**NCT 04612842**

# Engaging Older Adults in Fall Prevention Using Motivational Interviewing (MI)

**Study Protocol**

**Oregon Health & Science University IRB #8993**

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One-third of older adults fall every year in the United States. Many accidental falls can be prevented through fall risk assessment and evidence-based interventions. The interventions may include advice for exercise, medication adjustment, blood pressure management, environmental modifications, and improving vision. However, older adults do not consistently follow these recommendations for a number of reasons, including their perceptions about falls and fall prevention. Emerging evidence indicates that a recommendation alone is not sufficient to engage patients in fall prevention. Yet, studies that explore alternate ways to improve patients' engagement with fall prevention are rare. Thus, we propose Motivational Interviewing (MI), an intervention known to be effective in engaging individuals in developing healthier habits, to target older adults' barriers to fall prevention.

The goal of this mixed-methods, two-arm, randomized controlled trial of MI intervention for fall prevention is to evaluate the impact of Motivational Interviewing (MI) as a follow-up care to patients who received fall prevention recommendations at Oregon Health & Science University Internal Medicine and Geriatrics Clinic provided over 12-months. Older adult participants (older than 65) who are at increased risk for falling will be enrolled into the study. Patients will be randomly assigned to two groups: MI and the standard of care group. All participants will have a baseline and 6-months study visit that will include self-report and physiologic assessment. In addition, all participants will receive study measurement phone call at 3-, and 12-months. MI will be provided via video, phone, or in-person one week after the initial visit and then monthly for 6 months. All MI sessions will be recorded and encounter notes will be completed. Purposefully selected participants' MI sessions will be transcribed for qualitative analysis.

**Design**

We will use a mixed-methods randomized controlled trial to evaluate the longitudinal impact of the STEADI protocol. See Table 1. We will study STEADI patients, patients who have received STEADI RA and fall prevention recommendations at OHSU Internal Medicine and Geriatrics. We will have two-groups. The control group participants will only receive study measurements at baseline, 3-, 6-, and 12-months baseline assessment. The intervention group will receive all the same measurements as the control group, and in addition, receive MI-based communication about fall prevention at eight occasions during the 6-month period. MI is an evidence-based communication approach for various health behavior change, however, it has not been widely applied to fall prevention interventions. Our preliminary feasibility trial with inpatients has demonstrated effectiveness of MI on fall-related patient outcomes. This protocol will test the effectiveness of MI with outpatients.

Since COVID-19 pandemic occurred in March 2020, the OHSU internal medicine clinic has limited in-person patient care hours and patients are not being routinely screened for fall risks using the STEADI protocol, impacting the study implementation. As patient-care situations are unpredictable at this time, we have following modification plans to the study protocol. Major changes are listed below and described in relevant sections of this protocol.

1) Identification and screening of STEADI patients using healthcare records of the past year. This will be in addition to recruitment of patients who are seen at the clinic for STEADI FRA/clinic visit as originally included in this protocol.
2) Addition of at-home visits (video, phone, or in-person) in place of in-person study office visits.
3) Changes to ensure safety of study office visits once these visits are possible.
4) [ADDED 7/14/20] Modification to use the information sheet for participant consent.
5) [ADDED 7/22/20] Details about exclusion criteria.

We request modification to the protocol as we uncovered that more than half of potentially recruitable participants did not receive fall prevention recommendations, thus because ineligible for the study.

**Table 1. Study overview**

| | Baseline | 1 wk, 1 & 2 m | 3 m | 4 & 5 m | 6 m | 12 m |
|---|---|---|---|---|---|---|
| Study time points | T0 | T1, T2, T3 | T4 | T5, T6 | T7 | T8 |
| Study encounter type | Visit+ | Phone/video | Phone | Phone/video | Visit+ | Phone/video |
| **Intervention group only** | | | | | | |
| MI Intervention E | #1 | #2, 3, 4 | #5 | #6 & #7 | #8 | |
| **Intervention and control groups** | | | | | | |
| Self-report measures* | X | | X | | X | X |
| Physiologic measures** | X | | | | X | |
| Fall rates (mail-in) | X | X | X | X | X | X |

**Notes: Self-report measures*:** Fall Prevention Patient Engagement Scale, Fall Efficacy Scale International, Fall Behavioral Scale, Patient Activation Measure. **Physiologic measures**:** Timed Up and Go, 30-Seconds Sit-to-Stand, & 4-Stage Balance Test. **E:** Documented in study encounter notes (narrative descriptions of behavior change topic, behavioral goal, readiness to change, importance, confidence, commitment, barriers & facilitators for change, change from the last study encounter, satisfaction).
**wk**: week, **m:** month
+: Visits: includes 3 options: in-home (virtual and in-person) & study office in-person visits

## Study population

***Number of subjects.*** We estimated the sample size based on the key primary outcome measure, fear of falling as measured by FES-I, which has a reported effect size ranging from .03 to.42 depending on the setting and the type of intervention. The PI's MI intervention with inpatients found an effect size of .31 with high fall-risk inpatients. Using the power of 80% and alpha of 0.05, we need a minimum of 120 participants for an independent t-test calculation. To account for attrition, we aim to enroll 250 participants.

***Inclusion and exclusion criteria.*** The study inclusion criteria are: age ≥65, at moderate or high risk for falling using STEADI FRA, and without cognitive impairment. We will use any ICD-10 code to identify those who have been diagnosed with dementia. We will also use MOCA, SLUMS, or other cognitive assessment data in the electronic health records (EHR) to identify individuals with cognitive impairment. We will also use a telephone-based cognitive assessment tool such as the Telephone Interview for Cognitive Status (TICS: 11-item instrument). TICS cut off for cognitive impairment is 28 out of 41 possible points. We will also include individuals who are able to converse audibly and coherently in English Spanish, or other language that the study staff have expertise in, be able to receive and engage in study phone calls, and are ambulatory with or without assistive device use. The study exclusion criteria are: cognitively impaired patients, patients who have sensory difficulty with verbal communication (hard-of-hearing despite the use of hearing aids or speech is hard to understand despite a talking device, patients who are unable to stand without assistance by others, life-expectancy of less than 3-months, and patients participating in other studies that may impact fall-related behavior change. Cognitively impaired patients will be excluded from the study, as it will be difficult to engage in meaningful dialogue related to fall prevention via phone.

***Vulnerable populations.*** This study does not involve children, pregnant woman, neonates, decisionally impaired adults, or prisoners.

## Recruitment methods

Study staff will first identify patients who are age ≥65, received STEADI intervention, and identified to be at moderate to high risk for falling. Then, other study inclusion criteria discernable from EHR such as cognition will be reviewed to determine the eligibility for the study. Once an eligible participant has been identified, study staff will contact this individual via phone, email, EPIC, MyChart, mail, or video to seek their interest in the study. If the patient is interested in participating in the study, additional questions will be asked to

determine their eligibility. If they meet all of the inclusion criteria, a study visit at OHSU or their home will be scheduled. This visit will be scheduled within 3 months of the initial clinic visit. The study flier will be posted at the clinic to inform participants about a potential call from the study team.

[COVID-related changes]
Since the COVID-19 pandemic is unpredictable, the study will include retrospective screening approach in addition to currently proposed prospective approach. We propose to contact patients who received STEADI FRA/clinic visit in the past (April 1st 2019-March 31st, 2020). We will review EPIC to identify these patients. We will explore all primary clinic services and locations where patients are expected to receive STEADI FRA.

[Clarification about the study exclusion criteria]
Before the recruitment call is made, study staff with review EPIC for any documentation of cognitive assessment. If the patient has a diagnosis of dementia (any type), they their record will be reviewed for cognitive assessment scores and determination will be made about exclusion. If the results of cognitive assessment are documented within a year, and scores indicate normal cognition or mild cognitive impairment, no further assessment will be necessary. If there are no cognitive assessments conducted within the timeframe or results are variable, the study team will conduct a cognitive assessment during the recruitment interview using 6-item Callaham tool (https://pubmed.ncbi.nlm.nih.gov/12218768/). If the participants meets the cut off three or more errors, participant will not be able to participate in the study. During the recruitment call, the study staff will also ensure that the potential participant meets the following criteria: participant is able to converse audibly and coherently in English, and able to receive study phone calls, is willing to work with the study to set up video or in-person visits, and are ambulatory with or without assistive device use.

Thus, the study exclusion criteria are:
- Cognitively impaired patients as defined by Mini-Cog≤ 2 (https://mini-cog.com/mini-cog-instrument/scoring-the-mini-cog/), or SLUMS<19.5/<21.5 (no high school education/high school education), MMSE <26.5/<27.5; (no high school education/high school education) (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5395300/), MOCA <16 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6247398/), or 3 or more errors on 6-item Callaham tool
- Patients who have sensory difficulty with verbal communication (hard-of-hearing despite the use of hearing aids or speech is hard to understand despite a talking device)
- Patients who are unable to stand safely without assistance by others
- Life-expectancy of less than 3-months
- Patients participating in other studies that may impact fall-related behavior change

***The consent process.*** The study consent will be signed during the in-person encounter or via-mail. The consent form includes permission for the study to record the study encounters and access medical records, and for participants to take part in low-risk physiologic and self-reported measures (surveys), and modest compensation for their time.

[COVID-related changes]
We will consent potential participants using phone, video, mail, and email (depending on their preference) (and in-person if social distancing precautions are lifted) using the study information sheet and request waiver of documentation of the consent as an alternative proposed in https://www.ohsu.edu/research-integrity/irb-frequently-asked-questions-faqs. This change is made because we are changing the protocol to be remote to maintain social distancing precaution related to covid-19, and getting signed consent from older adults remotely will be challenging. Information sheet will only be used during modified operations. Once normal operations resume, written consent will be obtained for face to face encounters with participants.

This study is a minimal risk study as all physical measures in this study are the same ones they received as part of routine healthcare and pose no additional risk.

We will document in redcap that a consent discussion was held and participant's agreement to participate. We also request waiver of the signature for the HIPAA authorization with modification (expanding the provision for the study to document participants' contact information and basic demographics).

***Randomization.*** Participants who consent to the study will be randomly assigned to two groups based on their study ID to either the intervention group (n=125) or the control group (n=125) using the randomization sequence.

**Study procedures**

Study measurements. Several standardized study tools will be used at baseline, 3-months, 6-months, and 12-months after the benchmark STEADI clinic visit. The study domains and measurement tools are summarized in Table 2. The primary study outcome measures are: patient engagement with fall prevention recommendations (medication, exercise, blood pressure, vision, and environment), fear of falling, and fall prevention behaviors. The study will create, pilot test, and use the Fall Prevention Patient Engagement Scale created for the study to measure frequency and uptake of STEADI recommendations. Falls Self-Efficacy Scale-International (FES-I), a 16-item scale, is widely used to measure levels of concern related to preventing falls. Higher FES-I scores have been positively correlated with decreased activities, future falls, and injury. The 24-item version of Fall Behavioral Scale (FAB), will be used to capture patients' daily activities to prevent falling. FAB measures frequency of protective strategies to prevent falling and risky behaviors that facilitate a fall. Secondary study measures include physical function, patient activation, and fall rates. All participants will mail-in monthly fall calendar, the gold standard to capture fall rates. The chart reviews will be used to capture health status and other patient data.

[COVID-related change]

We will add a modified recruitment approach, to recruit patients who had the STEADI FRA/clinic visit up to a year ago. This clinic visit is when participants receive fall risk assessment and fall prevention recommendations. Since the duration between the time that they receive fall prevention recommendations and the initiation of the study could vary as much as a year, 1) we will add questions to assess what changes have taken place related to fall prevention since the clinic visit within Fall Prevention Patient Engagement Scale: pre-enrollment), 2) we will review STEADI recommendations at the baseline visit with all participants to refresh participants' memory on clinic recommendations, and 3) we will analyze the impact of the length of time between the STEADI clinic visit and study outcomes.

We propose to have multiple options available for baseline and 6-month study visits in addition to in-person study office visits as originally planned. This will allow for flexibility in participants' involvement with the study. We will have options for at-home virtual (phone or video) and in-person visits.

With the inclusion of virtual encounters, a visit may be divided up into multiple sessions due to unexpected internet or living situations. For example, baseline visit is expected to be conducted in 2 sessions for the control group, and 3 sessions for the intervention group. The first session will include a review of fall prevention recommendations made at the STEADI clinic visit, self-report questions (FESI, FAB, etc), instruction about the fall calendar, and processes for the physiologic measurement during the next session (equipment, support person, environment, physical condition, internet access). The second session will be for STEADI physiologic measures (30-second sit to stand, 4-stage balance test, time up and go, and orthostatic blood pressure if possible). The participants in the intervention group will have the third session for the MI intervention #1.

Once the clinic starts normal operations, we will contact patients who received STEADI FRA and recruit them into the study. The baseline visit will be conducted in 2 (control group) or 3 (intervention group) sessions as described above.

The 6-months physiologic assessment will be conducted at the same location as the baseline location.

[Responses to fall incidents during the study data collection period]
When participants report fall incidents through their fall calendar or during study visits, the study staff will follow-up on the incident. Unless participants have a planned study visit within a month, the study staff will make a brief caring call to inquire how they are doing after the fall. We will refer them to CDC resources on fall prevention and the study packet if they are interested in information, and encourage them to talk to their provider. If the study team assesses that the fall warrant healthcare or clinical intervention beyond the scope of the research, the study may contact the provider with participants' permission.

[Updates to enhance recruitment and retention]
We will send quarterly study newsletters via email and/or postal mail to all study participants to enhance their engagement with the research. We will work with IRB and OHSU Branding Department to use approved formats. Additionally, we will also send birthday cards to participants for retention. Content and final drafts of the study newsletters and birthday cards will be submitted to the IRB for approval before distribution.

[Update 1/19/23: Study evaluation interview with enrolled participants]
We will conduct interviews with maximum of 20 participants to understand study participants' experience with the study. This interview will be consistent with the current study protocol in which study staff interacts with participants via phone, recorded, transcribed, and analyzed.

Participants will be selected to represent control and intervention groups and based on data collected during the study. Participants' interest in this evaluative interview will be asked by phone or email. Participants will receive the information sheet about this study evaluation interview along with research questions prior to the interview. Each interview will be about 30-45 minutes. The interview guide, information sheet, and interview questions are submitted to IRB along with this modification request.

**Table 2. Study domains and measurement tools**

| Study Domains | Measurement tools |
|---|---|
| **Individual and unique patients** | |
| Cognition | Mini-Cog |
| Emotional barriers* | Encounter note (narrative; MI group only) |
| Values and goals* | Encounter note (narrative; MI group only) |
| Physical and cognitive limitations* | Encounter note (narrative: MI group only) |
| Physiologic measures (S) | 30-Second Chair to Stand Test, 4-Stage Balance Test, & Timed Up and Go Test |
| **Fall prevention recommendations** | Chart review |
| **Motivational Interviewing*** | Recorded MI sessions & encounter notes (narrative; MI group only) |
| **Patient engagement measures** | |
| Self-reported engagement with fall prevention recommendations (P) | Fall Prevention Patient Engagement Scale+ |
| Commitment to fall prevention recommendations* | Encounter notes (narrative; MI group only) |
| **Fall-related outcomes** | |
| Fear about falling (P) | Fall Self-Efficacy International |
| Fall prevention behaviors (P) | Fall Behavioral Scale |
| Patient activation (S) | Patient Activation Measure |
| Fall rates (S) | Fall incidences by calendar month |

**Notes: (P)** Primary outcome measure. **(S)** Secondary outcome measure. **(MI)** pertains only to the MI group. **⁺Fall Prevention Patient Engagement Scale** is an original tool created for the study and includes frequency of engagement with the recommendations. **Others:** Chart review will gather age, gender, diagnosis, and medications at baseline.

Safety regarding in-home STEADI physiologic assessment is described in the Data and Specimens section.

***Intervention group.*** The intervention group participants will receive Motivational Interviewing (MI) communication about fall prevention during the 12-month study period. Interventionists will facilitate MI sessions using the MI guide (baseline version outlined in Table 32) and a participant handout, "Menu of Options for Fall Prevention," which outlines potential topics for the discussion. MI sessions will be held at baseline, 1-week, then monthly for 6 months. MI sessions are mostly conducted via phone except the baseline and 6-months visit. The MI guide and the handout were created and tested by the study team through a feasibility study. Each MI session is targeted to be 15-minutes long. From our prior study we determined that this duration is most appropriate, short but possible to impact patient engagement with fall prevention. All of the study encounters will be audio recorded with participants' permission and study encounter notes will be completed.

[COVID-related changes]
MI sessions will be completed via phone or video depending on the availability for the participant. Although delivery methods differ slightly, the goal of this intervention will be the same.

**Table 3. Motivational Interviewing intervention guide (template for baseline study visit)**

| **Basic approach** | |
|---|---|
| Ask for permissions to discuss certain topics, use OARS (Open-ended questions, Affirming, Reflections, and Summarizing), and evoking as appropriate (make statements or ask questions to provoke alternative thinking about a situation) | |
| **MI intervention based on readiness to change** | |
| Establish rapport. Identify patient values and goals.<br><br>Observe patients' responses toward "Menu of Options for Fall Prevention" handout.*<br>Identify readiness to change & tailor the conversation based on the readiness. | Pre-contemplation: Focus on building trust (use OARS) and keeping the conversation going about fall prevention. Potentially focus on participant's strengths and goals in life. Ask permissions. Evoke as appropriate.<br><br>Contemplation & Ready: Focus on building trust (use OARS). Ask for permission. Evoke as appropriate. Identify one behavior that the participant is OK to talk more about (Behavior A). **Go to STEP #.**<br><br>Action & Maintenance: Focus on affirming, and adding more to the fall prevention activities. Anticipate future situations, or challenging situations (when sick). Identify one behavior that the participant is interested in talking more about (Behavior A). **Go to STEP #.**<br><br>**STEP #:** If behavior change topic has been identified…<br>Identify goals with this behavior<br>Identify readiness to change (importance and confidence) to change<br>Identify a specific plan to move toward the goal<br>Identify barriers and facilitators for change<br>Identify participant's commitment level to change |
| **Notes**: **"Menu of Options for Fall Prevention" handout** includes 20 conversation topics about mobility and health goals, fall risks, and fall prevention strategies. Follow-up MI interventions will assess changes related to Behavior A and discussion related to new behaviors (B, C, D... ) to change. | |

***Control group.*** Participants in this group will have their study measurements at baseline, 3-months, 6-months, and 12-months after the benchmark STEADI clinic visit. They will not receive study MI intervention calls after fall prevention recommendations are given at the clinic. If the participants have any questions about fall prevention during the data collection, study staff will relay this message to the clinic staff.

[COVID-related changes]
Study physiologic measurement at baseline and 6-months will be conducted in the same matter (i.e., at-home).

**Data and Specimens**

Source of materials. Research data used specifically for research purposes will be obtained directly from participants in self-report surveys and physical function tests, and from EHR chart review.

Protection against risk. As with any form of physical effort, there is a slight risk of injury. Physical function tests used in this study (timed up and go, 4-stage-balance, and sit-to stand tests) are considered the gold standard for physical function assessment for fall prevention. They are commonly performed in primary care settings and in research studies. However, in order to prepare for the unlikely but possible emergency, study staff will be trained to minimize participant burden and prevent participant harm.

- Falls: For mobility, balance, and strength tests (timed up and go test, 4-stage-balance test, and sit-to stand test), participants will wear a safety strap that can be grabbed by the testing technician if a participant becomes unstable and begins to fall. In all tests, a testing technician will stand next to the subject throughout all tests to provide additional support in case of a fall. The study staff will stop testing instantly if a subject experiences a serious imbalance. Therefore, it is highly unlikely that subjects will experience a fall capable of causing injury during testing.
- Fatigue and discomfort: For mobility tests, subjects will be standing and/or walking for a period of about 10 minutes. Participant fatigue and discomfort will be monitored verbally and rest breaks will be frequently provided.
- If a participant experiences significant discomfort or has a pre-existing condition that could be exacerbated by a particular test, s/he will be given the option to refuse to participate in that test(s). During testing visits, if a participant gets tired, s/he will be told he can stop answering research questions, or participating in function testing, and restart at a later time. If tiredness occurs during performance testing, participants may rest as often as needed. If a participant is anxious about answering the surveys questions, we will offer to ask the questions verbally and fill out the survey, if a participant is anxious about ability to complete physical function tests the participant will be given the option of discontinuing the test. If a participant is worried about privacy and confidentiality of data, the study staff will discuss the methods for maintaining confidentiality: individual data will be identified only by a study ID number and only one computer file will link ID numbers with identifiable data; all computer records will be protected by a password known only to authorized study personnel; paper documents, such as surveys or computer disks, will be kept in locked files, and results will presented as aggregated data only. To prevent the perception of coercion to participate, participants will be told they may decide to discontinue participation in the study at any time, that non-participation will not affect their usual care at their local clinic or at OHSU, and that data on non-participation will be kept confidential, using the methods described above. To minimize the perceived burden of study participation on patients we have limited each of the study session to 60. Participants are always provided the option to opt out of some or all study intervention and measures at any given time, though we will always provide the opportunity to reschedule when possible. The overall time commitment will be provided to participants so that they are fully informed of the time commitment with study participation.
- In addition, we have adequate study team members to ensure that human subjects are protected. Dr. Wilhelm, study physical therapist, will be available to advise on the study staff training for the physical function tests. Dr. Kiyoshi-Teo is a registered nurse with 11 years of direct-care experience, and Dr. Eckstrom is a currently practicing physician at OHSU and will be on-call to assist with emergency situations during study visits

[COVID-related changes]

The duration of each of the study encounter will be 60 minutes per session. Due to the unpredictable nature of virtual visits, a visit may be delivered over multiple sessions as described previously. For example, visit 1 is designed to be delivered over 3 sessions for the intervention group.

In addition, safety of in-home STEADI physiologic assessment will be ensured by having following mechanisms and can be conducted with study staff visiting their home or via video or phone.

- Participant meet the physical wellness criteria for safe testing (no fever, no dizziness felt).
- A support person will stand next to the participant throughout the tests to provide additional support in case of a fall. The support person will stop testing instantly if a participant experiences a serious imbalance.
- 30-second chair to stand test: need sturdy chair with a straight back without arm rests (seat 17" high), and a stopwatch. Enough space to sit and stand. Flat flooring without clutter. If using assistive device. Have in locked position and place it in front of the chair. Sufficient lighting. Wear glasses and hearing aides.
- 4-stage balance test: stand next to a sturdy chair.
- Timed up and go test: need 10 feet distance to walk to (marked) and chair.
- Orthostatic blood pressure: blood pressure measurement device (if do not have one, skip), bed or couch to lay down completely for 5 minutes.
- During testing visits, if a participant gets tired, testing can restart at a later time. If tiredness occurs during performance testing, participants may rest as often as needed.

The following in-person COVID-19 related safety precaution will be set for home visits and for when study office visits becomes a possibility for this study. These precautions may change according to guidelines offered by CDC, Oregon Health Authority, and OHSU.

- The participant and the study staff will be asked to take temperature and do symptom assessment before the start of the visit. This health data will be logged into REDCap. We will post-pone the visit and recommend that they contact their healthcare provider for fever>100.4, cough, fatigue, headache, other COVID-19 symptoms as outlined in CDC website https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.
- Participants are asked to wear masks if they have one. If not, the study will mail in the mask.

Staff will wear mask and practice hand hygiene Work hours are variable depending on the study status and the preference of the worker. It is expected to be 6-15 hours/week. The hours will not exceed 30 hours/ week.

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- Study staff will disinfect surface touched by participant between the visits.
- If possible, windows will be open for improved ventilation.
- The study visit will be conducted one participant at a time ensuring 6-feet distance between the staff and participant except to ensure safety during physiologic assessments.

**Analysis**

First, we will examine the following: recruitment, retention (numbers contacted, consented, screened out, and completed 70% of the intervention), and reasons for not participating or withdrawing. We will ask participants about challenges related to participation at 3-month, 6-month, and 12-month study encounters. Second, to determine the primary impact of MI as compared to a standard care group, patients' engagement with fall prevention recommendations (medication, exercise, blood pressure, vision, and environment), fear of falling, and fall prevention behaviors will be assessed quantitatively. The secondary impact will be measured by physical functions, patient activation, and fall rates. Descriptive statistics will be used to identify distributions and frequencies of the study outcomes. Third, we will use qualitative approach to determine how MI engages individuals in fall prevention behaviors. We will use quantitative findings to purposefully select the sample for the qualitative analysis. We will review the transcribed MI sessions and analyze the findings.

**[COVID-related changes]**

We will conduct additional analyses to evaluate 1) how the time between the STEADI FRA and the baseline study visit influence the recall of the FRA recommendations, engagement with fall prevention activities, and engagement with the study, 2) the difference in study outcomes between virtual vs. in-person visits, and 3) the impact of COVID-19 on fall prevention.

**Privacy, confidentiality, and data security**
The following processes are in place to reduce this risk that is unlikely but is possible. In this study, participants' privacy and confidentiality will be managed with the utmost care. Specifically, we will be minimally accessing the EHR records and these data will only be linked with Study ID. Third, the interview will occur via phone or in-person privately. Fourth, protected health information (PHI) will only be linked by study ID. PHI will be entered into a secure online HIPAA-compliant OHSU REDCap database and only IRB approved study staff will have access. Interviews will be audio recorded for data accuracy and for in-depth analysis. The informed consent includes the procedure for audio recording. The audio recordings will not be linked to PHI and will only be linked to the study ID.

**Risks and Benefits**
***Risks***. As with any form of physiological effort, there is a slight risk of injury during study measurements. Precautions to protect participants from harm are previously described. Additionally, protection from breach of confidentiality has been described previously.

To prepare for a rare but potential unintended situation in which MI interventions may trigger participants to disclose thoughts of harm to self or abuse, we now outline a plan to address this possibility.

First, we will keep track of incidences that can be considered as a threat to participants' welfare in the "Visit Note: Participant Welfare." We will track the relativity of the event to the study (did the study cause this incident?), immediacy, level of threat, and likelihood.

For all threats to welfare situations, study staff will document the condition and inform the PI. PI will then gather information, consult content matter experts, and make a determination about the response.

Respective actions will be taken based on the relativity of the situation to the study (did the study cause this situation?), immediacy, level of threat, and likelihood. A combination of the following approaches may be taken based on the situation and to minimize the harm to the participant.

- If the study may have caused the threat to the welfare, the study data collection and intervention will stop immediately. Adverse event protocols will be followed.
- If immediate danger is likely, study staff will call 911. If abuse is suspected, staff will report to 1-855-503-SAFE (7233) or the local DHS office (https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/de9373.pdf).
- If the incident can be considered to be not immediate, likely, or a great threat to welfare by the study staff and the PI, study staff will encourage the participant to talk to their provider. Depending on the significance of the issue, the study staff may ask for permission for the study staff to contact the provider as an effort to minimize the harm as stated in the consent. Study staff may provide information about the suicide hotline or loneliness hotline or other resources as well.
- If it is determined that the study staff should contact the provider by the PI, participants' consent to disclose the threat will be documented in the research records. In a rare occasion where the participant refuses the study staff to communicate with the provider, PI will consult the study's mentors, DSMP, or IRB appropriately.

In the case that the disclosure of research information is consented by the participant to reduce potential threat to the welfare, we will only communicate minimally necessary information so that

the participant can receive needed services or obtain appropriate consultations based on American Psychologists Association's 2002 Ethics Code (https://www.apa.org/monitor/jan03/10ways)

***Benefits.*** Participants will receive transportation cost and $15 for each of their study visits and $5 for participating in each of 7 study phone or video calls regardless of their performance in their fall prevention behaviors, for a maximum total incentive payment of $65(for the intervention group). The control group participant will be paid maximum of $35. There is a chance that participant incentives may influence patients' engagement with fall prevention activities. Thus, we will remind participants at every encounter that the payment is to recognize their time to participate in the study, and their performance on fall prevention behaviors will not influence the payment. Additionally, we will evaluate the influence of study payment at the end-of-the-study feedback opportunity from participants.

The proposed study examines the impact of MI for STEADI patients. This study will identify long-term impact of the STEADI intervention, and to examine the impact on MI in fall-related patient outcomes.

**Appendix 2: Document Roadmap for Follow-up on STEADI patients**

| **Study Documents** |
|---|
| Patient Invitation Letter |
| Study Flyer |
| Patient Consent Form |
| |
| **Data Collection** & Intervention |
| Draft Data Collection Tool |
| Participant Encounter Procedure Guide |
| Patient Fall Calendar |
| "Menu of Options for Fall Prevention" |
| |
| |

**[Added 12/30/22] Addition of qualitative study to 3. Follow-up on STEADI patients: Understanding how motivational interviewing intervention engages older adults in fall prevention behavior changes.**

The third element of the STEADI research involved following up on patients who were given STEADI fall prevention recommendations and to examine the impact of a patient communication approach, motivational interviewing (MI). This addition proposed on 12/30/22 will seek to examine how MI engages older adults in fall prevention behavior changes. The findings will inform the essential aspects of MI to be incorporated into future research studies and clinical practices.

**Design**

We will use a qualitative research approach to understand how MI engages older adults in fall prevention behavior changes with MI intervention that was provided for the intervention group of the STEADI follow-up patients.

**Study population**

One hundred and one older internal medicine patients enrolled in the STEADI follow-up study and randomly allocated to the intervention group. The study team will select participants for this qualitative study using qualitative and quantitative data collected from the STEADI follow-up study to represent high- and low-change with maximum variation for the analysis.

**Study procedures**
We will conduct qualitative interviews with purposefully selected individuals to examine how MI engages individuals in fall prevention behaviors. Each interview session is expected to be about thirty minutes. The interview questions and prompts will be based on questions identified from analysis of MI conversations from the STEADI follow-up study. The draft interview questions is included with this modification request. The qualitative interview will be conducted via phone or video call and will be recorded and transcribed.

**Data and Specimens**
**Source of materials.** We will obtain additional verbal consent for the qualitative interview (included with this modification proposal) with selected participants who have completed the STEADI follow-up study as the intervention group participants.
**Protection against risk.** The risk is minimal but there may be slight emotional or time burden for being part of the qualitative interview. The study personnel will be sensitive to the needs of the participant and may include breaks and shorten the interview to minimize the burden. The study team will evaluate the circumstance to improve the research approach for future participants.

**Analysis**
Coding and interpretation will be conducted iteratively. We will code the interview data based on initial group of codes to capture how MI engages older adults in fall prevention. We will fine tune the codes and code definitions to identify the final set of codes as we examine code reports to capture emerging themes from participant narratives.

**Privacy, confidentiality, and data security**
We will continue with processes to reduce privacy, confidentiality and data security risk that is unlikely but is possible.

**Risks and Benefits**
***Risks***. As with any form of interview, there is a slight risk of fatigue. Precautions to protect participants from harm are previously described. Additionally, protection from breach of confidentiality has been described previously.

***Benefits.*** There will be no monetary benefits for participation in the qualitative interview. However, participants may feel benefit that they are contributing to science and for the health of other individuals.