UNIVERSITY OF MALAYA

UM MEDICAL CENTRE

Research Proposal For Master Of Medicine

(Obstetrics And Gynaecology)

Department Of Obstetrics And Gynaecology

Universiti Malaya

Title:

Ear Plugs And Eye Mask To Improve Night Sleep Duration In Nulliparas. A Randomised Control Trial

Protocol Version : 2

Version Date: 4/12/2017

Candidate:
Dr Teo Ik Hui
MGG 150005

Supervisor
Professor Tan Peng Chiong

Table of Contents

1.0 Title

"Ear Plugs and Eye Mask To Improve Night Sleep Duration In Nulliparas. A Randomised Control Trial"

2.0 Introduction

75% of pregnant women experience some form of sleep disruption during pregnancy. [1] The rate of sleep disturbances also changes across trimesters, ranging from 13% in the first trimester, 19% in the second, and 66% in the third. Lack of sleep in third trimester has detrimental effect on pregnancy outcomes [2].

Women who reported less than 6 hours of sleep per night during the last month of pregnancy had a significantly longer mean duration of Labour (29 hours vs. ≥20 hours) and a higher rate of caesarean births (< 6 hours: 37%; 6-6.9 hours: 34%; 7+ hours: 11%, p-value < 0.05) [3]. Women who slept less than 7 hours at night are at increased risk of developing gestational diabetes, gestational hypertension and preterm birth [4][5][6].

Hypnotic drugs can have adverse effect on the mother and fetus, and such drugs safe for women to take during pregnancy are limited [7][8]. Psychological and behavioural therapies, acupuncture and herbal treatments have shown some promising result in treating insomnia during pregnancy [9].

Sensory deprivation methods such as eye masks and ear plugs have been shown to increase the sleep duration by 41-59% among in ICU patients [10][11][12].

We hypothesized that eye masks and ear plugs will increase night sleep duration among nulliparas in their third trimester who reported sleep duration less than 6 hours . (< 6hours represents lower half of reported night sleep duration in our center) [13].

We plan to perform a powered study on impact of eye mask and ear plugs in late third trimester at 34 to 36 weeks nulliparas utilising the actigraph device to objectively quantify night sleep duration.

3.0 Objectives:

Primary Objectives

1. To study the Effectiveness of ear plugs and eye mask in improving night sleep duration among nulliparas at 34-36 weeks gestation.

Secondary Objectives :

1. To study the effectiveness of eye masks and ear plugs in improving Wake after sleep onset (WASO) and Sleep efficiency (SE)
2. To Study the effect of eye masks and ear plugs in improving labour outcomes among pregnant mothers with sleep disturbances.

a. Maternal:

- Mode of delivery
- Indication for Caesarean delivery
- Need for Labor induction : Prostaglandin or Amiotomy.
- Peridelivery blood loss.
- Epidural requirement

b. Fetal

- Birth weight.
- Cord ph and base excess
- Apgar score at 5 minute.
- Neonatal admission and indication

3. Subjects' sleep satisfaction with sleep aid based on likert scale.

4.0 Research Hypothesis

Ear plugs and eye masks will increase night sleep duration among nulliparas with short self-reported night sleep duration in their late third trimester.

5.0 Methodology

5.1 Study type and design

This is a randomised control trial.

5.2 Study Population

Nulliparas who attend Antenatal Clinic at University Malaya Medical Center

5.3 Inclusion criteria:

- Nulliparous
- 34 – 36 weeks of gestation.
- Self-reported sleep of less than 6 hours.
- Singleton pregnancy

5.4 Exclusion criteria:

- Patients with known pre-existing sleep disorders: Chronic insomnia, Sleep apnea.
- Patients with known pre-existing psychiatric disorders eg: depression, schizophrenia etc.
- Patients with underlying medical disorders: SLE, Thyroid disorders, Epilepsy, Heart diseases etc.
- Night shift workers
- Active smoker
- Current alcoholic consumption
- Obesity > class II (BMI > 35)
- Intrauterine Death
- Care taker of other family members.
- Gross fetal anomaly

5.5 Study Period

Data collection is 6 months

Study period 12 months

5.6 Study Evaluation

Actigraphy – Actisleep Device

Polysomnography(PSG) is considered the "gold standard," for sleep study, however, they are expensive, often requiring participants to sleep in a laboratory, limiting their usability [14]. Wrist actigraphy is an acceptable alternative objective method to assess sleep duration [15]. When compared to PSG, wrist actigraphy demonstrates a correlation (*r*) of over 0.8 for sleep duration, including studies of pregnant women [16]. Actigraphy is often preferable for objectively measuring sleep duration because it is unobtrusive similar to a wristwatch, ambulatory, and can record for multiple days and nights at a much lower cost than PSG.

The ActiSleep is recommended to be worn at the wrist for general sleep assessment. However, in certain circumstances, waist placement or ankle placement may be allowed. The ActiSleep monitor does not need to make contact with the skin. It must simply fit snuggly against the body and not be allowed to wobble around. It can be worn exclusively during sleep episodes.

The patient should keep a record of Time in Bed (TIB) and Time out of bed (TOB) for each measured sleep episode. The patient should be instructed to return this completed sleep log with the ActiSleep monitor. The TIB and TOB are required for the analysis of sleep data.

Sleep Data

Manufacturer: Actigraph, 49 East Chase Street. Pensacola, FL 32502

Model number: GT3X+

Software version: ActiLife version 6

Data: total sleep time (TST), sleep efficiency (SE), sleep onset latency (SOL) and wake after sleep onset (WASO)

5.7 Study Design

This is a randomised control trial. Nulliparas, who are at 34 – 36 weeks who attend Antenatal clinic in UMMC and reported night sleep duration of 5 hours or less on average in the last 1 month will be informed regarding this study. Patient information sheet will be provided for those who fulfilled initial eligible criteria. Those who agreed to participate will be asked to provide written consent, and agree to participate in this study, will be recruited.

They will be provided with Actisleep and taught on methods to use it. They need to wear it when they sleep at night 7 consecutive nights. Time in bed (TIB) and Time out of bed (TOB) need to be recorded every night.

After 7 days, they need return to Antenatal clinic, their sleep data will be retrieved from the Actisleep device. They can proceed with the study only if 3 days of usable readings are recorded. Randomisation with the intention to treat with a specific intervention or placebo-sham method will follow.

They will be randomised into 2 groups. interventional group or Placebo using sham method, based on a randomisation sequence generated using random.org in a random block of 4 or 8 sequence, generated by investigator not involved in the recruitment process.
Randomisation is by the opening of sealed opaque and numbered envelope with lowest available envelope assigned in strict order.

A. Interventional Group: Eye masks and ear plugs.

Subjects are provided with eye masks and ear plugs to wear when they go to bed at night, for 7 consecutive nights. Time in bed(TIB) and time out of bed (TOB) needs to be recorded every night. They may remove the eye masks and ear plugs temporarily if they wake up from sleep at night.

At the end of 7 days, subjects will return to Antenatal clinic and have the Actisleep analysed and returned to the investigator.

Placebo Group

Subjects are provided with an elasticated headband to wear when they go to bed at night, for 7 consecutive nights. Headband shall be placed on their forehead loosely. Time in bed(TIB) and time out of bed (TOB) needs to be recorded every night.

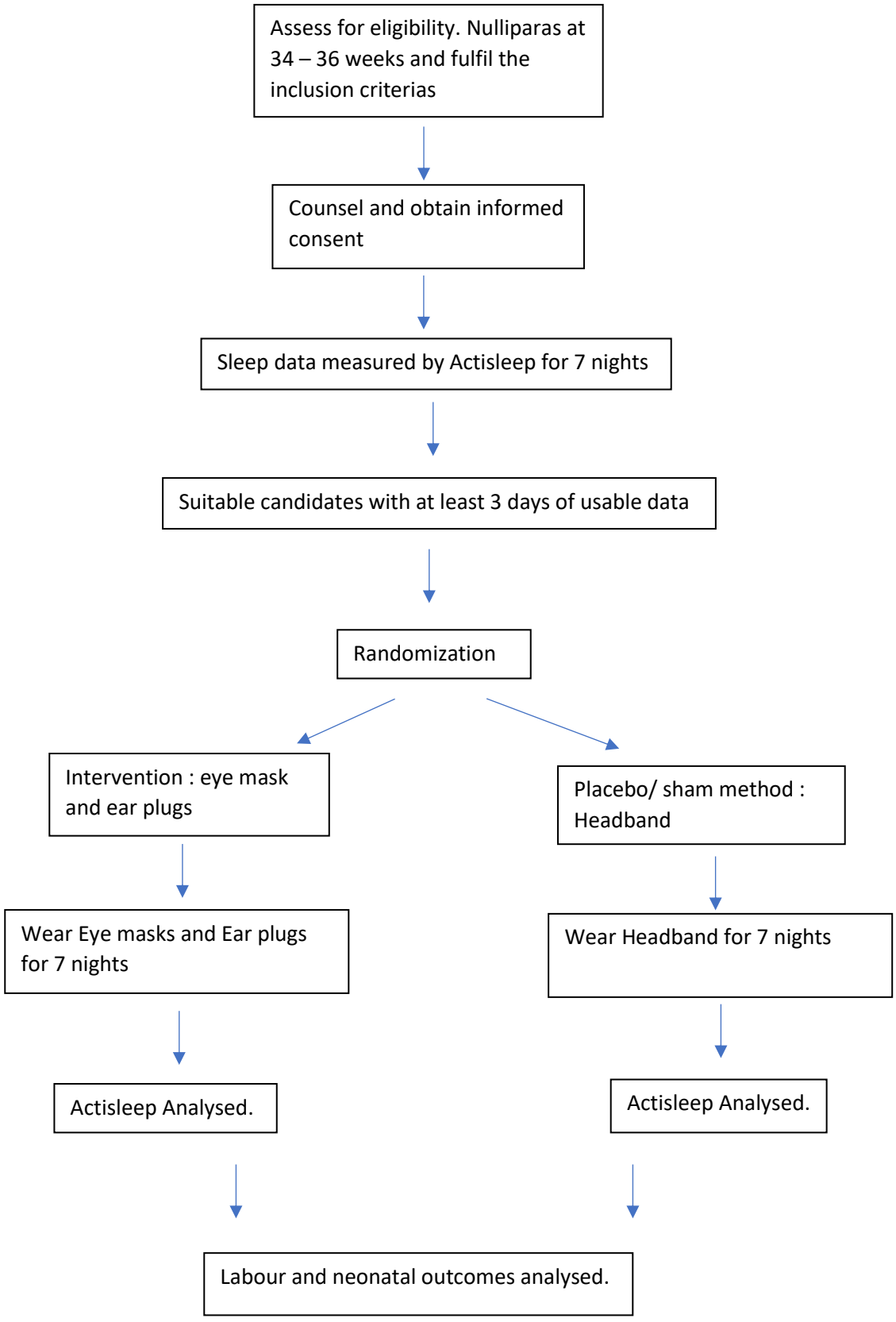
At the end of 7 days, subjects will return to Antenatal clinic and have the Actisleep analysed and returned to the investigator.

Patients labor and neonatal outcomes will be analysed after they delivered.

At the end of the study, subject's satisfaction on their sleep quality will be assessed based on likert satisfaction scale.

5.8 Schematic Diagram of study design

Eligibility



5.9 Statistical Analysis Plan

5.9.1 Sample size calculation

Our primary outcome is the increase of night sleep duration among nulliparas who reported short sleep duration of 5 hours or less.

There were no previous similar study regarding the use of Eye masks and Ear plugs in improving sleep in pregnancy.

Studies on ICU patients which increase of Total Sleep Time of 41 – 59% [10-12]. We postulate modest improvement of night sleep duration of 1 hour, which is 20% of 5 hours.

Assuming a normal distribution, standard deviation of 1.1hour, obtained from Lee and Gay[3]. 20 patients will be required in each arm to achieve statistical power of 90% (β 0.1) with alpha (α) of 0.05, 1 to 1 ratio across trial arms.

Factoring in dropout rate of 20%, we plan recruit 50 subjects for a suitably powered study

5.9.2 STATISTICAL ANALYSIS

Data will be entered into SPSS statistical software. Normally distributed continuous data will be analysed with Student's t test. Chi square test will be used for categorical or nominal data and Mann-Whitney U test will be used on non-normally distributed continuous or ordinal data. $P < 0.05$ is taken as level of significance.

5.10 Ethics of the study

This study is submitted to the UMMC Medical Research and Ethics committee, the local institutional review board for approval. Patient will be given an information sheet, have their oral queries addressed and written informed consent obtained to participate in the study.

GANNT Chart

Duration	July-August 2017	Aug – Sept 2017	Oct-Nov 2017	Dec- May 2018	June 2018	July 2018
Literature Review	✓					
Proposal preparation and Presentation	✓	✓				
Ethics Review			✓	✓		
Data Collection				✓	✓	
Data analysis and writing					✓	✓
Thesis Submission						✓

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Data Collection form :

Interventional / Placebo

Subject no: **Actisleep No:**

Age:

Height: **weight :**

Gravida: **Para:** **Abortion:**

Gestational Age:

Address:

Type of House: Bungalow / Semi D / Terrace / Condominium or Flat / Wooden /

Shared Bedroom (other than partner) : Yes / No

Bedroom: Air-conditioned / Fan / nothing **Night light** : Yes / No

Bed: Single / Double /

Occupation: **shift work** : Yes / No **Hours of work per day**:

Marital status : Single / Married / Widow

Conception : Planned / Unplanned

Antenatal Problems:

1.

2.

3.

Labor outcomes:

Induction : Yes / No **Method** : Foley's / Prostaglandin

Amniotomy : Yes / No

Analgesics: Nil / Entonox / Opoids / Epidural / Combined

Mode of delivery: SVD / Instrumental / Caesarean Delivery

Estimated Blood loss:

Neonatal outcome :

Apgar score _____ 1 minute _____ 5 minute

Birthweight :

NICU Admission: Yes / No **Indication** :

Cord pH: **Base Excess** :

Actisleep

Model Number

Week 1

Day	Time in Bed	Time out of Bed	Self reported sleep(Hours)
1			
2			
3			
4			
5			
6			
7			

Week 2

Day	Time in Bed	Time out of Bed	Self reported Sleep(hours)
1			
2			
3			
4			
5			
6			
7			

Satisfaction :

1. Since using the sleep aid for the last one week, I have slept better.

Strongly agree / agree / don't know / disagree / strongly disagree

2. Please rate your satisfaction with the use of your allocated sleep aid.

1	2	3	4	5	6	7	8	9	10

1: completely dissatisfied

10: completely satisfied

Version : 1

Version Date: 5/10/2017

PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM

1. **Title of study**:
   "Eye masks and Ear plugs to Improve Night Sleep Duration In Nulliparas. A Randomised Control Trial"

2. **Name of investigator and institution:**

   Dr Teo Ik Hui, University Malaya Medical Center

   Supervisor : Professor Tan Peng Chiong

3. **Name of sponsor:**
   Department of Obstetrics and Gynaecology, UMMC

4. **Introduction:**

You are invited to participate in this study because you reported night sleep of less than 6 hours. Short sleep duration is associated with longer labor , caesarean delivery and hypertension. We are looking at simple sleep aids to help you sleep better. They have been shown to increase sleep duration in ICU patients.

5. **What is the study procedure?**

If you are eligible to participate and agree to do so, having considered all the information provided you will be required to provide written consent.

We will teach you how to use the wrist watch (Actigraph device), it needs to be worn like a wrist watch during your bed time at night. You must wear it from the time you go to bed and take it off when you wake up in the morning. You should not take it off if you wake up during the night.

We will analyse your sleep for 7 nights using Actisleep. At the end of which, your sleep data will be recorded and analysed.

You will only proceed to the second part of the study if we can obtain sufficient sleep data, then, We will randomly allocate you using computer programme into either group of Ear plugs and eye masks versus Headbands.

You will be provided with the sleep aids which you need wear for another 7 nights while wearing the Actisleep. Your sleep data will be collected and analysed at the end of the study period.

You need to wear the sleep aid during the entire duration when you are in bed at night. However, you may take it off temporarily if you need to get out of bed in between your sleep but wear it back once you return to sleep. You only remove the sleep aids when you wake up in the morning.

Every morning we would want you to record your own recorded duration of your sleep the night before.

Your pregnancy care will not be affected in any way and will continue as usual.

6. **What is Actisleep? What should I do with the device?**

It is a watch-like portable device to wear it on your non- dominant wrist. You only need to wear it when you go to bed at night. It is very light and does not emit any sound or vibration. You need to wear it for the whole duration of your sleep to increase the accuracy of the data collected.

7. **What are my responsibilities when taking part in this study?**

It is important that you answer all the questions asked by the study staff honestly and completely. If your condition or circumstances change during the study, you must tell the study doctor.

8. **What are the potential risks and side effects of being in this study?**

The sleep aids use in this study are not expected to have significant risks or side effects during pregnancy. Please ask your study doctor if you need more information on risks and side effects.

9. **What are the benefits of being in this study?**

There may or may not be any benefits to you. Information obtained from this study will help improve the treatment or management of other patients with the same disease or condition.

10. **What are my alternatives if I do not participate in this study?**

Participation in this study is voluntary. Not consenting to participate of withdrawal of consent will not affect medical services entitled. You do not have to participate in this study to get treatment for your disease or condition.

11. **Withdrawal options**

You may withdraw from the study at any stage of the procedure, and the reasons will be recorded if available. However it is not advisable to do so especially if you are already in the procedure as it may affect the result of the study.

12. **Who is funding the research?**

By the Department of Obstetrics and Gynaecology, University Malaya Medical Center.

13. Can the research or my participation be terminated early?

If the study is stopped early for any reason you will be informed and arrangements made for your care.

14. Will I be informed regarding the study finding?

No, you will not be officially being informed regarding the study finding.

15. Will I be informed if new information relevant to consent becomes available?

Yes, you will be informed if any new information relevant to consent become available and you might need to re-consent in needed based on new information.

16. Will my medical information be kept private?

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Individuals involved in this study and in your medical care, qualified monitors and auditors, the sponsor or its affiliates and governmental or regulatory authorities may inspect and copy your medical records, where appropriate and necessary.

Data from the study will be archived and for the purpose of analysis, but your identity will not be revealed at any time.

20. Who should I call if I have questions?

If you have any questions about the study or if you think you have a study related injury and you want information about treatment, please contact the study doctor;

Dr Teo Ik Hui
Obstetrics and Gynaecology Department
University Malaya Medical Center
H/P: 0178510688

INFORMED CONSENT FORM

Title of Study: " Eye masks and Ear plugs To Improve Night Sleep Duration In Nulliparas. A Randomised Control Trial"

By signing below I confirm the following:

- I have been given oral and written information for the above study and have read and understood the information given.
- I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my participation is voluntary and I can at anytime free withdraw from the study without giving a reason and this will in no way affect my future treatment. I am not taking part in any other research study at this time. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the study doctor's (investigator's) instructions related to my participation in the study.
- I understand that study staff, qualified monitors and auditors, the sponsor or its affiliates, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL
- I will receive a copy of this subject information/informed consent form signed and dated to bring home.

I agree / disagre to participate in this study.

Subject:

Signature: I/C number:

Name: Date:

Investigator conducting informed consent:

Signature: I/C number:

Name: Date:

Impartial witness: *(Required if subject is illiterate and contents of patient information sheet is orally communicated to subject)*

Signature: I/C number:

Name: Date:

Version : 1

Version Date: 5/10/2017