Feasibility and Safety of a Portable Exoskeleton to Improve Mobility in Parkinson's Disease

NCT06028529

7/6/2025

Central Virginia Veterans Affairs Health Care System (CVHCS)
Richmond Institutional Review Board
Consent Form

Template Version Date: (6/15/2021)

Title of Research Study: Feasibility and Safety of a Portable Exoskeleton to Improve Mobility in Parkinson's Disease

Sponsor: Veterans Affairs RR&D Small Projects in Rehabilitation Research (SPIRE)

Protocol No.: 1729604

[redacted]

KEY INFORMATION:

We are asking you to consider participation in this research study about the use of a portable exoskeleton device for people with Parkinson's disease (PD). This initial information is provided to help you decide whether to participate in the study or not. By doing this study**,** we hope to learn if the exoskeleton device is safe to use in people with PD, and if it can improve mobility. The device is the Keeogo exoskeleton. The Keeogo is a powered walking assistance device that is attached to the waist and legs with cushioned straps and cuffs to stabilize and assist lower limb movement. It is Food and Drug Administration (FDA) approved to improve mobility in people with spinal cord injuries and strokes. It is not FDA approved for use in people with PD.

Your participation in this study includes 20 study visits and could last approximately 22 weeks. This includes 8-12 weeks to complete 16 training sessions with the exoskeleton, and testing before using the exoskeleton and at 1, 6, and 12 weeks after you finish using the exoskeleton. Training sessions may last about 90 minutes, while the baseline and follow-up visits may take longer to complete the assessments.

You may want to participate in this study because of a possible benefit to your mobility, and to help future PD patients**.** You may not want to participate because of the risk of falls and discomfort from wearing the device. You may choose to talk with your physician to discuss alternative options outside this study, such as physical therapy.

Additional detailed information is provided for your review in the sections below. Ask the research team questions until you feel you have enough information to make your decision to participate or not. Participating in this research study is completely

Richmond VAMC Institutional Review Board (IRB)
Effective Date: July 6, 2025

voluntary. Your decision whether to participate will have no effect on any of the services, benefits, or rights that you are otherwise entitled.

[redacted]

1. Whom should I contact for questions? (Contacts)
If you have any questions, concerns or complaints regarding this study, unexpected reactions, or you are injured and become ill as a result of participation in this study please call AM or PM*:*

Office	**Off Hours**
[redacted]	[redacted]

If you are unable to reach any of the study staff listed and need immediate medical assistance, please call the Richmond VAMC operator at [redacted] and ask for the Emergency Room physician to obtain advice or call the **Emergency Room directly at** [redacted]. If you have any questions, concerns or complaints about your rights as a research subject you may contact the **Richmond Institutional Review Board (IRB) at** [redacted] The IRB is responsible for reviewing research in humans and making sure that their safety and rights are protected.

2. What is this research study about? (Introduction)
This study involves research about using the Keeogo exoskeleton device in people with PD. Participants will be trained using the device in up to 16 sessions with a therapist. The purpose of this research study is to determine if the Keeogo exoskeleton is safe to use in the PD patient population and how effective it is for improving mobility. The expected duration of your participation is up to 22 weeks. We hope to enroll up to 30 participants.

3. What is expected of me? (Procedures)

This study will involve a total of 20 study visits, including 16 training sessions and 4 visits for functional assessments. You will be asked to complete tasks and questionnaires to help assess your PD symptoms, balance, walking, movement within your environment, life satisfaction, and study feedback.

SCREENING
First, you will be informed about the study and consented. Then you will be screened to ensure your eligibility to participate. This will include an assessment of your thinking, fall risk, hip and knee assessment, osteoporosis risk and a pregnancy test for females of child-bearing age. You will also complete a brief fitting and trial with the exoskeleton.
TRAINING SESSIONS

For the training visits, you will participate in robotic assist gait training (RAGT) walking with the exoskeleton, twice per week for 8 weeks (16 sessions). Study sessions will take place over 8 weeks (two sessions per week), but up to 12 weeks will be permitted if needed. You will be permitted to rest, as needed during the study visits. You will have up to one hour to complete individual training sessions that includes a minimum of 20 minutes of walking, per session. You can use a cane or walker if needed. You will be asked to complete tests of your walking and mobility. Overall, these visits will last 60 to 90-minutes but could take as long as 2-3 hours if needed.

FOLLOW-UP SESSONS
There will be 3 follow-up visits once training with the exoskeleton is complete. These will occur within 1 week, 6 weeks, and 12 weeks after training completion. You will again be asked to complete tests of your walking and mobility. These visits will last 60 to 90 minutes.

Training sessions will be video recorded including your face and voice to help the study team track your progress. These recordings will be securely stored electronically on the VA protected network and will not be disclosed outside the VA. The confidentiality of these recordings will be maintained according to professional standards of confidentiality and VA regulations.

4. Will my data and/or samples be kept for use in the future? (Future use of data/samples)
Your information collected as part of this research, even if identifiers are removed, will not be used or distributed for future research studies.

5. Will the research benefit me? (Benefits)
No benefit is guaranteed. It is possible that your mobility could improve by using the exoskeleton device. The information that you are providing for this research study may lead to new clinical or educational knowledge, tests, treatments, or products. By taking part in this study, you may provide information that will help others in the future.

6. What are my alternatives to being a research subject? (Alternative Therapy)
You do not have to participate in this study to receive treatment for your condition. You can discuss with your provider what other options are available, such as physical therapy.

7. What are my risks? (Risks, Inconveniences, Discomforts)
Participation in this study may involve risks that are unknown at this time. Your condition may stay the same, may improve, or may worsen from study participation.

Participation may increase the risk of falls while using the exoskeleton device. Wearing the device may also cause irritation or discomfort to the skin, joints, or muscles. You may become fatigued during the training sessions and experience a drop in blood pressure which may cause you to become dizzy.

Richmond VAMC Institutional Review Board (IRB)
Effective Date: July 6, 2025

Clinically relevant research results will be disclosed to you. This could include information such as a low bone density (osteoporosis), indications of dementia, or other medical concerns which should be followed up by your primary care team.

Loss of confidentiality is a potential risk to participants of this study. All study records will be maintained in secure databases and locked offices. Only study personnel will have access to study data that can identify you.

8. Will I get paid? (Compensation)
You will not be paid for participating in this study. However, the information that you are providing for this research study may lead to new clinical or educational knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives if this occurs.

9. Will I have to pay? (Cost of Participation)
You will not have to pay, and your insurance will not be billed for treatments or procedures that are part of this research study regardless of whether you are a Veteran or a non-Veteran. If you get a bill for research services, contact your study doctor or research coordinator. Some veterans are required to pay co-payments for medical care and services provided by the Central Virginia VA Health Care System (CVHCS). These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of the study.

10. Does pregnancy prevent me from participating? (Pregnancy)
Every effort will be made to have females enter this study. For females of child-bearing age we will ask you to use a medically accepted birth control method to enter this study. This may include, but is not limited to, birth control pills, IUD's, condoms, diaphragms, implants, being surgically sterile, or being in a post-menopausal state. However, no birth control method eliminates the risk of pregnancy. If you are a female and if pregnancy occurs there may be a risk of miscarriage, birth defects, other medical complications or unforeseen risks to yourself or to the unborn baby (i.e. embryo or fetus). If you are a female of childbearing age, you must have a negative pregnancy test before entering the study.

11. What if I get injured? (Research Related Injury)
A research injury is any injury or illness caused by your participation in the study. In the event of a research injury, necessary medical treatment will be provided to assist your recovery from the injury. If you are a CVHCS study participant (Veteran or Non-Veteran), the CVHCS (not you or your insurance) will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the CVHCS or arrangements may be made for care at another facility. You have not released this institution from liability for negligence. In the event of injury resulting from your participation in this research study,

you should contact your study team. If you want to speak to someone who is not a member of the study team to discuss problems, ask questions or voice concerns, you can call the Richmond IRB at [redacted]

This agreement does not include treatment for injury/illness that is not a result of the study. To help avoid injury, it is very important to follow all study directions. You are not giving up any of your legal rights by signing this form

12. Who Will See My Information? (Confidentiality)

Information about your participation in this study will be included in your medical record. It is important for other health care providers taking care of you to know any study drugs or study treatments you are receiving. The confidentiality of your research records will be maintained according to professional standards of confidentiality and Veterans Health Administration (VHA) regulations. Records identifying you may be reviewed by the members of the research team, the Research and Development Committee and its sub-committees, accrediting agencies, officials from the VHA, the Office of Research Oversight, the VA Office of the Inspector General, CVHCS, and other federal oversight agencies such as the Food and Drug Administration, Office for Human Research Protections, or as required by law.

All study records will be stored in a locked office at the CVHCS as well as on computers protected with passwords. Only the research staff has access to this data.

You will not have access to your research related health records while participating in this study.

The ways your study doctor will use your study-related health information and the people who may receive it are identified in a separate form entitled, Authorization for Use & Release of Individual Identifiable Health Information for Veterans Health Administration Research. You will be asked to sign that form to show that you give permission for these uses and sharing of your information. You do not have to sign the authorization form. However, if you do not sign, you will not be able to participate in the study.

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

Information published or presented about the results of this study will not identify you.

13. Do I have to participate in this study, or can I withdraw from the study? (Voluntary Participation and Withdrawal)

Participation in this study is voluntary and you may refuse to participate without penalty or loss of benefits to which you are otherwise entitled. The study staff will answer any questions you may have about the study. You are free to withdraw your consent and stop participation at any time. If you decide to withdraw from this study, you should contact [redacted] to discuss termination of your participation. It is important that you do this so that [redacted] can withdraw you safely. Stopping will in no way change the quality of care you receive now or in the future at this institution or your right to participate in other studies.

Any data collected prior to withdrawal will continue to be used for the study by the investigator and samples collected cannot be withdrawn.

Any significant new findings that develop during the research study that may affect your decision to continue participating will be provided to you as soon as possible.

Your participation in this research study may be ended without your consent for the following reasons:

- If the study doctor believes, for any reason, that it is within your best interest.
- If you develop side effects that are considered dangerous.
- If you fail to return for follow-up as recommended by your study doctor or fail to follow the study doctor's instructions.
- If you refuse to have tests that are needed to determine whether the exoskeleton is safe and effective.
- If you become pregnant.
- If other causes prevent continuation of the clinical research study.
- FDA and the Richmond IRB may also end the study at any time.

14. Date of Consent Form Revision 7/19/2023; 7/26/2024; 6/6/2025

Richmond VAMC Institutional Review Board (IRB)
Effective Date: July 6, 2025

Subject Name:_____ **Date:**_____

Title of Research Study: Feasibility and Safety of a Portable Exoskeleton to Improve Mobility in Parkinson's Disease

[redacted] **CVHCS:** Richmond

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me, all of the above.

[redacted](or an associate) has explained the study to me and answered all my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled. The results of this study may be published, but my records will not be revealed unless required by law. By signing below, I am agreeing to participate in this research study. I will receive a signed copy of this consent form.

_____ _____

Subject's Signature **Date**

_____ _____

Signature of Person Obtaining Informed Consent **Print name/Date**

Richmond VAMC Institutional Review Board (IRB)
Effective Date: July 6, 2025