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Timely short-term specialized palliative care service intervention for older people with frailty and their family carers in primary care: Development and modelling of the frailty+ intervention using theory of change

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Abstract

Background: Palliative care is advocated for older people with frailty and multimorbidity in the community. However, how to best deliver it is unclear.

Aim: To develop and model an intervention of short-term specialized palliative care that is initiated timely based on complex care needs and integrated with primary care for older people with frailty and their family, detailing the intervention components, outcomes and preconditions needed for implementation, using a novel theoretical approach.

Design: Observational study informed by the UK MRC guidance for complex interventions integrated with a Theory of Change (i.e. hypothetical causal pathway to impact) approach. We synthesized evidence from a systematic review, semi-structured interviews, group discussions and Theory of Change workshops.

Setting: Primary care in Flanders, Belgium.

Results: We identified patient and family carer-related long-term outcomes and preconditions to achieve them for example, service providers are willing and able to deliver the intervention. The intervention components included implementation components, for example, training for service providers, and a core component, that is, provision of timely short-term specialized palliative care by a specialized palliative home care nurse. The latter includes: short-term service delivery; collaborative and integrative working within primary care; delivery of holistic needs- and capacity-based care; person-centred and family-focussed; and goal-oriented pro-active care.

Conclusions: The Theory of Change approach allowed us to identify multiple intervention components targeting different stakeholders to achieve the desired outcomes. It also facilitated a detailed description of the intervention which aims to increase replicability and effective comparisons with other interventions.

Keywords

Older people, frailty, palliative care, primary care, integrated care, community care

What is already known about the topic?

- Timely short-term specialized palliative care service interventions have been advocated for older people with frailty and multimorbidity with complex care needs in the community.
- It remains unclear what these interventions entail and how or under what circumstances such interventions can best be implemented.

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What this paper adds

- We identified the different stakeholders that should be involved when aiming to improve care for older people with frailty with complex care needs in the community, and determined multiple preconditions (e.g. older people are identified in a timely manner according to prespecified criteria), and intervention components (e.g. delivery of short-term service, collaborative and integrative working, holistic needs- and capacity-based care, person-centred and family-focused and goal-oriented and pro-active care) needed to achieve the desired changes.
- Alongside more traditional outcomes in palliative care research such as addressing holistic needs and symptoms, we identified sense of security in care as an outcome important to and valued by older people and family carers.
- Following expert input from stakeholders, we integrated care approaches from different disciplines into the core of the intervention, such as combining palliative care with geriatric and rehabilitative care, and integration of goal-oriented pro-active care with advance care planning.

Implications for practice, theory or policy

- The Theory of Change of the intervention provided insight into the hypothetical causal pathway to achieve long-term outcomes and impact. This in-depth knowledge is needed to better understand how the intervention is likely to work in practice and how to evaluate implementation when delivered.
- This Theory of Change approach could serve as an example for researchers of how to build a programme theory of their intervention.
- Detailed reporting of the intervention will enable researchers and clinicians to replicate the intervention and to compare our intervention with others more effectively.

Introduction

As people live longer, many experience long periods of multimorbidity or frailty.[1,2] Different conceptualisations are used to describe frailty; some primarily focus on the physical/medical domain of frailty, particularly in the field of geriatrics, others tend to be broader and also include other domains such as the psychological and social, particularly in the social sciences.[3,4] In this study, we focused on the medical syndrome of frailty and described frailty as an age-related clinical condition, typically with deterioration in the physiological capacity of several organ systems, that causes an increased susceptibility to stressors.[3,5] Older people with frailty often experience a prolonged period of gradual decline that is punctuated by stressor events (e.g. acute illness) resulting in fluctuating palliative care needs in the last years of life.[1,3,6] Palliative care is indicated for addressing these needs. It encompasses generalist palliative care (i.e. provided by health professionals with a good basic knowledge of palliative care) and specialized palliative care services (i.e. provided by a multidisciplinary service or a clinician specifically trained in palliative care for patients with complex problems, and by family carers).[7] Timely integration of these services has been suggested to meet complex palliative care needs. This means initiation of specialized palliative care at times when needs cannot be addressed by generalist palliative care providers alone.[8,9] Although there is no standard definition of complex needs in palliative care, it is recognized that they can affect different domains, that is, physical, psychological, social or spiritual/existential.[10] Despite the fact that the need for timely integration of services has been recognized, research shows that these services are often initiated only shortly before death (e.g. the median number of days ranged from 15 in Belgium to 30 in Italy in a four-country comparison).[11] This is particularly the case for older people with frailty, who typically have an unpredictable disease trajectory that makes prognostication difficult.[12] Integration of specialized palliative care services is particularly relevant in primary care, as the majority of older people prefer to remain in their usual residence (e.g. home).[13]

A model of short-term integrated palliative and supportive care for older people with frailty in community settings in England has recently been developed aiming to provide timely short-term specialized palliative care services.[14] The intervention intends to deliver specialized palliative care during episodes of decline and complex symptom presentation and aims to facilitate integrated working between the specialized palliative care teams and existing community care providers (e.g. GPs and community nurses), involved in patient's care.[14] It foresees short-term delivery of the palliative care services, through one to three visits over a period of 3 months.[14] While it has been argued that such a model has potential benefit for older people and family carers, it remains unclear what this intervention entails, and how or under what circumstances it can best be implemented.

A major reason for this lack of clarity is the difficulty of describing a complex intervention in full detail. Most interventions in palliative care are complex interventions. They consist of several interacting components situated at different levels and interacting with contextual barriers and facilitators.[15] The established guidance on complex interventions of the UK Medical Research Council (MRC)

states that theoretical underpinning is needed when developing and evaluating complex interventions, to be able to understand the role of different components, their link to the desired outcomes and the hypothesized causal pathway of their effects.[15,16] In the absence of specific guidance concerning choice of theoretical models, we used the Aspen Institute's Theory of Change approach[17] which has rarely been used in the field of palliative care research.[18] Following the accepted definition of the Aspen Institute, a Theory of Change is defined as 'a theory of how and why an initiative works which can be empirically tested by measuring indicators for every expected step on the hypothesized causal pathway to impact'.[17,19] Such a programme theory is developed specifically for a given intervention based on current evidence and in collaboration with stakeholders using backwards-mapping processes.[17] The process starts with defining the impact and long-term outcomes (i.e. the outcomes that the intervention is able to change on its own) of the intervention and works backwards to determine the preconditions or intermediate outcomes to achieve the long-term outcomes. It then identifies intervention components needed to achieve the outcomes, the rationale behind them, and assumptions that must exist for them to be achieved. The specific objective of this work is to describe the hypothesized causal pathway or Theory of Change of a timely short-term specialized palliative care service intervention for older people with frailty with complex needs and their family carers in primary care.

Methods

Study design and setting

We applied an observational study design combining multiple qualitative data methods in a serial way informed by the UK MRC guidance to develop complex interventions[15] integrated with a Theory of Change approach.[17] We developed a Theory of Change of a timely short-term specialized palliative care service intervention (henceforth named the Frailty+ intervention) by synthesizing evidence from a systematic review on specialized palliative care services for older people in primary care,[20] findings from qualitative interviews and group discussions with patients and family carers, and Theory of Change participatory workshops with professional stakeholders. The different methods used and the synthesis process for developing and modelling the Theory of Change are described in Figure 1. The Theory of Change is visualized in a map and uses specific terminology described in Table 1. The intervention was developed over a 2-year period (Sept 2017 – Sept 2019). The qualitative interviews, group discussions and Theory of Change workshops were conducted in Flanders, the Dutch-speaking region of Belgium.

For reporting, we followed the Consolidated criteria for Reporting Qualitative research checklist,[21] the guidance for the reporting of intervention development[22] and the Template for Intervention Description and Replication (TIDieR) checklist.[23]

Population and sampling

Qualitative interviews and group discussions. We conducted individual semi-structured face-to-face interviews with older people and face-to-face group discussions involving older people and family carers. For the qualitative interviews, we purposefully selected a heterogeneous sample of older people using the following inclusion criteria: (1) had a functional impairment AND (2) had been hospitalized at least once in the past 2 years (for any reason). The same criteria were used to select a sample of older people for the group discussions. We used the following exclusion criteria: (1) person not living at home OR (2) person with impaired cognition that prevented participation. We also included family members in the group discussions and included those to whom the following applied: (1) a family carer of a person with a functional impairment AND (2) a family carer of a person who had been hospitalized at least once in the past 2 years (for any reason).

Theory of change workshops with professionals. We held Theory of Change workshops with professional stakeholders (e.g. researchers, policymakers and healthcare professionals). They were purposively sampled using the following criteria: (1) providing formal care (i.e. paid care services) to older people in any setting OR working in healthcare management, policy organizations or research that concerns care for older people, AND (2) having experience in palliative care through their professional work. Stakeholders could attend one or several workshops, because each of the workshops aimed for discussion and consensus on different elements of the Theory of Change map and constituted an iterative refinement of previous draft of the map, following relevant guidance.[17,19]

Recruitment

Qualitative interviews and group discussions. Participants of the group discussions were recruited from a public welfare centre and among day-care clients in a nursing home in Flanders. The coordinator of the centre approached eligible participants and asked whether they would be interested in participating. The first participants meeting the inclusion criteria who agreed were included. For the interviews, we recruited participants from a University Hospital (Ghent University Hospital) in Flanders. They were first approached by their treating physician (NVDN) and, if they

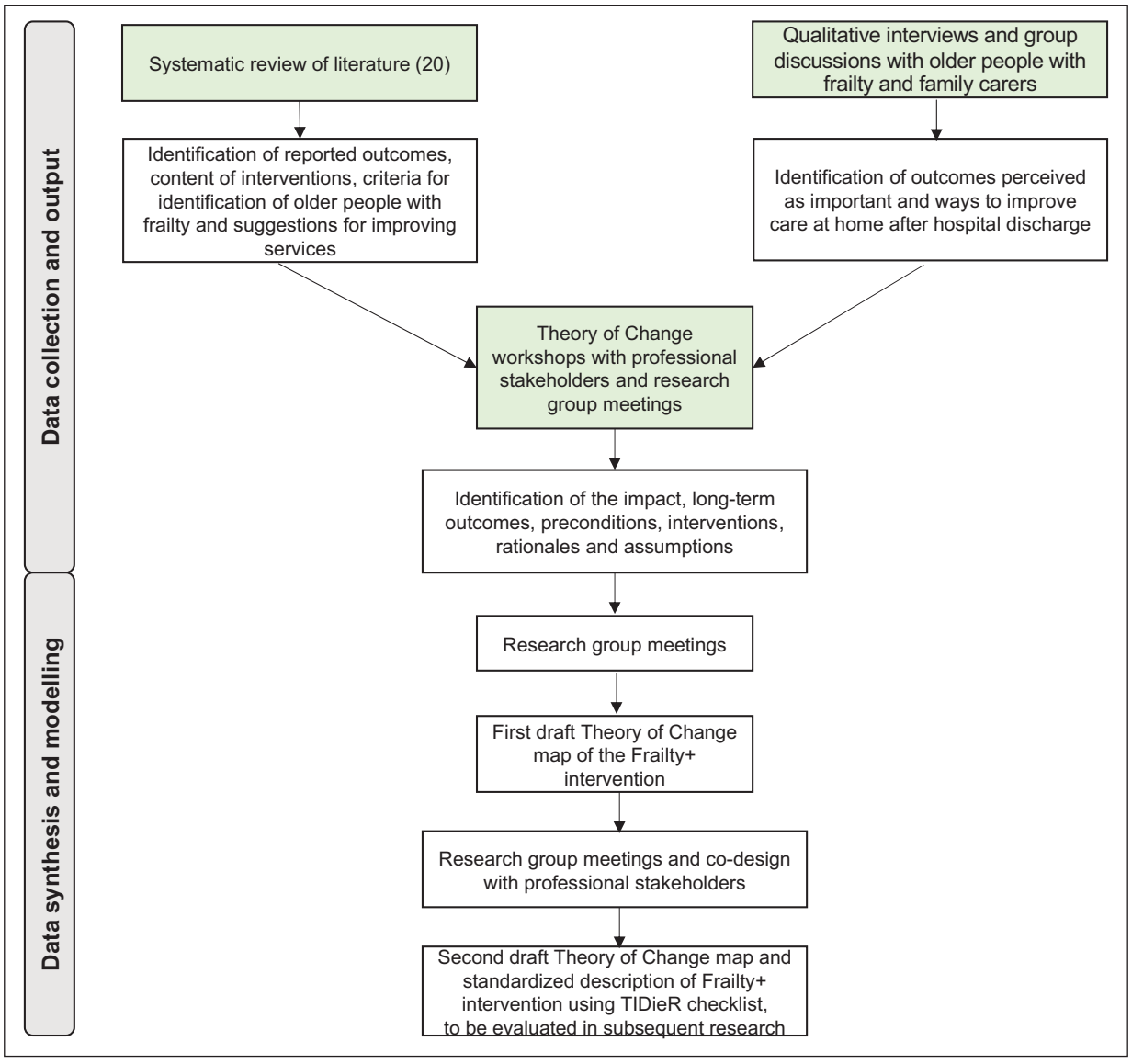

Figure 1. Diagram of information sources and synthesis process for developing the Theory of Change of the Frailty + intervention.

agreed, visited by a researcher during their hospital admission. The interviews were part of the multiple methods we combined to develop the theoretical model of the intervention. Our aim was not to reach data saturation but to ensure that the input of older people was included in the development process. We have therefore included a smaller sample than would likely be required to reach saturation.

Theory of change workshops with professionals. The research team identified stakeholders who met the inclusion criteria through the personal network of the research and clinical team supervising the study. The stakeholders were approached by the researcher (KdN) via email or phone regarding their participation in the workshop.

Data collection

Qualitative interviews and group discussions. All interviews were conducted face-to-face by the researcher (KdN) and the group discussions were conducted face-to-face by three researchers (KdN, LP and YP). We used case vignettes to prompt participants to explore which outcomes of care are important to them and how to improve care at home after hospital discharge. The use of vignettes provides a way of exploring possible sensitive topics without obliging participants to share personal experiences.[24] Participants were invited to reflect on the case vignettes and the possible role of a specialized palliative home care service in the situation described in the vignettes. All interviews and group discussions were audio-recorded.

Table 1. Common theory of change terminology.[17,18]

Terminology	Description
Impact (ultimate outcome, goal)	The ultimate real-world change we are trying to achieve. The intervention contributes towards achieving this impact but cannot achieve it solely on its own (e.g. personal factors, the health care system and a person's broader social and physical environment may influence this).
Ceiling of accountability	The level after which the intervention is not accountable for the outcomes on its own; line drawn between long-term outcomes and impact.
Long-term outcomes	The long-term outcomes are the changes that the intervention is directly accountable for. This will be the primary and secondary outcomes of the evaluation.
Preconditions (or intermediate outcomes)	A precondition is a necessary requirement, condition or element that needs to be realized for the long-term outcomes to be achieved.
Indicator	Things you can measure and document to determine whether you are making progress towards, or have achieved, each precondition.
Interventions (activities or strategies)	The different components of the complex intervention. These represent the 'actions' that need to be undertaken to bring about a specific precondition (intermediate outcome).
Rationales	The facts or reasons (based on evidence or experience) that support the choice of the interventions (activities or strategies) for each link between preconditions and long-term outcomes.
Assumptions	An external condition beyond the control of the intervention that must exist for a precondition to be achieved (e.g. 24/7 (telephone) availability of the specialized palliative home care services).

Theory of change workshops with professionals. The Theory of Change workshops were conducted face-to-face and facilitated by the researchers (KdN, LP, LVdB), in which we determined the elements of the Theory of Change map.[17] The workshop guide was developed based on the findings of the interviews and group discussions. We started with an introduction of the researchers, the project and the method. The workshops followed a structured format (see Supplemental Table 1). The procedure we used to create a Theory of Change map is called 'backwards outcome mapping'. This means that participants first identified the desired impact and long-term outcomes of the timely short-term specialized palliative care service intervention. Subsequently, they 'worked backwards' through identifying preconditions or intermediate outcomes that are needed to achieve the long-term outcomes.[25] We used the findings of the systematic review and qualitative research to guide the discussion. We asked questions concerning the identified themes, used the themes to inform and stimulate the discussion and as prompts to resolve discrepancies, while allowing for new themes to emerge. After each workshop, the researcher (KdN) created a draft Theory of Change map and discussed this during meetings with the research team (consisting of social science researchers, a general practitioner and a hospital geriatrician, all with experience in palliative care). The map was then presented in the next workshop. After the workshops, the research team discussed and reviewed the formulation and content of the different parts of the Theory of Change map. All workshops were audio-recorded.

Data analysis and integration

The researcher (KdN) analysed the qualitative interviews and group discussions in MS Excel using directed content analysis[26] and discussed this with the research team. The analysis followed a partly deductive and partly inductive coding approach. The interview transcripts were deductively coded in accordance with the pre-determined coding scheme that was based on the two key areas explored across the interviews and discussions, namely the outcomes important to patients and family carers and how to improve care at home after hospital discharge. Additional codes were developed during analysis for relevant data that could not be coded according to the predetermined coding scheme. The codes were then inductively categorized into overarching subthemes and themes.

Regarding the Theory of Change workshops, the researcher conducted directed content analysis in MS Excel[26] and discussed this with the team. The pre-determined coding scheme was based on elements of the Theory of Change checklist, that is, impact, long-term outcomes, preconditions, interventions.[27] In the workshops, participants generated many ideas and then they jointly developed the Theory of Change map until consensus was reached. These points on which consensus was reached were noted and summarized in written form by the researcher (KdN). We deductively coded this data in accordance to the pre-determined coding scheme, followed by the process of inductively categorizing the codes into overarching themes and subthemes. These themes and subthemes were included in the map and this resulted in a first draft Theory of Change map. Subsequently, the map was checked against relevant literature and rationales by the research team and co-designed with professional stakeholders. This resulted in a second draft Theory of Change map and an accompanied standardized description of the intervention using TIDieR checklist.[23]

Table 2. Characteristics of stakeholders involved in the workshops.

Characteristics	Workshop 1 (*N* = 5)	Workshop 2 (*N* = 16)	Workshop 3 (*N* = 13)	Workshop 4 (*N* = 11)	Total (*N* = 45)
Gender					
Female	5	12	7	4	28
Male	0	4	6	7	17
Primary profession					
Healthcare providers:					
General practitioner	0	2	3	1	6
Primary care nurse	0	5	3	2	10
Specialized palliative care nurse	5	2	1	3	11
Hospital geriatrician	0	1	1	0	2
Healthcare management and policy, in:					
Primary care	0	0	2	1	3
Frailty/older people	0	2	1	2	5
Palliative care	0	1	1	1	3
Reseacher in:					
Social and health sciences	0	3	1	1	5

Ethics

Ethics approval for this study was given by the Commission of Medical Ethics of the University Hospital Brussels (B.U.N. 143201732678). Older people and family carers gave written informed consent prior to recording and the professional stakeholders who participated in the Theory of Change workshops gave verbal consent. All obtained data were pseudonymised.

Results

Participants characteristics

We held two group discussions with older people (*n* = 11, mean age 78.3 years, female *n* = 8), one with family carers (*n* = 8, mean age 71.9 years, female *n* = 5) and individual semi-structured interviews with older people (*n* = 3, mean age 82.0 years, female *n* = 1). We conducted four half-day Theory of Change workshops with professional stakeholders (see Table 2, stakeholder characteristics).

Theory of change of the intervention

We present the impact and ceiling of accountability, long-term outcomes, preconditions, interventions, rationales and assumptions, as suggested by the checklist for reporting Theory of Change.[27] As limited data are available to determine standards or cut-offs for achieving a precondition, we have not yet developed the indicators. In the next stage, we will test the feasibility of the intervention and will use the data gained from that work to suggest indicators for measuring whether preconditions have been achieved. The Theory of Change map is presented Figure 2.

Impact and ceiling of accountability. Based on the qualitative research, we identified the real-world impact of the timely short-term specialized palliative care service intervention. This was defined as 'timely integration of specialized palliative home care services for older people with frailty with complex needs and their family carers', 'increased quality of life of older people with frailty with complex needs and their family carers' and 'increased job satisfaction among health professionals'. In the Theory of Change map, a line is drawn between the long-term outcomes and the impact, showing that the intervention, although it can contribute, is not directly and solely responsible for achieving the impact.

Long-term outcomes. We identified long-term outcomes of the timely short term specialized palliative care intervention, relating to older people with frailty and their family carer. Based on the qualitative interviews, we identified the outcome 'increased sense of security in care', explained as patients having the feeling that they can rely on their care providers. Through the Theory of Change workshops and the systematic review,[20] we identified 'increased well-being', 'fewer unmet needs and symptoms', 'increased continuity of care', 'fewer unnecessary hospital admissions' and 'longer stay at home' as important patient-related outcomes. The family carer-related long-term outcomes include: 'increased sense of security in care', valued as important outcomes in the group discussions by family carers and 'fewer family carer support needs', identified through the systematic review[20] and the Theory of Change workshops.

Preconditions. Based on the qualitative research, we identified several preconditions that need to be fulfilled

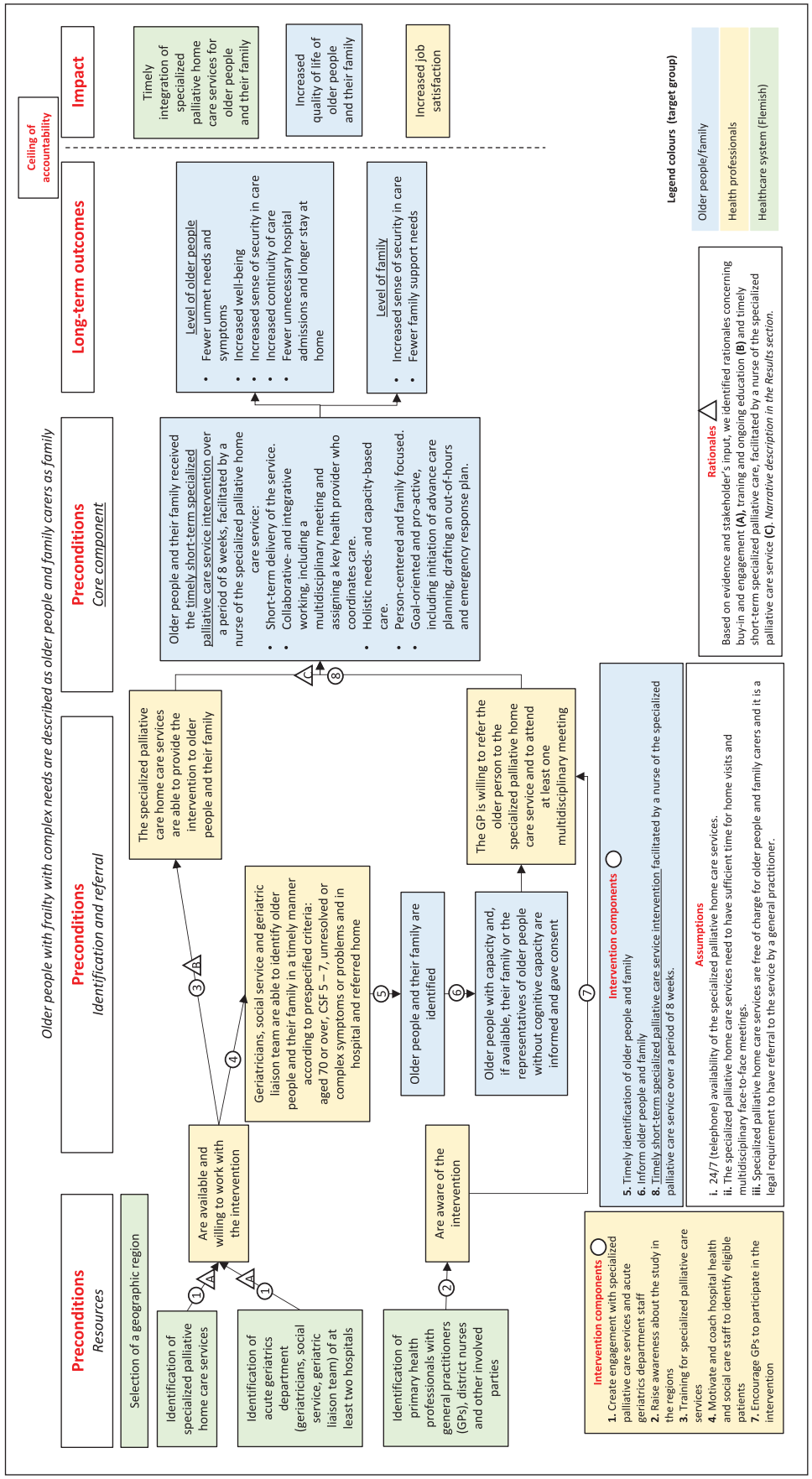

Figure 2. Theory of Change map of the Frailty + intervention: Timely short-term specialized palliative care service intervention for older people with frailty and their family carers in primary care.

Table 3. Summary description of the Frailty + intervention based on the TIDieR checklist.[23]

Intervention components	What - materials	What - procedures	Who – intervention providers	How – modes of delivery	Where	When and how much	Tailoring	How well – planned fidelity
Implementation components								
1. Create engagement with specialized palliative care services and acute geriatrics department staff	Information about intervention and co-design/refinement of intervention materials	Create engagement and co-design of intervention materials	Researchers	Face-to-face group meetings	Specialized palliative care service office and hospitals	Before the start of the study (duration ± 2 h)	Timing and location of meetings	Meetings: number of persons attended and topics discussed
2. Raise awareness about the study in the regions	Information brochures about the study	Raise awareness about the study among primary care providers through local primary care networks	Researchers	E-mail	In the region	Before the start of the study	–	Information brochures: number of brochures distributed to primary care providers
3. Training for specialized palliative care services	Training materials	Training sessions, intervision/peer coaching, geriatric advice	Clinical experts and researchers	Face-to-face group meetings	Specialized palliative care service office	Training sessions: before the start of the study (3 half-days) Peer coaching: 2 and 6 months after start of patient identification. Provision of geriatric advice and educational materials: ongoing	Timing and location of meetings	Training sessions: number of persons attended and topics discussed
4. Motivate and coach hospital health and social care staff to identify eligible patients	Information leaflet about the study	Motivate and coach staff to identify eligible patients and co-design of inclusion criteria	Researchers	Face-to-face group	Hospitals	Before the start of the study and ongoing meetings	Timing and location of meetings	Meetings: number, persons attended and topics discussed
5. Timely identification of older people with frailty with complex needs and their family carers	Inclusion checklist (i.e. aged 70 years or over, Clinical Frailty Score 5–7,[28] one or more unresolved or complex symptoms or problems in one of the four palliative care domains, are in a hospital and referred to return to their home). See Supplemental Table 2 for details inclusion criteria, including description of complex needs criterion.	Identification of older people with frailty through screening of patient lists	Hospital health and social care staff	Face-to-face group	Hospitals	Weekly (duration +/− 2 h)	Timing of when patients are screened	–

(Continued)

Table 3. (Continued)

Intervention components	What - materials	What - procedures	Who – intervention providers	How – modes of delivery	Where	When and how much	Tailoring	How well – planned fidelity
6. Inform older people with frailty and family carers about intervention	Information brochure and informed consent form	Inform older person with frailty and family carer and obtain informed consent	Researchers	Face-to-face meetings	Hospitals	Ongoing	Timing of when patients and family carers are visited by the researcher.	–
7. Encourage GPs to participate in the intervention	Information brochure and informed consent form	Encourage GPs to participate and obtain their informed consent	Researchers	Phone calls	In the region	Ongoing	Timing of when GPs are called by the researcher.	–
Core component								
8. Timely short-term specialized palliative care service intervention	Written semi-structured guides for home visits and multidisciplinary meetings (see Supplemental File 1 and 2)	Timely short-term specialized palliative care service intervention facilitated by a nurse of the specialized palliative home care service. The core consists of five subcomponents (see Table 4).	Nurses of the specialized palliative home care services in close collaboration with other involved healthcare providers.	Home visits: face-to-face individual Multidisciplinary meetings: face-to-face group	Patient's home	Over a period of 8 weeks, patients and their family carers receive home visits (1–4) and additional phone follow-up, according to needs. For each patient, at least one face-to-face multidisciplinary meeting (duration +/− 2 h).	The number of home visits and multidisciplinary meetings can be adapted based on the patient's needs. The written semi-structured guides contain topics which can guide the visits but the actual topics addressed can vary per patient as judged appropriate by the nurse.	Home visits: number, duration and topics discussed. Multidisciplinary meetings: number, timing, persons attended and topics discussed. Consultations between service and other health providers: number, and topics discussed.

GPs: general practitioners.

Table 4. Description of the five subcomponents at the core of the timely short-term specialized palliative care service intervention.

	Subcomponents
1	**Short-term delivery of the specialized palliative home care service:** The service is initiated timely in the older person's illness trajectory to meet complex care needs, that is, at times when needs are no longer met by generalist palliative care providers. The service is delivered on a short-term basis, that is, 1–4 home visits by the palliative care nurses with, if needed, additional phone follow-up, over a period of 8 weeks.
2	**Collaborative and integrative working:** The palliative care nurses are encouraged to ensure multiprofessional and multidisciplinary collaboration, coordination and continuity of care from the perspective of the patient and family. This includes the organisation of a multidisciplinary meeting with healthcare professionals involved in patient's care and identifying a key health provider for the patient and family within the primary care team who will coordinate care within the multidisciplinary team.
3	**Holistic needs- and capacity-based care:** The palliative care nurses are encouraged to identify and manage support/care needs in the four palliative care domains that is, physical, psychological, social and existential/spiritual, and to focus on disabilities as well as functioning and capacities (strengths and deficits).
4	**Person- centered and family-focused care:** Viewing family as both care recipients and care providers.
5	**Goal-oriented and pro-active care:** Focus on patient's individual health and care goals across several health, life and care domains; supporting the patient to define and meet realistic or attainable goals and determine how well these goals are being met. This includes the initiation of advance care planning conversations, drafting an out-of-hours plan and emergency response plan.

for the long-term outcomes to be achieved. These preconditions are presented in different colours in Figure 2, according to the level to which they are most applicable (i.e. the level of older people, family carers, health professionals or the healthcare system).

At the start of the intervention, the following stakeholders within a geographic region should be identified: specialized palliative home care services, acute geriatrics department (i.e. geriatricians, social service, geriatric liaison team) and primary health professionals including but not limited to general practitioners and district nurses. The specialized palliative home care services and the acute geriatrics staff should be available and willing to work with the intervention, and primary health professionals in the region should be aware of the intervention. To identify and refer older people with frailty and family carers to the specialized palliative home care service, a first precondition which should be fulfilled is: geriatricians, social service and geriatric liaison team are able to identify older people with frailty and their family carers in a timely manner according to prespecified criteria (see Supplemental Table 2 for more details inclusion criteria):

- aged 70 years or over,
- Clinical Frailty Score 5–7,[28]
- one or more unresolved or complex symptoms or problems in one of the four palliative care domains, these can include situations such as, but not limited to complex end-of-life issues such as being 'tired of living', highly conflicted decision-making, consideration of palliative sedation, requests for assisted dying or euthanasia or other end-of-life decisions; difficulties with advance care planning; patient characteristics or complexity due to cumulation of multiple problems; pre-existing complexity, for example long-standing difficulties with finances/housing or mental health needs; difficult interactions between the patient, family and healthcare professionals (e.g. dissonance or conflicts, older patients who refuse care),[9,29] and
- are in a hospital and referred to return to their home.

Other preconditions were: older people and their family carers are identified, informed about the intervention and asked for consent (representatives give consent for older people without cognitive capacity to do so); the specialized palliative home care services are able to provide the intervention; and the general practitioner is willing to refer to the service (as this is a legal requirement in Belgium). Patients and family carers should then receive the intervention facilitated by a nurse of the specialized palliative home care service to achieve the long-term outcomes.

Intervention components. Based on stakeholders' input and the systematic review,[20] the intervention components that are required to achieve each of the preconditions were identified. We distinguished implementation components and a core component with subcomponents. Following TIDieR, Table 3 summarizes for each of the components the materials and procedures; providers; the 'how', 'where', 'when' and 'how much' of delivery for each component, whether the component can be tailored, and the planned fidelity (i.e. strategies that will be used to maintain or improve intervention adherence).

Rationales. Based on existing evidence and stakeholder's input, we have identified several rationales that support the choice of the different intervention components. The rationales are marked in the Theory of Change map (see Figure 2) and elaborated here.

As implementation science studies have shown, buy-in and engagement of stakeholders (A) is needed to effect change and to create an environment conducive to the successful implementation of the intervention.[30–32] In addition, training and on-going education of the stakeholders (B) on how to use and integrate the intervention into practice is key for optimal implementation.[33] The intervention materials that were co-designed with the specialized palliative care services (i.e. the written semi-structured guides for home visits and multidisciplinary meetings) and the hospital health and social care staff (i.e. inclusion criteria), were produced with an understanding of the local context and meeting the needs of the stakeholders.[34]

Rationales supporting the core component (C) include research indicating that timely initiation and short-term delivery of specialized palliative care services is feasible and beneficial for patients with multiple sclerosis and has been proposed for older people with frailty and multimorbidity.[14,34–36] The professional stakeholders stressed the importance of collaborative and integrative working in primary care and particularly the need for organizing multidisciplinary team meetings, to ensure that there is a mutual understanding of patient's needs, goals and wishes, to allow continuity and coordination of care, identify a key care coordinator, and deliberate an out-of-hours and emergency response plan with the patient and family. This expert advice also corroborates with the multidisciplinary collaborative care model.[37–39] Recent work studying different service delivery models for older people highlighted the need for an integrated approach in this population combining palliative care (which mainly focuses on patients' needs, symptoms and concerns) with rehabilitation/geriatric care (focusing on maintaining and optimizing patient functioning and capacities).[40,41]

The professional stakeholders indicated that older people with frailty with complex needs often require support from family carers. This is also highlighted as a central part of a palliative care approach.[42] This intervention therefore follows a care approach that includes family carers as both care recipients and care providers.[43] The professional stakeholders mentioned goal-oriented care as well as advance care planning as important features; both part of a pro-active care approach which has been advocated as important in the care approach for older people.[44] Hence, as part of the core component, we included the need to have conversations about people's life, health, and care goals, including but not limited to medical care or end-of-life care.[45,46]

Assumptions. Based on the findings of the systematic review[20] and the qualitative research with patients, family carers and professional stakeholders, we identified that the following conditions must be in place to achieve the identified preconditions: (i) 24/7 (telephone) availability of the specialized palliative home care services, (ii) specialized palliative home care services need to have sufficient time for home visits and a multidisciplinary meeting and (iii) specialized palliative home care services are free of charge for patients and family carers.

Discussion

Using a participatory Theory of Change approach, we created a hypothetical causal pathway of a timely short-term specialized palliative care service intervention for older people with frailty with complex needs and their family carers in primary care. This is presented in a Theory of Change map that specifies through which changes and under which circumstances the intervention's long-term outcomes can be achieved. We identified long-term outcomes of the intervention related to the person with frailty (e.g. fewer unmet needs and symptoms), and the family carer (e.g. increased sense of security in care). We identified preconditions on different levels that need to be fulfilled to achieve the long-term outcomes. We have operationalized and systematically described the intervention components, consisting of a core component and implementation components, according to the TIDieR checklist.

The Theory of Change of the intervention provided detailed and comprehensive understanding and transparency of the presumed hypothetical pathway of the implementation and organization of the intervention. This detailed information is deemed crucial to understand how the intervention might work in clinical practice, and to facilitate replication and comparison with other studies.[15,16,23,47] By using this elaborate and participatory approach, we were able to identify all stakeholders that should be involved when aiming to improve care for older people with frailty with complex needs and their family carer in primary care, and determine the multiple intervention components targeting them to achieve the desired change.

We identified several long-term outcomes of the intervention, of which some were expected based on previous research such as fewer unmet needs and symptoms,[48,49] but others were less frequently reported in research such as increased sense of security in care. The patients, family carers and professionals all identified this subjective feeling concerning the provided care as a very relevant outcome in this population. One meta-ethnographic study on the effects of home palliative care[50] also highlighted 'the safety of care at home' but the concept has not been widely studied so far. Trials evaluating effectiveness of palliative care interventions or current outcome measures for a palliative care population (e.g. iPOS) have not yet focused on this as a possible outcome.

Through the participatory Theory of Change workshops with professional stakeholders, we revealed

intervention components that were not made explicit in many other previously developed palliative care interventions including those for older people with frailty in primary care,[20] such as steps to ensure buy-in and engagement with the professionals involved. In addition, we integrated care approaches from different disciplines as the core of the intervention, such as combining palliative care with geriatric and rehabilitative care, and the integration of goal-oriented pro-active care with advance care planning.[40,41] There was consensus among stakeholders that the focus of care should move beyond the purely medical domain to include broader health, life and care domains focusing on the things that matters most to the patient and his/her family, and that realistic or attainable goals should be discussed to guide care.[45,46]

The developed intervention has a short-term nature and outcomes are measured directly after the intervention period, that is, 8 weeks post-baseline. These data will not allow us to determine the sustainability of any positive intervention effects. Earlier studies of short-term palliative care for people with MS[51] and for older people with chronic noncancer conditions[52] both with a service delivery for a period of 12 weeks, showed that the effects appear to wane over time. The developed intervention might have the potential to sustain its effects through its integrative and collaborative care approach, including the organization of multidisciplinary meetings on palliative care with all involved health and social care providers in which ways for future communication and collaboration were established and a key health provider was assigned who coordinates care within the multidisciplinary team. This could enhance coordination and continuity of care after the intervention period and facilitate re-referral of the older person to the specialized palliative service in case of complex care needs. Further research is required to determine whether this can maintain positive intervention effects over time and how exactly.

Although growing attention is paid to involvement of specialized palliative care services based on needs rather than prognosis,[41,42] consensus on complex needs-based criteria for referring older people with frailty to these services is lacking. Following stakeholder's input and the systematic review,[20] we identified criteria for timely identification of older people with frailty to specialized palliative care services in primary care. These criteria were focused on patient characteristics, for example, frailty, and, to an important part, on complex needs. We identified that the necessity of involvement of specialized palliative care services can be based on complex needs in one of the four palliative care domains.

A Theory of Change map developed in one country is likely to be at least partly context-specific. All complex interventions, such as this one, are context-specific. The strength of Theory of Change is to specify the preconditions leading to outcomes so interventions can be more readily adapted. Making all steps in the pathway to change visible, will enable a scientific readership in other countries to evaluate the extent to which the identified preconditions, assumptions or rationales are applicable in their own health care system, and to consider which elements are transferable and which need further adaptation. Nevertheless, we argue that several parts of the developed map are transferable to other countries, particular to high-income countries, where primary care is the main place of care for older people with frailty, and palliative care services are available in primary care but often accessed late. For example the core intervention component, which includes integrated working, holistic, person-centred and goal-oriented care, which are identified as important palliative care approaches in primary care in many countries.[53] Elements that might not be generalizable are those that are most specific to a health care system such as fully reimbursed 24/7 access to specialist palliative home care.

It is notable that the components included in this intervention might not be unique to meet the specific needs of older people with frailty in the community. The model might therefore also be a model of care that is transferable to people with other serious illnesses, although this requires further research. Nevertheless, some parts of the intervention components highlighted by the stakeholders do seem to be more related to a geriatric care approach than to a palliative care approach (e.g. focus on capacity-based care).[41]

This study has some limitations. Although the findings of the interviews and group discussions with patients and family carers were discussed in the Theory of Change workshops, patients and family carers were not involved in constructing the Theory of Change map. In addition, although this approach helps to elucidate the components of a complex intervention, the resulting model remains a rather linear causal model and thus might be a simplification of a complex reality. While the Theory of Change approach (and other theoretical approaches to intervention development) receive increasing scientific attention,[27] it has until now not been proven that interventions that were guided by this approach lead to more effective interventions. It therefore remains to be studied in subsequent research whether this comprehensive development approach can increase intervention effectiveness and guide outcome and process evaluation. In this project, we will first assess the feasibility, acceptability and preliminary effectiveness of the intervention in a pilot randomized controlled trial and conduct an in-depth mixed-methods process evaluation (Trial registration number: ISRCTN39282347).[54] The Theory of Change map will be adapted according to these findings. If the intervention is determined feasible and acceptable, our research might be followed by a full-scale RCT.

Conclusion

We developed and modelled a timely short-term specialized palliative care service intervention for older

people with frailty with complex needs and their family carer, using a Theory of Change approach outlining how and in what circumstances it will lead to specific outcomes. The comprehensive and systematic description of the intervention components, outcomes and preconditions aims to increase replicability and comparability with other interventions.

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Author contributions

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Supplemental material

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