Research Methodology and Protocol

Development of a Coaching Protocol to Enhance Self-efficacy Within Outpatient Physical Therapy

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Abstract
Objective: To describe the development of the Specific, Measurable, Action-Oriented, Realistic, and Timed (SMART) Coaching Protocol to increase exercise self-efficacy in middle-aged and older adults participating in Live Long Walk Strong (LLWS) Rehabilitation Program. LLWS Rehabilitation Program is an innovative physical therapist (PT) delivered outpatient intervention for middle- and older-aged adults with slow gait speed. Design: Phase II randomized controlled trial (RCT) with masked outcome assessment. We applied the Knowledge to Action Framework to develop and implement the LLWS SMART Coaching Protocol within an RCT for the LLWS Rehabilitation Program. Data will be collected at baseline and post intervention at 2, 8 and 16 weeks. Setting: Outpatient; VA Boston Healthcare System. Participants: Community-dwelling veterans (N=198) (older than 50 years) with slow gait speed (<1.0 m/s).

KEYWORDS
Exercise; Physical therapy modalities; Rehabilitation; Walking speed.

List of abbreviations: LLWS, Live Long Walk Strong; PT, physical therapist; RCT, randomized controlled trial; SCT, social cognitive theory; SMART, Specific, Measurable, Action-Oriented, Realistic, and Timed; SPPB, Short Physical Performance Battery; VA, Veterans Affairs.

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Mobility is a major contributor to functional independence and a modifiable treatment target to improve overall physical functioning in older adults. To date, interventions targeting mobility have largely focused on exercise programs that have not addressed psychological factors involved in adopting a new exercise program. Based on the social cognitive theory (SCT) of behavior change, adoption of any new behavior, including exercise, is dependent on one’s level of self-efficacy. Self-efficacy is defined as an individual’s confidence in their ability to execute courses of action. Prior research has found that greater exercise self-efficacy is associated with attendance in exercise trials, long-term physical activity maintenance, and protection against declines in physical ability. Exercise self-efficacy is also an important treatment mediator in rehabilitative interventions designed to provide therapeutic exercise. Under these conditions, the effect of rehabilitative interventions on physical functioning is mediated by improvement in self-efficacy for engagement in therapeutic exercise.

Presently, there is a limited body of research combining physical therapy and behavioral interventions to improve functional outcomes in older adults. Early research showed that a home-based exercise program that included physical therapist (PT)-delivered cognitive-behavioral skills (ie, positive reinforcement, goals setting) produced significant improvements in lower extremity strength, tandem gait, and physical and overall disability scores compared with wait-list controls. In addition, a sample of older adults who received formal rehabilitation for hip fracture and were discharged home, those who received 3 sessions of a home-based exercise program that incorporated a cognitive-behavioral component demonstrated improved performance on the Short Physical Performance Battery (SPPB) at 6 and 9 months post hip fracture compared with an attentional control group that received the same amount of interpersonal interaction.

More recently, Lenze et al developed a PT-delivered Enhanced Medical Rehabilitation program providing motivation messages, goal setting tools, and positive reinforcement to older adults receiving postacute care in a skilled nursing facility. Those who received Enhanced Medical Rehabilitation compared with usual care showed greater improvement at discharge in recovery of basic activities of daily living and mobility function. However, no differences were found at discharge for length of admission, 10-m gait speed test, or 6-minute walk test. No long-term improvements were found in the Enhanced Medical Rehabilitation group at 30-, 60-, or 90-day follow-up.

Despite the burgeoning research infusing physical therapy with behavior change strategies, there remains limited well-controlled trials testing the efficacy of combined physical therapy with behavior change protocols for middle-aged and older adults. Moreover, variations exist in how cognitive-behavioral interventions are delivered by PTs and challenges of delivering both physical therapy and cognitive-behavioral interventions within a time-limited manner that is integrated and feasible. To address this gap, the Live Long Walk Strong (LLWS) Rehabilitation Program was developed in 2010. The LLWS Rehabilitation Program is a PT-led intervention that targeted community-dwelling older adults with mobility limitations. The PT uniquely served in a program coordinator role providing physical therapy addressing gait speed, posture and stability, and specific bodily functional and structures (eg, leg strength and power), as well as behavior change tools. The behavior change tools included a “health behavior contract” focused on Specific, Measurable, Action-Oriented, Realistic, and Timed (SMART) goals at the beginning of therapy, eliciting support from the patient’s friends and family, and use of self-monitoring tools (eg, exercise calendar). Patients who completed the program (n=166) attended an average of 10.8±3.9 sessions and demonstrated clinically meaningful change in physical functioning (SPPB=1.66 unit improvement).

In 2018, LLWS-Veterans was offered to veterans within a Veterans Affairs (VA) medical center outpatient clinic. Similar to the civilian version, LLWS-Veterans targeted older adults with mobility limitations but with a more explicit focus on exercise self-efficacy through introducing the concept of SMART goals early on in the course of therapy. LLWS-Veterans demonstrated proof of concept using a before and after design (n=66) among older veterans who participated in an average of 10 outpatient physical therapy sessions during 2 months with clinically meaningful change in gait speed (0.09m/s) and physical functioning (1.7 units on the SPPB).

Future iterations of LLWS Rehabilitation Program included a virtual (video-based) clinical demonstration project in light of the COVID-19 pandemic.

Precursor clinical demonstration projects culminated to the current randomized controlled trial (RCT) of LLWS Rehabilitation Program. In preparation for the RCT, we needed to fully develop the behavioral intervention component. We used the Knowledge to Action Framework, a conceptual framework guiding the translation of knowledge to action in the context of intervention development, delivery, and dissemination. This framework provided step-by-step framework for developing the new behavioral intervention component.
Coaching protocol to enhance self-efficacy for PT

Thus, we addressed several limitations to the prior behavior change components in prior iterations of LLWS Rehabilitation Program. First, we created a structured protocol for the PT to enhance standardization of the behavior change elements. Second, we created a patient version of the protocol to enhance self-monitoring, goal setting, and adherence. Finally, although we retained elements of the initial behavior change intervention, such as the exercise calendar, we provided new content that introduced and elaborated on the role of SMART goals and additional content on assessing and navigating barriers to exercise in veterans. Stemming from this pilot work, the current article presents the development of the SMART Coaching Protocol that is embedded in a larger ongoing phase II RCT of the LLWS Rehabilitation Program compared with the wait-list control group.

The LLWS Rehabilitation Program RCT intervention combines a novel outpatient physical therapy program with cognitive behavioral skills (ie, goal setting, addressing barriers, problem solving) based on SMART goals framework consistent with SCT. PTs deliver cognitive-behavioral interventions focused on creating, tracking, and monitoring exercise goals and problem solving internal (eg, low motivation, fatigue) and external barriers (eg, schedule) to using a SMART goals framework that is directly integrated with ongoing exercise goal setting.

One hypothesis for this RCT is that the intervention group will demonstrate statistically significant increase in self-efficacy, from baseline to post treatment compared with the wait-list control group. We will also test whether change in self-efficacy mediates the effect of the LLWS Rehabilitation Program on change in gait speed and whether those with higher self-efficacy at the end of the 8-week intervention show greater sustained improvements in physical functioning, as measured by gait speed, and at subsequent 8- and 16-week assessments. In the current article, we present the development and implementation of the LLWS SMART Coaching Protocol using the Knowledge to Action Framework to guide knowledge translation.

Methods

Overview of design

The LLWS Rehabilitation Program is a phase II RCT with masked outcome assessment registered at clinicaltrials.gov as NCT04026503. After providing informed consent, eligible participants (N=198) are randomized to the LLWS Rehabilitation Program (n=99) or wait-list control group (n=99). The wait-list control group receives the LLWS Rehabilitation Program after 8 weeks. Primary outcome of gait speed and secondary measure of self-efficacy are assessed at baseline and post intervention at 2, 8, and 16 weeks.

Participants

Participants are 198 U.S. veterans who meet the following inclusion criteria: (1) aged 50 years or older, (2) community-dwelling, (3) able to speak and understand English, and (4) having usual gait speed between 0.05-1.0 m/s. Participants were excluded based on the following criteria: (1) presence of a terminal disease, (2) major medical problem or psychiatric disorder interfering with safe and successful testing (ie, use of supplemental oxygen, substance abuse), (3) myocardial infarction or major surgery in previous 3 months, (4) planned major surgery, (5) baseline SPPB score <4, (6) use of a walker, (7) Montreal Cognitive Assessment Test Mini score <10, and (8) presence of significant disease specific impairment (eg, peripheral neurologic impairment). Participants are recruited from partnered primary care physicians at VA Boston Healthcare System via an electronic patient database identifying potentially eligible primary care patients within the VA Boston Healthcare System. Letters are sent to potential participants inviting them to indicate their interest in the study by contacting study staff via phone or mail. The study is approved by the VA Boston Healthcare System (Institutional Review Board #3246).

Assessment measures

Data will be collected by trained research staff at baseline and post intervention at 2-, 8-, and 16-week follow-up. The primary outcome, gait speed, is recorded by stopwatch over a 4-m walking course beginning from a standing start. The fastest of 2 trials is recorded in m/s. The secondary outcome, Self-efficacy for Exercise Scale, is assessed with a well-established self-report measure of an individual’s confidence to engage in exercise. We will assess baseline demographics (age, sex, marital status, fall history) with a self-report questionnaire. For complete protocol information, please refer to NCT04026503.

Implementation model

We used the Knowledge to Action Framework to develop and implement the SMART Coaching Protocol in the LLWS Rehabilitation Program.

Knowledge creation

Knowledge inquiry

The development of the SMART protocol began by reviewing the SCT model of behavior change applied in the precursor studies prior to the development of the current LLWS Rehabilitation Program. Based on the SCT, past research focused on increasing self-efficacy through mastery experiences (eg, meeting goals). In reviewing precursor studies, 2 key tools were noted: (1) a weekly exercise journal to be introduced early in the intervention and to be completed daily by the participant and (2) a monthly exercise calendar to be explained near the end of the intervention for tracking daily exercise and falls, emergency department visits, and hospitalizations (if any). However, behavioral change elements were provided as resources and not integrated into the PT’s work.

Next, we searched the research literature, professional organization websites, and VA resource websites for relevant materials. When reviewing the research literature, we identified possible protocols that combined cognitive and/or behavioral principles for use by a PT delivering a protocolized...
exercise intervention.\textsuperscript{27-29} We reviewed the published materials and contacted the primary author by email.

We also examined resources on the websites for \textit{Applied Sports Psychology}\textsuperscript{10} and the \textit{Society for Behavioral Medicine},\textsuperscript{31} as well as the \textit{Centre for Clinical Interventions}\textsuperscript{12} and the \textit{Trails to Wellness}.\textsuperscript{13} In addition, we reviewed resources available through the VA's Whole Health initiative.\textsuperscript{34} These resources included videos and handouts with general tips for exercise and increasing physical activity, as well as some specific to yoga and Tai Chi.

Knowledge synthesis

Materials were reviewed and discussed in an interprofessional team. Unfortunately, none of the protocols identified in the literature review were useful for our proposed intervention because (1) some involved extensive training of the physical therapist in behavioral change (eg, 8 hours of counseling training) combined with recording and monitoring for treatment fidelity, which was more extensive than we intended; (2) they were in languages other than English; or (3) they did not map well to the LLWS Rehabilitation Program protocol sessions and overall goals. Of the patient education materials we identified through organizational websites, we determined that while excellent, most were too general for our purposes. For example, materials spoke to the general benefits of exercise but did not map to the structure or specific goals of the LLWS Rehabilitation Program. Knowledge synthesis illuminated the need to create a week-by-week structure that mapped onto the SCT model, as well as the intervention design (ie, 10 visits during 8 weeks). Ultimately, we selected SMART goals framework as the foundation framework for this protocol.\textsuperscript{35}

**Create product tool**

First, we mapped the SMART goals coaching framework to the LLWS Rehabilitation Program intervention framework. We focused on creating an interactive protocol with each week’s content expanding on an aspect of SMART goal setting while also reviewing the past week and modifying and/or building on past week element. Second, we created our week-by-week protocol. The team adapted aspects of the SMART goals handout created by the VA Whole Health Program for our protocol.\textsuperscript{35} To do this mapping, we began by outlining the basic intervention structure. The protocol consisted of 10 sessions with 2 sessions per week in weeks 1 and 2, followed by weekly sessions thereafter, for a total of 10 sessions.

Third, we considered each aspect of the SMART protocol framework as educational goals and mapped each goal to specific week(s) (table 1). For example, we began by introducing the SMART goal framework at the first session. Then, we decided the second session would focus on how to set specific goals (the “S” of SMART goals); the third session introduced the weekly exercise log and the “M” or measurement aspect of SMART goals; the fourth session refined the specific goals by adding a timed element (the “T” of SMART goals). The team reviewed the overall mapping, noting that we wanted to devote multiple sessions to addressing exercise barriers, which we felt were consistent with the elements of goals being action oriented (“A”) and realistic (“R”). Thus, we distributed these educational goals to more than 1 session.

Once we determined the mapping, we proceeded to the second step, which was to write content for each session. Our goal was to create handouts for each session and/or module for the patient that would be part of an overall workbook that included approximately one-half page of text

| Table 1 | SMART Coaching Protocol contents |
|---------|----------------------------------|
| Title   | Session No. | Activities |
| SMART goals | 1 | Education on SMART goals |
| Specific goals | 2 | Education on creating specific exercise goals; create a short-term and long-term exercise goal with participant |
| Use of exercise journal to measure goals | 3 | Introducing exercise journal to track home exercise |
| Refine goals with time | 4 | Education on setting goals that have specific length, frequency, and time |
| Take action steps | 5 | Education and assessment of basic logistical barriers to exercise goals |
| Be realistic | 6 | Education and assessment of adjusting the goal or adding action steps given health or physical barriers |
| Address challenges | 7 | Education and assessment of psychological barriers to exercise goals |
| Take action steps for the future | 8 | Continued assessment and problem solving around barriers from earlier sessions as needed; introduce new goal of finding a community class |
| Measure goals with an exercise and falls calendar | 9 | Continued assessment and problem solving around barriers from earlier sessions as needed; introduce the exercise and falls calendar |
| Checklist and SMART Goals review | 10 | Review materials learned; review materials for community exercise |
written at the sixth grade reading level. One board-certified geropsychologist (J.M.) wrote the first draft of each lesson.

SCT posits that there are 4 main contributors to self-efficacy: mastery experiences (eg, success with meeting one’s goal), social modeling (eg, viewing similar individuals engage in the behavior), social persuasion (eg, dispelling myths of exercise in older adults), and improving or correcting physiological and psychological states (eg, reducing fear of falling, increasing enjoyment of exercise). As illustrated in table 2, we connected the elements of SCT model as represented in a SMART goals framework to show the translation of SCT to behavioral tools.

Action phase

Adapt knowledge to local contexts

The protocol was reviewed and edited by a team consisting of a PT (B.H) and second board-certified geropsychologist (P.B.). After creating a revised draft of the entire workbook, it was reviewed and edited by a physiatrist (J.B.). We edited, re-reviewed, and re-edited in an iterative process lasting 2 months (June-July 2020). In our reviews, specific focus was placed on adapting content to older adults. In particular, we drew from the literature on adapting psychotherapy to older adults and focused on the following adaptation and modifications: (1) increasing repetition, practice, modeling, and check-ins around comprehension of knowledge; (2) larger font size and avoidance of technical terms and jargon; and (3) flexibility for the PT to spend more or less time on certain portions of each module to make the protocol patient-centered vs content-centered. In this way, the PT was given flexibility in spending more time on a topic (eg, barriers) if the participant had many barriers to be addressed. Alternatively, if the participant reported relatively fewer barriers, the PT could move on to new content.

Assess barriers to knowledge use

Weekly debriefing meetings were conducted with the PT interventionist (C.K.) and the 2 geropsychologists on the team (P.B. and J.M.). These meetings focused on reviewing each participant, which session they were on, their learning of the material, and reviewing the PT’s problem solving of any challenges to delivering the intervention. Across 12 meetings we discussed the application of the SMART protocol for 10 participants. Process notes were collected and stored for future adaptations to the protocol after the end of data collection.

Select, tailor, and implement the intervention

During the debriefing meetings, we made minor changes to the protocol that did not affect the content to maintain the original methods of the RCT. For example, we made changes to some of the text size and formatting, and we added more detailed instructions in the therapist manual for concepts or procedures that were less clear. The LLWS SMART Coaching Protocol was implemented with 16 participants with who were enrolled in a clinical demonstration project of the LLWS Rehabilitation Program.

Monitor knowledge use

Although monitoring knowledge use is ongoing because the LLWS Rehabilitation Program is currently enrolling and running participants, we have early data on knowledge use for a subset of participants who have completed the LLWS Rehabilitation Program virtual clinical demonstration program and provided stakeholder feedback (table 3). Participants (n=16) who participated in the virtual clinical demonstration program of the LLWS Rehabilitation Program were on average aged 83.3±5.7 years and all male. To elicit knowledge use, our team created questions to assess participants perception of the usefulness of different elements of the LLWS SMART Coaching Protocol, as well as whether they believed the protocol affected their levels of motivation for exercise. Participants also answered 3 open-ended questions: (1) For participants who stated “no” they did not use the exercise journal, we asked: Can you tell us why you did not use the exercise diary during the course of LLWS? In addition we asked all participants: (2) What would you say helped you the most with your motivation and achieving your goals? and (3) Is there anything you would recommend we do differently in helping veterans meet their goals?

As displayed in table 3, most participants (75.0%) used the exercise journal. When the diary was not used, participants reported sensory impairment (ie, “I cannot see”) or alternative method (ie, “Use my [smart] watch”). One

| Determinant to self-efficacy | LLWS SMART Coaching tool |
|-----------------------------|--------------------------|
| Mastery experiences         | Creating SMART goals to facilitate achieving goals and creating mastery. Addresses barriers to exercise in a way that is positive and patient-centered. |
| Social modeling             | PT models exercise. |
| Social persuasion           | Provides examples of SMART goals with same-aged peers; PT provides corrective feedback to dispel myths about exercise with older adults. |
| Reducing negative physiological and psychological states and increasing positive physiological and psychological states | Focuses on exercise goals that elicit positive affect, such as enjoyment, purpose, and pleasure. Problem solves internal barriers, such as anxiety, fear, and low motivation that might decrease self-efficacy for exercise. Provides expert feedback on healthy and unhealthy physiological states when exercising (eg, normal soreness vs pain). Tailor exercises to medical conditions to reduce any untoward discomfort during exercise. |
participant reported they “forgot” to use their exercise journal during the course of the intervention. In terms of usefulness of the LLWS SMART Coaching elements, 75.0% found the exercise journal useful, 93.8% found the SMART goal formulation useful, and all participants found addressing barriers useful. Most participants (75.0%) reported that the LLWS SMART Coaching Protocol helped them become “somewhat” more motivated, and 25% reported “no change in motivation.”

In review of open-ended responses, we learned that participants reported a mix of “what helped most with your motivation.” Themes included: accountability (n=3, 18.8%), coming into the clinic (n=4, 25.0%), written materials and handouts (n=4, 25.0%), getting started (n=3, 18.8%), tangible change (eg, losing weight; n=1, 6.3%), and other (ie, “I just don’t like exercise; n=1, 6.3%). When considering how the program could be improved, themes included: more classes (n=7, 43.8%), bigger picture font (n=1, 6.3%), more advertising (n=1, 6.3%), or no recommendation or blank (n=7, 37.5%).

Discussion

This article provides the rationale and design of the LLWS SMART Coaching Protocol, a protocol of cognitive behavioral skills for PTs to deliver to foster exercise behavior change.

Design of the protocol was informed by a desire to integrate a SMART Coaching Protocol into the LLWS Rehabilitation Program in a way that was informed by SCT. The process of designing this protocol may be informative to other interprofessional teams targeting physical functioning in middle-aged and older adults using an integration of exercise and behavioral change tools. Moreover, the protocol itself may be useful to investigators in the adoption of frameworks for PTs to learn behavior change strategies. For example, PTs may adopt implementation of the SMART goal-setting process involving ongoing goal setting and review, consistent with SCT principles.

Initial stakeholder feedback from participants suggested a majority found usefulness in the cognitive behavioral tools and preference for more opportunities for formal exercise programs. Final results will examine change in primary (gait speed) and secondary outcomes (self-efficacy). We will test whether there is change in self-efficacy at 8 and 16 weeks between the intervention and control groups. We will also explore whether change in exercise self-efficacy mediates change in physical functioning. Additional stakeholder data are needed to determine participants’ knowledge use and perception of whether LLWS SMART Coaching content influenced their motivation for exercise.

Study limitations

The current project will examine the LLWS SMART Coaching Protocol within the LLWS Rehabilitation Program; thus, we are not testing the efficacy of the LLWS Rehabilitation Program compared with the LLWS Rehabilitation Program plus cognitive behavioral skills. While this is an interesting and important question, the current study is focused on the integration of cognitive behavioral tools in the LLWS Rehabilitation Program. Studies dismantling components of the LLWS Rehabilitation Program and comparing individual elements is an area for future research. PTs did not undergo extensive training or any fidelity evaluation of their use of the SMART Coaching Protocol. Our interventionist (C.K.) participated in several meetings with geropsychologists on use of the protocol during the early phase of the trial. However, we cannot speak to ongoing treatment fidelity. Future research stemming from this work may involve the creation of formal training videos that teach PTs to deliver the SMART Coaching Protocol. Standardization of learning would be essential for any replication of the protocol to other sites. Similarly, videotaping PTs delivering content would provide content for treatment fidelity ratings.

Conclusions

Incorporating cognitive behavioral tools in physical therapy intervention research is critical for targeting motivational processes needed for exercise behavior change. The integration of cognitive behavioral tools into physical therapy
research has the potential to identify the elements most acceptable to middle-aged and older adults at risk for mobility decline.

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