Design Improvements and Evaluation of a Knee Stress-Relief Powered Exoskeleton for Veterans with Knee Osteoarthritis (A3228-R)

NCT04653896

Principal Investigator: Christopher Cardozo, MD

Initial IRB Approval Date: 11/08/2021

Last Aim 1 Consent Approval Date: 09/02/2021

Last Aim 3 Consent Approval Date: 05/02/2024

1. Purpose of study and how long it will last:

You are being asked to participate in this research study because you have had a diagnosis of Grade 3 or 4 knee osteoarthritis (OA), have been prescribed a knee brace for at least 3 months, and have self-reported knee pain and limitations to mobility and walking activities. The purpose of this study is to evaluate in-laboratory mobility outcomes, pain perception, and user satisfaction with the Keeogo, a robotic exoskeleton for providing assistance to the knees during stand and swing for a population with impaired mobility, as compare with standard knee braces. The study team hypothesizes that participants could have improved performance outcomes on walk test, timed up and go test, stair test, pick up penny from floor test, and the Short Physical Performance Battery (SPPB) when using the Keeogo as compared with their prescribed knee braces.

A knee OA-specific tuning protocol will be developed and completed in 20 Veterans with knee OA at the James J. Peters VA Medical Center, Bronx, NY. This in-laboratory study is expected to demonstrate improved walking speeds, stair ascent/descent times, improved sit-to-stand, stand-to-sit, and picking up objects from the floor with reduced pain while using the Keeogo.

The Robotic exoskeleton used in this study is called Keeogo™ and is a powered walking assistance device. This device is based on B-Temia's Dermoskeleton™ technology (***Figure 1***) and has a motor by the knee to help its movement. Preliminary data on patients with several conditions have shown that the device can improve patient mobility and functional capacity. The data from previous clinical trials have suggested that the device may prove to be beneficial in improving mobility and functional ability, and that the device has been shown to be safe.

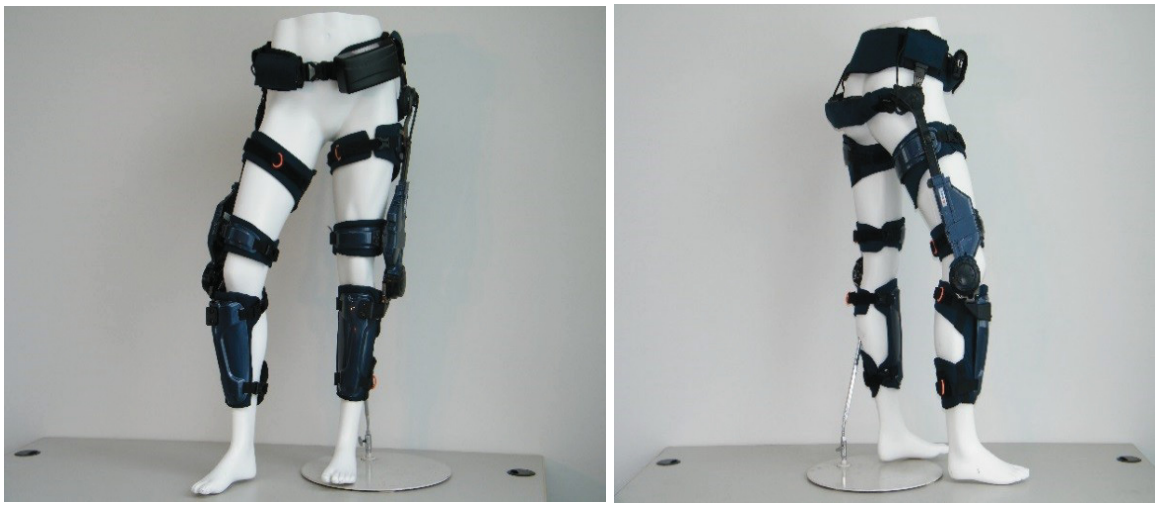

Figure 1 – B-Temia's Keeogo™ Dermoskeleton

This device does not yet have marketing approval by the Food and Drug Administration (FDA). This device is considered a Class II Powered Exoskeleton.

The first 8 participants will be asked to complete a tuning process in multiple sessions. Based on the possible setting adjustments, you should expect no more than 12 tuning sessions (up to 1 hour per session, 2 to 3 sessions per week). The tuning processes from the 8 participants will be analyzed and summarized into a draft tuning guide, which will include recommendations for setting up and adjusting the settings for each mode. The draft tuning guide will then be used as guide for the tuning process for the next 12 participants. A reduction in overall tuning time and number of parameter adjustments is expected for the 12 participants when compared with the first 8 participants. Testing and completing the tuning guide with the 12 participants will be done in 3 rounds, in groups of 4 participants.

The details of this protocol are described in the follow sections.

You qualify for the study if you fit the following criteria:

Inclusion Criteria:

1) Males and females between 18 and 89 years;
2) Medical diagnosis of knee OA of stage 3 or 4;
3) Self-reported knee pain when standing, walking, climbing stairs, squatting, or other mobility activities; and
4) Self-reported limitations to mobility and walking activities due to knee pain, stiffness, loss of range of motion.

Exclusion criteria:

1) Neurological paralysis causing an inability to stand, weight bear or take stepping movements;
2) Fixed contractures resulting in limited range of motion in the hip, knees, or ankles that prevent sitting, standing, walking, and/or squatting activities;
3) Able to walk at a normal walking speed (>1.2 m/s);
4) Anthropometric incompatibility with the device**;
5) Any medical complication or co-morbidity as judged by the study physician to be contraindicated for wearing the device or walking (e.g., cardiovascular disorders, pressure ulcers, open wounds, lower limb vascular disorders, or other medical conditions);
6) A score of <8/10 on the MacArthur Competence Assessment Tool for Treatment (MacCAT-T) 87 (as a proxy for cognitive competency screening); and
7) Pregnant or planning on becoming pregnant.

2. Description of the Study Including Procedures to be Used:

Baseline Phase

All participants (N=20) will first complete a questionnaire on demographics, disease history, and brace type and use. You will also go through an anthropometric session where your body weight, height, waist circumference, and upper/lower leg lengths will be measured. You will then start a baseline phase where you will use a prescribed knee brace to complete some standardized mobility tasks such as the 6 minute walk test (6MWT), a 30-second sit-to-stand test (30STST), and a timed 13-step stair test (13ST). If possible, you will go through these mobility tasks without the knee braces. The purpose

of the baseline phase is to identify the areas that require improvement for each mobility mode and determine a set of clinical goals that Keeogo™ could help achieve. You will have at least a 10-minute break between each test you can stop the test at any time due to pain, fatigue, and/or discomfort. This baseline phase is expected to be completed in 1 session. Your pain, via a numeric pain rating scale (NPRS) and rating of perceived exertion (RPE) via the Borg scale, will be recorded during these tests:

Evaluation Tests

6 Minute Walk Test (6MWT): Walk as far as possible for 6 minutes. Distance will be recorded in meters and speed in meter/second.

30-Second Sit-to-Stand Test (30STST): Stand up completely and then sit down completely while crossing arms at the wrists and holding against the chest on a chair without arm rests, with a seat height of 17 inches, for 30 seconds. Total number of stand-to-sit and sit-to-stand transitions will be counted.

13-Step Stair Test (13ST): Ascend and descend a 13-step stair as quickly as possible but safely. Time in seconds till both feet on the top as ascent time. Time in seconds till both feet on the bottom as descent time.

Numeric Pain Rating scale (NPRS): Rate pain on an 11-point numerical scale (0- no pain at all; 10- worst imaginable pain).

Rating of Perceived Exertion (RPE): Rate level of perceived exertion on a Borg Scale (6 – no exertion; 20 – maximum exertion).

Gait Assessments: Assessment of gait changes will be performed using the GaitRite Carpet (CIR Systems Inc). The GaitRite measurement will be obtained by walking over a carpet equipped with sensors, which provide information regarding cadence, step length and time spent on each foot. The 4.9-meter pressure sensitive walkway measures speed and spatial gait parameters such as the velocity, step length, step time, single support, and double support, and provides easy identification of gait anomalies. An electronic

goniometer will be strapped to each lower extremity for independent and simultaneous measurement and recording of knee ROM.

Rancho Los Amigos Observational Gait Analysis (Rancho OGA): The Rancho OGA is a moderately reliable and valid clinical tool that can be used to assess gait impairment and recommend treatment options.

Standardized Tests

During the 6MWT, a study staff member will perform the Rancho OGA. Additionally, the GAITRite® walkway will be used for the development of clinical goals for you, which will be agreed upon by both you and the study staff members. For sit-to-stand/stand-to-sit and stair ascent/descent, a custom checklist will be used to identify areas for improvement and determine clinical goals. The observational checklist for sit-to-stand/stand-to-sit will focus on knee strength during standing up, knee control during sitting down, and equal weight bearing on both feet. The observation checklist for stair ascent/descent will focus on foot clearance, leading knee extension strength while stepping up, and trailing knee control while stepping down. The clinical goals for these mobility modes may include: 1) appropriate weight support onto the affected knee and leg; 2) appropriate knee power during swing and stance phases; 3) appropriate knee control during stand-to-sit and stair descent; 4) appropriate amount of swing clearance; 5) appropriate step height and length; 6) desired speed of ambulation; 7) desired pain reduction; and 8) desired reduction in perceived exertion for each mobility mode. After finalizing the clinical goals for all mobility modes, the study staff will develop a list of desired characteristics with the clinical goals, which will be used for setting adjustments during the tuning process.

Tuning Guide Development Phase

The first 8 participants will first be fitted with Keeogo™ by a certified study staff member to ensure the correct alignment of hip and knee sensors. Next, the study staff member will calibrate the device with you in a relaxed, neutral posture. After calibration, you will be given as much time needed to acclimate to the Keeogo™ until you feel comfortable with performing the mobility tasks using the default parameters. The study staff will then use the set of clinical goals and desired characteristics from the baseline phase to determine which parameters should be adjusted. After each parameter is adjusted, you

will be asked to walk on the GAITRite® walkway while a study staff member performs the Rancho OGA. You will also be asked to provide your feedback on pain using the NPRS, RPE using the Borg scale, and perceived benefit (helpful/no change/worse). You will inform the study staff if pain is not reduced or increases, or you do not feel safe, in which you can stop at any time. Each parameter adjustment, study staff observation, user feedback, relevant gait measures from the GAITRite will be recorded on a tuning sheet. If an adjustment leads to an improvement based on the study staff member's judgement (i.e., observational and GAITRite results) and participant feedback (e.g., reduced pain or perceived exertion), the change will be recorded in the tuning sheet. If not, the parameter will be reset and recorded, and different values or another parameter will be tested to achieve the desired characteristics. These assessments will continue until all clinical goals are achieved. The tuning process for sit-to-stand, stand-to-sit, stair ascent, and stair descent will follow a similar process, except that a custom observational checklist (as mentioned in Baseline Phase Section) along with time taken to complete the tasks will be used to determine parameter adjustments towards the relevant clinical goals. For sit-to-stand and stand-to-sit, you will start with a timed task (e.g., 10 seconds) during initial tuning sessions and move to the 30STST as you progress. For stair ascent/descent, you will start with a timed 4-step ascent/descent task during initial tuning sessions and move to the 13ST as you progress.

Tuning Guide Review

When all 8 participants are completed, the tuning sheets for all sessions of all 8 participants will be reviewed and the study staff will compile a list of unique clinical goals for each mobility mode and the corresponding measures. The study team will be looking for trends in setting adjustments that lead to desired clinical goals. The study staff will also identify parameters that vary across all participants and those that remain relatively consistent. For those parameters that remain relatively consistent across participants, a recommended default value will be noted in the tuning guide. Those parameters that vary across participants will be examined to determine if the values are related to participant characteristics and baseline performance. Recommendations on how to adjust these parameters will be provided in the tuning guide and the average values across the participants will be provided as potential starting points.

Tuning Guide Evaluation Phase

The study staff will evaluate the draft tuning guide for the remaining 12 participants, in groups of 4 participants for three rounds. After each round of evaluation, the investigators will update the tuning guide based on the tuning sheets of the each group of 4 participants. You will follow the same protocol outlined in the last section, however, instead of a settings sweep for each mobility mode, settings will be modified in accordance with the targeted clinical goals determined during the baseline phase and the draft tuning guide.

Final Phase

All participants (N=20) will go through the same three mobility tests including 6MWT, 30STST, and 13ST while wearing Keeogo™ configured with the default and tuned parameters, respectively, in a random order. The comparison will allow the study team to validate the tuning effectiveness.

3. Description of any Procedures that may Result in Discomfort or Inconvenience:

As with any investigational study, there may be adverse events. This study involves an FDA investigational device and there may also be some risks that are currently unknown. The following list contains potential discomforts or inconveniences related to study procedures:

You may experience discomfort associated with wearing the exoskeleton. You may experience some skin pressure or friction that can lead to bruising, pain, or unusual swelling. Device use may even lead to skin breakdown or abrasions. This risk will be minimized by a thorough skin check performed by experienced research personnel during each training session. Adjustments to the device fit and additional padding will be assessed to decrease the risk of skin breakdown. The device used in this study will not be available to you after you complete this study.

While using the exoskeleton, you may experience some blood pressure instability. This is associated with physical activity during testing and training procedures. The risk associated with blood pressure alterations are reduced by your ability to take as many breaks as needed. An assessment of your level of effort is also determined. Study staff will also assess blood pressure and heart rate during the training. Activity will be stopped

in the event of instability of vital signs and as recognized by experienced research personnel.

Since this research may have unknown effects on an unborn child and should not be done during pregnancy, it is necessary for a pregnancy test to be done first. To your knowledge you are not pregnant at the present time. You also agree to avoid becoming pregnant (use contraceptives, take precautions against becoming pregnant, etc.) during this study.

4. Expected Risks of Study:

Participation in this study has a few risks that you should be made aware of. As you will be training, there is a chance that you could become unstable and fall. The risk of falling is minimized by having experienced research personnel with you during your study visits. You will also be able to use any conventional assistive device (cane, walker or other) that you need. You will be able to use these devices regardless of the group you are in and whether or not you are using the Keeogo powered exoskeleton. The risk of falling is minimized by excluding individuals with stroke who cannot stand and ambulate.

If you walk using the powered exoskeleton, the device may make you feel unstable or cause tripping. This risk is minimized by allowing you to use an assistive device such as a walker or cane. In addition, the settings of the device can be adjusted to reduce the instability. It is possible that the device itself could malfunction. The device has built-in mechanical stops to limit the devices ability to move through abnormal ranges of motion. In addition, the activities that will be performed with the device will be performed by trained research personnel to monitor device function during use.

There are additional risks such as skin abrasions/or irritation. This may be caused by rubbing from the device or by the strapping. Effort by the staff will be made to appropriately fit the device and add additional padding in order to reduce this risk.

You may have some peripheral edema or swelling of the legs.

There may also be other risks that are unknown and unforeseen.

If the research staff observe that you are unsafe while using the device or during general physical activity the training session will be terminated. If you continue to experience sessions that are unsafe, you may be withdrawn from participation in this study.

If you become pregnant during your participation in this study, you will be withdrawn. There may be risks to you or to the embryo or fetus, if the you are or become pregnant that are currently unforeseeable.

5. Expected Benefits of the Study:

It is possible that enrolled participants may derive no direct benefit as part of their participation in this study. However, some may experience some improvement in gait, pain and tolerance of over ground ambulation. Abnormal clinical findings from the study will be shared with individual participants so they can follow up with their primary care physician. Some participants may derive personal satisfaction knowing that their involvement in the proposed study may contribute to science and clinical care, subsequently helping other individuals.

Anticipated or potential derived benefits outweigh the perceived and/or known risks of the study procedures. The associated risks for the study are considered greater than minimal risk but they pose no known major long-term health risks. However, many alternative interventions exist such as use of pharmacological approaches which have side effects and may lead to addiction or invasive alternatives such as surgical procedures. In addition to a reduction in risk compared to some alternatives, the information derived from this study may show benefits to reduction in pain and improved ambulation speed with corresponding improvements in quality of life.

6. Other Treatments Available:

You could participate in physical therapy sessions or participate in another training program instead of participating in this research study.

7. Use of Research Results:

We (I) will let you and your physician know of any significant new findings made during this study which may affect your willingness to participate in this study. All data and research materials generated from this study will be restricted to research personnel located at the James J Peters VAMC. All data and records will be stored at the James J Peters VAMC according to VA regulations. Only authorized personnel will be given access to research records. Your electronic records will be stored on the VA network protected by the VA firewall. Any hard copies of research documents will be maintained, secured and stored at the James J Peters VAMC. Data that contains any identifiable information (i.e. your name, contact information, etc.) such as on this informed consent form, will be stored in locked cabinets within our research center and maintained separately from your other records. The documents that contain data collected from your participation will be coded. This means that you will have an identifier associated with your files that is unique to you. This identifier will not contain any information about you, and it will be a random number assigned to you so that the investigators know who the data belongs to. The link to breaking the code will remain secure at the James J. Peters VA Medical center. Records will be retained according to National Archives and Records Administration, in accordance with Records Schedule RCS-10-1.

□_____ By initialing, you agree to be contacted by the Principal Investigator or his investigative team at a future date for additional studies being conducted at the James J Peters VA Medical Center.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. No information by which you can be identified will be released or published unless required by law.

In order to comply with federal regulations, research records identifying you may be reviewed by the following: Representatives of the sponsor or sponsors VA RR&D, Authorized representatives of the Bronx VAMC (e.g. Institutional Review Board, Research Compliance Officer) and VA, including the Office of Research Oversight (ORO), Federal Agencies such as the Government Accounting Office (GAO), VA Office of Inspector General (OIG), Food and Drug Administration (FDA), and the Office for Human Research Protections (OHRP).

Because this research involves articles regulated by the FDA, the FDA may choose to inspect and copy medical or research records that identify individual research subjects. If this study was initiated on or after March 7, 2012, 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.

8. Special Circumstances:

A copy of your signed informed consent form and signed HIPAA authorization for participation in the study will be included in your medical health record.

9. Compensation and/or Treatment in the Event of Injury:

The VA must provide necessary medical treatment in accordance with applicable federal regulations to a research subject injured by participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees.

10. Voluntary Participation:

You are not required to take part in this study; your participation is entirely voluntary and you can refuse to participate in this study or withdraw your participation in this study after you consent without penalty or loss of VA or other benefits to which you are entitled.

11. Termination of Participation:

You may decline to participate now, or you can withdraw from the study at any time after signing this consent form. If you decline to participate or withdraw, your regular medical treatment will not be interrupted or withheld. If you decide to withdraw from the study later, you will be asked to sign a form to revoke your previous authorization.

You may be required to withdraw from the study if study staff or your doctor feels that your participation is not in your best interest. If you are not compliant with the procedures detailed in this study, you may be withdrawn. There may be other reasons observed during your participation that is thought to affect your safety that could lead to your withdrawal.

12. Costs and Reimbursements:

As a veteran or non-veteran, you will not be charged for any treatments or procedures that are part of this study. For veterans who are required to pay co-payments for medical care and services provided by VA, these co-payments will continue to apply for medical care and services provided by VA that are not part of this study. You will not receive a payment for your participation in this study.

You will be paid $25 for each visit you complete, up to the total of 12 maximum study visits. Total reimbursement will be determined based on total number of sessions completed. The maximum amount of sessions allotted, contingent on phase, will be 12 total sessions for $300. Payments will be made either on a monthly basis (4 total payment) or as one payment at the end of the study, according to your preference.

13. Contact Person(s):

To obtain answers to questions about the research and research subjects' rights, report or seek treatment for a research-related injury, or to voice concerns or complaints about the research contact the following (investigator/research team):

- During the Day: Ann Spungen, EdD at 718-584-9000 ext. 5814
- After Hours: Ann Spungen, EdD at 347-971-0413

To voice concerns or complaints about the research from someone outside of the research team, contact the following: I understand that should I wish to discuss my participation in this study with any other doctor or layperson, I can contact Mary Sano, Ph.D. ACOS/R&D Program by requesting an appointment at (718) 741-4228 hospital extension 4228, first floor in the research building, room 1F-01 If I have questions, concerns and/or complaints or to offer input. **RESEARCH SUBJECTS' RIGHTS:** I have read or have had read to me all of the above.

Dr. Spungen or his delegate has explained the study to me and answered all of 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 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. This study has been explained to me. I have had a chance to ask questions. I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

Subject Signature	Date

Person Obtaining Informed Consent (Print Name) (Investigator or Delegate as indicated on Assurance Page)	Signature of Person Obtaining Informed Consent	Date

1. Purpose of study and how long it will last:

You are being asked to participate in this research study because you have had a diagnosis of Grade 3 or 4 knee osteoarthritis (OA), have been prescribed a knee brace for at least 3 months, and have self-reported knee pain and limitations to mobility and walking activities. The purpose of this study is to conduct a functional mobility comparison between Keeogo™ and knee braces among Veterans with knee OA.

The following study will be completed in 26 Veterans with knee OA at the James J. Peters VA Medical Center, Bronx, NY. Eligible participants will be grouped by the very slow (≤0.90 m/s) and slow (0.91 m/s to 1.20 m/s) sub-groups based on a 6MWT. The grouping will allow us to examine how people with different levels of mobility limitations respond to Keeogo™'s assistance.

The Robotic exoskeleton used in this study is called Keeogo™ and is a powered walking assistance device. This device is based on B-Temia's Dermoskeleton™ technology (Figure 1) and has a motor by the knee to help its movement. Preliminary data on patients with several conditions have shown that the device can improve patient mobility and functional capacity. The data from previous clinical trials have suggested that the device may prove to be beneficial in improving mobility and functional ability, and that the device has been shown to be safe.

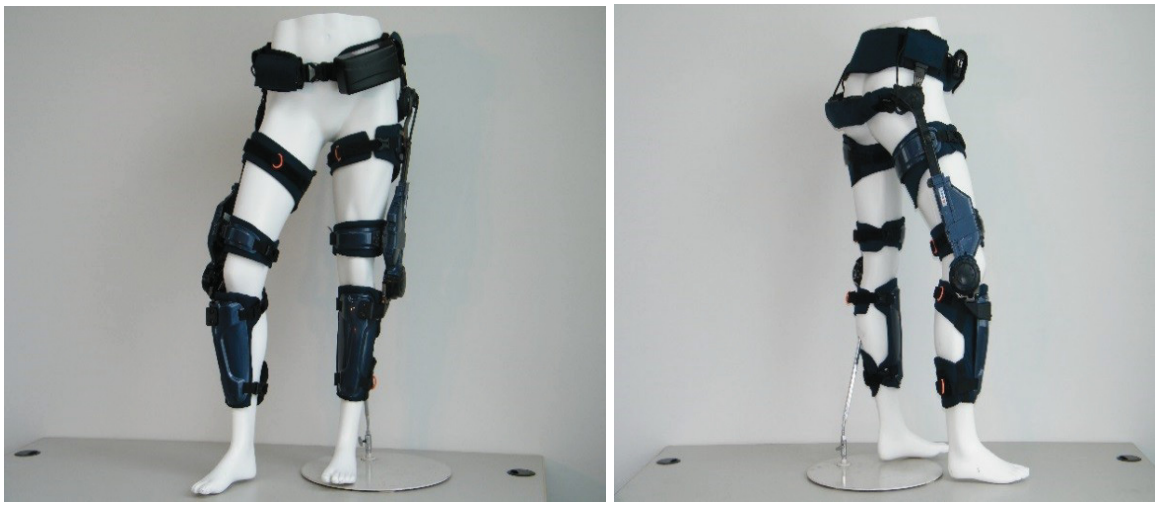

Figure 1 – B-Temia's Keeogo™ Dermoskeleton

This device does not yet have marketing approval by the Food and Drug Administration (FDA). This device is considered a Class II Powered Exoskeleton.

The present section of the entire study will use a tuning guide developed in first part of the overall study (Aim 1) to adjust the settings of the Keeogo™ for you until all clinical walking goals are achieved based on therapist judgement and participant feedback. The total number of sessions required for the tuning process will be determined upon the completion of Aim 1 but is expected to be no more than 12. You will plan to have 2-3 sessions (up to 1 hour) per week. Following the tuning process, and completing all of the clinical walking goals, you will then move to the final evaluation. Prior to beginning the final evaluation, you will be randomized into one of two groups. One group would start with your prescribed knee brace and then Keeogo™. The other group will then start with Keeogo™ and followed by the knee brace.

Participants will be evaluated through a series of mobility tests using your prescribed knee brace and the Keeogo™ set up with your tuned settings, respectively. You will also be asked to complete two usability questionnaires for Keeogo™ and have a brief interview with the investigators on your experience using Keeogo™ and anticipated challenges for using Keeogo™ as an everyday mobility device at home and community.

The details of this protocol are described in the follow sections.

You qualify for the study if you fit the following criteria:

Inclusion Criteria:

1) Males and females between 18 and 89 years;
2) Medical diagnosis of knee OA of stage 3 or 4 (Table 8);
3) Self-reported knee pain when standing, walking, climbing stairs, squatting, or other mobility activities; and
4) Self-reported limitations to mobility and walking activities due to knee pain, stiffness, loss of range of motion.
5) You have not participated in Aim 1 for more than 6 months.

Exclusion criteria:

1) Neurological paralysis causing an inability to stand, weight bear or take stepping movements;
2) Fixed contractures resulting in limited range of motion in the hip, knees, or ankles that prevent sitting, standing, walking, and/or squatting activities;
3) Able to walk at a normal walking speed (>1.2 m/s);
4) Anthropometric incompatibility with the device**;
5) Any medical complication or co-morbidity as judged by the study physician to be contraindicated for wearing the device or walking (e.g., cardiovascular disorders, pressure ulcers, open wounds, lower limb vascular disorders, or other medical conditions);
6) A score of <8/10 on the MacArthur Competence Assessment Tool for Treatment (MacCAT-T) 87 (as a proxy for cognitive competency screening); and
7) Pregnant or planning on becoming pregnant.

2. Description of the Study Including Procedures to be Used:

<u>Baseline Phase</u>

All participants (N=26) will first complete a questionnaire on demographics, disease history, and brace type and use. You will also go through an anthropometric session

where your body weight, height, waist circumference, and upper/lower leg lengths will be measured.

Tuning Phase

The total tuning time and frequency of setting adjustments will be collected for each participant (N=26). The total number of sessions required for the tuning process will be determined upon the completion of Aim 1 but is expected to be no more than 12. You will plan to have 2-3 sessions (up to 1 hour) per week. You will first be fitted with Keeogo™ by a certified study staff member to ensure the correct alignment of hip and knee sensors. Next, the study staff member will calibrate the device with you in a relaxed, neutral posture. After calibration, you will be given as much time needed to acclimate to the Keeogo™ until you feel comfortable with performing the mobility tasks using the default parameters. The study staff will then use the set of clinical goals and desired characteristics from the baseline phase to determine which parameters should be adjusted.

Final Evaluation

Functional mobility outcomes will be collected during the final evaluation where you will use both your prescribed knee brace and fine-tuned Keeogo™, to perform the 6 minute walk test (6MWT), Timed Up and Go (TUG), 13 step stair test (13ST), Pick up Penny from Floor Test (PUPFF), and Short Physical Performance Battery (SPPB). Both your rating of perceived exertion (RPE) and numeric pain rating scaled (NPRS) will be collected during all of the listed tests:

Evaluation Tests

6 Minute Walk Test (6MWT): Walk as far as possible for 6 minutes. Distance will be recorded in meters and speed in meter/second.

Time Up and Go (TUG): Time in second to stand up from a chair, walk 10 feet, turn, and walk back to the chair, and sit down.

13-Step Stair Test (13ST): Ascend and descend a 13-step stair as quickly as possible but safely. Time in seconds till both feet on the top as ascent time. Time in seconds till both feet on the bottom as descent time.

Pick up Penny from Floor Test (PUPFT): Time in seconds to bend, scoop, lunge, or squat to retrieve a penny from the floor and return to standing. Scored as: not able to perform, perform with physical assistance, perform unassisted

Short Physical Performance Battery (SPPB): Three tests to assess lower extremity functioning: ability to stand for 10 seconds with feet in 3 different positions (together side-by-side, semi-tandem, and tandem), two timed 4-meter walk, and time to rise from a chair five times. Overall score from 0 to 12 with higher score indicating better lower extremity function.

Numeric Pain Rating scale (NPRS): Rate pain on an 11-point numerical scale (0- no pain at all; 10- worst imaginable pain).

Rating of Perceived Exertion (RPE): Rate level of perceived exertion on a Borg Scale (6 – no exertion; 20 – maximum exertion).

At the conclusion of testing, use of the device and user satisfaction with Keeogo™ will be collected from you using the System Usability Scale (SUS), and Usefulness Satisfaction and Ease of Use Questionnaire (USE).

System Usability Scale (SUS): Reliable 10-item scale to evaluate device usability with a 5-point Likert scale from strongly disagree to strongly agree. Overall score from 0 to 100 with higher score indicating better usability.

Usefulness Satisfaction and Ease of Use Questionnaire (USE): Reliable 30-item scale to evaluate four dimensions of usability including usefulness, ease of use, ease of learning, and satisfaction with a 7-point Likert scale. Average score from 0 to 7 for each dimension with higher score indicating better usability.

Gait Assessments: Assessment of gait changes will be performed using the an electronic goniometer that will be strapped to each lower extremity for independent and simultaneous measurement and recording of knee ROM.

3. Description of any Procedures that may Result in Discomfort or Inconvenience:

As with any investigational study, there may be adverse events. This study involves an FDA investigational device and there may also be some risks that are currently unknown. The following list contains potential discomforts or inconveniences related to study procedures:

You may experience discomfort associated with wearing the exoskeleton. You may experience some skin pressure or friction that can lead to bruising, pain, or unusual swelling. Device use may even lead to skin breakdown or abrasions. This risk will be minimized by a thorough skin check performed by experienced research personnel during each training session. Adjustments to the device fit and additional padding will be assessed to decrease the risk of skin breakdown. The device used in this study will not be available to you after you complete this study.

While using the exoskeleton, you may experience some blood pressure instability. This is associated with physical activity during testing and training procedures. The risk associated with blood pressure alterations are reduced by your ability to take as many breaks as needed. An assessment of your level of effort is also determined. Study staff will also assess blood pressure and heart rate during the training. Activity will be stopped in the event of instability of vital signs and as recognized by experienced research personnel.

Since this research may have unknown effects on an unborn child and should not be done during pregnancy, it is necessary for a pregnancy test to be done first. To your knowledge you are not pregnant at the present time. You also agree to avoid becoming pregnant (use contraceptives, take precautions against becoming pregnant, etc.) during this study.

4. Expected Risks of Study:

Participation in this study has a few risks that you should be made aware of. As you will be training, there is a chance that you could become unstable and fall. The risk of falling is minimized by having experienced research personnel with you during your study visits. You will also be able to use any conventional assistive device (cane, walker or other) that you need. You will be able to use these devices regardless of the group you are in and whether or not you are using the Keeogo powered exoskeleton. The risk of falling is minimized by excluding individuals with stroke who cannot stand and ambulate.

If you walk using the powered exoskeleton, the device may make you feel unstable or cause tripping. This risk is minimized by allowing you to use an assistive device such as a walker or cane. In addition, the settings of the device can be adjusted to reduce the instability. It is possible that the device itself could malfunction. The device has built-in mechanical stops to limit the devices ability to move through abnormal ranges of motion. In addition, the activities that will be performed with the device will be performed by trained research personnel to monitor device function during use.

There are additional risks such as skin abrasions/or irritation. This may be caused by rubbing from the device or by the strapping. Effort by the staff will be made to appropriately fit the device and add additional padding in order to reduce this risk.

You may have some peripheral edema or swelling of the legs.

There may also be other risks that are unknown and unforeseen.

If the research staff observe that you are unsafe while using the device or during general physical activity the training session will be terminated. If you continue to experience sessions that are unsafe, you may be withdrawn from participation in this study.

If you become pregnant during your participation in this study, you will be withdrawn. There may be risks to you or to the embryo or fetus, if the you are or become pregnant that are currently unforeseeable.

5. Expected Benefits of the Study:

It is possible that enrolled participants may derive no direct benefit as part of their participation in this study. However, some may experience some improvement in gait, pain and tolerance of over ground ambulation. Abnormal clinical findings from the study will be shared with individual participants so they can follow up with their primary care physician. Some participants may derive personal satisfaction knowing that their involvement in the proposed study may contribute to science and clinical care, subsequently helping other individuals.

Anticipated or potential derived benefits outweigh the perceived and/or known risks of the study procedures. The associated risks for the study are considered greater than minimal risk but they pose no known major long-term health risks. However, many alternative interventions exist such as use of pharmacological approaches which have side effects and may lead to addiction or invasive alternatives such as surgical procedures. In addition to a reduction in risk compared to some alternatives, the information derived from this study may show benefits to reduction in pain and improved ambulation speed with corresponding improvements in quality of life.

6. Other Treatments Available:

You could participate in physical therapy sessions or participate in another training program instead of participating in this research study.

7. Use of Research Results:

We (I) will let you and your physician know of any significant new findings made during this study which may affect your willingness to participate in this study. All data and research materials generated from this study will be restricted to research personnel located at the James J Peters VAMC. All data and records will be stored at the James J Peters VAMC according to VA regulations. Only authorized personnel will be given access to research records. Your electronic records will be stored on the VA network protected by the VA firewall. Any hard copies of research documents will be maintained, secured and stored at the James J Peters VAMC. Data that contains any identifiable information (i.e. your name, contact information, etc.) such as on this informed consent form, will be stored in locked cabinets within our research center and maintained separately from your other records. The documents that contain data collected from your participation will be coded. This means that you will have an identifier associated with

your files that is unique to you. This identifier will not contain any information about you, and it will be a random number assigned to you so that the investigators know who the data belongs to. The link to breaking the code will remain secure at the James J. Peters VA Medical center. Records will be retained according to National Archives and Records Administration, in accordance with Records Schedule RCS-10-1.

□_____ By initialing, you agree to be contacted by the Principal Investigator or his investigative team at a future date for additional studies being conducted at the James J Peters VA Medical Center.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. No information by which you can be identified will be released or published unless required by law.

In order to comply with federal regulations, research records identifying you may be reviewed by the following: Representatives of the sponsor or sponsors VA RR&D, Authorized representatives of the Bronx VAMC (e.g. Institutional Review Board, Research Compliance Officer) and VA, including the Office of Research Oversight (ORO), Federal Agencies such as the Government Accounting Office (GAO), VA Office of Inspector General (OIG), Food and Drug Administration (FDA), and the Office for Human Research Protections (OHRP).

Because this research involves articles regulated by the FDA, the FDA may choose to inspect and copy medical or research records that identify individual research subjects. If this study was initiated on or after March 7, 2012, 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.

8. Special Circumstances:

A copy of your signed informed consent form and signed HIPAA authorization for participation in the study will be included in your medical health record.

9. Compensation and/or Treatment in the Event of Injury:

The VA must provide necessary medical treatment in accordance with applicable federal regulations to a research subject injured by participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees.

10. Voluntary Participation:

You are not required to take part in this study; your participation is entirely voluntary and you can refuse to participate in this study or withdraw your participation in this study after you consent without penalty or loss of VA or other benefits to which you are entitled.

11. Termination of Participation:

You may decline to participate now, or you can withdraw from the study at any time after signing this consent form. If you decline to participate or withdraw, your regular medical treatment will not be interrupted or withheld. If you decide to withdraw from the study later, you will be asked to sign a form to revoke your previous authorization.

You may be required to withdraw from the study if study staff or your doctor feels that your participation is not in your best interest. If you are not compliant with the procedures detailed in this study, you may be withdrawn. There may be other reasons observed during your participation that is thought to affect your safety that could lead to your withdrawal.

12. Costs and Reimbursements:

As a veteran or non-veteran, you will not be charged for any treatments or procedures that are part of this study. For veterans who are required to pay co-payments for medical care and services provided by VA, these co-payments will continue to apply for medical care and services provided by VA that are not part of this study. You will not receive a payment for your participation in this study.

You will be paid $25 for each visit you complete, up to the total of 12 maximum study visits. Total reimbursement will be determined based on total number of sessions completed. The maximum amount of sessions allotted, will be 12 total sessions for $300.

Payments will be made either on a monthly basis (4 total payment) or as one payment at the end of the study, according to your preference.

13. Contact Person(s):

To obtain answers to questions about the research and research subjects' rights, report or seek treatment for a research-related injury, or to voice concerns or complaints about the research contact the following (investigator/research team):

- During the Day: Ann Spungen, EdD at 718-584-9000 ext. 5814
- After Hours: Ann Spungen, EdD at 347-971-0413

To voice concerns or complaints about the research from someone outside of the research team, contact the following: I understand that should I wish to discuss my participation in this study with any other doctor or layperson, I can contact Mary Sano, Ph.D. ACOS/R&D Program by requesting an appointment at (718) 741-4228 hospital extension 4228, first floor in the research building, room 1F-01 If I have questions, concerns and/or complaints or to offer input.

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the above. Dr. Spungen or his delegate has explained the study to me and answered all of 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 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. This study has been explained to me. I have had a chance to ask questions. I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

Subject Signature	Date

Person Obtaining Informed Consent (Print Name) (Investigator or Delegate as indicated on Assurance Page)	Signature of Person Obtaining Informed Consent	Date