greater risk to their own health and that of their infants.	
Yako, E. 2007 Lesotho	To compare perceived stress in general, stress due to pregnancy, and postpartum complications between unmarried and married adolescent first-time mothers	Adolescents (15-19 years)	Cross sectional comparative and descriptive design 3 groups N=64 in each group (married, unmarried & non-pregnant adolescents)	Validated tools DHS FOPQ Demographic form Postpartum Complication checklist Infant form	SPSS v9 ANOVA T-test Chi-square Descriptives – infant characteristics	Both groups of adolescent mothers had higher levels of perceived stress compared to the non- pregnant adolescents (F (2,189) = 15.32, p<0.001) Adolescent mothers had more complications involving the breasts and nipples - engorged breasts (p=0.01) and cracked nipples (p=0.04).	The study provides baseline information on perceived stress levels among adolescent mothers in relation to their marital status, and the health outcomes of their infants. However, further research is required to determine the causes of stress among the adolescent mothers and to clearly analyse the relationship between confounding factors that contribute to stress and to measure health outcomes.	24
Duggan, R. & Adejumo O. 2012 South Africa	To explore adolescent maternity clients' (AMCs) perceptions of maternity care; To identify	Adolescents 12-19 years	Qualitative design N=18 (Grounded theory)	Individual interviews & 3 FGDs [n=4,4,5]	GT approach used – concurrent collection and analysis of data until saturation Memoing and	The study presents 3 categories of adolescent mothers' perceived needs/concerns: <i>Adolescent maternity</i> <i>clients (AMCs)</i> -	The study provides insights into what AMCs' needs are and their perspectives of what care they expect from the health care system. The study, therefore highlights	26

Cronin, C.	important characteristics of adolescent friendly maternity services	First-time	Qual. design	Individual	development of categories	health care provider (HCP) interactions – caring and non- judgemental attitudes by HCPs; health care system – long waiting time, uncomfortable settings, external support during birth/birth companion; and health education – lack of prior experience/assessment of educational needs. AMCs need continuous support throughout childbirth and maternity care. HCPs should demonstrate positive, non-judgemental attitudes toward adolescent mothers/ AMCs and supportive care	the pitfalls of the existing health care system in S/Africa (and in many parts of the world, particularly in low income settings) regarding adolescent reproductive health (ARH). The qualitative design/approach used provided a lens through which governments or health care systems can critically evaluate ARH programmes in order to meet and match their expectations. For instance, health education provided to AMCs should be holistic (address the physical and psychological needs) that will prepare them for parenthood.	25
2003 Ireland,	needs, perceptions	mothers <20 years	N=13	interviews & 3 FGDs	analysis Findings	were unprepared for their baby and	needs of first time mothers, most of whom	23

UK	and experience	 (n=6-9)	validated with	motherhood, and	are young and are not	
0IX	of first time	(11-0))	participants	needed assistance in	adequately prepared for	
	mothers in the		through an FGD	assuming	childbirth and the	
	postnatal		session	motherhood.	subsequent motherhood.	
	period		50551011	Mothers perceived	Although the health care	
	period			nurses/midwives to be	systems provide support	
				supportive during and	to women during	
				after birth, and that	pregnancy through	
				they provided	motherhood, such efforts	
				postnatal education on	have only been based on	
				caring of the baby	generalised care for all	
				after birth.	women/mothers (mostly	
				Most of the mothers	adult women).	
				felt pressurised to	Consequently, young	
				breastfeed by	mothers including	
				midwives. However,	adolescent mothers,	
				all of them bottle-fed,	remain disadvantaged due	
				despite the midwives'	to limited information and	
				efforts in promoting	experience of	
				breastfeeding.	childbirth/motherhood.	
				Mothers cited	ennuon ui/ mothernood.	
				instances of		
				conflicting advice		
				from midwives.		
				Support was provided		
				by diverse groups		
				including mother,		
				father, partner,		
				parents, extended		
				family, friends and		
				health professionals,		
				up to 9 months post-		
				birth; however, there		
				were incidences		
			L	were incluences		

Nesbitt et	To examine	Adolescent	Descriptive	Semi-	NVivo 8	Most mothers'	The study highlights the	30
al. 2012	the facilitating	mothers	qualitative	structured	Content analysis	decision to breastfeed	critical aspects pertaining	
Canada	influences and	15-19years	N=16	face-face	·	was made during	decision making on	
	barriers to	2		interviews +		prenatal period, and	breastfeeding among	
	initiating and			field notes		was influenced by	adolescent mothers.	
	continuing			Demographic		partner and family,	Although many studies	
	breastfeeding			questionnaire		and mainly motivated	have reported the positive	
	by adolescent			•		by knowledge of	influence of peer and	
	mothers					benefits of breastmilk	family support, this study	
						to their infants.	also identified the	
						Several factors were	negative influence of such	
						identified that	informal groups,	
						influence maternal	particularly based on their	
						decision to continue	own negative experiences	
						breastfeeding -	with breastfeeding.	
						impact of	Conflicting information	
						breastfeeding on	from HCPs also	
						intimate relationship;	contribute to	
						availability of social	young/adolescent	
						support; physical	mothers' challenges in	
						demands of	breastfeeding, hence	
						breastfeeding; and	HCPs should always	
						mother's perceived	provide consistent and	
						sense of comfort in	evidence-based	
						breastfeeding.	information	
						Mothers cited lack of		
						knowledge about		
						breastfeeding norms		
						and practices, and		
						incidences where		
						conflicting		
						information was		
						provided by		
						nurses/midwives.		

Smith, D.M. & Roberts, R. 2009 UK (England)	To investigate young parents' (mothers & fathers) antenatal and postnatal needs at the individual level; to explore interaction between psychological, social, economic and health factors	Young parents <22years (age ranged 15-25, mean=18)	Mixed methods, cross sectional study Quant: (n=47) Qual: 2 FGDs (n=10; 5,5)	Quant: Questionnair e Rosenberg's SES Qual: 2 FGDs (antenatal; postnatal) semi- structured interviews	Quant: Fisher's exact test Qual: Thematic analysis	Attendance to ANC classes was associated with high self-esteem (Fisher's test, p<0.001); those who did not attend (n=4) reported not having enough confidence and being scared to attend. 37% reported having been offered ANC support; 38.9% (n=14) reported receiving postnatal support, with 22 having not attended postnatal classes Relatives and friends were singled as useful sources of postnatal support, while professionals were thought to be less helpful; midwives were reportedly perceived as judgemental, while doctors were reportedly having no time for the young	The study highlights the antenatal and postnatal experiences of young parents. The inclusion of the male partner, who are often neglected in the healthcare system, provides rich information that might be useful in designing and implementing targeted care to young parents. Self-esteem, age and gender were also highlighted as influential factors on young parents attendance to support services – participants were uncomfortable attending with older women	27

						parents.		
Spear, H.J. 2006, USA	To examine breastfeeding experiences and related behaviours of adolescent mothers after hospital discharge	Adolescent mothers 14-19 years (mean age=17.7)	Cross sectional descriptive survey Mixed method N=53	Telephone interviews Questionnair e (10Qns) and Demographic s Qual = open- ended qns	SPSS v12 descriptives	3.8% (n=2) had attended prenatal classes. 94.3% intended to exclusively breastfeed but 69.8% did so; 30.2% reported supplementing due to: insufficient breastmilk, babies nursed too frequently or were still hungry after breastfeeding. Majority started weaning at 4-5 months. Mothers with high school level of education breastfed for an average 3.75 months, while those with less than high school education breastfed for an average 1.08 months	The study highlights the challenges faced by adolescent mothers regarding breastfeeding. With their limited attendance of prenatal classes, and low level of education, many of them consequently lack sufficient information that would enhance their decision-making and skills on effective breastfeeding	27
Sipsma et al. 2013 Connecticu t, USA	To examine breastfeeding behaviours among a longitudinal cohort of adolescents	Adolescent couples (14-21 years)	Longitudinal cohort study N=296	Questionnair es S/demograph ics CES-D (depression) Decision-	IBM SPSS Statistics v19 Descriptives – frequencies, means T-tests Chi-square	 86% had stopped breastfeeding by 6 months, and only breastfed for approx. 5 week. 70% reported having no difficulty stopping 	This study highlights the independent factors associated with breastfeeding among young women e.g. predictor factors such as breastfeeding difficulty,	29

	(14-21) and their male partners			Making scale MOSS-S (support) Automated computerised self- interview	Multivariate logistic regression Pearson's correlations & ANOVA Cox prop. Hazard ratios	breastfeeding, 85% reporting that their babies had no difficulty stopping to breastfeed. Reasons given for stopping to breastfeed— the baby did not like and that it hurt. Breastfeeding initiators were more likely to have intended to breastfeed (p<0.01), to have partners who supported breastfeeding (p<0.01), and to have used alcohol before pregnancy (p<0.05). Greater social support was associated with lower odds of breastfeeding (OR 0.94, 95% CI 0.89- 1.00).	maternal obesity and nutritional supplement programmes, all of which reduced exclusivity of breastfeeding, including labour and birth complications. In addition, the study presents intimate partner violence as a key finding, negatively associated with breastfeeding duration.	
Grassley 2010	To define aspects of social support that adolescents need from nurses when	Adolescent mothers	Literature review CINAHL MEDLINE databases (2000-2009)	18 studies were included in the review	N/A	The study highlights 5 areas of support for adolescent mothers – informational; instrumental; emotional; appraisal;	This literature review provides thematic areas of supportive care that adolescent mothers may benefit from Health care systems (esp.	25

	initiating breastfeeding in early postpartum.					 and network support as framework for defining supportive health care provider behaviours. The study highlights the need to integrate the five forms of support to enhance positive experiences in breastfeeding among the adolescent mothers by HCPs 	nurses and midwives) should therefore strive to integrate these areas in their provision of care The findings are, however, limited as only articles from two databases were searched and appraised	
Howard S.J. & Sater, J. 1985 Southern California, USA	To identify adolescent mothers perceived information needs in caring for themselves and their infants during early postpartum period	First-time adolescent mothers ≤18 years	Cross sectional descriptive survey N=66	Questionnair e and demographic s	Descriptives Analysis not adequately described	 Mothers expressed the need to learn both physiological and medical needs of the infant during early postpartum - needed to know about parenting to improve their skills and status. The infant medical concerns raised included – skin rash, cold, colic and constipation, jaundice, eye discharge and abdominal hernias. 84% expressed the 	Although the study's methodological rigour is not adequate, and the fact that is was conducted over 2 decades ago, it highlights some of the concerns new and/or young mothers still have today, particularly regarding the care of their infant and the possible medical problems they may encounter.	24

		need for information on how to be a good parent; and 91% on how to make the baby	
		happy	

Appendix 2.5: Quality assessment table for search 1 literature articles

				Quality	assessi	ment - H	lawker's	s checkli	ist: Scor	e range	1-4 for e	ach item	
Author/Year	Study population	Sample size	Design	Abstract and Title	Aims	Methods & data	Sampling	Data analysis	Ethics	Findings/Results	Transferability/Generalisability	Implications and usefulness	Total
Wambach et al. 2010, USA	Adolescent mothers - Primiparous 15-18 years	(Exp=128) (C1=128)	RCT (prospective, 3-group)	3	3	2	. 3	3	3	4	2	3	26
Apostolakis-Kyrus K. 2013 Ohio, USA	Adolescent mothers ≤19 years (Reference group >19 years)	(C2=134) N=288,142 [≤19 years n=30,402] [>19 years	Retrospective population-based cohort study	3	3	3	3	3	3	4	3	3	28
Angley et al. 2015 Connecticut, USA	Adolescent mothers (14-21 & their partners (>14 years)	n=257,840] n=231 couples	Longitudinal study	3	3	3	4	4	3	4	3	2	29
Bailey et al. 2008 UK	Postnatal mothers (16-24) & (25-40) years	N=145	Longitudinal study - 3 phases	3	3	3	3	1	3	3	3	2	24
Sipsma et al. 2013 Connecticut, USA	Adolescent couples (14-21 years)	N=296	Longitudinal cohort study	3	3	3	3	4	3	4	3	3	29
Wahn, E. H. & Nissen, E. 2008 Sweden	Teenage (15-19) & adult mothers (25-29) years	N=97	Descriptive comparative study	3	3	3	3	3	3	3	2	2	25
Atuyambe et al. 2008 Uganda	Adolescent (13-19) & adult (20-29) mothers	N=762 [442; 320]	Cross sectional design	3	3	3	3	3	4	4	2	2	27
Yako, E. 2007 Lesotho	Adolescents (15-19 years)	N=192 [64 in each group]	Cross sectional comparative	3	3	3	3	2	3	3	2	2	24
Venkatesh et al. 2014 USA	Primiparous adolescents	N=106	Secondary analysis of an RCT	3	3	3	3	3	3	4	3	3	28
De Vito 2007 New Jersey, USA	Adolescent mothers 13-19 years	N=126	Cross sectional (correlational)	3	3	3	3	3	3	3	3	3	28
Howard S.J. & Sater, J. 1985 Southern California, USA	First-time adolescent mothers ≤18 years	N=66	Cross sectional descriptive survey	2	. 3	3	2	2	3	3	3	3	24
Tucker et al. 2011 North Carolina, USA	Adolescent mothers ≤17 years	Quant - N=389 Qual n=20	Mixed methods study	3	3	3	3	3	2	3	3	3	26
Monteiro et al. 2014 Brazil	Adolescent mothers <19 years	(n=229) Qualitative (n=10)	Mixed methods, cross sectional -2 phases	3	3	3	3	2	3	3	3	3	26
Smith, D.M. & Roberts, R. 2009 UK (England)	Young parents <22years	Quant: (n=47) Qual: 2 FGDs (n=10; 5,5)	Mixed methods, cross sectional	3	4	3	3	2	3	3	3	3	27
Spear, H.J. 2006, US	Adolescent mothers 14-19 years	N=53	Mixed methods Cross sectional	3	3	3	3	3	3	3	3	3	27
De Vito 2010 New Jersey, USA	Adolescent mothers <19 years	N=126	Qual. design (Secondary	2	3	3	3	3	3	4	3	3	27
Duggan, R. & Adejumo O. 2012 South Africa	Adolescents 12-19 years	N=18	analysis) Qualitative design	3	3	3	3	3	3	3	3	2	26
Cronin, C. 2003 Ireland, UK	First-time mothers <20 years	N=13	Qual. design	3	4	3	2	3	3	3	2	2	25
Nesbitt et al. 2012 Canada	Adolescent mothers	N=16	Descriptive qualitative	4	4	3	4	4	2	3	3	3	30
Grassley 2010	Adolescent mothers	18 articles CINAHL MEDLINE databases	Literature review	3	3	2	2	3	3	3	3	3	25

Author/ Year	Objective	Study population	Design	Intervention	Data collection	Data analysis	Key findings	Appraisal of findings	Score
Bunik et al. 2010 Denver, Colorado (US)	To evaluate effectiveness of telephone breastfeeding support	Primiparous low income women (Pred.Latina) >18years	RCT N=341 [I=161] [C=180]	Daily telephone calls for 2 weeks postpartum	Breastfeeding Self efficacy tool Maternal satisfaction (likert scale) Focused telephone interviews (Qual.)	Descriptive statistics ITT analysis	Intervention did not increase breastfeeding duration or exclusivity (no significant differences), but reduced incidence of infant sickness in first month postpartum (25% vs 36%, p=0.05) Qualitative data - suggest that the women received little prenatal information on breastfeeding; mothers appreciated the intervention (satisfaction/acceptabil ity)	The findings suggest little effect of TSI on breastfeeding duration or exclusivity; however, it appears to improved infant outcomes (perhaps clinically significant). The acceptability of the intervention is informative of future trials.	26
Hannan, J. 2013 South Florida (USA)	To examine the effects of a low cost APN telephone intervention for 2 months postpartum in low	Primiparous mothers >18 years	RCT (2-arm) N=139 (I-70) (C-69)	APN follow up telephone calls up to week 8 post- discharge	Validated tools: Perceived stress scale Social support (MSPSS) Perceived maternal physical health	Descriptive statistics & two-sample t-tests	No baseline differences between groups; mean age=24.1 years; Range=18-36 years Intervention group had positive health outcomes (on all measures) and lower	The study suggests TSI improves maternal and infant health outcomes postnatal; the intervention is reportedly cost- effective, safe and easy to use across	25

Appendix 2.6: Critical appraisal of articles on TSI (Search 2 literature)

	income first time mothers						cost charges compared to control. Study proposes the use of mobile technology including cell phones and texting in future studies	all geographical boundaries. Having been carried out among low income mothers, the study may therefore be feasible in low income settings; however, the sample size was relatively small to enhance generalisability	
Di Meglio et al. 2009 US	To assess the effect of peer breastfeeding support on breastfeeding duration among adolescents	Adolescents <20years	RCT (2-arm) N=78 (I-38) (C-40)	Peer telephone contact 2,4,7 days then 2,3,4, 5 weeks	Standardised closed-ended questionnaires By telephone interviews (RA)	SAS software ITT analyses Unpaired t- tests, Fisher's test Log rank test RR/Hazard ratios	Peer telephone support did not demonstrate a significant effect on 'any breastfeeding' duration but seemed to have an effect of prolonging 'exclusive breastfeeding' The adolescent mothers seemed to be unresponsive to telephone contact by peers The study also reported a significant loss of peers, hence future studies need to consider this aspect when designing similar interventions	The study highlights the adolescent mothers' characteristics towards supportive health interventions (responsiveness), hence designing of health programmes targeting such a population. The minimal effect of TSI on breastfeeding suggests need for further research to explore underlying factors Methodological rigour was	26

								demonstrated in the study, hence biases are minimal	
Pugh et al. 2010 Maryland, US	To determine the effect of breastfeeding support team on breastfeeding outcomes during the first 24weeks postpartum	Postpartum mothers Low income (Age-non- specific)	RCT (2-arm) N=328 (I-168) (C-160)	Hospital visit + home visits + telephone call up to 24 weeks postpartum	No specific tools reported	Descriptive statistics ANOVA Bivariate analysis Multiple logistic regression	No significant baseline differences between groups Primary outcome described – to increase breastfeeding rates at 6, 12 and 24 weeks postpartum Study reports that most infants were fed with formula before enrolment, thus this provides a likely reason why exclusive breastfeeding was not considered Intervention group was more likely to be breastfeeding at 6weeks than control (p<0.05); and at 12 & 24 weeks (p>0.05) Participation rate=70.2%	The results suggest that TSI promotes the duration of breastfeeding during the immediate postpartum period, and thereafter although minimally. However, this study was conducted in a context of supplemental feeding, hence may not reflect an actual measure of the interventional effect. Moreover, this was a multiple intervention study, hence confounding effects of each aspect may not be deduced. The study, however, contributes useful information regarding breastfeeding and	26

								suggests that intensive early interventions can be effective.	
Pugh et al. 2002 US	To evaluate a community health nurse/peer counsellor intervention on breastfeeding duration and its cost- effectiveness	Postpartum mothers Low income (mean age = 20.9 years)	RCT (2-arm) N=41 (I-?) (C-?)	Hospital visit + home visits + telephone call up to 6 months postpartum	No specific tools reported ? validity/ reliability	Fairly reported	Primary outcomes reported—to increase breastfeeding duration; cost effectiveness of intervention Women in the intervention group breastfed longer than usual care group; infants in intervention group had fewer sick visits and less use of medications than infants in usual care group. The study reports of the potential cost- effectiveness of the intervention	The results suggest TSI may be cost effective measure in promoting maternal and infant health outcomes especially breastfeeding. However, the study does not explicitly describe methodological procedures e.g. randomisation, group assignment, blinding, including analyses thus it may be concluded that the risk of bias were more likely	23
Giallo et al. 2014 Australia	To assess the efficacy of a psychoeducat ional intervention (Wide Awake Parenting) to reduce	Postpartum mothers >18 years	RCT (3-arm) N=202 (I1-63) (I2-67) (C - 72)	Peer telephone, Self – Directed Written, Waitlist call up to 4 months postpartum	FAS FSS DASS-21 BSCS HSCBS Programme satisfaction Treatment adherence	Descriptive & ITT analyses Cost effectiveness analyses	Outcomes measures are fairly described: primary- postpartum fatigue; secondary – satisfaction, depression, anxiety, self-care belief Mothers in TSI and self-directed written	The 3-arm approach is commendable as it allows assessment of effectiveness of singular aspects of multiple interventions. However, the	26

	symptoms of postnatal fatigue						groups reported significantly higher self-efficacy and engagement in health and self-care behaviours than mothers in waitlist control group Participants in both interventions were satisfied with the program (TSI group rating items tested higher than the self-	sample size is small to permit generalisability and to measure and compare variables adequately. The findings, however, suggest a positive effect of TSI in self-care behaviours among mothers. Methodologically, the study was not	
							written group) Participants in TSI and self-directed written groups reported a reduction in perceived barriers to engage in health behaviours	explicit about recruitment, randomisation, hence more inherent with (performance and detection) biases. Age characteristics are also not described/omitted.	
Dennis et al. 2002 Toronto, Canada	To evaluate the effect of peer support on breastfeeding duration among first time breastfeeding mothers	Primiparous women ≥16 years	RCT (2-arm) N=252 (I-126) (C-126)	Peer telephone call up to 12 weeks postpartum	Maternal Breastfeeding Evaluation scale Likert tool – peer perception	Descriptive and ITT analyses	Outcome measures were explicitly described: primary outcome – self reported breastfeeding; Secondary – maternal satisfaction with breastfeeding, perceptions of peer support.	The findings suggest that TSI has a significant effect on breastfeeding (duration and exclusivity). Methodological rigour is demonstrated in the	27

							More mothers in peer support group were breastfeeding at 3 months (p=0.01) and all other follow up periods (4, 8, 12 weeks) than those on control group Intervention significantly predicted breastfeeding at 4 weeks, with mothers in intervention group being 2.5 times more likely to continue breastfeeding at all follow up periods More mothers in the intervention group were exclusively breastfeeding at 4 weeks (p=0.03) and at 12weeks (p=0.01).	study (randomisation, blinding and rigorous statistical analyses), hence enhancing the validity/reliability of the results (less biases, including minimal attrition rates).	
Dennis et al.2009 Ontario, Canada	To evaluate the effectiveness of telephone based peer support in the prevention of postnatal depression	Postpartum women (High risk of PND) >18 years	RCT multisite study (2-arm) N=701 (I-293) (C-293)	Peer telephone call up to 24 weeks postpartum	Validated tools used: Questionnaires EPDS Several tools for secondary outcomes Telephone interviews	SAS software Descriptive and ITT analyses	Outcomes measures are explicitly described (Primary outcome – postnatal depression; Secondary – anxiety, loneliness, health service utilisation, cost of care, maternal satisfaction) Women who received	The study findings suggest that peer telephone support is highly acceptable intervention, with demonstrable effect in reducing the risk of developing PND after birth. The follow up period for this	28

							intervention had less risk (14%) of developing PND than those in control group (25%) at 12 weeks Majority of the women were satisfied with the intervention (81%) There were no stat. significant differences for the other outcome measures	study was reasonably long enough to assess for the effect of TSI postpartum. Overall, methodological rigour is demonstrated in the study e.g. randomisation, blinding and rigorous statistical analyses, hence it can be concluded that the study overcame potential biases (selection, performance, attrition and detection biases)	
Tahir & Al-Sadat 2013 Kuala - Lumpur, Malaysia	To study the effectiveness of telephone lactation counselling on breastfeeding practices	Postpartum mothers >18 years	RCT (2-arm) N=304 (I-152) (C-152)	Telephone call up to 6 months postpartum	Adapted tools from previous studies (Questionnaire s) Pre-tested	SPSS software Descriptive (bivariate, multivariate)	Outcome measures explicitly described (Primary outcome – exclusive breastfeeding (EBF). Postnatal telephone- based lactation support was only effective in promoting EBF rates at the first month postpartum	The results suggest that TSI may only be effective in promoting EBF during the early postnatal period. The study proposes holistic policies on breastfeeding to be incorporated in the existing	28

							Reasons reported for stopping breastfeeding by mothers - lack of breastmilk and the need to return to work Intervention analysis – intervention was well received at the beginning but response declines progressively; average duration of calls per participant = 58.4 minutes	interventions including telephone counselling e.g. maternity leave up to 6 months	
Osman et al. 2014 Beirut, Lebanon	To assess the impact of 2 simple and flexible interventions on reducing postpartum perceived stress among first time mothers	All primiparous mothers	RCT (4-arm) N=452 (I1-127) (I2-121) (I3-101) (C-103)	Postpartum support film & Telephone hotline service call up to 12 weeks postpartum	validated tools were used (PSS-10) and translated to local language	SPSS v 16 software Descriptive analyses (bivariate, multivariate) ITT analyses (impact)	Outcomes measures explicitly described (Primary outcome – perceived stress; Secondary – maternal satisfaction with breastfeeding, perceptions of peer support) There was a significant reduction in stress levels among women in the intervention groups than in control. Study noted a high prevalence of stress during postpartum period. Attrition rate =18%. The study used an algorithm to address	The findings of the study demonstrate that parenting obligations during postpartum period pose a high risk of stress, which often predisposes to PND. However, this study revealed that TSI seems to be a useful interventional measure against stress related to childbirth. The multi-site nature of the study, with relatively large sample size also enhances the	28

						mothers' concerns by one support person - this potentially standardises the interventional measure and thus reduce intervention bias.	generalisability of the results. However, the use of music CD as a reference group is debatable as it may be a unique intervention in itself.	
Bangure et al. 2015 Zimbabwe	To measure the effectiveness of using short message services on immunizatio n coverage in Kadoma urban	Woman or care giver >18years	RCT 2-arms N=304 I=152 C=152	SMS reminders 6,10, 14 wks PP	Epi Info7	Outcomes measures explicitly described (Primary outcome – receipt of scheduled vaccinations at 6, 10, 14 weeks; Secondary – delay in immunisation appointment; age of infant when immunised; costs; willingness to receive SMS). At 6, 10 & 14 weeks, the immunization coverage was 97% vs 82%, 96% vs 80%, 95% vs 75% in the intervention and control groups respectively (p<0.001). About 15% of the children immunised at 6 weeks in the intervention group was	The findings demonstrate that telephone support (SMS reminders) is positively associated with infant immunisation prevalence and is widely acceptable and cost effective. Health care systems esp. in LMICs settings, may therefore consider adopting its use to scale up such health programmes, including MIC. The findings, however, may not be generalisable to other settings due to the context of the	25

							attributed to SMS reminders. The respondents who received SMS were 1.2 times and 1.3 times more likely to have their children immunised at 10 and 14 weeks respectively than those in non- intervention group. The use of SMS was associated with no immunisation delay (respondents who received SMS were 89%, 81% and 75% less likely to delay at 6, 10 and 14 weeks respectively than those in non-intervention group) All the respondents were willing to receive SMS reminders and perceived them to be beneficial.	study (largely single ethnic community).	
Gallegos et al. 2014 Australia	To test if an automated mobile phone text messaging intervention,	Postpartum mothers >18 years	A non- concurre nt compara tive trial (2-arm)	Telephone text message a week up to 6 months	Questionnaires Pre-tested	SPSS v21 software Descriptive Chi-square T-tests ANCOVA	Outcome measures explicitly described (Primary outcome – EBF; other measures - social support, accountability, self-	The study results reveal the potential effectiveness of TSI (text messaging) for postnatal mothers,	27

deliver one text ma a week could increas "any" breastf rates a improv breastf self-eff and co	e eeding nd eeeding icacy	N=234 (I-120) (C-114)	postpartum		Hierarchical regression	efficacy, active coping, emotions- focussed coping, process evaluation). EBF rates decreased by 6% and 14% in intervention comparison groups respectively. Mothers in the intervention group were significantly more likely to become problem focussed ($p = 0.001$) and to seek social support ($p = 0.003$); and less likely to blame self ($p = 0.003$); and less likely to blame self ($p = 0.003$), resort to wishful thinking ($p = 0.004$) or undertake avoidance compared to the comparison group ($p = 0.001$). The intervention group showed a significant increase in active coping and increases in perceived social support compared to the comparison group ($p = 0.001$).	especially in the promotion of breastfeeding. Besides support, the study also assessed the potential effect of the intervention on perceived coping among the mothers and the results suggested positive outcomes. Overall, the study is informative for future trials targeting postnatal care interventions	
Dennis, C- L., 2010 matern		Cross- sectiona	N/A	Validated tool PSEI + open-	Descriptive analyses and		The study highlights mothers'	28

Canada	perceptions of peer support received while participating in a trial	>18 years	l survey *RCT N=701 [n=293 per arm]		ended questions (qualitative) [measures – at 12 weeks postpartum]	Spearman's correlation Content analysis (qualitative data)	an RCT evaluating the effect of peer support in the prevention of PPD. Most mothers evaluated the relationship quality with their peer volunteers positively; most thought the peer support programme was beneficial ((stress and coping, social integration, and social construction); 80.5% (n = 161) of mothers agreed or strongly agreed that	perceptions of telephone-based peer support as a preventative strategy for PPD. The study proposes the need to design such interventions to allow for adaptive training to peer support persons to enhance the provision of appraisal support; and improved matching of peer support persons.	
							they were satisfied with their experience and 83.1% (n = 166) would recommend such support to a friend		
Dennis, C- L., 2002 Canada	To describe maternal and peer volunteer perceptions of their experience while participating in a	Primiparous breastfeeding mothers ≥16 years	Cross- sectiona l survey *RCT N=252 [126 per arm] 30 peer voluntee rs	N/A	Activity logs- PVAL Questionnaires – PPSQ; PVEQ Telephone interviews	Descriptive analyses and Spearman's correlation Content analysis – qual. data	This was a secondary analysis of data from an RCT evaluating the effect of telephone- based peer support in breastfeeding among primiparous women. Most of the 130 participants who received the peer	The study highlights maternal and peer volunteer perceptions of telephone support intervention in breastfeeding. Maternal perspectives reveal that they desired an	26

	breastfeeding peer support trial						support intervention perceived their experience positively 85% of mothers (n =110) stated they would have a peer volunteer again; 18 mothers would have liked their peer volunteers to telephone 'more frequently' and all (n=130) thought that every new breastfeeding mother should receive peer support.	actual supportive care. The study also reveals that peer volunteers need support, especially informational/traini ng support, and the need to share their experiences among themselves in order to provide effective maternal support.	
Hamade et al. 2013 Beirut, Lebanon	To assess the prevalence of breastfeeding in Beirut and to determine the factors that impact on breastfeeding behaviour.	All primiparous mothers	Longitu dinal study *RCT N=751	N/A	Validated tools used: PSS-10 EPDS SSTAI	SPSS v 16 software Descriptive analyses bivariate, multivariate multiple logistic regression VIF	This was a secondary analysis of data from an RCT assessing the impact of 24 hour telephone hotline and postpartum support film on postpartum stress among first time mothers. The prevalence of stress, depression and anxiety was high (50%, 33.6%. 47.7% respectively). 87.1% intended to breastfeed; 67%	The study highlights the independent factors influencing EBF (in Lebanon urban community) - age, mode of birth, employment status, income, infant health status, gestation age, intention to breastfeed and source of support. HCPs thus need to assess these factors	28

							breastfed at 8-12 weeks postpartum, 27.4% exclusively, 39.6% mixed feeding, and 33% formula fed. 41.2% of mothers20- 24 years exclusively breastfed compared to 30.4% of young mothers (p=0.003).	prenatally and during early postpartum to inform their postnatal interventions aimed at enhancing EBF, especially among young and/or first time mothers who often lack adequate information and previous experience in breastfeeding.	
Osman et al. 2010 Beirut, Lebanon	To test the feasibility of using telephone as an intervention in an RCT, and to test the use of algorithm to address parental concerns through telephone hotline	All primiparous mothers	Descript ive cross sectiona 1 N=353	N/A	Semi- structured questionnaire	SPSS v 16 software Descriptives – (mean, mode, frequencies) Chi-square T-tests	A total of 312 calls were received from the participants, with a total of 570 questions asked (139 were mother-related and 377 infant-related). Of questions related to the mother, 66% were about breastfeeding; while 60% of infant related questions were about routine care aspects such as normal feeding and elimination patterns, sleep, umbilical care, circumcision care or pacifier use.	Although the study lacks methodological rigour, it contributes useful information on the content/topical areas of concern experienced by first-time mothers, and the appropriate timing of its dissemination. Such information would help HCPs as they provide care to mothers, particularly after birth.	18

Shoray at	To avalora	Postastal	Descript		Somi	Thematic	Questions related to breastfeeding were highest immediately after birth and decreased gradually until 7 weeks postpartum. Calls related to infant fussiness were highest in the first 3 weeks then gradually decreased until 9 th week. Most calls were made by the mother herself (89.1%), 7.7% by her husband, and 2.9% by her mother. 24% (n=84) used the telephone outline. The midwife made follow up calls in 7.7% of total calls and made referrals in 18.6% of the calls	However, this study would have benefitted more from a qualitative research component. For instance, the paper reports of 2 participants who exceptionally called more times than the rest (24 & 43 times each), thus qualitative study would have explored the characteristic challenges experienced by such 'outlier' participants.	20
Shorey et al. 2015 Singapore	To explore mothers' perceptions on the content, delivery method, impact and suggestions	Postnatal mothers	Descript ive qualitati ve N=18 Based on Social	N/A	Semi structured interview guide Individual interviews	Thematic analysis	This was a qualitative study evaluating a prior RCT examining the effectiveness of a Postnatal psychoeducation programme (PPP) on maternal outcomes, conducted in a public	The study was a process evaluation following an RCT on PPP (home visit + telephone support) among new mothers in Singapore.	29

L C		1 . 1	0 11 4
for	exchang	tertiary hospital.	Overall, the
improvement	e &	Outcome measures of	findings suggest
of the	Self-	the main study (RCT):	that the PPP was
intervention	efficacy	Primary outcome –	highly effective in
{process	theories	exclusive	meeting the
evaluation}	(Bandur	breastfeeding at 8-12	mothers' parenting
	a 1997)	weeks postpartum;	needs (self-efficacy
		Intervention –	and general
		consisted of a 90 min	wellbeing).
		home visitation and 3	The study also
		weekly telephone	highlights the
		follow up and	various aspects of
		education booklet.	support for
		The study highlights 4	postnatal
		themes:	primiparous
		1. Challenges in	mothers such as
		postnatal period –	informational and
		negative emotions;	health systems
		difficulty in	support, and the
		breastfeeding; support;	health professional
		lack of knowledge in	attitudes expected
		newborn care, and	by mothers.
		confinement practices.	5
		2. Benefits of PPP –	
		increased knowledge	
		on newborn care, self-	
		care and breastfeeding;	
		increased confidence	
		level; enhanced help-	
		seeking behaviour;	
		increased emotional	
		wellbeing.	
		3. Strengths of PPP –	
		convenient and	
	1	convenient und	

	helpful; established trusting relationship with midwife; comprehensive educational booklet. <i>4. Future directions</i> – PPP as routine care; more health visits; more telephone follow up; more information in booklets; similar web-based intervention. Maiority expressed	
	high satisfaction and acceptability of the	
	PPP.	

				Quality	y assessme	ent - Hawke	r's checklist	: Score ran		each item	[Total score: Rang	ge = 9-36]	
Author/	Study	Sample	Design	Abstr	Introdu	Methods		Data	Ethics		Generasability/	Implica	Total
Year	population	size		act	ction	& data	Sampling	analysis	/bias	Results	Transferability	tions	score
Bunik et al.	Primiparous	N=341	RCT										
2010	low income	[I=161]	(2-arm)										
Denver,	women	[C=180]											
Colorado	(Pred.Latina)												
(US)	>18years			3	3	3	3	3	3	3	2	3	26
Hannan, J.	Primiparous	N=139	RCT										
2013	mothers	(I-70)	(2-arm)										
South Florida	>18 years	(C-69)											
(US)	2	`		3	3	3	3	2	3	3	2	3	25
Di Meglio et	Adolescents	N=78	RCT										
al. 2009	<20years	(I-38)	(2-arm)										
US		(C-40)	`	3	3	3	3	3	3	3	3	2	26
Pugh et al.	Postpartum	N=328	RCT										
2010	mothers	(I-168)	(2-arm)										
Maryland,	(Low income)	(C-160)											
US	[Pred. young -												
	mean=23yrs]			3	3	3	3	3	3	3	3	2	26
Pugh et al.	Postpartum	N=41	RCT										
2002	mothers	(I-?)	(2-arm)										
US	Low income	(C-?)											
	(mean=21 yrs)			3	3	2	2	3	2	3	2	3	23
Giallo et al.	Postpartum	N=202	RCT										
2014	mothers	(I1-63)	(3-arm)										
Australia	>18 years	(I2-67)											
		(C - 72)		3	4	3	3	3	3	2	3	3	26
Dennis et	Primiparous	N=252	RCT										
al.2002	women	(I-126)	(2-arm)										
Toronto,	≥16 years	(C-126)											
Canada				4	3	4	3	4	3	4	2	2	27
Dennis et	Postpartum	N=701	RCT										
al.2009	women	(I-293)	multisite										
Ontario,	(High risk of	(C-293)	study										
Canada	PND)		(2-arm)	3	3	3	3	3	3	4	3	3	28

Appendix 2.7: Quality assessment table for search 2 literature articles

	>18 years												
Tahir & Al-	Postpartum	N=304	RCT										
Sadat 2013	mothers	(I-152)	(2-arm)										
Malaysia	>18 years	(C-152)	()	3	3	3	3	3	3	3	3	3	27
Osman et al.	All	N=452	RCT										
2014	primiparous	(I1-127)	(4-arm)										
Beirut,	mothers	(I2 –121)	× ,										
Lebanon		(I3-101)											
		(C-103)		3	3	3	3	3	3	4	2	3	27
Bangure et	Woman or care	N=304	RCT										
al. 2015	giver	I=152	(2-arm)										
Zimbabwe		C=152											
	>18years			3	4	3	3	3	3	4	3	1	25
Gallegos et	Postpartum	N=234	A non-										
al. 2014	mothers	(I-120)	concurrent										
Australia	>18 years	(C-114)	comparativ										
			e trial	2	2	2	2	2	2	2	2	2	27
Dennis, C-L.,	Postnatal	N=701	(2-arm) Cross-	3	3	3	3	3	3	3	3	3	27
2010	mothers	n=701 [n=293 per	sectional										
Canada	>18 years	arm]	survey										
Callada	>10 years	am	*RCT										
			KC1	3	3	3	3	3	3	4	3	3	28
Dennis, C-L.,	Primiparous	N=252	Cross-	5	5	5	3	5	5		5	5	20
2002	breastfeeding	[126/arm]	sectional										
Canada	mothers ≥16	30 peer	survey										
	years	volunteers	*RCT	3	3	3	3	3	3	4	2	2	26
Hamade et	All	N=751	Longitudin										
al. 2013	primiparous		al study										
Lebanon	mothers		*RCT	3	3	3	3	3	3	4	3	3	28
Osman et al.	All	N=353	Descriptiv										
2010	primiparous		e cross										
Lebanon	mothers		sectional										
				3	3	2	2	1	1	1	2	2	17
Shorey et al.	Postnatal	N=18	Descriptiv										
2015	mothers		e										
Singapore			qualitative	4	3	3	3	3	3	4	3	3	29

Appendix 3.1: Research schedule

YEAR ON	E 2015/2016	– Prop	osal	writin	g								
	MONTH	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug
ACTIVITY													
Literature rev	view												
Research obj													
Questions for													
Research des													
formulation a													
Research too													
development													
Application a													
submission fo	or ethical												
review	(ID (D D D C												
Ethical review													
and MU-IRE	C) and												
approval	O 2016/2017	D	11										
		– Dat	a con	ection	r		1	Τ	1	Γ	1		ſ
Ethical review	· · · · · · · · · · · · · · · · · · ·												
IRECs) and a								-					
Developing i													
(Delphi study													<u> </u>
Training of R Piloting of in													<u> </u>
Recruitment													
Intervention	and												
	an and antwo					-							
Data collection	REE 2017/20	10 D	late c	nolvai	and '			na					
		10 – D	ala a	narysis		Inesi		ng					
Data analysis													
Update of lite review	erature												
Thesis writin	a												
Disseminatio	<u>s</u> n of results												
Disseminatio	ii of fesuits												

	Appendix 3.2: Research Instruments [Version1-01.07.2016] S.No
	Appendix 3.2A: Questionnaire (for young mothers)
<u>A1)</u>	BIODATA: 1. Age (yrs) 2. Parity: 3.Residence:
	4. Marital status: Married Single Separated Widowed Widowed Divorced Living with partner
	5. Religion: Catholic Protestant Muslim
	Hindu Other (Specify)
	6. Education level: Primary Secondary Tertiary None
	7. Occupation: Self-employment Formal employment Unemployed Student
	8. Baby's birth weight (grams) 9. Baby's sex: M F
	10. No. of ANC visits: None 1 2 3 4 >4
	11. Gestation at 1 st ANC visit (weeks):
	12. Mode of birth: SVD
	13. Primary support person: Parent(s) Partner Friend(s) None
	14. Labour complication: Yes (specify) No
	15. Distance to clinic (Km): Less than 5Km More than 5Km
	16. Preferred mode of text messaging: Normal sms Whatsapp
	17. Tel. contact:

A2) MATERNAL SOCIAL SUPPORT (Maternity Social Support Scale): Instructions: For each of the following statements, please tick ($\sqrt{}$) one box which shows how you feel about the support you have right now

~ • •		Always	Most of the	Some of the	Rarely	Never
S.No.	Stem statement		time	time		
1.	I have good friends who support me					
2.	My family is always there for me					
3.	My husband/partner helps me a lot					
	There is conflict with my					
4.	husband/partner					
	I feel controlled by my					
5.	husband/partner					
6.	I feel loved by my husband/partner					

A3) MATERNAL SELF-ESTEEM (Rosenberg Self-Esteem Scale):

<u>Instructions</u>: Below is a list of statements relating to your general feelings about yourself. Please indicate how strongly you agree or disagree with each statement by ticking ($\sqrt{}$) the appropriate box as indicated

	Stern statement	Strongly	Agree	Undecided	Strongly
S.No.	Stem statement	agree			disagree
1	On the whole, I am satisfied with myself				
2	At times I think I am no good at all				
3	I feel that I have a number of good qualities				
4	I am able to do things as well as most other people				
5	I feel I do not have much to be proud of				
6	I certainly feel useless at times				
7	I feel that I am a person of worth, at least on an equal plane with others				
8	I wish I could have more respect for myself				
9	All in all, I am inclined to feel that I am a failure				
10	I take a positive attitude toward myself				
Total s	cores				

A4) MOTHER-INFANT BONDING (The Postpartum Bonding Instrument): Instructions: Please indicate how often the following are true for you. There are no "right" or "wrong" answers: choose the response that most applies in your recent experience

Stem statement	Always	Very often	Quite often	Sometimes	Rarely	Never
I feel close to my baby		onten	orten			
I wish the old days when I had no						
baby would come back						
I feel distant from my baby						
I love to cuddle my baby						
I regret having this baby						
The baby does not seem to be						
mine						
My baby makes me tense						
My baby irritates me						
I feel happy when my baby smiles						
or laughs						
I love my baby enormously						
I enjoy playing with my baby						
My baby cries too much						
I feel trapped as a mother						
I feel angry with my baby						
I dislike my baby						
My baby is the most beautiful						
baby in the world						
I wish my baby would somehow						
go away						
I have done harmful things to my						
baby						
My baby makes me anxious						
I am afraid of my baby						
My baby annoys me						
I feel confident when changing						
my baby						
I feel the only solution is for						
someone else to look after my						
baby						
I feel like hurting my baby						
My baby is easily comforted						

A5) POSTNATAL DEPRESSION INDEX (Edinburgh Postnatal Depression Scale):

<u>Instructions</u>: Below is a list of statements relating to your general feelings over the past few days after birth. Please check the response that comes closest to how you have felt IN THE PAST 7 DAYS (not just how you feel today) by ticking ($\sqrt{}$) the appropriate box as indicated

In the past 7 days:

- I have been able to laugh and see the funny side of things
 - As much as I always could
 - □ Not quite so much now
 - Definitely not so much now
 - \Box Not at all
- I have looked forward with enjoyment to things
 - As much as I ever did
 - \Box Rather less than I used to
 - Definitely less than I used to
 - ☐ Hardly at all
- I have blamed myself unnecessarily when things went wrong
 - \Box Yes, most of the time
 - \Box Yes, some of the time
 - □ Not very often
 - □ No, never
- I have been anxious or worried for no good reason
 - \Box No, not at all
 - ☐ Hardly ever
 - ☐ Yes, sometimes
 - ☐ Yes, very often
- I have felt scared or worried for no very good reason
 - ☐ Yes, quite a lot
 - \Box Yes, sometimes
 - \Box No, not much
 - \Box No, not at all
- Things have been getting on top of me
 - Yes, most of the time I haven't been able to cope at all
 - ☐ Yes, sometimes I haven't been coping as well as usual
 - \Box No, most of the time I have coped quite well
 - \Box No, I have been coping as well as ever
- I have been so unhappy that I have had difficulty sleeping ☐ Yes, most of the time
 - \Box Yes, sometimes
 - \Box Not very often

 \Box No, not at all

- I have felt sad or miserable
 - \Box Yes, most of the time
 - ☐ Yes, quite often
 - □ Not very often
 - □ No, not at all
- I have been so unhappy that I have been crying
 - \Box Yes, most of the time
 - \square Yes, quite often
 - □ Only occasionally
 - \Box No, never
- The thought of harming myself has occurred to me
 - ☐ Yes, quite often
 - □ Sometimes
 - ☐ Hardly ever
 - □ Never

A6) MATERNAL-INFANT HEALTH WELLBEING

Instructions: Please indicate how often the following are true for you. There are no "right" or "wrong" answers: choose the response that most applies in your recent experience

Stem statement	Yes	No
Have you had any illness since giving birth?		
Have you taken any (self) medication since giving birth?		
Has your baby fallen ill since you were discharged from hospital?		
Have you ever given any medication to your baby since giving birth?		
Has your baby received due vaccinations since birth?		
Is your baby getting enough breast milk?		
Did you experience any difficulty in breastfeeding?		
Have you fed your baby with other feeds? And water?		
Are you using (or intend to use) any family planning method?		
Has your baby had any change in weight?		
If Yes, what is the most recent weight measured? (Please indicate in the box)		

[Version1-01.07.2016] S.No

Appendix 3.2B: Data extraction form (facility-based data)

MANCHESTER

<u>Instructions:</u> Below is a list of items relating to maternal/infant care that health care providers need to address and document in the patient records. Please <u>review</u> the patient records and indicate whether these aspects of care are sufficiently documented (and/or provided).

NB: DO NOT WRITE ANY INFORMATION THAT IDENTIFIES THE PATIENT/CLIENT such as name, file number or otherwise.

Item/description reflected in patient records?	Yes	No
Age		
Sex		
Parity		
Marital status		
Education level		
Religion		
Occupation		
Labour summary/partogram		
Mode of birth		
Antenatal care attendance/visits		
Family planning counselling/advice		
Exclusive breastfeeding counselling/advice		
Discharge summary		
Next appointment/visit given		

Please tick in the box as applicable.

Appendix 3.2C: Interview Guide for young mothers

MANCHESTER

Study title: A pilot randomised controlled trial to explore Telephone Support

Intervention as a means of supporting young mothers in the immediate postnatal period in

Western Kenya

INSTRUCTIONS TO THE INTERVIEWER

- A. Introduce yourself and the RA to the participants.
- B. Explain the purpose of the research.
- C. Assure the interviewee of confidentiality and anonymity.
- D. Obtain written consent from the interviewees.
- E. Do not write the name of the respondents on the schedule to ensure anonymity.

1.	How can you describe your experiences of childbirth?
	Probe: Feelings about childbirth; Experience of childbirth; Preparation for childbirth
2.	How have you been since giving birth?
	Probe: Feelings after birth/having a baby; Motherhood experience (breastfeeding experience, caring for baby, personal health)
3.	If you look back to after giving birth, did you get any form of support? Please share your experience.
	Probe: Expectations (from health system/family/partner/friends or peers)
4.	And now, do you think you still need support as before? What form of support would you need? Probe: Perceptions about self-competence; Challenges experienced (if any)
5.	Regarding (the) telephone support you received/{if you were to receive}, what were your experiences/{would be your perceptions}? What would you suggest for improvement?
	Probe: Perceptions about telephone support
6.	From your experience, what would you recommend to other young mothers like you? Probe: Recommendation to health system/family/partner
7.	Is there anything that you think we have missed out of this interview that you think is important?

Thank you for taking part in this interview/discussion.

[Version1-01.07.2016] S.No

Appendix 3.2D: Interview Guide for Midwives

MANCHESTER

Study title: A pilot randomised controlled trial to explore Telephone Support

Intervention as a means of supporting young mothers in the immediate postnatal period in

Western Kenya

INSTRUCTIONS TO THE INTERVIEWER

- A. Introduce yourself and the RA to the participants.
- B. Explain the purpose of the research.
- C. Assure the interviewee of confidentiality and anonymity.
- D. Obtain written consent from the interviewees.
- E. Do not write the name of the respondents on the schedule to ensure anonymity.

1.	How can you describe your experience as a midwife in helping young mothers during childbirth? Probe: Perceptions about young motherhood; Young/adolescent mothers' preparation for childbirth/motherhood
2.	What challenges do you think young/adolescent mothers face during the immediate postnatal period? Probe: If necessary [breastfeeding, infant care, maternal health]
3.	In your view, do you think young/adolescent mothers need additional support during childbirth/postnatal period? Probe: Form of support needed? From whom? Alternative ways of providing additional support?
4.	If we are to consider telephone support intervention as one of the ways of providing such a support to young/adolescent mothers, do you think it is feasible? Probe: How would it be received and supported by midwives? Other health service providers? What effect/impact would it have?
5.	If your institution is to implement such an intervention (TSI), what do you consider as possible challenges? Probe: Barriers and facilitators
6.	Based on your experience as a midwife, would you recommend telephone support intervention to your institution? Probe: Suggestions for improvement if such an intervention is to be considered in the institution/Recommendations
7.	Is there anything that you think we have missed out of this interview that you think is important?

Thank you for taking your time to take part in this interview.

[Version1-01.08.2016] S.No

Appendix 3.2E: Short demographics questionnaire for midwives (main study)

MANCHESTER

Study title: A pilot randomised controlled trial to explore Telephone Support Intervention as a means of supporting young mothers in the immediate postnatal period in Western Kenya

Please fill out the following background details to help us describe whose views we are presenting in the study. No identifying details will be reported in the research.

1.	What is your current position/designation?	
2.	How long have you been a qualified midwife/nurse- midwife?	Years:
3.	How long have you worked in the postnatal unit?	Years: Months:
4.	Age (please tick as applicable)	18 - 25 years $26 - 30$ years $31 - 35$ years $36 - 40$ years $41 - 45$ years $46 - 50$ years $51 - 55$ years $56 - 60$ yearsOver 60 years
5.	Gender (please tick)	Male Female
6.	What is your highest level of education? (please tick)	Certificate Diploma Degree Masters PhD Other, state

Thank you for your responses.

[Version1-20.06.2016]

Appendix 3.3: Participant Information Sheets

Appendix 3.3A: Participant Information Sheet (Mothers 18-19 years)

Study Title

A pilot randomised controlled trial to explore Telephone Support Intervention as a means of supporting young mothers in the immediate postnatal period in Western Kenya

Invitation

You are being invited to take part in this study exploring the use of telephone support intervention as a means of supporting young mothers during the immediate postnatal period. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish (e.g. your family members or your midwife). Please ask if there is anything that is not clear or if you would like more information (contact details are provided on the last page of this information sheet). Take time to decide whether or not you wish to take part. Thank you for taking the time to read this.

Who will conduct the study?

This study will be conducted by a team of researchers namely, Elijah K. Kirop, Prof. Dame Tina Lavender, Dr. Rebecca Smyth and Dr. Malcolm Campbell based in The University of Manchester, University Place, Oxford Road, M13 9PL, Manchester, UK.

What is the purpose of this study?

Young mothers need support after giving birth to enable them to successfully cope with the challenges in caring for themselves and the newborn baby after birth. However, this support is sometimes not readily available, especially after discharge from the hospital. Therefore this study aims to assess the feasibility and acceptability of telephone support intervention (telephone calls and short message services) as a means of supporting young mothers soon after birth in improving their physical, psychological and social wellbeing.

Why have I been chosen?

You are a young mother and we think you are best-suited to help us with our research. In the study, you will be allocated by computer to either be in the usual care group (who will receive usual level of support and care we provide as required by the ministry of health) or an intervention group (who will receive an additional telephone support). This will allow us to fairly compare the views and experiences of young mothers who have telephone support care with those who have usual care. We would be interested in understanding your views about participating in the study.

What would I be asked to do if I took part?

You will be explained the purpose of the study and provided with a participant information sheet (this leaflet) by the researcher or a member of the research team before you make a decision to take part. If you agree to take part, you will be required to complete the first questionnaire that collects information about your personal information such as age, number of children, birth information and the birth weight and sex of your baby. You will then be allocated by the computer (by chance) to either: a) a group that will receive the usual level of support, or b) a group that will receive additional support. You will not be able to choose the group and we will not know your allocation until after you have agreed to take part.

Group a: You will continue receiving usual level of support at the hospital, in the same way you were explained to before you were discharged. This will include health education on the care of your infant and yourself, keeping clinical appointments including immunisation of your baby and also using your Mother and Child booklet (the purple booklet you used during your antenatal clinics). This booklet will still be useful during this period.

Group b: You will receive the usual level of support and an additional support through the telephone. You will be contacted 3 times (after every 3 weeks) and by text message (SMS) every week from the second week until the 10th week after birth by the study midwife through a mobile telephone and a number only used for the study. The telephone calls will last between 10-15 minutes each time. This will basically provide supportive information on how you will care for yourself and your baby. You are also free to contact the research midwife at any time for any health assistance during this period through the mobile number provided.

Regardless of which group you are in, you will then be required to complete a second questionnaire at the end of the 10th week during the 2nd immunisation visit for your baby. The questionnaire collects information about your views and experiences about the level of support you received (your perceived social support, self-esteem, and bonding with your baby). You will also be asked if you wish to voluntarily participate in a focus group discussion or individual interview which might last between 30 min to 1 hour. The focus group will consist of up to 8 young mothers who also participated in the study, where you will share your views about the study (the level of support you received). You are encouraged to freely share your views and experiences and to discuss with 2 researchers in a private and safe environment for you and your baby within the immunisation centre. There are no right or wrong answers. It will be interesting finding out your views and to discuss with you about the study.

There are minimal risks to you for participating in this study. However, you may feel uncomfortable talking about your views and experiences as a young mother. However, we would like to reassure you that the research team will follow a guideline to address any discomfort you experience and will try to avoid causing any discomfort. If you feel uncomfortable, you do not have to answer, and you are allowed to stop the interview at any point, without giving a reason. If you feel very uncomfortable or upset by taking part in this study, you can be referred to a counsellor for additional support if such a need arises. The researchers will not feel disappointed if you choose to stop the interview.

What happens to the data collected?

The information obtained from this study will be used to improve the care for women, besides writing a PhD thesis (Author – Elijah Kirop). It will help us understand the potential usefulness of a telephone support intervention for young mothers and how it can be fairly tested. The data will only be seen by the researcher and supervisors.

How is confidentiality maintained?

All information collected will be strictly kept confidential. Computer (or electronic) data will be encrypted and stored in password-protected computers. All other data will also be stored in a locked cabinet in the Lead researcher's office which will always be under lock and key up to a maximum of 5 years after which it will be destroyed by shredding. We

will not ask you to indicate your name or any information that can identify you, so it will always remain anonymous. Interviews will be audio-recorded using an audio recorder, and will be destroyed by deleting from the recorder after the data will have been written in text. The transcript will then be destroyed by shredding with the other data as explained before. We will not use any quotes that include identifiable data. We will not use any information that would make it possible for anyone to identify you in any presentation or written reports about this study.

What happens if I do not want to take part or if I change my mind?

It's up to you whether to take part or not. The decision to take part is voluntary. If you decide to take part you will be asked to sign a consent or an assent form provided. If you agree to take part, you are still free to withdraw from the study at any time, without giving a reason and this will not affect the care you will receive now or in the future.

Will I be paid for participating in the study?

Participation in this study is voluntary and no payments will be made if you participate. However, you may be provided with re-imbursement for transport during the interviews.

What is the duration of the study?

The study will last for about 10 weeks, when you will be asked to complete a questionnaire and take part in group or individual interviews after you have been attended to at the clinic.

Where will the study be conducted?

The study will be conducted in the hospital in which you chose to give birth and to have your follow up clinical appointments. During the interviews, a private, safe and comfortable environment for you and your baby will be provided within the immunisation centre (and for the other mothers who will also participate).

Will the outcomes of the study be published?

Yes, the findings of this study will be shared through journal publications and relevant conferences. However, we will always ensure that no one can be identified in the thesis reports, presentations or publications.

Who has reviewed the study project?

The study has been jointly reviewed by the University of Manchester Research Ethics Committee (6) and the Institutional Research Ethics Committee of Moi University/Moi Teaching and Referral Hospital (Eldoret, Kenya).

What if something goes wrong?

We do not expect any problems in the study. However, we would like to reassure you that the research team will follow a guideline to address any discomfort you experience and will try to avoid causing any discomfort. If you feel uncomfortable, you do not have to answer, and you are allowed to stop the interview at any point. If you feel very much uncomfortable or upset by taking part in this study, you can be referred to a counsellor for additional support if such a need arises. If there is anything about the study that you are not happy with, please contact the Lead researcher, **MR. ELIJAH KIROP by telephone on** +254 721 222 325 **OR the Research midwife through the official telephone line for the study on** +254 741796797 immediately.

What if I want to make a complaint?

If you have any complaint then you need to contact the researcher(s) in the first instance.

Minor complaints

If there is anything about the study that you are not happy with, please feel free to contact the Lead researcher, MR. ELIJAH KIROP by telephone on +254 721 222 325 or by e-mail: <u>elijah.kirop@postgrad.manchester.ac.uk</u> or <u>elijah.kirop15@gmail.com</u>. You can also contact the Research midwife through the official telephone line for the study on +254 741796797.

Formal Complaints

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact the **Hospital** Ethics and Research committee (Human Subjects administrator) on +254 787 723 677 and fill the complaints form (Reporting Form for Research Complaints or Concerns) and e-mail to irec@mtrh.or.ke or send by post through the contacts provided in the form. You can also contact one of the research supervisors (contact details provided at the end of this information sheet) OR the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road. Manchester, **M13** 9PL, by e-mailing: research.complaints@manchester.ac.uk.

Any complaint you make will be taken very seriously.

What Do I Do Now?

If you have any queries about the study or if you are interested in taking part, please contact the researcher(s).

The Lead researcher **ELIJAH KIROP can be contacted by telephone** +254 721 222 325 **OR by email:** <u>elijah.kirop@postgrad.manchester.ac.uk</u> or <u>elijah.kirop15@gmail.com</u>. Other researchers included in the project are: **Prof. Dame Tina Lavender, Dr. Rebecca Smyth** and **Dr. Malcolm Campbell** and **the Research midwife**. [School of Nursing, Midwifery and Social Work, Jean McFarlane Building,

[School of Nursing, Midwifery and Social Work, Jean McFarlane Building, University of Manchester, Oxford Road, M13 9PL, Manchester, UK].

Please free to discuss this information with others, who may be your family members or midwife. You can also contact the research team to answer further questions through the contacts provided above.

If you would like to take part please fill the <u>consent</u> or <u>assent form</u> provided.

Thank you for taking your time to read this information.

Appendix 3.3B: Participant Information Sheet (Mothers - 12-17 years)

What if something goes wrong?

We do not expect any problems in the study. However, we would like to reassure you that the research team will follow a guideline to address any discomfort you experience and will try to avoid causing any discomfort. If you feel uncomfortable, you do not have to answer, and you are allowed to stop the interview at any point. If you feel very uncomfortable or upset by taking part in this study, you can be referred to a counsellor for additional support if such a need arises. If there is anything about the study that you are not happy with, please contact the Lead researcher, MR. ELIJAH KIROP through an official telephone line (Airtel) for the study on +254 721222325 OR the Research midwife through the official telephone line

for the study on +254 741796797 immediately.

What if I want to make a complaint?

If you have any complaint then you need to contact the researcher(s) in the first instance.

Minor complaints

If there is anything about the study that you are not happy with, please feel free to contact the Lead researcher, **MR. ELIJAH KIROP** through the official **telephone line** for the study on +254 721222325 or by e-mail:

elijah.kirop@postgrad.manchester.ac.uk. You can also contact the Research midwife through the official telephone line for the study +254 741796797.

Formal Complaints

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact the Hospital Ethics and Research committee (Human Subjects administrator) on +254 787 723 677 and fill the complaints form (Reporting Form for Research Complaints or Concerns) and e-mail to irec@mtrh.or.ke or send by post through the contacts provided in the form. You can also contact one of the research supervisors (contact details provided at the end of this information sheet) OR the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by e-mailing: research.complaints@manchester.ac.uk. Any complaint you make will be taken very seriously.

What Do I Do Now?

If you have any queries about the study or if you are interested in taking part, please contact the researcher(s).The Lead researcher ELIJAH KIROP can be contacted by telephone on +254 721222325 OR by email: elijah.kirop@postgrad.manchester.ac.uk. Other researchers included in the project are: **Prof. Dame Tina Lavender**, **Dr. Rebecca Smyth** and **Dr. Malcolm Campbell** and **the Research midwife**.

[School of Nursing, Midwifery & Social Work, University of Manchester, Oxford Road, M13 9PL, Manchester, UK]. Please free to discuss this information with others, who may be your family members or midwife. You can also contact the research team to answer further questions through the contacts provided above.

If you would like to take part please fill the <u>assent form</u> provided.





This Project Has Been Approved by the University of Manchester's Research Ethics Committee [UREC reference number 16427]

Thank you for taking your time to read this information.

Participant Information Sheet



Study Title

A pilot study (RCT) to explore Telephone Support Intervention as a means of supporting young mothers in the immediate postnatal period in Western Kenya

Invitation

You are being invited to take part in this interventional study exploring the use of telephone support intervention as a means of supporting young mothers during the immediate postnatal period. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish (e.g. your family members or your midwife). Please ask if there is anything that is not clear or if you would like more information (contact details are provided on the last page of this information sheet). Take time to decide whether or not you wish to take part. Thank you for taking time to read this information sheet.

Who will conduct the study?

This study will be conducted by a team of researchers namely, Elijah K. Kirop, Prof. Dame Tina Lavender, Dr. Rebecca Smyth & Dr. Malcolm Campbell based in The University of Manchester, UK.

What is the purpose of this study?

Young mothers need support after giving birth to enable them to successfully cope with the challenges in caring for themselves and the newborn baby after birth. However, this support is sometimes not readily available, especially after discharge from the hospital. Therefore this study aims to assess the feasibility and acceptability of telephone support intervention (telephone calls and short message services) as a means of supporting young mothers soon after birth in improving their physical, psychological and social wellbeing.

Why have I been chosen?

You are a young mother and we think you are best-suited to help us with our research. In the study, you will be allocated by computer to either be in the usual care group (who will receive usual level of support and care we provide as required by the ministry of health) or an intervention group (who will receive an additional telephone support). This will allow us to fairly compare the views and experiences of young mothers who have telephone support care with those who have usual care. We would be interested in understanding your views about participating in the study.

What would I be asked to do if I took part?

You will be explained the purpose of the study and provided with a participant information sheet (this leaflet) by the researcher or a member of the research team before you make a decision to take part. If you agree to take part, you will be required to complete the first questionnaire that collects information about your personal information such as age, number of children, birth information and the birth weight and sex of your baby.

You will then be allocated by the computer (by chance) to either: a) a group that will receive the usual level of support, or b) a group that will receive additional support. You will not be able to choose the group and we will not know your allocation until after you have agreed to take part.

Group a: You will continue receiving the usual level of support at the hospital, in the same way you as it was explained to you before you were discharged. This will include health education on the care of your infant and yourself, keeping clinical appointments including immunisation of your baby and also using your Mother and Child booklet (the purple booklet you used during your antenatal clinics). This booklet will still be useful during this period.

Group b: You will receive the usual level of support and additional support through the telephone. You will be

contacted by phone 3 times (after every 3 weeks) and by text message (SMS) every week from the second week until the 10th week after birth by the study midwife through a mobile telephone and a number only used for the study. The telephone calls will last between 10-15 minutes each time. This will basically provide supportive information on how you will care for yourself and your baby. You are also free to contact the research midwife at any time for any health assistance during this period through the mobile number provided.

Regardless of which group you are in, you will then be required to complete a second questionnaire at the end of the 10th week during the 2nd immunisation visit for your baby. The questionnaire collects information about your views and experiences about the level of support you received (your perceived social support, self-esteem, and bonding with your baby). You will also be asked if you wish to voluntarily participate in a focus group discussion or individual interview which might last between 30 min to 1 hour. The focus group will consist of up to 8 young mothers who also participated in the study, where you will share your views about the study (the level of support you received). You are encouraged to freely share your views and experiences and to discuss with 2 researchers in a private and safe environment for you and your baby within the immunisation centre. There are no right or wrong answers. It will be interesting finding out your views and to discuss with you about the study.

There are minimal risks to you for participating in this study. However, you may feel uncomfortable talking about your views and experiences as a young mother. However, we would like to reassure you that the research team will follow a guideline to address any discomfort you experience and will try to avoid causing any discomfort. If you feel uncomfortable, you do not have to answer, and you are allowed to stop the interview at any point, without giving a reason. If you feel very uncomfortable or upset by taking part in this study, you can be referred to a counsellor for additional support if such a need arises. The researchers will not feel disappointed if you choose to stop the interview.

What happens to the data collected?

The information obtained from this study will be used to improve the care for women, besides writing a PhD thesis (Author – Elijah Kirop). It will help us understand the potential usefulness of a telephone support intervention for young mothers and how it can be fairly tested. The data will only be seen by the researcher and his supervisors.

How is confidentiality maintained?

All information collected will be kept strictly confidential. Computer (or electronic) data will be encrypted and stored in

password-protected computers. All other data will also be stored in a locked cabinet in the Lead researcher's office which will always be under lock and key up to a maximum of 10 years after which it will be destroyed by shredding. We will not ask you to indicate your name or any information that can identify you, so it will always remain anonymous. Interviews will be audio-recorded using an audio recorder, and will be destroyed by deleting from the recorder after the data has been written in text. The transcript will then be destroyed by shredding with the other data as explained before. We will not use any quotes that include identifiable data. We will not use any information that would make it possible for anyone to identify you in any presentation or written reports about this study. However, strict confidentiality may not be guaranteed if we notice that your life or that of any other person is at risk as it is our duty to always prevent any harm to everyone.

What happens if I do not want to take part or if I change my mind?

It's up to you whether to take part or not. The decision to take part is voluntary. If you decide to take part you will be asked to sign an <u>assent form</u> provided. If you agree to take part, you are still free to withdraw from the study at any time, without giving a reason and this will not affect the care you will receive now or in the future.

Will I be paid for participating in the study?

Participation in this study is voluntary and no payments will be made if you participate. However, you may be provided with re-imbursement for transport during the interviews.

What is the duration of the study?

The study will last for about 10 weeks, when you will be asked to complete a questionnaire and take part in group or individual interviews after you have been attended to at the clinic.

Where will the study be conducted?

The study will be conducted in the hospital in which you chose to give birth and to have your follow up clinical appointments. During the interviews, a private, safe and comfortable environment for you and your baby will be provided within the immunisation centre (and for the other mothers who will also participate).

Will the outcomes of the study be published?

Yes, the findings of this study will be shared through journal publications and relevant conferences. However, we will always ensure that no one can be identified in the thesis reports, presentations or publications.

Who has reviewed the study project?

The study has been jointly reviewed by the University of Manchester Research Ethics Committee and the Institutional Research Ethics Committee of Moi University/Moi Teaching & Referral Hospital (Eldoret, Kenya).

Appendix 3.3C: Participant Information Sheet (Parent/Guardian)

Study Title

A pilot randomised controlled trial to explore Telephone Support Intervention as a means of supporting young mothers in the immediate postnatal period in Western Kenya

Invitation

You are being invited to provide consent for your daughter to take part in this study exploring the use of telephone support intervention as a means of supporting young mothers during the immediate postnatal period. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and/or to discuss it with others if you wish (e.g. the midwife). Please ask if there is anything that is not clear or if you would like more information (contact details are provided on the last page of this information sheet). Take time to decide whether or not you wish your daughter to take part. Thank you for taking the time to read this information sheet.

Who will conduct the research?

This study will be conducted by a team of researchers namely, Elijah K. Kirop, Prof. Dame Tina Lavender, Dr. Rebecca Smyth and Dr. Malcolm Campbell based in The University of Manchester, University Place, Oxford Road, M13 9PL, Manchester, UK.

What is the purpose of this study?

Young mothers often need support after giving birth to enable them to successfully cope with the challenges in caring for themselves and the newborn baby after birth. However, this support is sometimes not readily available, especially after discharge from the hospital. Therefore this study aims to assess the feasibility and acceptability of telephone support intervention (telephone calls and short message services) as a means of supporting young mothers soon after birth in improving their physical, psychological and social wellbeing.

Why have I been chosen?

Your daughter is a young mother and we would like her to help us with our research (together with other young mothers). In the study, your daughter will be randomly allocated by computer to either be in the usual care group (who will receive usual level of support and care we provide as required by the ministry of health) or an intervention group (who will receive an additional telephone support). This will allow us to fairly compare the views and experiences of young mothers who have telephone support care with those who have usual care. We would be interested in understanding her views about participating in the study. We have therefore chosen you as a parent/guardian to consider allowing your daughter to take part in this study.

What would I be asked to do if my daughter took part?

You will be explained the purpose of the study and provided with a participant information sheet (this leaflet) by the researcher or a member of the research team before you make a decision to

allow your daughter to take part. You will also be fully informed about the study (*read details of participation in the information sheet*).

Young mothers who will receive the intervention will be contacted through a telephone call 3 times (after every 3 weeks) and by text message (SMS) every week from the second week until the 10th week after birth by the research midwife. This intervention will provide supportive information on how they will care for their babies as well as their own health. They will also continue receiving the usual care at the hospital. This will include health education on the care of the baby/infant and herself, keeping clinical appointments including immunisation of the baby. They will also be encouraged to use their 'Mother and Child booklet' (the purple booklet they used during their antenatal clinics) and to contact any nearest health facility if they need an immediate medical assistance or to contact the research midwife by telephone. This booklet will still be useful during this period. As a parent/guardian, we also encourage you to allow them to freely contact the research midwife mainly by telephone or by any other means as necessary for any health assistance during this period (contacts provided at the end of this information sheet).

For young mothers who will not take part in the intervention, they will continue receiving the usual care at the hospital as required, which will include health education on the care of the infant and herself and keeping clinical appointments including immunisation of the baby. They will also be encouraged to use their 'Mother and Child booklet' (the purple booklet they used during their antenatal clinics). If they require any immediate medical assistance, they are encouraged to contact the hospital or the nearest health facility.

At the end of the 10th week during the 2nd immunisation visit for the baby, they will be required to complete a questionnaire that collects information about their views and experiences of the care they received. They will also be asked if they wish to voluntarily participate in a focus group discussion or individual interview which might last between 30 min to 1 hour. The focus group will consist of up to 8 young mothers who also participated in the study. The interviews will be audio-recorded to facilitate transcription later in the study. We would be interested in finding out their views and experiences as young mothers as well as about the study. Traveling expenses will be reimbursed for mothers who take part in the interviews.

There are minimal risks to the mothers, including your daughter while they participate in the study. However, we do understand that they may at times feel uncomfortable talking about their views and experiences as young mothers. We would like to reassure you as a parent/guardian that the research team will follow a clear guideline to address any discomfort that may arise and will try to avoid causing any discomfort or distress. In addition, they will be informed that whenever they feel uncomfortable, they do not have to answer, and they are allowed to stop the interview at any point. In the event that the researchers notice that any of them is very distressed by taking part in the study or otherwise, they will use their clinical judgement to provide further support including appropriate referral as necessary. If such an incident occurs, the researchers are obliged to stop the interview and provide care as necessary.

If you agree that she takes part, you will then be asked to sign a **parental consent form**. Your daughter will also be provided with a separate information sheet about the study. If she agrees to take part, she will also be asked to sign a **consent** or an **assent form** provided and to complete an initial short questionnaire that collects information about her personal information such as age, number of children, birth information and the birth weight and sex of her baby.

What happens to the data collected?

The information obtained from this study will be used to improve the health of women besides writing a PhD thesis (Author – Elijah Kirop). It will help us understand the potential usefulness of a telephone support intervention for young mothers and how it can be fairly tested.

How is confidentiality maintained?

All information collected will be strictly kept confidential. Electronic (or computer) data will be encrypted and stored in password-protected computers. All other data will also be stored in a locked cabinet in the Lead researcher's office which will always be under lock and key, up to a maximum of 5 years after which it will be destroyed by shredding. We will not ask you to indicate your name or any information that can identify you, so it will always remain anonymous. Interviews will be audio-recorded using an audio recorder, and will be destroyed by deleting from the recorder after the data will have been written in text. The transcript will then be destroyed by shredding with the other data as explained before. We will not use any information that would make it possible for anyone to identify you in any presentation or written reports about this study.

What happens if my daughter does not want to take part or if she changes her mind?

Your daughter's participation is voluntary. If your daughter decides to take part, she will be asked to sign an <u>assent form</u> provided. If you agree that she takes part, you will be asked to sign a <u>parental consent form</u> provided. However, your daughter is still free to withdraw from the study at any time, without giving a reason and this will not affect the care she will receive now or in the future.

Will I or my daughter be paid for participating in the study?

Participation in this study is voluntary and no payments will be made if she participates. However, she may be provided with re-imbursement for transport during the interviews.

What is the duration of the study?

The study will last for about 10 weeks. If your daughter will be in the intervention group, she will receive support telephone calls during the 3^{rd} , 6^{th} and 9^{th} week; and a weekly text message until the 10^{th} week, when she will be asked to complete a questionnaire and take part in group or individual interviews after receiving care at the hospital. We therefore encourage you to ensure that she has full-time and free access to a mobile telephone. If she will be in the usual care group, she will receive appropriate care as scheduled and she will also be asked to complete the same questionnaire and to take part in the interviews. The interviews might last between 30 min to 1 hour.

Where will the study be conducted?

The study will be conducted in the hospital in which your daughter gave birth and chooses to have her follow up clinical appointments. During the interviews, a private, safe and comfortable environment within the immunisation centre will be provided (for the mothers and their babies).

Will the outcomes of the study be published?

Yes, the findings of this study will be shared through journal publications and relevant conferences. However, we will always ensure that no one can be identified in the thesis reports, presentations or publications.

Who has reviewed the study project?

The study has been jointly reviewed by the University of Manchester Research Ethics Committee (6) and the Institutional Research Ethics Committee of Moi University/Moi Teaching and Referral Hospital (Eldoret, Kenya).

What if something goes wrong?

We do not expect any problems in the study. However, we would like to reassure you as a parent/guardian that the research team will strictly follow a guideline to address any discomfort to participants that may arise during the study and we will always try to avoid causing any discomfort/distress. If there is anything about the study that your daughter is not happy with, she is free to contact the Lead researcher, **MR. ELIJAH KIROP by telephone on** +254 721 222 325 **OR the Research midwife through the official telephone line for the study**

on +254 741796797 immediately.

What if I/she want(s) to make a complaint?

If you or your daughter has any complaint then you need to contact the researcher(s) in the first instance.

Minor complaints

If there is anything about the study that you are not happy with, or your daughter reports to be unhappy about, please feel free to contact the Lead researcher, **MR. ELIJAH KIROP by** telephone on +254 721 222 325 or by e-mail: elijah.kirop@postgrad.manchester.ac.uk or elijah.kirop15@gmail.com.

You can also contact the **Research midwife through the official telephone line for the study** on +254 741796797.

Formal Complaints

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact the Hospital Ethics and Research (Human Subjects administrator) on +254 787 723 677 and fill the complaints form (*Reporting Form for Research Complaints or Concerns*) and e-mail to <u>irec@mtrh.or.ke</u> or send by post through the contacts provided in the form. You can also contact one of the research supervisors (contact details provided at the end of this information sheet) OR the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk.

Any complaint you make will be taken very seriously.

What Do I Do Now?

If you have any queries about the study please contact the researcher(s). The Lead researcher **ELIJAH KIROP can be contacted by telephone** +254 721 222 325 OR **by email:** <u>elijah.kirop@postgrad.manchester.ac.uk</u> or <u>elijah.kirop15@gmail.com</u>. Other researchers included in the project are: **Prof. Dame Tina Lavender, Dr. Rebecca Smyth** and **Dr. Malcolm Campbell,** and **the Research midwife**.

[School of Nursing, Midwifery and Social Work, Jean McFarlane Building, University of Manchester, Oxford Road, M13 9PL, Manchester].

Please free to discuss this information with others, who may be your family members or midwife. You can also contact the research team to answer further questions through the contacts provided above.

If you would like your daughter to take part in this study, please fill and sign the <u>parental</u> <u>consent form</u> provided.

Thank you for taking your time to read this information sheet.

Appendix 3.3D: Participant Information Sheet (Midwives)

Study Title

A pilot randomised controlled trial to explore Telephone Support Intervention as a means of supporting young mothers in the immediate postnatal period in Western Kenya

Invitation

You are being invited to take part in this interventional study exploring the use of telephone support intervention as a means of supporting young mothers during the immediate postnatal period. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Please ask if there is anything that is not clear or if you would like more information (contact details are provided on the last page of this information sheet). Take time to decide whether or not you wish to take part. Thank you for taking the time to read this information sheet.

Who will conduct the study?

This study will be conducted by a team of researchers namely, Elijah K. Kirop, Prof. Dame Tina Lavender, Dr. Rebecca Smyth and Dr. Malcolm Campbell based in The University of Manchester, University Place, Oxford Road, M13 9PL, Manchester, UK.

What is the purpose of this study?

Young mothers often need support after giving birth to enable them to successfully cope with the challenges in caring for themselves and the newborn baby after birth. However, this support is sometimes not readily available, especially after discharge from the hospital. Therefore this study aims to assess the feasibility and acceptability of telephone support intervention (telephone calls and short message services) as a means of supporting young mothers soon after birth in improving their physical, psychological and social wellbeing.

Why have I been chosen?

You have been purposively chosen as a key informant to take part in this study because you are directly involved in the provision of midwifery care to women including young mothers. We believe you have vital information relevant to this study, and may be useful for midwifery practice. We would therefore be interested in understanding your views about telephone support intervention as a means of supporting young mothers (12-19 years) during the immediate postnatal care.

What would I be asked to do if I took part?

You will be explained the purpose of the study and provided with a participant information sheet (this leaflet) by the researcher or a member of the research team before you make a decision to take part. If you agree to take part, you will be required to complete a brief questionnaire that collects information about your personal information such as age, qualification and duration of service. If you consent to take part, you will be asked to fill and sign a written **consent form** provided. You will then be asked to share your views and/or experiences as a midwife regarding the use of telephone support intervention as a supportive care strategy during the immediate postnatal care, especially among young mothers.

What happens to the data collected?

The information obtained from this study will be used improve the health of women besides writing a PhD thesis (Midwifery)(Author – Elijah Kirop). Also, to enable others to learn from the study, the findings will be shared through journal publications and relevant conferences. However, we will always ensure that no one can be identified in the thesis reports, presentations or publications.

How is confidentiality maintained?

All information collected will be strictly kept confidential. Electronic data will be encrypted and stored in password-protected computers. All other data will also be stored a locked cabinet in the Lead researcher's office which will always be under lock and key up to a maximum of 5 years after which it will be destroyed by shredding. We will not ask you to indicate your name or any information that can identify you, so it will always remain anonymous. Interviews will be audio-recorded using an audio recorder, and will be destroyed by deleting from the recorder after the data will have been written in text. The transcript will then be destroyed by shredding with the other data as explained before. We will not use any information that would make it possible for anyone to identify you in any presentation or written reports about this study.

What happens if I do not want to take part or if I change my mind?

Your participation is voluntary and if you decide to take part you will be asked to sign a **<u>consent</u> <u>form</u>** provided. However, there will be no harm or detrimental effect whatsoever if you decline taking part or if you wish to withdraw your participation.

Will I be paid for participating in the study?

Participation in this study is voluntary and no payments will be made if you participate.

What is the duration of the study?

The interventional phase of the study will last for about 10 weeks. However, you will be requested to participate from the 10^{th} - 12^{th} week when you will be asked to take part in an individual interview. The interviews might last between 30 - 45 minutes.

Where will the study be conducted?

The study will be conducted at the hospital in an appropriate room and comfortable environment with minimal interruptions and noise. You may also suggest a convenient time and setting for the interview.

Will the outcomes of the study be published?

Yes, the findings of this study will be shared through journal publications and relevant conferences. However, we will always ensure that no one can be identified in the thesis reports, presentations or publications.

Who has reviewed the study?

The study has been jointly reviewed by the University of Manchester Research Ethics Committee (6) and the Institutional Research Ethics Committee of Moi University/Moi Teaching and Referral Hospital (Eldoret, Kenya).

What if something goes wrong?

We do not expect any problems in the study. However, we would like to reassure you that the research team will follow a guideline to address any discomfort that you may and/or the young mothers may experience and we will try to avoid causing any discomfort/distress. If there is anything about the study that you are not happy with, please contact the Lead researcher, **MR**. **ELIJAH KIROP by telephone on** +254 721 222 325 **OR the Research midwife through the official telephone line for the study on** +254 741796797 immediately.

What if I want to make a complaint?

If you have a complaint then you need to contact the researcher(s) in the first instance.

Minor complaints

If there is anything about the study that you are not happy with, please feel free to contact the Lead researcher, **MR. ELIJAH KIROP by telephone on** +254 721 222 325 or by e-mail: elijah.kirop@postgrad.manchester.ac.uk or elijah.kirop15@gmail.com. You can also contact the **Research midwife through the official telephone line for the study on** +254 741796797.

Formal Complaints

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact the **Hospital Ethics and Research committee (Human Subjects administrator) on** +254 787 723 677 and fill the complaints form (*Reporting Form for Research Complaints or Concerns*) and e-mail to irec@mtrh.or.ke or send by post through the contacts provided in the form. You can also contact one of the research supervisors one of the research supervisors (contact details provided at the end of this information sheet)

OR the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk.

Any complaint you make will be taken very seriously.

What Do I Do Now?

If you have any queries about the study or if you are interested in taking part, please contact the researcher(s). The Lead researcher **ELIJAH KIROP can be contacted by telephone** +254 721 222 325 OR by email: elijah.kirop@postgrad.manchester.ac.uk or elijah.kirop15@gmail.com. Other researchers included in the project are: Prof. Dame Tina Lavender, Dr. Rebecca Smyth and Dr. Malcolm Campbell and the Research midwife.

[School of Nursing, Midwifery and Social Work, Jean McFarlane Building, University of Manchester, Oxford Road, M13 9PL, Manchester].

Please free to discuss this information with fellow colleagues (midwives). You can also contact the research team to answer further questions through the contacts provided above. If you would like to take part please fill the **consent form** provided.

Thank you for taking your time to read this information.

[Version1-20.06.2016]

Appendix 3.4: Consent and assent forms

Appendix 3.4A: Consent form – Mothers (18-19 years)

Study title: A pilot randomised controlled trial to explore Telephone Support Intervention as a means of supporting young mothers in the immediate postnatal period in Western Kenya

If you are happy to participate please complete and sign the consent form below.

(Please write your initials in the box as appropriate)

I confirm that I have read the attached information sheet (version1-20.06.2016) on the	
above study. I understand why the study is being conducted, and why I have been asked	
to take part.	
I have had the opportunity to consider the information and ask questions and had them	
answered to my understanding and satisfaction.	
I understand that by agreeing to participate, I will be allocated to either an <i>intervention</i>	
group or the usual care group, and that I will continue receiving the care I deserve in	
either of these groups.	
I understand that my participation in the study is voluntary and that I am free to	
withdraw at any time without giving a reason. I understand that if I choose to withdraw,	
this will not affect the care provided to me now and in the future.	
I understand that my data will remain confidential.	
I understand that the interviews will be audio-recorded.	
I agree to the use of anonymous quotes.	

I agree to take part in this study.

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

Appendix 3.4B: Assent form – Mothers (12-17 years)

Study title: A pilot randomised controlled trial to explore Telephone Support Intervention as a means of supporting young mothers in the immediate postnatal period in Western Kenya

If you are happy to participate in this study, please complete and sign the <u>assent form</u> <i>below.

(Please write your initials in the box as appropriate)

I confirm that I have read and understood the information leaflet (version1-	
20.06.2016) on the above study, and why the study is being conducted.	
I have had the opportunity to consider the information, ask questions and had the	
questions answered to my understanding and satisfaction.	
I understand that by agreeing to participate, I will be allocated to either an	
intervention group or the usual care group and that I will continue receiving the	
care I deserve in either of these groups.	
I understand that my participation in the study is voluntary, and that I am free to	
withdraw at any time without giving a reason. I understand that if I chose to	
withdraw, this will not affect the care provided to me now and in the future.	
I understand that my parent/guardian has been asked about my participation and	
has agreed to my participation in the study.	
I understand that the information I provide shall not be shared with anyone who is	
not involved in the research, unless my life or that of another person may be in	
danger.	
I understand that my data will remain confidential and stored safely for use by the	
research team only, and that it can be shared only through publications/written	
reports or presentations without any identification.	
I understand that the interviews will be audio-recorded.	
I agree to the use of illustrative quotes from my data without any identification	
(anonymous quotes).	

I agree to take part in this study

Name of Participant

Date

Signature

Name of Person taking consent

Date

Signature

Appendix 3.4C: Consent form – Parent/Guardian

Study title: A pilot randomised controlled trial to explore Telephone Support Intervention as a means of supporting young mothers in the immediate postnatal period in Western Kenya

If you would like your daughter to take part in this study, please complete and sign the consent form below.

(Please write your initials in the box as appropriate)

I confirm that I have read the attached information sheet (version1-20.06.2016) on the	
above study. I have had the opportunity to consider the information and ask questions	
and had these answered satisfactorily.	
I understand that my daughter's participation in the study is voluntary and that she is	
free to withdraw at any time without giving a reason, and that this will not deny her any	
form of care during the study period or in the future.	
I understand that by participating, my daughter will be allocated to either an <i>intervention</i>	
group or the usual care group, and that she will continue receiving appropriate care in	
either of these groups.	
I understand that adequate measures have been put in place in case my daughter	
experiences discomfort or is distressed during the study.	
I understand that the data will remain confidential.	
I understand that the interviews will be audio-recorded.	
I agree to the use of anonymous quotes.	

I agree to my daughter taking part in this study

Name of Parent/Guardian	Date	Signature
Name of Participant (Daughter)	Date	Signature
Name of Person taking consent	Date	Signature

Appendix 3.4D: Consent form – Midwives

Study Title: A pilot randomised controlled trial to explore Telephone Support Intervention as a means of supporting young mothers in the immediate postnatal period in Western Kenya

If you would like to take part in this study, please complete and sign the <u>consent</u> <u>form</u> below.

(Please write your initials in the box as appropriate)

I confirm that I have read the attached information sheet (version1-20.06.2016) on	
the above study. I have had the opportunity to consider the information and ask	
questions and had these answered satisfactorily.	
I understand that my participation in the study is voluntary and that I am free to	
withdraw at any time without giving a reason or to decline participating, and that this	
will not have any detrimental effect to anyone and/or myself. However, we will use	
the data you have provided even after withdrawal.	
I understand that my data will remain confidential.	
I understand that the interviews will be audio-recorded.	
I agree to the use of anonymous quotes.	

I agree to take part in this study

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

Appendix 3.5: Distress policy

Title: A pilot randomised controlled trial to explore Telephone Support Intervention as a means of supporting young mothers in the immediate postnatal period in Western Kenya

Has the participant reported any discomfort/distress?

If ves: Stop the interview and reassure the participant as necessary.

Ask: Possible causes of the distress? Feelings about the study? Any concern related to motherhood?

Action:

- Reassure the participant and provide support as necessary.
- Listen and show empathy.
- Report to the PI and document the incident in the field notebook (provide summary of the actions taken and outcome).
- Make follow up contact (telephone call) in the evening and the following day and provide assistance as necessary.

Does the participant appear distressed?

If yes: Stop the interview and reassure the participant.

- **Ask:** How the participant is feeling?
 - Coping with motherhood?

Explore possible causes of the distress? Feelings about the study? Any concern related to motherhood?

Action:

- A. Reassure the participant and provide support as necessary.
- B. Listen and show empathy.
- C. Refer to counselling department for further assistance.
- D. Remind about the contact persons for subsequent follow up (refer to the appropriate information sheet).
- E. Explore whether participant is experiencing challenges at home including any form of violence.
- F. If they wish to leave, offer to accompany them to the bus stop and pay their bus fare home.
- G. Make follow up contact (telephone call) in the evening and the following day and provide assistance as necessary. Involve family members with consent from the participant.
- H. Report to the PI and document the incident in the field notebook (provide summary of the actions taken and outcome).

Is the participant still distressed?

If ves, Ask: How the participant is feeling?

Action:

- I. Reassure and listen with empathy.
- J. Arrange for follow up including assessment for postnatal depression.
- K. Involve family members with consent from the participant.
- L. Ensure subsequent follow up (telephone contact) as necessary (every 2-3 days).
- M. Report to the PI and document the incident in the field notebook (provide summary of the actions taken and outcome).

Yes No

No



Date: ______Researcher: _____ [Version1-20.06.2016]

Yes

Study number: _____

Appendix 3.6: Ethical approval

Appendix 3.6A: Ethical approval letter from UREC (UoM)

MANCHESTER

of Manchester

Ref: ethics/16427

Mr Elijah Kirop School of Nursing, Midwifery & Social Work Jean McFarlane Building

24th October 2016

2rd Floor Christie Building The University of Manchester Oxford Road M13 9PL Tel: 0161 275 2206/2046 *Emoil: <u>research.ethics@manchester.ac.uk</u>*

Research Governance, Ethics and Integrity

Dear Elijah,

Research Ethics Committee 4

Study title: A pilot randomised controlled trial to explore Telephone Support Intervention as a means of supporting young mothers in the immediate postnatal period in Western Kenya (ref 16427)

I write to thank Tina Lavender for coming to meet the Committee on 28th September 2016. I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form and supporting documentation as submitted and modified in your email of 20th October and approved by the Committee.

This approval is effective for a period of five years. If the project continues beyond that period an application for amendment must be submitted for review. Likewise, any proposed changes to the way the research is conducted must be approved via the amendment process (see below). Failure to do so could invalidate the insurance and constitute research misconduct.

You are reminded that, in accordance with University policy, any data carrying personal identifiers must be encrypted when not held on a secure university computer or kept securely as a hard copy in a location which is accessible only to those involved with the research.

Reporting Requirements:

You are required to report to us the following:

- 1. Amendments
- 2. Breaches and adverse events
- 3. Notification of Progress/End of the Study

Feedback

It is our aim to provide a timely and efficient service that ensures transparent, professional and proportionate ethical review of research with consistent outcomes, which is supported by clear, accessible guidance and training for applicants and committees. In order to assist us with our aim, we would be grateful if you would give your view of the sheet from us by completing а feedback received that you have service [https://survey.manchester.ac.uk/pssweb/index.php/155676/lang-en]

We hope the research goes well.

Yours sincerely,

Timothy Shable

Dr T P C Stibbs Acting Secretary to University Research Ethics Committee 4

Appendix 3.6B: Ethical approval letter from MU/MTRH IREC





INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL P.O. BOX 3 ELDORET Tel: 33471//2/3 REC) MOI UNIVERSITY SCHOOL OF MEDICINE P.O. BOX 4606 ELDORET

2nd February, 2017

Reference: IREC/2016/209 Approval Number: 0001811

Mr. Kirop K. Elijah, Moi University, School of Nursing, P.O. Box 4606-30100, ELDORET-KENYA.



Dear Mr. Kirop,

RE: FORMAL APPROVAL

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

"A Pilot Randomized Controlled Trial to Explore Telephone Support Intervention as a Means of Supporting Youth Mothers in the Immediate Postnatal Period in Western Kenya".

Your proposal has been granted a Formal Approval Number: FAN: IREC 1811 on 2nd February, 2017. You are therefore permitted to begin your investigations.

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

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

Sincerely,

PROF. E. WERE CHAIRMAN INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

CC	CEO	4	MTRH	Dean	-	SOP	Dean	-	SOM
	Principal	•	CHS	Dean	-	SON	Dean	•	SOD

Appendix 3.6C: Ethical approval from KCGH ERC

Telegram: "PROVMED", Kakamega Telephone: Kakamega 056-30050/1/2 When replying, please quote:

ERC REF: cgh/kak/gen/30/(63)



COUNTY GENERAL HOSPITAL P. O. Box 15 - 50100 KAKAMEGA

04TH NOVEMBER 2016

COUNTY GENERAL HOSPITAL, KAKAMEGA ETHICS AND RESEARCH COMMITTE

MR. KIROP, K. ELIJAH

P.O. Box 4606,

ELDORET.

Dear Sir,

REF: RESEARCH PROPOSAL APPROVAL (01/11/2016)

This is to inform you that the Ethics and Research Committee has reviewed and approved your work titled "A pilot randomised controlled trial to explore telephone support intervention as a means of supporting young mothers in the immediate postnatal period in Western Kenya, CGH, Kakamega."

The approval is valid for 1 year from the above date and any continuation thereafter will necessitate a request for renewal.

Note that this approval is only for the work that you have submitted to us. The committee must be notified of any changes or amendments, and any serious or unexpected outcomes related to the study. You will be expected to submit a final report at the end of the study and may be requested to do a presentation of the same to the hospital.

This information will form part of the database that will be consulted in future when processing related research studies so as to minimize chances of study duplication.

Thank you for your interest in research in our institution.

Yours Faithfully, MUK

VEDICAL SUPERINTENDENT PROVINCIAL GENERAL HOSPITAL KAKAMEGA

P.WECHULI Ag. CHAIRMAN ETHICS AND RESEARCH COMMITTEE

CC. Medical Superintendent CGH KAKAMEGA

Appendix 3.7: Formal (acceptance) letter for research instruments translation



The University of Manchester, Research Ethics Committee, Manchester, Oxford Rd, M13 9PL, UK.

Dear Sir/Madam,

Your Ref:.

RE: TRANSLATION OF RESEARCH INSTRUMENTS

I have been requested by Elijah Kirop, who is pursuing his further studies in your institution (PhD in Midwifery) to translate the research instruments he intends to use to Swahili for ease of understanding and/or preference by the participants. I am a Swahili teacher at Moi High School, Kabarak (a top performing school in Kenya). As a teacher, and one who values education and research, I was delighted to do this exercise to enable him achieve his goals as he carries out his study. I have been involved in similar tasks before for corporate institutions in the country.

Please feel free to contact me on +254711969998 or by e-mail: john.njane@yahoo.com in case of any queries. I will be glad to respond.

Thank you.

Yours sincerely,

ne

John Njane Ngigi, Department of Kiswahili.

"Remember God your creator in the days of your youth..." (Ecc 12:1)

Date	Time	Торіс	Evaluation/Remarks
Day 1 2-3pm 11/01/2017 2		Overview of research designsoQuant/Qual.	
	3-4pm	 Ethical principles in research Confidentiality of data Beneficence/non-maleficence Anonymity of participants Respect for individual rights and opinions (participants) 	
	4-4.10pm 4.15-5pm	Break Recruitment of research participants • Consenting process • Review of PISs, and Consent/assent forms	
	4.45-5.00pm	Q&A session	
Day 2 12/01/17	2-3pm	Review of Day 1 Randomisation and Blinding	
	3-4pm	Data collection procedures • Quant. – use of questionnaires • Qual. – interviews and field notes Sensitisation on the use of Distress Policy • Review of the Distress policy	
	4-4.10pm	Break	
	4.15-4.45pm	Recap of whole content	
		Q/A session	

Appendix 3.8: Training programme for Research Assistants

	[Toleo 1-01.07.2016] Namb
Kipengele 3.2: Vyombo ya Utafiti	MANCHESTER 1824
Kipengele 3.2A: Hojaji (Kwa mama wachanga)
A1) MAELEZO YA KIBINAFSI:	
1. Umri (Miaka) 2. Uzazi 3. Makaa	zi:
4. Ndoa: Kwenye Ndoa Mseja	Tushatengana
Mjane Nimetalikiana [Naishi na mchumba
5. Dini: Mkatoliki Mprotestanti	Muislimu
Mhindu Nyingineyo	(Itaje)
6. Elimu: Shule ya Msingi Shule ya upili	Chuo 🔲 Hamna 🗔
7. Kazi: Nimeajiriwa Nimeajiriwa] Sina kazi
Mwanafunzi	
8. Uzani wa mtoto (gramu) 9. Jinsia ya N	Atoto: Mume Kike
10. Mara ya kutembelea Kliniki: Hamna 1 2	2 3 4 >4
11. Muda wa uja uzito wakati wa kutembelea kliniki (w	viki):
12. Namna ya uzazi: SVD	
13. Watu waliosaidia: Wazazi Mume (Ma))Rafiki 🔤 Hamna 🔄
14. Matatizo wakati wa uzazi:Ndio [(Taja)	La
15. Umbali wa Kliniki(Km): Chini ya Kilomita 5	Zaidi ya kilomita 5
16. Njia ya ujumbe unayopendelea: Ujumbe mfupi 🕅	Whatsapp
Yingine yeyote(Itaje)	
17. Namba ya simu:	

A2) USAIDIZI KWA MAMA WAJAWAZITO (Maternity Social Support Scale):

<u>Maagizo</u> : Kwa kila mojawapo ya kauli zifuatazo, weka alama($\sqrt{}$) kwa kijisaduku kimoja kinachoonyesha unavyohisi kuhusu msaada unaoupokea sasa hivi.

		Kila	Wakati	Wakati	Mara	Haitokei
Namb.	Kauli ya shina	wakati	mwingi	mwingine	chache	
	Nina marafiki wazuri					
1.	wanaonisaidia					
2.	Familia yangu hunifaa kila wakati					
	Mume wangu/mchumba hunisaidia					
3.	sana					
	Kuna mgogoro baina yangu na					
4.	mume/mchumba wangu					
	Nasihi kuwa mume/mchumba					
5.	wangu ananitawala					
	Nahisi kupendwa na					
6.	mume/chumba wangu					

A3) KUJIAMINI KWA MAMA MJAMZITO (Rosenberg self-esteem scale):

<u>Maagizo:</u> Ifuatayo ni orodha ya kauli sinazohusu hisia zako kujihusu kijumla. Tafadhali onyesha unavyokubaliana au kukataa inavyosema kila kauli kwa kuweka alama ($\sqrt{}$) katika kijisanduku kifaacho ilivyoonyeshwa.

Namb.	Kauli ya shina	Nakubali Kabisa	Nakubali	Sijaamua	Nakataa Kabisa
	Kijumla, nimeridhika nilivyo				
1	mwenyewe				
	Kuna wakati nahisi mimi si mzuri				
2	hata kidogo				
3	Nahisi kuwa nina sifa kadhaa nzuri				
	Ninaweza kufanya mambo vizuri				
4	kama watu wengine				
5	Nahisi bsina mengi ya kujivunia				
	Hakika nahisi nikiwa mtu bure				
6	wakati mwingine				
	Nahisi mimi ni mtu wa dhamani,				
	angalau kwa kiwango sawa na watu				
7	wengine				
	Natamani ningalikuwa				
8	nimejiheshimu zaidi				
	Kwa kila hali, nahisi kwamba mimi				
9	sifanyi vizuri				
10	Nakuwa na mtazamo mzuri kujihusu				
Jumla ya	Jumla ya Alama				

A4) MWINGILIANO WA MAMA NA MTOTO (*The Postpartum Bonding Instrument*): <u>Maagizo:</u> Tafadhali onyesha ni kwa mara ngapi haya ni kweli.Hakuna majibu ya "Ndio" au "La": chagua jibu linalolingana na hali ambayo umekuwa ukipitia.

au "La": chagua jibu inalolingan Kauli ya shina	Kila	Mara	Mara	Wakati	Mara	Haitokei
	wakati	nyingi	kwa	mwingine	chache	
			mara	_		
Nahisi nikiwa karibu na mtoto						
wangu						
Natamani kurudi kwa siku zile						
ambapo sikuwa na mtoto						
Nahisi nikiwa mbali na mtoto wangu						
Napenda kumkumbatia mtoto wangu						
Najuta kumpata mtoto huyu						
Mtoto haonekani kama ni wangu						
Mtoto wangu hunifanya nihisi						
nikiwa na wasiwasi						
Mtoto wangu huniudhi						
Nafurahia wakati mtoto wangu						
anatabasamu au kucheka						
Nampenda mtoto wangu kupindukia						
Mimi hufurahia kucheza na mtoto						
wangu						
Mtoto wangu hulia sana						
Nahisi kuwekwa mtegoni kama						
mama						
Nahisi kukasirishwa na mtoto						
Simpendi mtoto wangu						
Mtoto wangu ndiye mtoto maridadi						
zaidi duniani						
Natamani kwa namna fulani mtoto						
wangu angeondoka						
Nimefanya mambo ya kumdhuru						
mtoto wangu						
Mtoto wangu hunifanya niwe na						
wasiwasi	ļ					
Namwogopa mtoto wangu						
Mtoto wangu huniudhi	<u> </u>					
Nina ujasiri ninapombadilisha mtoto						
nguo	<u> </u>					
Nahisi suluhisho la pekee ni mtu						
mwingine kumtunza mtoto wangu	 			ļ		
Nahisi nikiwa na nia ya kumdhuru						
mtoto wangu	<u> </u>					
Mtoto wangu hufarijika kwa wepesi						

A5) KIWANGO CHA MSONGO WA MAWAZO BAADA YA UZAZI (Edinburgh Postnatal Depression Scale):

<u>Maagizo:</u> Ifuatayo ni orodha ya kauli inayohusiana na hisia zako kijumla siku chache baada ya kujifungua.Tafadhari angalia jibu linalokaribiana na ambavyo umekuwa ukihisi KWA SIKU SABA ZILIZOPITA(Isiwe unavyohi leo tu)kwa kuweka alama($\sqrt{}$)kwa kisanduku kifaacho ilivyoonyeshwa.

Siku saba zilizopita:

- 1. Nimeweza kucheza na kuona uzuri wa mambo
 - 🗌 Kadri nilivyoweza
 - □ Sio sana
 - 🗌 Bila shaka sio sana
 - 🗌 Haijatokea
- 2. Nimetazamia wakati nitakaoweza kufurahia mambo
 - 🗌 Kadri ya uwezo wangu
 - 🗌 Kuliko mwanzoni
 - 🗌 Bila shaka kuliko mwanzoni
 - 🗌 Haijatokea hata kidogo
- 3. Nimejilaumu bila sababu wakati mambo yamekwenda vibaya
 - 🗌 Ndio, mara nyingi
 - □ Ndio, wakati mwingine
 - 🗌 Sio kila wakati
 - 🗌 La, sijawahi
- 4. Nimekuwa na wasiwasi bila sababu yoyote
 - 🗌 La, haifanyiki kabisa
 - 🗌 Ni vigumu
 - ☐ Ndio, mara nyingine
 - 🗌 Ndio, mara kwa mara
- 5. Nimekuwa nikihisi woga bila sababu yoyote
 - 🗌 Ndio, sana sana
 - □ Ndio, wakati mwingine
 - 🗌 La, sio sana
 - 🗌 La, haitokei
- 6. Mambo yamekuwa yakinilemea
 - ☐ Ndio, Mara nyingi sijaweza kukabiliana na hali kabisa
 - 🗌 Ndio, wakati mwingine sijaweza kukabiliana na hali kama ilivyo kawaida
 - 🗌 La, wakati mwingi nimeweza kukabiliana na hali vizuri sana
 - 🗌 La, nimekuwa nikikabiliana na hali kama kawaida

- 7. Nimekuwa sina furaha hadi nakuwa na ugumu wa kulala
 - 🗌 Ndio, wakati mwingi
 - □ Ndio, wakati mwingine
 - 🗌 La, si mara nyingi
 - 🗌 La, haitokei kabisa

8. Nimekuwa na hisia za huzuni au kufadhaika

- □ Ndio, wakati mwingi
- □ Ndio, wakati mwingine
- 🗌 La, si mara nyingi
- 🗌 La, haitokei kabisa
- 9. Nimekuwa sina furaha kabisa hadi nimekuwa nikilia
 - 🗌 Ndio, wakati mwingi
 - 🗌 Ndio, mara kwa mara
 - 🗌 Mara moja moja tu
 - 🔲 La, haijakuwa hivyo
- 10. Mawazo ya kujidhuru yamenipitia kichwani
 - 🔲 Ndio, mara kwa mara
 - □ Wakati mwingine
 - 🗌 Ni vigumu kabisa
 - 🗌 Haijatokea

A6) HALI YA AFYA YA MAMA ALIYEJIFUNGUA NA PIA MWANAWE

<u>Maagizo:</u> Tafadhali onyesha ni kwa mara ngapi haya ni kweli.Hakuna majibu ya "Ndio" au "La": chagua jibu linalolingana na ambayo umekuwa ukipitia.

Kauli ya shina	Ndio	La
Umewahi kuwa na ugonjwa wowote tangu ulipojifungua?		
Umewahi jitibu kwa kununua dawa tangu ulipojifungua?		
Mtoto wako awewahi kuwa mgonjwa tangu ulipoachiliwa kutoka hospitalini?		
Umewahi kumpa mtoto wako dawa yoyote tangu ulipojifungua?		
Mtoto wako amepokea chanjo tangu alipozaliwa?		
Mtoto wako anapata maziwa ya titi vya kutosha?		
Ulikuwa na matatizo yoyote kunyonyesha?		
Umewahi kumpa mtoto wako chakula kingine? Na maji?		
Unatumia (unanuia kutumia) njia yoyote ya kupanga uzazi?		
Je, mtoto wako amekuwa na mabadiliko ya uzani?		
Kama jibu ni ndio, uzani wake wa majuzi zaidi ni? (Tafadhali onyesha hapa)		

Kipengele 3.2C: Maelekezo ya kuwahoji mama wachanga

Mada ya utafiti: Jaribio la kutathmini msaada wa kupitia simu kwa mama wachanga kipindi tu

baada ya kujifungua eneo la Magharibi mwa Kenya

MAAGIZO KWA MHOJAJI

- Jitambulishe na utambulishe mtafiti msaidizi kwa washiriki
- Elezea lengo la utafiti
- Toa hakikisho kwa mhojiwa kwamba usiri utadumishwa
- Pata ukubalifu wa mhojiwa kwa maadishi
- Usiandike jina la mhojiwa ili kudumisha usiri

1.	Unaweza kueleza vipi uliyopitia wakati wa kijifungua mtoto?
	Tathmini: Hisia kuhusu kujifungua; Uliyopitia kuhusu kujifungua; Maandalizi ya
	kujifungua
2.	Umekuwaje tangu ulipojifungua?
	Tathmini: Hisia baada ya kujifungua/kuwa na mtoto; Unayopitia kama
	mama(unyonyeshaji, kumtunza mtoto, afya ya kibinafsi)
3.	Ukitaza nyuma kwa wakati baada ya kujifungua, ulipata usaidizi wowote? Tafadhari
	elezea uliyopitia.
	Tathmini: Matarajio (kutoka kwa wahudumu wa afya/ familia/ mchumba/ marafiki ama
	wanahirimu)
4.	Na sasa, unadhani bado unahitaji usaidizi kama hapo kabla? Unahitaji usaidizi wa aina
	gani?
	Tathmini: Mtazamo wako uwezo wako binafsi; changamoto zilizoshuhudiwa (kama
	zipo)
5.	Kuhusu usaidizi wa simu uliopokea (iwapo ulifaa kupokea), ulipitia yepi (maoni yako ni
	yepi)? Unapendekeza nini kuhusu uboreshaji?
	Tathmini: Mtazamo kuhusu usaidizi wa simu
6.	Kutokana na uliyopitia, unawapendekezea nini mamawachanga kama wewe?
	Tathmini: Mapendekezo kwa wahudumu wa afya /familia/ mume
7.	Kuna jambo ambalo unadhani hatujahusisha katika mahojiano haya ambalo ni muhimu?

Ahsante kwa kushiriki katika mahojiano haya.

Kipengele 3.3: Fomu za taarifa kwa wanaoshiriki katika utafiti

Kipengele 3.3A: Fomu ya taarifa kwa anayeshiriki (Wamama-Miaka 18-19)

Mada ya utafiti: Jaribio la kutathmini msaada wa kupitia simu kwa mama wachanga kipindi tu

baada ya kujifungua eneo la Magharibi mwa Kenya

Karibisho

Unakaribishwa kushiriki katika utafiti huu wa kutathmini msaada wa kupitia simu kwa mama wachanga kipindi tu baada ya kujifungua.Kabla ya kufanya uamuzi, ni muhimu uelewe ni sababu gani utafiti huu unafanywa na utahusisha mambo gani.Tafadhali chukua muda kusoma taarifa ifutayo kwa makini na uijadili na wengine ukipenda(kama vile, jamaa zako au mkunga).Tafadhali uliza iwapo kuna jambo ambalo si wazi ama iwapo unahitaji maelezo zaidi(maelezo ya kuwasiliana nao yamewekwa kwa ukurasa wa mwisho wa fomu hii).Chukua muda kufanya uamuzi wa kushiriki au kutoshiriki katika huu utafiti.Asante sana kwa kutumia muda wako kusoma fomu hii ya maelezo.

Nani atafanya utafiti huu?

Utafiti huu utafanywa na kikosi cha watafiti ambao ni, Elijah K. Kirop, Prof. Dame Tina Lavender, Dkt. Rebecca Smyth na Dkt. Malcolm Campbell kutoka Chuo Kikuu cha Manchester, kilichoko University Place, barabara ya Oxford, M13 9PL, Manchester, Uingereza.

Nia ya utafiti huu ni ipi?

Wamama wachanaga wanahitaji kusaidiwa baada ya kujifungua ili kuwawezesha kukabiliana na changamoto za kujitunza na pia kumtunza mtoto ayilezaliwa baada kujifungua.Hata hivyo, usaidizi huu wakati mwingine huwa haupatikani, hasa baada ya mama kutoka hospitalini.Hivyo basi, utafiti huu unalenga kutathmini uwezekano na kukubalika kwa msaada wa kupitia simu(kupiga simu na ujumbe mfupi) kama namna ya kuwasaidia mama wachanga punde tu baada ya kujifungua ili kuboresha hali yao kimwili, kimawazo na ustawi kijamii.

Mbona nimechaguliwa mimi?

Wewe ni mama mchanga na tunafikiri kuwa unafaa sana kutusaidia katika utafiti wetu.Katika utafiti, utawekwa kwa kundi kupitia tarakilishi kuwa katika kikundi cha kawaida cha kupokea usaidizi (kitakachopokea usaidizi wa kiwango cha kawaida inavyohitajika na wizara ya afya) ama kwa kundi la kuingilia ili kusaidia wakati usaidizi unahitajika(litakalopokea usaidizi zaidi wa simu).Hii ni kwa nia ya kutusaidia kulinganisha maoni ya wamama wanaotumia usaidizi kwa njia ya simu na wale wanapata usaidizi kwa njia ya kawaida.Tungependa kuelewa maoni yako kuhusu kushiriki katika utafiti huu. Iwapo utafiti huu utaonyesha kuwa kuna uwezekano na ukubalifu na udhihirishe kufanikiwa miongoni mwa kina mama wachanga, tuliwazia suala la kupendekeza utafiti zaidi kubaini ufanisi wake ili kutoa hatua mwafaka kwa wanaoshughulikia afya.

Nitaulizwa kufanya nini nikishiriki?

Utaelezewa kuhusu nia ya utafiti na vilevile utapewa fomu ya maelezo kwa mshiriki (kijikaratasi hiki) na mtafiti au mmojawapo wa wanakikosi cha utafiti kabla ya kufanya uamuzi kushikiriki. Iwapo utakubali kushiriki, utahitajika kujaza hojaji ya kwanza inayohitaji maelezo ya kibinafsi, kama vile, umri, idadi ya watoto, taarifa ya uzazi na uzani wa mtoto pamoja na jinsia ya mtoto wako.

Kisha utapangiwa kwa tarakilishi (kama itakuwa hivyo) kuingia kwa a) kikundi cha kupokea usaidizi wa kiwango cha kawaida, au b) kikundi cha kupokea usaidizi zaidi. Hautaweza kujiamulia kikundi na hatutajua ni kikundi kipi utakachowekwa hadi baada yako kukubali kushiriki.

Kundi A: Utaendelea kupokea usaidizi wa kawaida hospitalini, jinsi ile ile ulivyoelezewa wakati wa kuachiliwa kutoka hospitalini baada ya kujifungua. Hii itajumuisha elimu ya afya kuhusu kumtunza mtoto wako na kujitunza mwenyewe, kuendelea na kuhudhuria kliniki ikiwepo mtoto kupewa chanjo na pia kutumia kijitabu cha Mama na Mtoto (kijitabu cha zambarau ulichotumia wakati wa kliniki kabla kujifungua). Kijitabu hiki bado kitakuwa cha manufaa wakati huu.

Kundi B: Utapokea usaidizi wa kiwango cha kawaida na na usaidizi wa ziada wa kupitia simu. Utapigiwa simu mara 3(baada ya wiki 3) na kwa ujumbe mfupi kila wiki kuanzia wiki ya 2 hadi wiki ya 10 baada ya kujufungua kwa msaada wa mkunga wa utafiti kupitia namba ya simu inayotumika tu kwa utafiti. Simu utakayopigiwa itakuwa ya muda wa dakika 10-15 kila mara. Hii kwa msingi itatoa taarifa ya kusaidia jinsi utakavyo msaidia mtoto na pia kujitunza wewe mwenyewe. Uko huru pia kuwasiliana na mkunga wa utafiti wakati wowote kwa usaidizi wowote wa kiafya katika kipindi hiki kupitia namba ya simu iliyopendekezwa.

Bila kujalisha kikundi ulichoko, utahitajika kujaza hojaji ya pili baada ya wiki ya 10 wakati wa chanjo ya pili ya mtoto. Hojaji itakuwa inachukua taarifa ,maoni yako na uliyopitia katika katika kiwango cha usaidizi uliopokea(ulivyohisi kwa usaidizi kijamii, kujiamini kwako, mwingiliani na mtoto wako).Utaulizwa pia kama utapenda kushiriki kwa hiari kwenye mjadala wa kikundi cha uzingatifu(focus group) au mahojiano ya kibinafsi yatakayodumu kwa muda baina ya dakika 30 hadi saa1. Kikundi cha uzingatifu kitajumuisha wamama wachanga 8 ambao pia walishiriki katika utafiti , ambapo mtashiriki kutoa maoni kuhusu utafiti(kiwango cha usaidizi mlichopokea).Unahimizwa kushiriki maoni yako na uliyopitia kwa njia huru na kujadiliana na watafiti wawili faragani na katika mazingira salama kwako na kwa mototo wakokatika kituo cha chajo. Hakuna majibu mazuri au mabaya. Ni jambo nzuri sana kujua maoni yako na kujadiliana nawe kuhusu utafiti.

Hapana hatari yoyote kwako kwa kushiriki katika utafiti huu. Hata hivyo, huenda ikawa utahisi kutopendezwa na suala la kuongea kuhusu maoni yako na hata uliyopitia kama mama mchanga. Hata hivyo, tunakuhakikishia kuwa kikosi cha utafiti kitazingatia utaratibu maalum kushughulikia hali ya kutopendezwa ambayo unaweza kuwa nayo na watajaribu sana kuepuka kusababisha hali ya kutopendezwa.Iwapo unahisi utahisi kutoridhika kabisa ama kukasirishwa na kushiriki katika utafiti, unaweza kuelekezwa kwa mshauri kwa usaidizi zaidi itokeapo haja. Watafiti hawatahisi kuudhika iwapo utaamua kusitisha mahojiano.

Ni nini hufanyika na data inayochukuliwa?

Habari itakayopatikana kutokana na huu utafiti itatumiwa kuboresha utunzaji wa wamama, kando na kuadika tasnifu ya uzamifu (*PhD thesis*) (Mwandishi – Elijah Kirop). Itatusaidia kujua uwezekano wa matumizi ya msaada wa simu kama namna ya kusaidia wamama wachanga na jinsi inaweza kujaribiwa kwa njia nzuri. Data itaonekana na tu na mtafiti na mkaguzi wake.

Je, usiri utadumishwaje?

Habari zote zitakazochukuliwa zitawekwa kwa siri kabisa. Data ya tarakilishi au kifaa chochote cha tarakilishi italindwa kwa kutumia namba ya siri. Data nyingine yoyote pia itahifadhiwa na kulindwa vizuri na kufungiwa katika afisi ya kiongozi wa uatafiti ambapo itakuwa imefungiwa kila wakati kwa kipindi cha miaka kumi ambapo baada ya hapo itatolewa na kuharibiwa.

Hatutakuuliza kuandika jina lako ama habari nyingine yoyote yakukutambulisha, hivyo itabaki bila kujulikana ni ya nani. Mahojiano ya sauti yatarekodiwa kupitia kifaa cha kurekodi sauti, itaharibiwa kwa kuifuta baada ya data kuadikwa kwenye maandishi. Kasha nakala zitaharibiwa pamoja na data nyingine iliyotajwa hapo awali. Hatutatumia nukuu zozote zinazoleta utambulisho wa data. Hatutatumia habari yoyote itakayofanya mtu yeyote kukujua katika wasilisho lolote ama ripoti iliyoandikwa kuhusu utafiti huu. Hata hivyo, hatuwezi kukupa hakikisho la usiri kabisa iwapo tutajua kuwa maisha yako au ya mtu mwingine yako hatarini katika harakati za utafiti kwani ni jukumu letu kuhakikisha kuwa hapatokei dhara kwa mtu mwingine yeyote.

Nini kifanyikacho kama sitaki kushiriki ama nibadilishe nia yangu?

Ni hiari yako kushiriki au kutoshiriki. Uamuzi wa kushiriki ni wa kujitakia. Iwapo utaamua kushiriki, utaulizwa kutia sahihi kwenye <u>fomu ya kukubali</u> utakayopewa. Iwapo utakubali kushiriki, una uhuru wa kusitisha ushiriki wako wakati wowote, bila kupeana sababu na hili halitaathiri usaidizi utakaopokea sasa na siku za usoni.

Je, nitalipwa kushiriki katika utafiti?

Kushiriki katika utafiti ni kwa kujitolea na hakuna malipo yoyote yatakayofanywa iwapo utashiriki. Hata hivyo, utarejeshewa pesa utakazotumia kwa usafiri wakati wa kipindi cha utafiti.

Je, utafiti utachukua muda gani?

Utafiti utaendelea kwa kipindi cha wiki 10, wakati ambao utaulizwa kujaza hojaji na kushiriki mahojiano ya kikundi au ya kibinafsi baada ya kuhudhuria kliniki.

Je, utafiti utafanyika wapi?

Utafiti utafanyika hospitalini ambako uliamua kujifungulia na kuhudhuria kliniki kila wakati.Wakati wa mahojiano, mahali pa faragha, salama na pazuri kwako na kwa mtoto wako patatatolewa katika kituo cha chajo(na kwa kina mama wengine watakaoshiriki).

Je, matokeo ya utafiti huu yatachapishwa?

Ndio, matokeo ya utafiti yatawasilishwa kupitia majarida na makongamano mwafaka. Hata hivyo, kila wakati tutahakikisha kwamba hakuna mtu anayetambulishwa katika tasnifu, ripoti, mawasilisho au machapisho.

Nani amehakiki utafiti huu?

Utafiti huu umehakikiwa na Kamati ya Nidhamu ya Utafiti Chuo Kikuu cha Manchester kwa ushirikiano na Kamati ya Nidhamu ya Utafiti wa Kitaasisi ya Chuo Kikuu cha Moi/Hospitali ya Mafunzo na Rufaa ya Moi Eldoret (Eldoret, Kenya).

Itakuwaje jambo likikwenda vibaya?

Hatutarajii tatizo kutokea kwenye utafiti huu. Hata hivyo, tunatoa hakikisho kuwa kikosi cha watafiti kitafuata taratibu kushughulikia hali tata ambazo zinaweza tokea kwako au kwa mama wachanga na tutahakikisha tutafanya juu chini kuepuka hali yoyote ya kuleta tatizo ama dhiki. Iwapo pana jambo lolote kuhusu utafiti huu ambalo halikufurahishi, tafadhari wasiliana na Mtafiti Mkuu, **BW. ELIJAH KIROP** kupitia **namba rasmi ya simu iliyopendekezwa kwa utafiti huu** (+254721222325) AU mkunga wa uatafiti kupitia namba rasmi ya simu itakayotumika kwa utafiti huu (+254 741796797) mara moja.

Na je, nikitaka kutoa malalamishi?

Iwapo una malalamishi, unahitaji kuwasiliana na watafiti bila kusita.

Malalamishi madogo

Iwapo pana jambo lolote kuhusu utafiti huu ambalo halikufurahishi, tafadhali wasiliana na Mtafiti Mkuu, **BW.ELIJAH KIROP** kupitia **namba rasmi ya simu iliyopendekezwa kwa utafiti huu** (+254721222325) au kwa baruapepe: <u>elijah.kirop@postgrad.manchester.ac.uk</u>. Vilevile unaweza kuwasiliana na mkunga wa uatafiti kupitia namba rasmi ya simu itakayotumika kwa utafiti huu (+254 741796797).

<u>Malalamishi Rasmi</u>

Iwapo utahitaji kutoa malalamishi rasmi au hujaridhika na majibu uliyopata kutoka kwa watafiti kwa mara ya kwanza, basi tafadhari wasilina na Kamati ya Nidhamu na Utafiti katika Hospitali(Kiongozi wa masuala ya kushughulikia watu) kupitia namba hii +254 787 723 677 na ujaze fomu ya malalamishi (Fomu ya kuripoti malalamishi ya utafiti) na kwa baruapepe hii irec@mtrh.or.ke au uitume kwa kupitia anwani zilizotolewa kwenye fomu. Unaweza pia wasiliana na mmojawapo wa wasimamizi (maelezo ya anwani yaliyotolewa mwishoni mwa fomu hii ya maelezo) AU Meneja wa Udhitibiti wa Uadilifu wa Utafiti, Afisi ya utafiti, Jumba la Christie, Chuo Kikuu cha Manchester, Barabara ya Oxford, Manchester, M13 9PL, kupitia baruapepe: research.complaints@manchester.ac.uk.

Malalamishi yoyote yatachukuliwaa kwa umakini sana.

Nifanye nini sasa?

Iwapo una maswali yoyote kuhusu utafiti huu au iwapo ungependa kushiriki, tafadhari wasiliana na watafiti. Mtafiti mkuu **ELIJAH KIROP anaweza kufikiwa kwa namba hii** +254721222325 **AU kwa baruapepe:** <u>elijah.kirop@postgrad.manchester.ac.uk</u>. Watafiti wengine wanaohusika katika utafiti ni: **Prof. Dame Tina Lavender, Dkt. Rebecca Smyth** na **Dkt. Malcolm Campbell** na **wakunga wa utafiti.**

[Shule ya Utabibu, Ukunga na kazi ya jamii, Jumba la Jean McFarlane, Chuo Kikuu cha Manchester, Barabara ya Oxford , M13 9PL, Manchester, Uingereza].

Tafadhali kuwa huru kujadili habari hii na wengine, familia yako au mkunga. Unaweza pia kuwasiliana na kikosi cha utafiti ili ujibiwe maswali mengine kupitia anwani zilizoolewa hapo juu. Iwapo ungependa kushiriki utafiti tafadhari jaza **fomu ya kukubali** utakayopewa.

Asante kwa kutumia muda kusoma habari hii. Mradi huu umeidhinishwa na Kamati ya Nidhamu ya Utafiti ya Chuo Kikuu cha Manchester [Namba ya marejeleo ya UREC 16427].

Kipengele 3.3B: Fomu ya Habari Kwa Mshiriki (Mama Wa Miaka - 12-17)

Nani amehakiki utafiti huu?

Utafiti huu umehakikiwa na Kamati va Nidhamu va Utafiti Chuo Kikuu cha Manchester kwa ushirikiano na Kamati ya Nidhamu ya Utafiti wa Kitaasisi ya Chuo Kikuu cha Moi/Hospitali ya Mafunzo na Rufaa ya Moi Eldoret (Eldoret, Kenya).

Itakuwaje jambo likikwenda vibaya?

Hatutarajii tatizo kutokea kwenye utafiti huu. Hata hinyo, tunatoa hakikisho kuwa kikosi cha watafiti kitafuata taratibu kushughulikia hali tata ambazo zinaweza tokea kwako au kwa mama wachanga na tutahakikisha tutafanya juu chini kuepuka hali vovote va kuleta tatizo ama dhiki. Iwapo pana iambo lolote kuhusu utafiti huu ambalo halikufurahishi, tafadhari wasiliana na Mtafiti Mkuu, BW. ELIJAH KIROP kupitia namba rasmi ya simu iliyopendekezwa kwa utafiti huu (+254721222325) AU mkunga wa uatafiti kupitia namba rasmi ya simu itakayotumika kwa utafiti huu (+254 741796797) mara moja.

Na je, nikitaka kutoa malalamishi?

lwapo una malalamishi, unahitaji kuwasiliana na watafiti bila kusita.

Malalamishi madoqo

lwapo pana jambo lolote kuhusu utafiti huu ambalo halikufurahishi, tafadhari wasiliana na Mtafiti Mkuu, BW.ELIJAH KIROP kupitia namba rasmi ya simu ilivopendekezwa kwa utafiti huu (+254721222325) au kwa baruapepe: elijah.kirop@postgrad.manchester.ac.uk. Vilevile unaweza kuwasiliana na mkunga wa uatafiti kupitia namba rasmi ya simu itakayotumika kwa utafiti huu (+254 741796797).

Malalamishi Rasmi

lwapo utahitaji kutoa malalamishi rasmi au hujaridhika na majibu uliyopata kutoka kwa watafiti kwa mara ya kwanza, basi tafadhari wasilina na Kamati va Nidhamu na Utafiti katika Hospitali(Kiongozi wa masuala ya kushughulikia watu) kupitia namba hii +254 787 723 677 na ujaze fomu ya malalamishi (Fomu va kuripoti malalamishi va utafiti) na kwa baruapepe hii irec@mtrh.or.ke au uitume kwa kupitia anwani zilizotolewa kwenye fomu.

Unaweza pia wasiliana na mmojawapo wa wasimamizi (maelezo ya anwani yaliyotolewa mwishoni mwa fomu hii ya maelezo) AU Meneia wa Udhitibiti wa Uadilifu wa Utafiti. Afisi va utafiti. Jumba la Christie. Chuo Kikuu cha Manchester. Barabara ya Oxford, Manchester, M13 9PL, kupitia baruapepe: research.complaints@manchester.ac.uk.

Malalamishi yoyote yatachukuliwaa kwa umakini sana.

Nifanye nini sasa?

lwapo una maswali vovote kuhusu utafiti huu au iwapo ungependa kushiriki, tafadhari wasiliana na watafiti. Mtafiti mkuu ELIJAH KIROP anaweza kufikiwa kwa namba hii +254721222325 AU kwa baruapepe: Watafiti wengine waliojumuishwa kwa mradi huu wa utafiti ni: Prof. Dame Tina Lavender, Dkt. Rebecca Smyth na Dkt. Malcolm Campbell na wakunga wa utafiti.

[Shule va Utabibu, Ukunga na kazi va jamii, Jumba la Jean McFarlane, Chuo Kikuu cha Manchester, Barabara ya Oxford . M13 9PL. Manchester. Uingerezal.

Tafadhali kuwa huru kujadili habari hii na wengine, familia yako au mkunga. Unaweza pia kuwasiliana na kikosi cha utafiti ili ujibiwe maswali mengine kupitia anwani zilizotolewa hapo juu.





Mradi huu umeidhinishwa na Kamati ya Nidhamu ya Utafiti ya Chuo Kikuu cha Manchester [Namba ya marejeleo ya UREC 16427].

Asante kwa muda wako wa kusoma habari hii.

FOMU YA HABARI KWA KINA MAMA WACHANGA



Mada ya utafiti Jaribio la kutathmini msaada wa kupitia simu kwa mama wachanga kipindi tu baada ya kujifungua eneo la Magharibi mwa Kenya

Karibisho

Unakaribishwa kushiriki katika utafiti huu wa kutathmini msaada wa kupitia simu kwa mama wachanga kipindi tu baada va kujifungua.Kabla va kufanva uamuzi, ni muhimu uelewe ni sababu gani utafiti huu unafanywa na utahusisha mambo gani.Tafadhali chukua muda kusoma taarifa ifutayo kwa makini na uijadili na wengine ukipenda(kama vile, jamaa zako au mkunga). Tafadhali uliza iwapo kuna iambo ambalo si wazi ama iwapo unahitaji maelezo zaidi(maelezo ya kuwasiliana nao vamewekwa kwa ukurasa wa mwisho wa fomu hii).Chukua muda kufanya uamuzi wa kushiriki au kutoshiriki katika huu utafiti.Asante sana kwa kutumia muda wako kusoma fomu hii va maelezo.

Nani atafanya utafiti huu?

Utafiti huu utafanywa na kikosi cha watafiti ambao ni, Elijah K. Kirop, Prof. Dame Tina Lavender, Dkt. Rebecca Smyth na Dkt. Malcolm Campbell kutoka Chuo Kikuu cha Manchester. kilichoko University Place, barabara ya Oxford, M13 9PL, Manchester, Uingereza.

Nia ya utafiti huu ni ipi?

Wamama wachanaga wanahitaji kusaidiwa baada ya kujifungua ili kuwawezesha kukabiliana na changamoto za kujitunza na pia kumtunza mtoto ayilezaliwa baada kujifungua.Hata hivyo, usaidizi huu wakati mwingine huwa haupatikani, hasa baada ya mama kutoka hospitalini.Hivyo basi, utafiti huu unalenga kutathmini uwezekano na kukubalika kwa msaada wa kupitia simu(kupiga simu na ujumbe mfupi) kama namna ya kuwasaidia mama wachanga punde tu baada ya kujifungua ili kuboresha hali yao kimwili, kimawazo na ustawi kijamii.

Mbona nimechaguliwa mimi?

Wewe ni mama mchanga na tunafikiri kuwa unafaa sana kutusaidia katika utafiti wetu.Katika utafiti, utawekwa kwa kundi kupitia tarakilishi kuwa katika kikundi cha kawaida cha kupokea usaidizi (kitakachopokea usaidizi wa kiwango cha kawaida inavyohitajika na wizara ya afya) ama kwa kundi la kuingilia ili kusaidia wakati usaidizi unahitajika(litakalopokea usaidizi zaidi wa simu).Hii ni kwa nia ya kutusaidia kulinganisha maoni ya wamama wanaotumia usaidizi kwa njia ya simu na wale wanapata usaidizi kwa njia ya kawaida.Tungependa kuelewa maoni yako kuhusu kushiriki katika utafiti huu. Iwapo utafiti huu utaonyesha kuwa kuna uwezekano na ukubalifu na udhihirishe kufanikiwa miongoni mwa kina mama wachanga, tuliwazia suala la kupendekeza utafiti zaidi kubaini ufanisi wake ili kutoa hatua mwafaka kwa wanaoshughulikia afya.

Nitaulizwa kufanya nini nikishiriki?

Utaelezewa kuhusu nia ya utafiti na vilevile utapewa fomu ya maelezo kwa mshiriki (kijikaratasi hiki) na mtafiti au mmojawapo wa wanakikosi cha utafiti kabla ya kufanya uamuzi kushikiriki. Iwapo utakubali kushiriki, utahitajika kujaza hojaji ya kwanza inayohitaji maelezo ya kibinafsi, kama vile, umri, idadi ya watoto, taarifa ya uzazi na uzani wa mtoto pamoja na jinsia ya mtoto wako.

Kisha utapangiwa kwa tarakilishi (kama itakuwa hivyo) kuingia kwa a) kikundi cha kupokea usaidizi wa kiwango cha kawaida, au b) kikundi cha kupokea usaidizi zaidi. Hautaweza kujiamulia kikundi na hatutajua ni kikundi kipi utakachowekwa hadi baada yako kukubali kushiriki.

Kundi A: Utaendelea kupokea usaidizi wa kawaida hospitalini, jinsi ile ile ulivyoelezewa wakati wa kuachiliwa kutoka hospitalini baada ya kujifungua. Hii itajumuisha elimu ya afya kuhusu kumtunza mtoto wako na kujitunza mwenyewe, kuendelea na kuhudhuria kliniki ikiwepo mtoto kupewa chanjo na pia kutumia kijitabu cha Mama na Mtoto (kijitabu cha zambarau ulichotumia wakati wa kliniki kabla kujifungua). Kijitabu hiki bado kitakuwa cha manufaa wakati huu.

Kundi B: Utapokea usaidizi wa kiwango cha kawaida na na usaidizi wa ziada wa kupitia simu. Utapigiwa simu mara 3

(baada ya wiki 3) na kwa ujumbe mfupi kila wiki kuanzia wiki ya 2 hadi wiki ya 10 baada ya kujufungua kwa msaada wa mkunga wa utafiti kupitia namba ya simu inayotumika tu kwa utafiti. Simu utakayopigiwa itakuwa ya muda wa dakika 10-15 kila mara. Hii kwa msingi itatoa taarifa ya kusaidia jinsi utakavyo msaidia mtoto na pia kujitunza wewe mwenyewe. Uko huru pia kuwasiliana na mkunga wa utafiti wakati wowote kwa usaidizi wowote wa kiafya katika kipindi hiki kupitia namba ya simu iliyopendekezwa.

Bila kuialisha kikundi ulichoko, utahitaiika kuiaza hojaji va pili baada ya wiki ya 10 wakati wa chanjo ya pili ya mtoto. Hojaji itakuwa inachukua taarifa ,maoni yako na uliyopitia katika katika kiwango cha usaidizi uliopokea(ulivyohisi kwa usaidizi kijamij, kujiamini kwako, mwingiliani na mtoto wako).Utaulizwa pia kama utapenda kushiriki kwa hiari kwenye mjadala wa kikundi cha uzingatifu(focus group) au mahojiano ya kibinafsi yatakayodumu kwa muda baina ya dakika 30 hadi saa1. Kikundi cha uzingatifu kitajumuisha wamama wachanga 8 ambao pia walishiriki katika utafiti , ambapo mtashiriki kutoa maoni kuhusu utafiti(kiwango cha usaidizi mlichopokea).Unahimizwa kushiriki maoni vako na ulivopitia kwa nija huru na kujadiliana na watafiti wawili faragani na katika mazingira salama kwako na kwa mototo wakokatika kituo cha chajo. Hakuna majibu mazuri au mabaya. Ni jambo nzuri sana kujua maoni vako na kujadiliana nawe kuhusu utafiti.

Hapana hatari yoyote kwako kwa kushiriki katika utafiti huu. Hata hivyo, huenda ikawa utahisi kutopendezwa na suala la kuongea kuhusu maoni yako na hata uliyopitia kama mama mchanga. Hata hivyo, tunakuhakikishia kuwa kikosi cha utafiti kitazingatia utaratibu maalum kushughulikia hali ya kutopendezwa ambayo unaweza kuwa nayo na watajaribu sana kuepuka kusababisha hali ya kutopendezwa.lwapo unahisi utahisi kutoridhika kabisa ama kukasirishwa na kushiriki katika utafiti, unaweza kuelekezwa kwa mshauri kwa usaidizi zaidi itokeapo haja. Watafiti hawatahisi kuudhika iwapo utaamua kusitisha mahojiano.

Ni nini hufanyika na data inayochukuliwa?

Habari itakayopatikana kutokana na huu utafiti itatumiwa kuboresha utunzaji wa wamama, kando na kuadika tasnifu ya uzamifu (*PhD thesis*) (Mwandishi – Elijah Kirop). Itatusaidia kujua uwezekano wa matumizi ya msaada wa simu kama namna ya kusaidia wamama wachanga na jinsi inaweza kujaribiwa kwa njia nzuri. Data itaonekana na tu na mtafiti na mkaguzi wake.

Je, usiri utadumishwaje?

Habari zote zitakazochukuliwa zitawekwa kwa siri kabisa. Data ya tarakilishi au kifaa chochote cha tarakilishi italindwa kwa kutumia namba ya siri. Data nyingine yoyote pia itahifadhiwa na kulindwa vizuri na kufungiwa katika afisi ya kiongozi wa uatafiti ambapo itakuwa imefungiwa kila wakati kwa kipindi cha miaka kumi ambapo baada ya hapo itatolewa na kuharibiwa.

Hatutakuuliza kuandika jina lako ama habari nyingine yoyote yakukutambulisha, hivyo itabaki bila kujulikana ni ya nani. Mahojiano ya sauti yatarekodiwa kupitia kifaa cha kurekodi sauti, itaharibiwa kwa kuifuta baada ya data kuadikwa kwenye maandishi. Kasha nakala zitaharibiwa pamoja na data nyingine iliyotajwa hapo awali. Hatutatumia nukuu zozote zinazoleta utambulisho wa data. Hatutatumia habari yoyote itakayofanya mtu yeyote kukujua katika wasilisho lolote ama ripoti iliyoandikwa kuhusu utafiti huu. Hata hivyo, hatuwezi kukupa hakikisho la usiri kabisa iwapo tutajua kuwa maisha yako au ya mtu mwingine yako hatarini katika harakati za utafiti kwani ni jukumu letu kuhakikisha kuwa hapatokei dhara kwa mtu mwingine yeyote.

Nini kifanyikacho kama sitaki kushiriki ama nibadilishe nia yangu?

Ni hiari yako kushiriki au kutoshiriki. Uamuzi wa kushiriki ni wa kujitakia. Iwapo utaamua kushiriki, utaulizwa kutia sahihi kwenye **fomu ya kukubali** utakayopewa. Iwapo utakubali kushiriki, una uhuru wa kusitisha ushiriki wako wakati wowote, bila kupeana sababu na hili halitaathiri usaidizi utakaopokea sasa na siku za usoni.

Je, nitalipwa kushiriki katika utafiti?

Kushiriki katika utafiti ni kwa kujitolea na hakuna malipo yoyote yatakayofanywa iwapo utashiriki. Hata hivyo, utarejeshewa pesa utakazotumia kwa usafiri wakati wa kipindi cha utafiti.

Je, utafiti utachukua muda gani?

Utafiti utaendelea kwa kipindi cha wiki 10, wakati ambao utaulizwa kujaza hojaji na kushiriki mahojiano ya kikundi au ya kibinafsi baada ya kuhudhuria kliniki.

Je, utafiti utafanyika wapi?

Utafiti utafanyika hospitalini ambako uliamua kujifungulia na kuhudhuria kliniki kila wakati.Wakati wa mahojiano, mahali pa faragha, salama na pazuri kwako na kwa mtoto wako patatatolewa katika kituo cha chajo(na kwa kina mama wengine watakaoshiriki).

Je, matokeo ya utafiti huu yatachapishwa?

Ndio, matokeo ya utafiti yatawasilishwa kupitia majarida na makongamano mwafaka. Hata hivyo, kila wakati tutahakikisha kwamba hakuna mtu anayetambulishwa katika tasnifu, ripoti, mawasilisho au machapisho.

Kipengele 3.3C: Fomu ya Habari kwa Mshiriki (Mzazi/Mlezi)

Mada ya utafiti: Jaribio la kutathmini msaada wa kupitia simu kwa mama wachanga kipindi tu baada ya kujifungua eneo la Magharibi mwa Kenya

Karibisho

Unakaribishwa kutoa ruhusa kwa binti yako kushiriki katika utafiti huu wa kutathmini msaada wa kupitia simu kwa mama wachanga kipindi tu baada ya kujifungua.Kabla ya kufanya uamuzi, ni muhimu uelewe ni sababu gani utafiti huu unafanywa na utahusisha mambo gani.Tafadhali chukua muda kusoma taarifa ifutayo kwa makini na uijadili na wengine ukipenda(kama vile, jamaa zako au mkunga).Tafadhali uliza iwapo kuna jambo ambalo si wazi ama iwapo unahitaji maelezo zaidi(maelezo ya utakaowasiliana nao yamewekwa yamewekwa kwa ukurasa wa mwisho wa fomu hii).Chukua muda kufanya uamuzi wa kushiriki au kutoshiriki katika huu utafiti.Asante sana kwa kutumia muda wako kusoma fomu hii ya maelezo.

Nani atafanya utafiti huu?

Utafiti huu utafanywa na kikosi cha watafiti ambao ni, Elijah K. Kirop, Prof. Dame Tina Lavender, Dkt. Rebecca Smyth na Dkt. Malcolm Campbell kutoka Chuo Kikuu cha Manchester, kilichoko University Place, barabara ya Oxford, M13 9PL, Manchester, Uingereza.

<u>Nia ya utafiti huu ni ipi?</u>

Wamama wachanaga wanahitaji kusaidiwa baada ya kujifungua ili kuwawezesha kukabiliana na changamoto za kujitunza na pia kumtunza mtoto ayilezaliwa baada kujifungua.Hata hivyo, usaidizi huu wakati mwingine huwa haupatikani, hasa baada ya mama kutoka hospitalini.Hivyo basi, utafiti huu unalenga kutathmini uwezekano na kukubalika kwa msaada wa kupitia simu(kupiga simu na ujumbe mfupi) kama namna ya kuwasaidia mama wachanga punde tu baada ya kujifungua ili kuboresha hali yao kimwili, kimawazo na ustawi kijamii.

Mbona nimechaguliwa mimi?

Binti yako ni mama mchanga na tungependa atusaidie katika utafiti wetu(pamoja na mama wachanga wengine).Katika utafiti, binti yako atawekwa kwa kundi kupitia tarakilishi kuwa katika kikundi cha kawaida cha kupokea usaidizi (kitakachopokea msaada wa kiwango cha kawaida cha usaidizi inavyohitajika na wizara ya afya)ama kwa kikundi cha kuingilia ili kusaidia wakati usaidizi unahitajika(litakalopokea usaidizi zaidi kupitia simu).Hii ni kwa nia ya kutusaidia kulinganisha maoni ya wamamavwanaotumia usaidizi kwa njia ya simu na wale wanapata usaidizi kwa njia ya kawaida.Tungependa kujua maoni yake kuhusu kushiriki katika utafiti huu.Hivyo, tumekuchagua wewe kama mzazi/mlezi ili umruhusu binti yako kushiriki katika utafiti huu. Iwapo utafiti huu utaonyesha kuwa kuna uwezekano na ukubalifu na udhihirishe kufanikiwa miongoni mwa kina mama wachanga, tutaliwazia suala la kupendekeza utafiti zaidi kubaini ufanisi wake ili kutoa hatua mwafaka kwa wanaoshughulikia afya.

Nitaulizwa kufanya nini iwapo binti yangu atashiriki?

Utaelezewa kuhusu nia ya utafiti na vilevile utapewa fomu ya maelezo kwa mshiriki (kijikaratasi hiki) na mtafiti au mmojawapo wa wanakikosi cha utafiti kabla ya kufanya uamuzi kumruhusu bintiyo kushikiriki. Pia utafahamishwa kuhusu utafiti (*soma maelezo ya ushiriki katika fomu ya habari*).

Mama wachanga wakaopokea usaidizi wa kuingilia ili kusaidia watapigiwa simu mara 3(baada ya wiki 3) na kwa ujumbe mfupi kila wiki kuanzia wiki ya 2 hadi wiki ya 10 baada ya kujifungua kwa msaada na atakayewasiliana ni mkunga wa utafiti kupitia namba ya simu inayotumika tu kwa utafiti. Usaidizi huu utatoa habari muhimu za usaidizi kuhusu jinsi ya mama kumtunza mtoto na pia yeye mwenyewe kiafya.Vile vile, wataendelea kupokea usaidizi wa kawaida hospitalini. Hii itajumuisha elumu ya afya kuhusu kuntunza mtoto wake na kujitunza mwenyewe, kuendelea na kuhudhuria kliniki ikiwepo mtoto kupewa chanjo. Unahimizwa pia kutumia kijitabu cha Mama na Mtoto (kijitabu cha zambarau walichotumia wakati wa kliniki kabla kujifungua) na kuwasiliana na kituo cha afya kilicho karibu kama watahitaji msaada wa haraka wa kimatibabu au wapigie mkunga wa utafiti simu.Kijitabu hiki bado kitakuwa cha manufaa katika kipindi hiki.

Kama mzazi/mlezi, tunakuhimiza pia kumruhusu binti yako kuwasiliana na mkunga wa utafiti kwa njia huru hasa kwa simu ama kupitia njia nyingine palipo na haja ya msaada wa kiafya wakati wa kipindi hiki (namba za mawasiliano zimetolewa mwishoni mwa fomu hii ya habari).

Kwa mama wachanga ambao hawatashiriki kwenye njia ya kuingilia ili kusaidia, wataendelea kupokea msaada wa kawaida hospitalini kama inavyohitajika, ambapo pia itajumuisha elimu ya afya ya kumtunza mtoto na kujitunza mwenyewe na pia kuendelea kuenda kliniki ikiwepo chanjo kwa mtoto.

Mwishoni mwa wiki ya 10 wakati wa chanjo ya pili ya mtoto watahitajika kujaza hojaji . Hojaji itakuwa itakuwa inachukua habari kuhusu maoni yao na waliyopitia katika katika kiwango cha usaidizi waliopokea. Pia wataulizwa kama watapenda kushiriki kwa hiari kwenye mjadala wa kikundi cha uzingatifu (*focus group*) au mahojiano ya kibinafsi yatakayodumu kwa muda baina ya dakika 30 hadi saa1. Kikundi cha uzingatifu kitajumuisha wamama wachanga 8 ambao pia walishiriki katika utafiti, ambapo watashiriki kutoa maoni kuhusu utafiti. Mahojiano yatarekodiwa sauti ili yasaidie kuandikwa kwa maneno baadaye katika utafiti. Tungependa kujua maoni yao na waliyopitia kama mama wachanga na pia kama washiriki wa utafiti huu.Gharama za usafiri zitafidiwa kwa kwa kina mama walioshiriki mahojiano.

Hapana hatari kwa kina mama akiwemo binti yako kushiriki katika utafiti huu. Hata hivyo, tunaelewa huenda ikawa wakati mwingine watahisi kutopendezwa na suala la kuongea kuhusu maoni yao na hata waliyopitia kama mama mchanga. Hata hivyo, tunakuhakikishia kama mzazi/mlezi kuwa kikosi cha utafiti kitazingatia utaratibu maalum kushughulikia hali ya kutopendezwa ambayo inaweza kutokea na tutajaribu kabisa kuepuka kusababisha kutoridhika. Zaidi, watafahamishwa kuwa watakapo hisi kutoridhika, si lazima wajibu, wanaruhusiwa kusitisha mahojianao wakati wowote. Ikitokea kwamba watafiti watatambua yeyote miongoni mwao anadhiki sana kwa kushiriki katika utafiti ama vinginevyo, watatumia utathmini wa kimatitabu kutoa usaidizi ikiwepo kutumwa kwa kuangaliwa zaidi panapofaa. Iwapo tukio kama

hilo litapatikana, watafiti wanalazimika kusimamisha mahojiano na watoe usaidizi inavyohitajika.

Iwapo utakubali binti yako ashiriki katika utafiti huu, utahitajika kutia sahihi kwenye <u>fomu ya</u> <u>ruhusa</u>. Binti yako pia atapewa fomu tofauti kuhusu utafiti huu. Iwapo atakubali kushiriki, ataulizwa kutia sahihi <u>fomu ya kukubali</u> na ajaze hojaji fupi inayochukua habari kuhusu mambo yake ya kibinafsi, kama vile umri, idadi ya watoto, habari ya uzazi na uzani pamoja na jinsia ya mtoto wake.

Ni nini hufanyika kwa data inayochukuliwa?

Habari itakayopatikana kutokana na utafiti huu itatumiwa kuboresha utunzaji wa wamama, kando na kuadika tasnifu ya uzamifu (*PhD thesis*) (Mwandishi – Elijah Kirop). Itatusaidia kujua uwezekano wa matumizi ya msaada wa simu kama namna ya kusaidia wamama wachanga na jinsi inaweza kujaribiwa kwa njia nzuri.

Je, usiri utadumishwaje?

Habari zote zitakazochukuliwa zitawekwa kwa siri kabisa. Data ya tarakilishi au kifaa chochote cha kielektroniki italindwa kwa kutumia namba ya siri.Data nyingine yoyote pia itahifadhiwa na kulindwa vizuri na kufungiwa katika afisi ya kiongozi wa utafiti ambapo itakuwa imefungiwa kila wakati kwa kipindi cha miaka 10 ambapo baada ya hapo itatolewa na kuharibiwa.

Hatutakuuliza kuandika jina lako ama habari nyingine yoyote yakukutambulisha, hivyo itabaki bila kujulikana ni ya nani. Mahojiano ya sauti yatakayorekodiwa kupitia kifaa cha kurekodi sauti, itaharibiwa kwa kuifuta baada ya data kuadikwa kwenye maandishi. Kisha nakala zitaharibiwa pamoja na data nyingine iliyotajwa hapo awali. Hatutatumia nukuu zozote zinazoleta utambulisho wa data. Hatutatumia habari yoyote itakayofanya mtu yeyote kukujua katika wasilisho lolote ama ripoti iliyoandikwa kuhusu utafiti huu. Hata hivyo, hatuwezi kukupa hakikisho la usiri kabisa iwapo tutajua kuwa maisha yako au ya mtu mwingine yako hatarini katika harakati za utafiti kwani ni jukumu letu kuhakikisha kuwa hapatokei dhara kwa mtu mwingine yeyote.

Itakuwaje iwapo binti yangu hataki kushiriki au kama atabadilisha nia yake?

Ushiriki wa binti yako ni wa hiari. Iwapo ataamua kushiriki, ataulizwa kutia sahihi kwenye <u>fomu</u> <u>ya kukubali</u> atakayopewa (miaka 12-17).Iwapo utakubali ashiriki katika utafiti, pia nawe utahitajika kutia sahihi kwenye <u>fomu ya ruhusa</u> utakayopewa. Hata hivyo, binti yako angali na uhuru wa kujiondoa kutoka kwa utafiti wakati wowote, bila kupeana sababu na hili halitaathiri usaidizi ambao atapokea sasa ama siku za usoni.

Je, mimi au binti yangu tutalipwa kushiriki katika utafiti?

Kushiriki katika utafiti ni kwa kujitolea na hakuna malipo yoyote yatakayofanywa iwapo utashiriki. Hata hivyo, binti yako atarejeshewa pesa atakazotumia kwa usafiri wakati wa kipindi cha utafiti.

Je, utafiti utachukua muda gani?

Utafiti utaendelea kwa kipindi cha wiki 10. Iwapo binti yako atakuwa kwenye kikundi cha kuingilia kati kusaidia, atapokea simu za usaidizi katika wiki ya 3, 6 na 9; na arafa ya kila wiki hadi wiki ya kumi, wakati ambao ataulizwa kujaza hojaji na kushiriki mahojiano ya kikundi au ya kibinafsi baada ya kupokea usaidizi hospitalini.Tunakuhimiza hivyo basi kuhakikisha

kwamba anaweza kuwa na simu kila wakati na aifikie kwa uhuru. Kama atakuwa kwenye kundi la usaidizi wa kawaida, atapokea usaidizi kama ilivyoratibiwa na ataulizwa kujaza hojaji iyo hiyo na kushiriki katika mahojiano. Mahojiano yatadumu kwa muda baina ya dakika 30 hadi saa1.

Je, utafiti utafanyika wapi?

Utafiti utafanyika hospitalini ambako binti yako alijifungulia na kuhudhuria kliniki kila wakati. Wakati wa mahojiano, mahali pa faraga, salama na pazuri kwake na kwa mtoto wake patatatolewa katika kituo cha chanjo (na kwa kina mama wengine watakaoshiriki).

Je, matokeo ya utafiti huu yatachapishwa?

Ndio, matokeo ya utafiti yatawasilishwa kupitia majarida na makongamano mwafaka. Hata hivyo, kila wakati tutahakikisha kwamba hakuna mtu anayetambulishwa katika tasnifu, ripoti, mawasilisho au machapisho.

Nani amehakiki utafiti huu?

Utafiti huu umehakikishwa na Kamati ya Nidhamu ya Utafiti Chuo Kikuu cha Manchester kwa ushurikiano na Kamati ya Nidhamu ya Utafiti wa Kitaasisi ya Chuo Kikuu cha Moi/Hospitali ya mafunzo na rufaa ya Moi Eldoret(Eldoret, Kenya).

Itakuwaje jambo likikwenda vibaya?

Hatutarajii tatizo kutokea kwenye utafiti huu. Hata hinyo, tunatoa hakikisho kuwa kikosi cha watafiti kitafuata taratibu kushughulikia hali tata ambazo zinaweza tokea kwako au kwa mama wachanga na tutahakikisha tutafanya juu chini kuepuka hali yoyote ya kuleta tatizo ama dhiki. Iwapo pana jambo lolote kuhusu utafiti huu ambalo halikumfurahisha binti yako, ako huru kuwasiliana na Mtafiti Mkuu, **BW. ELIJAH KIROP** kupitia **namba rasmi ya simu iliyopendekezwa kwa utafiti huu** (+254 721 222325) AU mkunga wa utafiti kupitia namba rasmi ya simu itakayotumika kwa utafiti huu (+254 741 796797) mara moja.

Na je, nikitaka/atake kutoa malalamishi?

Iwapo una malalamishi, unahitaji kuwasiliana na watafiti bila kusita.

<u>Malalamishi madogo</u>

Iwapo pana jambo lolote kuhusu utafiti huu ambalo halikufurahishi au halimfurahishi binti yako, tafadhali wasiliana na Mtafiti Mkuu, **BW.ELIJAH KIROP** kupitia **namba rasmi ya simu iliyopendekezwa kwa utafiti huu** (+254721222325) **au kwa baruapepe:** <u>elijah.kirop@postgrad.manchester.ac.uk</u>. **Vilevile unaweza kuwasiliana na mkunga wa utafiti kupitia namba rasmi ya simu itakayotumika kwa utafiti huu (+254741796797)**.

<u>Malalamishi Rasmi</u>

Iwapo utahitaji kutoa malalamishi rasmi au hujaridhika na majibu uliyopata kutoka kwa watafiti kwa mara ya kwanza, basi tafadhari wasiliana na Kamati ya Nidhamu ya Utafiti katika Hospitali(Kiongozi wa masuala ya kushughulikia watu) kupitia namba hii +254 787 723 677 na ujaze fomu ya malalamishi (*Fomu ya kuripoti malalamishi ya utafiti*) na kwa baruapepe hii irec@mtrh.or.ke au uitume kwa kupitia anwani zilizotolewa kwenye fomu. Unaweza pia wasiliana na mmojawapo wa wasimamizi (maelezo ya anwani yaliyotolewa mwishoni mwa fomu hii ya maelezo) AU Meneja wa Udhitibiti wa Uadilifu wa Utafiti, Afisi ya utafiti, Jumba la Christie, Chuo Kikuu cha Manchester, Barabara ya Oxford, Manchester, M13 9PL, kupitia baruapepe: research.complaints@manchester.ac.uk.

Malalamishi yoyote yatachukuliwa kwa umakini sana. Nifanye nini sasa?

Iwapo una maswali yoyote kuhusu utafiti huu au iwapo ungependa kushiriki, tafadhari wasiliana na watafiti.

Mtafiti mkuu **ELIJAH KIROP anaweza kufikiwa kwa namba hii** +254 721 222 325 AU kwa **baruapepe:** <u>elijah.kirop@postgrad.manchester.ac.uk</u>. Watafiti wengine wanaohusika katika utafiti ni: **Prof. Dame Tina Lavender, Dkt. Rebecca Smyth** na **Dkt. Malcolm Campbell** na **wakunga wa utafiti.**

[Shule ya Utabibu, Ukunga na kazi ya jamii, Jumba la Jean McFarlane, Chuo Kikuu cha Manchester, Barabara ya Oxford , M13 9PL, Manchester, Uingereza].

Tafadhali kuwa huru kujadili habari hii na wengine, familia yako au mkunga. Unaweza pia kuwasiliana na kikosi cha utafiti ili ujibiwe maswali mengine kupitia anwani zilizoolewa hapo juu.

Iwapo ungependa binti yako kushiriki utafiti tafadhari jaza na utie sahihi <u>fomu ya ruhusa</u> utakayopewa.

Asante kwa kutumia muda wako kusoma karatasi hii ya habari.

Mradi huu umeidhinishwa na Kamati ya Nidhamu ya Utafiti ya Chuo Kikuu cha Manchester [Namba ya marejeleo ya UREC 16427].

Kipengele 3.4: Fomu ya Kukubali Na Ruhusa

Kipengele 3.4A: Fomu ya Kibali-Kina Mama (Miaka 18-19)

Mada ya Utafiti: Jaribio la kutadhmini usaidizi wa kupitia simu kwa mama wachanga kipindi tu

baada ya kujifungua eneo la Magharibi mwa Kenya

Iwapo umefurahi kushiriki tafadhali jaza na utie sahihi <u>fomu ya kukubali</u> hapa chini.

(Tafadhali andika ufupi wa majina yako kwa kisanduku inavyofaa)

Nadhibitisha kuwa nimesoma fomu ya maelezo ilitoandamanishwa (Toleo 1-	
20.06.2016) kuhusu utafiti. Ninaelewa ni kwa nini utafiti huu unafanywa, na ni kwa nini	
nimeombwa kushiriki.	
Nimepata nafasi kuitafakari habari na kuuliza maswali na yamejibiwa hadi nikaelewa na	
nikaridhika.	
Ninaelewa kuwa kwa kukubali kushiriki, nitawekwa kwa ama katika kundi la usaidizi	
wa kuingilia kutatua kwa simu au kikundi cha usaidizi wa kawaida, na nitaendelea	
kupokea usaidizi unaonifaa katika mojawapo wa hivi vikundi.	
Ninaelewa kuwa kushiriki katika utafiti huu ni hiari na nina uhuru wa kujiondoa wakati	
wowote bila kutoa sababu. Ninaelewa kuwa iwapo nitaamua kujiondoa, hili halitaathiri	
usaidizi ninaopokea sasa na siku za usoni.	
Ninaelewa kuwa data yangu inawekwa kwa siri.	
Ninaelewa kuwa mahojiano yatarekodiwa kwa sauti.	
Ninakubali matumizi ya nukuu zisizotajwa wenye kuzitoa.	

Nakubali kushiriki utafiti huu.

Jina la mshiriki	Tarehe	Sahihi
Jina la anayechukua ruhusa	Tarehe	Sahihi

Mradi huu umeidhinishwa na Kamati ya Nidhamu ya Utafiti ya Chuo Kikuu cha Manchester [Namba ya marejeleo ya UREC 16427].

Kipengele 3.4B: Fomu ya Kukubali-Kina Mama (Miaka 12-17)

Mada ya Utafiti: Jaribio la kutadhmini usaidizi wa kupitia simu kwa mama wachanga kipindi tu baada ya kujifungua eneo la Magharibi mwa Kenya

Iwapo umefurahi kushiriki tafadhali jaza na utie sahihi <u>fomu ya kukubali</u> hapa chini.

(Tafadhali andika ufupi wa majina yako kwa kisanduku inavyofaa)

Nadhibitisha kuwa nimesoma fomu ya maelezo (Toleo la 1-20.06.2016) kuhusu	
utafiti. Ninaelewa ni kwa nini utafiti huu unafanywa.	
Nimepata nafasi kuitafakari habari na kuuliza maswali na yamejibiwa hadi	
nikaelewa na nikaridhika.	
Ninaelewa kuwa kwa kukubali kushiriki, nitawekwa kwa ama katika kundi la	
usaidizi wa kuingilia kutatua kwa simu au kikundi cha usaidizi wa kawaida, na	
nitaendelea kupokea usaidizi unaonifaa katika mojawapo wa hivi vikundi.	
Ninaelewa kuwa kushiriki katika utafiti huu ni hiari na nina uhuru wa kujiondoa	
wakati wowote bila kutoa sababu. Ninaelewa kuwa iwapo nitaamua kujiondoa, hili	
halitaathiri usaidizi ninaopokea sasa na siku za usoni.	
Ninaelewa kuwa wazizi/walezi wangu wameulizwa kuhusu kushiriki kwangu	
katika utafiti huu na wawekubali nishiriki.	
Ninaelewa kuwa habari niliyoitoa haitatolewa kwa yeyote asiyehusika katika	
utafiti, ila tu wakati maisha yangu au ya mtu mwingine yatakuwa hatarini.	
Ninaelewa kuwa data yangu inawekwa kwa siri na itahifadhiwa vizuri kwa	
matumizi na kikosi cha watafiti pekee, na kwamba inaweza tu kuwasilishwa	
kupitia machapisho/ripoti zilizoandikwa bila kutambulishwa kokote.	
Ninaelewa kuwa mahojiano yatarekodiwa kwa sauti.	
Ninakubali matumizi ya nukuu zisizotajwa wenye kuzitoa kutoka kwa data yangu.	

Nakubali kushiriki utafiti huu.

Jina la mshiriki

Tarehe

Sahihi

Jina la anayechukua ruhusa Tarehe

Sahihi

Mradi huu umeidhinishwa na Kamati ya Nidhamu ya Utafiti ya Chuo Kikuu cha Manchester [Namba ya marejeleo ya UREC 16427].

[Toleo 1-20.06.2016]

Kipengele 3.4C: Fomu ya Ruhusa-Mzazi/Mlezi

Mada ya Utafiti: Jaribio la kutadhmini usaidizi wa kupitia simu kwa mama wachanga kipindi tu baada ya kujifungua eneo la Magharibi mwa Kenya

Iwapo ungependa binti yako ashiriki utafiti huu, tafadhali jaza na utie sahihi <u>fomu</u> <u>ya ruhusa</u> hapa chini.

(Tafadhali andika ufupi wa majina yako kwa kisanduku inavyofaa)

Nadhibitisha kuwa nimesoma fomu ya maelezo ilitoandamanishwa (Toleo 1-	
20.06.2016) kuhusu utafiti. Nimepata nafasi kuitafakari habari na kuuliza maswali na	
yamejibiwa hadi nikaelewa na nikaridhika.	
Ninaelewa kuwa kushiriki kwa binti yangu katika utafiti huu ni hiari na ana uhuru wa	
kujiondoa wakati wowote bila kutoa sababu, na hili halitaathiri usaidizi ninaopokea sasa	
na siku za usoni.	
Ninaelewa kuwa kwa kukubali kushiriki, binti yangu atawekwa kwa ama katika kundi la	
usaidizi wa kuingilia kutatua kwa simu au kikundi cha usaidizi wa kawaida, na	
nitaendelea kupokea usaidizi unaonifaa katika mojawapo wa hivi vikundi.	
Ninaelewa kuwa kuwa hatua kamilifu zimechukuliwa ikiwa binti yangu atahisi	
kutoridhika ama dhiki wakati wa utafiti.	
Ninaelewa kuwa data yangu inawekwa kwa siri.	
Ninaelewa kuwa mahojiano yatarekodiwa kwa sauti.	
Ninakubali matumizi ya nukuu zisizotajwa wenye kuzitoa.	

Nakubali binti yangu kushiriki utafiti huu.

Mzazi/Mlezi	Tarehe	Sahihi	
Jina la mshiriki (Binti)	Tarehe	Sahihi	
Jina la anayechukua ruhusa	Tarehe	Sahihi	

Mradi huu umeidhinishwa na Kamati ya Nidhamu ya Utafiti ya Chuo Kikuu cha Manchester [Namba ya marejeleo ya UREC 16427].

[Version1-01.07.2016] S.No

Appendix 4.1: Short demographics questionnaire for midwives (Delphi survey)

Study title: A pilot randomised controlled trial to explore Telephone Support Intervention as a means of supporting young mothers in the immediate postnatal period in Western Kenya

Please fill out the following background details to help us describe whose views we are presenting in the study. No identifying details will be reported in the research.

1.	What is your current position/role?	
1.		
2.	How long have you been a qualified midwife?	Years:
3.	How long have you worked in the postnatal unit?	Years: Months:
4.	Age (please tick)	18 - 20 years $21 - 30$ years $31 - 40$ years $41 - 50$ years $51 - 60$ yearsOver 60 years
5.	What is your highest level of education? (please tick)	Certificate Diploma Degree Masters PhD Other, state

Thank you for your responses.

TSI_Delphi1[Version1-01.07.2016] S.No

Appendix 4.2: Delphi 1 questionnaire

MANCHESTER

Study title: A pilot randomised controlled trial to explore Telephone Support Intervention as a means of supporting young mothers in the immediate postnatal period in Western Kenya Dear Colleague,

My name is Elijah K. Kirop, a PhD student (Midwifery) at The University of Manchester, UK. As part of my study exploring the use of telephone support intervention among young mothers aged 12-19 years during the immediate postnatal period (up to 10 weeks postpartum), I (together with my supervisors) would like to identify key areas for health messages that may benefit young mothers during this period. We would like to know your views on what motivational health messages may be useful for this group of mothers and their babies. As midwives, we believe you are best placed to identify and provide this information.

We would be most grateful if you answer the following questions as fully as possible.

1.	What health messages do you consider important for young/adolescent mothers during the postnatal period. Please list as much as possible.
	a) In caring for themselves, during the first week
	•••••••••••••••••••••••••••••••••••••••
	In weeks 2 to 6
	In weeks 7-10
	•••••••••••••••••••••••••••••••••••••••
	b) In caring for their babies, during the first week

	In weeks 2 to 6
	In weeks 7-10
2.	What other additional information do you think is useful for this group of mothers?

Thank you for your response.

Appendix 4.3: Delphi 2 questionnaire

MANCHESTER 1824

Dear Colleague,

My name is Elijah K. Kirop, a PhD student (Midwifery) at The University of Manchester, UK. As part of my study exploring the use of telephone support intervention among young mothers aged 12-19 years during the immediate postnatal period (up to 10 weeks postpartum), I (together with my supervisors) would like to identify key areas for health messages that may benefit young mothers during this period. A group of Senior midwives in Kenya identified what they believe are priority areas regarding the subject.

We would now like to know your views on what motivational health messages may be useful for this group of mothers and their babies at the **definitive periods** during early postpartum to help us **sequence the intervention most suitably**. As midwives, we believe you are best placed to identify and provide this information.

Please read the list and <u>tick 3 topical issues</u> you consider to be of <u>utmost priority</u> during each of the periods listed and indicate your <u>ranking in</u> <u>brackets (either 1, 2 or 3)</u>. You may briefly comment on your choice explaining your decision. We would be most grateful if you answer the following questions as fully as possible.

Finally, if there is any additional information that you believe is very important and has not been reflected in the list above, please write in the space provided.

Please return your form to the Unit Manager in your facility.

S.No.	Reference group	Period	Motivational health messages	Priority (rank♯)	Comments
А.	Maternal care	Week 1	Infection prevention		
			Nutrition		
			Rest		
			Personal hygiene		
			Breast care		

	Psychosocial support	
	Bleeding (PPH)	
	Pelvic floor/Kegel's exercises	
	High blood pressure (Pre-	
	eclampsia/Eclampsia)	
	Pain management	
	Partner involvement	
	pMTCT & STI screening and	
	prevention	
	Family budget adjustments	
	01	
Weeks 2-6	Sleep	
	Nutrition	
	Personal hygiene	
	Breast care	
	Psychosocial support	
	Mood changes	
	Pelvic floor/Kegel's exercises	
	Clinical appointment	
 	Pain management	
	Family budget adjustments	
	Contraception/family planning	
	pMTCT & STI screening and	
	prevention	
	Partner involvement	
Weeks7-10	Pelvic floor/Kegel's exercises	
VVCCK5/-10	Breast care	
	Psychosocial support Rest	
	Nutrition	
	Personal hygiene	
	Bleeding	

			Contraception/family planning	
			pMTCT & STI screening and	
			prevention	
			Partner involvement	
			Family budget adjustments	
В.	Newborn/infant	Week 1	Breastfeeding	
	care			
			Immunisation	
			Warmth	
			Cord care	
			Bathing	
			Colic pain management	
			Sleep patterns	
			Signs of infection	
			Bonding	
			Family budget adjustments	
			Partner/family involvement	
			Assessment of the baby –	
			breathing/body	
		Weeks 2-6	Immunisation	
		WEEKS 2-0		
			Breastfeeding	
			Infant feeding patterns Warmth	
			Cord care	
			Skin care	
			Clinical appointment	
			Family budget adjustments	
			Partner/family involvement	
			pMTCT & STI screening and	
			prevention	

Weeks7-10	Immunisation	
	Breastfeeding	
	Infant care	
	Sleep patterns	
	Infection prevention/hygiene	
	Family budget adjustments	
	pMTCT & STI screening and	
	prevention	
	Partner involvement	

Is there any other additional information that you think is useful for this group of mothers?

a) For the young mother:

b) For the newborn/infant:

Thank you for your responses and support.

Appendix 4.4: Delphi 3 questionnaire

MANCHESTER

Dear Colleague,

My name is Elijah Kirop, a PhD student (Midwifery) at The University of Manchester, UK. As part of my PhD study exploring the use of telephone support intervention among young mothers aged 12-19 years during the immediate postnatal period (up to 10 weeks postpartum), I (together with my supervisors) would like to identify key areas for health messages that may benefit young mothers during this period. A group of Senior midwives in Kenya identified what they believe are priority areas regarding the subject.

We would now like to know your views on what motivational health messages may be useful for this group of mothers and their babies at the **<u>definitive periods</u>** during early postpartum to help us <u>**sequence the intervention most suitably**</u>. As midwives, we believe you are best placed to identify and provide this information.

This survey (Delphi 3) is a follow up to the previous one (Delphi 2) in which you took part. The items include the ones that you ranked highly in the previous survey. Please read the list and <u>rank any 3 topical issues in week 1</u>; <u>3 in weeks 2-6</u>; and <u>3 in weeks 7-10</u>, both for the <u>Mother</u> (*refer to section A – Maternal care*) and for the <u>Baby/infant</u> (*refer to section B – Newborn/Infant care*) that you consider to be of <u>utmost</u> priority during each of the periods listed. In this survey, please indicate your <u>ranking in the column provided (rank \ddagger - <u>1, 2 & 3)</u> just as in the previous survey. You may briefly comment on your choice explaining your decision for prioritisation. We would be most grateful for your responses.</u>

Finally, if there is any additional information that you believe is very important and has not been reflected in the list provided, please write in the space provided.

S.No.	Reference	Period	Motivational health messages	Priority	Comments
	group			(rank♯)	
А.	Maternal care	Week 1	Infection prevention		
			Bleeding (PPH)		
			High blood pressure (Pre-		

Please return your form to the Unit Manager in your facility.

	eclampsia/Eclampsia)	
	Psychosocial support	
	Personal hygiene	
	Breast care	
	Nutrition	
	Schooling/education	
	Pre-conception care	
	Maternal danger signs	
	Monitoring of lochia changes	
	Economic empowerment/income	
	generating activities	
Weeks 2-6	Nutrition	
	Personal hygiene	
	Breast care	
	Clinical appointment/follow up	
	Contraception/family planning	
	pMTCT & STI screening and	
	prevention	
	Mood changes	
	Pelvic floor/Kegel's exercises	
	Schooling/education	
	Pre-conception care	
	Maternal danger signs	
	Monitoring of lochia changes	
	Economic empowerment/income	
	generating activities	
Weeks7-10	Contraception/family planning	
Weeks/-10	Pelvic floor/Kegel's exercises	
	Psychosocial support	
	Personal hygiene	
	Rest	
	RESI	

			Nutrition	
			Breast care	
			pMTCT & STI screening and	
			prevention	
			Bleeding	
			Family budget adjustments	
			Schooling/education	
			Pre-conception care	
			Maternal danger signs	
			Monitoring of lochia changes	
			Economic empowerment/income	
			generating activities	
			Schooling/education	
В.	Newborn/infant	Week 1	Breastfeeding	
	care			
			Warmth	
			Cord care	
			Bonding	
			Assessment of the baby –	
			breathing/body	
			Immunisation	
			Signs of infection	
			Partner/family involvement	
			Colic pain management	
			Weaning	
			Danger signs (Baby/infant)	
			Birth registration	
		Weeks 2-6	Immunisation	
		WEEKS 2-0	Breastfeeding	
			Cord care	
I			Infant feeding patterns	

	Clinical appointment/follow-up
	Warmth
	pMTCT & STI screening and
	prevention
	Weaning
	Danger signs (Baby/infant)
	Birth registration
Weeks7-10	Immunisation
	Breastfeeding
	Infection prevention/hygiene
	Infant care
	Sleep patterns
	pMTCT & STI screening and
	prevention
	Weaning
	Danger signs (Baby/infant)
	Birth registration

Please list any other information that may be useful during this period:c) For the young mother:

d)	For the newborn/infant
	Thank you for your responses and support.

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