RxFunction®
exclusive provider of walkasins®

A Pilot Study to Explore the Effects of Lower-Leg Mechanical Tactile Sensory Stimulation on the Gait Speed of Mildly Cognitively Impaired Individuals

NCT05723822
Consent Form

7576 Market Place Drive
Eden Prairie, MN 55344
March 7, 2023

RESEARCH SUBJECT CONSENT FORM

TITLE: A Pilot Study to Explore the Effects of Lower-Leg Mechanical Tactile Sensory Stimulation on the Gait Speed of Mildly Cognitively Impaired Individuals

PROTOCOL NO.: CIP 0007
WCG IRB Protocol #20230547

SPONSORS: RxFunction, Inc.

INVESTIGATOR: John Condon
861 E Hennepin Ave, Suite 450
Minneapolis, MN 55414

STUDY-RELATED PHONE NUMBER: [Deleted for ClinicalTrials.gov Submission]

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

Conflict of Interest Statement
Innovative Design Labs (IDL) is the sponsor of this study, which means IDL is providing funds to pay the study costs. The principal investigator is the president of IDL. If this study is successful, IDL and RxFunction, Inc., could benefit financially.

Introduction
You are being invited to participate in this research study because you are at least 65 years old and have mild cognitive impairment. You do not have to take part in this research. It is your choice.

The next page gives some key points to think about. After reading this summary, if you think you might be interested in taking part, read the rest of this form for more details about the study.

RESEARCH CONSENT SUMMARY

Informed Consent	It is important that you understand this research study so that you can make the decision that is right for you. This process is called informed consent. • Please ask questions about anything you do not understand. • Feel free to talk with your family, friends, or others before you decide. • After your questions have been answered, we will ask you some questions. If you meet the study requirements and you want to take part in the study, you will sign this consent form. • You will be given a copy of this form to keep.
Voluntary Participation	You do not have to take part in this research. It is your choice. You can also stop taking part at any time during the study.
Purpose	The main purpose of this study is to test whether Walkasins, a device that helps with balance, can help people with mild cognitive impairments walk faster.
Duration	You will be in this study for about an hour and a half (1½ hours).
Procedures	While you are in the study, you will . . . • Take two tests to see if you meet all the requirements to be in the study. • Do some standing and walking exercises. The exercises will be timed. • Answer questions about your balance.
Devices	One of the devices used in this study is called Walkasins. The other is called PhySens™ This form has more information about the devices.
Risks	The **main** risks from being in this study are as follows: • Falling during testing (Someone will walk by you to keep you as safe as possible.) • Getting tired during testing • Having some skin irritation
Benefits	There is no direct benefit to you. We hope to learn information that will help others in the future.
Alternatives	You may choose not to take part in this study.
Payment	You will be paid $50 for your participation in this study.

DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject or research participant.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.

- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to test whether the experimental device, Walkasins, will help people with mild cognitive impairments walk faster. The researchers want to learn as much as they can about how Walkasins might improve walking abilities for people with mild cognitive impairments.

Up to 20 subjects will take part in this research.

How long will I be in this research?

Your participation in this study will last up to 1½ hours.

What happens to me if I agree to take part in this research?

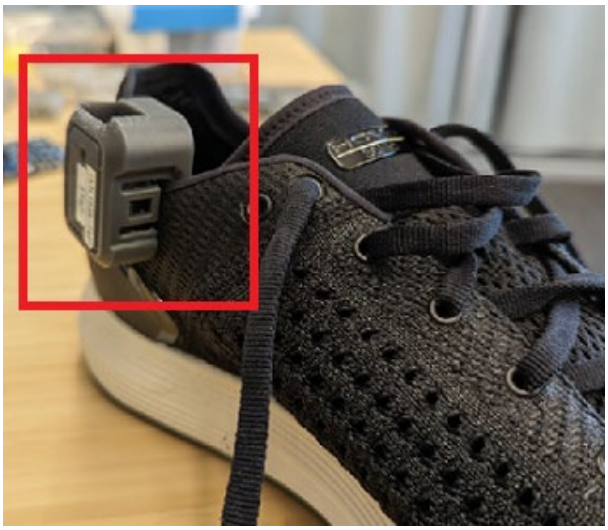
If you agree to be in this study, we will ask to do the following:

- Answer questions to make sure you meet the study requirements:
  - You are at least 65 years old.
  - You have mild cognitive impairment (MCI).
  - You can do the walking tests without a cane, walker, or other supportive walking device.
  - You do not have any serious diseases or conditions that affect your legs or walking ability.
- Provide some basic information about yourself such as your height, weight, and general health.
- Perform various standing and walking tasks while wearing Walkasins and the PhySens-IMM device.
- Answer some questions about how confident you are about your balance.

Walkasins have been developed to improve balance and walking by improving a person's ability to feel the pressure beneath his/her feet as he/she walks. The device uses an insert in the shoe (like a common shoe insole) to measure pressures beneath the feet. The insert is connected to a leg unit that makes gentle vibrations to the skin around the ankles (front, back, outside, inside) as foot pressures change. (The vibrations are like those a cell phone makes.) For example, if there is more pressure beneath your toes, the unit will vibrate the front of your ankles.

It looks like this.

The other device you will wear is the PhySens-IMM that measures your movement. It will be clipped on your shoe. It does not vibrate, and it looks like the picture below. You will also wear another clip on your belt or pocket to help track your movements.



What are my responsibilities if I take part in this research?

If you decide to be in this study, we (the study team) will ask you to provide truthful information about your medical history and current health. We also want you to tell us about any pain or discomfort you may feel during the study.

Could being in this research hurt me?

You may experience some discomfort from the equipment used in the study. For example, the foot pads in your shoes may be uncomfortable. If you feel discomfort from the devices, the study team will try to reduce or eliminate the discomfort.

The walking tests do not take a long time, but they may make you feel tired. If so, you may ask to rest or stop the study at any time.

There is a small risk of injury (tripping or falling) while walking and stopping during the testing. To lower the risk of injury, someone will walk with you while you are doing the tasks.

There may be unknown risks associated with your participation.

Will it cost me money to take part in this research?

There is no cost to you to take part in this study.

Will being in this research benefit me?

There is no direct benefit to you. We hope the information learned from this study may benefit other people with mild cognitive impairments. It may help the researchers develop new devices in the future.

What other choices do I have besides taking part in this research?

This study is not designed to diagnose, treat, or prevent any disease. Your option is not to take part in the research.

What happens to the information collected for this research?

Your private information will be shared with individuals and organizations that conduct or watch over this research, including the following:

- The research sponsors
- People who work with the research sponsors
- Government agencies, such as the Food and Drug Administration
- WCG IRB, the Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. But we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy or confidentiality.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

If your participation in this research study results in an injury, care for such injuries will be billed in the ordinary manner to you or your insurance company.

No funds have been set aside to pay for care for injuries resulting from your participation in this study. If you think you have experienced a research-related injury, notify a study team member or the principal investigator immediately at the phone number on the first page of this form.

You do not give up any of your legal rights by signing this form. Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

Can I be removed from this research without my approval?

We (the researchers) may stop your participation in the study without your consent if we feel that it is in your best interest, if you do not follow the study instructions, or if you experience a study-related injury. We may also need to end your participation for administrative reasons.

What happens if I agree to be in this research, but I change my mind later?

It is your choice whether you want to participate in this research. You can choose not to be in the study now without any penalty or loss of benefits to which you are entitled.

If you decide to be in the study, you can stop taking part in this research at any time simply by telling one of the researchers. Your withdrawal from the study will not result in any penalty or loss of benefits to which you are entitled. Deciding not to participate now or withdrawing later will not harm or in any way affect your current or future relationship with RxFunction, Inc., or IDL.

Will I be paid for taking part in this research?

You will receive $50 for taking part in this study. (For accounting purposes, we will ask you to sign a receipt for the gift card. This form will not be linked to your study data.)

What about my medical information?

The Health Insurance Portability & Accountability Act of 1996 (also known as HIPAA) establishes privacy standards to protect your health information. This law requires the researchers to obtain your permission (by signing this form) before they obtain, use, or disclose (share) your protected health information for research purposes.

By signing this form, you are authorizing IDL and RxFunction, Inc., including the Principal Investigator, John Condon, and other members of the research staff to use and share your health information for the following purposes:

- Confirm that you are eligible to be in the study.
- Conduct the study and make certain that the study is being carried out properly.
- Make sure that the information collected during the study is accurate and complete.
- Analyze the study results.
- Protect your safety and rights as a research subject.

This health information includes the following:

- Personal information such as your name, address, phone number, etc.
- Dates related to medical events
- Information about your medical history and general health
- Information collected about you during the research study tests

Your health information may be shared with authorized representatives of the following groups:

- Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services
- Food and Drug Administration (FDA) and other governmental, regulatory bodies in this country or other countries
- WCG IRB

Health information that has been shared may be shared by the recipient of the information. These other organizations may then share your health information with others without your permission.

You do not have to sign this form. If you decide not to sign, it will not affect your medical care, but you will not be able to participate in the research study.

There is no expiration date for this authorization.

You have the right to revoke this authorization. To take back your permission, you must send your **written** request to the Principal Investigator to inform him of your decision.

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If you take back your permission, the researchers may use and share only the protected health information already collected for this research study.

IDL and RxFunction, Inc., will not share your study information with you during the research study visit. You may request copies of records containing your health information after the research is completed. As noted above, you will receive a copy of this form.

Before you sign this form, a researcher will ask you these questions:

- How would you describe your brain health right now?
- What is this study about?
- If you decide to be in this study, what harm (risks) might occur?
- Will this study mainly help you or others?
- If you want to stop being in the study, when can you do this?
- Can you please explain how you decided to participate (or not participate) in this study?

Statement of Consent

By signing below, I agree that I have been provided time to read the information describing the research study in this consent form. The meaning of this information has been explained to me. I have been able to ask questions.

I voluntarily agree to participate in this study.

Printed Name of Participant	
Signature of Participant	Date
Signature of Person Obtaining Consent	Date