Randomized trial comparing the physiological and psychological effects of different relaxation interventions in Chinese women breastfeeding their healthy term infant

Jinyue Yu [1]MSc, MD, Jonathan Wells[1] PhD, Zhuang Wei [2] PhD, Mary Fewtrell [1]

[1]UCL Great Ormond Street Institute of Child Health, University College London, London, United Kingdom

[2]Child Care Centre, Beijing Children's Hospital, Capital Medical University, Beijing, China

Correspondence

Jinyue Yu

PhD candidate in ICH Population, Policy and Practice Programme,

UCL Great Ormond Street Institute of Child Health,

30 Guilford Street,

London, United Kingdom

WC1N 1EH

Tel: +44 (0) 7518719185

Email: jin.yu.16@ucl.ac.uk

Tables in the text: three

Figures in the text: one

Key words: breastfeeding, lactation, relaxation therapy, stress, anxiety

Declarations of interest: none

Word count: 3013 words

Abstract

Objective

To compare the effects of different relaxation techniques on physiological outcomes and perceived relaxation in primiparous Chinese mothers breastfeeding their healthy term infant.

Design

Twenty primiparous mothers who were breastfeeding were enrolled into a within-subject study, and attended six treatment sessions in randomised order (relaxation meditation tape (RM), music tape (M), relaxation lighting (L), combined RM+L, and combined M+L, and control session with no intervention), with a washout period of 1-3 days between sessions. Heart rate (HR), systolic and diastolic blood pressure (SBP, DBP), fingertip temperature and perceived relaxation were assessed before and after each session.

Results

Compared to the pre-test state, significant changes for all outcomes ($p<0.05$) were observed for RM, RM+RL, M+RL treatments, whilst differences for all outcomes apart from SBP were

observed for treatment M. Compared to the control, significant changes were found in all outcomes for RM treatment, and in fingertip temperature and perceived relaxation for all treatments.

Conclusion

Our findings suggest that simple relaxation techniques can reduce both perceived and physiological markers of stress in breastfeeding mothers. Overall, the RM was the most effective technique compared to the control state, considering the number of outcomes affected, effect sizes and simplicity, suggesting this merits further research in this population.

1. Introduction

Breastfeeding is of great importance for infant health and development [1]. Increasing evidence shows the effects of human breast milk on optimizing infant growth and development, as well as protecting against infection and developing the immune system [1-4]. A recent *Lancet* review also emphasised the psychological and cognitive benefit of human breast milk for infants [2]. Apart from the health benefits for infants, breastfeeding could provide mothers with a better postpartum recovery [1, 2], and is associated with decreased risk of osteoporosis, cardiovascular diseases, diabetes, and ovarian and breast cancer in 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]. Globally, only 39% of mothers exclusively breastfeed their infants up to six months (UNICEF 2012) [9]. Apart from the socio-economic and cultural factors which may influence mother's decision on breastfeeding, lactation performance such as breastfeeding duration and breastmilk volume is also influenced by maternal physiological and psychological condition [10].

Stress can influence the hypothalamic-pituitary-adrenal (HPA) axis thereby affecting lactation

[11]. A number of studies reported the effectiveness of relaxation techniques on reducing stress and anxiety and increasing milk yield in mothers with preterm infants [12, 13]. In a previous study, maternal psychological state was manipulated using relaxation meditation in 64 Malaysian mothers breastfeeding their full-term infant [14]. The therapy showed 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.

Apart from relaxation meditation, there are many well documented relaxation methods for the reduction of stress and anxiety, including relaxation training [15], guided imagery [12], music therapy [16], yoga and progressive muscle relaxation (PMR) [17]. Moreover, light therapy is another technique which may be used to promote relaxation. Evidence shows that light can stimulate the suprachiasmatic nucleus (SCN) in the hypothalamus 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 have 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 [23-25].

Most existing studies evaluating the effectiveness of relaxation therapies only look at one intervention rather than comparing different ones. Moreover, there is a lack of research investigating the effects of relaxation therapy specifically in breastfeeding mothers. A recent systematic review evaluated six studies (three observational, three experimental) investigating the effect of relaxation techniques on breastfeeding outcomes [26]. While the results showed that relaxation therapy might significantly improve milk yield, methodological issues were identified, such as high variability in the milk collection protocol and assessment time points among six studies. Hence, the aim of the present study was to compare the effects of different relaxation techniques on reducing stress in mothers breastfeeding their healthy term infant. We evaluated the effects of five different relaxation techniques on physical and psychological changes using a within-subject study design. Our aim was to identify the most effective relaxation technique for use in future research to test the hypothesis that reducing maternal

74 stress could result in enhanced milk ejection and improved breastfeeding outcomes.

75

76 **2. Materials and Methods**

77 ***Study design***

78 The study was conducted at a local community clinic attached to Beijing Children Hospital in
79 China. A within-subject design was used to evaluate the effectiveness of the five tested
80 interventions compared to a control situation. Recruitment was performed using flyers in the
81 local community, and advertisements posted in the hospital and community clinic. The study
82 information sheet was given to interested women. Eligibility criteria were: 1) primiparous
83 mothers who were currently breastfeeding their infants within 2 years after delivery; 2) aged
84 23 to 45 years; 3) generally healthy (without any diseases that could influence blood pressure,
85 heart rate, energy expenditure, or breastfeeding practice); 4) not currently participating in other
86 studies; 5) non-smoker.

87

88 After obtaining written informed consent, participants were invited to attend the clinic every
89 1-3 days on six occasions (five relaxation sessions and one control session). The six sessions

were coded as: 0= control, 1= RM, 2= M, 3=L, 4=RM+L, 5=M+L. The order of the six sessions was randomly assigned for each participant using a computerized random number generator. This was performed by an independent person who had no contact with the subjects. To control for circadian rhythm, all sessions were performed in the afternoon between 2:00 PM and 4:00 PM. The duration of each treatment was 10 minutes, with additional 10-minute pre- and post-test measurements. Each treatment was conducted in a breastfeeding room at the clinic where participants were comfortably seated and guided by the researcher. The participants were encouraged to report any comments about their experience to the researcher after each session; such issues were noted in the demographic questionnaire of the participants. The infants of participants were not present during the session. Ethical permission for the study was obtained from the Research Ethics Committee of University College London (ID: 12681/001) and the leaders of Centre for Child Health, Beijing Children Hospital. The trial was registered at clinicaltrials.gov (NCT03593551).

Interventions

The RM used in this study was a modified version of a guided imagery meditation tape, which

106 was originally developed by Sheri Menelli in 2004 for breastfeeding mothers. The researcher
107 translated it into Chinese (Mandarin) and shortened the content to focus on the relaxation part
108 with the assistance of a psychologist. The Mandarin version of the tape was recorded by a
109 certified yoga therapist with prior experience ofrecording meditation tapes. Two types of music
110 were used in this study; New-age music and traditional Chinese music played on a classical
111 instrument. Participants could choose their preferred music to enhance relaxation and stress
112 reduction. The light therapy used in the L, RM+L, and M+L treatments was generated using
113 the Philips Hue system, while the lighting during the non-light treatments (RM, M) was a
114 standard light. Participants could choose either the orange light ("Relax" setting) or the blue
115 light ("Energize" setting) to meet their preference and the intensity of the light could also be
116 altered.
117
118 ***Outcomes and measures***
119 The primary outcomes of this study were changes in heart rate (HR), blood pressure (BP),
120 fingertip temperature and perceived relaxation for each treatment compared to the control.
121 Systolic blood pressure (SPB), Diastolic blood pressure (DBP) and HR were measured in the

seated position using an automatic BP machine (Yuyue, China) by trained nurses with at least 10-min rest period before the pre-treatment measurement. The post-treatment measurement of BP will be conducted immediately after the treatment considering the participants were rested during the treatment. A digital body thermometer (Care1st, China) was used for measuring the fingertip temperature. These assessments were carried out three times and the mean of the closest two readings was used. Perceived relaxation was assessed by a visual analogue scale (VAS), which consists of a horizontal 10cm line with one end representing the maximum and the other end the minimum of the variable to be measured. The right anchor of the scale was identified as “completely relaxed” and the left anchor was labeled “completely unrelaxed”. Participants indicated their state of relaxation by marking a point along the line before each session and again at the end of each session. The distance from the left anchor to the mark made by participants was measured in millimeters and pre and post-test differences were compared.

Sample size calculation

Sample size for paired comparisons (between each treatment and the control situation) was calculated using the formula [21] :

$$\textit{Sample size (per equal-sized group)} = 8 \times \textit{standard deviation} \div (\textit{difference})^2$$

A previous study [22], which evaluated the effect of audio-visual imagery on patient anxiety and physiological parameters reported a significant reduction in HR with a mean of 0.75 and SD of 1. Accordingly, the estimated sample size was 14. To allow for drop-outs, we aimed to recruit 20 subjects.

Statistical analysis

Data were analysed using SPSS 23.0. Means and standard deviations (SD) were used to summarise the characteristics of the entire sample. Paired t-test was used to analyse changes in each of the outcomes before and after the different treatment sessions. Paired t-test was also computed to compare the mean difference of each treatment to the control state. Differences were considered statistically significant at $p<0.05$.

3. Results

The study was carried out from 3rd June to 28th June 2018. All participants attended the full six sessions. Descriptive characteristics of the participants are presented in Table 1. The mean age of the participating mothers was 32.2 (±3.29), the mean age of their infants was 7.55 months (±6.18). Sixteen participants were exclusively breastfeeding their infants, while four participants were using mixed feeding. No participants were unwell during the study period.

3.1. Changes in BP, HR, fingertip temperature, and perceived relaxation during each session

Table 2 shows the mean differences in the primary outcomes pre and post-test for each treatment. Overall, except for the control session, all relaxation sessions showed reduced blood pressure and heart rate and increased fingertip temperature and perceived relaxation after the session (Figure 1). The RM, RM+RL, M+RL treatments showed significant differences before and after the test for all primary outcomes ($p<0.05$). For treatment M, significant differences between pre and post-test were found for all outcomes except SBP.

3.2. Comparisons of mean changes in each outcome between relaxation sessions and the control

Paired t-tests were conducted to compare the changes in primary outcomes for each treatment with the control state. As shown in Table 3, significant changes were found in all primary outcomes in RM compared to the control. For fingertip temperature and perceived relaxation, significant differences were found for all treatments when compared to the control state ($p<0.01$). Additionally, the SBP and DBP were reduced in all treatments compared to the control state, though some of the changes were not significant (Table 3).

Four participants, with infants aged 1-3 months, experienced milk let-down (ejection) during the session using the RM treatment. This was not reported for the remaining four treatments or control session.

4. Discussion

This study showed that, compared to the control state, all five relaxation interventions tested had significant effects with increased fingertip temperature and perceived relaxation in Chinese mothers who are currently breastfeeding their infants. A significant reduction in blood pressure

and heart rate was also observed following the RM, RM+RL, M+RL treatments. When compared to the control state, the RM produced significant changes in all measured outcomes and resulted in the greatest change in SBP, DBP and HR, while the M+RL showed the greatest mean change in fingertip temperature and perceived relaxation.

A previous randomised controlled trial (RCT) compared the effects of music, progressive muscle relaxation, music assisted progressive muscle relaxation, and silence on measures of anxiety and perceived relaxation in 60 university students (15 randomly assigned to each treatment; mean age=22.2 years) [27]. Anxiety and perceived relaxation were measured by the State Trait Anxiety Inventory (STAI) and VAS respectively, and all participants achieved significant relaxation responses regardless of the treatment type. However, physiological responses were not examined in this study and the relaxation status was measured using a self-rating scale. This may result in reporting bias, where the participant may either expect to feel more relaxed after treatment, or believe that they are expected to report this by the researcher. The same criticism applies to the VAS used in our study but, to address this issue, we also measured three physiological outcomes - blood pressure, heart rate and fingertip temperature -

202 to objectively evaluate the relaxation response. Previous research suggested that positive
203 emotion could affect the endothelium vasoreactivity [28], which was associated with reduced
204 blood pressure and heart rate. We found that, compared to the pre-test state, the VAS was
205 significantly increased after all interventions but also after the control session (Table 2), whilst
206 the physiological outcomes did not show significant changes during the control session. This
207 could suggest that the VAS is indeed subject to reporting bias, or alternatively that the
208 subjective feeling of relaxation measured using the VAS reflects a different process from the
209 relaxation measured by physiological responses.
210
211 A previous RCT evaluated the effects of listening to different types of music versus no music
212 on perceived and physiological indicators of stress in 56 undergraduate students (mean age=21
213 years) [29]. Both physiological indicators (skin temperature, frontalis muscle tension, heart rate)
214 and a perceived indicator (ratings of relaxation, measured by self-rating scale) were assessed.
215 No significant differences in physiological indicators were found between different types of
216 music, whilst significant increases were found in perceived relaxation ($p=0.004$) in the classical,
217 self-selected relaxation music and no music groups. The author concluded that people who

reported that listening to certain types of music helped them to relax may not be classified as relaxed using physiologically indicators. As suggested by Gay Peterson [30], the stress response can be defined as a complex reaction which often includes physiological, cognitive, and behavioural components. Hence, certain relaxation technique could influence different components of an individual's stress response. Physiological and perceived indicators may detect a reduction in physiological and cognitive stress respectively. Thus, a significant cognitive relaxation effect may be detected by an indicator of perceived relaxation without changes in physiological indicators. However, more experimental studies in this area are needed to further investigate this interpretation.

Regardless of the perceived relaxation, comparisons of changes in physiological outcome measures from pre to post intervention showed that the RM resulted in the greatest mean difference for SBP, DBP and HR, whilst the greatest mean difference for fingertip temperature was found using RM+RL, followed by RM. Moreover, four participants were recorded to experience the let-down-reflex during the RM session but not in other sessions. The let-down-reflex is affected by maternal psychological state, and milk ejection could be stimulated by

reducing maternal psychological distress or increasing relaxation [26, 31]. Although this was reported in only four mothers, it is interesting that their infants were only 1-3 months of age (the youngest among the study participants) and thus feeding more frequently. This observation, combined with the observed effects on the outcome measures, suggests that the RM treatment may be particularly effective in promoting relaxation and milk ejection in breastfeeding mothers.

The strengths of the study include the use of a within-subject design, allowing several relaxation interventions to be tested and compared in a single study. All 20 participants attended their six sessions during the study period, reflecting a high level of engagement and sustained involvement. The study also has some limitations. First, only 20 participants from one community in Beijing were enrolled, so the population may not be representative. However, since the ultimate aim of this research was to select the most appropriate relaxation technique for breastfeeding mothers to be used in a subsequent trial which will be conducted in Beijing, the current study participants were recruited from the area where the main study will take place. A potential disadvantage of the within-subjects design is that there might be "carryover effects"

of one intervention on the next. However, the order of the six sessions was randomly assigned for each participant, there was a 1-3 day period between sessions and the expected effects of each intervention were expected to be short-lived. Finally, it is important to note that we evaluated short-term responses to the relaxation interventions after a single session; it is possible that responses to more prolonged, repeated use of the interventions would differ and this should be considered when designing future studies. Such studies should include a larger sample and, importantly, investigate the effects of the intervention on outcomes related to lactation performance such as the breastmilk volume, energy content, and breastfeeding duration.

5. Conclusion

Our findings suggest that simple relaxation techniques can reduce both perceived and physiological markers of stress in breastfeeding mothers. Overall, the RM was the most effective technique compared to the control state, considering the number of outcomes affected, effect sizes and simplicity, suggesting this merits further research in this population.

Acknowledgments

The authors would like to thank the Sanlihe community clinic, Beijing, China, for providing advice and instruments for this pilot study. Moreover, the authors would like to thank Ms Cheng Yulan for contributing to the relaxation tape recording work.

References

1. Gartner LM, Morton J, Lawrence RA, et al. Breastfeeding and the use of human milk. *Pediatrics.* Feb 2005;115(2):496-506.
2. Victora CG, Bahl R, Barros AJ, et al. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect. *Lancet.* Jan 30 2016;387(10017):475-490.
3. Ajetunmobi OM, Whyte B, Chalmers J, et al. Breastfeeding is associated with reduced childhood hospitalization: evidence from a Scottish Birth Cohort (1997-2009). *J Pediatr.* Mar 2015;166(3):620-625 e624.
4. Liu XH. [Research advances in breastfeeding]. *Zhongguo Dang Dai Er Ke Za Zhi.* Oct 2016;18(10):921-925.
5. Lawrence RA. Breastfeeding: benefits, risks and alternatives. *Curr Opin Obstet Gynecol.* Dec 2000;12(6):519-524.
6. Lawrence RM, Lawrence RA. Breastfeeding: more than just good nutrition. *Pediatr Rev.* Jul 2011;32(7):267-280.
7. Aune D, Norat T, Romundstad P, Vatten LJ. Breastfeeding and the maternal risk of type 2 diabetes: a systematic review and dose-response meta-analysis of cohort studies. *Nutr Metab Cardiovasc Dis.* Feb 2014;24(2):107-115.
8. Godfrey JR, Lawrence RA. Toward optimal health: the maternal benefits of breastfeeding. *J Womens Health (Larchmt).* Sep 2010;19(9):1597-1602.
9. UNICEF. Childinfo : Monitoring the Situation of Children and Women. . *Current status of breastfeeding 2012* [
10. Wells JC. Parent-offspring conflict theory, signaling of need, and weight gain in early life. *Q Rev Biol.* Jun 2003;78(2):169-202.
11. Pariante CM, Lightman SL. The HPA axis in major depression: classical theories and new developments. *Trends Neurosci.* Sep 2008;31(9):464-468.
12. Feher SD, Berger LR, Johnson JD, Wilde JB. Increasing breast milk production for premature infants with a relaxation/imagery audiotape. *Pediatrics.* Jan 1989;83(1):57-60.
13. Ak J, Lakshmanagowda PB, G CMP, Goturu J. Impact of music therapy on breast milk secretion in mothers of premature newborns. *J Clin Diagn Res.* Apr 2015;9(4):CC04-06.
14. Shukri NHM, Wells J, Mukhtar F, Lee MHS, Fewtrell M. mother-infant signalling

during breastfeeding: A randomised trial investigating the effects of a relaxation intervention in breastfeeding mothers on breast milk production, breast milk cortisol and infant behaviour and growth. *Maternal & Child Nutrition.* 2015;11:108-109.

15. Bastani F, Hidarnia A, Kazemnejad A, Vafaei M, Kashanian M. A randomized controlled trial of the effects of applied relaxation training on reducing anxiety and perceived stress in pregnant women. *J Midwifery Womens Health.* Jul-Aug 2005;50(4):e36-40.

16. Knight WE, Rickard Ph DN. Relaxing music prevents stress-induced increases in subjective anxiety, systolic blood pressure, and heart rate in healthy males and females. *J Music Ther.* Winter 2001;38(4):254-272.

17. Smith C, Hancock H, Blake-Mortimer J, Eckert K. A randomised comparative trial of yoga and relaxation to reduce stress and anxiety. *Complement Ther Med.* Jun 2007;15(2):77-83.

18. Johnson SA, Fournier NM, Kalynchuk LE. Effect of different doses of corticosterone on depression-like behavior and HPA axis responses to a novel stressor. *Behav Brain Res.* Apr 3 2006;168(2):280-288.

19. Ishida A, Mutoh T, Ueyama T, et al. Light activates the adrenal gland: timing of gene expression and glucocorticoid release. *Cell Metab.* Nov 2005;2(5):297-307.

20. Terman M, Terman JS, Quitkin FM, McGrath PJ, Stewart JW, Rafferty B. Light therapy for seasonal affective disorder. A review of efficacy. *Neuropsychopharmacology.* Mar 1989;2(1):1-22.

21. Volz HP, Mackert A, Stieglitz RD, Muller-Oerlinghausen B. Effect of bright white light therapy on non-seasonal depressive disorder. Preliminary results. *J Affect Disord.* May 1990;19(1):15-21.

22. Wehr TA, Rosenthal NE, Sack DA, Gillin JC. Antidepressant effects of sleep deprivation in bright and dim light. *Acta Psychiatr Scand.* Aug 1985;72(2):161-165.

23. Epperson CN, Terman M, Terman JS, et al. Randomized clinical trial of bright light therapy for antepartum depression: preliminary findings. *J Clin Psychiatry.* Mar 2004;65(3):421-425.

24. Cajochen C, Munch M, Kobialka S, et al. High sensitivity of human melatonin, alertness, thermoregulation, and heart rate to short wavelength light. *J Clin Endocrinol Metab.* Mar 2005;90(3):1311-1316.

25. Gaist PA, Obarzanek E, Skwerer RG, Duncan CC, Shultz PM, Rosenthal NE. Effects

of bright light on resting metabolic rate in patients with seasonal affective disorder and control subjects. *Biol Psychiatry.* Dec 1 1990;28(11):989-996.

26. Mohd Shukri NH W, JC, Fewtrell, M. The effectiveness of interventions using relaxation therapy to improve breastfeeding outcomes: A systematic review. *Maternal & child nutrition.* 2018;14(2):e12563.

27. Robb SL. Music assisted progressive muscle relaxation, progressive muscle relaxation, music listening, and silence: a comparison of relaxation techniques. *J Music Ther.* Spring 2000;37(1):2-21.

28. Miller M, Mangano CC, Beach V, Kop WJ, Vogel RA. Divergent effects of joyful and anxiety-provoking music on endothelial vasoreactivity. *Psychosom Med.* May 2010;72(4):354-356.

29. Burns J, Labbe E, Williams K, McCall J. Perceived and physiological indicators of relaxation: as different as Mozart and Alice in chains. *Appl Psychophysiol Biofeedback.* Sep 1999;24(3):197-202.

30. Gay Peterson L. Health psychology: A psychological perspective. *General Hospital Psychiatry.* 1987;9:453.

31. Beresford HJ. The success of breast feeding. *IPPF Med Bull.* Oct 1984;18(5):3-4.

Address and e-mail address for reprint requests or correspondence:

UCL Great Ormond Street Institute of Child Health,

30 Guilford Street,

London, United Kingdom

WC1N 1EH

Email: jin.yu.16@ucl.ac.uk