CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Title of the study: Promoting Optimal Physical Exercise for Life (PROPEL) – aerobic exercise and self-management early after stroke to increase daily physical activity: a randomized trial

Principal investigator
Avril Mansfield, PhD
Scientist, Toronto Rehabilitation Institute – UHN
Phone: 416-597-3422 ext. 7831

Contact Information
Anthony Aqui, MSc
Clinical Research Analyst, Toronto Rehabilitation Institute – UHN
Phone: 416-597-3422 ext 7826

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Introduction

You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on study's risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary.

Background and purpose

Research shows that physical exercise is good for people with stroke. However, many people with stroke do not perform enough exercise. The purpose of this study is to see if a fitness program delivered during rehabilitation helps people with stroke to be more physically active *after* leaving the rehabilitation hospital. You are being asked to participate in this study because you completed this fitness program during your rehabilitation stay at the Toronto Rehabilitation Institute.

Study visits and procedures

If you agree to participate in this study, we will measure how much physical activity you do over the 6-months after you finish out-patient rehabilitation at the Toronto Rehabilitation Institute. We will do this by asking you to wear an activity monitor on your wrist for three 1-week periods: 1-month, 4-months, and 6-months after you finish rehabilitation. The activity monitor looks like a watch and counts how many steps you take during the day. It also measures how fast your heart is beating. We will mail the activity monitor to you and ask you to return it in a postage-paid envelope. You can remove the activity monitor before you go to bed. You should remove the activity monitor before bathing/showing, if you go swimming, if it becomes uncomfortable to wear, or if you are requested to do so for any medical care.

Wrist activity monitor

Time	Time commitment	Tests and procedures	Location
Around the time of discharge from the hospital	~30 minutes	Tests of leg function, and memory Questionnaires about previous exercise habits and how you feel about exercise	Toronto Rehab
1-month post-discharge	~30 minutes	Activity monitoring Questionnaire about your physical activities	Your home (telephone call)
4-months post-discharge	~30 minutes		
6-months post-discharge	~30 minutes		

Some types of exercise might not be recorded by the activity monitor; for example, if you go swimming or do exercises where you don't walk around a lot (like seated exercises at home). For this reason, we will also ask you to complete a questionnaire about your physical activities. A research assistant will call you to ask you to complete this questionnaire three times: 1-month, 4-months, and 6-months after you finish rehabilitation. The questionnaire will take about 10-15 minutes to complete. At these time points, the research assistant will also ask you if there have been any changes to your health since he last spoke to you.

With your permission we will obtain information from your clinical chart such as your age, gender, height, weight, information about your stroke and the effects it has had

on you, and information about your medical conditions and medications. You do not have to do anything extra for this chart review. Before you are discharged from the rehabilitation hospital, we will also measure your leg function, and you memory and will ask you some questions about yourself, your previous exercise habits, and how you feel about exercise. It will take about 30 minutes to perform these measures; we will schedule the testing at a time that is convenient for you. This information is necessary in order to describe the group of people who are participating in this study.

Potential harms, discomforts and inconveniences

There is some extra time involved with participating in this study. You might find this a burden. We think it will take about 3 hours to complete all of the parts of this study. This time commitment will be spread out over 6 months. You might find that it is a burden to wear the activity monitor every day for three 1-week periods or to mail the activity monitors back to us.

There is a small chance that you will feel uncomfortable answering some of the questions related to the study. You are free to choose not to answer any question.

There is a small chance you will develop a skin irritation from wearing the activity monitor. Removing the activity monitor at night might help to prevent this from happening. If you do develop a skin irritation on your wrist, remove the activity monitor and call the research assistant to let him know.

Potential benefits

You will not directly benefit from being in this study. Information learned from this study may give us more information about how to increase participation in exercise in people with stroke after they leave rehabilitation. These results could be used to benefit other people with stroke in the future.

Reminders and responsibilities

It is important to remember the following things during the study:

- Tell the study staff your health history and medications as accurately as possible. This will help to prevent any harm to you.
- Ask the study staff about anything that worries you.
- Tell the study staff if anything about your health has changed.
- Wear the activity monitors every day for a week on three different occasions, and return them to us in the postage-paid envelope.

Confidentiality

Personal Health Information

If you agree to join this study, the research team will collect your personal health information. Personal health information is any information that could identify you and includes your:

- name,
- age,
- telephone number, and
- existing medical records, including types, dates and results of medical tests or procedures.

Representatives of the University Health Network Research Ethics Board may look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study is following proper laws and guidelines.

The research team will keep any personal health information about you in a secure and confidential location for 10 years. A list linking your study number with your name will be kept by the research team in a secure place, separate from your study file.

Study information that does not identify you

This is a multi-site study; Sunnybrook Research Institute is the lead site for this study. Some study information will be sent outside of the hospital to Sunnybrook Research Institute. Any information that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you.

All information collected during this study, including your personal health information, will be kept confidential. Information from the activity monitors will be stored on the manufacturer's web servers; however, this information will be completely anonymous and will not be associated with any information that could identify you. Your personal health information will not be shared with anyone outside of the study unless required by law. You will not be named in any reports, publications, or presentations that may come from this study.

Voluntary participation

You are encouraged to ask any questions that you may have about this study. If you do not wish to participate in this study, it will not affect any treatment that you receive at Toronto Rehabilitation Institute – UHN, either now or in the future.

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. We will give you any new information that is learned during the study that might affect your decision to stay in the study.

Withdrawal from study
If you chose to participate initially but wish to withdraw at a later date, for any reason, it will not affect the current or future care that you receive at Toronto Rehabilitation Institute – UHN. If you decide to withdraw from the study, the information that was collected before you leave the study will still be used in order to help answer the research question. No new information will be collected without your permission.

Costs and reimbursement
Participation in this study will not involve any additional costs to you. You will receive a $30 gift card after completing all parts of the study as a token of our appreciation for your participation.

Rights as a participant
If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

By signing this form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

Conflict of interest
Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.

Questions about the study
If you have any questions, concerns or would like to speak to the study team for any reason, please call the Principal Investigator Avril Mansfield at 416-597-3422 extension 7831. **If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849**. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.
You will be given a copy of this form.

Consent

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

In some cases when we are unable to contact you directly, may we leave a voice message (if applicable)? No personal health information will be included in the voice message.

❑ Yes_____(initials) ❑ No_____(initials)

If we have been unable to contact you after repeated attempts by telephone or mail, may we contact a friend or family member? We will ask for your friend or family member's contact information in a separate document. We will not share any of your personal health information with your friend or family member.

❑ Yes_____(initials) ❑ No_____(initials)

_____	_____	_____
Study participant's name	Signature	Date

My signature means that I have explained the study to the participant named above. I have answered all questions.

_____	_____	_____
Name of person obtaining consent	Signature	Date

Was the participant assisted during the consent process? ❑YES ❑NO
If **YES**, please check the relevant box and complete the signature space below:

❑The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

_____	_____	_____
Name of witness	Signature	Date

_____
Relationship to participant