

RESEARCH PROPOSAL FOR MASTERS OF MEDICINE

(OBSTETRICS AND GYNAECOLOGY)

DEPARTMENT OF OBSTETRICS AND GYANECOLOGY

UNIVERSITY MALAYA

TITLE:

A RANDOMISED CONTROLLED TRIAL : EYE MASK AND EAR PLUGS COMPARED TO HEADBAND IN NULLIPARAS TO IMPROVE NIGHT SLEEP AND SPONTANEOUS VAGINAL DELIVERY.

Protocol Version : 2 Version

Date: 4/12/2017

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 MGG 160005

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**1.0.Title:**

Eye Mask and Ear plugs Compared to Headband In Nulliparas To Improve Night Sleep and Spontaneous Vaginal Delivery :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 increases 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].
 Woman allocated to sensory deprivation methods such as eye masks and ear plugs compared to headband are most likely to improve the night sleep by at least 30 minutes compared to pre-intervention period, shown in a recent unpublished study in our centre by Dr Teo et all ( Ear plugs and Eye Masks To Improve Night sleep Duration In Nulliparas, A randomized control Trial.) In addition, this study also shows an improvement of spontaneous vaginal delivery rate (20/26 (76.9%) vs 15/26(57.7%) RR= 1.3 95% CI 0.9-1.9). This 20% difference which if reproducible in a powered study will be a major improvement in delivery outcome.

We hypothesized that eye masks and ear plugs may help to improve the spontaneous vaginal delivery among nulliparas in their third trimester.

Based on that, we plan to perform a powered study on impact of eye mask and ear plugs compared to headband as sleep aids among 34 to 36 weeks nulliparas on spontaneous vaginal delivery.

**3.0 .Objectives:**

**Primary objective:**

1. To study the effect of eye masks and ear plugs in improving spontaneous vaginal delivery among nulliparous at 34-36 weeks gestation

a. Maternal:

* Mode of delivery
* Indication for caesarean delivery
* Need for labor Induction: Prostaglandins or Amniotomy or Foley
* Peridelivery blood loss
* Epidural requirement
* Duration of active labour (from 4cm to delivery)
* Reported night sleep duration after 2 weeks

b.Fetal

* Birth Weight
* Cord ph and base excess
* Apgar score at 5 minutes
* Neonatal admission and indications

**Secondary objectives:**

1.To study the pregnancy outcome after the use of ear plugs and eye masks that helps to improve sleep

**4.0.Research hypothesis:**

Use of ear plugs and eye masks at 34-36 weeks during night time will improve the spontaneous vaginal delivery among nulliparas.

**5.0.Methodology**

**5.1. Study type and design**

This is a randomized controlled trial

**5.2.Study Population**

Nulliparas who attend Antenatal Clinic at University Malaya Medical Centre

**5.3.Inclusion criteria**

* Nulliparous (no prior pregnancy ≥ 20 weeks)
* 34-36 weeks of gestation
* Self- reported sleep less than 6 hours
* Singleton pregnancy
* Access to the phone

**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 disease
* Planned caesarean delivery (eg: Placenta praevia , breech , maternal request)
* Night shift workers or night care commitments
* Active smoker
* Current alcohol consumption
* Maternal obesity>class II (BMI>35)
* Intrauterine death
* Care taker of other family members
* Gross fetal anomaly

**5.5.Study period**

Study period is 6 months for data collection.

Estimated total deliveries in our centre is 5000 per year with 40 % being nulliparous, ie: 170 delivery every month. Taking recruitment rate as 30%, we estimate to recruit about 50 participants per month and will take around 6 month to help to get or sample size of 234 participants and for their delivery.

**5.6.Study evaluation**

No interim analysis or evaluation done

**5.7 Study Design**

This is a randomised control trial. Nulliparas, who are at 34 36 weeks who attend Antenatal clinic in UMMC will be approached 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. 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.

1. **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 up till the delivery. They may remove the eye masks and ear plugs temporarily if they wake up from sleep at night. At the end of 2 weeks, subjects will receive call from the investigator regarding the sleep quality using a sleep questionnaire. Subjects will be followed up till the delivery to analyse the spontaneous vaginal delivery as that is the primary objective.

1. **Placebo Group :**

Subjects are provided with an elasticated headband to wear when they go to bed at night up till the deilivery . Headband shall be placed on their forehead loosely.At the end of 2 weeks, subjects will receive call from the investigator regarding the sleep quality using a sleep questionnaire. Subjects will be followed up till the delivery to analyse the spontaneous vaginal delivery as that is the primary objective.

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

**5.8 Schematic Diagram of study design**

Assess for eligibility. Nulliparas at 34 -36 weeks and fulfil the inclusion criterias

Eligibility Assess for eligibility. Nulliparas at 34-36 weeks

 and fulfil the inclusion criterias

Counsel and obtain informed conscent

Randomization

Placebo/ Sham method:

Headband

Intervention :

Eye mask and Ear plugs

Wear headband during night sleep until delivery

Wear eye masks and ear plugs during night sleep until delivery

Sleep quality with the aids to be analysed after 2 weeks via a phone call using a sleep questionnaire

Labour and neonatal outcomes analysed

**5.9 Statistical Analysis Plan**

 **5.9.1 Sample size calculation**

Our primary outcome is the labor outcomes achieving spontaneous vaginal delivery among nulliparous at 34-36 weeks gestation . In a recent yet to be published study done in our centre by Teo et all on the use of ear plugs and eye mask to improve night sleep duration, the pilot data suggests that spontaneous vaginal delivery is 76.9% in the ear plugs and eye mask group compared to 57.7% in the headband group. [12]. Using statistical power of 80% with alpha (α) of 0.05, 1 to 1 ratio across trial arms, using chi-square test, 93 participants are required in each arm. Assuming dropout rate of 20%, 116.25 participants are needed in each arm, rounded up to 117 . Total participants required for a powered study is 234 .

**5.9.2 STATISTICAL ANALYSIS**

Data will be entered into SPSS statistical software. Normally distributed continuous data will be analysed with Students 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 a 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.

**ELLIGIBILITY FORM**

**Inclusion criteria**

* Nulliparous (no prior pregnancy ≥ 20 weeks) ( )
* 34-36 weeks of gestation ( )
* Self- reported sleep less than 6 hours ( )
* Singleton pregnancy ( )
* Acess to the phone ( )

 - H/P or house number : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**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 disease ( )
* Planned caesarean delivery (eg: Placenta praevia , breech , maternal request) ( )
* Night shift workers /night care commitments ( )
* Active smoker ( )
* Current alcohol consumption ( )
* Maternal obesity>class II (BMI>35) ( )
* Intrauterine death ( )
* Care taker of other family members ( )
* Gross fetal anomaly ( )

**GANNT Chart**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Duration  | Nov - Dec 2018 | Jan - Feb 2019 | March 2019 | April - Sept 2019 | Oct - Nov 2019 | Dec 2019 |
| Literature Review  | ✓ |  |  |  |  |  |
| Proposal preparation and Presentation |  | ✓ |  |  |  |  |
| Ethics Review  |  |  | ✓ |  |  |  |
| Data Collection  |  |  |  | ✓ |  |  |
|  Data analysis and writing  |  |  |  |  | ✓ |  |
| Thesis Submission  |  |  |  |  |  | ✓ |

**6.0 Referrences**

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**Data Collection form :**

**Interventional / Placebo**

**Subject no: Date of recruitment :**

 **Age:**

**Height: Weight :**

**Gravida: Para: Abortion:**

**EDD:**

**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:**

**Labour Induction** : Yes / No **Method** : Foleys / Prostaglandin/amniotomy /oxytocin

**Amniotomy** : Yes / No

 **Analgesics**: Nil / Entonox / Opoids / Epidural

**Mode of delivery**: SVD / Instrumental- Forceps, Vaccumm / Caesarean Delivery

If Caesarean delivery : **Indication:**

**Estimated Blood loss**:

**Neonatal outcome** : Apgar score \_\_\_\_\_\_ 1 minute \_\_\_\_\_\_ 5 minute

**Birthweight** :

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

**Cord pH**:

**Base Excess** :

**Date of delivery :**

**Date of discharge:**

***SLEEP QUESTIONAIRE :***

1. Since using the sleep aid for the last two week, I have slept better at night.

**Strongly agree**

 **Agree**

**Dont know**

**Disagree**

**Strongly disagree**

1. Please rate your satisfaction with your allocated sleep aid in helping you sleep better at night.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **0** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** |

  

0: completely dissatisfied 10: completely satisfied

1. In last 2 weeks, estimate your sleep duration on average each night?

|  |  |
| --- | --- |
|  | **0 hr** |
|   | **1 hr**  |
|  | **2 hrs** |
|  | **3 hrs** |
|  | **4 hrs** |
|  | **5 hrs** |
|  | **6 hrs** |
|  | **7 hrs** |
|  | **8 hrs** |
|  | **≥ 9 hrs (** Pls state the hrs:\_\_\_\_\_ ) |

Version : 1 Version Date: 5/02/2019

**PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM**

1. **Title of study**:

“A randomized controlled trial : Use of Eye Mask and Ear plugs Compared to Headband In Nulliparas To Improve Night Sleep and Spontaneous Vaginal Delivery.”

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

 Dr Vimaladevi Annamalai, University Malaya Medical Center

Supervisor : Professor Tan Peng Chiong

1. **Name of sponsor:**

Department of Obstetrics and Gynaecology, UMMC

1. **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 that may help you sleep better, so that your chance of a normal delivery is improved.

1. **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 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 at night during sleep until delivery . 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 remove the sleep aids when you wake up in the morning. Your pregnancy care will not be affected in any way and will continue as usual.
2. **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.

1. **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.

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

There may or may not be any benefits to you. Information obtained from this study may help improve care in late pregnancy .

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

Participation in this study is voluntary. Not consenting to participate or withdrawal of consent will not affect care.

1. **Withdrawal options**

You may withdraw from the study at any stage of the procedure without having to provide any reasons.

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

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

12. **Can the research or my participation be terminated early?**

If the study is stopped early for any reason you will be informed.

1. **Will I be informed regarding the study finding?**

No, you will not be individually informed but we intend to publish the findings.

1. **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.

1. **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.

1. **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 Vimaladevi Annamalai

Obstetrics and Gynaecology Department

University Malaya Medical Center

 H/P: 0164576116

**INFORMED CONSENT FORM**

**Title of Study: “ A randomized controlled trial : Use of Eye Mask and Ear plugs In Nulliparas Compared to Headband To Improve Night Sleep and Spontaneous Vaginal Delivery. ”**

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: