

UNIVERSITY OF ILLINOIS
AT URBANA - CHAMPAIGN



Informed Consent Agreement

Project title: Validation of a Fall Prevention Program Among Non-Ambulatory Wheeled Mobility Device Users with Multiple Sclerosis

You are being asked to participate in a research study. Researchers are required to provide a consent form such as this one to tell you about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you to make an informed decision. You should feel free to ask the researchers any questions you may have.

Principal Investigator: Dr. Laura A. Rice, Assistant professor
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The project is supported by funding from the National Multiple Sclerosis Society.

Why am I being asked?

You are being asked to be a subject in a research study to examine the effectiveness of a fall management program to prevent falls and develop fall recovery strategies for wheeled mobility device users living with Multiple Sclerosis.

You have been asked to participate in the research because you:

1. Have a diagnosis of Multiple Sclerosis
2. >18 years old
3. Main form of mobility is via a wheeled mobility device (Patient Determined Disease Steps Level 7)
4. Self reported ability to transfer with moderate assistance or less
5. Self-reported fall history (at least 1 fall/12 months)

6. Have not had an MS exacerbation in the past 30 days
7. Received a score of 10 or above on the Short Blessed Test
8. Able to sit upright for at least 1 hour.

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future dealings with the University of Illinois at Urbana-Champaign. **If you decide to participate, you are free to withdraw at any time without affecting that relationship.**

Approximately 120 subjects may be involved in this research at the University of Illinois at Urbana-Champaign, University of Illinois at Chicago and Shepherd Center (Atlanta, GA).

What is the purpose of this form?

This consent form gives you the information you will need to decide whether to participate in the study. Please read the form carefully. You may ask any questions about the research, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When all of your questions have been answered, you can decide if you want to be in this study or not.

What is the purpose of this study?

Approximately 25% of individuals living with Multiple Sclerosis (MS) are non-ambulatory. As a result, wheeled mobility devices, such as manual wheelchairs, power wheelchairs or scooters are used for functional mobility. Among individuals with MS, between 50-75% of the population report falling at least one time in a period of six months. Falls among individuals with MS often result in physical impairments that can range from minor injuries to more significant impairments, such as fractures or concussions that require hospitalization. Perhaps worse than any physical injury, falls can lead to a dysfunctional fear of falling that results in self-imposed activity curtailment, loss of confidence, difficulty performing typical societal roles, loss of independence and physiological deconditioning.

Given the adverse impact falls have on the health and well-being of persons with MS, a need exists to develop education programs to reduce the number of falls experienced by individuals with MS and develop strategies to recover (get up) from a fall.

The purpose of this project is to evaluate the effectiveness of a comprehensive fall management program. The purpose of the program is to decrease the number of fall experienced by wheeled mobility device users living with MS and help them to develop strategies to recover from a fall. The fall management program will focus on how to transfer (movement from a wheeled mobility device, such as a scooter or a wheelchair, to another surface, such as a bed or chair), wheelchair skills, exercise to improve sitting balance, assistive

device management, environmental factors associated with falls, general knowledge related to MS and fall risk and fall recovery strategies.

This research is very important because very few studies have investigated strategies to prevent falls in non-ambulatory living with MS. This proposed study has great potential to improve the health, well-being and quality of life of an often ignored segment of the MS community. This research is conducted under the guidance of Assistant Professor Laura Rice of the Kinesiology and Community Health Department at the University of Illinois at Urbana-Champaign.

What procedures are involved?

This research study will involve 3 research study visits that will take 2 hours each over a period of approximately 32 weeks (range: 28-36 weeks) and 6 education sessions that will take 2 hours each. The education sessions will be performed over 6 consecutive weeks.

Visit 1: We will ask you to complete surveys asking questions about your basic demographic information, fall incidence, fear of falling, knowledge of risk factors and management of falls, community participation, quality of life, and cognition. You may choose to leave any these questions blank that you do not feel comfortable answering.

Next, we will ask you to perform between 2-4 transfers (depending on your level of fatigue) from your wheeled mobility device to our mat table. While you transfer, one of the research assistants will evaluate the quality of your transfer skills. You will also be asked to sit on the mat table and perform a variety of movements to assess your sitting balance abilities. In addition, you will be asked to sit with your arms resting your lap with both your feet and back unsupported for 30 seconds on a force plate placed on a custom designed platform. Then, you will be asked to lean as far forward, backward and side- to side as possible in a circular pattern for 30 seconds. Lastly, you will be asked to perform a variety wheelchair skills to assess your ability to control your wheelchair. A research assistant will stand close by to assure your safety and stability. These assessments will require approximately 30 minutes of your time.

After you complete these baseline assessments, you will be asked to monitor fall frequency for a period of approximately 12 weeks (8-16 weeks) depending on when we are able to randomize you into either the intervention or wait-list control group. We will provide you paper calendars (fall diaries) to track the occurrence of falls. We will also call every other week to inquire about how often you have fallen and remind you to complete your fall diaries.

After approximately 12 weeks, you will be randomly assigned to either a training or wait-list control group. You will be notified over the phone of your group assignments. If you are assigned to the intervention group, you will be invited to participate in a 6-week group-based, educational course focused on management of fall risk delivered by a Physical or Occupational Therapist. The therapist will provide instruction on a variety of topics related to the management of fall risk including transfer and wheelchair skills, exercises to improve seated balance, equipment management, environmental factors associated with falls, general knowledge related to MS and fall risk and fall recovery strategies. Course sessions will be held over six consecutive weeks for a period of 2 hours each. If you are assigned to the wait-list control group, you will be asked to continue your normal routine. No matter what group you are assigned to, you will be asked to continue monitor fall frequency during and after completion of the intervention period.

Visit 2: The second visit will occur approximately 20 weeks (range: 16-24 weeks) after the first testing session. The same testing procedure will be performed as described above during visit 1

Visit 3: A final testing session will be conducted approximately 32 weeks (range: 28-36 weeks) after the first visit using the same measures and assessment as described above during visit 1.

Finally, you will be asked to record the frequency of falls experienced for 12 weeks after completion of the final visit with a fall diary. You will be asked to record if you have or have not fallen on a given day in the fall diary. You will also receive a phone call twice a month to inquire

if you have sustained a fall and to be reminded to complete the diary. If a fall is reported, fall details, information about injury and other associated information will be asked. At the end of the 12 week period we will ask you to mail the diary back in a preaddressed prepaid envelope to the research lab.

What are the potential risks and discomforts of this study?

The risks of this study are not greater than normal risks associated with daily life. Dr. Laura Rice is a licensed Physical Therapist in the state of Illinois and will oversee your safety during functional mobility activities. During the performance of the transfer assessment, wheelchair skills test and seated postural control assessment, there is a potential that you may fall. This risk however is no greater than the risk you would face when performing your daily activities that require you to perform weights shift, transfer and push/drive your wheelchair in your home environment. You may also experience minor muscle soreness and fatigue. At all testing locations, research assistants who have received in-person training from Dr. Rice and have demonstrated competence performing the assessments, will assist the participants in the performance of the outcome assessments. A variety of safety equipment, including gait belts, and transfer harness will be utilized to assure safety.

During the intervention period, licensed Physical and Occupational Therapists will be present to assist you during the time you practice various aspects of the education sessions.

The University of Illinois at Urbana-Champaign, University of Illinois at Chicago and Shepherd Center will not provide medical or hospitalization insurance coverage for participants in this research study nor will the University of Illinois at Urbana-Champaign, University of Illinois at Chicago and Shepherd Center provide compensation for any injury sustained as a result of participation in this research study, except as required by law.

Are there benefits to taking part in the research?

This study may assist you in the development of skills and knowledge to reduce the frequency of falls and develop strategies to facilitate recovery (getting up) after a fall occurs. While not benefiting you directly, the research will also help to develop evidenced based programs to improve the education clinicians provide to wheeled mobility device users living with MS to prevent falls and manage the events that occur in the immediate aftermath of a fall.

What other options are there?

If you decide to take part in the study, it should be because you really want to volunteer. You may choose not to take part at all or only answer the questions you feel comfortable answering. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. Your decision to participate, decline, or withdraw from participation

will have no effect on future relations with the University of Illinois at Urbana-Champaign, University of Illinois at Chicago or Shepherd Center.

Will my study-related information be kept confidential?

We will use all reasonable efforts to keep your personal information confidential, but we cannot guarantee absolute confidentiality. When this research is discussed or published, no one will know that you were in the study. But, when required by law or university policy, identifying information (including your signed consent form) may be seen or copied by:

- The Institutional Review Board that approves research studies;
- The Office for Protection of Research Subjects and other university departments that oversee human subjects research;
- University and state auditors responsible for oversight of research; and
- The study sponsor, the National Multiple Sclerosis Society

What are the costs for participating in this research?

There are no costs to you for participating in this research. If you must travel over 50 miles to reach our testing and education sessions, we will pay you \$30.00 per visit.

Will I be reimbursed for any of my expenses or paid for my participation in this research?

You will be compensated \$30 for completion of each study visit and you will receive an additional \$10 after returning your final fall diary (Total \$100). You will also be compensated \$30.00 if you travel over 50 miles to reach the research laboratory at each study visit and education session. In addition, free parking will be provided. You will be paid using Amazon gift cards.

Can I withdraw or be removed from the study?

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time.

The Researchers also have the right to stop your participation in this study without your consent if:

- *They believe it is in your best interests;*
- *You were to object to any future changes that may be made in the study plan;*
- *Miss 4 or more of the education sessions (if you are in the intervention group)*
- *If during the every other week follow up phone calls you report the occurrence of more than 4 falls in a period of 2 weeks, we will ask you to contact your physician to investigate the increased frequency of falls and make a recommendation as to if you should continue with the research study.*

In the event you withdraw or are asked to leave the study, you will still be compensated as described above.

What if I have questions?

If you have any questions about this research project, please contact: Dr. Laura Rice at 217-333-4650, email: ricela@illinois.edu

In the event of a research-related injury, please contact Dr. Rice

If you have questions about your rights as a participant in this study, or any concerns or complaints please contact the University of Illinois Institutional Review Board at 217-333-2670 or via email at irb@illinois.edu.

What are my rights as a research subject?

If you feel you have not been treated according to the descriptions in this form, or if you have any questions about your rights as a research subject, including questions, concerns, complaints, or to offer input, you may call the Office for the Protection of Research Subjects (OPRS) at 217-333-2670 or e-mail OPRS at irb@illinois.edu

Remember:

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I will be given a copy of this signed and dated form.

Signature

Date

Printed Name

Signature of Person Obtaining Consent

Date (must be same as subject's)

Printed Name of Person Obtaining Consent