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Use of eye masks and earplugs compared with standard advice to improve sleep in pregnancy

Submission date
03/05/2021

Recruitment status
No longer recruiting

Registration date
07/05/2021

Overall study status
Completed

Last Edited
24/06/2024

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Short sleep duration in pregnancy has been associated with poor pregnancy outcomes like longer labour, developing gestational diabetes or hypertension (high blood pressure), preterm birth and Caesarean birth. Sleep problems are very common in pregnancy. It may be possible to reduce these adverse pregnancy outcomes by improving sleep and finding sleep aids that can achieve that. This study aims to evaluate eye-masks and earplugs use at home to increase night sleep duration in pregnant women with short sleep at 34-36 weeks of pregnancy. Alternatively, the researchers will provide an advice leaflet to lengthen sleep. They want to find out if eye masks and earplugs are effective as a sleep aid.

Who can participate?
Pregnant women between 34 and 36 weeks gestation who report a short night sleep duration of fewer than 6 hours and fulfil other criteria

What does the study involve?
Participants will be asked to wear a wristwatch-like device when they go to bed at night. This device detects movement (actigraphy) and the information will be downloaded to give the night sleep duration. Participants will need to record in a diary the time they go to bed to sleep and the time they wake to get out of bed. This information is needed by the actigraphy software to work out night sleep duration. At the end of Week 1, participants will need to return for actigraphy data to be downloaded and analysed. They can continue to intervention week 2 if a minimum of 3 nights sleep data can be obtained from the 7 nights of recordings, and the average night sleep duration recorded is less than 6 hours. If assigned to the control group, participants will be asked to read the advice leaflet supplied at the beginning of intervention Week 2, and if assigned to the intervention group, they will need to use the eye-mask and earplugs when they go to bed at night for the next 7 nights.

What are the possible benefits and risks of participating?
There may or may not be any benefits to participants. Information obtained from this study will help improve the treatment or management of other patients with the same disease or condition. The use of the eye mask and earplugs is not expected to have any adverse effect during pregnancy.

Where is the study run from?
University of Malaya Medical Centre (UMMC) (Malaysia)

When is the study starting and how long is it expected to run for?
April 2021 to August 2022

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

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
202131-9894

Study information

Scientific Title
Eye masks and earplugs compared with advice leaflet to improve night sleep duration in pregnancy: a randomised controlled trial

Acronym
EMEP2

Study objectives
Home use eye masks and earplugs will increase actigraphy-derived night sleep duration among nulliparas and multiparas in their late third trimester.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/04/2021, University of Malaya Medical Centre-Medical Research Ethics Committee (UMMC-MREC, 2nd floor, Kompleks Pendidikan Sains Kejururawatan, Pusat Perubatan Universiti Malaya 59100 Kuala Lumpur, Malaysia; +60 (0)3 7949 3209 / 2251 / 8473 / 4656; ummc-mrec@ummc.edu.my), ref: 202131-9894

Study design
Single-centre interventional open randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Night sleep duration among sleep-deprived nulliparas and multiparas in their late third trimester

Interventions
Patient recruitment will take place in the antenatal clinic of the University of Malaya Medical Centre (UMMC). Suitability of recruitment into the trial will be assessed through patients' antenatal records and the use of the eligibility assessment form (EAF). Nullipara and multipara at a gestational age between 34 to 36 weeks, with a singleton pregnancy, and self-reported night sleep duration of less than 6 hours will be included. Potential participants will be asked to

fill in the Pittsburgh Sleep Quality Index (PSQI), a widely used and well-validated 19-item self-report instrument that measures sleep disturbances in adults. Exclusion criteria are patients with pre-existing sleep, psychiatric, or medical disorders, any ear/eye injury resulting in the participant not being able to wear the earplugs/eye-mask, active smokers, current alcohol consumption, body mass index above 35, multipara with co-sleeping child/children, night shift workers, care-taker of other family members, known gross foetal anomalies, or intrauterine fetal death. These criteria ensured similar sleep conditions between groups. Eligible women will be provided with the Patient Information Sheet [PIS] and verbally counselled with regard to trial participation - they will receive eye masks and earplugs [EMEP] or advice leaflet [AL], to help improve their sleep. Written informed consent will be obtained, and their relevant details and characteristics transcribed onto the Case Report Form [CRF]. All participants will then be provided with the ActiGraph wGT3X-BT device (Pensacola, Florida, USA) and instructed on its use. Participants will be informed that their self-reported short sleep will first be verified by a wristband actigraphy monitor. The device is to be worn like a wristwatch, and participants are asked to wear it to sleep at night for 7 consecutive nights (Baseline Week 1). They will be told to record their 'Time In Bed' (TIB) and 'Time Out of Bed' (TOB) for sleep, for calculation of sleep duration using the ActiLife software later. After seven days (Baseline Week 1), participants will need to return with their devices for data retrieval. They will only be allowed to proceed with the intervention portion of the trial if the device confirmed a mean night sleep duration of less than 6 hours from a minimum of 3 nights' worth of sleep data retrievable. For intervention Week 2, still eligible participants will be randomised. Allocation will be specified within a sealed numbered opaque envelope. Randomisation sequence for the numbering of these envelopes will be generated separately for nulliparas and multiparas online using random.org, 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. Randomisation will be implemented using strict sequential opening of the lowest-numbered remaining sealed envelopes.

The intervention group will be provided with eye-masks and earplugs (EMEP). The eye mask and earplugs are to be used for 7 consecutive nights when in bed for sleep concurrent with the ActiGraph wGT3X-BT device. The eye mask and earplugs can be removed when participants mobilise during the night, but to be re-worn on returning to bed to sleep. The eye mask, earplugs and the ActiGraph wGT3X-BT device are to be removed on the morning awakening.

Participants in the control group will be given an ad hoc trial advice leaflet (AL) on sleep, comprising the following advice;
1. Adopt a regular sleep schedule
2. Avoid caffeine, nicotine, alcoholic drinks and excessive fluid volume before bed
3. Exercise regularly
4. Avoid distraction in bed (television, computer, smartphones, tablets)
5. Set consistent, healthy mealtimes
6. Don't go to bed until you are sleepy, gradually move to an earlier bedtime

Instructions on ActiGraph wGT3X-BT device use into intervention Week 2 will be reinforced for all participants. On their second return visit after intervention Week 2, participants will be asked to return their devices. Data will be retrieved and analysed from these devices. The participants will also once again be asked to complete the Pittsburgh Sleep Quality Index (PSQI).

Intervention Type
Mixed

Primary outcome(s)

Night sleep duration measured using the Actigraph wGT3X-BT device at the end of Week 1 (baseline) and Week 2 (intervention)

Key secondary outcome(s))
1. Labour outcomes retrieved from patients' records post-delivery:
1.1. Mode of delivery
1.2. Need for labour induction (mechanical induction, prostaglandin, amniotomy)
1.3. Peri-delivery blood loss
1.4. Epidural requirement
2. Neonatal outcomes retrieved from patients' records post-delivery:
2.1. Birth weight
2.2. Cord pH and base excess
2.3. Apgar score at 5 minutes
2.4. Neonatal admission and indication
3. Subjects' sleep satisfaction with the sleep aid measured using the Pittsburgh Sleep Quality Index (PSQI) during recruitment, and the modified Pittsburgh Sleep Quality Index at the end of Week 2 (after intervention)

Completion date
31/08/2022

Eligibility

Key inclusion criteria
1. Nullipara (no prior pregnancy beyond 20 weeks gestation)
2. Multipara
3. 34 – 36 weeks of gestation
4. Self-reported sleep of fewer than 6 hours
5. Singleton pregnancy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Pre-existing sleep disorders: chronic insomnia, sleep apnea
2. Pre-existing psychiatric disorders: depression, schizophrenia etc
3. Pre-existing medical disorders: systemic lupus erythematosus, thyroid disorders, epilepsy, heart diseases etc.
4. Any ear/eye injury resulting in the participant not being able to wear the earplugs/eye-mask
5. Active smoker
6. Current alcohol consumption

7. Obesity >class II (body mass index >35)
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 fetal death

Date of first enrolment
08/06/2021

Date of final enrolment
31/07/2022

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
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59100

Sponsor information

Organisation
University Malaya Medical Centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Malaya Medical Centre

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Farah binti Mohd Faiz Gan (farah.faizg@ummc.edu.my).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2023	24/06/2024	Yes	No
Participant information sheet	version v1	01/03/2021	01/06/2021	No	Yes
Protocol file			01/06/2021	No	No