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

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List of Abbreviations

The following abbreviations appear in this protocol.

AE	Adverse Event
CITI	Collaborative Institutional Training Initiative (CITI Program)
FES	Falls Efficacy Scale
GCP	Good Clinical Practice
IDL	Innovative Design Laboratories
IRB	Institutional Review Board
MCI	Mild Cognitive Impairment
NSR	Nonsignificant Risk
RA/QA	Regulatory Affairs/Quality Assurance
SAE	Serious Adverse Event
SLUMS Exam	Saint Louis University Mental Status Exam
SPN	Sensory Peripheral Neuropathy
SPPB	Short Physical Performance Battery Protocol
SR	Significant Risk
TUG	Timed Up and Go
TUG-COG	Timed Up and Go Cognitive
UPIRTSO	Unanticipated Problem Involving Risks to Subjects or Others

Introduction

This protocol describes the procedures for a pilot study to evaluate the use of Walkasins, a sensory prosthesis currently indicated for use in patients with sensory peripheral neuropathy (SPN), in individuals with mild cognitive impairment (MCI). The pilot study will be developed and conducted according to U.S. standards of Good Clinical Practice (GCP) and in accordance with applicable federal regulations.

Background Information and Scientific Rationale

Description of Walkasins

Walkasins consist of two parts for each leg: the Haptic Module and the Receptor Sole (Figure 1). The Haptic Module wraps around the lower leg of the user and contains electronics for reading Receptor Sole pressure signals, a microprocessor, and four vibrating motors that provide gentle tactile sensory cues to the front, back, medial, and lateral surfaces of the user's leg. These cues reflect real-time foot pressure information at a location above the ankle where skin sensation is still present. The Haptic Module has a power button, two status LEDs, and a reset button (not shown in Figure 1). Power is supplied by a rechargeable internal battery. The Receptor Sole is a thin consumable insert that fits in a regular shoe. The Receptor Sole connects to the Haptic Module through a physical cable. (Walkasins are commercially available by prescription.)

Figure 1.

In previous studies, three Institutional Review Boards (IRBs) have determined that Walkasins meet the regulatory definition of a *non-significant risk* (NSR) device because they do not meet the definition for a *significant risk* (SR) device.

Under 21 CFR 812.3(m), an SR device means an investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

As a non-significant risk device, Walkasins . . .

- Are worn on the feet and legs and are not intended as an implant, and they do not present a potential for serious risk to the health, safety, or welfare of a subject;
- Are not purported or represented to be for use in supporting or sustaining human life, nor do they present a potential for serious risk to the health, safety, or welfare of a subject;
- Are not for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health, nor do they present a potential for serious risk to the health, safety, or welfare of a subject in this regard;
- Do not otherwise present a potential for serious risk to the health, safety, or welfare of a subject.

Summary of Previous Walkasins Research

The role of plantar cutaneous sensory afferent information for balance has been studied for more than two decades and is well-documented in peer-reviewed study literature.[1,2,3] Lars Oddsson, Ph.D., a scientist and widely published investigator on topics related to balance, co-invented Walkasins with Ph.D. student Peter Meyer during his tenure at Boston University's Neuromuscular Research Center. Their early work on the role of plantar cutaneous sensation for balance control,[2,3] combined with promising pilot data,[4] led to the NIH-funded development of Walkasins for patients presenting with gait and balance impairments related to SPN.

A randomized cross-over study of short-term, in-clinic effects of Walkasins use, conducted at the Minneapolis Veterans Affairs Medical Center (VAMC) and published in PLOS ONE, found clinically meaningful and statistically significant improvements in gait speed and functional balance in patients with SPN using Walkasins.[5] The authors stated that “findings suggest new sensory balance cues provided to the lower limb can modulate the activity of relevant nerve afferents and become integrated into sensorimotor control of balance and gait.”[5]

In 2020 a multi-site clinical trial of the long-term effects of daily Walkasins use (walk2Wellness, ClinicalTrials.gov #NCT03538756) was published in *Frontiers in Aging Neuroscience.*[6] The trial sites included Baylor College of Medicine, Hebrew Senior Life (a Harvard Medical School Affiliate), Johns Hopkins Medical Center, M Health Fairview, and Minneapolis Veterans Affairs Health Care System. After 10 weeks of Walkasins use, this long-term study demonstrated clinically meaningful improvements in Functional Gait Assessment (FGA) and gait speed, which is associated with a lower fall risk. The authors concluded that “a wearable sensory prosthesis may provide a new way to treat gait and balance problems and manage falls in high fall-risk patients with PN.”[6]

Most recently, an analysis of data from 26 weeks of Walkasins use in the walk2Wellness trial showed that “participants who reported falls over 6 months prior to the study had a 43% decrease in fall rate during the study as compared to self-report 6-month pre-study (11.8 vs. 6.7 falls/1000 patient days, respectively, $p < 0.004$), similar to the 46% decrease reported after 10 weeks of use.”[7]

Description of PhySens™ IMU Shoe Clip

In addition, participants will wear the PhySens™ Intelligent Motion Module (PhySens-IMM), Innovative Design Lab’s (IDL) compact motion sensing and processing platform. The PhySens-IMM is designed to sense motion information using its onboard MEMS accelerometer, gyroscopes, magnetometers, and barometer and to process this information in real-time using its onboard processors. Results are wirelessly transmitted via Bluetooth Low Energy (BLEv5) and stored on a local micro-SD card. To function across a wide variety of applications, the PhySens-IMM was designed to securely and repeatably attach to application specific, 3D printable, mounting clips. Uses for the PhySens-IMM range from exercise recognition to camera orientation estimation to wheelchair performance monitoring.

A photograph of the device appears below.

Figure 2.

This device is part of the PhySens™ ecosystem that includes a variety of sensor types designed to monitor important aspects of daily life such as sleep, exercise, cognitive state, gait, etc. The data obtained from the PhySens-IMM will be used to inform and complement the data collected from the Walkasins device and the functional assessments. (See IDL's website for more detailed information regarding this device.)

Ultra-Wideband (UWB) Real Time Location System

As a truth source, subject position will be tracked using the MDEK1001 Ultra-Wideband Real Time Location System, manufactured by Qorvo (formerly Decawave). This system uses a set of static "Anchor Nodes" positioned around the testing area to determine the relative position of "Tag Nodes" as seen in the figure 3 below.

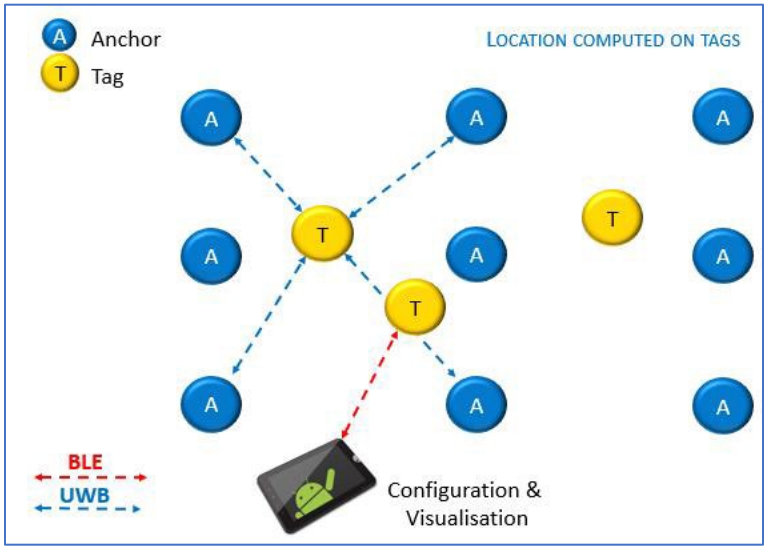


Figure 3.

The Anchor and Tag Nodes include a rechargeable battery and communicate wirelessly with each other, creating a mesh network. An additional node is attached to a laptop computer over USB to log the position of the Tag Node (subject) in real time. Both the Anchor and Tag Nodes are physically similar, as seen in figure 4 below—the Anchor node mounted on a tripod and the Tag Node attached to a clip to be worn on the subject's belt or pocket.

Figure 4.

The system has a maximum location rate of 10Hz and a typical accuracy <10cm. The maximum distance between nodes for reliable ranging is 25m. The ultra-wideband signal is compliant with IEEE802.15.4-2011 and complies with FCC & ETSI UWB spectral masks in the 3.5-6.5GHz range. These devices are commonly used in industry for real time location of equipment, people, and products in healthcare, warehousing, and industrial applications.

Rationale for the Pilot Study

The Walkasins system is one of a growing number of wearable devices that use various modalities of neuromodulation, defined as "the alteration of nerve activity through targeted delivery of a stimulus, such as electrical stimulation or chemical agents, to specific neurological sites in the body."[8] Because these technologies are relatively new, innovative applications of their use in various patient populations may lead to improvements in the care and quality of life of individuals who suffer from these life-altering diagnoses.

We have previously shown that individuals with peripheral neuropathy who have gait and balance problems walk faster with the Walkasins device.[5-7] This increase may be related to an improved automaticity of gait function, thereby decreasing the need for cognitive attention to the walking task, which is known to slow down gait.[9] Individuals

with mild cognitive impairment commonly show slow gait speeds,[10] likely due to a decline in executive function. There is a reason to think that sensory stimuli from the Walkasins device can improve the automaticity of gait in these individuals and thereby enhance gait speed.

Pilot Study Aim and Hypothesis

The primary aim of this pilot study is to investigate the effect of lower-leg mechanical tactile sensory stimulation on the gait speed and balance function of participants with mild cognitive impairment as measured by the SLUMS Examination. We hypothesize that participants will increase their gait speed and improve clinical outcomes, suggesting less reliance on compensatory executive control[9] when their Walkasins are turned on.

Pilot Study Design

Research Design

This pilot study will collect data from individuals with mild cognitive impairments who consent to participate in one assessment session. It will employ a pre- and post-test study design to evaluate whether wearing active Walkasins (i.e., Walkasins turned on) improves the participants' gait speed and other clinical outcomes of gait and balance function.

Study Site

The Pillars at Prospect Park, a senior living community located in Minneapolis-St. Paul, has agreed to allow RxFunction to recruit its residents and to use space at its facility to conduct this pilot study. The Pillars will not receive any funds for this project, and its employees will not be engaged in any research-related activities aside from potentially informing prospective participants about the availability of the research, providing prospective participants with the study team's contact information, and/or obtaining the prospective participants' permission for the study team to contact them.

Participant Selection

Up to 20 study participants will be enrolled in this pilot study. To participate, individuals must meet the following inclusion and exclusion criteria.

Inclusion Criteria

- Ambulatory person who is at least 65 years of age
- Ability to understand and provide informed consent: For this study we will assume participants are able to consent if they can satisfactorily answer the following 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 in this study?
- Ability to perceive vibrations from the Walkasins Haptic Module
- Ability to complete the functional outcome measures without the use of an assistive device
- Foot size that allows the Walkasins to function appropriately
- Mild Cognitive Impairment (MCI) as measured by the Saint Louis University Mental Status (SLUMS) Exam (scores between 20 and 24 + or -2 for those with less than a high school education and scores between 21-26 + or -2 for those who graduated from high school, which indicate mild cognitive impairment) and/or a diagnosis of MCI (or related term) in the person's medical record
- Slow gait speed (<1m/second or slightly faster, provided all other criteria are met)

Exclusion Criteria

- Use of ankle-foot orthosis for ambulation that prevents donning of Walkasins
- Self-reported acute thrombophlebitis including deep vein thrombosis
- Untreated lymphedema
- Untreated lesion of any kind, swelling, infection, inflamed area of skin or eruptions on the lower leg near product use
- Untreated fractures in the foot and ankle
- Self-reported severe peripheral vascular disease
- Other neurological conditions that impact walking (e.g., peripheral neuropathy)
- Weighs more than 300 pounds

Pilot Study Procedures

Specific Training

In addition to completing human subjects research training (e.g., CITI training), the RxFunction study team and any collaborators who assist with the pilot study will receive training on the protocol and procedures as well as their responsibilities and functions prior to their participation in study-related tasks.

Recruitment of Participants

Upon IRB approval of the study, participants may be recruited by flier, personal invitation, and/or referral. Study staff will inform interested individuals about the study and screen individuals for eligibility before inviting them to participate if they are eligible. (See Telephone Screening attachment.)

Consent Procedures

A qualified study team member will conduct the consent discussions in a private space. He/she will provide an overview of the pilot study, its purpose, risks and benefits, etc. Potential participants may take as much time as they need to read the consent form and to ask any questions they may have.

Before the potential participant signs the consent form, the study team member will ask the questions listed below. If the potential participant cannot answer the questions, the study team member may review the relevant points with him/her. If further review does not result in satisfactory responses, the study team member will advise the potential participant that he/she will not be able to take part in the study. (Consent will not be sought from a legally authorized representative or surrogate.)

- 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?

If the person consents to participate in the pilot study, he/she will sign the consent form and receive a copy for his/her records.

Documentation of Informed Consent Process

Documentation of the informed consent process will be maintained in study records. A study team member will note the date consent was obtained and affirm that consent was obtained prior to initiating any study-related procedures.

Study Visit Procedures

After subjects have signed the appropriate forms indicating their consent to participate in the study and to allow the study team to use their data (explained in the consent form), study staff will collect the following data points:

- Assigned identifying code for the participant
- Age
- Sex
- Race and ethnic demographics
- Height and weight
- Assistive device used if any
- Level of education (high school graduate or not)

The study team member will then check the inclusion and exclusion criteria to verify that participants meet the eligibility criteria and will enroll them into the study if they meet all criteria. As part of the eligibility verification, study staff will administer the SLUMS Exam, “an assessment tool for mild cognitive impairment and dementia.”[11]

Participants will remain eligible if they score as follows:

- High School Education: 21-26
- Less Than High School Education: 20-24

The final assessment for eligibility is a four-meter timed walk excluding an initial two meters to allow for acceleration. Participants will remain eligible for the pilot study if their gait speed is less than 1m/second. (At their discretion the investigator[s] may enroll individuals whose gait speed is slightly faster than 1m/second, provided they meet all other eligibility criteria.) This test may be repeated if necessary.

Participants who meet all eligibility criteria will then don a pair of Walkasins and the PhySens-IMM System. They will perform some brief balance exercises (i.e., sensory integration exercises) and then complete the following assessments with their Walkasins turned off and without the use of an assistive device:

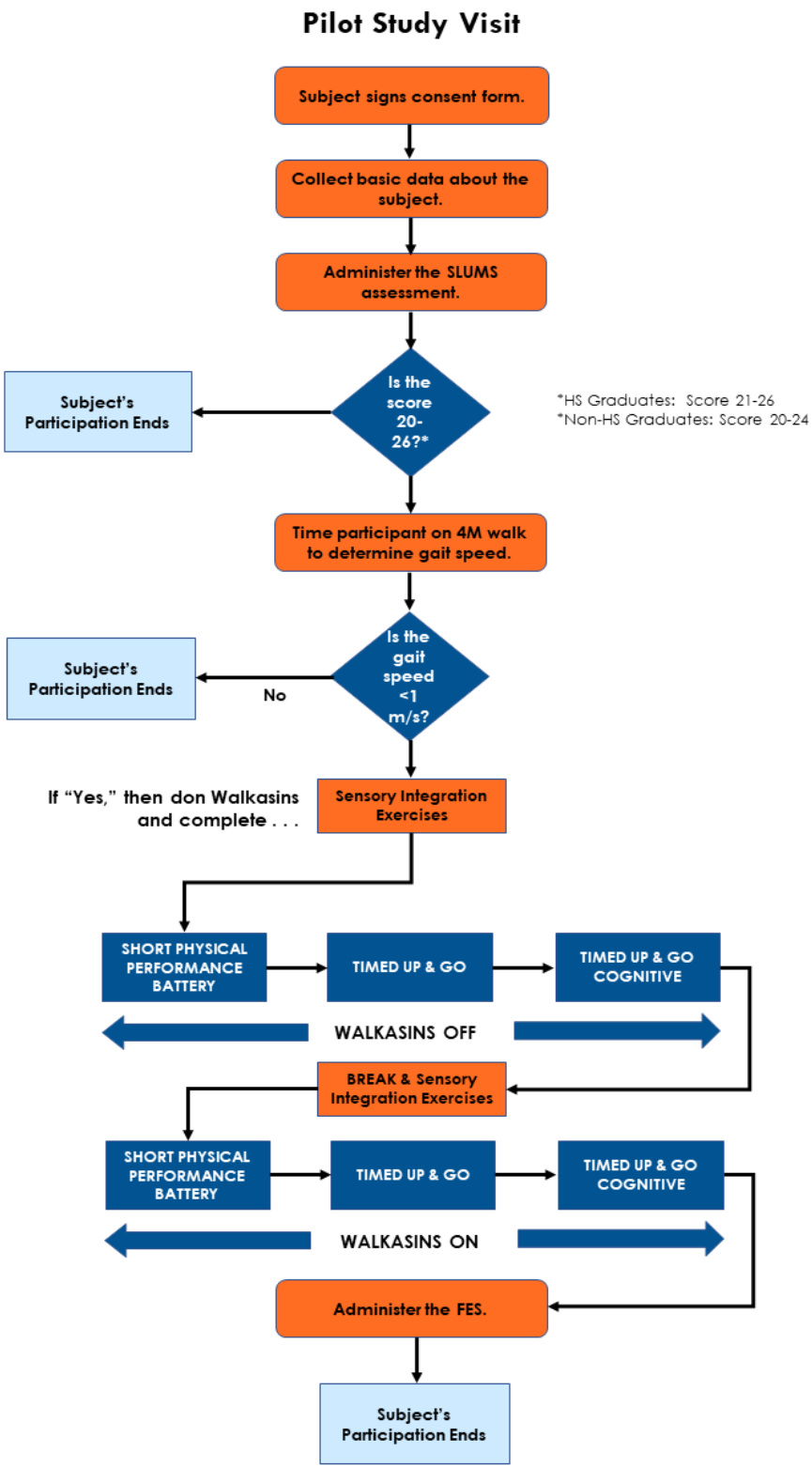
- Short Physical Performance Battery (SPPB): The SPPB "is a composite measure assessing walking speed, standing balance, and sit-to-stand performance." Research has shown it to be "predictive of an increased risk of falling" among other outcomes associated with older populations.[12] (Complete instructions for the SPPB are available at https://geriatrictoolkit.missouri.edu/SPPB-Score-Tool.pdf.)
- Timed Up and Go (TUG): The TUG is part of the Centers for Disease Control-recommended STEADI test protocol for balance function.[13] From a seated position in a standard armchair, the participant is asked to do the following:
  1) Stand up from the chair.
  2) Walk to a line on the floor 10 feet away normal pace.
  3) Turn.
  4) Walk back to the chair at normal pace.
  5) Sit down again.

  The tester will record the time taken from the command "Go" until the participant sits down again.
- Timed Up and Go Cognitive (TUG-COG): The TUG-COG is performed as described above; in addition, the participant is asked to count "backwards by threes from a randomly selected number between 20 and 100."[14] To standardize the assessment for this pilot study, the study team member who conducts the TUG-COG will use the same starting number for all participants (e.g., the same odd number for the first TUG-COG assessment and the same even number for the second TUG-COG assessment).

After a five-minute break, study staff will then guide the participants through the same sensory integration exercises they performed before the first set of assessments. Participants will then retest participants on the same assessments with Walkasins turned on and without the use of assistive devices. Upon completion of the assessments with their Walkasins turned on, participants will remove their Walkasins and the PhySens-IMM System and complete the Falls Efficacy Scale (FES).[15] The subjects' participation in the study will then be over.

Pilot Study Duration

The pilot study will involve one visit that may last 1 to 1-1/2 hours. (A flow chart of the study visit appears on the following page.) We anticipate that all data collection will be completed within three months after study initiation.


Pilot Study Visit
Subject signs consent form.
Collect basic data about the subject.
Administer the SLUMS assessment.
Is the score 20-26?*
Subject's Participation Ends
*HS Graduates: Score 21-26
*Non-HS Graduates: Score 20-24
Time participant on 4M walk to determine gait speed.
Is the gait speed <1 m/s?
No
Subject's Participation Ends
If "Yes," then don Walkasins and complete . . .
Sensory Integration Exercises
SHORT PHYSICAL PERFORMANCE BATTERY
TIMED UP & GO
TIMED UP & GO COGNITIVE
WALKASINS OFF
BREAK & Sensory Integration Exercises
SHORT PHYSICAL PERFORMANCE BATTERY
TIMED UP & GO
TIMED UP & GO COGNITIVE
WALKASINS ON
Administer the FES.
Subject's Participation Ends

Data Management and Quality Plan

Data Deidentification

Study staff will assign identification numbers to the participants' data, and they will use those numbers when analyzing the collected data.

Data Confidentiality, Storage, and Retention

All research team members will observe standard data confidentiality and security measures including, but not limited to, the following:

- Study staff will collect only the minimum identity information needed.
- Any portable electronic devices utilized in the study will be stored in secure locations when they are not in use.
- Physical and electronic access to the pilot study data will be limited to authorized personnel only.
- No information that can identify individual participants will appear in any publications or presentations that may result from analysis of the pilot study data.

Pilot study data will be retained indefinitely in a limited-access spreadsheet or spreadsheets. Any printed materials (e.g., consent forms) will be confidentially shredded when the period for their retention has passed (i.e., two years after study completion).

Data Quality

Data entry will occur directly as the study visits are conducted. Quality control measures to ensure data accuracy and integrity procedures for this pilot study include the following measures:

- Validation checks will be incorporated into cells as much as possible to help ensure that data entries are logically consistent with questions asked or tasks performed.
- No imputation methods will be used to infer missing values of any outcome measures.
- Data collection forms will be reviewed for completeness and consistency. Errors will be corrected, following standard GCP procedures.

Data Sharing

RxFunction may share information from the pilot study with researchers at other companies or institutions in accordance with standard data sharing agreements that

protect the confidentiality of study participants. Only RxFunction company officers may approve data sharing agreements.

Sharing of Results with Participants

At its discretion RxFunction may share information from the study with participants, providing only their own data or via reports summarizing results on all participants if requested (e.g., through a newsletter or RxFunction website posting).

Statistical Analysis Plan

We will use descriptive statistics as well as regression analysis to investigate trends in changes for the various outcomes measured. Walkasins on versus off conditions will be compared using paired t-test as well as Wilcoxon Signed Rank Test for non-normally distributed data. Test of normality will be conducted using the Shapiro–Wilk test. In addition, we may conduct qualitative analyses on participants' comments to answer research questions.

Risks and Potential Benefits

Potential Benefits

There are no direct benefits to individuals who participate in this pilot study; however, we hope that the information gleaned through their participation will enhance our understanding of Walkasins' potential role in the treatment of gait difficulties experienced by individuals with mild cognitive impairments.

Pilot Study Risks and Their Mitigation

- The device being tested may distract the participants while they are walking and increase the risk of falling. To help prevent falling during the testing at the research site, a spotter will walk next to the participants to help them regain balance if a fall starts to occur.
- There is a very low chance that participants may find the device stimulations uncomfortable. If this occurs, the participants can decide if they wish to end participation in the pilot study.
- RxFunction personnel may request participants' medical information relevant to the study, but they will limit the data collected to the minimum necessary to conduct the study.
- There may be other unknown side effects that could occur.

Every effort will also be made to minimize potential risks by the following means:

- Investigators and study personnel will include individuals who are experienced in research and trained in the study assessments.
- Clearly defined inclusion/exclusion criteria will help to ensure that only appropriate participants are enrolled.
- Maintaining participant safety through practices such as spotting the participants during study assessments will help to ensure their physical safety.

Provisions to Protect the Privacy Interest of Study Participants

RxFunction study personnel will exercise all standard precautions to ensure that only authorized individuals will access pilot study records. The collection of sensitive information about participants is limited to the amount necessary to achieve the aim of the pilot study.

Early Withdrawal of Participants

RxFunction's Withdrawal of Participants

Study personnel may end a subject's participation in the study without the participant's consent if they feel that it is in the participant's best interest. They may also end a subject's participation if he/she experiences a study-related injury or unacceptable side effects.

Participants' Requests for Withdrawal from the Pilot Study

Participants wishing to withdraw from the pilot study may advise the principal investigator or study staff of their wish to withdraw at any time during their participation. From the point of withdrawal, RxFunction will not collect further data from the participant for inclusion in the pilot study; however, any data collected up to the point of withdrawal will remain in the pilot study to protect its integrity. The consent form will advise participants of their right to withdraw and the limitations on data removal from the pilot study.

Adverse Events and Unanticipated Problems

Given the short duration of subjects' participation in this pilot study, we do not anticipate that any adverse events will occur; however, in the unlikely event such an incident should occur, RxFunction and its study team will evaluate the event according to the definitions and procedures described below.

Definitions

Adverse Event (AE): The FDA defines "an adverse event [as] any undesirable experience associated with the use of a medical product in a patient."[16] An adverse event (AE) can, therefore, be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of an investigational product whether or not it is related to the study product.

Serious Adverse Event (SAE): If the "patient outcome" of the adverse event meets any of the criteria below, it is a serious adverse event that must be reported to the FDA.[16]

- Results in death
- Is life threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability/incapacity
- Requires medical or surgical intervention to prevent permanent impairment to body structure or a body function
- An "important medical event" that "does not fit the other outcomes, but [which] . . . may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes"[16]

Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs): The Office of Human Research Protections (OHRP, 45 CFR 46.108[a][4]) and FDA (21 CFR 56.108[b]) require that researchers report the occurrence of any unanticipated problem involving risks to subjects or others (UPIRTSO) to their institutional officials, the IRB, and FDA for FDA-regulated research and/or to OHRP for other types of research (depending on funding source and IRB reporting requirements). For an incident to be classified as a UPIRTSO and for it, therefore, to be reportable, it must meet all three criteria described in OHRP guidance:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the

IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.[17]

UPIRTSOs may be either adverse medical events or non-medical events (e.g., a data breach), but only those events that meet the criteria listed above will be classified as UPIRTSOs.

Classification of the Event's Relationship to the Device

The principal investigator and/or the clinician conducting the assessments will determine whether there is a reasonable possibility that Walkasins caused or contributed to an AE, and he/she will record the determination on the Adverse Event Log per the categories in the table below. Determinations should be based on assessment of temporal relationships, association (or lack of association) with underlying disease, and presence (or absence) of a more likely cause.

Definitions for determination of the relationship include the following:

Study Intervention's Relationship to the Adverse Event

CATEGORY	DEFINITION
Definitely Related	The AE is related to the device. There is objective evidence establishing a cause and effect relationship between the AE and the device.
Possibly Related	The AE could be related to or caused by the device; however, there is no clear evidence establishing a link/relationship. The participant's condition or concomitant therapy could have caused the AE.
Definitely Not Related	There is no evidence that the study device caused the reported event. The AE can reasonably be explained by the participant's condition and/or another cause or concomitant therapy. Alternatively, the temporal sequence between the device and the AE is such that the relationship is improbable or clearly unrelated.

Recording of and Responding to Adverse Events

If an adverse event (or unanticipated problem) occurs, study staff will document it on the appropriate log within five business days of its occurrence or of study staff becoming aware of the event. If the event is serious, staff will report the event within 24 hours of its occurrence or of becoming aware of its occurrence. They will also take appropriate actions to help ensure the participant's safety.

Notification of Adverse Events and UPIRTSOs

Adverse events will be reported internally to RxFunction's director of RA/QA according to the relevant quality policy; he will report the event to the FDA if the event meets FDA medical device reporting requirements. UPIRTSOs and AEs will be reported according to IRB guidelines.

Ethical Considerations

The research team will obtain and maintain IRB approval for the pilot study throughout its duration.

Participant Stipends or Payments

Participants will receive $50 in compensation for taking part in the study. (For accounting purposes, they will sign a form, indicating receipt of the gift card. This form will not be linked to linked to their study data.)

Publication Plan

Rx Function, Inc., as the pilot study sponsor, is committed to dissemination of significant findings that may result from the pilot study. The study team will observe International Committee of Medical Journal Editors (ICMJE) guidelines when determining author contributions.

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