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

NCT 04026503

8.8.2019

Primary Outcome: The primary outcome for all aims of this study is usual Gait Speed,.[53,54] Gait speed is recorded by stopwatch over a 4-meter walking course beginning from a standing start. The fastest of 2 trials is recorded in meters/seconds. Declining gait speed is associated with heightened risk for adverse health outcomes (hospitalization, disability, death) over 1-4 years of subsequent follow up. [53,54] Changes in gait speed of .05 and 1.0m/s are characterized as small and large clinically meaningful differences respectively. [24,55] For Aims 2 & 3, we will identify factors that mediate changes in gait speed. Our experience with LLWS and related clinical trials identifies that the majority of participants (> 70%) exceed a .09 m/s change after treatment.**]**

Timing and coordination of gait

Smoothness of walking is our primary measure of timing and coordination and is an integrated measure of motor control of walking. [37,56] It is assessed during usual over ground walking. Linear acceleration of the body is measured along three axes (vertical, anterior-posterior and medial-lateral) using a tri-axial accelerometer attached to the skin over the lumbar spine (L3 segment). Trunk accelerations are sampled at 200 Hz and used to calculate the harmonic ratio following the methodology of Menz. [37,56] The harmonic ratio is derived in the vertical, medial-lateral and anterior-posterior directions. Higher harmonic ratios indicate greater levels of functioning. Our prior work reports mean changes of 25-30% in smoothness of walking occur with training. [18]

Gait variability will be a secondary outcome and is defined as fluctuations in gait characteristics from one step to the next.[57] It is an indicator of impaired mobility in older adults[40] and will serve as a secondary indicator of timing and coordination. Gait variability is quantified using established measures of temporal and spatial gait characteristics including stance time, step length, and step width. Variability will be calculated as the standard deviation of the set of steps recorded over 4 passes on the ZenoMat, an instrumented walkway. Approximately 32 steps will be collected from 4 passes on the ZenoMat which will be more than adequate to achieve a stable measure of gait variability. Our prior work has shown that 20 steps are sufficient to achieve a reliability of 0.75 and 30 are sufficient for 0.80.[40,58] In general, lower variability is better.

Leg Power, Leg strength and Leg Velocity will be measured separately for each leg by determining a 1 repetition maximum (1RM) from 6 to 12 trials on a leg press machine (Keiser Pneumatic Leg Press; Fresno, CA). Leg muscle power is measured separately on each leg using the same equipment. Five repetitions will be performed at 40% and 70% 1RM. The highest value of the repetitions will be recorded. Peak leg velocity is derived from power recorded at 40% of the 1RM, by the formula Velocity=power/0.4(1RM). The test-retest reliability of these measures is excellent (r >.85).[42,59,60] Leg power will be our primary outcome measure whereas leg strength and leg velocity will be secondary outcomes. A 9-10% change in leg power is clinically meaningful and our proposed treatment approach can exceed that threshold (see study 3, preliminary work). [61]

Trunk Extensor Muscle Endurance is measured using a technique that is reliable and valid among community dwelling older adults. [31] This is measured while the participant is lying prone on a specialized plinth positioned 45 degrees from vertical. Subject's feet are supported on a footplate and fixed in position. A portion of the table that is hinged and positioned at waist level is lowered to the horizontal plane and subject is asked to maintain their position as long as possible with their arms across his chest. The test is terminated when the subject can no longer maintain the unsupported position or after 150 seconds. Time is recorded in seconds and only one trial is performed. Reliability for the trunk measure is excellent (r=.88-91).[31] We have observed mean changes of 48% with LLWS (see study 3, preliminary work).

Self-Efficacy Scale for Exercise is an established, reliable and valid scale measuring an individual's confidence to engage in exercise. [45,62] It is sensitive to change and successfully utilized within studies of older adults with mobility problems, including our previous RCT among hip fracture patients.[45,62]

Secondary Outcome Measures: **[**The SPPB total score will be a secondary outcome for each aim. The SPPB is a well-established, valid and reliable physical performance measure used extensively in aging research. It is a composite measure of three functional tasks: usual gait speed over 4 meters from a standing start, 5 times repeated chair stand, and progressive standing balance. Each task is scored between 0-4 (higher score corresponds to better performance), with a maximum summary score of 12. Each increment decline in SPPB total score is associated with heightened risk for adverse health outcomes.[53,54] Changes in SPPB of 0.5 units and 1.0 units are characterized as a small and large clinically meaningful differences respectively. [24,55]The Late Life Function and Disability Instrument (LLFDI) will also be a secondary mobility outcome. The LLFDI is a reliable patient-reported (by interview or phone) measure of functional mobility validated in a wide range of older adult populations, having been used in over 70 clinical trials worldwide.[63] We have previously reported that LLFDI-Function and its sub domains are very sensitive to change. [35] Scores for all domains are scaled between 0-100 and clinically important differences are defined.**]** [64]

*Covariates & potential confounding variables***:** Clinical characteristics including age, gender, educational attainment, race, and marital status will be recorded. Height and weight will be measured using standardized methods and body mass index (BMI) will be calculated as weight (kg) divided by height in squared meters..[65] Comorbidity will be measured using a valid and reliable questionnaire that allows for the characterization of whether these conditions require treatment or impact physical function. [66] Depression will be measured by the 10-item Center for Epidemiologic Studies-Depression Scale (CES-D), [67,68] a widely used screening tool for symptoms of depression that discriminates well between general population samples. The Brief Pain Inventory questionnaire will measure pain.[69,70] Falls, fall related injuries and illnesses will be recorded via monthly calendars.[71] Also, we will administer the Activities-specific Balance Confidence (ABC) Scale, which is a well-established and validated scale measuring confidence with balance and mobility.[62,72] Given the strong association between mobility skills and cognition, participants will also undergo the NIH toolbox cognition battery. [73] Knee and ankle range of motion will be measured using a goniometer. Maximal knee flexion and extension are measured in degrees, while the ankle range of motion is measured as a binary measure for both dorsiflexion (ability or inability to dorsiflex to 90 degrees) and plantarflexion (ability or inability to plantarflex 20 degrees). Reliability for this measure is excellent (r=.82-.98).[74] **[**Every 4 weeks of study participation, we will assess physical activity and exercise engagement among all participants. Physical activity will be measured via the Phone-Fitt, [9] a measure ascertainable by phone or in person that is validated against actigraphy measures. Exercise engagement will be measured by self-report as specified in section 3.G.vi.**]**