



**JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(MEDICAL RESEARCH & ETHICS COMMITTEE)
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA**

Kompleks Institut Kesihatan Negara (NIH)
No.1, Jalan Setia Murni U13/52,
Seksyen U13 Bandar Setia Alam,
40170 Shah Alam, Selangor.

Tel: 03-3362 8398/8399/8404/8408

Ref : **23-03379-IUT**

Date: **27-03-2024**

MOHAMAD AZMEER BIN SADALI
HOSPITAL SUNGAI BULOH

Dear Dato'/ Dr/ Sir/ Madam,

LETTER OF ETHICAL APPROVAL:23-03379-IUT (IIR)

Protocol No : Psychological intervention for tinnitus, version 2.0, 23 February 2024

Clinical Efficacy of Audiologist-Delivered Low Intensity Psychological Intervention for Chronic Tinnitus Patients in Malaysia

This letter is made in reference to the matter above.

2. The Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (MOH) has provided ethical approval for this study. Please take note that all records and data are to be kept strictly **CONFIDENTIAL** and can only be used for the purpose of this study. All precautions are taken to maintain data confidentiality. Permission from the District Health Officer / Hospital Administrator/ Hospital Director and all relevant heads of departments /units where the study will be carried out must be obtained prior to the study. You are required to follow and comply with their decision and all other relevant regulations.
3. The investigators and sites involved in this study are:
HOSPITAL SUNGAI BULOH
 - a) Dr Wan Syafira Binti Ishak (Co / Sub Investigator at the site)
 - b) Dr MAHADIR AHMAD (Co / Sub Investigator at the site)
 - c) Encik MOHAMAD AZMEER BIN SADALI (Principal / Coordinating Investigator)Hospital Universiti Kebangsaan Malaysia (HUKM)/Pusat Perubatan Universiti Kebangsaan Malaysia (PPUKM)
 - a) Dr Wan Syafira Binti Ishak (Co / Sub Investigator at the site)
 - b) Dr MAHADIR AHMAD (Co / Sub Investigator at the site)
 - c) Encik MOHAMAD AZMEER BIN SADALI (Principal / Coordinating Investigator)
4. The following study documents have been received and reviewed with reference to the above study:

List of documents received and reviewed:

1. Cover Letter to MREC_version_2.0 23-Feb-2024
2. Declaration of Conflict of Interest (COI form)_version_2.0 23-Feb-2024
3. Protocol Review Checklist_version_2.0 23-Feb-2024
4. Research Protocol_version_2.0 23-Feb-2024
5. Patient Information Sheet (PIS) & Informed Consent Form (ICF)_version_2.0 Malay 23-Feb-2024
6. Patient Information Sheet (PIS) & Informed Consent Form (ICF)_version_2.0 English 23-Feb-2024
7. Patient Information Sheet (PIS) & Informed Consent Form (ICF) Review Checklist_version_2.0 English 23-Feb-2024
8. Clinical Form Report / Data Collection Form_version_2.0 23-Feb-2024
9. Questionnaire_version_2.0 Malay 23-Feb-2024
10. Questionnaire_version_2.0 English 23-Feb-2024
11. Questionnaire_version_2.0 Malay 23-Feb-2024

12. Project Gantt Chart_version_2.0 23-Feb-2024
13. Investigator's documents : Declaration of Conflict of Interest (COI), IA-HOD-IA, and CV:
- a) MOHAMAD AZMEER BIN SADALI
 - b) Wan Syafira Binti Ishak
 - c) MAHADIR AHMAD
 - d) MOHAMAD AZMEER BIN SADALI
 - e) Wan Syafira Binti Ishak
 - f) MAHADIR AHMAD

5. Please note that the approval is valid until **27-03-2025**. The following are to be reported upon receiving ethical approval. Required forms can be accessed from the National Medical Research Registry (NMRR) website.
- i. Ethical approval is required in the case of **amendments / changes** to the **study documents/ study sites/ study team**. MREC reserves the right to withdraw ethical approval if changes to study documents are not completely declared.
 - ii. **Continuing Review Form** has to be submitted to MREC within 2 month (60 days) prior to the expiry of ethical approval.
 - iii. **Closure Notification** upon study completion to the MREC. A **Study Final Report** has to be submitted to MREC upon study completion.
 - iv. **Applicable for Clinical interventional Studies only:** Report occurrences of **all Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reaction (SUSARs)** and **Protocol Deviation/Violation** at all MREC approved sites to MREC. SAEs are to be reported within 15 calendar days from awareness of event by investigator. Initial report of SUSARs are to be reported as soon as possible but not later than 7 calendar days from awareness of event by investigator, followed by a complete report within 8 additional calendar days.
6. There will be **26 participants** involved in this study within Malaysia.
7. Please take note that the reference number of this letter must be stated in all future correspondence related to this study to facilitate the administrative processes.
8. The Medical Research & Ethics Committee, Ministry of Health Malaysia, operates in accordance to the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). Any member of the MREC who is involved in the study/ project under review will not participate in the approval of the study/ project.

Comments (if any): None

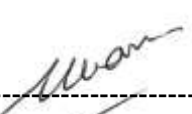
Project Sites:

HOSPITAL SUNGAI BULOH
Hospital Universiti Kebangsaan Malaysia (HUKM)/Pusat Perubatan Universiti Kebangsaan Malaysia (PPUKM)

Decision by Medical Research & Ethics Committee:

- () Approved – by MREC Full Board
() Disapproved

Date of Approval : 27-03-2024


DR NURAIN BINTI MOHD NOOR
Chairperson
Medical Research & Ethics Committee
Ministry of Health Malaysia
MMC No: 31576



**JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(MEDICAL RESEARCH & ETHICS COMMITTEE)
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40170 Shah Alam, Selangor.

Tel: 03-3362 8398/8399/8404/8408

Ruj.Kami: **23-03379-IUT**
Tarikh : **27-03-2024**

MOHAMAD AZMEER BIN SADALI
HOSPITAL SUNGAI BULOH

Dato'/ Dr/ Tuan/ Puan,

SURAT KELULUSAN ETIKA:23-03379-IUT (IIR)

Protocol No : Psychological intervention for tinnitus, version 2.0, 23 February 2024

Clinical Efficacy of Audiologist-Delivered Low Intensity Psychological Intervention for Chronic Tinnitus Patients in Malaysia

Dengan hormatnya perkara di atas adalah dirujuk.

2. Bersama dengan surat ini dilampirkan surat kelulusan saintifik dan etika bagi projek ini. Segala rekod dan data subjek adalah SULIT dan hanya digunakan untuk tujuan kajian dan semua isu serta prosedur mengenai *data confidentiality* mesti dipatuhi. Kebenaran daripada Pengarah Hospital / Institusi di mana kajian akan dijalankan mesti diperolehi terlebih dahulu sebelum kajian dijalankan. Dato'/ Tuan/ Puan perlu akur dan mematuhi keputusan tersebut dan undang-undang lain yang berkaitan.
3. Penyelidik- penyelidik dan lokasi penyelidikan yang terlibat ialah:
HOSPITAL SUNGAI BULOH
 - a) Dr Wan Syafira Binti Ishak (Co / Sub Investigator at the site)
 - b) Dr MAHADIR AHMAD (Co / Sub Investigator at the site)
 - c) Encik MOHAMAD AZMEER BIN SADALI (Principal / Coordinating Investigator)Hospital Universiti Kebangsaan Malaysia (HUKM)/Pusat Perubatan Universiti Kebangsaan Malaysia (PPUKM)
 - a) Dr Wan Syafira Binti Ishak (Co / Sub Investigator at the site)
 - b) Dr MAHADIR AHMAD (Co / Sub Investigator at the site)
 - c) Encik MOHAMAD AZMEER BIN SADALI (Principal / Coordinating Investigator)
4. Dokumen- dokumen berikut telah diterima dan disemak dengan merujuk kepada kajian di atas:

Senarai dokumen yang diterima dan disemak:

1. Cover Letter to MREC_version_2.0 23-Feb-2024
2. Declaration of Conflict of Interest (COI form)_version_2.0 23-Feb-2024
3. Protocol Review Checklist_version_2.0 23-Feb-2024
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13. Investigator's documents : Declaration of Conflict of Interest (COI), IA-HOD-IA, and CV:

- a) MOHAMAD AZMEER BIN SADALI
- b) Wan Syafira Binti Ishak
- c) MAHADIR AHMAD
- d) MOHAMAD AZMEER BIN SADALI
- e) Wan Syafira Binti Ishak
- f) MAHADIR AHMAD

5. Adalah dimaklumkan bahawa kelulusan ini adalah sah sehingga **27-03-2025**. Tuan/Puan perlu menghantar dokumen-dokumen seperti berikut selepas mendapat kelulusan etika. Borang-borang berkaitan boleh diakses daripada laman web *National Medical Research Registry (NMRR)*.
- i. Mendapat kelulusan etika sekiranya terdapat **pindaan ke atas sebarang dokumen kajian/ lokasi kajian/ penyelidik**. Pihak JEPP mempunyai hak untuk menarik balik kelulusan etika sekiranya terdapat perubahan dokumen kajian yang tidak diisytiharkan.
 - ii. **Continuing Review Form** harus dihantar kepada JEPP selewat-lewatnya dalam tempoh 2 bulan (60 hari) sebelum tamat tempoh kelulusan ini bagi memperbaharui kelulusan etika.
 - iii. **Closure Notification** pada penghujung kajian. **Study Final Report** harus dihantar kepada JEPP pada penghujung kajian tersebut.
 - iv. **Kajian berkenaan intervensi klinikal sahaja**: Laporan mengenai **all Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reaction (SUSARs)** dan **Protocol Deviation/Violation** di lokasi kajian yang diluluskan oleh JEPP jika berkenaan. SAE perlu dilaporkan dalam tempoh 15 hari kalender dari kesedaran kejadian (*awareness of event*) oleh penyelidik. Laporan awal SUSAR perlu dikemukakan seawal mungkin tapi tidak melewati 7 hari calendar dari kesedaran kejadian oleh penyelidik, disusuli dengan laporan lengkap dalam tempoh tambahan 8 hari kalender.
6. Bilangan **peserta** yang akan terlibat dalam kajian ini di Malaysia adalah **seramai 26 orang**.
7. Sila ambil maklum bahawa sebarang urusan surat-menyurat berkaitan dengan penyelidikan ini haruslah dinyatakan nombor rujukan surat ini untuk melicinkan urusan yang berkaitan.
8. Jawatankuasa Etika & Penyelidikan Perubatan, Kementerian Kesihatan Malaysia, beroperasi mengikut *Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)*. Mana-mana ahli JEPP yang terlibat dalam kajian/ projek yang dinilai tidak akan mengambil bahagian dalam kelulusan kajian/ projek.

Komen (Jika ada) : tiada

Lokasi Kajian:

HOSPITAL SUNGAI BULOH

Hospital Universiti Kebangsaan Malaysia (HUKM)/Pusat Perubatan Universiti Kebangsaan Malaysia (PPUKM)

Keputusan Jawatankuasa Etika dan Penyelidikan Perubatan

() Lulus – *by MREC Full Board*

() Tidak Lulus

Tarikh kelulusan etika : **27-03-2024**

DR NURAIN BINTI MOHD NOOR

Chairperson

Medical Research & Ethics Committee

Ministry of Health Malaysia

MMC No: 31576