

# Improvement in night sleep duration and the effect on diabetes in pregnancy

<b>Submission date</b> 02/07/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 14/07/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/02/2024	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Pregnancy is associated with changes in sleep structure. Both abnormally long and short duration of sleep at night will have an impact on sugar metabolism and may affect bodily functions in the long term. This study will focus on improving the duration of sleep at night and reducing the risk of developing gestational diabetes in pregnancies less than 34 weeks.

### Who can participate?

Pregnant women between the age of 18 to 40 years old, who report a duration of sleep of fewer than 7 hours

### What does the study involve?

The participants will be divided into two groups, the intervention group and the control group. All participants will need to fill the questionnaire before and after the study. All the participants will be provided with an ActiGraph wGT3X-BT device and a sleep diary. The intervention group will be provided with an eye mask and earplugs and need to wear them for 7 consecutive nights. After completion of 7 days, all participants regardless of the intervention group or control group will need to return the device for data retrieval and a glucose test will be performed.

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

The use of an eye mask and earplugs is not expected to cause any harm to the pregnancy. If proven to be effective, the use of these simple interventions such as eye masks and earplugs will improve the duration of sleep at night and reduce the risk of developing diabetes in pregnancy. This can be identified as a modifiable risk factor and thus reducing the risk of developing gestational diabetes mellitus among pregnant women who are at risk.

### 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?

May 2021 to September 2022

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

Who is the main contact?  
Dr Normala Binti Mohammad Som  
normala.som@ummc.edu.my

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Normala Mohammad Som

**Contact details**  
T.B.G 132 Kg Kuantan  
Klang  
Malaysia  
41300  
+60 (0)164144953  
normala.som@ummc.edu.my

**Type(s)**  
Scientific

**Contact name**  
Dr Jesrine Hong Gek Shan

**Contact details**  
Jln Profesor Diraja Ungku Aziz, Lembah Pantai  
Kuala Lumpur  
Malaysia  
59100  
+60 (0)177202689  
jesrine@um.edu.my

**Type(s)**  
Scientific

**Contact name**  
Dr Nurulhuda binti Ahmad Sani

**ORCID ID**  
<http://orcid.org/0000-0002-5340-2201>

**Contact details**  
University of Malaya Medical Centre  
UMMC  
Jalan Profesor Diraja Ungku Aziz

Kuala Lumpur  
Malaysia  
59100  
+60 (0)3 79492049  
huda.sani@ummc.edu.my

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

MECID.No:202157-10120

## Study information

### Scientific Title

Eye-masks and earplugs to improve night sleep duration in pregnancy and the effect on the oral glucose tolerance test: a randomized trial

### Acronym

EMEPOG

### Study objectives

Home use of eye masks and earplugs will increase actigraphy-derived night sleep duration among nulliparas and multiparas and this will improve the fasting and 2-hour glucose tolerance test.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 01/07/2021, Medical Research Ethics Committee University of Malaya Medical Centre (Jln Professor Diraja Ungku Aziz, 50603, Wilayah Persekutuan Kuala Lumpur, Malaysia; +603 (0) 7949 8473; email: not applicable), ref: 202157-10120

### Study design

Single-center randomized controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Other

**Participant information sheet**

See study outputs table

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

Glucose tolerance in pregnancy

**Interventions**

The eligibility and suitability of the patient will be identified when presented to the antenatal clinic. Once identified, participants will be asked to fill in the Pittsburgh Sleep Quality Index (PSQI). The researchers will verbally counsel them regarding the trial and written consent will be obtained if they agree to participate. Participants will then be provided with the Patient Information Sheet (PIS). Participants fill in the PSQI and will be randomized into two groups (intervention group and control group). The intervention group will be provided with an eye mask, earplugs and sleep diary and the control group will be provided with a sleep diary.

All participants will then be provided with the ActiGraph wGT3X-BT device and instructed on its use. The device is to be worn like a wristwatch and participants are asked to wear it continuously for 7 consecutive nights on their dominant wrist. Participants need to perform an oral glucose tolerance test (OGTT) upon returning the device and complete a modified PSQI. Participant's details and all the necessary information will be transcribed onto the Case Report Form (CRF).

**Intervention Type**

Behavioural

**Primary outcome measure**

1. Night sleep duration measured using the Actigraph wGT3X-BT device at the end of week 1
2. Fasting blood sugar and 2-hour post glucose tolerance test measured using oral glucose tolerance test performed at the end of week 1

**Secondary outcome measures**

1. Actigraphy-derived Wake After Sleep Onset (WASO) and actigraphy-derived sleep efficiency measured using the Actigraph wGT3X-BT device at the end of week 1
2. Sleep satisfaction measured using the Pittsburgh Sleep Quality Index (PSQI) during recruitment, and the modified Pittsburgh Sleep Quality Index at the end of week 1

**Overall study start date**

06/05/2021

**Completion date**

14/09/2022

**Eligibility****Key inclusion criteria**

1. Self-reported sleep less than 7 hours
2. Gestation less than 34 weeks
3. Singleton pregnancy
4. Aged 18 to 40 years old

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

40 Years

**Sex**

Female

**Target number of participants**

240

**Total final enrolment**

240

**Key exclusion criteria**

1. Inability to use eye mask and earplugs
2. Inability to use ActiGraph wGT3X-BT device
3. Pre-existing sleep disorders: chronic insomnia, sleep apnea
4. Pre-existing psychiatric disorders: depression, schizophrenia etc
5. Pre-existing medical disorders: diabetic mellitus, systemic lupus erythematosus, thyroid disorders, epilepsy, heart diseases etc
6. Active smoker
7. Current alcohol consumption
8. Multipara with co-sleeping child/children
9. Night shift workers
10. Night care-taker of other family members
11. Gross fetal anomalies
12. Intrauterine fatal death
13. Body mass index (BMI)  $\geq 35$  kg/m<sup>2</sup>

**Date of first enrolment**

19/07/2021

**Date of final enrolment**

24/08/2022

**Locations**

**Countries of recruitment**

Malaysia

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

Jalan Professor Diraja Ungku Aziz  
Wilayah Persekutuan Kuala Lumpur  
Malaysia  
50603

**Sponsor information****Organisation**

University Malaya Medical Centre

**Sponsor details**

Jln Profesor Diraja Ungku Aziz, Lembah Pantai  
Wilayah Persekutuan Kuala Lumpur  
Malaysia  
59100  
+60 (0)3 7949422  
ummc@ummc.edu.my

**Sponsor type**

Hospital/treatment centre

**Website**

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

**ROR**

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

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

University Malaya Medical Centre

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

31/12/2024

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Tan Peng Chiong (pctan@um.edu.my). Individual participant data will be available, particularly, individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices). Other documents that will be available include the Trial Protocol. Data will be available beginning 3 months and ending 5 years following article publication, to investigators whose proposed use of the data has been approved by an independent review committee identified for the purpose of individual participant data meta-analysis only. Consent from participants was required and obtained. The data will be anonymously generated.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			04/08/2021	No	Yes
<a href="#">Protocol file</a>			04/08/2021	No	No