PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

1. Title of study: The effectiveness of pressure garment in the management of spasticity and upper extremity function among stroke patients.

2. Name of investigator and institution: Ooi Hwa Kee
Occupational Therapy Unit,
Universiti Kebangsaan Malaysia.

3. Introduction:

You are invited to participate in a research study because you have stroke that can cause poor functional use in the affected upper limb. Therefore, a new intervention using pressure garment (Figure 1) will be carried out to measure the effectiveness. The details of the research 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 therapist 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 therapist with information on your health history; you may harm yourself if you are not truthful with the information provided.

Figure 1. Pressure garment – Glove.

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.

4. What is the purpose of the study?

The purpose of this study is to evaluate the effectiveness of pressure garment in the management

of spasticity and hand function among stroke patients. This research is necessary because the existing treatment such as air splint and hand splint, the effectiveness is only short term and these treatment is reduced hand function when apply on your hand.
According to research that had done in oversea, pressure garment was able to reduce spasticity and able to improve hand function at the affected side.

A total of forty-six subjects like you will be participating in this study. The whole study will last about one year and your participation will be about six weeks only.

5. What kind of study procedures will I receive?

If you agree to participate in the study, the therapist 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.

Group 1:

a) Participants will be given pressure garment (custom fitted long glove) at the upper extremity affected side. Your affected hand and forearm will be measured by therapist.
b) Participants will be monitored by therapist once a week. Necessary adjustment will be made on the pressure garment to maintain its tight fit.
c) Participants will be required to wear the pressure garment for six hours a day for six weeks continuously and a checklist will be given to record the wearing time. They will be instructed to wear three hours in the morning, another three hours in the afternoon and remove pressure garment at night.
d) Participants will undergo Occupational Therapy programme as usual for two hours a week for six weeks continuously. They will be required to wear pressure garment during their weekly Occupational Therapy programme.
e) During the study period, participants are not allow to wear hand splint.

Group 2:

a) Participants will undergo Occupational Therapy programme as usual for two hours a week for six weeks continuously.

Measurements of the following areas will be obtained by the researcher pre- (Initial assessment) and post-intervention (after 6 weeks) for all participants in both groups:
1) Spasticity to be measured using Modified Modified Ashworth Scale (MMAS).
2) Upper extremity function to be measured using Jebsen-Taylor Hand Function Test for performance-based measurement.
3) Disabilities of Arm, Shoulder and Hand (DASH) Outcome Measure for self-report upper extremity function.

For participants in the group 1, measurements of all outcomes post intervention will be performed an hour after the pressure garment was removed.

6. When will I receive the pressure garment and how should it be kept?

Before the study start on the first week of intervention, pressure garment will be given by therapist to participants in group 1. You must not give pressure garment to anyone else. The study therapist will instruct you on how the pressure garment must be handled and stored. Please ensure that you bring the pressure garment when you have follow up at Occupational Therapy Unit.

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

It is important that you answer all of the questions asked by the study therapist honestly and completely. If your condition or circumstances change during the study, you must tell the study therapist. You must inform your study therapist immediately if you make any changes to any of your current treatments.

It is very important that your study therapist 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 therapist's instructions throughout the entire duration of the study.

8. 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 therapist will discuss the best alternatives for your future treatment with you.

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

The potential risks of applying pressure garment in this study are:
a) Upper extremity become discoloured (white/ blue) or skin allergy.
b) Pain and loss of sensation in the affected hand.
c) The pressure garment is too tight and painful.
The participants are allow to remove pressure garment if these symptoms occur and inform your therapist immediately.

10. 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.

11. 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 therapist. In the event of a bodily injury or illness directly resulting from the pressure garment or a procedure required for this study, the hospital will pay for reasonable and necessary treatment. The hospital

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 therapist or the study site or any third parties. You do not lose any of your legal rights to seek compensation by signing this form.

12. 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 condition. You can continue with the treatment you received.

13. Who is funding the research?

This study is funded by the therapist herself. No external funding or grant is received. Therefore, no payment will be given to participants for participating in this study. The participants will not be charged for the treatment and procedures related to the study.

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

The study therapist 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. All the participants will have the opportunity to see their own measurement result in the final follow up visit.

15. Will my medical information be kept private?

Yes. All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. No personal identifiers will be noted. All the data will be grouped and not reported individually. Once the data have been gathered and the research completed, the raw materials will be kept in the locked file cabinet in the office of the Principle Investigator. Electronic data will be securely kept using password. Only the Principle Investigator will have access to the material. After 3 years, the material will be shredded and discarded.

A separate optional consent will be obtained from you if new information relevant to consent becomes available in the study. When publishing or presenting the study results, your identity will not be revealed without your expressed consent.

16. 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 therapist, Mrs Ooi Hwa Kee at telephone number 016-5322535.

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 03-2287 4032.

INFORMED CONSENT FORM

Title of Study: The effectiveness of pressure garment in the management of spasticity and upper extremity function among stroke patients.

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 anytime 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 therapist's (investigator's) instructions related to my participation in the study.
- All personal details will be treated as CONFIDENTIAL.
- I will receive a copy of this subject information/informed consent form signed and dated to bring home.

Subject:

Signature: I/C number:

Name: Date:

Investigator conducting informed consent:

Signature: I/C number:

Name: Date:

Impartial witness:

Signature: I/C number:

Name: Date: