INFORMED CONSENT FORM (ENGLISH VERSION)

Official Title: Intervention Effectiveness Towards Improving Physical and Mental Health for Post-stroke Patients.

ClinicalTrials.gov Identifier: NCT04941482.

Document Type: Study Protocol.

Version: 2.0 – 25 December 2021.

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Introduction and Invitation:

Hello Mr./Mrs. _____,

Thank you for taking the time to consider this research study. My name is **Nguyen Thi Phuong Thao**, and I am a physician and doctoral researcher at the Institute for Preventive Medicine and Public Health, Hanoi Medical University. We are conducting a study to evaluate a program aimed at improving the **physical and mental health of people after a stroke**. I am inviting you (or your legally authorized representative) to participate in this study because you have experienced a stroke and received treatment at the National Geriatric Hospital.

Before you decide, I would like to explain the study to you and what participation involves. Please feel free to ask any questions at any time. It is important that you understand all the information I provide. You have the **right to choose whether or not to participate**. If you decide not to take part or if you withdraw later, it will **not affect the care or benefits** you are entitled to at the hospital.

Why is this study being done?

Stroke can lead to many long-lasting problems in physical ability (like difficulty moving or taking care of oneself) and mental health (such as depression, fatigue, or memory issues). This study is being done to:

- **Assess the current state** of physical and mental health in stroke survivors, and identify any related factors or problems they are facing. Early detection of these issues is important so that patients can get timely help.

- **Test a new intervention program** that we have developed to improve physical and mental health after stroke. This program includes new methods of care, such as motivational counseling and use of home-based exercises and technology to monitor health. We want to see how effective this program is in helping stroke patients recover better.
The overall goal is to use the findings from this research to improve care for stroke patients. The results may guide health policymakers and doctors in providing better support and early

interventions for people after stroke. The study may also help raise community awareness about the needs of older adults recovering from stroke.

What will happen if I agree to participate?

If you agree to join the study, you will first undergo a **health evaluation interview** with our research team. We will ask you some questions and use survey forms to assess various aspects of your health, including: your medical history and stroke details, how the stroke has affected your movement and daily activities, your mood and energy levels, and some questions to evaluate your memory and thinking. This initial assessment will take about **20–30 minutes** of your time. The questions may cover topics like any difficulties in walking or self-care, feelings of sadness or fatigue, and your daily routines. You can skip any question that makes you uncomfortable or take a break at any time during the interview.

After this assessment, **one of two things may happen** as part of the study:

- If our evaluation shows that you have some physical or mental health challenges after your stroke (for example, signs of depression, fatigue, or difficulty with daily activities), you will be **invited to join an early intervention program** that we are testing. This program involves new methods of care to help improve your health. Specifically, the program includes **Motivational Interviewing therapy** (a type of one-on-one counseling to support you emotionally and motivate you in rehabilitation) and a **Home-Based Rehabilitation exercise program** (where a therapist will guide you through exercises you can do at home to improve your physical function). We believe these methods together can enhance your recovery.
- If you do not have any significant issues identified, or if you choose not to join the intervention program, you will continue to receive the standard care that all patients get after stroke. This includes routine check-ups and any necessary referrals (for example, if you show symptoms of depression, we would refer you to a specialist as per usual care).

Important: This study is **randomized**, which means that if you are eligible for the intervention program, a computer will randomly assign you to one of two groups: one group will receive the new intervention program (counseling + home exercise), and the other group will receive **standard care** (regular medical care and general advice) for the same duration. Neither you nor the researchers will choose the group – it is like a flip of a coin. This is done to fairly compare outcomes between those who get the new program and those who do not, in order to see if the new program really makes a difference. If you are assigned to the standard care group, you will **not** receive the special counseling sessions or therapist home visits during the study, but you will still receive all the usual treatments and follow-up that you normally would for your condition. **No matter which group** you are in, if our initial assessment or any follow-up finds a serious health concern, we will ensure you get proper medical referral or attention.

What will the intervention involve (if I receive it)? If you are in the intervention group, you will:
- Participate in **Motivational Interviewing sessions** with a trained counselor. These are private

talks (about 1 hour each) focused on helping you adjust to life after stroke, set personal recovery goals, and overcome any worries or lack of motivation you might have. The counselor will meet you approximately once a week in the first month, then every two weeks for the next two months. In total, there will be about 8 sessions over 3 months. These sessions will take place at the hospital (or by phone/online if in-person is not possible) at scheduled times convenient for you.

- Follow a **Home-Based Rehabilitation exercise plan** for 6 months. A physiotherapist will design exercises tailored to you (for example, exercises to strengthen your weak side, improve balance, practice walking or using your arm). The therapist will visit you at your home (or have you come to the hospital outpatient department) to guide you through exercises: initially once a week, then less frequently as you improve (biweekly, then monthly towards the end). There will be about 10–12 visits in total. You and your family will be taught how to safely do exercises daily. We will give you some educational materials (like a booklet or video) to assist with practicing exercises. The therapist will also check on your progress and advise on any difficulties you face at home.

- Undergo **periodic evaluations**: We will ask you to come for follow-up visits at approximately 1 month, 3 months, and 6 months after the start of the program. At each of these follow-ups, we will repeat some of the initial survey questions (like filling out the PHQ-9 for mood, etc.) to see how you are doing. At some visits, we may also do a brief non-invasive measurement of your brain activity using a device called fNIRS (functional near-infrared spectroscopy) – this involves wearing a sensor headband on your forehead for a few minutes while doing a thinking task, to measure blood flow in the brain. This device is safe and painless (it just shines light into the scalp). We do this to see if there are improvements in brain function corresponding to improvements in your mood. We will explain the procedure in detail beforehand if you undergo this test.

The **total duration** of your participation will be about **6 months**. During this time, aside from the study-specific activities, you will continue to receive your regular medical care from your doctors. We will coordinate the study visits with your routine appointments when possible to avoid extra trips. Each study follow-up visit (for assessments) will last about 20-30 minutes, similar to the baseline interview.

If you are in the **standard care group**, your involvement will be:
- Continue with the standard medical care plan prescribed by your doctors (this could include medications, routine physical therapy referrals, etc., as needed).

- We will invite you for the same follow-up evaluation visits at 1, 3, and 6 months to fill out the surveys (PHQ-9, etc.) and possibly do the fNIRS measurement at 3 and 6 months. This is so we can compare your progress with those receiving the special program.

- You will receive general advice on post-stroke care and may be given some informational brochures about exercises and healthy habits. However, you will **not** receive the personalized counseling sessions or home visits from our therapists during the 6-month study period. (After

the study is over, we can offer you the intervention if it is found to be beneficial, or refer you to similar services, should you be interested.)

Regardless of group, the **study team will stay in contact** with you. We may call you periodically to remind you of appointments or check on how you are doing. If you experience any problems or have questions during the study, you can contact us anytime (see contact information below).

How long will I be in the study?

Your active participation in this research will last for about **6 months** from the time of enrollment. The initial interview is a one-time visit (~30 minutes). The intervention program (if you receive it) runs over 6 months with varying frequency of sessions (as described). The follow-up assessments at 1, 3, and 6 months will each take about 30 minutes. In total, if you are in the intervention group, you might spend a few hours per month on study activities (including doing exercises at home). If you are in the standard care group, your time commitment is only the follow-up assessment visits. After the final 6-month visit, your involvement in the study ends, and no further data will be collected from you.

The entire study (for all participants) is expected to be conducted in 2021–2022. We plan to include about **92 participants** in total in this study (approximately 46 people in each group). You will be one of these participants if you agree to join. (Initially, we anticipated up to ~162 people might be screened to end up with the required number of participants for the intervention trial.)

What are the risks or discomforts of participating?

This study **does not involve any invasive medical procedures or experimental drugs**. Therefore, the risks are very low. However, here are some possible considerations:

- **Emotional Discomfort:** Some of the questions we ask (especially about your mood or difficulties after stroke) may be personal or sensitive. Talking about these issues might make you feel upset or sad. Please remember you **do not have to answer any question** that makes you uncomfortable. You can decline to discuss any topic or take a break at any time. Our team is trained to handle these conversations sensitively. The goal is to help, not to make you distressed. If you do feel upset, we can pause the interview or stop entirely. We can also refer you to counseling or support services if needed.

- **Fatigue or Inconvenience:** Participating in the intervention means committing time and effort to attend sessions and do exercises. Some people might find the exercises tiring (though they will be tailored to your ability). We will schedule sessions at convenient times and locations to minimize burden. If you ever feel too tired or unwell to continue an activity, you can inform the therapist and rest or reschedule. We aim to integrate the exercises into your routine so that it doesn't feel overwhelming.

- **Privacy:** We will be collecting personal health information about you. There is a very small risk of loss of confidentiality. However, we have strict safeguards in place to protect your data (see the confidentiality section below).

- **Physical Risk:** The exercises are generally low-risk and part of standard stroke rehabilitation (like moving your limbs, walking practice). There is a minor risk of muscle soreness or strain, or losing balance during an exercise. A trained therapist will be supervising initially to ensure safety. They will teach you and your family how to do exercises safely. We advise having someone nearby during your home exercises in case you need assistance. We will also ask you to use any prescribed assistive devices (cane, walker) as recommended to prevent falls. If you ever feel pain or dizziness while exercising, you should stop and inform the therapist or your doctor. We will adjust the program to your comfort.

- **fNIRS procedure:** The fNIRS brain monitoring involves wearing a sensor cap that snugly fits on your forehead. It shines weak infrared light into the scalp. This procedure is **non-invasive and painless**. You may feel slight pressure from the headband. There are no known risks from fNIRS; it does not emit any harmful radiation (it's just light). A potential minor discomfort is sitting still for several minutes during the measurement. If you feel uncomfortable at any time, we can stop the measurement.

Aside from these, we do not expect any other risks. The interventions used (motivational interviewing and guided rehabilitation) are generally beneficial and part of accepted care practices. We will closely monitor your health. If any unexpected medical issue happens during the study (for example, if you have another stroke or any complication), we will ensure you get prompt medical attention. You are free to withdraw from the study if continuing becomes too risky or burdensome for you.

What are the benefits of participating?

While we cannot guarantee personal benefits, possible **benefits to you** may include:

- **Free Health Evaluation:** By joining the study, you receive thorough assessments of your mental and physical health at no cost. This might identify issues that can be addressed early. For instance, if we detect high fatigue or depressive symptoms, we will inform you and can refer you for appropriate care.

- **Intervention Program (if applicable):** If you are selected for the intervention group, you will receive personalized counseling and rehabilitation guidance without any charge. These services might not typically be available in a standard care setting, and they could help improve your recovery, mood, and independence. Many patients find motivational interviewing helpful in coping with life changes, and structured exercise can significantly improve strength and daily functioning.

- **Standard Care:** If you are in the standard care group, you still benefit from close follow-up. The regular check-ins and questionnaires might indirectly benefit you by increasing awareness of your own health progress. If any of your responses suggest a problem (like severe depression), we will alert your treating doctor or help arrange consultation as appropriate, even if you are not in the intervention group. In other words, no one will be neglected.

- **Contribution to Science and Future Patients:** By participating, you are contributing valuable information that could help improve treatment for future stroke patients. The

knowledge gained might lead to better programs or services for people like you on a wider scale. While this is an altruistic benefit, many participants take satisfaction in knowing they helped others by advancing medical understanding.

It is important to note that **you will not receive any monetary compensation** for participating in this study. However, you will not have to pay for any study-related procedures or materials, and the intervention (if you receive it) is provided free of charge. We will cover the costs of the counseling sessions and any materials (like exercise equipment, if needed for training, or travel support for therapists).

We also hope the study might benefit the community and healthcare system by providing evidence to support early integrated rehabilitation programs. This could influence health policy to allocate more resources for stroke aftercare.

Do I have to pay anything to be in this study?

No. There is no cost to you for any part of the research. All the evaluations (interviews, questionnaires, fNIRS tests) and the intervention program (counseling sessions, therapist home visits, exercise materials) are provided by the study without charge. We will try to schedule study activities alongside your regular hospital visits to avoid additional travel expenses. If you do incur any reasonable travel costs solely due to study participation (for example, coming to an extra follow-up appointment), please let us know – the study may be able to reimburse or assist with transport to ease that burden. We want to ensure that taking part does not cause you financial hardship. There is no special compensation for participating, but again, you will not have to pay for any research procedures.

Can I leave the study once I start?

Yes, absolutely. Participation is entirely voluntary. You have the right to withdraw from the study at any point, for any reason. If you decide to participate now but later change your mind, you can stop. This includes during the initial interview or at any time during the 6-month study period. You do not need to give a reason for withdrawing (though it would be helpful for us to know if, for instance, you found something uncomfortable, so we can learn from it).

If you choose to withdraw:

- It will **not affect your medical care or legal rights** in any way. You will continue to receive the standard treatment for your condition from the hospital, just as you would if you never joined the study.

- We will ask you if we can continue to use the data we collected from you up to that point. If you prefer that we do not use it, we will destroy your identifiable study data as per your request. However, data that has already been analyzed or included in aggregate results cannot be removed.

- If you withdraw from the intervention program, we might ask if you are okay with a final follow-up or sharing why you withdrew (to help improve future studies), but that is completely

up to you. Even after completing the study, if you later have concerns about your data or participation, you can contact us.

The study team or sponsor can also withdraw you from the study if necessary (for example, if your doctor thinks continuing is medically not in your best interest, or if the study is halted for any reason). If that occurs, we will explain why and ensure your care continues appropriately outside the study.

How will my information be kept confidential?

We take your privacy very seriously. **All information you provide will be kept confidential** to the fullest extent allowed by law. Here are the steps we take to protect your data:

- When you join the study, we assign you a **participant code (ID number)**. This code, rather than your name, is used on all data forms, survey answers, and in the computer database. Your consent form with your name will be stored separately from the data.

- The data (questionnaire scores, etc.) we collect is stored in a secure computer database. This database is password-protected and encrypted. Only the principal investigator and authorized research staff have access to the password. Any paper records (like your initial survey answers on paper) are kept in a locked file cabinet in a secure research office. Only the study team can access these files.

- We will not share your personal data with anyone outside the research team without your permission. Your treating doctors will be informed you are in the study only if needed for medical coordination, but they will not see your answers to surveys unless there is something clinically important (for example, if we find you are severely depressed and at risk, we would inform a doctor to help you – but we would discuss that with you).

- In any reports or publications of the research, **your name or any identifying details will not be used**. Results will be presented in aggregate (for example, "the intervention group's average PHQ-9 score decreased by X points") or using coded IDs if describing individual cases. It will not be possible for readers to identify you from the published results.

- All research personnel are trained in research ethics and confidentiality. They will not disclose any personal information about participants. We also have a certificate of ethical approval, which means we are bound to these confidentiality standards.

- The only exception to confidentiality would be if required by law – for example, if during the study you reveal intent to harm yourself or others, or abuse that we are obligated to report to authorities for safety – then we might have to break confidentiality to ensure safety. However, such situations are rare and would be handled with care and only to the necessary extent.

- After the study is over, we will archive the data without identifiers. We may keep the de-identified data for future research or educational purposes. Your identity will not be linked to the data in any future use. If you do not want your data used for any purpose beyond this study, you can let us know and we will destroy it after this study's main analyses are done. By signing the consent, you agree that the research team can collect and use your information

for the purposes of this study. We will ask a separate permission if, in the future, there is a need to use identifiable information or contact you for follow-up studies.

Your Rights as a Research Participant:

Participating in research is completely voluntary. You have the right to:
- Decide not to participate at all – in which case your medical care and rights will not be affected in any way.

- Participate now and change your mind later. You can withdraw from the study at any time. There is no penalty or loss of benefits if you do so.

- Refuse to answer any specific question or refuse any specific procedure in the study. For example, if you are okay with the interviews but do not want the fNIRS test, you can decline that. We will continue to include you in other parts as you wish.

- Be given a copy of this Information and Consent Form to keep (if you want) so you can review it and think about it or discuss with family before making a decision.

- Ask questions at any time. If there is any part of the study or this form you do not understand, please ask the investigator to explain. We want you to be fully informed.

- Receive new information. If we discover any new significant information during the study that might affect your willingness to continue (for example, if any risk comes to light), we will inform you promptly.

- Access your data. You may request to see the information we have collected from you during the study and correct it if necessary (to the extent that it does not compromise the study integrity, which is usually not an issue).- Contact the investigators or the ethics committee if you have concerns about your rights or issues with the study (contact info below).

Statement of Approval:

This research protocol has been reviewed and approved by the Ethics Committee of Hanoi Medical University. The ethics approval code is **494/GCN-HDDDNCYHN-DHYHN**, dated December 05, 2021. This means an independent committee has examined the study to ensure that your rights and welfare are protected, and that the study meets ethical standards. If you have any ethical concerns or questions about your rights as a participant, you can contact this committee through the provided channels (we can provide contact details if you wish, such as the Secretary of the IRB at HMU).

Contacts for Questions or Problems:

If you have **any questions** about this study or if you experience any problems related to the research, you may contact the principal investigator or the study team at any time. You can reach us at: **Dr. Nguyen Thi Phuong Thao** – Principal Investigator
Phone: **0916 911 897,** Email: **dr.nguyenthiphuongthao.hmu@gmail.com.**

You can call for any reason – whether it's to ask for clarification about the study procedures, report how you feel during the study, or if you decide to withdraw. If you have questions about your rights or if you have any complaints that you prefer to address to someone not directly part of the research team, you may contact:

- **Hanoi Medical University IRB (Ethics Committee)** – (Address: 1 Ton That Tung, Dong Da, Hanoi.

We are very grateful for your time and consideration. Whatever you decide, we thank you for your willingness to learn about this study. If you do choose to participate, you will be given a copy of this signed consent form for your records.

Participant's Statement:

I have read (or had read to me) the information above. I have had the opportunity to ask questions and received satisfactory answers. I understand the purpose of the study and what is expected of me. I understand that my participation is voluntary and that I can withdraw at any time without affecting my healthcare. I agree to participate in this study.

Signature (or Thumbprint) of Participant: ____

Date:___

Name of Participant (printed): _____

Person Obtaining Consent (Investigator or Designee):

I confirm that I have explained the study to the participant named above and answered all questions truthfully. I believe that the participant understands what is involved and freely agrees to participate.

Signature of Researcher: ____

Date: ___

Name of Researcher (printed): _____

(Each signer will receive a copy of this form)