Research Participant Information and Consent Form

Title of Study:	**Getting Older adults OUTdoors (GO-OUT): A randomized controlled trial of a community-based outdoor walking program**
Protocol number:	Clinical Trials.gov: NCT03292510
Co-Principal Investigator:	Dr. Ruth Barclay University of Manitoba, R106-771 Mc Dermot Avenue, Winnipeg, MB R3E 0T6 Phone: 204-787-2756
Co-Principal Investigator:	Dr. Nancy Salbach Department of Physical Therapy, University of Toronto, 160-500 University Avenue, Toronto, Ontario, M5G 1V7 Phone: 416-946-8558
Sponsor:	Canadian Institutes of Health Research 160 Elgin Street, 9th Floor Address Locator 4809A Ottawa, Ontario K1A 0W9

You are being asked to participate in a Clinical Trial (a human research study). Please take your time to review this consent form and discuss any questions you may have with a qualified member of the research team. You may take your time to make your decision about participating in this clinical trial and you may discuss it with your regular doctor, friends and family before you make your decision. This consent form may contain words that you do not understand. Please ask the research team member to explain any words or information that you do not clearly understand. The research team is financially supported by the Canadian Institutes of Health Research to conduct this study.

Purpose of Study

This Clinical Trial is being conducted to investigate the value of providing a walking workshop and walking group to older adults who report that they do not walk outside very much. You are being asked to take part in this study because you: 1) are aged 65 years or older, 2) are living independently in the community, 3) are able to walk continuously on a flat surface for at least 1 block (50 metres or 164 feet), on your own with or without a walking aid and with no supervision, and 4) have reported that you have problems walking outdoors. This clinical trial is being conducted in Winnipeg, Edmonton, Toronto and Montreal. In Winnipeg, we will recruit 60 individuals.

The purpose of this study is to evaluate two different programs to improve outdoor walking in older adults who report that they have problems walking outdoors. This research is being done because there have not been any specific studies to evaluate if a workshop and outdoor walking practice can overcome some of the barriers to outdoor walking. Many older adults report that they are afraid to walk outside. In order to establish community-based programs and ensure that they receive needed funding, there needs to be evidence that they achieve desired outcomes.

Before proceeding to the study, we will ask you to complete a brief questionnaire about your level of physical activity. This will take less than five minutes. We will ask you questions by telephone call at a time that is convenient to you to ensure that the study is right for you. If you pass the telephone screen, we will schedule an in-person session so we can check your heart rate and blood pressure. If you pass this in- person screen, then we will ask you to sign this consent form and then we will conduct a full evaluation.

To confirm that you can safely participate in this outdoor walking study, we will be contacting your family doctor to share with him/her your responses to the physical activity questionnaire. We will ask your doctor to contact us if they feel it is not safe for you to participate. They will contact us through a password protected phone line or by the fax facility at the College of Rehabilitation Medicine on the 3rd floor of the Rehabilitation Hospital at 800 Sherbrook St. Winnipeg.

Study Procedures

In this study, you will be "randomized" into one of the two groups described below. "Randomized," means that you are put into a group by chance, like flipping a coin.

The first group will participate in an educational workshop and receive weekly reminders about walking outdoors (workshop plus reminders group). The workshop will be conducted inside and involve 8 stations where participants will learn strategies and skills related to safe outdoor walking. They will be shown how to use step-counters (pedometers), and Nordic walking poles, and learn about fall prevention, foot care, proper clothing and footwear etc. Participants in this group will receive a workbook that will present the Canadian physical activity guidelines, the benefits of increasing outdoor walking, and information specific to each workshop station. Each participant will receive a pedometer for personal use and goal setting. Participants will use the workbook as an information resource and to record their community walking goals, planning routes, and walking time. All participants will be encouraged to walk outside in their own neighbourhoods with a partner, such as a family member, for safety.

The second group will also participate in the workshop followed by a 10 week supervised outdoor walking program (workshop plus walking group). The walking group will meet twice a week for a 60-minute session designed according to physical activity recommendations for older adults. Each session will include a 10-minute warm-up, a planned walk in an outdoor community environment, and a 10-minute cool down. Based on the needs of each group member, continuous walking exercise will gradually increase from 10 to 60 minutes in time walked, as well as difficulty. Participants will meet at locations with public access and availability of rest places and public washrooms (such as a large park). There will be a variety of surfaces and environmental factors to challenge the participants, e.g., carrying objects, diverting the walker's attention, crossing at a light, walking up and down curbs, slopes, and level or uneven surfaces.

Participation in the study will be for one year. You will undergo four evaluations that will take place at the time that you enter the study and 3 and 5.5 and 12 months later. Each evaluation will last for 2 to 2.5 hours and take place in RR367 at the Rehabilitation Hospital, 800 Sherbrook Street, Winnipeg. Trained assessors who do not know which group you are in will conduct all of the assessments. In an emergency, this information will be made available.

At each evaluation, you will be asked to complete some tests of your balance and your walking ability. We will also ask you to complete some questionnaires that ask questions about your physical and mental health, mood, and usual activities. You will also be asked to wear an accelerometer and global positioning system (GPS) unit, which will be attached to a waist belt, during waking hours for 8 days. Participants in the workshop plus walking group will also be asked to wear the accelerometer and GPS during two of the 24 outdoor mobility sessions to obtain descriptive data on the level of physical activity achieved.

You will be assigned to either one of two groups after the workshop. You will be told about the group that you are in after you complete the workshop.

After the 5.5 month and 12 month evaluations, we may invite you to be part of a focus group or an in person or phone interview to hear your comments about the study, so that we can improve aspects of the interventions for the future. A person experienced in interviewing will ask questions of the participants. All discussion will be digitally audio-recorded, and will remain confidential.

The researchers may decide to take you off this study in circumstances such as in your best medical interest or if your condition worsens during the study period.

You can stop participating in the study at any time. However, if you decide to stop participating, we encourage you to talk to the research team members and your regular doctor first. If you are interested in the results of the study, you may contact the Principal Investigator at the end of the study.

Risks and Discomforts

There is very little risk involved in participating in this program. There are some common anticipated risks with any walking program such as muscle pain, falls or tiredness. However, careful efforts will be taken to demonstrate and inform all study participants on the safe execution of the walking program. We will screen all participants for falls risk. The workshop will provide education and training on how to walk safely and minimize falls risk. We will advise all participants to walk with someone for safety when walking without the walking group. The walking group leader will carry a cellular phone and be trained in cardiopulmonary resuscitation (CPR). When walking in challenging terrain, the group will be divided by ability and an appropriate ratio of facilitators to participants will be provided.

During the study evaluations, some individuals may feel uncomfortable answering questions about feelings and experiences. Participants do not have to answer all of the questions. There will be no medications or chemicals used of any kind, and no uncomfortable procedures, such as blood tests.

If any problems arise during the study, appropriate treatment or follow-up will be arranged. If a fall occurs during the workshop or walking group, the trainers present will provide care as necessary or contact emergency services if required. If you fall while on your own, please contact us, so that we are aware, and modifications will be made as appropriate. Your condition may not improve or may worsen while participating in this study.

Benefits

By participating in this study, you will be providing information that will show the effects of the workshop, reminders, and walking group for older adults with difficulties in walking outdoors. There may or may not be direct benefit to you from participating in this study. Many people do derive benefit from participating in these programs. Your participation, however, will provide us with information on how best to meet the needs of people like you in the future.

Costs

All participation and evaluations, which will be performed as part of this study, are provided at no cost to you. There will be no cost for the study intervention that you will receive. You will be responsible for transportation to the study location. You will be reimbursed by cash/cheque or gift card up to a maximum of $40 for costs related to vehicle parking or transportation incurred while participating in the study activities. Half of the amount will be paid at the second evaluation and the remainder at the last evaluation.

Payment for Participation
You will be provided a $20 gift card if you complete all four evaluations.

Confidentiality
Information gathered in this research study may be published or presented in public forums; however, your name and other identifying information will not be used or revealed. Medical records that contain your identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba. Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. Health Canada may review the research and medical records for this study. Data collected at site (RR367, 800 Sherbrook St. Winnipeg) will be locked up there and entered into REDCap, which is a secure web application that is ideal for building and managing online surveys and databases for multi-site studies. For individuals who are potentially eligible and have completed a permission to contact form, the recruiter will logon to the REDCap system using the encrypted study laptop and create a record on REDCap, which will assign each individual an ID number. The evaluators will logon to REDCap using the encrypted study laptop and enter data collected throughout the study. More information about REDCap is provided under Confidentiality and Data Safety Procedures.

All study documents related to you will bear only your assigned study code. All records will be kept safe in a locked filing cabinet within a secure space in a locked office in Faculty of Health Sciences, College of Rehabilitation Sciences, in RR 367, 800 Sherbrook St Winnipeg, and in a highly secured web based portal based in Toronto. Details of your age, gender, socio-economic status and any chronic medical conditions will be obtained in person. Any personal information you provide (name, address) and any information that is collected from your assessments will be kept strictly confidential. The University of Manitoba Research Ethics Board may review research-related records for quality assurance purposes. Only the Principal Investigators and the study coordinators will have access to the confidential data collected in the study and information in medical records. If any of your medical/research records need to be copied to any of the above, your name and all identifying information will be removed prior to that action. For individuals in the workshop plus walking group, your name and contact information (address, email and telephone number) will be given to the walking group leader so the leader can contact you if there is a need to cancel a session.

Information such as your age, sex, socio-economic status, and details about your performance on a variety of tests conducted during the study will be entered into a secure computer and analyzed using a statistical software program. The information from the program will be in the form of statistical tables and summarized into graphs. No identifying information from any individual will be released. The results of this research may be presented at meetings or in publications but your identity will not be revealed. Your name will not appear in any publication or report from this study. In the future, the information we gather may be used by other researchers to answer additional research questions about safe walking programs for older adults, and for this reason all data, including the digital audio recordings will be kept for 25 years. The recordings will be destroyed after 25 years.

It is required that this study be registered on ClinicalTrials.gov, a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website any time.

Voluntary Participation/Withdrawal from the Study
Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decision not to participate or to withdraw from the study will not affect your other medical/therapeutic care at this site. If the research staff feels that it is in your best interest to

withdraw you from the study, you will be removed without your consent. We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study. Participants who are students or employees of the University of Manitoba can be assured that a decision to not participate will in no way affect their performance evaluation.

Data that are collected from a potential participant who ultimately is excluded or refuses to participate will be deleted from electronic systems (ie REDcap). Any paper forms with data on a potential participant who is ultimately not included in the study will be shredded

Medical Care for Injury Related to the Study
If any problems arise, appropriate treatment and follow-up will be arranged. By accepting to participate in this study, you are not waiving any of your legal rights by signing this consent form or releasing the investigator(s) or the sponsor(s) from their legal and professional responsibilities.

Questions
You are free to ask any questions that you may have about your treatment and your rights as a research participant. If any questions come up during or after the study or if you have a research-related injury, contact the Principal Investigator Dr. Ruth Barclay at (204) 787-2756 or the study coordinator at (204) 787-8015. For questions about your rights as a research participant, you may contact the University of Manitoba, Health Research Ethics program at (204) 789-3389.

The research study you are participating in may be reviewed for quality assurance to make sure that the required laws and guidelines are followed. If chosen, (a) representative(s) of the Human Research Ethics Program (HREP) may access study-related data and/or consent materials as part of the review. All information accessed by the HREP will be upheld to the same level of confidentiality that has been stated by the research team.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Statement of Consent

I have read this consent form. I have had the opportunity to discuss this research study with a qualified member of the research team. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any research team member to participate in the research study by any statement or implied statements. Any relationship (such as employee, student or family member) I may have with the research team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this clinical trial is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of my research records by The University of Manitoba Health Research Ethics Board for quality assurance purposes. Health Canada may review the research and medical records for this study.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

Participant signature_____ Date _____
(Day/month/year)

Participant printed name: _____

I agree to be contacted for future research studies □

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent.

Printed Name: _____ Date _____
(Day/month/year)

Signature: _____ (Qualified member of the research team)month