VERSION NO: 2
VERSION DATE: *29 January 2026*

UNIVERSITY OF MALAYA MEDICAL CENTRE

RESEARCH PROTOCOL

1. Particulars of Researcher

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Research expertise (List up to 5 fields of expertise):

2. List of Co-researchers (Include all who have participated in the drafting of this proposal)

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   Email:

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TITLE OF RESEARCH PROPOSAL

Effectiveness of Eye Mask and Earplug versus Sleep Hygiene Leaflet on Sleep Quality and IVF Outcomes among Women Undergoing In Vitro Fertilisation: A Randomised Controlled Trial

KEY WORDS

IVF, controlled ovarian stimulation, sleep deprivation, actigraphy, MII, FORT, FOI, randomized controlled trial

BACKGROUND/ JUSTIFICATION

Poor sleep during IVF may impair ovarian response. We will test whether simple, low-cost sleep aids (eye-mask + earplugs) used nightly during controlled ovarian stimulation (COS) improve the number of mature (MII) oocytes at oocyte pick-up (OPU), compared with a sleep-hygiene leaflet. Eligible IVF patients with poor sleep (PSQI > 5) 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 MII oocyte count; secondary outcomes include FORT, FOI, clinical pregnancy, PSQI and actigraphy-derived sleep parameters.

OBJECTIVES & EXPECTED OUTCOMES

- Primary: To determine whether eye-mask 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.

METHODOLOGY

Methodology: Randomised controlled trial

Human subjects: Yes — Patients in UMMC; target n ≈ 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≈1.25–1.30 at α=0.05; 10–20% attrition; target ≈170 participants.

Vulnerable groups: No

Inclusion criteria:
- Women 21–42 years undergoing IVF at UMMC
- PSQI > 5 prior to COS
- BMI < 35 kg/m²
- Able to consent, wear actigraphy, and complete questionnaires

Exclusion criteria:
- Known obstructive sleep apnea
- Current shift-work employment
- Use of hypnotic/sedative medications during COS
- Ovarian endometrioma requiring surgical management during cycle

Recruitment process:
Participant's selection will be done by the Primary Investigator upon their first encounter at the Reproductive Clinic, UMMC.

The objective of the study will be explained to the potential participant and her partner, together with Patient Information Sheet (PIS).
If they agree to participate in the study, consent form will be given and informed consent will be obtained.
Then, PSQI questionnaire will be given.
Only those participants with PSQI score > 5 and fulfilled all the inclusion criterias will be recruited. They will need to wear the actigraph for 1 week to verify the PSQI score. Those with sleep duration less than or equal to 360 minutes (6 hours) will be randomised into 2 interventional groups; Group 1 for Eye mask and ear plug; Group 2 for Sleep Hygiene Leaflet.
For the Group 1, participants will be given a set of sleep aid kits consisting of night eye mask and earplugs in which they need to wear at night during their COS period up until the day of OPU together with an actigraph watch.
While for Group 2, they will be given a Sleep Hygiene Leaflet and an actigraph watch during their COS period.

RESEARCH DATA

Where will the data be kept?
Coded dataset on UMMC secure drive; linkage key stored separately; paper forms in locked cabinet.

Who will have access to data?
Primary investigator and named co-investigators; role-based, logged access.

How long will data be kept?
≥7 years post-completion (or per UMMC policy).

How will results be disseminated?
Aggregate, de-identified results via journals, conferences, and departmental reports.

BUDGET / FINANCIAL SUPPORT (IF APPLICABLE):

No	Budget Detail	Amount (RM)
1.		
2.		
3.		
	Grand Total	

GANTT CHART

ACTIVITIES \ YEAR	2026								
	0	1	2	3	4	5	6	7	8-12
1. Ethics submission									
2. Questionnaire validation									
3. Participants recruitment									
4. Data collection									
5. Data entry & analysis									
6. Manuscript writing									
7. Submission for publication									
8. Research progress report & presentation									

REFERENCES (up to 10 references)

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POTENTIAL IMPACT

Benefits to subjects:
Potential improved sleep and ovarian response; contributes to evidence.

Risks/burdens to subjects & minimisation: Minor mask/earplug irritation; actigraphy discomfort. Mitigation: hypoallergenic materials; instruction; discontinue if irritation. Risks/burdens to researchers & minimisation: Minimal; standard clinic infection-control and data security practices.

3. Please state whether you have submitted this research proposal for funding, now or before
   - ☐ Yes: If Yes, which grant? _____
   - ✓ No

This proposal will be kept strictly private and confidential. It will not be shared with anyone without your prior approval.

Name of Researcher (CAPITAL):

Signature of Researcher: NURUL HAFIZA BINTI MD KHAIRI

Date: 18.11.2025