

# **Investigation of different relaxation interventions on physical and psychological changes in breastfeeding mothers in China: A pilot study**

Jinyue Yu <sup>1</sup>

Mary Fewtrell <sup>1</sup>

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From: <sup>1</sup> The Childhood Nutrition Research Centre, Institute of Child Health, University College London.

Principal Investigator: Mary Fewtrell, Institute of Child Health, University College London.  
30 Guilford Street, London. WC1N 1EH  
Email: [m.fewtrell@ucl.ac.uk](mailto:m.fewtrell@ucl.ac.uk)

## 1. Introduction and Rational

Breastfeeding is of great importance for infant health and development [1]. Accumulated evidence show the effects of human breast milk on optimizing infant growth of brain and body, as well as protecting against infection and developing the immune system [1-4]. In a recent *Lancet* review [2], which summarised the findings of 28 systematic reviews and meta-analyses, the psychological and cognitive benefit of human breast milk for infants are emphasised. Moreover, the protective effects of breastfeeding on reducing the risk of obesity, type 2 diabetes, cardiovascular disease, and allergic disorders such as asthma are identified for infants later in life. Apart from the health benefits on infants, breastfeeding could also provide mothers with a better postpartum recovery [1, 2], and associated with decreased risk of osteoporosis, cardiovascular diseases, diabetes, and ovarian and breast cancer in their later life [2, 5-8]. However, despite a number of health programmes designed to promote breastfeeding, it is widely recognised that the exclusive breastfeeding (EBF) rates in many countries are disappointingly low and resistant to change [2]. Overall, less than half of the world population exclusively breastfeed their infants up to six months, with a global rate of 39% reported by UNICEF (2012) [9]. Apart from the socio-economic and cultural factors which may influence mother's decision on breastfeeding, lactation performance is also influenced by maternal physiological and psychological condition [10].

Stress can be one of the factors that influence the successful breastfeeding [11]. Accumulated evidence show that stress can influence the stress-related hypothalamic-pituitary-adrenal (HPA) axis thereby affect the lactation. A number of studies reported the effectiveness of relaxation techniques on reducing stress and anxiety, which were associated with improved endothelial function [12, 13]. In a previous MOM study, maternal psychological state was manipulated using relaxation therapy in 58 Malaysian mothers breastfeeding their full-term infant. The therapy show significant effects in reducing maternal stress during lactation, favourably affecting breast milk composition (higher fat/energy and higher total carbohydrate) and positively influencing infant sleeping behaviour and growth.

However, there are lack of studies evaluating the effectiveness among different relaxation techniques. There are many relaxation methods, including relaxation training [14], guided imagery [12], music

therapy [15], yoga and progressive muscle relaxation (PMR) [16]. Most of these use the cognitive and/or behavioural relaxation approach which emphasizes the development of a relaxation response to counteract the stress response of anxiety [17]. The relaxation response refers to a set of integrated physiological mechanisms and 'adjustments' that are elicited when a subject engages in a repetitive mental or physical activity and passively ignores distracting thoughts [17].

Light therapy is another technique which may be used to promote relaxation. Evidence shows that light could stimulate the suprachiasmatic nucleus (SCN) located in the hypothalamus on top of the optic chiasm and influence the secretion of cortisol and adrenocorticotrophic hormone by mediating the HPA axis [18]. Research also indicates that light may induce gene expression ("circadian clock" - related or "sleep"-related genes in depression) in the adrenal gland via the SCN-sympathetic nervous system [19]. An increasing number of studies reported the application of light therapy for the treatment of a range of mental disease, namely seasonal affective disorder (SAD) [20], non-seasonal depression [21], total sleep deprivation [22], and antepartum depression [23]. Studies also show that exposure to blue light is associated with reduced heart rate and blood pressure [24], while improved resting metabolic rate was observed in patients with SAD following exposure to bright light [25].

This pilot study aims to find the most effective relaxation technique to help mothers who are firstly breastfeeding their infant. Hence, we will evaluate the effects of five different relaxation techniques on physical and psychological changes in Chinese mothers who are firstly breastfeeding their infant. The ultimate aim of this study is to select the most appropriate therapies for breastfeeding mothers to be used in a subsequent trial investigating the impact of relaxation theory on breastfeeding outcomes in mothers who deliver a late preterm infant. Five types of intervention used in this study include: guided relaxation meditation tape, music tape, relaxation lighting, combined relaxation meditation and lighting, and combined music and lighting.

## **2. Objectives**

To compare and evaluate the impact of five relaxation interventions on changes of heart rate (HR), blood pressure (BP), fingertip temperature (FT) and level of relaxation among Chinese breastfeeding women. Additionally, participants' perceptions and feelings about each relaxation technique will also be evaluated.

### 3. Hypotheses

**Primary:** Compared to the control state, all five relaxation interventions associated with increased perceived relaxation in varying degrees and reduced perceived stress.

**Secondary:** The two combination treatments (guided relaxation tape with relaxation lighting, and music tape with relaxation lighting) might show more effectiveness than other three treatments.

### 4. Study Design

The present study will be conducted at Beijing Children Hospital, Beijing, China. A within-subject design will be used to evaluate the effectiveness and participants' feeling towards the five tested interventions compared to a control situation.

#### 4.1 Population and recruitment

The study population will be Chinese women who are currently breastfeeding their infants. Recruitment will be take place through social media and community flyers in Beijing Children Hospital. After obtaining approval. Advertisements will be posted in the hospital while flyers will be sent to local communities. Interested women can contact us by email. Details about the study will be explained in the information sheet. After checking the eligibility and obtaining written informed consent, all eligible participants will be enrolled in the study.

#### 4.2 Sample size calculation

To estimate the sample size of this pilot study, standard formulas (21) used for calculation are:

*Sample size (per equal-sized group) =  $16 \times \text{standard deviation} \div (\text{difference})^2$*

Here the effect size and standard deviation (SD) are estimated from a previous research (22), which evaluated the effect of audio-visual imagery on patient anxiety and physiological parameters. A

sample of 51 patients was able to demonstrate a significant reduction in HR (mean change (Z)= -0.75, SD= 1.00; p=0.01). Accordingly, the estimated sample size (per equal-sized group) would be 28. However, since the present study will use a within-subject design, a sample of 14 participants will likely be able to demonstrate changes. Considering the potential drop-off rates, we intend to involve a total of 15-20 subjects in this study.

#### 4.3 Eligibility criteria

Inclusion Criteria	Exclusion Criteria
Women (primips) who are exclusively breast feeding their infants	Women who are breastfeeding their second infant and have previous experience of breastfeeding for their first infant
Between 1 month to 4 months after delivery and stay at home	After 3 months of delivery and back to the work place
Generally healthy	Women who have mastitis, or any condition that may affect breastfeeding, blood pressure, heart rate, energy expenditure, hearing ability or vision
18-45 years of age	Smokers
	Did not attend any other clinical trials within the latest 12 months

#### 5. Study Procedures

After obtaining informed consent, all participants enrolled in this study will be asked to attend for 30 minutes once to three times per week for five relaxation treatments and one control (no treatment). The emotions and feelings of participants in both intervention and control treatment will be assessed before and after each treatment or control.

The duration of this study is six weeks. In order to fit with the subject's schedule and control the circadian rhythm, all treatments and control sessions will take place on different days each week. Each participant can choose a 30-minute time slot to fit their timetable. To make the outcome assessment more consistent, participants are encouraged to come at the same time of the day they chose. The order of interventions will be randomly assigned for each participant. Both relaxation interventions and control will be conducted in the breastfeeding room located at Beijing Children Hospital. This room is private, quiet and has comfy seating. Participants will be asked to leave their personal belongings, including any electronic devices, books and magazines, and personal work, during the experiment period.

## **6. Treatment of Subjects**

A total of five interventions will be used in this study, in which, three basic interventions are: guided relaxation meditation tape, music tape, and relaxation lighting (Philips Hue). Moreover, since we hypothesised that a potential larger effect might be observed when using combined relaxation interventions to stimulate different senses (vision and audition) at the same time, we combined the guided relaxation tape with lighting and the music tape with lighting as two additional interventions in this study. All participants will receive all five treatments and control in random order.

### **6.1. Guided Imagery Relaxation Tape**

Participants will listen to a modified Chinese language version of a guided imagery meditation tape designed for breastfeeding mothers (23). Previous randomised controlled trials have shown efficacy for this relaxation method on reducing stress and anxiety among breastfeeding mothers (4, 24). The tape will be translated into Chinese. Moreover, since the original content of this tape is designed for women who are breastfeeding their infants, while the subjects in the present study are students without breastfeeding, the tape will also be modified by cut down the breastfeeding-related content to adapt to our sample. The duration of this tape will be cut down to about 10 minutes by removing the parts specific to breastfeeding.

## 6.2. Music Tape

Participants will select music from the following two music lists: 1) traditional Chinese classical music (played by classical Chinese instruments), which has been traditionally used in China for patients with depression or chronic pain; 2) New-age music, a popular style that is often used for relaxation, which often draws on images of nature, the desert, the sea, and other natureescapes. These tracks are enhanced by electronic or computer-generated sounds. Since the music is created or enhanced through electronic means, the underlying rhythm and pulse can be manipulated to create a surging or pulsing effect to induce a relaxation response (25). Studies indicate that the effectiveness of music therapy on relaxation will be affected by personal preference. Hence, to enhance the effect of music therapy for relaxation, we will use the selection method to achieve a more individualized music experience for all participants.

## 6.3. Relaxation lighting

Compared to bright light therapy and blue light therapy which mostly show effects on people with depression, the light technique used in this study will be designed to induce relaxation. The Philips Hue system will be used. Previous studies evaluating the effects of environmental intervention on mood show that certain aspects of the imaging environment could be effective for pleasantness control (26). Clinical research also indicates that colourful ambient lighting has been shown to improve patient satisfaction and reduce pain ratings (27). Moreover, based on the research from Philips, which evaluated the feedback from patients and their staff, the colour preference of lighting may be cultural with people. Results show that people in Singapore preferring cool blue as more relaxing colour, whereas Germans preferring the warm orange. In the present study, participants will be asked to select either the “Relax”, “Energize” or “Concentrate” settings using the Philips Hue bulb, which correspond to orange, blue, and light cream respectively. The intensity of the light will be fixed.

## 6.4. Guided relaxation tape with relaxation lighting and music with lighting

Previous research compared the effects of guided imagery (verbal protocol) and verbal protocol with background music (24) and found that participants using the verbal protocol with background music

reported lower relaxation compared to the verbal protocol only group. The authors proposed that this might be due to confusion during the intervention when both verbal sounds and background music were experienced by participants. Therefore, in this study, we aim to evaluate the effectiveness of guided relaxation meditation with relaxation lighting as well as the music therapy with relaxation lighting, to find out whether the combined treatment could increase the relaxation level by stimulating vision (lighting) and audition (tape) together. It can be hypothesised that the effects of this combination therapy might be enhanced since the light and sounds will affect the HPA axis through different pathways.

## **7. Outcome measurements**

Primary outcomes of this study will be perceived relaxation level, HR, BP and FT, while the secondary outcomes will be the perceptions and feeling about each treatment, including general satisfaction, perceived effectiveness, and likelihood of wanting to use the intervention in future. Evaluation will base on the design and content of the relaxation technique.

The HR, BP and FT will be measured at both the start and the end of the experiment. An automatic BP machine will be used for the measurements of HR and BP. The BP will be measured three times and the mean of three will be calculated and recorded. A thermometer will be used for the FT measurement. For the evaluation of levels of relaxation and feelings of each intervention, a visual analogue scale will be employed at the beginning and end of each intervention.

## **8. Statistical Analysis**

Data will be analysed using SPSS 24.0. Paired t-test will be used to detect changes in each of the primary outcomes before and after the treatment. One-way ANOVA will be conducted to find differences between control and each intervention group. Post-hoc analysis will be used to compare the effectiveness of each treatment. Differences will be considered statistically significant at  $p < 0.05$ .



## 9. Ethical Consideration

For any participant who are experiencing high BP or has previously been diagnosed as hypertension, we will advise them to contact with their GP and discuss whether they could take part in this study. Moreover, as compensate, each participant will be given a gift for taking part in this study.

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