Development of a Multifunctional Rehabilitation Device for Persons With Parkinson's Disease

NCT05586490

1/30/2024

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:
Development of a Multifunctional Rehabilitation Standing and Stepping Device for persons with Parkinson's disease. Sub-study 3: Pilot randomized control clinical trial comparing in-home MRSSD to [redacted] standing desk vs. regular standing vs. usual care in PwP

Company or agency sponsoring the study: National Institutes of Health (NIH)
Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator:
James Richardson, MD, PI, Professor of Physical Medicine & Rehabilitation at the University of Michigan

Study Coordinator: Abbey Biddix, BSc, Department of Radiology at the University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

In this study, for a period of 12 weeks, you will be put into one of 3 groups. 2 of the groups will have a standing desk placed at their home and one group is the control group, with no desk at home. You will be asked to use this desk for a certain amount of time per day. You will be able to do any activity that you can do on a sitting desk as well. Before and after this 12-week period you will come to the lab for a battery of tests and questionnaires.

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There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include the rare risk of falling and the very rare risk of tripping while standing or taking steps while using the [redacted] table. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by contributing to a widely applicable approach to treating inactivity. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be two test days (4-6 hours each) and the use of the desk at home, as well as participating in one weekly exercise group (one hour long)

You can decide not to be in this study. Alternatives to joining this study include not participating in this research study. Participating in this study is completely voluntary.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

This research collects information about sitting too long and being physically inactive. It has become apparent that being inactive, or sedentary, has a lot of negative health effects. This is why standing desks have become more popular in recent times. We have developed a new type of standing desk that [redacted] encourages the user to make small steps, and this may help alleviate some discomfort that is common with standard standing desks. This research study helps us learn about the standing desk- compared to normal standing desks. You will be randomly assigned (like a flip of the coin) to one of three groups. The first group is a 12 week in home intervention with the new standing desk, the second group is a 12 week in home intervention with a standard standing desk , and the last group is a 12 week non standing desk control group. All the groups will have to attend a weekly exercise class. Before and after the 12-week period you will come to our lab where you will undergo a battery of tests and answer some questionnaires. This in-home intervention period will last 12 weeks plus or minus 1 week. You will complete various assessments. The testing includes but is not limited to motor testing, memory and thinking tests and muscle testing. You will also undergo a DXA scan, and we will collect data from sensors that youwill wear for a couple of days.

3. WHO MAY PARTICIPATEIN THESTUDY

Taking part in this study is completely **voluntary.** You do not have to participate if you do not want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

People with Parkinson's disease can participate in this study. All participants need to be over the age of 45 years. Participants should be willing and able to comply with study requirements. Men and women may participate. Subjects with other neurological, psychiatric, unstable medical conditions, or that experience a drop in blood pressure upon standing (orthostasis) may be excluded. In addition, subjects who, in the opinion of the investigators, would be at increased risk or who are unable to perform or tolerate the research procedures will be excluded.

Exclusion criteria:

1. PD dementia (based on the Emre et al. diagnostic criteria {Emre, 2007 #2155}- cognitive and instrumental activities of daily living assessment);
2. Parkinsonism plus syndromes;
3. Inability to stand, step or walk without an assistive device;
4. History of symptoms in stance that preclude safe and comfortable participation, such as severe dizziness and lightheadedness, severe orthostasis, severe symptomatic leg or back musculoskeletal pain, painful neuropathy, significant ankle edema or medication side effects;
5. History of symptomatic cardiovascular or pulmonary disease interfering with stance;
6. History of active rheumatic arthritis;
7. History of uncontrolled chronic pain syndrome;
8. Any other history of medical or psychiatric comorbidity precluding safe participation in the project;

Venous stasis or severe varicosities.

3.2 How many people are expected to take part in this study?

Up to 25 subjects are expected to participate in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you agree to take part in this study, you will be asked to sign this informed consent form before testing will begin, this will take about an hour. You will take part in two laboratory visits. Between the first and second laboratory visits, everyone will take part in a 12-week physical activity program which means, completing a one-hour group exercise program every week. Whether you will use the [redacted] table, or will receive no device in your home will be decided at random (like the flip of a coin). If you are selected to receive a desk at home, trained research staff under the supervision of a Physical therapist (PT) will come to the home to instruct on proper body positioning at the desk, individual adjustment of height, proper positioning of arms, use of anti-fatigue mat, and optimal monitor height. An anti-fatigue mat is a rectangular rubber mat designed to reduce fatigue caused by standing for long periods on hard surfaces. The PT will also perform an in-home safety assessment of the office or room in which the table will be placed to ensure safety not only for the users but also for family members or children.

Study Blinding: This study is a so-called single blinded study. This means that most study team members do not know if you have a table at your home or not. Only the study team member who tells you if you will receive a table and those that visit you at your home will know. Please refrain from telling any other study team members whether you have a table at your home or not. We will let you know when the "blinding" is over, and you are free to openly discuss the study with the study team. Importantly, if there are any immediate safety concerns or any other urgent issues that require our immediate attention then please discuss this with a study team member and disclose the at-home table status.

Schedule of Activities for Sub Study #3

Visit #	Activities
Optional Screening Visit (if needed)	Neurological exam, medical history questions, demographics.
Clinical Testing Visit 1	Motor Testing, cognitive testing, muscle testing, activity monitor, questionnaires, DXA bone scan, Continuous Glucose Monitoring, VO2 energy expenditure measure
Activity monitor Day 1	x
Activity monitor Day 2	x
Activity monitor Day 3	x
Table Set Up	Assemble study device in patient home, in-home safety assessment, proper instructions on how to use table, anti-fatigue mat placement.
12-week study device desk use	For participants in the study device desk group
12-week standing [redacted] desk use	For participants in the [redacted] standing desk group
12-week non-desk use	For participants in the non-desk group
12-week exercise sessions	All participants will have weekly exercise sessions for 12 weeks.
Table Pick Up	Study device and anti-fatigue mat removed from the patient's home.
Clinical Testing Visit 2	Motor Testing, cognitive testing, muscle testing, activity monitor, questionnaires, DXA bone scan, Continuous Glucose Monitoring, VO2 energy expenditure measure
Activity monitor Day 1	X
Activity monitor Day 2	X
Activity monitor Day 3	X

Visit 1: Pre-Intervention: 4-6 hours

Clinical tests:

We may take health related information including the measurements of weight, height, pulse and blood pressure as well as an evaluation of your ability to move and walk. We will also ask you questions about your health and medication, screen your cognitive abilities (activities of thinking, understanding, learning, and remembering). You will receive a physical and neurological examination ("medical check-up") as well as an evaluation of your ability to move and walk. In addition, we will ask you some general demographic (identifying) and clinical information. Also, feet and ankle measurements may be taken. Bone density and body mass will be assessed with a DXA scanner. Optionally, muscle strength will be assessed with a handheld dynamometer, and power will be assessed with the Vertical Jump Test. Additional measures include the glucose (Dexcom continuous glucose monitor) and the VO_2 energy

expenditure (Cosmed device).

Vital Measures:

_____(initials) I discussed the vital measurements and **agree** to participate in vital measures.

_____(initials) I discussed the vital measurements and **do not agree** to participate in vital measures.

Muscle Testing:

_____(initials) I discussed the muscle testing and **agree** to participate in muscle testing.

_____(initials) I discussed the muscle testing and **do not agree** to participate in muscle testing.

Vertical Jump Test:

_____(initials) I discussed the vertical jump test (VJT) and **agree** to participate in the VJT.

_____(initials) I discussed the vertical jump test (VJT) and **do not agree** to participate in the VJT.

Motor tests: We will place small sensors at your wrist, ankles, and around your chest to measure your body movements while you perform different balance and gait tasks. You will be standing at the study device desk for up to two hours. Optional grip and core strength tests may also be performed. Core strength will be assessed with a timed lateral plank.

Grip and Core Strength Testing:

_____(initials) I discussed the grip and core strength testing and **agree** to participate in grip and core testing.

_____(initials) I discussed the grip and core strength testing and **do not agree** to participate in grip and core testing.

Visual tests: We will test your vision as you are exploring or detecting small items on a screen or a sheet of paper.

Neuropsychological and neurobehavioral tests: The neuropsychological tests are designed to get an overall estimate of your cognitive abilities. These functions will be measured with standard pencil and paper tests. We will also ask you questions about your health, habits, and mood. We will also ask your questions about your experience using the device.

Assessment of Daily Life Activity**:** At the end of each laboratory visit, you will be sent home with an activity monitor and will be asked to wear it for three days to monitor your normal overall daily-life movement, so-called “actigraphy”. This device is very similar to a pedometer that some people use to count the number of steps that they take every day. We will provide instructions on how to attach this device to your body and when to use it. This requires also keeping track in a logbook when you were

wearing the device and document selected activities (for example when you took the device off to take a shower or when you were playing sports).

Intervention:

Weekly Exercise Sessions: Between your first and second laboratory visits, you will be required to participate in weekly (lx/wk) one-hour long group exercise sessions or comparable physical therapist approved exercise for 12 weeks (during the same time period than the in-home- standing table use, if selected). These sessions are free and facilitated by Parkinson's disease support groups (Ann Arbor, Howell, Rochester, and/or West Bloomfield). If you are unable to attend these sessions, you may attend weekly sessions facilitated by another group instead. Please ask the physical therapist for approval before attending exercise sessions facilitated by any other groups.

In-Home Standing Table Use - and Static): As mentioned above, you may be selected (at random) to use- standing table or the "Multifunctional Rehabilitation Standing & Stepping Device" in your home for 12 weeks between your first and second laboratory visits. If you are selected, you will be asked to use the table for a total of 2 hours per day, over the course of the entire day, for at least 5 days per week. The- standing table and "Multifunctional Rehabilitation Standing & Stepping Device" are height-adjustable standing desks [redacted] You may use the table to perform typical desk activities, such as using a computer, reading/writing emails, playing games, watching videos on your computer, listening to music, reading, etc. While other individuals in your house are allowed to use this table (e.g. you share the computer with them), we ask you to prohibit them from using it in the——.In other words, they are only allowed to use it as a regular standing desk. During the in-home portion of this study, we will beusing a video monitoring system developed by Lauro Ojeda, one of our engineering collaborators. This monitoring system will be used to give us an accurate measure of how often you are using the table and for how long. The system will be motion activated when you stand in front of the desk and will record a snapshot every 30 seconds while you are using the desk. This will enable us to know who was using the desk and for how long. Recordings are being used so that we can distinguish between you using the desk and anyone else. As a reminder, please do not have anyone besides yourself use the investigational device. **You will have the** opportunity to consent to this at the endof the document (signature box). You can choose to agree or not agree to video recording (please see signature box at end of Consent), This table will be delivered and installed in your home in the week following your first laboratory visit. After completion of the in-home intervention, the study team will retrieve the study table at no cost to you.

Home Visit and Biweekly Phone Calls: After the first laboratory visit, trained research staff under the supervision of a physical therapist will visit your home. If you are selected to use the-standing table or Multifunctional Rehabilitation Standing & Stepping Device, trained research staff under the supervision of the physical therapist will give you instructions on proper body positioning at the table and proper use of the anti-fatigue mat, will adjust the height of the table, and will also adjust the height of your computer monitor, if needed/applicable. If you are not selected to use either of the tables, trained research staff under the supervision of the physical therapist will give you instructions on proper body positioning at your own home workstation. Trained research staff under the supervision of the physical therapist will also perform an in-home safety assessment of the room in which the table will be placed or in which your own workstation is located to ensure your safety and the safety of others in your

home. A physical therapist will also call you every two weeks or as needed to make sure that you are using the table, if applicable, and to answer any questions that you may have. We may ask about your experience using the desk or discomfort. These phone calls will take approximately 5-10 minutes.

Open Label Extension of Table Use:
For participants who receive a desk, [redacted], they will have the option to keep the desk in their home for up to 2 years. Participants will have the option to provide user feedback to the study team during this period. The study team may ask participants about discomfort while using the desk and ease of use. You will be able to decide if you would like to keep the desk following the 12-week intervention period.

_____(initials) I discussed the extending the device usage period and **agree** to keep the device in my home for up to two years **AND** provide optional user feedback.

_____(initials) I discussed the extending the device usage period and **agree** to keep the device in my home for up to two years. **I do not agree provide optional user feedback.**

_____(initials) I discussed the extension of using the device and **do not agree** to keep the device in my home for up to two years or provide optional user feedback.

Visit 2: Post Intervention: 4-6 hours

Clinical tests: We may take health related information including the measurements of weight, height, pulse, and blood pressure as well as an evaluation of your ability to move and walk. We will also ask you questions about your health and medication, screen your cognitive abilities (activities of thinking, understanding, learning, and remembering). You will receive a physical and neurological examination ("medical check-up") as well as an evaluation of your ability to move and walk. Optional measurements of weight, height, pulse and blood pressure, feet and ankle measurements may be taken. In addition, we will ask you some general demographic (identifying) and clinical information. Bone density and body mass will be assessed with a DXA scanner. Optionally, muscle strength will be assessed with a Biodex and power will be assessed with the Vertical Jump Test. Additional measures include the glucose (Dexcom continuous glucose monitor) and the VO_2 energy expenditure (Cosmed device).

Motor tests: We will place small sensors at your wrist, ankles, and around your chest to measure your body movements while you perform different balance and gait tasks. You will be standing at the study device desk for up to four hours. Optional measures of grip and core strength may also be taken. Core strength will be assessed with a timed lateral plank.

Visual tests: We will test your vision as you are exploring or detecting small items on a screen or a sheet of paper.

Neuropsychological and neurobehavioral tests: The neuropsychological tests are designed to get an overall estimate of your cognitive abilities. These functions will be measured with standard pencil and paper tests. We will also ask you questions about your health, habits, and mood. We will also ask your questions about your experience using the device.

Assessment of Daily Life Activity**:** At the end of each laboratory visit, you will be sent home with an activity monitor and will be asked to wear it for three days to monitor your normal overall daily-life movement, so-called "actigraphy". This device is very similar to a pedometer that some people use to count the number of steps that they take every day. We will provide instructions on how to attach this device to your body and when to use it. This requires also keeping track in a logbook when you were wearing the device and document selected activities (for example when you took the device off to take a shower or when you were playing sports).

Besides the information about the main study, the following information is specific to unspecified future use of identifiable data and/or biospecimens. We would also like your permission to keep some of your medical information collected in the main study, so that we may study it in future research. The future research may be similar to this study or may be completely different.

You can take part in the main study even if you decide not to let us keep your medical information for future research.

If you give us your permission, we will use your medical information for future research. Even if you give us permission now to keep some of your medical information, you can change your mind later and ask us to destroy it.

We may share your medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your medical information with other researchers, we will not be able to get it back.

Future use of your identifiable data and/or specimens will be conducted in compliance with applicable regulatory requirements.

Allowing us to do future research on your medical information will not benefit you directly.

With appropriate permissions, collected information may also be shared with other researchers here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

4.2 How much of my time will be needed to take part in this study?

This study will take course over the period of 14 weeks. You will have three study visits that take place at the Functional, Neuroimaging, Cognitive and Mobility Lab which will take 4-6 hours each. You will spend 12 weeks using the "Multifunctional Rehabilitation Standing & Stepping Device", the [redacted] table desk, or no desk for 2 hours per day, over the course of the entire day, for at least 5 days per week. You will wear an ActivPAL for a week after the first and second laboratory visits. Subjects will also participate in 12 exercise group sessions, each lasting about 45-60 minutes, weekly. You will also wear the activity and glucose monitor for a total of 6 days.

4.3 When will my participation in the study be over?
Study participation will end after all sessions have been completed. Most subjects will complete their part in the study within about 4 months.

4.4 What will happen with my information and/or biospecimens used in this study?
With appropriate permissions, your biospecimens and collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
The known or expected risks will be defined as: Likely - occurring in more than 25% of people (more than 25 out of 100 persons); Common – occurring in 10% - 25% of people (in 10 to 25 out of 100 persons); Infrequent - occurring in 1 - 10% of people (1 to 10 out of 100 people); Rare - occurring in less than 1% of people (fewer than 1 out of 100 persons); or Very Rare - occurring in less than 0.1% of people (fewer than 1 in 1,000 persons).

- The known or expected risks will be described in normal script.

The actions that the researchers take to minimize these risks will be described in italic script, as demonstrated in this paragraph.

General Risks:
There is a **very rare** risk of breach of confidentiality, which may affect privacy, self-esteem, social standing, employability, and insurability.
Section 9.1 will provide more detailed information on how we protect your privacy. In general, study records will be kept in databases maintained by the investigators. These databases are kept separate from identifiable records, are protected by passwords, and only accessible to personnel involved in the study. If you withdraw from the study at any time, a record of the withdrawal and the reasons given for withdrawing may be kept as part of the study record.

This risk of confidentiality is also applicable to the video monitoring system. The recordings the device obtains will only be stored on the memory card in the device. The research team will be the only people to have access to this memory card once we pick up the device. After we have analyzed how long you used the table for, the memory card will be erased.

Clinical tests:

There is a **very rare** risk of physical fatigue during the clinical examination.

Trained research staff will conduct all the tests and administer all the questionnaires. The staff will be prepared to respond to your concerns by temporarily suspending testing and/or breaking up testing sessions into several brief visits if needed

There is a **likely** risk of experiencing some pressure when pushing against the handheld dynamometer for the muscle strength assessment.

The pressure will disappear if you release the dynamometer.

There is an **infrequent** risk of boredom, frustration, and/or mental fatigue while performing the tasks. *Trained research staff will conduct all the tests and administer all the questionnaires. These tests can be temporarily suspended if needed.*

Motor testing:

Many of the tests are comparable to normal standing and walking conditions that you may experience in everyday life. Nonetheless, there is an **infrequent** risk of falling or near-falling during these tests which may result in fall-related injuries.

Trained research staff will remain in close proximity to you at all times and observe ('spot') you to prevent you from falling.

There is a **very rare** risk that the sensors to measure overall movement and balance and those to measure muscle activity may become detached and that you may trip. You may also trip on the pressure sensitive mat.

We will regularly check the sensors for appropriate attachment, and you will be closely monitored.

There is a **very rare** risk that the sensors to measure overall movement and balance and those to measure muscle activity may become detached and that you may trip. You may also trip on the pressure sensitive mat.

We will regularly check the sensors for appropriate attachment, and you will be closely monitored.

There is a **rare** risk that you may experience some minor anxiety ('test anxiety'), become worried, or have an anxiety reaction in response to any of the tests and procedures. For example, you may suddenly experience anxious feelings while performing the metabolic assessment or become worried about your health.

Neuropsychological and neurobehavioral tests:

There is an **infrequent** risk of boredom, frustration, and/or mental and physical fatigue during the neuropsychological and neurobehavioral testing.

Trained research staff will conduct all the tests and administer all the questionnaires. The staff will be prepared to respond to your concerns by temporarily suspending testing and/or breaking up testing sessions into several brief visits if needed.

Vision Testing:

There is a **very rare** risk that you may experience some minor eye strain when doing the visual tracking tests.

Rest breaks will be provided if needed. Any minor eye strain will disappear shortly after the test.

Standin table intervention [redacted]):

There is a common risk of muscle and bone pain or discomfort with prolonged standing.

The ad libitum sit-stand design of the study will allow you to sit down at any time. Therefore, you will be advised to return to a seated position if you experience physical discomfort from using the standing table. You are also allowed to lean on the tabletop without any restriction. To prevent musculoskeletal discomfort, you will be standing on an anti-fatigue mat. You will also be advised that you have the option to completely stop the study if you feel too uncomfortable with the [redacted] standing desk.

There is **a infrequent** risk of worsening or developing enlarged veins (varicosis) with upright postures in the legs. You will be screened for lower extremity venous stasis and/or excessive varicosis. However, the risk of varicosis is greater for static (i.e., standing without any movement)- standing. [redacted] as the lymphatic pump function of calf musculature is less effective with static standing. Subjects with mild varicosis are commended to wear low-pressure support stocks in the range of 20-30 mm Hg to reduce the possible risk of varicosis during the study.

You will be screened for lower extremity venous stasis and/or excessive varicosis. Subjects with mild varicosis are commended to wear /ow-pressure support stocks in the range of 20-30 mm Hg to reduce the possible risk of varicosis during the study. There is a reduced risk of deep venous thrombosis with standing compared to sitting.

There is a **rare** risk of injury/falling or tripping with the table use. You will be standing upright behind a table making small steps. This is not different from normal standing conditions that can be encountered during normal daily routines. Therefore, the risks are deemed comparable to the risks of everyday life.

Trained research staff under the supervision of *the physical therapist will perform an in-home safety assessment of the office or room location where the table will be placed to ensure safety not only for you but also for your family members or children. To minimize the risk of falling, the table will be placed preferentially close to walls (within 18-20 inches) or in a corner **(i.e.,** you would lean back on wall instead of falling) and away from sharp objects. Overall, risk of falling is very small given that you can lean on the table, . Also, although other individuals in/visiting your household will be able o s t he* [redacted]

There is an **infrequent** risk of minor foot swelling.

Given that the table use requirement is a total (does not have to be consecutive) of two hours per day for at least five days per week, you will be able to take as many rest breaks as needed. Minor foot swelling may disappear over time. You may elevate your feet a little bit while lying in bed.

There is an **infrequent** risk of lightheadedness, dizziness, a decrease in blood pressure, feeling disoriented, or feeling off balance. With the- table, you may also experience some motion sickness.

If you experience any of these symptoms, you can try sitting down, drinking water, eating a snack, or engaging your lower extremity muscles (i.e. clenching your muscles). These symptoms should subside upon sitting down and resting.

Assessment of daily life activity:

Actigraphy: There is a **very rare** risk that the movement monitoring device (activPAL™) will detach from you, which may result in you tripping.

Subjects will receive instruction for proper attachment of the activity monitoring device. Trained personnel will attach the equipment to you, and it will be worn only for 10 minutes for each measurement. You will receive instructions for proper attachment of the activPAL™. The activPAL™ device consists of an acceleration sensor and an ambient light sensor. Hence, the activPAL™ only measures overall movement. It does not store any personal/medical/identifiable information. It does not record your geographical location or specific activities that you are performing. And such locations and activities cannot be derived at a later point from the data that is stored in the device. Therefore, there would be no breach of confidentiality/privacy/anonymity in the event of a loss of an activPAL™ device.

DXA scan:

During the course of this study, you will be exposed to radiation from the DXA scan.

The biological effect of radiation in humans is measured in terms of Sieverts (Sv) or mSv (1/1000 Sv), which is a unit of uniform whole body exposure. Radiation to which you will be exposed from this research project will be approximately 0.0477 mSv for the three DXA scans combined. The effects on the body of this radiation exposure will be added to your overall lifetime radiation risk. The US Federal Government requires that the annual amount of radiation exposure of radiation workers does not exceed 50 mSv per year; the maximum radiation to which you will be exposed with the DXA scans is less than 0.1% of this amount. Subjects in the control group who will also complete the optional testing sessions, which includes an additional DXA scan, will receive a total of 0.0636 mSv radiation. This is 0.1% of the allowed annual amount for radiation workers.

No DXA scans will be performed on pregnant, nursing, or potentially pregnant women.

A urine pregnancy test will be performed on all women of childbearing potential within 48 hours prior to the DXA scanning session.

Continuous Glucose Monitor:

There is an **infrequent** risk of bruising, bleeding or soreness associated with the CGM. There is a very **rare risk** of infection. There is an **infrequent** risk that you may feel dizzy or lightheaded or may even faint.

The FDA safety information for the CGM includes the following contraindications:

1) Sensor and transmitters need to be removed before Magnetic Resonance Imaging, Computed Tomography scan, or diathermy treatment.
It is unlikely that you will have any of those tests for personal reasons while enrolled in this study because we will be carefully selecting research participants. If you do however need one of these tests, then you will be scheduled to participate in this research study during different days than you would have those tests. We will also remind you regularly about this contraindication.

2) **Taking medications with acetaminophen while wearing the sensor may falsely raise glucose readings.**

We will remind you to avoid acetaminophen during the study and to use alternative painkillers if needed.

The safety information for the CGM system also contains the following possible adverse device effects of inserting a sensor and wearing the adhesive patch:

local infection
inflammation
pain or discomfort
bleeding at the glucose sensor insertion site
bruising
itching
scarring or skin discoloration
hematoma
tape irritation
sensor or needle fracture during insertion
wear or removal

All these adverse events are considered minor and easy to resolve. We will train you on the insertion of the sensors and we ask that you communicate with us immediately in the event of any adverse effect.

Cosmed:
There is an **infrequent** risk of feeling minor discomfort from wearing the oxygen mask or telemetry unit during the metabolic assessment.

You may remove the mask or unit if these create discomfort.

MicroFET3 Handheld Dynamometer:
When measuring muscle strength with the microFET3 system there is a **common** risk to feel some pressure against the muscle that is tested as well as some fatigue afterward. There is an **infrequent** risk for some minor muscle pain after testing, which can appear 1-3 days afterwards and should resolve by itself.

Only personnel who are trained in the use of the microFET3 *system will be allowed to test you.*

Lateral Plank:
When completing a timed lateral plank, there is a **common risk** to feel some pressure and fatigue in the obliques and hips. There is an **infrequent risk** for muscle pain after testing.

Support pillow will be used, and the test is optional for those who do not feel comfortable completing this assessment.

As with any research study, there may be additional risks that are unknown or unexpected.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, some subjects may see improvement in their mobility functions after the group exercise sessions and/or after the in-home study device table use. Possible benefits of the research for society (or for future patients with Parkinson's disease) include the translation of its results to clinical rehabilitation in subjects with Parkinson's disease and/or other conditions associated with mobility changes. 5.5 Will the researchers tell me if they learn of

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
You may decide not to participate in this study. Participation in this study is completely voluntary.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
There is no harm in leaving the study before it is finished. We would ask that you return the movement sensor.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

There are no costs or billing for this study.

8.2 Will I be paid or given anything for taking part in this study?
You will receive $50 per laboratory visit and screening visit completed and $10 per exercise session attended. You will be paid after your last study visit or, in case you decide to withdraw from the study, you will be paid for the portions that you have completed. Parking is free at the study locations.

8.3 Who could profit or financially benefit from the study results?
The company whose product is being studied:

In the interest of transparency, we will inform you that Dr. Nicolaas Bohnen, who is the director of the Functional, Neuroimaging, Cognitive, and Mobility Lab, is the owner of Tulip Make Me Move Desk, LLC, a rehabilitation device research company related to the study.

Tulip Make Me Move Desk, LLC, will be the manufacturer of a research desk device being studied.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

Miriam Bohnen is the spouse of Dr. Nicolaas Bohnen. She may not obtain informed consent, including reconsent, from human subjects in this study.

Researchers conducting the study, the University of Michigan, and other researchers that obtain your deidentified samples and clinical data will not profit directly from them. However, if research using your samples leads to new tests, drugs, or other commercial products as a result of knowledge gained using your samples, you will not share in any profits.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
Your research records will be stored in a secure location to which only the investigators have access. All research records will be stored under code numbers, without attached names or other identifying information. The “key” linking these records to subject names will be stored in a separate, locked file.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Child abuse and neglect, or harm to self or others will be reported by the principal invesitgator.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers
- Other information – Your Social Security number is needed to provide payment to you.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

9.5 Will I be contacted for other studies?
No, unless you indicate by initialing below that you may be contacted by researchers at the University of Michigan for studies for which you may eligible. If you agree to be contacted for other studies, we will keep your name and contact information in a separate password-protected database.

_____(initials) I agree to be contacted about other research studies for which I may qualify. If I cancel my permission for this study, I will not be contacted for other studies. If I do participate in another study, data obtained in this study may also be used for that study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:	James Richardson, MD
Mailing Address:	Functional Neuroimaging, Cognitive and Mobility Lab Domino's Farms Lobby B-1200, PO Box 362 24 Frank Lloyd Wright Dr. Ann Arbor, MI 48106
Telephone:	734-998-8400

Study Coordinator:	Abbey Biddix, B.S
Mailing Address:	Functional Neuroimaging, Cognitive and Mobility Laboratory Domino's Farms, Lobby B- Suite 1200 24 Frank Lloyd Wright Drive P.O. Box 362 Ann Arbor, MI 48106
Email:	abiddix@med.umich.edu
Telephone:	734-936-5366

Study Device Coordinator:	Alexis Griggs
Email:	gralexis@med.umich.edu
Telephone:	734-998-8420

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent/Assent to video recording solely for purposes of this research
This study involves video and/or audio recording and/or photography. If you do not agree to be recorded, you can still take part in the study.

_____ Yes, I agree to be video/audio recorded/photographed.

_____ No, I do not agree to be video/audio recorded/photographed.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-D

Consent to Collect for Unspecified Future Research
This project involves the option to allow the study team to keep your identifiable specimens/data for use in future research. I understand that it is my choice whether or not to allow future use of my specimens. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ **Yes**, I agree to let the study team keep my specimens for future research.

_____ **No**, I do not agree to let the study team keep my specimens for future research.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____