# The Effect of a Standing Intervention on Falls in Long Term Care: a Secondary Analysis of a Randomized Controlled Trial



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## ABSTRACT

#### Background

Older adults in long term care (LTC) spend over 90% of their day engaging in sedentary behaviour. Sedentary behaviour may exacerbate functional decline and frailty, increasing the risk for falls. The purpose of this study is to explore the impact of a 22-week standing intervention on falls among LTC residents at 12-month follow-up.

#### Methods

This was a planned secondary analysis of the Stand if You Can randomized controlled trial. The original trial randomized 95 participants (n = 47 control; n = 48 intervention) to either a sitting control or a supervised standing intervention group (100 minutes/week) for 22 weeks. Falls data were available to be collected over 12 months post-intervention for 89 participants. The primary outcome was a hazard of fall (Yes/No) during the 12-month follow-up period.

#### Results

A total of 89 participants (average age 86 years  $\pm$  8.05; 71.9% female) were followed for 12-months post-intervention. Participants in the intervention group (n=44) had a significantly greater hazard ratio of falls (2.01; 95% CI = 1.11 to 3.63) than the control group (n=45) when accounting for the history of falls, frailty status, cognition level, and sex.

### Conclusion

Participants who received a standing intervention over 22 weeks were twice as likely to fall 12 months after the intervention compared with the control group. However, the prevalence of falls did not surpass what would be typically observed in LTC facilities. It is imperative that future studies describe in detail the context in which falls happen and collect more characteristics of participants in the follow-up period to truly understand the association between standing more and the risk of falls.

Key words: clinical trial, falls, sedentary behaviour, frailty

## **INTRODUCTION**

Falls are two to three times more frequent among residents living in long-term care (LTC) facilities than counterparts living in the community.<sup>(1)</sup> This is in part due to a higher prevalence of fall risk factors such as cognitive impairment, low physical function, and multiple chronic conditions.<sup>(2)</sup> Falls are a devastating event affecting quality of life, as they may lead to fractures, disability, fear of falling, social isolation, and chronic pain.<sup>(3)</sup> A common practice to prevent falls in LTC is to promote sitting activities and, in some cases, the use of physical restraints.<sup>(4)</sup> However, prolonged sitting activities, often referred to as sedentary behaviour, could reduce

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lower-extremity stability, neuromuscular function, strength, and balance—ultimately increasing the risk of falls.

#### Studies have shown that sedentary behaviour is associated with an increased risk of falls for older adults living in the community.<sup>(5,6)</sup> Only a few studies have examined the impact of reducing sedentary behaviour on the risk of falls among older adults living in a LTC facility. As previously reported by our group, people living in LTC facilities spend over 90% of their time engaging in sedentary behavior,<sup>(7)</sup> which may provide a window of opportunity for fall prevention interventions in this population.

Previous interventions in LTC settings have focused on structured exercise programming, such as balance, functional exercise, and aerobic training.<sup>(8,9)</sup> However, their effectiveness in reducing falls in LTC facilities is inconclusive. A 2020 systematic review found that exercise interventions were only effective in LTC facilities that excluded frail residents.<sup>(9)</sup> It was suggested that older adults with high levels of frailty might not tolerate traditional forms of exercise due to their low physiological reserve. As such, targeting a reduction in sitting time may benefit older adults living in LTC settings where many cannot perform traditional forms of exercise.

Our group conducted a pilot trial that explored how many residents in LTC settings would attend an organized standing intervention.<sup>(7)</sup> This pilot demonstrated that supervised standing sessions were safe and feasible in a LTC setting. However, falls outside of the supervised standing sessions were not studied, which warrants further observation.

The main objective of the current study was to explore the effect of a 22-week standing intervention on falls among LTC residents during the 12 months following a standing intervention.

# **METHODS**

## **Study Design**

This was a planned secondary analysis of falls 12 months after the "Stand if You Can" randomized controlled trial (1:1 allocation ratio) was conducted (ClinicalTrials.gov NTC03796039). Residents of LTC facilities were initially recruited and randomized to either a 22-week standing intervention or a sitting control condition among four LTC facilities to evaluate the effect of standing on gait speed. The main analysis showed no effect of the standing intervention on gait speed for people living in LTC. (ClinicalTrials.gov NTC03796039).

## Participants

Participants were recruited from four LTC facilities. Potential study candidates were identified by facility staff based on the following recruitment criteria: 1) able to walk 10 meters with or without a walking aid, and 2) able to provide consent. After being deemed eligible, informed consent was obtained from either the participant or substitute decision-maker before starting any study procedures.

Participants were excluded for the 12-month follow-up analysis if they no longer resided in the facilities at the beginning of the 12-month follow-up.

#### **Sample Size**

Sample size calculations were originally performed based to detect a clinically important effect of the standing intervention on gait speed (0.1 m/s). Consequently, we recruited according to the primary outcome of the original trial: gait speed. The clinically important difference for gait speed is 0.1 m/s<sup>(10)</sup> and was used to determine the sample size. An estimated small-to-moderate clustering effect (intraclass correlation coefficient = 0.075) was included, with a within-group standard deviation of 0.10 m/s, an alpha of 0.05, and 80% power. As a result, this study required at least 36 participants per group. To account for an expected dropout of 20–30%, it was determined to recruit a minimum of 47 participants per group.<sup>(11)</sup>

#### Randomization

After recruitment of all participants and baseline data collection, a study investigator not involved in the recruitment, data collection, or implementation of the interventions used a random number generator to construct a permuted-block randomization list (block size = 2; two homes in the control group and two homes in the intervention group). Participants were cluster-randomized by LTC facility to either the intervention group or the control group on a 1:1 basis. Randomization only occurred after baseline testing so that assessors were blinded during baseline data collection. LTC staff who were responsible for measuring outcomes were blinded to randomization of the two intervention groups, but participants were not.

#### Intervention

Participants in the active arm were offered sessions to stand with supervision for 100 min per week. Standing sessions were offered twice a day, five days a week (Monday–Friday), for a total of 20 min per day for 22 weeks. Participants could take up to five breaks per session, as needed. The research assistants planned social activities (e.g., puzzles, storytelling, music) for each session. To match the social exposure, participants in the control group received the same social visits as the intervention group but they were completed while sitting.

#### **Outcome Measure**

The main outcome for this follow-up study was fall events during the 12-month follow-up, measured in days. Falls are routinely collected data in LTC facilities and are reported through incident reports, noting the date of the fall event. To quantify the history of falls, the number of falls data was pulled from the residences' data six months prior to the intervention. Time to fall was measured in days, calculated using the first post-intervention day as Day 1. The follow-up period ended upon reaching 12-months post-intervention follow-up or time of withdrawal (e.g., death or facility transfer).

#### Participant Characteristics & Potential Confounders

Age, sex, transfer status, frailty status, the primary reason for admission, cognitive level, gait speed, leg strength, and sedentary behaviour were all collected at baseline. Transfer status was assessed by LTC staff following jurisdiction regulations on a scale of one to three.<sup>(12)</sup> Residents were categorized as requiring no assistance to transfer from sitting to stand (independent), requiring staff assistance to stand (assisted transfer), or requiring staff and mechanical assistance to stand (dependent).

The LTC rehabilitation staff were asked to assess the participants' frailty status using the Clinical Frailty Scale. <sup>(13)</sup> It is a validated tool used to assess the overall level of the frailty of an older adult using clinical judgment.

Daily standing time before the start of the intervention was measured using activPALs (v8.10.6.33, PAL Technologies Ltd., Glasgow, Scotland). The activPALs were attached to the participants' right thigh and worn for seven consecutive days at baseline. ActivPAL data were categorized into standing time using the CREA beta algorithm by PALbatch software (v8.10.6.33, PAL Technologies, Glasgow, Scotland). Average weekly standing time in minutes was recorded.

The Mini-Mental State Examination (MMSE) questionnaire<sup>(14)</sup> was used to assess cognition and was completed by research assistants at baseline only. Scored out of 30, the questionnaire categorized a person as having no, mild, or severe cognitive impairment.<sup>(15)</sup>

Gait speed was measured over 10 meters at a self-selected pace with or without an assistive device. Two trials were conducted per participant. Gait speed was reported as the average time over the two trials.

Leg strength was measured using a handheld dynamometer while performing knee extension (Lafayette Hand-Held Dynamometer, Lafayette Instrument, Lafayette, IN). Peak strength was recorded in kilograms (kg). Leg strength was assessed twice on each leg, with an additional trial if the first two differed by more than one kg. The best score from each leg was averaged and reported.

#### **Statistical Analysis**

Descriptive statistics are presented as means (standard deviation) or frequencies (%). An Andersen-Gill model was used to compare the hazard ratio of falling between the intervention and control group over the 12-month post-intervention follow-up period. The Andersen-Gill model extends the Cox proportional hazard survival (time-to-event) model that allows for recurring events.<sup>(16)</sup> The result was expressed as a hazard ratio estimate. The model full adjusted model included variables available from the original RCT based on the literature while avoiding collinearity. As a result, number of previous falls, frailty status, cognitive level, and sex were included in the model. Previous falls are considered one of the greatest predictors of future fall events and were, therefore, included in the model.<sup>(17)</sup> Frailty status is associated with falls.<sup>(18)</sup> Cognitive impairment is also associated with falls, especially when the MMSE score is 24 or lower.<sup>(19)</sup> In LTC facilities, males are more likely to fall.<sup>(20)</sup> The predictor variables were added to the Andersen-Gill model. Tests for the Cox proportional hazard assumption did not find evidence of egregious violations (global chi-square p = .77). The data were analyzed using SPSS (SPSS Version 27.0) for descriptive statistics, as well as R (R Version 4.10) and the survival package for the Andersen-Gill model.

# RESULTS

A total of 95 participants were recruited to the original study, of which 89 (93.7%) were included in the 12-month followup analysis (Figure 1). Six participants were lost at follow-up due to death. The intervention and the control groups were composed of 44 (49.4%) and 45 (46.8%) participants, respectively (Table 1). Overall, participants had a mean (SD) age of 86 years (8.05), and 64 (71.9%) were female. The intervention group presented more signs of frailty at baseline: 56.8% of the intervention group had a Clinical Frailty Score of 7–9 compared to 37.2% of the control group. Similarly, according to the MMSE score, 54.6% percent of the intervention and 37.8% of the control group had severe cognitive impairment.

The Andersen-Gill model showed that participants in the intervention group had a greater likelihood of falling 2.01 (1.11 to 3.63) than the control group (p = .02) when accounting for the number of falls during the six months prior to the intervention, frailty status, cognition, and sex (Figure 2).

# DISCUSSION

The objective of this trial was to investigate the effect of a standing intervention on falls among LTC residents over 12-months of follow-up. The residents who received the standing intervention experienced a two-fold increase in their risk of falling compared to those in the control group.

Although participants in the standing intervention may have increased the hazard for falls compared to participants in the control group, the prevalence of falls did not surpass what would be typically observed in LTC facilities. Previous research has reported that 50–75% of older adults in LTC facilities fall at least once each year.<sup>(21)</sup> In our study, over the total 12-month follow-up period, 44% of participants in the control group and 57% of participants in the intervention group reported falls, suggesting that the intervention did not lead to a greater-than-expected falls rate for residents of LTC facilities.

Compared to other physical activity interventions in LTC our inclusion and exclusion criteria were quite broad. Most exercise trials in LTC facilities do not include participants with cognitive impairments due to their inability to adhere to specific exercise protocols or perform outcome measures.<sup>(4)</sup> This makes it difficult to compare findings from our study to others in the literature. However, given that most LTC residents have a form of cognitive impairment, their inclusion is critical for external validity. Based on the characteristics of participants in the two groups, the intervention group had an 8.5% lower cognitive level than the control group at baseline. Poor cognition is an important predictor of falls,<sup>(20)</sup> so it is possible that the higher levels of cognitive decline in the intervention group help explain the higher rate of falls experienced by participants in this group.

In our sample, 20% more participants in the intervention group had a clinical frailty score of 7 or higher (severely frail) than the control group. Additionally, only 16% of the intervention group was categorized as independent transfer compared with 53% of the control group. This is consistent with findings from a previous study from our group which found that independent ambulators are 1.7 times less likely to experience a fall compared with those who are not independent ambulators.<sup>(20)</sup> Despite standing being a low-intensity activity on the movement spectrum, it is also possible that the volume of standing offered may have led to physical overload, reducing the potential effectiveness of reducing falls.<sup>(9)</sup> A recent systematic review found that exercise interventions were only effective in LTC facilities when frail participants were excluded.<sup>(9)</sup> In our study, 47% of participants lived with severe frailty levels (7-9 on the Clinical Frailty Scale) and had an average gait speed of 0.41 m/s, indicating functional impairments.<sup>(10)</sup> Given that frailty is a state of low physiological reserve and poor ability to respond to minor stresses,<sup>(22)</sup> severe levels of frailty may have reduced the participants' responsiveness to the intervention. It is difficult to restore physical function with high frailty levels.<sup>(23)</sup> This suggests that residents of LTC facilities with a higher functional capacity might benefit from this type of intervention. Our findings contradict the conclusions made from a standing pilot study with the same population by Lee *et al.*<sup>(7)</sup> where it was concluded that a standing intervention might be more beneficial among LTC residents who are frailer and need assistance to transfer as they have less standing exposure.

The potential benefits of standing may have been outweighed by the inability of study participants to reach the targeted 100 minutes of standing per week (ClinicalTrials.gov NTC03796039). Of the 100 minutes of offered standing time, participants reached an average of 42 minutes, which puts into question the acceptability of standing as an intervention for residents in LTC facilities. Even if replacing sedentary time with light activities such as standing is associated with healthy aging,<sup>(6)</sup> the exposure might need to be individualized. Our intervention introduced standing for 20 minutes daily five days per week, but participants may have benefited from more frequent bouts in shorter bouts as previously suggested.<sup>(24)</sup>

Falls are multifactorial and complex, resulting in many interacting intrinsic and extrinsic risk factors. Research suggests that multifactorial interventions that target multiple risk

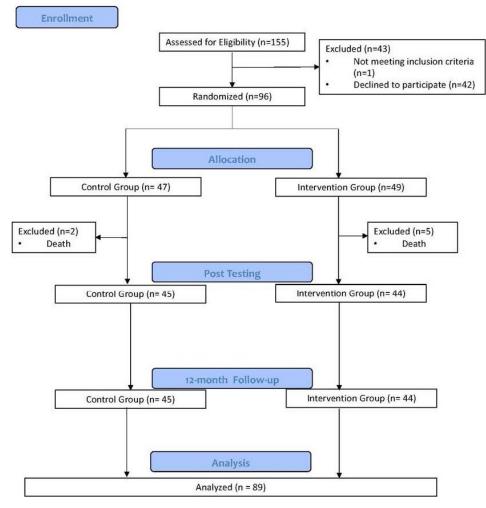


FIGURE 1. Participant flow diagram

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	Control (n = 45)	Intervention $(n = 44)$
Age (years)	84.9 (7.65)	87.2 (8.38)
Sex (Female)	31 (68.9%)	33 (75.0%)
<i>Transfer Status</i> Independent Transfer Assist Transfer Dependent Transfer	24 (53.3%) 12 (26.7%) 9 (20.0%)	6 (16.0%) 28 (63.6%) 10 (22.7%)
<i>Frailty Score (1-9)</i> Fit (1-3) Moderate Frailty (4-6) Severe Frailty (7-9)	0 (0%) 28 (62.2%) 17 (37.2%)	6 (13.6%) 13 (29.5%) 25 (56.8%)
Main Reason for Admission Dementia CVD <sup>b</sup> Neuromuscular <sup>c</sup>	25 (55.0%) 15 (33.3%) 4 (8.9%)	30 (68.2%) 4 (9.1%) 4 (9.1%)
Cognition (MMSE) Mild (24-30) Moderate (18-23) Severe (0-17)	16.89 (8.99) 13 (28.9%) 14 (31.1%) 17 (37.8%)	15.45 (9.43) 12 (27.3%) 8 (18.2%) 24 (54.6%)
Physical Function Gait Speed (m/sec) Leg Strength (kg)	0.46 (0.22) 7.70 (5.40)	0.37 (0.17) 9.31 (6.14)
Standing Time <sup>d</sup> Standing (min/day)	93.7 (82.6)	95.3 (127.1)

TABLE 1.Participant Characteristics (n = 89)<sup>a</sup>

<sup>a</sup>Data presented as mean (SD) and N(%).

<sup>b</sup>CVD includes stroke, coronary artery disease and chronic heart failure. <sup>c</sup>Neuromuscular includes Parkinson's disease, multiple sclerosis, and hemiplegia.

<sup>d</sup>N = 47 (24 control; 23 intervention).

BMI = body mass index; min = minutes; MMSE = Mini-Mental State Examination.

factors could be more beneficial in this setting.<sup>(25)</sup> As with other single-component interventions, standing alone may not have had a great enough effect to reduce falls given the other risk factors LTC residents face.<sup>(26)</sup>

Some may argue that the intervention participants were gaining an inappropriate sense of confidence from standing and were doing more independently, increasing their risk of falls. However, we believe it is unlikely that any false sense of functional capacity was carried forward over the 12-month follow-up.

Future work investigating the effect of increasing standing time in LTC settings should carefully monitor falls, risk factors for falls, and other adverse events. Interim analysis may be warranted to ensure safety, and the intervention stopped if necessary. In addition, similar interventions could include some falls-prevention education before allocation. Residents in LTC residences are heterogeneous and perhaps standing interventions need to be tailored to sub-groups having similar baseline characteristics.

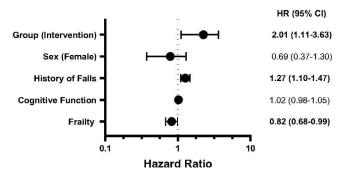


FIGURE 2. Hazard risk of falls over 12-month follow up for the intervention group vs. the control group

#### Limitations

This is one of the first studies to explore the effect of a standing intervention on falls in LTC settings. Despite the novelty of the present study and the interesting findings, limitations need to be mentioned. The first is the sample size, as the sample size was calculated for the main outcome of the trial. As such, this study was underpowered to detect the true effect of the standing intervention on falls. Many baseline characteristics increasing the risk of falls, based on the literature, were not balanced between the two groups. The second is the reliance of the LTC facilities to report falls. It is possible that some falls were missed or not reported, resulting in misclassification and bias. The third is that falls are complex events, and this study is missing the context around the reported falls, such as time of day, slippery floor, and medication usage. The fourth is that characteristics of participants were not re-tested at follow up. Knowing changes in frailty status, cognitive status, or mobility could have given more context to the fall rate in both groups. Finally, a small number of sites with a cluster design increases the probability of prognostic imbalance between the groups, as observed in Table 1.

## CONCLUSIONS

In the current study, participants receiving a standing intervention over 22 weeks were twice as likely to fall 12 months after the intervention compared with the control group. However, the prevalence of falls did not surpass what would be typically observed in LTC facilities. More studies are needed to understand the role of standing as an intervention for people living in LTC settings with extra caution for fall prevention gathering much information about the context in which falls occur.

This study emphasizes that older adults living in LTC are a high fall-risk population. Special consideration is needed when replacing sitting time with standing in this population. It is imperative that future studies describe in detail the context in which falls happen and collect more characteristics of participants in the follow-up period in order to truly understand the potential role of standing in this population.

Data Sharing: The data that support the findings of this study are available on request from the corresponding author, Dr. Bouchard. The data are not publicly available due to information that could compromise the privacy of research participants.

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Not applicable.

# **CONFLICT OF INTEREST DISCLOSURES**

We have read and understood the *Canadian Geriatrics Journal's* policy on disclosing conflicts of interest and declare that we have none.

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