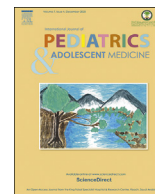


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Original article

## Vestibular stimulation with Indian hammock versus music intervention in the prevention of infantile colic in term infants: An open-labelled, randomized controlled trial



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### ABSTRACT

**Background and Objectives:** To determine whether vestibular stimulation offered by Indian hammock and music intervention are useful in reducing the occurrence of infantile colic in term infants.

**Methods:** This open-labelled randomized clinical trial was conducted among 465 term neonates who were randomly assigned to one of three groups: music group, hammock group and control group. The music intervention was given for a cumulative duration of at least 4 h a day with one stretch of at least 1 h. In the hammock group, babies were put to sleep inside the Indian hammock and were swung gently until they sleep, and were allowed to sleep in it, until they wake up. For the control group, routine pre-discharge counselling was given. All parents were provided a cry log and were instructed to record the log of cry events and duration. The primary outcome measure was occurrence of infantile colic episode as defined by ROME IV criteria. The infants were followed up from birth until the age of 3.5 months, and the cry log was collected during each follow-up visit.

**Results:** Of the 435 term neonates who completed follow-up, 59 infants developed infantile colic (13.6%). The prevalence of infantile colic in the control group, music group and the Indian hammock group was 25.6%, 5.4% and 9.6% respectively; there was a significant reduction in the prevalence of infantile colic in the intervention groups as compared to the control group.

**Conclusions:** Vestibular stimulation by Indian hammock and music intervention individually reduced the occurrence of infantile colic.

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## 1. Introduction

Infantile colic is a common condition worldwide: about one in five infants younger than three months develops colic [1]. It is one of the most common causes of emergency department visit in the early infancy. Estimated prevalence of colic in infants ranges from 8% to 40% [2–7]. Although infantile colic is considered to be a self-limiting and benign condition, it often results in significant stress

for the parents [1,8] and can be associated with maternal depression and shaken baby syndrome [9]. An ideal colic treatment modality must be able to console the infant quickly as well as alleviate the parental stress. To date, there is insufficient evidence regarding the effective treatment options for infant colic [1]. Although supplementation of lactase and probiotics have shown benefits, further studies are needed [10]. One of the traditional methods used in south India for pacifying young infants is the traditional Indian hammock called as “thooli”. Indian hammock offers vestibular stimulation to the child, which has been proven to produce a soothing effect [11]; it is also known to benefit child’s development [12]. Another intervention that offers a soothing effect is music. Music has been proven to be efficacious in reducing pain to neonates [13]. Traditionally, hammock and music have been used by

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generations of people to console crying infants. There are no studies to date that has attempted to study the effect of these traditional practices in the management of infantile colic. Hence, we have planned this study to evaluate the efficacy of traditional Indian Hammock and music in preventing the episodes of infantile colic in term breastfed infants in a randomized controlled trial.

## 2. Methods

**Trial design:** This was an open-labelled, prospective randomized controlled trial (Fig. 1).

**Participants:** We recruited 465 healthy term infants weighing more than 1500 g and randomized them into three groups. Those term neonates who were sick due to any cause needing intensive care unit admission were excluded from the study. The study was conducted in the Department of Pediatrics of a tertiary care teaching hospital in south India. The study involved healthy term neonates. The primary objective was to compare the prevalence of infantile colic in three groups of term infants over a 3.5-month follow-up period: one group received music intervention, one group received vestibular stimulation by Indian hammock, and the control group received no intervention. The study was approved by the Institute Ethics Committee (IHEC/2017/02/26).

### 2.1. Study interventions

**Group 1- Music intervention group:** The music intervention consisted of pre-recorded music based on guidelines by Schwartz [14], who suggested that the music must be simple with gentle rhythms, flowing and lyrical melodies, simple harmonies and soft timbre. Accordingly, lullabies and songs (of the south Indian culture) in the vernacular language were sung and recorded for duration of 30 min. For another 30 min, a soft soothing instrumental music of popular lullabies was recorded (total of 1 h duration). The intervention was presented to the child using a CD player with speakers in home beginning two weeks after birth. The speakers were placed accordingly to provide a binaural experience. Parents who did not own a CD player were given the option of playing the recorded music using a portable device e.g. any cell

phone, tablet or laptop. Parents were instructed to bring any of these devices to assess the sound using digital sound level meter, and the loudness level was adjusted in such way that it did not exceed 80 dB, which is considered developmentally appropriate for infants [14]. While playing the music, the parents were instructed to keep the device 30 cm away from the baby. Beginning from the day of discharge from hospital, the music intervention was given for a cumulative duration of at least 4 h a day with one stretch of at least 1 h (they were encouraged to use it for more time if they wished). The parents were instructed to record duration of music exposure.

**Group 2- Indian hammock group:** The neonate was encouraged to be roomed-in with the mother in the first two weeks. After the first two weeks, the parents were advised to put the baby to sleep inside the hammock and swing him/her gently in a to-and-fro motion till the infant sleeps, and allow him to sleep in hammock until he/she wakes up. This was shown to them in a demonstrative video. It was instructed that the child must be rocked in the hammock and put to sleep only after adequate burping following feeds. Parents were instructed to take care to provide enough ventilation for the baby inside the hammock and to take measures for preventing vector bites to the infant. The parents were instructed to record the number of hours the child was put in the hammock.

Both the interventions were started before infantile colic onset. This ensured that the infant would get conditioned to get a soothing effect by the interventions.

**Group 3- Control group:** In this group, no specific interventions were done. Routine pre-discharge counselling was done. The infants in this group were followed up at the same time intervals as the other two groups.

Parents in all the three groups were instructed to record the log of cry events, and it was checked during every follow-up visit.

**Data collection:** A “cry log” was provided to every mother of the infants participating in the study. In this sheet, they were told to record the duration of any incessant cry that the infant has. Parents were being instructed to omit hunger cry that is satiated by feeds and short duration cry (lasting less than 30 min) and cry due to any obvious causes. The parents were also advised to record any cry lasting more than 30 min with an identifiable cause on the cry log with a mention of the possible cause (vaccination, illness, trauma, bites/stings etc). Based on the cry log, infants who satisfied the study definition for infantile colic were noted. Data were periodically entered on to a database, and the data were kept anonymized and secure.

**Follow up:** Three follow-up visits coinciding with the vaccine visits (1.5, 2.5 and 3.5 months of age) were scheduled. To improve compliance for maintaining the log of cry events, interventions, and follow up, the parents were contacted through telephone at regular intervals. In the unlikely event of being unable to come for follow-up visit, the filled-up cry log was instructed to be sent through messenger application (WhatsApp) or collected through a peripheral social worker who worked in their area. For those babies who developed colic, parental counselling was done in accordance with the departmental guidelines, such as advice on scheduling the day with reduction of activities that affect the circadian rhythm. No pharmacological agents including probiotics were prescribed for the treatment of colic.

**Sample size:** Assuming an alpha error of 5%, power of 80%, prevalence of infantile colic in term breast fed infants to be 30% and expecting that the interventions would reduce the prevalence by 50%, the sample size in each group was calculated to be 121 using OpenEpi software version 3.0. Allowing for an attrition of 25%, the final sample size was computed to be 155 in each of the groups. A total of 465 neonates were randomized into three groups of 155

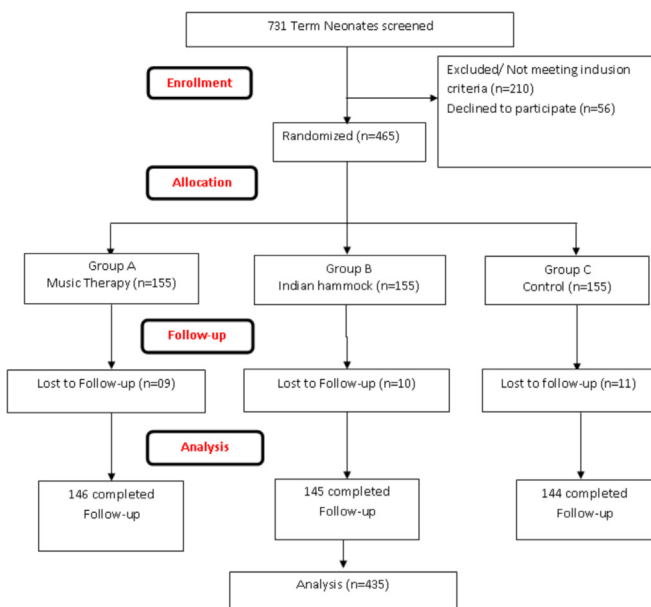


Fig. 1. Consort flow diagram summarizing the methodology.

neonates each.

**Randomization:** The randomization was done using computer generated software, and the allocation was concealed in sealed opaque covers which were kept in the postnatal ward. The recruited subjects were randomly allocated into one of the three groups. One of the principal investigators enrolled the participants and assigned them to the interventions. It was an open-labelled trial.

**Study definition:** The currently used diagnostic criteria for infantile colic is the Rome IV criteria [15], which include all of the followings: paroxysms of irritability with fussing or crying that start and stop without obvious causes, symptoms lasting at least 3 h a day and occurring at least three days a week for at least one week, and absence of failure to thrive, in infants from birth to five months of age.

### 3. Results

During the study period from January 2017 to June 2018, a total of 731 term neonates were screened for eligibility of which 465 neonates were eligible and were randomized into three groups of 155 children each. A total of 435 infants completed the follow up and were included for the statistical analysis.

All three groups were similar with respect to all the baseline variables (Table 1). A total of 59 of the study infants developed infantile colic (13.6%). All the infants in the study developed colic episodes during or after the third week of life. Maximum numbers of infants had their onset of colic episodes between the fourth week and the eighth week ( $n = 36$ ). Two infants had their onset during the third week and two infants had their onset between the eighth and the tenth week of life.

The prevalence rate of infantile colic among the control group was 25.6%, which was significantly less in both the intervention groups (Table 2). Although the prevalence of colic was less in both the intervention groups as compared to control group, there was no

difference among both the intervention groups. None of the study subjects developed any complications or experienced any adverse event due to the study interventions. Thus, both the interventions used in the study were safe.

### 4. Discussion

The prevalence of infantile colic in our study was observed to be 25.6% in the control group. This is the first prospective study on infantile colic among Indian infants using the recent standard definition. There are no similar Indian studies on infantile colic prevalence as on date for comparison. The data were collected using a 24-h log chart, which has been recommended by many studies as the method of choice to follow up colic events [16]. Hence, these data on the prevalence of infantile colic obtained in our study is of immense importance for future studies in the region.

Infantile colic is also considered as a behavioral syndrome of early infancy and a normal variant of crying curve in infancy [17]. The discomfort and the crying behaviour of the infant is the final common pathway. In this study, we targeted the aspect of alleviation of discomfort due to the colic. To date, no pharmacologic remedies for alleviating the pain in infantile colic are approved for regular use. Although various non-pharmacological interventions such as rocking, swinging, use of pacifiers and playing of lullabies and white noise have been tried as a treatment, robust evidence for the efficacy of such treatment measures are lacking. Culturally, in India, hammock (thooli) and music have been routinely used to pacify a crying baby and hence tried in the study.

The prevalence of infantile colic in the music intervention group (5.4%) and in the Indian hammock group (9.1%) was significantly less as compared to no interventions (25.6%) in term Indian infants. Music interventions have been found to have a beneficial effect in alleviating the discomfort in infantile colic by reducing the pain and reducing the maladaptive behaviour [13]. Studies also have shown that music helped to decrease stress symptoms in the babies and

**Table 1**

Table showing comparison of baseline variables among all the three groups.

| Predictors                   | Group 1 (music) | Group 2 (hammock) | Group 3 (control) | Chi square value ( <i>p</i> value) |
|------------------------------|-----------------|-------------------|-------------------|------------------------------------|
| <b>Gender</b>                |                 |                   |                   |                                    |
| Male                         | 71              | 69                | 63                | 0.78, <i>df</i> = 2 (0.68)         |
| Female                       | 75              | 76                | 81                |                                    |
| <b>Maturity</b>              |                 |                   |                   |                                    |
| Early term                   | 77              | 85                | 76                | –                                  |
| Full term                    | 69              | 57                | 66                |                                    |
| Late term                    | 0               | 3                 | 2                 |                                    |
| <b>Birth weight</b>          |                 |                   |                   |                                    |
| AGA                          | 135             | 133               | 131               | 1.12, <i>df</i> = 4 (0.89)         |
| SGA                          | 9               | 10                | 9                 |                                    |
| LGA                          | 2               | 2                 | 4                 |                                    |
| <b>Age of mother</b>         |                 |                   |                   |                                    |
| ≤20                          | 5               | 3                 | 7                 | 3.34, <i>df</i> = 6 (0.77)         |
| 21–25                        | 57              | 58                | 60                |                                    |
| 26–30                        | 68              | 69                | 58                |                                    |
| >30                          | 16              | 15                | 19                |                                    |
| <b>Parity</b>                |                 |                   |                   |                                    |
| Primipara                    | 72              | 66                | 77                | 1.83, <i>df</i> = 2 (0.40)         |
| Multipara                    | 74              | 79                | 67                |                                    |
| <b>Mode of delivery</b>      |                 |                   |                   |                                    |
| Vaginal delivery             | 81              | 78                | 72                | 4.45, <i>df</i> = 2 (0.11)         |
| LSCS                         | 65              | 67                | 72                |                                    |
| <b>Education status</b>      |                 |                   |                   |                                    |
| Illiterate                   | 1               | 2                 | 5                 | 3.49, <i>df</i> = 4 (0.48)         |
| School certificate           | 126             | 124               | 119               |                                    |
| Graduate                     | 19              | 19                | 20                |                                    |
| <b>Feeding Status</b>        |                 |                   |                   |                                    |
| Exclusive breast feeding     | 138             | 138               | 137               | 0.08, <i>df</i> = 2 (0.96)         |
| Non-Exclusive breast feeding | 8               | 7                 | 7                 |                                    |

**Table 2**  
Proportion of infants who developed infantile colic among all three groups and difference in the prevalence due to intervention.

| Infantile colic satisfying ROME IV Criteria                   | Group 1 (music)<br>(n=146) | Group 2 (hammock)<br>(n=145)                                | Group 3 (control)<br>(n=144) |
|---|----------------------------|---|------------------------------|
| Total number of infants positive for infantile colic (n = 59) | 8                          | 14  | 37                           |
| Prevalence  | 5.4%                       | 9.6%  | 25.6%                        |
| Difference in prevalence                                      | Group 3 vs Group 1         | 20% (95% Confidence limits = 12–28%)<br><b>P &lt; .0001</b> |                              |
|   | Group 3 vs Group 2         | 16% (95% Confidence limits = 7–25%)<br><b>P = .0003</b>     |                              |
|   | Group 2 vs Group 1         | 4% (95% Confidence limits = 2–10%)<br><b>P = .178</b>       |                              |

<sup>a</sup> Any *P* value < .05 was considered as significant.

positively affected the temperament of babies [14]. The possible explanation for the beneficial effect of music intervention is that the auditory stimuli is carried to the brain and positively influences the limbic system and autonomic nervous system thereby inducing comfort and relaxation [18,19].

Controlled vestibular stimulation has been proven to reduce central pain by activating parieto-vestibular cortex [20]. In addition, literature has shown that swinging stimulates endorphin secretion through 'repetitive and rhythmic' movements and may hence be beneficial in relieving pain in babies [21]. In support of this fact, previous studies have reported that swinging does help to console and put the babies to sleep [22–24].

The mothers in both the groups were very happy and were compliant with the interventions. The mothers in the music group reported more satisfaction with the intervention as compared to the mothers in the Indian hammock group. Studies have shown that mothers exposed to music reported positive feelings such as serenity, and relaxation. Music and singing lullabies have also been proven to reduce stress in the mother [25]. Inadequate mother-infant interaction, anxiety in the mother and difficult infant temperament have all been known to contribute to the development of infantile colic [26]. Music improves mother infant interaction and hence could prevent colic.

Few mothers in the hammock group reported that it was exhausting for them to swing the hammock at times especially when the child had to be consoled during nights when she did not have the support of a caregiver. One reason could be, the hammock required active effort on the part of the mother to swing resulting in physical exhaustion. On the other hand, music was passive and could be relaxing to the mother simultaneously. Music interventions could also be started immediately after discharge from hospital as it did not affect rooming in. Further studies on the impact of both these interventions on the temperament of the mother using validated scales for mood assessment would be interesting.

The study has the following strengths. This is the first such study on the prevalence of infantile colic among Indian infants. In addition, we have used a recent standard definition i.e the ROME IV criteria, for the diagnosis of infantile colic. A cry log where the parents can note down the crying episodes in 24 h was designed and used in the study. This helped in robust collection of data. There was good follow-up with very low attrition rate. We have tried to validate the use of culturally common infant-rearing practices. The study has some limitations. Those babies who developed infantile colic could not be followed up beyond 3.5 months, until resolution took place. There was a possibility of a record bias, because the mothers were responsible for recording the crying durations. Mixed interventions were observed in some of the subjects of both the intervention groups; few of the children who were randomized to receive music intervention were noted to use the Indian hammock as it is a traditional practice used for putting infants to

sleep and mothers of few of the children who were allocated to the Indian hammock group reported to be singing lullabies to put the child to sleep simultaneously with swinging. However, their numbers were less and the use was not consistent unlike the planned intervention duration. Hence, we believe this would not affect the interpretation of the results. A formal hearing screening could not be done for all neonates. Nevertheless, for all the neonates, we checked for the presence of startle reflex at recruitment and at discharge. Moreover, on follow up, none of the neonates had hearing concerns.

## 5. Conclusion

The prevalence of infantile colic among healthy term south Indian infants was 25.6%. Infants born to primiparous mothers had significantly higher prevalence of infantile colic as compared to those born to multiparous mothers. In this randomized controlled trial, we proved that vestibular stimulation offered by the Indian Hammock and Music intervention individually reduce the occurrence of infantile colic in south Indian infants. Thus, both these culturally acceptable, safe and simple interventions can be advocated to the infants as a part of routine baby-care advice to parents.

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None.

## Author contributions

RS and DG planned the study. SR, RS and DG conducted the study and followed up the study subjects. RS and SR drafted the manuscript. DG, SS and PS critically reviewed the manuscript. All authors have approved the final version of the manuscript.

## Declaration of competing interest

No financial or non-financial benefits have been received or will be received from any party related directly or indirectly to the subject of this article.

## CRedit authorship contribution statement

**Senthikumar Ravikumar:** Data curation, Formal analysis, Investigation, Resources, Software, Methodology, Writing - original draft. **Rangan Srinivasaraghavan:** Conceptualization, Data curation, Formal analysis, Methodology, Supervision, Writing - original draft, Writing - review & editing. **Dhandapany Gunasekaran:** Conceptualization, Project administration, Resources, Software, Supervision, Writing - review & editing. **Sumathy Sundar:** Conceptualization, Investigation, Methodology, Writing - review & editing. **Palanisamy Soundararajan:** Project administration,

Resources, Software, Supervision, Writing - review & editing.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jciclepro.2020.000000>.

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