



RBT and fitness

CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Title of the study: Effect of perturbation-based balance training on physical fitness post-stroke

Principal investigator

Avril Mansfield, PhD
Scientist, Toronto Rehab - UHN
550 University Ave, Toronto, ON, M5G 2A2
Phone: 416-597-3422 ext. 7831
e-mail: avril.mansfield@uhn.ca*

Study personnel

Azadeh Barzideh
PhD student
Rehabilitation Sciences Institute,
University of Toronto
Phone: 416-597-3422 ext 7626
e-mail: azadeh.barzideh@mail.utoronto.ca*

Cynthia Danells, MSc, BScPT
Clinical Research Coordinator, Toronto
Rehab – UHN
Phone: 416-597-3422 ext 7884
e-mail: cynthia.danells@uhn.ca*

David Jagroop, MHS, CSEP-CEP
Clinical Research Analyst, Toronto Rehab
– UHN
Phone: 416-597-3422 ext 7614
e-mail: david.jagroop@uhn.ca*

Paul Oh, MD, FRCPC
Senior Scientist, Toronto Rehabilitation
Institute (TRI)
Phone: 416-597-3422 ext 5267
e-mail: paul.oh@uhn.ca*

Susan Marzolini, R.Kin, PhD
Scientific Associate, TRI-REPS
supervisor, Toronto Rehab – UHN
Phone: 416-597-3422 ext 5246
e-mail: susan.marzolini@uhn.ca*

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

Funding

This study is being funded by the Heart and Stroke foundation of Canada.

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/purpose

Regular exercise is important for everyone, including people who have had a stroke. There are different types of exercise, including exercise that improves heart function ('cardio' or aerobic exercise), exercise that increases muscle strength, and exercise that improves balance. People should do all types of exercise regularly to keep fit. But most people find that they do not have time to do all types of exercise. Some exercises may improve heart function, strength, and balance at the same time. The purpose of this study is to see if a new type of exercise that improves balance will also improve heart function and strength in people who have had a stroke. You are being asked to participate because you have had a stroke more than 6 months ago and might like to improve your balance and fitness. Up to 70 people will participate in this study at Toronto Rehabilitation Institute and it will take 3 years complete.

Study visits and procedures

Briefly, this study involves three parts: 1) testing balance, leg muscle strength, and aerobic fitness; 2) exercise program; and 3) falls reporting. You will be involved with this study for about a year.

Testing balance, leg muscle strength, and aerobic fitness

If you agree to participate in the study, you will also be asked to come for testing to Toronto Rehab (Rumsey Centre, close to Bayview and Eglinton) and University of Toronto (Department of Physical Therapy, close to University Avenue and Dundas Street West) for four visits. Two of the visits will be before you start the exercise program, and two will be after the end of the exercise program. Each testing session will last 1-3 hours. The first session will be longer than the other four. You can take rest breaks as often as you need during the testing sessions. Your blood pressure and pulse will be recorded at the start of each visit.

Toronto Rehab- University Centre visits

- Information about you and your health (5-10 minutes, before-exercise visit only) – we will ask you questions about your stroke, your other medical conditions, and any prescription medications you are taking. It might be useful for you to bring a list of medications with you. If you were previously a patient at Toronto Rehab, we will review your hospital chart to get some more detailed information about your

RBT and fitness

stroke that you might not know, like exactly what part of your brain was injured when you had your stroke. This information will help us to describe the group of people who participate in this study and might help us to learn who benefits most from the exercises.

- Stroke function tests (20 minutes, before-exercise visit only) – during the first test session 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 need this information to describe the kind of people who participate in the study.
- Questionnaires (10 minutes) – we will ask you to complete standardized questionnaire about your balance confidence. We would like to know if balance confidence improves after completing the exercise program. You are free to choose not to answer any of the questions. You can take the questionnaire away with you and answer them at home if you like.
- Balance and mobility tests (30 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 reaching to pick up an item from the floor. 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 exercise program. The balance tests will be videotaped so that we can check how you performed on the tests after you finish your appointment. Only study personnel will have access to your video images. We will not share the videos with anyone outside of the study without your consent.

University of Toronto visit

- Leg muscle strength (30 minutes) – during the muscle strength test, you will be asked to push or pull your leg as hard as possible. You may feel that your thigh muscles are tired after the test and your leg muscles may feel sore the next day. These are normal responses to muscle testing. The tiredness will recover in a few hours after the test and the muscle soreness (if any) will recover by 1 or 2 days after the test. We will also have you do a warm-up to stretch your legs before the muscle strength tests to reduce the chances that you may feel muscle soreness.

Toronto Rehab – Rumsey Centre visits

- Aerobic exercise test (1.5 hours) – this test measures how well your heart can pump blood around your body. The test will be supervised by a physician and health professionals who have expertise in exercise testing. You will be asked to pedal on a stationary bicycle or walk on a treadmill. The difficulty of the pedaling or speed of the treadmill will be gradually increased until you reach your maximum abilities, you indicate that you would like to stop, or the physician stops

the test. During the test, you will breathe into a machine that measures the amount of oxygen and carbon dioxide in your breath. You will also wear a heart monitor.

Exercise program

You will be assigned to one of two exercise programs, which are run by a trained physiotherapist. The exercise program for both groups will take place three times per week for twelve weeks. Each exercise session will last 1 hour. You will be asked to come to Toronto Rehab (University Centre site, downtown Toronto) to complete the exercise program.

The two exercise programs are:

1. Fitness exercise, you will complete an exercise program developed by a group of scientists and physiotherapists who are experts in rehabilitation of balance after stroke. This exercise program is based on exercises that have been shown to improve strength and heart function in people who have had a stroke.
2. Balance exercise you will complete exercises that challenge your balance and cause you to lose your balance. You will practice movements to stop yourself from falling after a loss of balance. During these exercises, you will wear a safety harness attached to an overhead support so that you will not fall to the floor if you are unable to regain your balance.

Falls reporting

At the end of the twelve-week exercise program you will be asked to report any falls you have for one year. 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 that you experience. We will ask you to return the calendar to us by mail every two weeks. The cost of return postage will be covered by the study. If you experience a fall, it is important that you get the medical care you may need. After your medical care is addressed, we will ask you to contact us to answer some questions about the 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 15-20 minutes to answer.

About every 4 months during this one-year period we will ask you to complete some questionnaires about your physical activities. These questionnaires can be completed over the telephone.

RBT and fitness

Summary of tests and procedures

Time	Visit type	Time commitment	Number of visits	Location	Contact person
Week 1-2	Medical history review Strength, balance and mobility testing	3 hours	1	University of Toronto	Azadeh Barzideh
	Aerobic exercise test	1.5 hours	1	Toronto Rehab-Rumsey Centre	Susan Marzolini
Weeks 2/3-13	Exercise program	Three times per week, 1-hour per session	36	Toronto Rehab – University Centre	Cynthia Danells
Week 14-15	Strength, balance and mobility testing	2 hours	1	University of Toronto	Azadeh Barzideh
	Aerobic exercise test	1.5 hours	1	Toronto Rehab – Rumsey Centre	Susan Marzolini
Week 14/15-62/63	Falls reporting	<1 hour (total)	Every day for a year	Your home	Azadeh Barzideh

Study design

This study is what is known as an ‘assessor-blinded randomized non-inferiority trial’.

- ‘Assessor blinded’ means that the person who is collecting all of the information for the study should not know which exercise program you are in.
- ‘Randomized’ means that you do not have a choice of which exercise program you will complete. You have 50% chance of being assigned to 1 of the 2 groups and the assignment is decided randomly, like flipping a coin.
- ‘Non-inferiority’ means that we think both exercise programs will have similar benefits; that is, one exercise program will not be inferior to the other.
- ‘Trial’ is another word for ‘study’.

Risks

This study involves being assigned to one of two different groups. One group might do better than the other group.

There is some extra time involved with participating in this study. You will be asked to travel to Toronto Rehab (University and Rumsey Centres) and University of Toronto for testing or exercise 40 times in total over a 4 to 5 month period. 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.

Taking part in this study has risks. Some of these risks we know about. These risks are similar to the risks of taking part in any other exercise program that is not part of a study. There is also a possibility of risks that we do not know about. The risks we know of are listed below.

Likely (20-49% of people):

- Muscle soreness. People who start a new exercise program will often experience muscle soreness. This soreness is normal and expected with exercise, and should go away in 2-3 days. If your muscles feel sore before or during the exercise session, tell the study staff; they will modify the exercise program.
- Fatigue. You might find the exercises or balance tests to be tiring. You will be provided regular rest breaks and can request additional breaks. You can stop the testing at any time if you are too tired to continue or are uncomfortable.

Less likely (1-19% of people):

- Joint pain. Some people report joint pain while doing the balance exercises. Joint pain may be more likely for people who have a history of arthritis or joint injury. Tell the study staff if you experience any joint pain; they will modify or remove any exercises that might be causing you pain.

Rare (<1% of people)

- Falling. The balance exercises and tests are challenging to balance; there is a risk that you might not be able to recover your balance and 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.

Rare but serious (<1% of people)

- Cardiovascular complications, like heart trouble, feeling pain or pressure in the chest, or pain down the arm, increased/decreased heart rate or blood pressure, or shortness of breath. The chance of these complications is very low (<1% of tests). We will minimize the risks taking a detailed medical history before the exercise

RBT and fitness

test (we will not proceed with the test if we think it will not be safe for you), and by monitoring your heart tracing during the exercise test. The exercise test is supervised by a physician and clinical staff with expertise in exercise testing for people with stroke. If you experience any of these complications, we will stop the test and ensure that you are provided with appropriate medical care. If you have any questions about the risks of the exercise test, we will write them down and share them with the study physician. Regardless of whether you have questions about the exercise test, our study physician or his designate will call you after your first visit at Toronto Rehab- University Centre and before the exercise test itself, to have a more detailed discussion about these risks. He will also answer your questions during this telephone conversation. You will have another opportunity to have your questions answered in person when you go to Rumsey Centre for the exercise test. If you are not comfortable with the risks of the exercise test, you can choose to withdraw from the study.

Other risks

- There is a risk that the tests will reveal possible health problems of which you were previously unaware (e.g., from monitoring your heart during the exercise test). In this event, you will be informed of the situation and will be urged to see your doctor. Additionally, if you agree to provide us with you doctor's contact information, the abnormal results will be sent to your doctor.

Benefits

If you participate in this study, you will participate in an exercise program. Physical exercise is known to be beneficial for general health. You may or may not benefit from the study.

The results of this study will let us know if one type of exercise can improve different types of fitness at the same time. These results 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.
- Tell the study staff if you experience any of the risks listed above.

Alternatives to being in a study

The healthcare system currently does not provide rehabilitation to people with stroke after a certain amount of time. If you think you should improve your heart function, strength, or balance, you can hire a private physiotherapist, kinesiologist, or fitness instructor who can help you to improve your fitness. You may also seek out community exercise programs that could benefit you. Our study staff are aware of some of these programs and help to connect you with a program.

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,
- address,
- age,
- OHIP number, and
- if you were a previously a patient at Toronto Rehab, existing medical records, including types, dates and results of medical tests or procedures.

To confirm eligibility for the exercise test, your medical history will be obtained using your Ontario Health Insurance Plan (OHIP) number, which will be collected by the Rumsey Centre staff when you confirm your appointment for the exercise test. Medical history will first be checked by a member of our research team at Rumsey Centre and later on by the medical doctor present during the exercise test.

The following people may look at the study records and 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, because they oversee the ethical conduct of studies at UHN and University of Toronto:

- Representatives of the University Health Network (UHN) including the UHN Research Ethics Board; and
- Representatives of the University of Toronto Research Ethics Board.

The research team will keep any personal health information about you, including the videos, in a secure and confidential location for 10 years. All study data will be destroyed after 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. The list linking your name to your study number will be destroyed after you have completed the 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.

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

You are free to choose to leave the study if you no longer wish to participate. You may also be withdrawn from the study by the research team, for example, if there is a significant change in your health that might increase the risks of participating. If you choose to leave the study, or if you are withdrawn, your participation will be stopped. However, 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 (i.e. parking or TTC tokens) that you may have as a result of participating in this 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.

RBT and fitness

Data safety monitoring

A Data Safety Monitoring Board is a group of independent experts who will be reviewing the data throughout this research study to see if there are unexpected or more serious side effects than described in this form. The experts in the group are not members of this study team.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. This website will not include information that can identify you. The website will include a summary of the results at the end of the study. You can search this website at any time.

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 copy of this form.

RBT and fitness

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

I would like to provide you with contact information for my doctor (e.g., family doctor, cardiologist, or neurologist) YES NO

If **YES**, please write your doctor's name, phone number, and address below:

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

Other.

Describe other assistance or communication aids:

