Mass General Brigham

Institutional Review Board
Intervention/Interaction Detailed Protocol

Principal Investigator: Paolo Bonato, PhD

Project Title: A Mobile Tai Chi Platform for Fall Prevention and Cognition in Older Adults

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1. Background and Significance

Non-pharmacological early-intervention strategies to slow the growing epidemic of age-related cognitive decline and dementia, and their well-established impact on functional outcomes, must include the targeting of executive function (EF). EF encompasses several essential higher cognitive skills, including attentional control, planning, response inhibition and working memory.[1] In addition to portending Alzheimer's disease,[2–5] executive dysfunction in older adults is associated with impaired gait and balance and higher fall risk,[6–11] which significantly decrease functional independence and overall quality of life (QOL).[12]

Exercise is considered a promising intervention for preservation and restoration of cognitive function in older adults, including EF,[13–16] with literature reviews suggesting that multimodal training that integrates physical and cognitive training may have advantages over unimodal interventions.[17–19] Tai Chi (TC) is an increasingly popular multimodal mind-body exercise that incorporates physical, cognitive, social, and meditative components within the same activity.[20,21] Recent meta-analyses show that TC is a promising intervention for EF and global cognitive function in older adults. In several studies, TC was found to be superior to conventional exercise.[22–24]

The CDC and many other agencies endorse TC. Yet surprisingly, a comprehensive 2014 national survey found that only 1.2% of the entire adult population reported using TC for health, suggesting potential limitations in access to training programs.[25] Limited access to community training programs is also indicated by the fact that a significant percentage of survey respondents reported learning TC from online or video courses.

During phase I of the SBIR NIH grant, we developed algorithms based on information gathered from wearable sensors to estimate adherence, proficiency, and safety metrics. During the non-clinical stages of phase II, we developed a complete beta-version of the Tele-TC platform. The Tele-TC system consists of a set of 5 wearable sensors and an app installed on a commercially available tablet.

As a preliminary step toward designing a future study to assess the clinical benefits of the Tele-TC platform as a training system for elderly with mild cognitive impairments, we herein propose to assess:

- If the system enables monitoring longitudinally of adherence, proficiency, and safety.
- If the system is acceptable and user-friendly for its intended use in the home setting.
- As an exploratory aim: if a 12-week training program using the Tele-TC platform leads to improvements in cognitive function, balance, physical activity, self-efficacy, health-related quality of life, and gait.

If this preliminary study leads to positive results, we will embark on a follow-up study to assess the potential clinical benefits of using the technology as part of a clinical intervention on cognition, balance, physical activity, gait, self-efficacy, and health-related quality of life.

2. Specific Aims and Objectives

The overall goal of the study is to test the delivery of a novel Tele-Tai Chi (TC) intervention in a single-arm feasibility study for community-dwelling TC-naïve older adults with mild cognitive impairment (N=20 total). We will assess feasibility and acceptability measures of the Tele-TC intervention and its specific components through both qualitative and quantitative feedback, as well as the systematic tracking of adherence data to inform future trials and potential clinical use of the Tele-TC system. We will also explore changes in clinically relevant outcome measures including cognitive function, physical activity, self-efficacy, quality of life, balance, gait, and evaluate changes in TC proficiency.

Primary aims

- Aim 1: *To evaluate the feasibility, acceptability, and safety of a novel home-based Tele-TC intervention by tracking recruitment, retention, adherence, and adverse events.*
    - Hypothesis 1: We will be able to recruit 20 older adults with mild cognitive impairment and limit withdrawals to 20% or less.
    - Hypothesis 2: Participants will complete >60% of recommended Tele-TC sessions.
    - Hypothesis 3: Protocols for assessing safety can be developed and reliably administered, and preliminary evidence will support Tele-TC can be delivered safely.

Figure 1: Study system.

Exploratory aims

- Aim 2: *To evaluate changes in the level of proficiency of TC during a 12-week simplified TC program using the Tele-TC platform at home.*
    - Hypothesis 1: We will be able to collect reliable data on TC proficiency during Tele-TC use by study participants.
    - Hypothesis 2: Proficiency scores will improve over 12 weeks of training using the Tele-TC program supporting protocol learnability.
- Aim 3: *To gather feedback from end-users on ease of use of the Tele-TC platform*. We plan to collect feedback from elderly subjects to assess if the system is user-friendly enough to envision its use in a clinical setting.
    - Hypothesis 1: We will be able to collect reliable data on ease of use of the platform using qualitative and quantitative measures.
- Aim 4*: To explore changes in clinically relevant outcome measures including cognitive function, physical activity, self-efficacy, quality of life, balance, and gait.*
    - Hypothesis 1: We will be able to collect reliable outcomes data at each testing visit.
    - Hypothesis 2: We will see clinically relevant changes in outcomes measures at 12 weeks.

3. General Description of Study Design

As a preliminary test of our platform's suitability as a home-based TC program for people with mild cognitive impairments, we will recruit a convenience sample of 20 community-dwelling TC-naïve older adults with mild cognitive impairments into a single-arm longitudinal study of home-based TC learning, combined with remote and in-person data collections. In-person data collection will take place at the Spaulding Rehabilitation Hospital Motion Analysis Laboratory.

4. Subject Selection

Inclusion criteria:

Eligibility criteria are purposefully broad to maximize generalizability of the study results. To be eligible to participate in the study, individuals will have to meet the following criteria:

- Men and women between 60 and 85 years old
- TC naïve (never practiced TC)
- With mild cognitive impairments (Montreal Cognitive Assessment (MoCA)-Blind score between 17 and 13).
- Self-reported ability to walk continuously for 15 minutes without an assistive device
- Working email address
- Prior experience with and current access to a computer, smart phone or tablet device

Exclusion criteria:

Individuals will not be eligible to participate in the study if they exhibit any of the following:

- Chronic neuromuscular conditions (e.g. Parkinson's disease, multiple sclerosis, stroke)
- Acute medical conditions requiring hospitalization within the past 6 months or that could interfere with safely participating in the study
- Active cancer
- Significant musculoskeletal conditions requiring chronic use of pain medication
- Significant cognitive impairment (Diagnosed with dementia (self-reported), or Montreal Cognitive Assessment (MoCA)-Blind score < 13)

All subjects will be recruited by IRB approved study staff for this protocol. Recruitment strategies will include the use of the following sources:

- Physicians and therapists may refer interested patients to the study (we will provide physicians and therapists with study flyers and brochures to inform clinicians of the study details).
- Flyers posted in outpatient clinics, therapy gyms, and public spaces both inside and outside the hospital campus.
- PowerPoint presentation to inform clinicians and prospective participants about the study.
- Contacts at local senior and community centers.
- Recruitment letters sent to patients within the Partners network who have previously expressed interest for participating in research studies.
- Via contacts with patients who have consented to be directly contacted in the Partners Research Patient Data Registry (RPDR) or RSVP for Health.
- Via contact to the patients listed for direct contact in the Partners Research Patient Data Registry (RPDR) and Patient Gateway (via research invitation letters), as appropriate. A manual medical record review will be performed on all potential participants identified in this manner to ensure they are appropriate candidates for participation.
- Via targeted medical records review (i.e. current inpatients/outpatients within relevant departments at MGB institutions) using EPIC. Potential participants identified in this manner will be contacted through Patient Gateway (via research invitation letters) or mailed letters as appropriate.
- Via the Partners Clinical Trials (Rally) website.
- Via newsletters or community boards such as the Osher Center for Integrative Medicine newsletter.

Recruitment will also occur through the Spaulding Research Registry, which is a database of persons who have had a stroke, traumatic brain injury, or spinal cord injury and wish to be considered for participation in research studies at Spaulding Rehabilitation Hospital - Boston and other affiliated Harvard institutions. Patient information kept in the registry includes name, contact information, diagnosis with date of onset, laterality and language involvement for stroke, level of injury for SCI, severity for TBI, date of birth and gender. In addition, a record of referrals to specific studies, with dates and enrollment status, will be maintained for each registry member. The information is patient reported and is maintained in an encrypted, Mass General Brigham approved database. When investigators with IRB approved protocols request assistance

in identifying potential subjects, the Registry will create a list of those in the database with the desired characteristics. The Investigator will provide a letter describing the study which the Registry will send to those on the list. Patients receiving these letters contact the Investigator directly to pursue potential participation in the study.

Subjects who are interested and willing to participate in the study will undergo an initial screening over the phone or in-person to determine their eligibility. Subjects who underwent the phone screening and qualify will be sent study information and will be scheduled to visit the lab where they will undergo a final screening in-person to assess whether they meet all the inclusion and exclusion criteria. Testing will only be performed after obtaining signed consent from the subject.

The study entails no cost to the subject. We will cover parking costs for all participants who park at the SRH garage while taking part in the study. Participants will be compensated for their time at study completion.

5. Subject Enrollment

The study procedures will be carried out remotely using a Zoom Enterprise Partners account or in person. Prior to the first visit, we will perform a phone screening to determine eligibility of prospective study volunteers. Individuals will be informed that identifiable information may be recorded during the phone screening. If a subject is deemed eligible, identifiable information (e.g. name, contact info) will be collected, and an informed consent form will be emailed to subjects for review. Baseline testing at a future date will be scheduled.

Eligible subjects will undergo the informed consent process in person, by phone or on Zoom Enterprise with a trained research assistant at the beginning of the baseline testing visit. Once consented, subjects will undergo baseline assessments (visit #1) in person using REDcap Survey. After baseline testing, subjects will participate in the Tele-TC intervention, with recommended training sessions at least three times a week, along with two or more supplementary one-on-one live sessions (lasting upwards to 45 minutes) with TC instructors. TC proficiency using wearable sensors will be assessed at visit #1 baseline, at two follow-up assessments (visit #2 and visit #3) at approximately 4 and 8 weeks, and at a final assessment (visit #4) at 12 weeks. A semi-structured qualitative interview will also be performed at visit #1 and #4.

6. STUDY PROCEDURES

Below, we provide a detailed description of the study procedures.

1. *Screening and Informed Consent (Visit #1A)*

Prior to beginning the consent process, study staff will ensure subjects' eligibility using a brief questionnaire. This, in addition to the phone screening done as part of the recruitment process prior to the first visit, will ensure the eligibility of prospective study volunteers. The phone

screening is not only undertaken to allow researchers to confirm the subjects' eligibility, but it is also an opportunity for the volunteer to ask any additional questions they might have regarding the study. The phone screen includes administration of the Montreal Cognitive Assessment (MoCA)-Blind, an adapted version of the original MoCA, a validated, rapid screening instrument for mild cognitive impairment. Informed consent will be obtained by trained study staff in

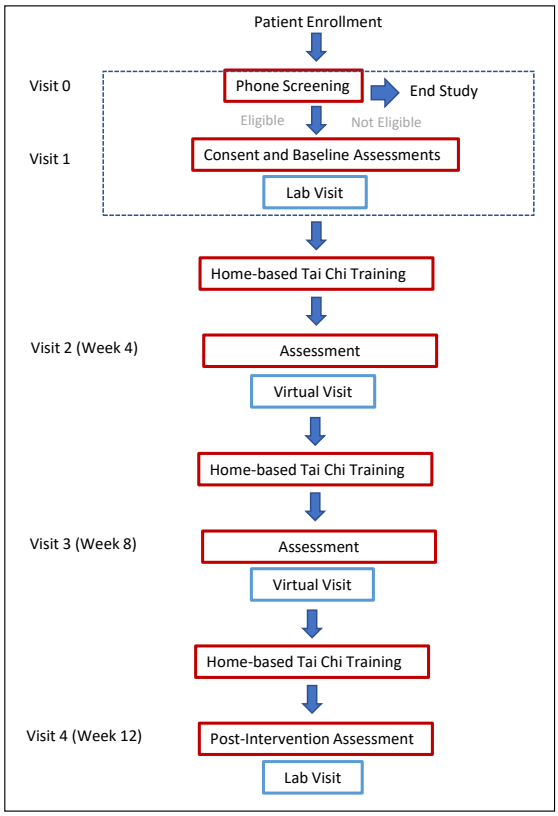

Figure 2: Flow Chart of the study.

person. Study staff will explain all the study procedures, equipment, and the risks associated with them as outlined in the informed consent form (ICF). The devices will be provided to the subjects after consent.

Subjects will be provided among others with two mobile devices and requisite chargers, a tablet travel stand, tripod, two GeneActiv watches, 5 wearable sensors, each of them with elastic bands and with chargers and wires. Of the two mobile devices, one will be used to interact with the developed TC app and the other will be used an extra mobile device and stand for virtual visits and video recording.

2. *Assessments (Visits #1B, #2, #3 and #4)*

At *Visit #1B*, subjects will be instructed in how to use the tablet-based Tele-TC program. The mobile devices and the sensors will be provided to each participant and will be preprogramed will all required software. It is worth emphasizing that, as part of the consent process, all subjects will be asked permission to be videorecorded during the assessments via Zoom Enterprise.

Visits will be divided into two components: 1) clinical assessments and 2) instrumented monitoring of TC performance.

The following clinical assessments will be performed during *Visits #1B and #4*.

The following questionnaires will be provided to the subjects through REDcap Survey with an email link. It will take around 45 minutes to complete all of the questionnaires.

- *Activities Specific Balance Confidence (ABC):* 16-item self-report measure in which patients rate their balance confidence for performing activities.
- *PROMIS® (Patient-Reported Outcomes Measurement Information System) 29 (PROMIS-29)* instrument: 29-item questionnaire assessing each of the following domains: anxiety, depression, fatigue, physical function, pain interference, pain intensity, sleep disturbance, and ability to participate in social roles and activities. The instrument contains four items from each primary domain plus a single pain intensity rating.
- *Physical Activity Scale for the Elderly (PASE):* self-reported level of physical activity in individuals aged 65 years or older during the previous 7 days.
- *Exercise Self-efficacy Questionnaire (SEE):* A 9-item questionnaire that focuses on the self-efficacy expectations for exercise for older adults; specifically, the ability to continue to exercise despite barriers.

Clinical assessments which take around 15 minutes will include tests such as:

- *Trail Making Test A/B:* Executive function will be assessed using the Trail Making Test. Participants will be timed while sequentially connecting a series of numbered circles (part A), as well as connecting an alternating series of numbers and letters (part B). The adjusted trail making score (i.e., part B minus A, sec) is sensitive to changes in executive function and frontal lobe pathology in older adults. The trail making Test will be camera-recorded.
- *Controlled Oral Word Association Test (COWAT):* examines working memory span. COWAT requires the participant to produce as many words as possible that begin with a given letter of the alphabet (F,A,S). There is 1 minute allowed for each of the three letters. The score is the sum of all acceptable words produced in the three trials. COWAT has good reliability and validity. The test will be audio-recorded and transcribed to ensure accurate collection of subjects' verbal responses.
- *Digit Span Test:* widely used measure of short-term memory, i.e. the number of digits a person can absorb and recall in correct serial order. Two trials of eight number sequences

are read aloud. The number sequences start out easy, with just two numbers, and get progressively more difficult, the last being nine digits. Scores are based on the number of sequences correctly recalled (i.e., until the participant consecutively fails two trials of the same digit span length). BDS has good reliability and validity.

- *Grip Strength:* we will measure the grip strength of both upper limbs using a hand grip dynamometer. We will repeat the measure three times.
- *Instrumented and camera-recorded monitoring of balance in each leg separately:* Subjects will be asked to stand on one leg for 30 seconds.
- *Instrumented and camera-recorded Timed-Up-and-Go:* Subjects will be asked to stand up from a chair, walk at their normal speed around a cone, turn around, and come back to sit in the chair.
- *Instrumented and camera-recorded Timed-Up-and-Go dual task:* Subjects will be asked to complete the previous task while counting backwards by three.
- *Instrumented and camera-recorded Sit-to-Stand:* Subjects will be asked to stand up from a chair while keeping their arms crossed across their chest during 30 seconds.
- *Instrumented and camera-recorded monitoring of balance in both legs* with feet shoulder-width apart and as close as possible without touching.
- *Instrumented and camera-recorded monitoring of gait:* Subjects will be asked to walk back and forth for 2 minutes.
- *Instrumented and camera-recorded monitoring* the *miniBEST:* It is a shortened version of the Balance Evaluation System Test (BESTest). It is a 14-item test scored on a 3-level ordinal scale. It aims to target and identify different balance control systems.

Instrumented and camera-recorded monitoring of TC performance will be performed during Visits #1B, #2, #3 and #4:

- Participants will be instrumented with 5 sensors (one on each limb and one on the trunk) and they will be following the instructions from the Tele-TC platform.

Study staff will use Zoom to communicate with subjects during the visits done remotely. The performance of TC exercises will also be videorecorded and scored using the proficiency metric described in our preliminary studies section to provide a gold standard. We will try to use the sensors during the remote visits, but if it is not possible, we will document the reasons and continue the TC exercises only with video.

Subjects will be asked to don one Smart GeneActiv watch by ActivInsights* on their wrist to monitor activity during approximately a week after visits ***#1B*** and a week before visit ***#4.***

We will ask the participants to send the GeneActiv back to the lab after wearing it. We will be sending another GeneActiv about two weeks before visit #4.

3. TC Training Sessions the Tele-TC Platform (12 weeks)

Study volunteers will participate in a 12-week simplified TC program that we have used in multiple prior clinical studies. In this pilot study, the intervention will be delivered via our platform-based application. All participants will be provided with a tablet with the Tele-TC software installed. The structured intervention, designed for older adults, emphasizes essential TC movements that are easily comprehensible and can be performed repetitively in a flowing manner. The protocol includes up to six core TC movements based on the traditional Cheng Man-Ch'ing's Yang-style short form. Additionally, a complementary set of traditional TC warm-up exercises that focus on loosening the physical body, incorporating mindfulness and imagery into movement, promoting overall relaxation, and coordinating breathing awareness are included. Chairs are used in the protocol for a subset of seated warm-up exercises, as well as for stability and rest as needed. Participants will be asked to practice the protocol (45-60 min) at home for at least 3 days a week for 12 weeks. In addition to data on practice frequency, duration, protocol adherence and training proficiency being automatically collected through our platform, a weekly REDcap survey will be used to monitor adverse events. The TC program will also include 2 or more live instructional sessions via Zoom with a TC instructor.

4. *Remote Monitoring of Falls and Other Adverse Events*

We will monitor falls during the subject's participation in the intervention study. Falls will be defined as any event in which the participant unintentionally comes to rest on the ground or other lower level, not as a result of a major intrinsic event or an overwhelmingly external hazard. Falls will be systematically monitored in two ways. As part of our safety and adverse events (AE) monitoring, participants will be asked to complete a weekly REDcap adverse events survey about their TC practice and activities of daily living. Study staff will follow-up by phone with participants as necessary. During study visits #1b-#4, study personnel will inquire about and record characteristics and details of falls and other adverse events.

5. *Feedback from the Subjects*

During the last visit (visit #4), we will conduct a semi-structured qualitative interview to gather feedback from the subjects regarding the feasibility and acceptability of the study overall, and more specifically the usability of the Tele-TC platform. We will ask them to provide us with feedback regarding general characteristics of the platform, possible improvements of the system, and whether they would consider using the system on a daily basis at home. The qualitative interview will be audio recorded. In addition, at the end of the study, we will use an adapted version of the System Usability Scale (SUS).

6. *Return of devices*

The subjects will be asked to return the devices (mobile devices, sensors, tablet stands) during visit#4. The final payment for the study ($70) will be contingent on the return of the study equipment.

7. *Data variables analysis to be collected*

The primary outcomes of the study are the retention and the protocol adherence during the study, and the System Usability Scale collected post-intervention.
The exploratory outcomes will include the following:

- The ease of use of the Tele-Tai Chi platform measure with the qualitative interview collected post intervention.
- The changes in outcomes collected at baseline and post-intervention: the Activities-specific Balance Confidence (ABC) scores, PROMIS 29 scores, the Physical Activity Scale for the Elderly (PASE), the Trail Making Test A/B scores, Self-Efficacy Exercise (SEE) scores, the grip strength, the Controlled Oral Word Association Test (COWAT), the Digit Span Test, the Timed-Up-and-Go, the Timed-Up-and-Go dual task single leg stance, the Sit-to-Stand performance, the balance on both legs with feet shoulder-width apart, the balance on both legs with feet close to each other, the normalized-to-height stride length and stride time variability, the activity level, and the Mini-Balance Evaluation Systems Test (MiniBEST) collected only in individuals who are willing to be tested in the MAL.
- The changes in The Tai Chi proficiency scores collected at baseline, 4 weeks, 8 weeks, and post-intervention.

8. *Remuneration*

Subjects will be compensated based on the procedures undertaken. Subjects will receive up to $240. The compensation amount will be as follows:
• Virtual visits: $50 for each follow-up testing session (4-week, 8-week) for a total of $100
• In-person visits: $70 for baseline and post-intervention testing session for a total of $140
If during the study the study staff determines that the participant cannot safely complete the session, he/she will be asked to stop – but he/she will still receive $35 for their time and effort.

Additionally, associated travel fees accrued by subjects to participate in the study (e.g. parking fees at SRH) will be covered by the Motion Analysis Laboratory.

7. Risks and Discomforts

TC is likely to be safe, as there have been no reports of serious adverse impacts in the TC literature. We experienced no serious adverse events in our pilot studies with COPD, heart failure, vestibulopathy, and osteopenic populations. However, there may be some potential expected risks to participants including the following:

1. TC and other motor tasks included in the clinical evaluations of balance and gait may cause some muscle soreness in highly deconditioned individuals. This soreness is likely to only last a short time. In addition, shortness of breath, dizziness, or falls are possible. However, these risks are unlikely and will be discussed in both the protocol and consent form.

2. Possible discomforts associated with using the sensors are the same as those experienced when wearing other wearable devices such as bracelets, watches and heart monitor straps. Prolonged use of the sensors may cause sweating and skin irritation.

There is a possibility that subjects could fall or trip during the experimental procedures, or that they may experience an allergic reaction or minor skin irritation to the band used to attach the sensors to the body. There is also a possibility that subjects may become fatigued or experience muscle soreness.

The risk of falling during the TC exercises and balance tests will be minimized by excluding subjects with balance impairments and risk of falls based on medical history, self-reported previous falls, and some clinical tests to assess potential balance impairments in study participants, whose outcome will be used by a rehabilitation specialist to determine if the subject can safely perform the TC exercises. If a subject falls during remote visits or TC practice, they will be referred to their physician or to urgent care as needed.

Fatigue and muscle soreness will be minimized by allowing subjects to rest at any point during the experimental procedures.

Subjects will be encouraged to contact MAL staff with any questions or concerns they may have at any time during the study or after its completion.

Overall, the potential risks to participants are modest and are likely to be viewed as reasonable in relation to the anticipated benefits to subjects and others.

When - according to a rehabilitation specialist during in-person testing, or research staff during virtual testing - subjects are unable to safely perform the TC exercises that are part of the experimental procedures, the experiment will end. Subjects will be told why the experiment must stop and will be advised to seek medical care if appropriate.

Subjects will be told that the study procedures may be associated with discomfort due to wearing the sensors and by fatigue/muscle soreness. In case subjects experience discomfort or excessive fatigue, they will be free to remove the sensors and end their participation in the study.

Unintentional loss/disclosure of Protected Health Information may occur and is considered a minimal risk due to the security measures enforced at SRH. Confidential information will be kept in a locked filing cabinet, on REDcap, and on password-protected computers in the MAL.

8. Benefits

Study participants are not expected to directly benefit from their participation, but it is possible that subjects will experience some positive impact on cognition, physical and mental health as a result of their performing TC exercises, as has been shown in prior TC studies. Information gained during the study is expected to contribute to the development of systems to facilitate the deployment of TC-based interventions.

9. Statistical Analysis

Descriptive statistics will be derived for all the above-described clinical assessment outcomes and correlations will be sought with the sensor-based estimates of the metrics of adherence, proficiency and safety derived using the previously developed algorithms. Exploratory statistical analyses will be performed to power future clinical studies aimed to test the relationship between the proposed metrics of adherence and proficiency and the clinical outcomes of the intervention. Whereas conclusive statistical analyses to explore such correlations are beyond the scope of the proposed project, the data collected in this pilot study are expected to provide justification for a future trial aimed to assess the efficacy of the Tele-TC Platform as a training system for older adults with mild cognitive impairments.

10. Monitoring and Quality Assurance

Because this study's procedures pose minimal risk to the subjects, bimonthly data and procedural reviews by the PI in consultation with study staff will be sufficient to identify and ameliorate any potential safety issues. Any safety concerns about the equipment or testing protocol will be brought to the immediate attention of Dr. Bonato. Study staff will conduct bimonthly audits to ensure compliance with regulatory requirements for study documentation.

Approval of protocol, informed consent procedures, and recruitment will be obtained from the IRB during annual reviews.

Adverse event reporting will be done according to Partners Human Research Policy. Remedial action to prevent reoccurrence of the event will be instituted prior to the resumption of study procedures.

Study staff will conduct quarterly audits to ensure compliance with regulatory standards for study documentation.

11. Privacy and Confidentiality

- ☒ Study procedures will be conducted in a private setting
- ☒ Only data and/or specimens necessary for the conduct of the study will be collected
- ☒ Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas)
- ☐ Specimens collected will be maintained in a secure location with appropriate protections (e.g. locked storage spaces, laboratory areas)
- ☒ Data and specimens will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol
- ☒ Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g. encrypted files, password protection, using chain-of-custody procedures, etc.)
- ☒ All electronic communication with participants will comply with Mass General Brigham secure communication policies
- ☒ Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary members of the research team required to conduct the research
- ☒ All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens
- ☒ The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research
- ☐ Additional privacy and/or confidentiality protections

The MAL will assign each new subject an alphanumeric identifier, which will henceforth be the sole means of identification connected to their data. All data will be collected under this identifier and will be kept isolated from any personal health information. All data will be stored on REDcap. Information shared with individuals outside of Partners will be labeled using an alphanumeric identifier and will be devoid of personal health information.

Video recordings and photos will be stored securely in the MAL; only investigators listed on the study will have access to them. Patients will be given the choice to have video/photo material used for academic articles and presentations.

This project is supported by the National Institutes of Health via an STTR award to BioSensics (primary site) and the involvement of researchers at SRH and BWH. De-identified data will be shared with BioSensics.

12. References

1. Miyake A, Friedman NP, Emerson MJ, Witzki AH, Howerter A, Wager TD. The unity and diversity of executive functions and their contributions to complex "Frontal Lobe" tasks: a latent variable analysis. Cogn Psychol. 2000;41(1):49-100. doi:10.1006/cogp.1999.0734
2. Hamel R, Köhler S, Sistermans N, et al. The trajectory of cognitive decline in the pre-dementia phase in memory clinic visitors: findings from the 4C-MCI study. Psychol Med. 2015;45(7):1509-1519. doi:10.1017/S0033291714002645
3. Kirova A-M, Bays RB, Lagalwar S. Working memory and executive function decline across normal aging, mild cognitive impairment, and Alzheimer's disease. Biomed Res Int. 2015;2015:748212. doi:10.1155/2015/748212
4. Seo EH, Kim H, Lee KH, Choo IH. Altered Executive Function in Pre-Mild Cognitive Impairment. J Alzheimers Dis. 2016;54(3):933-940. doi:10.3233/JAD-160052
5. Rapp MA, Reischies FM. Attention and executive control predict Alzheimer disease in late life: results from the Berlin Aging Study (BASE). Am J Geriatr Psychiatry. 2005;13(2):134-141. doi:10.1176/appi.ajgp.13.2.134
6. Montero-Odasso MM, Sarquis-Adamson Y, Speechley M, et al. Association of Dual-Task Gait With Incident Dementia in Mild Cognitive Impairment: Results From the Gait and Brain Study. JAMA Neurol. 2017;74(7):857-865. doi:10.1001/jamaneurol.2017.0643
7. Montero-Odasso M, Verghese J, Beauchet O, Hausdorff JM. Gait and cognition: a complementary approach to understanding brain function and the risk of falling. J Am Geriatr Soc. 2012;60(11):2127- 2136. doi:10.1111/j.1532-5415.2012.04209.x
8. Mirelman A, Herman T, Brozgol M, et al. Executive function and falls in older adults: new findings from a five-year prospective study link fall risk to cognition. PLoS One. 2012;7(6):e40297. doi:10.1371/journal.pone.0040297
9. Yogev-Seligmann G, Hausdorff JM, Giladi N. The role of executive function and attention in gait. Mov Disord. 2008;23(3):329-342; quiz 472. doi:10.1002/mds.21720
10. Asimakopulos J, Boychuck Z, Sondergaard D, Poulin V, Ménard I, Korner-Bitensky N. Assessing executive function in relation to fitness to drive: a review of tools and their ability to predict safe driving. Aust Occup Ther J. 2012;59(6):402-427. doi:10.1111/j.1440-1630.2011.00963.x
11. Miller SM, Taylor-Piliae RE, Insel KC. The association of physical activity, cognitive processes and automobile driving ability in older adults: A review of the literature. Geriatr Nurs. 37(4):313-320. doi:10.1016/j.gerinurse.2016.05.004
12. Bender AC, Austin AM, Grodstein F, Bynum JPW. Executive function, episodic memory, and Medicare expenditures. Alzheimers Dement. 2017;13(7):792-800. doi:10.1016/j.jalz.2016.12.013
13. Northey JM, Cherbuin N, Pumpa KL, Smee DJ, Rattray B. Exercise interventions for cognitive function in adults older than 50: a systematic review with meta-analysis. Br J Sports Med. 2018;52(3):154-160. doi:10.1136/bjsports-2016-096587
14. Kramer AF, Hahn S, Cohen NJ, et al. Ageing, fitness and neurocognitive function. Nature. 1999;400(6743):418-419. doi:10.1038/22682
15. Kramer AF, Colcombe S. Fitness Effects on the Cognitive Function of Older Adults: A Meta-Analytic Study-Revisited. Perspect Psychol Sci. 2018;13(2):213-217. doi:10.1177/1745691617707316
16. Smiley-Oyen AL, Lowry KA, Francois SJ, Kohut ML, Ekkekakis P. Exercise, fitness, and neurocognitive function in older adults: the "selective improvement" and "cardiovascular fitness" hypotheses. Ann Behav Med. 2008;36(3):280-291. doi:10.1007/s12160-008-9064-5
17. Lauenroth A, Ioannidis AE, Teichmann B. Influence of combined physical and cognitive training on cognition: a systematic review. BMC Geriatr. 2016;16:141. doi:10.1186/s12877-016-0315-1

18. Law LLF, Barnett F, Yau MK, Gray MA. Effects of combined cognitive and exercise interventions on Contact PD/PI: Bonato, Paolo References Cited Page 92cognition in older adults with and without cognitive impairment: a systematic review. Ageing Res Rev. 2014;15:61-75. doi:10.1016/j.arr.2014.02.008
19. Diamond A. Effects of Physical Exercise on Executive Functions: Going beyond Simply Moving to Moving with Thought. Ann Sport Med Res. 2015;2(1):1011. http://www.ncbi.nlm.nih.gov/pubmed/26000340.
20. Wayne PM, Kaptchuk TJ. Challenges inherent to t'ai chi research: part I--t'ai chi as a complex multicomponent intervention. J Altern Complement Med. 2008;14(1):95-102. doi:10.1089/acm.2007.7170a
21. Wayne PM, Kaptchuk TJ. Challenges inherent to t'ai chi research: part II-defining the intervention and optimal study design. J Altern Complement Med. 2008;14(2):191-197. doi:10.1089/acm.2007.7170b
22. Miller SM, Taylor-Piliae RE. Effects of Tai Chi on cognitive function in community-dwelling older adults: a review. Geriatr Nurs. 35(1):9-19. doi:10.1016/j.gerinurse.2013.10.013
23. Zheng G, Liu F, Li S, Huang M, Tao J, Chen L. Tai Chi and the Protection of Cognitive Ability: A Systematic Review of Prospective Studies in Healthy Adults. Am J Prev Med. 2015;49(1):89-97. doi:10.1016/j.amepre.2015.01.002
24. Wayne PM, Walsh JN, Taylor-Piliae RE, et al. Effect of tai chi on cognitive performance in older adults: systematic review and meta-analysis. J Am Geriatr Soc. 2014;62(1):25-39. doi:10.1111/jgs.12611
25. Wu G, Keyes L, Callas P, Ren X, Bookchin B. Comparison of telecommunication, community, and home-based Tai Chi exercise programs on compliance and effectiveness in elders at risk for falls. Arch Phys Med Rehabil. 2010;91(6):849-856. doi:10.1016/j.apmr.2010.01.024