



Research Methodologies and Protocols

Developing and Testing Implementation Strategies to support the Centers for Disease Control and Prevention's Initiative for Falls Risk Management in Outpatient Physical Therapy: A Protocol



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List of abbreviations: CFIR, Consolidated Framework for Implementation Research; EBP, evidence-based practice; EBQI, evidence-based quality improvement; EHR, electronic health record; MMR, mixed-methods research; STEADI, Stopping Elderly Accidents, Deaths, and Injuries; TUG, timed Up and Go.

Supported by the National Institutes of Health (NIH, [K76AG074920](https://pubmed.ncbi.nlm.nih.gov/36400000/), [K24AG069176](https://pubmed.ncbi.nlm.nih.gov/36400000/), [K24AG057728](https://pubmed.ncbi.nlm.nih.gov/36400000/)) and the Translational Research Institute ([KL2 TR003108](https://pubmed.ncbi.nlm.nih.gov/36400000/), [UL1 TR003107](https://pubmed.ncbi.nlm.nih.gov/36400000/)) through the National Center for Advancing Translational Sciences of the NIH. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH. It was also supported by a Center for Health Services Training and Research (CoHSTAR) Pilot Grant [CNVA00045970](https://pubmed.ncbi.nlm.nih.gov/36400000/) (710850-10).

Disclosures: Dr Vincenzo has served as a consultant for PhysiU and continued.com. The other authors have nothing to disclose.

Cite this article as: Arch Rehabil Res Clin Transl. 2023;5:100268

<https://doi.org/10.1016/j.arrct.2023.100268>

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KEYWORDS

Implementation science;
Rehabilitation;
Postural control and aged

Abstract Objectives: To develop and test implementation strategies to support implementing the Centers for Disease Control and Prevention's Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative for falls prevention and falls risk management in a novel setting, outpatient physical therapy.

Design: A feasibility implementation study engaging key partners involved in or affected by the implementation throughout the study.

Setting: Five outpatient physical therapy clinics embedded in a health system.

Participants: Key partners (physical therapists, physical therapist assistants, referring physicians, administrative clinic staff, older adults, and caregivers) involved in or affected by the implementation (N=48) will participate in surveys and interviews to identify barriers and facilitators prior to implementation and post implementation. Twelve key partners representing at least 1 of each group will participate in evidence-based quality improvement panels to identify which barriers and facilitators are most important and feasible to address and to assist in choosing and designing implementation strategies to support the uptake of STEADI in outpatient rehabilitation. STEADI will be implemented in 5 outpatient physical therapy clinics as a standard of care for the ~1200 older adults attending those clinics annually.

Outcomes: Primary outcomes include clinic- and provider-level (physical therapists and physical therapist assistant) adoption and fidelity to STEADI screening, multifactorial assessment, and falls risk interventions for older adults (65 years or older) attending outpatient physical therapy. Key partners' perceived feasibility, acceptability, and appropriateness of STEADI in outpatient physical therapy will also be measured using validated implementation science questionnaires. Exploratory clinical outcomes of older adults' falls risk pre- and post rehabilitation will be investigated.

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Falls among adults older than 65 years are a leading cause of morbidity, mortality, and high health care costs in the US.¹ Many falls are preventable with a multifactorial falls prevention approach, which includes screening, assessment, and targeted interventions to ameliorate risks.²⁻⁴ Clinical practice guidelines^{5,6} and the World Guidelines for Falls Prevention and Management for Older Adults (developed by the World Falls Taskforce, spanning 39 countries across 5 continents)⁷ indicate that all health care providers, which includes physical therapists, should be conducting falls prevention for *all* older adults. However, research shows that physical therapists are not adhering to guidelines. Only 13% of Medicare beneficiaries at high risk for falls reported that falls were addressed during outpatient rehabilitation,⁸ and claims data revealed that only 10.7% of older adults who had an upper extremity fracture (most likely because of a fall) had a falls risk assessment by a physical therapist.⁹ Research is needed to understand the gap in the adoption of falls prevention in outpatient physical therapy and to develop strategies to support adoption.

Pragmatic trials of falls prevention in outpatient settings have been focused in primary care using the Centers for Disease Control and Prevention—developed Stopping Elderly Accidents, Deaths, and Injuries (STEADI), but implementation barriers, including challenges with workflow, follow-up, and management of numerous medical conditions, limit uptake and sustainability.¹⁰⁻¹⁵ By contrast, physical therapists are well positioned to implement falls prevention for all older adults in outpatient physical therapy using STEADI considering that (1) older adults at high risk for falls are

3 times more likely to receive rehabilitation,¹⁶ (2) 1 in 5 older adults attends rehabilitation annually,¹⁷ (3) physical therapists have used STEADI in community screenings,¹⁸⁻²¹ (4) physical therapists are qualified to provide falls prevention within their scope of practice,⁵ and (5) physical therapists are afforded more 1-on-1 time and frequent follow-up than primary care providers. Despite these promising data, no studies have investigated the feasibility or how to best support implementing STEADI in outpatient physical therapy.

Implementation science provides a means to address gaps in adoption and investigate the feasibility of STEADI in rehabilitation. Implementation science is the scientific study of how to best support the uptake of evidence-based practices (EBPs), with consideration of multilevel (eg, clinic-, provider-, and patient-level) key partner perspectives to improve the quality and effect of health services.²²⁻²⁴ Implementation science uses formative evaluation, contextual analysis of implementation needs, key partner-driven implementation strategy development, and implementation frameworks to improve the adoption of EBPs. Table 1 defines common implementation science terms.²⁵

Few studies conducted on falls prevention or STEADI used an implementation science approach to support implementation or to measure implementation outcomes, such as feasibility or program adoption, which influence clinical outcomes. Eckstrom et al used implementation strategies (eg, education and electronic health record [EHR] revisions) that improved STEADI adoption and fidelity in primary care,²⁶ and Johnston et al found that adoption affected

Table 1 Implementation science terms

Term	Definition
Formative evaluation	Assessment conducted prior to and/or concurrent with implementation that provides data for immediate use to improve the implementation process
Fidelity	Degree to which an EBP is implemented as intended
Adoption	Uptake of EBP by clinics and/or providers
Implementation strategies	Tools/activities to facilitate the adoption of and fidelity to EBP
Feasibility	Extent to which implementation can be completed given available resources
Acceptability	Degree to which the implementation is agreeable to stakeholders
Appropriateness	Perceived fit and compatibility of the intervention in clinical practice

clinical outcomes. Older adults with a provider-documented falls prevention intervention were 0.6 times less likely than older adults who did not have a documented intervention to have a fall-related hospitalization.¹¹

To our knowledge, no studies have investigated the feasibility of STEADI in outpatient physical therapy or used implementation science to facilitate the adoption of STEADI in outpatient physical therapy. Results of implementation studies on STEADI conducted in primary care are not directly transferrable to outpatient physical therapy. The care settings are distinct and governed by different rules and regulations.

Therefore, the goal of this research is to use an implementation science approach to identify the barriers and facilitators to implementing STEADI for falls prevention in outpatient physical therapy and to develop and test the effect of implementation strategies on implementation outcomes (primary) and exploratory clinical outcomes (secondary). This research will result in implementation strategies to support the adoption of STEADI for falls prevention in outpatient physical therapy that are feasible and acceptable to key partners to be investigated in a future hybrid type III study.²⁷ To achieve this outcome, we will complete 3 aims:

Aim 1: Identify clinic-, provider-, and patient-level barriers to and facilitators of implementing STEADI in outpatient physical therapy. Guided by the Consolidated Framework for Implementation Research (CFIR),²⁸ we will use a concurrent mixed-methods research (MMR) design using data from surveys and interviews with key partners (N=48) associated with 5 outpatient physical therapy clinics to identify barriers and facilitators associated with the feasibility, acceptability, and appropriateness of implementing STEADI in outpatient physical therapy. Key partners are people who are involved in or affected by the implementation, including older adults, caregivers, physical therapists, physical therapist assistants, administrative front desk staff, and referring physicians.

Aim 2: Develop implementation strategies to support the adoption of STEADI in outpatient physical therapy. Based on results from aim 1, we will use an evidence-based quality improvement (EBQI) process to engage key partners to develop implementation strategies (clinic-, provider-, and patient-level) consistent with the CFIR framework and matched to identified barriers and facilitators to support implementing STEADI in outpatient physical therapy.

Aim 3: Pilot test the effect of implementation strategies for STEADI in outpatient physical therapy on implementation

outcomes (clinic- and provider-level) and exploratory clinical outcomes. We will use an explanatory MMR approach to identify whether the implementation support strategies are feasible, acceptable, appropriate, and result in the adoption and fidelity of STEADI, and we will explore clinical outcomes of older adults' falls risk.

Methods

Aim 1 (#274749), aim 2 (#274892), and aim 3 (#274898) were reviewed and deemed exempt by the University of Arkansas for Medical Sciences institutional review board.

Theoretical framework

We will use the CFIR, which facilitates the implementation of health services research findings into practice.^{28,29} CFIR is used as a guide to identify and select strategies to mitigate barriers and capitalize on facilitators. It has been used as a framework in nursing research to identify factors that influence the adoption of falls prevention (not STEADI) in inpatient oncology³⁰ and in hospital settings.^{31,32} The study design and reporting follows Smith Implementation Research Logic Model³³ (fig 1) and the Standards for Reporting Implementation Studies/StarRI checklist³⁴ by Smith et al. Figure 1, aim 1 delineates the 5 CFIR constructs and their operationalization for this research. Aims and methods are delineated in table 2.

Aim 1: Identify clinic-, provider-, and patient-level barriers to and facilitators of implementing STEADI in outpatient physical therapy

Design

We will use a convergent MMR approach to complete this aim.³⁵ We will use validated surveys in implementation science to collect quantitative data to identify stakeholders' baseline perception of the feasibility, acceptability, and appropriateness³⁶ of implementing STEADI in outpatient physical therapy. Semistructured interviews using a CFIR-based guide and questions regarding feasibility, acceptability, and appropriateness will enable us to understand the

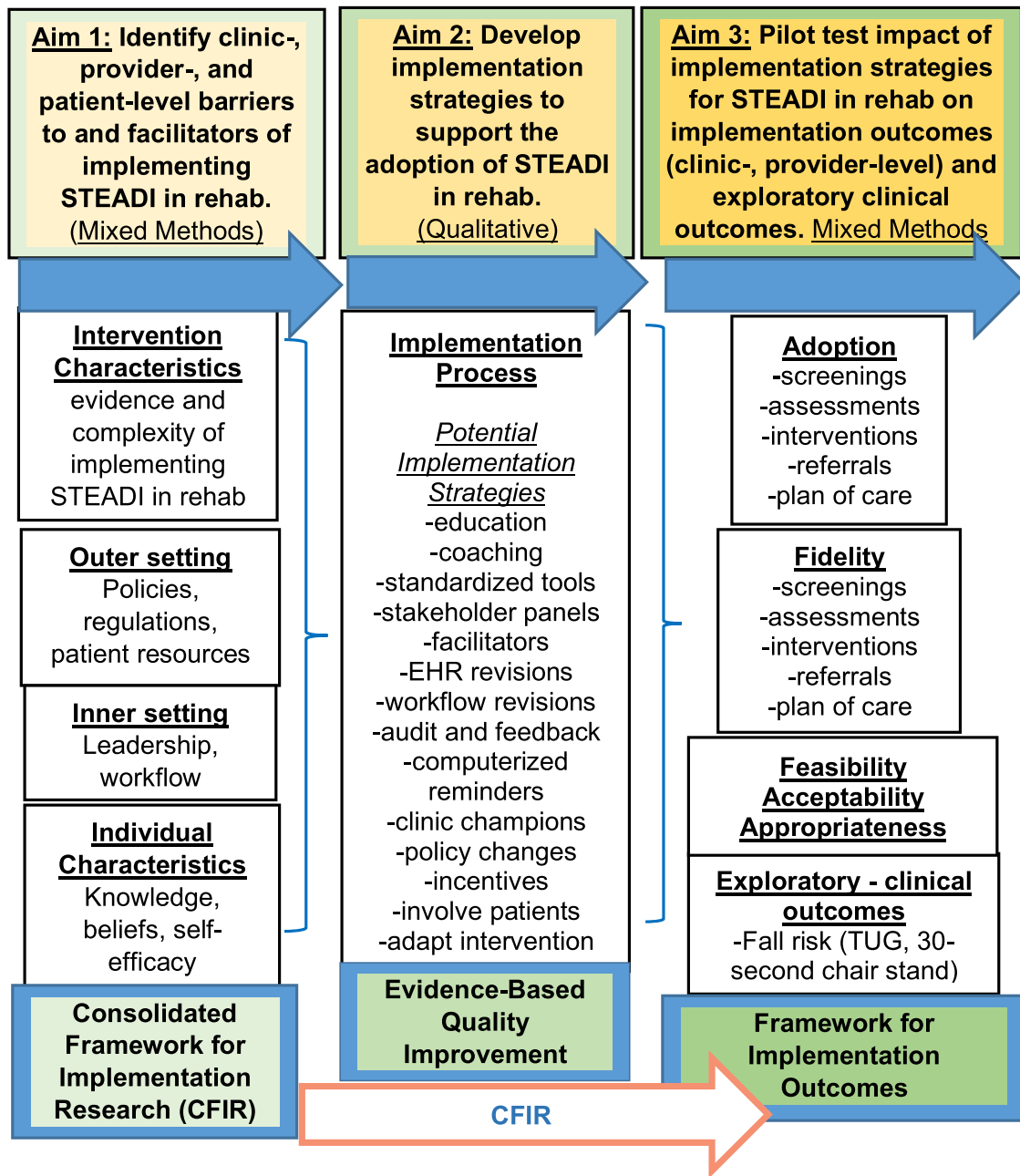


Fig 1 Protocol implementation research logic model³³

barriers and facilitators to implementing STEADI (qualitative data) to inform aim 2.

Methods

We will conduct this study in 5 outpatient physical therapy clinics housed in the same health system. We will purposefully recruit, survey, and interview key partners (N=48) directly involved in unique roles in implementation or affected by the implementation. We aim to interview all of the clinic-level key partners at the 5 clinics (2 managers, 5 administrative assistants, and 16 physical therapists or physical therapist assistants). Clinic leadership and staff will identify external partners for recruitment (eg, referring physicians, older

adults, and caregivers). We aim to conduct interviews with 2 patients and 2 caregivers who have experienced outpatient physical therapy at each clinic (total 10 patients, 10 caregivers) and 1 outside referring physician per clinic. A sample size of 5-10 per homogenous group is necessary to gain data saturation in individual interviews.^{35,37} We will pilot test and modify interview guides using CFIR constructs and additional questions about feasibility, acceptability, and appropriateness as well as barriers and facilitators to implementation of STEADI. After undergoing informed consent, key partners will complete surveys in Research Electronic Data Capture on perceived feasibility, acceptability, and appropriateness of implementing STEADI in outpatient physical therapy (quantitative data) and participate in 30- to 60-minute semistructured interviews (qualitative data).³⁸ We will attempt to conduct

Table 2 Aims and methods

<p>Aim 1: Identify clinic-, provider-, and patient-level barriers to and facilitators of implementing STEADI in outpatient physical therapy.</p>	<p>Aim 2: Develop implementation strategies to support the adoption of STEADI in outpatient physical therapy.</p>	<p>Aim 3: Pilot test effect of implementation strategies for STEADI in outpatient physical therapy on implementation outcomes (clinic- and provider-level) and exploratory clinical outcomes.</p>
<p><u>Mixed methods</u> Survey and interview sample of key partners involved in or affected by implementation (N=48) <u>Surveys</u> - validated feasibility, acceptability, and appropriateness surveys in implementation science. <u>Interviews</u> - based on constructs in consolidated framework for implementation research</p>	<p><u>Evidence-based quality improvement</u> Workgroup of sample of key partners (n=12). <u>6 sessions</u> - Identify implementation barriers to address and choose and tailor implementation strategies.</p>	<p><u>Mixed methods</u> <u>Step 1</u> -> Examine adoption, fidelity, and explore implementation outcomes 6 months after implementation using data extracted from electronic health records and chart audits. <u>Step 2</u> -> Repeat methods in aim 1 with sample of key partners (n=10). <u>Step 3</u> -> Repeat methods in aim 2 to revise implementation strategies as needed. <u>Step 4</u> -> Reexamine adoption and fidelity outcomes and explore implementation outcomes 1 year after implementation. <u>Step 5</u> -> Repeat methods in aim 1 to identify barriers, facilitators, feasibility, acceptability, and appropriateness post implementation.</p>

interviews in person but may conduct them by Zoom if necessary. Interviews will be recorded, and notes will be taken for audit trails.

Analyses

Quantitative

We will calculate survey means, SDs, and 95% CIs for perceived feasibility, acceptability, and appropriateness for homogenous key partner groups and all key partners combined. Survey questions are based on a Likert scale ranging from 1-5, where answers below 3 indicate a lack of feasibility, acceptability, and appropriateness.³⁶ These data will enable us to compare changes in these implementation outcomes in aim 3 (eg, compare physical therapists' preimplementation perceived acceptability of STEADI to the postimplementation acceptability).

Qualitative

Audio-recorded interviews will be transferred to a secured server, transcribed verbatim with software, and analyzed. We will conduct a focused analysis of factors relevant to implementation with a CFIR codebook and codes for feasibility, acceptability, and appropriateness using a rapid-content analysis technique based on methods described by Nevedal et al.³⁹ This approach compiles summary information from each transcript to quickly capture a priori themes related to CFIR constructs while maintaining rigor in the analysis. We will create a results summary matrix to compile all coding from individual interview templates into 1 document for presentation during the EBQI process in aim 2. Once coding is complete, we will compile all data segments and integrate quantitative and qualitative data.³⁵ We will use themes and quotes from

interviews to explain participants' ratings of the feasibility, acceptability, and appropriateness of implementing STEADI and identify barriers and facilitators to implementation.

Aim 2: Develop implementation strategies to support the adoption of STEADI in outpatient physical therapy

Design

Based on results from aim 1, we will use a scientifically driven EBQI process that supports a researcher-clinician partnership to facilitate the adoption of EBPs by directly working with key partners to inform the development and tailoring of the implementation strategies.^{38,40} We will engage key partners to develop implementation strategies (clinic-, provider-, and patient-level) consistent with the CFIR framework and matched to identified barriers and facilitators to support implementing STEADI in outpatient physical therapy. We will present the evidence on effectiveness and implementation of STEADI in primary care to the panel (because there are no studies on STEADI implementation in outpatient physical therapy), define barriers and facilitators to implementation gathered in aim 1, and suggest evidence-based implementation strategies to address barriers to implementation. Through an iterative process, key partners will choose and tailor strategies to support STEADI in outpatient physical therapy.

Methods

We will use the data in aim 1 and the process of EBQI with key partners to (1) rate barriers and facilitators to

implementation based on their importance and feasibility,⁴¹ (2) select the most important and feasible barriers to address, (3) match barriers and facilitators to implementing STEADI in outpatient physical therapy with potential implementation strategies, (4) tailor implementation strategies for the current study context (outpatient physical therapy), and (5) finalize implementation strategies to support implementing STEADI in outpatient physical therapy.⁴² In accordance with other studies using EBQI, we will recruit an EBQI panel of 12 key partners, which will include at least 1 representative from each key partner group interviewed in aim 1.^{42,43} The panel will meet for six 2-hour sessions (table 3) over 9 months. Sessions will take place by Zoom and will be recorded for reference and audit. Key partners will also identify target adoption and fidelity rates of primary outcome measures/components of STEADI, which, to our knowledge, are not in the existing literature.

Analyses

After each EBQI meeting, we will complete an EBQI summary template to assimilate the input from the panel; document discussions, consensus, and decisions; and translate it into actionable plans for the next meeting. We will compile descriptive statistics from the concept mapping exercise (EBQI session 1) to identify differences among key partners. We will plot potential implementation strategies by importance (x-axis) and feasibility (y-axis). Strategies rated above the mean with both high importance and high feasibility will be considered to tailor for context to support implementation.

Implementation strategies

As noted above, we will summarize the literature in EBQI session 2. We will present findings from the Expert Recommendations for Implementing Change, which refined strategy terminology, generated a consistent language and descriptions, and provided supporting evidence for 73 distinct implementation strategies and 9 purposive categories.⁴⁴ We will then present the barriers and facilitators to STEADI implementation from aim 1, matched to potential implementation strategies based on priorities defined by the CFIR framework,⁴⁵ existing evidence, and expertise provided by the team. Because no studies have been conducted implementing STEADI in outpatient physical therapy, we will

refer to research on strategies that improve health care across multiple settings,⁴⁶ falls prevention,^{11,47,48} or physical therapist practice.^{49,50} We will follow an EBQI process to develop feasible implementation strategies that match specific contexts. The process will provide us with a mutually agreed on, literature-supported, and feasible set of strategies to be tested. Refer to table 4 for potential implementation strategies and targets.

Specific aim 3: Pilot test the effect of implementation strategies for STEADI in outpatient physical therapy on implementation outcomes (clinic- and provider-level) and exploratory clinical outcomes

Design

This is the first time that implementation science will be used to support the adoption of STEADI in outpatient physical therapy; therefore, we will conduct a pilot feasibility implementation study using a sequential, explanatory MMR approach to assess and refine the implementation strategies developed in aim 2 to maximize our ability to test well-specified, feasible, implementation strategies in a future hybrid effectiveness-implementation type III cluster randomized controlled trial.²³

Methods

Preimplementation phase: 3 months

We will spend the first 3 months of this aim training clinic sites and key partners (eg, physical therapists, administrators) in STEADI and falls prevention, deploying the EHR strategies and implementing other strategies developed in aim 2 to prepare to launch the pilot phase. We will maintain a tracking log to record detailed descriptions of deployed strategies²⁴ to enable replication.

Implementation phase

We will deploy the implementation strategies to support the adoption and fidelity of STEADI in 2 subsequent 6-month implementation phases. This 2-phase design will allow us to measure, evaluate, and refine the implementation strategies to support adoption, fidelity, and exploratory clinical outcomes from the first 6 months to the subsequent 6

Table 3 Evidence-based quality improvement stakeholder panel sessions, goals, and activities

EBQI Session	EBQI Panel Goal	Activities to Achieve Goal
Session 1	Reach consensus on barriers and facilitators from aim 1 to drive implementation strategy selection	-Ranking of importance and feasibility of addressing barriers -Implementation mapping ⁴¹
Session 2	Reach consensus on initial implementation support strategies	-Provide panel with literature-supported implementation strategies
Sessions 3 and 4	Choose design specifications for implementation strategies	-Facilitate panel discussion
Session 5	Provide revisions to implementation strategies	-Provide developed implementation strategies and facilitate panel discussion
Session 6	Approve implementation strategies	-Review and vote on strategies

Table 4 Potential implementation strategies to support STEADI integration in rehabilitation

CFIR Construct	Potential Implementation Strategies	Example	Target
<u>Intervention characteristics</u> Complexity	Develop a formal implementation blueprint	EBQI panel of key partners decides on strategies to optimize implementation of STEADI in clinics	MDs, management, admins, clinicians, patients, caregivers
<u>Outer setting</u> Leadership	Policies - Mandate change	Clinic leadership is mandating STEADI implementation in all clinics	Management, admins, clinicians
<u>Inner setting</u> Workflow	Adapt and tailor - change records (EHR) systems	Revise EHR; reminders, practice advisories, digital measures	Clinicians and admins
<u>Inner setting</u> Goals and feedback	Audit and feedback	Key partners set goals - receive audit and feedback on regular time intervals	Management, clinicians, admin
<u>Individual characteristics</u> Knowledge	Train and educate key partners	Provide key partners with education (meetings and print) regarding the use of STEADI and falls prevention	Clinicians, admins, patients, caregivers
<u>Individual characteristics</u> Personal attributes	Engage consumers	Develop strategies with patients and caregivers to improve uptake and adherence	Patients, caregivers

months. After the first implementation phase, we will extract and analyze the adoption, fidelity, and exploratory clinical outcomes data derived from EHR data (table 5). We will use a Fidelity checklist⁵¹ for auditing a random selection of 10 charts at each clinic (n=50 charts). We will also conduct feasibility, acceptability, and appropriateness surveys and semistructured interviews with a sample of key partners (n=10) to understand the implementation data and the barriers to implementation following methods described in aim 1. We will then reconvene the EBQI panel and refine the implementation strategies, followed by a second 6-month implementation phase in which we will deploy the revised implementation strategies. At the end of the 12-month

implementation pilot trial, we will measure implementation outcomes (adoption, fidelity) and conduct surveys (feasibility, acceptability, and appropriateness) and semistructured interviews with the same groups of key partners (N=48) following our methods described in aim 1 to inform the results of our study.

Outcomes

Adoption

Adoption is defined as the uptake of an EBP,⁵³ which, in our study, refers to the components of STEADI that are involved

Table 5 Adoption outcomes for implementation

Components of STEADI	Adoption (clinic- and provider-level)	Target
Screening	No. with response to screening questions or Fall Risk Questionnaire compared with no. eligible	>65% ²⁶
Gait/balance assessment	No. with a documented TUG test ¹ compared with no. screened positive	>50% ⁵²
Strength assessment	No. with documented 30-second chair stand test ¹ compared with no. screened positive	>50% ⁵²
Other falls risk assessment	No. with documented falls risk assessments of other factors (eg, footwear, home safety, vision, orthostatic hypotension) ¹ compared with no. screened positive	>65% ²⁶
Gait, balance, strength interventions	No. with documented gait, balance, and/or strength intervention compared with no. at risk on those assessments	>61% ¹¹
Other interventions in physical therapist scope of practice	No. who received 1 or more falls prevention interventions for home safety or feet/footwear issues compared to no. identified as at risk in those areas	75% ²⁶
Referrals to other health care providers	No. referred to another health care provider compared to No. with risk factors (eg, vision, orthostatic hypotension, medication) requiring referral.	TBD
Plan of care	No. with falls prevention documented in plan of care compared to No. who referred for intervention(s).	TBD

Abbreviations: TBD, to be determined by key partners.

in screening, assessment, and intervention and within a physical therapists' scope of practice.⁵ We aim to meet pre-determined adoption targets derived from the literature using STEADI in primary care or implementing an EBP in outpatient physical therapy (see [table 5](#)). Items without a pre-determined target will have a target identified by the EBQI panel in aim 2. We will measure adoption at the clinic and provider levels using extracted EHR data. Adoption outcomes will be also compared from 6 months to 12 months.

Fidelity

Fidelity is defined as the degree to which an intervention is implemented as described in the original protocol.^{52,54} We will use a fidelity checklist to audit a random selection of 10 charts from the EHR at each clinic at 6 months and 12 months post implementation (n=50 charts). The research team will conduct fidelity checks on the same charts until we consistently attain 0.8 interrater reliability on the results of the audits using a fidelity checklist.⁵¹ We will obtain an overall fidelity score (fidelity of all 8 items) and subscores for each item at both the clinic and provider levels. We define the fidelity of each component of STEADI according to the Centers for Disease Control and Prevention⁵⁵ and the clinical guidance statement for physical therapists to manage falls prevention for older adults as follows.⁵

Screening: Correctly identify an older adult as screening positive for falls risk based on answering yes to falling in the past year, unsteadiness, or worry about falls, or STEADI falls risk questionnaire score ≥ 4 .⁵⁶ **Gait/balance assessments:** correctly identify an older adult as at risk of falls if timed Up and Go (TUG) test is >12 seconds or the older adult has decreased balance during the TUG test.⁵⁶ **Strength assessment:** correctly identify an older adult as at risk of falls if the 30-second chair stand test is lower than age- and sex-matched normative values.^{56,57} **Other falls risk assessment:** correctly identify other risk factors for falls (eg, orthostatic hypotension, home safety, footwear).⁵ **Interventions for gait, balance, strength:** correctly provide individualized exercises to address deficits (eg, balance exercises involve decreasing the base of support, progressively less upper extremity support, and progressively challenging movements).^{58,59} **Other interventions within physical therapist scope of practice:** provide appropriate interventions for feet/footwear issues and/or home safety (eg, home safety brochure).⁵ **Referrals to other health care providers:** refer to appropriate provider(s) to address risk factors outside of physical therapist scope of practice (eg, health-related risks- refer to primary care provider).⁵ **Plan of care:** correctly include falls prevention and plan to ameliorate identified risk(s) (eg, an older adult with identified balance deficits should have balance training to decrease falls risk including in the plan of care).

Exploring clinical outcomes

Implementation outcomes are primary for this project, but we will also explore baseline and discharge clinical outcomes of STEADI (TUG test, 30-second chair stand test). We will extract data from the EHR from older adults with a documented falls prevention intervention.

Feasibility, acceptability, and appropriateness

As described using the methods above and in aim 1, we will use surveys to measure the feasibility, acceptability, and appropriateness of implementing STEADI with a sample of key partners 6 months post implementation (n=10) and all key partners 12 months post implementation (N=48). In addition, we will use semistructured interviews to assess the implementation process (feasibility, acceptability, and appropriateness), including barriers and facilitators to implementation, to gain a deeper understanding of the adoption and fidelity results following methods in aim 1.

Analyses

Adoption

We will analyze rates of adoption as described in detail above at the clinic and provider levels. We will compare adoption rates to a priori target rates (see [table 5](#)). We will estimate the proportion and associated 95% CI. We will also compare adoption rates at 6 months and 12 months post implementation. We will use repeated-measures *t* tests to examine the change in these scores.

Fidelity

We will measure fidelity according to the details above at the clinic and provider levels. We will estimate the proportion and associated 95% CI 6 months and 12 months post implementation. We will use repeated-measures *t* tests to examine the change in these scores.

Feasibility, acceptability, and appropriateness

We will calculate means, SDs, and 95% CIs for feasibility, acceptability, and appropriateness for key partners groups and all key partners combined. Mean scores >3 of 5 indicate feasibility, acceptability, and/or appropriateness. We will compare scores on surveys completed in aim 1 with surveys completed in aim 3 using repeated-measures *t* tests to examine changes in scores.

Exploring Clinical Outcomes

We will estimate means and SDs for TUG test and 30-second chair stand test pre- and post therapy. We will compare baseline scores to cut points for falls risk. A TUG test time >12 seconds or decreased balance while performing the TUG test is indicative of increased falls risk.^{56,60} Performing lower than age- and sex-matched normative values on a 30-second chair stand test is indicative of falls risk.⁵⁶ We will use repeated-measures *t* tests to examine the change in these scores.

Integration of quantitative and qualitative data

We will use an explanatory, sequential mixed-methods design to understand the potential effectors to implementation.³⁵ We will analyze semistructured interviews as described in aim 1. We will integrate the data using joint displays.³⁵ For example, to understand the feasibility of implementing STEADI in outpatient physical therapy, we will construct a table that links clinics with high and low scores of feasibility and/or adoption to interview data.⁶¹

Sample sizes and statistical power

PASS 2020 was used for appropriate effect size calculations.^a Sample size for adoption outcomes is limited to the number of clinics (5) and providers (16) in this study and, like other studies of STEADI in primary care, is not designed for power for implementation outcomes.^{11,13,26} We are not proposing hypothesis tests for adoption outcomes but will compare percentages with criteria in [table 5](#) and compare differences in these measures 6 months and 12 months post implementation. The sample size for fidelity will be $n=50$ chart reviews. The sample size for exploratory clinical outcomes (TUG test, 30-second chair stand test) will be based on the number who are eligible, screen positive, and receive an assessment and intervention. Based on literature regarding outpatient physical therapy services utilization data and falls risk, we conservatively expect 40% of the 1200 eligible patients will screen positive,⁸ and according to our target rate, at least 50% of those will be given assessments²⁶ for $N=(1200 \times 0.4 \times 0.5) = 240$. Based on a repeated-measures t test with 2-sided $\alpha=0.05$ assuming a correlation between pre- and postassessments of $r=0.5$, this sample size ($N=240$) would yield 80% power to detect standardized mean differences as small as $d=0.22$. For context, other community-based falls prevention intervention studies using within-participant designs with pre- postintervention measures of TUG test have found $d=0.68$ and $d=0.48$.^{62,63} Sample size for measures of feasibility, acceptability, and appropriateness will be $N=48$. Based on a repeated-measures t test with 2-sided $\alpha=0.05$ assuming a correlation between pre- and postassessments of $r=0.5$, this sample size ($N=48$) would yield 80% power to detect standardized mean differences as small as $d=0.5$, or a difference of half an SD.

Discussion

To our knowledge, this is the first study to investigate the feasibility of STEADI for falls risk management of all older adults attending outpatient physical therapy. This study is innovative and significant for several reasons. We will be the first to test the feasibility of implementation strategies on implementation outcomes of STEADI in outpatient physical therapy, shifting the approach of using STEADI for falls prevention solely in primary care to using it in outpatient physical therapy to reach more older adults. According to Medicare and clinical guidelines, physical therapists should implement falls prevention and management within their scope of practice for all older adults,⁵ yet research indicates physical therapists are not adhering to these guidelines.^{8,9} Improving falls prevention adoption in outpatient physical therapy may be more feasible than primary care because physical therapists are afforded more time and visits with older adults attending outpatient physical therapy, enabling physical therapists to also address patient-specific barriers to adopting and adhering to falls prevention (eg, adherence, accountability and support).⁶⁴ Our study is also innovative because we are engaging key partners throughout our study to address feasibility through implementation science approaches to develop and test the effects of implementation strategies on the adoption of STEADI in outpatient physical therapy. Proctor et al, leaders in the field of implementation science, call for moving beyond studies

investigating barriers to implementation to those of building and testing strategies for implementation.⁶⁵ Our research answers this call using contextual analysis with multilevel (clinic-, provider-, and patient-level) key partner perspectives to drive the development of implementation strategies and pilot test them on implementation-level and exploratory patient-level outcomes.^{22–24}

Study limitations

There are limitations to our protocol. First, our study is a non-randomized feasibility study and is not powered to detect clinical differences among older adults who do and do not receive falls prevention. Second, the study will be conducted in outpatient physical therapy clinics within 1 health system, but the clinics do vary in number of older adults seen annually (~170-500) and number of clinicians (2-7). Third, engaging key partners throughout the study will require buy-in, which can be challenging. We obtained leadership and management support prior to the study to decrease these challenges.

Conclusions

The findings from this implementation feasibility study will develop and test strategies to support STEADI for all older adults attending outpatient physical therapy. This will provide the groundwork for other health systems and clinics to engage in similar practices. In addition, this study will support a future hybrid type III study²⁷ to compare the effects of different implementation strategies to support STEADI in outpatient physical therapy.

Supplier

a. PASS 2020 power analysis and sample size software; NCSS.

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Acknowledgment

We thank the University of Arkansas for Medical Sciences Translational Research Institute and Center for Implementation Research for their support.

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