Trials

STUDY PROTOCOL

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Study protocol for a pragmatic, cluster, randomized controlled trial of a multifaceted fracture prevention model for long-term care: the PREVENT trial

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Abstract

Background Each year, half of all long-term care (LTC) residents will sustain a fall, and many will sustain a fall-related fracture. Fifty percent of all fractures in this vulnerable cohort occur at the hip, which is a life-changing health event leading to hospitalization, impaired physical functioning, and increased risk of premature mortality. National osteoporosis guidelines for the prevention of fractures are not consistently used in LTC homes. Improving osteoporosis guideline implementation may prevent hip fractures and other fractures. This study will examine whether the PREVENT (Person-centered Routine fracture prEVENTion) model can reduce hip fracture rates over one year compared to usual care in LTC homes.

Methods Our study design is a pragmatic, cluster, randomized controlled trial. We will recruit 122 for-profit and not-for-profit LTC homes across Ontario, Canada. Homes will be randomized in a 1:1 ratio to intervention (PREVENT model) or control (usual care) arms. Eligibility criteria include a minimum of 50 occupied beds and access to the PointClickCare (PCC) electronic medical record system. One or two local opinion leader(s) and a leadership team consisting of five to ten healthcare providers will be recruited within each LTC home to support the implementation of the fracture prevention knowledge translation (KT) intervention. Generalized estimating equations (GEE) will be used to examine the effect of the PREVENT intervention vs usual care on hip fracture incidence (primary outcome), adjusting for important resident and LTC home characteristics; and secondary outcomes, including new osteoporosis medication prescriptions, non-hip fracture rates, falls, hospitalizations, death, LTC quality indicators, pain, mobility, responsive behaviors, and healthcare utilization costs. The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement was used to guide the development of this study protocol.

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Discussion Preventing hip fractures in LTC has significant health, economic, and personal benefits. To our knowledge, the PREVENT trial is the first KT study of its kind in LTC to measure hip fracture as the primary outcome. If the PREVENT trial successfully improves hip fracture rates, it may lead the way for implementing a standardized approach to preventing hip fractures in LTC homes across Canada and internationally.

Trial registration ClinicalTrials.gov NCT04947722. Registered on July 1, 2021.

Keywords Hip fractures, Falls, Long-term care, Knowledge translation, Osteoporosis, Prevention, Interdisciplinary, Audit and feedback

Administrative information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).

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Role of sponsor {5c}	The funder of this study had no direct role in the study design or execution of the trial.

Introduction

Background and rationale {6a}

Fractures represent a significant concern for individuals living in long-term care (LTC) homes, occurring at rates 1.8 times higher than non-institutionalized seniors [1]. High rates of falls also contribute to the increased risk for fractures [2, 3], with up to 8% of falls among LTC residents resulting in fractures [4, 5]. More than 80% of all fractures in LTC are attributed to osteoporosis [6]. LTC residents have multiple risk factors for falls and fractures, including osteoporosis, frailty, cognitive impairment, and reduced mobility. Hip fractures constitute half of all reported fractures in LTC homes [7] and can have devastating impacts on daily function, quality of life, and survival of residents [8–10]. Furthermore, hip fractures are costly to our healthcare system, with cost estimates doubling when patients are discharged to a LTC home [6]. As the demand for LTC increases [11], there is a critical need for evidence-based practices to effectively prevent and reduce the health and economic burden of fractures.

In 2015, Canada established recommendations for fracture prevention in LTC to improve fracture risk assessment and treatment [12]. These practice guidelines, using the GRADE approach, recommend a multifaceted approach for preventing fractures in LTC, including identification of high fracture risk residents, calcium and vitamin D supplementation, pharmacotherapy, use of hip protectors, exercise, and a multi-factorial falls reduction approach [12, 13]. Despite this guidance, current practice often falls short of these recommendations, and many LTC homes are not consistently applying evidence-based practices for falls and fracture prevention [13–15]. In LTC settings, factors such as time constraints, staffing challenges, limited resources, challenges to multidisciplinary team collaboration, and varying levels of organizational support and leadership engagement present barriers to the uptake of practice guidelines [16–18].

Knowledge translation (KT) focuses on bridging the gap between research evidence and the effective and sustained implementation of this knowledge into clinical practice [14, 15]. Designing a successful KT intervention for fracture prevention in LTC requires strategies that address LTC-specific barriers and leverage known

facilitators such as leadership and champions, resident-centered care strategies, adequate services, and resources and tools to support better practice [14, 19, 20]. Our team has previously demonstrated the effectiveness of multifaceted KT models for improving vitamin D, calcium, and osteoporosis medication prescribing in Canadian LTC homes [21–23]. Importantly, the vitamin D and osteoporosis study (ViDOS) findings showed that process and policy changes were sustained in intervention sites beyond the study period [24]. Building on this foundation, the iCare longitudinal study confirmed the feasibility of the PREVENT intervention and refined the methodology for the current trial [25].

To date, no large-scale randomized controlled trial conducted in LTC has evaluated KT strategies for reducing hip fractures as a primary outcome. The Bavarian Fall and Fracture Prevention study, a non-randomized implementation project, reported an 18% reduction in hip fractures using a multi-component approach including staff education, medication review, vitamin D supplementation, hip protectors, environmental adaptations, falls documentation, and exercise programming [26–28]. This study relied on external personnel to deliver interventions, which may challenge long-term sustainability and scalability within LTC homes. To address previously identified barriers to fracture prevention in LTC and build on the prior success of a KT model [25], we developed the PREVENT (Person-centered Routine Fracture PreEVENTion) trial.

Objectives {7}

The primary objective of this trial is to examine whether the PREVENT model can reduce one-year hip fracture rates among high-risk LTC residents in intervention versus usual care LTC homes. Secondary objectives include evaluating the effect of the multifaceted PREVENT model on osteoporosis medication prescribing, incidence of non-hip fractures, time to fracture, falls, hospitalizations, mortality, pain, mobility, responsive behaviors, and additional LTC quality indicators (e.g., falls, pressure ulcers, and worsened physical function, and pain) [29]. The trial will also include an economic evaluation of the differences in direct healthcare utilization costs between the intervention and control arms.

Trial design {8}

PREVENT is a pragmatic cluster RCT comparing an 18-month, multifaceted KT intervention with a usual care control group in LTC homes. The unit of randomization will be the LTC home, rather than individual practitioners, to reduce the risk of contamination inherent in the team-based model common in LTC settings. Figure 1 illustrates the overall study design. This trial scores 43 on the PRECIS-2 tool (see Additional file 1), indicating a high level of pragmatism in its design [30].

Methods: participants, interventions, and outcomes

Study setting {9}

The trial will be conducted in for-profit and not-for-profit LTC homes in Ontario, Canada. In Canada, LTC homes are government-regulated facilities for adults who require primarily long-term, onsite nursing care and personal support [31]. In Ontario, with a total population of over 16 million people, there are 626 licensed LTC homes with a total of approximately 77,000 long-stay beds. Our recruitment strategy will include LTC homes located in communities of all sizes and geographical regions in Ontario. Our intervention is directed toward interdisciplinary leadership teams at each participating LTC home, comprising physicians, nurse practitioners, administrators/care directors, nurses, consultant pharmacists, personal support workers, and allied health professionals including physiotherapists, occupational therapists, and recreational therapists.

Eligibility criteria {10}

Eligibility criteria will include both organizational and resident-level factors. At the LTC home level, inclusion criteria are as follows: (1) a minimum of 50 occupied beds, (2) access to and use of the PointClickCare (PCC), a cloud-based healthcare software provider offering an integrated Electronic Medical Records (EMR) system [32], to access the fracture risk scale (FRS), and (3) located within Ontario, Canada. During data analysis, the following resident-level exclusion criteria will be applied: (1) end-stage disease (1.2% of all LTC residents), (2) comatose (0.3% of all LTC residents), (3) receiving hospice or respite care (1.8% of all LTC residents), or an expected short stay of 90 days or less (9.2% of all LTC residents) [33].

Who will take informed consent? {26a}

Once the appropriate representative(s) from the LTC home have agreed to participate in the study, a formal letter of agreement (in place of a consent form) will be executed between each participating LTC home, McMaster University, Hamilton Health Sciences, and the Principal Investigator (PI). For intervention LTC homes, implied consent will be assumed for individual healthcare providers participating in sessions who voluntarily complete a study participant demographic questionnaire. Obtaining informed consent at the individual resident

Timeline	Control	Intervention
Screening	-	-
Baseline (time 0)	A	A
Randomization	-	-
Months 0-3	B	C, D, E, F
Months 3-6	B	G
Months 7-18	B	H
Month 18	I	I

A	Baseline assessment.
B	Usual care.
C	Three train-the-trainer sessions with the local opinion leader(s) and study team (study introduction).
D	Audit and feedback report to obtain information on low and high fracture risk residents.
E	Educational session presented by the local opinion leader(s) to LTC leadership team.
F	Accredited Continuing Professional Development with osteoporosis/LTC experts (Ontario College of Family Physicians)
G	Care planning for fracture management for residents at high risk for fracture.
H	Continued implementation of the PREVENT program and quarterly meetings between the local opinion leader(s) and study team.
I	Post-intervention data pull for baseline, month 3, month 6, and month 18 outcome indicators (ICES Data Repository (ICES)).

Fig. 1 Depiction of PREVENT intervention and assessments

level would be impracticable due to the large volume and turnover of residents. A waiver of consent to perform the data collection and analysis from ICES (formerly named the Institute for Clinical Evaluative Sciences), which provides health administrative data in Ontario, has been provided by the Hamilton Integrated Research Ethics Board (#13622). An independent, non-profit research institute funded by an annual grant from the Ontario Ministry of Health and the Ministry of Long-Term Care (MOHLTC), a prescribed entity under Ontario's privacy legislation, ICES is authorized to collect and use health care data without consent for health system evaluation and improvement.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

N/a: No further consent provisions apply to this study. Biological specimens will not be collected for this trial.

Interventions

Explanation for the choice of comparators {6b}

Given the pragmatic nature of our proposed trial, the comparison against usual care is justified. Usual care in LTC homes may include physical or occupational therapy, quarterly medication reviews, nutritional screening and assessment. All LTC homes in Ontario must have a fall prevention program that reviews all falls, implements prevention strategies, and monitors high-risk residents [34]. Control homes have access to the Fracture Prevention Toolkit [35]—an open-access resource that includes risk assessment resources, best practices for osteoporosis and fracture prevention in LTC, standard order sets, and quick reference guides for fracture risk assessment and prevention recommendations. At the end of the study period, all control LTC homes will receive access to the materials needed to implement the PREVENT intervention in their home.

Intervention description {11a}

Co-design

The PREVENT KT intervention was co-designed in consultation with healthcare professionals, the Ontario Association of Residents' Councils, and Family Councils Ontario. The intervention was piloted in the iCare study with interdisciplinary care teams at three Ontario LTC homes; and participants identified several facilitators that were integrated within the current study design [25]. These included having local opinion leaders (i.e., co-champions) from the LTC homes, automating audit and feedback reports, and providing KT tools for facilitating discussions about fracture prevention medications.

Guiding frameworks

PREVENT has been developed and tailored to the LTC setting in accordance with the Knowledge-to-Action (KTA) Cycle by Graham et al. [15]. The "Action Cycle" is based on planned-action theories and represents phases of activities that "are needed for knowledge applications to achieve a deliberately engineered change in groups that vary in size and setting" [15, 36]. Development of our intervention has also been informed by The Behaviour Change Wheel, a theory- and evidence-based tool for designing and evaluating behavior change interventions [37, 38]. By systematically analyzing both individual and organizational or system-level factors, the Behaviour Change Wheel identifies mechanisms requiring change and guides the selection of evidence-based intervention functions, or strategies, that lead to effective change. Based on the framework, the PREVENT model incorporates multiple intervention functions and behavior change techniques (Fig. 2), with a specific focus on three core functions: education, training, and modeling [25, 39, 40]. The following sentences illustrate the specific behavior change techniques associated with each of these core functions: *Education* enhances understanding by providing information, feedback, prompts, and cues. *Training* builds practical skills through instruction and hands-on practice, while *modeling* demonstrates and reinforces the behavior. All intervention components are described according to standardized terminology from the Cochrane Effective Practice and Organisation of Care (EPOC) Taxonomy [39].

Overview of PREVENT intervention

1. Fracture Risk Scale: The FRS is a validated and standardized instrument for predicting fractures for LTC residents over a 1-year period using risk factors that are directly relevant for LTC residents such as prior fractures, dementia, and falls. The FRS is embedded in the Resident Assessment Instrument Minimum Data Set Version 2.0 (RAI-MDS 2.0), a mandatory assessment tool for LTC homes in Canada [41–43]. The FRS will be used to identify residents at high fracture risk (FRS scores 4 to 8; see Additional file 2) at each quarterly or annual assessment.
2. Local opinion leaders: One or two local opinion leaders from each intervention home will be recruited to act as LTC home co-champions [44]. These professionals are considered influential in their LTC home and play a key role in facilitating behavior change [40]. Preferred co-champions will be one professional already involved in the assessment and management of osteoporosis medications and one involved in care planning and in regular communication with the resident/family and the physician providing care.
3. Train-the-trainer sessions: Local opinion leaders within the intervention homes will participate in three, 60–90-min virtual train-the-trainer sessions to learn about the PREVENT KT strategies and familiarize themselves with the recommendations for fracture prevention (Fig. 2). The first session includes an overview of the PREVENT intervention, an orientation to the Fracture Prevention Toolkit and viewing multidisciplinary expert video modules. The second session outlines the process for collecting data from PCC and generating and presenting an audit and feedback report for their interprofessional team. In the final session, champions give a mock presentation of the session they will be moderating in their LTC home, with the opportunity to receive feedback.
4. Educational meetings: Local opinion leader(s) will deliver an educational session for the interdisciplinary leadership and/or falls prevention program committee, who typically meet quarterly. All attending physicians and nurse practitioners practicing in the LTC home will also be encouraged to participate during work hours. Session content includes: 1) reviewing recommendations for fracture prevention in LTC (Fig. 2) [12]; 2) reviewing results of the audit and feedback report; and 3) completing action planning templates and care planning for residents identified at high risk for fractures based on their FRS scores.
5. Educational materials: All educational materials will be accessible to interdisciplinary teams in the intervention homes via a password-protected online Portal (GerasPREP) including (1) the Fracture Prevention Toolkit (open access) [35] based on the recommendations for fracture prevention in LTC (Table 1); and (2) evidence-based osteoporosis geriatric drug summaries and infographics via a collaboration with GeriMedRisk, a non-profit provincial consultation service for medication optimization [45]. Developed through rapid review methodology and validated by content experts, these geriatric drug information materials improved geriatric pharmacotherapy knowledge uptake and retention among clinicians [46].
6. Audit and feedback reports: Reports for intervention homes will be generated using PCC. LTC homes will have the option to independently conduct the audit report using PCC or authorize PCC to perform the audit report on behalf of their home. Reports will include the total number of high fracture risk residents (FRS scores > 4, indicating an annual hip fracture rate of 3.1%; all fracture rate of 4.4%), fractures

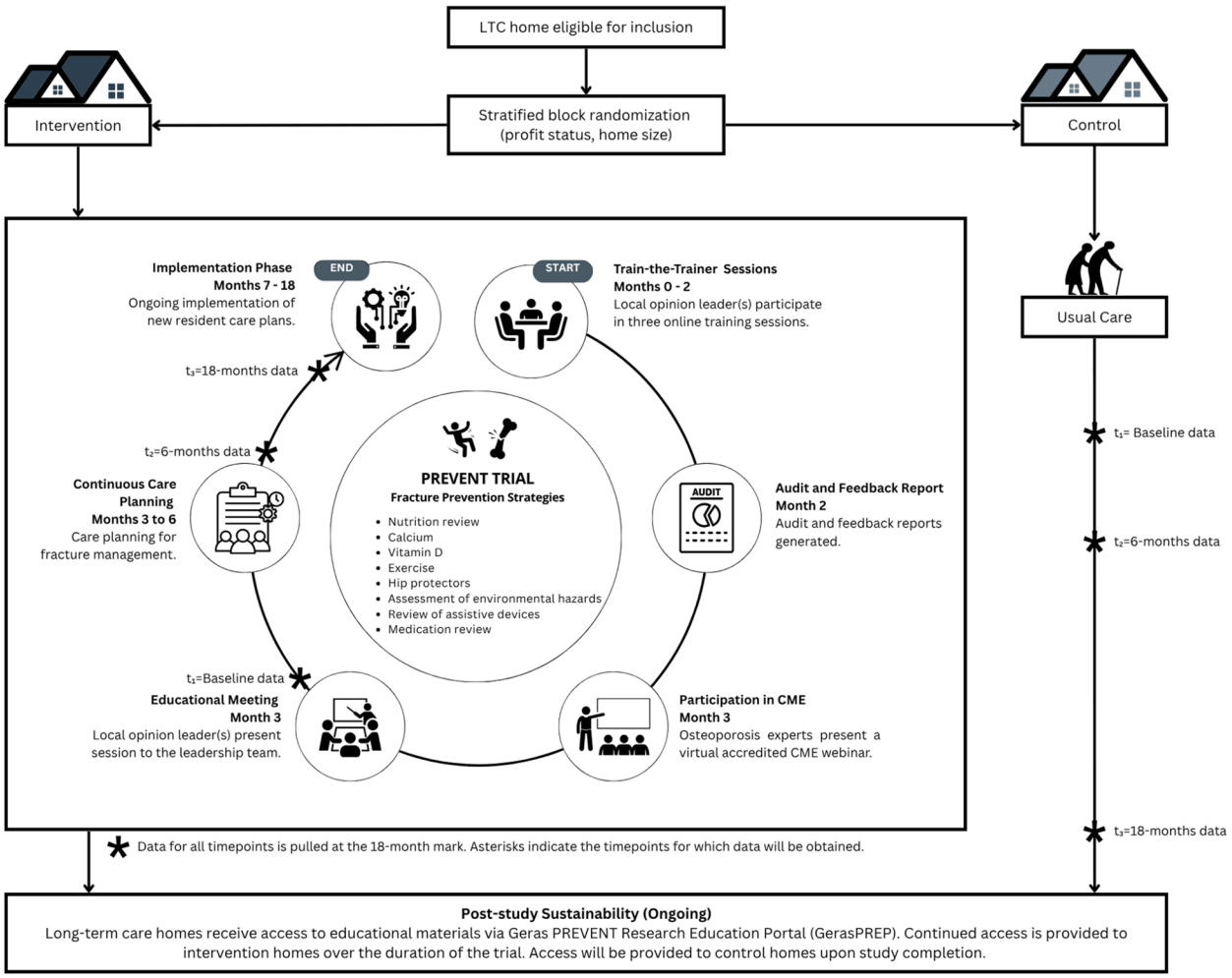


Fig. 2 Overview of PREVENT intervention: vitamin D and calcium supplementation, use of hip protectors, exercise, multifactorial interventions to prevent falls, and pharmacologic therapies

by type (hip, vertebral, pelvis, distal radius, or other), and the number of osteoporosis medications prescribed by type. Aggregate data will be presented in a graphical format at the educational session [47]. Audit and feedback will focus solely on internal performance metrics within each LTC home to motivate the assessment of current practices and drive improvements in osteoporosis care. Confidential, individual performance audit reports will be provided to each prescriber.

7. Inter-professional education: An osteoporosis expert and an experienced long-term care physician will deliver an accredited, case-based Continuing Professional Development (CPD) module on the clinical application of the 2015 recommendations for fracture prevention in LTC. This CPD activity, delivered in a webinar facilitated by the Ontario College of Family Physicians, will be offered to all prescribing physicians within the intervention LTC homes. Local champions and other members of the leadership team will also be encouraged to attend this webinar.
8. Action planning for quality improvement: Designed around continuous quality improvement (CQI) techniques to help with organizational-level process change, a Plan-Do-Study-Act cycle [48–50] will be incorporated over a series of quarterly meetings in the year following the initial educational session. Action planning templates will be utilized to guide this process and assist teams with assigning roles and identifying barriers and facilitators to implementing the PREVENT intervention [51].
9. Resident care planning (ongoing): After developing the LTC home Action Plan from step 8, interdisciplinary teams will focus on creating and implementing personalized care plans for residents, guided by the Fracture Prevention in LTC Care Planning Flowchart

(see Additional file 3). All members of the interdisciplinary team will be involved in this (e.g., physicians, nursing/care staff, dietitian, and occupational/physical therapy). The study team will meet with the interdisciplinary leadership teams on a quarterly basis for progress updates and discussion.

Sustained knowledge use

To ensure sustained knowledge application after study completion, the local opinion leader(s) will be instructed to continue to promote best practices for fracture prevention using the online GerasPREP portal as a resource to support the implementation of the fracture prevention recommendations. All control homes will receive access to the portal upon study completion with the option to meet with the study team to review all resources to ensure adequate support of all participating LTC homes post-trial.

Criteria for discontinuing or modifying allocated interventions {11b}

For any participating LTC home, trial investigators will discontinue their involvement if the home wishes to withdraw from the study.

Strategies to improve adherence to interventions {11c}

Research personnel will meet on a quarterly basis with local opinion leader(s) of LTC homes to ensure adherence to study interventions/timelines and assist them to resolve challenges, or barriers, to study implementation. Choosing local opinion leaders as the co-champions and providing adequate training via the train-the-trainer model will support adherence to the planned intervention and sustainability both during and after the study [44, 47, 52]. The study investigators will also be available to the local opinion leader(s), physicians, and other members of the interdisciplinary leadership teams via email, telephone, or virtual meeting platform to discuss questions related to study implementation or fracture prevention recommendations.

Relevant concomitant care permitted or prohibited during the trial {11d}

N/a: LTC homes are permitted to maintain their existing care practices while implementing the fracture prevention guidelines to ensure the continuation of best practices for the home and residents.

Provisions for post-trial care {30}

This trial complies with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans definition of minimal risk, where participants can regard the probability and magnitude of possible harms to be no greater than those that would be encountered in their everyday life. Fracture prevention recommendations and educational materials are based on established guidelines that have been available since 2015 [12]. No provisions are available for ancillary or post-trial care. There will be no compensation to LTC homes or residents for any harm suffered, as the study intervention is deemed low risk.

Outcomes {12}

The primary outcome is the rate of incident hip fractures from baseline to 18 months. Secondary clinical outcomes

Table 1 Fracture prevention recommendations[a]

Intervention components[a]	Description and dose	ARM 1: Control	ARM 2: PREVENT Model
Usual care	Continue usual care practices	X	
Nutritional assessment[b]	• Dietary review and consider supplementation o Dietary Calcium: 1200 mg per day o Calcium supplementation: 500 mg per day (if dietary calcium levels are not met) o Vitamin D3: 800 to 2000 IU per day		X
Multifactorial fall and fracture prevention[b]	• Assess predisposing and precipitating factors, environmental hazards • Consider hip protectors • Prescribe exercise: Balance, strength and functional training • Review environmental hazards and assistive devices		X
Medication review[b]	• Perform a review of residents' osteoporosis and other medication prescriptions associated with falls and fractures • Consider osteoporosis therapies for residents at high fracture risk based on their Fracture Risk Scale score		X

[a] Strategies will be implemented on an individual resident basis as indicated/appropriate

[b] Evidence-based strategies recommended based on the recommendations for fracture prevention in LTC [12] are outlined as a part of the study intervention for the purposes of this trial but may be used in the usual care practices in LTC homes

include (1) one-year incidence of osteoporosis medication prescriptions, falls, non-hip fractures, time to hip fracture, hospitalization, and mortality; (2) LTC quality indicators, pain, mobility, and responsive behaviors (from MDS-RAI scales); and (3) Direct costs associated with healthcare resource utilization for each trial arm.

Participant timeline {13}

The timeline for LTC homes' participation in the study trial is outlined in Fig. 3.

Sample size {14}

Evidence suggests that pharmacologic medications reduce hip fractures in high-risk LTC residents by as much as 55% (varies depending on the type of medication) [12]. Hip fracture is the most common fracture type in LTC, accounting for 49% of all fractures [7]. A total of 5.2% of LTC residents experience a fracture each year, and annual hip fracture rates for high-risk individuals (FRS score of ≥ 4) range from 3.1% to 12.6% [54]. Fracture rates among individuals in LTC have been shown to be similar across Canada [55]. Based on these assumptions, we will need to recruit 122 homes (61 intervention and 61 control) to detect a 2% absolute difference in hip fracture rates between groups after 18 months (5% [56] and 3% [12] in control and intervention groups, respectively) with an intraclass correlation coefficient (ICC) of 0.017 [57], a 10% LTC home dropout rate [58], 80% power, and an alpha level of 0.05.

Recruitment {15}

Rolling recruitment of LTC homes will occur via several recruitment strategies including (1) contacting the home administrator, director of care, or medical director of eligible LTC homes and providing basic information on the trial (e.g., role of PREVENT opinion leader(s) and leadership team, treatment arms, and time commitment); (2) contacting the leadership of LTC organizations (e.g., chief medical officer, chief operating officer, vice president of LTC operations); (3) partnering with pharmacy providers who will assist our team with recruitment, particularly not-for-profit LTC homes; (4) study promotion through social media, professional conferences (e.g., Ontario Long-Term Care Clinicians annual conference), and LTC-related organizations (i.e., Ontario Long Term Care Association, Family Councils of Ontario); and (5) recruitment webinars about the trial targeting healthcare professionals and other staff working in LTC.

Assignment of interventions: allocation

Sequence generation {16a}

An independent statistician will prepare a computer-generated allocation sequence using PASS software. Stratified randomization will be used to randomly allocate eligible LTC homes to one of two treatment arms (control or intervention) in a 1:1 ratio. LTC homes will be stratified based on home size (< 100 vs ≥ 100 beds) and ownership (for-profit or not-for-profit). Stratification has been selected as it is anticipated that resources available within LTC homes to support the PREVENT implementation may vary by size and ownership type [59]. Additionally, quality of care and population characteristics may differ depending on home size, ownership, and province [60–62].

Concealment mechanism {16b}

Research staff directly involved in the study will not have access to the computer-generated allocation sequence. The allocation sequence will be uploaded to the Research Electronic Data Capture (REDCap) where the randomization module will then be used to randomize LTC homes. This module ensures concealed allocation and prevents selection bias.

Implementation {16c}

A LTC home's eligibility to participate in the trial will be assessed by the study research coordinator and assistant following an initial screening meeting. Once eligibility is confirmed, the research coordinator will use REDCap to randomize the home and notify them via email of their assigned treatment group for the duration of the trial. A letter of agreement, based on the assigned treatment group, will be attached. The LTC home will be officially enrolled in the trial once a fully executed agreement is in place, defined as having obtained signatures from all parties on the letter of agreement.

Assignment of interventions: blinding

Who will be blinded {17a}

Due to the nature of the intervention, the LTC home and participating healthcare professionals in each home will be unblinded to the treatment assignment. Although not formally blinded, the residents in each LTC home may not be directly aware of the treatment assignment. The research coordinator and assistant(s) will be unblinded to the treatment arms. The PI and the study statistician will be blinded.

Procedure for unblinding if needed {17b}

N/a: No procedures have been implemented for unblinding a LTC home during the trial, as the trial targets healthcare professionals and does not directly intervene with LTC residents.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Demographic and clinical study outcomes will be obtained through administrative data sources (e.g., RAI-MDS 2.0 within the Continuing Care Reporting System in Canada (CCRS) housed at the ICES Data Repository). Administrative datasets from ICES will be linked using encrypted patient-specific identifiers and analyzed using ICES health services records [63]. Baseline data will be collected using an 8-year retrospective lookback window (Fig. 3). For the analyses, we will evaluate the difference in hip fracture rates between treatment arms and assess secondary outcomes 1-year post-intervention (18 months).

Primary outcome

Clinical data from the RAI-MDS 2.0 will be linked to the Discharge Abstract Database (DAD) and the National Ambulatory Care Reporting System (NACRS) to capture incident hip fracture (i.e., new hip fracture occurring from baseline to study end) and determine the residents' FRS. Hip fractures will be captured based on the definition of the Public Health Agency of Canada (PHAC) in the Revised Framework for National Surveillance on Osteoporosis and Osteoporosis-Related Fractures and International Classification of Disease 9 or 10 codes (ICD-9, ICD-10) S72.0, S72.1, S72.2).

Secondary outcomes

Several databases will be utilized to capture secondary outcomes (Fig. 3). The Ontario Drug Benefit (ODB) database will be used to obtain data on prescription medication claims for LTC residents 65 years or older covered under the provincial drug program. Drug identification numbers (DINs) will be used to identify osteoporosis medications (i.e., bisphosphonates and denosumab licensed for use to treat osteoporosis in Canada) as outlined by the PHAC. Calcium and vitamin D supplementation will not be assessed as these data are not available in ICES administrative datasets. We will also examine mean pain, mobility, and responsive behavior scores from RAI-MDS 2.0 scales, located within the CCRS. In addition, LTC health quality indicators, non-hip fracture rates, falls, and pain will be obtained from the CCRS database. Hospitalizations and emergency department visits will be derived from DAD and NACRS, and mortality will be obtained from the Registered Persons Database (RPDB).

Costing analysis

Our study will compare healthcare costs between the intervention and control groups by capturing costs associated with various types of healthcare resource utilization captured in ICES databases, including hospitalizations (inpatient hospital stays and same-day surgeries), LTC, prescription drug benefit claims, and other healthcare services such as emergency department visits, hospital outpatient clinic visits, and physician billings. Healthcare utilization data will be sourced from administrative datasets held at ICES (see Additional file 4) and costed using the ICES GETCOST macro [64, 65]. Using a bottom-up (micro level) costing approach, this macro assigns unit costs to publicly funded healthcare services.

Plans to promote participant retention and complete follow-up {18b}

As a KT cluster RCT, our intervention is targeted at healthcare teams. To examine adherence with the PREVENT standardized curriculum, we will track the attendance of healthcare providers at the educational session. Audit and feedback report results will be developed by PCC to reduce the burden of data collection on healthcare professionals at the home's discretion. Resident-level data will be available via provincial-level administrative databases and should not have loss to follow-up.

Data management {19}

All demographic questionnaires will be de-identified using a participant identification code containing letters and numbers. Completed physical/paper data forms will be stored in locked filing cabinets in a secure location at the Juravinski Research Centre in St. Peter's Hospital, Hamilton Health Sciences. Adherence and demographic data of healthcare providers in the intervention homes will be entered by data entry personnel into REDCap. Online demographic questionnaires may be completed by the healthcare providers in intervention homes,

(See figure on next page.)

Fig. 3 Schedule of enrollment, interventions and assessments. RAI-MDS 2.0 = Resident Assessment Instrument – Minimum Data Set 2.0; REB = research ethics board; ADL = activities of daily living; CIHI = Canadian Institute for Health Information; DIN = drug identification number. t_0 = Initiation of training of local opinion leader(s), t_1 = Baseline (enrollment date in control group, completion of the educational session in intervention group), t_2 = initial implementation of current residents completed (sensitivity analysis (6 to 18 months)), t_3 = initial implementation of newly admitted and change in status completed; at the 18-month timepoint, data pulls of baseline, 3-month, 6-month, and 18-month timepoints completed. *Based on the Revised Framework for National Surveillance on Osteoporosis and Osteoporosis-Related Fractures of the Public Health Agency of Canada [53]

	STUDY PERIOD				
	Enrolment	**Allocation**	**Post-allocation**		
TIMEPOINT	$-t_1$	t_0	t_1	t_2	t_3
			Baseline	**6-months**	**18-months**
ENROLMENT:					
Eligibility screen	X				
Confirmation of site-specific REB requirement	X				
Confirmation of site-specific participation	X				
Allocation		X			
INTERVENTIONS:					
Usual care			◆—	—	—◆
PREVENT model			◆—	—	—◆
ASSESSMENTS:					
Baseline Variables					
Demographics			X		
Prior major osteoporotic fracture(s)			X		
Prior fall(s) in the last year			X		
Dementia diagnosis			X		
Comorbidities			X		
Current osteoporosis or other medication prescription(s)			X		
Primary Outcome					
Hip fracture incidence (baseline to 1.5 years) *ICD-10 Codes: hip (S72.0, S72.1, S72.2)**			X	X	X
Secondary Outcomes					
LTC health quality indicators *CIHI indicators on LTC: falls in last 30 days, stage 2-4 pressure ulcers, worsened physical function, worsened symptoms of depression, pain)* (29)			X	X	X

Fig. 3 (See legend on previous page.)

Osteoporosis medication prescriptions *DIN Codes: osteoporosis medications [i.e., bisphosphonates (i.e., risedronate, alendronate, zoledronic acid)], denosumab romosozumab and teriparatide*			X	X	X
Non-hip fracture rates *ICD-10 Codes: spine (S22.0, S22.1, S32.0, S32.7, S32.8), humerus (S42.2), forearm (S52.x, S62.x) and pelvis (S32.1, S32.3, S32.4, S32.5, S32.7, S32.8)**			X	X	X
Time to hip fracture				X	X
Death			X	X	X
Hospitalizations			X	X	X
Incident falls *RAI-MDS 2.0 codes: number of falls in last 30 days (J4A) and number of falls in last 31-180 days (J4B)*			X	X	X
Pain Scale *RAI-MDS 2.0*			X	X	X
Mobility *RAI-MDS 2.0 ADL Hierarchy Scale and Locomotion off unit (G1f)*			X	X	X
Responsive behaviours *RAI-MDS 2.0* *Aggressive Behaviour Scale*			X	X	X
Uptake of PREVENT strategies in intervention homes (Completion of the Strategy)				X	X
Healthcare resource utilization costs			X	X	X

Fig. 3 (continued)

automatically entering data into the REDCap database upon completion of the questionnaire. The REDCap database will be password protected and kept on a secure network system. All data entered in REDCap will be audited by a research coordinator or assistant to assess accuracy and missing data. Only the research team and biostatistician will have access to the final trial database.

De-identified audit and feedback reports (part of the PREVENT model for intervention homes) completed either by the LTC home directly or via PCC will be transferred through a secure file transfer protocol system to the study team (and back to the LTC homes if PCC completed the reports). The study team will send data for the 122 recruited LTC homes including the name and address of the LTC home, institution number, and the trial enrollment and completion date, through a secure drive to ICES. All electronic data files will be password protected.

Confidentiality {27}

Physical de-identified demographic questionnaires will be stored in locked filing cabinets in a secure location at St. Peter's Hospital, Juravinski Research Centre, Hamilton Health Sciences. Electronic de-identified demographic questionnaires will be stored on McMaster's REDCap. Following completion of the trial, these files will be stored on a secure network at Hamilton Health Sciences accessible only with a password and encryption software.

Audit and feedback data collected by PCC will be sent through a secure file transfer protocol to the study team at the Geras Centre for Aging Research and will be de-identified using unique residents' identification numbers. Audit and feedback data collected by the LTC home will be sent through a secure SharePoint to the study team. These files will be stored on a secure network at St. Peter's Hospital, Hamilton Health Sciences, accessible only with a password and encryption software. Final audit and feedback reports including de-identified aggregate-level LTC home-level data and individualized physician-level data will be transferred to the LTC home through a secure electronic portal.

A waiver of consent to perform the data collection and analysis from the ICES Data Repository has been provided by the Hamilton Integrated Research Ethics Board (#13622). ICES is authorized to collect and use health care data, without consent, as a prescribed entity under Ontario's privacy legislation. The use of the data in this project is authorized under Section 45 of Ontario's Personal Health Information Protection Act. Secure access to these data is governed by policies and procedures that are approved by the Information and Privacy Commissioner of Ontario.

Data collected from the ICES Data Repository will be de-identified, and the research team will not be able to re-identify residents living in LTC homes. As the research team is a separate entity from the ICES analyst, the strict policies of ICES mean that the study team cannot produce analytic outputs with cell sizes fewer than six or that could foreseeably be used to re-identify an individual. The research team will only share the LTC home information that is known in the ICES environment. All information is shared securely on ICES servers, which are reviewed by the Privacy Commissioner of Ontario. All other forms of data (i.e., demographics, adherence, audit and feedback) collected, shared, and maintained will be de-identified to protect confidentiality before, during, and after the trial.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

N/a: This study does not include the collection, laboratory evaluation, or storage of biological specimens for genetic or molecular analysis, either for the current trial or for future use in ancillary studies.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

Baseline characteristics will be reported as mean (standard deviation) or median (inter-quartile range) values for continuous variables and as counts (percent) for categorical variables. Data will be summarized in tabular or graphical form. The primary outcome is hip fracture incidence from baseline to 18-months (total duration of the PREVENT intervention). Differences between control and intervention arms for the primary and secondary outcomes will be assessed with the GEE technique, assuming an exchangeable correlation structure. For the model, the unit of analysis will be the resident, and the unit of inference will be the LTC home. Unadjusted and adjusted odds ratios and corresponding 95% confidence interval will be reported. These analyses will be adjusted for the stratified variables (home size, profit status) and baseline resident characteristics associated with fracture. All p-values will be reported to three decimal places with those less than 0.001 reported as $p < 0.001$. The criterion for statistical significance will be set a priori at alpha = 0.05. Analyses will be performed using SAS.

To evaluate the secondary outcome of time to hip fracture, we will use a Cox proportional hazards model to examine the effect of the PREVENT intervention vs usual care on time to hip fracture, while adjusting for important resident and LTC home characteristics.

Unadjusted and adjusted hazards models will be expressed as hazard ratios (HRs) and their 95% confidence intervals (CIs). We will use the Kaplan–Meier method to estimate and visualize the cumulative fracture incidence over time.

For the costing analysis, we will compare the costs incurred from baseline to 18-months between the control (cost associated with healthcare resource use only) and the intervention (cost associated with healthcare resource use, cost of implementing the intervention) arms. The cost of implementing the intervention will be derived from the trial (e.g., cost associated with training the LTC home or developing the educational material). To deal with the clustered nature of the data and the skewness of the cost data, a GEE model using a logarithm link function, a Gamma distribution, and an unstructured correction matrix will be used to compare the costs between the arms. In addition to unadjusted analyses, the model will adjust for stratification factors and baseline resident characteristics associated with costs (e.g., age, sex, comorbidities, prior fracture). The analyses will be conducted from a healthcare payer perspective. Subgroup analyses will be performed as per the clinical analyses (see next section).

All analyses will be performed by ICES Data and Analytic Services and results will be provided at the aggregate level.

Interim analyses {21b}

No interim analysis is planned given the short duration and nature of our intervention (i.e., an adjunct to usual care).

Methods for additional analyses (e.g., subgroup analyses) {20b}

We will perform sensitivity analyses to examine the results between imputation and complete case analyses. We will also perform a sensitivity analysis from 6 months to 18 months. Exploratory subgroup analyses will be conducted for home size, rurality (i.e., urban, rural), ownership (i.e., for profit, not for profit). Sex differences will also be explored given that the prevalence of osteoporosis and fractures are higher in females as compared with males [6]. Further, females represent a higher proportion of the LTC population: approximately 60% of the population are female [66]. Therefore, the burden of fractures and the effect of the intervention may vary by sex. All secondary outcomes and sensitivity analyses will be considered exploratory rather than confirmatory. We will not be able to ascertain gender as a social construct from the electronically mandated, routinely collected LTC data for our outcomes. This is a limitation of our study and will be addressed in the publication of trial findings.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

To handle missing data from the intention-to-treat perspective, we will conduct multiple imputation of missing values to minimize bias and maintain the balance between groups achieved through randomization.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

The corresponding author can be contacted for reasonable access to the full protocol and statistical code. There are no plans to share datasets given that trial data will be under the governance of the ICES Data Repository.

Oversight and monitoring

Composition of the coordinating center and trial steering committee {5d}

The study coordinating centre is at the Geras Centre for Aging Research at Hamilton Health Sciences. The study research coordinator and assistants will be responsible for recruitment, enrolling LTC homes, receiving and storing study agreements, and day-to-day trial management including implementation logistics, monitoring adherence, adverse events, and overseeing data collection. The study steering committee will be comprised of all study co-investigators, chaired by the trial PI, and will meet approximately every 3 months or more frequently, as needed. The steering committee will provide oversight and guidance to ensure that the study is in line with the protocol and ethical standards, while also ensuring adherence to timelines and addressing any challenges that arise during the study.

Composition of the data monitoring committee, its role and reporting structure {21a}

A Data Safety and Monitoring Board has not been created as a part of this trial as the possible harms to study participants are found to be no greater than those that would be encountered in everyday life.

Adverse event reporting and harms {22}

Adverse events or harm at the healthcare provider level from any source will be reported to the research team and reported in a structured form. Adverse events or harm are not collected at the resident level. Direct risks to the residents are minimal as none of the multifaceted fracture prevention recommendations being implemented are novel. Each element has been shown to be safe individually, and the various interventions in the model are already available to LTC residents but often not targeted to high-risk residents (the group who can benefit the most). This trial does not affect LTC residents' rights or

welfare and does not involve the use of new therapeutic interventions.

Frequency and plans for auditing trial conduct {23}

In addition to the Steering Committee, an External Scientific Advisory Committee will be put in place to guide and maintain the scientific integrity of the trial. This committee will be chaired by the PI and will meet twice annually but may meet on a more frequent basis at the joint request of majority members or as deemed necessary by the PI. Meeting agendas shall be circulated in advance of meetings and accompanied by minutes sent after a meeting taken by the research coordinator or assistant.

Plans for communicating important protocol amendments to relevant parties (e.g., trial participants, ethical committees) {25}

All modifications to the study protocol (i.e., changes to eligibility criteria, outcomes, and analyses) will be communicated to relevant parties (i.e., investigators, research teams, LTC homes, and trial registries) and submitted to the applicable research ethics board for review and approval.

Dissemination plans {31a}

Trial results will be disseminated in publications and presentations at international conferences (e.g., International Osteoporosis Foundation, American Medical Director's Association (Post-Acute and Long-Term Care Medical Association or PALTmed), Canadian Geriatrics Society, American Geriatrics Society). In addition, study collaborators—including Osteoporosis Canada, Ontario LTC Associations, the RAI-MDS network, LTC residents and family councils—will disseminate results through webinars, social media, and traditional media releases. The investigator team is also active in fracture-prevention policy and strategy work at provincial, national, and international levels. Trial resources created to facilitate implementation of fracture prevention recommendations in LTC will be available on the Osteoporosis Canada and Geras websites.

Discussion

The PREVENT trial is the first adequately powered trial to evaluate the effectiveness of a multifaceted, interdisciplinary KT intervention aimed at preventing fractures in LTC homes. A literature search in MEDLINE and EMBASE databases using the search terms *fracture*, *LTC/nursing home*, and *RCT* did not yield any similar trials. If successful, the PREVENT trial will offer a standardized model of care that can be adopted in LTC homes across Canada and internationally. As PREVENT is an organizational-level intervention, the findings may inform future studies examining the uptake of evidence-based practices for other clinical complications in LTC homes such as pain, falls, wounds, and behavioral and psychological symptoms of dementia. This trial may also serve as a foundation for advancing clinical trial research in LTC settings by providing insight on existing barriers and strategies for overcoming barriers in LTC.

The PREVENT intervention is designed to address modifiable barriers that limit the translation of evidence-based recommendations into practice in LTC settings [16, 17]. In designing this trial, we considered organizational contextual factors—including leadership, culture, available resources, and staff capacity—that can influence the effective implementation of innovative models of care in LTC homes [18]. Drawing on insights from our successful pilot trial [21, 22] and factors that can enhance guideline uptake [16, 17], the intervention incorporates several key strategies: stakeholder engagement, co-design and co-delivery of the intervention with local champions, capacity development with educational sessions, and integration of study-related activities into usual care practices. These components are intended to improve LTC context readiness, implementation success, and sustainability of behavior. Further refinement of the intervention was informed by our longitudinal study [25], which led to the inclusion of co-champions, automated audit and feedback reports, and practical tools to facilitate conversations around prescribing fracture prevention medications.

The PREVENT intervention addresses the complexity of decision-making regarding the use of best practice evidence-based fracture prevention recommendations that healthcare professionals navigate in delivering care in LTC [17]. Our intervention takes a collaborative multidisciplinary approach as opposed to focusing on individual healthcare professionals. The intervention is tailored to be incorporated into real-world LTC settings given the pragmatic nature of the trial. To monitor knowledge use throughout the trial, we will assess the results of the audit and feedback report, completed action plans will be reviewed, and outcomes will be evaluated using administrative datasets. Post-study sustainability mechanisms have been put in place through ongoing access to educational resources and materials via GerasPREP and continued support for fracture management by the local champions. The mechanisms and opportunities for interdisciplinary information exchange, group learning, and problem solving embedded in the intervention are targeted at fostering a supportive and connected learning and mentoring environment, which can increase the likelihood of care teams utilizing appropriate fracture

prevention strategies. Additionally, the development of automated audit and feedback at the home level supports post-study sustainability.

Guided by the well-known behavior change wheel framework [37, 38], we designed the intervention around three functions—education, training, and modeling—to address this challenge and facilitate behavior change. Overall, the process of developing and tailoring the PREVENT intervention to the context of LTC followed the established Knowledge-to-Action cycle [15] as described in our previous work [19]. If the expected changes in practice are achieved, the success of this intervention could lead to a reduction in fracture rates in the intervention LTC homes.

Trial status

This article outlines the protocol (V6 – February 12, 2025). The first LTC home was enrolled in June 2024, and LTC homes are currently being recruited. Recruitment will be completed by end of 2026.

Abbreviations

LTC	Long-term care
KT	Knowledge translation
PREVENT	Person-centered Routine Fracture PreEVENTion
RCT	Randomized controlled trial
PCC	PointClickCare
EMR	Electronic medical records
FRS	Fracture Risk Scale
RAI-MDS	Resident Assessment Instrument Minimum Data Set
ICES	ICES Data Repository
CME	Continuing medical education
GerasPREP	Geras PREVENT Research Education Portal
REDCap	Research Electronic Data Capture
PI	Principal Investigator
CCRS	Continuing Care Reporting System in Canada
MOHLTC	Ministry of Health and Long-Term Care
GEE	Generalized estimating equation
ICC	Intraclass correlation coefficient

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-025-09398-1.

Additional file 1. PRECIS-2 Score for PREVENT Trial.

Additional file 2. Brief clinical reference guide: interRAI Fracture Risk Scale.

Additional file 3. Care planning flowchart for fracture prevention for long-term care residents.

Additional file 4. Administrative Databases.

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Authors' contributions {31b}
AP is the PI and grant holder; she contributed to study conceptualization, funding acquisition, study methodology, project administration, study resources, overall study supervision, investigation, visualization, original draft, review and editing. SF contributed to study conceptualization, funding acquisition, study methodology, study resources, review and editing. PK contributed to review and editing. APC contributed to study conceptualization, funding acquisition, study methodology, review and editing. CK contributed to study conceptualization, funding acquisition, study methodology, original draft, review and editing. JDA contributed to funding acquisition, review and editing. HB contributed to review and editing. LG contributed to funding acquisition, review and editing. GH contributed to funding acquisition, review and editing. PH contributed to funding acquisition, study methodology, study resources, original draft, review and editing. JH contributed to funding acquisition, review and editing. JHL contributed to funding acquisition, review and editing. MH contributed to review and editing. JHo contributed to review and editing. SJ contributed to funding acquisition, review and editing. SK contributed to funding acquisition, review and editing. LK contributed to review and editing. AL contributed to review and editing. JL contributed to review and editing. CM contributed to study conceptualization, funding acquisition, study methodology, study resources, review and editing. SM contributed to funding acquisition, review and editing. DO contributed to review and editing. IBR contributed to study resources, review and editing. KS contributed to review and editing. HS contributed to review and editing. SS contributed to funding acquisition, review and editing. ST contributed to review and editing. JET contributed to funding acquisition, review and editing. LT contributed to study conceptualization, funding acquisition, study methodology, review and editing. SH contributed to review and editing. JT contributed to review and editing. LMH contributed to funding acquisition, study methodology, review and editing. LLK contributed to investigation, project administration, study resources, visualization, original draft, review and editing. AMA contributed to original draft, review and editing. TDD contributed to project administration, review and editing. GI contributed to study conceptualization, funding acquisition, study methodology, project administration, study resources, overall study supervision, investigation, visualization, original draft, review and editing.

Funding {4}
This trial has been funded by the Canadian Institutes of Health Research (CIHR) Project Grant. The funder had no direct role in the study design or execution of the trial.

Data availability {29}
The Geras Centre for Aging Research will be the data custodian for this trial. Access to the final trial dataset will be considered upon request to the corresponding author.

Declarations

Ethics approval and consent to participate {24}
This study was approved by the Hamilton Integrated Research Ethics Board (#13622). Implied consent will be obtained from all participants within a LTC home, and a fully executed letter of agreement will be put in place to enroll all participating homes. LTC homes are responsible for obtaining their own site-specific REB review, if applicable, as REB approval can only extend to the overall approval of the research activity.

Consent for publication {32}
Not applicable.

Competing interests {28}
The authors report no conflicts of interest related to this trial.

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References

1. Crilly RG, Tanner DA, Kloseck M, Chesworth BM. Hip fractures in long-term care: is the excess explained by the age and gender distribution of the residents? J Aging Res. 2010. https://doi.org/10.4061/2010/291258.
2. Norris M, Walton R, Patterson C et al. Prevention of falls in long-term care facilities. London, Ontario: Canadian Task Force on Preventive Health Care; 2003:55.
3. Berry SD, Kiel DP. Falls as risk factors for fracture. In: Marcus Feldman's Osteoporos. 2013. p. 633–46.
4. McArthur C, Gonzalez DA, Roy E, Giangregorio L. What are the circumstances of falls and fractures in long-term care? Can J Aging. 2016. https://doi.org/10.1017/S0714980816000556.
5. Chandler JM, Zimmerman SI, Girman CJ, Martin AR, Hawkes W, Hebel JR, et al. Low bone mineral density and risk of fracture in white female nursing home residents. JAMA. 2000;284(8):972–7.
6. Osteoporosis P, Findings KEY. 2022 Osteoporosis Canada Facts and Stats. Osteoporos Canada. 2022;2021–3. Available from: https://osteoporosis.ca/facts-and-stats/.
7. Papaioannou A, Kennedy CC, Ioannidis G, Cameron C, Croxford R, Adachi JD, et al. Comparative trends in incident fracture rates for all long-term care and community-dwelling seniors in Ontario, Canada, 2002-2012. Osteoporos Int. 2016;27(3):887–97.
8. Tarride J-E, Burke N, Leslie WD, Morin SN, Adachi JD, Papaioannou A, et al. Loss of health related quality of life following low-trauma fractures in the elderly. BMC Geriatr. 2016;16(1):84.
9. Dyer SM, Crotty M, Fairhall N, Magaziner J, Beaupre LA, Cameron ID, et al. A critical review of the long-term disability outcomes following hip fracture. BMC Geriatr. 2016;16(1):158.
10. Papaioannou A, Wiktorowicz M, Adachi JD, et al. Mortality, independence in living, and re-fracture, one year following hip fracture in Canadians. J SOGC. 2000. https://doi.org/10.1016/S0849-5831(16)31115-6.
11. Milligan KS, Schirle T. The Economics of Long-Term Care in Canada. SSRN Electron J. 2023. https://doi.org/10.3386/w31875.
12. Papaioannou A, Santesso N, Morin SN, Feldman S, Adachi JD, Crilly R, et al. Recommendations for preventing fracture in long-term care. CMAJ. 2015;187(15):1135–44.
13. Duque G, Iuliano S, Close JCT, Fatima M, Ganda K, Bird S, et al. Prevention of osteoporotic fractures in residential aged care: updated consensus recommendations. J Am Med Dir Assoc. 2022. https://doi.org/10.1016/j.jamda.2021.12.041.
14. Grimshaw JM, Eccles MP, Lavis JN, Hill SJ, Squires JE. Knowledge translation of research findings. Implement Sci. 2012. https://doi.org/10.1186/1748-5908-7-50.
15. Graham ID, Logan J, Harrison MB, Straus SE, Tetroe J, Caswell W, et al. Lost in knowledge translation: time for a map? J Contin Educ Health Prof. 2006. https://doi.org/10.1002/chp.47.
16. McArthur C, Bai Y, Hewston P, Giangregorio L, Straus S, Papaioannou A. Barriers and facilitators to implementing evidence-based guidelines in long-term care: a qualitative evidence synthesis. Implement Sci. 2021. https://doi.org/10.1186/s13012-021-01140-0.
17. Cammer A, Morgan D, Stewart N, McGilton K, Rycroft-Malone J, Dopson S, et al. The hidden complexity of long-term care: how context mediates knowledge translation and use of best practices. Gerontologist. 2014. https://doi.org/10.1093/geront/gnt068.
18. Bunn F, Goodman C, Corazzini K, Sharpe R, Handley M, Lynch J, et al. Setting priorities to inform assessment of care homes' readiness to participate in healthcare innovation: a systematic mapping review and consensus process. Int J Environ Res Public Health. 2020. https://doi.org/10.3390/ijerph17030987.
19. Papaioannou A, Ioannidis G, McArthur C, Hillier LM, Feldman S, Giangregorio L, et al. Preventing fractures in long-term care: translating recommendations to clinical practice. J Am Med Dir Assoc. 2021. https://doi.org/10.1016/j.jamda.2020.07.003.
20. Wensing M, Bosch M, Grol R. Developing and selecting interventions for translating knowledge to action. Can Med Assoc J. 2010. https://doi.org/10.1503/cmaj.081233.
21. Kennedy CC, Ioannidis G, Giangregorio LM, Adachi JD, Thabane L, Morin SN, et al. An interdisciplinary knowledge translation intervention in long-term care: study protocol for the vitamin D and osteoporosis study (ViDOS) pilot cluster randomized controlled trial. Implement Sci. 2012;7(1):48.
22. Kennedy C, Ioannidis G, Thabane L, Adachi JD, Marr S, Giangregorio LM, et al. Successful knowledge translation intervention in long-term care: final results from the vitamin D and osteoporosis study (ViDOS) pilot cluster randomized controlled trial. Trials. 2015. https://doi.org/10.1186/s13063-015-0720-3.
23. Ioannidis G, O'Donnell D, Navare H, Kennedy C, Giangregorio LM, Cheung A, et al. A Randomized Multifaceted Intervention in Long Term Care (LTC) Increased the Use of Osteoporosis Medications in Residents at High Risk for Fracture: Gaining Optimal Osteoporosis Assessments in LTC (GOAL) Study. Annual Scientific Meeting of the American Geriatrics Society; Long Beach, CA. J Am Geriatr Soc. 2016;64(Suppl 1):S95.
24. Kennedy CC, Thabane L, Ioannidis G, Adachi JD, Papaioannou A. Implementing a knowledge translation intervention in long-term care: feasibility results from the vitamin D and osteoporosis study (ViDOS). J Am Med Dir Assoc. 2014;15(12):943–5.
25. Rodrigues IB, Ioannidis G, Kane LL, Hillier LM, Adachi J, Heckman G, et al. Assessing the feasibility of an integrated collection of education modules for fall and fracture prevention (iCARE) for healthcare providers in long term care: a longitudinal study. PLOS Glob Public Health. 2024. https://doi.org/10.1371/journal.pgph.0003096.
26. Becker C, Cameron ID, Klenk J, Lindemann U, Heinrich S, König HH, et al. Reduction of femoral fractures in long-term care facilities: the Bavarian fracture prevention study. PLoS One. 2011;6(8):e24311.
27. Schulz C, Lindlbauer I, Rapp K, Becker C, König H-H. Long-term effectiveness of a multifactorial fall and fracture prevention program in Bavarian nursing homes: an analysis based on health insurance claims data. J Am Med Dir Assoc. 2017;18(6):552.e7-552.e17.
28. Roigk P, Becker C, Schulz C, König HH, Rapp K. Long-term evaluation of the implementation of a large fall and fracture prevention program in long-term care facilities. BMC Geriatr. 2018;18(1):233.
29. Canadian Institute for Health Information. Long-term care: Indicators. [cited 2025 Sep 2]. Available from: https://www.cihi.ca/en/topics/long-term-care/indicators.
30. Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe K, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. BMJ. 2015;350:h2147.
31. What is long-term facilities-based care? [Internet]. Available from: https://www.canada.ca/en/health-canada/services/home-continuing-care/long-term-facilities-based-care.html.
32. Electronic Medication Administration Record (eMAR) from PointClickCare. [cited 2025 Jul 30]. Available from: https://pointclickcare.com/products/emar/?abherocampaign=emar-ab-testing-april-2025-a.
33. Alamri SH, Kennedy CC, Marr S, Lohfeld L, Skidmore CJ, Papaioannou A. Strategies to overcome barriers to implementing osteoporosis and fracture prevention guidelines in long-term care: a qualitative analysis of action plans suggested by front line staff in Ontario, Canada. BMC Geriatr. 2015;15:94.
34. Fixing Long-Term Care Act, 2021. [cited 2025 Sep 2]. Available from: https://www.ontario.ca/laws/statute/21f39.
35. Fracture Prevention Toolkit. [cited 2025 May 5]. Available from: https://www.gerascentre.ca/fracture-prevention-toolkit/.

36. Straus SE, Leung E. Section 3.1: The Action Cycle. [cited 2025 Jul 30]. Available from: https://cihr-irsc.gc.ca/e/41929.html.
37. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci. 2011. https://doi.org/10.1186/1748-5908-6-42.
38. Michie S, Atkins L, West R. The Behaviour Change Wheel: A Guide to Designing Interventions. Silverback. 2014.
39. EPOC T. Effective Practice and Organisation of Care (EPOC). EpocCochrane-Org/Epoc-Taxonomy. 2015;1–12. Available from: https://epoc.cochrane.org/epoc-taxonomy.
40. Flodgren G, O'Brien MA, Parmelli E, Grimshaw JM. Local opinion leaders: Effects on professional practice and healthcare outcomes. Cochrane Database Syst Rev. 2019;(6):CD000125. https://doi.org/10.1002/14651858.CD000125.pub5.
41. Morris JN, Nonemaker S, Murphy K, Hawes C, Fries BE, Mor V, et al. A commitment to change: revision of HCFA's RAI. J Am Geriatr Soc. 1997. https://doi.org/10.1111/j.1532-5415.1997.tb02974.x.
42. Hawes C, Morris JN, Phillips CD, Fries BE, Murphy K, Mor V. Development of the nursing home resident assessment instrument in the USA. Age Ageing. 1997. https://doi.org/10.1093/ageing/26.suppl_2.19.
43. Hirdes JP, Ljunggren G, Morris JN, Frijters DH, Finne Soveri H, Gray L, et al. Reliability of the interRAI suite of assessment instruments: a 12-country study of an integrated health information system. BMC Health Serv Res. 2008. https://doi.org/10.1186/1472-6963-8-277.
44. Hall AM, Flodgren GM, Richmond HL, Welsh S, Thompson JY, Furlong BM, et al. Champions for improved adherence to guidelines in long-term care homes: a systematic review. Implement Sci Commun. 2021. https://doi.org/10.1186/s43058-021-00185-y.
45. GeriMedRisk. Geriatric Drug Information for Healthcare Professionals. [cited 2025 Aug 8]. Available from: https://www.gerimedrisk.com/consult/summaries/.
46. Tung J, Bodkin RJ, Laughton T, Neat C, Benjamin S, An H, et al. Efficiency and effectiveness of geriatric drug infographics: a randomized, controlled trial. J Am Geriatr Soc. 2021. https://doi.org/10.1111/jgs.17193.
47. Ivers N, Jamtvedt G, Flottorp S, Young JM, Odgaard-Jensen J, French SD, et al. Audit and feedback: Effects on professional practice and healthcare outcomes. Cochrane Database Syst Rev. 2012;(6):CD000259.
48. Grol R, Baker R, Moss F. Quality improvement research: Understanding the science of change in health care. Qual Saf Health Care. 2002;11(2):110–1.
49. Langley GL, Moen R, Nolan KM, Nolan TW, Norman CL, Provost LP. The Improvement Guide: A Practical Approach to Enhancing Organizational Performance (2nd Edition) | IHI - Institute for Healthcare Improvement. San Francisco, California, USA: Jossey-Bass Publishers; 2009.
50. Jain M. Plan-do-study-act cycle rejuvenates a marriage. Ann Intern Med. 2008. https://doi.org/10.7326/0003-4819-149-3-200808050-00013.
51. Facility Action Plan Template. Available from: https://www.ahrq.gov/hai/quality/tools/cauti-ltc/modules/resources/tools/implement/action-plan.html.
52. O'Brien MA, Rogers S, Jamtvedt G, Oxman AD, Odgaard-Jensen J, Kristoffersen DT, et al. Educational outreach visits: Effects on professional practice and health care outcomes. Cochrane Database Syst Rev. 2007;(2):CD000409.
53. O'Donnell S, Canadian Chronic Disease Surveillance System (CCDSS) Osteoporosis Working Group. Use of administrative data for national surveillance of osteoporosis and related fractures in Canada: results from a feasibility study. Arch Osteoporos. 2013;8(1–2):143.
54. Ioannidis G, Jantzi M, Bucek J, Adachi JD, Giangregorio L, Hirdes J, et al. Development and validation of the fracture risk scale (FRS) that predicts fracture over a 1-year time period in institutionalised frail older people living in Canada: an electronic record-linked longitudinal cohort study. BMJ Open. 2017;7(9):e016477.
55. Negm AM, Ioannidis G, Jantzi M, Bucek J, Giangregorio L, Pickard L, et al. Validation of a one year fracture prediction tool for absolute hip fracture risk in long term care residents. BMC Geriatr. 2018;18(1):320.
56. Perlman CM, Hirdes JP. The aggressive behavior scale: a new scale to measure aggression based on the minimum data set. J Am Geriatr Soc. 2008;56(12):2298–303.
57. Elley CR, Kerse N, Chondros P, Robinson E. Intraclass correlation coefficients from three cluster randomised controlled trials in primary and residential health care. Aust N Z J Public Health. 2005;29(5):461–7.
58. Kennedy C, Ioannidis G, Thabane L, Adachi JD, Marr S, Giangregorio LM, et al. Successful knowledge translation intervention in long-term care: final results from the vitamin D and osteoporosis study (ViDOS) pilot cluster randomized controlled trial. Trials. 2015. https://doi.org/10.1186/s13063-015-0720-3.
59. McGregor MJ, Cohen M, McGrail K, Broemeling AM, Adler RN, Schulzer M, et al. Staffing levels in not-for-profit and for-profit long-term care facilities: Does type of ownership matter? CMAJ. 2005;172(5):645–9.
60. McGregor MJ, Tate RB, McGrail KM, Ronald LA, Broemeling AM, Cohen M. Care outcomes in long-term care facilities in British Columbia, Canada: does ownership matter? Med Care. 2006;44(10):929–35.
61. You K, Li Y, Intrator O, Stevenson D, Hirth R, Grabowski D, et al. Do nursing home chain size and proprietary status affect experiences with care? Med Care. 2016;54(3):229–34.
62. Hirdes JP, Mitchell L, Maxwell CJ, White N. Beyond the "iron lungs of gerontology": using evidence to shape the future of nursing homes in Canada. Can J Aging. 2011;30(3):371–90.
63. ICES. Working with ICES data 2020. [cited 2025 Aug 7]. Available from: www.ices.on.ca/Data-and-Privacy/ICES-data/Workingwith-%0AICES-Data.
64. Wodchis WP, Bushmeneva K, Nikitovic M, McKillop I. Guidelines on person level cost using administrative databases in Ontario. Health System Performance Research Network Working Paper Series. 2013;1.
65. Kuwornu P, Wodchis W, Calzavara A. A Methodological Guide on Using the GETCOST Macro for Costing Studies. ICES Central. 2017.
66. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDier) checklist and guide. BMJ. 2014. https://doi.org/10.1136/bmj.g1687.

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