

# Eye-masks and earplugs as sleep aids to reduce blood pressure in pregnancy

<b>Submission date</b> 06/02/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/02/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/03/2025	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Short sleep duration in pregnancy is common and tends to worsen into late pregnancy. The risk of pregnancy-induced high blood pressure increases with sleep deprivation. This study aims to evaluate the effects of the use of eye masks and earplugs as sleep aids on blood pressure in women with borderline high blood pressure and short sleep duration in late pregnancy over a one-week study period.

### Who can participate?

Adult women in late pregnancy with sleep deprivation and pre-hypertension

### What does the study involve?

In this study, participants will be assigned by a computer to use an eye mask and earplugs for sleep or normal care (no eye mask and earplugs). Participants will be given a wristwatch-like device (ActiGraph) to wear continuously for the week and be required to record their blood pressure in a blood pressure diary twice a day. This needs to be done before bedtime at night and after awakening in the morning using the automated blood pressure machine provided and as instructed. Participants will complete a sleep questionnaire at recruitment and at the end of the study.

### What are the possible benefits and risks of participating?

The use of eye masks and earplugs may increase sleep duration but there is at present no evidence to show that pregnancy outcomes will improve. The impact of the use of an eye mask and earplugs on blood pressure in pregnancy is not established. The use of eye masks and earplugs is not expected to have any adverse effect.

### Where is the study run from?

University Malaya Medical Centre (Malaysia)

### When is the study starting and how long is it expected to run for?

November 2022 to March 2024

Who is funding the study?  
University Malaya Medical Centre (Malaysia)

Who is the main contact?  
Dr Shahira Aqilah Zulkifli, shahiraqilah@gmail.com (Malaysia)

## Contact information

### Type(s)

Principal Investigator

### Contact name

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## **Additional identifiers**

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
Nil known

## **Study information**

**Scientific Title**  
Eye-masks and earplugs as sleep aids to reduce blood pressure in pregnancy: A randomised controlled trial

**Study objectives**  
Eye masks and earplugs as sleep aids will reduce blood pressure in women with pre-hypertension (suboptimal blood pressure) and short night sleep duration in late pregnancy.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Approved 18/01/2023, Medical Research Ethics Committee, University Malaya Medical Centre, (Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +603-79493209 ext 2251; ummc-mrec@ummc.edu.my), ref: 20221215-11811

**Study design**  
Parallel-arm randomized control trial design

**Primary study design**  
Interventional

**Secondary study design**  
Randomised controlled trial

**Study setting(s)**  
Home, Hospital

**Study type(s)**  
Prevention

**Participant information sheet**

See study outputs table

## **Health condition(s) or problem(s) studied**

Pre-hypertension in late pregnancy in mothers with sleep deprivation

## **Interventions**

This is an interventional randomized controlled study in which participants will be assigned by a computer (only revealed after the opening of an envelope after mothers consent to participate) into two groups for seven consecutive days of the study:

1. Wear an eye mask and ear plugs as sleep aids and wear an actigraphy watch
2. No sleep aids and wear an actigraphy watch

At recruitment participants will complete a sleep questionnaire.

During the one-week study period, participants will need to:

1. Use the eye mask and earplugs for sleep OR normal care (no eye mask and earplugs) for sleep, as randomly allocated
2. Wear the wristwatch-like device (ActiGraph) continuously for the week, most importantly during sleep (night sleep as well as daytime naps)
3. Record their sleep in a Sleep diary as the time they go to bed to sleep and the time they wake to get out of bed for both night sleep as well as any daytime naps. This information is needed by the actigraphy software to work out your sleep duration when in bed for sleep.
4. Record their blood pressure in a Blood Pressure diary twice a day, before bedtime at night and after awakening in the morning using the automated blood pressure machine provided and as instructed

After the one-week study period, participants will need to:

1. Return the Actigraph device for sleep data to be downloaded and analysed
2. Return the Sleep and Blood Pressure diaries
3. Complete the sleep questionnaire again

## **Intervention Type**

Device

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Commercially available sleep aids (eye masks and ear plugs), actigraph watch (wGT3X-BT)

## **Primary outcome measure**

1. Systolic blood pressure measured using an automated blood pressure machine from recruitment to during the intervention period
2. Diastolic blood pressure measured using an automated blood pressure machine from recruitment to during the intervention period

## **Secondary outcome measures**

Maternal outcome:

1. Mean arterial pressure measured using an automated blood pressure machine from recruitment to during the intervention period
2. Pregnancy-induced hypertension (systolic BP  $\geq 140$  and/or diastolic  $\geq 90$  mmHg) on 2 occasions at least 4 hours measured using an automated blood pressure machine apart during

the intervention period

3. Actigraphy derived-night sleep duration measured using data recorded in the watch app during the intervention period

4. Sleep quality measured using the Pittsburgh Sleep Quality Index (PSQI) at recruitment and at the end of the intervention period

5. Pregnancy outcome measured using data recorded in patient medical notes:

5.1. Labour induction

5.2. Mode of delivery

5.3. Peri-delivery blood loss

Neonatal outcome measured using data recorded in patient medical notes after birth:

1. Birth weight

2. Cord arterial blood pH and base excess

3. Health evaluation measured using APGAR scoring at 1 and 5 minutes after birth

4. Neonatal intensive care unit (NICU) admission

### **Overall study start date**

01/11/2022

### **Completion date**

06/03/2024

## **Eligibility**

### **Key inclusion criteria**

1. Blood pressure within suboptimal/pre-hypertension range (systolic 120-139 and/or diastolic 80-89 mmHg)

2. Self-reported sleep of less than 6 hours

3. Gestation 34-36 weeks

4. Age more or equal to 18 years old

5. Singleton pregnancy

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Female

### **Target number of participants**

140 participants

### **Key exclusion criteria**

1. Anticipated delivery in the next week

2. Significant visual and/or hearing impairment

3. On antihypertensives for gestational hypertension or chronic hypertension
4. Known sleep disorders: Chronic insomnia, sleep apnoea
5. Known psychiatric disorders: Depression, schizophrenia etc.
6. Known major medical disorders: Diabetic Mellitus type 1 or 2, SLE, thyroid disorders, epilepsy, heart diseases etc.
7. Inability/unwillingness to use an eye mask and earplugs
8. Inability/unwillingness to use ActiGraph wGT3X-BT device
9. BMI >35
10. Active smoker
11. Current alcohol consumption
12. Multipara with co-sleeping child/children
13. Night shift workers
14. Night caretaker of other family members
15. Gross fetal anomalies
16. Intrauterine fetal death

**Date of first enrolment**

07/03/2023

**Date of final enrolment**

28/06/2023

## Locations

**Countries of recruitment**

Malaysia

**Study participating centre****University Malaya Medical Centre**

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## Sponsor information

**Organisation**

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**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<https://www.ummc.edu.my>

**ROR**

<https://ror.org/00vkrxq08>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Universiti Malaya Medical Centre

**Alternative Name(s)**

University of Malaya, University Malaya, Malayan University, UM

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Malaysia

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal

**Intention to publish date**

01/10/2024

**Individual participant data (IPD) sharing plan**

The data sharing plans for the current study are unknown and will be made available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 1.0	14/12/2022	16/02/2023	No	Yes