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Research Protocol

Neonatology Section

# Effect of Tactile and Kinaesthetic Stimulation in Preterm Neonates with Hyperbilirubinaemia: A Study Protocol

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## ABSTRACT

**Introduction:** Elevated Total Serum/Plasma Bilirubin (TSB) levels in the blood manifest as hyperbilirubinaemia, which is commonly observed among newborns and can result in significant long-term consequences.

**Need for the study:** Long-term phototherapy may have negative effects on newborns. These effects can potentially be mitigated if tactile and kinaesthetic stimulation are proven to be effective as adjuvants to phototherapy, thereby reducing its duration.

**Aim:** The study aims to investigate the effect of tactile and kinaesthetic stimulation among preterm neonates with hyperbilirubinaemia.

**Materials and Methods:** Eighty two neonates with hyperbilirubinaemia admitted to a Neonatal Intensive Care Unit (NICU) will be recruited and allocated through block randomisation into two groups: the experimental group (massage therapy+tactile stimulation+phototherapy) and the control group (only phototherapy). TSB levels, Transcutaneous Bilirubin (TcB) levels, and weight gain in neonates will be measured as outcomes at baseline and each day for two days following treatment.


**Keywords:** Bilirubin, Massage, Newborn, Phototherapy

## INTRODUCTION

Neonatal hyperbilirubinaemia results from an imbalance between the production and excretion of bilirubin, attributed to the immaturity of the liver. This immaturity hinders the achievement of the necessary equilibrium required for bilirubin excretion. Typically, bilirubin is eliminated through both fecal and urinary excretion pathways [1]. Idiopathic hyperbilirubinaemia is observed in about 60-80% of neonates and is a common cause for hospitalisation within the first week of life [2]. In cases of severe hyperbilirubinaemia, the concentration of serum bilirubin in the bloodstream, known as Total Serum Bilirubin (TSB), becomes a crucial parameter in clinical diagnostics. When the TSB level exceeds 20 mg/dL, it can lead to the development of bilirubin encephalopathy or kernicterus, which is associated with a delayed neurodevelopment. The potential toxicity of bilirubin can result in significant morbidities related to bilirubin encephalopathy, such as hypotonia, poor sucking, and lethargy [3]. Furthermore, its progression is marked by hypertonia, primarily affecting the extensor muscle group. Over time, children may experience developmental and motor delays in the form of choreoathetosis cerebral palsy [4]. The American Association of Paediatrics (AAP) recommends measuring TSP levels for accurate assessment of bilirubin in the blood [5,6]. To avoid repeated blood samples, Transcutaneous Bilirubin (TcB) measurement can be conducted [7].

Pharmacological management of hyperbilirubinaemia involves the use of metalloporphyrins and other medications such as phenobarbital, D-penicillamine, and clofibrate [8]. However, studies have shown that these medications may increase bilirubin levels in the brain, leading to adverse effects like cognitive impairments [9,10]. While previous literature acknowledges the use of herbal remedies in addressing hyperbilirubinaemia, the efficacy and safety of these remedies have yet to be conclusively determined [11].

Phototherapy is the gold standard treatment for newborns with hyperbilirubinaemia to lower excessive bilirubin levels. However, prolonged exposure to phototherapy in neonates has negative effects, including damage to the cornea and genital area, dehydration, and may even lead to Bronze Baby Syndrome [12]. Recent research states that massage therapy, given in conjunction with phototherapy, helps reduce its duration and bilirubin levels faster than phototherapy alone [2]. The kinaesthetic stimulation involves the application of passive flexion and extension movements, initially targeting the right and left arm, followed by the right and left leg, and finally both legs simultaneously. Studies conducted on newborns have demonstrated a more favourable outcome in the intensive care unit setting, specifically in terms of enhancing weight gain among preterm neonates [13]. There is also evidence that tactile stimulation, combined with kinaesthetic stimulation, improves weight gain in preterm neonates by enhancing vagal tone, resulting in increased gut mobility, increased stool frequency, and thus faster elimination of bilirubin from the body [14]. To the best of authors knowledge, no research has focused on demonstrating the impact of tactile and kinaesthetic stimulation in infants with hyperbilirubinaemia. Therefore, the purpose of the present study is to analyse the efficacy of tactile and kinaesthetic stimulation on weight gain and bilirubin levels among preterm neonates with hyperbilirubinaemia.

## REVIEW OF LITERATURE

Hyperbilirubinaemia in preterm neonates can lead to mortality or severe neurodevelopmental conditions [15]. Besides being the gold standard treatment for hyperbilirubinaemia, phototherapy may lead to negative effects following prolonged exposure [16]. A previous randomised trial concluded that preterm neonates receiving massage therapy, in addition to phototherapy, had a smaller increase in bilirubin levels compared to neonates receiving phototherapy alone [2].

The literature reflects that massage therapy, along with phototherapy, helps in reducing elevated bilirubin levels and may promote physiological stability. The majority of clinical trials have described significant benefits in weight gain, which can be explained by greater vagal stimulation, gastric activity, and their relationship with energy intake and sleep-wake behaviour [14,17,18]. The proposed physiological effects of massage therapy include an increase in vagal tone, leading to increased gastrointestinal activity and stool frequency, promoting faster elimination of bilirubin from the neonate's body. An alternative hypothesis suggests that massage therapy enhances the circulation of blood, lymph, and tissue fluid in the subcutaneous tissue, facilitating the uptake and elimination of waste substances such as bilirubin [19]. Additionally, tactile stimulation is believed to be a cost-effective and safe therapy when administered to infants.

Multiple research studies have indicated that the application of tactile and kinaesthetic stimulation has a beneficial effect on the behaviour of newborns. This includes improvements in motor development and self-regulation, as evidenced by consistent breathing, heightened alertness, balanced muscle tone, diverse body positions, coordinated movements, and enhanced control of hand-to-face movements, suction, grip, and support. Furthermore, this form of stimulation has been found to expedite weight gain, thereby reducing the length of hospitalisation required for newborns [18,20].

## MATERIALS AND METHODS

The proposed study is a randomised clinical trial. Neonates will be recruited from the Neonatal Intensive Care Unit (NICU) of a tertiary hospital using convenience sampling. Informed consent will be obtained, and it will be duly signed by the parents before recruiting the neonates for present study.

**Ethical considerations:** The study protocol adheres to the principles outlined in the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [21]. The research protocol has received approval from the Institutional Research Advisory Committee (RAC), and ethical clearance has been obtained from the Institutional Ethical Committee (MMDU/IEC/2155) on October 13, 2021. The study has been registered in clinicaltrials.gov PRS with ID NCT05077787 and with the Universal Trial Number (UTN) U1111-1242-9663. However, an extension to the trial was necessary due to the medical condition of the primary investigator, which took almost a year to recover. The research will be conducted in accordance with the 2013 revision of the Helsinki Declaration and the 2017 National Ethical Guidelines for Biomedical Research Involving Human Participants [22].

**Study sample and recruitment:** The study aims to include preterm neonates (<37 weeks) with hyperbilirubinaemia, specifically total bilirubin levels between 10 mg/dL-17 mg/dL [23], who are admitted to the NICU and are more than 48 hours old with stable vitals.

**Inclusion and Exclusion criteria:** Neonates with birth weight ranging between 1000-3500 g and those with any congenital anomalies, sepsis, gastrointestinal obstruction, or biliary atresia will be excluded from the study [24]. Relevant birth information, including birth details, gender, gestational age, occipitofrontal circumference, Apperance, Pulse, Grimace, Activity, Respiration (APGAR) score, and weight at birth, will be extracted from the hospital records as maintained in the file.

**Sample size calculation:** G*Power tool was used to calculate the sample size under the statistical test category of difference between two independent means, with an anticipated effect size of 0.8 and a desired power of 90%, resulting in a sample size of 68 [25]. The significance level was set at 0.05. Additionally, accounting for a 20% dropout rate, the final sample size considered was 82, with 41 neonates in each group.

### Randomisation

Neonates will be recruited based on the selection criteria and using block randomisation with 4 blocks and a matrix design of 4×21. They will be allocated to one of the two groups in a 1:1 ratio using Sequentially Numbered Opaque Sealed Envelopes (SNOSE) [26,27].

### Intervention

**Experimental group:** In the experimental group, infants will receive tactile and kinaesthetic stimulation in three phases, each lasting for 15 minutes, regularly for three consecutive days, in addition to phototherapy and conventional NICU treatment. During the initial phase, a five-minute massage therapy session will be administered. In the subsequent phase, a five-minute kinaesthetic stimulation session will be conducted. Finally, in the third phase, another five-minute massage therapy session will be provided. It is important to note that this comprehensive intervention should be administered one hour after the neonate has been fed [28]. A summary of massage therapy in the experimental group is provided in [Table/Fig-1,2a-c] [29].

For kinaesthetic stimulation, the neonate will be positioned in the supine position, and six repetitions of each of the following movements will be performed: a) Flexion and extension of the arm, with each movement lasting five seconds as illustrated in [Table/Fig-2d]; b) Flexion and extension of the leg, with each movement also lasting five seconds; c) Simultaneous flexion and extension of both legs, with each movement lasting five seconds [8,30].

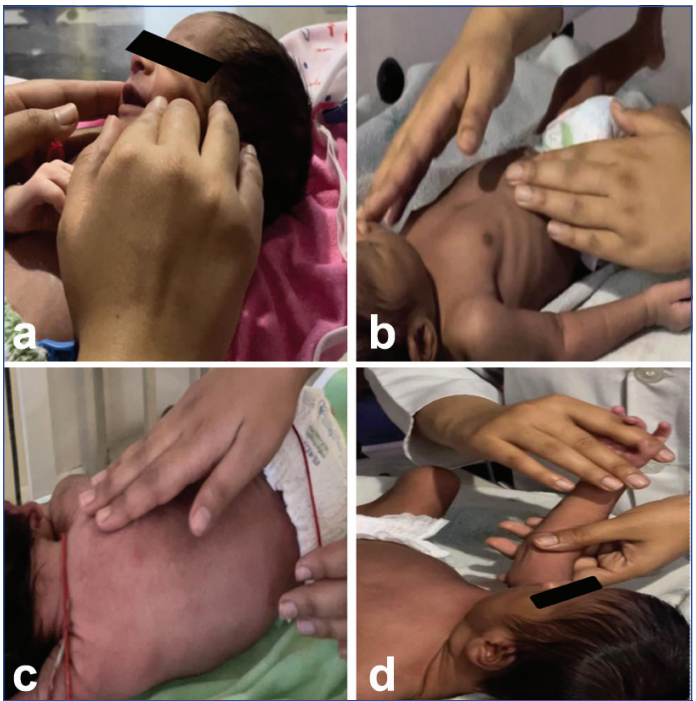
**Control group:** In the control group, neonates will receive phototherapy alone with conventional NICU care for three days. Reduction of Total Serum Bilirubin (TSB) will be documented on a daily basis (initially done by the nursing staff) from blood drawn from the capillary site, such as the newborn's heel prick, for both groups. TcB levels will also be measured every day for the first three days.

Phototherapy: Neonates in both groups will receive double surface phototherapy, with a blue light double lamp used while the neonate is lying supine and naked in the incubator, with eyes and genitals covered. This will be accompanied by regular NICU care. According to AAP guidelines, the distance between the surface where the neonate is lying and the light source should be about 30 centimeters, with a light intensity of 10-14 μW/cm$^2$/nm [31].

| Area | Neonate position | Technique | Treatment time/repetitions |
|---|---|---|---|
| Face | Supine lying | Stroking will be given on face by therapist using fingers pads of all four fingers of both hands together simultaneously on both sides of face from forehead to chin for 20 seconds. | Four strokes in each 5 seconds i.e., 16 strokes for 20 seconds X 2 |
| | | Kneading will be given for 20 seconds pressure is exerted using finger pads of index, middle and ring finger slightly bent and are moved in circular motions using finger tips in 4 'o'clock to 1 'o' clock position with left hand and 8 'o'clock to 11'o'clock position with right hand [Table/Fig-2a]. | Six kneads in five seconds on the forehead and cheek region, using both hands simultaneously of bilateral side X 2 |
| | | Tapping will be given all over the face starting from forehead towards chin, using finger pads of index, middle and ring finger it is given simultaneously in a rhythmic fashion. | Tapping will be given for 5 seconds X 2 |
| | | Effleurage- It will be given for 10 seconds, 1 stroke from under the chin, 1 stroke above the mouth, then 1 stroke from the point where nose starts and then 1 stroke from the forehead, thus will be drain the just below the ear into the subauricular glands. | 5 seconds X 2 |

| | | | |
|---|---|---|---|
| Chest and abdomen | Supine lying | Stroking- eight Strokes will be given using fingers pads moving from midline of chest towards side of thorax on bilateral side simultaneously for 10 seconds i.e., four strokes in each five seconds. Eight strokes will be given on the abdomen in vertically downwards direction for 10 seconds, four strokes in each five seconds [Table/Fig-2b]. | 10 seconds<br>four strokes in 5 seconds<br>X 2 |
| | | Kneading- Flat finger kneading will be given using palmar surface of second to fourth digit on chest and abdomen six kneads will be given for 20 seconds starting from second costoclavicular space, then at nipple level, then just two fingers below nipple level, then at the level of lower ribs, then at level on the both sides of an imaginary line from umbilicus, and then in both inguinal regions [Table/Fig-2b]. | 10 seconds<br>X 2 |
| | | Rolling- For 20 seconds over the abdomen starting from area just below the lower ribs and skin will be rolled from midline towards the sides by holding skin with index and middle finger on one side and thumb abducted on other side of both hands then adduct the thumb and pushing the skin towards the fingers, where the palm should lift off gradually but fingers tips contact should be maintained with the skin this procedure will be repeated on either side of spine from midline to side upto the imaginary line drawn from both Anterior Superior Illiac Spine (ASIS). | 10 seconds<br>X 2 |
| | | Tapping- Tapping for 20 seconds will be given over abdomen using finger pad of index finger, middle finger and ring finger singly in a rhythm. | 10 seconds<br>X 2 |
| | | Vibration- It will be over the chest for 10 seconds from area adjacent to manubrium of sternum towards the axillary region, then from area adjacent to body of sternum towards the axillary region then from just adjacent to xiphisternum to the sides on bilateral sides of sternum simultaneously. In abdomen vibration will be given for 10 seconds from umbilicus in the middle towards anterior superior iliac spine bilaterally using both hands together. | 10 seconds<br>X 2 |
| | | Effleurage for 20 seconds chest will be given from center line towards the nipple and effleurage will be given from midline towards the groin region. | 10 seconds<br>X 2 |
| Back | Prone lying | Stroking- Strokes will be given for 20 seconds from proximal to distal direction i.e., from intrascapular region to an imaginary line between posterior superior iliac spine, using finger pad simultaneously on bilateral side of vertebral column [Table/Fig-2c]. | 10 seconds<br>X 2 |
| | | Kneading using finger pad kneading will be given in 4 'o'clock to 1 'o'clock clock position with left hand and 8 'o'clock to 11'o'clock position with right hand simultaneously six kneads in 20 seconds will be given on bilateral sides starting from intrascapular area, then at the medial aside of inferior angle of scapula, then following the same direction downwards kneading will be given-up till an imaginary line drawn between two Posterior Superior Iliac Spine (PSIS). | 20 Seconds<br>Three kneads each five seconds<br>X 2 |
| | | Rolling- It will be given for 20 seconds on back starting from the intrascapular area skin rolling will be directed from sides of vertebral column towards the sides and this procedure will be repeated on either side of spine from midline to side. | 10 seconds<br>X 2 |
| | | Tapping- For 20 seconds will be given over the back on both side of the spine from upper back to vertically downwards direction. | 10 seconds<br>X 2 |
| | | Vibrations- In abdomen vibration will be given for 10 seconds from umbilicus in the middle towards anterior superior iliac spine bilaterally using both hands together. | 10 seconds<br>X 2 |
| | | Effleurage will be given for 20 seconds from the center or spine towards the axillary region. | 10 seconds<br>X 2 |

**[Table/Fig-1]:** Summary of massage intervention.




**[Table/Fig-2]:** a) Kneading given on bilateral cheeks; b) Stroking given on the abdomen; c) Stroking given on the back; d) Arm movements.

## Outcome Measures

**Total Serum Bilirubin (TSB):** TSB will be measured on a daily basis. Newborns with a TSB level of more than 10 mg/dL and a rate of rising of more than 0.5 mg/dL/h in the first 24 hours, ≥12 mg/dL on the second day, ≥15 mg/dL on day 3, and ≥17 mg/dL on the fourth and fifth day are known to have hyperbilirubinaemia [32].

**Transcutaneous Bilirubin (TcB):** TcB will be measured using a Bilirubinometer. Measurements will be taken from unexposed sites [33] using the Bili check Transcutaneous Bilirubinometer (MBJ20), such as the glabellar region of the forehead just above the internasal area covered by an eye mask, from the chest at the level of the manubrium sterni [34], and from a point over the anterior superior iliac spine [35]. It is a non invasive and effective tool for screening increased bilirubin levels in neonates, and it is kept in vertical contact with the neonate's skin over the mentioned sites. An average will be calculated by summing the three readings from these three sites and dividing it by three. TcB will be measured every day. Using a bilirubin meter, levels more than 3.39 mg/dL will be measured with specificity and moderate sensitivity. Average TcB levels significantly correlate with TSB levels in newborns with a gestational age of ≥28 weeks (r=0.72), showing the reliability of TcB [36]. As TSB is the gold standard for measuring bilirubin levels in neonates, TcB could be used as an alternative for frequent blood samples.

## Weight Gain

A weighing scale will be used to measure weight gain. The newborn will be placed on the weighing machine without clothes and in a clean diaper.

The schedule of enrollment, interventions, and assessments of the study protocol has been illustrated in [Table/Fig-3].

| | STUDY PERIOD | | | | | |
|---|---|---|---|---|---|---|
| | Enrolment | Allocation | Post-allocation(treatment) | | | Close-out |
| TIMEPOINT** | $t_0$ | $t_0$ | $t_0$ | $t_1$ | $t_2$ | $t_3$ |
| ENROLMENT: | | | | | | |
| Eligibility screen | X | | | | | |
| Informed consent | X | | | | | |
| *[GA, CGA, OFC, BW and APGAR ]* | X | | | | | |
| Allocation | | X | | | | |
| INTERVENTIONS: | | | | | | |
| *[Experimental Group]* | | | ← | — | — | → |
| *[Control Group]* | | | ← | — | — | → |
| ASSESSMENTS: | | | | | | |
| *[Total serum bilirubin levels]* | X | | X | X | X | X |
| *[Transcutaneous Bilirubin]* | X | | X | X | X | X |
| *[Weight]* | X | | X | X | X | X |

**[Table/Fig-3]:** Schedule of enrolment, interventions and assessments of the study protocol.
BW: Birth weight, CGA: Corrected gestation age; NICU: Neonatal intensive care unit; OFC: Occipital frontal circumference; GA: Gestational age

## STATISTICAL ANALYSIS

Data will be analysed using IBM Statistical Package for the Social Sciences (SPSS) software, version 20.0. The assessment of normality will be conducted using the Kolmogorov-Smirnov Test. Once the data has been determined to have a normal distribution, repeated measures Analysis of Variance (ANOVA) will be employed for within-group analysis, while an independent t-test will be used for between-group comparison. In cases where the data does not follow a normal distribution, the Friedman's test is typically employed for within-group analysis, while the Mann-Whitney U test is commonly utilised for between-group analysis. The descriptive statistics will be expressed as the mean plus or minus the standard deviation, as well as the median and interquartile range, respectively. The Post-hoc analysis will be performed using G-power software, version 20.

### Strength and Limitation(s)

The strengths of the study are that it is a multicentre study and kinaesthetic stimulation has been proven to improve weight among neonates. Additionally, to the best of authors knowledge, the proposed study will be the first of its kind to prove the effectiveness of tactile and kinaesthetic stimulation in reducing bilirubin levels among neonates. However, there are some weaknesses in the proposed study. First, it is not blinded as the intervention needs to be given by a researcher. Second limitation is that neonates are not divided into subcategories of preterm. To address this, further studies can be planned with data stratification based on subcategories of preterm neonates.

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