UNIVERSITY OF MALAYA MEDICAL CENTRE

TRIAL PROTOCOL [TP]

1. Pregnant women attend scheduled antenatal clinic UMMC for routine follow up.
2. Suitability for recruitment assessed through antenatal record and **Eligibility Assessment Form [EAF]**.
3. Patients will also be asked to fill in the **Pittsburgh Sleep Quality Index [PSQI]**.
4. Patients who fulfill both inclusion and exclusion criteria are approached for recruitment and provided with a **Patient Information Sheet [PIS]** and a verbal explanation with regard to trial participation.
5. Patients who agree to participate in the study will sign and date the **Consent Form**.
6. If the patient does not agree, they will be excluded from recruitment and subsequent care will be according to standard treatment protocols.
7. Participants' relevant details and characteristics will be transcribed onto the **Case Report Form [CRF]** by the investigator.
8. Participants are informed that they will receive either eye-masks and earplugs (EMEP), or advice leaflet (AL), to help improve their sleep.
9. We will inform participants that their self-reported short sleep will first be verified by wristband actigraphy monitor.
10. All participants will be provided the ActiGraph wGT3X-BT device and instructed on its use – worn like a wristwatch to sleep at night for 7 consecutive nights **(Baseline Week 1)**. Participants will be told to record their 'Time In Bed' (TIB) and 'Time Out of Bed' (TOB) for sleep.
11. After seven days (Baseline Week 1), participants will need to return with their devices for data retrieval.
12. They will only be allowed to proceed with the intervention portion of the trial if the device confirmed mean night sleep duration of less than 6 hours from a minimum 3 nights' worth of sleep data retrievable.
13. The devices are to be returned to the investigator if participants are deemed not eligible for the trial.
14. Participants recruited into **Intervention Week 2** will be randomised into the intervention group (eye-masks and earplugs) or the control group (advice leaflet).
15. Instructions on ActiGraph wGT3X-BT device use into Intervention Week 2 will be reinforced for all participants.
16. Participants in the control group will be given an ad hoc trial **Advice Leaflet (AL)** on sleep.
17. The intervention group will be provided with **Eye-Masks and Earplugs (EMEP)**.
18. The eye-mask and earplugs are to be used for 7 consecutive nights when in bed for sleep concurrent with 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.
19. 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.
20. At this point, participants will be asked to complete the modified Pittsburgh Sleep Quality Index (PSQI).
21. Data collection by the investigator will be completed when:
    - Participants' sleep data has been retrieved after Intervention Week 2
    - Case Report Forms are completed with participants' TIB and TOB
22. Data entry and analysis will be done using SPSS Statistics Software.