# Boston Alcohol Research Collaboration on HIV/AIDS (ARCH) Frailty, Functional Impairment, Falls, and Fractures (4F) Fall Prevention Intervention Pilot Study

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# 1 List of Abbreviations

| Abbreviation | Abbreviation definition |
|---|---|
| ARCH | Alcohol Research Collaboration on HIV/AIDS |
| ASI | Addiction Severity Index |
| BEDAC | Biostatistics and Epidemiology Data Analytics Center |
| HACCX | HIV-associated comorbidity and complications |
| PLWH | People living with HIV infection |
| RA | Research Assistant |
| RC | Research Coordinator |

# 2 Protocol Summary

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|---|---|
| **Title:** | Boston Alcohol Research Collaboration on HIV/AIDS (ARCH) Frailty, Functional Impairment, Falls, and Fractures (4F) Fall Prevention Intervention Pilot Study |
| **Population:** | Up to 50 participants from the Boston ARCH 4F Study |
| **Intervention:** | The fall prevention intervention has 3 main components: home exercises, virtual group sessions and weekly phone check-ins. Home exercise will be customized to match the current fitness level of participants. Participants will be asked to complete assigned exercises 3 times per week. Additionally, there will be a weekly virtual group session led by an occupational therapist member of the study team trained in group facilitation via Zoom. The virtual group sessions will be used to help answer any questions and lead a discussion around challenges related to falls. Finally, a member of the research team will check-in with participants once per week to answer any remaining questions that participants have, provide individual feedback on exercises, and set up reminders for the upcoming week. Reminders will be tailored to the individual participant's needs to remind the participant to complete the intervention's components. |
| **Objectives:** | To examine the association between alcohol use and falls and fractures and whether frailty mediates these associations in people living with HIV (PLWH). |
| **Design/Methodology:** | The Fall Prevention Pilot will recruit participants from the Boston ARCH 4F Study to test the acceptability and feasibility of a randomized trial of a 10-week virtual intervention to reduce fall risk PLWH who consume alcohol. Eligible cohort participants with an elevated risk for falls will be randomized to either the intervention or control (usual care plus educational brochure). |
| **Total Study Duration:** | 1 year |
| **Subject Participation Duration:** | 10 weeks |

# 3 Background/Rationale & Purpose

## 3.1 Background Information

Up to a third of middle-aged people living with HIV infection (PLWH) experience falls each year.[1] Although not well-described in PLWH, falls are the most common cause of non-fatal injury in the US (8 million falls per year; 2.6 million treatment episodes; 750,000 hospitalizations, 22,000 deaths)[2,3] and the cost in the elderly is enormous ($20 billion/year), mostly from emergency department visits and hospitalizations (which have risen 50% in 7 years).[2] Falls are a common and significant problem in PLWH, and alcohol is a potent risk factor, increasing risk up to 17X.[1,4–11] Alcohol, illicit drug use, and polypharmacy likely contribute to falls (e.g. from over-sedation and risk-taking behavior), risk factors for falls (e.g. frailty), and fall consequences (e.g. fracture, need for acute healthcare use). Interventions are needed to address falls in PLWH who use alcohol but none have been tailored for this population.

Efficacious interventions for the elderly exist[12,13]; however, fall prevention interventions developed for the elderly generally do not address alcohol, other drugs, HIV medications, and HIV-associated comorbidity, but they would likely need to in order to be successful in PLWH. A focus on risks, including the interplay of common exposures (e.g. alcohol, illicit drugs, medications) and mediators (e.g. frailty), is therefore critical in order to develop tailored preventive interventions to reduce falls and related morbidity effective for PLWH.

## 3.2 Rationale and Purpose

Study Rationale:
Falls are a common and significant problem among PLWH for various reasons.[1,4–11] Antiretroviral therapy (ART) can control HIV viremia even in substance use-affected populations. But HIV-associated comorbidity and complications, in the context of possible premature aging —or more accurately—the earlier development of comorbidities in PLWH seen in older adults without HIV infection, now contribute to substantial impairment in people with HIV infection. These complications, including Frailty and impaired physical Function, can contribute to Falls and Fractures, and can be hastened by alcohol, illicit drug use, and polypharmacy (5+ medications). Fall prevention interventions developed for the elderly generally do not address alcohol, other drugs, or HIV medications, but would likely need to in order to be successful in PLWH. A focus on risks, including the interplay of common exposures (e.g. alcohol, illicit drugs, medications) and mediators (e.g. frailty), is therefore critical in order to develop tailored preventive interventions to reduce falls and related morbidity effective for PLWH.

Purpose:
This study is being conducted to assess the acceptability and feasibility of conducting a randomized trial of a 10-week virtual intervention aimed at reducing fall risk in PLWH who consume alcohol. This pilot trial will be used to inform feasibility of this study design prior to conducting a large-scale trial. To achieve this, we propose to recruit up to 50 participants from the Boston ARCH 4F Study, 40 of whom

will be randomized, to pilot test this fall prevention intervention. Further, we will assess the acceptability and feasibility of the intervention component by assessing number of virtual group intervention sessions attended and administering the Client Satisfaction Questionnaire (CSQ-8)[14] at the conclusion of the intervention.

# 4 Objectives

## 4.1 Study Objectives

The primary aim of the intervention is to assess acceptability and feasibility of a randomized trial of a 10-week virtual fall prevention intervention.

## 4.2 Study Outcome Measures

### 4.2.1 Primary Outcome Measures

To assess intervention acceptability and feasibility, the primary outcomes include number of weekly intervention sessions attended (out of 10 sessions) and overall satisfaction with the intervention [assessed at study conclusion using the Client Satisfaction Questionnaire (CSQ-8)].[14]

### 4.2.2 Secondary Outcome Measures

There are also several secondary outcome measures:

- Falls from participant self report, defined as an unexpected event, including a slip or a trip, in which a participant lost their balance and landed on the floor, ground, or lower level, or hit an object like a table or a chair.
- Physical Function measured using the Short Physical Performance Battery assessment
- Frailty phenotype[15], which includes measures of exhaustion, low activity, weight loss, slowed walking, weak grip.
- Alcohol and other drug use from self report measured using the validated Addiction Severity Index (ASI)[16–18]

# 5 Study Design

The Boston ARCH 4F Fall Prevention Pilot is a sub-study of the Boston ARCH 4F Study, a longitudinal cohort study of 251 HIV infected men and women who have a spectrum of alcohol and other drug use. The Boston ARCH 4F study aim is to examine the association between alcohol use and falls and fractures and whether frailty mediates these associations in people living with HIV (PLWH). The Fall Prevention Pilot will recruit participants from the Boston ARCH 4F Study to test the acceptability and feasibility of a randomized trial of a 10-week virtual intervention to reduce fall risk PLWH who consume alcohol.

Eligible cohort participants with an elevated risk for falls will be randomized to either the intervention or control (usual care plus educational brochure).

Standardized assessments will be administered to all participants in-person at Boston University Medical Campus (BUMC) to assess various domains including fall risk, fear of falling, physical performance measures (such as grip strength, balance, and gait speed), substance use, and other related measures at baseline and at trial completion. The fall prevention intervention has 3 main components: home exercises, virtual group sessions and weekly phone check-ins. Home exercise will be customized to match the current fitness level of participants. Participants will be asked to complete assigned exercises 3 times per week. Additionally, there will be a weekly virtual group session led by an occupational therapist member of the study team trained in group facilitation via Zoom. The virtual group sessions will be used to help answer any questions and lead a discussion around challenges related to falls. Finally, a member of the research team will check-in with participants once per week to answer any remaining questions that participants have, provide individual feedback on exercises, and set up reminders for the upcoming week. Reminders will be tailored to the individual participant's needs to remind the participant to complete the intervention's components.

# 6 Potential Risks and Benefits

## 6.1 Risks

Potential risks for participants include psychological stress from the research interviews or from recognizing health disorders during the interviews or tests, loss of confidentiality, and social harms. These are minimal risks, consequences are not likely, and will be minimized further.

*Psychological stress from research interviews or study visits*: Participants may experience psychological stress from talking about their health or from recognizing health disorders during the assessments or intervention components. Participants may get tired during the visits. Additionally, participants may find it inconvenient to take time for the visits, and they may find it inconvenient to be contacted by study staff when they remind participants of an upcoming research visit. Participants will not be explicitly asked questions about self-harm and/or suicidal ideation as a part of this research study. However, if active/current suicidal ideations are identified via research assessment or expressed by participants during study visits, study physicians are available to respond to participant concerns with referrals as needed (remotely if during a remote visit or in-person if during an in-person interview). This process will be determined prior to the visit taking place, per recommendation of the staff facilitating the visit or phone call.

*Discomfort from exercise assignments*: Participants may experience muscle soreness, discomfort, and fatigue after completing the exercise assignments. There is the unlikely risk that a participant could get injured while doing the exercise assignments. However, all exercise assignments will be tailored to the individual's needs and skill levels, and study staff will make sure the participant has been provided with thorough instructions/demonstrations on how to properly do the exercises before they are instructed to proceed with doing the exercise assignments on their own. Participants are welcome to ask any questions during virtual group sessions or weekly phone check-ins.

*Loss of confidentiality*: Loss of confidentiality by someone seeing the responses to interview assessments is potentially the most serious risk of the proposed study, though it is very unlikely because specific procedures will be implemented to prevent such disclosure. In addition, much of the most sensitive information (HIV and alcohol use) is already in medical records and the additional increase in risk of

recording it for research purposes, particularly given the protections in place for such records that is far greater than clinical records, is small. There is a risk that participants may experience loss of confidentiality when research assistants make attempts to contact them for follow-up. All participants will be informed and provide their consent for the study to reach them through contacts they have provided as a part of the Boston ARCH 4F study (the participant will be linked to the Boston ARCH 4F study through their unique Study ID number). When research assistants attempt to make any contact to the participant or other contacts, all communications will be identified as coming from a "health study," not an alcohol abuse or HIV study. When study visits (such as group meetings or individual check-ins) are conducted via phone or confidential video conference, study staff will advise participants to take precautions to minimize the risk of a breach of confidentiality such as participating in the study visit in a private location. Participants will be provided the option to keep their camera off during study visits, if they would like. Prior to virtual group meetings, study staff will ask all participants not to talk about the discussions outside the group, and research study staff will remind the participants to respect the privacy of fellow participants and not repeat what is said in the group meetings to others. Participants will be asked to only provide their first name or a pseudonym.

*How risks will be minimized.*

*Loss of confidentiality*: To assure confidentiality, research data collection and data entry forms will be labeled only with the unique Boston ARCH 4F Study ID number, and will contain no other individual identification. Only the written informed consent forms, participant locator information, and a master list of participants and participant study identification numbers will have the participant number and identifying information on them. There will be only one master list of names and identification numbers. These data will be kept in a secure electronic environment accessible to the principal investigator, the study research staff and data managers. Study staff will use the tracking information that the participants provided during the Boston ARCH 4F study, and study staff will confirm that the tracking information is up to date and accurate. Computer data will be password protected, and accessible only to research assistants needing the information for follow-up purposes. When study visits (such as group meetings or individual check-ins) are conducted via phone or confidential video conference, study staff will advise participants to take precautions to minimize the risk of breach of confidentiality. Study staff will remind participants that they should participate in study activities in a private location. Participants will be provided the option to keep their camera off, if they would like. Prior to virtual group meetings, we will remind participants that they should not talk about the discussions outside the group. All of these procedures are likely to be effective, based on our experience with similar studies. Comments on the home exercise YouTube videos have been disabled to further protect participant confidentiality.

*Psychological stress*: The minimal risk of psychological distress from interviews and study visits will be minimized by using trained interviewers and a standardized interview process. To further minimize this risk, we will enroll participants who understand the study and are willing to participate. Participation is voluntary and participants can withdraw at any time. Additionally, we will take steps to mitigate the risk of psychological stress during the weekly virtual group sessions. The occupational therapist member of the research team is trained using Zoom to facilitate group sessions and will re-direct any inappropriate questions or topics. Each virtual group session will begin with a reminder of best practices and available resources. For example, we will remind participants that they are welcome to leave the group meeting at any time and follow up with a study team member if they experience psychological stress during the group session without any penalty. Study staff will be available by phone if undue stress arises, and they will be able to make recommendations or referrals as appropriate. Study team members will have a list of mental health and alcohol use resources that can be provided to participants who inform a study

team member that they are experiencing psychological distress as a result of the research study. Participants will also be reminded that phone check-ins can be used as an opportunity to discuss experiences of psychological distress, and participants are welcome to save sensitive or uncomfortable topics for discussion during the phone check in rather than the virtual group session.

*Discomfort from exercise assignments*: Participants will only be assigned exercises that have been tailored to their individual needs, skill level, and goals, which will be determined during the baseline assessment. The exercises and modifications will be demonstrated during the first virtual group session. We will ask that participants only perform the exercises exactly as instructed, and they should not do any exercises that make them feel uncomfortable (not including general muscle soreness or fatigue, which is a common and temporary risk). Video demonstrations of the exercises and modifications will be available on YouTube as "unlisted" videos that can be accessed only through a direct link that we will provide participants. Participants can refer to these demonstrations at any time. Participants will also be encouraged to discuss any discomforts that have resulted from exercise assignments with members of the research team during weekly virtual group meetings and phone check-ins.

*Plans for ensuring necessary medical or professional intervention in the event of adverse effects to participants*: If consequences arise due to research procedures (e.g., distress, anxiety, suicidal thoughts) the physician investigators will be available to assess participants and make appropriate interventions or referrals based on the clinical circumstances, immediately. This will be done either remotely or in person, whichever mode reflects the research activity being conducted. Three study physicians have extensive clinical experience with patients with substance use disorders and related mental health complications that arise, two have clinical expertise with HIV infection.

### 6.2 Potential Benefits

Participants in the control group may benefit from receiving educational information related to falls and alcohol use.

Participants in the intervention group may benefit from the intervention components of the study. They may gain strength from weekly exercises, which may put them at lower risk for experiencing a fall. Participants may benefit from discussing their experiences related to falls and alcohol use with other peers during weekly virtual group meetings, and participants may benefit from discussing their experiences with falls and alcohol use with an occupational therapist member of the research team during the weekly phone check-ins.

### 6.3 Analysis of Risks in Relation to Benefits

The principal risks of this study are loss of confidentiality and psychological stress. We will take an abundance of caution to protect the confidentiality of participants, and participants will be reminded of best practices prior to each weekly virtual group session. Participants will be provided various opportunities to discuss psychological distress with trained study staff and physician investigators. These risks are outweighed by the potential benefits that participants may receive from the intervention.

Participants who are assigned to the control arm may benefit from the provided educational materials.

Participants who are assigned to the intervention arm may benefit from weekly virtual group sessions and phone check-ins. These sessions will provide participants with the opportunity to discuss challenges

related to falls and alcohol use and ideas for overcoming these challenge. During preliminary qualitative research, Boston ARCH 4F participants expressed that group meetings and individual check-ins would be beneficial. Additionally, the home exercises may improve strength and balance in the participants. Furthermore, this intervention is tailored to address fall risk and alcohol use in this specific population, and it has the potential to reduce falls among PLWH who use alcohol more than a traditional fall prevention program.

The benefits outweigh the risks.

## 7 Study Subject Selection

### 7.1 Subject Inclusion Criteria

- Male or female at least 18 years old
- Prior or current participant in the Boston ARCH 4F Cohort
- Any alcohol consumption in the last 30 days using Addiction Severity Index
- Deemed a Fall Risk using the CDC STEADI Fall Risk Assessment Form[19]
- Has reliable access to a phone or computer with internet connection

### 7.2 Subject Exclusion Criteria

- Requires wheelchair for mobility

## 8 Study Procedures

8.1 Recruitment- Up to 50 participants will be recruited to the Fall Prevention Pilot study from the Boston ARCH 4F Study cohort. To identify potentially eligible participants, the Boston University Medical Campus (BUMC) Biostatistics and Epidemiology Data Analytics Center (BEDAC) will generate a list of potentially eligible participants from the Boston ARCH 4F cohort who previously (at prior Boston ARCH 4F Study cohort assessments) endorsed alcohol use and fall history based on responses to the Addiction Severity Index (ASI) and the AIDS Clinical Trials Group (ACTG) Fall History Questionnaire.[20–22] Participants who have not provided their written informed consent to be contacted about other research studies will be excluded from this list. Research assistants (RAs) and the research coordinator (RC) approach participants on this list for phone screening.

8.2 Phone Screening of Eligibility -The RAs and RC will reach out to Boston ARCH 4F participants who have been identified as potentially eligible based on the criteria described above. Participants interested in the study, if they agree, will be screened over the phone by interview/questionnaire for eligibility. If the participant meets all inclusion criteria and does not meet any exclusion criteria, they will be offered participation in the Boston ARCH 4F Fall Prevention Intervention Pilot Study. All eligible participants will be informed about the study and their written consent will be sought.

8.3 Baseline Assessment - Enrolled participants will complete a baseline research interview (a series of questionnaires to assess fall history and efficacy, substance use, prescription medications, physical and social environment, food security, and frailty) and physical assessments (physical function measures

including grip strength, short physical performance battery, and vision acuity) in-person at BUMC with an RA or RC. Additionally, an occupational therapist member of the study team will conduct the Canadian Occupational Performance Measure to assess the participant's exercise-related skills, needs, and goals.

If a participant's baseline is scheduled to occur more than 2 weeks (14 days) after the initial screening questionnaire was administered, an RA or RC will re-administer the screening questionnaire with the participant to confirm eligibility prior to conducting informed consent and the baseline research interview. The RA will re-administer the screening questionnaire within 24 hours prior to the scheduled baseline assessment. If the participant does not meet eligibility criteria based on the re-administered screening questionnaire assessment, then the participant is ineligible for the study, and they will be instructed to not attend their scheduled baseline assessment. However, if the RA is unable to get in touch with the participant prior to the scheduled baseline assessment, and the participant arrives at BUMC campus for the assessment, then the RA may re-administer the screening questionnaire in-person. If the participant does not meet eligibility criteria based on the re-administered screening questionnaire assessment, then the participant is ineligible for the study, the baseline questionnaire will not be administered, and the participant will be compensated $15 for their time.

If the participant's baseline research interview is scheduled within 2 weeks (14 days) after the initial screening questionnaire was administered, the RA or RC will not re-administer the screening questionnaire prior to completing the informed consent and the baseline research interview. However, if a participant reports no past 30 day alcohol use during the baseline research interview, the participant will be considered ineligible for the study and will not be randomized to either the intervention or control arm of the Fall Prevention Pilot, and no further follow-up will occur with the participant unless he or she is re-screened and determined eligible at a later date. The participant will still, however, be compensated for the baseline research study visit.

At the end of the baseline assessment, the RAs or RC will inquire about the participant's general availability, which will be used to identify the times during which the intervention's weekly group check-ins will be held and determine whether the participant will be randomized. A participant will not be randomized if they have limited availability that cannot be accommodated. This decision will be made on a case-by-case basis. Additionally, after the baseline assessment has been administered, the RAs or RC will provide participants with technological assistance that may be helpful prior to the intervention. Although not all participants who complete a baseline assessment will be randomized to the intervention arm, the baseline assessment will be the only point of in-person contact prior to initiating the intervention. Therefore, the RAs or RC will utilize this in-person time point to provide technological assistance with Zoom, such as setting up the Zoom app on a personal cell phone or computer, demonstrating the process of calling into a Zoom conference room (with or without the Zoom app), and identifying Zoom features that may be beneficial to understand (such as turning video and audio on and off). This technological assistance will be completely voluntary. Study staff will remind participants that

they will only use Zoom during the Fall Prevention Pilot study if they are assigned to the intervention arm.

The baseline assessment will take approximately 2 hours to complete.

### 8.4 Intervention Arm Assignment/Randomization

Randomization: Once at least 6 participants have completed the baseline assessment, which we expect to occur between 2 and 4 weeks after study staff administer the first participant's baseline assessment, they will be randomized to either the intervention or control group using an automatic REDCap randomization module. These participants will be randomized in the "first wave" to either the intervention or control group using a 1:1 ratio on the factor of sex. The "first wave" of participants will be informed of their randomization assignment by study staff via phone call and will proceed with their assignment within the next week. After the "first wave" of participants are randomized, study staff will continue to screen and conduct baseline assessments for randomization in the "second wave" (similar to the first wave, the second wave will aim for n of at least 6). It will be acceptable for recruitment to occur over multiple randomization waves until recruitment goals have been met (to reach n=40 randomized participants). Procedures for subsequent recruitment wave(s) will be conducted in the same manner as the first wave. Participants will be randomized and informed of their randomization assignment after the baseline assessments for that wave have been conducted, which we expect to occur between 2 and 4 weeks after study staff administer the first baseline assessment of each subsequent wave.

In the event that study staff determine that the availability provided by a participant at baseline is too limited and cannot be accommodated (e.g., matched with other participants' availability so that two weekly group meeting days/times can be identified), that participant will not be randomized. This procedure is in place because a participant's limited availability will impact the participant's ability to participate in an entire component of the intervention (weekly virtual group meetings). During the subsequent wave(s) of recruitment and baseline assessments, study staff may re-contact participants who were enrolled in the Fall Prevention Pilot during a previous recruitment wave but were not randomized to a study arm due to limited availability at the time of the previous recruitment wave. Any participants who are re-contacted and provide an increased level of availability that study staff believe can be accommodated (e.g., matched with other participants' availability so that two weekly group meeting days/times can be identified) may be randomized during a subsequent wave(s). This will be determined on a case-by-case basis.

### 8.5 Control Arm Assignment

Participants who are assigned to the control arm will be informed of their assignment via phone call. Study staff will explain that being in the control group means that they will be receiving educational materials on fall prevention and alcohol use. The participant’s mailing address will be confirmed, and the educational materials will be mailed by certified mail (or emailed, depending on participant preference)

to their preferred address. The educational materials will only be mailed once, unless the participant misplaces the educational materials and requests to have study staff re-mail (or re-email, depending on participant preference) the educational materials.

Intervention Arm Assignment: Participants who are assigned to the intervention arm will be informed of their assignment via phone call. Study staff will explain that being in the intervention group means that they will be participating in a 10-week intervention, which includes weekly home-based exercises, a weekly phone check-in, and weekly virtual group sessions. During this phone call, study staff will also obtain detailed availability from each participant, which will be used to schedule the weekly virtual group sessions.

8.6 Scheduling

Virtual Group Session: Virtual group session scheduling will occur in waves that align with the waves of randomization. After the "first wave" of randomization has occurred, study staff will reach out to all participants (at least 3) who have been assigned to the intervention arm to request days and times at which they are available and/or unavailable to participate in study activities. This availability will be used to help study staff identify the time slots in which the weekly virtual group sessions will be held. Once time slots for weekly virtual group sessions have been identified (up to two time slots), study staff will reach out to participants via phone call to schedule each participant for one of the two weekly virtual group sessions. Study staff will aim to assign an equal number of participants to each weekly virtual group session time slot; however, an equal allocation of participants to each group is not required. An unequal number of participants may be assigned to each group, provided that there are at least 3 participants assigned to the smallest group. Furthermore, study staff may also choose to assign all participants to one weekly virtual group session time slot if all participants' availability aligns with the same time slot or if having two groups would not allow for the minimum required number of participants (at least 3 per group). Procedures for scheduling the two additional weekly virtual group sessions for the subsequent wave(s) of randomized participants will be conducted in the same manner as the "first wave" of randomized participants.

Phone Check-in: Participants will be scheduled for their initial phone check-in when study staff contact the participants via phone call to schedule the participants for one of the two weekly virtual group sessions. The first phone check-in will be scheduled to occur between the first and second weekly virtual group sessions. During each weekly phone check-in, study staff will schedule the participant for the next week's phone check-in.

Conflicts and Rescheduling: If a participant experiences a scheduling conflict with a scheduled group session, they will miss that visit. Study staff will inquire about the upcoming week during a participant's weekly phone check-ins. Participants who indicate that they will have a scheduling conflict with their assigned weekly virtual group session time will be offered participation in the other group for that week only. Further, if a participant experiences a scheduling change that causes them to be unavailable for

either of the 2 group sessions, the participant will miss the group meetings. However, the participant will to continue to participate in the intervention by attending the weekly phone check-ins and conducting the weekly exercise assignments, and participants will be encouraged to attend future virtual group meetings if they experience a schedule change that allows for their attendance. The weekly virtual group meeting sessions will be combined into one session if weekly participation drops below 3 participants per session for at least two consecutive weeks.

8.7 Educational Component (Control Group Only)

Fall Prevention and Alcohol Use Educational Materials: The RAs and RC will call participants to inform them that they have been randomly assigned to the control group, and as a result they will be receiving educational materials about fall prevention and alcohol use. The RAs and RC will provide the participant with a brief overview of the educational materials that they will receive. The educational materials will be sent to the participant by certified mail (or by email, if this is the participant's preferred method) within one week of being informed of their randomization arm assignment. The educational materials will only be mailed once, unless the participant misplaces the educational materials and requests to have study staff re-mail (or re-email, depending on participant preference) the educational materials.

8.8 Intervention Process (Intervention Group Only)

Note: None of the below research activities will be recorded (audio or visual).

Virtual Group Session via Video/Phone: Weekly virtual group sessions will be held at up to two time points each week. Participants will be assigned to one of up to two time points and will be asked to attend the virtual group session for about 30 minutes each week for 10 weeks. The weekly virtual group sessions will be led by a licensed occupational therapist member of the study team, who is trained in group facilitation via Zoom. RAs will help coordinate and schedule the sessions with participants. Participants will have the option of using video or phone to participate (use of video will be encouraged). If two groups were scheduled at the outset of the intervention and any of the groups decrease in attendance to only two people, the two groups will be combined to form one group that will meet for the remaining weeks of the intervention period.

The group sessions will be led by experienced occupational therapists who have been trained in group theory and facilitation as well behavioral health and fall prevention. The social learning model will be used as the theoretical basis for all groups. Situated learning theory, which is derived from social learning theory, posits that behavior results from interaction between the person and the situation. The learner is placed in contexts (the intervention group and practicing at home) that allow for simulated and actual application to everyday situations, whereas peers enhance the learning experience with feedback. In social situations, individuals gain motivational support from others and access both expertise and collaborative thinking, increasing opportunities to acquire and apply new knowledge. This approach has successfully been used in effectiveness studies with individuals who were homeless,

mentally ill, had an intellectual disability, as well as across a wide age span from 12-79 years of age. Group participants functioning at a variety of levels are likely to benefit from others' experiences of completing the intervention activities and identifying strategies to follow through with recommendations.

The occupational therapist member of the study team will begin each group by reviewing the purpose and reminding participants that they can choose how much to share or not share. The purpose will be described as a forum to share their experiences with the intervention, discuss any falls during the week and identify strategies to address any challenges. The discussion will begin with a quick check in with each group member to provide a structured opportunity for every participant to speak at least once during the group. The check in will be a brief structured question such as, "Identify one exercise you liked doing this week and one that you might have had some difficulty with." This structure gives the participants permission to have challenges with the intervention to help alleviate discomfort or embarrassment with having to initiate this topic. It also ensures that every group member participates verbally should they be less active in the remainder of the discussion. Based on the check in responses, the occupational therapist member of the study team will facilitate a group discussion among participants that encourages them to share strategies and commonalities with each other. Group members find advice from peers to be more valid than from a professional. The occupational therapist member of the study team will use their expertise to ensure the conversation stays on the topic of falls and intervention strategies and to correct any misinformation that might be shared. The therapist will have a list of common topics to interject if the participants exhaust their own concerns or if the group conversation veers off course. Topics will include common issues related to fall prevention such as identifying and removing environmental obstacles, finding time to complete exercise, maintaining good nutrition to support physical health, and how to speak with your doctor about medication side effects such as dizziness, etc. Finally, group time may be spent reviewing exercises if needed. If individuals raise concerns that cannot be addressed in the group due to time or because the topic is beyond the scope of the group, they will be redirected to their individual session or another resource.

Independent Home Exercises: Home based exercises will be tailored to each participant's individual needs and skill sets, which will be determined at the baseline assessment. The general categories of the exercises include air squats, bicep curls, burpees, and single leg stands. Links to the exercises can be found below. Participants will complete assigned exercises on their own at home and will be instructed to record the exercises they complete on the Home Exercise Form, which is a tool for personal use by the participant and will not be returned to the study team. The exercise assignments will take about 30 - 60 minutes to complete per time the participant exercises. During the first virtual group sessions, an occupational therapist member of the study team will describe and demonstrate the assigned exercises. Participants may use this time to ask questions about the exercises. Further, if a participant was unable to attend the first virtual group session, the assigned exercises will be demonstrated by an occupational therapist member of the study team during the first phone check-in. In the case that assigned exercises will be demonstrated at the first phone check-in, the phone check-in will occur using Zoom instead of phone call.

Participants will be able to refer back to video demonstrations of the assigned exercises on a YouTube channel called "Boston ARCH Home Exercises". The YouTube channel will include videos of occupational therapist members of the study team demonstrating the assigned exercises. The videos on the YouTube channel will remain at a visibility status of "unlisted", which means they can only be accessed by a URL. Comments on the videos have been disabled. Study staff will provide participants with the limited access URLs at the first virtual group session, phone check-in, or by email upon participant request. Participants will be encouraged to keep the limited access URLs private and not share the links with people outside of the study.
URLs:
https://youtu.be/BGR69rKSMCA
https://youtu.be/mfrOBDuRP7M
https://youtu.be/2IeSb2UXsm4
https://youtu.be/3ypbuWluf3M

### 8.9 Individual Check-In via Phone Call

The phone check-in will occur between the first and second weekly virtual group sessions, and follow-up check-ins will occur once weekly after the initial check-in for the entirety of the intervention period, for a total of 10 weekly check-in calls. These phone calls will be conducted with an occupational therapist member of the study team. As the study's primary aim is to assess acceptability and feasibility, there is no set limit of missed weekly check-ins that triggers dropping participant from the study. If a participant stops participating in weekly exercises, the occupational therapist conducting the weekly check in with the participant will inquire as to the reasons why the participant stopped completing the exercises. This feedback will be used to modify the exercises going forward (e.g., frequency, intensity). Additionally, individualized reminders (e.g. phone alarm, calendar update) for the various intervention components will be set during the individual check-ins.

Post-Study Assessment- After the 10 week intervention is complete, all randomized participants (intervention and control groups) will be asked to complete a post-study interview (a series of questionnaires to assess fall history and efficacy, substance use, prescription medications, physical and social environment, food security, and frailty) and physical assessments (physical function measures including grip strength, short physical performance battery, and vision acuity) in-person at BUMC with an RA or RC. Additionally, an occupational therapist member of the research team will conduct the Canadian Occupational Performance Measure. The post-study assessment will take approximately 2 hours to complete. The RAs and RC will reach out to participants approximately 8-9 weeks after randomization to schedule the post-study assessment, and the post-study assessment will be completed approximately 10 weeks (up to 14 weeks) after randomization.

## 9 Informed Consent

Consent will be sought by trained research staff under the supervision of the study investigators. Research study staff will have a conversation with the potential participant about the study, reviewing all pertinent elements of informed consent. If potential participants wish to review the information and consider their options they may do so and return to enroll at a later date if they remain eligible. Written consent will be documented. Consent will be obtained when potential participants arrive for their first research interview. Their clinical care will not be interrupted or interfered with. Research staff will review the elements of consent with participants (that this is a research study, description of the study procedures including that their study ID will link information from the Fall Prevention Pilot to the Boston ARCH 4F Study, that we will use contact information that was provided for the Boston ARCH 4F study, the risks and discomforts, the benefits, the alternative to participating in the study including to not participate in the research, the purpose and duration of the study, confidentiality, and that participation is voluntary). After research staff review the elements of consent with participants, they will use a "teachback" process among all participants to ensure participant comprehension. The study will begin immediately after informed consent by an RA.

10. Adverse Event Reporting

This study is not greater than minimal risk. Unanticipated Problems, Adverse Events, and protocol deviations will be reported to the IRB as required by IRB policies. The Principal Investigator at BU Medical Campus will report all adverse events and Unanticipated Problems to the IRB in compliance with IRB policy, Federal/State regulations, and sponsor requirements (as applicable).

11. Data Monitoring

The PI will be responsible for ongoing quality control. This includes all aspects of the study related to safety, but also data integrity and protocol compliance. Quality control will include self-audits of data collection and storage as well as compliance with the informed consent procedure. The review of data and procedures may result in early termination of the study, amendment of the protocol or data collection plans, or amendment of study forms. The IRB will be notified and all amendments approved prior to study implementation. In addition, the participants will be notified of any significant new findings that develop during the course of research (e.g., other potential risks) that may affect their wish to continue participation in the study.

The study clinicians, research coordinator, and Principal Investigator will monitor study progress including enrollment, adherence to inclusion/exclusion criteria and study protocol, as well as any adverse events. The Principal Investigator will be responsible for ensuring that adverse events are reported to the local Institutional Review Board in compliance with local and federal requirements. Any changes to the protocol will be made in accordance with local IRB policies. The Principal Investigator will supervise all study activities, including those of the research coordinator and co-investigators, and will be available 24 hours a day by page or telephone.

12. Data Handling and Record Keeping

## 12.1 Confidentiality

The study ID number assigned to participants in the pilot study will be the same study ID number used in Boston ARCH 4F. This ID number is the only link that connects their identifiers (e.g. names) in the tracking database (information required to contact and follow participants) and the separate study database. This code is stored in a separate secure database accessible only to study staff and investigators.

We will communicate with participants via phone, BU Zoom Meetings for HIPAA, or BU Teams, and when using BMC email, we will type "secure" in the subject line which creates a secure messaging system, or for BU email we will use the BU approved DataMotion SecureMail email service. We note that since technology changes frequently, it is possible that BMC and BU's secure email systems could change and if they do, we will follow BU or BMC IT procedures for such emails. Similarly, if a new secure platform recommended for such communications becomes supported by BU and BMC and/or recommended by the IRB we will use those platforms. One problem that arises with secure email is that it is very difficult for participants to use, particularly the most vulnerable subjects, who have less advanced technology available to them. Thus, if the patient or research subject has agreed, we shall use non-secure communications. In those cases, communication will generally be limited to the minimal detail necessary, and participants will be informed that they should delete messages and take care to keep their information not visible to others on their devices. Please note that this language is based on BU IRB recommendations, and applies to all sections describing participant contact.

Data Management and Security to Protect Privacy: The Biostatistics and Epidemiology Data Analytics Center (BEDAC) will assure high quality forms, monitor data quality, and track and link the multiple data sources. Data will be linked and entered using multiple checks. BEDAC will develop data collection forms and questionnaires, implement procedures for quality control, and provide statistical programming and collaborate in report writing and presentation of study results.

Data will be collected by interview via web-based data capture system on tablets. Study staff in collaboration with BEDAC will design, develop and maintain the electronic data collection forms, and underlying SQL database systems, and implement procedures for data quality control, including multiple checks for entered data. Study staff will use the same secure electronic data capture system that has been successfully implemented in the Boston ARCH 4F study for tracking and contact information. Electronic data collection forms will be designed to read easily, have clear instructions, preprogrammed skip patterns, real-time range checks and internal logic to minimize missing data, resulting in “cleaner” data at capture. The website and accompanying database is located on secure, password-protected servers, behind the Boston University firewalls. The web and database servers use Secure Socket Layering (SSL) to ensure data security and confidentiality. Servers incorporate RAID hard drives for data redundancy. A separate web server dedicated for Cold Fusion applications is also available. Hard copies of the signed informed consent form will be stored in locked filing cabinets and locked offices at Boston University School of Public Health.

Data transmission will be protected through SSL encryption. Eligibility for participants will be verified by the web data capture application. For the pilot trial, allocation is concealed from study staff and participants until the assignment is made to avoid interviewer bias. BEDAC will maintain data management protocols and analytic plans. Study staff will use the Boston ARCH 4F participant tracking system that includes an innovative real-time crosscheck used in prior studies to prompt contact with participants when they appear for care. Because the server is part of the BUMC network, only

connections from users authenticated from the domain controller are accepted, thus providing a secure environment for all data. Specifically, the policies for computer systems security implemented at BUMC are as follows:

> Provide physical security of data. The server resides in the same building as the BUMC Office of Information Technology (OIT) servers. The lobby of the building in which the systems reside is under the security purview of the Boston University General Services Security Office and is under surveillance. All central systems are physically secured behind two card-access doors with access to the primary door restricted to key personnel in the OIT. Access through the primary door is also protected by a keypad alarm system that is tied directly into the on-site central emergency response security control center. Written policies exist for contingencies to provide access to the room to those not explicitly authorized.
>
> Provide virtual security via connectivity. Internal access to all systems is done via MicroSoft Challenge Handshake Authentication Protocol. With the exception of internet provider-based services, external client access must first gain access to the internal network before connecting to the systems. This connection is initiated via a Virtual Private Network connection using Point-to-Point Tunneling Protocol or through the University's modem pool which require Kerberos authentication. All web-based mail is encrypted with high-encryption domestic SSL.

All data are protected with disaster recovery via several methods:

> Hardware redundancy: Several stages of redundancy exist at the hardware level to minimize failure: Dual-redundant power supplies exist on each disk array; hot-spare disk is configured to automatically self-heal in the event of a disk failure in the array; emergency power generators ensure a 100% electrical uptime; and uninterrupted power supplies present the systems with conditioned steady-state power.
>
> Data backup: Backups are completed daily over the BUMC network using both on-site and off-site disk-based backup devices.
>
> Data Security: All data are stored on servers that are password-protected. To protect against security breaches, data will be electronically encrypted so that only the intended recipient can decode.

BEDAC will use Microsoft SQL Server software for all database development and storage, providing a secure environment for data storage. They will work closely with the BUMC Office of Information Technology (OIT) to secure institutional hardware, software, and network services for data transmission, storage, and archiving to support all URBAN ARCH Consortium research activities.

The BUMC OIT and BEDAC are physically located in the same building; all web and database servers used by BEDAC will be housed in a secure, professionally managed server room under the control of the BUMC OIT. Staff from BEDAC and BUMC OIT work to continually enhance their systems, procedures and processes to ensure compliance with industry and government standards for data security. All central systems are secured physically behind locked doors with access restricted to key personnel in the BUMC OIT. All databases will be backed up automatically on a nightly basis.

## 13. Statistical Plan

We will enroll up to n=50 participants to accommodate any situation in which an enrolled participant is not randomized to the intervention or control group. We aim to randomize up to n=40 participants

(approximately 20 randomized to the study intervention and approximately 20 randomized to the control group).

The goal of this pilot is to describe feasibility of the proposed trial and intervention and obtain preliminary estimates of falls related outcomes. This pilot is not intended to provide adequate statistical power for a formal comparison of the intervention and control groups on falls-related outcomes.

Confidence intervals for mean number of sessions attended, for those participants randomized to the intervention, will have a width of 0.44 standard deviations, and assuming approximately 80% of the approximately n=40 study participants complete follow-up, a confidence interval for the percent completing the study will have a width of 12 percentage points. While this pilot is not intended to test differences between the intervention and control groups, a t-test comparing means across groups (for example, on frailty scores) requires a large effect (corresponding to a Cohen's d of 1.0) to achieve 80% power, assuming 80% follow-up.

To describe acceptance of the intervention among those randomized to intervention, mean and 95% confidence intervals will be provided for the number of sessions attended and overall satisfaction with the intervention. Compliance with the study protocol will be described the percent and 95% confidence of participants completing the study follow-up evaluation (of all participants). Estimates of intervention effects will be described through odds ratios and 95% confidence intervals for any falls during the intervention period, using logistic regression to control for baseline fall history. Mean differences and 95% confidence intervals for physical function score at the end of the study period, controlling for baseline physical function score, will be estimated through linear regression models.

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