Study Protocol for a Pilot Randomized Trial of a Virtual Occupational Therapy Fall Prevention Intervention for People With HIV and Alcohol Use

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ABSTRACT

BACKGROUND: People living with HIV (PLWH) are at risk for falls due to polypharmacy, unhealthy substance (risky alcohol and/or illicit drug) use, low physical activity, and frailty combined with typical age-related physical changes. Fall prevention is needed to reduce the morbidity related to falls and fractures, however, there is a paucity of data on the design of a fall prevention intervention and whether it can be delivered virtually. We describe the protocol of a pilot randomized trial of a virtual occupational therapy fall prevention intervention for people with HIV at high risk for falls and recent alcohol and/or drug use.

METHOD: PLWH will be recruited from the Boston ARCH 4F Cohort study, an observational study of PLWH to examine the impact of alcohol on falls. Trial participants will be randomized to either an occupational therapy-led fall prevention intervention or provided with written education about fall prevention and alcohol use (control). The 10-week fall prevention intervention was based upon results from qualitative interviews with PLWH about falls and will consist of weekly virtual group sessions, home exercises and phone-check-ins, delivered by occupational therapists. The primary outcome measures will be number of groups attended and a participant-completed satisfaction survey. Change in number of falls, alcohol and other drug use, and physical functioning will be examined.

DISCUSSION: A virtual occupational therapy fall prevention intervention addresses the emerging concern of fall risk in PLWH and alcohol use. This pilot study will provide preliminary estimates of fall-related outcomes as well as feasibility of study procedures for a larger trial.

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Introduction

Improved access to highly effective antiretroviral therapy has increased the life expectancy of people living with HIV (PLWH).[1] It is estimated that half of the PLWH are 50 or older[2] and PLWH, who adhere to an antiretroviral treatment regiment, can live well into their seventies.[3] This change in life expectancy has shifted the treatment of HIV infection from the acute care of AIDS-related infections to the management of HIV-associated chronic conditions such as diabetes,[4] hypertension,[5] and cardiovascular diseases.[6]

Falls are an emerging area of concern in PLWH. Up to one-third of middle-aged people living with HIV experience a fall each year, a rate similar to older adults.[7] People with unhealthy substance use (risky alcohol and/or any illicit drug) are over-represented among PLWH[8] and it is well-established that falls and resulting injuries are associated with unhealthy substance use.[9,10] Illicit drug use increases the odds of falling twofold in men living with HIV.[11] Additional risk factors such as polypharmacy, low physical activity, and frailty[7,11,12] combined with typical age-related physical changes contribute to high fall risk. Falls can lead to devastating consequences, such as fractures and costly hospitalization events due to low bone mineral density[13] found in this population. A qualitative study found that PLWH expressed concerns about falls with regard to maintaining independence and feeling a "diminished sense of self."[14] Therefore, it is critical to develop a tailored preventative intervention to reduce falls and related morbidity effective for PLWH.

Efficacious fall prevention interventions exist for older adults, focusing on exercise[15,16] and home modification.[17,18]

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However, these fall prevention interventions generally do not encompass the risk factors specific to PLWH whose alcohol or drug use contributes to falls. Moreover, many existing fall prevention interventions that take place in community centers and senior centers are underutilized. Virtual interventions have the potential to increase accessibility and serve as a substitute for in-person sessions. Virtual interventions and mobile health tools have previously been leveraged to address stigma against PLWH,[19] antiretroviral medication adherence,[20,21] and smoking cessation[22] in PLWH. Whether a virtual fall prevention intervention customized to the needs and concerns of PLWH at risk of falls is effective remains unexamined. The purpose of this paper is to describe the protocol of a pilot randomized trial of a 10-week virtual intervention aimed at reducing fall risk for PLWH with alcohol use. The objective of the pilot trial is to assess feasibility for the design of a larger trial. Acceptability of the intervention will be assessed with measures such as the number of weekly virtual group intervention sessions attended and a participant-completed satisfaction survey. A secondary objective is to generate preliminary data on potential outcomes of a larger trial including number of falls, physical functioning, and substance use.

Methods

Study design

This is a pilot randomized trial of a fall prevention intervention for PLWH to reduce falls. Up to 50 participants will be recruited from the Boston ARCH Frailty, Functional Impairment, Falls, and Fractures (4F) Study and enrolled in the pilot fall prevention intervention. The Boston 4F study is a longitudinal cohort study which focuses on HIV-associated comorbidities in persons living with HIV with a range of alcohol and/or illicit drug use. Participants in the Boston ARCH 4F study (n = 251) are adults with documented HIV infection in their medical records and (i) risky alcohol use[23] (AUDIT-C score of ⩾3 for women, ⩾4 for men), (ii) any illicit drug use in the past 12 months, or (iii) enrollment in the previous Boston ARCH study.[12]

Study eligibility for the fall prevention intervention pilot trial will include: (1) *any* alcohol consumption in the last 30 days measured by the Addiction Severity Index,[24] (2) fall risk measured by the CDC STEADI Fall Risk assessment form,[25] (3) access to a phone or computer with internet connection, and (4) willingness and ability to participate in a 10-week intervention with home based exercises and weekly virtual group sessions. Inclusion of a recent fall in the eligibility criterion was explored, however this would reduce the pool of eligible participants making a randomized trial not feasible. Also, the CDC STEADI Fall risk includes an assessment of whether a participant had fallen in the past year. In addition, people who have not had a fall but deemed at risk for falling may benefit from a fall prevention intervention. Participants that require a wheelchair for mobility will be excluded because the intervention focuses on increasing static standing and dynamic standing balance instead of seated balance. However, participants that require assistive devices (ie, cane) will be included in the study.

Participants in the pilot trial will be randomized to either the 10-week fall prevention intervention delivered virtually or to the control arm, which will consist of written materials on substance use and fall prevention. Written informed consent will be obtained for all participants prior to enrollment. This study was approved by the Boston University Institutional Review Board and conformed to the Declaration of Helsinki.

In-person baseline and follow-up assessment

All participants will be invited to the General Clinical Research Unit at Boston University for an in-person baseline assessment and 1 follow-up assessment 1 to 4 weeks after the 10-week intervention concludes. During the in-person assessment, a trained research assistant will administer standardized assessments to assess recent history of falls, home environment and assistive device use, prescription medications, alcohol and other drug use, and physical performance measures (grip strength, gait speed, balance, and visual acuity).

A licensed occupational therapist (OT) will administer the Canadian Occupational Performance Measure (COPM).[26] The COPM assesses participants' self-perception of their performance with activities of daily living and their satisfaction with the level of their ability to perform activities of daily living. The COPM is administered as a semi-structured interview in which participants are encouraged to identify problems in self-care, productivity, and leisure. Participants rate the importance of the identified concerns on a 10-point scale from "not important at all" (score of 1) to "extremely important" (score of 10). Participants then rate their performance and satisfaction on the identified concerns on a 10-point scale with higher scores reflecting better performance and satisfaction. For participants randomized to the intervention, the COPM findings will be used to inform the virtual group topics by identifying which areas of activities of daily living are priorities. The COPM demonstrates moderate test-retest reliability and discriminant validity.[27]

Randomization

The pilot will consist of several waves, with 6 to 20 participants enrolled during each wave. In each wave, after at least 6 participants have completed an in-person baseline assessment, between 2 and 4 weeks after the first participant's in-person baseline assessment, participants will be randomized into either the intervention or control group using an automatic REDCap randomization module. A minimum of 6 participants was determined to be the least number of participants to enroll so that the intervention group will have at least 3 participants. Participants will be randomized into the intervention or control

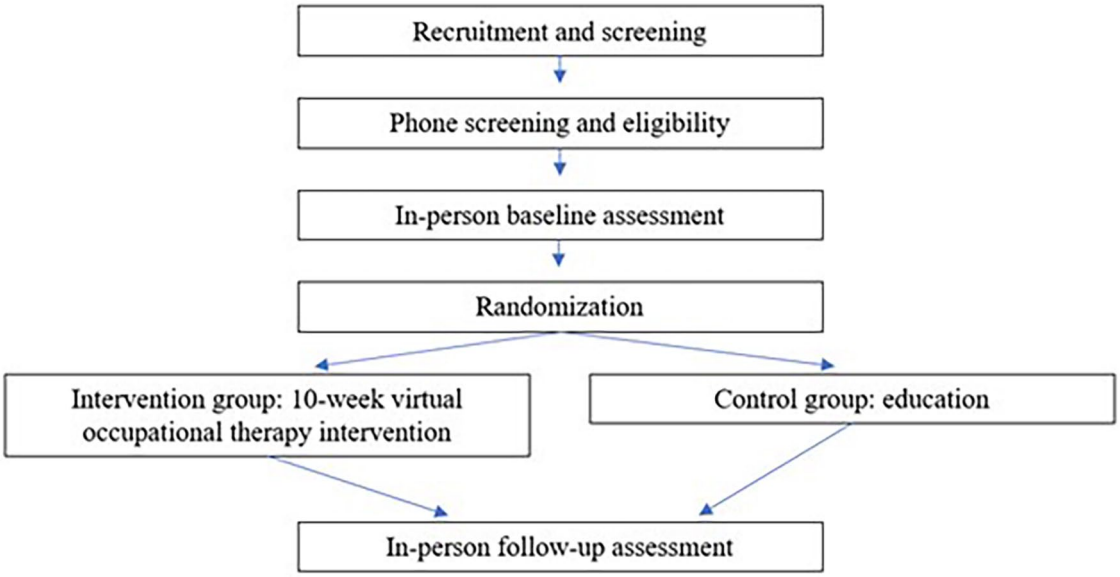

Figure 1. Flow chart of study design.

group using a 1:1 ratio with sex as the determining factor. Participants will be informed of their group assignment by study staff via phone call. During the phone call, they will be asked to provide their schedules for differing components of the intervention and to confirm that their availability did not change since the baseline assessment.

Design of the fall prevention intervention

The 10-week fall prevention intervention will consist of 3 components: a 30 to 60-minute virtual group, a customized home exercise program, and a weekly phone check-in (Figure 1).

Given the paucity of data on fall prevention in PLWH with alcohol use, the design of the fall prevention intervention was based upon findings from qualitative interviews conducted with participants enrolled in the Boston 4F study to explore their perceptions of the causes of falls in PLWH. The interviews were conducted prior to the pilot randomized trial in January of 2020. Participants were purposively selected for those who had a history of multiple falls. Maximum diversity was achieved by considering participants' severity of falls, substance use, identity, and age until saturation was reached to inform content for focus groups. Five homogenous, 90-minute focus groups were held with participants representing diverse demographics to explore their interest in participating in a fall prevention intervention and to inform intervention development for acceptability and feasibility with this population. Focus group data were analyzed via constant comparative analysis and triangulated with key informant interviews and the literature. Data were analyzed to inform the intervention content and structure/format.

The virtual nature of the focus groups provided some information about the feasibility of delivering a fall prevention intervention remotely because all focus group participants were able to participate by phone. Participants expressed concerns about falls and their interest in interventions to reduce fall risk. They also expressed enthusiasm for a virtual fall prevention intervention because a virtual format would eliminate problems with transportation to an in-person intervention. In fact, several participants reported that transportation problems might preclude participation in a face-to-face fall prevention group.

Other findings from the interviews revealed 5 major themes regarding participants' perceptions about falls. First, participants felt that grip strength and decreased balance were contributing to their falling. Second, falls related to substance use were perceived to be different than those caused by difficulty with balance. Falls precipitated by substance use were deemed to be less serious and were not thought of as possible causes of injury, highlighting the need for balance and strength exercises. Third, participants that had adaptive equipment recommended or prescribed from their medical providers reported they did not use them because they did not deem the equipment to be useful, accessible, or affordable. As participants experienced periodic homelessness, walkers and canes were lost and could not be replaced. This information was used to ensure that the home exercises in the fall prevention intervention could be performed with minimal equipment and as body weight exercises like pushups. Fourth, socioeconomic challenges and structural barriers limited participants' ability to improve their fall risk status. Participants were under-resourced, food and housing insecure, and had limited access to rehabilitation services like occupational or physical therapy. Lastly, the focus group findings indicated that participants had a strong desire to take part in an intervention, an interest in the intervention including both group and individual coaching components, and a need for participating in a social network. A team of 3 occupational therapists integrated the results of the analyses to create the fall prevention intervention.

Virtual group

The virtual group sessions will be facilitated by licensed occupational therapists trained in group theory and facilitation as well as behavioral health and fall prevention. The group sessions will take place on the HIPAA compliant Zoom platform. Social learning theory will be used as the theoretical basis for all group sessions.[28] Situated learning theory, derived from social learning theory, posits that behavior results from the interaction between the person and the situation.[29] The learner is placed in contexts that allow for simulated and actual application to everyday situations (the virtual group and practicing within their homes). Peers enhance the learning experience with feedback. In social settings, the learner gains motivational support from others and access to both collaboration and expertise, which increases opportunities to acquire and apply new knowledge. Group participants with various functional levels related to fall risk are likely to benefit from others' experiences of completing intervention activities (home exercises and phone check-ins) by identifying effective strategies used by their peers. The virtual group will allow participants to provide peer support to one another. Peer support posits that people who have faced adversity can provide mentorship through support and encouragement to others facing similar situations.[30]

During each week of the intervention, the virtual group will be centered around a discussion topic derived from the qualitative analyses that is relevant to falling in PLWH with substance use (see Table 1). Along with the formative qualitative analyses, the selection of group discussion topics will be informed by the COPM. The facilitating OTs will correct any misinformation that may arise during free-flowing conversations and redirect conversations to the topic of the week. The purpose of these discussions will be to provide a forum for participants to share their experiences with the intervention, discuss any falls from the previous week related to the topic, and to identify strategies that may address any challenges. The discussion will begin with the facilitating OTs checking in with each participant to provide a structured opportunity for every participant to speak at least once in the group. For example, "please identify one exercise you enjoyed this past week and one that was more challenging." This structure will allow participants to disclose possible challenges in a safe, structured way and to alleviate any discomfort in initiating conversation about the topic. This structured method will encourage the participants to detect commonalities and to provide validation and affirmation to one another.

Table 1. Virtual group schedule.

WEEK	TOPIC

Week 1	• Introduction
	• Ground rules for Virtual Zoom Group
	  ◦ Collaborative effort to create safe space to share
	• Exercises
	  ◦ Grip Strength
	  ◦ Balance
	  ◦ Strength
	  ◦ Endurance
	• Reminder about phone check-in schedule

Week 2	• Environment
	  ◦ Home
	  ▪ Clutter
	  ▪ Railings
	  ▪ Rugs
	  ▪ Poor lighting
	  ◦ Community
	  ▪ Weather conditions
	  ▪ Stairs
	  ◦ Social
	  ▪ Neighbors
	  ▪ Stigma
	  ▪ Friends

Week 3	• Reminder system
	  ◦ Phone calendar application
	  ◦ Alarm system on phone
	  ◦ Daily planner/calendar

Week 4	• Substance use (risky alcohol and/or illicit drug use)
	  ◦ Alcohol anonymous
	  ◦ Narcotics anonymous

Week 5	• Medication management ◦ HIV medication

Week 6	• Support System
	  ◦ Family
	  ◦ Neighbors
	  ◦ Peers

Week 7	• Community reintegration following COVID-19
Week 8	• Managing relationships
Week 9	• Adapting environment or equipment

Week 10	• Instrumental activities of daily living
	  ◦ Shopping
	  ◦ Meal prep
	  ◦ Laundry
	• Feedback on fall prevention intervention
	• Debrief

Home exercise program

Participants will be asked to engage in a 30-minute home exercise program 3 times a week for the duration of the intervention. The selected exercises will be focused on increasing strength, balance, and endurance and will be informed by the results of the quantitative analyses. The type, intensity, and frequency of the exercises will be determined by the OT. Since client factors (body structures/functions), contexts (environmental factors), and performance skills (motor skills) are part of the OT practice framework,[31] OT is uniquely qualified to provide exercise recommendations that are customized to each participant's ability. The exercises include air squats, burpees, bicep curls, shoulder presses, and single leg stands all modified to each individual's needs, skillset, and available resources. The qualitative findings demonstrated that participants were under resourced, therefore the equipment required for the exercises, if any, will be everyday household items. For example, a participant that does not have access to handheld weights or

kettlebells will be asked to perform bicep curls with a can of food or a jug of milk. If a participant has difficulty completing burpees, the OT will suggest laying prone on the floor and returning to their feet in a slow, controlled manner.

During the first virtual group session, an OT will describe and demonstrate the exercises. If a participant cannot complete an exercise, the occupational therapist will provide ways to modify the exercises. As participants' strength and balance abilities increase, the occupational therapist will continuously increase the difficulty of the exercises as appropriate.

Weekly phone check-ins

An OT will call each participant in the intervention group once per week following the virtual group sessions. Participants will be asked about their frequency of exercising, possible difficulty with the exercises, and potential modifications. After the conversation about exercising, participants will be asked about falling and any changes in substance use behavior. Lastly, participants will be asked if they would like to debrief about the previous virtual group sessions. The phone check-ins will provide participants with an opportunity to ask questions or to provide feedback in a one-on-one setting about anything that they were reluctant to raise during the group sessions.

Outcomes Measures

Primary outcome

Acceptability of the intervention will be assessed with the number of weekly virtual group interventions and weekly phone check-in sessions attended out of 10. Satisfaction with the intervention will be measured using the CSQ-8,[32] which includes 8 items that yield a single score measuring overall satisfaction. The 8-items are all assessed using a Likert scale ranging from 1 to 4, with higher scores indicating greater satisfaction.

Secondary outcomes

Short physical performance battery (SPPB). The SPPB is a validated functional assessment which assesses everyday movements such as gait speed and balance while performing different movements and sitting/getting up from a chair.[33] This tool demonstrates high validity and reliability.[34] Participants in the intervention group are expected to improve their SPPB scores via completing the exercises focusing on balance and cardiovascular endurance. The SPPB will be administered by trained members of the research team.

Grip strength. Grip strength will be measured using a handheld Jamar dynamometer. Both hands will be tested 3 times, alternating between the 2 hands. Since grip strength was identified as being linked to falling during the qualitative analysis, it is included as an outcome of interest. We expect participants in the intervention group to improve grip strength by completing a variety of exercises prescribed for the home exercise program.

Fried frailty phenotype. The Fried et al Frailty phenotype[35] identifies a phenotype of frailty based on the presence of 3 or more of the following components: (1) unintentional weight loss of ⩾10 pounds in the prior year or ⩾5% of body weight in prior year; (2) grip strength in the lowest 20% at baseline adjusted for gender and body mass index; (3) poor endurance and energy as indicated by self-report of exhaustion; (4) slow gait speed based on time to walk 15 feet as the slowest 20% of the population as defined at baseline; and (5) low physical activity level as indicated by self-report.

Alcohol and other illicit drug use. The fifth edition of the Addiction Severity Index (ASI) will be used to quantify past 30-day use of alcohol, illicit drugs, and prescription medications not prescribed or more than prescribed.[36,37]

Statistical analysis

The primary aims of this pilot study are to establish feasibility of the proposed intervention and study procedures and to gather preliminary data on fall-related outcomes. To describe acceptance of the intervention, the average number of sessions attended and CSQ-8 scores on satisfaction with the intervention will be used. Estimates of intervention effects will be made with odds ratios and 95% confidence interval for any fall experienced during the intervention period, using logistic regression controlling for number of falls at baseline. Mean differences and 95% confidence interval for change in physical function scores and grip strength will be estimated with linear regression models controlling for baseline measures of the outcomes. Number of days with any alcohol and/or drug use at the end of the study period will be analyzed with regression models for count data, with the choice between Poisson, negative binomial, and zero-inflated Poisson models depending on the distribution of these outcomes.

We aim to randomize 40 participants, approximately 20 to the study intervention and 20 to the control group. This study 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 the mean number of sessions attended for those participants randomized to the intervention, will have a width of 0.44 standard deviations. Assuming that approximately 80% of the 40 study participants complete the follow-up visit, a confidence interval for the percent completing the study will have a width of 12 percentage points.

Discussion

The pilot randomized trial will test a novel fall prevention intervention for PLWH with alcohol use who are at risk of

experiencing a fall. The trial is unique in its combination of multiple components (ie, a virtual group intervention, home exercise program, and phone check-ins). The trial includes aspects of fall prevention interventions that have been effective in other populations such as exercise and home modifications. However, it is novel in the use of a virtual participation format and exercises that are tailored to the needs of under-resourced, vulnerable populations.

For this population, a holistic intervention is necessary to reduce falls due to the high number and variety of fall risk factors and possible solutions. Variability in their access to resources and unstable housing may prove to be challenging in implementing a traditional fall prevention intervention. However, our customized exercises are designed to be accessible regardless of participants' environments. Since participants may have unstable housing conditions, weekly virtual groups and phone check-ins present the opportunity for continuously tailoring home modifications to participants' surroundings.

With regard to alcohol use, one of the goals of the intervention is to reduce risky alcohol consumption to levels less likely to result in a fall. The overall strategy will be to identify areas—such as levels of functioning for self-care, productivity, and leisure—that participants are dissatisfied with—and discuss how alcohol (and/or illicit drug use) might be related to these areas of concern. This will be addressed in weekly group sessions and individual phone check-ins with the OT. Participants will be encouraged to share strategies to limit negative consequences of alcohol use which may include limiting alcohol intake or visiting support groups. For participants not interested in reducing alcohol consumption, a "harm reduction" approach will be used to reduce risk for injuries instead of focusing on alcohol consumption patterns. Previous literature demonstrates that harm reduction approaches can be as effective for reducing alcohol-related morbidity.[38]

The intervention incorporates components that are within the scope of occupational therapy practice. For example, occupational therapists commonly address home modifications as part of clinical practice and in fall prevention interventions for older adults.[39,40] The use of an occupational therapy lens to construct an intervention that blends existing knowledge from previous interventions with qualitative and quantitative data from PLWH and substance use is a strength of this trial.

Successful exercise programs prioritize compliance[41] and supervision,[42] which are often difficult to maintain in a vulnerable and underserved population.[43] This intervention was created to intentionally address the need for home modifications and difficulty with compliance via weekly virtual groups and phone calls. The information from previous trials used to shape this intervention came from a variety of disciplines. The current trial was interdisciplinary and included researchers from multiple disciplines including occupational therapy, public health, rehabilitation science, and biostatistics. Thus, this trial contributes to the current literature extolling the importance of interdisciplinary teams when tackling large questions related to rehabilitation.[44,45] This trial will generate valuable information to implement a larger intervention trial to reduce fall risk in PLWH.

Author Contributions

All authors contributed to the design of the study, critically revised the manuscript for important intellectual content, and approved the final manuscript.

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