ClinicalTrials.gov

Protocol title: Reactive Balance Training Targeting Both Slip- and Trip-Induced Falls

NCT04308239

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Protocol

Participants were first assigned to either the reactive balance training (RBT) or control intervention using minimization to balance groups with respect to age, sex, and physical activity level. During a baseline assessment session, participants were exposed to an unexpected laboratory-induced slip or trip based upon random assignment. Starting approximately one week later, participants completed four sessions of their assigned intervention, with these sessions scheduled twice a week for two weeks. The post-intervention assessment occurred the following week, during which participants were exposed to the other perturbation (slip or trip) that they did not experience during the baseline assessment. As such, each participant was exposed to one laboratory-induced slip and one laboratory-induced trip during the study, with one occurring during the baseline assessment before intervention, and the other during the post-assessment after intervention. This design was selected to evaluate gait and reactive balance prior to any training intervention, and to avoid any unintended training effects induced by exposing participants to the same perturbation more than once.

Baseline and post-control/post-RBT assessments included reactive balance tests. Reactive balance was assessed in response to an unexpected laboratory-induced slip or trip while walking. Participants were instructed to walk along a 10-meter level walkway at a self-selected pace "as if you have somewhere to go" and, if slipped or tripped, to recover balance and continue walking. After initial walking trials to determine a self-selected gait speed, subsequent trials were constrained to within 0.1 m/s of this speed using verbal feedback to participants after each trial. After a minimum of 10 trials, participants were exposed to a slip or trip. In brief, slips were induced by spreading a thin layer of vegetable oil over a 0.9×0.9 meter section of the walkway while participants were facing away, and slips occurred when the heel of the dominant foot contacted the oil. Trips were induced using a tripping obstacle that was initially concealed and level with the walkway. Upon proper placement of the stance foot relative to the obstacle while walking, we activated and thus quickly raised the obstacle 8.6 cm. A trip occurred when the dominant foot contacted the obstacle near the middle of the subsequent swing phase. All participants wore the same model of rubber-soled shoes during slip and trip assessments. During all trials, participants wore a fall protection harness affixed to a ceiling mounted track that spanned the length of the walkway. The length of the harness lanyard was set so that the distance between the participant's knee and the floor when kneeling in the harness was approximately 20 cm.

Both interventions (RBT and control) involved a total of four training sessions conducted twice per week for two weeks, and in groups of 1-2 participants. Each session lasted approximately 0.5 to 1.0 hours, with an active training time for each participant of approximately 30 minutes. Training for each participant began with a five-minute warm-up of walking on a treadmill and light stretching.

RBT involved both slip and trip training. One of the first two training sessions involved only slip training, while the other involved only trip training, with the order of presentation counterbalanced within each participant group. The subsequent two training sessions involved equal proportions of both slip and trip training. For both slip and trip training, perturbation magnitudes were individualized to participant capabilities, and varied in magnitude, direction, and stepping foot to improve motor learning. To prevent falls, the fall protection harness was

worn during all RBT sessions. Participants wore their own walking or athletic shoes during training.

RBT for slip training involved participants repeatedly stepped onto a low-friction interface (nylon fabric placed over a 0.9 × 0.9 meter polycarbonate sheet) while practicing controlling/decelerating the slipping foot and properly positioning the non-slipping foot under the pelvis. Both of these actions are critical to prevent a fall after slipping while walking. Training was individualized to participant capability, beginning with a single step onto the fabric to induce short, slow, self-initiated slips, and progressing to walking several steps then onto the fabric to induce longer, faster slips, with the goal of simulating slipping during gait. Participants completed 60-80 slip-like perturbations during each training session dedicated solely to slip training, and 30-40 slip-like perturbations during each training session that also involved trip training.

RBT for trip training involved participants standing on a modified treadmill. At a random time, the treadmill belt was quickly accelerated posteriorly to an investigator-selected speed within approximately 40 ms to elicit a forward loss of balance that mimicked a trip while walking. Participants attempted to step to avert a fall, and to establish a stable gait on the treadmill, after which the treadmill speed was slowed to zero to complete the trial. Perturbation speeds were varied pseudo-randomly, individualized to participant capability, and progressively increased as performance improved. To prevent participants from anticipating forward losses of balance, backward losses of balance (induced by anterior belt accelerations) were pseudo-randomly interspersed throughout training. Participants completed 30 trip-like perturbations during each training session dedicated solely to trip training, and 20 trip-like perturbations during each training session also involving slip training.

The control intervention involved general balance exercises adapted from the Otago Exercise program. Briefly, all four sessions involved balance exercises and strength exercises using ankle weights, and were progressively increased as performance improved by increasing ankle weights or the difficulty of the balance exercises (e.g., not holding onto a wall or support).

Statistical Analysis Plan

Separate statistical analyses were completed for slips and trips, with each analysis involving comparisons between three groups: 1) baseline participants exposed to a slip (or trip) during the baseline assessment, 2) post-control participants exposed to a slip (or trip) after the control intervention, and 3) post-RBT participants exposed to a slip (or trip) after RBT. In each analysis (slips or trips), the three groups involved were mutually exclusive. Significant differences between baseline participants and post-RBT participants would provide evidence of efficacy based upon RBT-induced changes in fall incidence and reactive balance, while differences between post-control participants and post-RBT participants would provide stronger evidence for efficacy based upon RBT-induced changes compared to a control intervention.

The primary outcome measures were peak slip speed for the slip analysis, and trunk angle at touchdown for the trip analysis. Welch's analysis of variance was used to compare continuous measures between the three groups to accommodate heterogeneity of variances between groups. When one group exhibited no variability, the nonparametric Kruskal-Wallis test was used. Where relevant, pairwise comparisons were performed using the Games-Howell Test, or nonparametric Wilcoxon test. Fisher's Exact test was used to compare fall incidence between the three groups, as well as other nominal measures. All statistical analyses were performed using JMP Pro 12 (SAS Institute Inc., Cary, NC) and a significance level of $p \leq .05$.

VirginiaTech

Institutional Review Board
Research Protocol

Once complete, upload this form as a Word document to the IRB Protocol Management System: https://secure.research.vt.edu/irb

Section 1: General Information

1.1 DO ANY OF THE INVESTIGATORS OF THIS PROJECT HAVE A REPORTABLE CONFLICT OF INTEREST? (http://www.irb.vt.edu/pages/researchers.htm#conflict)

☒ **No**
☐ **Yes,** explain:

1.2 IS THIS RESEARCH SPONSORED OR SEEKING SPONSORED FUNDS?

☐ **No,** go to question 2.1
☒ **Yes,** answer questions within table →

IF YES
Provide the name of the sponsor [if NIH, specify department]: The Virginia College of Osteopathic Medicine
Is this project receiving or seeking federal funds? ☒ No ☐ Yes **If yes,** **Does the grant application, OSP proposal, or "statement of work" related to this project include activities involving human subjects that are <u>not</u> covered within this IRB application?** ☐ No, all human subject activities are covered in this IRB application ☐ Yes, however these activities will be covered in future VT IRB applications, these activities include: ☐ Yes, however these activities have been covered in past VT IRB applications, the IRB number(s) are as follows: ☐ Yes, however these activities have been or will be reviewed by another institution's IRB, the name of this institution is as follows: ☐ Other, explain: **Is Virginia Tech the primary awardee or the coordinating center of this grant?** ☐ No, provide the name of the primary institution: ☐ Yes

Section 2: Justification

2.1 DESCRIBE THE BACKGROUND, PURPOSE, AND ANTICIPATED FINDINGS OF THIS STUDY:

Falls are the leading cause of injuries among adults age 65 and older in the United States. Moreover, the number of annual falls among older adults continues to grow at a rate that is faster than the growth rate of

the older adult population. Falls are also the second leading cause of injury in the workplace. These staggering statistics, despite years of effort toward fall prevention, highlight the need for more effective methods to reduce falls.

Improved clinical evaluations are needed to identify individuals at an increased fall risk so that fall prevention interventions can be prescribed. While general clinical tests of balance and mobility are available that associate with fall risk, these tests do not provide mechanistic information on specific pathologies, and their association with types or falls (slips or trips). A better understanding of the relationship between specific pathologies and types of falls would allow more targeted, and likely more effective, fall prevention interventions to be prescribed. Common musculoskeletal pathologies encountered in clinical practice include joint pain, soft tissue pain, neuromuscular control limitations, and bone pain. These pathologies can result in gait alterations that increase fall risk such as asymmetry, lower foot clearance during swing (which increases trip risk), or higher shear forces between the shoes and ground (which increases slip risk). A standard osteopathic structural and postural evaluation is commonly used to characterize these pathologies. However, the ability to use an osteopathic evaluation to identify individuals with alterations in gait that increase fall risk has not been determined. This ability would increase the clinical utility of osteopathic evaluations in identifying individuals needing interventions to reduce fall risk, and provide information on the likely type of fall for this individual.

Improved methods to train and improve balance to reduce fall risk are also needed. Task-specific, reactive balance training is a novel targeted approach to fall prevention that has the potential to substantially reduce the number of falls. Based on well-established motor learning principles, this type of balance training involves repeatedly exposing individuals to realistic slip-like or trip-like perturbations in a safe, controlled manner. Through repetition, this task-specific, or targeted, training can improve reactive balance after slipping and tripping better than general balance training. This work targets slipping and tripping because they are the most common causes of falls among older adults and in the workplace. For example, slipping causes an 25-40% of falls among older adults, and 40-50% of all fall-related injuries in the workplace, while tripping causes up to 50% of falls among older adults, and 23-32% of falls among workers.

While task-specific, reactive balance training shows promise in reducing fall risk, current methods to administer this training have important limitations. First, current methods require significant equipment and space resources, which severely limits their feasibility for use outside of the research setting. Second, current methods only attempted to train reactive balance after slipping or after tripping, but not both. The high prevalence of these types of falls warrants efforts to reduce both while not increasing the risk of either type of fall. Thus, methods are needed to train reactive balance after both slipping and tripping, and do so in a manner that is low-cost and requires manageable space resources to facilitate its use outside the lab.

We have two research objectives. First, we aim to explore the relationship between standard osteopathic musculoskeletal evaluation and lab-based gait measures associated with fall risk. Second, we aim to evaluate the efficacy of the Virginia Tech Balance Training System (System) on improving reactive balance and fall rates after lab-induced slips and trips. No studies have attempted low-cost and low-tech reactive balance training that would make it feasible outside of the lab, and simultaneously train reactive balance after slipping and tripping. Thus, the proposed work will address an important barrier to progress in balance training, and help secure Virginia Tech's position as a world-leader in state-of-the-art balance training for fall prevention.

Our anticipated findings are that 1) an osteopathic musculoskeletal evaluation will be predictive of lab-based gait measures associated with fall risk; 2) the System will improve reactive balance and fall rates after lab-induced slip and trips. This latter is based upon our work showing improved reactive responses tripping perturbations among older adults, and improved reactive response after slip training among young adults.

2.2 EXPLAIN WHAT THE RESEARCH TEAM PLANS TO DO WITH THE STUDY RESULTS:

For example - publish or use for dissertation

We plan to disseminate our results through journal publications and presentations at professional conferences.

Section 3: Recruitment

3.1 DESCRIBE THE SUBJECT POOL, INCLUDING INCLUSION AND EXCLUSION CRITERIA AND NUMBER OF SUBJECTS:

Examples of inclusion/exclusion criteria - gender, age, health status, ethnicity

Subjects will include 36 community-dwelling adults aged 50-75 years. Inclusion criteria will require subjects to pass a medical screening that includes a history and osteopathic evaluation, and not have osteoporosis of the proximal femur as assessed by DXA.

Subjects will first be required to pass a questionnaire, over the phone or in person, to ensure the prospective subject meets the eligibility requirements. Subjects must be 1) age 50-75, 2) able to stand and/or walk for 30 minutes without pain or any mobility aid, 3) not have experienced a fragility fracture within the last 10 years, 4) not currently smoke, or 5) not currently receive physical therapy.

After passing this questionnaire, a DXA scan (in the Human Integrative Physiology Lab on the VT campus) will be performed to exclude individuals with a proximal femur t-score < -2.0.

After passing the DXA scan, the medical screening will be performed, and will include a history and osteopathic evaluation. The goal of this history and osteopathic evaluation is two-fold: First, it will exclude from futher testing adults who may be at an increased risk for medical harm during our balance testing and training protocol described below. It will exclude adults with major unstable cardiopulmonary disease, or evidence of any progressive or unstable medical condition that could account for possible imbalance and falls (i.e. history of cerebrovascular event, Parkinsons, transient ischemic attack, serious uncorrected visual or somatosensory impairment). Second, the data from the osteopathic evalution will be used to explore its relationship with balance testing described below.

Medical screenings, as well as adjudication for participation in subsequent balance testing and training, will be performed by Drs. Woodson or Brolinson.

3.2 WILL EXISTING RECORDS BE USED TO IDENTIFY AND CONTACT / RECRUIT SUBJECTS?

Examples of existing records - directories, class roster, university records, educational records

☐ **No,** go to question 3.3
☒ **Yes,** answer questions within table

IF YES
Are these records private or public? ☐ Public ☒ Private, describe the researcher's privilege to the records: **The Virginia Tech Center for Geronology keeps a list of local residents who are interested in participating in research on campus. We will leverage this list to help us with recruitment.**
Will student, faculty, and/or staff records or contact information be requested from the University? ☐ No ☒ Yes, provide a description under Section 14 (Research Involving Existing Data) below.

3.3 DESCRIBE RECRUITMENT METHODS, INCLUDING HOW THE STUDY WILL BE ADVERTISED OR INTRODUCED TO SUBJECTS:

Subjects will be recruited from the university and local community using subject lists from the VT Center for Gerontology, email listservs, posted fliers, and visits to local community organizations.

3.4 PROVIDE AN EXPLANATION FOR CHOOSING THIS POPULATION:

Note: the IRB must ensure that the risks and benefits of participating in a study are distributed equitably among the general population and that a specific population is not targeted because of ease of recruitment.

Subjects will include individuals aged 50-75 years old, so as to include individuals in the two higher risk fall groups of older adults (i.e. age 65 and older) and working age individuals.

Section 4: Consent Process

For more information about consent process and consent forms visit the following link: http://www.irb.vt.edu/pages/consent.htm

If feasible, researchers are advised and may be required to obtain signed consent from each participant unless obtaining signatures leads to an increase of risk (e.g., the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting in a breach of confidentiality). Signed consent is typically not required for low risk questionnaires (consent is implied) unless audio/video recording or an in-person interview is involved. If researchers will not be obtaining signed consent, participants must, in most cases, be supplied with consent information in a different format (e.g., in recruitment document, at the beginning of survey instrument, read to participant over the phone, information sheet physically or verbally provided to participant).

4.1 CHECK ALL OF THE FOLLOWING THAT APPLY TO THIS STUDY'S CONSENT PROCESS:

- ☐ Verbal consent will be obtained from participants
- ☒ Signed consent will be obtained from participants
- ☐ Consent will be implied from the return of completed questionnaire. Note: The IRB recommends providing consent information in a recruitment document or at the beginning of the questionnaire (if the study only involves implied consent, skip to Section 5 below)
- ☐ Other, describe:

4.2 PROVIDE A GENERAL DESCRIPTION OF THE PROCESS THE RESEARCH TEAM WILL USE TO OBTAIN AND MAINTAIN INFORMED CONSENT:

Informed consent will be obtained in person, after the telephone questionnaire that determines subject eligibility, and prior to the DXA scan. A member of the research team will meet the subject at a convenient location on campus and walk to the Human Integrative Physiology Lab in War Memorial Hall. Prior to performing the DXA subjects will be provided a copy of the informed consent, and a description of the experimental protocol (including potential risks). Subjects will be provided as much as as needed to review the consent form, and all questions will be answered. Subjects who agree to participate will then be asked to sign.

Signed consent forms will be kept in a locked office, accessible only to members of the research team.

4.3 WHO, FROM THE RESEARCH TEAM, WILL BE OVERSEEING THE PROCESS AND OBTAINING CONSENT FROM SUBJECTS?

Leigh Allin or Sunwook Kim

4.4 WHERE WILL THE CONSENT PROCESS TAKE PLACE?

War Memorial Hall

4.5 DURING WHAT POINT IN THE STUDY PROCESS WILL CONSENTING OCCUR?

Note: unless waived by the IRB, participants must be consented before completing any study procedure, including screening questionnaires.

As described above, subjects will first be required to pass a questionnaire, over the phone or in person, to ensure the prospective subject meets the eligibility requirements. After passing this questionnaire,

consent will be obtained prior to the next step within the overall protocol, which is the DXA scan to screen for osteoporosis.

4.6 IF APPLICABLE, DESCRIBE HOW THE RESEARCHERS WILL GIVE SUBJECTS AMPLE TIME TO REVIEW THE CONSENT DOCUMENT BEFORE SIGNING:

Note: typically applicable for complex studies, studies involving more than one session, or studies involving more of a risk to subjects.

Subjects will be provided as much time as needed to read the consent form and ask questions to investigators prior to signing.

☐ Not applicable

Section 5: Procedures

5.1 PROVIDE A STEP-BY-STEP THOROUGH EXPLANATION OF ALL STUDY PROCEDURES EXPECTED FROM STUDY PARTICIPANTS, INCLUDING TIME COMMITMENT & LOCATION:

Screening questionnaire
Subjects will first be required to pass a questionnaire, over the phone or in person, to ensure the prospective subject meets the eligibility requirements. Subjects must be 1) age 50-75, 2) able to stand and/or walk for 30 minutes without pain or any mobility aid, 3) not have experienced a fragility fracture within the last 10 years, 4) not currently smoke, or 5) not currently receive physical therapy. (5 minutes)

DXA Scan
Subjects will be required to pass a DXA scan (in the Human Integrative Physiology Lab on the VT campus) to exclude individuals with a proximal femur t-score < -2.0. (30 minutes)

Medical History and Osteopathic Evaluation
A medical history and standard osteopathic musculoskeletal evaluation will be performed at the Virginia College of Osteopathic Medicine (VCOM). The osteopathic evaluation will involve appendicular palpation and evaluation of spinal curves, somatic dysfunction, reflexes, and motor activity. (30 minutes)

Pre-Intervention Evaluation
Gait and reactive balance after slipping or tripping will be evaluated. These sessions will take place in the laboratory (556 Whittemore Hall). Subjects will be instructed to walk repeatedly back-and-forth along a 10-m long walkway and, if slipped or tripped, recover balance naturally and continue walking. Walking speed will be constrained to 1.3 ± 0.1 m/s. Subjects will initially perform a minimum of 20 walking trials to familiarize themselves with the experimental setup. After completing these walking trials, subjects will be slipped or tripped. Slips will be induced by spreading a thin layer of oil-based lubricant over a 1 m^2 section of the walkway. Trips will be induced by releasing a tripping obstacle. The tripping obstacle is a 7.5 cm wide aluminum bar that spans the width of the walkway, and is initlally embedded in the walkway. Upon release, the obstacle quickly rotates so that it is perpendicular to the walkway. All subjects will wear the same model of shoes during slip and trip trials. (1.5 hours)

Intervention session: The intervention will involve four 45-minute individual sessions, completed twice a week for two weeks. These sessions will take place in the laboratory (556 Whittemore Hall). Half of each training session will involve repeatedly exposing subjects to slip-like perturbations using a protocol developed by our group. During slip training, subjects step onto a low-friction interface to induce a "slip" and practice slip-recovery responses. The other half of each training session will involve repeatedly exposing subjects to trip-like perturbations. Half of subjects will experience trip-like perturbations induced by a modified treadmill, while the other half will experience trip-like perturbations induced by release from a static forward lean. The modified treadmill induces trip-like perturbations by quickly accelerating from static to a prescribed speed, causing a forward loss of balance and requiring steps to recover balance. Release from a static forward lean involves holding subjects at a prescribed forward lean angle using a belt that is tethered to a wall. Release of the tether causes a forward loss of balance and

requires steps to recover balance. Perturbations for each type of training will be individualized to subject capabilities, and be varied to improve motor learning. (each of these sessions will be 45 minutes)

Post-Intervention Evaluation
The same protocol as during the Pre-Intervention Evaluation will be repeated. (1.5 hours)

5.2 DESCRIBE HOW DATA WILL BE COLLECTED AND RECORDED:

The data that will be recorded for further analysis will be obtained during: 1) the osteopathic evaluation, 2) the pre-intervention evaluation, and 3) the post-intervention evaluation.

Data from the osteopathic evaluation will include paper forms completed by Drs. Woodson or Brolinson during these evaluations. Data during the pre-intervention and post-intervention evaluations will include non-invasive measurements of movement during walking trials, slipping trials, and tripping trials. Non-invasive measurements of movement will be obtained using a motion capture system, interial measurement unit, electromyography, and force platforms embedded in a walkway. These data will be saved on a limited-access computer network.

5.3 DOES THE PROJECT INVOLVE ONLINE RESEARCH ACTIVITES (INCLUDES ENROLLMENT, RECRUITMENT, SURVEYS)?

View the "Policy for Online Research Data Collection Activities Involving Human Subjects" at http://www.irb.vt.edu/documents/onlinepolicy.pdf

☒ **No,** go to question 6.1
☐ **Yes,** answer questions within table

IF YES
Identify the service / program that will be used: ☐ www.survey.vt.edu, go to question 6.1 ☐ SONA, go to question 6.1 ☐ Qualtrics, go to question 6.1 ☐ Center for Survey Research, go to question 6.1 ☐ Other **IF OTHER:** Name of service / program: URL: This service is… ☐ Included on the list found at: http://www.irb.vt.edu/pages/validated.htm ☐ Approved by VT IT Security ☐ An external service with proper SSL or similar encryption (https://) on the login (if applicable) and all other data collection pages. ☐ None of the above (note: only permissible if this is a collaborative project in which VT individuals are only responsible for data analysis, consulting, or recruitment)

Section 6: Risks and Benefits

6.1 WHAT ARE THE POTENTIAL RISKS (E.G., EMOTIONAL, PHYSICAL, SOCIAL, LEGAL, ECONOMIC, OR DIGNITY) TO STUDY PARTICIPANTS?

There are potential risks for subjects in the proposed work. As with any physical activity, there is the potential for subjects to experience musculoskeletal soreness after testing or training. During testing and training, there is the potential for muscle strains, joint strains, other soft tissue injury, or broken bones.

6.2 EXPLAIN THE STUDY'S EFFORTS TO REDUCE POTENTIAL RISKS TO SUBJECTS:

Risks will be minimized by using a medical screening to exclude individuals at an increased risk of injury, experienced personnel and safe research practices, and a fall prevention harness system to prevent impact with the foot in the event of a fall. The fall prevention harness will be worn during all gait trials, balance training, and trials that may involve a slip and trip. The harness will be adjusted such that, in the event of an unsuccessful balance recovery, neither the fingertips or knees will be able to touch the floor.

To prevent injury or discomfort to the toe during trials that my involve a slip or trip, subjects will wear sneakers with a stiff toe.

6.3 WHAT ARE THE DIRECT OR INDIRECT ANTICIPATED BENEFITS TO STUDY PARTICIPANTS AND/OR SOCIETY?

Subjects may benefit from training by way of an improved ability to recover balance after slipping or tripping. Subjects may also benefit from the medical screening and DXA. For example, in prior work requiring DXA, we were able to diagnose individuals with osteoporosis who did not realize they had it.

The benefit to society would be an improved understanding of how osteopathic assessments can be used to evaluate fall risk, and further development of the Virginia Tech Balance Training System that can be used to help prevent slip and trip-induced falls in subsequent work.

Section 7: Full Board Assessment

7.1 DOES THE RESEARCH INVOLVE MICROWAVES/X-RAYS, OR GENERAL ANESTHESIA OR SEDATION?

☐ **No**
☒ **Yes**

7.2 DO RESEARCH ACTIVITIES INVOLVE PRISONERS, PREGNANT WOMEN, FETUSES, HUMAN IN VITRO FERTILIZATION, OR INDIVIDUALS WITH MENTAL DISORDERS?

☒ **No,** go to question 7.3
☐ **Yes,** answer questions within table

IF YES
This research involves: ☐ Prisoners ☐ Pregnant women ☐ Fetuses ☐ Human in vitro fertilization ☐ Individuals with a mental disorder

7.3 DOES THIS STUDY INVOLVE MORE THAN MINIMAL RISK TO STUDY PARTICIPANTS?

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily activities or during the performance of routine physical or psychological examinations or tests. Examples of research involving greater than minimal risk include collecting data about abuse or illegal activities. Note: if the project qualifies for Exempt review (http://www.irb.vt.edu/pages/categories.htm), it will not need to go to the Full Board.

☐ **No**
☒ **Yes**

IF YOU ANSWERED "YES" TO ***ANY ONE*** OF THE ABOVE QUESTIONS, 7.1, 7.2, OR 7.3, THE BOARD MAY REVIEW THE PROJECT'S APPLICATION MATERIALS AT ITS MONTHLY MEETING. VIEW THE FOLLOWING LINK FOR DEADLINES AND ADDITIONAL INFORMATION: http://www.irb.vt.edu/pages/deadlines.htm

Section 8: Confidentiality / Anonymity

For more information about confidentiality and anonymity visit the following link: http://www.irb.vt.edu/pages/confidentiality.htm

8.1 WILL PERSONALLY IDENTIFYING STUDY RESULTS OR DATA BE RELEASED TO ANYONE OUTSIDE OF THE RESEARCH TEAM?

For example – to the funding agency or outside data analyst, or participants identified in publications with individual consent

☒ **No**
☐ **Yes,** to whom will identifying data be released?

8.2 WILL THE RESEARCH TEAM COLLECT AND/OR RECORD PARTICIPANT IDENTIFYING INFORMATION (E.G., NAME, CONTACT INFORMATION, VIDEO/AUDIO RECORDINGS)?

Note: if collecting signatures on a consent form, select "Yes."

☐ **No,** go to question 8.3
☒ **Yes,** answer questions within table

IF YES
Describe if/how the study will utilize study codes: Each participant will be assigned a study identification number. All study materials will contain the study ID number, and no other identifying information.
If applicable, where will the key [i.e., linked code and identifying information document (for instance, John Doe = study ID 001)] **be stored and who will have access? A key assigning each subject to an ID number will be saved on a restricted-access computer. The document will only be accessible to investigators.** *Note: the key should be stored separately from subjects' completed data documents and accessibility should be limited.*
The IRB strongly suggests and may require that all data documents (e.g., questionnaire responses, interview responses, etc.) do not include or request identifying information (e.g., name, contact information, etc.) from participants. If you need to link subjects' identifying information to subjects' data documents, use a study ID/code on all data documents.

8.3 HOW WILL DATA BE STORED TO ENSURE SECURITY (E.G., PASSWORD PROTECTED COMPUTERS, ENCRYPTION) AND LIMITED ACCESS?

Examples of data - questionnaire, interview responses, downloaded online survey data, observation recordings, biological samples

Data will be stored on a password-protected computer kept in a restricted-access office. Only study investigators will have access to these data. Physical data (questionnaires and data collection worksheets) will be stored in a locked office, only accessible to investigators.

8.4 WHO WILL HAVE ACCESS TO STUDY DATA?

study investigators

8.5 DESCRIBE THE PLANS FOR RETAINING OR DESTROYING STUDY DATA:

We plan to retain the data for the foreseeable future for publications and conference presentations.

8.6 DOES THIS STUDY REQUEST INFORMATION FROM PARTICIPANTS REGARDING ILLEGAL BEHAVIOR?

☒ **No,** go to question 9.1
☐ **Yes,** answer questions within table →

IF YES
Does the study plan to obtain a Certificate of Confidentiality? ☐ No ☐ Yes (Note: participants must be fully informed of the conditions of the Certificate of Confidentiality within the consent process and form) *For more information about Certificates of Confidentiality, visit the following link:* *http://www.irb.vt.edu/pages/coc.htm*

Section 9: Compensation

For more information about compensating subjects, visit the following link: http://www.irb.vt.edu/pages/compensation.htm

9.1 WILL SUBJECTS BE COMPENSATED FOR THEIR PARTICIPATION?

☐ **No,** go to question 10.1
☒ **Yes,** answer questions within table →

IF YES
What is the amount of compensation? $100
Will compensation be prorated? ☒ Yes, please describe: **Subjects who withdraw after the pre-intervention evaluation session will be paid $30. Subjects who withdraw after completing the four training sessions will be paid $70.** ☐ No, explain why and clarify whether subjects will receive full compensation if they withdraw from the study? *Unless justified by the researcher, compensation should be prorated based on duration of study participation. Payment must not be contingent upon completion of study procedures. In other words, even if the subject decides to withdraw from the study, he/she should be compensated, at least partially, based on what study procedures he/she has completed.*

Section 10: Audio / Video Recording

For more information about audio/video recording participants, visit the following link: http://www.irb.vt.edu/pages/recordings.htm

10.1 WILL YOUR STUDY INVOLVE VIDEO AND/OR AUDIO RECORDING?

☐ **No,** go to question 11.1

☒ **Yes,** answer questions within table

IF YES
This project involves: ☐ Audio recordings only ☒ Video recordings only ☐ Both video and audio recordings
Provide compelling justification for the use of audio/video recording: Video recordings are used to identify types of recovery responses, and validate motion capture data. If necessary. Video recordings may also be used for future presentations.
How will data within the recordings be retrieved / transcribed? Video recordings will be accessed by investigators to obtain qualitative data from video recordings. Any data obtained will be saved on a restricted-access computer network.
How and where will recordings (e.g., tapes, digital data, data backups) be stored to ensure security? Digital copies of video recordings will be saved on restricted-access hard drives, only accessible to investigators.
Who will have access to the recordings? study investigators
Who will transcribe the recordings? N/A
When will the recordings be erased / destroyed? Recordings will be maintained for the foreseeable future for use in future presentations.

Section 11: Research Involving Students

11.1 DOES THIS PROJECT INCLUDE STUDENTS AS PARTICIPANTS?

☒ **No,** go to question 12.1
☐ **Yes,** answer questions within table

IF YES
Does this study involve conducting research with students of the researcher? ☐ No ☐ Yes, describe safeguards the study will implement to protect against coercion or undue influence for participation: *Note: if it is feasible to use students from a class of students not under the instruction of the researcher, the IRB recommends and may require doing so.*
Will the study need to access student records (e.g., SAT, GPA, or GRE scores)? ☐ No ☐ Yes

11.2 DOES THIS PROJECT INCLUDE ELEMENTARY, JUNIOR, OR HIGH SCHOOL STUDENTS?

☒ **No,** go to question 11.3
☐ **Yes,** answer questions within table

IF YES
Will study procedures be completed during school hours? ☐ No ☐ Yes **If yes,** **Students not included in the study may view other students' involvement with the research during school time as unfair. Address this issue and how the study will reduce this outcome:** **Missing out on regular class time or seeing other students participate may influence a student's decision to participate. Address how the study will reduce this outcome:**
Is the school's approval letter(s) attached to this submission? ☐ Yes ☐ No, project involves Montgomery County Public Schools (MCPS) ☐ No, explain why: *You will need to obtain school approval (if involving MCPS, click here: http://www.irb.vt.edu/pages/mcps.htm). Approval is typically granted by the superintendent, principal, and classroom teacher (in that order). Approval by an individual teacher is insufficient. School approval, in the form of a letter or a memorandum should accompany the approval request to the IRB.*

11.3 DOES THIS PROJECT INCLUDE COLLEGE STUDENTS?

☒ **No,** go to question 12.1
☐ **Yes,** answer questions within table

IF YES
Some college students might be minors. Indicate whether these minors will be included in the research or actively excluded: ☐ Included ☐ Actively excluded, describe how the study will ensure that minors will not be included:
Will extra credit be offered to subjects? ☐ No ☐ Yes **If yes,** **What will be offered to subjects as an equal alternative to receiving extra credit without participating in this study?** **Include a description of the extra credit (e.g., amount) to be provided within question 9.1 ("IF YES" table)**

Section 12: Research Involving Minors

12.1 DOES THIS PROJECT INVOLVE MINORS (UNDER THE AGE OF 18 IN VIRGINIA)?

Note: age constituting a minor may differ in other States.

☒ **No,** go to question 13.1
☐ **Yes,** answer questions within table

IF YES
Does the project reasonably pose a risk of reports of current threats of abuse and/or suicide? ☐ No ☐ Yes, thoroughly explain how the study will react to such reports: *Note: subjects and parents must be fully informed of the fact that researchers must report threats of suicide or suspected/reported abuse to the appropriate authorities within the Confidentiality section of the Consent, Assent, and/or Permission documents.*
Are you requesting a waiver of parental permission (i.e., parent uninformed of child's involvement)? ☐ No, **both** parents/guardians will provide their permission, if possible. ☐ No, **only one** parent/guardian will provide permission. ☐ Yes, describe below how your research meets **all** of the following criteria (A-D): Criteria A - The research involves no more than minimal risk to the subjects: Criteria B - The waiver will not adversely affect the rights and welfare of the subjects: Criteria C - The research could not practicably be carried out without the waiver: Criteria D - (Optional) Parents will be provided with additional pertinent information after participation:
Is it possible that minor research participants will reach the legal age of consent (18 in Virginia) while enrolled in this study? ☐ No ☐ Yes, will the investigators seek and obtain the legally effective informed consent (in place of the minors' previously provided assent and parents' permission) for the now-adult subjects for any ongoing interactions with the subjects, or analysis of subjects' data? If yes, explain how: *For more information about minors reaching legal age during enrollment, visit the following link:* *http://www.irb.vt.edu/pages/assent.htm*
*The procedure for obtaining assent from minors and permission from the minor's guardian(s) must be described in **Section 4** (Consent Process) of this form.*

Section 13: Research Involving Deception

For more information about involving deception in research and for assistance with developing your debriefing form, visit our website at http://www.irb.vt.edu/pages/deception.htm

13.1 DOES THIS PROJECT INVOLVE DECEPTION?

☒ **No,** go to question 14.1
☐ **Yes,** answer questions within table

IF YES
Describe the deception:
Why is the use of deception necessary for this project?
Describe the debriefing process:

Provide an explanation of how the study meets <u>all</u> the following criteria (A-D) for an alteration of consent:

Criteria A - The research involves no more than minimal risk to the subjects:
Criteria B - The alteration will not adversely affect the rights and welfare of the subjects:
Criteria C - The research could not practicably be carried out without the alteration:
Criteria D - (Optional) Subjects will be provided with additional pertinent information after participation (i.e., debriefing for studies involving deception):

By nature, studies involving deception cannot provide subjects with a complete description of the study during the consent process; therefore, the IRB must allow (by granting an alteration of consent) a consent process which does not include, or which alters, some or all of the elements of informed consent.

The IRB requests that the researcher use the title "Information Sheet" instead of "Consent Form" on the document used to obtain subjects' signatures to participate in the research. This will adequately reflect the fact that the subject cannot fully consent to the research without the researcher fully disclosing the true intent of the research.

Section 14: Research Involving Existing Data

14.1 WILL THIS PROJECT INVOLVE THE COLLECTION OR STUDY/ANALYSIS OF EXISTING DATA DOCUMENTS, RECORDS, PATHOLOGICAL SPECIMENS, OR DIAGNOSTIC SPECIMENS?

Please note: it is not considered existing data if a researcher transfers to Virginia Tech from another institution and will be conducting data analysis of an on-going study.

☐ **No,** you are finished with the application
☒ **Yes,** answer questions within table

IF YES
From where does the existing data originate? Virginia Tech Center for Gerontology
Provide a detailed description of the existing data that will be collected or studied/analyzed: The Virginia Tech Center for Geronology keeps a list of contact info of local residents who are interested in participating in research on campus. We will leverage this list to help us with recruitment
Is the source of the data public? ☒ No, continue with the next question ☐ Yes, you are finished with this application
Will any individual associated with this project (internal or external) have access to or be provided with existing data containing information which would enable the identification of subjects: ▪ **Directly** (e.g., by name, phone number, address, email address, social security number, student ID number), or ▪ **Indirectly through study codes** even if the researcher or research team does not have access to the master list linking study codes to identifiable information such as name, student ID number, etc or ▪ **Indirectly through the use of information that could reasonably be used in combination to identify an individual** (e.g., demographics) ☐ No, collected/analyzed data will be completely de-identified ☒ Yes, **If yes,**

Research will not qualify for exempt review; therefore, if feasible, written consent must be obtained from individuals whose data will be collected / analyzed, unless this requirement is waived by the IRB.

Will written/signed or verbal consent be obtained from participants prior to the analysis of collected data? Yes, signed consent will be obtained

This research protocol represents a contract between all research personnel associated with the project, the University, and federal government; therefore, must be followed accordingly and kept current.

Proposed modifications must be approved by the IRB prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects.

Do not begin human subjects activities until you receive an IRB approval letter via email.

It is the Principal Investigator's responsibility to ensure all members of the research team who interact with research subjects, or collect or handle human subjects data have completed human subjects protection training prior to interacting with subjects, or handling or collecting the data.

----------END----------

APPROVED
May 30, 2018
WIRB®

RESEARCH SUBJECT CONSENT FORM

TITLE:	Innovative Strategies for Fall Prevention using Osteopathic Evaluation and Balance Training
PROTOCOL NO.:	18-486 WIRB® Protocol #20181340
SPONSOR:	Virginia College of Osteopathic Medicine
INVESTIGATOR:	Michael L. Madigan, PhD 250 Durham Hall (0118), 1145 Perry Street Blacksburg, VA 24061 USA
STUDY-RELATE PHONE NUMBER(S):	Michael L. Madigan Daytime Phone Number: 540-231-3543 24-hour Phone Number: 540-250-0471

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to 1) determine if osteopathic evaluations can be used to identify individuals at an increased risk of falling, and 2) use the Virginia Tech Balance Training System to train and improve balance.

About 40 subjects will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last about four weeks. This includes a two-stage medical screening, and a total of six experimental sessions: two 90-minute evaluation sessions, and four 45-minute balance training sessions. All sessions will be scheduled at your convenience, and take place on the Virginia Tech campus.

What happens to me if I agree to take part in this research?

You will be asked to first pass a two-stage medical screening. The screening is used to exclude individuals who are at an elevated risk of injury during the study. The first stage will involve a bone-density scan to ensure that you do not have osteoporosis. This will be accomplished by taking a low-dosage x-ray (dual-energy x-ray absorptiometry) of your hip bone. This x-ray applies the same approximate dosage of radiation as flying across the country in an airplane. The second stage will involve a medical history and osteopathic evaluation performed by a physician.

For subjects who pass the medical screening, participation involves six experimental sessions: two 90-minute evaluation sessions, and four 45-minute balance training sessions. All six sessions will be scheduled at your convenience, and take place in the laboratory in 556 Whittemore Hall on the Virginia Tech campus.

The 90-minute evaluation sessions will involve repeatedly walking along a walkway. Data will be collected non-invasively using reflected markers and electrodes attached to your skin or clothing using double-sided tape. You may experience a slip, trip, or neither while walking along the walkway. If you do experience a slip or trip, simply recover your balance and continue walking to the end of the walkway. During all trials, you will wear a full-body safety harness to keep you safe and prevent a fall to the floor.

The 45-minute balance training sessions will involve the Virginia Tech Balance Training System, which includes balance training exercises. During training, you will also wear a full-body safety harness to keep you safe and prevent a fall to the floor.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to:

- Answer questions truthfully during the screening process.
- Follow the instructions of the investigator(s).
- Arrive to sessions on time.
- Notify investigators in advance if you are unable to keep your scheduled appointment(s).

Could being in this research hurt me?

There are potential risks for subjects in the proposed work.

- As with any physical activity, there is the potential for subjects to experience musculoskeletal soreness.

- There is a risk of muscle strains, joint strains, other soft tissue injury, broken bone, or other unexpected injury.
- There is a risk of skin irritation or discomfort resulting from adhesive used to adhere sensors to your skin.

These risks will be minimized by using a medical screening to exclude individuals at an increased risk of injury, experienced personnel and safe research practices, and a fall prevention harness system to prevent impact with the floor in the event of a fall.

Will it cost me money to take part in this research?

Taking part in this research may lead to added costs to you by way of transportation to the location of the study.

Will being in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include identifying an unknown medical condition through the medical screening, and a possible improvement in your balance after training.

In addition, possible benefits to others include helping the scientific community develop new ways to help prevent falls.

What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- The Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Data or specimens collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

We would like to be able to take photographs or videos of the experiment for our use in future reports, papers, or presentations. We will only take these photographs and/or videos if you give your permission to do so. Indicate your decision below by initialing in the space provided.

_____ I give my permission for photographs/videos to be made of me during my participation in this research study.

_____ I do not give my permission for photographs/videos to be made of me during my participation in this research study.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

If you are injured or get sick because of being in this research, a list of local services will be provided. Any expenses accrued for seeking or receiving treatment will be the responsibility of the subject and not that of the research project, research team, or Virginia Tech. If you are injured as a result of this study, you do not give up your right to pursue a claim through the legal system.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- You become pregnant
- The research is canceled by the sponsor
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

If you decide to leave this research, contact the research team as soon as possible so that the investigator can cancel your appointments and contact replacement subjects.

There are no adverse consequences to a subject who withdraws.

Will I be paid for taking part in this research?

For taking part in this research, you may be paid up to $100. If you choose to withdraw from the study prior to its completion, compensation will be prorated as follows:

$30 if the two-stage medical screening is completed
$70 if the two-stage medical screening and the four training sessions are completed.

Statement of Consent:

Your signature documents your consent to take part in this research.

Signature of adult subject capable of consent	Date

Signature of person obtaining consent	Date

Division of Scholarly Integrity and Research Compliance
Institutional Review Board
North End Center, Suite 4120 (MC 0497)
300 Turner Street NW
Blacksburg, Virginia 24061
540/231-3732
irb@vt.edu
http://www.research.vt.edu/sirc/hrpp

MEMORANDUM

DATE: May 30, 2019

TO: Michael L Madigan, Maury A Nussbaum, Karen A Roberto, Sun Wook Kim, Leigh Allin, Per Gunnar Brolinson, Briana Mary Beach, Colleen Bannigan

FROM: Virginia Tech Institutional Review Board (FWA00000572, expires January 29, 2021)

PROTOCOL TITLE: Innovative Strategies for Fall Prevention using Osteopathic Evaluation and Balance Training

IRB NUMBER: **18-486**

The Virginia Tech Institution Review Board (IRB), acknowledges the Amendment request for the above-mentioned research protocol.

This acknowledgement recognizes the item(s) identified in the Special Instructions section.

NOTE: Amendments that must be submitted to BRANY for review and approval include changes to funding, conflict of interest, ANY and ALL changes to study procedures and study documents. If your study qualified for Not Human Subjects or for an Exemption please review the information at the end of your approval Letter.

SPECIAL INSTRUCTIONS:

The Virginia Tech IRB acknowledges the transfer of IRB oversight from WIRB to BRANY for this protocol. Please read the information below for more details.

Dear Investigators:

This email serves as a notice that your protocol is under active transfer from WIRB to BRANY. We ask that you do not submit any further requests to WIRB or to the Virginia Tech IRB.

FAQ's:

Q. How will I know when my protocol has been accepted by BRANY?

A. BRANY IRB will send you a notification indicating your transferred study has been accepted.

Q. Has the Virginia Tech IRB drafted guidance?

A. Yes. We have created guidance and it is available on a PID protected website.

https://internal.research.vt.edu/sirc/hrpp/brany-transfer

This link will be provided on all Authorization Letters.

Q. How do I gain access to BRANY's IRBManager?

A. This section is very important. Not everyone listed as study personnel needs to have access to IRBManager. The PI, active Co-I(s), and study coordinators are the typical research team members that will need to have access. In order to gain access, each person will need to complete the Request for User Access form and sign it with wet ink. Digital signatures and script style font are not accepted. [http://www.brany.com/wp-content/uploads/2018/07/BRANY-User-Access-Form-complete-sign-return-2
0170323-V2_.pd]

Q. I need to submit an amendment to my protocol. What should I do?

A. Once your protocol has been accepted in the BRANY IRBManager system, you will be able to submit requests directly to BRANY for review in their IRBManager system. Refer to the guidance provided by the Virginia Tech IRB using the web link above.

Q. I need to revise my list of study personnel. What should I do?

A. You will no longer submit personnel changes to the Virginia Tech IRB. You will submit personnel changes to BRANY through their IRBManager system. You should follow the guidance provided by the Virginia Tech IRB using the web link above.

Q. I am actively working with research subjects (including recruiting, consenting, enrolling, collecting data). Do I need to alter my consent forms? Do I need to notify my participants of the change of IRB oversight?
A. This section is very important. When you receive the notification from BRANY that your study has been accepted, instructions will be included regarding consent needs.

Q. How will I know that I need to submit a Continuing Review request?

A. BRANY will send reminder emails 45, 30, and 15 days prior to the expiration date. The automated reminders will cease when either a continuing review or closure application is received and processed by BRANY IRB.

Date*	OSP Number	Sponsor	Grant Comparison Conducted?
05/14/2018	P57MN7YQ	Edward Via College of Osteopathic Medicine (Title: Innovative Strategies for Fall Prevention using Osteopathic Evaluation and Balance Training)	Not required (Not federally funded)

* Date this proposal number was compared, assessed as not requiring comparison, or comparison information was revised.

If this protocol is to cover any other grant proposals, please contact the HRPP office (irb@vt.edu) immediately.

To: Michael Madigan, PhD

From: Raffaella Hart, MS, CIP

CC: VT IRB Office

Date: 05/31/2019

Re: Study information received for Edward Via College of Osteopathic Medicine Protocol # Innovative Strategies for Fall Prevention using Os / BRANY File # VT18-486-568(TRX) / 18-486

Study Title**: **Innovative Strategies for Fall Prevention using Osteopathic Evaluation and Balance Training

Welcome to BRANY IRB! This serves as notice that BRANY IRB oversight for the above referenced study is effective 5/31/2019. An assessment of the records provided to BRANY IRB for the study is in progress. The records will now reside in BRANY's IRBManager system, and are being evaluated for completeness. You will be notified once the record evaluation is complete.

Thank you for the opportunity to serve you! Next Steps:

- Notify study subjects of the change in IRB oversight using one of the forms attached.

  Use the **Consent Form Addendum** for your study if you will continue to have in-person encounters with the subjects. Subjects may sign the addendum at the next study visit.

  Use the **Letter to Subjects** for your study if no in-person subject encounters remain (e.g., subjects are in long-term follow-up). You should mail the letter to these subjects as soon as possible, but no later than within the next 30 days.

- You received some guidance from the Virginia Tech IRB Office about working with BRANY IRB. Training sessions on the use of IRBManager will be made available in the coming weeks. On-demand viewing of "how-to" webinars demonstrating common tasks in IRBManager are also available at https://www.brany.com/irb-manager.

- Submit a Request for User Access form if you have not already done so. This one-time form is needed to establish your IRBManager user account. See the FAQs from the VT IRB Office for more information.

Note! BRANY IRB approval for this research will expire on **05/30/2020**. If the status of the study changes, or it is completed prior to this date, notify the IRB. All submissions must be made via IRBManager. For amendments, personnel changes, changes in study status, and reportable events, see Which xForm should I use? If you have any questions or require any additional information, please contact me at 516-470-6909 or rhart@brany.com. Thank you.

Date: _____

Dear Study Participant:

You are receiving this letter because you have been participating in the following research study: ***Innovative Strategies for Fall Prevention using Osteopathic Evaluation and Balance Training***.

Since you signed the Informed Consent Form for this study, there has been a change regarding whom to contact with any questions, complaints, or concerns about this research. This change does not affect your participation in this study, or your legal rights.

All other text and information in the study informed consent form(s), the document you signed prior to joining the study, remains unchanged.

Questions and Concerns

If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Michael Madigan, PhD at 540-231-3543.

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

Thank you,

Michael Madigan, PhD

Study Principal Investigator

BRANY
Version 05/31/2019

BRANY

INFORMED CONSENT FORM ADDENDUM

Study Title: Innovative Strategies for Fall Prevention using Osteopathic Evaluation and Balance Training

Edward Via College of Osteopathic Medicine Protocol: Innovative Strategies for Fall Prevention using Os

Investigator: Michael Madigan, PhD

Introduction

You have been participating in the above referenced research study. This is an addendum to the informed consent form you previously signed for this research.

The purpose of this document is to inform you about a change regarding whom to contact with any questions, complaints, or concerns about this research.

Questions and Concerns

If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Michael Madigan, PhD at 540-231-3543.

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

This change does not affect your participation in this study, or your legal rights. All other text and information in the consent form you previously signed remains unchanged.

CONSENT

Sign below to acknowledge receipt of this information. You will receive a copy of this signed Informed Consent Form Addendum.

Subject: Name (Print)	Signature	Date

Person Obtaining Consent: Name (Print)	Signature	Date