The Live Long Walk Strong Rehabilitation Program: What Features Improve Mobility Skills?

NCT04026503

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Project Title:	The Live Long Walk Strong rehabilitation program: What features improve mobility skills?	
Principal Investigator:		**Version #: 11**

1. OVERVIEW OF THE RESEARCH STUDY:

We are asking you to be in a research study that is being supported by the Rehabilitation Research and Development service of the Veteran's Health Administration. Before you decide to take part, you should know why the study is being done and what it will involve. This form tells you what to expect if you agree to be in the study. Taking part in this study is completely voluntary; it is your decision whether or not to participate in the study.

We are doing the research to evaluate the efficacy of the Live Long Walk Strong rehabilitation program in veterans 50 years and older. If you agree, you will undergo testing to determine eligibility, and if you are eligible you will undergo rehabilitation training at the VA Boston Jamaica Plain campus. You will be in the study for approximately 6 to 7 months if you decide to stay for the whole study. We will describe your involvement in more detail later in this form.

You might choose to volunteer in the study because you want to improve your walking, leg strength, trunk strength, balance, and physical function. You will find more information about benefits later in this form.

You may choose not to volunteer to be in the study because you may not want to experience potential muscle fatigue or soreness. You will find more information about these risks later in this form.

Your doctor may also be an investigator in this research study. Being an investigator means your doctor is interested in both you and the study. You may want to get a second opinion about being in the study. You can do so now or at any time during the study. Another doctor who is not an investigator can give you a second opinion about being in the study. You do not have to agree to be in this study even though it is offered by your doctor.

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

2. WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research study is to evaluate the efficacy of the Live Long Walk Strong rehabilitation program in veterans 50 years and older. The study will also evaluate if there are changes in individual's mobility and exercise self-efficacy after the program.

You have been asked to be in this study because you have been identified as a veteran 50 years of age or older who is at risk of mobility limitations. The length of your participation in the study will be approximately 6-7 months. All study sessions will be delivered in-person at JP VABHS. During the in-person baseline assessment, you will complete a series of questionnaires, mental performance, and mobility performance tests.

Within the following 2 weeks, you will start the rehabilitation portion of the study, which will be delivered in-person at the Jamaica Plain campus. The rehabilitation portion will be completed one on one with a physical therapist. Each session will last for 60 minutes. These sessions will take place over an 8-week period where there will be 2 sessions per week for the first 2 weeks and then 1 session per week for the remaining 6 weeks. This will total 10 in-person rehabilitation sessions. Upon completing the rehabilitation portion, we will repeat the tests that you completed at the beginning of the study. This testing will also be completed in-person. We will again repeat these tests 8 weeks and 16 weeks later. This will total to 15 study sessions including the informed consent session, rehabilitation sessions, and study assessment sessions. A total of 198 participants will be enrolled in this part of the study.

3. HOW LONG WILL I BE IN THE STUDY? WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

You will complete 2 study sessions to begin the study: 1) Informed Consent session and 2) in-person baseline session.

After the in-person baseline session, the rehabilitation phase will be sessions 3-12. The in-person rehabilitation sessions will be 60 minutes of a physical therapy session that will include a warm-up, exercises to target leg power, trunk muscle endurance, the timing and coordination of gait, self-efficacy for exercise, and a cool-down period.

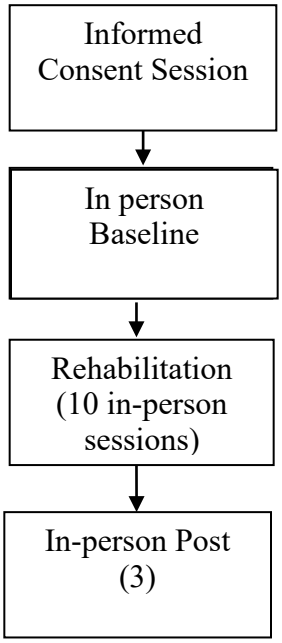
The last 3 study sessions (in-person) will occur once the rehabilitation sessions have been completed. The first will occur within 1-2 weeks after completion of the rehabilitation phase. The second will occur 8 weeks after completion of the rehabilitation phase. And the third (and last overall session) will occur 16 weeks after completion of the rehabilitation phase.

Following the baseline study session, you will be randomly assigned, like the flip of a coin, into one of two study groups.
1 group will begin the rehabilitation phase immediately.
1 group will begin the rehabilitation phase following an 8 week wait period as the control group.

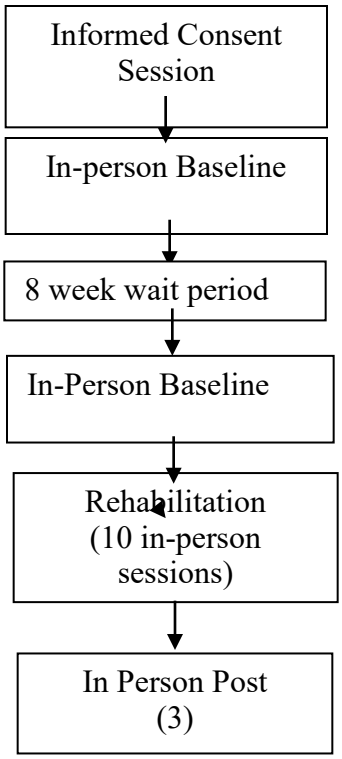
If you are randomized to the wait list, you will be asked to repeat a baseline assessment session (in-person) prior to starting the intervention.
If you are randomized to start immediately, you will have 15 study sessions total if you complete the study.
If you are randomized to the control wait group, you will have 16 study sessions total if you complete the study.

Session Flow Diagram

Randomized- Start Immediately



Randomized- Wait List



In-Person Informed Consent Session (Study Session #1): Duration 0.5 - 1 hour
Informed consent: During the informed consent session, study staff will review the informed consent form with you and answer any questions you have about the study, so that you understand the purpose of the study and what is being asked of you. If you decide you would like to participate, we will ask you to sign the informed consent form. We will also review the

HIPAA Authorization form with you and answer any questions you have about the form and study. If you decide to participate, we will ask you to sign the HIPAA Authorization form.

Eligibility screen 1: Study staff will administer a mental performance questionnaire to determine the first part of eligibility in the study. Should you be eligible following the questionnaire, we will continue with the in-person baseline session. Regardless of eligibility, you will be compensated for your time.

In-person Baseline Session (Study Session #2): Duration: ~1.5 hours
Eligibility Screen 2: Study staff will administer a screening test to make sure that you are a good fit for the study. The test will assess your balance, your ability to walk 13 feet, and your ability to get up from a chair.

There is a chance that you may not be able to continue participating in this study based on the results of these screening tests. If the screening tests show that you may continue in the study, you will proceed with the other baseline assessments. Regardless of eligibility, you will be compensated for your time.

During the in-person baseline session we will assess your trunk muscle endurance, your leg power with a 4-stair climbing test and leg press machine, and your walking coordination and variability with 2 short walking tests. We will ask you to walk at your normal walking pace over a 4-foot wide, computerized walkway. You will walk back and forth several times. We will assess your aerobic capacity with a 6-minute walking test, where you will be able to walk at a self-selected speed over a period of 6 minutes. We will administer questionnaires regarding your background and personal characteristics (i.e age, gender), mood, pain, physical activity, and assessment of your own physical capabilities. We will also ask about your recent history of falls, hospitalizations, emergency room visits, and Physical Therapy care. We will also administer cognitive performance testing. This portion of the study will be audiotaped; however, if you would prefer that it is not audiotaped, you can still remain in the study.
To maintain compliance with VA Boston standard operating procedures, we will complete Binax NOW testing prior to the performance measures at each of our study visits while required by the healthcare system. Study staff will complete appropriate training to maintain safety and compliance with the requirements of VA Boston to report results of testing.

Rehabilitation Training 10 Sessions (Rehabilitation Session #3 – 12): Duration: 1 hour each

A. Sessions at the Jamaica Plain campus will occur 2 times per week for the first 2 weeks of the rehabilitation training.

B. Sessions will occur 1 time per week for the next 6 weeks of the rehabilitation training.

C. Each rehabilitation session will consist of a warmup, several progressive resistance exercises through use of a weighted vest, timing and coordination of gait training, exercise self-efficacy exercises, and a cool-down period. All of the exercises and training will occur under the guidance of a physical therapist. The exercises will increase in difficulty by increasing the resistance, the number of repetitions and/or number of sets. We will complete Binax NOW testing immediately prior to each session while required by VA Boston. We will follow VA Boston Healthcare System policies for any positive tests. We will allow up to 2 rehabilitation sessions to be made up within 2 weeks of the scheduled rehabilitation training period.

Vital signs, heart rate and blood pressure, will be monitored before and after the exercise session by the physical therapist.

In-Person Post-Rehabilitation Training Phase: (Study Session # 13- 15): Duration: 1.5 hours

A. Post Assessments:
   a. In-Person Post Assessment:
      i. We will complete physical performance tests: standing balance, walking speed, ability to stand from a chair, trunk muscle endurance, stair climbing, leg strength and power and walking. We will ask you to walk at your normal walking pace over a 4-foot wide, computerized walkway. You will walk back and forth several times.
      ii. We will administer questionnaires regarding your mood, pain, physical activity, and assessment of your own physical capabilities.
      iii. We will administer cognitive performance tests.

B. We will perform the first in-person post-assessment session within approximately 2 weeks following the end of your rehabilitation training.

C. The second in-person post assessment session will occur approximately 8 weeks following the end of your rehabilitation training.

D. The third in-person post assessment session will occur approximately 16 weeks following the end of your rehabilitation training.

If any of the tests completed as part of the assessment reveals an abnormality, your primary care doctor will be promptly notified, and you may be held from continuing in the study or may be required to complete further testing to determine eligibility.

4. WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?
Reasonably foreseeable discomforts or inconveniences of the study:

A. There may be difficulty completing the in-person informed consent session and/or completing 1-2 rehabilitation training sessions each week for 8 weeks in the required time. Note that the rehabilitation training will only last 8 weeks.
B. There may be discomfort completing the Binax NOW testing before the in-person assessment and intervention sessions. Study staff will complete training by the VA to make this process as agreeable as possible; however, some people may find it unpleasant.

C. The questionnaires and the rehabilitation training may be fatiguing. Therefore, the appropriate rest periods between rounds will be provided. Although careful medical supervision will help to make these tests as agreeable as possible, some people may find them unpleasant.

D. Questionnaires that require people to answer about their daily activities, health history, sleep habits, medications, diet, and personal history may, in some cases, be a source of emotional distress. You will have the option to skip any question you don't feel comfortable answering.

Reasonably foreseeable risks of study:

A. Physical risks are similar to the risks involved with participating in a physical therapy program. The walking and balance testing could potentially result in a fall. However, all assessments are conducted with a chair or counter available for support, and a trained research staff member nearby at all times. You may have muscle or joint pain during or after study sessions. This muscle soreness usually does not last long, and it typically goes away within a few days. This is a normal response of your muscles to rehabilitative testing and resistance training. Proper technique in addition to the warm-up, cool down, and stretching sessions will be taught and monitored to avoid an injury to the muscle. Another risk is for stress on your heart. We will screen for cardiac issues with a review of your medical history.

B. An additional risk relates to your confidentiality. We take many precautions to keep your information safe. If you agree to be in this research study, you will be assigned a subject ID code. That ID code will be used to identify the data we collect during the study sessions. This data will be stored in a password protected database and any individual case report forms will be kept in binders in a locked office.

C. In addition to the risks listed above, you may experience a previously unknown risk or side effect.

D. If a serious adverse event occurs during rehabilitation training sessions staff will initiate the safety procedures within the campus or utilize the medical services in the urgent care center at the campus.

5. WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no known direct benefits to you for being in this study.

6. DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this study is completely voluntary. Refusal to participate in the study will involve no penalty of loss of benefits to which you are otherwise entitled. You may discontinue taking part in the study at any time without any penalty or loss of benefits.

You may withdraw and still receive the same standard of care that you would otherwise have received.

If you withdraw from the study, the researchers may still use the data they have already collected.

If you withdraw from the study at any time you will only receive payment for the sessions that you have completed.

If you decide to withdraw from the study, you may be asked to complete the form to have your withdrawal from the study in writing: Revocation of Authorization for Use and Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research.

7. WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

Other treatment to that described above may include outpatient physical therapy or a physical rehabilitation program and will be under the supervision of your doctor or caregiver.

8. RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The Principal Investigator along with your Primary Care Doctor may decide that participation in this research study is a risk to your health and remove you from the study.

9. HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Information collected for the purpose of this research study will be kept confidential as required by law. The results of this study may be published for scientific purposes, but your records or identity will not be revealed unless required by law.

Information about you is protected in the following way: We will store your information in ways we think are secure. We take many precautions to keep your information safe. All information that is collected will be stripped of any information that would reveal your identity. If you agree to be in this research study, you will be assigned a subject ID code. That ID code will be used to identify the data we collect during the study sessions. This data will also be coded and computerized and the data will be stored in a password protected database and any individual case report forms will be kept in binders in a locked office. Data will be identified only by the study participant number assigned to you. The electronic data will be stored in a password protected file on a password protected computer network. Only the study staff will have access to the data. Finally, all of the staff involved in this study will be trained to understand the importance of maintaining the confidentiality of study participants.

Identifiers might be removed from the identifiable private information that is collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

While this study is being conducted, you will not have access to your research related health records. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care.

Your research records will be kept indefinitely or until the law allows their destruction per the VA Record Control Schedule (www1.va.gov/VHAPUBLICATIONS/RCS10/rcs10-1.pdf). Records will be destroyed, when allowed, in the following manner:

- Paper records will be shredded
- Electronic records will be destroyed in a manner in which they cannot be retrieved.

If any part of your assessment is audiotaped, your information will be protected in the following way: your name will not be used to identify the audiotape, only your study ID will be linked to it. The audio recorder is encrypted and information contained on the recorder is uploaded onto an encrypted computer that meets VA privacy standards. After it is uploaded, the information on the recorder is deleted.

____ Please initial here if you **agree** to have part of your assessment audio-recorded.

Your data will be entered into a data repository, for the Rehabilitation Promoting Prevention And Improved Resilience program (REPPAIR, PI) and may be used for future studies approved by an IRB. Your data will be stored in a password protected file on a password protected computer network on an encrypted computer that meets VA privacy standards. Only trained research staff, who have met the requirements for VA research credentialing, with approval from the VA IRB will have access to the data repository. All shared data will be de-identified. You may remain in this study without sharing your data into the REPPAIR data repository.

_____ Please initial here if you **agree** to have your data shared with the REPPAIR data repository

An unsigned copy of this consent form will be posted on clinicaltrials.gov or Regulations.gov after all study participants have completed the study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

10. WHO ELSE MIGHT SEE MY DATA?

You consent to the access of your VA research and medical records that may identify you by persons approved for this purpose. Such access may be by the Institutional Review Board and Research & Development Committees of VABHS, the VA, Federal agencies, or national

research oversight and accreditation organizations. You may expect the same confidentiality from these persons that is given to you by the Investigator and his research staff.

11. WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

You will be told of any significant new findings that come to light during the course of this study and that may relate to your wanting to stay in the study.

12. WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY?

A participant will not be required to pay for medical care and services received as a participant in an approved VA research study. Some participants are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services (including, but not limited to, dental services, supplies, medicines, orthopedic and prosthetic appliances, and domiciliary or nursing home care) provided by the VA that are not part of this research study.

You will be compensated $130 for your time and effort for taking part in this study if you complete all the study assessments. For attending the screening session, you will receive $10. For the in-person baseline assessment you will receive $30. If you are randomized into the wait list group, we will ask you to complete a second baseline assessment in which you will be compensated $30. For the 3 in-person post-assessment sessions, you will receive $30 for each session. All compensation will be processed during your last session and will be prorated should you decide to withdraw at any time prior to the completion of the approved protocol. You can choose to withdraw from the study at any time but will only receive payment for the sessions you have completed. If you withdraw from the study before all sessions are completed, the researchers may still use the data they have already collected.

You consent to the release of personally identifying information about you including your name, address, and the last 4 of your social security number to the Fiscal Office of the VA Boston Healthcare System so that we may provide compensation to you. If payment is made to you by the VA (whether by check, electronic fund transfer, or Direct Express Debit card), an IRS Form 1099 will be generated regardless of the amount you are paid.

13. WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

In the event that you are injured as a result of your being in this research study, you will receive medical care, including emergency treatment. This care or treatment is governed by federal law and VA policy. You would also have the right to file any legal action, as in any instance of alleged negligence.

14. WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

I understand that if I have any medical questions about this research study, I can call during normal working hours.

I understand that if I have any general questions about this research study, I can call during normal working hours.

I understand that if I have any medical problems that might be related to this study that **during the day** I can call and **after hours** I can call ***the Medical Center operator at and ask for the fellow on call for the GRECC service.***

I understand that, if at any point during or after this study I have any questions about my rights as a research participant or I want to discuss problems, complaints, concerns, and questions about the research, obtain information, or offer input, I may contact the Research Compliance Officer at

15. AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

I have read or have had read to me all of the above. Study staff have explained the study to me and answered all of my questions. I have been told of the discomforts and risks of the study. I have been told of other choices of treatment that I could have.

I understand that my participation in this study is voluntary, that I do not have to take part in this study and that, if I do take part, I may withdraw from the study at any time. I also understand that, if I refuse to take part or if I decide to withdraw, I will not suffer any penalty, loss of rights, or loss of VA or other benefits that I have a right to receive.

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I voluntarily consent to be in this study. I will receive a signed copy of this consent form.

Participant's Signature **Month Day Year** **Name (print)**