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

H-51229- ORTHOFEET: A PROSPECTIVE PROOF OF CONCEPT TRIAL TO EVALUATE EFFICACY, ACCEPTABILITY, AND PERCEPTION OF BENEFIT OF AN INNOVATIVE PAIN RELIEF FOOTWEAR

Concise and Focused Presentation

This is a clinical study at Baylor College of Medicine, to evaluate the benefits and effectiveness of pain relief shoes, called Orthofeet. The study is 12-weeks long. Participation is voluntary, alternative include you may choose not to participate in this study. There are no potential risks to this study. There are no direct benefits.

Background

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study.

It has been estimated 10% of people will experience foot pain in their lifetime, resulting in approximately 600,000 outpatient visits annually. Few studies including ours (Wrobel et al, JAPMA, 2015) suggested that specialized footwear provide short-, intermediate-, and long-term benefit for decreasing pain and improving function in plantar fasciitis (heel inflammation). However, the acceptability of conventional orthoses (devices that support joint alignment or protect existing limbs) is limited and often are costly. Furthermore, very few studies explored benefit of footwear intervention in improving function including daily physical activities, gait, and balance.

The Orthofeet shoes were first created in 1984 by engineers to combine attractive footwear styling with innovative therapeutic features. The shoes contains special 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.

Purpose

The purpose of this study is to evaluate the benefits and effectiveness of the shoe (Orthofeet) in reducing foot pain, increasing daily activities, and improving functional performance in people suffering from foot pain.

Procedures

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

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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):

Screening: Measurements will take place in Baylor Clinic.
You 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.

Foot Pain: Foot pain will be assessed by the revised Foot Function Index (FFI). Foot pain will be assessed at baseline, week-1, week-6, week-7, and week-12.

Postural Balance test: Your balance will be assessed in double stance and semi-tandem stance while standing 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 sensors attached to each shin and thigh and your waist.

Activities of daily living: ADL will be monitored using a validated pendant sensor (PamSysTM) during a period of one week at baseline (week-1), 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). A pre-paid envelop will be provided to collect the sensor.

Quality of life and mobility: Quality of life will be assessed using the self-reported Patient-Reported Outcomes Measurement Information System (PROMIS) questionnaire and mobility will be assessed by a questionnaire called Functional Assessment Therapy General (FACT-G). These questionnaires will be completed 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 Anxiety and Distress Thermometer questionnaire; cognition will be assessed using Montreal Cognitive Assessment (MoCA).
Patient-reported outcomes will be assessed at baseline, week 6 and week 12. 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. You 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 requested. These questionnaires are asked to review you holistically and assess changes in your 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.

The research coordinators may take digital photographs of you while performing exercise or during assessments for the purpose of publication and analysis of the assessments (conferences/manuscripts). Your face will always be censored out to protect your privacy.

Physical frailty: Frailty will be assessed by trauma-specific frailty index and a validated wearable frailty meter technology.

At Visit 2 (1 Week Follow Up) you will be 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) you 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 study participation until 12 Week Follow Up.

At Visit 4 (7 Week Follow Up) you will be 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) you will complete all the same assessments and questionnaires as baseline. All participants will return OrthoFeet shoes by this point.

Clinically Relevant Research Results

The results generated from this research study are not expected to have any clinical relevance to you.

Sharing and Future Research Studies with Identifiable Private Information

Information that identifies you may be removed from your identifiable private information collected as part of this research, and after such removal, your information may be used for future research studies or distributed to another investigator for future research studies without additional consent/authorization from you.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Full Social Security #
- Photographs, videotapes, and/or audiotapes of you

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, and Baylor St. Luke's Medical Center (BSLMC).

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research does not involve treatment. Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) may not condition (withhold or refuse) treating you on whether you sign this Authorization.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project,

the Institutional Review Board, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine, and Baylor St. Luke's Medical Center (BSLMC) may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Bijan Najafi, PhD One Baylor Plaza, MS: BCM 390 Texas, Houston, 77030

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

This is an observational, minimally invasive study. Study visits will be held within the clinic. We believe that there are minimal psychological, legal, or social risks.

Your participation is entirely voluntary and you can stop/leave the study at any time.

There may be unknown risks or discomforts involved. Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

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Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand how the shoe will benefit others in the future.

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Alternatives

The following alternative procedures or treatments are available if you choose not to participate in this study: You may choose to not participate in this study.

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Subject Costs and Payments

There will be 5 visits total.

Each in person visit (baseline, 6 week follow up, 12 week up) will be compensated 25 dollars. 2 visits are over the phone (1 week, 7 week) and will be compensated 30 dollars per call.

You will be given a debit card called "ClinCard" at the first day of the study. Each time you complete a visit or a phone call, the coordinator will load the payment. Please note that it may take up to 72 hours for the amount to be loaded in the card. The research coordinator will provide you with some instructions and useful information about your card.

We will be requesting your SSN in order to issue payments.

If you do not complete the study, you will be paid for all visits and months completed.

At every visit at the research site, we will validate your parking.

If you have no transportation to bring you to the research site, and you do not want the research team going for the visit to your home, we may arrange an Uber trip to pick you up from your house and take you to the research site.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, BIJAN NAJAFI, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: BIJAN NAJAFI at 7137987536 during the day and Maria N oun at 713-798-7538 after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date