VERSION NO: 2
VERSION DATE: 6/8/2025

UNIVERSITY OF MALAYA MEDICAL CENTRE

RESEARCH PROTOCOL

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TITLE OF RESEARCH PROPOSAL

EYE MASK AND EARPLUGS AS SLEEP AIDS TO REDUCE PRE-CAESAREAN ANXIETY: A RANDOMISED SHAM-CONTROLLED TRIAL

KEY WORDS

BACKGROUND/ JUSTIFICATION

Global caesarean section rates have been increasing. Elective caesarean section rates increased from 10.7% in 2013-2014 to 18.3% in 2023-2024 in the UK, representing an increase of 71% over the past 10 years.(1)

Preoperative anxiety is an unpleasant restless or tense state in which the patient is worried about illness, hospitalization, anaesthesia, surgery or the unknown.(2) Preoperative anxiety leads to increased postoperative complications including pain, analgesia use, nausea, vomiting, dizziness and overall lower satisfaction rates.(2-4) The prevalence of pre-elective caesarean section anxiety is around 67.9%.(5)

Due to the adverse effects of preoperative anxiety, treatment has been advocated. Assessment and intervention should be done from the time surgery is scheduled as this is the time anxiety starts. Non-pharmacological options are gaining in popularity as they have lower risk of adverse effects.(6)

A meta-analysis has concluded that Improving sleep quality leads to better mental health including a significant positive effect on anxiety.(7) However, studies on improving sleep as an intervention to reduce pre operative anxiety is lacking.

Sensory deprivation with eye mask and earplugs (EMEP) in the home bedroom environment in late pregnancy resulted in a significant prolongation of night sleep duration.(8, 9) Sleep quality in late pregnancy is also improved with eye masks and earplugs use as sleep aid compared to a sham intervention.(8, 9) Sensory deprivation by flotation tank treatment decreased stress, depression, anxiety, and worst pain whereas optimism and sleep quality increased(10), suggesting a beneficial effect from sensory deprivation alone.

Wrist actigraphy is an objective method delivering objective and accurate sleep or wake activity data over the course of days or weeks.(11) Polysomnography is considered the “gold standard”, however it is deemed impractical for outpatient sleep research studies as it is expensive, not readily available(12) and requiring attendance at a sleep laboratory.

We hypothesize that EMEP use started from the time surgery is scheduled would improve anxiety assessed on admission for their planned caesarean section through improving sleep.

OBJECTIVES & EXPECTED OUTCOMES

Objectives:
Improving anxiety (PAS-7 questionnaire) assessed within 24 hours of planned caesarean section.

Expected outcomes:
We hypothesize that EMEP use started from the time surgery is scheduled would improve anxiety assessed on admission for their planned caesarean section through improving sleep.

METHODOLOGY

Study design

Patient recruitment will take place in the antenatal clinic of UMMC (minimum of 3 days up to maximum of 14 days before their scheduled caesarean section). 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) Headband and actigraph watch as sham-control

Randomisation

Randomisation sequence will be generated using https://www.sealedenvelope.com/simple-randomiser/v1/lists, in blocks of 4 or 8, in 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 for 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 on the run up to planned caesarean section. Upon admission for caesarean section, the wristwatch-like device will be retrieved for actigraphy data to be downloaded and analysed.

Intervention

The allocated intervention will take place during the period leading up to the date of scheduled caesarean section.

All participants will be provided with the ActiGraph wGT3X-BT device (Pensacola, Florida, USA) and instructed on its use. The device is to be worn like a wristwatch, and participants are asked to wear it to sleep at night up until the day of their planned caesarean section. They will be told to record in a sleep dairy their ‘time to bed’ and ‘time out of bed’ as well as their own estimated total sleep time.

Participants randomised to EMEP shall wear the eye mask and earplugs before going to sleep each night. If the patient has to mobilise, EMEP can be removed and to be replaced on returning to bed.

Participants randomised to the control arm shall wear the elasticated headband before going to sleep each night and to remove it on awakening to get out of bed. The headband serves as a sham/placebo control.

Upon admission for planned caesarean section, the sleep diary and actigraph watch will be retrieved and participant’s PAS-7 scores and satisfaction post intervention recorded. The ‘Time to bed’ and ‘Time out of bed’ (TOB) recorded will be used for calculation of sleep duration using the ActiLife software later.

Blinding

Due to the obvious nature of the EMEP or control headband intervention, blinding is not considered feasible.

Stopping rule

EMEP is a simple intervention that is not anticipated to generate clinical complications.
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.

Inclusion criteria

1. Planned caesarean section (minimum of 3 days up to maximum of 14 days in advance)
2. Singleton pregnancy
3. Term pregnancy (≥37 weeks at planned caesarean section)
4. Viable pregnancy

Exclusion criteria

1. Known psychiatric illnesses (e.g., depression, bipolar disorder, schizophrenia, etc.)
2. Known sleep disorders
3. Known anxiety disorders
4. Known hearing or vision impairments
5. Gross fetal anomalies
6. Perioperative complications anticipated (e.g., morbidly adherent placenta spectrum, anticipated major intraabdominal adhesions, etc.)

Sample size

We have done a multicentre survey to collect data on 100 patients undergoing elective caesarean section. From this data, we found 66% of patients to be anxious identified by the PAS-7 questionnaire. Assuming a 30% relative reduction in the anxiety rate, using OpenEpi online sample size calculator https://www.openepi.com/SampleSize/SSCohort.htm, inputting alpha 0.05, beta 0.2, risk ratio 0.7, 106 participants are needed in each arm for a powered study (total 212).

Data 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 of continuous data that is normally distributed, 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 the level of significance. Analysis will be on intention to treat basis.

RESEARCH DATA

Where will the data be kept? (Please provide details)

- Manual records: stored in secured locker with a lock in Obstetrics and Gynaecology Department UMMC. The key will be kept only by primary investigator
- Digital records" password-protected computers accessible only to researchers

Who will have access to the research data?

- Principle investigator and approved co-investigators

How long will the data be kept? (suggestion: at least 7 years)

- Minimum of 7 years after completion of the study

BUDGET / FINANCIAL SUPPORT (IF APPLICABLE):

No	Budget Detail	Cost Per Unit	Units	Total Cost (RM)
1.	Eye Mask	**RM 1.98**	**106**	**RM 209.88**
2.	Earplugs	**RM 0.43**	**106**	**RM 45.58**
3.	Headband	**RM 2.20**	**106**	**RM 233.20**
4.	GT3XP-BTLE 4GB Activity Monitor (Actigraph Watch)	**USD 352.00**	**5**	**USD 1,760.00 (RM 7,434.77)**
5.	Adjustable Velcro Wrist Band (fits 6" to 9")	**USD 17.05**	**5**	**USD 85.25 (RM 360.13)**
6.	GT3XP/ASP USB Cable	**USD 9.66**	**5**	**USD 96.60 (RM 40.80)**
7.	ISRCTN	**£ 250.00**	**1**	**£ 250.00 (RM 1,406.01)**
8.	Photocopying/ Printing	**RM 0.30**	**4240**	**RM 1,272.00**
	Grand Total			**RM 11,002.37**

GANTT CHART

	Year	**2024**		**2025**							**2026**						
	Activities	S	O	N	J	A	S	O	N	D	M	J	J	A	S	O	N
1.	Proposal Defence Presentation	■															
2.	Pilot study		■	■													
3.	Approval from Ethics Committees				■	■											
4.	Participants Recruitment and Data Collection						■	■	■	■	■	■	■				
5.	Data Analysis / Interpretation											■	■	■			
6.	Thesis Defence Presentation														■		
	Thesis Submission															■	■

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POTENTIAL IMPACT

We plan to publish findings of this study to help guide care before a planned caesarean section to manage anxiety.

3. Please state whether you have submitted this research proposal for funding, now or before
   - ☐ Yes: If Yes, which grant? _____
   - ✓ No

This proposal will be kept strictly private and confidential. It will not be shared with anyone without your prior approval.

Name of Researcher (CAPITAL):

Signature of Researcher: 

Date: 06/08/2025