**Patient’s information sheet and consent** **(English version)**

ID NO:

**INFORMATION SHEET**

**PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM**

*(for adult subjects and interventional studies)*

1. **Title of study**: Influence Of Stroke Riskometer© In Making Lifestyle Changes Among Urban Dwelling Stroke Caregivers: A Pilot Study.
2. **Name of investigator and institution:** Dr Radhiyah Hussin, Department of Family Medicine, University Kebangsaan Malaysia.
3. **Name of sponsor**: None
4. **Introduction:**

You are invited to participate in a research study because you have the risk to develop stroke since you are related to a family member who had a stroke. Stroke is a condition which occurs when there is a blood clot which blocks the blood supply to the brain or can occur as a result of bursting brain arteries. Stroke can affect the victim in many ways namely; sudden paralysis of one side of body, trouble speaking and seeing, and trouble with memory. Stroke patients usually need help in taking care of themselves. Person who takes care of their daily needs are called caregiver.

You qualify for this research because you are a stroke caregiver. We would like to include you in our study to assess how does a new mobile health application that calculate your risk of getting stroke will affect your lifestyle towards healthier choice after 3 months in the study. 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.

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.

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

* The purpose of this study is to determine if Stroke Riskometer Application will help to influence you to make the necessary lifestyle changes to prevent yourself from getting a stroke.
* To assess risk of stroke among stroke caregivers at 5 and 10 years.

A total 80 subjects like you from Klang Valley area will be participating in this study.

The whole study will last about 6 months and your participation will be about 12 weeks. You will be seen by our team 3 times during the whole 3 months and will be contacted through phone to check your progress. The first visit will be during recruitment and assessment, second visit will be at intervention phase and third visit will be at the end of intervention. We will collect information like age, education, income, medical problem, medication and lifestyle habit. We will measure your weight, height, blood pressure and waist circumference.

1. **What kind of study products 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.

The study products do not contain porcine, bovine or animal components.

You will be allocated to one of the two types of treatment arms.

* Group 1(Intervention arm) :

Stroke Riskometer Application as intervention, downloaded to your smartphone for free. There are 20 questions that can be answered within 2 minutes using recall method. Your percentage of getting stroke in 5 and 10 years will be calculated and shown to you. We will be monitoring your risk factors in 3 months and look whether you are able to change your lifestyle towards healthier choice after knowing your risk of getting stroke. You will be able to use the application and monitor yourself for the next 3 months.

* Group 2 ( Control arm) :

If you are allocated to this arm you will receive standard assessment using Stroke

Riskometer application and calculate your risk of getting stroke but you will not have access to the application.

1. **What will happen if I decide to take part?**
2. At the first visit an interview session will be conducted by researcher to assess your background socio-economic data, caregiving status and any medical or mental illness. There will be an assessment for your lifestyle such as diet, physical activity, smoking, alcohol intake.
3. During the first assessment, we are going to measure your weight, height, blood pressure and sugar profile. It will be performed by a trained health care provider.
4. Upon entering the study, you will be taught on how to download the application and how to use it.
5. After 12 weeks we are going to assess your risk of getting stroke and physical examination again and compare with previous data.
6. There will be no blood taking or bodily fluid sample taken other than blood capillary sugar during first and final visit.
7. During the trial if we found out any medical issues that need to be addressed and treated we are going to refer to the primary team
8. **When will I receive the trial product and how should it be kept?**

You will be given access to the Stroke Riskometer App to use throughout the period of the study. You must not use the app to enter anyone else’s information other than your own during the study. The study staff will instruct you on how the product must be handled.

1. **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. It is very important that your study doctor be informed immediately if you experience any changes to your health during your participation in the study.

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

The 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.

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

There are no known potential risks or side effects while being in this study in both intervention and control group.

1. **What are the benefits of being in this study?**

There may or may not be any benefits to you. Information obtained from this study will help improve the treatment or management of other participants with the same disease or condition. The Stroke Riskometer application can be used by you to monitor your progress to reduce your own risk for developing stroke, and guide you to make healthy lifestyle choices.

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

You do not have to participate in this study to get treatment for your disease or condition. The study doctor will discuss in more details the benefits and risks of those treatments with you.

1. **Who is funding the research?**

This study is self-sponsored. 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.

1. **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.

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

1. **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 doctor,

Dr. Radhiyah binti Hussin at telephone number 012 3258192 or

Associate Professor Dr Aznida Firzah Abdul Aziz (Tel: 03 91456117)

**INFORMED CONSENT FORM**

Title of Study: Influence of Stroke Riskometer in making lifestyle changes among urban dwelling stroke caregivers; a pilot study.

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 participant information sheet is orally communicated to subject)*

|  |  |  |  |
| --- | --- | --- | --- |
| Signature: |  | I/C number: |  |
| Name: |  | Date: |  |