# Supplementary Material 2 – Characteristics of RCTs included

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| **Study** | **Objective** | **Method** | **Participants** | **Intervention** | **Outcomes** | **Notes** | **Main results and conclusions** | **Quality of the study (Risk of Bias 2) for the outcome studied** |
| Acharya 2014 | Compare the effect of KMC and conventional methods of care on weight gain, occurrence of hypothermia and apnea and duration of hospital stay among LBW babies. | 2 groups:  63 NB included in the Intervention group (KMC).  63 NB included in the Control group (Conventional care).  Duration of the study: one year  Place: Nepal | LBW babies with birth weight < 2000 g  Intervention group – N=63  Control group – N=63  Inclusion criteria: LBW with birth weight < 2000 g admitted in newborn Nursery.  Exclusion criteria: critically ill babies requiring ventilatory or ionotropic support or radiant warmer, babies with chromosomal and  life threatening congenital anomalies, babies whose mothers are critically ill and babies whose mothers do not consent for study. | The mother wore a loose blouse, and the baby was held upright between the breasts and the limbs were flexed and the head was turned to one side not much flexed or extended. Babies wore only diaper and a cap during the period of KMC. The blouse covered the infant’s trunk and extremities but not the head. The baby was further supported by 3 meters long flannel clothes which was wrapped around mother’s chest from outside her blouse. Then the mother  was seated in a comfortable position. The mother was encouraged to hold her baby in this position for at least 1 hour. If the baby passed urine and/or stool  during the procedure and she felt discomfort she was  asked to change the diaper and continue KMC. Just before starting KMC, baby was breast fed or tube fed; no feeding was given during KMC. When babies were not in KMC, they were adequately clothed and kept covered. The mothers were provided KMC chart to keep the records of duration of KMC. The babies were subjected to KMC of at least 6 hours per day in not more than 4 sittings, each sitting of at least 1 hour.  Randomized n= 126, analyzed n= 126. | Weight gain, hypothermia, apnea, and duration of hospital stay. | Adverse effect: not reported.  Communication with the author: no.  Conflict of Interest: This article is based on the final thesis, submitted to Department of Paediatrics and  Adolescent Medicine,BP Koirala Institute of Health Sciences, Dharan. | Median daily weight gain and mean weight gain higher in the intervention group.  Higher incidence of hypothermia in the control group.  Duration of hospital  stay was less in the control group.  Conclusions: LBW babies with birth weight < 2000 g submitted to KMC showed better weight gain than those in the control group and less incidence of hypothermia. | High risk of bias |
| Ali 2009 | To study the efficacy of Kangaroo mother care (KMC) as compared to conventional care for LBW babies. | 2 groups:  58 neonates included in the Intervention group (KMC).  56 neonates included in the Control group (Conventional care).  Duration of the study: one year and six months  Place: India | neonates delivered by vaginal route weighing between 1200 g and 1800 g.  Intervention group – N=58  Control group – N=56  Exclusion criteria:  Neonates delivered by caesarean section, with major life threatening congenital malformation,  severe perinatal complication and parental refusal for KMC intervention. | The neonates were given skin-to-skin contact as soon as they became hemodynamically  stable, between the mother's breasts in  an upright position dressed with a cap, socks and diaper and supported in bottom with a sling/binder. Front open gowns were made available for the mothers and privacy was provided to them. Comfortable  chairs and beds were provided to the  mothers practicing KMC in the nursery and postnatal wards.  Skin-to-skin contact was given for a  minimum of 1 hour at a stretch and at least for 4-6 hours/day, duration was gradually increased to as long as comfortable to the mother and baby. Skin-to-skin contact was continued at home after discharge from the hospital.  Infants in both the groups were discharged when demonstrated weight gain for at least 3 consecutive days, no overt illness, no IV medications and essentially on exclusive breast feeds.  Randomized n= 114, analyzed n= 114. | Effect on growth, physiological parameters, length of hospital stay, morbidity, mortality, and exclusive breastfeeding rates. | Adverse effect: not reported.  Communication with the author: no.  Conflict of Interest: not reported. | Infants in the intervention group showed higher mean  weight gain per day, reduction in respiratory rate, higher rectal  temperature, increase in oxygen saturation, shorter duration of hospital stay, lower incidence of  nosocomial sepsis and severe infection, higher proportion of exclusive  breastfeeding. No statistically significant difference was observed in the mortality rates between the two groups.  Conclusions: KMC is feasible method of care for LBW babies once they have overcome major adaptation to extra-uterine life and it is at least as safe and effective as the conventional care. | Some concern |
| Gathwala 2008 | To determine whether KMC facilitates mother baby attachment in LBW infants. | 2 groups:  Neonates included in the intervention group (KMC).  Neonates Included in the Control group (Conventional care).  Duration of the study: 16 months.  Place: India. | Neonates with birth weight ≤  1800 g  Intervention group – N=50  Control group – N=50  Inclusion criteria: neonates with birth weight ≤  1800 g stable  cardiopulmonary status, Apgar score of ≥ 7 at 1 and 5  minute, tolerating enteral feeds and maintaining  temperature.  Exclusion criteria: Babies who  were sick, unstable or with major congenital malformations. Mothers who were unwell and unable to come and those who refused consent. | During KMC the mother  wore a front open gown and sat in an inclined posture in  a chair. The baby was positioned inside her dress in skin-to-  skin contact between her breasts. The baby was naked except for a cap and nappy. The gown covered the baby’s trunk and extremities but not the head. The intervention group was subjected to KMC for at least 6 hours per day in not more than 4 sittings. The KMC was given for a minimum of one hour at a stretch and continued for as long as it was comfortable to baby and mother.  Randomized n= 100, analyzed n= 100. | Duration of KMC, duration of hospital stay, and mother Baby Attachment. | Adverse effect: not reported.  Communication with the author: no.  Conflict of Interest: not reported. | The duration of KMC in the first month was 10.21 hours, in the 2nd month was 10.03 hours and in the 3rd month was 8.97 hours per day. The duration of hospital stay was significantly shorter in the KMC group, and the total attachment score in the KMC group was significantly higher  than in the control group. The mothers were more significantly involved in the usual care and they went out without their babies less often.  Conclusions: KMC facilitates mother- baby attachment in LBW infants. | Some concern |
| Ghavane 2012 | To study the effect of KMC in the Kangaroo ward in comparison  with conventional care at neonatal unit on growth and breastfeeding in VLBW infants at 40 weeks’ corrected gestational age. | 2 groups:  Infants included in the Intervention group (KMC).  Infants included in the Control group (Conventional care).  Duration of the study: one year and 10 months  Place: India | VLBW infants with birth weight <1500 g  Intervention group – N=71  Control group – N=69  Inclusion criteria: VLBW (birth weight <1500 g) infants, tolerating spoon feeds of 150 mL⁄ kg ⁄ day and hemodynamically stable, not on oxygen or respiratory support, no apnoea for 72 h, not on any intravenous fluids.  Exclusion criteria: with major malformation. | In the KMC ward,  mother-infant dyads were together, and care of the baby was supervised by a trained nurse. Neonates were given  skin-to-skin contact between the mothers’ breasts in an upright position dressed with a cap, socks and diaper and supported at the bottom with a cloth sling ⁄ binder. Front open gowns were made available for the mothers and privacy was provided to them. Comfortable chairs and beds  were provided for the mothers practicing KMC. Mothers were encouraged to do KMC for as many hours per day as  possible, ensuring a minimum of eight hours per day. When not in KMC position, infants were placed in open cribs well covered with clothes, socks and mitten. Infants were discharged home at a minimum weight of 1300 g or when gaining weight at a rate ≥10 g ⁄ day on three consecutive days.  Randomized n= 140, analyzed n= 136. | Weight gain (g⁄kg⁄day) till term gestational age (40 weeks), weight gain (g⁄kg⁄day) from randomization to hospital discharge,  proportion  of babies on exclusive breastfeeding, and number of  hospital days after randomization. | Adverse effect: not reported.  Communication with the author: no.  Conflict of Interest: not reported. | There were no differences in average time to reach full enteral feeds or in time to regain birth weight between study groups. There was no difference in the weight gain from randomization to hospital discharge.  Mortality and morbidities as sepsis, hypothermia, apnoea, and hypoglycaemia  were similar between the two groups.  On average 11.5 days of hospital stay was reduced in the intervention group.  Conclusions: KMC in the Kangaroo ward is as effective as conventional care in the neonatal unit without any increase in morbidity or mortality in stable VLBW infants. | Low risk of bias |
| Kadam 2005 | Determine the feasibility and acceptability of KMC in a tertiary care hospital in India.  Compare the effects of both KMC and conventional care on physiological parameters and to see if KMC had any beneficial or deleterious effects as compared to  conventional care. Also, assess the  acceptance of KMC from parental point of view. | 2 groups:  Neonates included in the intervention group (KMC).  Neonates included in the Control group (Conventional care).  Duration of the study: one year  Place: India | Neonates with birth weight <1800 g  Intervention group – N=44  Control group – N=45  Inclusion criteria: all neonates with birth weight <1800 g,  stable  cardiopulmonary status in air, Apgar's score of ≥ 7 at 5  minutes and on feeds (breast feeds or spoon *wati* feeds  with expressed breast milk).  Exclusion Criteria: sick and unstable babies, major congenital malformations, and refusal of parental  consente. | The baby was placed on mother's chest in between the breasts in vertical position supported by a cloth dupatta, with mothers sitting in a semi-reclining position.  KMC was given for a minimum of one hour at a stretch and continued for as long as comfortable to the  baby and mother.  Randomized n= 89, analyzed n= 89 | Physiological parameters, apnea, sepsis, hyperbilirubinemia, serious illness, onset of breastfeeding, weight gain and duration of stay in  hospital, and acceptability. | Adverse effect: not reported.  Communication with the author: no.  Conflict of Interest: not reported. | There was significant reduction of hypothermia, higher oxygen saturations, and decrease in respiratory rates in the intervention group. There were no statistically significant differences in the incidence of hyperthermia, sepsis, apnea, onset  of breastfeeding and hospital stay in two groups.79% mothers felt comfortable with KMC and 73% mothers said that they would continue KMC at home.  Conclusions: KMC is a simple and feasible intervention acceptable to most mothers admitted in hospitals. There may  be benefits in terms of reducing the incidence of hypothermia. | Low risk of bias |
| Ramanathan 2001 | Study through a RCT the effect of KMC on breastfeeding rates, weight gain and length of hospitalization of very low birth neonates and assess the  acceptability of KMC by nurses and mothers. | 2 groups:  Neonates included in the intervention group (KMC).  Neonates included in the Control group (Conventional care).  Place: India | Very low birth neonates with birth weight <1500 g  Intervention group – N=14  Control group – N=14  Inclusion criteria: babies whose birth weight was <1500 g  once their cardiopulmonary status was stable, when tolerating enteral feeds and  maintaining temperature in the thermoneutral  environment.  Exclusion criteria: babies whose mothers were unable to come to the nursery because of illness or disability. | During KMC each mother wore a cover gown and sat in an inclined chair. The baby was positioned inside her dress and  between the breasts. The gowns covered the infant's trunk and extremities, but not the head, which was covered with a cap. The mother was encouraged to hold her baby in this position whenever she came to visit her baby. The baby was nursed in warmer/ incubator for the  rest of the time. KMC was for at least 4 hours per day and not more than 3 sittings. The babies were discharged once they meet the criteria of weight greater than 1400 g, gestation over 34 weeks, only on enteral feeds, mother's readiness to go home/confidence to look after the baby, gaining weight adequately, no overt illness, no intravenous medications and essentially on exclusive breast feeds.  Randomized n= 28, analyzed n= 28. | Breastfeeding rates, speed in weight gain, and KMC acceptability. | Adverse effect: not reported.  Communication with the author: no.  Conflict of Interest: not reported. | Babies in the KMC group demonstrated significantly better weight gain after the first week of life. Also the duration of hospital stay for the KMC groups was  significantly shorter. The number of mothers exclusively breastfeeding their babies at 6 week follow-up was double in the KMC group.  Conclusions: KMC  had significant benefits in terms of weight gain, earlier hospital discharge and, more impressively higher exclusive breastfeeding rates. KMC appears as an excellent adjunct to the routine preterm care in a nursery. | Some concern |
| Suman Rao 2008 | Compare the effect of KMC and conventional care on growth in  LBW babies (<2000 g). | 2 groups:  Neonates included in the intervention group (KMC).  Neonates included in the Control group (Conventional care).  Duration of study: 9 months  Place: India | LBW babies with birth weight <2000 g  Intervention group – N=103  Control group – N=103  Inclusion criteria:  singleton intramural  neonates with birth weight <2000 g.    Exclusion criteria: critically ill  babies requiring ventilatory or inotropic support,  babies with chromosomal and life-threatening congenital anomalies, babies requiring transfer, or whose mothers were critically ill, or unable to comply with the follow up schedule. | Mothers in the KMC group were explained in detail about KMC adoption in the presence of their family. KMC was initiated as soon as the baby was stable. The mothers provided skin to skin contact using a specially tailored “Kangaroo  bag” made of soft flannel cloth. The mothers were  encouraged to keep the baby in KMC as long as possible during the day and night with a minimum  period of one to two hours at a time seated in a  comfortable chair placed close to the baby’s cradle.  Randomized n= 206, analyzed n= 206. | Weight gain, morbidity, mortality, and duration of hospital stay. | Adverse effect: not reported.  Communication with the author: no.  Conflict of Interest: not reported. | The KMC  babies had better average weight gain per day, weekly  increments in head circumference and length. A significantly higher number of babies in the control group suffered from hypothermia, hypoglycemia, and sepsis. There was no effect on time to  discharge. More KMC babies were exclusively breastfed. KMC was acceptable to most mothers and families at home.  Conclusions: Kangaroo mother care improves growth  and reduces morbidities in LBW infants. It is simple, acceptable to mothers and can be continued at home. | Low risk of bias |
| Boo 2007 | Compare weight gain, breastfeeding rates, and head growth in VLBW infants with or without exposure to short duration of skin-to-skin contact during their stay in a NICU. | 2 groups:  Infants included in the intervention group (KMC).  Infants included in the Control group (Conventional care).  Duration of study: 34 months  Place: Malaysia | VLBW infants with birth weight <1501 g  Intervention group – N=64  Control group – N=62  Inclusion criteria:  infants who were in stable condition after recovering from all major adaptation  problems to extrauterine life, nursed in a closed incubator, not requiring ventilatory support other than nasal continuous positive airway pressure (nCPAP), able to tolerate enteral feeds of at least 50% of the required fluid volume, and having at least one parent or guardian who was willing to  participate in skin-to-skin contact.  Exclusion criteria: babies with lethal or major malformations, severe perinatal asphyxia with evidence of hypoxic ischaemic encephalopathy,  transfer to another hospital, abandoned by parents or  parental refusal to participate. | Parents wore clothing that buttons down their front to allow easy exposure of their chests and carried out with their bras removed. During KMC a parent sat in a standard type of sofa.  He/she was taught how to hold his/her infant prone on their naked chest, in a semi-upright position and between his/her  breasts. The infant wore only a nappy and a bonnet, a clean thermal blanket was provided to cover the infant.  If an infant  showed signs of searching for feeds during KMC session, its mother was encouraged to offer her breast to the infant for suckling.  Parents were encouraged to perform KMC for at least 1 h daily. They were provided with charts to document each of the KMC sessions.  Randomized n= 126 analyzed n= 118. | Weight gain, body length, head growth, breastfeeding rates, and duration of hospital stay. | Adverse effect: not reported.  Communication with the author: no.  Conflict of Interest: not reported. | Infants in the  KMC group had better mean weekly increase in head circumference and higher breastfeeding rate at discharge. The weight gain in the control group was higher at discharge with longer period of hospital stay.  Conclusions: exposure to short duration of MKC may promote head growth in VLBW infants. | Some concern |
| Chwo 2002 | Test the hypotheses that KMC infants would have higher mean tympanic temperatures, less weight loss, more optimal behavioral states, and lower length of stay. | 2 groups:  Infants included in the Intervention group (KMC).  Infants included in the Control group (Conventional care).  Place: Taiwan | Infants at 34-36 weeks GA.  Intervention group – N=17  Control group – N=17  Inclusion criteria: eligible mothers had no pre-existing medical problems, were willing to breastfeed, and had no other problems that would prevent them from going to the nursery. Eligible infants were 34 to 36 weeks, had a 5-minute Apgar score ≥7, had no need for continuous respiratory assistance, and were admitted to the normal newborn nursery or  observation nursery. | Skin-to-skin contact and on-cue self-regulatory feedings during the six one-hour study feeding periods.  Randomized n= 34, analyzed n= 34. | Tympanic temperatures, weight, behavioral states and length of hospital stay. | Adverse effect: not reported.  Communication with the author: no.  Conflict of Interest: not reported. | KMC infants compared to control infants had higher mean tympanic temperature. No significant difference was found between groups on pre-test temperatures. No significant difference on mean weight between the two groups. KMC infants were in quiet sleep (States 1 and 2) during most (61.7%) of the observations. In spite of more time spent sleeping, KMC infants were in an inactive awake behavioral state (alert  inactivity and quiet awake), more often than the control infants. Length of hospital stay for KMC infants was higher than for control group.  Conclusions: KMC was a safe intervention and had beneficial effects on tympanic temperature, variability, and behavioral state. | Some concern |
| Lumbanraja 2016 | Determine maternal factors that influence on anthropometric parameters in LBW babies that received KMC. | 2 groups:  NB included in the intervention group (KMC).  NB included in the Control group (Conventional care).  Duration of study: 6 months  Place: Indonesia | Babies  with birth weight  1000–2500 g.  Intervention group – N=20  Control group – N=20  Inclusion Criteria: babies with birth weight 1000–2500 g, stable hemodynamic  status, needed neither oxygen nor continuous intravenous fluids, and mothers were healthy enough and willing to practice KMC.  Exclusion criteria: babies with congenital anomalies, severe perinatal complications  that required NICU care, experienced a malignancy,  metabolic disorders, and cardiovascular disorders. | KMC was initiated as soon as the babies were stable. Previously, the mothers were educated on how to practice KMC. Mothers were seated at comfortable chair close to the babies’ cradle. Mothers were shown how to hold their babies vertically and strapped to the middle of mothers’ chests. Babies’ skin should touch their mother’s skin, when not in KMC, babies were placed in the cradle with bodies covered. This method was conducted for 4–6 hours each day.  Randomized n= 40, analyzed n= 40. | Weight gain, length, and head circumference. | Adverse effect: not reported.  Communication with the author: no.  Conflict of Interest: not reported. | Weight parameters were significantly higher in the KMC group. Duration of hospital stay did not differ between conventional and KMC groups. Gestational age influences head growth.  Conclusions: KMC was associated with increased weight gain in LBW infants. Gestational age influences head growth in infants who received KMC. | Some concern |
| Mwendwa 2012 | Determine the effect of partial KMC on growth rates and duration of hospital stay of LBW infants. | 2 groups:  Infants included in the intervention group (KMC)  Infants included in the Control group (Conventional care  Duration of study: 9 months  Place: Kenya | LBW infants weighing 1000 g to 1750 g.  Intervention group – N=85  Control group – N=81 | In the first session the mothers were taught how to place the baby in the kangaroo position and a kangaroo suit was tied tightly to hold the baby on the mother's trunk. This position was practiced for 8 hours daily and the babies were returned to the incubator or cribs at night.  Randomized n= 166, analyzed n= 157. | Weight gain, duration of hospital stay, infection, mortality, and breastfeeding rate. | Adverse effect: not reported.  Communication with the author: no.  Conflict of Interest: not reported. | The KMC group had significantly higher growth rates, higher mean head circumference gain. Infants with < 1500 g the duration of hospital stay was significantly shorter. Overall duration of stay was similar between the groups.  Conclusions: LBW infants achieved rates of growth within the recommended intrauterine growth but babies managed using partial KMC grew faster and were thus discharged earlier. | Some concern |
| Tessier 1998 | Investigate the impact of KMC on the mother’s perception of giving birth as well as on the  mother and child’s responsiveness to each other. | 2 groups:  NB included in the intervention group (KMC).  NB included in the Control group (Traditional care).  Duration of study: 13 months  Place: Colombia | Infants weighing <2001 g  Intervention group – N=246  Control group – N=242  Inclusion criteria: the mother or a relative was willing to follow instructions, and if the infant had overcome all major adaptation problems to extrauterine life, had a positive  weight gain and suckled and swallowed properly.  Exclusion criteria: death of infant, had been referred to another institution, had lethal or major malformations, had sequelae arising from perinatal problems, had been abandoned or given for adoption. | The infants were in an upright position on the mother’s chest, with direct skin-to-skin contact 24 hours a day. Breastfeeding  is the prime source of nutrition, infants also may receive preterm formula and vitamin supplements when necessary, and infants are monitored on a regular basis daily until a weight gain of at least 20 g per day.  Randomized n= 488, analyzed n= 488. | The Mother’s perception of premature birth: mother’s attachment behavior,  feelings and perceptions of  her premature birth experience, including her sense of  competence, feelings of worry and stress, and perception  of social support, mother and child’s responsivity to  each other during breastfeeding, duration of hospital stay and necessity of NICU. | Adverse effect: not reported.  Communication with the author: no.  Conflict of Interest: not reported. | KMC group showed shorter duration of hospital stay in  infants weighing <1501 g. In infants weighing >1500 g there was no difference. In the KMC group there was a “bonding effect” where the mothers felt more competent in stressful situations and felt more isolated.  Conclusions: KMC should be promoted actively and that mothers should be encouraged to use it as soon as possible. KMC should be viewed as a means of humanizing the  process of giving birth in a context of prematurity. | Some concern |

RCTs – Randomized clinical trials

KMC – Kangaroo mother care

LBW - Low birth weight

VLBW - Very low birth weight

NB – Newborn

N – Number of participants

GA – Gestational age

NICU –Neonatal intensive care unit

nCPAP – Nasal continuous Positive Airway Pressure