Compare

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-38050
Status: Closed
Initial Submit Date: 10/16/2015

Section Aa: Title & PI

A1. Main Title

OHI--RANDOMIZED CONTROL TRIAL TO EVALUATE EFFICACY, ACCEPTABILITY, AND PERCEPTION OF BENEFIT OF AN INNOVATIVE CUSTOM ANKLE FOOT ORTHOSIS

A2. Principal Investigator

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Section Ab: General Information

A4. Co-Investigators

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A5. Funding Source:

Organization: ORTHOTIC HOLDINGS, INC.

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

BCM: Baylor College of Medicine
Baylor St. Luke's Medical Center (BSLMC)
HCHD: Harris County Hospital District Ben Taub
Thomas A. Glazier Senior Education Center
U.S. Renal Care- Baylor Scott Street Dialysis Center

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?
Not set yet

A9. ClinicalTrails.gov Registration

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Falls are a major health concern for the rapidly growing older adult population (above 65 years of age). Estimates of the proportion of elderly that fall each year have ranged from 22.1% to almost 40% (Hausdorff et al., 2001, Shumway-Cook et al., 2009). Miller et al. found that 8.3% of seniors treated for a fall at an emergency department, returned for treatment of a secondary fall within 6 months of the initial fall (Miller et al., 2009). The cost of treating a fall requiring any medical care averages $4100 for Medicare subjects (Shumway-Cook et al., 2009). Falls by older adults treated in an emergency department are reported to average $11,408 in costs and increase to $29,363 if hospitalization is required (Woolcott et al., 2012).

While falls are often multifactoral in cause and subsequently their prevention will require interprofessional interventions, podiatry is one area of medicine that has recently been increasing its efforts to better understand and prevent falls (Najafi et al., 2013a). Prospective research has shown foot and ankle problems which are highly prevalent in older adults (Dunn et al., 2004), increase the risk of falls (Menz et al., 2006a). This relationship has implications for quality of life and occurrence of depression (Downton and Andrews, 1991, Quach et al., 2013). The contribution of footwear to falls has in part been demonstrated by work that showed an association between indoor falls of older adults and lack of shoe use indoors, suggesting that shoes may help prevent falls (Menz et al., 2006b). Previous research has shown that a multifaceted podiatric intervention utilizing home based foot and ankle exercises, assistance with the purchase of safe footwear, and provision of prefabricated foot orthoses can reduce the rate of falls in older people with disabling foot pain (Spink et al., 2011).

Foot problems, loss of proprioception and decreases in ankle strength and range of motion associated with aging have been tied to deteriorations in balance and increased fall risk (Anon, 2011b, Bok et al., 2013). Ankle foot orthoses (AFO) are intended to keep the foot and ankle in optimal positions and are commonly prescribed with the intent of improving gait and balance. Previous work with non-pathologic samples has suggested that AFO can facilitate proprioception via stimulation of cutaneous mechanoreceptors (Feuerbach et al., 1994) and mitigate the impact of fatigued ankle muscles upon stability (Vuillerme and Pinsault, 2007). In the case of peripheral neuropathy subjects, AFO reduced gait variability while walking on uneven surfaces by stabilizing the ankle (Richardson et al., 2004, Son et al., 2010). In 2006, there were 75,240 AFO prescribed under Medicare alone (HCPCS/Alpha-Numeric, 2008). While there is a large volume of studies that have shown the benefits of AFO for individuals that have suffered a stroke, multiple sclerosis, Charcot, or non-progressive brain lesions (Geboers et al., 2002, Menotti et al., 2014, Tyson and Kent, 2009), research involving a less restrictive sample of the older adult population is lacking (Hijmans et al., 2007).

Although a direct objective predictor of fall risk has not been discovered yet, several studies have determined a strong association between poor postural balance and increased risk of falling. Abnormal postural sway measured by the range of sway, for example, has been introduced as a significant independent predictor of recurrent falls (Maki et al., 1994,Thapa et al., 1996), or as a distinguishable factor among fallers and non-fallers (Lajoie and Gallagher, 2004, Maki et al., 1994).

Therefore if an AFO were able to improve postural stability while avoiding limiting the ankle range of motion, it may subsequently reduce fall risk in the general older adult population. Hence, the purpose of this investigation was to determine the immediate effect of a custom-made flexible AFO on balance and functional reach distance in a less restrictive sample of older adults than has been utilized in previous AFO research. We hypothesize that an open gauntlet style custom made AFO could improve postural stability. Secondarily, we hypothesize that such an AFO might influence ankle function in the anterior posterior direction as well as tasks of daily living. To validate the later hypothesis, we examined the immediate impact of AFO on timed-up and go (TUG) completion times as a surrogate of motor function performance during activities of daily living and plantar pressure as measured using a computerized pressure mapping insoles named Fscan.

Section D: Purpose and Objectives

We propose a randomized control trial to evaluate long term effects and effectiveness of Ankle foot orthoses (AFO) in reducing risk of falling in older adults.

Primary Endpoints ¿ Characterize the impact of AFO on balance, gait, risk of falling, frailty status, and adverse events

Secondary Endpoints ¿ Characterize the Impact of AFO on spontaneous daily physical activities ¿ Characterize the feasibility of the AFO device on patient adherence, acceptability, user-friendliness, and perception of benefit for daily usage

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)

Ethnicity:
All Ethnicities

Primary Language:
English, Spanish

Groups to be recruited will include:
Both patients and healthy, non-patient, normals

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.
Participants will be recruited based on referral from their clinician.

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.

Specifically: 1. No minors will be consented. 2. Subjects are given as much time as needed to ask questions and read over the consent. They are will be given a copy of the consent and can return at a later date if they need to discuss it with family members, etc. 3. Subjects will be seen in a dedicated research room with no other subjects in the room.

There will be 40 subjects included in this study. There will be 20 subjects in each of the 2 treatment groups (Intervention and Control). Subjects will be randomized using a 1:1 ratio. Subjects assigned to the treatment group will complete all the assessments while wearing the AFO measurement device. Subjects assigned to the control group will do all the same assessments as the treatment group, except they will not be using the AFO device. Subjects will be randomized at the first visit which is Day 0. Please see page 9 of the protocol attached in Section S.

Inclusion Criteria:

50 total subjects will be recruited. Those eligible will meet the following inclusion criteria: - Male or female - 65 years or older - High risk of fall (confirmed by either a fall in the past 6 months or 13 seconds or more in the Timed Up and Go test).

Exclusion Criteria:

Exclusion criteria: - Patients with active wound infection - Patients currently on any drugs that may have unstable (fluctuate over time) or temporally (less than one month) impact on gait and balance according to the judgement of the physician. - Acute fractures of the foot - Patients with any acute or unstable medical condition which may unstable or temporally impact gait or balance according to the judgement of the physician. - Participation in an interventional Study 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 foot amputation. - Patients who are unable or unwilling to participate in all procedures and follow up evaluations

F2. Procedure

Subjects will be screened to ensure that they meet the inclusion criteria of the study. 50 subjects will be recruited and consented for participation in the study and to achieve the primary endpoints. The subjects will be randomized 1:1 into either the intervention group or the control group. The study will be fully explained and written informed consent will be obtained from each subject prior to the initiation of screening procedures. We will be measuring the subject¿s plantar pressure (Using computerized pressure insoles named FScan), balance, activities of daily living, and gait by using non-invasive wearable technology. A series of health related questionnaires (Falls Efficacy Scale International (FES-I); Short form Health Survey (SF-12); Visual Analog Pain Scale (VAS)) will be used to evaluate quality of life and pain intensity levels. Additionally, the intervention group will be asked to complete a Technology Acceptance questionnaire to provide feedback on the tested device. Information related to medical history and demographics will be obtained for statistical analysis. Subjects will be performing all core measurements as listed below. If necessary, ancillary measurements will also be done. At the end of the screening visit, the subjects will be randomized into the control or intervention group. Those that are in the intervention group will be fitted for a custom AFO device and will be asked to return two weeks later to receive and get educated on it. The control group won't complete the visit at Day 14. They will complete all the other visits and assessments.

Core Measurements

Timed-up-and-go: subject will be asked to stand up from a chair, walk 3 meters, walk back to the chair, and sit down as fast and safely as possible.

Postural Balance test: will be assessed in double stance and semi-tandem stance while subjects stand straight with hands crossed around chest for up to 30 seconds with eyes open and closed.

Gait assessments: will be done during habitual speed, dual-task (count backward) and during fast walking for a distance of maximum 20 m.

Activities of daily living: ADL will be monitored using a validated t-shirt embedded sensor (PamSysTM) during a period of 48 hours (pre and post intervention).

Ancillary Measurements

Questionnaires: Quality of Life (SF-12), Fear of falling (FES-I), Cognitive Impairment (MMSE), Paper Trail Making task, Foot Questionnaire and Examination, Fried Frailty for frailty assessment, Visual Analog Pain scale for pain assessment, Depression (CES-D), Demographics.

Chair Stand test: may be asked to stand up and sit down from a chair to observe lower leg strength and balance.

Alternate step test: may be asked to alternatively touch a step board (18 cm high and 40 cm deep) with left and right foot 8 times.

Plantar Pressure: F-scan Plantar Pressure insole (Tekscan Inc) is an in-shoe pressure measurement system that provides useful information for assessing plantar pressure during walking. It is similar to a standard insole but includes ultra-thin pressure sensors capturing timing and pressure information for foot function and gait analysis. F-scan is a commercially available product for the purpose of research and has been used in many prior clinical researches including ours and no known adverse events were reported. During the visit, we will ask the participant to walk a small distance (approx 15 ft) with their regular shoes and the study shoes and AFO. After your walk while wearing F-scan insoles, the research team will take them off.

ECG, Heart Rate and HRV: Patients will connect a cardiac activity monitoring patch to his/her body using standard recording electrode.

Digital Photographs ¿may take digital photographs of the subjects while performing exercise or during assessments for the purpose of publication (conferences/manuscripts).

*All measures above will take approximately 1 hour.

Assessing gait and balance using wearable sensors The study will implement two validated technologies based on wearable sensors named LegSys and BalanSens for assessing respectively spatio-temporal parameters of gait and postural control in a clinical setting together with other clinically routine assessment (Figure 1). The LegSys device uses five sensor modules, respectively attached to right and left anterior shins, right and left anterior thighs, and posteriorly to the lower back. Each sensor measures the angular velocity of the segment around the medio-lateral axis (flexion-extension). The method for calculating spatio-temporal parameters of gait and balance has been described in detail in previous publications.

The following procedures are research-related:

Visit 1 (Baseline) During the first visit you will be required to fill validated health related questionnaires to measure your pain level, quality of life, and fear of fall. Additionally balance and walking abilities, and activities of daily living will be quantified using non-invasive inertial sensors. For this purpose, a set of sensors will be attached to your body using elastic straps. You will be provided with a sensor embedded t-shirt to wear for 2 days to collect data related to activities of daily living. Your medical history (from your clinic chart) and demographic information will be obtained, such as age, gender, weight, and height.

At the end of the study visit, you will be randomized into either the control or intervention group by a computer-generated list. If you are randomized (assigned) into the intervention group, the podiatrist will fit you with an AFO device which will be picked up two weeks later (Visit 2). Control group will not visit clinic for Visit 2.

Visit 3 ¿ 5 (Months 1, 3, and 6) You will be asked to return to the clinic at one, three, and six months after your first visit. During these visits, you will be required to fill validated health related questionnaires to measure your pain level, quality of life, and fear of fall. Additionally balance and walking abilities will also be collected. On Visit 3 we will collect Plantar Pressure.

Visit 6 (Month 12) 12 months after the baseline visit, you will be asked to return to clinic. During this final visit, the protocol followed during Visit 1 will be repeated. Additionally, we will also ask you to fill a satisfaction questionnaire related to acceptability of intervention (if you were in intervention group). You will also be provided with a sensor embedded t-shirt to wear for 2 days to collect data related to activities of daily living. We will also collect Plantar Pressure.

Please note that subjects in the control group will not complete Visit 2. Visit 2 is only for the intervention group. Subjects in the control group will complete all other visits same as the intervention group.

**No subjects will be screened and no screening assessments will be done unless the subject has signed the consent.

Please see page 9 of the protocol for the schedule of activities.

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:

50 subjects will be recruited and consented for participation in the study and to achieve the primary endpoints.

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?

Data analysis will be done to determine if efficacy points are met and to compare different measurements against others.

Section H: 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 subjects of this study is considered to be minimal because all that is required is simple walking in a controlled environment with an attendant present (all subjects will be mobile, and walking as a regular part of their activities of daily living this research routine will not place them at higher risk than normal activities of daily living. No more risk of harm or discomfort is associated with these tests than the discomfort normally incurred while walking or during normal muscle stretching. Subjects will be allowed rest time between trials as needed. All efforts will be exhausted to minimize the risk of subjects tripping on cords or stepping on objects while walking. A research team member will stand near the subjects throughout the experiments to prevent any accident during the measurement.

There is a risk of falling in this study. The PI and staff will be sure to inform the patient about this during the consenting process.

We will perform initial screening to ensure the safety of the device.

The study devices are completely non-invasive, safe, non-toxic and non-ionizing. The potential risks to you are minimal. 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 cell-phone battery), in order to avoid any risk of shock the monitor should not be submerged or saturated with fluids during operations or cleaning.

Zephyr BioHarness approved via Class 2 devices 510k; 21CFR 870.1025. In addition, for monitoring heart rate, the device may be attached to the skin using EKG electrodes. Some subjects may have allergies to the adhesive or the adhesive can damage sensitive skin. If the subject thinks they may have allergies to the adhesive or they have sensitive skin, we will ask them to inform our staff. In this case, we may use a belt to record EKG instead of electrodes or not measure your EKG, upon their preference. There is a risk of interference from Zephyr Bioharness in the functionality of pacemaker/ICD devices. Therefore, we will ask the subject if they have a pacemaker/ICD device. In this case, we will avoid using Zephyr on the subject.

Fscan insoles risk bring no more than minimal risk to the participant as it is non-invasive and they can be easily slipped on and off the participant's shoe. There is a small risk of tripping and discomfort as in order to connect F-scan, an elastic band has to be wrapped around the participant's waist and there are wires that go down to the subject's ankle where it attaches to the insole. The research team will work hard on minimizing these risks by verbalizing them to the participant as well as staying close to them as they perform research procedures while wearing Fscan.

All information we will collect about the subject will be stored in a secure location and coded in a way to maintain confidentiality. Only study personnel will have access to their records. Data collected during the study may be published and made publicly available. Data may also be shared with other research groups. However, data that could in any way identify them will not be made public or shared.

The assessments described above are expected to be minimal risk and probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Please note that there is also the possibility for loss of confidentiality. The PI and the research team will minimize the possibility of for loss of confidentiality by keeping all the physical data locked in cabinets only accessible to the research team. The electronic data will be kept on network password protected institutional computers. And, subject PHI will be coded as much as possible to minimize the potential for loss of confidentiality.

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

Subjects will be helping to increase the body of evidence based knowledge that we have on the relationship between disorders affecting lower extremity kinematics and gait, balance and ADL measures.

There may be the possibility of benefit in this study including an increase in ankle strength and a reduction in the amount of falls you have. What the researchers find out from this study may help other people who are also at a high risk of falls. It is part of a prevention initiative to reduce the high number of falls associated with foot problems, loss of proprioception and decreases in ankle strength and range of motion associated with aging.

Describe potential benefit(s) to society of the planned work.

It will also help to design feasible low-cost interventions for those suffering from balance and gait disorders. In doing so, subjects will be aiding our understanding of the mechanisms that underlie deterioration in gait and balance which is the first step towards improving the efficacy of treatment.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

As the study is minimal risk study and it might provide the possibility of benefit, the anticipated benefits outweigh any risk that may be involved.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

NA

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

NA

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.

Research Staff will be located at Baylor Clinic and the study sites for several days of the week in order to recruit participants.

Subjects will be recruited from the Co-PI's own practices. We may get some referrals from their colleagues that work in the same clinic. We have included a Waiver of Partial Consent to cover our screening process. The Co-PIs will identify eligible subjects and alert the coordinator. The coordinator will review all the details of the study with the subject and/or their family. If the subject agrees to participate in the study, they will be screened and then enrolled into the study.

Please note that all subjects will be consented before any screening procedures are done.

Spanish speakers will be consented using a full Spanish version of the consent. We have Spanish speaking coordinators on staff that can translate the consent for the patients. The coordinator who translates the consent will sign off on the Translator signature line of the ICF.

Are foreign language consent forms required for this protocol?

Yes

Which of the following ways will you document informed consent in languages other than English?

A full-length informed consent document

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?
NA

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

Specific information concerning alcohol abuse:
NA

Specific information concerning drug abuse:
NA

Specific information concerning sickle cell anemia:
NA

Specific information concerning HIV:
NA

Specific information concerning psychiatry notes:
NA

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

Full Social Security #:
NA

Partial Social Security # (Last four digits):
NA

Billing or financial records:
NA

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

Other:
NA

At what institution will the physical research data be kept?
NA

How will such physical research data be secured?
NA

At what institution will the electronic research data be kept?

NA

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

NA

Such electronic research data will be secured via Other:

NA

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?

NA

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.

NA

Will you obtain a Certificate of Confidentiality for this study?

No

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

There are no further confidentiality issues related to this study.

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.

There is no cost to the subjects for participation in this study except for their time.

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:

180

Distribution Plan:

Participants will be compensated for their time by an amount of $20 per visit. There are 6 visits associated with this study. The total reimbursement for completion of the study is $120 dollars. The subject will be requested to fill out a payment reimbursement form. Subject¿s information will be kept in a locked cabinet to protect privacy.

Extra visits may be required for unforeseen questions or issues with fitting. Subject will be compensated up to three unscheduled 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 study need an IDE?

No

Regarding your device study, could potential harm to subjects be life-threatening?

No

Regarding your device study, could potential harm to subjects result in permanent impairment of a body function?

No

Regarding your device study, could potential harm to subjects result in permanent damage to a body structure?

No

Section Q. Consent Form(s)

None

Section R: Advertisements

Mode of Advertising: Bulletin Board

Exact language of Advertisement:

Are you concerned about falling?

OHI Randomized Control Trial to Evaluate Efficacy, Acceptability, and Perception of Benefit of an Innovation Custom AFO (H-38050)

Are you an adult (65 years or older) with a concern about falling? AND Are you interested in volunteering for "high-tech¨ studies targeted to prevent falls and improve balance ?

IF SO, YOU MAY QUALIFY FOR ONE OF OUR STUDIES

Benefits of Participation Include:

¿« Comprehensive foot examination by a trained professional ¿« Potential improvement of balance and better walking performance. ¿« Advancement of scientific knowledge to help others

For more information please contact the research coordinators listed in the following:

Contacts:

Ivan Marin Research Coordinator (713) 798-7538 Ivan.Marin@bcm.edu

Nesma Khalil Research Coordinator (713) 798-8814 Nesma.Khalil@bcm.edu

Michael E. DeBakey Department of Surgery One Baylor Plaza, Mail Stop BCM390, Houston, Texas 77030 Phone: 713-798-8070 | Fax: 713-798-8460 www.bcm.edu/icamp

Fall Prevention Study 713 798 7538

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Mode of Advertising: Bulletin Board

Exact language of Advertisement:

Are you Concerned about falling?

If yes, you may qualify for a unique study that could improve your balance and walking performance as well as reduce the number of your falls.

Contact Baylor College of Medicine iCAMP at (713) 798-7538 or (713) 798¿ 8714 for more information. H-38050

Are you? Are you an adult (65 years or older) with a concern about falling? If so... Are you interested in volunteering for ¿high-tech¿ studies targeted to prevent falls and improve balance?

THEN¿ You are eligible to participate in a novel study that uses state-of-the-art technology to assess benefit of a novel footwear to improve your mobility, balance and risk of falling . Objectives BCM iCAMP at the Department of surgery has been partnered with Orthopedic Holing Inc. to test an innovative Ankle Foot Orthosis (AFO) device for improving balance and reducing fall risk. If proven effective, the technology could help enhance mobility, quality of walking, and promote a strong and healthy life.

What exactly do I do? We will provide you with a new pair of New Balance shoes. We study your walking and balance patterns throughout a year long period. During this period you will ONLY be seen 6 times. Qualifying participants will be eligible to receive an innovative footwear to reduce risk of falls at NO cost.

Why participate? Falls represent an important source of preventable morbidity and mortality in older adults, with one in three people 65 years and older falling each year; 20% to 30% of those falls result in injuries Due to aging, foot strength and flexibility are reduced causing increase in risk of falling. Appropriate footwear could reduce risk of falling and enhance mobility performance. Being safely active could reduce frailty and retain mobility status over time

Equipment

Custom-made Ankle Foot Orthosis (AFO) easily made to fit into your shoes.

LEGSys (Locomotion Evaluation and Gait System) is a wearable system that allows measurements of gait using sensors attached to shins, thighs, and lower back.

Enroll now! In order to enroll, see the front side of this pamphlet for contact information

Mode of Advertising: Other: Study Flyer

Exact language of Advertisement:

Are you concerned about falling?

OHI Randomized Control Trial to Evaluate Efficacy, Acceptability, and Perception of Benefit of an Innovation Custom AFO

(H-38050)

Are you an adult (65 years or older) with a concern about falling? AND Are you interested in volunteering for "high-tech¨ studies targeted to prevent falls and improve balance ?

IF SO, YOU MAY QUALIFY FOR ONE OF OUR STUDIES

Benefits of Participation Include:

¿« Comprehensive foot examination by a trained professional ¿« Potential improvement of balance and better walking performance. ¿« Advancement of scientific knowledge to help others

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