



STUDY PROTOCOL FOR A RANDOMIZED CONTROLLED TRIAL TO EVALUATE THE EFFICACY OF 'BREASTFEEDING – SUPPORTIVE CARE' (B - SUCA) ON INITIATION, DETERMINANTS OF BREASTFEEDING AND PERINATAL OUTCOMES IN MOTHER-NEWBORN DYADS

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KEYWORDS

Efficacy, Breastfeeding – Supportive Care' (B - SUCA), Skin-to-skin contact (SSC), initiation of breastfeeding, determinants, perinatal outcomes, mother-newborn dyads

Abstract

Background: Breast milk is the best ever gift a mother can give to her newborn baby. During the olden times, early and exclusive breastfeeding was the custom and so was closeness between the mother and her baby. **Methods:** This randomized controlled trial (RCT) aims to test the primary outcomes on efficacy of 'Breastfeeding – Supportive Care' (B - SUCA) on time to initiate breastfeeding, determinants of breastfeeding, maternal- neonatal bonding. The secondary outcomes are to assess the B - SUCA on perinatal birth outcomes (maternal & neonatal) and check the acceptability of B - SUCA among the mothers in the experimental group. A block randomization technique is adopted among 160 participants 80 each in experimental and control group. Data collection is done after the approval from the ethics committee and patient's informed consent.

Results: At the time of writing, data collection was still being in process. After data collection it will be analyzed and results will be published as separate manuscripts.

Conclusions: This study will offer insights into the prospect of improving breastfeeding rate for early initiation through breast crawl and skin-to-skin contact (SSC). It will determine the technique as a natural, simple, easy, feasible and effective way to improve the breastfeeding rate thus, enhance the newborn health status.

Trial Registration: CTRI/2022/03/040974.

Introduction:

Breast milk is the best ever gift a mother can give to her newborn baby. During the olden times, early and exclusive breastfeeding was the custom and so was closeness between the mother and her baby. The new Lancet Series on breastfeeding concluded that breast milk makes the world healthier, smarter, and



more equal. The deaths of 8,23,000 children each year could be averted through universal breastfeeding, along with economic savings of billions (Lancet, 2016). In fact, children who are not put to the breast within the first hour of life also face a higher risk of common infections (Smith & R. Emily, 2017). Breastfeeding is a cornerstone of infant and young child survival nutrition even in the face and scare of highly infectious disease like COVID -19 (WHO, 2020)

In spite of multiple benefits from breast milk only 42% of last-born children in the two years before the 2015-2016 survey who ever breastfed were breastfed within one hour of birth, and 81% of children began breastfeeding within one day of birth (National Family Health Survey (NFHS-4). A meta-analysis on the links between the delayed breastfeeding initiation and infant survival shows that newborns who began breastfeeding between 2 and 23 hours after birth had a 33% greater risk of dying compared with those who began breastfeeding within 1 hour of birth (Smith et al., 2017; Khan et al., 2015).

The neonatal mortality rate in India is 39/1000 population as per National Family Health Survey (NFHS-3) conducted in 2005-2006, 25 deaths/1000 live births in 2016, and 18 deaths/1,000 live births in 2017. The figures on breastfeeding rates in the modern India are unsatisfactory. According to NFHS-3, only about 23.6% of the newborns were breastfed within half an hour of birth and only 24.5% of the newborns within 1 hour after birth. (WHO & UNICEF, 1989).

In Sikkim, majority of mothers practice breastfeeding however, not in the form of exclusive breastfeeding. In spite of the fact that breastfeeding is almost universal, India with 95.7%, Sikkim 98.1%, only 46.4% in the country. The neonatal mortality rates are high in India, whereas the breastfeeding rates are still low. Hence, need exists for a simple and easily applicable intervention, which may counter these challenges (Srivastava, Gupta, Bhatnagar & Dutta, 2014). According to NFHS -5 Sikkim shows 33.0% of babies were breastfed within 1 hour after birth. Table 1 shows the number of infants who was exclusively breastfeed. (NFHS, 2019, 2020)

Exclusive breastfeeding	NHFS-5			NHFS-4	NHFS-3
	Urban	Rural	Total	Total	Total
India	59.6%	65.1%	63.7%	54.9%	46.4%
Sikkim	-	29.7%	28.3%	54.6%	37.2%

Table 1: Exclusive breastfeeding rate in Sikkim and India according to NHFS-5, NHFS-4, NHFS-3.

The World Health Organization (WHO) recommends the practice of Skin-to-skin contact (SSC) for at least one hour after birth. SSC is defined as placing the naked baby on the mother's bare abdomen or chest immediately or less than 10 minutes after birth or soon after birth. (WHO, 2017). Infants who received skin-to-skin contact (SSC) had higher stability of the cardio-respiratory system, and higher blood glucose levels. The review also supports using immediate or early skin-to-skin contact to promote breastfeeding (Moore, Bergman, Anderson & Medley, 2016). UNICEF is highlighting a natural occurrence called the 'breast crawl', which can benefit mothers and newborns around the world. The breast crawl is the first skin-to-skin contact the baby has with the mother right after the birth. (George & Paul, 2018). Breast crawl is the most natural, spontaneous, and logical method for initiation of



breastfeeding (Kulkarni, 2007). A strong correlation between the mother-infant bonding scores was also seen at 3days and at 12 weeks of birth (Taylor A et al., 2005).

In many cultures, babies are generally cradled naked on their mother's bare chest at birth. Previously, this was necessary for the baby's survival. In recent times, such as in industrialized countries more babies are born in hospital, and as part of usual hospital care babies are often separated and swaddled or dressed before being given to their mothers. It is, however, significant that an intervention related to skin-to-skin contact (SSC) and Breast Crawl; to be practiced at birth should have measurable effects towards postnatal mother and newborn (Moore, Anderson, Bergman, Dowswell, 2014). However, for initiating breastfeeding within the first hour of life, mothers need adequate support, direction and encouragement on positioning and feeding their newborns (Unicef WHO, 2018). Irrespective of all the benefits, continuous childbirth support is not universally implemented probably due to a high rate of utilizing medical interventions such as epidural anesthesia in hospital settings (Bianchi, Adams, 2004). Consequently, midwives might spend more time attending to technology and routine interventions than offering continuous support during childbirth (Albers, 2007). In the absence of continuous support, women might feel deserted, distraught and petrified (Kritzinger, 2006; Burman, Robinson, Hart, 2013).

Objectives: In this RCT, the study will assess the efficacy of 'Breastfeeding – Supportive Care' (B - SUCA) on time to initiate breastfeeding, determinants of breastfeeding, maternal- neonatal bonding. The primary objective of this study is to assess the time to initiate breastfeeding-using the B-SUCA technique on the experimental group and routine care without B-SUCA technique for the control group. The secondary outcomes are to assess the B - SUCA on perinatal birth outcomes (maternal & neonatal) and check the acceptability of B - SUCA among the mothers in the experimental group.

Research Hypothesis: tested at 0.05 level of significance

H₁: There will be a significant difference in time to initiate breastfeeding among experimental and control group.

H₂: There will be a significant difference on determinants of breastfeeding among experimental and control group.

H₃: There will be a significant difference on maternal- neonatal bonding among experimental and control group.

H₄: There will be a significant difference in the perinatal birth outcomes among newborns in the experimental and control group.

Methods & Procedures:

Approach: Evaluative research approach.

Trial/ Research design: This trial is a RCT with an experimental and a control group, with participants being individually allocated to either of the groups. The allocation ratio is 50:50 using a CONSORT diagram and is as follow:

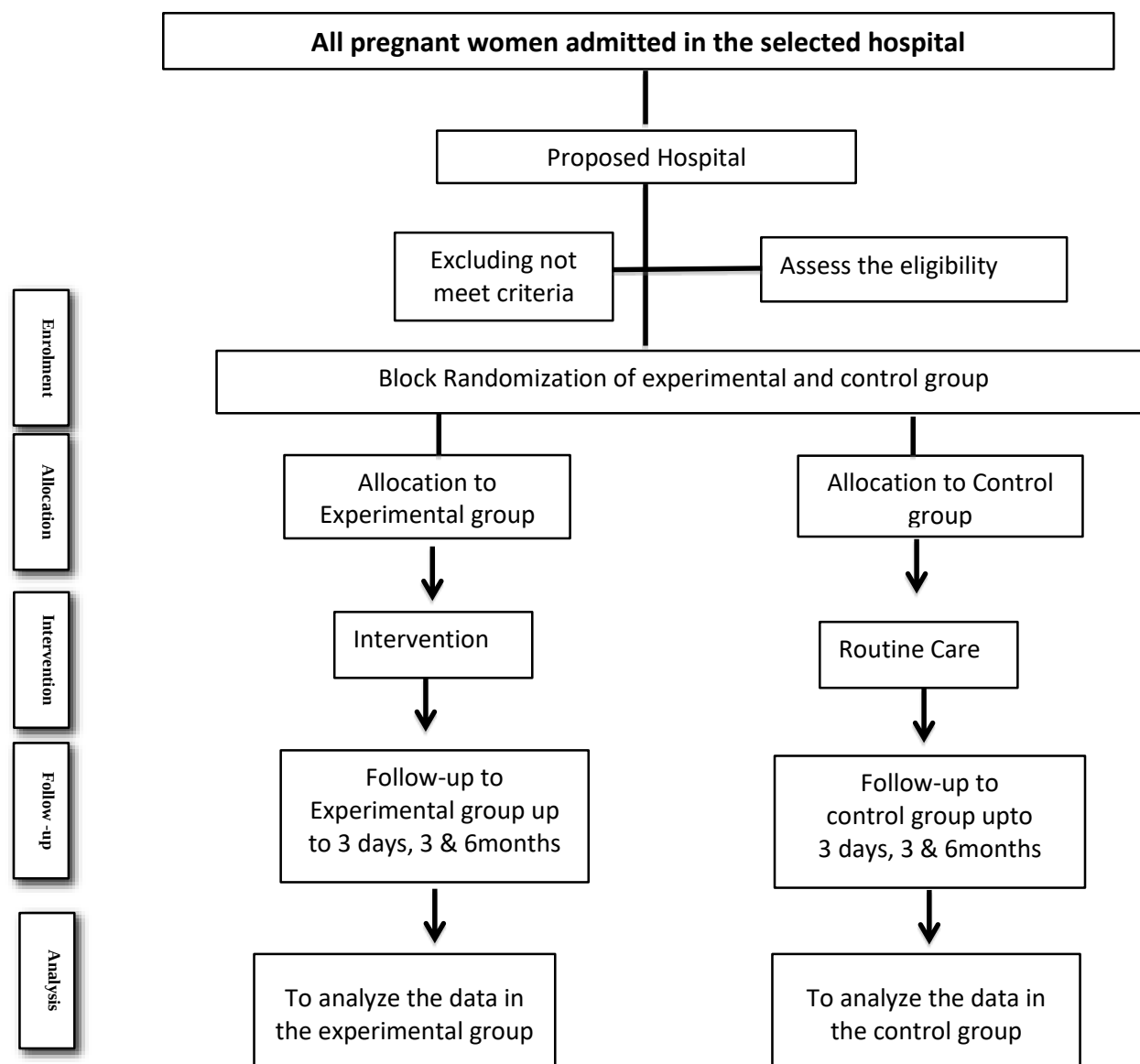


Figure 1: CONSORT schematic diagram of the research study design

Setting: The study is conducted in the selected tertiary hospital among the low risk primi-gravid women whose POG is $\geq 36^{+6}$ days.

Sample size:160 (80 each group)

For the sample size calculation, we consider the comparison of two means. The primary outcome variable i.e. time for initiation of breastfeeding is calculated using the effect size, where 'n' is the sample size in each group, $Z_{1-\alpha/2}$ is 1.96 at 5% level of significance,



$Z_{1-\beta} = 0.84$ at 80% power and $\Delta = \text{effect size} = 0.5$ (medium effect)

$$n = \frac{2 \left(Z_{1-\alpha/2} + Z_{1-\beta} \right)^2}{\Delta^2}$$

Using the above-mentioned inputs, the sample size was found to be 64 in each group. After accounting for dropout rate of 15%, the sample size was found to be 76 in each group. The total sample size is 80 in each group.

Randomization technique: The researcher adopts a *block randomization* technique.

Criteria:

The inclusions are:

- low risk primigravid women who are term ($\geq 36^{+6}$ WGA)
- women from antenatal period just before delivery to 1 hour after delivery and who are diagnosed having cephalic presentation

The exclusions are:

- primigravid women who are with any complications of pregnancy and labour (pre-eclampsia, labour complications like prolonged, precipitate, sepsis, infections), twin gestation, infection, congenital anomalies, severe IUGR, mental health disorders (comorbid mental health illness during pregnancy)
- mother admitted with COVID-19 positive and newborn with complications e.g.: APGAR score < 7 , jaundice etc. will be excluded.

Ethical consideration

- Data collection is done after taking ethical permission from the institutional ethical clearance (IEC) and written consent from the participants.
- The personal details of the sample will be kept confidential and it will be coded so as to avoid biasness.
- However, the study has been approved by the IEC, Registration of trial under Clinical registry of India (CTRI) is CTRI/2022/03/040974.

Intervention

Steps for Breastfeeding Supportive Care (B-SUCA) for the experimental group:

- sensitize the mother and the husband/family members about the technique (Breast Crawl and SSC) and its importance
- education and supportive care will be given to the mother during the antenatal period before the delivery
- after the delivery the baby is shown to the mother first and then is placed on her abdomen
- baby is placed in the prone position facing the mother
- mother's head be slightly raised so that the baby can see the mother
- baby is covered with pre-warm cloth and guarded/supported by the mother's hand/health workers/family members (if needed)
- baby is given the time to crawl and reach the mother breast
- if needed slightly assist the baby to crawl so as to reach the mother breast.
- the researcher assesses the time for initiation of breastfeeding.



Step for Skin-to-skin contact (SSC):

- mother will be advised to wear a comfortable clothing/gown during the delivery for easy skin-to-skin contact (SSC) with the newborn
- once the initiation of breastfeeding start, then baby and mother is kept together for skin-to-skin contact.
- cover the body of newborn and mother with warm cloth leaving face exposed
- continue, assist and support skin to skin contact till the baby finishes her first breastfeed.

Statistical methods: First, descriptive statistics will be generated for each group i.e; primary analysis to assess the efficacy of Breastfeeding – Supportive Care' (B- SUCA) on time to initiate breastfeeding among experimental group using frequency percentage, mean, SD and t-test and compare with the routine care on time to initiate breastfeeding among the control group. Repeated measures ANOVA will also be used to analyze the maternal newborn bonding of the experimental and control group. It is also to assess the efficacy of B - SUCA on determinants of breastfeeding i.e. duration of SSC, LATCH, Neonatal behavioral assessment scale and exclusive breastfeeding using the frequency percentage, mean, SD and t-test among the experimental and compare it with the control group. Descriptive statistics will also be used to assess the efficacy of B – SUCA on maternal- neonatal bonding among experimental group and control group. Second, a frequency percentage of B - SUCA on perinatal birth outcomes (maternal & neonatal) for both experimental and control group will be used. Last, descriptive and inferential statistics for acceptability of B - SUCA among the mothers in the experimental group will be analyzed statistically.

Dissemination plans: The results of the research will be published in peer-reviewed journals of general and specific interest and presented at national or international conferences.

Expected Outcomes: The findings of the study will help the health care professionals to initiate the supportive care required for breastfeeding using the B-SUCA intervention. The expected outcomes will be early initiation of breastfeeding, improved determinants of breastfeeding, improved perinatal outcomes and also improved exclusive breastfeeding rates. Moreover, it may also help in improving the bonding between the mother-infant dyads. The intervention may also help in improving the perinatal outcomes. The positive outcome can be achieved through the acceptance, the join efforts and participation of health care professionals working in the labor room. The outcome if found to be successful, then Breastfeeding: Supportive care (B-SUCA) can be a best practice that can be adopted and included as standard of practice in the labor room of the tertiary referral hospital, so as to improve the perinatal outcomes and thereby reduce the morbidity as well as the mortality rates in the newborn.

Discussion: This study protocol describes an RCT to examine the efficacy of Breastfeeding: Supportive care (B-SUCA) on early initiation of breastfeeding and exclusive breastfeeding immediately after delivery till 6 months respectively. The ultimate goal is to improve the less than average breastfeeding rates in the golden hour following birth as well as third stage, fourth stage of labour and early postnatal period to follow. Evidence about the benefits of skin-to-skin contact (SSC) from Cochrane Review and meta-analysis shows that mothers who had skin-to-skin contact (SSC) were more likely to be breastfeeding at one to four months after birth, had longer breastfeeding, exclusively breastfeed to six months after birth. Infants who received skin-to-skin contact (SSC) had higher stability of the cardio-respiratory system, and higher blood glucose levels. The review also supports using immediate or early skin-to-skin contact to promote breastfeeding (Moore, Bergman, Anderson & Medley, 2016).All



newborns, when placed on the mother's abdomen soon after birth, have the ability to crawl to their mother's breast and begin feeding on their own. Evidence shows that early initiation of breast-feeding can prevent 22% of all deaths among babies below one month in the developing countries (George & Paul, 2018). 32% had not initiated breastfeeding in the first hour of birth (Rukindo et al., 2021).

Acknowledgement: The authors gratefully acknowledge the contributions of all the participants.

Funding: self-funding.

Availability of data and materials: Not applicable

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