

**SEKRETARIAT ETIKA PENYELIDIKAN UKM • UKM RESEARCH ETHICS COMMITTEE**

Reference : UKM PPI/111/8/JEP-2024-420

Date : 04 June 2024

**Dr. Wan Syafira Ishak**  
Audiology Programme  
Center For Healthy Ageing And Wellness (H-Care)  
Faculty of Health Sciences  
The National University of Malaysia

Dear Professor/Datuk/Dato'/Datin/Sir/Madam,

**ETHICAL APPROVAL TO CONDUCT RESEARCH IN THE NATIONAL UNIVERSITY OF MALAYSIA**

Research title: Efficacy Of The Adapted Version Of Audiologist-Delivered Low Intensity Psychological Intervention In Improving Severity And Distress Among Chronic Tinnitus Patients In Malaysia

Ethics Ref. No.: JEP-2024-420

Approval period: 30 May 2024 – 29 May 2026

Study Site:

1. Otorhinolaryngology (ENT) Clinic, Hospital Sungai Buloh
2. Audiology Clinic, Department of Medical Rehabilitation Services, Hospital Canselor Tuanku Mukhriz

Sample Size: **Phase 1:**  
8 patients

**Phase 2:**  
26 patients for each group (audiologist-delivered low intensity psychological intervention for tinnitus (ADPIT) and standard audiological care)

With reference to the above.

2. The Research Ethics Committee, The National University of Malaysia (RECUKM) has provided ethical approval for above study. Please be reminded permission from the Deputy Dean of research of the faculty or Director of Institute/Centre 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. Please note that the investigator's responsibility is to ensure that:

- i. All Adverse Events should be reported to RECUKM as soon as possible.
- ii. Progress report should be submitted every **6 Months**.
- iii. All changes / amendments to the study documents / study sites / study team must be notified to the RECUKM. All changes must be approved by RECUKM before continuation of the study.
- iv. Application for renewal of the approval has to be submitted to RECUKM within one month (1 month) prior to the expiry of ethical approval.



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- v. Final Report should be provided to RECUKM when the project is complete.
- vi. 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 to be taken to maintain data confidentiality.

Required forms can be obtained from the The Research Ethics Committee, The National University of Malaysia (RECUKM) website: <https://www.ukm.my/jepukm>

Thank you.

Yours sincerely,

**PROFESOR DR. MOHD SHAHRIR MOHAMED SAID**  
Chairman  
Research Ethics Committee  
The National University of Malaysia

- c.c. - **Director**  
Hospital Canselor Tuanku Muhriz  
UKM Medical Centre
- **Deputy Dean (Research & Innovation)**  
Faculty of Health Sciences  
National University Of Malaysia
  - **Head of Audiology Programme**  
Faculty of Health Sciences  
National University Of Malaysia
  - **Associate Professor Dr. Mahadir Ahmad**  
Centre For Community Health Studies (Reach)  
Faculty of Health Sciences  
National University Of Malaysia
  - **Mohamad Azmeer Bin Sadali (P127323)**  
Audiology Programme  
Faculty of Health Sciences  
National University Of Malaysia
  - Approval letter File 2024



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<b>NAME OF ETHICS COMMITTEE/IRB:</b> Research Ethics Committee, The National University of Malaysia	<b>ETHICS COMMITTEE/IRB REF NO :</b> UKM PPI/111/8/JEP-2024-420
<b>PROTOCOL TITLE:</b> Efficacy Of The Adapted Version Of Audiologist-Delivered Low Intensity Psychological Intervention In Improving Severity And Distress Among Chronic Tinnitus Patients In Malaysia	
<b>PRINCIPAL INVESTIGATOR:</b> Dr. Wan Syafira Ishak Audiology Programme Center For Healthy Ageing And Wellness (H-Care) Faculty of Health Sciences The National University of Malaysia	

The following items  have been received and reviewed in connection with the above study to be conducted by the above investigator.

**Documents**

Research Application Form (UKM-JEP-BO01)  
 Review Form (UKM-JEP-BO02)  
 Non-Disclosure Agreement (UKM-JEP-BO03)  
 Conflict Of Interest Form  
 Research Proposal / Protocol  
 Participant Information Sheet:  
 Malay  English  Others :  
 Participant Consent Form:  
 Malay  English  Others :  
 Questionnaire:  
 Malay  English  Others :  
 Case report Form:  
 Malay  English  Others :  
 Curriculum Vitae of Researchers:  
 Principal  Co-researcher  Student  
 Good Clinical Practice Certificate (GCP)  
 Project Agreement

The Research Ethics Committee, The National University of Malaysia operates in accordance to the International Conference of Harmonization Good Clinical Practice Guidelines.

Comments (if any): -----

**Date of Approval: 30 May 2024**

**PROFESSOR DR. MOHD SHAHRIR MOHAMED SAID**  
Chairman  
Research Ethics Committee  
The National University of Malaysia



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