Title: "Once 'Stepping On" Ends: Continuing a Group Falls Prevention Program via the Internet

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Project Summary:
Falls, and their associated hospitalizations and entry into long-term care, pose a critical and costly public health issue that will increase as Wisconsin's population ages. Stepping On (SO) is an effective small-group program, using self-efficacy and adult learning theories and progressive exercise to reduce falls. We have disseminated SO throughout Wisconsin and the U.S. Our data show that, like other behavioral programs, post-program adherence declines without a leader, peer support and built-in accountability. Our long-term objective is to develop, demonstrate effectiveness of, and widely disseminate, an online, long-term group-based falls prevention exercise maintenance program for SO graduates. The program was initially called Keep On Stepping on (KOSO) but in early testing it was found the target group did not identity with that name and thus the name is changed for Phase 2 and forward for dissemination to Stepping Online. Our first specific aim entails the (Phase 1a.) participatory development and (Phase 1b.) pilot testing of Stepping Online. In <u>Phase 1a</u>, SO graduates, one-fourth of whom will be African American, and SO leaders and peer leaders from Milwaukee and Dane counties will inform KOSO/Stepping Online content via focus groups, interviews, and multiple cycles of prototype testing. Academic partners will adapt and integrate technologies: (a) facilitated small group and exercise sessions via Google Hangouts; (b) asynchronous support blogs, and (c) theory-based behavior change tools for SO graduates on ElderTree (a new adaptation of the Comprehensive Health Enhancement Support System—CHESS). <u>In Phase 1b,</u> we will conduct one 3-week pilot test in Milwaukee and Dane counties, with up to 20 graduates, 4 leaders and 4 peer leaders per county. Graduates will test KOSO/Stepping Online features including online fall prevention tips; SO and other fall prevention exercises demonstrated by avatars or videos with narration describing proper technique and safety precautions; guest expert video presentations with opportunity for questions and answers; user-tailored 'to do' lists with options for reminders and tracking accomplishments; feedback from coach as well as coach available for questions and answers, suggested homework; group online discussion around tips and homework; resources for fall prevention; messaging (private and small group) to other SO participants/graduates and leader/peer leader and coach; and opportunity to use Google Hangouts to meet online in dyads or triads with other KOSO participants to do balance and strength exercises.

Analysis of pilot data from Phase 1a:As expected with the formative evaluation phase of any educational program development that engages end-users, we have learned about barriers to our proposed program interface and research plan. We have modified the KOSO/Stepping Online curriculum, which we believe will make Stepping Online be more easily maintained and disseminated. These modifications have not altered our specific aims or the scope of the research.

(1) <u>Delivery of </u>Stepping Online/**KOSO curriculum:**
   a. *Barriers:*
  Online exercise sessions: Google Hangout's interface was found to be confusing and both GOOGLE HANGOUTS and Google Hangout have limited capacity to accommodate more than 3-4 computers at a time. In addition leaders and peer leaders were reluctant to commit to leading real time exercise and online learning sessions.

   b. *Modifications:* Since only Google Hangouts includes a feature that permits recording, and recording Google Hangouts exercise sessions will be valuable for assessing safety, we will use Skype for the pilot. Both Google Hangout and Google Hangouts are continuously revising their interfaces. We will continue to assess which is easier for SO graduates to use for the final program. Additionally, rather than planned exercise sessions lead by leaders/peer leaders, graduates will be encouraged to form dyads or tryads with fellow group members to meet together to exercise. Safety will be assessed in the pilot. In addition Stepping Online/KOSO will be built on the Elder Tree platform. Gustafson (research collaborator) is completing a randomized trial of Elder Tree in Wisconsin. Elder Tree provides facilitated online learning forums, self-management tools, and information for several topics including falls prevention (for non-Stepping On graduates). The Elder Tree fall prevention coach (Lecey) will expand her duties as the Stepping Online/KOSO fall Prevention Coach. To date, the Elder Tree team has prototyped these new services for Stepping Online/KOSO: (1) Fall Prevention To Do List to set, track goals, get reminders, share successes and get feedback, (2) Video library

including exercise avatars and guest expert lectures with associated homework and shared learning activities. (3) We have developed online activities for each of the Stepping On topics.

KOSO/Stepping Online is being developed based on this and will be tested in the Phase 1b (3-week pilot).. After Phase 1b, we will revise KOSO/Stepping Online for Phase 2 (Aim 2) implementation. In Aim 2, we will use the RE-AIM framework [*Reach, Effectiveness, Adoption, Implementation Maintenance*] to assess the feasibility of implementing Stepping Online. We will conduct a 6-month randomized controlled trial with up to 80 SO graduates, 16 SO leaders, 16 SO peer leaders drawn from Stepping On workshops that took place in Dane, Milwaukee, Rock, Adams, Green Lake, Marquette and Waushara counties. Quantitative and qualitative measures will assess reach to SO participants, adoption by SO leaders, implementation fidelity and barriers, and participant maintenance of exercise and behavior change. Preliminary data on effectiveness, measured with validated instruments, will frame a proposal for a large, multi-site randomized control trial to test Stepping Online's effects on falls, physical performance, balance, falls risk behaviors, quality of life, exercise self-efficacy, and loneliness. Our proposal strongly aligns with WPP's mission.

Background and Significance:

Background: One-third of older adults fall each year, resulting in costly, debilitating outcomes that threaten independence. Wisconsin's population is becoming older, more isolated, and vulnerable to falls that lead to hospitalization and entry into long-term care.[1] Falls prevention programs using social cognitive learning and progressive balance exercises reduce falls among older adults.[2,3, 4] As Wisconsin's population ages, preventing falls will be ever more crucial.

Stepping On (SO), an evidence-based, widely used falls prevention program in Wisconsin, has effectively prevented falls by encouraging adoption of falls risk reduction behaviors, home modifications, and progressive balance and strength exercises. However, many people stop exercising and reduce their practice of falls prevention behaviors after SO ends. With CDC support, Jane Mahoney, MD (PI) has researched and disseminated **Stepping On (SO)**,[5] an evidence-based, small-group, multi-factorial, seven-week falls prevention program throughout Wisconsin and nationally over the past eight years. Our pilot research found that, similar to other self-management programs,[6] falls preventions *behavioral maintenance—especially exercise—was difficult* after SO ended. New real-time, video-enabled social media, like GOOGLE HANGOUTS and Google Hang Out, foster connection,[7, 8] and reduce age-related social isolation due to mobility and travel limitations.[9] Older adults are the fastest growing group of Internet users,[10, 11] and our pilot testing found that older adults embrace web-based tools to learn about falls prevention and to participate in video-enabled Google Hang Out group discussion and exercise.

Preliminary data: Four pilot studies demonstrate the importance and feasibility of this proposal:
1. *Barriers and facilitators to maintaining SO behaviors: Implications for e-Learning***:** 35 SO graduates completed a survey and participated in a focus group (n=19) or individual phone interview (n=16). Grounded theory analysis found that SO's fun, face-to-face engagement with peers, a leader who individualized the exercise regimen, and the active learning and accountability built into the weekly sessions, were key to adopting SO's falls prevention behaviors.[12] However, without these features, similar to other self-management programs,[13] *behavioral maintenance—especially exercise—was difficult* after SO ended. (Notably, graduates who lived in the same apartment complex did their daily SO exercises together.) In fact, graduates adopted home and outdoor safety behaviors, but maintaining exercise was more challenging—about half were doing their daily SO exercises three to 6 months post SO, citing the loss of group connection, motivation, and accountability. [14]
2. *On implementation and dissemination in Wisconsin:* With CDC and AOA support, Wisconsin through its county-level Aging and Disability Resource Centers has offered 420 SO workshops in 59 counties to 3,765 older adults since 2008. Pre-post workshop fall risk behaviors (FaB scale) improved significantly, but from post-workshop to 8-month follow-up, FaB scores dropped nearly to the baseline scores, significant at P= .006.
3. *Usability and pilot testing of ElderTree falls prevention tools*: Using rapid-cycle usability and pilot testing techniques, Mahoney and Gustafson engaged older adults in Dane, Milwaukee, Waukesha and Richland

counties over the course of the past 18 months to help develop ElderTree falls prevention tools. Older adults were willing to use ElderTree, were candid in what worked and what did not, and enjoyed communicating in the asynchronous blog. These tests have resulted in a simple and easy to use interface that includes falls prevention tips and video vignettes, resources for home safety, and a tailored falls risk assessment.

4. *Google Hang Out pilot test with SO graduates:* Five SO graduates participated in a falls prevention session with the lead SO trainer and 3 researchers via Google Hang Out to discuss coping with winter ice and to practice one SO exercise. In the debriefing, older adults felt that continuing SO exercises via Google Hang Out would be fun and beneficial. We observed that participants were engaged throughout the session. ***Implications:*** Stepping Online/***KOSO, a real-time web/video-enabled program, might sustain exercise, maintain FaB scores at 8-month follow-up, and ultimately reduce falls.***

We therefore will develop and test the feasibility of **Stepping Online/Keep On Stepping On** (KOSO), a long-term SO continuation program. Stepping Online/KOSO will offer real-time video-enabled online group learning and exercise (through Google Hangouts or similar technology), video animations to teach new exercises and make old ones more challenging, and tailored online falls resources from **ElderTree**, a new adaptation of the widely used and tested Comprehensive Health Enhancement Support System (CHESS) program.[15,16] Stepping Online/KOSO content will be developed and posted by a falls prevention coach who is a certified SO leader.   If this study is successful, we will conduct a Wisconsin-wide study to definitely test Stepping Online to determine if it reduces falls more than does SO alone.

Significance: Stepping Online/KOSO addresses a significant and growing public health problem in Wisconsin and the U.S. Falls among older adults are frequent and costly. In an aging society with shrinking resources, prevention and self-management will be ever more crucial—not only for falls but for multiple chronic conditions. Research across chronic conditions and the adult lifespan show that community-based health behavior change programs have positive effects on behavioral adoption, but follow-up evaluation shows that maintenance of a health behavior (and associated health outcomes) drops off substantially once the program ends.[17] [18] Relapse wastes the healthcare dollars spent on an intervention, exacting a steep price tag for individuals, caregivers and communities with increased risks for disease progression, frailty and disability.

To our knowledge, Stepping Online/KOSO will be the first web-based, video-enhanced small group behavior change and exercise maintenance program that extends the benefits of a community-based program. If successful, Stepping Online/KOSO could serve as a model for development of other long-term web-based maintenance programs to extend the benefits of short-term community exercise, cardiac rehabilitation, and chronic disease self-management programs, improving health for many older adults.

Stepping Online/KOSO, if successful, will serve public health needs of Wisconsin elders, 1/3 of who fall each year, and over 6000 of whom have already taken SO. Stepping Online/KOSO might alleviate disparities for older adults who are unable to drive and lack transportation. This research supports community-university partnerships, promotes health and might reduce injury; builds on the innovative CHESS program; accelerates use of Google Hangouts technology; supports the translation and application of an existing evidence-based program, and leverages community programs that can help it sustain.

This research, with its safety plan and its subject population who have received previous training from a health professional on how to properly perform strength and balance exercises and safety precautions, poses minimal risk to human subjects—and will provide opportunities to maintain falls prevention activities and to increase social connection of older adults

Specific Aims/Study Objectives:

This three-year study will develop Stepping Online/KOSO and test the feasibility for conducting subsequent large-scale effectiveness and dissemination studies. *Note this IRB submission seeks approval for Phase 1b*

and Phase 2 activities having received approval for Phase 1a previously

Our *specific aims are to:*

Aim 1: Develop and pilot test Keep On Stepping On (KOSO), a real-time video-enabled long-term SO maintenance program that integrates small group discussion and exercise practice with avatar modeled instructional exercise animations and falls prevention tools from **ElderTree**, a new adaptation of the widely used and tested CHESS program.[19, 20,21]   The main objectives of the pilot are to (1) learn how SO grads, leaders and peer leaders use KOSO and identify revisions needed for Phase 2 and (2) establish the safety of the exercise features in KOSO.

In Phase 1a.: We engaged Stepping On graduates, leaders and peer leaders in Milwaukee and Dane counties to develop KOSO. SO graduates participated in focus groups to help the developers identify appropriate informational content, social support mechanisms, and tools to support their long-term maintenance of falls prevention behaviors. Two sets of focus groups were held. The first set of focus groups asked questions about the overall concepts planned and the real-time video-enabled online group learning and exercise. The second set of focus groups investigated planned elements of KOSO, with the main focus on elements planned to a part of Elder Tree. Information learned from the focus groups led to investigating other planned elements of KOSO. SO graduates also engaged in rapid cycle prototype testing of KOSO components as they were developed and revised. We also engaged Stepping On leaders and peer leaders in rapid cycle prototype testing of KOSO components. The rapid cycle prototype testing was a non-research activity to improve design and reveal any bugs in the system. (Months 1-16)

In Phase 1b.: After bugs are fixed, a 3-week pilot test will be held during which SO leaders, peer leaders and graduates will access KOSO on Elder Tree and will try out the features. Content such as falls prevention information, guest expert presentations, video exercise demonstrations, goal-setting, questions and answers and private messaging options will be continuously be developed during the trial as was done in Elder Tree research. If interested, they will also pilot use of Google Hangouts to exercise with one or two other SO participants from their class. (The original plan was to pilot the evaluation measures to use in Phase 2, however since Phase 2 is also a pilot for a larger randomized trial proposal, it was decided that testing the measures did not need to occur in the 3 week pilot and would present too much burden for pilot subjects, given their other evaluations regarding KOSO satisfaction and safety with KOSO use.

Aim 2. Conduct a 6-month study to test the feasibility of conducting a large randomized control effectiveness trial of Stepping Online and a subsequent dissemination study.

We will identify SO workshops that are planned to begin within our designated few week enrollment timeframe and invite leaders and peer leaders of these groups to take part in the Stepping Online randomized trial. For groups with either a leader or peer leader (or both) interested in participating, we will obtain educational level information of participants (without identifiers) from baseline surveys that are completed by participants at the start of each SO class as part of the SO program. The average educational level of participants from each SO class will be determined and used to pair groups, matching on educational level, for randomization by group, to control (no maintenance program following SO) or Stepping Online intervention. We plan to enroll up to 80 SO graduates, 16 SO leaders, 16 SO peer leaders drawn from Stepping On workshops that took place in Dane, Milwaukee, Rock, Adams, Green Lake, Marquette and Waushara counties. The number of pairs of groups will depend on how many enroll from a group. We anticipate that 5 SO participants will join the RCT per SO group, and we will continue pairing and randomizing until we reach the desired number.

We will use the RE-AIM framework (*Reach, Effectiveness, Adoption, Implementation, and Maintenance)* to inform a proposal for a larger randomized control trial to test Stepping Online's effects on falls, balance, physical performance, falls risk behaviors, quality of life, exercise self-efficacy, and loneliness. Our sample will be too small to detect significant between-group differences; however we expect to see trends showing Stepping Online's ability to improve these measures, compared to the control group.

Research Design and Methods:

This research is an academic/community collaboration. Academic partners include faculty and researchers at the University of Wisconsin-Madison. Community partners include Safe Communities of Madison/Dane County, the Milwaukee County Department on Aging, the Rock County Council on Aging and the Aging and Disabilities Resource Center of Adams, Green Lake, Marquette and Waushara counties, which coordinate Stepping On in their respective counties. Each county Stepping On coordinator will facilitate the research team connecting with Stepping On leaders and participants/graduates to participate in Stepping Online development and study activities. County coordinators and others representatives of the counties have been added to the research team so they may help with recruitment in Phase 2. The same procedure will be used as Phase 1b. Recruitment will be conducted by a research team member, either from UW or from the community site.

The phased research activities include:

1. Phase 1: (a): KOSO development and (b): KOSO pilot tests
2. Phase 2: Feasibility testing (group randomized control trial)

The research activities and the samples differ for each aim.

Aim 1 (Phase 1a. (ongoing)

Study population:

a. **Stepping On Graduates**
might participate in focus group, and rapid cycle testing in Phase 1a.,

Inclusion criteria:
Set 1 Focus Groups (completed): Inclusion criteria for Stepping On graduates is having completed Stepping On (attending at least 5 of the sessions) within the past 6 months or will complete in the next 4 weeks, and either attended or plan to attend their group's booster session (or wanted/want to but it was/is not possible).
Set 2 Focus Groups: Stepping On graduates who have indicated to research staff they are willing to be contacted to help with KOSO development and have provided contact information.

Exclusion criteria:
Set 1&2 Focus groups: Exclusion criteria include not available during the study timeline or is hard of hearing (making participation in a group discussion difficult)

The purpose of the focus groups with Stepping On graduates is to inform the development of KOSO. The purpose of the rapid cycle prototype testing is to observe first hand and to hear reactions from Stepping On graduate how different features of KOSO work and how they could be improved.

Procedures:
Set 1 Focus Groups (completed)*: Invitation:* We will follow procedures used in our previous exploratory research with Stepping On graduates.
- SO leaders in both counties, whose classes meet the criteria for participation will be asked by the SO coordinator for their county to send a letter with a self-addressed (to the county coordinator), date-sensitive opt-out card to all people who graduated from Stepping On within the prior six months—along with addressed envelopes. The leader will sign each letter. *The*

letter will explain the purpose of the research and the research and non-research activities (focus group and prototype testing). The letter will ask if they are willing to have the leader share contact information with the study coordinator, who will call them to explain the project, invite them to participate and answer any questions they may have. The letter will explain opt-out procedures and inform them that someone from the study may call them after a certain date.

County coordinators will provide contact information to the study coordinator to all people who did not opt out

Recruitment and consenting via telephone:

Set 1 Focus Groups (completed): We will recruit, consent and enroll up to 24 Stepping On graduates (up to 12/county).

The Research Scientist will call potential participants from both Dane, and Milwaukee counties. For Milwaukee county, she will preferentially recruit participants from class sites in African American communities.

She will use a screening/recruitment script to:
- Introduce herself,
- Remind them of the letter they received from their Stepping On leader,
- Ask if it is a good time to talk.
- Confirm when they graduated
- Describe the study and Phase 1a research activities (focus group)
- Ascertain interest in participating in our research. Whether they attended or are planning to attend the booster (and if not why). If the informant is not planning to attend the booster, because they are not interested in continued contact with SO, say thank you and end the call. This person will not be invited to participate in study activities.
- If interested:
  - Describe risks, benefits and how confidentiality is maintained.
- Schedule them into a slot for the focus group
- Mail copy of consent form
- Send a confirmation of the appointment with the consent form to the subject.

Set 2 Focus Groups: (ongoing) We will recruit, consent and enroll additional Stepping On graduates from Dane, and Milwaukee counties to potentially enroll up to 60 total SO graduates for Sets 1&2 focus groups.

Invitation: Using a list of Stepping On graduates that were contacted for the rapid cycle testing, research staff will contact graduates who have already indicated they were willing to be contacted to help with KOSO and have provided contact information (phone number, email address or mailing address). They will be contacted by phone or email.

Focus Group:

Set 1 Focus Groups (completed): We will convene one focus group of SO graduates in each county.

Participants: 8-12 will be recruited (see above)

Set 2 Focus Groups: We will convene up to 10 additional focus groups in Milwaukee, and Dane counties.

Participants: 6-12 will be recruited for each focus group meeting.

Sets 1&2 Focus Groups:
The study office will place a reminder call the day before the focus group.

Focus group staff: 1 KOSO researcher will facilitate, 1 KOSO researcher will demonstrate aspects of the planned intervention, and 2 KOSO researchers will observe and take extensive notes.

Mahoney - Stepping Online Ph 2b SO Participant consent 8-11-16docx.docx

Prior to beginning the focus group, research staff will meet individually with the graduates to review consent forms and obtain signatures for informed consent. Participants will be asked to complete the brief demographic survey.

The Focus Group meeting will be audiotaped. After brief introductions and an overview, the activities will include a demonstration, and eliciting ideas about how the following KOSO features might be used for long-term fall prevention behavioral maintenance.

- Real-time Google hang Out with a Stepping On leader
- Exercise avatars
- Information
- Social support

If time permits, participants may be offered the opportunity to try out aspects of some planned elements of KOSO such as exercising with others online, accessing falls prevention information and videos, etc. (Set 1 Focus Groups only)

We will also ask their ideas about transitioning from SO to KOSO

We will wrap up and provide opportunities for participants to express interest in testing prototypes of KOSO features as they are developed.

All informants who have completed the focus group will be sent a thank you letter, reminding those who have expressed interest that we might call them to participate in prototype testing and $20.

After analyzing focus group data with rapid qualitative content analysis, the KOSO development team will identify how existing ElderTree and/or SO features could be adapted, what topics should be covered in group Google Hangout sessions, what self-guided exercise avatar animations might, or might not, be appropriate for KOSO, and what the training should contain.

Prototype Testing: We will use a non-research development process used by CHESS that entails three waves of testing prototypes of Stepping Online's /KOSO's content, Google Hangout/Google Hangouts configurations, avatar animations, and adaptations of ElderTree tools. Developers will observe and debrief SO graduates as they navigate through a pre-determined series of tasks, and then interview them about suggested improvements, which will be incorporated for the next test. The final tests will also include testing orientation and training materials for learners.

b. Stepping On leaders and peer leaders for Phase 1a. Activities (completed):

Interviews
We will conduct in-person interviews with 4 Stepping On Leaders and 4 Stepping On Peer Leaders (2 each from each county).

Leaders:
Phase 1a:
Inclusion criteria for leaders include being an experienced Stepping On leader in Dane or MKE county who:
1. has led at least 2 Stepping On workshops in the previous year
2. is identified by the county coordinator as one of their best Stepping On leaders and
3. has a computer and is at least moderately comfortable using technology (such as doing online searching, using social media such as facebook or Google Hangouts
4. Willing to participate in KOSO development

Peer Leaders:
Phase 1a:
Inclusion criteria for Peer leaders include being an experienced Stepping On peer-leader in Dane or

Milwaukee county who has peer-led a SO workshop within the previous year.

Exclusion criteria for leaders and peer leaders: Is not available during study timeline

Invitation:
- Leaders: Each county SO county coordinator will identify 2-3 Stepping On leaders to potentially participate in a KOSO interview and provide the study coordinator with contact information for those who agree to be contacted for more information.
- Peer Leaders: Each SO county SO coordinator will identify 2 peer leaders to potentially participate in a KOSO interview and provide the study coordinator with contact information for those who agree to be contacted for more information.
- Names and contact information will be passed on to the research scientist.

Recruitment by telephone: The research scientist will then call the SO leaders and peer leaders. She will explain the interview. She will describe risks, benefits and how confidentiality is maintained. If the potential subject agrees, the research scientist will then schedule an in-person interview.

Prior to beginning the interview, research staff will review the consent form with the subject, answer any questions, and obtain a signature for informed consent.

One audio-recorded in-person interview with 4 SO leaders (2/county) and 4 peer leaders (2/county): We will explore what contributes to a great group session, barriers and facilitators they observe to adopting (and maintaining) exercise, the promises and pitfalls of translating SO to an online KOSO program including demonstrating some features, and a wish list of technological features for leading a KOSO group. The interviews will take place in a private room in public building that is convenient for the leaders/peer-leaders. This will be determined when subjects have been identified.

Interview, focus group usability data analysis:
Our goal for the qualitative and observational data analysis is to inform the development of the Stepping Online/ KOSO intervention. Therefore, our analysis must be rapid and focused. The qualitative researcher will lead the UW researchers to identify themes using a priori and exploratory approaches. Examples of a priori themes are shown in column 1 of the Table 1. Exploratory themes will add rich dimension to the key themes, and are shown in columns 2 and 3 as barriers/challenges or facilitators/strategies. Implications for Stepping Online/KOSO development, shown in column 4, represent the interpretation of the data in columns 2 and 3. We will test and refine the implications in the rapid cycle testing activities.

Table 1. Grid to Guide the Qualitative Analysis

	Barriers/ Challenges	Facilitators/ Strategies	New Dimensions	Implications for KOSO
Falls Prevention				
Exercise				
Problems solving				
Aid and devices				
Home Safety				
Stepping Online /**KOSO Features and Issues**				
Information and tips				
Guest Experts				
Google Hangouts				
ElderTree features				
Exercise Avatars				
Asynchronous Social Support				
Online support for behaviors				

Mahoney - Stepping Online Ph 2b SO Participant consent 8-11-16docx.docx

Exercise				
Safety				
Transitioning SO- Stepping Online/KOSO				
Sessions scheduling				
Technology Use				
New Themes				

Stepping Online/ **KOSO Intervention Development:**

Researchers will integrate SO participants' and leaders' suggestions for the focus groups, interviews and rapid cycle prototype tests into a coherent technological and theoretical framework. Table 2 displays how the integration of 3 technologies supports Stepping Online /KOSO goals: **(1)** Google Hangouts, a real-time video-enabled application that can connect up to 3 computers, **(2)** ElderTree's information and interactive learning tools will be tailored for SO graduates; **(3)** Animations that use realistic modeling and have been found to be as effective as live modeling and therapist instruction will guide exercise advancement. [22] [23] [24] [25] [26]

Table 2. Technology and Stepping Online/KOSO Features

	Google Hang Out/Google Hangouts	Elder Tree [1]			
		Information	Blog	Interactive Tools	Exercise Avatar [2]
Development					
New	■				■
Re-purpose		■			
Stepping Online/ **KOSO Features**					
Real-time Sessions of dyads or triads	■				■
Group Exercise (dyad or triad)	■				
Advance exercise	■			■	*Primary*
Social support	■		■		*Hypothesized*
Independent Learning		■	■	■	■

Stepping Online's/KOSO's theory-driven functions and features, shown in table 3, will be based on self-efficacy[27] and adult education[28] theories. Table 2 shows how the components within Stepping Online/KOSO group sessions, Stepping Online/KOSO group exercise, and the independent learning tools of ElderTree and the exercise avatar promote the theoretical behavioral maintenance processes of social modeling, motivation, habituation, accountability, destigmatization, reinforcement, and competence.

Table 3. Stepping Online/KOSO Features and Theoretical Behavioral Maintenance Processes

Stepping Online /**KOSO Activities, led by Falls Coach—Google Hangouts**							
	Social modeling	Motiv-ation	Habitu-ation	Account-ability	Destig-matize	Rein-force	Compe-tence
Composite of:	■	■	■	■	■	■	■
Information [1]	■				■		■
Storytelling	■				■	■	
Problem solving	■						■
Exercise Avatar [2]	■	■	■	■	■	■	■
ET Exercise Log [3]		■	■	■		■	■
Stepping Online/KOSO Exercise in Dyads or triads, Real-time Video—Google Hangouts							
Group Exercise	■	■	■	■	■	■	■
Independent Learning: ElderTree (ET) and Exercise Avatar							
Composite of:	■	■	■	■	■	■	■
Exercise Avatar [2]	■	■	■	■		■	■
ET Exercise Log [3]			■	■		■	■
ET Interactive Tools [4]		■	■	■		■	■
ET Blogs [5]	■	■		■	■	■	
ET Information [6]					■		■

Table 3 Legend:

[1] Stepping Online/**KOSO Information Videos**: mini lectures by guest expert, Exercise Avatar

[2] **Exercise Avatar** teaches how to progress familiar Stepping On Otago exercises, and how to adopt and progress in new Otago exercises. Avatar learning can be independent or integrated into the Google Hangouts Sessions, and tracked into the ElderTree exercise log.

[3] **ElderTree Exercise Log**: Links to other ElderTree interactive tools, like goal setting and feedback, and the Exercise Avatar. Participants can track their private or share in Stepping Online/KOSO

[4] **ElderTree Interactive Tools**: content-free infrastructure for us to develop fall-prevention exercise action plans that include (1) goal-setting survey, (2) self-tracking tools, such as an exercise log that participants can keep private or share in their Google Hangouts groups, (4) feedback with tailored information (4) reminders to email, (5) Calendar

Mahoney - Stepping Online Ph 2b SO Participant consent 8-11-16docx.docx

[5] **ElderTree Blog**: asynchronous social support blogs, organized by topic. Participants write, read and respond to others' messages

[6] **ElderTree Information**: tailored falls prevention tips, video vignettes, resources

Stepping Online/KOSO will use direct instruction, social modeling and support, goal setting and reminders, and self-monitoring and feedback tools to support self-directed learning and exercise maintenance:

(1) Continue SO's structured facilitated group learning whose absence challenged graduates' exercise and behavior maintenance. Videos from guest experts and posts from falls prevention coach will have forums for online discussion. Exercise videos using Avatars will be available for graduates to use to practice Stepping On exercises or to learn new strength and balance exercises. Falls coach's posts about exercise videos will provide forum for group discussion, facilitated by coach.

(2) Expand group exercise practice. SO graduates wished there had been more time for exercise in the weekly sessions, and felt that having the group to exercise with would facilitate exercise adherence. Stepping Online/KOSO users will be able to meet in pairs or triads to practice together using Google Hangouts.

(3) Reduce monotony of SO exercise by helping graduates advance the challenge of their original SO exercises and learn new evidence-based exercises. Like SO, we will select from broad range of evidence-based progressive balance and strength exercises that are in the public domain. Heiderscheit (co-PI) will develop and test avatar-modeled instructional exercise animations, which have been found to be as effective as live or video modeling or therapist-led instruction.21,22, 23, 24, 25,   In phase 1b, testing will consist of querying the participants regarding the importance of the avatars to learning the home exercises and to the Stepping Online/KOSO program as a whole. A physical or occupational therapist will also monitor participant safety, observing participants' exercise techniques in-person and via viewing Google Hangouts recordings.

(4) Integrate goal setting, problem-solving and self-monitoring features of ElderTree with group exercise and falls prevention learning: We will integrate existing ElderTree tools (e.g., asynchronous social support blogs, calendar, action plans, games, tips and video vignettes with Stepping Online's/KOSO's Google Hangouts platform, and exercise animations, building new content specific to SO graduates. Gustafson (co-PI), Wise (collaborator) and Gustafson, will lead this effort based on their expertise in developing innovative features for CHESS programs. New content will include ability for participants to generate exercise and home safety to-do lists, receive reminders to exercise, track their exercise performance, and receive feedback from the coach.

Rapid cycle usability testing of KOSO prototype features (ongoing):

The second part of Phase 1a is a product development (non-research) activity which consists of prototype development. We will work with the County coordinators to obtain a list of current and former Stepping On participants, leaders, and peer leaders from Milwaukee, and Dane counties who are willing to talk with KOSO developers about potentially assisting with prototype development by giving trying out and providing feedback on various stages of development using a rapid cycle testing format. This product development involves the development team (not researchers). They create a semi-functional interface and sit down with 3 to 5 users to find out whether they find it navigable and comprehensible. Depending on the results, they might do between one to three rounds of this. They will not gather any personal information for these tests, as they are just trying to get feedback on (1) the user interface (UI) and (2) the desirability of the general approach. This is a method that has been used by CHESS in development of their products and has not been considered a research activity.

Note the current IRB submission seeks approval for Phase 2bactivities.

Aim 1 Phase 1b.

Collaborating sites (not engaged in research): County coordinators for Safe Communities of Madison/Dane

County, and the Milwaukee County Department on Aging, who coordinate Stepping On in their respective counties, will help us to connect with SO leaders, peer leaders and participants.

KOSO pilot tests: We will conduct 1 pilot tests to test KOSO implementation for the randomized feasibility test in phase 2 and establish safety of KOSO exercise components.   A 3-week pilot test will be conducted simultaneously in Dane and Milwaukee counties.   Conducting the pilot simultaneously in both counties will provide a larger pool of subjects interacting on the site, thus more activity and better data. Revisions will be made for Phase 2 based on what is learned from the pilots. Originally we planned to test the tools for the randomized trial but have decided against it since the randomized trial is a pilot also and it is too much burden for participants for Phase 1b, where we are focusing on safety and usability.

Study population:
  a. We will enroll 1-4 SO leaders, 1-4 SO peer leaders, and 10-20 SO participants per county
    1. Inclusion criteria:
      i. SO Leaders/ Peer leaders: leading/co-leading a SO workshop during the timeframe for the pilot
      ii. SO Participants: taking part in an eligible SO workshop (one taking place during the enrollment window and with a leader or peer leader wanting to participate in pilot.
    2. Exclusion criteria
      i. Leaders/Peer Leaders: not available to participate over the month following enrollment
      ii. SO participants:
        1. Not available to participate over the month following enrollment
        2. Not deemed safe by SO leader to exercise at home
      iii.
    3. Procedures:
      i. All subjects (SO leaders, peer leaders and participants/graduates will be given access and trained to use Elder Tree and KOSO. Subjects will use either their own laptop computer and internet service or if they do not have this we will loan them a laptop and provide an internet connection for them for the 3 week pilot study period.
      ii. Subjects will use KOSO as they wish (no specific expectations – our goal is to learn how they would use it. Subjects will be trained on using Google Hangouts and the class leader will help participants find partners for 'Google Hangoutsrcise' for all who wish to use it.
      iii. Data collection: (See attached documents Measures by Construct, Measures, Phase 1b Pilot,
        1. Leaders:
          a. study visits:
            i. Leaders: leaders will (1) complete a 15 minute written baseline survey at enrollment; (2) complete a 20 minute written survey by mail at end of pilot; and (3) complete a recorded phone interview (30 min). (4) Data on the use of KOSO will be automatically collected.
            ii. Participants/graduates: will complete (1) a 10 minute written baseline survey at enrollment; (2) have a home visit (50 min) where they will be observed (and filmed) doing exercises and using KOSO, and complete a recorded interview; (3) have a one hour home visit where they will be (1) observed and filmed doing exercises and complete a recorded interview. Data on their KOSO usage will be automatically collected, and If they used GOOGLE HANGOUTS, recordings of Google Hangouts sessions will be downloaded for review.
            iii. Peer leaders will complete a 10 minute written baseline survey at enrollment, (2) have a home visit (50 min) where they will be observed (and filmed) doing exercises and using KOSO, and

Mahoney - Stepping Online Ph 2b SO Participant consent 8-11-16docx.docx

complete a recorded interview; (3) have a one hour home visit where they will be (1) observed and filmed doing exercises and complete a recorded interview, and (4) complete a 20 minute phone interview. (5) Data on their KOSO usage will be automatically collected, and If they used GOOGLE HANGOUTS, recordings of Google Hangouts sessions will be downloaded for review.

4. Research staff will pick up the loaned equipment and delete ET and KOSO access at the end of the pilot. Recruitment: We worked with County coordinators from our collaborating sites to develop a plan for creating a recruitment pool, using a method similar to that used for Phase 1a. Details of this were worked out with county coordinators based on our experience with Phase 1a recruitment, and we received approval of Phase 1b.
    i. Identify potential subjects:
        1. With help from county coordinators, we will identify SO workshops that are planned to begin within our designated few week enrollment timeframe
        2. The county coordinators will contact the leaders and peer leaders of the groups to see if they are willing to talk with research staff about the project. The county coordinator will follow a script (which will include minimal information about Stepping Online/KOSO - enough for the leader/peer leader to determine whether they wish to learn more about it. Coordinator will record whether they are interested in learning more or not (and reason why not). County coordinator will keep a count of all leaders and peer leaders approached and response.
        3. Coordinator will provide research team with names and phone numbers of the leaders and peer leaders who are interested and research staff will contact (phone) those who are willing to talk with us about Stepping Online/KOSO, using a script to describe study and activities.
        4. Groups with a leader or peer leader who express interest in participating will be placed in a pool of potential groups to recruit from.
    ii. Recruitment:
        1. Leaders and Peer leaders: Researchers will contact leaders and peer leaders who indicated interest. They will use a script to describe what will be involved in taking part in the research and to screen for eligibility. Leaders and peer leaders will be approached based on the order of approach which will be based on making sure that we get at least one leader and one peer leader among the pilot subjects, classes that are going on around the same time, and also giving preference in Milwaukee to targeting groups held in locations known to attract African American SO participants.
    iii. SO Participants:
        1. A researcher will come to the SO class in Session 3 or 4 and tell participants about Stepping Online and inform them that the leader or peer leader (or both) will be participating. The researcher will pass out cards that ask each SO class member to identify whether they would be interested in being contacted by research staff to learn more about the study, and if no, why not. The leader will collect the cards and identify any class participants that they think could potentially be unsafe for Stepping Online. Researcher will contact the participants who are interested and deemed safe by phone, using a script to describe the research and screen for eligibility
    iv. Consenting Leaders and Peer leaders:
        1. Eligible leaders and peer leaders interested in joining the study will be scheduled to meet with researcher for consenting. This will take place in a private location in a site convenient for the leader/peer leader such as the location where they lead SO or their home. A copy of the consent form will

Mahoney - Stepping Online Ph 2b SO Participant consent 8-11-16docx.docx

be mailed in advance with a number to call if they have questions or change their mind.
   2. SO participants/graduates: Eligible participants who are interested in joining the study will be scheduled for an appointment where the researcher will come to their home, provide informed consent, have subject complete the baseline survey, install computer and Internet connection as needed (those not interested in trying Google Hangouts will be able to use their own computer and internet connection if suitable) and train the subject on use of ET and Stepping Online. A copy of the consent form will be mailed in advance with a number to call if they have questions or change their mind.
   Recruitment efforts will continue until we have at least a minimum of 1 leader, 1 peer leader and 10 participants/grads in each county.
   v. Subjects will be provided with a copy of their signed consent form.

   5. Data will include: (see attached Pilot measures table)
      - Leaders, peer leaders and graduates: Participant baseline information and satisfaction surveys for different /KOSO components (ease of use, perceived usefulness, how to improve).
      - Peer Leaders and SO Participants/graduates: Researcher/observation of exercise demonstrations and Google Hangouts recordings – peer leader and graduates. All subjects: Automatically collected use data for the frequency of KOSO features
      - Leaders and Peer leaders: Follow-up interviews of KOSO leaders and peer leaders on how different features worked, did not work, and how to improve them. Using a checklist and comments box.

We will analyze pilot data as follows. Descriptive statistics will be used for the frequency of KOSO features, exercise performance and safety, and satisfaction surveys. Content analyses will be used for the interview data and any comments typed into KOSO. The results will be shared with leaders, peer leaders, developers and learners to determine revisions, which will be tested in the randomized feasibility trial.

Aim 2: Test feasibility of implementing a Stepping Online **randomized trial**
(Phase 2, months 19-36)

Collaborating sites: Safe Communities of Madison/Dane County, the Milwaukee County Department on Aging, Rock County Council on Aging, and the Aging and Disability Resource Center of Adams, Green Lake, Marquette and Waushara counties, which coordinate Stepping On in their respective counties, will help us to identify Stepping On Classes to recruit and randomize. Non- UW staff who will be collaborating include the following:

Christa Glowacki (christaglo@hotmail.com). She is not employed right now. The UW IRB will serve as her IRB of record. She is working as an independent contractor for this study. She may help with data collection.

Valeree Lecey (vlecey1955@gmail.com) works for the Ozaukee County ADRC. She is working as an independent contractor for this study. Her work on this study is not related to her employment but there is a letter of support from her employer attached in supplemental information. The UW IRB will serve as her IRB of record.

Carol Pociecha-Palm (carol.pociecha-palm@communitycareinc.org) works for the Community Care. A letter of support from her employer is attached in supplemental information. The UW IRB will serve as her IRB of record. She may help with data collection.

Michael McKinnis (Michael.McKinnis@cuw.edu) will be working as an independent contractor outside his work duties at Concordia College. His employer is aware of and approves of his activity. Concordia IRB will defer IRB review to the UW IRB. He may help with data collection.

Ashley Hillman (ahillman@safer community.net)works for Dane County Safe Communities which is one our sites. She will help with recruitment. We are requesting UW IRB serve as the IRB of record

Anne Hvizdak (Anne.Hvizdak@dhs.wisconsin.gov) works for Wisconsin Department of Health Services, Division of Long Term Care,Bureau of Aging and Disability Resources,Office on Aging. She will help with recruitment in Dane county.   We are requesting UW IRB serve as the IRB of record.

Amanda Kutcher (Amanda.Kutcher@co.waushara.wi.us) works for the Aging and Disability Resource Center of Adams, Green Lake, Marquette and Waushara counties which is one our sites. She will help with recruitment. We are requesting UW IRB serve as the IRB of record

Jennifer Lefeber (Jennifer.Lefeber@milwaukeecountywi.gov) is self employed and contracted by Milwaukee County, which is one our sites. She will help with recruitment. We are requesting UW IRB serve as the IRB of record.

Joyce Lubben (JOYCE.LUBBEN@co.rock.wi.us) works for the Rock County Council on Aging which is one of our sites. She will help with recruitment. We are requesting UW IRB serve as the IRB of record

Julie Seeman (JULIE.SEEMAN@co.rock.wi.us)works for the Rock County Council on Aging which is one of our sites. She will help with recruitment. We are requesting UW IRB serve as the IRB of record

Anne Stone (astone@cil.oregon.wi.us) works for the village of Oregon, and in her postion works with Dane County Safe Communities to coordinate programs (including Stepping On) offered in Oregon, WI. She will help with recruitment. We are requesting UW IRB serve as the IRB of record.

Shannon Myers (Shannon.myers@wihealthyaging.org) works for the Wisconsin Institutes for Healthy Aging. She may help with recruitment and data collection. We are requesting UW IRB serve as the IRB of record.

 Study population: we will enroll 40-80 Stepping On participants/graduates along with up to 16 SO leaders and 16 peer leaders. We use methodology similar to pilot for subject identification and enrollment. We estimate that we will approach approximately 16 SO groups 16 SO leaders, and 16peer-leaders

Each SO workshop has approximately 10 participants. We anticipate about a third will want to participate in this KOSO intervention study. We will identify SO workshops that are planned to begin within our designated few week enrollment timeframe and invite leaders and peer leaders of these groups to take part in the KOSO randomized trial using the same methods as the pilot. Similar to the pilot, eligible groups will be determined by interest of leaders and peer leaders. In addition, groups will be paired by the statistician based on average educational level of the group and randomized in pairs to intervention or control (no intervention).

We estimate about 15 (75%) of Milwaukee County participants will be non-white. The leaders and peer leaders will be randomized to the same arem as their SO class. To assure adequate Stepping Online group size, we will combine all SO groups randomized to the intervention to create 1 Stepping Online group, but each SO class will know the Stepping Online usernames of their classmates and leaders, so that they can message each other separately from the full Stepping Online group. This will allow learners to expand their social network, while maintaining some familiarity.

Invitation, enrollment, group randomization: We will identify SO workshops that are planned to begin within our designated few week enrollment timeframe and invite leaders and peer leaders of these groups to take part in the Stepping Online randomized trial, using the same methodology as was used in the pilot. For groups with either a leader or peer leader (or both) interested in participating, we will obtain educational level information of participants (without identifiers) from baseline surveys that are completed as part of the SO program. The average educational level of all such groups will be determined and used to pair groups for randomization by group, to control (no maintenance program following SO)l or Stepping Online intervention. We plan to enroll at least 20, and up to 80 graduates, and at least 2 and up to 16 leaders and peer leaders from each county. The number of pairs of groups will depend on how many enroll from a group.

Phase 2b:
Randomization of paired Stepping On groups (having varied size and enrollment rates) led to unequal randomized group size. In order to calculate effect sizes for a large-scale randomized control trial the size of the control group will be increased to be more equal to the intervention group by enrolling up to 25 Stepping On graduates from workshops taking place in Milwaukee, Dane, Rock, Adams, Green Lake, Marquette and Waushara counties. We currently have 25 in the intervention and 10 in the control group.

The same methods used in phase 2a will be used to identify and approach potential subjects. We will find out the Stepping On workshops in the counties we are currently working with, and choose the ones that are the earliest to end, approach those groups, one group at a time, as before, and recruit them to the study as before. County coordinators will discuss the project with leaders of eligible workshops in their counties as and if the leader agrees to being contacted by research staff, will provide contact information. A staff member will call leaders, explain the project and ask permission to visit their workshop to describe the project briefly, for the purpose of identifying people willing to hear more about the project. The same methods approved for Phase 2a will be used to recruit and screen Stepping On graduates, approaching one group at a time until we enroll at up to 20.

Recruitment, enrollment, group randomization: Once the groups to approach have been determined based on pairing and, needing involvement of at least 1 leader and 2 peer leaders, recruitment will be conducted in the same manner as the pilot. County coordinators and others representatives of the counties have been added to the research team so they may help with recruitment. The same procedure will be used as Phase 1b. Recruitment will be conducted by a research team member, either from UW or from the community site.

Consenting: Researchers will meet with leaders, peer leaders and graduates privately in a private space at the SO meeting location or a location convenient to the subjects   The researchers will then answer any questions about the study, describe risks, benefits and how confidentiality is maintained, enroll interested participants, obtain informed consent using an IRB-approved consent form.,
After the subject signs the consent form and completes the baseline assessment, subjects will be informed if they are assigned to intervention or control. Those who were randomized to intervention will be scheduled for a home visit to install equipment as needed and training on ET and Stepping Online.

Procedures: All intervention subjects (leaders, peer leaders and SO participants/graduates) will be given access to and trained to use Stepping Online. Subjects will use either their own laptop computer and internet service, or if they do not have this we will loan (and set up in their home) a laptop and provide an internet connection for them to use for the 6 month study period. We will also set them up on Google Hangouts if needed and train them in its use. Leaders will help SO participants/graduates find an exercise partner for Google Hangouts if they wish. Leaders and peer leaders will receive suggestions on how to participate in Stepping Online as leaders or peer leaders. Subjects will use Stepping Online as they wish (no specific expectations, we want to learn about their use).

>   Phase 2b: The same methods approved for Phase 2a will be used to recruit and screen Stepping On graduates, approaching one group at a time until we enroll at up to 20.

Mahoney - Stepping Online Ph 2b SO Participant consent 8-11-16docx.docx

Data Collection: See attached Phase 2 Measures by construct and Ph 2 Measures RCT

- o Data that is automatically collected: Types of data that will be automatically collected include:
  - SO participant (control and intervention) data routinely collected in SO workshops in WI includes (demographics including education level, falls history, use of assistive devices, health status and social support) The county coordinator will obtain the information either directly from the questionnaires she receives from leaders of the enrolled groups or obtain from Wisconsin Institute for Healthy Aging (who maintains the data). WIHA has participant permission to share the data. Names of SO participants who are eligible but who do not wish to join KOSO will be removed and replaced with workshop ID number.
  - SO Participant (control and intervention) attendance at SO workshop. This data is collected by WIHA from SO class leaders for all SO classes, and will be shared with county coordinators for all classes in the sample pool. For non-joiners, names will be removed and replaced with workshop ID number)
  - Leaders/Peer leaders (control and intervention): WIHA maintains data (professional training, year of experience in leading SO and # of workshops led, experience leading other evidence based health programs, work status on leaders. Data is available for some peer leaders.
  - SO Participants, leaders and peer leaders (intervention only) 'Stepping Online' online use data (participation in curriculum such as time spent, services, postings, etc.)
  - Participants (intervention only) 'Stepping Online' online use regarding exercise (# of exercises done –change over time, tracking, notes re advancement, etc.)
- o Data collected from Subjects:
  - SO Participants(Control and Intervention):
    - T1 Baseline visit at enrollment: physical performance and balance, surveys regarding health and mobility, computer/internet use, falls risk, loneliness, quality of life, and self-efficacy to exercise. Participants will be offered the choice between completing all surveys at the visit or taking part of the survey home to return by mail in a stamped, self-addressed envelope research staff will provide. At a minimum the physical performance and balance measures must be done at the baseline visit. If surveys are taken home and not returned by mail within 1 week, then a researcher will call to obtain information by phone.
    - T2: 3 months after beginning Stepping Online: same as T1 except not falls risk and computer use
    - T3 End of 6 month trial: same as T1 except no computer use.
    - Monthly falls calendar (by mail). We will provide sufficient stamped self-addressed envelopes for each month. If a calendar is not returned within 10 days of the start of the following month, then we will call by phone within the next week to obtain information by phone.
  - SO Participants (intervention only)
    - Monthly 'Google Hangouts exercise' calendar, using the same methods as above for the falls calendar.
    - Within 2 weeks after T3: phone interview related to barriers and facilitators of using Stepping Online.
  - Leaders and Peer leaders ((intervention and control):
    - T1 Baseline visit at enrollment: Survey collecting information on leader/co-leader background and experience, if not available from WIHA, and in addition questions related to computer use and enthusiasm regarding Stepping Online.
  - Leaders and Peer leaders (intervention only):
    - T2 End of month 1: phone interview regarding enthusiasm, barriers and facilitators
    - T3 Exit interview at end of 6 month trial: phone interview regarding enthusiasm, barriers and facilitators.

Phase 2 Stepping Online **Feasibility Evaluation:**

We will use the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation, Maintenance) to evaluate the feasibility of implementing Stepping Online, randomizing SO groups, and collecting data for a future, large randomized control trial to test Stepping Online effectiveness. RE-AIM is designed to evaluate whether a program can be implemented, shown to be effective and ultimately sustained and disseminated.[29]

RE-AIM uses various data sources and mixed research methods to assess processes (Reach, Adoption, Implementation and Maintenance) and outcomes (Effectiveness).

Processes:
Reach will be assessed as the percentage of SO graduates participating in Stepping Online, the characteristics of joiners and refusers, and motivation to participate or not.

Adoption will be assessed as the percentage of SO leaders interested in participating in Stepping Online. We will also assess leaders' motivation to participate or not (via interview).

Implementation will be assessed as leaders' and participants' barriers and facilitators to using Stepping Online via exit interviews, and adverse effects, and intervention satisfaction survey questions. Google Hangouts

Maintenance will be assessed by participants' Stepping Online usage and level of engagement (via automatically collected data on online use and message content), and leaders' enthusiasm (via interviews).

Data analysis:

The qualitative researcher will lead the research to identify a priori (barriers and facilitators) and new in vivo theme associated with the pre-effectiveness RE-AIM components. Interview data for Reach, Adoption, Implementation and Maintenance will be analyzed via content analysis, which was under Phase 1a. Exemplar quotes will be captured for publication. We will use a form shown in Table 4.

Table 4. Qualitative Analysis Form REACH Process Data

	Barriers	Facilitators	New themes	Implications	Quotes
Reach					
Implementation					
Maintenance					
Adoption					

Satisfaction Survey data and online use data and logs will be analyzed with descriptive statistics.

Stepping Online **Effectiveness—Outcome data**:
Preliminary data to measure effectiveness will include diary data, survey data, and physical performance measures. These data are preliminary and will be used to inform a large randomized controlled effectiveness study.

Collection of data:
We will collect data at three time points as follows:

T1 (at enrollment (or within a week if subjects opt to take some of the survey home and return by mail), T2 (Month 3 of Stepping Online), and T3 (month 6 of Stepping Online): We will administer the physical tests and then the surveys. We will offer subjects the option of taking part of the survey home and returning by mail.

Measures:

The primary outcome will be falls measured by the gold standard of self-administered mailed monthly calendar over 6 months.[30]

Secondary outcomes will include balance via the tandem walk test,[31] and physical performance via the Short Physical Performance Battery (SPPB),[32] which have been shown to be reliable, valid, and sensitive to change resulting from interventions. These will be administered by a trained health professional at the enrollment site for the first assessment, and by home visit at T2, T3 and T4. Other secondary outcomes will be measured by validated survey instruments for falls risk behavior (FaB scale),[33] loneliness (UCLA Loneliness Scale),[34] quality of life (PROMIS short form),[35],[21] and self-efficacy to reduce barriers to exercise (Physical Activity Barriers Self-Efficacy).[36] We are dropping the social bonding measure, which we feel is of lesser importance, to decrease participant burden.

Phase 2b:

Data collection will be the same as currently approved(surveys and physical performance and balance observations at baseline,3 months and 6 months) and will take place at the SO workshop meeting location or in a private area within a public building convenient to subjects. Subjects will be offered the opportunity to complete all of the surveys at the site, or take some home and return in postage paid mailer. Falls calendars (intervention and control) will be self-administered at home and returned by postage paid mailer. Their data will be included in analysis with the control group.

Statistical and Qualitative Data Analysis Considerations:

Power analysis: This feasibility study is not powered to detect significant differences in our outcome measures. The sample size was determined by the scope of this study to assess the feasibility to implement Stepping Online intervention and administer the measures. Preliminary data on effectiveness will be used to determine effect sizes for a subsequent RCT.

Primary outcome—Falls: We will use a within-subjects logistic regression (conditional Poisson regression) model to assess change in falls rates over time as a function of intervention group while accounting for within subject correlation in falls rates over time.

Secondary outcomes—FaB, PROMIS, loneliness, Tandem Walk and SPPB: We will use mixed effects regression models to assess change in outcomes over follow-up with visit, intervention group and their interaction as categorical fixed effects and subject as a random effect. We do not expect significance in change with this small sample size, but these data will be used for power calculations for a subsequent randomized trial.

Information from medical records: None

Specimen/data collection: None

Confidentiality protections, data sharing and disposition:

Interview and focus group data will be entered into a password protected electronic document with data identified only by study IDs. No identifying information such as name, address, phone will be included in this document. Focus group and interview audio and video recordings will be kept in locked cabinets in Dr.

Mahoney's office or as password protected files. Data will be kept for analysis. A list will be maintained in a separate password protected file, that links subject ID with contact information. All password protected files will be housed on the UW Department of Medicine server. Linking information will be kept for 6 weeks after data from all subjects has been collected. It will then be destroyed. At this point there will be no direct way to identify the subjects identity.

Signed consent forms will be kept in a locked file in the principal investigator's office; only the investigators will have access to this. They will be stored separate from completed questionnaires and interview responses. Consent forms will be retained until September 2024 (7 years after the end of the study).

In regards to automatically collected data regarding Stepping Online usage such as minutes or use, features used, number of times features are used, problems with use: Data is uploaded to web applications prohibiting access to it on local PCs or smartphones. Web services use technical safeguards mandated by Health Information Technology for Economic and Clinical Health Act (HITECH) of 2009 for the transmission and maintenance of protected health information (PHI) and personal health records (PHR); this includes using two way encryption, check sum, double-keying, message authentication, digital signature, Secure Sockets Layer (SSL) and password protected accounts that define levels of access.133 Electronic study information will be kept in a file service that is secure, encrypted and protected by password. Only authorized people will be allowed to see this information. The usage data will be stripped of identifiable information by the database manager at CHSS. Once the use data is 'de-identified' we keep it indefinitely.

In regards to Google Hangout data: As a means of restricting Google account access to the study team only, domain managed Google/Google+ accounts will be created and provisioned out to study staff and participants. These accounts will be able to be created without using subjects' real names. Google Hangout settings will be configured to allow recording with charges to go to our UW account. For the purpose of recording and storing Google Hangout sessions between study participants, subjects will be instructed how to record these online exercise sessions with other Stepping Online participants. This recording process will use Google Hangouts On Air in conjunction with You Tube to create and temporarily store videos. At the end of 3 weeks, when we return to the home for evaluation, we will ask the participants to open up their google recordings and then we will "share" them with the principal investigator. Only the PI and research team will have access to the videos. Once it is shared we will download it to a password protected server, we will review files within 3 months and keep them on the server for 3 years (longer if person gives permission for it to be used for educational purposes). The study administrator will delete the video from the google cloud once it has been shared and downloaded to the secure server and the google account will be deleted.

Phase 1b: In regards to Google Hangout data: Subjects who are interested in trying out Google Hangouts to exercise with another Stepping Online user will be provided with a computer.

Technology Provided will be:
Acer Chromebook 15 (Selected for economy of price relative to technological budget, technological requirements, simplicity/manageability/support-ability/secure-ability/reliability of operating system environment in a remote location in the hands of older adults)
Participants would be provisioned a domain managed Google account with preset policies as a means to access their secured/encrypted local user home directory within Chrome OS platform on the Acer Chromebook 15. The Chromebook was in part selected as the base technology given the seamless integration (offering a single point of authentication making the overall interaction with technology process easier for older adults) with Google Hangouts to perform the video calling as an integrated component into the provisioned domain Google account.
Verizon Mobile Hotspot (Internet connectivity solution)
Video Calling/Recording Capture, Transfer, Storage, and Disposal Process

An older adult on study will initiate a Google Hangouts call using their own unique study provisioned domain managed Google account with another older adult on study.

The Google Hangouts call will be recorded by the older adult using a locally installed application called Screencastify directly to the Chromebook within the provisioned account's home directory in an encrypted state.

The older adult would then save the video recording using a designated naming convention to an accessible folder within the same provisioned account's encrypted home directory.

In a follow-up visit by the research team with the older adult, the research team would then save the video to an encrypted flash drive and collect the provisioned technology.

The technology would be securely wiped of all of its contents including the recorded video.

The recorded video on the flash drive would be moved to a secured and encrypted server within the SMPH environment for storage for 3 years or potentially longer with consent of the older adult.

Only the PI and research team will have access to the videos.

Once transferred the flash drive would then also be securely wipe.

Data and Safety Monitoring Plan:
For minimal risk studies:
Phase 1a:

Potential Physical and Psychological Risks: This study is minimal risk. The potential risks of participating in the focus group and interviews are very low. During the focus group it is possible the subjects may try doing some of the simple, balance and strengthening exercises, which could pose a slight risk of muscle soreness or of falling. This risk is minimized because these are the same exercises that they learned when they took the Stepping On workshop, and had been instructed to practice at home. In addition, all participants were told what the SO class involved and encouraged to check with their doctor beforehand. In the original Stepping On study and in subsequent implementation in Australia and other parts of Wisconsin there have been no falls during workshops. If a participant falls and appears to be injured in any way, an ambulance will be called for them. Participants will be instructed to inform the research staff member at their site if a problem, such as injury arises. The staff member will gather the information and report to Dr. Mahoney who will review within the week and report to IRB when required.

During focus groups or interviews there is a small risk that answering questions could make participants tired or uncomfortable. They will be informed they do not have to answer any questions they do not want to and make ask to stop participation at any time.

Phases 1b and 2:

Potential Physical and Psychological Risks: This study is minimal risk. Phases 1b and 2 include the same potential risks as Phase 1a. There is a risk of falling or muscle soreness when doing Stepping Online/KOSO home exercises or doing physical performance or exercise performance assessments. There is a risk of getting wrong information from Stepping Online/KOSO discussion groups but the falls prevention coach will monitor groups to ensure information is correct. There is a risk that somebody may say something in a Stepping Online /KOSO discussion group that could make participants uncomfortable but researchers will monitor discussion groups and address inappropriate comments if they occur. Participants may reveal personal, sensitive, or identifiable information in the online discussion group for study participants, but they will be instructed to NOT share personal information publicly. They will also be instructed to use an unidentifiable user name in Stepping Online/KOSO, and share this only with their Stepping Online /KOSO users from their original SO group as well as the leader and/or peer leader if they are taking part in Stepping Online/KOSO. There is a risk that some survey questions may make you tired or uncomfortable, but you don't need to answer anything that makes you uncomfortable, you can stop at any time, and you can take part of the survey home to do later.

Safety Plan: During Phase 1b three goals will be satisfied in regards to safety:

Safety Plan: During Phase 1b three goals will be satisfied in regards to safety:
1. Establish safety with exercising on Google Hangouts. This will be established in Phase 1b by:
   a. Graduates and peer leaders will be instructed to record all Google Hangouts exercise sessions. Recordings will be uploaded at the end of the pilot. A research team therapist will review the recordings for safety.
b. In order to make sure they are safe doing exercises at home a research team physical or occupational therapist will observe each participant in person doing exercises. .
c. Those found to be unsafe to exercise at home will be instructed not to perform exercises that they are deemed unsafe doing.

3. Establish safety with new exercises. This will be established in Phases 1b by:
   a. We will develop safety tips that will be included in video and avatar exercise demonstrations. They will also be included in the Stepping Online/ KOSO training guide. These safety tips will deal with being safe while exercising.
   b.   We will create a brief video of the falls coach talking about safety measures, principles of progressing exercises and what to watch out for. This applies for new and existing exercises.
   c.   In order to make sure they are safe doing exercises at home a research team therapist (OT or PT) will observe each participant in person doing exercises using the Stepping Online/KOSO exercise videos/avatars within the first week of Stepping Online /KOSO use.
   Those found to be unsafe to exercise at home will be instructed not to exercise using Google Hangouts and not to perform the specific exercises they are deemed unsafe doing. (if Google Hangouts is installed on our computer it will be removed).

4. Ensure continued safety with existing exercises. Participants are already familiar with existing exercises and have learned how to do them safely.

To ensure continued safety we will do the following:
    a. The Stepping Online /KOSO coach will frequently review principles of exercise safety with progressing existing exercises.
    b. Participants will be invited to watch a video vignette of the falls coach, who is an occupational therapist and the national Stepping On trainer, discussing principles of safe exercising (See 2a).
Each avatar exercise demo will begin with safety instructions.

By the end of Phase 1b we will have assured that participants can exercise safely on Google Hangouts and practice existing exercises and learn new exercises via Google Hangouts and exercise avatar videos with instructions.
Phase 2: Based on information learned from Phase 1b, we will train Stepping Online /KOSO leader and peer leader on safety measures to teach, principles of progressing exercises, and how to work with participants on how to exercise safely with the avatars or while on Google Hangouts No one-on-one observations will be part of Phase 2 as we will have established the safety of exercising using Google Hangouts or avatars.

Ongoing safety methods will include:
    a. The Stepping Online KOSO exercise avatar videos will begin by reminding the user of the safety tips for exercising .
    b. Participants will view a safety video before learning any new exercise.

Study Timeline.

Table 5 study timeline. Phase 1b in blue, phase 2 in yellow

Tasks	Phase 1: KOSO Development						Phase 2 KOSO Feasibility Test					
	Y1 Q1	Y1 Q2	Y1 Q3	Y1 Q4	Y2 Q1	Y2 Q2	Y2 Q3	Y2 Q4	Y3 Q1	Y3 Q2	Y3 Q3	Y3 Q4
Project Management	■(blue)	■(blue)	■(blue)	■(blue)	■(blue)	■(blue)	■(blue)	■(yellow)	■(yellow)	■(yellow)	■(yellow)	■(yellow)
IRB (prior to funding)												
Recruit grads & leaders	■(blue)	■(blue)	■(blue)	■(blue)	■(blue)	■(blue)						
Focus groups (2)	■(blue)											
Interview SO leaders	■(blue)											
Develop Stepping Online/KOSO	■(blue)	■(blue)	■(blue)	■(blue)	■(blue)							
Rapid Cycle Testing	■(blue)	■(blue)	■(blue)	■(blue)								
Pilot Test Stepping Online KOSO (2)						■(blue)	■(blue)					
Analyze Phase 1 Data	■(blue)	■(blue)	■(blue)	■(blue)	■(blue)	■(blue)						
Develop Surveys						■(blue)						
Recruit Stepping Online/KOSO Leaders						■(blue)		■(yellow)	■(yellow)			
Train leaders in Stepping Online/KOSO						■(blue)	■(blue)	■(yellow)	■(yellow)			
Recruit participants						■(blue)	■(blue)	■(yellow)	■(yellow)			
Train Stepping Onlin/eKOSO participants						■(blue)	■(blue)	■(yellow)				
Randomize groups									■(yellow)	■(yellow)	■(yellow)	■(yellow)
Implement Stepping Online/KOSO									■(yellow)	■(yellow)	■(yellow)	■(yellow)
Evaluate Stepping Online/KOSO RE-AIM									■(yellow)	■(yellow)	■(yellow)	■(yellow)
Analyze RE-AIM Data									■(yellow)			
Manuscripts						■(green)					■(green)	■(green)
Final report												■(green)
Write Funding Proposal											■(green)	■(green)

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Table 5. Stepping Online Timeline