BMC Public Health

STUDY PROTOCOL

Open Access

Study protocol: process and outcome evaluation of the Walk with Ease program for fall prevention

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Abstract

Background Falls are the leading cause of injury related morbidity and mortality in older adults. Primary and secondary prevention strategies that address modifiable risk factors are critically important to reduce the number of falls and fall related injuries. A number of evidence-based fall prevention programs are available, but few offer potential for broad dissemination and public health impact due to implementation barriers, such as a need for trained program leaders and clinicians.

Methods The study will use a randomized controlled trial design to evaluate incorporating physical therapy exercises (primary prevention strategy) within an existing intervention called Walk with Ease. While Walk with Ease has an established evidence-base related to the management of arthritis pain and symptoms, the present study will determine the potential to also reduce falls and fall risk in community-dwelling older adults. The integrated process and outcome evaluation will determine the relative effectiveness of individually-prescribed exercises (compared to standardized exercises) as well as the potential of 'habit training' resources (relative to generic behavior prompts) to improve compliance with exercises in this population.

Discussion The study, conducted through a local clinical-community partnership will advance both the science and practice of community-based fall prevention programming, while also informing implementation strategies needed to promote broader dissemination.

Trial registration ClinicalTrials.gov, NCT05693025, Registered January 20, 2023, Updated March 1, 2023.

Keywords Physical activity, Healthy aging, Falls, Falls prevention, Physical therapy

Background

Falls are the leading cause of fatal and non-fatal injuries among older adults [1], and the severity of the issue has recently elevated fall prevention as an international priority [2]. Primary prevention is the ideal goal, but this is particularly challenging since fall risk is influenced by an array of individual variables (e.g., vision), functional indicators (e.g., gait, balance), confounding medical conditions (e.g., arthritis), as well as the medications used to treat these conditions and environmental risks (e.g., tripping hazards). A variety of strategies have been

Nicholas R. Lamoureux conducted pilot research on the protocols as part of a doctoral dissertation while completing his Ph.D. work at Iowa State University. The project provided foundational pilot data for the CDC funded trial (U01CE003490: Process and Outcome Evaluation of the Walk with Ease program for Fall Prevention) described in the paper. Details on the pilot research are available by request.

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evaluated to help reduce fall risk in older adults, but a key need is for community-based programming that can help address the problem at population levels.

Exercise has been a key component of many community-based prevention programs designed to improve gait and balance [3]. Exercise has shown an ability to prevent falls as a single intervention and a number of programs have been shown to document utility [4]. For example, the Otago program is one of the most widely studied programs and is grounded in the use of individually-prescribed, balance-related exercises [5]. Various enhancements and delivery models have been tested and most have shown utility in improving balance, but advantages over the original Otago program weren't evident [6]. However, a follow-up meta analysis indicated that group based programs yielded greater improvements than the individual format [7]. Various versions of Tai Chi have similarly shown value in improving balance and various implementation strategies have also been actively studied [8, 9]. While there are a number of promising programs, the need for home audits or visits, the need for clinical expertise (e.g., physical therapists, occupational therapists), and the need for specialized training to deliver programming (e.g., Tai Chi instructors) create barriers to broad dissemination.

The present manuscript describes a hybrid approach that integrates clinical and community strategies for fall prevention. The manuscript specifically describes the potential of incorporating individually prescribed physical therapy exercises (primary prevention strategy) within an evidence-based exercise intervention called Walk with Ease (WWE) to reduce falls and fall risk in community-dwelling older adults. The original WWE program was developed by the Arthritis Foundation to help older adults learn how to safely make physical activity a part of their everyday life [10, 11]. Foundational research demonstrated the utility for improving balance, strength, and walking pace, as well as reducing pain, for individuals with arthritis. The scope was broadened, and the delivery made more flexible to enable implementation through a self-directed program or in a group setting. Subsequent research supported both approaches, as both conditions demonstrated declines in disability and arthritis symptoms, while also improving balance, strength, and walking pace [12].

WWE has been endorsed within the Centers for Disease Control and Prevention (CDC) as a Lifestyle Management Program because it offers potential to address many health conditions and to serve multiple populations [13]. While it was developed for arthritis, pilot research has demonstrated potential for WWE to influence physical function and reduce risks for falling [14]. A potential advantage of WWE as a fall prevention program is that the focus on walking and basic exercises (i.e., stretching / body weight movements) make it appealing and accessible to most adults. It also alleviates the need for specialized training of leaders (e.g., Tai Chi instructors) or clinicians (e.g., Physical Therapists) that typically deliver fall prevention programming. There is considerable potential for broad dissemination of WWE, but studies to date have not formally evaluated WWE as a falls prevention program. Thus, the purpose of the study is to evaluate the potential of the 'in-person' (group) version of WWE to serve as a community-based fall prevention program.

The standard version of WWE has already shown to help older adults in reducing pain and improving functional mobility [12], but we hypothesize that the personalized exercise prescriptions will be more effective at reducing fall risk since they would be customized based on individual needs and documented deficits. Thus, the study will directly compare the effectiveness of standard exercises versus individually prescribed, physical therapy exercises. An advantage of the group-based format used in the present study is that there is built in accountability and support to facilitate completion of the recommended exercises. This built in accountability fills a gap that has been previously documented in an evaluation of the Otago program [15]. Because the long-term effectiveness of exercise programming is predicated on sustained behavior change, we will further evaluate the effectiveness of enhanced behavioral training based on habit formation strategies with support provided by trained health coaches. Consistent with the prominent Health Action Process Approach [16], the enhanced techniques are expected to help participants identify their own reasons for engaging in physical activity (PA) (autonomous motivation), help them develop the skills required to engage in PA, overcome obstacles to sustaining PA in the long-term (self-efficacy), and to help them to integrate PA into their daily routines (habit formation). Thus, the hypothesis with this condition is that supplemental health coaching, based on motivational interviewing, will lead to internalized habits and more success with sustained walking and exercising and ultimately reduce the risk of future falls.

The study was designed as an implementation / effectiveness trial, so we will conduct a robust process evaluation as well as an outcome evaluation as key project objectives. Conducted through a local clinical / community partnership, the study will advance both the science and practice of fall prevention interventions while also informing implementation strategies needed to promote broader dissemination.

Methods / design

This clinical trial protocol was written in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [17]. An overview of the WWE program is provided below followed by details of the design, measures, and analyses. See Fig. 1 for a summary of the protocol.

Overview of Walk with Ease

The WWE intervention is a 6-week group exercise program designed to build functional capacity in older adults. Sessions are held 3 days a week for an hour each session. Each session includes a 10-minute warmup including strength/flexibility exercises, a 30-minute bout of walking and a 10-minute cool-down including strength/flexibility exercises. Individuals who have completed the Arthritis Foundation WWE Leader Training lead session activities, as well as deliver generic educational content. Throughout the program participants are guided to complete standard exercises recommended in the base program both during sessions and at home between sessions.

Participants also receive access to an online portal with weekly tips and education content, goal setting options and a daily tracking system for logging walking and exercises performed. They receive instruction on how to use the portal and are encouraged to use the integrated eBook and resources to supplement the group exercise programming. Weekly video-based lessons provide standard knowledge-based training about how to become more physically active. Paper versions of materials were provided upon participant request to facilitate evaluation.

Research design

The randomized controlled trial, funded by the CDC (U01CE003490-01), employs a 2 x 2 factorial design to identify the most effective implementation strategies to address established risk factors of strength and balance impairments that are associated with falls among community-dwelling, older adults. Participants are randomly assigned to either a Standard Implementation (SI) condition that would include generalized exercises as provided in the WWE guide or to an Enhanced Implementation

	Study Period					
TIMEPOINT	**Enrollment**	**Allocation**	**Intervention**		**Follow Up**	
	$-t_1$	0	*0 wk*	*6 wk*	*6 mo*	*1 yr*
Eligibility screen	X					
Informed consent	X					
Program Information	X					
Allocation		X				
Exercise Intervention		SI or EI	●	●		
Behavior Intervention		SE or EE	●	●		
ASSESSMENTS AND MEASURES						
Fall Incidence Reported Falls and Medical Record Data		X	X	X	X	
Health Related Function STEADI Functional Assessments			X	X		
Physical Activity International Physical Activity Questionnaire			X	X	X	X
Capability to Walk Walking self-efficacy			X	X	X	X
Opportunity to Walk Self-Report behavioral automaticity scale			X	X	X	X
Motivation to Walk Behavioral Regulation of Exercise v3			X	X	X	X
Enjoyment of Walking PACES			X	X	X	X
Perceived Health PROMIS Global Health Questionnaire (Physical and Mental Health subscales)			X	X	X	X
Self-Reported Function PROMIS Physical Function 20a			X	X	X	X
Fear of Falling PROMIS Fear of Falling Questionnaire			X	X	X	X
Falls Self-Efficacy Falls Efficacy Scale – International			X	X	X	X
Grip Strength Dynamometer			X	X		

Fig. 1 Summary of enrollment, interventions, and assessments in the Walk with Ease trial. Note – SI: Standard Implementation, EI: Enhanced Implementation, SE: Standard Education, EE: Enhanced Education, STEADI: Stopping Elderly Accidents, Deaths, and Injuries, PACES: Physical Activity Enjoyment Scale, PROMIS: Patient-Reported Outcomes Measurement Information System

(EI) condition that includes a clinical evaluation by a physical therapist (PT) and PT-prescribed exercises based on individual needs. Participants in both groups are further randomized into one of two online behavior change treatments. The Standard Education (SE) group will be guided by the base content and educational videos provided with the online WWE portal. The Enhanced Education (EE) group is guided in a similar way but with specific training on action planning and habit formation to help individuals establish personal habits for exercise. Details on each condition are provided below with the specific behavior change techniques (BCTs), categorized based on an established taxonomy [18].

- Type of exercise implementation
  - Standard Implementation (SI): Participants in the Standard Implementation (SI) model complete the standard WWE intervention as recommended by the Arthritis Foundation. Participants are guided to learn and perform a series of stretching and strengthening exercises recommended in the base WWE program. Primary BCTs include Instruction on how to perform behavior (#4.1) and Graded tasks (#8.7).
  - Enhanced Implementation (EI): Participants in the Enhanced Implementation (EI) model follow the same 6-week structured WWE group exercise program but receive a personalized clinical evaluation and exercise prescription from a licensed PT prior to starting the intervention. Participants may perform the same exercises as those in the SI group but they are also guided to learn and perform specific exercises prescribed by a physical therapist to improve balance and reduce risks of falling. The primary BCTs include Instruction on how to perform behavior (#4.1), and Graded tasks (#8.7) from the basic program as well as additional Information on health consequences (#5.1) and Credible source (#9.1) provided during the PT evaluation.

- Type of behavioral educational support
  - Standard Education (SE): Participants in the Standard Education (SE) model follow the standardized WWE training that is built into the online portal developed by the Osteoarthritis Action Alliance to support behavior change. Participants are provided with goal setting tools and an online tracker to monitor their progress. Weekly video-based lessons and resources provide tips and strategies to supplement the content from the integrated WWE eBook that is available within the portal. Primary BCTs supported through the portal include Goal Setting (#1.1) and Self-monitoring (#2.3).
  - Enhanced Education (EE): Participants in the Enhanced Education (EE) model follow the same guided content and flow as provided in the SE implementation but receive customized content and guidance based on principles of habit formation with approaches grounded in self-determination theory [19]. The weekly education-based videos in SE are replaced with lessons focused on habit-formation training. Student coaches are also assigned to individual participants to support behavior change efforts using motivational interviewing strategies. Thus, in addition to the use of Goal setting (BCT #1.1) and Self-monitoring (#2.3), the ET model includes two additional theory- and evidence-based BCTs: (1) Habit formation training that includes action and coping planning (#1.2, #1.4) and (2) Health coaching, based on motivational interviewing (#3.3).

Details and descriptions of the specific BCTs are provided in Table 1. It is important to document that, in addition to the condition-specific BCTs, participants also received general social support (BCT #3.1) from session leaders, peers, and student volunteers during the program.

The factorial design makes it possible to evaluate the independent and interactive effects of individualized / prescribed exercises and behavior change programming designed to target the key processes of behavior change. The primary hypothesis is that the participants in the EI condition will have lower incidence of falls and larger reductions in fall risk than those in the SI condition. The secondary hypothesis is that participants receiving the EE resources will have greater compliance to the prescribed exercise, higher levels of physical activity, and better fall risk reduction outcomes than those receiving SE resources.

Statistical power and sample size

We will recruit 240 participants into the overall trial and project a final sample of 180 completers, based on a 25% dropout rate seen during pilot testing, providing a final sample size of 90 participants per treatment group for each of the main hypotheses, and 45 participants per group for testing of potential interactions between groups. Based on outcomes from a related clinical trial by Li et al. [20] we would have 80% power to detect a 14% reduction in fall frequency between conditions and 95% power to detect a 18% reduction in fall frequency between conditions.

Table 1 Overview of behavior change techniques and implementation

Behavior change technique	Implementation	Included in study conditions
Behavioral support		
Goal setting (1.1)	Through the WWE participant guidebook participants are provided guidelines on how to set effective goals, and when logging into the participant portal participants are asked to set a walking goal for the coming week	SE, EE
Self-monitoring (2.3)	Participants are asked to track their minutes of weekly walking each time they access the participant portal. When logging in they are also presented with bar graphs indicating their previous weekly walking minutes and their weekly goals	SE, EE
Action planning (1.2)	Participants are asked to watch a video explaining the importance of developing a suitable plan in order to accomplish goals and guiding them through the process. They are then asked to develop their own plan according to these guidelines.	EE
Coping planning (1.4)	Participants are guided to observe common barriers to their developed action plan over a week of implementation, before being asked to watch a video on preemptively developing plans to address these barriers. They are then asked to develop coping plans in response to the barriers they have identified.	EE
Health coaching based on motivational interviewing (3.3)	Participants receive a brief telephonic Motivational Interviewing session during biweekly check-in calls. While the specific details of the calls vary based on participant and program progress, coaches help participants build autonomous motivation and provide a source of accountability	EE
Program implementation		
Instruction on performing behavior (4.1)	All group sessions are led by a trained WWE program leader who provides participants with instructions and reminders about effectively warming up, stretching, and engaging in the walking sessions.	SI, EI
Graded tasks (8.7)	Walking sessions are self-paced, allowing participants to walk at a duration and intensity that they are individually comfortable with. Over time, participants are encouraged to progress their walking duration or intensity as their abilities allow.	SI, EI
Information on health consequences (5.1)	Physical therapists provide patients with information on the consequences of their functional limitations and the positive outcomes that can result from engaging with their walking and exercise routines.	EI
Credible source (9.1)	Individual instruction and prescription provided by licensed physical therapists reinforces the importance of engaging in walking and exercise routines.	EI
Additional behavior change techniques		
Social Support (General) (3.1)	All participants are engaging in group exercise programming, allowing for relationships and accountability to support the behavior change process and potentially act as role models of successful behavior change. Sessions are also supported by a student implementation team, providing additional opportunities for social support.	All participants

Behavior Change Techniques are indicated according to the taxonomy outlined by Michie, Richardson [18]

SI Standard implementation, *EI* Enhanced implementation, *SE* Standard implementation, *EE* Education education

Study coordination, setting and timeline

The study is coordinated in collaboration with the Iowa Community Hub (HUB), a state-wide community care hub that serves to facilitate connections and partnerships between clinical health care systems and community-based programs (CBOs) across the state of Iowa, USA. The HUB uses an integrated web-based platform designed for community care hubs (Workshop Wizard). The system handles clinical and community referrals as well as tracking data compiled through the WWE portal. The platform provides centralized coordination of the project while also following and evaluating procedures that would be used for broader state-wide dissemination. The study began in August of 2022, with implementation and data collection continuing through at least July of 2025.

Recruitment, eligibility screening and enrollment

The primary recruitment strategy for enrollment in WWE is through clinical and community referrals since a goal of the pragmatic trial is to build connections and partnerships to support system level changes. However, more localized recruitment efforts are also employed to recruit older adults that are at higher risk of falls through direct referrals from physicians. Community referrals are expected to come primarily through community-based screening efforts. Screening events range from large groups to individual sessions, but the collective goal is to

screen up to 720 individuals. Based on past profiles, we expect that approximately half of these individuals may have documented fall risk based on an established clinical screening tool (Stopping Elderly Accidents, Deaths and Injuries; STEADI) [21]. We project that 50% of these individuals will follow up for the proposed intervention based on a conservative estimate of previous fall screening interventions [22]. This would lead to the target of 180 participants in the trial (90 in each treatment group).

The data collected from community-based screening are entered into an online portal to enable sharing with the HUB. A trained HUB navigator contacts referred individuals to determine interest and eligibility for the study, based on the following inclusion criteria: 65 years of age and older, able to stand for 10 minutes without increasing pain, and approval from medical provider. Interested individuals are scheduled for visit to a campus outreach building to confirm eligibility based on the following exclusion criteria: already physically active and not at risk of falling (based on standard STEADI criteria) [23, 24]. Regular physical activity is determined using the International Physical Activity Questionnaire - Elderly (IPAQ-E) [25] with an average of more than 15 minutes of PA serving as the criteria for exclusion. Fall risk status is determined based on established STEADI criteria, with evaluations including both the 12-item survey and the functional assessments. Individuals are admitted into the study if they are both below the 15-minute threshold of PA and if they have a documented risk of falling based on the survey and/or functional assessments.

Participants that meet criteria and sign the informed consent are officially enrolled in the trial and are provided with additional instructions about the programming. They receive a participant binder and are guided on how to register for the WWE online portal maintained by the OAAA on behalf of the Arthritis Foundation. The portal is linked to start dates of the programming and participants are encouraged to review the weekly newsletters, video content and to review the weekly eBook content at the baseline assessment meeting, then provided reminders and troubleshooting help at weekly walking sessions.

Randomization and allocation into intervention groups

Participants are randomly assigned to one the four treatment conditions using standard procedures in REDCap to achieve equal allocation in the 2x2 design. Participants are not informed of their allocation to an enhanced or standard group to avoid biasing their perceptions; however, given the nature of exercise programming, it is not possible to blind participants to the intervention condition. Individuals responsible for data collection and analysis are blinded to participant group allocation. The intervention was delivered in the same way in both the Enhanced and Standard conditions. Thus, the conditions were differentiated by type of implementation and type of training as delineated below with documentation of distinctions in BCTs based on a widely used taxonomy [18].

Outcomes and research measures

Process measures

The process evaluation will capture data on the overall procedures and protocols used to recruit and enroll participants as well as the overall fidelity of implementation. Methods and indicators will follow standardized guidelines for effective process evaluations [26, 27]. The prioritized measures include the following:

- Recruitment – promotion and screening strategies used to recruit older adults to enroll in WWE, including the number, location, and attendance of screening events, clinical or community group presentations, and other public advertisements.
- Reach – the proportion of individuals screened and enrolled based on demographics, to ensure programming is reaching the intended populations.
- Context – cultural, social, and environmental factors that impact WWE implementation through a clinical/community partnership, captured through coded notes and minutes of quarterly meetings with clinical and community partners involved in the local fall prevention coalition.
- Dose Delivered – the degree to which WWE intervention elements were delivered in community-based settings, assessed using a self-report checklist from program leaders that indicates whether each component was delivered, duration, and perceived quality.
- Dose Received – the degree to which participants engaged with recommended programming, captured as both exposure and satisfaction.

    - Exposure – documented as the number of weekly engagements with intervention materials and sessions, including weekly walking sessions, steps at each walking session, weekly exercises performed, and habit training modules completed.
    - Satisfaction – participant provided ratings of satisfaction with both the program generally, as well as with specific aspects of the program and personal barriers that impacted their participation.

Primary outcome measures

All patient-reported measures will be collected from participants at 4 time-points (baseline, immediately post-program, 6 months post-program, 12 months

post-program) See Fig. 1 for an overview of trial procedures and assessments. The following outcomes and measures are used to evaluate the results of the trial.

- *Falls and Health Related Function:* Reported falls will be tracked using surveys as well as electronic medical record data. Reductions in fall risk will be evaluated using indicators from the established STEADI protocol, with continuous fall risk scores computed using a validated algorithm, developed based on 4-year fall risk data from a large sample of older adults in the National Health and Aging Trends Study [28].
- *Physical Activity Behavior:* Self-reported behavior will be captured using the International Physical Activity Questionnaire – Elderly (IPAQ-E) at all time points to estimate minutes of physical activity. The IPAQ-E has been validated against criterion measures of physical activity and has demonstrated adequate sensitivity and specificity for evaluating physical activity among adults aged 65 years and older [25].

Secondary outcomes – correlates of physical activity behavior

A brief battery of psychosocial correlates will be used to evaluate the behavioral components of the intervention (and the associated mechanisms of change). We will measure correlates at baseline, program-end (6 weeks), 6 months, and 12 months. The key constructs, organized in the COM-B (Capability-Opportunity-Motivation and Behavior) framework of behavior change factors [29] are summarized below along with a supplemental assessment of enjoyment:

- *Capability (to walk or exercise)* will be captured with single-item ratings of self-efficacy for sustained walking and stretching/strengthening exercise as these are the primary behavioral targets of the WWE intervention.
- *Opportunity (to walk or exercise)* will be captured as habit strength for walking. Habit formation will be assessed with the self-report behavioral automaticity scale [30], a 4-item scale that assesses the perceived automaticity with which someone engages in his/her goal activities.
- *Motivation (to walk or exercise)* will be captured with the established Behavioral Regulation of Exercise Questionnaire (BREQ-3) which captures intrinsic motivation to exercise [31, 32].
- *Enjoyment (of walking or exercise)* will be captured using a short version of the established physical activity enjoyment scale (PACES-S) tool (4 items) that capture enjoyment and pleasure as these are the main indicators of interest [33].

Secondary outcomes - correlates of falls and health related functioning

A set of established indicators of fall risk and function will be used to provide additional indicators for a more comprehensive evaluation and to better understand potential mechanisms of change. We will measure the following constructs at baseline, program-end (6 weeks), 6 months, and 12 months. The indicators are below:

- *Perceived Health:* The PROMIS Global Health Questionnaire is used to capture overall perceptions of health [34]. The Global Health questionnaire includes 10 items with single items capturing perceptions of global health and well-being. Two sets of subscales (4 items each) capture mental health and physical health. All items are 5-point Likert items that would be used individually (or as an average) with higher scores reflecting stronger perceptions or more favorable perceptions of health.
- *Physical Function:* Selected items from the PROMIS Physical Function 20a [based on the widely used Health Assessment Questionnaire (HAQ) survey] are used to evaluate change in physical function [35]. The tool asks participants to rate the difficulty in performing twenty common activities of daily living but only those eight questions related to physical activity behavior and function were included. The total score will be used to evaluate changes in physical function.
- *Fear of Falling:* The PROMIS Fear of Falling Questionnaire is used to capture changes in perceptions of fall risk [34]. The instrument includes a single question (1-5 scale) about fear of falling and additional items (relative degree of concern, likelihood of falling, likelihood of injury, preventability, and perceptions about the role of physical activity for fall prevention). The single fear item will be evaluated independently with higher scores reflecting stronger fear of falling, with subsequent items providing additional insight into the basis for any fears that exist.
- *Fall Efficacy:* The Falls Efficacy Scale International (FES-I) is used to evaluate confidence in being able to perform activities of daily living [36].The measure includes a series of 16 common activities of daily living that may pose challenges for older adults with a fear of falling. Participants are asked to rate their level of concern towards performing each activity without falling on a scale of 1 to 4, with 4 indicating very high levels of concern. The FES-I has demonstrated sensitivity to detect between-group differences based on

demographic and fall risk factor differences and is suitable for detecting changes in fear of falling among older adults [37]. The FES-I will be scored by summing the response to each of the 16 presented activities to an overall total, with scores ≥23, of a possible 64, indicating high concern about falling.

- *Grip Strength:* A standard research grade dynamometer is used to evaluate grip strength (as a proxy of overall body strength). Grip strength is a widely used clinical indicator of physical function and will be used primarily as a descriptive variable to better understand the levels of function in the population [38, 39]. Assessments will be captured alternately on both right and left side and then repeated with the highest score reported separately for both hands.

Coordination, quality control procedures and data management

The project is conducted as a collaboration between the campus-based research team, the physical therapists with the local health care system, and the local community recreation centers. Linked Smartsheet forms are used to facilitate communication and coordination of the project.

Referrals are managed through the Iowa Community HUB to enable the evaluation of strategies to promote and sustain clinical / community partnerships to address fall risks on a statewide level. Referrals can be received from clinicians or organizations, and individuals can also self-refer into the study. The HUB navigators assist with obtaining physician approval and checking other inclusion criteria, but final eligibility (based on documented fall risk) is determined by the research team as part of the baseline assessment.

The data collection for baseline (screening) and follow-up visits are conducted at an off-campus research facility staffed by the Project Manager and a student evaluation team. The students are trained through a practicum course at Iowa State University that provides foundational training and practice in adult fitness assessment and promotion. Students are re-trained at the start of each semester and the survey data and physical function data collected are scored using standard methods to determine potential fall risk. The Data Management Plan for the project specifies procedures for evaluating the inter- and intra-rater reliability of the Evaluation Team (details available on request).

For the baseline visit, individuals are first screened using the standard STEADI protocol. Individuals first complete the STEADI Stay Independent Survey and are then guided to complete the 4 Stage balance test, the Timed Up and Go test, and the 30 second chair stand [40]. Risk status is evaluated using standard STEADI algorithms and individuals with documented risks are eligible to participate in the trial. Individuals are provided with the informed consent document and given opportunities to ask any questions they may have prior to completion. The participant then completes the remaining functional tests (i.e., two-minute step test, gait speed test, grip strength test) and survey items included in the baseline evaluation. Participants are not provided any compensation or incentives for their involvement in study procedures.

Once all data are collected, the Project Manager completes the remaining enrollment procedures in REDCap which automatically handles the randomization procedures needed to allocate participants into the treatment groups. The Project Manager provides further instructions based on the allocation and confirms that the participants will be contacted by the community WWE Program Leader to begin joining program sessions.

The WWE Program Leader completed formalized training through the Arthritis Foundation and has also received supplemental training in coordinating and facilitating use of the WWE online portal developed by the OAAA to support WWE implementation. The Program Leader contacts all participants the weekend before programming begins and answers any questions prior to the first session. The Program Leader also coordinates a student Implementation Team that attends sessions and provides technical and social support for program participants. The student leaders completed training in adult fitness programming through a practicum course at Iowa State University and assist the participants in completing the recommended exercises (either the prescribed exercises in the ST group or the generic exercises in the SI group). The Program Leader also provides in-person mini-lessons that complement the eBook and behavioral content that participants receive through the online OAAA portal.

The separation of the Evaluation Team and the Implementation Team is intentional as it helps to ensure the naturalistic implementation of the programming and the rigor of the evaluation. Baseline assessments are conducted within (7) days of initiating program participation and post-program data are collected using the same procedures no more than 7 days after the completion of the WWE program. Primary outcomes are evaluated at the end of the 6-week program but follow up data collection of survey measures at 6 months and 12 months post-program enable an evaluation of long-term outcomes. All data collected through the project are entered into a secure web server, accessible only to members of the research team. Data are managed and analyzed by members of the research team using de-identified datasets. Adverse events are immediately reported to the study

management team by the Implementation Team for tracking and to allow for evaluation of study procedures and ensure participant safety.

Data monitoring

The trial does not have a data monitoring committee but is coordinated in collaboration with the Iowa Community HUB Advisory Board. The project is conducted as a Program Project grant in collaboration with leaders from the CDC so data monitoring and oversight of the project are coordinated through these meetings.

Formalized process evaluations are conducted on an annual basis to refine implementation. Data are also processed at the end of each semester of implementation and annually to ensure appropriate strategies are in place for data management.

Ancillary and post-trial care

Participants are provided with recommendations and strategies for ways to maintain physical activity habits over time. They are informed of opportunities to continue walking and exercising at local facilities and are also connected to the group Facebook page and other group lists to enable individuals to stay connected to the project. No other post-trial care is provided.

Dissemination policy

The findings of this trial will be disseminated through peer-reviewed journals and scientific conferences. Authorship eligibility of trial findings will be determined based on contributions to the particular evaluation being disseminated.

Protocol amendments

Updates on the protocol and results will be made through the Clinical Trial registration.

Statistical analyses

Process evaluation

The analytic approach for the process evaluation will be guided by the established framework developed by Linnan and Steckler [26] to guide public health research and later refined by Saunders et al. [27]. The specific process evaluation will focus on the previously defined process measures: recruitment, context, reach, dose delivered, and dose received. Collectively, these indicators will capture overall fidelity (i.e., the degree to which WWE was implemented as planned). A composite score of individual implementation indicators will also be computed to reflect the degree to which the intervention was delivered and received by participants; however, emphasis will be on the evaluation of each component individually.

The data from each component of the process evaluation will be used in both formative and summative ways. The formative evaluation will enable the research team to monitor and adjust program implementation to ensure alignment with the standardized guidelines for WWE implementation. The summative evaluation will be used to help explain differences in program outcomes across individuals, groups, or over time. For example, the indicators of adherence to the habit formation training will be linked to the quantified indicator of habit formation captured as a secondary outcome. The stratification based on physical activity is expected to mediate or explain differences in fall risk.

Outcome evaluation

The three primary outcomes are the number of reported falls, the fall risk score quantified by the STEADI index, and physical activity as assessed by the IPAQ-E questionnaire. The STEADI index is a discrete value with a 44 point range that has previously been used to predict fall risk [28]. Because some components of the fall risk score are unlikely to change over the 12 month follow up period (and almost certain to not change over the 6 week treatment period), we will also use as a primary outcome a modified fall risk score that includes only those components likely to change over the short term.

The properties of the STEADI index and modified STEADI index as a response variable are not known. An innovative statistical contribution will be to understand those properties, develop appropriate models for their analysis, and evaluate the relative sensitivity of the modified STEADI index.

All four primary outcomes will be analyzed with the same basic statistical model. This model includes the two-way factorial treatment structure (standard or enhanced exercise x standard or enhanced behavioral education) crossed with observation times (6 week, 6 month, or 12 month) treated as repeated measures. Baseline values for each individual will be used as a covariate, with a different regression coefficient for each observation time. The number of falls will be modeled with a negative binomial distribution to account for potential overdispersion. The other three outcome variables (fall risk score, modified fall risk score and physical activity) will be modeled with normal distributions, perhaps after transformation. We will consider different models for the repeated measures correlation structure and use AIC to choose the most appropriate structure.

The primary hypothesis is that the enhanced program will decrease the number of falls, decrease the average fall risk and increase average physical activity. This will be quantified by the differences between the standard and enhanced programs, averaged over the two behavioral

treatments. These differences will be estimated for each post-treatment observation time (6-week, 6-month, or 12-month) and averaged over observation times if there is little to no evidence of an interaction between program and observation time, i.e., the differences between programs are similar at all 3 post-treatment observation times.

The secondary hypothesis is that participants receiving habit formation modules as part of behavioral training will have greater compliance to the prescribed exercise, higher levels of physical activity, and better fall risk reduction outcomes than those in the standard group. This will be quantified by the differences between the standard and habit-formation behavior treatments, averaged over the two types of programs. As with the primary hypothesis, these differences will be estimated for each post-treatment observation time (6 week, 6 month, or 12 month) and averaged over observation times if there is little to no evidence of an interaction. These outcomes will also be evaluated with several sub-hypotheses that build on variations from the basic model.

Discussion

The present study is designed to evaluate the potential of the established WWE intervention to help reduce risks for falls in older adults. A key advantage of WWE for coordinated fall prevention is the potential for broad dissemination. The WWE intervention is promoted nationally with coordination provided by the National Association for Chronic Disease Directors (NACDD) in collaboration with the national Osteoarthritis Action Alliance (OAAA) which supports the Arthritis Foundation in dissemination efforts.

If findings support the efficacy of WWE as a fall prevention program there is potential for broader reach to address fall risk at a population level. Major advantages of WWE over other community-based fall prevention programs are that programming can be easily delivered by trained community leaders and that it emphasizes activities that are easy for older adults to perform. There are also potential advantages of WWE as a primary prevention strategy to help maintain function and to reduce frailty in older adults. Research has specifically documented the importance of walking as a key to independence in seniors [41] and reductions in sedentary behavior have been shown to yield additional benefits in this population [42].

It is noteworthy that the WWE intervention is very well aligned with the MoveYourWay initiative released with the U.S. PA Guidelines for Americans campaign [41] to enhance population health. The group format of the intervention may be particularly beneficial for older adult participants as it offers a social element in addition to the intervention content itself. This social element increases the likelihood that older adults engage in the program and beyond, as social support is a key determinant of older adult leisure time physical activity [43].

Previous research has supported the potential of walking-based interventions for reducing fall rates in walkers [44]. A study by Okubo et al. [45] specifically demonstrated that a brisk walking intervention may be more effective than balance training among low-risk older adults. A noteworthy observation in this study is that both groups reported a similar number of falls, but the walking group reported significantly higher exposure (e.g., active days and steps taken). Walkers had more 'trips' (defined as the act of stumbling over an object without landing on any part of the body) but fewer falls (defined as unintentionally coming to rest on the ground, floor, or other lower level) per step, suggesting an inoculation effect. Given the prevalence and accessibility of walking, walking programs may offer an effective method of reducing falls at a widespread scale, particularly among rural communities where fall rates are higher and access to trained program leaders is lower [46].

The 2x2 factorial design will make it possible to evaluate the independent and interactive effects of exercise prescription programming and behavioral training. The exercise prescription factor evaluates the relative effectiveness of two implementation strategies for the group WWE format (Standard vs Enhanced). The behavioral training factor compares Standard content to Enhanced content focused on building habit formation. This feature will enable the simultaneous evaluation of strategies to promote compliance with exercise prescriptions, an ongoing limitation of current physical therapy-based approaches to fall prevention [47, 48]. Thus, the results will determine the relative effectiveness of individually-prescribed exercises (compared to standardized exercises) as well as the potential of 'habit training' approaches to improve compliance with exercises in this population. The outcome evaluation will evaluate whether the intervention 'works' to accomplish the intended goals, but the linked process evaluation will provide key insights to understand 'how' the intervention works – and importantly how to make it work better [49].

The naturalistic study design with referrals coordinated through a statewide community care hub and with implementation through a community-based program enables the evaluation to provide insights needed to promote broader dissemination. While our primary focus is on conducting the randomized controlled trial in our local community, the long-term goal is to facilitate the broader dissemination of the programming by fitness leaders and older adult agencies across the state. A recent state-wide dissemination study on the Matter

of Balance program demonstrates the potential of coordinated statewide efforts to address fall risk in older adults [50]. Conducting similar process evaluations to determine the implementation factors that influence the successful adoption and sustainability of programming will help provide practitioners with additional opportunities to offer evidence-based fall prevention in their communities.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12889-024-20138-z.

Supplementary Material 1.

Supplementary Material 2.

Acknowledgements
We want to acknowledge contributions by leaders on the CDC project team in reviewing the manuscript and providing suggestions. Special thanks to Andrea Carmichael, Yara Haddad and Jill Klosky.

Authors' contributions
NL and GW conceptualized and planned the original study, NL, GW, TRS and JL created data collection materials and procedures, AP created behavioral support intervention materials, PD developed the analysis plan, and MD and LSC contributed to the conceptual design and proposal. All authors critically reviewed and edited the manuscript and have approved the final manuscript.

Funding
This project is supported through a Cooperative Agreement (U01CE003490-01: Process and Outcome Evaluation of the Walk with Ease program for Fall Prevention) with the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services (HHS). Annual funding allocations are approximately $350,000 per year (100% funded by CDC/HHS), with funding contingent on demonstrating continued progress and documented effectiveness with program implementation and evaluation. The contents are those of the authors and do not necessarily represent the official views of, nor an endorsement, by CDC/HHS, or the U.S. Government. The original application went through a primary peer preview and secondary review as part of the extramural research program operations funding process: https://www.cdc.gov/injury/erpo/extramural-research.html
As part of this peer review, the application received a peer review score and summary statement similar to how NIH conducts peer review of applications.

Availability of data and materials
The project is conducted as a Program Project grant in collaboration with leaders from the CDC. Appropriate data sharing practices have been developed in accordance with the CDC grant requirements. A de-identified data set will be created 1 year after the study is completed, and will be made available under data-sharing agreements that document a commitment to using the data for research purposes only.

Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This study protocol was reviewed and approved by the Institutional Review Board at Iowa State University (IRB Protocol: 22-286). Informed consent will be obtained from all participants who will be informed of the purpose, intervention components, and possible risks and benefits of the study by researchers responsible for data collection. Participants will provide digitally signed informed consent prior to participating in research procedures.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Received: 30 November 2023 Accepted: 19 September 2024
Published online: 28 September 2024

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