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An evaluation of a walking and socialization program in long-term care: Impact on injurious falls

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ABSTRACT

The effects of a walking program in long-term care (LTC) are affected by multiple comorbidities and the LTC milieu. We randomly assigned residents 60 years and older into three groups (walking, socializing and control). Interventions were delivered five days weekly up to 30 minutes daily. Measurements were performed at baseline, 8, 16, 24 and 32 weeks, and included falls, grip strength, Berg Balance Scale, Senior Fitness Test, and Geriatric Depression Scale Short Form. Survival analysis with 168 participants for time to first injurious fall showed a significant (p=0.001) interaction between age and sex, with fall risk increasing with age in females, but lowest in the oldest age group in males. The hazard ratio for first injurious fall was more than doubled by the use of an antidepressant (HR=2.198, p=0.005), decreased by the score on the Berg Balance high fall risk rating (HR=0.471, p=0.010), but not affected by the activity-socialization intervention. The increased hazard of injurious falls related to antidepressants, but not depressive symptoms, suggests that the high prevalence of antidepressants in LTC needs re-evaluation. Further research efforts will need to control for alternate physical activities.

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Keywords: Walking; Falls; Long-term care; Longitudinal studies

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Introduction

Injurious falls are very common in older adults, especially within care facilities or frail elderly individuals, such as long term care (LTC) homes. These falls can result in various adverse outcomes including fractures, pain, and other events[1]. Various risk factors for falls have been described[2], of which some, such as age may not be modifiable, but others, such as the use of psychotropic medications[3], low levels of vitamin D[4] and rates of inactivity[5], can be modified. With respect to vitamin D, while effects of vitamin D have not been consistently found with respect to fall rate or risk, there is moderate-quality evidence to recommend vitamin D supplementation in the LTC setting[6], especially in those with low vitamin D status[7]. Depressive symptoms have also been reported to be independent risk factors for falls[8] through various mechanisms which include fear of falling, weight loss, and sleep fragmentation[9]. Depressive symptoms can improve through exercise [10] or increased social interaction[11], potentially reducing fall risk.

The evidence for beneficial outcomes related to exercise interventions for older adults in LTC has been limited and equivocal[12]. Many studies were methodologically limited and could not allow for the adequate separation of the effects of exercise from socialization. Moreover, much of the evidence did not involve adjustment for important risk factors for falls such as use of psychotropic medications, although antipsychotic[13], antidepressant[14;15], anxiolytic, sedative and hypnotic drugs [16], are all known risk factors for falls and fractures.

The LTC milieu presents challenges to the administration and evaluation of a standardized walking program. In particular, it is difficult to separate the impact of interpersonal interaction from the benefits of walking programs. Our initial goal was to study the impact of an individualized, progressive walking program compared to injurious falls on injurious falls and other physical and psychological measures[12]. The hypothesis was that regular walking would reduce injurious falls. As walking includes socialization, that might also affect injurious falls through multiple complex physical and social interactions (for example through the impact of improved mood or decreased fear of falling on risk), so our second research group only received stationary socialization and the third participated in care as usual. We planned to account for additional potential confounding variables by measuring use of psychotropic medications and by eliminating low levels of Vitamin D through supplementation of all participants.

Methods

Ethics approvals

The study was approved by all applicable institutional Research Ethics Boards.

Study design

This paper is part of a larger investigation of falls in LTC, for which study methods and design were published in detail by Dal Bello-Haas et al.[12]. In summary, this study involved a prospective, randomized, three-group experimental design with multiple outcome variables. Residents of long-term care facilities were randomly assigned within each facility into one of three groups: 1) Walking Group – individuals participated in a supervised, progressive walking program five days per week, for up to 30 minutes per day; (2) Socializing Group - individuals participated in a one-on-one stationary interpersonal interaction over a 30 minute period; and (3) Control Group - individuals received care as usual. Assessments were conducted at baseline, 8 weeks and 16 weeks after the intervention was started, and 8 weeks and 16 weeks after the active intervention was completed.

Direct measurements included: vital signs, height, weight, waist, arm and calf circumference, grip strength using a hand-held dynamometer (measured in kilograms as the best score over both hands), the Berg Balance Scale[17] (BBS), the Senior Fitness Test[18](SFT),

the Older Adult Resource Services Physical Activities of Daily Living- Physical ADL subscale[19] (OARS-PADL), the Geriatric Depression Scale Short Form[20](GDS), the Cornell Scale for Depression in Dementia[21] (CSDD), the Revised Memory and Behavior Problems Checklist[22] (RMBPC), the Short Portable Mental Status Questionnaire[23] (SPMSQ) and the Colored Analogue Scale for pain[24] (CAS).

Chart information collected included demographic information (baseline age, sex), adverse health events for any reason, hospitalizations, deaths (date and cause when available), medication use, and the number and impact of falls (using standardized Health Region falls reporting forms which include date and time of occurrence, actions/situation immediately prior to the fall, details of the fall i.e. from a chair or bed, location and description of injuries, pain (0-5) expressed due to the injury, care required after the injury, functional outcome of the injury (none to death) and persistent pain from the injury). Many minor falls not resulting in obvious injuries and not observed by staff would not have been captured. We used information from the most recent full Resident Assessment Instrument-Minimum Data Set[25](RAI-MDS 2.0) as well as the following MDS scales[26]: Activities of Daily Living Long Form Scale, Changes in Health, End-Stage Disease and Signs and Symptoms Scale (CHESS), Cognitive Performance Scale (CPS) and Depression Rating Scale (DRS).

Target population, inclusion and exclusion criteria

The target population consisted of permanent LTC residents expected to remain in the same LTC facility for the duration of the study, who were over the age of 60, able to follow simple instructions, able to walk with or without a walking aid for at least 10 meters, available Monday-Friday for interventions, willing to be randomized into one of three intervention groups and willing to be followed over another 16 weeks for standardized assessments. Potential participants had to be either capable of consenting to the study themselves, or express assent to participation and receive consent to participation from the substitute decision-maker (SDM) who normally consented to their health care decisions. Potential participants were excluded if they had experienced a recent cardiovascular event (within past 6 months) or had severe cardiac instability, severe, mobility limiting arthritis or vestibular disorder, uncontrolled hypertension, uncontrolled epilepsy, fracture acute care admission within the past 4 months, were scheduled for surgery or hospitalization within the next 6 months, had participated in another regular exercise program or exercised independently for half an hour or more, three or more times per week , or who were for any other reason unable to satisfactorily comply with the protocol requirements.

Recruitment

Potential participants identified by staff members of participating LTC were approached by research assistants (RAs) and asked if they wished to receive information about the study. Participants who understood the study protocol were invited to sign the consent form. For those who assented but did not appear to fully understand the information provided or his or her capacity was unclear, the research assistant asked permission to contact the substitute decision-maker (SDM) who normally consented to health care decisions. If the participant agreed to this contact, the SDM was approached and the research protocol was explained in detail. The consent form was signed by only the SDM when the participant clearly lacked capacity to provide informed consent and by both the participant and the SDM when capacity was unclear or diminished. Only residents who assented to the study were entered, regardless of SDM consent.

Study assessment procedures

Potential participants had baseline assessments including reassessment of eligibility to enter the study. Residents not

meeting requirements for the study after these assessments were not included in the randomization process. Family physicians of participants enrolled in the study at this point were asked to prescribe Vitamin D 1,000 IU if the participant was not already taking 1,000 IU or more, and there was no contra-indication. Participants already taking Vitamin D 1,000 IU or more continued taking this.

Training of RAs was conducted by appropriate health care professionals for each instrument. For example, RAs were trained in the administration of physical measures by a licensed physiotherapist. Licensed physiotherapists continued to be available to RAs during the study to advise on practical and safety issues related to either the active interventions or the physical assessments. RAs were periodically observed in their assessment and intervention activities by either the physiotherapist, or senior research staff.

Intervention procedures

Participants within each facility were randomly assigned to one of three intervention groups with no attempt to balance gender. The participants randomized to the walking group received an individualized, progressive, one-to-one daily supervised walking program for the first 16 weeks, up to 30 minutes, five days per week, facilitated by RAs and supervised by a licensed physiotherapist. The distance walked was initially determined for each individual based on how far the person could walk before visibly becoming fatigued or short of breath, reporting pain or requesting to sit down or rest. The distance walked and the intensity of the walking program during the 16-week period was gradually increased as tolerated by the participant. Overall interaction time, distance walked and time spent walking was recorded. Participants in the socialization group received approximately 30 minutes per day, five days per week, interpersonal interaction time for the first 16 weeks while engaging in stationary tasks of their choosing such as talking, looking at pictures or playing board games. Interaction time was recorded. No control, socializing and walking group participants had active interventions for the second 16 weeks, but received scheduled assessments. Participants in the control group participated in the usual LTC activities (including recreation and therapies) throughout the 32-week study period, receiving the usual care except for scheduled research assessments. Participants in the walking or socializing groups were withdrawn from active interventions if they withdrew consent or assent to the active intervention or developed contraindications to the study protocol. Falls data was collected from standardized LTC falls reporting forms for all participants up to 32 weeks from the active study start date. Attempts were made to collect end of study assessment data for all participants regardless of when they left the study.

Statistical analysis

Many patients in LTC are frail and were expected to suffer medical events requiring hospitalization and/or withdrawal from active interventions, and even some deaths might occur during the study period. Follow-up times were therefore expected to fluctuate so the analytic approach needed to adjust for that in the assessment of falls outcomes. We were also aware that falls are common in LTC and would not always be observed or charted by nursing staff, so we restricted our analysis to those resulting in injuries requiring nursing intervention. The most appropriate statistical method to allow for both incorporation of length of observation period for the falls and multiple potential confounders is a hazard analysis, using an intention to treat approach. We therefore employed Cox regression analysis to explore predictors of the time to first injurious fall using SPSS Statistics for Windows, Version 24.0[27]. Independent baseline variables entered from the Senior's Fitness Test[18] were the number of meters that could be walked in six minutes (the Six Minute Walk Test), and the number of seconds needed to get up from a

seated position, walk 8 feet, and return to a seated position (8 Foot Up-and-Go). Variables entered from the Berg Balance Test[17] were the total score, and the high fall risk categorical variable (high risk coding score 0-36 =1, otherwise score >36=0) (Shumway method[28]). Medication variables included from the chart were regular antidepressant and antipsychotic use at baseline. Too few participants were taking regular and anxiolytics/sedatives or hypnotics to allow for statistical analysis. The dates of collection of the most recent MDS varied from up to three months before the study started, so the MDS data was excluded from the final model building. Baseline independent variables (including RA collected measures and chart information) were initially explored by univariate analysis, including two and three-way interactions between the core demographic data (sex, age) and walking group. Age and sex were explored alone and in interaction using both continuous and categorical (multiple cut-points explored) analysis. Variables with $p<0.1$ (including interactions) in the univariate model were entered into the initial multivariate model, with variables removed sequentially in reverse order of their significance.

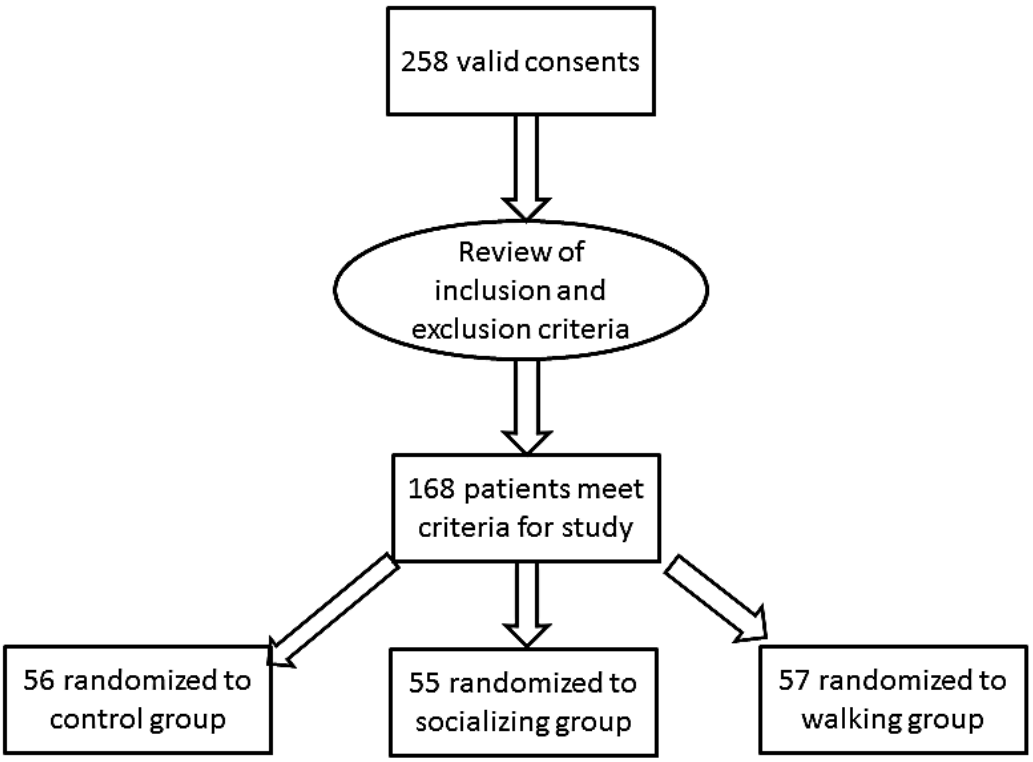

Figure 1: Participants in a 32-week walking and socialization study

Results

Participant enrollments are shown in Figure 1. Valid consents were obtained from 258 older adults aged 60 years and older residing permanently in a LTC facility. After baseline review of chart information and structured individual assessments, 168 potential participants were found to still meet study inclusion criteria. These consenting 168 participants from 11 LTC facilities were randomized (within each LTC) into the three intervention groups: 57 into the walking group (mean age 84.2, M=16, F=41), 55 into the socializing group (mean age 84.1, M=19, F=36), and 56 into the control group (mean age 85.4, M=16, F=40). Basic characteristics of the groups are shown in Table 1. There was no significant difference between the three intervention groups in any of the baseline measures.

Table 1: Baseline characteristics of participants by treatment arm

Baseline measures (SD)		Intervention Group			Total Group
		Control	Socializing	Walking	
Male	N	16	19	16	51
	% within Group	28.6%	34.5%	28.1%	30.4%
	Mean age, years	86.9(6.7)	82.5(8.1)	83.0(8.9)	84.0(8.1)
	GDS, (0-15)	4.8(3.7)	4.3(3.6)	3.1(2.8)	4.1(3.4)
	CSDD (0-38)	4.4(4.0)	4.4(4.5)	3.9(2.5)	4.2(3.7)
	Grip strength[a]	19.8(7.5)	26.9(11.3)	25.6(5.3)	24.3(9.0)
	RMBPC	3.9(8.3)	1.6(2.1)	1.5(2.2)	2.2(5.0)
	OARS-PDL(0-14)	8.3(2.0)	8.2(2.4)	9.9(2.4)	8.7(2.4)
	SPMSQ (0-10)	6.3(2.8)	5.4(2.6)	5.8(2.9)	5.8(2.7)
	SMWT in meters	93.1(51.5)	100.0(63.3)	117.3(86.7)	103.3(67.8)
	8 UG in seconds	39.6(21.5)	61.8(41.0)	42.9(24.5)	48.9(32.1)
	CAPS	3.6(2.5)	3.3(3.0)	2.0(2.3)	3.0(2.7)
	BBS	30.4(11.0)	21.8(13.4)	29.7(13.6)	27.0(13.2)
	BBS high fall risk	68.8%	89.5%	62.5%	74.5%
	Antidepressant use, %	43.8(51.2)	47.4(51.3)	25.0(44.7)	39.2(49.3)
	Antipsychotic use, %	25.0(44.7)	42.1(50.7)	31.3(47.9)	33.3(47.6)
	Sedative/hypnotic, %	0(0%)	3(15.8%)	0(0%)	3(5.9%)
Female	N	40	36	41	117
	% within Group	71.4%	65.5%	71.9%	69.6%
	Mean age, years	84.7(7.0)	85.0(8.8)	84.7(8.8)	84.8(8.1)
	GDS, (0-15)	3.2(2.8)	3.9(3.3)	3.5(3.0)	3.5(3.1)
	CSDD (0-38)	4.7(4.0)	4.3(4.0)	4.1(3.8)	4.0(3.8)
	Grip strength[a]	15.7(7.1)	15.9(5.9)	18.6(6.3)	16.1(6.3)
	RMBPC	2.1(4.1)	3.8(6.8)	2.7(8.5)	2.8(6.7)
	OARS-PDL(0-14)	8.4(2.1)	11.6(15.2)	8.9(3.0)	9.5(8.7)
	SPMSQ (0-10)	6.2(2.9)	6.3(2.4)	6.6(2.3)	6.4(2.5)
	SMWT in meters	97.0(78.5)	107.5(81.3)	100.8(81.1)	101.5(79.7)
	8 UG in seconds	56.1(53.6)	47.8(32.1)	49.9(30.6)	51.3(39.8)
	CAPS	2.5(3.2)	2.5(2.4)	2.1(2.5)	2.4(2.7)
	BBS	27.3(17.6)	29.2(13.4)	27.9(14.3)	28.1(15.2)
	BBS high fall risk	52.5%	66.7%	70.7%	63.2%
	Antidepressant use, %	50.0(50.6)	50.0(50.7)	39.0(49.4)	46.2(50.1)
	Antipsychotic use, %	25.0(43.9)	25.0(43.9)	29.3(46.1)	26.5(44.3)
	Sedative/hypnotic, %	2(5%)	2(5.6%)	0(0%)	4(3.4%)

GDS: Geriatric Depression Scale; CSDD: Cornell Scale for Depression in Dementia; RMBPC: Revised Memory and Behavior Problem Checklist Total Frequency (0-24); SMWT: Six-Minute Walk Test, in meters; 8 UG: 8 Foot up and go, in seconds; CAPS: Coloured Analogue Pain Score; BBS: Berg Balance Scale, total score (0- 56); BBS high fall risk: Berg Balance Scale (Shumway , 1997) percentage high fall risk; Antidepressant use: Regular use; Antipsychotic use: Regular use; Sedative/hypnotic use: Regular use [a] Grip Strength was coded as the best score over both hands in kg P-value based on ANOVA. Note: none of the differences were statistically significant

There were 51 withdrawals in total prior to 32 weeks which included 24/57 (42.1%) in the walking group, 13/55 (23.6%) in the socialization group, and 14/56 (25.0%) in the control group. Lack of adherence and health related issues were more frequent reasons for withdrawal in the walking group compared to the other groups but numbers were too small for statistical significance testing.

The total number of falls in individual study participants ranged from none to 23 during the study period, with a few participants having a large number of falls, but most participants having two or fewer falls. There were 234 total falls charted for our participants: 162 in females and 72 in males. By age group, there were 41 falls in those <80 years of age (17.5% of all falls), 127 in those 80-89 years (54.3% of all falls) and 66 in those 90+ years (28.2% of all falls). Less than half (F 45%, M 47%) of all charted falls resulted in injuries (most mild, see below), which were reported in 73 females and 34 males. In females the rate of injuries related to falls increased with age, whereas in males the middle age group had a lower injury rate. Functional change resulting from the fall was coded by nurses as 1-No functional change, 2-mild/moderate functional change, 3- marked functional change, 4-totally incapacitated, 5-death. No falls resulted in death, one fall resulted in complete incapacitation, and 16 falls resulted in marked functional change. Most (F 94%, M 90%) of the falls resulted in no or mild to moderate functional change.

Table 2: Cox regression analysis for time to first injurious fall

				95.0% CI for HR	
	B	**P-value**	**HR**	**Lower**	**Upper**
Age	-0.05	0.11	0.95	0.90	1.01
Sex	-11.4	.001	0.00	0.00	0.01
Berg high fall risk	-0.8	.010	0.47	0.27	0.83
Antidepressant at baseline	0.8	.005	2.20	1.26	3.83
Age*Sex	0.1	.001	1.14	1.05	1.23

To take into account differences in participation time in the three intervention groups we used Cox Regression to explore the time to first injurious fall while adjusting for all available baseline independent variables (described in the section on statistical analysis). Baseline use of anxiolytic, sedative and hypnotic drugs could not be added in our initial models as only seven participants (three males and four females) were taking these regularly at baseline.

Results of the final model from the survival analysis are shown in Table 2 (proportionality requirements were met) and Figure 2. Survival analysis for time to first injurious fall showed that there was a significant (p=0.001) interaction between age and sex, with the hazard for injurious fall rates increasing with age in females, but decreasing with age in males. The hazard ratio for first injurious fall was doubled by the baseline use (for any reason) of an antidepressant (HR=2.198, p=0.005), halved by baseline high fall risk score from the Berg (HR=0.471, p=0.010), but not affected by baseline depression ratings, intervention group, use of an antipsychotic or any other baseline measurement.

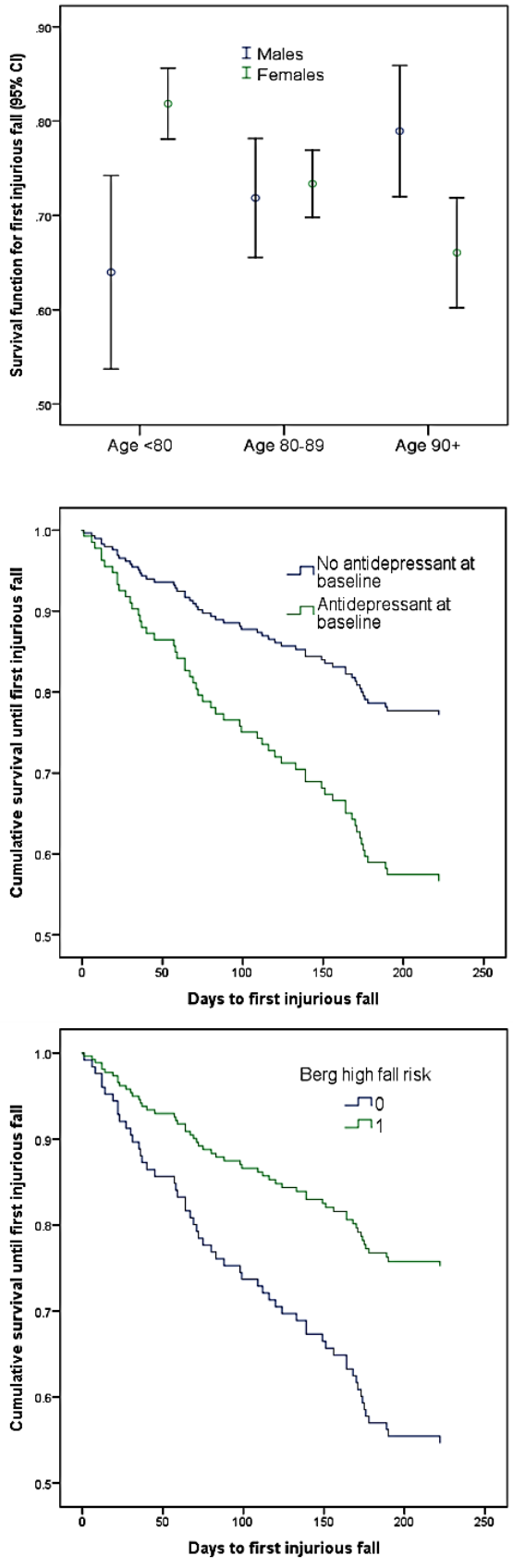

Figure 2: Cox regression analysis for time to first injurious fall

Discussion

Although our initial plan was to study the impact of increased physical activity (walking) on various health-related outcomes, the primary finding resulting from this study was the clear demonstration that antidepressants but not

depressive symptoms substantially increase the risk of injurious falls (HR=2.198, p=0.005) within the LTC environment. This is of great clinical interest in view of the high rates of antidepressant use (36.1 %) in LTC reported by the Canadian Institute for Health Information in 2014 [29] yet greater public health concern about antipsychotic medication use. Our findings were consistent with other research finding that selective serotonin reuptake inhibitor (SSRI) antidepressants increase rates of fractures[14, 15], and that this effect is more pronounced than the effect of antipsychotics[30], with mechanisms linked to changes in bone metabolism[31] and increased frequency of falls[32].

Physical activity and exercise have been found to have positive effects on improving or maintaining functional status in older adults living in LTC[33], yet we found no significant effect on injurious falls risk as a function of our walking intervention. We postulate that our research methods might have inadequately reflected the complexity of physical exercise and potential interactions with other factors in our frail LTCF population. Further obscuring the impact of walking was an increase in the institution of regular exercise programs in the LTC, so research participants in the control and socialization groups also had undocumented activity.

We found no significant effect of baseline vitamin D use on injurious falls. This could have been a result of almost universal supplementation of Vitamin D in our participants because of guidelines recommending vitamin D supplementation in Canadian LTC[6] and known greater effects of Vitamin D in reducing falls and fractures among people with low vitamin D status[7].

Our study had some limitations. Our main intervention included walking with a research assistant rather than exercising as part of a group activity which might have promoted greater relatedness[34] and potentially improved other outcomes. Our walking intervention also did not include balance training, which might also have decreased falls in interaction with the physical activity.

Conclusions

Our finding of a greater increase in injurious falls with age in women compared to men was consistent with Canadian data on fall-related hospitalization rates[35]. It was also consistent with our data demonstrating a trend to lowest scores in the OARS physical activity of daily living score in women 90 years and older (p=.067). No such pattern was seen in males, where the lowest mean baseline OARS score (not significant) was seen in the 80-89 age group. The decreased hazard ratio for falls (HR=0.471, p=0.010) in those participants who had the highest baseline fall risk on the Berg was likely related to decreased baseline activity level and therefore less opportunities for falling and increased vigilance by nursing staff.

In summary, in spite of the methodological challenges, we believe that this is a valuable health promotion strategy; albeit one that still needs further evaluation. Future research should be aimed at controlling for levels of physical activity that are not part of the study intervention.

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Author contributions:

All authors; study design and concept, interpretation of data, critical revisions and final approval of the manuscript. TH; primary writer of the team grant that funded the study and overall team leader. LT; supervised acquisition of the data, analyzed the data and drafted the manuscript

Sponsor's role: The sponsor had no role in the design, conduct, analysis or publication of this material

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