PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Effectiveness of Breathing Exercises, Foot Reflexology and Back Massage (BRM) on Labour Pain, Anxiety, Duration, Satisfaction, Stress Hormones, and New-born Outcomes among Primigravidae during the First Stage of Labour in Saudi Arabia: A Study Protocol for a Randomised Controlled Trial
AUTHORS	Baljon, Kamilya; Romli, Muhammad Hibatullah; Ismail @ Daud, Adibah Hanim; Khuan, Lee; Chew, Boon

VERSION 1 - REVIEW

REVIEWER	Dr Julie McCullough Ulster University UK
REVIEW RETURNED	11-Nov-2019

GENERAL COMMENTS	Thank you for the opportunity to review this protocol. I enjoyed reading it very much. Identifying non-pharmacological methods of pain relief during labour and childbirth is an important area for research, for women, their babies and families but also for midwives. The use of natural treatments in the perinatal period are congruent with the wants and needs of women who desire a natural childbirth and for midwives as it meets their needs for professional autonomy. This study has been well planned in terms of recruitment, personnel and outcome measures. However, there are a number of issues that require attention and further elaboration. Some additional ideas for consideration have also sated below. There are also some minor points for clarification. I feel that these could be quickly resolved and clarified and, therefore, minor revision is required. Issues that require attention • In the background section and in Figure 1 the authors have given an overview of the possible mechanisms of action of massage therapy. Much of this also relates to reflexology, however a separate diagram for reflexology would be helpful. However, the authors have not added therapist-client interaction, rapport, etc, or the placebo effect which are all considered important factors in the beneficial outcomes of CAM therapies. • Diurnal variation all have an impact on cortisol levels. Have the team considered how they will manage diurnal variation in this population? Discuss in limitations. • It is presumed that any woman who has oxytocin for labour augmentation will be excluded. Please clarify. And discuss any possible limitations to the study.

	• Oxytocin is an interesting biochemical to measure in this population. Are the authors investigating oxytocin released as part of childbirth or in response to CAM therapies? How will this affect results? • ACTH is the precursor for cortisol, what is the collection of these two biochemical at a single time point likely to tell the research team? • Information has been provided for the massage training, however, there is no detail about the reflexology training. Reflexology is a specialist treatment and therapists require specific training. Maternity reflexology training is additional to general reflexology. The expertise and experience of the reflexologist is considered an important factor in the quality of treatment provided and this should be considered. As there are four therapists, what steps has the team include to validate the CAM treatments. Is this a limitation of the study? • How will the assessor recorded outcome measures be validated and verified? • In addition to the reflexology routine provided please state the reflexes to which pressure will be applied and the rational for this. • Please provide details of the blood analyses that will be completed. • In the case of the usual care arm of the RCT what does a massage therapist in the room with labouring women add to the study? It is unlikely that this would be part of the usual care a woman would receive and therefore the inclusion of another person in the labour room would not be normal usual care and is likely to have an effect on the woman and midwife and, thus, should not be included in the protocol. Additional ideas for consideration • Given that your sample is labouring women you may wish to consider including additional labour specific outcome measures, such as labour duration, type of childbirth which may be easily collected from women's delivery room medical record. Minor issues • Please add details of outcome measure tools to the abstract • Please define all acronyms at first mention. • The authors have used 'masseuse', however 'massage therapist' is the preferred term used by professionals. • On page 5, line 26 the two references talk about post-traumatic stress disorder (PTSD). Therefore, to accurately refer to the impact on mental health the word anxiety should be replaced by stress. • On page 8, line 6 the acronym CAM refers to Complementary and Alternative Medicine. • On page 11 line 22-29 Please clarify the term 'in equal numbers'. Also, it would seem that women of 26 weeks' gestation would not be in attendance at the hospital as during that time they are offered monthly appointments. Therefore, it may be more accurate to say all women, between 28-34 weeks' gestation, attending the antenatal clinic will be approached. • Also, what is the rational for not approaching women of 34+weeks gestation? • The first mention of blood samples appears on page 15, and outcome measures PBI and VAS appears on page 17. Please clarify, in a step-wise fashion, how the data will be collected in the main body of the manuscript. • On page 19, line 49-56 please add a reference for 'By timing the intervention after cervical dilation of 6 cm and above, the effect of the combined BRM could exert its most influences if there is any on the labour experience of the primigravidae and neonatal outcome because this period is believed to be with the highest levels of labour pain.'

	• By convention reflexology is carried out on the right foot first. • Please add further clarification to CIUW-shape: C-shape; I-shape; U-shape, and W-shape, **MST-shape: M-shape, S-shape, and Tshape. (Page 36, line 13) and please clarify the reflexology routine, the reference and the training involved/received so that it could be repeated by other teams. • The description provided for the VAS describes a pain measurement scale it does not describe a VAS. Please clarify throughout what you intend to use. If you are using a VAS please indicate the length and the descriptors at either end. • The reference list is extensive, however, some of the references are dated and more recent up to date literature is available. For example, one reference in date 1921 Hayes, M.H.S. and Patterson, D.G. The VAS is a commonly used scale and this reference adds little to the manuscript. The reviewer provided a marked copy with additional comments. Please contact the publisher for full details.

VERSION 1 – AUTHOR RESPONSE

Reviewer(s) Reports: Please leave your comments for the authors below. Thank you for the opportunity to reviews this protocol. This study has been well planned in terms of recruitment, personnel and outcome measures. However, there are a number of issues that require attention and further elaboration. Some additional ideas for consideration have also sated below. There are also some minor points for clarification. I feel that these could be quickly resolved and clarified and, therefore, minor revision is required. Thank you for the opportunity to review this protocol. Thank you for your comments and suggestions, we hope we have made the revision sufficiently good enough for the timely publication of the trial protocol.	
7.In the background section and in Figure 1 the authors have given an overview of the possible mechanisms of action of massage therapy. Much of this also relates to reflexology, however a separate diagram for reflexology would be helpful.	We have added this in the revised manuscript, page 7 line 14, and figure 1.
8.However, the authors have not added therapist-client interaction, rapport, etc, or the placebo effect which are all considered important factors in the beneficial outcomes of CAM therapies.	We have added this in the revised manuscript page 21 line 4-6.
9.Diurnal variation all have an impact on cortisol levels. Have the team considered how they will manage diurnal variation in this population? Discuss in limitations.	We have added this in the revised manuscript page 15 line 20-22, and page 16 line 1-4.
10.It is presumed that any woman who has oxytocin for labour augmentation will be excluded. Please clarify. And	We have added this in the revised manuscript page 16 line 8-13.

discuss any possible limitations to the study.	
11.Oxytocin is an interesting biochemical to measure in this population. Are the authors investigating oxytocin released as part of childbirth or in response to CAM therapies? How will this affect results?	We have added this in the revised manuscript page 16 line 13-17.
12.ACTH is the precursor for cortisol, what is the collection of these two biochemical at a single time point likely to tell the research team?	We have added this in the revised manuscript page 16 line 5-8.
13.Information has been provided for the massage training, however, there is no detail about the reflexology training.	The principal investigator who has completed the professional massage and reflexology training at a certified training centre in Malaysia (Tim Body Care Training Centre 1403695-D) for six months including training and working. We have added this in the revised manuscript page 13 line 20-21, and page 14 line 1-2.
14.Reflexology is a specialist treatment and therapists require specific training. Maternity reflexology training is additional to general reflexology. The expertise and experience of the reflexologist is considered an important factor in the quality of treatment provided and this should be considered. As there are four therapists, what steps has the team include to validate the CAM treatments. Is this a limitation of the study?	We agree with the comment that expertise and experience of the reflexologist is considered an important factor in the quality of treatment provided and this may underestimate the effect of BRM. We have included this under the limitation of the trial in the Discussion section, see page 21 line 10-13.
15.How will the assessor recorded outcome measures be validated and verified?	As mentioned above on the training of the massage therapists, the outcome assessors are similarly trained by the principal investigator and tested of their competency in a pilot study with all possible queries answered and standardised. Additional quality control measures are planned as below: the outcome assessors will be assigned to the same control delivery room or the intervention delivery room on the same day. All completed assessment forms are reviewed and kept by the research coordinator in a safe location in the delivery room. Any issues on the form such as blank spaces and extreme values will be immediately clarified and resolved. We have added this in the revised manuscript page 21 line 13-18
16.In addition to the reflexology routine provided please state the reflexes to which pressure will be applied and the rational for this.	We have added this in the revised manuscript page 6 line 5-15.
17.Please provide details of the blood analyses that will be completed.	We have provided further details in Table 3 ad page 15 line 14-19.
18.In the case of the usual care arm of the RCT	This arrangement is mainly to blind the outcomes assessor during the period of the outcome's assessment. Additionally, the massage

what does a massage therapist in the room with labouring women add to the study? It is unlikely that this would be part of the usual care a woman would receive and therefore the inclusion of another person in the labour room would not be normal usual care and is likely to have an effect on the woman and midwife and, thus, should not be included in the protocol.	therapist in the control group is trained to provide what the practicing midwifes are doing in the standard usual labour room care.
Additional ideas for consideration	
19.Given that your sample is labouring women you may wish to consider including additional labour specific outcome measures, such as labour duration, type of childbirth which may be easily collected from women's delivery room medical record.	Thank you for your suggestion. The trial does include labour duration as one of the secondary outcomes, see page 1 line 17-19. With regards to the type of childbirth, although we believe most of the participants will deliver their babies per vagina according to our eligibility criteria and with recruitment at 6 cm cervical dilatation, but we will retrieve types of childbirth in terms of spontaneous vaginal delivery with or without induction of labour, instrumental delivery or caesarean section.
Minor Issues	
20.Please add details of outcome measure tools to the abstract	We have added details of outcome measure tools to the abstract in the revised manuscript. Page 1 line 17-19.
21.Please define all acronyms at first mention.	We have first defined all acronyms at first mention in the revised manuscript.
22.The authors have used 'masseuse', however 'massage therapist' is the preferred term used by professionals.	We have replaced 'masseuse' with 'massage therapist' throughout the text in the revised manuscript.
23.On page 5, line 26 the two references talk about post-traumatic stress disorder (PTSD). Therefore, to accurately refer to the impact on mental health the word anxiety should be replaced by stress.	We have made the correction as pointed out page 4 line 13.
24.On page 8, line 6 the acronym CAM refers to Complementary and Alternative Medicine.	We have made the correction as pointed out page 7 line 17-18.
25.On page 11 line 22-29 Please clarify the term 'in equal numbers'.	The text 'in equal numbers' means about an equal number of primigravidae at each week of gestation of 26, 28, 30, 32 and 34 are recruited in order to spread out the occurrence of labour of the eligible participants to increase the feasibility of the BRM intervention. We have improved the sentence and added this clarification on page 11 line 7-11.
Also, it would seem that women of 26 weeks' gestation would not be in attendance at the hospital as during	The text means that the trial will also approach and invite women of 26 weeks' gestation when they are at the clinic. This is possible because the recruitment is done on daily basis at the clinic.

that time they are offered monthly appointments. Therefore, it may be more accurate to say all women, between 28-34 weeks' gestation, attending the antenatal clinic will be approached.	
26.Also, what is the rational for not approaching women of 34+weeks gestation?	As the participants recruitment and training of the research team members including pilot study is estimated to last up to two to three months, women of 34+ weeks gestation cannot be recruited during this period because they will inevitably go into labour without being captured by the research team members. We have added the rational page 11 line 11-14.
27.The first mention of blood samples appears on page 15, and outcome measures PBI and VAS appears on page 17. Please clarify, in a step-wise fashion, how the data will be collected in the main body of the manuscript.	The timeline of outcomes measurement in both the intervention and control groups are depicted in Figure 5 (a) and (b), respectively. We notice this figure does not appear well in the submitted manuscript (pdf). We have improved the clarity on both pages, as well as the cross-reference to the Figure 5a and 5b.
28.On page 19, line 49-56 please add a reference for 'By timing the intervention after cervical dilation of 6 cm and above, the effect of the combined BRM could exert its most influences if there is any on the labour experience of the primigravidae and neonatal outcome because this period is believed to be with the highest levels of labour pain.'	We have added references to the statement, which are (Sekhavat and Behdad, 2009) and (Reynolds, 2010). Page 19 line 15-20.
29By convention reflexology is carried out on the right foot first.	We have corrected the mistake in table 1, page 39-40 line 1-2.
30. Please add further clarification to CIUW-shape: C-shape; I-shape; U-shape, and W-shape, **MST-shape: M-shape, S-shape, and T shape. (Page 36, line 13)	We have further clarified the shapes in the footnotes of Table 1 page 39-40, line 3-6. These shapes refer to the letters signify the orientation and placement of the palms and knuckles of the therapist. CIUW sequence is used on the lateral foot and anklebone combined. Within the said sequence on the lateral foot, the right big toe is fixed by the left hand and the right hand of the reflexology therapist is fixed in a C-shape. the knuckles of the index fingers are pressed in an I shape. knuckle press of the anklebone is carried out as U shape. Straight knuckling is done at the top of the foot in W shape, MST shape shall be applied on the right foot. First, both the thumbs are pressed on either side of the right instep of the middle toe, moving up straight to the ankle in M shape. Hands are then placed on the ankle in S shape and the ankle is then kneaded in a circular movement. The ball sole is knuckled in a T shape. We have improved on the BRM routine during the intervention in

	Table 1. See earlier on the reference and the training involved/received by the massage therapists.
and please clarify the reflexology routine, the reference and the training involved/received so that it could be repeated by other teams.	We have added the details on page 6 line 15-17. Foot reflexology applying pressure to different areas of the feet, which is believed to be helpful during labour (Hakim, et. Al., 2019). Toe opening: pressure on the toe, which helps to open the reflex point in the pelvis. Heel opening: pressure on the heel, which helps to open the reflex point in the pelvis (Levy et al., 2020). The bottom points represent the pelvis area, which facilitate the cervix dilation and ease contractions. The reflexology session usually begins with the right foot and is followed by the left (Yılar, et al., 2018).
31.The description provided for the VAS describes a pain measurement scale it does not describe a VAS. Please clarify throughout what you intend to use. If you are using a VAS please indicate the length and the descriptors at either end.	We have added details of the self-report Visual Analog Scale (VAS) on page 14 line 6-11. The outcome assessor will ask the pregnant women to pick a colour on an A-4 sized paper contains six different coloured parts VAS, from no pain (score 1) to most severe pain (score 6) based on the level of pain she is experiencing. This is done before, during and after the BRM intervention. The researcher selected the VAS questionnaire because it is an acceptable tool and relatively easy to administer to women in labour.
32The reference list is extensive, however, some of the references are dated and more recent up to date literature is available. For example, one reference in date 1921 Hayes, M.H.S. and Patterson, D.G. The VAS is a commonly used scale and this reference adds little to the manuscript.	We have added another reference on page 20 line 5-7.

VERSION 2 – REVIEW

REVIEWER	Julie McCullough Ulster University, Northern Ireland, UK
REVIEW RETURNED	11-Mar-2020

GENERAL COMMENTS	Thank you, once again I enjoyed reading this protocol of a well planned and organised study. The added clarification has added value to the protocol and will undoubtedly enhance and facilitate the study and the experiences of women taking part. I very much look forward to reading the outcomes of this planned work. Three small points below (all pages have been marked as page 20 so I cannot give exact locations within the manuscript): In the Rational section McCullough et al. [44] is cited as a reference for 'the secretion of the endogenous endorphins'. This is not an accurate reference as this paper does not discuss endorphins. None of the papers cited for McCullough et al, [63-64] report evidence of a secretion of endorphin in response to reflexology.

	Rational section: CAM =Complementary and Alternative Medicine, not methods In the methods section it is stated that 'The reflexology therapist will apply pressure many times on specific points of the feet'. By convention pressure is commonly applied 3 times to reduce any possible over stimulation of the reflex point.

VERSION 2 – AUTHOR RESPONSE

Reviewer comments	Authors response	Page and line
Please state any competing interests or state ‘None declared’: None declared	Added per suggestion	Page 23, line 10
In the Rational section McCullough et al. [44] is cited as a reference for 'the secretion of the endogenous endorphins'. This is not an accurate reference as this paper does not discuss endorphins. None of the papers cited for McCullough et al, [63-64] report evidence of a secretion of endorphin in response to reflexology.	Thank you for your comments. It is true that McCullough et al reported a decrease in salivary beta-endorphin level (instead of an increase as expected) in their pilot 3-arm RCT of either six reflexology or footbath treatments or usual care. We have corrected the sentences and replaced the references: “As with skin-to-skin contact during massage, reflexology point pressure could trigger the release of endogenous endorphins and encephalins that help to reduce labour pain, stress, fatigue and anxiety [43–46].” “The three aforementioned therapies (i.e. BRM) for labour pain management have been shown to influence the secretion of certain stress hormones such as cortisol, adrenocorticotropic hormone (ACTH), [39,59], oxytocin (OT), [59], and possibly also the endorphins [44,45].”	Pages 7, lines 8-10 Pages 9, lines 6-9
Rational section: CAM =Complementary and Alternative Medicine, not methods	We have made the correction Complementary and Alternative Methods to Complementary and Alternative Medicine (CAM).	Page 8, line 21-22
In the methods section it is stated that 'The reflexology therapist will apply pressure many times on specific points of the feet'. By convention pressure is commonly applied 3 times to reduce any possible over stimulation of the reflex point.	Thank you for your comment. Indeed, the reflexology applies pressure three times on specific points of the feet.	Page 7, line 6-7