VERSION NO: 1.1
VERSION DATE: 1/8/2024

EYE MASK AND EARPLUGS TO IMPROVE SLEEP AFTER EPIDURAL LABOUR ANALGESIA AT NIGHT IN NULLIPARAS: A RANDOMISED CONTROLLED TRIAL

BY

DR. LELA NADIA BINTI KHALID

S2135534

SUPERVISOR

PROF. DR. TAN PENG CHIONG

DR. WONG THAI YING

RESEARCH PROPOSAL FOR MASTER OF MEDICINE

(OBSTETRICS AND GYNAECOLOGY)

DEPARTMENT OF OBSTETRICS & GYNAECOLOGY

UNIVERSITY OF MALAYA

CONTENTS

1.0 INTRODUCTION

Labor is characterized by regular, painful uterine contractions which increase in frequency and intensity with progression.[1] Nulliparas have longer labor[2] and report higher pain scores[1]. Labor may take more than 6 hours to progress from 4 to 5 cm and more than 3 hours to progress from 5 to 6 cm of dilation. Nulliparous and multiparous women appeared to progress at a similar pace before 6 cm. However, after 6 cm, labor accelerated much faster in multiparous than in nulliparous women.[3] Epidural analgesia provides the most effective pain relief during labor.[4, 5] A study of 13 high-income countries shows rates intrapartum epidural anesthesia at 10% to 64%.[6]

Short sleep duration prior to labor induction is associated with a longer induction-to-delivery interval and Caesarean delivery.[7] In a prospective study of women in their ninth month of pregnancy, women who slept less than 6 hours at night had longer labors and were 4.5 times more likely to have cesarean deliveries.[8]

In human and animal studies, spontaneous onset of labour is proven to have a circadian rhythm with a preference for start of labour in the evening.[9] Disruption to the circadian rhythm from working rotating shifts was associated with preterm delivery, an infant small for gestational age, preeclampsia, and gestational hypertension compared to those who worked a fixed day shift.[10]

In intensive care units, the use of eye masks and/or earplugs (EMEP) resulted in a significant increase in total sleep time, sleep efficiency, rapid eye movement time, significant reduction of awaking, and sleep arousals index based on polysomnography.[11] EMEP use at home prolong sleep in sleep-deprived nulliparas in late pregnancy measured by actigraphy[12, 13] and significantly improve sleep quality and satisfaction late into the third trimester[14].Similar to the intensive care unit, the labor ward and room is affected by ambient light and noise from monitoring devices, constant activity and clinical intervention, lending to plausible benefit from EMEP as sensory deprivation sleep aid.

In 2019, the International Olympic Committee (IOC) for the first time, addressed on sleep as a major contributor to athletic performance.[15] The impact of improving sleep during active first stage of labor on intrapartum and delivery performance have not been explored.

Leveraging on the plausibility of getting quality sleep in the absence labor pain following an effective epidural, a more prolonged labour in the nullipara and bolstering the circadian rhythm by aiding nighttime sleep through the use of EMEP, it is hypothesized that EMEP will lengthen intrapartum actigraphy-derived sleep duration as the primary outcome and may improve labor and delivery performance as secondary metrics.

2.0 OBJECTIVE OF THE STUDY

2.1 PRIMARY OUTCOMES

1. Sleep duration – using actigraphy

2.2 SECONDARY OUTCOMES

1. Intervention to delivery interval
2. Maternal satisfaction with sleep during labour (0-10 numerical rating scale)
3. Mode of delivery
4. Indication for operative delivery (cesarean and instrumental vaginal delivery)
5. Perineal condition
6. Estimated blood loss
7. Birth weight
8. Apgar score at 1 and 5 minutes
9. Umbilical cord artery blood pH and BE
10. Neonatal admission
11. Indication for neonatal admission

3.0 RESEARCH HYPOTHESIS

We hypothesize the sleep duration in labour in nulliparous on epidural is longer with the use of eye mask and earplugs.

4.0 MATERIALS AND METHODOLOGY

4.1 STUDY DESIGN

This is a randomized controlled trial.

4.2 PLACE OF STUDY

Labour Ward, University Malaya Medical Centre (UMMC).

4.3 STUDY POPULATION

Nulliparous women in labour admitted to Labour Ward, University Malaya Medical Center (UMMC) who had epidural inserted at night

4.4 ETHICAL CONSIDERATIONS

This proposal will be submitted to the Medical Research and Ethics Committee (MREC) of University of Malaya Medical Centre, the local institutional review board for approval. Written informed consent will be obtained from all participants. This study will also be registered with ISRCTN.

4.5 INCLUSION CRITERIA

1. Nulliparous (no prior pregnancy >22 weeks)
2. Singleton pregnancy

3. 37 weeks of gestation and above
4. Epidural analgesia sited from 1800H to 0600H
5. Cervical dilatation less than 6 cm
6. Normal fetal heart rate tracing

4.6 EXCLUSION CRITERIA

1. Need for frequent monitoring
2. Known sleep disorders
3. Major hearing (using hearing aids) or visual impairment (refractive errors acceptable)
4. Gross fetal anomalies
5. Intrauterine fetal death

4.7 METHODOLOGY

Participants

Patient recruitment will take place in the Labour Ward of UMMC in anticipation of epidural analgesia. Prior to approaching these women, we will screen for baseline eligibility through their Electronic Medical Records (EMR) with the use of the eligibility assessment form (EAF). Potentially eligible women will be approached, provided with the Patient Information Sheet (PIS) and counselled with regards to trial participation. Queries about the study will be invited and answered by the recruiting care provider-investigator. Written informed consent will be obtained, and their relevant details and characteristics transcribed onto the Case Report Form (CRF).

Consented patients will be randomised to
(1) Eye mask and earplugs plus actigraph watch
OR
(2) Actigraph watch only as control

Randomisation

Randomisation sequence will be generated online using https://www.sealedenvelope.com/simple-randomiser/v1/lists, in blocks of 4 or 8, following a 1 to 1 ratio, by a co-investigator who will not be involved in the recruitment process. Allocation will be sealed within a numbered opaque envelope. Randomisation will be implemented using strict sequential opening of the lowest-numbered remaining sealed envelopes to the latest recruit.

All participants will be asked to wear a wristwatch-like device during the study. This device detects movement (actigraphy) and the information will be downloaded to derive sleep duration from intervention to active pushing or decision for Caesarean. After delivery the wristwatch-like device will be retrieved for actigraphy data to be downloaded and analysed. The used eye mask and earplugs will be discarded.

Intervention

Participants randomised to EMEP shall wear the eye mask and earplugs when trying to sleep. They will also wear the actigraph watch from the epidural to pushing or decision for caesarean delivery. Attempt to sleep characterised by ‘time to bed’ to

'time out of bed' shall be recorded and the recording of these times repeated if there were multiple attempts to sleep.

Participants randomised to the control arm shall wear the actigraph watch from the epidural to pushing or decision for caesarean delivery. Attempt to sleep characterised by 'time to bed' to 'time out of bed' shall be recorded and the recording of these times repeated if there were multiple attempts to sleep.

The sleep diary and actigraph watch will be retrieved after delivery.

Care providers may interrupt sleep as clinically indicated at any time, to make observations, get responses or effect interventions.

Blinding

Due to the obvious nature of the EMEP intervention, blinding is not considered feasible and not attempted.

Stopping rule

EMEP is a simple intervention that is not anticipated to generate clinical complications, the primary outcome is sleep duration during labour and the targeted sample size is a total of 126 participants; a specific stopping rule for the study is not considered to be essential but any major harm that the intervention could have contributed to will be brought in the first instance to the department research oversight panel.

Outcomes:

Primary outcome:

Sleep duration will be measured using actigraphy, a validated method of objectively measuring sleep parameters.

Secondary outcomes:

1. Intervention to delivery interval
2. Maternal satisfaction with sleep and with pain relief from the epidural during labor (0-10 numerical rating scale)
3. Mode of delivery
4. Indication for operative delivery (cesarean and instrumental vaginal delivery)
5. Perineal condition
6. Estimated blood loss
7. Birth weight
8. Apgar score at 1 and 5 minutes
9. Umbilical cord artery blood pH and BE
10. Neonatal admission
11. Indication for neonatal admission

4.8 SAMPLE SIZE CALCULATION

We assume for this proof of concept study that the standard deviation in sleep duration (from epidural to pushing or cesarean) is one hour for both arms and EMEP increases mean sleep duration by 30 minutes[12] compared to control. Using OpenEpi online

sample size calculator https://www.openepi.com/SampleSize/SSMean.htm, inputting alpha 0.05, beta 0.2, delta 0.5 hours and standard deviation of one hour in sleep duration, 63 participants are needed in each arm for a powered study (total 126).

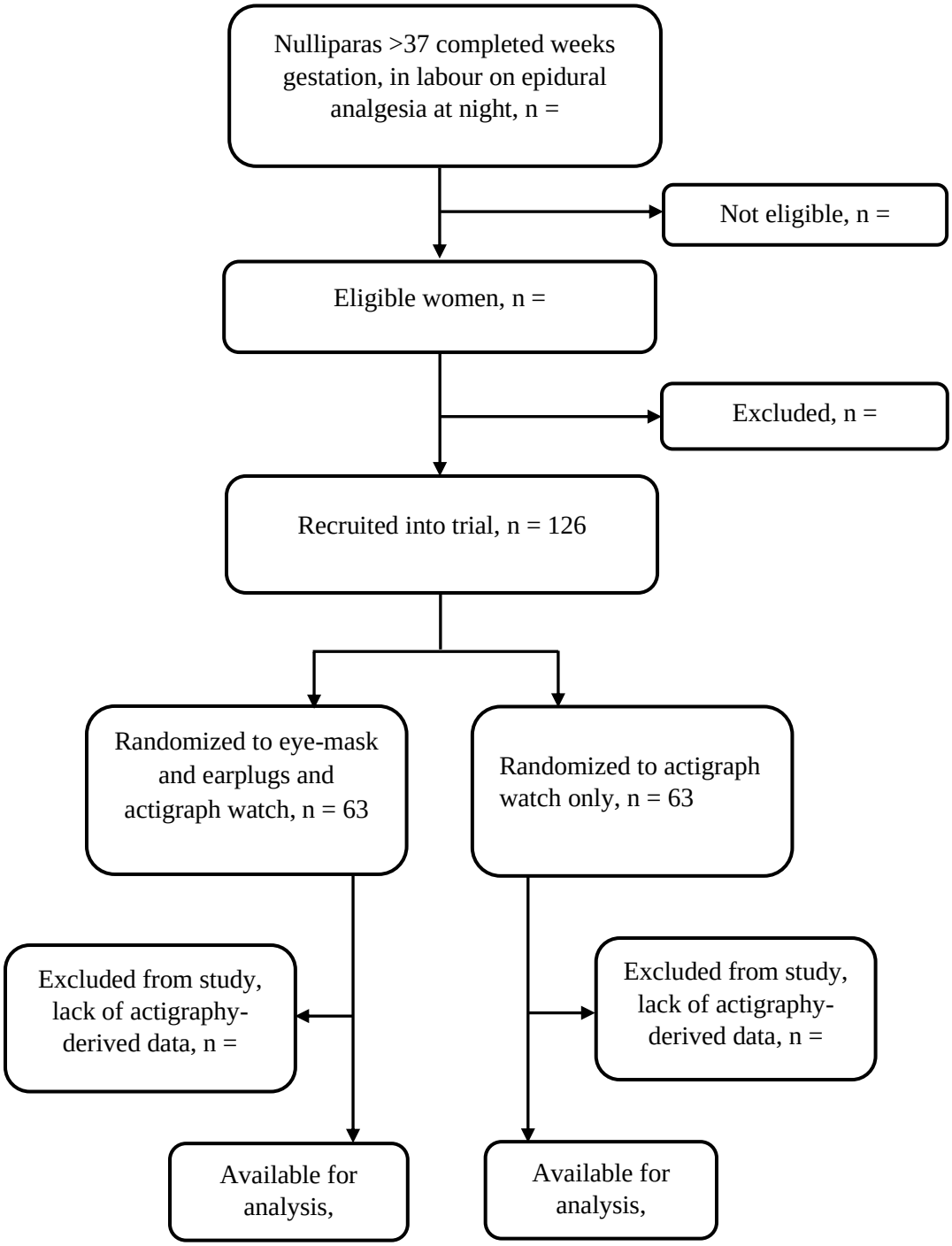
4.9 STATISTICAL ANALYSIS

Data will be entered into a statistical software package SPSS (Version 26, IBM, SPSS Statistics). The Student t test was used to analyse means with normal data distribution, the Mann-Whitney U test for non-normally distributed data or ordinal data, and Chi-square test for categorical data. Two-sided P values will be reported and $p < 0.05$ taken as significant. Analysis will be on intention to treat basis.

Interim analysis

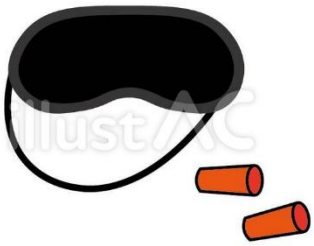
There is no plan for an interim analysis.

FLOW CHART PROTOCOL



4.10 TRIAL DEVICES

The ActiGraph wGT3X-BT device [ActiGraph Pensacola, FL, USA] is an actigraphy activity monitor resembling a wristwatch. Recorded data are subjected to a proprietary algorithm in ActiLife software [ActiGraph Pensacola, FL, USA] which produces estimates of sleep-wake variables. Actigraphy has been validated against polysomnography {PSG) in multiple populations, with an estimated agreement ranging from 91 to 93%, and a correlation coefficient of at least 0.85 in healthy individuals.[16]



Eye mask and earplugs will be sourced commercially from online vendors.

5.0 GANTT CHART

	2024						**2025**										
	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N
Literature Review																	
Proposal Defence Presentation																	
Approval from Ethics Committees																	
Participants Recruitment and Data Collection																	
Data Analysis / Interpretation																	
Thesis Defence Presentation																	
Thesis Submission																	

6.0 REFERENCES

1. Labor, S. and S. Maguire, *The Pain of Labour*. Reviews in Pain, 2008. **2**(2): p. 15-19.
2. Tilden, E.L., et al., *The duration of spontaneous active and pushing phases of labour among 75,243 US women when intervention is minimal: A prospective, observational cohort study.* EClinicalMedicine, 2022. **48**: p. 101447.
3. Zhang, J., et al., *Contemporary patterns of spontaneous labor with normal neonatal outcomes.* Obstet Gynecol, 2010. **116**(6): p. 1281-1287.
4. *Clinical guideline [CG190]. Intrapartum care for healthy women and babies. Pain relief. National Institute for Health and Care Excellence, United Kingdom. Dec 3 2014 (Last updated Dec 14 2022). Accessible on https://www.nice.org.uk/guidance/cg190/ifp/chapter/pain-relief. Last accessed Mar 18 2023.*
5. Zuarez-Easton, S., et al., *Pharmacologic and nonpharmacologic options for pain relief during labor: an expert review.* American Journal of Obstetrics and Gynecology, 2023. **228**(5): p. S1246-S1259.
6. Stock, S.J., et al., *Variations in use of childbirth interventions in 13 high-income countries: A multinational cross-sectional study.* PLOS Medicine, 2020. **17**(5): p. e1003103.
7. Teong, A.C.A., et al., *The Impact of Self-Reported Sleep on Caesarean Delivery in Women Undergoing Induction of Labour: A Prospective Study.* Sci Rep, 2017. **7**(1): p. 12339.
8. Lee, K.A. and C.L. Gay, *Sleep in late pregnancy predicts length of labor and type of delivery.* Am J Obstet Gynecol, 2004. **191**(6): p. 2041-6.
9. Bakker, J.J., et al., *Morning versus evening induction of labour for improving outcomes.* Cochrane Database Syst Rev, 2013(2): p. Cd007707.
10. Cai, C., et al., *The impact of occupational shift work and working hours during pregnancy on health outcomes: a systematic review and meta-analysis.* Am J Obstet Gynecol, 2019. **221**(6): p. 563-576.
11. Karimi, L., et al., *The Efficacy of Eye Masks and Earplugs Interventions for Sleep Promotion in Critically Ill Patients: A Systematic Review and Meta-Analysis.* Front Psychiatry, 2021. **12**: p. 791342.
12. Teo, I.H., et al., *Eye Masks and Earplugs to Improve Night Sleep Duration in Nulliparas: A Randomized Trial.* Cureus, 2022. **14**(12): p. e32226.
13. Gan, F., et al., *Eye-mask and earplugs compared with sleep advice leaflet to improve night sleep duration in pregnancy: a randomized controlled trial.* Sleep, 2023. **46**(12).
14. Hong, J.G.S., et al., *Eye-masks and earplugs compared to headband in nulliparas on increasing spontaneous vaginal delivery: a randomized trial.* BMC Pregnancy Childbirth, 2023. **23**(1): p. 378.
15. Reardon, C.L., et al., *Mental health in elite athletes: International Olympic Committee consensus statement (2019).* Br J Sports Med, 2019. **53**(11): p. 667-699.
16. Sadeh, A., et al., *The role of actigraphy in the evaluation of sleep disorders.* Sleep, 1995. **18**(4): p. 288-302.