An Engineering-Based Balance Assessment and Training Platform

NCT03994770

May 16, 2023

Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date: _____

Title of Study: **An Engineering-Based Balance Assessment and Training Protocol (BATP)**

Principal Investigator: **Joseph (Jay) Barton, PhD** Facility: **VA Maryland Health Care System**

IRB Study Number: HP-00084321

Sponsor: Veterans Administration (VA), Office of Research & Development (ORD).

INTRODUCTION

You are being asked to participate in a research study that is being carried out at the VA Maryland Health Care System (VAMHCS). Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive.

Read the information below closely and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

CONCISE SUMMARY

As people age, some become less able to maintain their balance when performing everyday activities and experience falls that they would not have when they were younger. Certain conditions associated with aging, such as stroke, make it even more difficult to maintain balance and prevent falling. We want to understand how aging and age-related disabilities such as stroke affect balance, and whether balance training can help such people regain their balancing capacity. To determine if you qualify for the study, you will undergo a medical history and physical exam, and possibly a simple balance test and standing task. The study consists of two phases. In the first phase, you will be asked to complete several common clinical tests of balance and perform the Balanced Reach Assessment, which consists of standing and pointing to a target moving unpredictably around you, requiring you to lean in various directions to maintain contact with it. The first phase (including a brief physical exam) will take approximately 2-2.5 hours to complete over each of two half days. Some subjects who participate in this first phase will be asked to participate in a second phase. This phase consists of three "training sessions" during which you again perform the Balanced Reach task, but for a longer period of time. You will perform three training sessions over the course of 1-2 weeks, 48-72 hours apart. Each session will take approximately 2-2.5 hours. Then, after completion of the Phase 2 training programs, you will repeat the phase 1 assessments to see how your balance capacity was affected by training. Perhaps the most obvious risk associated with these tests and training sessions is the risk of falling, but we have taken measures to minimize the chance of this happening. There is no cost to you to perform the tests, and you will be paid 50-$100 upon completion of your participation ($50 for each phase). Though we will be evaluating the potential benefits of these balance training regimens, we cannot guarantee any direct benefit to you resulting

from your participation. Your balance may improve, and you may learn more about your own balance and reaching functions. There is also the possibility that additional health issues will be discovered that could alert you to possible health problems you might not have known about. Aside from these, there are no other direct benefits of the research to you other than contributing to knowledge about balance and reach in people with high fall risk and stroke.

If you are interested in learning more about this study, please continue reading below.

RESEARCH DETAILS

PURPOSE OF THE STUDY

The purpose of this study is to develop a Balance Assessment and Training Protocol (**BATP**) to assess and improve older and older disabled individuals' ability to maintain balance. The BATP's Assessment phase (Phase 1) quickly establishes your Limit of Balance (**LoB**), and then measures performance during a reaching task while at the LoB. This is to better expose balance deficits for identification and evaluation. The goal of the BATP Training phase (Phase 2) is to increase your LoB (and improve balance function) by continuously challenging you with increasingly more difficult reaching tasks. Older individuals who have experienced a stroke are needed for this study, as well as young healthy control subjects.

In all, we are seeking 40 people to participate and complete this study at VAMHCS. Taking part in this research study is voluntary and you can ask questions at any time, including questions about your rights as a test volunteer.

STUDY PROCEDURES:

All visits and testing/training procedures for this research study are summarized below. They will occur at one or more of the Human Motor Performance Labs (HMPL), located in the VA Annex in downtown Baltimore, the Baltimore VA Medical Center, and the Loch Raven VA Medical Center.

<u>Consenting/Screening:</u>

To verify eligibility for participation, young healthy subjects **(18-40 years of age)** will be assessed for eligibility for safe participation based on self-report, and older subjects **(60 years of age and above)** will undergo a medical history and physical exam performed by a licensed medical clinician. They may also be asked to perform some simple balance and standing tasks, such as:

1. **Four-square step test, which consists of stepping** over a set of canes laying on the ground. This will help assess your fall risk.
2. **Standing Tolerance, which consists of standing** as long as you can, up to 5 minutes without using an assisted device. This is to assess whether you can tolerate the testing and training procedures.

3. Eye Wear (~5min): You may be asked to wear a set of virtual reality "goggles" for up to 5 minutes to test how well you tolerate wearing them.

Subjects participating in other studies at the Baltimore VA and University of Maryland Baltimore (UMB) in the past three months will undergo an abbreviated history and physical to screen for eligibility and safe participation, assuming they had the full screening exam in the prior study. If you receive your healthcare at the VA, we will access your medical file to obtain additional information. If you receive your care from a non-VA doctor, you might be asked to complete a form asking for permission for your doctor to send additional information of your medical history. The screening evaluation will also include administration of a cognitive assessment such as the Montreal Cognitive Assessment to screen potential participants for dementia. As an additional part of screening, you may be asked to perform a small battery of minor physical tasks.

If all screening assessments verify eligibility for safe participation, scheduling for Phase 1 balance assessment testing will occur, as described below.

Phase 1- Baseline Testing – Balanced Reach Assessment
The Balance Reach Assessments consists of **two main parts,** which together should take approximately 2-2.5 hours. These may be repeated a second time as part of a double baseline testing process.

1. The ***first part*** consists of common **Clinical Measures** of Balance, such as those listed below:
   a. Physical Tests:
      i. Multi Directional Reach Test
      ii. Mini Balance Evaluation Systems Test (Mini-BESTest)
      iii. Four Square Step Test (FSST)
      iv. Physiological Profile Assessment (PPA).
      v. Berg Balance Scale (for stroke participants only)
   b. Questionnaires:
      i. Falls Efficacy Scale, which assesses Fear of Falling (FoF)
      ii. The Activities–specific Balance Confidence (ABC) Scale, which also assesses FoF.
      iii. Disabilities of Arm, Shoulder and Hand (DASH) Test (for stroke participants only).

   During and throughout the first year after enrollment, we will also keep a record of any falls that you experience, and the conditions in which you fell.
2. The ***second part*** of the assessment phase consists of the **Balanced Reach Assessment**, which measures your balance function more precisely. The testing consists of a series of trials in which you will be presented with a target moving in an unpredictable fashion displayed as a disk moving around a large projection screen, or as a virtual target using virtual reality eyewear that

you may wear. You will stand, fix your sight on the target, and point with your index finger of your dominant hand to the center of the target as it moves. If you have had a stroke, you may use both the unaffected and affected arms, if possible.

Your body's movements will be measured with small markers fixed with tape or elastic bands to your head, arms, back, chest, legs, and feet. The platform you stand on contains sensors that will measure the forces your feet exert against the ground when you move. The movement of your eyes in your head may also be measured, using an "Eye Tracker" that consists of a pair of goggles that you may wear. Finally, your muscle activity may be measured using small "EMG" sensors fixed with tape to the skin over certain muscles of interest. A researcher will stand nearby to spot you to ensure you do not lose your balance during testing and training. None of the procedures will involve breaking of the skin and none should produce any pain. If at any time you experience pain, discomfort, or fatigue, tell us immediately and the procedure will be stopped. For a clear view of the joints and muscles of your arms and legs, you will be required to wear snug-fitting clothing. You may bring your own or we can provide you with a freshly washed pair at the lab. You should also wear comfortable walking shoes (tennis shoes are best) that do not have a high-heel and do not come up above the ankle. Non-slip socks will be provided for the completion of the Balance Reach Assessment.

There are two components to the Balanced Reach Assessment.

1. In the first component we will use the pointing task to measure your limit of balance (LoB) in various directions.
2. We will then use these results to program the motion of the target to remain at your LoB, and you will then track the target for 90 sec. After a 2 ½ minute rest, you will track the target a second time for 90 sec. Both the tracking and resting durations may be varied to optimize measurement quality and accommodate your individual needs and capabilities.

Both parts of the Baseline – the Clinical Measures of Balance and the Balanced Reach Assessment, may be repeated a second time. You should complete all phases of the baseline Balanced Reach Assessment within one week.

Phase 2- The Study Intervention

After the Phase 1 balance assessment tests are completed we will randomly select half of the stroke subjects who participated in the Balanced Reach Assessment Test to also participate in Balanced Reach Training. Selection will be at random (like flipping a coin), and you will have a 1 in 2 chance of being selected. If you are selected and you agree, training will begin one to two weeks after the assessment tests are completed. It will consist of three training sessions over 1-2 weeks with each session being at least 24 hours apart. Individual training sessions will last approximately 2-2.5

hours. During training the Phase 1 assessment tests will be repeated immediately before the first training session and immediately after the last training session.

Balanced Reach Training will involve the participant's use of the same set up used in the Balanced Reach Assessment. At the beginning of each training session, you will perform the pointing task as before to measure your limit of balance (LoB) in various directions; and we will program the motion of the target to remain at your LoB. After a rest period, you will then track the target for a brief period without stepping, followed by a rest period. You will repeat this 15 times. Both the tracking and resting durations may be varied to accommodate your individual needs and capabilities. Each training session will last 2-2.5 hours (including putting on and taking off the instrumentation described above and setting up the measurement systems) with the goal of completing 60 minutes of actual training.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

All materials and data will be obtained and used for research purposes only. You will be informed of any results that have clinical relevance. If clinically significant abnormalities are noted, the data may be shared to direct appropriate care for you. Results are only shared with your physicians at your request and with your written permission. If for any reason you are disqualified from participation, you will be informed as to the nature of the disqualification and will be referred for appropriate care. Upon request, you may obtain a summary of your baseline and post-intervention functional performance measures at the end of the program. The principal investigator maintains complete control over all the data.

FUTURE USE OF DATA AND RE-CONTACT

In the future, researchers may need more information about you, or may ask you if you are willing to participate in a new study. Please initial below your preference for being re-contacted. You may change your mind about providing information in the future by calling or texting the study team at (410) 605-7000 Ext. 53241, 53279, or 53242 (call only) or (443) 421-2358 (call or text).

_____Yes, my information may be stored in the registry, and I may be re-contacted.

_____No, my information may not be stored in the registry, and I may not be re-contacted.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible for keeping all scheduled appointments and following all instructions issued by the principal investigator and study staff. Additionally, any change in health status or pain/discomfort because of study participation should be immediately reported to the study team.

POTENTIAL RISKS/DISCOMFORTS:

1. Privacy Risk: Loss of confidentiality is a possible risk but unlikely. Your personal information will not be included with the research data. The data will only be reviewed and analyzed by the Principal Investigator (PI) or other members of the research team. All data collected will be stored either in locked file cabinets in locked rooms (if on paper) or on password protected computers that will be locked in research team's offices. All data will be backed up to secure network servers.
2. Risk of Medical Event: During physical activity in Phase 1 and Phase 2 there is a small risk of experiencing a cardiovascular event or some other kind of significant abnormal health event. To safeguard against these risks, you have been carefully screened by appropriate clinicians. If, however, you do experience, demonstrate, or express significant abnormal health signs and symptoms, the trained supervising staff will stop you and you will receive appropriate care. Additionally, the following safeguards are put in place:
   a. Testing and training sessions are supervised by exercise physiologists with CPR/BLS training who are required to follow health and safety protocols enforced by the Geriatric Research Education Clinical Center, this includes checking vitals (blood pressure, heartrate, and blood glucose [only if you have Type I or II diabetes]) before and after exercise.
   b. Medical clinicians are always available by phone or on-site to answer/address any medical questions and concerns during testing and training.
   c. An Automated External Defibrillator (AED) is available on-site and should there be any unanticipated medical emergencies staff can initiate emergency care by calling 911. If 911 is activated, you would be taken to the nearest available hospital for care. Medical emergencies can also be treated in VAMHCS medical facilities.
   d. The Baltimore VA internal safety monitoring board provides additional oversight for the conduct of this research.
3. Risk of Fall: During the physical activities within all the portions of this study that deal with balance and exercise, there is the risk of loss of balance, stumbling, or fall, and potential injury. To minimize these risks, trained staff are stationed appropriately to spot participants during all portions of physical activity within the study. In addition, during the Balanced Reach Assessment and Balanced Reach Training, a harness may be used to further ensure your safety.
4. Risk of Physical Discomfort: During and after exercise, there is a mild risk of tenderness, swelling around joints and/or muscles, or muscle soreness. This is normal. The risk of more serious injury such as a sprain is small. This risk will be minimized by having trained specialist

instruct you with proper exercise technique. As previously stated, the trained staff will stop you if you have any significant symptoms of medical complications including those related to injury, and you will receive appropriate care.

5. Risk of minor skin irritation: During the Balanced Reach Assessment and Balanced Reach Training, there is a minor risk of skin irritation and/or discomfort from wearing test instrumentation. These incidents are known to be minor, and the irritation/discomfort ends as soon as the equipment is removed. Should you experience this issue, the instrumentation will be removed, and you will be instructed to rest until the symptoms cease.
6. Risk of Disorientation: During portions of the study which involve the Balanced Reach Assessment and Balanced Reach Training, there is the small risk of experiencing minor disorientation due to the nature of the balance task, equipment set up, or the equipment worn. This is known to be very minor and quickly resolved after stopping activities. To reduce the risk, rest periods are incorporated into testing sessions and can be adjusted to suit your needs.
7. Unknown Risk: Finally, in addition to the risk described in this form there may be risks/discomforts in this study which are not yet known. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in the study.

POTENTIAL BENEFITS

We cannot guarantee any direct benefit to you resulting from your participation in this study, but your balance may improve, and you may benefit indirectly by learning more about your own balance and reaching functions. There is also the possibility that additional health issues will be discovered that could alert you to possible health problems you might not have known about. Your participation in this study will also increase our knowledge about balance and reach in people with high fall risk and stroke.

ALTERNATIVES TO PARTICIPATION

Your alternative is to not take part. If you choose not to take part, your healthcare at VAMHCS will not be affected.

COSTS TO PARTICIPANTS

- Transportation costs to the Baltimore VA Medical facilities that are part of this study are the only costs to you. Parking at the locations is free to patients and research participants.
- You will not be charged for any treatments or procedures that are performed for research purposes in this study. It will not cost you anything to take part in this study.

PAYMENT/REIMBURSEMENT TO PARTICIPANTS

As compensation for your time, you will receive the following:

- $100.00 for **full** participation in both the assessment and training phases of the tests, at the end of your last visit
  - $50 at the completion of the Assessment Phase;
  - $50 at the completion of the Training Phase, if you take part in the second phase.
- Should you not complete or be unable to complete all the procedures, we will pay a partial amount based on how much you did complete.
- You will be reimbursed by the Baltimore VAMHCS, either in cash or with a pre-loaded "ClinCard", which can be used like a credit card to make purchases or withdraw cash.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

The VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85). Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VAMHCS will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. This care may be limited by local or federal law.

If you should have a medical concern or get hurt or sick because of taking part in this study, call or text the study team at (410) 605-7000 Ext. 53279, 53242, or 53241 (call only) or (443) 421-2358 (call or text). (call only) or (443) 421-2358 (call or text).

The VA does not normally provide any other form of compensation for injury. However, by signing this form, you have not waived any legal rights or released the VAMHCS or its agents from liability for negligence.

CONFIDENTIALITY AND ACCESS TO RECORDS

The study requires the collection of some personal information. Access to this information will be limited to the research team members. Confidentiality will be maintained to the fullest extent permitted by law. Your study records will be considered confidential. Your name will not be used in reports or publications. Experimental information will be identified by code number rather than your name. Personal information and experimental data will be stored separately in secure areas. Personal information will be destroyed after the study is complete.

Study records can be reviewed by federal agencies, private sponsors, and the IRB. People designated by the University of Maryland will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law. Organizations that may inspect and copy your information include **University of Maryland**

IRB, VA Office of Research and Development, VA Office of Research Oversight, VA Office of Inspector General, Office of Human Research Protections, VAMHCS Office of Research Compliance, and the Veterans Health Administration (VHA) and its Offices.

Your research records will be stored at the VA Maryland Health Care System (VAMHCS). Your research records and/or identifiers will be retained in accordance with the VA records control schedule. The "records control schedule" is a set of rules set by the federal government that states when federal agencies are allowed to dispose of records. The VA and VHA must follow these rules.

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information at the VAMHCS will work to keep your personal information confidential. Your personal information will not be given out unless required by law or authorized by you in the VAMHCS "HIPAA Authorization to Obtain, Use and Disclose Protected Health Information for Research". However, if your information is disclosed to other entities, the VAMHCS no longer has control of that information. Please see the HIPAA Authorization for this study for further details.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If you are a patient in the VAMHCS, the results of your medical tests for this study may be included in your medical record. Your medical and research records will be kept strictly confidential to the fullest extent permitted by law.

HEALTH INFORMATION PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, allergies, lab results, any conditions that could affect your balance, research tests, and exercise training records.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the University of Maryland Institutional Review Board (IRB), the Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the VAMHCS Office of Research Compliance (ORC), the Government Accountability (GAO), the Office of Human Research Protections (OHRP), and the VA Office of the Inspector General (OIG).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility, or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, the research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment, or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled.

There are no adverse consequences (physical, social, economic, legal, or psychological) to your decision to withdraw from the research. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. Your participation will not affect the way you now pay for medical care at the VAMHCS.

If you decide to stop taking part, have questions, concerns, or complaints, or if you need to report a medical injury related to the research or wish to confirm that this study is in fact IRB approved and is being conducted at the VAMHCS please call or text the study team at (410) 605-7000 Ext. 53242, 53241, or 53279 (call only) or (443) 421-2358 (call or text).

If you withdraw from this study, data that has already been collected may not be removed from the study database. You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.

If you are an employee or student, your employment status or academic standing at UMB will not be affected by your participation or non-participation in this study.

CAN I BE REMOVED FROM THE RESEARCH?
The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions of the research staff, or the Principal Investigator decides that the research study is no longer in your best interest. The sponsor can also end the research study early. The Principal Investigator will tell you about this and you will have the chance to ask questions if this happens.

The VA Maryland Health Care System (VAMHCS) has designated the University of Maryland Baltimore (UMB) Institutional Review Board (IRB) to review this research study.

If you wish to confirm that this study is in fact IRB approved and is being conducted at the VAMHCS, or if you have any questions, concerns, complaints, you may contact:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

You may also contact the VAMHCS Research Protections Officer (RPO)**.**

VAMHCS Research Protections Officer
Baltimore VA Medical Center
10 North Greene Street, Mail Stop 151
Baltimore, MD 21201
410-605-7000, extension 56582 or 56568

Participant Name: _____ Date: _____

Title of Study: **An Engineering-Based Balance Assessment and Training Protocol (BATP)**

Principal Investigator: **Joseph (Jay) Barton, PhD** Facility: **VA Maryland Health Care System**

The VAMHCS Research Protections Officer may contact you in the future to ask you about your experiences with this research study.

Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date: _____

Title of Study: **An Engineering-Based Balance Assessment and Training Protocol (BATP)**

Principal Investigator: **Joseph (Jay) Barton, PhD** Facility: **VA Maryland Health Care System**

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Your signature indicates that the research team member obtaining consent has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

Furthermore, by signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name (Print)	_____ Participant's Signature	_____ Date

_____ Person Obtaining Consent (Print)	_____ Consenter's Signature	_____ Date