CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Study title: Determining the optimal dose of reactive balance training after stroke – a pilot study

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*Please note that communication via e-mail is not absolutely secure. Thus, please do not communicate personal sensitive information via e-mail.

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IMPORTANT: You are being invited to take part in a research study. Before you agree to take part, it is important that you read the information below. The information describes the purpose of the study, the risks or benefits to you, and your right to withdraw at any time. You should take as much time as you need to make your decision. You should ask the study doctor or 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.

Objective of the study
People who have had a stroke tend to have 'poor' balance and are more likely to fall than those who have not had a stroke. A new type of exercise, called 'reactive balance training', might help reduce fall rates after discharge from stroke rehabilitation. Some studies suggest that people can benefit from even small amounts of reactive balance training, but we do not know how much reactive balance training is necessary to improve balance and prevent falls. Our long-term goal is to determine the ideal number of reactive balance training sessions that will improve reactive balance control and prevent falls. We are currently conducting a small pilot study to determine the feasibility of a larger study to address this long-term goal.

You are being asked to participate because you have had a stroke within the last 6 months, you are attending outpatient rehabilitation at Toronto Rehab, and you are able to walk without assistance of another person.

Up to 36 people will participate in this study and it will take approximately 18 months to recruit all participants.

Study visits and procedures
If you agree to participate in the study, we will review your chart, you will complete balance training, we will test your balance and function, and we will ask you to report falls. The parts of the study are described below.

Chart review
We will review your hospital chart to get some information about your stroke, your previous medical history, and your current prescription medications. We use this information to confirm that you are eligible for the study and to describe the type of people who have participated in the study. You do not need to do anything additional for the chart review.

Reactive balance training
Reactive balance is the kind of balance that you need to stop yourself from falling after you stumble, trip, or get bumped, or jostled. Reactive balance requires you to step very quickly when you have lost your balance, to prevent a fall. In order for you to re-learn reactive balance, you need to lose your balance so that you can practice recovering with rapid steps. This is called **reactive balance training.**

Reactive balance training will be completed by your physiotherapist, and/or by a research physiotherapist. Reactive balance training is done in a safe, supportive, supervised environment. You will wear a harness which is attached to an overhead frame. The harness is worn so that when you lose your balance, you do not risk falling all the way to the floor. The physiotherapist will be there as well to assist you should you be unable to recover your balance on your own.

The physiotherapist will ask you to do exercises that cause you to lose your balance. He or she will do this in one of two ways:

1. he or she will have you practice tasks that gradually challenge your balance and result in a loss of balance, or
2. he or she will gradually pull or push you until you lose your balance.

Images removed for publication

Example of task to challenge balance: tapping on unstable surfaces with alternating feet

Example of 'pull' by physiotherapist to left

You will receive 1, 3, or 6 reactive balance training sessions; each session will be 45-minutes long and will replace 1, 3, or 6 of your regular physiotherapy sessions. The timing of the sessions during your outpatient rehabilitation will be determined by your physiotherapist.

Balance and functional testing
You will be asked to complete three testing sessions: 1) just before you start the reactive balance training; 2) at the time of discharge from rehab; and, 3) 6-months after you finish the training. Each testing session will last 2-2.5 hours. The first session will be longer than the other two. You can take rest breaks as often as you need during the testing sessions. During these test sessions, we will ask you several questions and conduct several tests.

- Information about you (10 minutes) – we ask you some questions about you and your life. We will ask questions about your employment, education history, and social networks. We use this information to describe the type of people who have participated in this study.

- Stroke function tests (20 minutes, first visit only) - we will do some quick tests of your vision, memory, sense of touch, and arm and leg function. These tests tell us how your stroke has affected you. We use this information to describe the kind of people who participate in the study.

- Questionnaire (10 minutes) - we will ask you to complete a standardized questionnaire about your balance confidence. We would like to know if balance confidence improves after completing the training. You are free to choose not to answer any of the questions. You can take the questionnaire away with you and answer it at home if you like.

- Leg and foot recovery (10 minutes) – we will ask you to do a few movements with your leg and foot that have been affected by the stroke, such as bending the knee or wiggling the toes. We would like to know if your ability to move the leg and foot improves after completing the training.

- Balance test (15 minutes) - we will ask you to do several activities that challenge your balance and mobility, such as walking as quickly as you can, standing with your eyes closed, and recovering your balance once released from a leaning position. A research assistant will stand near you when you complete the tests to provide any assistance you might need. The research assistant will rate how you perform on each test. We would like to know if your ability to perform these tests improves after completing the training.

- Balance reaction test (1 hour) - we will test your balance reactions on a movable platform. During this test, you will wear a safety harness attached to an overhead beam and you will be outfitted with reflective markers. We will ask you to walk forward on the platform 8-10 times. During 2 of the walking trials, the platform will move suddenly, requiring you to react to regain your balance. If you are unable to use your own balance reactions to prevent a fall, the safety harness will catch you. We would like to know if your balance reactions improve after completing the exercise program. Setting up for this test takes quite a bit of time, but the tests themselves will only take about 10-15 minutes.

All of the balance tests will be videotaped so that we can check out you performed the tests after you finish your appointment. The videotaping is mandatory for the study. Only study personnel will have access to your video images. We may ask for your permission to show the videos to some people outside the study (e.g., for educational purposes). We will ask you to provide this permission by signing a separate consent form, but you do not have to provide this permission. We will not share the videos with anyone outside of the study without your permission.

Falls reporting
We will ask you to complete a six-month falls monitoring period. When you have completed the assessment at the end of rehabilitation you will be provided with a calendar that you will be asked to fill out daily. You will use this calendar to record any falls or near falls that you experience. We will ask you to return the calendar to us every two weeks. If you experience a fall or a near fall, it is important that you get the medical care you may need. After your medical care is addressed, we will ask you (or a family member) to contact us to answer some questions about the fall or near fall. You can answer these questions over the telephone. The questions include what you were doing when you fell, what you think caused the fall, and whether you have a fear of falling. The questions should take 15-30 minutes to answer.

If you do not return a calendar we will call you to remind you to return it. We will also call you three times during this six month monitoring period (about every 2 months) to ask you questions about your physical activities. These questions should take about 15-30 minutes to answer.

Study design

This is an assessor blind pilot randomized trial.

- 'Assessor blind' means that the person who is collecting all of the information for the study should not know which exercise program you are in.
- 'Pilot' means a small study to test out the study procedures before planning a larger study.
- 'Randomized' means that you do not have a choice of which group you are in. You have an equal chance of being assigned to one of the three groups and the assignment is decided randomly, like rolling a die.
- 'Trial' is another word for 'study'.

Potential harms, discomforts and inconveniences

This study involves being assigned to one of three different groups. One group might do better than the other group. If you participate in this study you will get the same or better standard of care than if you did not participate in the study.

There is some extra time involved with participating in this study. You will be asked to do two assessments during outpatient rehabilitation that are 'in addition' to your regular physiotherapy. You will be asked to travel to Toronto Rehab for testing one time after your outpatient rehabilitation program is over; this will be approximately 6 months after the end of the reactive balance training sessions. You might find this a burden. If you require a family member to assist you with transport they might also find that it is inconvenient to travel with you to the study appointments.

You might find the balance training or tests to be challenging or tiring. To minimize the risk of physical harm, we do not allow people with certain medical conditions to participate in this study. The sessions will be supervised by a trained physiotherapist who will monitor you for any negative effects. You will be provided regular rest breaks, and can request additional breaks. You can stop the testing or training at any time if you are too tired to continue or are uncomfortable. During the exercises and balance tests, there is a risk that you will not be able to regain balance by yourself and will start to fall. You will wear a safety harness to prevent you from falling to the floor. Additionally, the researchers can help you to regain your balance. There is a very small chance you will have an injury (such as a sprain or a bruise), even if you are caught by the safety harness. However, we have done these types of tests and exercises with hundreds of people with stroke without any injuries.

If you agree to participate in this study you will have to fill out the falls monitoring calendar every day and return it to us every two weeks. We will also call you frequently to ask you questions about your falls and physical activities. You might find that the calendars and the phone calls are inconvenient.

If you have difficulty understanding or speaking English you may need a family member or friend to help you to participate in this study. They may need to translate some of the study documents and questionnaires, speak to our research personnel on the telephone. This may inconvenience your family member or friend.

Potential benefits
If you participate in this study you will participate in reactive balance training. It is possible that this training will benefit your balance.

The results of this study will give us more information about the amount of training that is required to improve balance reaction. These results will be used to inform the next research study and could be used in rehabilitation programs and benefit other stroke patients 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.
- Return the falls calendars regularly and report any falls to the study staff as soon as possible.

Alternatives to being in a study
You do not have to join this study to receive treatment for your stroke. Your outpatient rehabilitation program will be provided as scheduled.

Confidentiality
Your data will be shared as described in this consent form or as required by law. All personal information such as your name, address, and phone number will be removed from the data and will be replaced with a number. A list linking the number with your name will be kept by the study investigator in a secure place, separate from your file.

Personal Health Information
If you agree to join this study, the research team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could identify you and includes your:

- name,
- address,

- age, and,
- new or existing medical records, that includes types, dates and results of medical tests or procedures.

Representatives of the University Health Network (UHN) including the UHN 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, including the videos, in a secure and confidential location for 10 years after we have finished collecting data for this study. All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. You will not be named in any reports, publications, or presentations that may come from this study.

Research information in shared clinical records
If you participate in this study, information about you from this research project may be stored in your hospital file and in the UHN computer system. The UHN shares the patient information stored on its computers with other hospitals and health care providers in Ontario so they can access the information if it is needed for your clinical care. The study team can tell you what information about you will be stored electronically and may be shared outside of the UHN. If you have any concerns about this, or have any questions, please contact the UHN Privacy Office at 416-340-4800, x6937 (or by email at privacy@uhn.ca).

Alternatives to being in the study
The usual treatment for people with stroke at Toronto Rehab includes the treatment of balance when indicated. Your treatment will include all regular therapy programs as well as the addition of reactive balance training sessions.

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 might receive at Toronto Rehab or the University Health Network in the future. If you chose to participate initially but wish to withdraw at a later date, for any reason, it will not affect any future care that you receive at Toronto Rehab or the University Health Network. We will give you any new information about the study that might affect your decision to stay in the study.

Withdrawal from the study
If you choose to leave the study, the information that was collected before you left 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
You will be reimbursed for any travel expenses that result from the follow-up appointments. These travel expenses may include TTC fare, taxi fare, or parking. You will receive a $50 gift card upon completion of the study.

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 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 signed copy of this consent 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.

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 person signing below acted as an interpreter for the participant during the consent process and attests that the study as set out in this form was accurately interpreted has had any questions answered.

Name of interpreter	Signature	Date

Relationship to participant	Language

❑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