



**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,
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Tel.: +(6)03-33628888/ 33628205

Ref. : KKM/NIHSEC/P20-2613(12)
Date : **1-February-2021**

**MOHD NAQUIDDIN BIN JOHAR
HOSPITAL RAJA PEREMPUAN ZAINAB II**

Dear Dato'/ Dr/ Sir/ Madam,

LETTER OF ETHICAL APPROVAL:

NMRR-20-2715-57464 (IIR)

EFFECTIVENESS OF CARER-MEDIATED GAME-BASED CIRCUIT EXERCISE ON FUNCTIONS AND QUALITY OF LIFE AMONG STROKE SURVIVORS: A PROTOCOL FOR RANDOMIZED CONTROLLED TRIAL

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 including the Access to the Biological and Benefit Sharing Act 2017.

3. The investigators and sites involved in this study are:

Hospital Raja Perempuan Zainab II

Mohd Naquiddin Bin Johar (Principal / Coordinating Investigator)
Dr. Yusliza Azreen Binti Mohd Yusoff

4. The following study documents have been received and reviewed with reference to the above study:

Documents received and reviewed with reference to the above study:

1. Cover letter to MREC (Version 2.1, dated 28-01-2021)
2. Declaration of Conflict of Interest (COI) (Version 1, dated 15-12-2020)
3. Protocol (Version 2.1, dated 28-01-2021)
4. English: Patient Information Sheet/ Informed Consent Form (Version 2.1, dated 28-01-2021)
5. Malay: Patient Information Sheet/ Informed Consent Form (Version 2.1, dated 28-01-2021)
6. Questionnaire (Version 1, dated 15-12-2020)
7. Data Collection Form (Version 1, dated 15-12-2020)
8. Follow-up Review Report (Version 2.1, dated 28-01-2021)
9. IA-HOD-IA, CV and GCP Certification of:
 - Mohd Naquiddin Bin Johar
 - Dr. Yusliza Azreen Binti Mohd Yusoff

5. Please note that the approval is valid until **31-January-2022**. The following are to be reported upon receiving ethical approval. Required forms can be obtained from the National Medical Research Registry (NMRR) website.

- i. **Continuing Review Form** has to be submitted to MREC within 2 months (60 days) prior to the expiry of ethical approval.
- ii. **Study Final Report** upon study completion to the MREC.
- iii. 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.
- 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 **82 subjects/ patients/ respondents** targeted to be enrolled 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.

Project Sites:

HOSPITAL RAJA PEREMPUAN ZAINAB II

Decision by Medical Research & Ethics Committee:

() Approved

() Disapproved

Date of Approval : **01-February-2021**



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DR. HJH SALINA BINTI ABDUL AZIZ
Chairperson
Medical Research & Ethics Committee
Ministry of Health Malaysia
(MMC No: 27117)

c.c:

HRRC Hospital Perempuan Zainab II, Kelantan