

**A STUDY TO COMPARE MORBIDITY OF
VERY LOW BIRTH WEIGHT NEONATES
BETWEEN 1.3 AND 1.5 KG RECEIVING
KANGAROO MOTHER CARE VERSUS
STANDARD INTENSIVE CARE AT THE
UNIVERSITY TEACHING HOSPITAL, IN
LUSAKA, ZAMBIA**

BY

DR. BRIGHTON MUSAFILI

(BSc. HB, MBChB)

**A Dissertation Submitted to the University Of Zambia in Partial Fulfilment of the
Requirements of the Degree of Master of Medicine in Paediatrics and Child Health**

(School of Medicine)

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DECLARATION

I declare that this dissertation is my own work. It is being submitted for the Master's degree in Pediatrics and Child Health at the University of Zambia, Lusaka. It has not been submitted before for any degree or examination at this or any other University.

Candidate

Dr. Brighton Musafili

(BSc. HB, MBChB)

Supervisor.....

Dr. Sylvester Sinyangwe

(BSc. HB, MBChB, MMED, MPH)

Supervisor.....

Dr. Monica Kapasa

(BSc. HB, MBChB, MMED)

Signed.....

Head of Department

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Approval

The University of Zambia approves this dissertation of Dr. Brighton Musafili as fulfilling the requirement for the award of the degree of Master of Medicine of Pediatrics and Child Health.

Head of Department

Name :

Signed :

Date :

Examiner- 01

Name :

Signed :

Date :

Examiner- 02

Name :

Signed :

Date :

Examiner- 03

Name :

Signed :

Date :

ABSTRACT

Background - New born deaths account for approximately 40% of all deaths under five years of age in developing countries with the three major causes being birth asphyxia, infections, and complications due to prematurity and low birth weight (LBW). Birth weight is a significant determinant of newborn survival. Prematurity is the largest direct cause of neonatal mortality accounting for an estimated 29% of the 3.6 million neonatal deaths every year (**Lawn et al. 2010**).

Kangaroo Mother Care (KMC) is a strategy that was created and developed by a team of pediatricians in Bogota, Colombia. Its introduction was associated with significant reduction in neonatal morbidity, however, the most dramatic result, documented through a pre- and post-intervention study was a drop in neonatal mortality from 70% to 30%. The benefits of KMC in neonatal development have been documented by studies worldwide. Despite the recognition, benefits and longevity of KMC, few developing countries have made the intervention available and accessible to families with LBW babies.

The Department of Paediatrics, UTH, has introduced Kangaroo Mother Care KMC as one of the strategies in the management for Very Low Birth Weight Neonates. This study investigated the effect of Kangaroo Mother Care KMC, on the morbidity of Very Low Birth Weight VLBW neonates at the University Teaching Hospital Lusaka, Zambia.

Methodology- The study was an observational cohort study conducted in the NICU and KMC wards of the UTH in Lusaka, Zambia. Enrolment of all eligible participants was

from June to November, 2015. Neonates with birth weight above 1.0 kg and less than 1.49 kg delivered in UTH, local clinic or home either via spontaneous vaginal delivery or caesarean section who meet the study definition of stable neonate were enrolled in the study.

The two study groups were naturally obtained due to limited space on the KMC ward which is unable to accommodate all eligible neonates for admission and results in neonates being admitted to the NICU thus providing two cohorts of neonates within the same weight band receiving two different modalities of neonatal care. No randomizing or assigning was involved in the process. Initial clinical state and progression was assessed with daily weight, six hourly temperature, respiratory rate and heart rate in addition to monitoring the frequency of clinical events including apneic spells, fevers and respiratory infections in each group. The data was then compared between the two groups. All data collected during the course of the study was collected by standard and routine procedures which are performed as part of daily care. No additional procedures invasive or otherwise were performed for study purposes.

Results - This study found an average weight gain in the KMC group of 9 grams per day compared to an average of 5 grams per day in the NICU group. The mean follow-up weight for the KMC group was 1.38 kg, 95% CI (1.32 – 1.45) compared to baseline mean weight 1.30 kg, 95% CI (1.24 – 1.35) while the mean follow-up weight for the NICU group was 1.34 kg, 95% CI (1.32 – 1.35) compared to baseline mean weight 1.34 kg, 95% CI (1.29 – 1.38). The mean hospital stay for the NICU group was 6.8 days (SD = 1.2) whereas for the KMC group 4.1 days (SD = 1.3). In addition, The NICU cohort

showed an increased frequency of clinical events at 21% compared to 5% observed in the KMC cohort. The KMC cohort further showed more thermal stability in core body temperature and indeed the heart rate and respiratory rates showed less fluctuations in follow up relative to the NICU cohort.

Conclusion - KMC was associated with a shorter hospitalization of 4.1 days relative to 6.8 days in the NICU group. This was associated with an average weight gain of 9 grams per day compared to an average of 5 grams per day that was observed in the NICU group. In addition, KMC was associated with more thermal and cardio-respiratory stability with less fluctuations during follow up relative to the NICU group. The NICU cohort showed an increased frequency of clinical events at 21% compared to 5% observed in the KMC cohort during the six months of the study duration.

Key words- Apnea, Necrotizing Enterocolitis, Kangaroo Mother Care, Cardio-respiratory.

DEDICATION

I dedicate this work to my mother for providing me with the support and parental guidance throughout my education, for without her support I would not have pulled through this long and demanding journey. Above all I am indebted to my ever loving wife, Mwiche Namonje Musafili for supporting me throughout this research and career.

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TABLE OF CONTENTS

Declaration.....	i
Copyright.....	ii
Abstract.....	iv
Dedication	vi
Acknowledgements.....	vii
Table of Contents.....	viii
List of Tables and Figures.....	x
Abbreviations and Acronyms/Glossary.....	x
CHAPTER 1.....	1
Introduction.....	1
Statement of the Problem.....	4
Study Justification.....	4
Research Question	5
Objectives.....	5
CHAPTER 2.....	6
Literature Review.....	6
CHAPTER 3.....	13
Materials and Methods.....	13
Study Design.....	13
Target Population.....	13
Study Site.....	13
Eligibility.....	14
Sample Size.....	14
Sampling Methods.....	15
Study Definitions.....	15
Data Management.....	16
Ethical Issues.....	16
CHAPTER 4	17

Results.....	17
CHAPTER 5.....	24
Discussion.....	24
Study Limitation.....	28
CHAPTER 6.....	29
Conclusion.....	29
Recommendation.....	29
CHAPTER 7.....	31
References.....	31
Appendices.....	
Appendix i.....	
Appendix ii.....	

LIST OF TABLES AND FIGURES

TABLE 1: Birth Weight Summary Statistics.....	19
TABLE 2: Maternal Age Statistics.....	20
TABLE 3: Maternal Parity vs Study Group Cross-tabulation.....	20
TABLE 4: Mode of Delivery vs Study Group Cross-tabulation.....	21
TABLE 5: Bivariate Analysis Summary.....	21
TABLE 6: Hospital Stay Group Statistics.....	22

ABBREVIATIONS AND ACRONYMS/GLOSSARY

ERES	Excellence in Research Ethics and Science
ICD	International Classification of Diseases
ELBW	Extremely Low Birth Weight
IUGR	Intrauterine Growth Retardation
KMC	Kangaroo Mother Care
LBW	Low Birth Weight
MDG	Millennium Development Goals
NEC	Necrotizing Enterocolitis
NICU	Neonatal Intensive Care Unit
VLBW	Very Low Birth Weight
UTH	University Teaching Hospital
UNICEF	United Nations Children’s Fund
USAID	United States Agency For International Development

VLBW Very Low Birth Weight
WHO World Health Organization

CHAPTER ONE

1.0 INTRODUCTION

Newborn deaths currently account for approximately 40% of all deaths of children under five years of age in developing countries the three major causes being birth asphyxia, infections, and complications due to prematurity and low birth weight (LBW).

To achieve Millennium

Development Goal (MDG) 4, developing countries must address and reduce the excessively high neonatal mortality rate. More than 20 million babies are born premature and/or with LBW each year, with 95% occurring in the developing world.

Birth weight is a significant determinant of newborn survival. LBW is an underlying factor in 60–80% of all neonatal deaths. In fact, prematurity is the largest direct cause of neonatal mortality accounting for an estimated 29% of the 3.6 million neonatal deaths every year (**Lawn et al. 2010**).

LBW infants are approximately 20 times more likely to die, compared with heavier babies. One-third of LBW babies die within the first 12 hours after delivery. One of the main reasons that LBW/premature babies are at greater risk of illness and death is that they lack the ability to control their body temperature-i.e., they get cold or hypothermic very quickly. A cold newborn stops feeding and is more susceptible to infection.

In most countries, the use of incubators is standard for thermal care of LBW babies. However, “Incubator care” is not widely available in developing countries, especially outside of large cities. Even in the limited cases where incubator care is available, the use of this method can be very challenging. Problems such as poor maintenance, power outages and lack of replacement parts reduce the number of available, functional

incubators. In addition, excess demand resulting from too many LBW/preterm newborns and insufficient machines results in many babies sharing an incubator. This practice, along with inadequate disinfection of incubators, can lead to increased infection rates. Untrained or poorly trained health personnel or insufficient staff available on a 24-hour basis can also impact the quality of incubator care provided in these settings. Since it largely excludes the participation of the mother, incubator care can also lead to decreased breastfeeding and maternal-newborn bonding.

Given the cost of incubators and the operational and programmatic challenges, making Incubator care available and accessible to the majority of families of LBW babies is simply not an option in most developing countries. Fortunately, there is an alternative approach for providing thermal care for and improving survival of LBW infants that is both effective and affordable. This care is called Kangaroo Mother Care, or KMC.

Low birth weight is defined as birth weight less than 2500 grams regardless of gestational age (**WHO ICD - 10**). Low birth weight is further sub-classified into very low birth weight (1000grams – 1500 grams) and extremely low birth weight (less than 1000 grams).

16% of neonates or nearly 20 million are born as low birth weight each year with the highest incidence observed in South Asia and Africa (**WHO 2008**).

Low birth weight is caused by preterm delivery, intrauterine growth restriction (IUGR) or both. Once a LBW neonate is born it encounters challenges with adaptation to extra uterine life. These include thermal instability, hypoglycemia, apneic episodes, risk of infection, and risk of necrotizing enterocolitis (**Ludington, et al 1998**).

For this reason neonatal intensive care is required to facilitate this adaptation and enable the neonate to gain weight before discharge. Traditional neonatal intensive care requires trained manpower, constant monitoring and the use of very expensive equipment which require a stable source of electricity for operation. This results in the availability of this service in semi – urban and rural areas being very limited especially in low resource settings such as ours.

Traditional incubator care in low resource settings demands sharing of incubators among neonates which exposes them to nosocomial infections. In addition, the duration spent by the neonate in the incubator delays the establishment of an emotional bond with the mother and other members of the family **(Conde-Agudelo, et al 2011)**.

The Department of Pediatrics, UTH, as of 2014 has introduced Kangaroo Mother Care KMC, as first line management for Stable Very Low Birth Weight Neonates. However, due to limited space on the KMC ward, it is unable to accommodate all neonates who qualify for admission resulting in a portion of Stable Low Birth Weight Neonates being admitted to the Neonatal Intensive Care NICU.

This has provided a unique opportunity to analysis the processes involved in these two modalities of care and compare the two interventions in the care of Very Low Birth Weight Neonates.

1.2 STATEMENT OF THE PROBLEM

Prematurity and Low Birth Weight is one of the leading causes of morbidity and mortality in the Neonatal Intensive Care Unit at UTH as well as worldwide.

Limited Neonatal Intensive Care facilities result in the sharing of incubators and other facilities which predispose to increased risk of infection.

Standard intensive care is associated with long hospital stay at a high cost for both institution and care givers.

KMC receives very low coverage at UTH with minimal integration in maternal and child health programmes

1.3 STUDY JUSTIFICATION

With high mortality rate associated with Standard Incubator Care for VLBW it becomes pertinent to pursue alternative management modalities to reduce morbidity and mortality.

Evidence based documentation of outcomes of VLBW neonates managed with KMC is needed to compare with Standard Intensive Care.

Favourable outcomes with KMC, will justify incorporation of KMC into the standard management of VLBW neonates and indeed extend to ELBW neonates where the highest mortality with Standard Care is demonstrated.

Demonstrated efficacy of KMC will justify the implementation of the program in other hospitals and clinics in Lusaka and country wide roll out.

1.5 RESEARCH QUESTION

Is Kangaroo Mother Care (KMC) associated with reduced morbidity compared to Standard Intensive Care in the Neonatal Intensive Care Unit (NICU) in the care of Very Low Birth Weight neonates between 1.3 kg and 1.5 kg at the University Teaching Hospital (UTH), Lusaka, Zambia?

1.6 OBJECTIVES

1.6.1 General Objective

To demonstrate the difference in morbidity of Very Low Birth Weight neonates between 1.3 kg and 1.5 kg receiving Kangaroo Mother Care and Standard Intensive Care at the University Teaching Hospital (UTH), Lusaka, Zambia.

1.6.2 Specific Objectives

- Compare the duration of hospital stay.
- Compare the rate of weight gain.
- Compare cardio-respiratory stability
- Compare the frequency of clinical events including apnoeic spells, fevers, necrotizing enterocolitis (NEC) and respiratory infections.

CHAPTER TWO

2.0 REVIEW OF LITERATURE

Kangaroo Mother Care (KMC) is a strategy created and developed by a team of pediatricians in the Maternal and Child Institute in Bogota, Colombia. It was invented by Dr. Edgar Rey in 1978, and developed by Dr. Hector Martinez and Dr. Luis Navarrete **(Rey, et al 1983)**. In 1994 the Kangaroo Foundation was created. KMC was an innovative method developed to provide thermal care for LBW newborns. The first trial of KMC was launched to address over-crowding, cross-infection, poor prognosis and extremely high LBW mortality rates. The goals of the trial were to improve outcomes for LBW infants, humanize their care, and reduce the length and cost of hospitalization. While much of this was accomplished, the most dramatic result, documented through a pre- and post-intervention study of the trial, showed a drop in neonatal mortality from 70% to 30% **(Rey, et al 1983)**.

Thirty-two years later, KMC is now recognized by global experts as an integral part of essential newborn care. KMC must not be confused with routine skin-to-skin care (SSC), which the World Health Organization (WHO) recommends immediately after delivery for every baby as part of routine care to ensure that all babies stay warm in the first two hours of life, and for sick newborns during transport for referral. **(WHO, 1997)**.

LBW infants, however, require skin to skin care for a longer period of time depending on their weight and condition. KMC is “the early, prolonged, and continuous skin-to-skin contact between the mother (or substitute) and her low birth weight infant, both in hospital and after early discharge, until at least the 40th week of postnatal gestation age, with ideally exclusive breastfeeding and proper follow-up” (**Cattaneo, Davanzo, Uxa 1998**). Ideally, small babies should stay in the skin-to-skin position all day and night to maintain a stable temperature (**WHO, 1997**).

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KMC for LBW babies is initiated in the hospital after the condition of the baby is stabilized. Infants who are not stable and require medical attention can practice intermittent KMC (spending some hours in the KMC position, gradually increasing the time as the baby gets stronger). Early discharge after delivery is a hallmark of the KMC approach and occurs when the baby is suckling well and growing, and when the mother or family caregiver demonstrates competency in caring for the baby on her own. The pair is discharged to continue KMC at home with an agreed-upon schedule for follow-up visits at the hospital, outreach clinic or at home to monitor the health of the baby (**Ruiz-Pelaez et al 2004**).

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Kangaroo Mother Care (KCM) consists of placing a diaper clad neonate in an upright position on a parent’s bare chest with maximal skin to skin contact. The baby is positioned in flexion with the ear above the parent’s heart and secured with a wrap around the parent’s naked torso to maintain position and provide support (**Charpak, et al 1997**).

Vestibular stimulation from the parents breathing and chest movements, auditory stimulation from the parent's voice and heart beat and tactile stimulation from the parent's skin and the natural tendency of the parent to place hands on the neonate all provide beneficial stimulation for adaptation and development (**Acoulet, et al 2010**).

Despite the recognition, benefits and longevity of KMC, few developing countries have made the intervention available and accessible to families with LBW babies. With the exception of Colombia, South Africa, Malawi and Brazil, most developing countries have only a handful of facilities that offer KMC services (**WHO, 1997**). Notably, South Africa, after recognizing the benefits of KMC, choose to integrate KMC with facility-based services for LBW babies despite the fact that most of its health facilities have accessible incubator care.

Introducing and expanding KMC services on a national level require commitment from the government, in particular, ministries of health, and the support of local professional bodies, local "champions," international organizations, and governmental and nongovernmental agencies. The U.S. Agency for International Development (USAID), United Nations Children's Fund (UNICEF) and the Bill & Melinda Gates Foundation, among others, have supported the initiation and expansion of KMC services in a number of countries through different global programs.

In countries with limited KMC services, the services provided are often initiated by personally motivated doctors who have learned about KMC through colleagues, at conferences or through sponsorship by donor organizations. However, to improve the

survival of LBW infants and contribute significantly to the reduction of newborn death in developing countries, it is imperative that limited KMC services be scaled up nationwide and made available and accessible to the majority of families with LBW infants. A national scale-up means expanding KMC services from the current handful of facilities to cover most, if not all, hospitals and health centers where deliveries take place. **(Blencowe H et al, 2008 Bogale W et al 2005).**

The Cochrane Collaboration conducted a review of KMC in 2003. For this review, three trials of KMC for LBW infants were assessed (14 initially identified, 11 excluded for various methodological reasons). Results of these three studies, which assessed 1,362 infants, found that KMC “reduced severe illness, infection, breastfeeding problems and maternal dissatisfaction with method of care, and improved some outcomes of mother-baby bonding **(Conde-Agudelo, et al 2003)**. Infants cared for with KMC also demonstrated better weight gain after the first week of life, compared with babies cared for with incubators.

At the time of the 2003 study, however, the Cochrane Collaboration stated that there was insufficient evidence to recommend the routine use of KMC for LBW infants. In 2011, an updated Cochrane review assessed 35 studies. This second review demonstrated even more positive results. Compared with conventional neonatal care, KMC was found to reduce: mortality at discharge and at the latest follow-up, severe infection/sepsis, nosocomial infections, hypothermia, severe illness, lower respiratory tract disease and length of hospital stay. The 2011 review also revealed that KMC resulted in improved weight and length, head circumference, breastfeeding, mother-

infant bonding and maternal satisfaction with the method of care, as compared with conventional methods (**Conde-Agudelo, et al 2011**).

Hypothermia and thermal instability are acute problems associated with VLBW neonates. Both incubator care and KMC primarily aim at preventing hypothermia. Serial recordings of skin temperature on Very Low Birth Weight neonates showed more thermal stability in Kangaroo Mother Care KMC neonates receiving skin-to-skin contact relative to Incubator care. (**Lincento, et al 2000**). Kangaroo Care performed in a quiet, low light environment reduces crying and assists the baby to learn transition from one sleep state to another. More quiet sleep is noted in neonates receiving Kangaroo Mother Care compared to Incubator care at 62% versus 22% and less crying at 2% versus 6% (**Chwo, et al 2010**). Evidence of the effects of KMC on temperature showed almost no fluctuation among babies cared for with KMC, compared with considerable swings in temperature for babies receiving incubator care. A comparative study of KMC and incubator re-warming of hypothermic newborns demonstrated that, within the same time period, a higher proportion of KMC-warmed babies reached normal body temperature faster than incubator-warmed babies (**Chwo, et al 2010**).

Kangaroo Mother Care (KMC) allows for easy and natural access to the breast with neonates in continuous KMC for more than 50 minutes eight times more likely to breast feed spontaneously than neonates in incubator care (**Gomez, et al 1998**). Associated exclusive breast feeding rates are higher in Kangaroo Mother Care compared to Standard Intensive Care at 73.9% versus 31.6% (**Almeida, et al 2010**). The higher rates of exclusive spontaneous breast feeding associated with KMC results in a faster weight gain and shorter hospitalization compared with neonates on NICU who receive two

hourly feeds of expressed breast milk (EBM) calculated based on neonatal weight. Neonates receiving Kangaroo Mother Care showed a shorter duration of hospitalization of 1.3 versus 4.9 days primarily in neonates <1.8 kg compared with neonates receiving incubator care. (**Charpak, et al 1997**).

In two studies of weight gain (**Ramanathan et al. 2001, Cattaneo et al. 1998**), KMC babies gained more weight (15.9 gm per day in one study, 21.3 gm in the other) than those in the control group (10.6 gm, 17.7 gm). The studies also showed that KMC babies were discharged from the hospital three to seven days earlier. There were lower rates of serious and nosocomial infections among KMC-managed newborns, as compared with control newborns. Only 5% of KMC-managed babies had a serious illness versus 18% in the control group. The rates of respiratory infection in the KMC and the control groups were 5% and 13%, respectively.

While most studies examined the effects of providing KMC to LBW newborns only after the babies were stabilized, two studies suggest that infants could be put in the KMC position during stabilization. The first, (**Bogale and Assaye 2001**), determined that KMC leads to faster stabilization than Incubator care, resulting in 16% fewer infant deaths.

The second, (**Bergman, et al 2004**), found that:

- Newborns receiving KMC became stable sooner compared to newborns in incubators.
- Eight of 13 incubator babies suffered from hypothermia, compared with none of the KMC babies.
- Mean temperature was higher in the KMC group in the first hour.

Neonates in incubators cry 10 times more than neonates in Kangaroo Mother Care. Spectrographic cry analysis shows that their crying is more painful and distressful compared to crying experienced by neonates in Kangaroo Mother Care (**Michealson, et al 2001**).

In a 2010 meta-analysis of three randomized controlled trials from low- or middle-income settings (**Lawn et al. 2010**), researchers found that, when initiated in the first week of life, KMC significantly reduced neonatal mortality almost 50%, compared with incubator care. Despite some questions regarding study design and implementation, the meta-analysis concluded that there is clear evidence that KMC is at least as good as incubator care in reducing mortality among LBW infants.

The duration of hospitalization of VLBW neonates is not only determined by the rate of weight gain but the frequency of clinical events including apneic spells, fevers, respiratory infections and necrotizing enterocolitis. Kangaroo Mother Care shows a four-fold decrease in episodes of apnea relative to Incubator care. (**Ludington, et al 1998**) with neonates receiving continuous Kangaroo Mother Care showing a more regular heart rate and respiratory rate relative to incubator care neonates. (**Gale and Vandenburg, 1998**). The saturations of oxygen in inspired air are higher in neonates held skin-to-skin in an upright position in Kangaroo Care compared to the horizontal position in Incubator care. (**Acoulet, et al 2010**).

CHAPTER THREE

MATERIALS AND METHODS

3.1 STUDY DESIGN

The study was designed as an observational cohort study to be carried out over a period of 6 months on the Kangaroo Mother Care ward (B11) and Neonatal Intensive Care Unit (NICU) of the UTH, Lusaka.

3.2 TARGET POPULATION

Eligible neonates on the KMC ward and the NICU between 1.3 to 1.5 kg meeting the study inclusion criteria were enrolled in the study.

3.3 STUDY SITE

The University Teaching Hospital, Department of Paediatrics and Child Health, Neonatal Intensive Care Unit (NICU) and Kangaroo Mother Care Ward (B11).

3.4 ELIGIBILITY

3.4.1 Inclusion Criteria

- Stable Very Low Birth Weight neonates between 1.3 - 1.5kg
- Born in the labour ward and theatre at UTH or,
- Born at local clinics or,
- Home delivery.

3.4.2 Exclusion Criteria

- Birth weight outside the weight band 1.3 -1.5 kg.
- Unstable Low Birth Weight neonates requiring intervention.
- Formula fed neonates.

3.5 STUDY CASE DEFINITIONS

- Apnea: Cessation of breathing for more than 15 seconds or cessation of breathing of any duration with associated bradycardia (HR < 100/minute) and/or cyanosis.
- Standard Intensive Care: Medical care provided on the Neonatal Intensive Care Unit (NICU) including incubator and cot care and monitoring equipment.
- Stable Neonate: A neonate with normal range heart rate, respiratory rate and perfusion who is not in need of active medical intervention.

3.6 SAMPLE SIZE

The sample size was calculated using Epi Info version 3.5.1 at power of 80%. Using a hypothetical percentage of outcome among controls of 50% and a ratio of exposed to unexposed of 1:1 a total sample size of **160** participants (**Fleiss**) with **80** in each group is needed at a confidence level of 95% and a precision of +/- 5%.

3.6 SAMPLING AND STUDY METHODS

- The study was designed as an observational cohort study to be done over a period of 6 months in the KMC ward (B11) and Neonatal Intensive Care Unit (NICU)
- Eligible neonates on the KMC ward and in the NICU between 1.3 to 1.49 kg meeting the study inclusion criteria were enrolled in the study.
- Clinical state of the neonates at enrolment and progression was assessed with daily weight, six hourly temperature, respiratory rate and heart rate in addition to monitoring the frequency of clinical events including apnoeic spells, fevers and respiratory infections in each group.
- The neonates were followed up until their weight is above 1.5 kg which was the discharge weight of the study. The end points of the study were discharge or roll back from KMC to NICU.
- No randomizing or assigning was involved in the process. The two study groups were naturally obtained due to limited space in the KMC ward which was unable to accommodate all neonates eligible for admission resulting in neonates eligible for admission on the KMC ward being admitted to the NICU.
- All data collected during the course of the study was collected by standard and routine procedures which are performed as part of daily care. No

additional procedures non-invasive inclusive were performed for purposes of the study.

- No invasive procedures were performed on the study participants.

3.7 DATA MANAGEMENT.

A standardized data extraction sheet for each study participant was used for data collection including follow up. No personal details that could help identify participants appeared on the form. Double data entry was performed and data bases matched. Data was entered on an Epi Info database.

3.8 ETHICAL ISSUES

Ethical clearance was sought from the Research Ethics Committee (ERES), **Ref.no 2014-Sept-014**. Permission to carry out the study was obtained from The Department of Paediatrics and Child Health at UTH.

As an observational study no additional procedures invasive or otherwise were performed on the study participants except those which are performed as part of daily patient care. All patient data was collected and entered on a standard study data entry sheet which is attached.

Patient data was treated as strictly confidential and the data entry sheets were locked in a secure cabinet and all electronic entries were password protected.

CHAPTER FOUR

4.0 RESULTS

4.1 STATISTICAL ANALYSIS

Data were analysed using the statistical software package SPSS version 21. All statistical tests were at 5% significance level. Independent samples T-test and Wilcoxon Signed Ranks Test were used to compare means and medians, respectively, between groups. The Pearson's chi-squared test was used for comparison of proportions between groups.

4.2 CHARACTERISTICS OF THE ENROLLED NEONATES

There were a total of 160 very low birth weight neonates recruited for this study, 80 in Kangaroo Mother Care (KMC) and 80 in Standard Intensive Care in NICU. The median age of the neonates was 2 days (IQR = 2). The mean birth weight was 1.32 Kg (SD = 1.40). The mean maternal age was 27.7 years (SD = 6.32). About 25% and 30% of the mothers had parity of 2 and 3, respectively. Body temperature, heart rate, and respiratory rate were measured 6 hours from recruitment on day 1. The mean body temperature was 36.4 (SD = 0.85), the mean heart rate was 145.4 (SD = 6.41), and mean respiratory rate was 45.7 (SD = 7.09).

4.3 BASELINE COMPARISONS OF KCM AND NICU GROUPS

4.31 Age

The median age for the KMC group was 2 days (IQR = 2), and the median age for the NICU group was 2 days as well (IQR = 1). There was no significant difference in age at enrolment, (P-value = 0.13).

4.32 Birth Weight

The mean birth weight for the KMC group was 1.3 Kg (SD = 0.16) and the mean birth weight for the NICU group was 1.3 Kg as well (SD = 0.12). There was no significant difference in birth weight at enrolment, (P-value = 0.21).

Table 1: Birth Weight Summary Statistics

Study Group	N	Mean	Std Deviation	Std Error Mean
NICU	80	1.3390	.11651	.02093
KMC	80	1.2945	.15504	.02785

4.33 Maternal Age

The mean maternal age for the KMC group was 27.6 years (SD = 6.69), and the mean maternal age for the NICU group was 27.8 years (SD = 5.81). There was no significant difference in maternal age between the two study groups, (P-value = 0.90).

Table 2: Maternal Age Group Statistics

Study Group	N	Mean	Std Deviation	Std Error Mean
NICU	80	27.80	5.810	1.061
KMC	80	27.60	6.69	1.257

4.34 Maternal Parity

Within the KMC study group 51/80 (63.3%) had parity in the range 1 to 2, while in the NICU group 35/80 (43.3%) had parity in the range 1 to 2. The difference in maternal parity, however, was not statistically significant, (P-value = 0.12). Table 1 shows the cross-tabulation of maternal parity versus study group.

Table 3. Maternal Parity Category versus Study Group Cross-tabulation

			Study Group		Total
			KMC	NICU	
Parity	Parity 1 to 2	Count	51	35	85
		% within Study Group	63.3%	43.3%	53.3%
	Parity 3 and above	Count	29	45	75
		% within Study Group	36.7%	56.7%	46.7%
Total	Count	80	80	160	
	% within Study Group	100.0%	100.0%	100.0%	

4.35 Mode of Delivery

Within the KMC study group 10/80 (12%) were delivered by C/Section, while in the NICU group 12/80 (15%) were delivered by C/Section. The difference in delivery

mode, however, was marginally significant, (P-value = 0.06). Table 2 shows the cross-tabulation of mode of delivery versus study group

Table 4. Mode of Delivery versus Study Group Cross-tabulation

			Study Group		Total
			KMC	NICU	
Mode of Delivery	C/Section	Count	10	12	22
		% within Study Group	12%	15%	13.0%
	SVD	Count	70	68	138
		% within Study Group	88%	85%	87.0%
Total	Count		80	80	160
	% within Study Group		100.0%	100.0%	100.0%

Table 5: Bivariate Analysis Summary at 5% significance level

	KMC	NICU	P-value
Variables			
Categorical variables			
Age (median, IQR)	2.0(2)	2.0(1)	0.13
Birth Weight (median, IQR)	1.3 (0.16)	1.3 (0.12)	0.21
Maternal Age	27.6 (6.69)	27.8 (5.81)	0.9
Maternal Parity			
1 to 2 (n, %)	51 (63.3%)	35 (43.3%)	0.21
3 and above (n, %)	29 (36.7%)	45 (46.7%)	
Mode of Delivery			
C/section (n, %)	10(12%)	12 (15%)	0.06
SVD (n, %)	70(88%)	68 (85%)	

4.4 FOLLOW-UP COMPARISONS OF KCM AND NICU GROUPS

4.41 Follow-up Hospital stay

Table 4 shows group summary statistics for hospital stay. The mean hospital stay for the KMC group was 6.8 days (SD = 1.2) whereas for NICU group 4.1 days (SD = 1.3).

There was no significant difference in hospital stay between the two groups, (P-value = 0.76).

Table 6: Hospital Stay Group Statistics Summary

Study Group	N	Mean	Std Deviation	Std Error Mean
NICU	80	6.8	1.159	.212
KMC	80	4.1	1.311	.239

4.42 Follow-up Weight

The overall mean baseline weight was 1.32, 95% CI (1.28 – 1.35) and overall mean follow-up weight was 1.36, 95% CI (1.33 – 1.39). The mean follow-up weight for the KMC group was 1.38, 95% CI (1.32 – 1.45) compared to baseline mean weight 1.30, 95% CI (1.24 – 1.35).

The mean follow-up weight for the NICU group was 1.34, 95% CI (1.32 – 1.35) compared to baseline mean weight 1.34, 95% CI (1.29 – 1.38). The weight gain was not statistically significant. The average weight gain in the KMC group was 9 grams per day compared to an average of 5 grams per day in the NICU group. Furthermore, there

was no significant difference in follow-up weight between the two study groups, (P-value = 0.16).

4.43 Body Temperature

The mean body temperature on day 1 was not significantly different between the two groups, (P-value = 0.77), however, there was significant difference in follow-up body temperature between the two study groups taken at 18 hours, (P-value < 0.001). The mean body temperature at this hour in KMC group was 36.1 degrees centigrade and the NICU group 37.2 degrees centigrade.

4.44 Heart Rate

The mean heart rate on day 1 was statistically different between the two groups, (P-value = 0.02). The mean heart rate in the KMC group was 143.7 per minute and NICU group 155.4 per minute. The follow-up mean heart rate continued to be different between the two study groups (P-value = 0.01), with the NICU group having a higher heart rate, 156.3 per minute versus 142.5 per minute.

4.45 Respiratory Rate

The mean respiratory rate between the two study groups was different on day 1, (P-value = 0.02), with the NICU group having higher respiratory rate, 48.0 per minute versus 44.0 per minute. The mean follow-up respiratory was different too, (P-value < 0.001), with the NICU group continuing to have higher respiratory rate, 52.9 per minute versus 43.3 per minute.

4.46 Clinical Events

Out of the 80 neonates followed up in KMC over six months clinical events were noted in only 4 neonates which resulted in flow back to NICU. This represented 5% of the cohort. Two neonates that were flowed back due to recurrent apnoeic episodes which required apnoeic monitoring and possible CPAP, one was flowed back due to Pneumonia with associated increased temperature and increased respiratory rate which required oxygen therapy. The fourth neonate developed increasingly high temperature with associated lethargy and poor feeding. This neonate was transferred to NICU and investigated for possible sepsis. NEC was not observed as a clinical event in the KMC cohort.

The NICU cohort showed an increased incidence of clinical events at 21%, with apnoeic episodes and late onset Sepsis noted in 7 neonates and suspected NEC in 3 neonates.

CHAPTER FIVE

5.1 DISCUSSION

5.11 Follow up and Comparison in Weight Gain

The overall mean baseline weight was 1.32 kg, 95% CI (1.28 – 1.35) and overall mean follow-up weight was 1.36 kg, 95% CI (1.33 – 1.39). The mean follow-up weight for the KMC group was 1.38 kg, 95% CI (1.32 – 1.45) compared to baseline mean weight 1.30 kg, 95% CI (1.24 – 1.35).

The mean follow-up weight for the NICU group was 1.34 kg, 95% CI (1.32 – 1.35) compared to baseline mean weight 1.34 kg, 95% CI (1.29 – 1.38). The average weight gain in the KMC group was 9 grams per day compared to an average of 5 grams per day in the NICU group. The weight gain was not statistically significant, P-value = 0.16.

The average weight gain obtained in the study results was lower than the average weight gain in literature review. A study conducted in in India by Ramanathan et al, demonstrated an average of 15.9 grams per day in the KMC group and 10.6 grams per day in the Intensive care group respectively. In addition, Cattaneo et al. in a randomized controlled trial carried out at three tertiary centres in Ethiopia, Mexico and Indonesia demonstrated an average of 21.3 grams per day in the KMC and 17.7 grams per day in the NICU group respectively (**Ramanathan et al. 2001, Cattaneo et al. 1998**)

Factors noted during the study to have contributed to this disparity include the lack of knowledge by mothers on KMC and the resultant reluctance to perform KMC on the ward. In spite of continued education on the benefits of KMC provided on the KMC

ward, maternal reluctance was experienced throughout the course of the study .Thus the study has recommended incorporation of KMC education in routine antenatal education to improve maternal knowledge and prevent such attitude.

5.12 Follow up and Comparison in Hospital Stay

The mean hospital stay for the NICU group was 6.8 days (SD = 1.2) whereas for the KMC group 4.1 days (SD = 1.3). There was no significant difference in hospital stay between the two groups, P-value = 0.26. The shorter duration of hospitalization observed with the KMC group was not only reflective of the higher average weight gain of the group relative to the NICU group but the significantly lower frequency of clinical events associated with this group. In addition, the continued thermal and cardio-respiratory stability observed in the KMC group were factors that contributed to more effective breast feeding and general neonatal wellbeing. The study results were comparable to literature review which equally showed a shorter duration of hospitalization with KMC neonates relative to NICU neonates. A study performed in India showed that neonates receiving KMC had a shorter duration of hospitalization of 1.3 days versus 4.9 days primarily in neonates <1.8 kg compared with neonates receiving incubator care .(**Charpak, et al 1997**).

Furthermore, in a randomized controlled trial carried out at three tertiary centres in Ethiopia, Mexico and Indonesia and a further study in India it was demonstrated that KMC babies were discharged from the hospital three to seven days earlier relative to neonates receiving intensive care. (**Ramanathan et al. 2001, Cattaneo et al. 1998**)

5.13 Follow up and Comparison of Body Temperature

The mean body temperature on day 1 was not significantly different between the two groups, P-value = 0.77. However, there was significant difference in follow-up body temperature between the two study groups taken at 18 hours, P-value < 0.001. The mean body temperature at this hour in the KMC group was 36.1 centigrade and the NICU group 37.2 centigrade further follow up temperatures performed at 36, 72, 96 and 120 hours respectively showed more thermal stability with the KMC group relative to the NICU group who showed marked fluctuation in core body temperature. These results were consistent with a study in Mozambique where serial recordings of skin temperature were performed on Very Low Birth Weight neonates and found more thermal stability in Kangaroo Mother Care KMC neonates receiving skin-to-skin contact relative to neonates receiving Incubator care. **(Lincento, et al 2000), (Chwo, et al 2010).**

In addition, NICU neonates receiving cot care showed more hypothermic temperature fluctuations relative to KMC neonates. These results were equally shown in a study by Bergman in which 8 of 13 VLBW neonates receiving incubator babies suffered from hypothermia, compared with none in the same weight band receiving KMC. **(Bergman, et al 2001).**

5.14 Follow up and Comparison of Heart Rate and Respiratory Rate

The mean heart rate on day 1 was statistically different between the two groups, P-value = 0.02. The mean heart rate in the KMC group was 143.7 and NICU group 155.4. The follow-up mean heart rate continued to be different between the two study groups P-value = 0.01, with the NICU group having a higher heart rate, 156.3 versus 142.5. Concurrently, the mean respiratory rate between the two study groups was different on Day 1, P-value = 0.02, with the NICU group having higher respiratory rate, 48.0 versus 44.0. The mean follow-up respiratory rate was different too, P-value < 0.001, with the NICU group continuing to have higher respiratory rate, 52.9 per minute versus 43.3 per minute respectively.

Neonates receiving continuous KMC have been shown to have more regular heart rate and respiratory rate relative to neonates receiving incubator care. In addition to regulation in the heart and respiratory rates, Acoulet demonstrated that saturations of oxygen in inspired air are higher in neonates held skin-to-skin in an upright position in Kangaroo Mother Care compared to the horizontal position in Incubator care. (**Acoulet, et al 2010**).

5.15 Comparison of Frequency of Clinical Events

Out of the 80 neonates followed up in KMC over six months clinical events were noted in only 4 neonates which resulted in flow back to NICU, representing 5% of the cohort. Two neonates were flowed back due to recurrent apnoeic episodes which required apnoeic monitoring and possible CPAP, one was flowed back due to Pneumonia with associated increased temperature and increased respiratory rate which required oxygen

therapy. The fourth neonate developed increasingly high temperature with associated lethargy and poor feeding. This neonate was flowed back and investigated for possible sepsis. NEC was not observed as a clinical event in the KMC cohort.

The NICU cohort showed an increased frequency of clinical events with apnoeic episodes and late onset Sepsis noted in 7 neonates respectively and suspected NEC in 3 neonates, representing 21% of the cohort.

The study results were in concurrence with results obtained from two studies, the first in India and the second a randomized controlled trial carried out at three tertiary centers in Ethiopia, Mexico and Indonesia where there were lower rates of serious and nosocomial infections among KMC-managed newborns, as compared with control newborns. Only 5% of KMC-managed babies had a serious illness versus 18% in the control group. The rates of respiratory infection in the KMC and the control groups were 5% and 13%, respectively. **(Ramanathan et al. 2001, Cattaneo et al. 1998)**

In addition, the frequency of clinical events between the two cohorts was a mirror of results demonstrated by other studies around the world. In 2011, a Cochrane review upon assessing 35 studies demonstrated that compared with conventional neonatal care, KMC was associated with a reduction in severe infection/sepsis, nosocomial infections, and lower respiratory tract disease. Furthermore, Ludington demonstrated that Kangaroo Mother Care has a four-fold decrease in episodes of apnoea relative to Incubator care. **(Ludington, et al 1998)**

5.2 LIMITATIONS

The study results had possible dilution as neonates on NICU received intermittent KMC during feeding. Mothers with neonates on NICU were encouraged to provide intermittent KMC during the two hourly feeds.

Roll back from KMC ward to NICU for neonates observed to have changed condition was at the discretion of the attending physician. Thus participants in the study were rolled back to NICU even when they still remained eligible. Once a participant was rolled back, the participant automatically dropped out of the study.

CHAPTER SIX

6.0 CONCLUSION

In conclusion, at the University Teaching Hospital UTH, Lusaka, VLBW neonates receiving KMC had an average weight gain of 9 grams per day compared to an average of 5 grams per day in the NICU group. This represented a higher follow up weight of 1.38 kg, 95% CI (1.32 – 1.45) compared to the NICU group which had a follow up weight of 1.34 kg, 95% CI (1.32 – 1.35) the difference in follow-up weight between the two study groups was not significant, (P-value = 0.16), however, it was associated with a shorter duration of hospitalization mean 4.1 days relative to 6.8 days observed in the NICU group. Furthermore KMC was associated with more thermal and cardio-respiratory stability with less fluctuations during follow up relative to the neonates in NICU. The NICU cohort showed an increased frequency of clinical events at 21% compared to 5% observed in the KMC cohort over the six months of data collection. The study results were in keeping with results of numerous studies conducted around the world.

6.1 RECOMMENDATIONS

1. This study provides evidence to the multiple benefits of KMC in reducing morbidity in the VLBW neonatal weight band and recommends an expansion of the current KMC ward so as to cater for the high turnover and resultant demand for neonatal care at UTH.
2. This study recommends antenatal maternal education on the benefits of KMC as the simplicity of the method attracted a lot of reluctance and resistance from mothers on the KMC ward
3. This study recommends a deliberate policy towards the implementation of KMC in hospitals and clinics in Lusaka and other urban centres and a systematic roll out into the rural areas.
4. To apply KMC to VLBW neonates undergoing stabilization and receiving interventional therapy and not limit it to already stable neonates.
5. This study recommends extension of the practice of KMC to Extremely Low Birth Weight Neonates ELBW initially only at UTH as this is the weight band associated with the highest mortality in spite of standard intensive care.

CHAPTER SEVEN

7.0 REFERENCES

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Appendix- 1 Data Collection Sheet

NAME	DATE				
BIRTH WEIGHT		Day 1	Day 2	Day 3	Day 4
AGE	WEIGHT				
MATERNAL AGE	TEMPERATURE	6hrs			
		12hrs			
		18hrs			
		24hrs			
MATERNAL PARITY	HEART RATE	6hrs			
		12hrs			
		18hrs			
		24hrs			
MODE OF DELIVERY	RESPIRATORY RATE	6hrs			
		12hrs			
		18hrs			
		24hrs			
CLINICAL EVENTS	APNEIC SPELLS				
	RESPIRATORY SYMPTOMS				
	NECROTIZING ENTEROCOLITIS				