

# Do eye masks and earplugs improve sleep quality and IVF outcomes?

<b>Submission date</b> 23/04/2026	<b>Recruitment status</b> Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/04/2026	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/04/2026	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Poor sleep during IVF may impair ovarian response. This study aims to test whether simple, lowcost sleep aids (eye mask + earplugs) used nightly during controlled ovarian stimulation improve the number of mature oocytes (eggs) at oocyte pickup, compared with a sleep hygiene leaflet.

### Who can participate?

Adults aged 21–42 years with poor sleep (PSQI > 5) undergoing IVF.

### What does the study involve?

Participants will be randomized 1:1 to intervention or leaflet. All will wear a wrist actigraphy device to measure sleep objectively and complete short questionnaires. Routine IVF care is unchanged. Primary outcome is oocyte count; secondary outcomes evaluate follicular development, ovarian responsiveness, and successful pregnancy and actigraphyderived sleep parameters.

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

Benefits and risks not provided at time of registration

### Where is the study run from?

Obstetric and Gynaecological Department, University Malaya Medical Centre, Malaysia.

### When is the study starting and how long is it expected to run for?

May 2026 to May 2027.

### Who is funding the study?

1. Investigator initiated and funded
2. University of Malaya Medical Center, Malaysia

### Who is the main contact?

Dr Nurul Hafiza MD Khairi, hafizakhairi@gmail.com, ummc@ummc.edu.my.

# Contact information

## Type(s)

Principal investigator, Scientific, Public

## Contact name

Dr Nurul Hafiza MD Khairi

## Contact details

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# Additional identifiers

# Study information

## Scientific Title

Effectiveness of eye mask and earplugs versus sleep hygiene leaflet on sleep quality and IVF outcomes among women undergoing in vitro fertilisation: a randomised controlled trial

## Study objectives

- Primary: To determine whether eyemask and earplugs during COS increase the number of MII oocytes at OPU compared to a sleep hygiene leaflet.
- Secondary: To compare FORT and FOI between arms.
- Secondary: To compare clinical pregnancy rate between arms.
- Secondary: To compare sleep quality (PSQI) and actigraphy metrics (TST, SE, WASO) between arms.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 09/04/2026, Medical Research Ethics Committee (MREC), University of Malaya Medical Centre (Lembah Pantai, Kuala Lumpur, 59100, Malaysia; +60 03-79493209/2251; mrec@ummc.edu.my), ref: 20251118-15900

## Primary study design

Interventional

## Allocation

Randomized controlled trial

## Masking

Blinded (masking used)

## **Control**

Active

## **Assignment**

Parallel

## **Purpose**

Supportive care

## **Study type(s)**

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

Sleep quality

## **Interventions**

Methodology: Randomised controlled trial

Human subjects: Yes — Patients in UMMC; target n  $\approx$  170

Sample size justification:

Negative binomial regression for MII oocyte; assumption difference of 2 oocytes between intervention group and control group is significance, 90% power for RR $\approx$ 1.25–1.30 at  $\alpha$ =0.05; 10–20% attrition; target  $\approx$ 170 participants.

Vulnerable groups: No

This is a single-blinded (assessor) study with two arms - intervention (eye mask and ear plug) versus control (sleep hygiene leaflet).

The intervention group will be given an eye mask and earplugs (EMEP) for 1 week during their IVF stimulation period. The control group will be given a sleep hygiene leaflet during the same period. Then, both arms will undergo oocyte pick-up, when the number of MII oocytes will be compared between the two groups. Randomization was allocated by using random.org with sealed envelopes.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

1. The number of metaphase II oocytes (MII) measured using data collected from medical notes at ovum pick-up (OPU)

## **Key secondary outcome(s)**

## **Completion date**

30/06/2027

## **Eligibility**

### **Key inclusion criteria**

1. Women 21–42 years undergoing IVF at UMMC
2. PSQI > 5 prior to COS
3. BMI < 35 kg/m<sup>2</sup>
4. Able to consent, wear actigraphy, and complete questionnaires

### **Healthy volunteers allowed**

Yes

### **Age group**

Adult

### **Lower age limit**

21 years

### **Upper age limit**

42 years

### **Sex**

Female

### **Total final enrolment**

0

### **Key exclusion criteria**

1. Known obstructive sleep apnea
2. Current shiftwork employment
3. Use of hypnotic/sedative medications during COS
4. Ovarian endometrioma requiring surgical management during cycle

### **Date of first enrolment**

04/05/2026

### **Date of final enrolment**

30/04/2027

## **Locations**

### **Countries of recruitment**

Malaysia

## **Sponsor information**

### **Organisation**

University Malaya Medical Centre

### **ROR**

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

# Funder(s)

## Funder type

### Funder Name

Department of Medicine, University of Malaya

### Alternative Name(s)

Faculty of Medicine - Universiti Malaya, Medicine Department - Faculty of Medicine - Universiti Malaya, medicineumalaya, University of Malaya Faculty of Medicine

### Funding Body Type

Government organisation

### Funding Body Subtype

Research institutes and centers

### Location

Malaysia

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other files</a>	version 1	18/11/2025	24/04/2026	No	No
<a href="#">Participant information sheet</a>	version 1	18/11/2025	24/04/2026	No	Yes
<a href="#">Protocol file</a>	version 2	29/01/2026	24/04/2026	No	No