**Title:** Stand if You Can: A Standing Intervention in Long Term Care
**NCT Number:** NCT03796039.
**Version Date:** May 1 2020

## METHODS

### Study Setting

The *Stand if You Can* trial is a multi-center, parallel group, RCT using intention-to-treat analysis. For pragmatic reasons, this trial is a single blinded study. It will take place in four different LTC facilities within two cities in the Province of New Brunswick, Canada. Two of the selected facilities will be in each city. Each facility is designated by the Province of New Brunswick as a level three LTC facility (1). This means that the clients have health limitations which require assistance and supervision on a 24-hour basis (1,2). Three of the four facilities are sister nursing homes, meaning they follow the same policies, similar procedures, and have identical floor plans. Registered nurses, licenced practical nurses and rehabilitation assistants are regular staff at all the participating homes. Each of the chosen LTC facilities have the space and resources necessary to assist in the operation and delivery of the trial.

### Participant timeline

All of the outcome variables, and participant characteristics will be collected at pre (T1) and post (T2) testing. Data regarding fall information will have two additional data collection time points, including 6 months prior to the intervention (-T) and 6 months follow-up (T3). Attendance will be collected during the intervention, between T1 and T2. See Figure 1 for timeline**.**

### Eligibility Criteria

Inclusion criteria:

1) Participants must be a resident of one of the four participating LTC facilities at the time of recruitment.

2) Participants must be able to provide consent or have Substitute Decision Maker agree on their behalf to participate in the study if required.
3) Participants must be able to walk for 10 meters, with or without a walking aid.

Exclusion Criteria:

1) Residents identified by the LTC facility's rehabilitation staff as being too high risk for falling, or unable to participate for safety reasons.

**Interventions**

***Social Standing Intervention***

Participants residing in one of the facilities randomized to the intervention will be offered up to 100 minutes of supervised standing per week, for 22 weeks. To achieve 100 minutes of standing each week, participants will stand (either on their own or with a group of their peers) for ten minutes at a time, twice per day, five days per week (Monday-Friday). Participants will be allowed up to five breaks per session of undefined length to assist in attaining the objective of 100 minutes of standing per week. During the standing time research assistants (RA) will engage socially with the participants, with a 1:4 ratio of RA and participants. If the LTC facility is hosting a stationary group activity during the standing time participants will be allowed to partake, provided they can do so while standing. If a participant is able, they will be allowed to stand for 20 consecutive minutes by week 11 and onward, as opposed to two separates 10-minute sessions. The opportunity to have two separate sessions will still be an option for those who do not wish to stand for 20 minutes in one session. A session will be terminated if the maximum time is reached, if the participant takes all five permitted breaks, or if the participant requests to stop or shows signs of physiological distress. Participants will be encouraged to stand five days each week. However, if the participant displays strong verbal disinterest, refuses participation, is

non-compliant, or is physically unable to attend, they will be allowed to miss the planned session. Participants will not be excluded from the study or subsequent analyses due to non-compliance to the intervention. Following a request from a consenting participant, LTC facility staff, or the Substitute Decision Maker will a participant no longer be asked to participate in the standing sessions. Adherence to the intervention will be monitored and tracked using a daily log. Participant attendance, total standing time, number of breaks taken, and total group size (if applicable) will be recorded at each session. These logs will be kept at the local research institution and brought to the LTC facility by RAs each day.

***Social Exposure (control)***

Participants residing in the control facilities will spend 20 consecutive minutes engaging in social activities with the RA. Social activities will be structured similarly to the intervention group. Some examples include sharing jokes and stories, playing charades, and signing along to music. Social activities will be completed in groups or individually, with participants allowed to join the activity by whatever means of transportation they chose. There will be no limit to the number of participants allowed to attend each group social activity session, with the number of staff ranging from one to two. Adherence to the social activity will be monitored and tracked using a daily log noting attendance, total group size (if applicable), the length of the activity. These logs will be kept at the local research institution and brought to the LTC facility by RAs each day.

**Variables and Measures**

*Participant Characteristics*

Participant age, sex, height, weight, medical condition, length of stay in the LTC facility, transfer status, and frailty status will be collected from LTC staff at pre-testing (T1) and post-testing (T2) using the most recent data from participants' LTC health records.

*Primary outcome*

The primary outcome of this study is gait speed. To measure gait speed, participants will perform a 10-meter walk at pre and post testing, with the first and last two meters used as acceleration and deceleration zones. Gait speed will be measured over the intermediate 6 meters. If required, participants will be permitted to use an assistive device while closely monitored by RA with an available wheelchair made available for safety. Participants will be instructed to walk at a comfortable speed and to start walking when signalled. Using a stopwatch, a RA will manually start timing the participant once the participant's foot or walking aids crosses the 2-meter mark, whichever occurs first. The timer will be stopped once the participant or the walking aid reaches the 8-meter mark and the total time will be recorded in seconds. Once a participant completes the first trial, the participants will take a brief pause and a second trial will be completed. The average of the two values will be used for analysis.

*Secondary Outcomes*

Physical activity and sedentary behavior will be tracked for seven consecutive days at pre and post testing using an activPAL (PAL Technologies LTD., Scotland, UK). The activPAL will be placed mid-thigh and held in place using Tegaderm$^{TM}$ tape. Participant sedentary time, upright time, stepping time, total number of steps and total transitions from sitting to standing will be recorded. ActivPAL data will be considered valid if the participant wears the device over at least four consecutive days(3).

Leg power will be assessed using the 30-Second Chair Stand at pre and post testing, following the Senior Fitness Test protocol (4). Participants will be seated in a standardized, armless chair with their arms crossed across their chest. The participant will stand completely and return to a seated position as many times as possible in 30 seconds. RAs will provide guidance as needed during the test for those with cognitive impairments. If participants are unable to complete the test following protocol, their score will be recorded as 0.

Isometric lower leg strength will be assessed using a handheld dynamometer (Lafayette Hand-Held Dynamometer, Lafayette Instrument, Sagamore, USA) at pre and post. The dynamometer will be positioned mid-tibia, with the padding snug against the participant's leg. To ensure each participant experiences the same resistance throughout the test, RA will use a non-elastic woven strap that will interlace around the handle of the dynamometry and chair leg. With arms crossed across their chest, participants will then be instructed to extend their leg as forcefully as possible into the dynamometer for 10 seconds, with peak strength recorded as maximal kilograms (kg) achieved. Leg strength will be assessed twice on each leg, with an additional trial if the first two differ by more than one kg. RA will provide motivational cues and encouragement during each test.

Balance will be assessed using the BrainBlox software (5)on a Wii Balance Board (Nintendo, Kyoto, Japan) at pre and post testing. The balance board measures ground reaction forces that are then computed into centre of pressure measures. Participants will conduct three trials of 30 seconds with eyes open. Participants will stand in a neutral position, feet hip-width distance apart with their arms at their sides. The balance assessment will be conducted three times, with intermittent breaks as needed. If required, participants will be permitted to use an assistive standing device.

Metabolic profile will be assessed as participant high-density lipoprotein, low-density lipoprotein, total cholesterol, triglyceride, and blood glucose using a CardioChek Professional Analyzer system (PTS Diagnostics, Whitestown, Indiana, USA). Following a finger prick conducted using a single use lancet, approximately 60 µL of whole blood will be collected. Forty µL will be used to assess blood lipids via a Lipid Panel (PTS Diagnostics, Whitestown, Indiana, USA), with the remaining 20 µL used to assess blood glucose via a Glucose Panel (PTS Diagnostics, Whitestown, Indiana, USA).

Cognition will be assessed using the Mini-Mental State Examination (MMSE) questionnaire(6). Participants who score 18 or above will be asked to complete subsequent questionnaires pertaining to their psychosocial health. These questionnaires include the Geriatric Anxiety Inventory(7), Falls Efficacy Scale – International (FES-I) (8), Geriatric Depression Scale Short Form (9), the DeJong Loneliness Scale (10) and the UCLA Loneliness Scale (11).

Falls, injuries due to falls, and hospitalization will be collected from the participants accident report provided by the LTC facility. At 6 months follow-up, data will be collected retrospectively from 6 months prior to the intervention and up until the 6-month follow up. This data includes the number of falls, type and number of injuries as well as the number of hospital visits.

Attendance will be collected throughout the intervention. The daily total standing time, number of breaks, the use of an assistive the device as well as the group size will be recorded.

**Sample Size**

Sample size was estimated based on anticipated changes in gait speed, the primary outcome of this trial. The minimum clinically important difference in gait speed is 0.1 m/sec

(18). With a cluster size of two, and assuming a small-to-moderate clustering effect (intraclass correlation coefficient = 0.075), within-group standard deviation of 0.10 m/s, and alpha = 0.05, recruiting 36 participants per group will provide 80% power to detect a clinically important change in gait speed. To account for an expected loss to follow-up of 20%, we plan to recruit 44 participants per group (total n=88).

**Recruitment**

The Director of Care for each of the LTC facilities will be contacted to aid in the identification of residents who may benefit most from a low-intensity physical activity intervention. A letter will be sent from the LTC facility on behalf of the research team to each potential resident, or their Substitute Decision Maker to inform them of the study. Once the letters are distributed members of the research team will contact residents or their power of attorney to formally inquire about participation and obtain informed consent for participation.

**Allocation**

RAs not participating in the trial procedures will use a random number generator to construct a permuted-block randomisation list (block size = 2). All participants will be cluster-randomized to the intervention or control group on a 1:1 basis. Group assignments will be concealed from participants, outcome assessors, and research staff completing the data analyses. RA's conducting pre-testing evaluations will be blinded at pre-testing, but will conduct post testing evaluations unblinded, due the diversity of evaluations requiring training and experience.

**Data Management**

Each participant will be assigned an ID number. All the data collected will be recorded under this number in their participant file. Each file will have the data manually written, and then transferred from the files into an excel on password protected computers. The data will be entered and revised by two different RAs to reduce potential data entry errors. Only researchers engaged in collection, analysis and dissemination will have access to data, with approval of the primary investigators. Hard copies of the collected data will be stored in filing cabinets, in a locked working space at each university. Data will be kept for a period of seven years, at which point it will be destroyed.

**Statistical Analysis**

As this is an intention to treat trial, all data will be evaluated based on the randomized group allocation. Generalized linear models – specifically an ANOVA analysis, will be used to compare the dependant variable (gait speed) between intervention groups while accounting for potential confounders (e.g., age, sedentary level). Secondary outcomes such as sedentary behaviour, leg strength, sit to stand ability, balance performance, psychosocial outcomes, and blood lipids and blood glucose will each be analyzed with separate linear models as well, in relation to intervention group. Consistent with an intention-to-treat approach, the models will estimate missing values. When possible, general linear models will also be used to evaluate subgroup analyses, where health conditions will be considered a fixed variable in relation to gait speed performance.

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