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MACQUARIE University
SYDNEY·AUSTRALIA

Information Statement and Consent Form

HREC Project Number: 520231306850151

Research Project Title: Effectiveness of a mobility booster program (*HiWalk*) in long-term community stroke rehabilitation

Chief Investigator: Dr Kate Scrivener, Senior Lecturer

You are invited to participate in a trial of the HiWalk program. This document provides information about this trial. Please take the time to read the information carefully and ask any questions you may have.

If you decide to take part, you will be asked to sign the consent section and complete the check boxes. This tells us you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the use of your personal and health information as described.

What does this research study aim to do?

Walking in the longer-term after a stroke can be challenging. Walking speed can be slow and it can be harder to walk long distances. Improving walking speed and distance can help stroke survivors to complete their daily life activities and to access the community.

This trial investigates a walking booster program – HiWalk. HiWalk is a physiotherapy-led program that occurs daily for 3-weeks. HiWalk consists of individually modified exercises and activities designed to improve walking after stroke.

In this trial we are investigating if the addition of HiWalk after stroke is acceptable to stroke survivors and if there are signs of benefit e.g. improvement in walking.

What does participation in this research involve?

If you agree to participate in this trial you will undergo an assessment with a physiotherapist. The assessment will take approximately one hour. The therapist will collect some health information and measure your walking and balance ability.

You may be asked to wear a device that is taped on your leg for a few days in order to measure your activity levels. The investigator will explain the device and any risks to you in the session. You may decide to accept or decline wearing the device without impacting your overall study participation.

After the assessment session each participant in the trial will be randomly assigned to one of two groups. The first group will receive the HiWalk program (walking training up to 3-hours a day, 5 days per week for a period of 3-weeks). The second group will not receive the intervention, they will continue their usual activities. This group will be monitored regularly and will be measured at the same times as the first group. At the completion of the trial, this group will be offered a physiotherapy consultation that is free of charge.

Regardless of which group you are assigned to, you will participate in two further assessments at 4-weeks and 6-months after commencing the study. These assessments will take approximately one hour. Additionally, each month you will be called by a study team member and asked questions about your walking, these calls will take approximately 10 minutes.

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All assessments and training will be conducted at a community rehabilitation gym, those volunteering to participate will need to have/arrange their own transport to the gym.

After the study, you may be invited to participate in an interview about the study and your opinion of the HiWalk program. The interview will be completed online with a study team member and will take approximately 30 minutes. You may decide to accept or decline participation in the interview without impacting your overall study participation.

Is participation voluntary?

Yes, participation in this study is entirely voluntary. If you do consent to participate, you may withdraw at any time during the study without having to give a reason and without consequence.

If you are assigned to the HiWalk program group, you may withdraw your consent for program participation but remain in the study and complete the assessments, or you may withdraw from the study completely. Further, if you are participating in wearing the activity monitor or completing the interview you can choose to withdraw your consent from that component but continue your participation in the main study.

If you decide to withdraw from the study, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team. The withdrawal of consent can occur at any time up to the date of your final assessment in the study.

If you decide to leave the research study, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research study.

Are there any possible benefits in taking part?

While we intend that this research study furthers medical knowledge and improves treatment of stroke in the future, it may not be of direct benefit to you.

Are there any risks or disadvantages in taking part?

There are no associated costs for participation in this research, nor will you be paid.

Although it is unlikely, there is a small risk that participants in the walking training group could injure themselves while training. To minimise this risk, you will receive an individually tailored program that is supervised by a trained health professional. The level of difficulty will only be progressed by the physiotherapist when it is safe to do so. In the unlikely event of an injury occurring, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. As you are eligible for Medicare, any medical treatment required to treat the injury or complication, will be provided free of charge as a public patient in any Australian public hospital.

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If you decide to wear an activity monitor the risk involved is skin irritation where the monitor is taped to your leg. You will receive instructions and advice on how to manage this if it occurs.

You can seek additional support or report any concerns to Dr Kate Scrivener (kate.scrivener@mq.edu.au or 02 9850 6625).

Can I have other treatments during this research project?

Whilst you are participating in this research project, you may continue to receive any other treatments and interventions.

Who can participate in this investigation?

To be eligible to take part in this study, you must be:

- Be an adult (aged 18 years or older)
- Have had a stroke more than 6 months but less than 8 years ago
- Be able to walk a short distance without aid or physical assistance, however find walking challenging
- Be able to follow instructions to participate in the therapy
- Demonstrate adequate English language fluency

What will happen to information about me?

By signing the consent form you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. No individual will be identified in any data or information published. The only people who will have access to the study data will be the HiWalk investigators and any research assistants working on this study. On study completion, all data not yet de-identified will have any identifying information such as your name or contact information removed. The de-identified data will be stored on a secure storage platform from Macquarie University and only relevant study team members will have access. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

It is anticipated that the results of this research study will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission.

Will the data from the study be safe?

Yes, procedures are in place to manage the safety of your data. Most data will be de-identified meaning it will only contain your study participant number and will not include details such as your name. However, if you are assigned to the HiWalk program group; your name, contact details and any important clinical information will be provided to the therapists facilitating your program. This information will be provided in a password protected file, via a secure University storage platform and the therapists will only have access whilst the program is occurring.

Study data will be stored for the duration of the study on a secure storage platform from Macquarie University, and only relevant study team members will have access.

Interview recordings will be stored on the same secure server before they are transcribed. During transcription, all your personal information will be removed so that only de-identified information is

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analysed. The video/audio recordings of the interview will be destroyed after the study has been analysed.

After completion of the study your anonymised data will be archived in a data repository where other researchers will have open access to the data and would be able to reanalyse it. If you do not wish for this to occur, you may indicate this on the consent form below, in this case your data will not be added to the open data repository.

Who is organising and funding the research?

Dr Kate Scrivener is the study's coordinating principal investigator. The investigator team includes experienced stroke rehabilitation researchers from Macquarie, Monash and Sydney University. The interview component of this study is being conducted by Elisha Ball to meet the requirements of her Doctor of Philosophy in Health Sciences program at Macquarie University under the supervision of Dr Scrivener. The research study is being funded by the Stroke Foundation.

Additional research team members include: Prof Cath Dean (Macquarie University), A/Prof Joanne Glinsky (Macquarie University), Prof Natasha Lannin (Monash University), Prof Louise Ada (Sydney University) and A/Prof Petra Graham (Macquarie University).

Who has reviewed this research?

Ethical requirements for this study will be approved by the Macquarie University Human Research Ethics Committee. If you have any reservations or complaints about any of the ethical aspects of participating in this research, you may contact the Ethics Committee through the Director of Research Ethics (Telephone: (02) 9850 7854; or email ethics@mq.edu.au). Any complaint you make will be treated as confidential and investigated, and you will be informed of the outcomes.

Can I contact the research team?

Yes, if you have any questions, please do not hesitate to contact:

Name	Dr Kate Scrivener
Position	Senior Lecturer in Physiotherapy
Telephone	(02) 9850 6625
Email	kate.scrivener@mq.edu.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you can contact:

Reviewing HREC name	*Macquarie University Human Research Ethics Committee*
Telephone	*(02) 9850 4459*
Email	*Ethics.secretariat@mq.edu.au*

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Am I able to obtain the results of this study?

Yes, a short report of the overall results of this study will be available once the study is completed. You may also request your individual report of your results. If you are interested in obtaining a copy of these results, please email Dr Kate Scrivener (kate.scrivener@mq.edu.au).

When you have read this information, an investigator will discuss it with you further and answer any questions you may have.

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Participant Consent Form
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I, _____ (participant's name) have read (or where required have had read to me) and understand the information above and any question I have asked has been answered to my satisfaction. I agree to participate in this research, knowing I can withdraw from further participation in the research at any time during the study without consequence. I have been given a copy of this form to keep.

☐ I do	☐ I do not	Consent to wearing the activity monitor as directed.

☐ I do	☐ I do not	Consent to participating in the interview.

☐ I do	☐ I do not	Consent to the storage of an anonymised copy of my balance and mobility assessment data in an open data repository.

Participant's Name:_____

(Block letters)

Participant's Signature: Date:_____

Investigator's Name:_____

(Block letters)

Investigator's Signature: Date:_____

The ethical aspects of this study have been approved by the Macquarie University Human Research Ethics Committee. If you have any complaints or reservations about any ethical aspect of your participation in this research, you may contact the Committee through the Director, Research Ethics (telephone (02) 9850 7854; email ethics@mq.edu.au). Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

(INVESTIGATOR'S/ PARTICIPANT'S COPY)