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Pain relief effect of breast feeding and music therapy during heel lance for healthy-term neonates in China: A randomized controlled trial

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ABSTRACT

Objectives: to test the effectiveness of breast feeding (BF), music therapy (MT), and combined breast feeding and music therapy (BF+MT) on pain relief in healthy-term neonates during heel lance.
Design: randomised controlled trial.
Setting: in the postpartum unit of one university-affiliated hospital in China from August 2013 to February 2014.
Participants: among 288 healthy-term neonates recruited, 250 completed the trial. All neonates were undergoing heel lancing for metabolic screening, were breast fed, and had not been fed for the previous 30 minutes.
Interventions: all participants were randomly assigned into four groups – BF, MT, BF+MT, and no intervention – with 72 neonates in each group. Neonates in the control group received routine care. Neonates in the other three intervention groups received corresponding interventions five minutes before the heel lancing and throughout the whole procedure.
Measurements: Neonatal Infant Pain Scale (NIPS), latency to first cry, and duration of first crying.
Findings: mean changes in NIPS scores from baseline over time was dependent on the interventions given. Neonates in the BF and combined BF+MT groups had significantly longer latency to first cry, shorter duration of first crying, and lower pain mean score during and one minute after heel lance, compared to the other two groups. No significant difference in pain response was found between BF groups with or without music therapy. The MT group did not achieve a significantly reduced pain response in all outcome measures.
Conclusions: BF could significantly reduce pain response in healthy-term neonates during heel lance. MT did not enhance the effect of pain relief of BF.
Implications for practice: healthy-term neonates should be breast fed to alleviate pain during heel lance. There is no need for the additional input of classical music on breast feeding in clinic to relieve procedural pain. Nurses should encourage breast feeding to relieve pain during heel lance.

Introduction

Currently, in many countries around the world, routine medical care for healthy-term neonates involves heel lance for taking blood samples, which is a common source of pain experienced

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by healthy neonates (American Academy of Pediatrics, 2006). Painful stimuli in neonates may induce short-term physiological and behavioural changes such as excessive crying and vomiting (Mainous and Looney, 2007; Meek, 2012), as well as long-term consequences such as altered pain response in later infancy (Grunau et al., 2006).

The objective assessment of pain in neonates is difficult due to the subjective nature of pain and the inability of neonates to communicate. Recently, a number of reliable and valid measurement tools have been developed to assess pain for preterm or term infants (Cignacco et al., 2007). The Neonatal Infant Pain Scale (NIPS) has been successfully used with preterm and full-term infants for objective evaluation of the pain experience (Yilmaz and Arikan, 2010; Gabriel et al., 2013). The first cry following pain was also found to be the most sensitive response to noxious stimuli (Grunau and Craig, 1987). Previous studies have used latency to first cry and duration of first crying as a primary measure of pain (Upadhyay et al., 2004; Ou-Yang et al., 2013).

Significant progress in understanding the consequences of procedural pain and great advances in pain assessment for neonates have resulted in more attention to pain management (Gallo, 2003; Golianu et al., 2007). However, pain in healthy-term neonates caused by heel lance is still not treated in mainland China. Health care professionals' lack of knowledge about pain, the neonates' inability to express pain, and the short duration of the heel lance may contribute to the disregarding of pain (Liaw et al., 2010; Zhu et al., 2012). Thus it is important to examine the effectiveness of pain relief of different interventions for healthy-term neonates during heel lance.

Pharmacological treatments are rarely used to alleviate neonatal pain during heel lance because of doubtful efficacy (Shah et al., 1998; Jain et al., 2001) and potential adverse effects for the medically fragile neonates (Golianu et al., 2007). A variety of non-pharmacological methods of pain management have been evaluated for the treatment of pain in neonates undergoing venepuncture or heel lance, including sucrose (Liaw et al., 2013), non-nutritive sucking (Liaw et al., 2010; Fernandes et al., 2011), swaddling (Prasopkittikun and Tilokskulchai, 2003), breast feeding (Gabriel et al., 2013), kangaroo care (Campbell-Yeo et al., 2013), and sensorial saturation or music (Hartling et al., 2009). These approaches have been proved to be beneficial for the management of mild to moderate pain in the neonates (Golianu et al., 2007). Given the efficacy and cost-effectiveness of non-pharmacological intervention in the management of pain, Fernandes et al. (2011) pointed out that non-pharmacological intervention should be the first choice for common painful procedures such as heel lance. Regardless of the available evidence, appropriate systematic pain management is often underused for some minor procedures (American Academy of Pediatrics, 2006; Campbell-Yeo et al., 2011).

Music is increasingly being used in neonatal units to improve behavioural or physiological outcomes or to manage pain during common medical procedures. A systematic review published in 2009 included nine randomised trials to examine the efficacy of music for procedural pain management and concluded that music was beneficial in terms of physiological parameters, behavioural states and pain for heel lance procedures (Hartling et al., 2009). However, due to the poor quality of some studies included in the review and the large variation in reported outcomes, Hartling et al. (2009) indicated that additional methodologically rigorous, randomised, controlled trials were warranted to confirm the benefits of music for pain relief in neonates.

Breast feeding is a natural, readily available, and potentially risk-free measure which has been assessed for management of neonate pain in many studies (Efe and Savaşer, 2007; Codipietro et al., 2008; Leite et al., 2009; Okan et al., 2010; Gabriel et al., 2013). A Cochrane review included 20 randomised controlled trials to evaluate the effect of breast feeding or supplemental breast milk on procedure pain in neonates (Shah et al., 2012). This review found that neonates in the breast fed group had a significantly lower increase in heart rate, reduced proportion of crying time, and less pain during heel lance and venepuncture. Thus, Shah et al. (2012) recommended that breast feeding or breast milk should be used to alleviate procedure pain in neonates undergoing a single painful procedure. However, breast feeding has not been universally implemented to alleviate procedural pain (Gray et al., 2006; Codipietro et al., 2011). In mainland China, nurses still do not suggest breast feeding during heel lance because of lack of knowledge about the pain relief of breast feeding (Zhu et al., 2012). More randomised clinical trials are warranted to establish evidence for breast feeding practice during heel lance in China.

To the best of our knowledge, no research has been conducted to compare the effects of pain relief of breast feeding (BF), music therapy (MT), and combined breast feeding and music therapy (BF+MT) for healthy-term neonates during heel lancing. Therefore, the aim of this study was to investigate the pain relief of BF, MT, and combined BF+MT versus no intervention on latency to first cry, duration of first crying, and NIPS during blood sampling through heel lance in healthy-term neonates. The hypotheses of this study were as follows:

1. When compared with the no-intervention group, neonates in the BF, MT, and BF+MT groups would have a reduction in pain levels over time.
2. When compared with the no-intervention group, neonates in the BF, MT, and BF+MT groups would have longer latency to first cry, shorter duration of first crying, and lower pain levels during and after heel lance.
3. BF+MT would be more effective in pain relief than MT or BF alone for healthy-term neonates during heel lance.

Methods

Design

This is a prospective, randomised, controlled study involving pre-testing and post-testing of four groups.

Setting and participants

In total, 288 neonates were recruited by the Head Nurse from the postpartum units of a university-affiliated hospital. Eligible neonates were all born at $\geq$37 weeks gestation, had APGAR scores $\geq$7 at five minutes after childbirth, were aged $\geq$24 hours, weighed between 2000 g and 4000 g, had passed the hearing screen, were undergoing heel lancing for metabolic screening between three and five days after childbirth, were breast fed, and had not been fed for the previous 30 minutes. Multiple births and operative deliveries were also included in this study if the neonates met the above inclusion criteria. Exclusion criteria were as follows: at-risk pregnancy, neonates with medical instability, those receiving artificial feeding, those who were subjected to any painful stimulus other than intramuscular vitamin K injection, those who had received a sedative and a major pain relief during the previous 48 hours, and those who received heel lance twice due to an unsuccessful first procedure.

Sample size calculation

In order to detect a medium effect size at 0.5 to achieve a power of 80% with an α level at 0.05 (two-sided), a total of 256

participants with 64 neonates in each group should be required. We decided to include 72 neonates in each group, with 288 participants in total to account for drop-out or potential problems with video recording.

Randomisation

During the study period (August 2013–February 2014), on average 400 neonates per month were born in the participating hospital. On every Saturday morning during the study period, 10–12 neonates were assessed by the Head Nurse for eligibility for the study. The neonates who met the selection criteria and whose mothers agreed to participate in the study were recruited. Before the study began, the main researcher (ZJM) used the online Research Randomizer (2013) to randomly generate 72 sets of numbers; each set containing four numbers ranging from 1 to 4 with random order. A total of 288 unique codes were generated based on the 72 sets of randomly ordered {1, 2, 3, 4} (e.g. Set1Group1, Set1Group3, Set1Group4, Set1Group2) and were then placed in a box, where the randomised blocking was not retained. After consent taking, the main researcher randomly picked one code for each neonate to ensure the 288 neonates were equally allocated into four groups based on the group number of each code: group 1 (no intervention group), group 2 (MT group), group 3 (BF group), and group 4 (BF+MT group).

Intervention

All blood sampling was performed in a quiet nursery room between 9 a.m. and 11 a.m., 30 minutes to 1 hour after breast feeding. If the neonates were crying before the heel lance, we consoled them until they were settled for at least five minutes before the sampling. The neonates were taken to the nursery, wrapped in blankets and placed supine on the examination table. This was the routine blood collection procedure used during the standard screening test in the study venue. The whole procedure was video-recorded from five minutes before sampling to five minutes after the procedure.

For the MT group, three classical music pieces – *Souvenirs D'enfance*, *A Comme Amour*, and *Ballade Pour Adeline* played by Richard Clayderman – were played on a loop at least five minutes before heel lance and maintained during blood sampling. The music has been used successfully in previous studies of Chinese neonates for their soothing effects (Li and Wang, 2006; Hu, 2013). The level of music was maintained in the range of 55–60 dB, based on American Academy of Pediatrics (1997) recommendations and guidelines. The music speakers were placed bilaterally and kept 20 cm from the infants' heads. In the BF group, the neonates were breast fed in their mothers' arms, starting five minutes before the procedure and continuing throughout. The heel lance did not start until the neonates were observed to be sucking at the breast (with a large amount of the areola in the mouth, active jaw movement, and swallowing after sucking). Mothers were allowed to speak to their babies in the BF group. Neonates were wrapped in blankets during heel lance for all groups, so mothers did not provide skin-to-skin contact with their neonates. In the BF+MT group, neonates were breast fed and classical music was played to them at the same time. The no-intervention group received routine care.

To minimise variability, the blood collection was performed in a standardized manner by the same nurse, who is experienced in blood sampling. During the heel lance, the nurse prepared the materials, massaged the heel site, cleaned the heel, applied the lancet, squeezed the heel to collect blood, then pressed and applied a bandage to the heel. If the blood sample was not large enough to make three dried spots on the filter card, a new heel lance was performed within a few seconds. In this study, the neonates who received the heel lance twice were excluded for data analysis.

Two research assistants were trained to observe the video and recorded the findings on NIPS, the latency to first cry, and the duration of first crying in 30 sessions. The inter-rater reliability was 0.87. The observers could stop and restart the videotape as many times as they needed to establish a score.

Measurements

The primary outcome was the NIPS pain score following heel lance; secondary outcomes were latency to and duration of first cry. Socio-demographic and clinical data such as the mother's gestation age, neonatal age, sex, birth weight, and duration of sampling were also recorded.

The NIPS is a validated scale for the assessment of procedural pain in full-term or preterm neonates (Lawrence et al., 1993). It measures six indicators of pain including movement of arms, movement of legs, breathing patterns, crying, facial expression, and state of arousal. The indicator of crying is graded as 0, 1, or 2, and the others are graded as 0 or 1, where a score of 0 indicates no pain and a positive digit indicates pain. The total NIPS score ranges from 0 to 7, with higher scores representing more severe pain. An NIPS score of <4 means no pain to mild pain. An NIPS score of ≥ 4 means moderate to severe pain. NIPS ratings were evaluated one minute before sampling, at their highest value during sampling, and one minute and five minutes after sampling. Cronbach's alpha values of NIPS for before, during and after the procedure were 0.95, 0.87 and 0.88, respectively (Lawrence et al., 1993). Cronbach's alpha values of the Chinese version were found to be 0.97, 0.81, and 0.95, respectively, before, during and after the heel lance, which was satisfactory (Yao et al., 2011).

The latency to first cry was assessed by reviewing digital recordings and was defined as the time between the lancet puncture and the start of crying (heard as continuous distressed vocalisation). The duration of the first cry was defined as the time between the start of crying and the end of crying. The end of crying was defined as silence for >5 s. Duration of sampling was counted from the moment the lancet punctured the neonates' foot to the completion of three dried blood spots on the filter card. If the neonates did not cry for the whole procedure, the latency of the first cry was recorded as the duration of sampling, and the duration of crying time was recorded as zero. If the neonates cried for the whole procedure and did not stop at five minutes after the sampling, the duration of crying time was recorded as the sum of duration of sampling and five minutes.

Ethical considerations

Ethical approval was obtained from the health research ethics boards of the university and participating hospital. The main researcher provided the written information to mothers and explained the purposes and nature of the research, confidentiality of data collected, anonymity, and the maternal right of refusing participation to the mothers of potential participants. Mothers who were willing to participate in the study provided written consent and subsequently were recruited to this study. This study was not registered with Current Controlled Trials due to insufficient funding.

Data analysis

All data analyses were performed using IBM SPSS Statistics 21.0 (IBM Corp.). Descriptive statistics were used to analyse the neonates' demographics data and duration of sampling. Repeated measures analysis of covariance (ANCOVA), adjusted for neonates'

demographic data (gender, birth weight, gestational age, and neonatal age), duration of sampling, and baseline NIPS scores was used to determine whether the interventions were effective in reducing the pain levels of neonates over time (during heel lance, and one minute and five minutes after the heel lance). ANCOVA adjusted for neonates' demographic data (gender, birth weight, gestational age, neonatal age) and duration of sampling was used to test the difference in latency to first cry, duration of first crying, and NIPS scores at different time points between the BF, MT, MT+BF and no-intervention groups. The Bonferroni correction was applied to compare means between groups. The level of statistical significance was set at $p < 0.05$.

Findings

Socio-demographic data

Among 313 neonates who were assessed for eligibility, 22 neonates did not meet the selection criteria and three mothers refused to participate. The main reasons for exclusion from the study were that the neonates did not pass the hearing test ($n=7$), the mothers could not breast feed their neonates because of positive Hepatitis B antigen ($n=12$), and the mothers did not want to see their babies undergo heel lance ($n=3$). Two hundred and eighty-eight neonates were recruited to this study and randomised with 72 neonates in each group. Among the 288 neonates, 250 completed the protocol and all tests. Nine mothers withdrew from the study as their neonates cried considerably before heel lance, four did not want to be recorded, two mothers did not want to breast feed in front of research staff, and eight neonates could not latch onto the breast well and failed to meet the successful breast feeding standard (with a large amount of the areola in the mouth, active jaw movement, and swallowing after sucking). The main researcher decided to exclude those unsuccessful breast fed neonates from data analysis as this would affect the effects of the interventions (Fig. 1). Two hundred and fifty neonates remained in the study and their demographic and clinical characteristics are shown in Table 1. No notable differences were found between groups in terms of gestational age, sex, birth weight, and duration of sampling. There was a small difference between groups in mean neonatal age, differences being at most 0.26 days.

Comparison of mean change of neonates' NIPS scores by group over time

Results of repeated measures ANCOVA adjusted for baseline NIPS scores, gestational age, neonatal age, birth weight, gender, and duration of sampling are shown in Table 2. The mean changes among the four groups were significant ($F(3, 244)=30.63$, $p < 0.001$). There was no significant mean change in NIPS scores for four groups across four time points ($F(3, 242)=0.32$, $p=0.709$). There was statistically significant interaction effect ($F(9, 732)=5.39$, $p < 0.001$). This indicated that mean changes in NIPS scores from baseline over time were dependent on the interventions given.

Comparison of mean latency to and duration of first cry by group

Table 3 shows the ANCOVA results for comparing latency to and duration of first cry by group, adjusted for gestational age, neonatal age, birth weight, gender and duration of sampling. ANCOVA showed that the four groups differed significantly in latency to first cry and duration of first crying, with mean latencies considerably longer and mean durations considerably shorter in breast fed neonates. Neonates in the BF group had significantly longer latency to first cry than those in the MT group ($p < 0.001$) and those in the no-intervention group ($p=0.001$). The combined BF+MT also significantly prolonged the latency to first cry in comparison to the MT ($p=0.025$) and no-intervention ($p=0.020$) groups. Neonates in the BF group experienced significantly shorter duration of first crying than those in the MT group ($p < 0.001$) and those in the no-intervention group ($p < 0.001$). In addition, the duration of first crying was significantly shorter in the BF+MT group, compared with those in the MT group ($p < 0.001$) and no-intervention group ($p < 0.001$) (p-values for comparing pairs of groups were Bonferroni-corrected).

Comparison of mean NIPS scores by group between time points

Fig. 2 shows a graphical representation of the mean change in NIPS scores for four groups at four time points. Table 3 also shows mean NIPS scores by group before heel lance, during the procedure, and one and five minutes after the procedure, together with ANCOVA comparisons adjusted for gestational age, neonatal age, birth weight, gender and duration of sampling. ANCOVA showed that the four groups differed significantly in mean NIPS scores during the procedure and one minute after the procedure, with mean pain scores lower in breast fed neonates. Following heel lance, NIPS scores in the BF group had a mean increase of 3.05 and the BF+MT group had a mean increase of 4.38, compared to a mean increase of 6.06 and 6.43 in the MT and no-intervention groups. The neonates in the BF group achieved a significantly lower NIPS score, compared to those in the MT group ($p < 0.001$) and no-intervention group ($p < 0.001$). NIPS scores in the BF+MT group were also significantly lower than those in the MT group ($p=0.003$) and no-intervention group ($p=0.001$).

One minute after the procedure, neonates' NIPS scores decreased to 0.35 in the BF group and decreased to 0.24 in the BF+MT group, compared to a mean decrease to 1.98 and 2.34 in the MT group and control group respectively. The neonates showed significantly lower NIPS scores in the BF group, compared to those in the MT group ($p < 0.001$) and no-intervention group ($p < 0.001$). The BT+MT group also had significantly reduced NIPS scores, compared to the MT ($p < 0.001$) and no-intervention ($p < 0.001$) groups. No significant difference was found between the four groups five minutes after the procedure.

There was no significant difference between the BF and BF+MT groups in terms of latency to first cry, duration of first crying, and NIPS mean scores during and one minute after the procedure. In addition, the above indicators of pain response did not significantly differ between the MT and control groups.

Discussion

In mainland China, provision of breast feeding and music to relieve pain for heel lance is often underused. Pain caused by heel lance for healthy-term infants is still not recognised, assessed, or managed in many maternal-infant units worldwide (Henry et al., 2004; Codipietro et al., 2011; Zhu et al., 2012). Our study investigated the effectiveness of BF, MT, and combined BF+MT in order to recommend evidence-based practice to reduce pain in healthy-term neonates undergoing heel lance. This study was the first of its kind in mainland China.

In our study, the adjusted repeated measures ANOVA indicated that mean changes in NIPS scores from baseline over time was dependent on the interventions given. Moreover, this study found that both BF and BF+MT did significantly diminish the pain response in healthy-term neonates during heel lance. However, BF+MT did not prove to be more efficacious than BF alone in pain

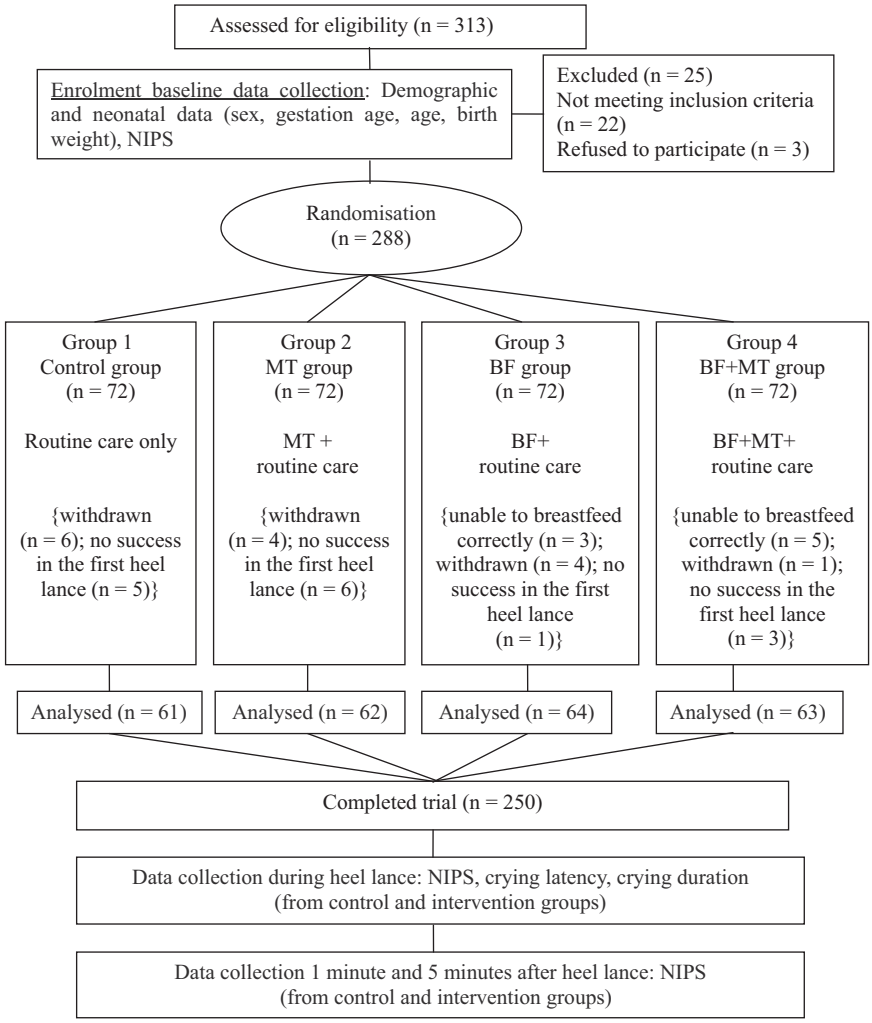


Fig. 1. Consolidated Standards of Reporting Trial (CONSORT) flowchart. *Note*: MT=music therapy; BF=breast feeding; BF+MT=combination of breast feeding and music therapy.

Table 1
Neonatal baseline demographic and clinical characteristics (n=250).

	Control group (n=61)	MT group (n=62)	BF group (n=64)	BF+MT group (n=63)
Gestational age (day)	273.70 (8.82)	275.26 (11.44)	277.12 (8.22)	276.24 (6.94)
Neonatal age (day)	3.11 (0.49)	3.37 (0.58)	3.34 (0.48)	3.24 (0.50)
Birth weight (kg)	3.14 (0.35)	3.28 (0.30)	3.29 (0.41)	3.18 (4.50)
Male	51%	52%	58%	46%
Duration of sampling (second)	61.11 (47.96)	65.34 (51.18)	47.60 (31.04)	53.73 (42.69)

Note: BF=breast feeding; BF+MT=combination of breast feeding and music therapy; MT=music therapy. Results are expressed as mean (SD).

relief and MT did not provide significant pain relief when compared with the results from the no-intervention group in our study. Thus the study indicated that the addition of music therapy did not appreciably enhance the effectiveness of breast feeding in pain relief.

Breast feeding has been extensively evaluated for its effectiveness on procedural pain in neonates (Shah et al., 2007). In our study, neonates given BF had significantly less pain, longer latency to first crying, and shorter duration of first crying compared to those in the MT and no-intervention groups. Concurring with our study, Codipietro et al. (2008) documented that breast feeding decreased pain and duration of first cry even better than orally administered sucrose. Weissman et al. (2009) conducted a prospective study of 180 term neonates undergoing heel lancing and also reported that infants who were breast fed during the procedure showed the lowest increase in heart rate, lowest neonatal facial score, and lowest cry duration, compared with non-nutritive sucking, holding by mothers, or oral glucose solution. The touch and smell of the mother, the contained position of the infant, the sweetness of breast milk, and diversion of attention might be the potential mechanism by which breast feeding could help in reducing pain in neonates (Golianu et al., 2007; Campbell-Yeo et al., 2011).

Our study could not identify positive effects on the pain response of healthy-term infants exposed to MT, such as NIPS, latency to first cry, and duration of first crying. This was different from Hu's (2013) study, which identified a pain-relieving effect when Chinese infants ranging from one month to three years of age were exposed to classical music while undergoing venepuncture. The difference between the two studies could be related to

the age of the target population – that is, two to five days old in our study and one month to three years in Hu's (2013) study. Butt and Kisilevsky (2000) found that neonates with difference gestation ages have different responses to music. In their study, preterm neonates older than 31 weeks gestation showed significantly less pain response with music provided, although preterm neonates younger than 31 weeks gestation demonstrated no significant effect from music.

Bo and Callaghan (2000) reported that intrauterine maternal pulse sounds with soothing music provided significantly pain management for neonates after the heel stick in intensive care units, which was also different from the result of our study. The major difference between our study and Bo and Callaghan's study is the type of music chosen; that is, classical music in our study versus intrauterine maternal pulse sounds with soothing music in Bo and Callaghan's study. It is possible that the human fetus has the ability to learn and remember auditory stimuli from their intrauterine environment and this memory could have a soothing effect (Campbell-Yeo et al., 2011). The lack of significant findings regarding the efficacy of music in pain relief in our study may also be due to the music chosen. Hartling et al. (2009) suggested a definite conclusion on the effectiveness of music could not be made because of the heterogeneity in study populations, interventions and outcomes used to examine the efficacy of music therapy for procedural pain relief. Additional randomised controlled trials were warranted to compare the benefits of playing different types of music to infants of different ages to establish more clinical evidence about music's ability to help relieve procedural pain.

Combined pain management has been gaining popularity in research into effective pain relief in neonates undergoing painful procedures (Henry et al., 2004; Cignacco et al., 2007). In our study, the combination of BF+MT provided significant pain relief, compared with MT alone and no intervention. Literature has inconclusive findings. For example, Whipple (2008) documented the effectiveness of combining music and non-nutritive sucking on behavior state and stress level in a sample of neonates from 32 to 37 weeks gestation. However, Johnston et al. (2009) reported that mothers' singing did not enhance the pain relief of kangaroo mother care during heel lance in preterm neonates. Our study found no significant pain relief effect of MT alone, and BF+MT was not superior to BF alone. There is insufficient evidence to support the synergetic pain relief effect of BF and MT. The results of this study can be interpreted that there is no need for the additional input of MT when BF is used in a clinic to relieve procedural pain, as BF alone is more cost-effective than combined BF+MT. Moreover, BF alone would provide satisfactory pain relief effect for healthy-term neonates undergoing heel lance.

Strengths and limitations of this study

This study has a number of strengths. The design of this study was a randomised, controlled trial with sufficient sample size. Multiple outcome variables were used to measure the pain response of healthy full-term neonates undergoing heel lance. An experienced nurse performed the heel lance based on standard protocols to minimise variability. This study also has important relevance to neonatal practices in mainland China as breast feeding has not been applied in clinics to relieve procedural pain in neonates.

This study has several limitations. This was a single-centre trial. The observers conducting the recording were not blinded to the allocation. We could not apply the double-blind method due to the nature of the observation, as the video record showed who was breast fed and who was not. Future studies could conduct multicenter trials and also include different minor procedures for which pain management is needed.

Recommendations for future studies

Further research on music and breast feeding is definitely warranted. A variety of music, such as lullabies, could be used in further studies to test its efficacy with regard to pain relief in neonates undergoing minor procedures. In our study, the neonates were wrapped in blankets during heel lance, so there was no skin-to-skin contact between the neonates and their mothers during

Table 2
Comparison of mean change of neonates' NIPS in four groups over time* ($n=250$).

Group	Mean change over time †	Mean difference from control group	Group effect F (p-value)	Time effect F (p-value)	Interaction effect (Time*Group) F (p-value)
BF+MT	4.36	−2.07	30.63 (< 0.001)	0.32 (0.709)	5.40 (< 0.001)
BF	3.05	−3.38			
MT	6.06	−0.33			
Control	6.43				

Note: BF=breast feeding; BF+MT=combination of breast feeding and music therapy; MT=music therapy.

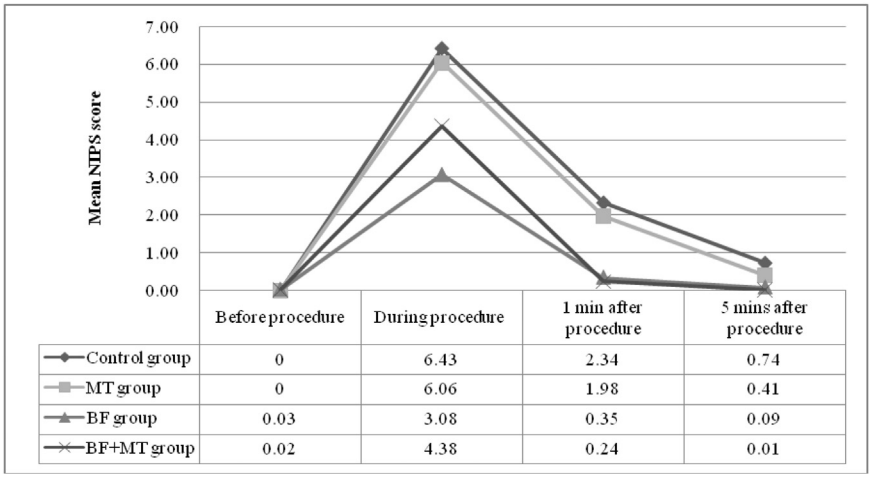
* Repeated measures ANCOVA adjusted by baseline NIPS scores, gestational age, neonatal age, birth weight, gender, and duration of sampling.

† Mean change over time=NIPS mean score during procedure – baseline NIPS mean score.

Table 3
Comparison of neonates' pain response between four groups for the whole procedure ($n=250$).

	Control (n=61)	MT (n=62)	BF (n=64)	BF+MT (n=63)	F	p
Latency to first cry (second)	4.83 (2.45)	5.03 (2.41)	13.65 (2.34)	14.89 (2.37)	5.59	< 0.001
Duration of first crying (second)	101.61 (9.43)	90.86 (9.27)	27.32 (9.01)	27.17 (9.12)	13.17	< 0.001
NIPS score						
Before procedure	0.00 (0.01)	0.00 (0.02)	0.03 (0.02)	0.02 (0.02)	0.62	0.761
During procedure	6.43 (0.23)	6.06 (0.22)	3.08 (1.88)	4.38 (2.20)	20.56	< 0.001
1 minute after procedure	2.34 (0.29)	1.98 (0.29)	0.35 (0.27)	0.24 (0.28)	6.26	< 0.001
5 minutes after procedure	0.74 (0.18)	0.41 (0.17)	0.09 (0.16)	0.01 (0.17)	1.89	0.065

Note: BF=breast feeding; BF+MT=combination of breast feeding and music therapy; MT=music therapy; NIPS=Neonatal Infant Pain Scale.
ANCOVA adjusted by gestational age, neonatal age, birth weight, gender, and duration of sampling.
Results are expressed as mean (SD).



	Before procedure	During procedure	1 min after procedure	5 mins after procedure
Control group	0	6.43	2.34	0.74
MT group	0	6.06	1.98	0.41
BF group	0.03	3.08	0.35	0.09
BF+MT group	0.02	4.38	0.24	0.01

Fig. 2. Change in neonates' NIPS mean scores over four time points. *Note*: MT=music therapy; BF=breast feeding; BF+MT=combination of breast feeding and music therapy.

the whole procedure. Campbell-Yeo et al. (2011) indicated that both breast feeding and skin-to-skin contact has been consistently associated with a reduction in behavioural pain response. Further studies may explore the synergic effect of breast feeding and skin-to-skin contact on pain relief during heel lance. For babies who are not breast fed, more research is needed to explore ways to relieve their procedural pain. The findings of these studies would help health care professionals to implement evidence-based intervention to help relieve pain in neonates undergoing heel lance.

Conclusions and implications for practice

This study provides clinical evidence that breast feeding could provide pain relief in healthy-term neonates during minor invasive procedures. Although breast feeding is primarily mother-driven, breast feeding during heel lance is ultimately nurse-enabled. The understanding of the effectiveness of breast feeding on pain relief could help to promote its use during heel lance in clinical practice.

The results of this study confirm the effectiveness of breast feeding on pain relief for healthy-term neonates undergoing heel lance. Healthy-term neonates should be breast fed to relieve pain during heel lance. In addition, our study indicates that music therapy cannot enhance the effectiveness of breast feeding on pain relief and there is no need for the additional input of classical music in clinics where breast feeding is used to relieve procedural pain. Health care professionals such as nurses and midwives need to be trained in the effectiveness of breast feeding on pain relief and how to use it and incorporate it into practice.

Conflict of interest

We declare that there is no conflict of interest.

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Author contributions

Study Design: ZJM, CWCS.
Data Collection and Analysis: ZJM, ZXZ, WHX, GYR, HHG.
Manuscript Preparation: ZJM, HHG, CWCS, LZG, YBL, ZXZ, WHX, GYR.

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