Informed Consent Form

(National Geriatric Hospital)

Title of Project: **A MULTIDOMAIN INTERVENTION PROGRAM FOR OLDER PEOPLE WITH DEMENTIA: A PILOT STUDY**

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NCT#: NCT04948450

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Participant ID:_____

We invite you/ your loved one (in case the participant does not have the capacity to consent) to take part in a research study: ***A multidomain intervention programs for older people with dementia: a pilot study*** at nursing homes in Hanoi, Vietnam, which seeks to identify a more effective means of treating dementia. Taking part in this study is entirely voluntary. We urge you to discuss any questions about this study with us. Talk to your family and friends about it and take your time to make your decision. If you decide to participate/ you decide to let your loved one participate, you must sign this form to show that you want to take part.

Some of the essential information you will need to make the decision whether or not to participate in the research study has been outlined below.

Approximately 60 people will take part in this research in Hanoi, Vietnam.

Purpose of the Research

You are being offered the opportunity to take part in this research study because you are 60 years and older, have a diagnosis of dementia, and currently live in a nursing home in Hanoi. The purpose of this research is to assess the feasibility of a multidomain intervention program (physical, cognitive, social intervention, and management of metabolic and vascular risk factors) for older people with dementia and to investigate the effect of a multidomain intervention program on challenging behaviors, quality of life, functional ability, falls and sleep, global cognition and the specific cognitive domains (e.g., attention, memory, fluency and executive function), utilization of healthcare services, death rate for older people with dementia.

Procedures and Time Duration of the Procedures and Study

If you agree to take part in this study, you will be asked to complete the questionnaires at baseline, 6 months of intervention (45 minutes per interview) on cognition, quality of life, challenging behaviors, functional ability, falls, and sleep.

You will be randomly assigned to one of two treatment groups. Participants in both the intervention and control groups will be treated for dementia according to the recommendations of the Vietnam Alzheimer Disease and Neurocognitive Disorders Association.

You will meet the study physician to have an examination at baseline, 3 months, and 6 months. At each examination, you will undergo a physical examination, anthropometry (e.g., weight, and hip and waist circumference), blood pressure determination, pulse rate and rhythm, risks of cardiovascular and metabolic diseases (e.g., smoking, drinking, hypertension, coronary artery disease, dyslipidemia, atherosclerosis, diabetes) and blood test (e.g., lipid profile, HbA1C, and fasting glucose if you have diabetes).

Intervention group

In addition to what is given to both groups, if you are assigned to the intervention group, you will receive four components of the intervention: (1) physical activity intervention, (2) cognitive intervention, (3) social intervention, and (4) management of metabolic and vascular risk factors within 6 months. Physical activity and cognitive stimulation interventions will be performed on separate time.

(1) Physical activity intervention

Progressive resistance training (PRT) for the physical intervention will be provided at the nursing home for 45 minutes twice a week. You and your care staffs will be instructed to follow the prescribed PRT exercises for the rest of the week. You will be asked to write down the number of repetitions performed, practice duration, and days when you practice on your own in a training diary.

(2) Cognitive Intervention

Cognitive intervention will be organized twice weekly. Each session lasts about 45 minutes. You and your care staffs will be instructed on how to practice the assignments at nursing home for the rest of the week. You will be asked to write down the number of repetitions performed, practice duration, and days when you practice on your own in a training diary.

(3) Social intervention

Social intervention will be combined with physical and cognitive interventions through doing these in a group, playing games during exercises (dancing, throwing ball to each other) or doing cognitive stimulation therapy in a group.

(4) Management of metabolic and vascular risk factors

Metabolic and vascular risk factors of participants in the intervention group will be

evaluated by cardiologists and endocrinologists in the study.

You will be assessed the incidence rate of new chronic disease, change in blood pressure, weight and BMI, and hip and waist circumference, blood test (e.g., glucose, lipid parameters, fasting glucose and HbA1C if the person with dementia has diabetes) at 3 and 6 months. Blood tests are only to help doctors adjust for metabolic and vascular risk factors.

Control group

If you are assigned to the control group, you will receive general health advice every 3 months based on your physical examination and blood results. You will be provided information on the vascular risk factors for dementia and instruction and handouts on diet and exercise.

Discomforts and Risks

- Burden due to participation: you have to take time to participate in the intervention. You need to spend time to participate in cognitive, physical, and social intervention four times a week within 6 months and an examination at baseline, 3 months, 6 months.
- You may experience discomfort (pain, tiredness, injury) during the physical exercise, cognitive exercise, and blood test.
- You may experience risk of post-exercise such as muscle soreness/joint pain, risk of fall while doing the intervention.

Potential Benefits

The possible benefits that participants may experience from the intervention described in this research include increased cognitive status (or less cognitive decline in cognitive), increased quality of life, increased functional ability, and decreased number of falls, decreased sleep disturbances, reduction in the number of hospitalizations and visits to the emergency. However, there is no guarantee that you will benefit from being in this research.

The results of this research may guide the future treatment of dementia.

Statement of Confidentiality

A description of this clinical trial will be available on http:///www.ClinicalTrials.gov, identifier: NCT04948450, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the web site at any time.

Privacy and confidentiality measures

Your research records that are reviewed, stored, and analyzed at the National Geriatric Hospital will be kept in a secured area. Data under physical format (i.e., papers) will be stored at the Scientific Research Department, National Geriatric Hospital during the study and for 5 years after study completion. Paper-based data will be placed in compartments with locks and access is only given to study members. Only de-identified data will be made available to authorized personnel such as members of Hanoi Medical University ethics committee, the study's safety officer, the National Institute on Aging in the US upon request. Your samples collected for research purposes will be labeled with a code number and your initials.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Costs for Participation

Costs: No costs that subjects may be responsible for because of participation in the research.

Treatment and compensation for injury

If you are injured because of this intervention, you will be given free medical treatment at the National Geriatric Hospital.

Compensation for Participation

You will not receive any compensation for being in this research study.

Research Funding

The research study is funded by the Vietnam Alzheimer's Research Network (VAN) which is supported by the National Institute of Aging (NIA) of the National Institutes of Health (NIH).

Voluntary Participation

Taking part in this research study is voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled.

Contact Information for Questions or Concerns

You have the right to ask any questions you may have about this research. If you have questions, complaints or concerns or believe you may have developed an injury related to this research, please contact Dr. Nguyen Xuan Thanh at 0983277646.

If you have questions regarding your rights as a research participant or you have concerns or general questions about the research, please contact the research subjects protection advocate in the Subjects Protection Office at the National Geriatric Hospital at 02435764558.

I will provide a document with more information about participation in a research study and the Institutional Review Board (IRB), a group that reviews research to protect your rights. You can also visit the National Geriatric Hospital IRB for further details (1A Phuong Mai, Đong Đa, Ha Noi, Vietnam)

Signature and Consent/Permission to be in the Research

Before making the decision regarding enrollment in this research you should have:

- Discussed this study with an investigator,
- Reviewed the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Participant: By signing this consent form, you indicate that you are voluntarily choosing to take part in this research.

[Signature of participant] [date] [time] [print name]

Participant's Legally Authorized Representative (LAR): By signing below, you indicate that you give permission for the participant to take part in this research.

[Signature of participant's LAR] [date] [time] [print name]

(Signature of Participant's Legally Authorized Representative is required for people unable to give consent for themselves.)

Description of the Legally Authorized Representative's Authority to Act for Participant:

[Description of the authority]

Person Explaining the Research: Your signature below means that you have explained the research to the participant/participant representative and have answered any questions he/she has about the research.

[Signature of participant] [date] [time] [print name]

Only approved investigators for this research may explain the research and obtain informed consent. A witness or witness/translator is required when the participant cannot read the consent document, and it was read or translated.