Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: **H-51229**
Status: Approved
Initial Submit Date: 1/27/2022
Approval Period: 6/15/2022 - 6/14/2027

Section Aa: Title & PI

A1. Main Title

ORTHOFEET: A PROSPECTIVE PROOF OF CONCEPT TRIAL TO EVALUATE EFFICACY, ACCEPTABILITY, AND PERCEPTION OF BENEFIT OF AN INNOVATIVE PAIN RELIEF FOOTWEAR

A2. Principal Investigator

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

A4. Co-Investigators

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A5. Funding Source:

Baylor College of Medicine (Internal Funding Only)

A5a. Associated ESP2 funding proposal linked to this protocol:

A6a. Institution(s) where work will be performed:

BCM: Baylor College of Medicine
Baylor St. Luke's Medical Center (BSLMC)

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?
No

A9. ClinicalTrials.gov Registration

Does this protocol/trial require registration on ClinicalTrials.gov due to it: meeting the definition of an Applicable Clinical Trial, being required under the terms and conditions of an award, or being proposed to be published in ICMJE journals?
No, this clinical is not a clinical trial, or does not meet the definition of an Applicable Clinical Trial, or does not need to be registered under the terms and conditions of an award, or is not a clinical trial with results intended to be reported in an journal belonging to the ICMJE. Registration is not required.

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

It has been estimated that approximately 10% of people will experience foot pain in their lifetime, resulting in approximately 600,000 outpatient visits annually. The economic burden of plantar fasciitis in 2007 was estimated to be $192 million to $376 million indirect costs. Few studies including ours (Wrobel et al, JAPMA, 2015) suggested that orthoses provide short-, intermediate-, and long-term benefits for decreasing pain and improving function in plantar fasciitis. However, the acceptability of conventional orthoses is limited and often are costly. Furthermore, very few studies explored the benefits of footwear intervention in improving function including daily physical activities, gait, and balance.

Objective assessment of pain and function are important outcome measures for foot-related pathology. While conventional self-reported health-related quality-of-life instrument that measures a patient's physical, mental, and social wellbeing demonstrated that self-reported physical function disability from plantar fasciitis, this assessment may not be sensitive enough to detect changes over time in specific disease states or in response to treatment. Moreover, the responsiveness of these measures to detect important clinical changes has recently been called into question with the use of activity monitors. These assessments rely on self-reporting and recall and, therefore, are subjective and prone to biases. In addition, they may not be accurate in older adults or patients with cognitive decline. Furthermore, they often fail to capture the dynamic nature of pain and its effect on activities of daily living. Recent advances in wearable technologies open new opportunities to evaluate fine-grain information about patients' activity patterns and behavior and thus provide a better picture of the benefit of pain relief on function and daily physical activities in a natural condition outside of gait laboratories. Results from recent studies suggest that these objective measurements may represent the functional weight-bearing capacity of an individual in detecting important clinical changes due to pain management.

Therefore, the purpose of this prospective proof of concept study is to examine the effectiveness of a new pain relief footwear (Orthofeet) on function and daily activities over short (one week) and intermediate (4 weeks). We hypothesize that ortho feet will reduce foot pain leading to an increase in daily physical activities, measured objectives using validated wearables (PAMSys and Garmin wristwatch), and functional performance (gait and balance). In addition, we hypothesis that reduction in foot pain is associated with reduced physiological stress response (HRV) and better community engagement (assessed by life space questionnaire).

The Orthofeet shoes were first created in 1984 by engineers to combine attractive footwear styling with innovative therapeutic features. The shoes contains anatomical orthotic insoles that have helped millions of users improve mobility, enhance comfort from heel to toe, and get relief of heel, foot, knee, and lower pain. The insoles provide arch support with super cushioning with a mild rocker design. The shoes may reduce pressure under the heel and soften your step while you walk.

Section D: Purpose and Objectives

The purpose of this prospective proof of concept study is to examine effectiveness of a new pain relief footwear (Orthofeet) on function and daily activities over short (one week) and intermediate (6 weeks). We hypothesize a reduction in foot pain might lead to an increase in daily physical activities, measured objective using validated wearables (PAMSys and Garmin wrist watch) and functional performance (gait and balance). In addition, we hypothesis that reduction in foot pain is associated with reduced physiological stress response (HRV) and better community engagement (assessed by life space questionnaire).

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:
Both

Age:
Adult (18-64 yrs), Geriatric (65+ yrs)

Ethnicity:
All Ethnicities

Primary Language:
English

Groups to be recruited will include:
Patients

Which if any of the following vulnerable populations will be recruited as subjects?

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?
No

E5. Children

Will children be enrolled in the research?
No

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

c) Pilot

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

The study will be performed at the Baylor College of Medicine. Approval from Site Review Authority will be obtained. Subjects will be recruited from outpatient clinics at Baylor College of Medicine.

We propose a randomized crossover trial (Phase I/II) to evaluate acceptability as well as short (1 week) and intermediate (6week) benefits and effectiveness of Orthofeet in reducing foot pain, increasing daily physical activities, and improving functional performance in ambulatory patients suffering from foot pain.

We are proposing a clinical study at the Baylor College of Medicine, to evaluate short and intermediate benefits and effectiveness of a novel pain relief footwear, called Orthofeet. This is a randomized crossed over trial. The duration of the study would be 12-week. We will recruit 50 eligible ambulatory adults (age 50 years or older) with moderate to severe self-reported foot pain. Participants will be randomly assigned to Group A (25 subjects) and Group B (25 subjects). There is no difference in assessments or eligibility between Group A and Group B, the only difference is when they have the opportunity to try the shoes for 6 weeks. Group A will receive a pair of Orthofeet shoes with adjustable insoles and will be asked to wear it every day activities of daily living for duration of six weeks. Participants will be also encourage to wear the shoes inside of home if possible. Group B will be followed for duration of six weeks. At six weeks the groups will be switched and group B will receive and a pair of Orthofeet shoes with adjustable insoles and Group B will follow-up for six week without Orthofeet shoes. Participants will be assessed at baseline, week-1, week-6, week 7, and week 12.

The primary outcome includes changes compared to baseline in foot pain intensity.

The secondary outcomes includes changes compared to baseline in various metrics of daily physical activities (e.g., daily step, longest walking bout, cadence, standing duration, and standing duration).

Other outcomes include gait parameters (e.g., gait speed, gait steadiness, gait variability, double stance, and limp assessed using a validated wearable gait analyzer), static balance (assessed using a validated wearable balance assessment system), acceptability and perception of benefit (assessed by technology acceptance model), adherence (daily duration of wearing orthofeet), physiological stress response (e.g., heart rate variability, HRV, rest heart rate, HR-rest assessed by a wrist worn sensor), community engagement (life space assessed by a questionnaire). Standard questionnaires and assessments will be performed to evaluate subject¿s perception of benefit, user-friendliness, satisfaction, adherence, pain, sleep quality, concerns for fall, frailty, moving ability, risk of falling, anxiety, and quality of life.

Resources available to conduct the Human Research

The PI is a Professor of Surgery at the Baylor College of Medicine and has been involved in multiple clinical trials along with numerous publications in the area of outcomes evaluation, foot care, pain management, physical activity monitoring, gait and balance assessments in relation to diseases such as diabetes, cancer, plantar fasciitis, and aging population. Other team members include biomedical engineers/research scientists and study coordinators who are well acquainted with the study site, culture, and society. The wearable sensor technology is available at our center (iCAMP) for this study and includes LegSys (to assess Spatio-temporal parameters of gait), BalanSens (to assess postural control) and PAMSys (to monitor daily physical activity pattern and behavior), and Garmin (to assess daily physical activities and physiological stress response). All persons assisting with the study have received appropriate training and are extremely knowledgeable in their study-related duties and functions.

Inclusion Criteria:

50 total subjects will be recruited. Those eligible will meet the following inclusion criteria: Male or female 50 years or older Self-reported foot pain including heel, arch, or ball of foot pain

Exclusion Criteria:

Exclusion criteria: Patients with plantar ulcer Patients with major foot deformity (e.g., Charcot foot, Pes Cavus) Patients with lower extremity amputation including minor amputation. Foot pain because of nail disorder or keratotic lesions (e.g. corns, calluses) Patients with unstable conditions (e.g., recent stroke, anticipated changes in medication regime) Acute fractures of the foot Participation in an interventional Study such as exercise intervention within the last 30 days Non-ambulatory or unable to stand without help or walk a distance of at least 6 feet without assistance. Patients with major cognitive impairment or major depression Patients who are unable or unwilling to participate in all procedures and follow up evaluations

F2. Procedure

7) The research will be conducted at the following location(s): Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC). Duration of study: 12 weeks

Research staff may contact you for any study related questions throughout your participation in the study

Visit 1 (Baseline): Maximum duration 120 minutes

Screening: Measurements will take place at your home, or in Baylor Clinic based on your preference. Participants will be randomly placed in either Group A or Group B. Group A wears the OrthoFeet shoes from baseline to 6 week follow up and Group B wears OrthoFeet shoes from 6 week follow up to 12 week follow up.

All the same assessments and questionnaires are completed at each visit for all participants.

Foot Pain: Foot pain will be assessed by the revised Foot Function Index (FFI). FFI was developed in 1991 to measure the impact of foot pathology on function in terms of pain, disability, and activity restriction. It is a self-administered index consisting of 23 items divided into 3 sub-scales. Both total and sub-scale scores are produced. The FFI has been shown to be a reasonable tool for use with low functioning individuals with foot disorders, patients with rheumatoid arthritis, and non-traumatic foot or ankle problems. It can be used in both clinical and research settings. Foot pain will be assessed at baseline, week-1, week-6, week-7, and week-12.

Postural Balance test: will be assessed in double stance and semi-tandem stance while subjects stand straight with hands crossed around the chest for up to 30 seconds with eyes open and closed. Gait assessments: A validated and FDA-approved wearable platform (LEGSysTM, Biosensics LLC) will be used to assess gait. Gait will be assessed over a distance of 20m using LEGSys¿, which uses five inertial measurement units attached to the anterior of each shin and, thigh, and posteriorly to the lower back. The system estimates spatiotemporal gait parameters such as stride velocity, stride length, stride time, double support, single support, and stride-to-stride variability, and gait initiation. In addition, the COM range of motion during walking will be calculated based on the data from the sensor attached to the lower back. Gait will be assessed under habitual speed and walking at maximum speed during a single task and dual-task condition.

Activities of daily living: ADL will be monitored using a validated pendant sensor (PamSysTM) during a period of one week at baseline (week-1) and week-6, and week-12. We used our validated algorithms to determine postures (lying, sitting, and standing postures), walking parameters (cadence, longest walking bout, total steps per day), sleep (time in bed, sleep efficacy, sleep onset latency), and activity behavior (sedentary, light, and moderate to vigorous activity) of each patient to monitor their performance. The algorithm for activity monitoring has been validated against direct observation, motion tracking system, as well as the patient diary. The algorithm for monitoring sleep was validated against Polysomnography and actigraphy in a sleep lab. The day-to-day reliability was also demonstrated in the geriatric population. In addition, we will use a Garmin wristwatch to track physiological stress response, daily activities, and sleep quality during the entire duration of the study. A pre-paid envelop will be provided to collect the sensor.

Quality of life and mobility: Health-related quality of life will be assessed using the Functional Assessment of Cancer Therapy ¿ General (FACT-G) survey. General (FACT-G) is a 27-item questionnaire designed to measure four domains of quality of life: Physical, social, emotional, and functional well-being. Quality of life and mobility will be assessed at baseline, week 6 and week 12.

Patient acceptability: We will use a Technology Acceptance Model (TAM) survey adapted for footwear to determine perceived benefit, perceived ease of use, acceptability, and attitude toward daily use. Patient acceptability will be assessed at the end of week 6 active use of OrthoFeet (6- week for Group A and 12 week for group B) or the conclusion of the study for early endpoint.

Ancillary Measurements Patient-reported outcomes: Self-reported pain level will be extracted from FACT-G; ADL will be assessed using Katz Index of Independence in ADL; Community engagement will be assessed using the Life-Space Assessment questionnaire; The Fall Efficacy Scale-International (FES-I) questionnaire to determine concern for falls. Anxiety will be assessed using the Beck Anxiety Inventory questionnaire; cognition will be assessed using Montreal Cognitive Assessment (MoCA). Patient-reported outcomes will be assessed at baseline, week 6 and week 12. The subjects will not be advised or counseled based on the results of the questionnaires, these tools are not diagnostic, but the coordinators will try to provide possible resources if asked by the subject.

Digital Photographs ¿may take digital photographs of the subjects while performing exercise or during assessments for the purpose of publication (conferences/manuscripts). Physical frailty: Frailty will be assessed by trauma-specific frailty index and a validated wearable frailty meter technology.

Health related questionnaires: A series of health related questionnaires will be used to evaluate your quality of life , fear of falling, fall history, mobility, activities of daily living, depression, frailty, mental exams, foot examinations, pain intensity levels. Your medical history (from your clinic chart such as: medication use, prior surgery, diagnosis, progress notes, etc.) and demographic information will be obtained, such as age, gender, weight, and height. These questionnaires are asked to review the subject holistically and assess changes in their overall health, including mental and physical, over the 3 month span. The relevance to foot pain is to see how these components of health are related to foot pain such as finding a connection between their foot pain and fear of falling doing different activities.

At Visit 2 (1 Week Follow Up) the participant is called by the research staff to complete the pain questionnaire, document adverse events, and answer any study-related questions.

At Visit 3 (6 Week Follow Up) the participant will complete all the same assessments and questionnaires as baseline. At this visit, Group A will stop wearing OrthoFeet shoes and continue the study without them. Group B will be supplied with OrthoFeet shoes to wear for the rest of their study participation until 12 Week Follow Up.

At Visit 4 (7 Week Follow Up) the participant is called by the research staff to complete the pain questionnaire, document adverse events, and answer any study-related questions.

At Visit 5 (12 Week Follow Up) the participant will complete all the same assessments and questionnaires as baseline. All participants will return OrthoFeet shoes by this point.

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 50 Worldwide: 50

Please indicate why you chose the sample size proposed:

This is a proof of concept study. The sample size is 50 eligible participating in a randomized crossover study. The sample size is convenient and is selected to detect a between group difference for the primary outcome (change in foot pain) with medium effect size (Cohen¿s d=0.50) with a dropout rate of 15%, alpha of 5%, and power of 80%. The anticipated effect size was estimated from our prior study (Najafi et al, Journal of Foot and Ankle Research, 2014) in which we observed a significant drop in foot pain after orthotic therapy compared to sham orthotics. Based on this pilot study, we will propose a Phase II study to validate the observed effect in the follow-up study.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

We will utilize REDCap, a HIPAA compliant database application, to ensure uniformity of data entry. A qualified postdoc will provide ongoing oversight and reporting of data quality, including missing data, timeliness of data entry, responsiveness to data queries, etc. Data meetings will be held twice monthly, and specific challenges will be addressed. Baseline descriptive statistics among randomized groups will include demographic and clinical variables, summarized as mean (SD) (or median, IQR) for continuous variables and frequency (percent) for categorical variables. For each baseline variable, the magnitude of group differences will be summarized as pairwise standardized mean/proportion differences (group difference divided by SD). Distributions of continuous trial outcomes will be evaluated for normality; normalizing transformations will be completed if needed. Group comparisons on primary outcomes will be by intent to treat. Statistical testing on the outcomes will be evaluated at alpha=0.05 each. Group comparisons on secondary and exploratory outcomes will control for multiple comparisons (false discovery rate) using the Benjamini-Hochberg method. In all models, outcomes will be summarized as mean group levels (with 95% CI) and mean group differences (with 95% CI). Results of the user experience questionnaires will be calculated as median (range) for each Likert-scale question. Unpaired t-tests, Mann-Whitney u-tests, and Chi-square will be used for baseline between groups comparison to verify effectiveness of randomization. To evaluate the effect of gender as biological variable, we will examine whether acceptability and benefits of footwear (between groups as well as compared to baseline) are different between men and women.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

The risk to participants of this study is considered to be minimal in a controlled environment with an attendant present. This research routine will not place subjects at higher risk than normal activities of daily living, and no more risk of harm or discomfort is associated with these tests than the discomfort normally incurred while performing normal activities.

Subjects may experience mild discomfort from the shoe. We will inform the subject to please notify the investigators if the shoe is uncomfortable.

Should the subject agree to the assessment involving the wearable sensor (PAMSys), the potential risks are considered minimal as well. This sensor will be used for assessing mobility performance and will perform physical tasks such as walking, sit-to-stand transitions, standing, physical activity monitoring etc. These assessments are non-invasive, safe, non-toxic, and non-ionizing as the other procedures described in this study. However, like any battery powered systems, there is a minimum risk of sensor malfunctioning. In addition, the study devices are not waterproof, and although they use a low powered battery (similar to a cellphone battery), in order to avoid any risk of shock the monitor should not be submerged or saturated with fluids during operations or cleaning. It does not emit any radiation to the human body, and does not offer any significant risk to the subject. The wearable sensors weigh less than .25 kg.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?
No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?
No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?
No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.
Characterize the impact of OrthoFeet on foot pain

Describe potential benefit(s) to society of the planned work.
Characterize the feasibility of the OrthoFeet device on patient adherence, acceptability, user-friendliness, and perception of benefit for daily usage

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.
This study brings no more than minimal risk to subjects as it only involves a non-invasive device. There are some risks associated with lack of comfort.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?
No

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?
No

J2. Consent Procedures

Who will recruit subjects for this study?
PI
PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.
Participants will be recruited based on referral from their clinician or through recruitment flyers placed in Baylor Clinic. The eligible subject will contact us or be approached by the research personnel after being referred by the clinical physician and his clinical staff (part of the research team). The subject will be fully informed about the study, and should voluntarily agree to participate with the guidelines as stipulated in the informed consent. The study coordinator or designee will introduce the study, present the written consent form, and spend as much time as necessary to ensure the potential subject completely understands the protocol. Emphasis will be placed on the voluntary nature of participation and the subject will be assured that his/her care will not be compromised in any way whether or not they choose to participate. The subject will be informed s/he can withdraw from the study at any time without loss of benefits. Consent forms will then be signed and dated by the subject and individual obtaining consent (PI, co-PI, study coordinator, or designee). Once written consent is obtained, the protocol may begin immediately or a follow-up appointment may be made. The individual (PI, co-PI, study coordinator, or designee ¿ interns) obtaining consent will be given a thorough training of the process and go through several mock consent scenarios. The consent training consists of understanding the study and being able to fully explain it to the participant providing all pertinent information (procedures, risks, benefits, alternatives to participant), giving sufficient time to the participant to consider whether or not they would like to participate, and answer any questions which the subject may have. The training will have a strong emphasis on subject comprehension of the research study by asking open-ended questions to the subject.

The original documents (with signature) will be maintained per IRB policy. Any critical information will be sent for inclusion

in the medical records, if it affects patient¿s wellbeing and any future treatment. A copy of signed consent form will be offered to the patient for personal records. Informed consent will be obtained prior to performance of any study procedures.

Are foreign language consent forms required for this protocol?
No

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?
No

J4. Children

Will children be enrolled in the research?
No

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?
No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?
No

J7. Prisoners

Will Prisoners be enrolled in the research?
No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?
Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
Yes

Specific information concerning alcohol abuse:
No

Specific information concerning drug abuse:
No

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
No

Demographic information (name, D.O.B., age, gender, race, etc.):
Yes

Full Social Security #:
Yes

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
Yes

Identifiable biospecimens
No

Other:
No

At what institution will the physical research data be kept?
The physical research will be kept in our BCM offices housed in the Mcnair Building room B10.401.

How will such physical research data be secured?
Data will be kept in locked file cabinets that only the research team has access to.

At what institution will the electronic research data be kept?
Data will be kept locked on network computers in our BCM offices, under the password protected server.

Address:\\discovery1.ad.bcm.edu\bcm-dept-icamp

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):
Yes

Such electronic research data will be secured via Other:
No

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?
Yes, identify the classes of the persons:
Yes, identify the classes of the persons: People who ensure quality from the institutions where the research is being done, federal and other regulatory agencies will have access to all of the research data.

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.
Transmissions, if any, will only happen via secure emails.

Will you obtain a Certificate of Confidentiality for this study?
No

Please further discuss any potential confidentiality issues related to this study.
NA

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.
All clinical/standard procedures will be billed to the subject's insurance. These include, physician visits, debridement, medications prescribed by physician.

There will be no research procedures charged to the subject or their insurance. This includes, the research device, materials provided by the research team, visits with the research team.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:
135

Distribution Plan:
For taking part in this research, the subject may be paid a total of $135. Their compensation will be broken down as follows:

Subjects will be paid $25 for 3 in person visits, $30 for every visit completed over the phone. There are a total of 5 visits. Payments will be done using the ClinCard method. Their SSN will be requested for the research team to issue the payments. The research study will also cover the subject's parking or transportation expenses to go to their research visits.

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?

No

O1. Current Drugs

Is this study placebo-controlled?

No

Will the research involve a radioactive drug?

No

Section P: Device Studies

Does this research study involve the use of ANY device?

Yes

Device 1: Legsys

Device 2: Kent Camera

Device 3: Frailty Meter

Device 4: Balansens

Device 5: Pamsys

Device 6: Orthofeet Shoes

Section Q: Consent Form(s)

A PROSPECTIVE PROOF OF CONCEPT TRIAL TO EVALUATE EFFICACY, ACCEPTABILITY, AND PERCEPTION OF BENEFIT OF AN INNOVATIVE PAIN RELIEF FOOTWEAR -ORTHOFEET

Section R: Advertisements

Mode of Advertising: Bulletin Board

Exact language of Advertisement:

Foot Pain Research Trial What have you tried to manage foot pain? Do you experience mild to severe foot pain? Would you want to try on new shoes meant for relief for 6 weeks? If you answer yes to the following questions, you may qualify for our clinical trial with OrthoFeet shoes! Benefits of participation include Help to advance scientific knowledge about foot pain Use new shoes for foot pain relief! You will receive compensation for your time For more information, please contact our research coordinators. Anmol Momin 713-798-8714 Anmol.momin@bcm.edu Nesreen El-Refaei 713-798-7470 Nesreen.el-refaei@bcm.edu