PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM

(for adult subjects and interventional studies)

1. **Title of study**: Telephone delivered psychoeducational intervention to reduce psychophysical burden among dementia caregivers in east and west coast of Malaysia

2. **Name of investigator and institution:** Hashima E Nasreen, Universiti Islam Antarabangsa Malaysia; Nora Mat Zin, Universiti Islam Antarabangsa; Mohd Aznan Bin Md Aris, Universiti Islam Antarabangsa; Karimah Hanim Bt Abd Aziz, Universiti Islam Antarabangsa; Noorlaili Binti Mohd Tohit, Universiti Kebangsaan Malaysia.

   Study site: Hospital Tengku Ampuan Afzan (HTAA), Kuantan; Sultan Ahmad Shah Medical Centre (SASMEC), Kuantan and Universiti Kebangsaan Malaysia Medical Centre (UKMMC).

3. **Name of sponsor**: Ministry of Higher Education, Malaysia
   (FRGS/1/2021/SKK04/UIAM/02/1/0

4. **Introduction:**

   You are invited to participate in a research study because you may have negative experiences associated with the dementia caregiving, such as feeling overwhelmed, depression, frustration, loss of contact with family and friends, conflict in family, neglecting your own health, exhaustion, too much pressure of caregiving that requires psychoeducational intervention. The details of the research trial are described in this document. It is important that you understand why the research is being done and what it will involve. Please take your time to read through and consider this information carefully before you decide if you are willing to participate. Ask the study staff if anything is unclear or if you like more information. After you are properly satisfied that you understand this study, and that you wish to participate, you must sign this informed consent form. To participate in this study, you may be required to provide your doctor with information on your health history; you may harm yourself if you are not truthful with the information provided.

   Your participation in this study is voluntary. You do not have to be in this study if you do not want to. You may also refuse to answer any questions you do not want to answer. If you volunteer to be in this study, you may withdraw from it at any time. If you withdraw, any data collected from you up to your withdrawal will still be used for the study. Your refusal to participate or withdrawal will not affect any medical or health benefits to which you are otherwise entitled.

   This study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

5. **What is the purpose of the study?**

   The purpose of this study is to assess the efficacy of the telephone delivered psychoeducational intervention by the occupational therapists to reduce depressive symptoms and burden, and to improve caregiving self-efficacy and quality of life in distressed dementia caregivers. This

research is necessary because this will develop an invaluable and novel model of psychoeducational intervention for dementia caregivers. This will help in lowering the psychophysical burden of dementia caregivers and subsequently avert the income loss caused by it. Given the shortage of psychiatrists and geriatricians in Malaysia, and inaccessible care including lack of transport, living in rural settings, time pressure of caregiving, stigma associated with help seeking, this telephone delivered intervention has the potential to be emerged as a viable tool to bridge the mental health treatment gap among dementia caregivers.

In this study, the psychoeducation intervention will be compared with the usual care, which is currently available in the psychiatric clinics. This usual care is clinic based and does not address the specific needs for informal dementia caregivers in the community. However, the psychoeducational intervention based on cognitive behavioural therapy, developed according to the specific needs of the homebound dementia caregivers, which will be delivered by the trained occupational therapists over the phone for 10 sessions.

A total of 144 distressed dementia caregivers (72 in each arm) will be participating in this study in Malaysia. All subjects will be recruited in April-May 2022 and the intervention will provided over 12 weeks (3 months). In addition, we would like to meet with you before, mid (six week of intervention) and after intervention for checking your physical and mental health state at your doorstep. Each participant is expected to participate in the study including the baseline and post-intervention assessment for approximately 16 weeks (12 weeks $for\ intervention + 4\ weeks\ for\ assessments$).

6. What kind of study procedure will I receive?

If you agree to participate in the study, the doctor may need to perform some tests and examinations to determine if you are suitable for the study. If you are deemed suitable, you will be randomly (by chance, like flipping a coin) assigned to one of the treatment groups below. You have equal chance of being assigned to each of the groups. Neither you nor the doctor will know which group you are assigned to but in case of emergencies, this information is available to your doctor.

Group 1: Psychoeducation intervention consists of 10 sessions which will be delivered by the trained occupational therapists in a synchronized way via telephone or video call (WhatsApp or zoom) over the period of 12 weeks (3 months).

Please note that none of the audio or video calls will be recorded. The audio and video calls are only for the purpose of delivering the psychoeducation intervention, not for the purpose of any information collection.

Group 2: Usual care provided by the Jabatan Kesihatan Negeri of the Ministry of Health, Malaysia.

7. What will happen if I decide to take part?

The psychoeducation intervention will be delivered by 10 telephone calls over a period of 12 weeks (3 months).

- The initial call, will be conducted during the first week and will provide information about dementia, common psychosocial, emotional and medical effect of caregiving, skills of communicating with patients, resources available in the community and what will happen in the next future calls will be given. The call will last for about 30 – 40 minutes.
- At the second stage (2 – 11 weeks), 8 follow-up calls will be conducted to identify any new problems encountered, to discuss positive or negative changes in caregivers or patients, to apply psychoeducational information for a particular situation, and to assist caregivers in solving the problems. Each call will last for about 30 minutes.
- The last call (at 12 week) will address issues of termination by allowing caregivers to anticipate psychoeducation telephone contact come to an end, and encouraging reliance on the support network established during the intervention.

The assessment of the intervention will be conducted in three phases:

1. Baseline: Baseline assessment will be conducted before the intervention. Trained research assistant blinded with the intervention will assess the participants at their doorsteps for sociodemographic and economic information, social support, caregiving burden, caregiving self-efficacy, depressive symptoms, and quality of life through structured questionnaires.
2. Mid- and post-intervention: Mid- and post-intervention assessments will be conducted in the same way as the baseline assessment is conducted at the six and 13 weeks of intervention for caregiving burden, caregiving self-efficacy, depressive symptoms, and quality of life through structured interviews.

8. When will I receive the trial product and how should it be kept?

You will be given the psychoeducation intervention by telephone throughout the treatment period of the study. You must not share the intervention to anyone else. The study staff will instruct you on palliative care, person-centredness, zero-tolerance to abuse, adjustment strategies, other available support and consequences of transition. Please ensure that you follow their instructions and discuss with the study staff via phone call, message or in the next session if you have any problem.

9. What are my responsibilities when taking part in this study?

It is important that you answer all of the questions asked by the study staff honestly and completely. If you do not understand any topic please don't hesitate to ask the study staff for clarification. If your condition or circumstances change during the study, you must tell the study doctor. There may be certain medications that you cannot take while participating in this study. The doctor will discuss those medications with you. You must not take any other medications without consulting your study doctor. You must inform your study doctor immediately if you make any changes to any of your current treatments, even those which you have been taking for a long time.

It is very important that your study doctor be informed very rapidly of any eventual changes to your health during your participation in the study. For your own security, it is important that you follow your study doctor's instructions throughout the entire duration of the study.

10. What kind of treatment will I receive after my participation in the trial?

No study product will be given to you at the end of your participation in the study. Whether you complete the study or withdraw early, your doctor will discuss the best alternatives for your future treatment with you.

11. What are the potential risks and side effects of being in this study?

There will be minimal risk with the proposed intervention in participants' lives as the psychoeducational intervention has already been proven as beneficial in western countries as well as in Hong Kong, Taiwan and Japan. The intervention itself may introduce more stress or anxiety as it affects participant's schedule-works. However, a high dose of flexibility to adjust participants' time for delivering the intervention and good rapport will help minimizing those risks.

Please ask your study doctor if you need more information on risks and side effects. The trial staff will inform you in a timely manner about any new findings or changes about the study product which may affect your willingness to continue in this study. Where necessary, you may be asked to reconsent to participate.

12. What are the benefits of being in this study?

If you participate in this research, you will have following benefits: any care related stress and burden is expected to be reduced and thereby the quality of life and caregiving self-efficacy might be improved.

13. What if I am injured during this study?

If you are injured as a result of being in this study, you should contact your study doctor. In case of any injury resulting from the psychoeducation intervention of this study, the sponsor will pay for reasonable and necessary treatment.

The sponsor is not responsible for medical expenses due to pre-existing medical conditions, any underlying diseases, any ongoing treatment process, your negligence or willful misconduct, the negligence or willful misconduct of your study doctor at the study site or any third parties. You do not lose any of your legal rights to seek compensation by signing this form.

There will be no anticipated prorated payment for reimbursement for participating in the study. We shall give you a token of appreciation valued of RM10 per participation for three times after each assessment (baseline, mid- and post-intervention).

14. What are my alternatives if I do not participate in this study?

Your participation in this research is entirely voluntary. You do not have to participate in this study to get treatment for your disease or condition. You may refuse to take part in the study or you may withdraw yourself from participation in the study at any time. You will not face any problem for that.

15. Who is funding the research?

This study is sponsored by the Ministry of Higher Education, Malaysia under the Fundamental Research Grant Scheme (FRGS/1/2021/SKK04/UIAM/02/1) who will pay for all study requirements and procedures. All other drugs and procedures that are not required by the study but are part of your routine medical care will have to be paid by you or your insurance.

16. Can the research or my participation be terminated early?

The study doctor or the sponsor may due to concerns for your safety, stop the study or your participation at any time. If the study is stopped early for any reason you will be informed and arrangements made for your future care. You may be asked to attend a final follow-up visit.

17. Will my medical information be kept private?

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Individuals involved in this study and in your medical care, qualified monitors and auditors, the sponsor or its affiliates and governmental or regulatory authorities may inspect and copy your medical records, where appropriate and necessary. You will be informed about the study findings if you are interested in.

Data from the study may be archived for the purpose of analysis, but your identity will not be revealed at any time.

18. Who should I call if I have questions?

If you have any questions about the study or if you think you have a study related injury and you want information about treatment, please contact the study doctors:

1. Associate Professor Dr. Nora Mat Zin, Department of Psychiatry, Kulliyyah of Medicine, International Islamic University Malaysia, Kuantan Campus, Jalan Sultan Ahmad Shah, 25200 Kunatan, Pahang at telephone number 012-9819679.
2. Associate Professor Dr. Noorlaili Binti Mohd Tohit, Department of Family Medicine, Pre - Clinical Block, UKM Medical Center, 56000, Cheras, Kuala Lumpur at 019-3371167.

If you have any questions about your rights as a participant in this study, please contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-3362 8407 / 8205 / 8888.

INFORMED CONSENT FORM

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By signing below, I confirm the following:

- I have been given oral and written information for the above study and have read and understood the information given.
- I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my participation is voluntary and I can at any time free withdraw from the study without giving a reason and this will in no way affect my future treatment. I am not taking part in any other research study at this time. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the study doctor's (investigator's) instructions related to my participation in the study.
- I understand that study staff, qualified monitors and auditors, the sponsor or its affiliates, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL
- I will receive a copy of this subject information/informed consent form signed and dated to bring home.
- I agree/disagree* for my family doctor to be informed of my participation in this study.

Subject:

Signature: I/C number:

Name: Date:

Investigator conducting informed consent:

Signature: I/C number:

Name: Date:

Impartial witness: *(Required if subject is illiterate and contents of patient information sheet is orally communicated to subject)*

Signature: I/C number:

Name: Date: