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Evaluation of the Strengthening a Palliative Approach in Long Term Care (SPA-LTC) programme: a protocol of a cluster randomised control trial

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ABSTRACT

Introduction Despite the high mortality rates in long-term care (LTC) homes, most do not have a formalised palliative programme. Hence, our research team has developed the Strengthening a Palliative Approach in Long Term Care (SPA-LTC) programme. The goal of the proposed study is to examine the implementation and effectiveness of the SPA-LTC programme.

Methods and analysis A cross-jurisdictional, effectiveness-implementation type II hybrid cluster randomised control trial design will be used to assess the SPA-LTC programme for 18 LTC homes (six homes within each of three provinces). Randomisation will occur at the level of the LTC home within each province, using a 1:1 ratio (three homes in the intervention and control groups). Baseline staff surveys will take place over a 3-month period at the beginning for both the intervention and control groups. The intervention group will then receive facilitated training and education for staff, and residents and their family members will participate in the SPA-LTC programme. Postintervention data collection will be conducted in a similar manner as in the baseline period for both groups. The overall target sample size will be 594 (297 per arm, 33 resident/family member participants per home, 18 homes). Data collection and analysis will involve organisational, staff, resident and family measures. The primary outcome will be a binary measure capturing any emergency department use in the last 6 months of life (resident); with secondary outcomes including location of death (resident), satisfaction and decisional conflict (family), knowledge and confidence implementing a palliative approach (staff), along with implementation outcomes (ie, feasibility, reach, fidelity and perceived sustainability of the SPA-LTC programme). The primary outcome will be analysed via multivariable logistic regression using generalised estimating equations. Intention-to-treat principles will be used in the analysis.

Ethics and dissemination The study has received ethical approval. Results will be disseminated at various presentations and feedback sessions; at provincial, national and international conferences, and in a series of manuscripts that will be submitted to peer-reviewed, open access journals.

Trial registration number NCT039359.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ There have been no previous trials conducted in Canada to evaluate a programme, such as Strengthening a Palliative Approach in Long Term Care, in long-term care homes.
⇒ The focus on both the implementation and effectiveness of the programme using a cross-jurisdictional, effectiveness-implementation type II hybrid design is innovative.
⇒ The palliative programme is based on global best practices, but Canada's relatively lower staffing level and the impact of the COVID-19 disease may limit fidelity.

INTRODUCTION

As the population ages, more people are likely to die in long-term care (LTC) homes. In Canada, annual mortality rates of residents in LTC range from 27% to 52.3%.[1] Research has shown that care for the dying is suboptimal in LTC with the lack of attention given to advance care planning (ACP) and issues of loss, grief and bereavement, and unnecessary emergency department (ED) use.[2–5] Many challenges to caring for dying residents and their families have been identified; including staff discomfort and uncertainty about how and when to initiate early discussions about goals of care; lack of training and capacity building for staff, particularly unregulated staff (who provide the majority of bedside care); high rates of cognitive impairment among residents; and a failure to identify

impending death.[6 7] As a result, clinical decision-making becomes challenging for LTC residents who often have multiple comorbidities, and where prognostication is challenging.[8] Unfortunately, failure to proactively and pre-emptively discuss and identify end-of-life (EOL) issues in LTC creates added stress and burden for family and staff.[2 9]

A palliative approach promotes a seamless transition from admission to LTC to EOL, beginning with ACP to activate critical communication early with residents and families so that decisions regarding EOL care can be made.[10] To implement a palliative approach, developing opportunities for education and improving staff's capacity to communicate with families and residents are fundamental.[11 12] Pilot evaluation of Comfort Care Rounds (CCRs) in an interdisciplinary group of staff in LTC showed that staff reported: (a) new learning about palliative care; (b) improved communication among staff members; (c) increased confidence in providing palliative and EOL care; (d) empowered personal support workers/aides; (e) provided opportunities for debriefing and reflection; and (f) increased awareness and use of palliative care human resources.[13–16]

Despite the high mortality rates in LTC, most LTC homes do not have a formalised palliative programme. Hence, our research team has developed the Strengthening a Palliative Approach in Long Term Care (SPA-LTC) programme.[17] It consists of the following core, evidence-informed components: (a) an interdisciplinary Palliative Champion Team (PCT) (to provide leadership, support implementation and sustainability), (b) CCRs among staff (for capacity building and reflection), (c) informational pamphlets (to help prepare residents and families better as their condition/disease progresses), (d) Palliative Care Conferences (PCCs) (to strengthen relationships between residents, families and staff and discuss changes in health and planning for EOL care) and (e) postbereavement follow-up (for residents, families and staff).

Recent pilot work involved developing a variety of tools and practices to help implement the SPA-LTC programme by exploring: (a) resident and family needs within a palliative approach to care[9] and related staff knowledge gaps,[18] (b) quality improvement strategies to reduce ED use at EOL,[5] (c) strategies to provide education and support to residents and families soon after admission to LTC using pamphlets,[19] and later on when EOL is near by holding PCCs[20] and offering bereavement support.[9] Most recently, pilot findings of the SPA-LTC programme using a pre-post design have shown: (a) a 55% reduction in ED visits and 21% decrease in inappropriate ED visits at EOL,[21] (b) increased family satisfaction, (c) 67% of residents and family members are more comfortable with exploring ACP issues after reading a pamphlet[19] and (d) 82% of participating residents (and their families) had a PCC before they died. However, there have been no large-scale clinical trials conducted in Canada to evaluate a programme, such as SPA-LTC; research is needed to evaluate the effectiveness of SPA-LTC using a more rigorous design (ie, randomised control trial (RCT)) to inform decisions regarding widespread use and scaling up.[22 23]

Objectives

The goal of the proposed study is to examine: (a) the implementation (feasibility, reach, fidelity, adaptability, sustainability) and (b) effectiveness (ED use in the last 6 months of life (primary), location of death, family satisfaction and decisional conflict, staff knowledge and confidence implementing a palliative approach) of the SPA-LTC programme.

METHODS

Design

We will use a cross-jurisdictional, effectiveness-implementation type II hybrid cluster RCT design[22] to assess the SPA-LTC programme. The implementation component is designed as a formative evaluation to explore how to adapt the SPA-LTC programme in real time. The effectiveness component is designed to achieve the goals of comparative effectiveness research: (a) informing clinical and policy decisions, (b) comparing the intervention to usual care, (c) employing patient-relevant outcome measures and (d) conducting the trial in real-world settings. It was decided to randomise at the level of the LTC home within the province, to avoid contamination of the control group. Hybrid type II designs provide a more direct blending of effectiveness and implementation research to support more rapid translation and are best suited when there is 'implementation momentum' within the clinical system.[22] The effectiveness component is designed to achieve the goals of comparative effectiveness research which includes: (a) informing clinical and policy decisions; (b) comparing the intervention to usual care; (c) employing patient-relevant outcome measures; and (d) conducting the trial in real-world settings.[24] The Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2) tool was used to design the trial, with emphasis on maximising pragmatism across the tool's nine domains[25] (see table 1). A pragmatic design was adopted to test the programme in a context that mirrored real world practice as closely as possible, in order to reduce the research-practice gap.[26] The intervention arm of the study will include a 3-month preintervention period followed by 12 months of intervention and 3 months of follow-up. In the control arm, the 3-month preintervention will be included and the 1-month follow-up will occur 15 months later. In the control arm, research staff will be available for up to 6 months after the follow-up period to provide support for SPA-LTC implementation.

Study setting

We will engage our study partners (ie, regional health managers, palliative consultants) in each province (SK,

Table 1 Pragmatic Explanatory Continuum Indicator Summary chart (chart of intervention stage)

Domain	Score	Rationale
Eligibility	5	All English-speaking LTC residents nearing end of life (PPS score 50% or less or RAI-MDS CHESS score of 2 or greater) and/or their family will be invited to participate in the study regardless of their responsiveness, comorbidities or past compliance
Recruitment	3	Some effort is needed to recruit participants over and above what would be used in the usual care setting to engage with residents and their families
Settings	5	Setting is the same as where SPA-LTC will be implemented; sites are diverse geographically
Organisation	4	All LTC staff will be involved in implementing SPA-LTC programme, regardless of the discipline or expertise, although additional training will be provided outside of usual care; only ordinary attention to dose and side effects
Intervention flexibility (delivery)	5	Instructions on how to implement the SPA-LTC programme are highly flexible, offering LTC staff considerable leeway in deciding how to implement it
Intervention flexibility (adherence)	5	Residents/family: no obtrusive measurement of participant compliance; no special strategies to maintain or improve compliance are used Staff: we will be assessing the extent to which practitioners implement the SPA-LTC programme but will not be using a manual of procedures to allow for flexibility
Follow-up intensity	4	There is a combination of formal follow-up to complete the staff and family interviews and other routinely collected follow-up data (hospital use)
Primary outcome	5	The primary outcome (ED use at end of life) is an objectively measured, clinically meaningful outcome
Primary analysis	4	The analysis includes all patients regardless of direct participation. However, we will be using intention-to-treat analysis. Our goal is to examine if the SPA-LTC programme works under usual conditions with all the 'noise' inherent therein
Total score	40/45	Rather to very pragmatic trial

Each item is scored from 1=very explanatory; 2=rather explanatory; 3=equally explanatory.
CHESS, Changes in Health, End-Stage Disease and Signs and Symptoms; ED, emergency department; LTC, long-term care; PPS, Palliative Performance Scale; RAI-MDS, Resident Assessment Instrument-Minimum Data Set; SPA-LTC, Strengthening a Palliative Approach in Long Term Care.

MB, ON) to recruit LTC homes. Our provincial partners will work closely with LTC homes and have identified 6–12 homes that have at least 100 residents and are willing to participate in the study. These homes will be informed that they may or may not be randomly selected, and if selected they may be in the intervention or control group.

Eligibility criteria

Consistent with a pragmatic trial, our approach to eligibility aims to identify study participants with the condition of interest (nearing EOL in LTC) under usual conditions representative of the three provinces included in this study.[24] All English-speaking LTC residents who have a Palliative Performance Scale (PPS) score of 50% or lower or Resident Assessment Instrument-Minimum Data Set (RAI-MDS) Changes in Health, End-Stage Disease and Signs and Symptoms (CHESS) score of 2 or greater, or their proxies who are English-speaking, will be asked to participate.[25] LTC residents must also have been at the current LTC home for a minimum of 6 months.

Intervention

SPA-LTC builds on the team's previous work, including the following core components: (a) developing an onsite interdisciplinary PCT[14 26]; (b) providing an informational pamphlet,[19] (c) holding resident and PCCs[20 27]; (d) conducting CCRs with staff[16]; and (e) providing bereavement care (see figure 1). Intervention homes will receive the SPA-LTC components alongside usual care, whereas control homes will only receive usual care during the intervention period. Individual participants may withdraw from the study at any point.

Interdisciplinary PCT

All intervention sites will be asked to develop a PCT with representatives from all disciplines.[14 28] Onsite opinion leaders will be recruited to the team to optimise implementation of the intervention. The PCT will be instrumental in identifying challenges to implementation and adaptations required. All PCT members will be invited to attend four, 1 hour virtual educational workshops, as well as complete self-paced online modules.[29] Educational workshops will be based on existing tools and resources that have been previously evaluated.[16 21] The PCT team meetings will involve discussions related to: (a) reviewing resident status and prioritising timing of PCCs for each resident, (b) planning the delivery of informational pamphlets and other resources, (c) debriefing about previous residents deaths, (d) any new initiatives needed in the home to help support implementation of the SPA-LTC programme, (e) review of internal policy and

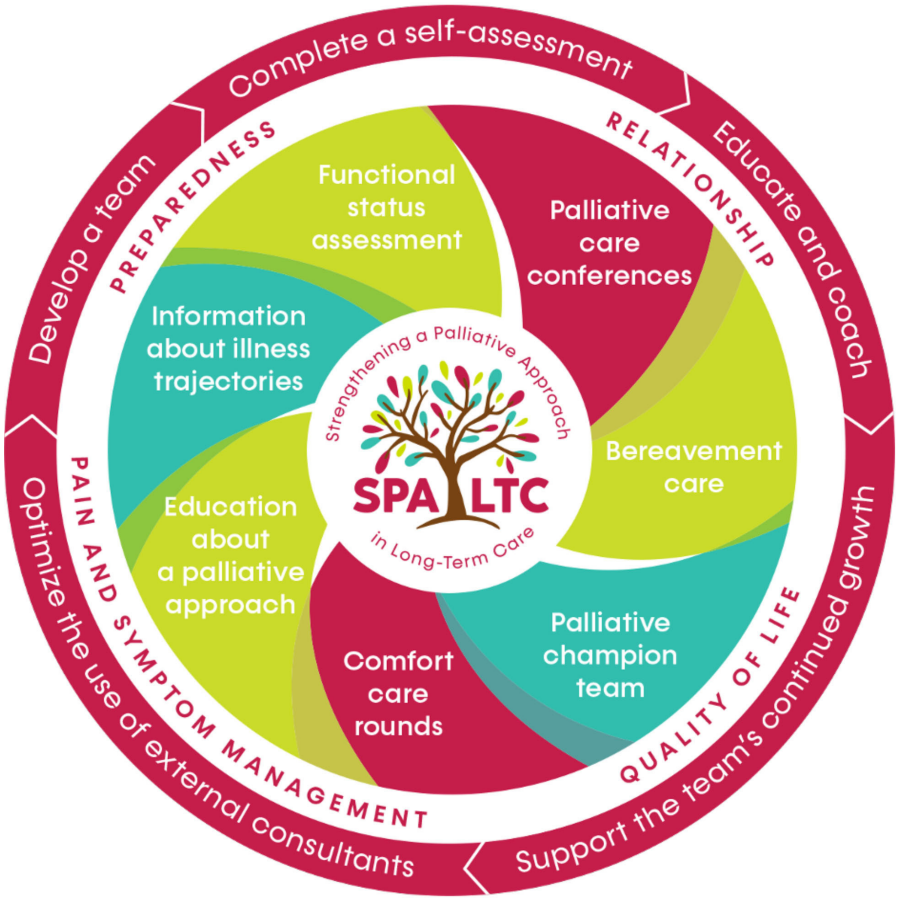

Figure 1 Conceptual model of Strengthening a Palliative Approach in Long Term Care (SPA-LTC).

processes and (f) planning grief and bereavement activities for residents, family and staff.

Illness trajectory pamphlets

Participants (residents and families) at all intervention sites will receive an SPA-LTC informational pamphlet before attending a PCC to provide information to residents and family about the expectations of each illness, prompting questions from family and availability of resources from LTC.[19 30] The control sites may use or distribute the informational pamphlets as part of their usual care. The pamphlets focus on five life-limiting chronic illnesses that are most prevalent and inadequately addressed in LTC; frailty, dementia, heart failure, kidney disease and lung disease (see https://spaltc.ca/resource-library/?category=family-caregiver). Survey results suggested that access to pamphlets encouraged residents and families/friends to reflect on future care (48/57, 84%), clarified what questions to ask (40/57, 70%) and increased comfort in talking about EOL care (36/57, 63%).[19]

Palliative Care Conferences

PCCs will be held with residents (where possible) and their families when triggered by staff, family or residents (where possible). We will encourage staff to prioritise residents whose PPS scores are lower (<40%). PCCs aim to clarify goals of care, consider site of care options, share information and develop meaningful partnerships between the resident, family and staff.[20 27 31] We will encourage staff to stagger recruitment so PCCs can be staggered to offset workload burden to staff, with the goal of completing one or two PCCs per week.

Comfort Care Rounds

Are intended for all intervention site staff to provide a forum for resident-focused discussions about those who have recently died or who are approaching or receiving EOL care.[16] They will be led by members of the PCT on a bimonthly basis; focused on providing palliative care education, reflecting on resident issues, and providing staff peer support. Staff may use the supporting guidebooks to help peers identify resident issues or debrief about a recent resident death.[32 33] The results of the pilot study evaluation of the SPA-LTC programme showed that staff reported: (a) new learning about palliative care; (b) improved communication among staff members; (c) increased confidence in providing palliative and EOL care; (d) empowered PSWs/care aides; (e) additional opportunities for debriefing and reflection; and (f) increased awareness and use of palliative care human resources.[16] CCRs will also be used for triggering a PCC and/or completing the PPS.

Bereavement supports

Following a resident death, family members can experience a sense of loss and abandonment.[28 34 35] To address

this loss, 1 month following the death of a resident, a staff member (member of PCT or designate) in the intervention site will either call family members or offer the family an informational pamphlet. The informational pamphlet addresses common reactions in bereavement and potential resources. The PCT members will also consider strengthening organisational approaches to supporting grief and bereavement for all members of the LTC community, including grieving residents, by reviewing the guide booklet (https://spaltc.ca/wp-content/uploads/2022/08/SPA-LTC2012_Bereavement_in_LTC_Booklet-5-EN-FINAL.pdf).

Measures/outcomes

Table 2 provides the list of variables, measures and timing. We will have a 3-month time period to collect baseline data (T_1), 12-month intervention period, followed by a 3-month postintervention (T_3). The primary outcome is any ED visit in the last 6 months of life. Secondary outcomes include: location of death, family satisfaction and decisional conflict, and staff knowledge of and confidence with implementing a palliative approach. Additionally, we will explore the implementation outcomes (feasibility, reach, fidelity, adaptability, sustainability) of implementing the SPA-LTC programme in three provinces (T_2).

Resident outcomes

ED visits in the last 6 months of life (primary outcome), number of hospital admissions (secondary outcome) and location of death (eg, hospital vs LTC home; secondary outcome) will be assessed using administrative data at each study site. For postintervention measurements, we will assess the same outcomes for LTC residents who have died and been enrolled in the study for at least 6 months.

Family outcomes

Two family outcomes (family satisfaction with care and decisional conflict) will be assessed at baseline and postintervention for both groups. First, family satisfaction will be assessed using the Canadian Health Care Evaluation Project Lite Long Term Care Questionnaire.[36 37] It is a 22-item scale with each item rated both in terms of importance and satisfaction on a scale from 1 (not at all important/satisfied) to 5 (extremely important/completely satisfied) with the option of do not know or no basis to judge for the satisfaction items.[38] The total possible score ranges from 22 to 110 for importance and satisfaction. Research supports its internal consistency for each subscale (α 0.69–0.94) and strong correlations among global rating of satisfaction and quality of life instruments.[39] The second outcome will be measured using the Decisional-Conflict Scale. It includes 16 items, each rated on a scale from 1 (strongly agree) to 5 (strongly disagree) with a total possible score of 0–80. Research supports its reliability with test–retest correlations and Cronbach alpha coefficients exceeding 0.78 and for construct validity correlated to related constructs of knowledge, regret and discontinuance.[40 41]

Staff outcomes

Staff participants in both the intervention and control sites will complete a baseline and postintervention survey. Staff knowledge, self-efficacy and self-reported actions as related to a palliative approach will be assessed using the End of Life Professional Caregiver Survey (ELPC),[42] the Rotterdam MOVE2PC questionnaire[43] and the Person-Directed Care questionnaire.[44] The ELPC is a 28-item scale with strong internal consistency (alpha=0.96).[42 45] Each item is scored on a 5-point Likert scale ranging from 1 (lowest level of skill) to 5 (greatest level of skill). It includes three subscales: a 12-item Patient and Family-Centred Communication); 8-item Cultural and Ethical Values; and 8-item Effective Care Delivery. The Rotterdam MOVE2PC questionnaire is a 63-item questionnaire of which five questions are used in this study to measure knowledge and opinions around palliative care.[43] Items are scored on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). Internal consistency is acceptable (alpha=0.77) and intra-rater agreement is moderate to good ($k>0.5_{kmax}$).[43] The Person-Directed Care questionnaire includes 35 items comprising five subscales to measure self-reported person-directed care. The 'Knowing the Person' (7-items) and 'Supporting Relationships' (6-items) subscales are included in this study and are measured using a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree).[44] Cronbach alpha coefficient estimates for the two sub-scales are both 0.91.[44]

Intervention fidelity

Research assistants (RAs) will work closely with LTC staff at each intervention site to assess the fidelity of implementing the SPA-LTC programme using an Intervention Fidelity Checklist (see table 3). RAs will conduct biweekly visits to complete the checklists.

Participant timeline

The proposed duration of the treatment period for each participating resident is dependent on the timing of their death since the final resident and family outcomes are assessed postdeath. The intervention itself within each site (intervention sites only) will run for 12 months from June 2022 to January 2024.

We will engage staff during the baseline period to complete a survey and they will remain involved through the intervention period and into the 3-month postintervention period.

Sample size

A sample size of 18 clusters in the trial (nine clusters per arm, six clusters per province) with an overall sample of 594 (297 per arm) is needed to detect a group difference in the primary outcome (proportion with an ED visit) of 0.40 (intervention) and 0.60 (control). These proportions are based on the effect sizes observed in the pilot

Table 2 Variables, measures, intervention and/or control group, and timing of data collection

Objective	Variable/outcome	Measure	Study group(s)	Timing	Method of analysis
Effectiveness outcomes					
Resident/family	Primary outcome: emergency department visits—binary (≥1 or none) Hospital admissions—binary (≥ 1 or none) Hospital deaths—binary (≥1 or none)	Chart audit	Intervention and control	6-month lookback from T1 and 6-month lookback for residents who have died during intervention period T3 (not going beyond start of study)	Descriptive analysis T1–T3 (treatment effect); GEE
	Family member survey: satisfaction with EOL care, decisional conflict	CANHELP Lite Long-Term Care Questionnaire[36 37] Decisional Conflict Scale (16-item statement format)[40]	Intervention and control	T1, T3	TI–T3 (treatment effect); GLMM
	Acceptability of intervention	Reflection on PCC experience, experience with EOL care provided to relative, relations with LTC staff, bereavement pamphlet, recommendations for LTC facilities to support bereaved families	Intervention	T3	Thematic analysis; T3
Staff	Demographics form; staff survey Knowledge of a palliative approach Palliative care self-efficacy Self-reported palliative approach	Demographics (ie, age, education level, occupational class, gender identity, religious identity, racial identity, duration of employment) 'Rotterdam MOVE2PC questionnaire'[43] 'End-of-life professional caregiver survey'[42] 'Person-directed care' measurement tool[44]	Intervention and control	T_1, T_3	Descriptive analysis T_1–T_3 (treatment effect); GLMM
Implementation outcomes	Fidelity of SPA-LTC components (PCT, CCR, PCC, ITP, bereavement pamphlets)	Fidelity scale/checklist of organisational and resident level activities	Intervention	T_2, biweekly	Descriptive analysis
	Perceptions of intervention or standard care by study residents/family Members	Interview guide; interview transcripts	Intervention and control	T_2–T_3	Qualitative description analysis
	LTC staff perceptions of intervention	Demographics (ie, gender, age, profession, employment status, years worked, palliative training, EOL involvement, etc) Focus group transcripts (ie, preparedness, comfort level and experiences with EOL care for residents and families, feedback on intervention components)	Intervention and control	T_3	Qualitative description analysis

T_1: baseline, T_2: during the intervention period, T_3: postintervention.
CANHELP, Canadian Health Care Evaluation Project; CCR, Comfort Care Round; EOL, end-of-life; GEE, generalised estimating equations; GLMM, generalised linear mixed methods; ITP, illness trajectory pamphlets; LTC, long-term care; PCC, Palliative Care Conference; PCT, Palliative Champion Team.

Table 3 Fidelity indicators assessed over 12-month intervention period

Indicator	Data source	Achieved if*
Study participation rate	RA records	80% of eligible residents and/or families enrolled
PPS or RAI-MDS CHESS scores	LTC staff documentation	95% of residents in the home have PPS or CHESS scores within 3 months of the intervention period
Frequency of PCT meetings	RA meeting notes/ LTC staff documentation	80% of homes meeting bimonthly
PCT meeting attendance	RA meeting notes/ LTC staff documentation	80% of homes have attendance from at least three different disciplines at each meeting
Frequency of CCR	RA/LTC staff records	80% of homes meeting bimonthly (eg, every other month)
CCR attendance	RA/LTC staff records	80% of homes have attendance from at least three different disciplines at each meeting
PCC (n)	RA/LTC staff records; completed PCC documentation forms	80% of enrolled residents had a PCC before death
PCC attendance	RA/LTC staff records; completed PCC documentation forms	Attendance of staff from at least three different disciplines and resident/family member/friend
PCC form use	RA/LTC staff records; completed PCC documentation forms	Forms completed for 80% of PCCs
ITP use	RA/LTC staff tracking records	80% of homes display pamphlets onsite; 80% of residents/families receive one at 6-week postadmission conference
Postbereavement follow-up	RA records	80% of families are contacted by LTC staff within 2 months postdeath
Bereavement pamphlets	RA records	80% of families receive pamphlet within 2 months postdeath

*All cut-offs for fidelity indicators are based on previous pilot work.[21]
CCR, Comfort Care Round; CHESS, Changes in Health, End-Stage Disease and Signs and Symptoms; ITP, illness trajectory pamphlets; LTC, long-term care; PCC, Palliative Care Conference; PCT, Palliative Champion Team; PPS, Palliative Performance Scale; RA, research assistant; RAI-MDS, Resident Assessment Instrument-Minimum Data Set.

study.[21] This calculation assumes a 95% confidence level, 80% power and an intraclass coefficient no greater than 0.10 for the primary endpoint of interest. We have also based this calculation on our previous pilot work demonstrating that we will be able to recruit a mean of 33 residents/LTC home that has at least 100 residents.

Recruitment

To recruit resident and family participants in the SPA-LTC programme, we will work with LTC staff at each site to select eligible residents and families based on our inclusion criteria to obtain consent. At baseline, LTC staff will be offered training on the PPS tool. They will then assess the PPS score for all residents in both the intervention and control homes. For those residents who have a PPS score of ≤50%, an LTC staff member will approach the resident (only if resident is able to consent), and their family member/substitute decision maker to invite them to participate in our study. The PPS is a valid and reliable tool used to measure progressive decline in a person suffering from terminal/incurable illness; it can be divided into three stages: stable, 100%–70%; transitional, 60%–40%; EOL, 30%; or less.[46 47] For those LTC homes that are under-resourced, we will offer them the option of using the RAI-MDS CHESS score instead of the PPS since it is routinely completed and will minimise extra study burden. In these cases, we will use a CHESS score of two or greater for recruitment since both the PPS and CHESS scores are comparable.[48]

The LTC staff will provide the site RA with the contact information of eligible families and residents (where possible) and the RA will contact eligible participants and invite them to participate in the study using the research staff recruitment script. For participant enrolment, if the resident is able to attend the first enrolment meeting, they will be invited to sign a consent form giving research staff permission to access their medical information for chart audit purposes, as well as complete a demographics questionnaire. If the resident is unable to sign on behalf of themselves, their family will sign for research staff to have permission to review the resident's medical records as part of the family consent form, which also includes a demographics questionnaire and baseline survey. Once recruited we will work closely with staff to implement the SPA-LTC programme.

Recruitment challenges

We anticipate that clinical demands on LTC staff will be a challenge, however based on our previous experience we have identified a number of mitigation strategies.

Involving staff at all levels will help to overcome these challenges. Additionally, external consultants, such as palliative consultations will help with study implementation, though we recognise that regions are unique in how LTC and palliative consultants are structured and funded. Supporting the development of a PCT will provide each setting with a working group to consult as challenges arise, which will be documented and included in the final tools and reports developed from this project.

At the resident/family level, our rate of compliance with implementing the individual SPA-LTC components is very good in a pilot study of 39 participants, with 100% of all residents having a PPS completed (39/39) and 81% of family attending a PCC before a resident death (21/26).[21] Based on our previous work and current death rates in Canadian LTC homes, we anticipate at least a 27% annual death rate.[5] We will therefore account for this loss in recruitment and to ensure feasibility measures are met.

At the site level, it is possible that an LTC home may drop out during the study. To mitigate this challenge a staged approach has been developed to implementing the SPA-LTC programme to help offset burden and support staff with the training and skills that are needed to implement it successfully, thereby reducing the likelihood of an intervention home dropping out.

Patient and public involvement

From the inception of SPA-LTC in 2014, we have actively pursued the involvement of LTC residents, their families, healthcare providers and decision-makers. We have a long-standing commitment to patient and public involvement, starting back in our early pilot studies in 2008 where we interviewed residents and families to get a sense of their needs and preferences. All of the SPA-LTC tools developed have involved residents and/or families, such as receiving feedback after PCCs and adapting them and involving staff in how to best implement them from their perspective. At least four family advisors who have been involved in piloting a family survey will help with reviewing findings and later dissemination.

Allocation

Within each of the three provinces, six LTC homes will be randomly selected to participate in the study (if greater than six identified), and then if selected they will be randomly allocated using a 1:1 ratio (three homes in the intervention and control groups), stratified according to province, to either the intervention or control group using a computer-generated list (three homes in each of the intervention and control groups). The random selection of LTC homes to participate in the study and randomisation of selected homes to trial groups will be based on randomly established sequences set up by a biostatistician (KF) not involved in recruitment.

Blinding

The data analysts and statisticians will be blinded to group allocation while performing data analysis.

Data collection

Our data collection methods (focus groups, interviews, surveys, chart reviews) have been piloted and adapted through two separate studies to ensure feasibility for this larger RCT. Data collection is described separately for each study objective (see table 2).

Data management

All qualitative data generated from focus groups, field notes, interviews and meeting deliberations will be managed with Dedoose, a web based qualitative software programme designed for accommodating multiple users in different geographical locations.[49] Quantitative data will be collected and managed using Research Electronic Data Capture (REDCap), a secure, web-based software platform designed to support data capture for research studies, providing (a) an intuitive interface for validated data capture; (b) audit trails for tracking data manipulation and export procedures; (c) automated export procedures for seamless data downloads to common statistical packages; and (d) procedures for data integration and interoperability with external sources.[50 51]

Data analysis

At the individual (participant) level, the primary outcome (any ED visit, binary—yes/no) will be analysed via multivariable logistic regression using generalised estimating equations (GEE) to address the non-independence of the data (ie, clustering effects of participants in the same LTC home). GEE is one of two methods (the other—generalised linear mixed methods, or GLMM) used in the analysis of individual-level data in cluster RCTs.[52] Compared with GLMM, GEE has been shown to perform better for binary outcomes[53] and is more conservative.[54] GEE model results will be expressed as ORs with corresponding 95% CIs, assume an exchangeable correlation matrix, and employ a small sample adjustment to correct for bias that occurs in estimating the SE when a small number of clusters is used.[55 56] Confounding is not expected to be a significant issue due to randomisation, although cluster randomisation does not necessarily achieve balance on individual-level covariates, thus sites will be compared on key factors and any variables showing large imbalances by randomisation group will be added as covariates to the GEE model. Consolidated Standards of Reporting Trials (2004 for cluster RCTs) recommends that adjustment covariates be prespecified, thus the following covariates will be examined: age, number of chronic conditions, days from randomisation to death, ED visits in the 6 months prior to baseline and cluster-level variables (hospital transfer rate, number/rate of hospital deaths). Intention-to-treat (ITT) will be used, meaning participants will be analysed in the groups to which they were randomised and adjustment for biases arising from missing data will be addressed using multiple imputation (or alternative methods, such as inverse probability weighting) with models including covariates and accounting for the clustered data structure.[52] Sensitivity

analyses will be performed to compare the results with the ITT analysis, and these will consist of a complete case analysis and the testing of key assumptions made in the multiple imputation (or alternate method). The analysis of secondary outcomes will be conducted on individual-level data and use complete case data (no ITT). The analysis method chosen will allow for the clustered nature of the data and be selected based on the data type of the secondary outcome, for example, binary outcome data will use GEE (resulting in ORs) and continuous outcome data will use GLMM (producing mean differences).

Imputation will be applied to address missing data. Multiple imputation is considered the best method for addressing the most common and realistic missing data patterns seen in RCTs. A range of auxiliary variables will be used in the imputation model to improve accuracy. Sensitivity analyses will be performed using the complete case dataset.

All quantitative analyses will be done using R V.4.0.2 (2020-06-22), all statistical tests and CIs will be two-sided and assume a 5% level of significance (α=0.05), and reported measures will include p values, CIs and SEs.

For qualitative data, conventional content analysis will be conducted for all qualitative sources of data including: a careful reading of the transcripts and materials, the development of an initial coding frame, constant comparison between new and existing data to ensure consistency, relevance and comprehensiveness, and the application of final codes to all text with attention to maintaining the 'trustworthiness' of findings and promoting triangulation of all data sources.[57]

Data monitoring

A Trial Steering Committee, consisting of the site leads (SK, GT, PH, AW-G) will meet weekly in the beginning of the implementation phase and then biweekly after the initial 6 months, to oversee the trial and monitor any safety issues that emerge, and also help guide implementation and evaluation of the research project. Meetings will be held virtually for the duration of the project. We have averaged 90% attendance at our Steering Committee meetings in prior studies.

Ethics and dissemination

The study has received ethical approval from the Research and Ethics Committees of the following Research Ethics Boards (REB): Hamilton Integrated Research Ethics Board (HiREB), #7047; Brock University Social Science Research Ethics Board, #19-214; University of Manitoba Research Ethics and Compliance, #HS23631; University of Saskatchewan Research Ethics Board, #1785; and as per the Saskatchewan Multi-Jurisdictional Human Research Ethics Review Agreement, the University of Regina accepts the ethics review completed by the University of Saskatchewan. Any protocol modifications will be communicated with the REBs, Clinical Trials Registry and investigators. The results will be disseminated as follows: at various presentations and feedback sessions with each participating LTC home; with regional health managers and other key stakeholders within each province; at provincial, national and international conferences, and in a series of manuscripts written by the investigators and their teams that will be submitted to peer-reviewed, open access journals. All investigators will have access to the final trial dataset, and there are no contractual agreements that limit such access for investigators All information stored on the secure database will be deidentified data. Any identifying details (such as name, location, room number) on forms will be removed and paper copies stored in a locked filing cabinet. Digital copies will be stored on a secured server in password protected spreadsheets.

Discussion

The proposed study aims to advance knowledge to improve quality of healthcare for LTC residents and their family members and incorporate a palliative approach into the LTC sector. Reformation of healthcare systems and the delivery of a palliative approach across provinces by supporting key transition points along the living-dying continuum, reducing unnecessary hospital use at EOL and creating a more compassionate and holistic view of EOL care are goals of this study. We also aim to create and apply health-related knowledge to implement a palliative approach in LTC in Canada.

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Contributors SK drafted the proposal and KF drafted the quantitative analysis for the study protocol. SK, PH, LM, GT, AW-G, TS, LV provided substantial input into the main conceptualisation of the SPA-LTC program and its implementation, including the design of associated clinical resources. SK, PH, LM, GT, AW-G, TS, LV codesigned the study protocol, including the selection of measures and qualitative research questions. SK, AW-G, PH, GT, JK, LM, TS, LV, SSh, SAB, VB-G, TH, MM, RM-M, SM, DP, JPe, JPl, SSi and KF provided methodological and editorial input for this manuscript.

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