Specialised palliative home care for older people: towards a new service model

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CHAPTERS ARE BASED ON THE FOLLOWING PUBLICATIONS

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De Nooijer K, Pivodic L, Deliens L, Miccinesi G, Vega Alonso T, Moreels S, Van den Block L. Primary palliative care for older people in three European countries: a mortality follow-back quality study. *BMJ Supportive & Palliative Care.* 2019 Oct;bmjspcare-2019-001967. doi: 10.1136/bmjspcare-2019-001967.

Chapter 2

De Nooijer K, Van Den Noortgate N, Pype P, Van den Block L*, Pivodic L*. Palliative care symptoms, concerns, and well-being of older people with frailty and complex care needs who are discharged from hospital to home. Submitted

Chapter 3

De Nooijer K, Penders YWH, Pivodic L, Van Den Noortgate N, Pype P, Van den Block L. Specialist palliative care services for older people in primary care: a systematic review using narrative synthesis. *Palliative Medicine.* Jan 2020;34(1):32-48. doi: 10.1177/0269216319874978.

Chapter 4

De Nooijer K, Pivodic L, Van Den Noortgate N, Pype P, Evans C, Van den Block L. Timely short-term specialized palliative care service intervention for frail older people and their family carers in primary care: development and modelling of the Frailty+ intervention using Theory of Change. *Palliative Medicine.* 2021 Dec;35(10):1961-1974. doi: 10.1177/02692163211040187.

Chapter 5

De Nooijer K*, Pivodic L*, Van Den Noortgate N, Pype P, Van den Block L. Timely short-term specialised palliative care service intervention for frail older people and their family carers in primary care: study protocol for a pilot randomized controlled trial. *BMJ Open.* 2021 Jan;11(1):e043663. doi: 10.1136/bmjopen-2020-043663.

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De Nooijer K, Pivodic L, Van Den Noortgate N, Pype P, Van den Block L. Timely short-term specialised palliative care for older people with frailty and their family in primary care: easier said than done. Submitted

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GENERAL INTRODUCTION

1. BACKGROUND

1.1 OLDER PEOPLE, SYMPTOM BURDEN, FRAILTY

Population ageing and serious health-related suffering

According to a recent report of the United Nations (UN), the number of people aged 60 or over is growing (1). Previous estimations suggest that serious chronic diseases are the leading cause of illness burden (2). Many of these serious chronic conditions become more common with age such as cancer, heart diseases, and dementia (3). In addition, older people are more likely to have multimorbidity (i.e. several chronic conditions simultaneously), frailty, disabilities and/or other health problems (3). It has been projected that by 2060, the total number of deaths will increase to more than 100 million due to the combination of the growing number of older people and those with serious illnesses (4), and this is likely to result in greater levels of avoidable suffering (5). This suffering is primarily expected to increase among the people aged 70 years and over (5).

Symptom burden of older people in the last years of life and disease trajectories

There is a large variation among older people in terms of their health status, social, demographic and cultural characteristics (6). At the end of life, older people often face multidimensional concerns, symptoms and problems that transcend physical, psychosocial, and spiritual domains, and have more than one serious chronic condition (7–11). Looking closer at their physical symptoms and problems, sarcopenia (i.e. loss of skeletal muscle tissue (12)), falling, weight loss, pain, urinary continence, and exhaustion are common in the last years of life (6,13). Next to these physical needs are the social difficulties and problems older people are more likely to experience, compared with younger people (14), which can put them at risk of loneliness or social isolation in the last years of life (15). In addition, depressive symptoms are frequent among older people at the end of life (16), especially among those with frailty (17). A recent systematic review on palliative care needs of older people with multimorbidity and frailty reported that a large proportion of them may be affected by high levels of emotional suffering, as well as functional support needs and cognitive impairment (9). While we should acknowledge that many older people spend a large proportion of their life in relatively good health, and not all older people approaching the end of life face these symptoms, concerns or problems, the complex care needs of those who do experience them often remain unmet. For instance, older people are often affected by pain. Yet, pain is often under-recognized and undertreated in this population (18). It is particularly important to timely and adequately address pain, as it may negatively affect their quality of life and everyday functioning (18). In addition, depression is often underdiagnosed, hindering older people from accessing effective treatments and interventions (13).

Three different disease trajectories of functional decline towards the end of life have been proposed, often distinguished as pertaining to patients with cancer, organ failure and frailty/dementia (19). The disease trajectory of older people with frailty and multimorbidity has been described as a slow decline in functioning that might take up to several years before death (20). The identification of the functional decline trajectory, which might facilitate health and care planning, is more complex in older people due to the wide degree of variation between individuals in the last years of life. Those without major serious chronic diseases experience a slow decline in function, while others experience fast functional decline due to multiple medical and mental problems and co-morbidities at the same time such as cancer, dementia and osteoporosis (19). The problems, symptoms and concerns they experience may therefore occur and fluctuate throughout the whole disease trajectory and not only during the last days/weeks before death, and are often more complex than the needs of their younger counterparts (10).

Frailty in old age

Frailty is common in old age. People with frailty are at high risk of falls, disabilities and hospital admissions (21–24). The estimated global prevalence of frailty widely varies; the pooled prevalence ranges from 11% to 17% between studies (25–27). This is mainly because research on frailty uses a wide range of different terms, conceptualisations, and definitions and is focused on different stages of frailty. Most definitions are focused on the medical and clinical aspects. A frequently used definition described frailty as a condition that *'is characterised by a decline in the physiological capacity of several organ systems that cause an increased susceptibility to stressors'* (28–30). Some of these definitions moved beyond this and used a more holistic definition that focused also on psychological, social, and cognitive aspects (28,31,32). Although different conceptualisations of frailty have been used, there is a consensus among researchers about the considerable variety of the care needs, health and functional status of those affected by frailty (33). Several pivotal elements are also common in all the different definitions (32,34). Specifically, it is an age-related condition and it can be described as 'dynamic', that is, individuals can fluctuate between states and levels of frailty, but mostly worsening rather than improving (32,34). Various models can be used to asses frailty, such as the frailty phenotype (based on physical functioning) (35) and the frailty index (based on deficits across multidimensional domains) (36). There are also more simple tools, often used as clinical starting point, like the Clinical Frailty Scale, that concerns assessment of activities of daily living (ADL) (37).

1.2 PALLIATIVE CARE FOR OLDER PEOPLE IN PRIMARY CARE

Palliative care

It is stated that palliative care should be integrated in the care response for people with serious chronic conditions, including those with frailty, multimorbidity, disabilities and complex care needs (38). According to the World Health Organisation (WHO), palliative care is defined as *'an approach that aims to improve the quality of life of patients and their families who are facing problems associated with life-threatening illness, through the prevention of suffering by early identification, measurement and treatment of multidimensional problems, symptoms and concerns'* (39). Palliative care can be divided into generalist and specialised palliative care (40,41). Ideally, the generalist palliative care providers, with their good basic knowledge and skills regarding palliative care, aim to manage the palliative care needs of all patients with serious chronic conditions in a variety of settings, such as home and nursing home, to support their families and caregivers, and to provide bereavement care (42). Specialised palliative care providers, who are specially-trained in palliative care provision, aim to deliver holistic care for those patients with complex palliative care needs that cannot be managed by generalist palliative care providers alone, and their families (40,41). Their role and tasks involve for instance providing support in complex end-of-life care situations and decisions and to provide education, training and support for other healthcare providers (41,43) There is wide agreement in clinical care and research domains that integration and input of specialised palliative care services should be based on level of complex palliative care needs rather than illness diagnosis and/or life-expectancy (44,45). However, there is currently no agreement regarding the definition, or the level of complex care needs required for referral to specialised palliative care services.

Palliative care for older people

A multidisciplinary integrated holistic needs-based care approach is needed to manage the often multidimensional and complex care needs of older people for long periods of time (19). As older people are often cared for by multiple health and social care providers, such as general practitioners and district nurses, specialised palliative care teams should therefore be integrated into these existing services (13). The WHO guidelines on Integrated Care for Older People report that integration and coordination across settings and professions can be best organised around the goals and wishes of older people and those close to them (46). The care approach for older people aims to improve their quality of life and autonomy, as well as includes the family carer as a critical part of the care process, while improving family carer outcomes and addressing their support and care needs (19). Research has shown that palliative care involves shared common goals and concepts with geriatric/rehabilitative care, specifically, both involve a multidisciplinary care approach that is needs-based rather than prognosis-based and focused on patients and their families (19,46). However, there are differences between the two specialties. Generally, the geriatric care approach is more focused on improvement and maintenance of patient functioning, situation and capacities (47). It is therefore repeatedly suggested that an integrated palliative care and geriatric/rehabilitative care approach should be adopted for older people with palliative care needs, and referral to appropriate services should then be triggered by patient and family needs, goals and wishes (13,48). However, in practice this ideal seems far from being reached. First studies testing integrated palliative care and rehabilitative/geriatric care approaches have only been conducted very recently (49,50).

Low and late access to palliative care

Older people still have low and late access to palliative care services, especially the terminal phase, hence in the literature they are often referred as the 'disadvantaged dying' (13,52). There are several possible reasons that potentially explain the inequality in palliative care for older people. First, ageism, that is described as *'discrimination against older people across societal systems',* for instance in health care settings (52). Palliative care researchers have identified that ageism also has an influence on the access of older people to healthcare services at the end of life (53). Second, their disease trajectory and palliative care needs are often described as unpredictable and unclear, in other words, it is difficult for healthcare providers to precisely estimate the end of life (13). Related to this, there is still limited available evidence on their specific palliative care needs and illness trajectories (19). Lastly, palliative care might not always be considered as relevant care for those who are older with multiple diseases, frailty and disabilities (54). These reasons, together with the predictions that they will have the largest palliative care needs in the upcoming years (5), highlight the urgent need of optimal and adequate palliative care provision for them.

The importance of palliative care at home for older people

The majority of older people are living at home in the last years of life (10) and also reported to prefer to remain there as long as possible (55). However, care transitions at the end of life are common among older people living in high-income countries. Older people are often admitted to and die in nursing homes, care homes or hospitals, rather than at home (10). A mortality follow-back study in England showed that 12% of older people 65 years or over with complex care needs were often admitted to the emergency department; this was particularly the case for those with multiple diseases (56). This percentage is even higher for people with frailty with complex care needs, with almost 25% of them regularly admitted to the emergency department (57). This evidence underscores the necessity for high-quality and cost-effective palliative care at home that is in line with patient and family preferences, wishes and conditions.

There is growing evidence showing the beneficial effects of palliative home care services for people with serious chronic conditions, such as reduced symptom burden (58,59). One of the reviews identified common elements of palliative home care services across the studies, such as multidisciplinary integration across professions and services, and a holistic-needs based care approach (58). In addition, it was identified that the 'core need' of patients receiving home-based care is to have feelings of security at home (60,61). However, these studies mainly involved research concerning patients with advanced cancer. Currently, there is still very limited evidence on which services or structures work best in identifying and managing the palliative care symptoms and concerns of older people with frailty and multimorbidity and their families living at home.

1.3 SERVICE MODELS OF PALLIATIVE CARE IN PRIMARY CARE FOR OLDER PEOPLE

New and promising service models have been proposed for older people living at home and their families. It has been stated that constant and prolonged access to specialised palliative care services for all older people is neither clinically needed nor sustainable for healthcare systems (13,19), and that referral to these services should be in periods when care needs are too complex to be resolved through generalist palliative care providers alone (40,41). Consequently, the so-called 'short-term' integrated models of palliative care in primary care have been proposed as a way to meet the complex palliative care needs of older people with frailty and multimorbidity and their families living at home.

Short-term palliative care services for older people with frailty living at home

A model of short-term specialised palliative care integrated in primary care has recently been developed and evaluated for patients with neurological conditions; patients were recruited from several hospitals in the UK (62,63). Based on these findings, such a model of care has also been designed for older people with serious non-cancer conditions, frailty and multimorbidity (64). It has been described as palliative care provision by multidisciplinary specialised palliative care teams that focus on both patients as well as their families through comprehensive assessment and coordination and continuity of care with their primary care providers, such as general practitioners (64,65). The primary care providers remain the main generalist palliative care providers, and patients can be re-referred to the service in future periods of complex care needs, or at points when their health deteriorates (64). The service model was tested in southern England in a randomised controlled trial (RCT) in which 50 patients were randomised to standard care (n = 26) or to short-term palliative care (n = 24), that is, one to three home visits for a period of three months (65). The short-term palliative care intervention showed to be effective in reducing symptom and concerns experienced by older people with frailty and other serious non-cancer diseases (effect size = 0.071) (65). In addition, the intervention showed to be effective in integrating specialised palliative care services with primary care providers, such as general practitioners and community nurses.

This RCT provided first important evidence of the benefits of a short-term palliative care model for older people. However, the evidence has certain shortcomings. Firstly, this intervention has only been evaluated in a small region; it therefore remains unclear whether this type of intervention would be beneficial for older people with frailty and complex care needs elsewhere. Secondly, the intervention lacks a full description of the intervention components and processes; this hinders us in understanding whether and how the intervention can be transferred to other settings or countries (66). Related to this, it remains unclear which intervention components and processes have led (or have the potential to lead) to changes in outcomes for older people and their family carers. Moreover, important knowledge is lacking on how and under what conditions such interventions can be best implemented in routine clinical practice.

In this thesis, we will develop and model a theory-based timely short-term specialised palliative care intervention for older people with frailty and complex care needs and their families in primary care (i.e. Frailty+ intervention). We will conduct a pilot randomised controlled trial and an embedded process evaluation in Flanders, Belgium. We aim to assess the feasibility, preliminary effectiveness, and implementation of the Frailty+ intervention. The theory-based approach to intervention development and the in-depth process evaluation will provide us comprehensive understanding and transparency of the implementation of the intervention.

1.4 METHODOLOGICAL ASPECTS OF COMPLEX PALLIATIVE CARE INTERVENTIONS

Better understanding of complex palliative care interventions

There are several difficulties in describing and evaluating health service interventions, often due to the level of complexity of such interventions (67). It is particularly challenging to conduct high-quality palliative care trials; frequently reported problems are for instance recruiting the planned number of participants in the planned timeframe resulting in failure in reaching recruitment targets, high attrition rates and difficulties in selection outcomes that best fit with the intervention studied (68). The Methods Of Researching End of Life Care (MORECare) collaboration published guidance on how to deal with common methodological palliative care problems and difficulties (69). Yet, this guidance does not provide detailed guidance for implementation of palliative care research. Palliative care studies often do not provide detailed understanding on the implementation of the intervention in daily practice but mainly focus on evaluating the effectiveness of the intervention. This hinders understanding why (or why not) an intervention was effective. In the literature, this is often called the 'black box' of the intervention, referring to the essential components and processes of an intervention (70,71). Understanding what the black box entails is challenging, probably because of the complexity of most health and care interventions (67). According to the established UK Medical Research Council (MRC) guidance, complex interventions are defined as *'those containing multiple interacting intervention components'* (67). Moreover, the MRC guidance states that such complexity is related to several levels, such as the difficulty of behavioural change required by the stakeholders involved in the intervention (67). Although difficulties are acknowledged in defining this complexity, both previously mentioned guidance documents highly recommend researchers to describe essential procedures and activities of the complex intervention that potentially lead to the changes in outcomes, and how and under what circumstances the intervention should be implemented (67,69).

To facilitate this understanding, the UK MRC recommends using a theory in the development of complex health interventions (67). The use of theories in complex intervention studies has received significant scientific attention, especially the use of mid-range theories from the social sciences (72). Such mid-range theories are often more specific to use in practice and less 'abstract' compared to the grand theories (73). However, a recent guidance on developing complex health interventions by O'Cathain et al (2019) (74) recommends developing and building a programme theory (also called a theory underlying the programme or intervention). Programme theories shed light on how an intervention can lead to the desired change and under what circumstances (74,75). A good example is the participatory Theory of Change that has recently been introduced in advance care planning and palliative care research (76). This Theory of Change can be informed by other mid-range and grand theories, evidence and (professional) stakeholder input, including patients and families, and shows the underlying causal pathways of an intervention (70). In particular, it specifies which changes are needed to achieve the desired intervention outcomes and impact (70,74). Next to providing theoretical understanding, it is advised to provide in-depth information on implementation processes and strategies (67,69). According to the MRC guidance for process evaluations, a thorough description and evaluation of three key process components is required i.e. what is implemented in clinical practice, mechanisms through which the intervention produced change and key contextual factors associated with implementation and outcomes (71). Although it is accepted that it is crucial to conduct process evaluations integrated with outcome evaluations, they are still not always comprehensively (i.e. focusing on the three essential process components) conducted in our field.

Pilot studies before conducting full-scale RCTs

Those developing complex interventions should first assess feasibility and acceptability and pilot trial methods prior to testing the intervention in a full-scale RCT (67). While there is not yet an accepted definition of pilot studies, a recent consensus-based framework described pilot studies as *‘those studies in which the parts or the complete future full-scale evaluation, are conducted on a smaller scale, i.e. piloted, to evaluate whether it is possible’* (77). These studies are particularly important to explore the acceptability of the intervention, integrity of the study protocol, recruitment, retention and randomisation procedures, data collection methods, and selection of relevant outcomes (78). Depending on the results of the pilot study, it may be necessary to conduct another pilot study prior to full-scale evaluation (67). A recent review showed that more palliative care pilot studies have been conducted over the last years (79), yet, they are not always focused on testing the intervention as well as RCT methods and procedures.

2. RESEARCH AIMS

The purpose of this dissertation was to provide an overview of current palliative care provision for and palliative care needs and well-being of older people nationally and internationally. Moreover, we aimed to develop, implement, and pilot a timely short-term specialised palliative care service intervention for older people with frailty and complex care needs and their family carers in primary care. Two specific research aims, each divided into three objectives, guided this dissertation:

Research aim 1 (Part 1): to describe palliative care for older people in primary care and older people's palliative care needs
Objective 1: To examine the quality of primary palliative care for older people in three European countries (Chapter 1).
Objective 2: To examine the symptoms, concerns, and well-being of older people with frailty who are discharged home from the hospital (Chapter 2).
Objective 3: To review evidence on specialised palliative care services for older people in primary care in terms of the activities and outcomes (Chapter 3).

Research aim 2 (Part 2): to describe the development and pilot evaluation of a timely short-term specialised palliative care service intervention for older people with frailty in primary care.
Objective 4: To develop and describe the Theory of Change that outlines the hypothesized causal pathway of a timely short-term specialised palliative service intervention for older people with frailty in primary care (Chapter 4).
Objective 5: To develop the study protocol of a pilot randomized controlled trial and process evaluation to evaluate its effects on patient and family carer level, implementation, mechanisms of change and contextual factors of the intervention (Chapter 5).
Objective 6: To evaluate the feasibility, acceptability, and preliminary effectiveness of timely short-term specialised palliative care service intervention for older people with frailty and their family in primary care (Chapter 6).

3. METHODS

3.1 PALLIATIVE HOME CARE SETTING IN BELGIUM

In Belgium, palliative care is delivered by primary care providers and specialised palliative home care teams. In total, there are 27 palliative care networks in Belgium: 15 in Flanders, eight in Wallonia, one in Brussels and one in the German-speaking community) (80). The multidisciplinary specialised palliative care teams usually consist of nurses, a psychologist, and a palliative care physician. The core tasks of these teams is to support other healthcare professionals, such as general practitioners, and informal carers involved in the provision of palliative home care and to manage and coordinate palliative care between different health and social care providers (80). In Belgium, a general practitioner's permission is required to initiate the service (81)

3.2 OVERVIEW OF METHODS USED IN THE DISSERTATION

In this dissertation, different study designs and methods were used. To provide an overview of current palliative care provision for and palliative care needs and well-being of older people, we used a mortality follow-back study investigating end-of-life care using representative samples of deaths for the whole population of people who died non-suddenly in Belgium, Italy, and Spain (Chapter 1). In addition, we conducted a cross-sectional study using the baseline survey of the pilot RCT to address the objective regarding the symptoms, concerns, and well-being of older people with frailty following hospital discharge (Chapter 2). We also conducted a systematic literature review to provide an overview of articles regarding specialised palliative care services for older people in primary care (Chapter 3). Following the UK MRC guidance for developing and evaluating complex interventions integrated with a Theory of Change approach, we developed and modelled a timely short-term specialised palliative care service intervention for older people with frailty in primary care (Chapter 4) through integrating evidence from Chapter 3 and qualitative research. Accordingly, we designed and conducted a pilot RCT with an embedded process evaluation (Chapter 5 and 6).

3.3 METHODS USED TO ANSWER RESEARCH AIM 1

3.3.1 A mortality follow-back study

To address research objective 1, we used data that were collected as part of the European Sentinel General Practitioner Networks Monitoring End-of-Life Care (EURO-SENTIMELC) study. This is a nationwide representative mortality follow-back study that monitored end-of-life care in population-based samples of people who died non-suddenly only (82). Data were collected through existing nationwide epidemiological surveillance networks (i.e. sentinel networks) of general practitioners (82). The participating general practitioners in Belgium, Italy, and Spain, registered weekly all deaths of patients in their practices who were 18 years or older. General practitioners were asked to judge whether deaths were sudden or non-sudden. In this study, data were collected from 2013 to 2015. We included all patients aged 65 years and over and excluded sudden deaths. We applied a validated set of nine quality indicators (83), comprising: pain measured by the general practitioner often or very often in last three months of life, general practitioner thinks that patient was able to accept their approaching end completely or for the most part, general practitioner discussed at least three illness-related topics with patient, general practitioner was aware of patient preferences about medical treatments, general practitioner discussed at least three illness-related topics with family, multidisciplinary consultation at least once a week during the last month of life, palliative care services involved in last three months of life, patient did not die in hospital and general practitioner contacted or plans to contact relatives about bereavement counselling.

Analysis

We used generalised linear mixed models (GLMMs) to analyse the differences between countries in characteristics and quality indicators scores of those aged 65-84 years and those aged 85 years or older, with country and potential confounders as fixed effects and GP practice as random effect.

Ethical considerations

In Belgium, ethical approval was obtained from the Medical Ethics Committee of the University Hospital Brussels. In Italy, the Local Ethical Committee Comitato Etico della Azienda Sanitaria Firenze, Tuscany, gave approval. No ethics approval was required in Spain.

In all sentinel networks, participation by general practitioners is voluntary. In Italy, general practitioners received financial compensation for participation.

3.3.2 Cross-sectional survey study

To address objective 2, we conducted a cross-sectional study using baseline survey data from the pilot RCT of a short-term specialised palliative care service intervention for older people with frailty and complex care needs (Chapter 5 and 6). Patients were recruited at the participating hospitals and the eligibility criteria are outlined in the section named ‘pilot randomised controlled trial’. All eligible patients were approached by the data managers and the researcher. A structured questionnaire was administered in interview format to patients who agreed to participate, at a place and time of their preference. To measure the symptoms and concerns, we used the IPOS (84). We used the ICECAP-SCM to measure patients’ well-being (85) and the IPOS-VoC to measure the quality of life (86). Descriptive statistics were used to describe the characteristics of the study population, their symptoms, concerns, and well-being. We also tested for Spearman correlations between palliative care needs and well-being, and between the two well-being measures.

3.3.3 Systematic literature review

To meet research objective 3, we conducted a systematic literature review and narrative synthesis with the aim of identifying criteria for referral of older people to specialised palliative care services; who provides specialised palliative care; through which activities and with which frequency; which outcomes are reported; and which suggestions are made to improve services. The electronic databases Embase, Medline, Web of Science, Cochrane, Google Scholar, PsycINFO and CINAHL EBSCO databases were systematically searched. First, we screened titles and abstracts, then full texts. We extracted data from the included articles, including population of older people who were referred to specialised palliative care services, the healthcare professionals involved in these services, activities through which care was delivered and with what frequency. In addition, information was retrieved on the outcomes of specialised palliative care, and, according to the authors of the included research, how the provision of the specialised palliative care could be improved. Following data extraction, we conducted a narrative synthesis (87) and reported patterns of findings across the included studies (87).

3.4 METHODS USED TO ANSWER AIM 2

3.4.1 Intervention development and modelling

We applied an observational study design informed by the UK Medical Research Council (MRC) guidance for developing and evaluating complex interventions (67) integrated with a Theory of Change approach (70). We used the Aspen Institute's Theory of Change of approach (88), that defined a Theory of Change 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'* (88). The Theory of Change is visualised in a Theory of Change map that illustrates through which preconditions (i.e. intermediate outcomes) the intervention's long-term outcomes and impact can be achieved and under which circumstances. We followed the Theory of Change to develop and model the theoretical model of the intervention (Chapter 4) and to inform the development and implementation of the pilot randomised controlled trial with a process evaluation (Chapter 5 and 6).

To address research objective 4, we developed an intervention that aims to provide timely short-term specialised palliative care for older people with frailty and their family carer in primary care. We synthesized evidence from the systematic literature review (Chapter 3) with qualitative research to develop the Theory of Change of Frailty+ (see Figure 1):

- findings from qualitative interviews and groups discussions with older people and their family carers. We purposefully selected a sample of older people who: 1) had a functional impairment according to their physician and 2) had been hospitalized at least once in the past two years. We also selected their family carers. All interviews and group discussions were conducted face-to-face and we used case vignettes to explore which outcomes of care are important to participants and how to improve care at home after hospital discharge.
- findings from the Theory of Change participatory workshops with professional stakeholders (researchers, policymakers, and healthcare professionals). Stakeholders were purposively sampled using the following criteria: 1) providing formal care 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 work. The workshops were conducted face-to-face. We followed a structured format and used a ‘backwards outcome mapping’ approach in the workshops to create the Theory of Change map. This means that participants identified the long-term outcomes of the intervention and subsequently the changes, or preconditions, that are needed to achieve those outcomes. The findings of the systematic literature review and the qualitative research were used to guide the discussion.

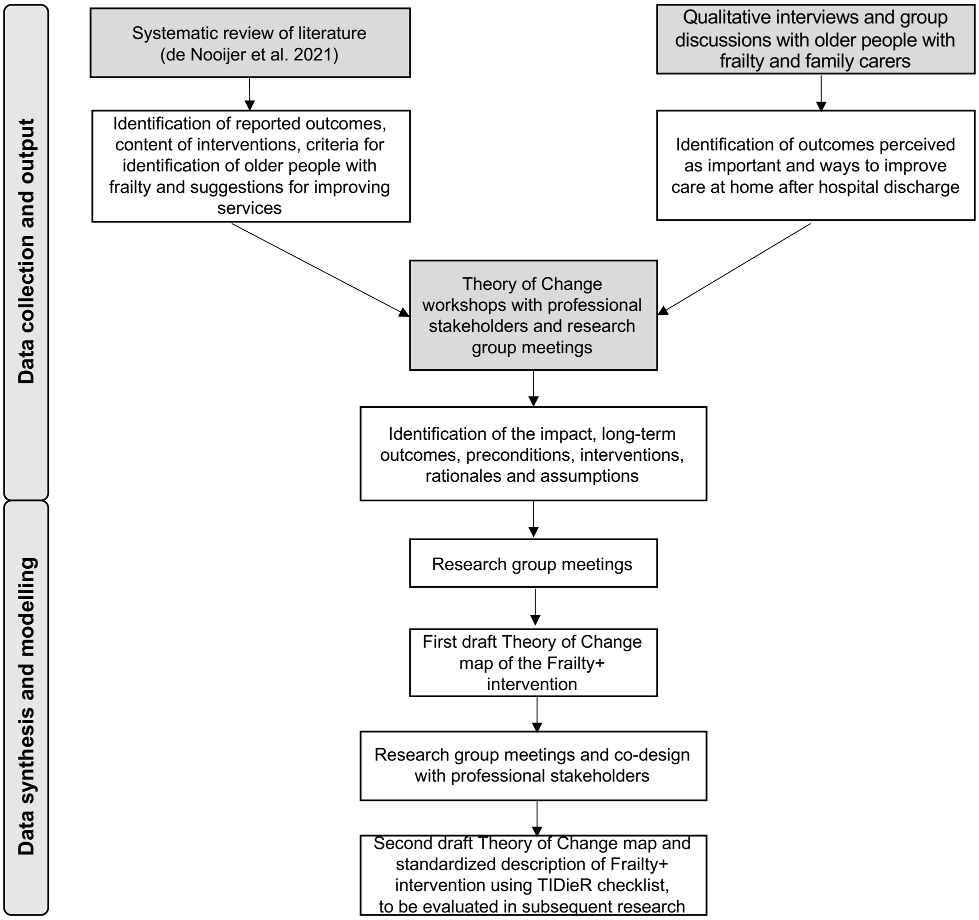

Figure 1. Diagram of information sources and synthesis process for developing the Theory of Change of the Frailty+ intervention.

Analysis

The interviews and group discussions were analysed using directed content analysis. Then the data of the Theory of Change workshops were analysed also using a directed content approach. This resulted in a first draft of the map. The map was checked against relevant literature and co-designed with professional stakeholders. This resulted in the second draft of the Theory of Change map and a detailed description of the Frailty+ intervention using the template for intervention description and replication (TIDieR) checklist (66).

Ethical consideration

The ethical approval for this study was given by the Commission of Medical Ethics of the University Hospital Brussels (B.U.N. 143201732678, date: July 6, 2017).

Participants provided written consent to audiotape the qualitative interviews and group discussions. Oral informed consent was given by the professional stakeholders to audiotape the Theory of Change workshops. All demographic information of the participants was changed when transcribing the recordings of the interviews, group discussions and workshops. The audio-files were deleted immediately after transcription.

3.4.2 Pilot randomised controlled trial

We designed and conducted a pilot randomised controlled non-blinded trial with a parallel group design that aimed to assess the feasibility, acceptability, and preliminary effectiveness of the Frailty+ intervention (Objective 5 and 6). Patient recruitment started in February 2020 and finished in December 2020 (last patient follow-up in February 2021). Patients were recruited at the acute geriatrics department and via the geriatric liaison team of two hospitals (one university hospital). Patients were eligible if they: 1) were aged 70 years or over; 2) had a Clinical Frailty Scale (CFS) score between 5 mild to 7 severe frailty (37) ; 3) had one or more complex unresolved symptoms or problems in one of the four palliative care domains; 4) were in a hospital and referred to return to their home.

Patients were randomised to the control group (standard care) or the intervention group (Frailty+ intervention) (1:1). Patients assigned to the intervention group received the Frailty+ intervention alongside standard care. Patients received 1 – 4 home visits by the specialised palliative care nurse over a period of 8 weeks. The nurses followed a semi-structured guidance to provide holistic needs- and capacity-based care, person-centred and family-focused, and goal-oriented and pro-active care, including initiation of advance care planning conversations and drafting an out-of-hours plan and emergency response plan. Nurses were also encouraged to provide integrative working, including the organisation of a multidisciplinary meeting on palliative care, using a semi-structured guidance document.

The first objective was to assess the feasibility of the RCT methods and procedures. We therefore collected data during and after the intervention period through quantitative methods (registration in standardised documents) and qualitative methods (interviews and focus groups). The second objective was to test the preliminary effects of Frailty+ in older people with frailty and their family carers. The primary outcome was to assess the effects of Frailty+ on five key palliative care symptoms (i.e. breathlessness, pain, anxiety, constipation, fatigue) measured by the Integrated Palliative Care Outcome Scale (IPOS) (84). Other secondary and exploratory outcomes related to patients and family were measured, for instance palliative care needs assessed with the IPOS (84) and well-being measured by the ICECAP-Supportive Care measure (ICECAP-SCM) (85). We used structured questionnaires (interview format) testing for differences in mean changes from baseline to 8-weeks post-baseline in the primary, secondary, and exploratory outcomes between the intervention and control group.

3.4.3 Mixed-methods process evaluation

An in-depth mixed-methods process evaluation was embedded with the pilot RCT to explore the implementation, mechanisms of change and contextual factors potentially affecting implementation and outcomes of the Frailty+ intervention (Chapter 5 and 6). The mixed-methods approach include the registration in standardised documents, the use of structured data extraction form to scan electronic patient records, qualitative interviews, and focus groups. The process evaluation was guided by the MRC process evaluation framework (71) and the Theory of Change map that was created in Chapter 4. We evaluated the following aspects in detail:

- Components and activities that were delivered as part of the Frailty+ intervention, their ‘dose’ or ‘quantity’, and the adaptations that were made to the initial intervention description.
- Views of and experiences with the timely short-term specialised palliative care service intervention, according to healthcare professionals (palliative home care services, GPs, geriatric liaison teams, geriatricians), patients and family carers.
- Occurrence and type of unexpected or adverse effects, according to healthcare professionals (palliative home care services, GPs, geriatric liaison teams, geriatricians), patients and family carers.
- Which external factors, if any, influenced the implementation and outcomes of the Frailty+ intervention.

Analysis

We used descriptive statistics and graphs to describe the quantitative process evaluation and feasibility data of the pilot RCT. The qualitative data were analysed thematically. The effects data was analysed on an ‘intention-to-treat’ principle. We evaluated for differences in mean change from baseline to 8-weeks in the primary, secondary, and exploratory outcomes between the intervention and control group. Generalised linear mixed-model analyses were used with treatment, time, and treatment-by-time interaction as independent variables. We included one random factor for patient ID, to account for the clustering of the two measures within patients.

Ethical considerations

The pilot RCT of the Frailty+ intervention with embedded process evaluation was approved by the Commission of Medical Ethics of the University Hospital Ghent (B.U.N. B670201941807, date: January 22, 2020).

We followed a comprehensive informed consent procedure, taking into account potential cognitive impairment. All collected data was pseudonymised. In addition, we used safety measures to protect the data.

Distress protocol

We developed and used a distress protocol. In case of specific concerns, the researchers together with the patients and family examined which of the regular healthcare providers was available to provide help. Additionally, there was an external psychologist available.

Trial registry

The pilot randomized controlled trial is registered at isrctn.com (Trial registration number: ISRCTN39282347). Date of registry: September 10, 2019.

4. DISSERTATION OUTLINE

The dissertation consists of an introduction, the findings are divided into two parts with related aims and objectives, and a discussion. The first part describes current palliative care provision for and palliative care needs and well-being of older people nationally and internationally. Chapter 1 focuses on the use and quality of primary palliative care for older people in Belgium, Italy and Spain. Chapter 2 explores the symptoms, concerns, and well-being of older people with frailty who are discharged home from the hospital. Chapter 3 presents the results of a systematic literature review on specialised palliative care services for older people in primary care. The second part outlines the development and pilot evaluation of a timely short-term specialised palliative home care service intervention for older people with frailty and their family. Chapter 4 shows the development of the hypothesized causal pathway of a timely short-term specialised palliative service intervention for older people with frailty in primary care through synthesizing evidence of Chapter 3 and qualitative research. Chapter 5 outlines the study protocol of a pilot randomized controlled trial with an embedded mixed methods process evaluation. Chapter 6 analyses the feasibility and preliminary effectiveness of the developed intervention. Finally, this dissertation contains an overview of the main findings, a discussion of the findings, provides the strengths and limitations of the research methods used and implications and recommendations.

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PART 1

Palliative care for older people in primary care

CHAPTER 1

The quality of primary palliative care for older people in three European countries: a mortality follow-back study

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ABSTRACT

Background Many older people with serious chronic illnesses experience complex health problems for which palliative care is indicated. We aimed to examine the quality of primary palliative care for people aged 65 – 84 years and those 85 years and older who died non-suddenly in three European countries.

Methods Nationwide representative mortality follow-back study. General practitioners (GPs) belonging to epidemiological surveillance networks in Belgium (BE), Italy (IT), and Spain (ES) (2013 - 2015) registered weekly all deaths in their practices. We included deaths of people aged 65 and excluded sudden deaths judged by GPs. We applied a validated set of quality indicators.

Results GPs registered 3,496 deaths of which 2,329 were non-sudden (1,126 aged 65-84, 1,203 aged 85+). GPs in BE (reference category) reported higher scores than IT across almost all indicators. Differences with ES were not consistent. The score in BE particularly differed from IT on GP-patient communication (aged 65-84: 61% in BE vs 20% in IT [OR=0.12, 95%CI:0.07 to 0.20] aged 85+: 47% in BE vs 9% in IT [OR=0.09, 95%CI:0.05 to 0.16]). Between BE and ES, we identified a large difference in involvement of palliative care services (aged 65-84: 62% in BE vs 89% in ES [OR=4.81, 95%CI:2.41 to 9.61] aged 85+: 61% in BE vs 77% in ES [OR=3.1, 95%CI:1.71 to 5.53]).

Conclusions Considerable country differences were identified in the quality of primary palliative care for older people. The data suggest room for improvement across all countries, particularly regarding pain measurement, GP-patient communication and multidisciplinary meetings.

INTRODUCTION

There is a rising number of deaths in old age (1) accompanied by serious chronic conditions, such as cardiovascular diseases, cancer and dementia (2). Many older people are affected by multimorbidity, which is the simultaneous presence of multiple chronic conditions (3). The end of life of older people is thus often characterized by complex health problems, symptoms and disabilities that require palliative care (4). According to the World Health Organization, palliative care aims to improve the quality of life of patients with a life-threatening disease (5). Yet, concerns have been raised about the access to palliative care for older people, especially in primary care, as most approaching the end of life wish to be cared for and to die in their usual place of care (6–8). Evidence shows that older people who are dying from serious chronic conditions may be receiving poor end-of-life care, such as poor communication regarding wishes and preferences for care and care planning (1,4,9–13). Similarly, access to palliative care and symptom control is increasingly problematic in old age (10).

Despite these concerns, there is insufficient population-based data to assess the quality of palliative care for older people dying from serious chronic conditions and to determine whether there are specific patient groups or care domains where improvements in quality can be made. In particular, there are few cross-national studies that permit comparison of the quality of palliative care in different health care systems. This precludes evidence-informed policy-making to ensure high-quality palliative care for older people. Existing population-based studies assessing the quality of palliative care for older people focus on the last week of life only (14) or are limited to a particular diagnosis such as cancer (14) or dementia (15), thereby excluding large groups of older people for whom palliative care may also be relevant.

Measuring the quality of palliative care is complicated because palliative care often involves multiple healthcare professionals in various disciplines and health care settings, has a multidimensional nature and is integrated within a larger spectrum of healthcare services (16,17). In many countries, general practitioners (GPs) have a good view of the care their patients received from them and other health care providers, hence our use of representative epidemiological surveillance networks based in general practice provides an important opportunity for evaluation (18).

The systematic evaluation of quality can be achieved by using a core set of quality indicators defined as ‘measurable items referring to the outcomes, processes, or structure of care’ (19) judged as critical in the evaluation of the quality of palliative care (16,20). The quality indicators assessed in general practice can therefore measure quality across different settings as delivered by various healthcare professionals and can be used to capture the quality of care on an aggregated, e.g. national, level (19).

We conducted this study in three countries, Belgium, Italy and Spain. All three countries have legislation and/or national strategies for primary palliative care provision (21-23), but there are also important differences in the way primary palliative care is organized. For instance, GPs in Spain fulfil a gatekeeping function to specialist palliative care services (18). In Belgium and Italy, GPs have a partial gatekeeping function in that their referral is required for certain specialist palliative care services (such as specialist palliative home care in Belgium) but not for others (e.g. involvement of a mobile palliative care team in the hospital) (18). GPs in Belgium and Italy still have an important coordinating role within health care, and most people in these countries have a GP whom they consult regularly (18). Furthermore there are differences between these countries in how certain aspects of dying and palliative care are approached that may impact on the quality of primary palliative care (24). This includes, but is not limited to, communication about end-of-life, disclosure of diagnosis and prognosis and reliance on family care (24).

The overall aim of this study was to answer the following research question: what is the quality of primary palliative care for people aged 65 – 84 years and those 85 years and above who died non-suddenly in Belgium, Italy and Spain?

METHODS

Study design and procedure

The data were collected as part of the European Sentinel General Practitioner Networks Monitoring End-of-Life Care (EURO-SENTIMELC) study, which was a cross-national mortality follow-back study that monitored end-of-life care in population-based samples of deceased people (18). The data were collected through nationwide sentinel networks of GPs. In Belgium and Spain, these are existing regional and national epidemiological surveillance networks consisting of representative samples of GP practices or community-based physicians. In Italy, a new network was formed for this study by the Italian Society of General Practitioners through a procedure similar to that in the other countries; GPs were only informed about the procedure and not about the subject of the surveillance in order to avoid overrepresentation of those with a particular interest in palliative care. The networks in Belgium and Italy were nationwide; in Spain we collected data only from two autonomous regions: the Valencian Community and Castile and Leon.

All deaths of patients aged 18 years or over were registered weekly by the participating GPs using a standardized registration form and classified as sudden and totally unexpected or non-sudden, a common method in palliative care research for retrospectively identifying people for whom palliative care was a realistic option (25,26). In Belgium and Spain this was done from January 2013 to December 2014 and in Italy from June 2013 until May 2015.

Setting and participants

We included deaths of patients who were 65 years or older which were non-sudden as judged by the GP.

Measurements

The standardized registration form consisted of open- and closed-ended items. As well as assessing quality indicators, it asked about patient characteristics such as age, sex, primary cause of death, dementia diagnosis, main place of residence in the last year of life and place of death.

Main outcome measure – Quality Indicators

The quality indicators used in this study are based on the work of Leemans et al, 2015 (27). They measure the quality of palliative care services by assessing nine important domains of palliative care (i.e. physical, psychosocial, communication with patients, communication with relatives, multidisciplinary consultation, type of end-of-life care, continuity of care, support for relatives and structure of care). From that set, the EUROSENTIMELC consortium selected those applicable to primary care and reformulated them into questions suitable to be answered by GPs. The questions underwent review by primary palliative care experts from Belgium, Italy, Spain, France and the Netherlands and were then ranked; those with a score of at least 7.5 (scale 1 – 10) remained, ensuring that there was at least one question per domain of quality indicators of palliative care. The quality indicators were selected through a multi-step process which can be found elsewhere (15,28). The final core set consisted of nine quality indicators, of which two (3.1 and 4) cover the third palliative care domain:

> 1: percentage of patients whose pain was known by the GP to be monitored regularly during the last three months of life
>
> 2: percentage of patients known by the GP to have accepted that they were nearing the end of life
>
> 3.1 and 4: extent to which patients and relatives receive information from the GP about diagnosis, prognosis, disease progression, advantages and disadvantages of treatments and palliative care options
>
> 3.2: percentage of patients who expressed a specific wish about a medical treatment
>
> 5: repeated (on several occasions) formal multidisciplinary consultation with and between care providers (between settings, including GP) about care goals and palliative care option
>
> 6: percentage who received palliative care services (29) involved in last three months of life
>
> 7: percentage who did not die in a regular hospital unit

8: percentage for whom the GP contacted or planned to contact the relatives regarding bereavement counselling.

Statistical analyses

Differences between countries in characteristics and quality indicator scores of those aged 65 – 84 years and those aged 85 years or over were analysed by using generalised linear mixed models (GLMMs) with country and potential confounders (patient characteristics that differed significantly between countries) as fixed effects and GP practice as random effect. Using GLMMs allows us to account for clustering of patient data within GP practices (possibility that one GP provided data on several patients). All analyses were completed with SPSS25.0 (IBM Corp, Armonk, NY).

Ethical approval

In Belgium the study protocol was approved by the Ethical Review Board of Brussels University Hospital of the Vrije Universiteit Brussel. In Italy the ethical approval for data collection was obtained from the Local Ethical Committee Comitato Etico della Azienda Sanitaria Firenze, Tuscany. No ethics approval was required in Spain.

RESULTS

Patient characteristics

General practitioners registered 3,496 deaths of which 2,329 were non-sudden. The people aged 65-84 years (n=1126) were predominantly male and those aged 85 years and older (n=1203) predominantly female (Table 1). In both age groups the majority did not have a diagnosis of dementia and significant differences between the countries were only found among those aged 65-84 years (p=0.003). In the last year of life, between 77% in Belgium and 93% in Spain of those aged 65-84 years resided at home (p=0.000), and 45% in Belgium to 88% in Italy of those aged 85 years and older resided at home (p=0.000). The most common cause of death in those aged 65-84 years was cancer (p=0.015) and of those aged 85 years and older cardiovascular diseases (p=0.014).

Table 1. Patient characteristics (n = 2329)

Patient characteristics	People aged 65 – 84 years (n=1126)				People aged 85 years and older (n=1203)			
	Belgium (n=718)	Italy (n=254)	Spain (n=154)		Belgium (n=690)	Italy (n=342)	Spain (n=171)	
	n (%)	n (%)	n (%)	Pvalue†	n (%)	n (%)	n (%)	Pvalue†
Mean age at death (SD)	76.7 (5.7)	77.7 (5.3)	77.3 (5.5)	0.080	90.1 (4.2)	90.5 (4.0)	90.7 (4.3)	0.140
Gender, female	337 (47.1)	123 (49.2)	55 (35.7)	**0.020**	462 (67.2)	230 (68.0)	103 (60.2)	0.320
Dementia diagnosis								
None	467 (69.5)	182 (72.2)	130 (86.1)	**0.003**	328 (50.2)	164 (48.8)	87 (52.1)	0.799
Mild	83 (12.4)	35 (13.9)	13 (8.6)		136 (20.8)	79 (23.5)	39 (23.4)	
Severe	122 (18.2)	35 (13.9)	8 (5.3)		190 (29.1)	93 (27.7)	41 (24.6)	
Longest place of residence in the last year of life	515 (77.3)	231 (92.0)	136 (92.5)	**0.000**	290 (45.0)	300 (88.2)	129 (75.9)	**0.000**
At home	151 (22.7)	20 (8.0)	11 (7.5)		354 (55.0)	40 (11.8)	41 (24.1)	
Care home*								
Main cause of death								
Cancer	348 (51.4)	121 (50.2)	104 (68.0)	**0.015**	160 (24.4)	53 (15.6)	39 (22.8)	**0.014**
Cardiovascular disease	89 (13.1)	40 (16.6)	14 (9.2)		172 (26.2)	126 (37.1)	45 (26.3)	
Nervous system disease	75 (11.1)	21 (8.7)	7 (4.6)		75 (11.4)	32 (9.4)	21 (12.3)	
Respiratory disease	54 (8.0)	26 (10.8)	6 (3.9)		72 (11.0)	43 (12.6)	9 (5.3)	
Stroke (CVA)	39 (5.8)	12 (5.0)	3 (2.0)		61 (9.3)	34 (10.0)	18 (10.5)	
Other	72 (10.6)	21 (8.7)	19 (12.4)		116 (17.7)	52 (15.3)	39 (22.8)	

SD, standard deviation; CVA, cerebrovascular accident.
People aged 65 – 84 years: Missing data, n (%): gender, 6 (0.5), dementia diagnosis, 51 (4.5), longest place of residence in the last year of life, 62 (5.5), main cause of death, 55 (4.9).
People aged 85 years and older: Missing data, n (%): gender, 7 (0.6), dementia diagnosis, 46 (3.8) , longest place of residence in the last year of life, 49 (4.1), main cause of death, 36 (3.0).
† Tested for differences between countries using generalised linear mixed models to account for clustering at GP level.
* Includes care/nursing homes, 'elsewhere' not included in analysis.

Quality of primary palliative care in Belgium, Italy, and Spain

Higher quality indicator scores were reported in Belgium than in Italy in both age groups (Table 2). Exceptions are discussions between GPs and family of illness-related topics (aged 65-84: 76% in Belgium vs 82% in Italy [OR=1.50, 95%CI: 0.90 to 2.49]; aged 85+: 81% in Belgium vs 83% in Italy [OR=1.17, 95%CI: 0.72 to 1.90]) and bereavement counselling (aged 65-84: 68% in Belgium vs 68% in Italy [OR=1.29, 95%CI: 0.73 to 2.29]; aged 85+: 64% in Belgium vs 69% in Italy [OR=0.93, 95%CI: 0.54 to 1.63]). We found a difference in discussions between GPs and patients regarding illness-related topics for more patients in Belgium than in Italy (aged 65-84: 61% in Belgium vs 20% in Italy [OR=0.12, 95%CI: 0.07 to 0.20]; aged 85+: 47% in Belgium vs 9% in Italy [OR=0.09, 95%CI: 0.05 to 0.16]). Among those aged 65-84 years, we also found a difference for the quality indicator regarding GP awareness of patient preferences about medical treatments (44% in Belgium vs 15% in Italy [OR=0.16, 95%CI: 0.10 to 0.27]). Among those aged 85 years and older, there were differences in the quality indicators on involvement of palliative care services in the last month of life (61% in Belgium vs 18% in Italy [OR=0.18, 95%CI: 0.11 to 0.30]) and pain measurement in the last three months of life (45% in Belgium vs 15% in Italy [OR=0.20, 95%CI: 0.11 to 0.39]).

We also identified important differences between Belgium and Spain in involvement of palliative care services in the last three months of life (aged 65-84: 62% in Belgium vs 89% in Spain [OR=4.81, 95%CI:2.41 to 9.61]; aged 85+: 61% in Belgium vs 77% in Spain [OR=3.1, 95%CI:1.71 to 5.53]) (Table 2). In those aged 65-84 years we found differences for the quality indicator on GP awareness of patient preferences about medical treatments (44% in Belgium vs 18% in Spain [OR=0.18, 95%CI: 0.11 to 0.31]) and in those aged 85 years and older on multidisciplinary consultations during the last month of life (38% in Belgium vs 10% in Spain [OR=0.15, 95%CI: 0.08 to 0.30]).

Table 2. Quality indicator scores for people aged 65 – 84 years and people aged 85 years and older between Belgium, Italy, and Spain (n = 2329)

	People aged 65 – 84 years (n=1126)					People aged 85 years and older (n=1203)				
	Belgium (n=718)	Italy (n=254)		Spain (n = 154)		Belgium (n=690)	Italy (n=342)		Spain (n = 171)	
	n (%)	n (%)	OR (95% CI)	n (%)	OR (95% CI)	n (%)	n (%)	OR (95% CI)	n (%)	OR (95% CI)
1. Pain measured often or very often in last 3 months of life	318 (46.2)	58 (23.2)	**0.25 (0.14 – 0.43)**	87 (64.9)	**2.75 (1.41 – 5.37)**	303 (45.1)	50 (14.8)	**0.20 (0.11 – 0.39)**	75 (46.6)	**1.94 (1.00 – 3.77)**
2. GP thinks that patient was able to accept their approaching end completely or for the most part*	393 (55.4)	98 (39.2)	**0.33 (0.20 – 0.52)**	69 (49.6)	0.70 (0.40 – 1.22)	423 (62.8)	167 (49.1)	**0.44 (0.25 – 0.76)**	64 (38.8)	**0.27 (0.15 – 0.49)**
3.1. GP discussed at least 3 illness-related topics† with patient	381 (60.8)	50 (19.7)	**0.12 (0.07 – 0.20)**	44 (44.0)	**0.28 (0.16 – 0.48)**	254 (46.9)	32 (9.4)	**0.09 (0.05 – 0.16)**	21 (32.8)	**0.49 (0.25– 0.96)**
3.2. GP was aware of patient preferences about medical treatments	309 (43.5)	37 (14.6)	**0.16 (0.10 – 0.27)**	28 (18.4)	**0.18 (0.11 – 0.31)**	235 (34.3)	39 (11.6)	**0.21 (0.12 – 0.35)**	19 (11.2)	**0.20 (0.11 – 0.37)**
4. GP discussed at least 3 illness-related topics† with family	492 (76.4)	209 (82.3)	1.50 (0.90 – 2.49)	114 (86.4)	**1.92 (1.03 – 3.57)**	514 (81.2)	282 (82.5)	1.17 (0.72 – 1.90)	127 (82.5)	1.19 (0.67 – 2.10)
5. Multidisciplinary consultation at least once a week during the last month of life	246 (35.2)	46 (18.5)	**0.38 (0.23 – 0.63)**	35 (25.9)	**0.44 (0.26 – 0.74)**	259 (38.4)	44 (13.1)	**0.29 (0.17 – 0.52)**	16 (10.0)	**0.15 (0.08 – 0.30)**
6. Palliative care services involved in last 3 months of life	407 (62.3)	113 (48.1)	**0.56 (0.35 – 0.88)**	112 (88.9)	**4.81 (2.41 – 9.61)**	376 (60.5)	57 (18.3)	**0.18 (0.11 – 0.30)**	102 (77.3)	**3.1 (1.71 – 5.53)**
7. Patient did not die in hospital§	468 (66.5)	162 (63.8)	1.05 (0.70 – 1.58)	88 (61.1)	0.94 (0.59 – 1.48)	507 (74.9)	246 (72.4)	**1.71 (1.18 – 2.48)**	109 (67.3)	1.02 (0.66 – 1.57)
8. GP contacted or plans to contact relatives about bereavement counselling	482 (68.2)	170 (67.7)	1.29 (0.73 – 2.29)	109 (72.7)	1.20 (0.67 – 2.14)	436 (64.1)	229 (68.6)	0.93 (0.54 – 1.63)	112 (67.1)	0.97 (0.55 – 1.73)

OR, odds ratio; CI, confidence interval; GP, general practitioner.

Reference group = Belgium.

Tested for the differences between countries using generalised linear mixed models to account for clustering at GP level and to adjust for patient characteristics that differed between the countries.

People aged 65 – 84 years: Missing data, n (%): Pain measured, 53 (4.7), accepted death, 27 (2.4), discussion with patient,145 (12.9), preference medical treatments,10 (0.9), discussion with family, 96 (8.5), multidisciplinary consultation, 44 (3.9), palliative care services involved, 112 (9.9), place of death, 24 (2.1), bereavement counselling, 18 (1.6).

People aged 85 years and older: Missing data, n (%): Pain measured, 32 (2.7), accepted death, 24 (2.0), discussion with patient, 255 (21.2), preference medical treatments, 11 (0.9), discussion with family, 74 (6.2), multidisciplinary consultation, 31 (2.6), palliative care services involved, 138 (11.5), place of death, 24 (2.0), bereavement counselling, 22 (1.8).

* Excluded 'don't know' (people aged 65 – 84 years, 293, people aged 85 years and older, 387).

† The topics discussed were: diagnosis, course of the disease/prognosis, the approaching end of life, advantages and disadvantages of the treatments, options in terms of end-of-life care.

§ Regular hospital wards excluding palliative care units

DISCUSSION

In both age groups, for almost all quality indicators, higher scores were found for Belgium than Italy, and fewer consistent differences were found between Belgium and Spain. General practitioners in all countries reported relatively low scores on pain measurement in the last three months of life, discussions between GPs and patient and multidisciplinary consultations during the last month of life. At the same time, relatively high scores were reported in all countries regarding discussions between GP and family of illness-related topics and bereavement counselling.

The three countries in the study have palliative care frameworks and strategies that specify standards and aims regarding the organization and provision of palliative care (21-23); however, having frameworks and strategies alone is not enough to achieve high quality palliative care. We identified that the overall quality of primary palliative care for the older population in Italy was considerably lower than in Belgium. The relatively high scores in Belgium may be explained by the well-established palliative home care teams and region-wide palliative care networks that promote collaboration and sharing of knowledge and expertise with GPs (30,31). In Italy, on the other hand, palliative home care is still mainly provided to people with cancer (32), which may contribute to lower quality indicator scores for the population included in this study. The differences between Belgium and Spain were not consistently in the same direction. In Spain, we identified relatively high quality indicator scores on the involvement of specialized palliative care services in the last three months of life. In the last decade, considerable efforts have been made in Spain to expand palliative care services from cancer to non-cancer patients (33,34), with a close collaboration between GPs and palliative care services (33). The differences in the scores on the involvement of specialized palliative care services are not necessarily concerning; GPs often provide palliative care themselves. However, this needs further research as we can expect exacerbations and complex situations among an older population where specialized advice and collaboration with the GP can be highly beneficial.

In all three countries there is room for improvement in the quality of primary palliative care for the older population. This is an urgent matter given the rising number of people who are in need of palliative care, the current ageing of populations and trends in chronic morbidity (1). We identified that pain was not regularly measured in the older population. This is concerning given that poor pain assessment has been cited as an important barrier to adequate pain control (35). Research shows pain is an important symptom in around a third of the older population (4,35,36); it is therefore crucial that frequent comprehensive pain assessment is provided (37).

We found that in all countries more than half of GPs did not communicate with the patient (except for those aged 65-84 years in Belgium) regarding illness-related topics and were not aware of their preferences about medical treatments. These low scores may be influenced by the difficulty of prognosis in older people (38), something seen as an important barrier to the initiation of discussion with the patient, i.e. difficulties in deciding the ‘right’ time to broach the topic (38). Decline in e.g. speech and cognition could also hinder communication (39) and cultural factors are also likely to influence it; in several countries, including Italy, partial or non-disclosure in advanced diseases is still common (24).

General practitioners in all countries reported relatively high scores on communication with the family carer. As most people resided at home in the last year of life, especially in Italy and Spain, it seems that the family carer was highly involved in care and that GPs tend to communicate with them as an alternative to communicating with the patient.

The complex needs and problems of older people require joint working and interdisciplinary collaboration between different healthcare professionals (4). In our study, we identified that for most people there were no regular multidisciplinary meetings conducted in the last month of life (i.e. fewer than one a week). As multidisciplinary meetings are crucial in facilitating interdisciplinary collaboration (40), they should be conducted regularly. In Spain and Belgium, efforts have been made to encourage and provide guidance in facilitating interdisciplinary collaboration (41,42). The Spanish Association of Palliative Care (SECPAL) developed a model recommending multidisciplinary meetings, but does not yet provide a clear guidance on how to organize such meetings (41). The Belgian Health Care Knowledge Centre (KCE) has developed a position paper that makes recommendations for organising these meetings in an efficient manner, such as by using a shared care plan or a shared patient medical record (42). In addition, appointing a key person responsible for organizing such multidisciplinary meetings could improve their quality (40).

Strengths and limitations

To our knowledge, this is the first cross-national population-based study using a validated minimum quality indicator set to measure the quality of primary palliative care for older people. We used existing sentinel networks of GPs in the three European countries and therefore obtained samples of deaths representative for the GP population in the three countries (18). Another strength is that GPs conducted registrations weekly, limiting recall bias (18). The identification of non-sudden deaths as denominator is an advantage compared with including patients who died suddenly and unexpectedly because the patients who died non-suddenly were likely to have received palliative care. Our study also has limitations. We used only GP estimations of the care provided by themselves and not by others, so misclassifications might have occurred. Future studies should consider to also include the views of other healthcare professionals who are important providers of generalist palliative care, such as district and community nurses.

Conclusion

This study found that there are considerable cross-country differences in the quality of primary palliative care for older people, probably reflecting different healthcare systems and cultures. Our findings show that the overall quality of primary palliative care for older people could be improved. Initiatives are needed to support regular pain measurement, communication between GP and patient and frequent multidisciplinary meetings in the last month of life. These focal points should become a priority for policy-makers and healthcare professionals, given the rising number of older people in need of palliative care.

Contributors: LD, GM, TVA and LVdB designed the study. LVdB, LD and LP contributed to the construction of the quality indicators. SM, GM and TVA monitored data collection. KdN and LP analysed the data. All authors contributed to data interpretation. KdN drafted the article. All authors critically reviewed the article and gave final approval of the version to be published.

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CHAPTER 2

Palliative care symptoms, concerns and well-being of older people with frailty and complex care needs upon hospital discharge

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Submitted

ABSTRACT

Background: Little is known about the nature and intensity of palliative care needs of older people who are hospitalised. We aimed to describe the palliative care symptoms, concerns, and well-being of older people with frailty and complex care needs upon discharge from hospital to home, and to examine the relationship between palliative care symptoms and concerns, and well-being.

Methods: Cross-sectional study using baseline survey data of a pilot randomised controlled trial. Hospital staff identified patients (>=70y) about to be discharged home, with a clinical frailty score of 5 to 7 and complex care needs based on pre-defined criteria. Patients completed structured interviews, using the Integrated Palliative Care Outcome Scale (IPOS), ICECAP Supportive Care Measure and IPOS Views on Care quality of life item.

Results: We assessed 37 older people with complex care needs (49% women, mean age 84). Symptoms rated as causing severe problems were weakness (46%) and poor mobility (40%); 75% reported that their family felt anxious at least occasionally. Of the 17 IPOS items, 86% of patients rated at least one symptom as causing severe problems. Eighty-seven percent expressed feeling supported. There was a negative correlation between symptoms and concerns (IPOS) and well-being (ICECAP); r = -0.41.

Conclusions: We identified a large variety of symptoms experienced by older people identified as having frailty and complex needs upon hospital discharge. Many were severely affected by multiple symptoms and concerns. This population should be considered for palliative care follow-up at home.

INTRODUCTION

People are living longer and many are confronted with multimorbidity and frailty (1). It has been reported that community-dwelling older people often experience diverse and multiple complex health and social care needs in the last years of life (2,3). Many of them are regularly admitted to the hospital (4). A recent study in England showed that almost 25% of older people with deteriorating health and complex care needs were admitted to the emergency department in the last year of life (5).

Palliative care is indicated to manage the symptoms and problems experienced by older people as they near the end of life (6). It is considered as an important component of integrated and comprehensive care for people with complex care needs (6). Such needs of older people near the end of life need to be addressed by health and social care providers, in the hospital and particularly when these patients are discharged home. Suboptimal management of their complex symptoms and concerns may lead to negative outcomes such as readmissions to the hospital and emergency department visits (7–10).

However, little is known about what the extent of these complex needs is in the various domains relevant to health and care towards the end of life, that are, the physical, psychological, social, and spiritual domains. Previous research concerning older people upon hospital discharge mainly focused on their clinical characteristics and physical symptoms such as level of frailty (11), functional status (12,13), or on specific symptoms or concerns such as pain and anxiety (14). But these data do not comprehensively cover the multidimensional needs and concerns relevant towards the end of life and their inter-relationship. Moreover, previous studies did not identify patients judged as having complex care needs, thus failing to capture an important at-risk group concerning poor health outcomes and poor well-being. A reason for this is the difficulty of obtaining patient-reported research data among older people in very poor health, who are also a potentially vulnerable population (15).

Within a recent pilot randomised controlled trial (RCT) (16), we collected extensive data on multidimensional needs and well-being of older people upon discharge from the hospital. The aim of this analysis is to describe the palliative care symptoms, concerns, and well-being of older people who are identified by clinicians as having frailty and complex care needs upon hospital discharge to their home, and to examine the relationship between palliative care symptoms and concerns, and well-being.

METHODS

Study design

We conducted a cross-sectional study using baseline survey data from a pilot randomised controlled trial (RCT) testing the feasibility, acceptability and preliminary effectiveness of a short-term specialised palliative care service intervention for older people with frailty and complex needs in primary care in Flanders, Belgium (16). Data were collected from February to December 2020. The study was approved by the ethics committee of Ghent University Hospital (B.U.N. B670201941807, date: January 22, 2020).

Setting and participants

We aimed to include 50 eligible patients; details on the sample size calculation are reported in the study protocol of the pilot RCT (16). Patients were recruited at the acute geriatric department and through the geriatric liaison teams of two hospitals in Flanders, one of which is a university hospital. The aim of multidisciplinary geriatric liaison teams is to support other hospital care staff according to geriatric care provision and to provide care for all hospitalised people with a geriatric profile admitted to a non-geriatric unit (17). Patients were eligible for this study if they were:

- aged 70 or over,
- had a Clinical Frailty Scale score (CSF) between 5 and 7 (18),
- had one or more unresolved or complex symptoms or problems in one of the four palliative care domains as judged by their treating physician, these can include situations such as, but not limited to complex end-of-life issues such as being ‘tired of living’, difficulties with advance care planning, mental health problems, and difficulties in communication among patients, family and professionals (19,20),
- were admitted to a hospital and about to be discharged home, and
- were Dutch-speaking.

The data managers (KE, AJ) and the researcher (KdN) informed eligible patients. Those patients who were interested in the study were asked to provide consent. In case a person lacked capacity to consent, the appropriate representative as specified in the Belgian law for patient rights was approached (21).

Data collection and questionnaires

All eligible patients were approached by the study’s data managers /researcher. Hospital staff extracted the following characteristics from the medical files of patients who had consented to participate: age, gender, living situation, clinical frailty scale score (18), and medical diagnosis. The researcher and data managers administered a structured questionnaire in interview format at the patient's place of preference. The questionnaires surveyed patient's socio-demographic characteristics, symptoms, concerns, and well-being.

To measure symptoms and concerns we used:

- Integrated Palliative Care Outcome Scale (IPOS) (22): the measure includes free text responses and a 17-item measure of frequent palliative care needs among people with serious chronic conditions (22,23). Individual item scores range from 0 (absent) to 4 (overwhelming), while total scores range from 0 (minimum burden) to 68 (maximum burden) (24). The higher the score, the greater the palliative care symptoms and concerns.

To measure well-being, we used:

- ICECAP Supportive Care Measure (ICECAP-SCM) (25): a capability end-of-life measure. Patients were asked to rate aspects of well-being across seven domains: choice, love and affection, freedom from physical suffering, freedom from emotional suffering, dignity, support, and preparation. Individual attribute scores range from 1 (no capability) to 4 (full capability).
- One item of the IPOS Views on Care (VoC) measure (26): patient's rating of the overall quality of life on the same day. The item score ranges from 1 (very poor) to excellent (7).

Statistical analysis

Descriptive statistics were used to describe the characteristics of the study population, their symptoms, concerns, and well-being. We used frequencies and percentages for the categorical variables. We used means and standard deviations for the continuous data. We calculated Spearman correlations between palliative care needs (IPOS total scores) and well-being (ICECAP-SCM total scores and IPOS VoC quality of life item score) and between the two well-being measures (IPOS VoC quality of life item score and ICECAP-SCM total scores). All analyses were performed with IBM SPSS statistical software version 27. We considered p-values lower than 0.05 as statistically significant.

RESULTS

In total, 145 eligible patients were approached to participate in the pilot RCT, of whom 47 consented and 37 were enrolled (10 were not enrolled due to the following reasons: patient admitted to nursing home (n=1), patient died or was hospitalised before next visit (n=2), not possible to approach before discharge (n=1), not interested anymore (n=3), concerns about COVID-19 (n=3)). The patients who were not enrolled in the study (n=108), were more likely to live alone than those enrolled (48% vs. 35%) but mean age and gender proportions were comparable. Of the 37 enrolled patients, 8 patients lacked capacity. 57% of the patients were recruited at the acute geriatrics department and the others through the geriatric liaison teams from other departments. Their demographic characteristics are shown in Table 1. They were 51% male, with a mean age of 84 years. The majority were living at home with a partner/child/other (65%). Twenty-eight percent had cancer; among non-cancer conditions, nervous system diseases were most prevalent category (19%).

Table 1. Demographic and care-related characteristics (N=37)

Characteristics	**Descriptive statistics**
Age (years)	
Mean (SD)	83.8 (6.1)
Range	74 – 98
Gender n(%)	
Female	18 (48.6)
Male	19 (51.4)
Living situation n(%)	
Home, alone	13 (35.1)
Home, with partner/children/other	24 (64.9)
Clinical Frailty Score (CFS)[a,b]	
Mean (SD)	5.8 (0.8)
Medical diagnosis[b,c] n(%)	
Cancer	11 (27.8)
Nervous system disease	7 (19.4)
Cardiovascular disease	6 (16.7)
Renal disease	6 (16.7)
Respiratory disease	5 (13.9)
Gastrointestinal disease	4 (11.1)
Psychiatric disorder	3 (8.3)
Recurrent falls	3 (8.3)
Liver disease	2 (5.6)
Bone fracture	2 (5.6)
Other	6 (16.7)
Highest education completed n(%)	
No education	2 (5.4)
Primary education	4 (10.8)
Lower secondary education	12 (32.4)
Upper secondary education	13 (35.1)
Higher college education	6 (16.2)

SD: Standard deviation

Missing data: Medical diagnosis (n= 1), CSF (n= 2).

[a] The CFS is scored from 0 to 9, with higher scores representing higher frailty. We recruited patients scoring 5 to 7, corresponding to 'mildly to severely frail'.

[b] Reported by the treating physician in the hospital.

[c] Number of medical diagnoses per patient: one (n=18), two (n=16), three (n=2).

Palliative care symptoms and concerns

The total mean IPOS score was 21.8 (SD = 11.4) out of a maximum of 68. Seventy-three percent of the patients had at least slight/moderate weakness in the previous week, and 46% experienced severe weakness (see figure 1 for details). Seventy-eight percent had been at least slightly/moderately affected by poor mobility, and 40% severely affected. More than half were at least slightly/moderately affected by a sore mouth (62%), drowsiness (59%), pain (54%), shortness of breath (54%) and poor appetite (51%) in the previous week. Most patients were not affected by vomiting (93%) and nausea (73%). Fifty-four percent had felt at least occasionally anxious, and 61% had felt at least occasionally depressed in the past week. Seventy-five percent reported that their family had felt at least occasionally anxious or worried about them. Most patients received as much information as they wanted most or all of the time (76%). Forty-nine percent shared their feelings most or all of the time with their family or friends as much as they wanted and felt most or all of the time at peace (46%). Six percent indicated that their problems were not addressed or hardly addressed, while 64% had no problems or their problems were addressed.

Of the 17 IPOS items, 86% of the patients rated at least one symptom, problem, or concern as causing severe problems, and 41% rated at least five symptoms, problems, or concerns as causing severe problems (Table 2).

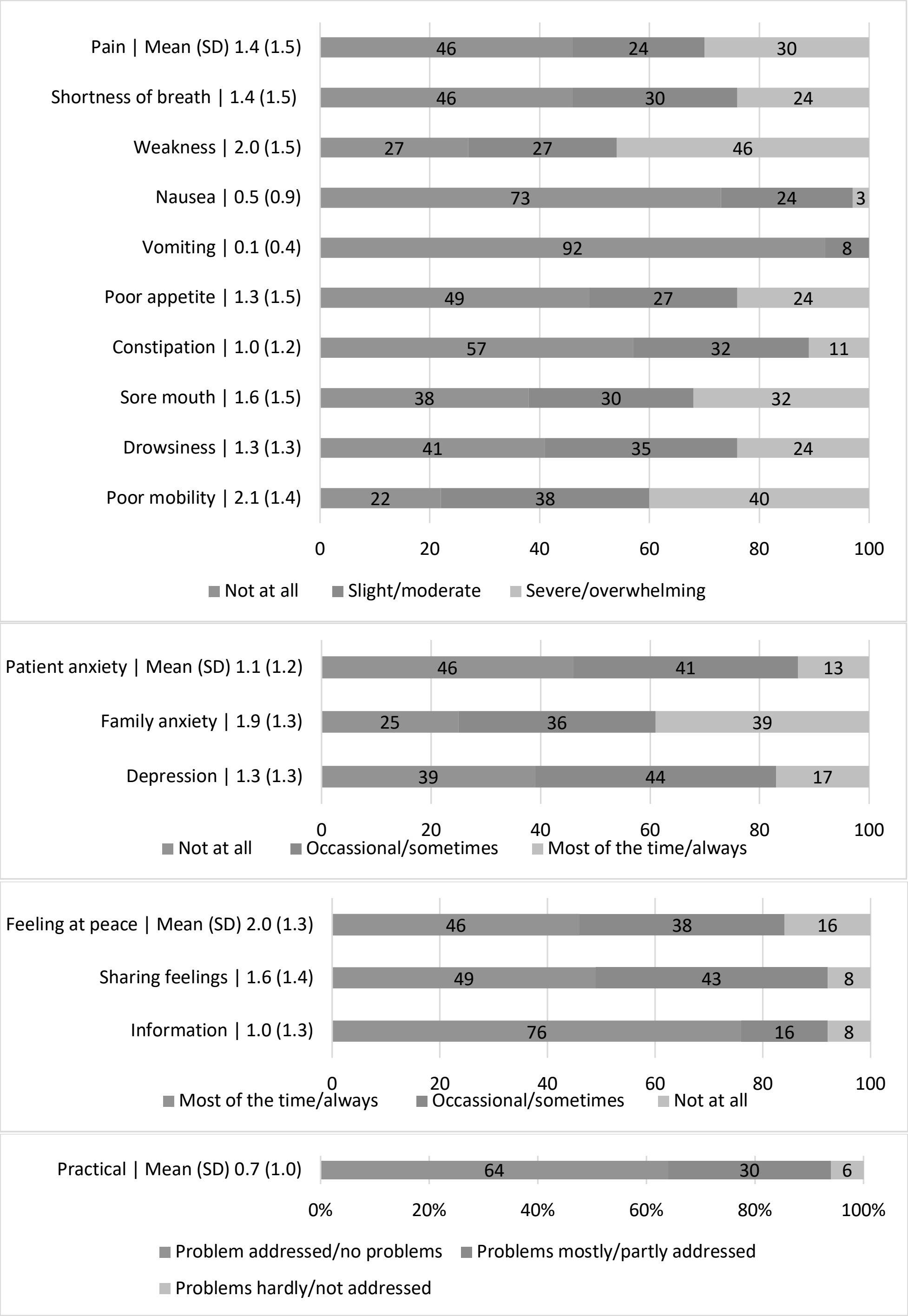

Figure 1. Palliative care symptoms, problems, and concerns of older people with frailty (n=37) measured by IPOS: Mean (standard deviation) and proportion (%).

Table 2. Number of symptoms and concerns specified as severe or overwhelming, as measured by IPOS (N=37)

Number of symptoms/concerns by which respondents were severely or overwhelmingly affected	N (%)
0	5 (13.5)
1	5 (13.5)
2	3 (8.1)
3	5 (13.5)
4	4 (10.8)
5	5 (13.5)
>- 6	10 (27.1)

Well-being

The total mean ICECAP-SCM score was 22.8 (SD = 3.9) out of a maximum of 28. Between 62% and 87% of patients expressed feeling supported most of the time, able to maintain their dignity most of the time, able to be with people who care about them most of the time and being able to have a say about their life and care most of the time (see figure 2 for details). Thirty-five percent of patients rarely experienced physical suffering and 38% indicated rarely experiencing emotional suffering. The total mean IPOS VoC quality of life item score was 4.5 (SD = 1.5) out of a maximum of 7. Thirty-two percent assessed their overall quality of life in the past day with a score of 3 or lower, while 22% assessed their quality of life with a score of 6 or 7.

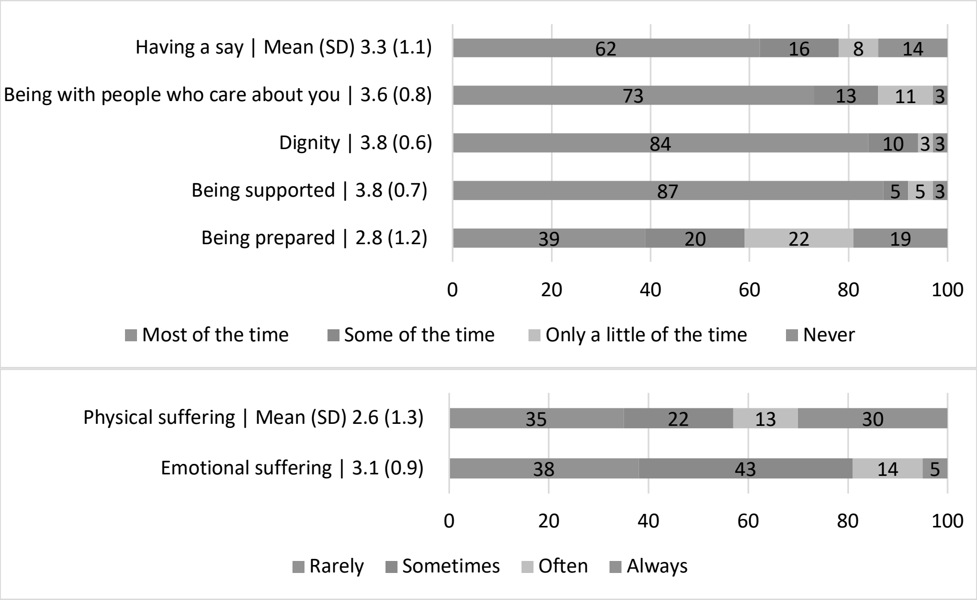

Figure 2. Well-being of older people with frailty (n=37) measured by ICECAP-SCM: Mean (standard deviation) and proportion (%).

Association between palliative care needs and well-being

There were moderate negative correlations between palliative care needs (IPOS total score) and well-being (ICECAP-SCM total score) (Spearman’s r = -0.41; p = 0.013) and between palliative care needs (IPOS total score) and well-being (IPOS VoC quality of life item) (Spearman’s r = -0.47; p = 0.003). There was a moderate positive correlation between the two well-being measures (ICECAP-SCM total score and IPOS VoC quality of life item) (Spearman’s r = 0.39; p = 0.016).

DISCUSSION

We assessed the palliative care symptoms, concerns, and well-being of older people upon hospital discharge to their home who were judged as having frailty and unresolved or complex needs. The data showed important heterogeneity in experienced symptom burden; some patients were severely affected by a range of symptoms and problems in multiple domains, others reported they were not severely affected by any symptom or concern. Weakness, sore mouth, pain, and patient and family anxiety were most frequently rated as causing severe problems. In terms of well-being, most patients expressed feeling supported, being able to maintain their dignity, being able to be with people who care about them and having a say about their life and care. We found that greater palliative care needs were moderately correlated with lower well-being, and a moderate positive correlation between the two well-being measures.

Reported symptom burden upon hospital discharge varied substantially between individuals identified as having complex care needs and frailty. These findings confirm recent research reporting that there is large heterogeneity among older people with multimorbidity and frailty in terms of their health status and symptoms and problems (27). These findings point towards the importance of careful routine screening of each patient's multidimensional (i.e. physical, psychological, social, and spiritual) needs; this is an essential part of preparing a care response following hospital discharge to home that is tailored to older people's individual needs.

Many older people who had complex care needs according to their clinician had multiple unmet palliative care symptoms and concerns upon hospital discharge. This group should be considered for palliative care follow-up at home which might include referral to specialised palliative home care services. This also has implications for the role and tasks of current specialised palliative care services. If patients are referred to these services, this is typically in the terminal phase last days and primarily for problems related to a cancer diagnosis (28,29). Adapting their work to an older patient population with multidimensional complex needs, frailty and multimorbidity, who are not necessarily in a terminal stage of illness, may require a reorientation of their current care approach, training, and integration and collaboration with other services and models of care (30). More work is needed to understand what palliative care structures or models are effective in addressing the complex care needs of community-dwelling older people, including identification of indicators for referral to specialised palliative care home care services.

Frequently reported problems and symptoms of older people in this study were pain, shortness of breath, weakness, sore mouth, drowsiness, family anxiety and depressive feelings. Comparable levels of symptom burden were reported in recent cross-sectional studies among community-dwelling older people with multimorbidity in Sweden and the UK (31,32). Those care needs are often not well-addressed. Over the recent years there has been increasing attention given to the development of evidence-based clinical practice guidelines of symptom management in older people. Some of these focus on the management of disease specific symptoms and concerns, for instance in frailty there are guidelines for sarcopenia and fatigue (33), and some on more general symptoms in older people such as pain (34). Yet other frequent symptoms in older people towards the end of life, e.g. cachexia, still lack evidence-based guidelines of best practice for those with serious non-cancer conditions (35,36).

Increased research is needed into the development and evaluation of such evidence-based clinical practice guidelines to improve symptom control in older people with complex care needs.

We found negative moderate correlations between palliative care needs and well-being of older people with complex care needs upon hospital discharge. These results are in agreement with a previous study showing that, among older people with multimorbidity, higher levels of symptoms and concerns were associated with a lower quality of life (37). However, the correlations were only modest, so this does not necessarily mean that patients with high levels of symptoms and problems have low well-being. Previous qualitative studies also found that older people with multimorbidity and frailty reported to have a relatively good quality of life and well-being (38,39). Based on these findings, and aligned with the action plan of the United Nations on Healthy Ageing (40), it may be particularly appropriate that healthcare providers caring for these patients not only focus on the identification and management of symptoms and concerns, but also on supporting existing abilities and capacities (38).

This study has limitations. As we recruited patients from two hospitals that were the sites of the pilot RCT from which this data were drawn, generalisability of these findings may be limited to older patients in urban areas and university hospitals. The small sample size may also compromise generalisability. These findings should therefore be considered a first screening of the multidimensional needs of the specific group of older people judged as having complex care needs. Moreover, the respondents had agreed to take part in a pilot trial about a specialised palliative care intervention; which may have introduced a selection bias towards those interested in palliative care (research).

Conclusion

We identified large variation in the experienced symptom burden among older people upon hospital discharge whom their treating physician judged as having frailty and unresolved or complex needs, and a high and multidimensional symptom burden for many patients. This population should be considered for palliative home care follow-up which might include referral to specialised palliative care services. Greater palliative care symptoms and concerns were only moderately correlated with lower well-being, suggesting the important role of protective factors even for those affected by burdensome symptoms. Healthcare professionals should seek to identify such abilities, alongside multidimensional symptoms, and concerns. This first analysis should prompt larger-scale studies of the prevalence, interaction and temporal evolution of the multidimensional symptoms and concerns, and well-being of older people with complex care needs, including population-based and longitudinal studies.

Authorship: All authors have contributed to the following categories for authorship.

1a) Study conception and design: de Nooijer, Pivodic, Van Den Noortgate, Pype, Van den Block;
1b) Acquisition of data: de Nooijer;
1c) Analysis and interpretation of data: de Nooijer, Pivodic, Van Den Noortgate, Pype, Van den Block;
2) Drafting the manuscript: de Nooijer;
3) Critical revision: de Nooijer, Pivodic, Van Den Noortgate, Pype, Van den Block.

All authors have approved the final manuscript and agree to be accountable for all aspects of the work. Questions related to the accuracy or integrity of any part of the work will be appropriately investigated and resolved.

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CHAPTER 3

Specialist palliative care services for older people in primary care: A systematic review using narrative synthesis

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ABSTRACT

Background There is recognition that older people with incurable conditions should have access to specialist palliative care services. However, it remains unclear which activities and outcomes these services entail for older people in primary care and to which patients they are provided.

Aim The aim of this review was to identify: the criteria for referral to specialist services; who provides specialist palliative care; through which activities and with which frequency; which outcomes are reported; and which suggestions are made to improve services.

Design Systematic review of literature and narrative synthesis. Quality appraisal and selection of studies were performed independently by two researchers. Participant characteristics, intervention features, outcome data and suggestions for improvement were retrieved.

Data sources Embase, Medline, Web of Science, Cochrane, Google Scholar, PsycINFO and Cinahl ebsco databases (until June 2019).

Results Ten eligible articles, three qualitative, three quantitative, three mixed-method and one narrative review, were identified. Referral criteria were mainly based on patient characteristics such diagnosis. The specialist services involved a variety of activities and outcomes and descriptions were often lacking. Services could be improved regarding the information flow between healthcare professionals, greater in-depth palliative care knowledge for case managers and social workers, identification of a key-worker and support for family carers.

Conclusions The limited evidence available shows areas for improvement of the quality of and access to specialist services for older people, such as support for family carers. In addition, this review underscores the need for comprehensive reporting of interventions and the use of consensus-based outcome measures

INTRODUCTION

Life-expectancy worldwide continues to increase, but the added years are not always spent in good health.[1] Many older people experience long periods of illness and are confronted with multimorbidity (i.e. the simultaneous presence of multiple chronic conditions), frailty (i.e. a progressive physiological decline in multiple organ systems marked by increased vulnerability to disease and death), disabilities or other physical and/or mental health problems.[2] The increased susceptibility of older people to adverse health outcomes paired with the cumulative effects of various chronic health problems results in prolonged, complex and fluctuating needs and symptoms in the last years of life.[3,4]

According to the World Health Organisation[5], palliative care should be provided to any person with a life-threatening illness. Given the prolonged and complex needs of older people with progressive and incurable chronic conditions,[6] provision of specialist palliative care in primary care may be a way to meet their needs. Specialist palliative care services involve healthcare professionals who are specifically trained in palliative care and typically support primary care providers in delivering it, either by advising them or by delivering it themselves directly to the patient.[7,8] It has been argued that early referral and continuous access to specialist palliative care services for all older patients is not sustainable for healthcare systems.[2,8] Episodic involvement of specialist palliative care services in primary care is proposed for periods in which the patient's palliative care needs become too complex to be handled in primary care alone.[2,7,8]

Early-initiated, short-term specialist palliative care interventions in primary care have demonstrated feasibility and beneficial outcomes for people with life-threatening chronic diseases such as cancer and multiple sclerosis.[9-11] Preliminary findings about such interventions have also indicated acceptability and potential benefits for older people with frailty or other progressive conditions in improving key symptoms, and have provided evidence of cost savings.[12,13]

Despite this growing evidence of effectiveness,[9-13] it has been hard to extend, and further substantiate, this evidence-base to the growing population of older people with progressive and incurable chronic conditions. A recently conducted review by Evans et al[14] provided insights on end-of-life care provision models for older people and identified two service models: 1) the model of integrated geriatric care that focused on maintenance of functioning, and 2) the model of integrated palliative care that focused on reducing symptom distress and concerns. However, this review does not specifically focus on specialist palliative care services. In addition, the review did not focus on palliative care in primary care.[14] It therefore remains unclear what specialist palliative care services should entail for older people in primary care. More specifically, due to the uncertainty of prognosis, it is difficult to predict the optimal timing for referral to specialist palliative care services.[3] In addition, understanding to whom, among the older population, specialist palliative care is provided, by whom and through what activities, which outcomes are measured, and how services could be improved, is crucial in the development and evaluation of specialist palliative care services.

AIM AND RESEARCH QUESTIONS

To date, a systematic and comprehensive overview of articles regarding specialist palliative care services for older people in primary care is not available. Therefore, based on current international evidence, this review aims to answer the following questions:

1. Which criteria are used for referral of older people to specialist palliative care services in primary care?
2. Which healthcare professionals are involved in specialist palliative care services, through which activities is care delivered, and with which frequency?
3. What are the outcomes identified in studies concerning specialist palliative care services for older people in primary care?
4. How could the provision of specialist palliative care for older people in primary care be improved according to the existing literature?

METHODS

A literature review is considered systematic if it is guided by a research question and if the processes of identification, selection, appraisal and synthesis of the literature are explicitly described. Mixed studies reviews do not differ in this respect. [15,16]

Search strategy

A systematic electronic search was developed with the help of a biomedical information specialist. The following electronic databases were used: Embase, Medline, Web of Science, Cochrane, Cinahl ebsco, PsycINFO and Google scholar. Articles were retrieved until June 2019, and we did not use any restrictions regarding year of publication. The electronic search strategy is provided as Supplementary Table 1.

Screening and study selection

Duplicates of the retrieved studies were removed. Titles and abstracts were screened independently by two reviewers (KdN and YP) for potential eligibility, applying the inclusion and exclusion criteria (Box 1). In cases of disagreement, consensus was reached through discussion with LP and LVdB. The full texts of the articles selected for full text screening were acquired, if not available through electronic databases, through email from the first author, ResearchGate or inter-library lending. The articles were entered in a Zotero database. Full text screening was done by one reviewer (KdN) while three others (YP, LP, and LVdB) each screened a random 10% selection of articles. The results were compared and in cases of disagreement differences were resolved through consensus. Studies were excluded based on a hierarchical set of exclusion criteria. The web-based software platform www.covidence.org was used for screening and reviewing the articles.

Box 1. Inclusion and exclusion criteria.

Inclusion criteria	**Exclusion criteria**
All connected by 'AND'	*All connected by 'OR'*
Study concerns older people (or synonyms used in the search string)	Study does not concern older people (or synonyms used in the search string)
Study concerns the primary/community care setting (including transitions to and from)	Study reports exclusively about hospital, nursing home or another institutional care setting (or transitions between these settings)
	Study focuses exclusively on a specific therapeutic treatment or action (e.g. dialysis or chemotherapy)
Study concerns specialist palliative care [a] (or synonyms used in the search string)	Study does not concern specialist palliative care[a] (or synonyms used in the search string) OR specialist palliative care is an outcome of another intervention rather than the intervention itself
Study concerns empirical research (either quantitative, qualitative, case study, systematic review, literature review, meta-analysis, or book chapter)	Conference reports or abstract, book, opinion piece, editorial or discussion article, evaluation of local programme, questionnaire or training session, or a PhD submission
Study published in the English, Dutch, Spanish, Portuguese, Italian, French or German language	Study not published in the English, Dutch, Spanish, Portuguese, Italian, French or German language

[a] Specialist palliative care as described by Gomes et al.[17]

Quality assessment

Assessing the methodological quality of quantitative, qualitative and mixed-methods studies is challenging because they constitute distinct traditions with unresolved ontological and epistemological differences.[15,16] We therefore used existing, but different, scales to assess the methodological quality of the research included in the review. For primary studies, we used the qualitative and quantitative scales developed by Gomes et al., 2013.[17] The quality assessment for articles concerning qualitative research ranged from 0 (poor) to 30 (good). The quality assessment for articles concerning quantitative research ranged from 0 (poor) to 16 (good). Articles using both qualitative and quantitative methods were evaluated using both scales. For review articles, we used the quality Assessment of Multiple Systematic Reviews (AMSTAR) tool, which resulted in scores of 0 – 4 (low), 5 – 8 (medium) and 9 – 11 (high).[18] KdN scored the methodological quality of the included articles. YP scored the methodological quality of a random 10% selection of the included articles. Disagreements were resolved by discussion with LP and LVdB. The scores were not used to exclude articles from the review but to inform the reader about the quality of the research and to guide the interpretation of the findings.

Data extraction and data synthesis

In order to systematically extract relevant data from the included articles we created a data extraction form in MS Excel. This form included items on general methodological characteristics (e.g. year of publication and study design) and specific characteristics of the study. We used the terminology as described in the source articles. The extraction form included the population of older people who were referred to specialist palliative care services, the healthcare professionals involved in these services, activities care was provided through and with what frequency. Additionally, information was retrieved on the outcomes of specialist palliative care, and, according to the authors of the respective research, how the provision of specialist palliative care could be improved. We assigned the outcomes of specialist palliative care to the level which they target, e.g. level of healthcare professionals, level of patients and/or their family carers. KdN completed the extraction form for each of the included studies. YP assessed the data extraction of a random 10% selection of the included studies to check the accuracy of the procedure. Disagreement between the reviewers was solved by discussion with LP and LVdB. Following data extraction, we conducted a narrative synthesis because this brings the broad knowledge from a variety of methodologies and approaches together. We followed the guidance of Popay et al[15] to narrative synthesis in order to systematize the process of analysis. This seeks to report patterns of findings across the included studies and thus provides a way of interpreting and categorizing information.[15]

RESULTS

The database search yielded 5,072 articles as potentially eligible for this review (Figure 1). After removal of duplicates, 2,888 articles were identified for screening based on the title and abstract. After exclusion of 2,573 articles, the remaining 315 articles were screened based on the full text. Ten articles were included for analysis.

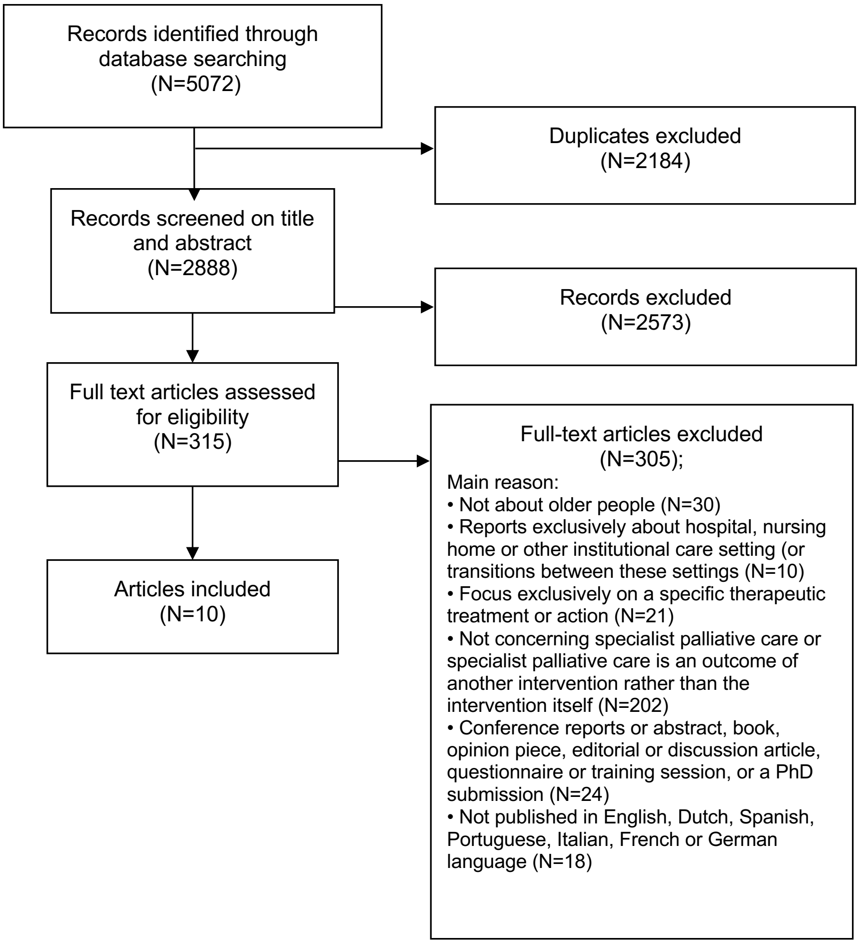

Figure 1: Process of study selection (PRISMA flowchart)

Study characteristics and methodological quality

Table 1 shows the main characteristics of the ten articles included in this systematic review. Three articles had a qualitative design,[19-21] three a quantitative design,[22-24] three a mixed-method design,[12,25,26] and one was a narrative review.[27] The research described in all articles was performed in Europe and the USA, except for one where it was performed in Taiwan.[21] Of the six articles using a qualitative method, the mean total methodological quality score was 17 out of 30 (range: 14 – 23). Of the six articles using a quantitative method, the mean methodological quality score was 9 out of 16 (range: 3 – 12). The narrative review had a score of 2 out of 11.

Table 1. Characteristics of the included articles (n = 10).

Qualitative study design (n = 3)					
First author, year	**Country**	**Research question(s)**	**Data collection**	**Participants**	**Quality score [a] (range: 0 – 30)**
Deitrick, 2011	USA	The examine 1) the role of the nurse practitioner from the perspective of themselves and other staff members and 2) the implications of this service model for an expanded role for nurse practitioners.	Semi-structured in-depth interviews	Nurse practitioners (n = 3), medical director (n = 1), program director (n = 1) and the clinical coordinator of the palliative medicine outpatient service (n = 1)	14
Geiger, 2016	Germany	To identify 1) which tasks and challenges general practitioners see with regard to the care for frail older people in the last phase of life and 2) what self-awareness do general practitioners have regarding their own role and responsibilities in this healthcare setting.	Semi-structured interviews	General practitioners (n = 14)	18
Lee, 2013	Taiwan	To examine the family’s experiences and needs over a 1-year data collection period in relation to the provision of hospice home care to the terminally ill elderly people with cancer in Taiwan	Field notes and semi-structured interviews	Family caregivers (n = 44)	14
Quantitative study design (n = 3)					
First author, year	**Region**	**Research question(s)**	**Data collection**	**Participants**	**Quality score [a] (range: 0 – 16)**
Chen, 2014	USA	To investigate the effectiveness of a home-based palliative care service model for vulnerable patients with life-limiting disease in Rochester, Minnesota in reducing the frequency of hospitalizations, length of hospital stays, and proper addressing of advanced directives.	Chart review	Home-bound high-risk, frail patients with life-limiting illnesses (Intervention group: n = 54; Control group: n = 108)	11
Martoni, 2018	Italy	To compare the oldest-old patients with younger groups within the patient population assisted by the comprehensive home palliative care program in the Bologna metropolitan area.	Electronic patient database review	Home-bound patients with advanced (metastatic or locally advanced) cancer (compare different age groups, total n = 1777)	11
Radwany, 2014	USA	To describe the feasibility and present the outcomes of the advance care for elders randomized pilot study.	Randomised pilot study	Patients (> 60 years old) with chronic illnesses (Intervention group: n = 40; Control group: n = 40)	12
Mixed-method study design (n = 3)					
First author, year	**Region**	**Research question(s)**	**Data collection**	**Participants**	**Quality score [a] Qual. design (range: 0 – 30), Quan. design (range: 0 – 16)**
Bone, 2016	England	To elicit and synthesize perspectives from older people, carers and other key stakeholders to inform model development prior to a feasibility evaluation in clinical practice.	Stakeholder consultations and consensus	Stakeholder consultation and consensus survey respectively: informal carers (n = 4; 2), volunteer carers (n = 2; 0), general	Qual. design: 23 Quan. design: 7

			survey, and focus groups	practitioners (n = 5; 5), community nursing services (n = 11; 7), palliative medicine consultants (n = 4; 4), specialist palliative care nurses (n = 7; 3), other specialist nurses e.g. heart failure (n = 3; 3), hospice e.g. education and management leads (n = 2; 1), allied health professional (n = 0; 1), care home e.g. manager (n = 1; 1), end-of-life care commissioner (n = 1; 0), voluntary sector representatives e.g. Alzheimer's Society (n = 12; 8), academic/researchers (n =11; 7). Focus groups: nursing home residents (n = 6), day centre attendees (n = 2), informal carers (n = 2), volunteer carers (n = 7)	
Holley, 2009	USA	To understand 1) how caregivers of patients who died defined a successful home palliative care experience and 2) to use these definitions to improve care and help avoid terminal hospitalization in cases in which home death was preferred, the predominant preference of most patients.	Chart review, telephone interviews and in-depth interviews	Chart review: patients (n = 74). Telephone interviews: primary caregivers (n = 22). Face-to-face in-depth interviews: primary caregivers (n = 13).	Qual. design: 19 Quan. design: 8
Kramer, 2013	USA	To understand 1) what are the end-of-life care needs most frequently addressed by social workers, 2) to what extent will social workers report high levels of perceived success in addressing end-of-life care needs that they address, 3) What roles do social workers have in assisting older adults, family caregivers, and team members in the care Wisconsin partnership program and 4) how do perceptions of the social workers' roles compare between elderly, family caregivers, team members and social workers.	Surveys, in-depth interviews and focus-groups	Surveys completed by social workers: client deaths (n = 120). In-depth interviews: older people (n = 14) and informal caregivers (n = 10). Five discipline-specific focus-groups: registered nurses (n = 2), nurse practitioners (n = 1), social workers (n = 2).	Qual. design: 16 Quan. design: 3
Review (n = 1)					
First author, year		**Research question(s)**	**Review type**	**No. of studies included in our review [b]**	**Quality score [a] (range: 0 – 11)**
Ladha, 2013		To describe 1) frailty among the elderly, 2) how frail patients might benefit from palliative care and 3) several community-based programs that can improve the quality of life for home-bound frail elders.	Narrative review	2	2

[a] Quality score: concerning qualitative research using the guidelines for methodological quality assessment of the Dutch Cochrane Centre (range: 0 – 30), concerning quantitative research using the COREQ checklist (range: 0 – 16), studies using both quantitative and qualitative research were evaluated using both scales, and review was classified using AMSTAR tool (range: 0 – 11).

[b] Studies included in the review that met our inclusion criteria: Holley et al., 2009 and Deitrick et al., 2011.

Referral criteria for older people to specialist palliative care services

Age was used as one of the criteria for referral to specialist palliative care services, though the exact age of referral differed, with some services referring people as of 65 years or over,[21,23-25] others as of 70 years or over,[20] and another as of 75 years or over[12] (Table 2). In addition, referral criteria were focused on specific diseases, such as advanced cancer,[21,23] 'complex illnesses',[19,24] and frailty.[12,20,22,26,27] Scales were used to identify frail older people; namely the CSHA-Clinical frailty scale (cut-off stage 6/7), the SHARE FI,[20] and the Elders Risk Assessment Index (cut-off >16).[22] In one article, people were not referred to specialist palliative care services by focusing on their disease but by focusing on their limited life-expectancy as defined by the surprise question.[25] People were referred to specialist palliative care services by the primary care physicians,[12,22,25] or at hospital discharge.[22] Another article reported that people had requested the primary care physician to refer them to specialist palliative care services.[23]

Who provided care, through which activities and with what frequency

Specialist palliative care was provided by multidisciplinary teams consisting of physicians and nurse practitioners.[19,22-27] (Table 2). Social workers and case managers were involved in the teams,[22,24-26] and other healthcare professionals could be consulted when needed, such as occupational therapists and social services.[22,24] The specialist palliative care service was affiliated with the hospital,[21,22,25] operating from the hospital,[19] or integrated into the local public healthcare system.[23,25] While there were differences in the care activities across the articles, some were described similarly between them (Table 2). Multidisciplinary team meetings were conducted weekly,[21,22,26] or after the second home-visit of a care manager.[24] Nurse practitioners, case managers or social workers collaborated with and advised primary care providers and other specialists.[12,19,24-27] A team member (e.g. nurse practitioner, social worker) was assigned to coordinate referral, scheduling, communication with patients and relatives and liaison with community-based organisations.[12,22,24-26] An initial home visit included a comprehensive patient and family carer needs assessment.[12,19,24,26] Ongoing care included symptom management and holistic supportive care,[12,19,21,25-27] patient and family carer education and empowerment,[18,22,24-26] conversations and documentation about the patient's goals and wishes,[12,19,22,24,25,27] and development of an emergency response plan.[22,,24] The frequency of home visits varied (Table 2); one article reported visits twice weekly for six months,[21] two based the frequency on the patient's needs,[25,26] and three involved short-term services of one to three visits,[12,22,24] with additional phone follow-up at least monthly,[23] or described the frequency as every three weeks to three months.[19] Additional 24-hour call services were provided by the specialist palliative care team or intervening phone calls in case of emergency.[12,19,20,22-25]

Table 2. Articles reporting about specialist palliative care in primary care for older people.

Qualitative study design (n = 3)						
	Research question 1		**Research question 2**		**Research question 3**	**Research question 4**
First author, year	**Referral criteria for older people to specialist palliative care services**	**Who is involved in specialist palliative care services**	**Through which activities is specialist palliative care provided**	**Frequency of specialist palliative care provision**	**Outcomes of specialist palliative care** *Level [a]*	**How could the provision of specialist palliative care be improved**
Deitrick, 2011	- Patients with a serious, progressive complex illness, identified as Advanced Complex Illness.	- Optimising Advanced Complex Illness Support program provided by physicians and nurse practitioners. - Operated from an academic community hospital in Pennsylvania.	- The nurse practitioner gathered all health care providers involved in the patient's care together into a team. - The nurse practitioner provided medical knowledge and specialist training in palliative care to primary care and specialist physicians. - Home visits were conducted by the nurse practitioner who provided an initial comprehensive patient assessment and ongoing care management and coordination, medical management, psychosocial support, education about the prognosis and treatment options, and supported patient-empowerment and conversations about goals of care and helped to ensure a smooth transition to hospice care.	- Initial house call visits, duration 1 – 2 hours. - Follow-up house call visits, duration 45 minutes, every 3 weeks to 3 months. - Intervening phone calls in case of emerging health issues and exacerbations.	*Outcomes according to experiences/views of respondents* *Healthcare professionals level* - Increased viability, productivity and shared learning with referring physicians through collaboratively caring for this population. *Patient and/or their family carers level* - Better and more effective patient care. - Better symptom control. - Avoiding hospitalisations. - Increased medical knowledge and palliative care skills of patients and relatives - Better adherence to treatment protocols. - Increased calmness and reduced anxiety of patients and relatives. - Increased quality of life of the patient.	- Authors stated that the full utilisation of nurse practitioners in the provision of specialised palliative care services could increase the access and quality of specialist palliative care at a lower cost than a comparable physician service.
Geiger, 2016	- Community-dwelling elderly patients with moderate to	No description	No description	- Specialist palliative care teams provided a	*Outcomes according to experiences/views of respondents*	- General practitioners stated a need for improved information flow from the specialist palliative care

	severe frailty (stage 6/7 according to the CSHA-Clinical Frailty Scale) and being frail according to SHARE FI, age ≥ 70 years.			qualified 24/7 call service.	*Healthcare professionals level* - Reduced personal workload and psychological stress of general practitioners. *Patient and/or their family carers level* - Improved quality of patient care.	services in the joint care of patients.
Lee, 2013	- Patients with advanced cancer, age ≥ 65 years.	- Hospice home care organisation was affiliated with a hospital in Northern Taiwan.	- Hospice home care staff meetings. - Home visits were conducted by the nurse who provided symptom alleviation and holistic supportive care (physical, emotional, and spiritual aspects).	- Weekly hospice home care staff meeting. - Home visits twice weekly for 6 months.	*Outcomes according to experiences/views of respondents* *Patient and/or their family carers level* - Increased self-confidence of family carers in caring for the patient at home.	- Family carers stated a need for emotional support and advanced information throughout the entire caring process.
Quantitative study design (n = 3)						
	Research question 1		**Research question 2**		**Research question 3**	**Research question 4**
First author, year	**Referral criteria for older people to specialist palliative care services**	**Who is involved in specialist palliative care services**	**Through which activities is specialist palliative care provided**	**Frequency of specialist palliative care provision**	**Outcomes of specialist palliative care** *Level* [a]	**How could the provision of specialist palliative care be improved**
Chen, 2015	- Homebound, high risk and frail individuals with life-limiting illnesses. Eligibility: Elder Risk Assessment score cut-off >16, four-year mortality prognostic index >14, and homebound (as defined by Centres for Medicare and	- Palliative Care Homebound Program provided by registered nurses, nurse practitioners, geriatricians, and palliative care consultants. Social services, pharmacists, and case management services also readily available. - In terms of staffing, one full time nurse	- Interdisciplinary team meetings. - Registered nurses were assigned to service hospital enrolment, phone triage, follow-up calls, scheduling, and liaison with community-based organisations. - Home visits were conducted by the nurse practitioner who provided consistent advance care planning and goals of care discussion. Additionally, chronic disease management, home safety assessments,	- Weekly one-hour interdisciplinary team meeting. - Twice annually on average home visits by the medical doctor. - Acute visits within one business day of an acute symptom report.	*Outcomes of chart review* *Patient and/or their family carers level* - Intervention group had decreased hospital admission rate and average total hospital days compared to control group. - Intervention group had increased number of scanned advance care directive documentation and goals of care	Not stated

	Medicaid services). - Referrals made by primary care physicians or hospital discharge patients who fit the criteria.	practitioner covered a panel of 20-35 patients at a time. One registered nurse for two nurse practitioner panels. - Operated from the Mayo Clinic in Rochester, a combined internal medicine and family medicine practice.	community resource referrals, education on self-management of illness, contingency planning strategies, and emergency contacts if the symptoms are not under control.		discussions compared to control group. - Intervention group had a steeper decline in overall survival within the first five months compared to the control group.	
Martoni, 2018	- Homebound patients with advanced (metastatic or locally advanced) cancer aged ≥ 18 years. - Patients may request their general practitioner to activate the Comprehensive Home Care Program instead of community home care services.	- Program provided by doctors and nurses (experts in palliative care), and psychologists. - Program integrated into the palliative care network of the local public healthcare system.	- Home visits were conducted by doctors and nurses who provided psychological support, social and health services (e.g. rehabilitation, enteral/parenteral nutritional support, pharmaceutical coverage, and health facility provision).	- Multidisciplinary team of doctors provided 24-hour home care assistance.	*Outcomes of chart review* *Patient and/or their family carers level* - Greater proportion of people aged 85 years and older died at home compared to the other age groups (18 – 64 years and 65 – 84 years).	Not stated
Radwany, 2014	- New enrollees in Ohio's community-based long-term care Medicaid waver program, age ≥ 65 years, who passed a mental status screening and had one of the following: congestive heart failure and being	- Promoting Effective Advance Care for Elders program provided by hospice and palliative medicine specialist, geriatrician, care manager, palliative care nurse specialist, social worker, spiritual advisor, and a pharmacist. Extended team	- Interdisciplinary team meetings to review the findings of the care manager's assessment and development of care plans. - Care manager collaborated with a health system-based geriatrics/palliative care interdisciplinary team and the client's primary care physician. - Initial home visit was conducted by the care manager who provided first a	- Interdisciplinary team meeting after the second home visit of the care manager. - First three home visits by care manager. - Follow-up meetings by telephone, at least monthly, for 12 months.	*Outcomes of randomised pilot study* *Patient and/or their family carers level* - No significant differences between the intervention group and the control group for the primary outcomes (symptom management, quality of life, mood, decision	- Authors stated that the model could be improved by hiring a single trained palliative care specialist care manager who could more easily assure that comprehensive assessments, consumer goal setting, and advance care planning all take place. - Authors stated that the model could be improved if

	actively treated; chronic obstructive pulmonary disease and on home oxygen; diabetes with renal disease, neuropathy, visual problems, or coronary artery disease; end-stage liver disease or cirrhosis; cancer except skin cancer; renal disease and actively receiving dialysis; amyotrophic lateral sclerosis with history of aspiration; Parkinson's disease stages 3 and 4; or pulmonary hypertension.	members, consulted when needed, included physical and occupational therapists, dietitian, geriatric advanced practice nurse, and a psychologist.	geriatric / palliative care biopsychosocial needs assessment, second visit concentrated on consumer goal setting, during the third visit, the care plans were discussed and follow-up meetings intended to implement the care plan, based on: teaching disease and symptom management, identifying symptom management needs, developing an emergency response plan, addressing functional needs, teaching caregivers about disease/symptom management, assisting with access to community resources, referring to a counsellor as needed for psychological support, assessing/assisting with spiritual needs, addressing unmet medical needs, reviewing medications, facilitating client/primary care physician/family communication, and completing legal documents.	- 24-hour availability of the care manager or a hospital-based team member.	making/care planning and spirituality). - Intervention group had fewer hospital visits and nursing facility placements compared to the control group.	care managers are trained through a formal training model such as the Respecting Choices certification course. - Authors stated that outcomes should reflect the Triple Aim (i.e. measure the medication appropriateness, health care utilization, patient activation, activities of daily living, and instrumental activities of daily living, hospice enrolment/place of death, consumer satisfaction, completion of the modified POLST, spirituality, anxiety, depression, and quality of life).
Mixed-method study design (n = 3)						
	Research question 1		**Research question 2**		**Research question 3**	**Research question 4**
First author, year	**Referral criteria for older people to specialist palliative care services**	**Who is involved in specialist palliative care services**	**Through which activities is specialist palliative care provided**	**Frequency of specialist palliative care provision**	**Outcomes of specialist palliative care** *Level [a]*	**How could the provision of specialist palliative care be improved**
Bone, 2016	- Frail older people, age ≥ 75 years, with non-malignant	- Short-term integrated palliative and supportive care (SIPS) model.	- Integrated professional working between specialist and generalist for advice and support, including single	- Short-term service of 1 – 3 visits.	*Hypothesised outcomes* *Patient and/or their family carers level*	- Authors stated a need for a skilled key worker. Could be the one with the greatest care involvement

	conditions living at home or in a care home. - Referral to specialist palliative care by the primary care physician if there is complex symptom presentation.		phone contact point for specialist palliative care. - Patient and carer holistic assessment (i.e. symptom management, encompassing physical and psychosocial distress, facilitate end-of-life discussions). - Skilled key worker to be the point of contact for patients and carers to coordinate services and care.		- SIPS model potentially improves symptom management (including psychosocial such as anxiety). - SIPS model potentially improves carer wellbeing and management or carer burden. - SIPS model potentially reduces hospital admission rate.	or could vary depending on patients' need and corresponding service involvement.
Holley, 2009	- Patients, age ≥ 65 years, enrolled in Medicare Part B, existing University of Chicago affiliation, homebound (as defined by Medicare), and have a limited life-expectancy defined by the patient's primary care provider as "not being surprised if the patient died in the next year".	- Palliative Access Through Care at Home (PATCH) program provided by geriatricians, advanced practice nurse, social worker. - PATCH developed through the University of Chicago's Section of Geriatrics and Palliative Medicine.	- Advanced practice nurse coordinated communication with pharmacies, home health agencies, and other professionals. - Advanced practice nurse coordinated referrals, scheduling, and communication with patients and family carers - Home visits included: symptom management, education regarding medication use, coordination of care, home assessment, discussions of prognosis and about cardiopulmonary resuscitation, documentation of patient and family wishes regarding rehospitalisation, explanation of hospice and referral when appropriate, counselling of family about disease management, and determination of caregiver burden.	- Frequency of visits based on patients' needs, from weekly to every 3 months. - Advanced practice nurse available by phone daily to triage and manage emergent patient issues. - Social worker available for home visits as well as by phone and in clinic. - 24-hour answering service with direct access to an on-call geriatrician.	*Outcomes of chart review* *Patient and/or their family carers level* - Greater proportion of intervention group died at home or in an inpatient hospice setting compared to control group. *Outcomes according to experiences/views of respondents* *Patient and/or their family carers level* - Increased feelings of reassurance experienced by patients and family carers. - Better transition between acute, hospital-based care and home-based, end-of-life care.	Not stated
Kramer, 2013	- Older people with advanced chronic diseases who were frail (i.e. eligible for nursing	- Care Wisconsin Partnership Program consists of: nurse practitioner, a master's level social	- Interdisciplinary team meeting to review the care plans of older people. - Social workers redirected the team to focus on the person's	- Weekly interdisciplinary team meetings. - Frequency of visits based on patient's	*Outcomes according to experiences/views of respondents*	- Authors stated a need for additional training for social workers in the factors influencing the perception of pain, ethical

	home level of care) and poor (i.e. Medicaid recipients).	worker, and two registered nurses (experts in palliative care). This team worked with the patient's physician. - This is a program of the Elder Care of Dane County, a not-for-profit organisation, a community-based service that integrates primary and acute care services with long-term care services.	wishes, taught communication skills, provided emotional support and back-up relief, and facilitated acceptation of non-action. - Interdisciplinary team worked with the patient to create a comprehensive, personalised, biopsychosocial service plan. - At least one of the team members accompanied the patient to medical appointments. - Nurses monitored health, identified home care needs, and provided health and prevention education. - Social workers addressed emotional, social, and mental health needs, provided resources and supportive counselling to the patient and family carers, and coordinated mental health, financial, housing and community services.	functioning and needs.	*Patient and/or their family carers level* - Increased feelings of being cared for by patients and family carers.	consideration, and how to assess and intervene appropriately employing a wide variety of nonpharmacological interventions and serving as advocates for medical intervention.
Review (n = 1)						
	Research question 1		**Research question 2**		**Research question 3**	**Research question 4**
First author, year	**Referral criteria for older people to specialist palliative care services**	**Who is involved in specialist palliative care services**	**Through which activities is specialist palliative care provided**	**Frequency of specialist palliative care provision**	**Outcomes of specialist palliative care** *Level* ^{a}	**How could the provision of specialist palliative care be improved**
Ladha, 2014	- Patients diagnosed with frailty syndrome.	- Interdisciplinary team consisted of physicians trained in palliative medicine.	- Assistance of palliative care providers to primary care physicians in discussions about treatments and patient's goals and priorities. - Interdisciplinary team provided symptom management and shared	No description	*Outcomes according to a narrative review* *Patient and/or their family carers level* - Increased quality of life. - Best care provided for the frail elders.	- Authors stated that discussions regarding goals tend not to be one-time event and shared decision-making needs to evolve as the patient's clinical status and psychosocial situation changes.

		decision-making with patients and family carers.		- Authors stated that providing specialist palliative care will not necessarily require the invention of new programs or new resources. Communities often have comprehensive home-care programs for frail elderly people that include components of palliative care.

[a] Outcomes assigned to the level of healthcare professionals and the level of patients and/or their family caregivers.

Outcomes of specialist palliative care

All included articles reported outcomes or hypothesized outcomes of specialist palliative care provision that targeted different levels; healthcare professionals and patients and/or family carers (Table 2). On the level of healthcare professionals, articles with a qualitative design described increased productivity and shared learning between specialist palliative care services and the referring physicians through collaboratively caring for the person who was dying.[19] Another article described reduced personal workload and stress of general practitioners.[20] On the level of patients and/or their family carers, articles with a qualitative design reported better and more effective patient care,[19,20] increased feelings of reassurance, self-confidence and being cared for by the person who was dying and those close to them,[19,21,25,26] and other patient-reported outcomes such as better symptom control.[19] The articles with a quantitative design reported decreased hospital admission rates in the intervention group,[22,,24] increased numbers of goals of care discussions and documentation in the intervention group,[22] steeper decline in overall survival within first five months in the intervention group,[22] and a greater proportion of the intervention group dying at home,[23,24] especially among the oldest people (85 years and more).[23] The narrative review reported increased quality of life of the patient and better and more effective patient care.[27]

How the provision of specialist palliative care could be improved

The provision of specialist palliative care could be improved regarding several aspects (Table 2). One article with a qualitative design suggested the full utilization of nurse practitioners in specialist palliative care services. This might address the service gap regarding the growing demand for quality end-of-life care and the predicted shortage of primary care physicians, and therefore provide quality care at lower costs than a comparable physician service.[19] Two other articles with a qualitative design stated a need to improve the information flow between specialist palliative care services and general practitioners,[20] and the need for emotional support and advanced information for relatives.[21] One article with a quantitative design reported that the specialist palliative care service model could be improved by hiring a single trained palliative care specialist care manager, trained through a formal course such as Respecting Choices®, and that the outcomes of the intervention should reflect the Triple Aim.[24] One article with a mixed-method design mentioned the need to identify a skilled key-worker,[12] and another the need for additional palliative care training for social workers.[26] The narrative review stated that discussions about the goals and wishes of the person who is dying should be conducted throughout the disease trajectory and that specialist palliative care provision does not necessarily require a new programme or resources.[27]

DISCUSSION

This systematic review provided an overview of how specialist palliative care in primary care is currently being provided to older people in primary care. Ten articles were included, mostly with a low to moderate methodological quality score. We found that people who were referred to specialist palliative care services had to meet criteria regarding a specific age (such as people of 65 years or over, or people of 70 years or over), having a diagnosis of a life-limiting chronic disease (such as complex illnesses) or having a limited life-expectancy. Specialist palliative care was provided by multidisciplinary teams which, if described, consisted of at least physicians and nurse practitioners trained in palliative care. During the multidisciplinary team meetings, patient information was discussed and specialist palliative care teams supported primary care providers and other specialists regarding the provision of palliative care. The specialist palliative care teams often provided an initial patient and family carer needs assessment and ongoing supportive holistic care through home visits or by phone calls of varying intensity and duration. The reported outcomes of specialist palliative care were mainly targeting the patient and/or their family carers, such as increasing their self-confidence and symptom control. In addition, the authors of the included research stated a need for an improved information flow between healthcare professionals, greater in-depth palliative care knowledge of case managers and social workers, the identification of a skilled key-worker and emotional and informational support for family carers.

Criteria for referral to specialist palliative care services were mainly focused on patient characteristics, such as age and diagnosis, or patients having a limited life-expectancy. This is remarkable because it is recommended that referral to these services should not only be based on these characteristics but also on their needs and symptoms.[4,14] This is particularly important for older people, who are often facing multiple chronic conditions with ambiguous medical prognoses.[6,28] These older people have special needs, as the problems they are facing are often more complex compared to patients with other terminal diseases.[2,6] In addition, previous research stated that the timing of referral to specialist palliative care services is also dependent on other factors such as the palliative care skills and knowledge of primary care physicians, local practice patterns and the availability of specialist palliative care services.[29] Therefore, the optimal timing for referral to specialist palliative care services for older people in primary care is not a 'one size fits all' matter but is highly dependent on the complex interplay between the older patient, the family carer, their primary care physician and the specialist palliative care services.[29]

Multidisciplinary teams provided specialist palliative care through a needs-based holistic approach, including education, information and the goals of care discussions with patients and/or family carers. Other activities of the specialist palliative care team were focused on coordination and collaboration with primary care providers and other specialists. This is in line with a previous review about the core elements of effective home-based palliative care models.[30] Based on these findings, the content and frequency of activities and procedures do not appear to differ between older patients (with or without a terminal diagnosis) and patients of any age with a terminal diagnosis. Yet, we might wonder if these services should be the same. The disease trajectory of older people with multiple chronic disorders is often characterized by highly complex and fluctuating needs,[6] therefore the ideal frequency and content of visits by specialist palliative care services might be different compared to for example adult oncology patients (with a disease trajectory often characterized by maintaining comfort and functioning for a substantial period, followed by a relatively rapid decline in the final weeks and days before death).[2] Older patients with multiple chronic diseases might have more benefit from a short-term specialist palliative care service, that is only involved in these periods of complex palliative care needs and problems. [2,7,8]

The specialist palliative care services included in the review were not homogenous and varied widely in the content and frequency of activities and procedures. In addition, the articles included in the review did not always provide a full description of the intervention activities and procedures. Therefore, transparency was often lacking regarding which healthcare professional conducted home visits and with what frequency, or who attended (and who did not attend) the multidisciplinary team meetings. These incomplete descriptions are problematic, especially regarding the 'active ingredients' of such interventions and how they achieve their effects.[30] Detailed information is needed to understand how the interventions might be replicated, as well as to generalise knowledge on how to implement the intervention and increase the potential impact of research on health.[32,33] This highlights the need for improving the quality and completeness of reporting in specialist palliative care research for older people in primary care. In response to this crucial issue and on the basis of our findings, we recommend the use of standardised forms such as the Template for Intervention Description and Replication (TIDieR) checklist, which should be routinely completed by evaluators of interventions to ensure comprehensive reporting.[32]

The reported outcomes of specialist palliative care for older people in primary care were in line with those reported in earlier published systematic reviews about integrated and coordinated palliative care for people with terminal diagnoses in primary care.[34,35] We identified that the articles included in the review used a wide variety of outcomes such as self-confidence, symptom management and survival. Radwany et al.[24] suggest that future interventions should focus on outcomes reflective of the Triple Aim to achieve better health, better care and lower costs. As we identified important outcomes on the level of healthcare professionals as well, such as reduced stress of general practitioners, we suggest that outcomes should be reflective of the Quadruple aim, adding the goal of improving the working life of healthcare professionals.[36] The wide variety of outcomes, targeting different levels (e.g.

patient and/or family carer level, healthcare professionals) and reflecting short-, mid- or long-term outcomes, made comparisons between the included specialist palliative care services for older people in primary care complicated, but also hinders comparisons with services that target patients with other terminal diagnoses. Therefore, we highly recommend the use of a set of core outcomes, which is defined as 'an agreed minimum set of outcomes to be measured and reported in all trials of a particular treatment or condition'.[37] The routine measurement of the same core set of outcomes that evaluate the effectiveness of specialist palliative care services for older people in primary care will allow benchmarking of services. This evidence-base would be highly valuable in the further development and evaluation of specialist palliative care services.[38]

The authors of the included research stated areas for improvement of specialist palliative care services for older people in primary care. Geiger et al.[20] reported a need for improved information flow between primary care providers and specialist palliative care services. Previous research also showed that multidisciplinary teamwork, in the shared care for this vulnerable population, is challenging.[39] Older people with multiple chronic conditions are often cared for by numerous healthcare professionals from different organisational structures that use different communication tools and different patient medical record systems.[39] High quality communication and collaboration between those professionals is needed to achieve a mutual understanding of the needs, goals and wishes of the older patient and to allow continuity and tailored patient-centered care.[39,40] The communication between healthcare professionals could be facilitated by the implementation of shared online patient records and regular multidisciplinary meetings.[39] In addition, suggestions are made for the inclusion of a skilled key worker in the care for older people, to coordinate their care and services.[12] This is confirmed in a qualitative study, where older people with advanced diseases in hospices place a high value on having a named professional as a point of contact to coordinate their care.[39] However, who this 'point of contact' should be is not clear. It could be any involved healthcare professional or even the patient and/or the family carer themselves.[43] Bone et al.[12] suggested choosing the person with the greatest involvement in patient care, which may vary over time. Specialist palliative care services for older people could also be improved by greater in-depth palliative care knowledge of case managers and social workers in the care for older people, specifically regarding advance care planning and pain assessment.[24,26] Older people have been found to be at a great risk of poor pain control, which might be due to communication problems and/or difficulties in pain assessment in this population.[41] Radwany et al.[24] suggesting the need for formal training for healthcare professionals, such as Respecting choices ®, which might facilitate the communication process between healthcare professionals and older people. Respecting choices ® is focused on a shared decision-making process that involves all healthcare providers, individuals and family carers and keeps the focus on patient-centered care.[42] Lastly, family carers reported the need for more emotional support and advance information throughout the disease trajectory.[21] As family carers play a pivotal role in the care of older people,[44] we should acknowledge and consider their needs for support in the development and evaluation of specialist palliative care services.

Strengths and limitations

To the best of our knowledge, this is the first systematic review that provides an overview of all published articles regarding specialist palliative care services for older people in primary care. The strengths of this review are that we used a comprehensive search strategy in seven databases and a broad operational definition of specialist palliative care, and were therefore able to include articles that used terms other than 'specialist palliative care' to describe all interventions that in practice are specialist palliative care. The study also has several limitations. Firstly, there might be subjectivity in the quality and grading criteria; however, this involved independent reviewers, disagreement checks and the use of existing scales for quality appraisal which increase objectivity. Secondly, despite our broad search string, we may have missed potentially relevant studies that did not use the term 'specialist palliative care'. Thirdly, due to the different study types we included in the review, comparison between methodological quality scores of different study types was not possible. Related to this, not all studies included in the review were of high quality, but still yielded valuable information on the provision of specialist palliative care services for older people in primary care.

Conclusion

This review shows that there is limited evidence available regarding specialist palliative care services for older people in primary care. Referral criteria were mainly based on limited patient characteristics, whereas it is more appropriate to base referral on patients' needs. A wide variety of activities and procedures, which were often poorly described, were included under the term specialist palliative care service. We therefore highly recommend the use of standardized intervention description tools to ensure comprehensive reporting. We identified a wide range of outcomes of specialist palliative care services; consensus-based outcomes are needed to facilitate comparisons and benchmarking of these specialist palliative care services. We identified areas for improvement of the quality of and access to specialist palliative care services for older people, such as increased information flow between healthcare professionals and emotional support for family carers.

Authorship: All authors have contributed to the following categories for authorship.

1a) Study conception and design: de Nooijer, Penders, Pivodic, Van Den Noortgate, Pype, Van den Block;

1b) Acquisition of data: de Nooijer, Penders, Pivodic, Van Den Noortgate, Pype, Van den Block;

1c) Analysis and interpretation of data: de Nooijer, Penders, Pivodic, Van Den Noortgate, Pype, Van den Block;

2) Drafting the manuscript: de Nooijer, Penders, Pivodic, Van Den Noortgate, Pype, Van den Block;

3) Critical revision: de Nooijer, Penders, Pivodic, Van Den Noortgate, Pype, Van den Block.

All authors have approved the final manuscript and agree to be accountable for all aspects of the work. Questions related to the accuracy or integrity of any part of the work will be appropriately investigated and resolved.

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Supplementary Table 1. Search terms.

1 .Embase

('frail elderly'/de OR 'frailty'/de OR ('vulnerable population'/de AND 'very elderly'/de) OR (frail* OR (functional* NEAR/3 impair* NEAR/3 (elder* OR old*)) OR oldest-old* OR very-old* OR ((vulnerab* OR multimorbid*) NEAR/3 (old* OR elder*)) OR nonagenerian* OR octogenerian* OR centenarian* OR supercentenarian*):kw,ab,ti) AND ('palliative therapy'/exp OR 'palliative nursing'/de OR 'terminal care'/de OR 'end of life'/de OR 'terminal disease'/de OR 'terminally ill patient'/de OR (palliat* OR terminal* OR 'advance care' OR (end NEAR/3 life) OR (last NEAR/3 (hour* OR day* OR week* OR year* OR month*) NEAR/3 life) OR (last-phase NEAR/3 life)):kw,ab,ti) NOT ([Conference Abstract]/lim OR [Letter]/lim OR [Note]/lim OR [Editorial]/lim) and [english]/lim

2. Medline

(Frail Elderly/ OR (Vulnerable Populations/ AND Aged, 80 and over/) OR (frail* OR (impair* ADJ3 (elder* OR old*)) OR oldest-old* OR very-old* OR ((vulnerab* OR multimorbid*) AND (old* OR elder*)) OR nonagenerian* OR octogenerian* OR centenarian* OR supercentenarian*).kw,ab,ti.) AND (Palliative Care/ OR Palliative Medicine/ OR "Hospice and Palliative Care Nursing"/ OR Terminal Care/ OR Terminally Ill/ OR (palliat* OR terminal* OR advance care OR (end ADJ3 life) OR (last ADJ3 (hour* OR day* OR week* OR year* OR month*) ADJ3 life) OR (last-phase ADJ3 life)).kw,ab,ti.) NOT (letter OR news OR comment OR editorial OR congresses OR abstracts).pt. AND english.la.

3. PsycINFO

((frail* OR (functional* ADJ3 impair* ADJ3 (elder* OR old)) OR oldest-old* OR very-old* OR ((vulnerab* OR multimorbid*) ADJ3 (old OR elder*)) OR nonagenerian* OR octogenerian* OR centenarian* OR supercentenarian*).ab,ti.) AND (Palliative Care/ OR Terminally Ill Patients/ OR (palliat* OR terminal* OR advance care OR (end ADJ3 life) OR (last ADJ3 (hour* OR day* OR week* OR year* OR month*) ADJ3 life) OR (last-phase ADJ3 life)).ab,ti.) NOT (letter OR news OR comment OR editorial OR congresses OR abstracts OR books).pt. AND english.la.

4. Cinahl

(MH Frail Elderly OR TI (frail* OR (functional* N2 impair* N2 (elder* OR old)) OR oldest-old* OR very-old* OR ((vulnerab* OR multimorbid*) N2 (old OR elder*)) OR nonagenerian* OR octogenerian* OR centenarian* OR supercentenarian*) OR AB (frail* OR (functional* N2 impair* N2 (elder* OR old)) OR oldest-old* OR very-old* OR ((vulnerab* OR multimorbid*) N2 (old OR elder*)) OR nonagenerian* OR octogenerian* OR centenarian* OR supercentenarian*)) AND (MH Palliative Care OR MH "Hospice and Palliative Nursing" OR MH Terminal Care OR MH Terminally Ill Patients OR TI (palliat* OR terminal* OR advance care OR (end N2 life) OR (last N2 (hour* OR day* OR week* OR year* OR month*) N2 life) OR (last-phase N2 life)) OR AB (palliat* OR terminal* OR advance care OR (end N2 life) OR (last N2 (hour* OR day* OR week* OR year* OR month*) N2 life) OR (last-phase N2 life))) NOT PT (letter OR news OR comment OR editorial OR congresses OR abstracts OR books) AND LA(english)

5. Cochrane

((frail* OR (functional* NEAR/3 impair* NEAR/3 (elder* OR old)) OR oldest-old* OR very-old* OR ((vulnerab* OR multimorbid*) NEAR/3 (old OR elder*)) OR nonagenerian* OR octogenerian* OR centenarian* OR supercentenarian*):kw,ab,ti) AND ((palliat* OR terminal* OR 'advance care' OR (end NEAR/3 life) OR (last NEAR/3 (hour* OR day* OR week* OR year* OR month*) NEAR/3 life) OR (last-phase NEAR/3 life)):kw,ab,ti)

6. Web of Science

TS=(((frail* OR (functional* NEAR/2 impair* NEAR/2 (elder* OR old)) OR oldest-old* OR very-old* OR ((vulnerab* OR multimorbid*) NEAR/2 (old OR elder*)) OR nonagenerian* OR octogenerian* OR centenarian* OR supercentenarian*)) AND ((palliat* OR terminal* OR "advance care" OR (end NEAR/2 life) OR (last NEAR/2 (hour* OR day* OR week* OR year* OR month*) NEAR/2 life) OR (last-phase NEAR/2 life)))) AND DT=(article) AND LA=(english)

7. Google scholar

"frail|oldest|very|vulnerable old|elderly" palliative|terminal|terminally|"advance care"|"end of life" "primary health|care|healthcare"|"home care"|"general|family practitioner|practice|physician|doctor"|community|"in|at home"|hospice|"independent living"

PART 2

Development and pilot evaluation of a timely short-term specialised palliative home care service intervention for older people with frailty

CHAPTER 4

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 (ie. 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 e.g. service providers are willing and able to deliver the intervention. The intervention components included implementation components, e.g. training for service providers, and a core component, i.e. 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-centered and family-focused; 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.

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, i.e. 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 three 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).

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).

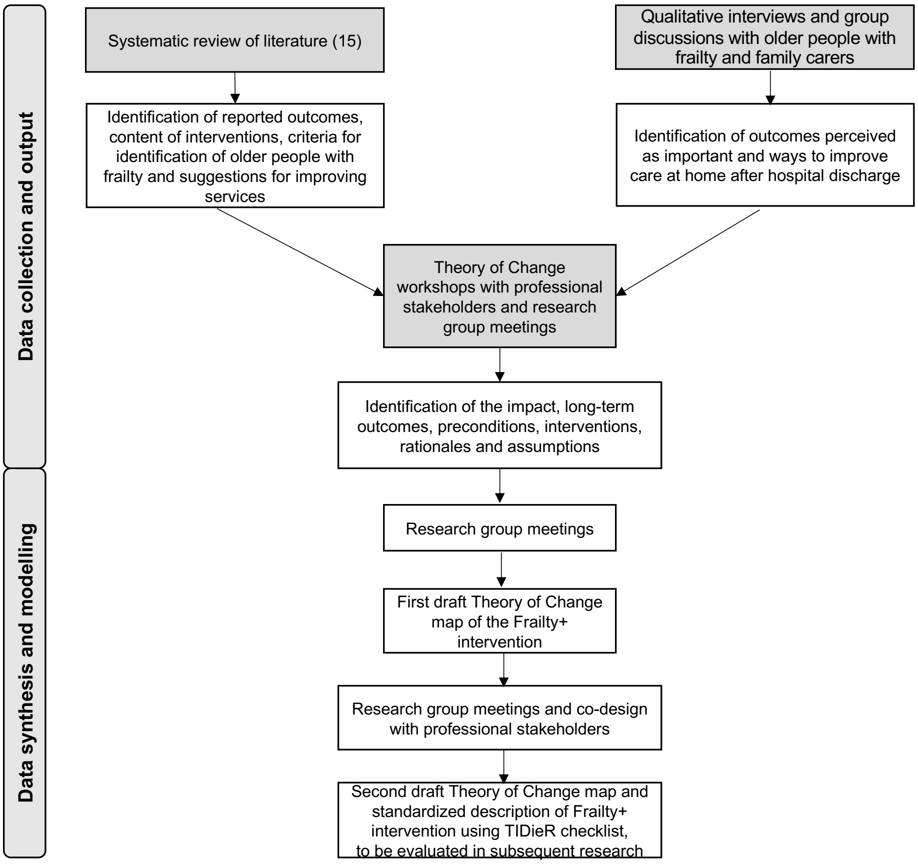


Figure 1. Diagram of information sources and synthesis process for developing the Theory of Change of the Frailty+ intervention.

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 two 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 two 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 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.

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 Supplementary 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 pre-determined 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, i.e. 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).

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).

Table 2. Characteristics of stakeholders involved in the workshops.

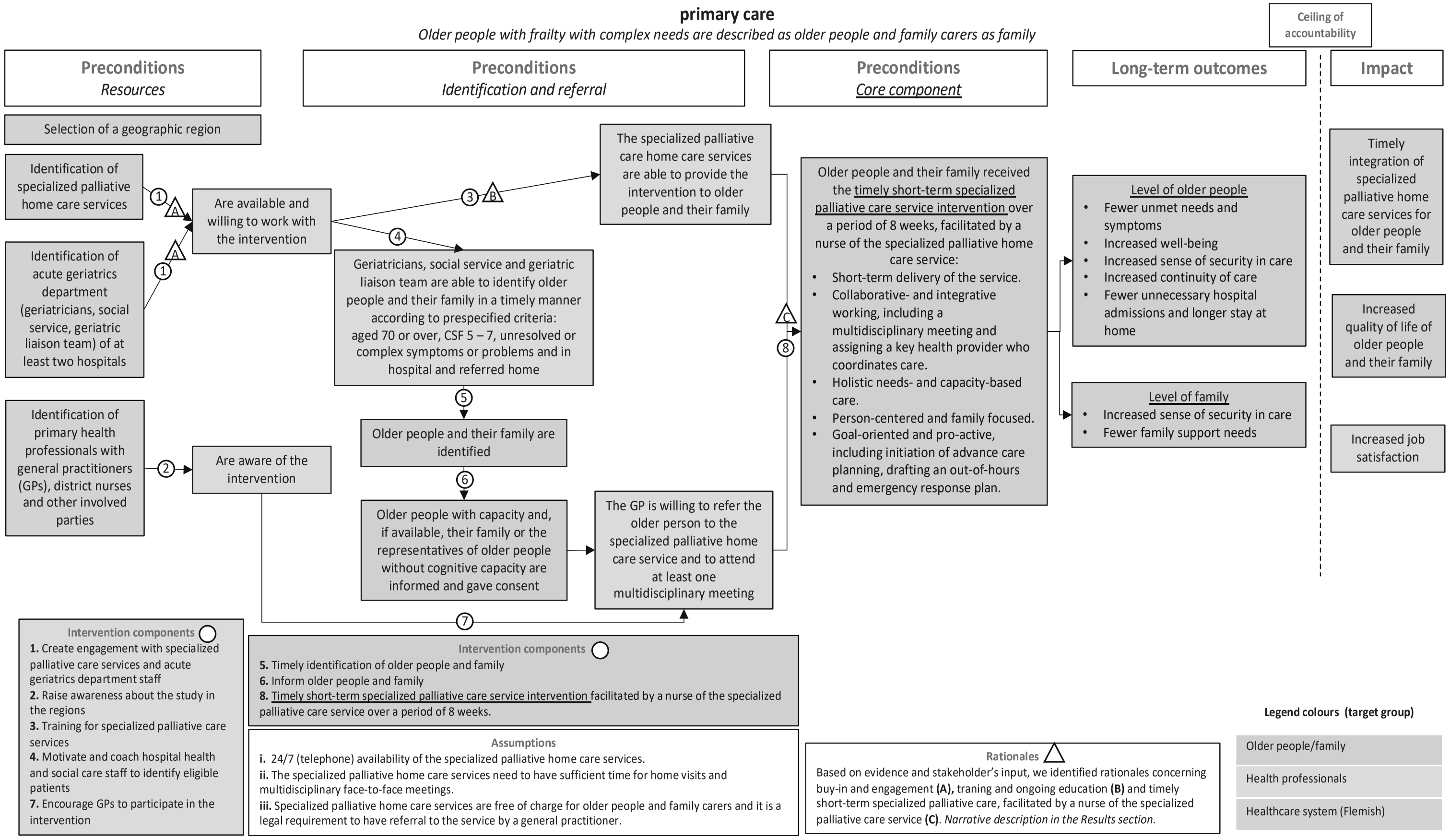
Characteristics	Workshop 1 (N=5)	Workshop 2 (N=16)	Workshop 3 (N=13)	Workshop 4 (N=11)	Total (N=45)
Gender					
female	5	12	7	4	28
male	0	4	6	7	17
Primary profession					
Healthcare providers:					
General practitioner	0	2	3	1	6
Primary care nurse	0	5	3	2	10
Specialized palliative care nurse	5	2	1	3	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
Researcher in:					
Social and health sciences	0	3	1	1	5

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.

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

Older people with frailty with complex needs are described as older people and family carers as family



Intervention components ○

1. Create engagement with specialized palliative care services and acute geriatrics department staff
2. Raise awareness about the study in the regions
3. Training for specialized palliative care services
4. Motivate and coach hospital health and social care staff to identify eligible patients
7. Encourage GPs to participate in the intervention

Intervention components ○

5. Timely identification of older people and family
6. Inform older people and family
8. Timely short-term specialized palliative care service intervention facilitated by a nurse of the specialized palliative care service over a period of 8 weeks.

Assumptions

i. 24/7 (telephone) availability of the specialized palliative home care services.
ii. The specialized palliative home care services need to have sufficient time for home visits and multidisciplinary face-to-face meetings.
iii. Specialized palliative home care services are free of charge for older people and family carers and it is a legal requirement to have referral to the service by a general practitioner.

Rationales △

Based on evidence and stakeholder's input, we identified rationales concerning buy-in and engagement **(A)**, traning and ongoing education **(B)** and timely short-term specialized palliative care, facilitated by a nurse of the specialized palliative care service **(C)**. *Narrative description in the Results section.*

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 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 Supplementary 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) (9,51), 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).

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 hours)	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	Information leaflet about the study	Motivate and coach staff to identify eligible	Researchers	Face-to-face group	Hospitals	Before the start of the study and	Timing and location of meetings	Meetings: number, persons

health and social care staff to identify eligible patients		patients and co-design of inclusion criteria				ongoing meetings		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 Supplementary 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 hours)	Timing of when patients are screened	-
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	Information brochure and	Encourage GPs to participate and obtain their	Researchers	Phone calls	In the region	Ongoing	Timing of when GPs are called by the researcher.	-

the intervention	informed consent form	informed consent						
Core component								
8. Timely short-term specialized palliative care service intervention	Written semi-structured guides for home visits and multidisciplinary meetings (see Supplementary 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 hours).	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 5 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, i.e. at times when needs are no longer met by generalist palliative care providers. The service is delivered on a short-term basis, i.e. 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.

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 (29–31). 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 (32). 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 (33).

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 (14,33–35). 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 (36–38). 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) (39,40).

The professional stakeholders indicated that older people with frailty with complex needs often require support from family carers. This is also highlighted as an central part of a palliative care approach (41). This intervention therefore follows a care approach that includes family carers as both care recipients and care providers (42). 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 (43). 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 (44,45).

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 (15,16,23,46). 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 (47,48), 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 (49) 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 (39,40). 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 (44,45).

The developed intervention has a short-term nature and outcomes are measured directly after the intervention period, i.e. 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 (50) and for older people with chronic noncancer conditions (51) 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 (40,52), 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, e.g. 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-centered 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) (40).

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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1a) Study conception and design: de Nooijer, Pivodic, Van Den Noortgate, Pype, Evans, Van den Block;
1b) Acquisition of data: de Nooijer, Pivodic, Van den Block;
1c) Analysis and interpretation of data: de Nooijer, Pivodic, Van Den Noortgate, Pype, Evans, Van den Block;
2) Drafting the manuscript: de Nooijer
3) Critical revision: de Nooijer, Pivodic, Van Den Noortgate, Pype, Evans, Van den Block.

All authors have approved the final manuscript and agree to be accountable for all aspects of the work. Questions related to the accuracy or integrity of any part of the work will be appropriately investigated and resolved.

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Supplementary table 1. Main areas discussed during Theory of Change workshops.

Workshop	Areas
1 and 2	• Identify and describe the population of older people with frailty in need of specialized palliative care services in primary care. • Reach consensus among the participants on the **impact** of timely short-term specialized palliative care service intervention for older people with frailty in primary care. • Identify the **long-term outcomes**. • What are the **preconditions** or intermediate outcomes needed to achieve the **long-term outcomes**?
3	• Presentation of the draft Theory of Change map. • In-depth review and discussion of the map. • Identify **intervention components** or activities needed to attain the preconditions. • Why do we think a given precondition will lead to reach the one that follows it (i.e. identify **rationales**) or that a given intervention will help achieve a specific precondition? • Formulate **assumptions** or prerequisites that need to be in place for successful implementation of the intervention.
4	• Presentation of the draft Theory of Change map • In-depth review and discussion of the map.

Supplementary Table 2. Inclusion and exclusion criteria for patients

Inclusion criteria *All connected by 'AND'*	1. aged 70 years or over 2. have a Clinical Frailty Scale (CFS) score (28) between 5 and 7 i.e. mild to severe frailty, as judged the treating physician in the hospital[a] 3. have one or more unresolved or complex symptoms or problems, as judged by the treating physician in the hospital[b] 4. are in a hospital and referred to return to their home in the regions covered by the participating specialized palliative home care services 5. are able to speak and understand Dutch, and provide informed consent to participate in the study. If a person lacks capacity to consent the representative specified in the Belgian law for patient rights will be approached (55). 6. have a family carer who is eligible and willing to participate[c] OR do not have a family carer corresponding to the inclusion criteria
Exclusion criteria *All connected by 'OR'*	1. have had one or more palliative care consultations (i.e. specialized palliative home care service and/or palliative care unit) in the 6 months prior to inclusion in the study 2. have taken/are taking part in another research study that evaluates a palliative care intervention 3. have urgent palliative care needs and/or are deteriorating rapidly (and should therefore be referred to specialized palliative care)

a The CSF is a scale based on activities of daily living which categorizes frailty on a scale of 0 - 9, with higher scores indicating greater frailty (28)

b Unresolved or complex symptoms or problems can include situations such as, but not limited to: complex needs of patient and/or family in the physical, psychological, social and/or spiritual domain; 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 (for example, dissonance or conflicts, older patients who refuse care etc.) (8,56)

c Inclusion criteria for family carers: person for whom the patient (or representative if patient does not have cognitive capacity) indicated that they are the most important family carer or representative AND person lives with the patient or has in-person contact with him or her at least twice a week.

Supplementary file 1. Written semi-structured guide for home visits

This guide has been developed for use in Dutch, and the English version is approximate and for information only.

- This document is intended as a guide for nurses in the specialized palliative care services and contains five categories with several related topics.
- The goal of the guide is to structure conversations with patients and/or family carers.
- Not all topics will be addressed on every home visit; the order is not fixed and is dependent on the specific situation. The goal is to address all categories throughout eight weeks. Please describe in the electronic patient record what has been discussed.

Introduction/role of the specialized palliative home care team

Patient: Needs, functioning and capacities
Physical, psychological, social, spiritual
Other (such as practical or information needs)

Discuss the present and future
Coping, how to deal with the current situation and uncertainties
Realistic life, health and care goals and preferences for the future
Goals of care and preferences for the future, including place of care
Information about advance care planning and its importance
Discuss wishes and preferences regarding end-of-life care and decisions (last weeks/-days of life)
Documentation of advance directives
Appointment of a representative

Caregivers and coordination of care
Discuss formal and informal networks of health and social care services: Who is involved in the patient's care (professionals, family carers and the patient him/herself)
Point of contact for patient and family carer
Discuss 'emergency response plan' and 'out-of-hours plan'

Family carer: Care recipient and care provider
Family carer as care provider: Support needs in caring for the patient
Family carer as care recipient: Support needs, capacities and burden

Supplementary file 2. Written semi-structured guide for multidisciplinary meetings on palliative care in primary care

This guide has been developed for use in Dutch, and the English is approximate and for information only.

- This document is intended as a guide for nurses in the specialized palliative care services to structure the multidisciplinary meeting on palliative care in primary care.
- Ideally, the nurse of the specialized palliative care service initiates this meeting. The concrete implementation (e.g. date, location) can, if desired, proceed in the form of standard multidisciplinary meetings organized by health insurance funds or social services.
- The goal is to structure the meeting with all involved professionals, family carers and patients and to achieve coordination.
- Not all topics will be addressed at every meeting; the order is not fixed and is dependent on the specific situation. Preferably all themes will be addressed.
- The space below the themes is for your own notes. *Please describe in the electronic patient record what has been discussed.*

Introduction of current informal and formal networks of health and social care services: **Who has currently which role or task in the patient's care (professionals, family carers, the patient him/herself?** **Who is attending the meeting, who participates by telephone?**

What is the desired direction of the patient's care? Which goals do we want to reach? What is our shared vision? **To provide person-centred and goal-oriented care, it is important to work from a shared vision based on patient needs, preferences and realistic goals for the future.**

Future informal and formal networks of health and social care services: **Who is needed to achieve the set goals?** **Who is the key person who coordinates the patient's care (and ensures that agreements are respected)?** **Think also of: What if the specialized palliative care service (after x weeks) is no longer actively involved in the patient's care?**

Discuss and draft an '<u>emergency response plan'</u> and <u>'out-of-hours plan'</u>. It is also recommended to discuss this (on paper) with the patient and family carer.

Discuss and record ways for ensuring future collaboration and communication. **Where will this be recorded?** **How will we communicate in the future?** **Are additional multidisciplinary meetings needed? Who will inform care providers not attending the meeting?**

CHAPTER 5

Timely short-term specialized palliative care service intervention for frail older people and their family carers in primary care: study protocol for a pilot randomized controlled trial

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ABSTRACT

Introduction There is limited evidence regarding the effectiveness of timely integration of short-term specialized palliative care services for older people in primary care. Using a Theory of Change approach, we developed such an intervention, the Frailty+ intervention. We present the protocol of a pilot randomized controlled trial (RCT) with a process evaluation that aims to assess the feasibility and preliminary effectiveness of the Frailty+ intervention.

Methods and analysis We will conduct a pilot RCT in Flanders, Belgium. Frail older people who are discharged to home from hospital will be identified and recruited. Seventy-six will be randomly assigned either to the control group (standard care) or the intervention group (Frailty+ intervention alongside standard care). Data will be collected from patients and family carers. At the core of the Frailty+ intervention is the provision of timely short-term specialized palliative care facilitated by a nurse from the specialized palliative home care service over a period of eight weeks. We will assess feasibility in terms of recruitment, randomization, acceptability of the intervention, retention in the programme and data completion. The primary outcome for assessing preliminary effectiveness is a mean score across five key symptoms that are amenable to change (i.e. breathlessness, pain, anxiety, constipation, fatigue), measured at baseline and eight weeks post-baseline. The process evaluation will be conducted in the intervention group only, with measurements at eight to eleven weeks post-baseline to evaluate implementation, mechanisms of change and contextual factors.

Ethics and dissemination The study has been approved by the ethics committee of University Hospital Ghent. Results will be used to inform the design of a full-scale RCT and will be published in a peer-reviewed, open access journal.

Trial registration number The study is registered at ISRCTN registry (no. ISRCTN39282347). It has been registered in September 2019. Patient recruitment has started in January 2020.

INTRODUCTION

A growing number of people worldwide are living into old age, yet the added years of life are not always spent in good health (1); many experience long periods of illness and multimorbidity (i.e. the simultaneous presence of multiple chronic conditions) or frailty. Different conceptualizations and operational definitions are used to define frailty, although many focus on the physical/medical domain of frailty. Some also include other domains such as the psychological and social (2–4). In this study, we use the definition of the British Geriatrics Society, defining frailty as 'a distinctive health state that is related to the aging process in which multiple body systems gradually lose their inbuilt reserves' (2). Frailty is a common condition in old age, and an estimated 26% in those aged 80 and over are frail (5). The increased susceptibility of frail older people to adverse health outcomes paired with the cumulative effects of various chronic health problems results in prolonged, complex and fluctuating needs and symptoms in the last years of life (6,7). As populations are ageing, the number of frail older people with such complex needs and symptoms is expected to rise considerably in the near future. Although these problems are known, evidence is lacking regarding which interventions are effective in addressing the resulting needs. Hence, there is an urgent need to develop and evaluate interventions that can improve care for frail older people towards the end of life.

Palliative care is suggested by the World Health Organization (WHO) as a way to address the problems associated with life-threatening illness by means of early identification, assessment and treatment of physical, psychosocial and spiritual problems (8). However, it has traditionally been limited to cancer patients and is often started in the terminal phase. Over the past decade, the WHO, researchers and clinicians have made strong calls for it to be initiated early in the course of any serious or advanced illness, even alongside life-prolonging treatments, to improve quality of life (7–9). Nevertheless, research shows that access to palliative care is lower for older than for middle-aged and younger people (10) and is 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)). Frail older people may benefit from timely initiation of palliative care, especially in the community setting, as the majority of older people prefer to live at home as long as possible (12).

Two complementary palliative care service models have been advocated across patient populations: generalist palliative care from healthcare professionals who provide basic management of symptoms, and specialized palliative care from a multidisciplinary service or a clinician whose core activity is to support primary care professionals in caring for patients and family carers (13,14) In particular at times when palliative care needs become too complex to be handled by generalist providers alone, the involvement of specialized palliative care services is recommended (13,14). The EAPC Atlas of Palliative Care showed that, although typology varies, similar services are established in most European countries (15).

Building on an integration of generalist and specialized palliative care, a new model of short-term integrated palliative and supportive care for people with multiple sclerosis has demonstrated feasibility and beneficial outcomes (16,17). This model consisted of episodic involvement of a specialized palliative care service integrated with existing primary care providers (16,17). It has also been proposed for older people with frailty or other progressive conditions (18–21).

This protocol concerns a pilot randomized controlled trial (RCT) with a process evaluation that aims to assess the feasibility, acceptability and preliminary effectiveness of a timely short-term specialized palliative care service intervention for frail older people and their family carers in primary care (henceforth named the Frailty+ intervention). We will conduct a pilot RCT as there is currently insufficient evidence on the feasibility and acceptability of such an intervention and RCT design.

Additionally, we will seek to answer the same research questions in the specific population of frail older people with a cancer diagnosis. This sub-analysis is part of a research project (with LP as PI) linked to this pilot RCT. While previous studies have shown that palliative care, including early palliative care, can improve key symptoms in people affected by cancer (16,22,23), they have not tested whether this also applies to the specific health problems and disease trajectory experienced by older people with cancer. The cancer trajectory in older people is considerably different from that of younger patients. An estimated 80% of people aged over 85 experience multimorbidity (24); 43% of cancer patients aged 70 or over are frail (25). Moreover, cancer and cancer treatment can worsen a number of geriatric syndromes (e.g. bone loss, anaemia, depression, fatigue, insomnia) (26). The cumulative effects of these conditions can lead to complex and unpredictably fluctuating symptoms over the course of several years (7). It is therefore important to test whether a timely short-term specialized palliative care service can be beneficial in this patient group as well.

The specific objectives of the pilot RCT are:
1. To pilot the Frailty+ intervention and evaluate its implementation, mechanisms of change and contextual factors potentially affecting implementation and outcomes.
2. To test the feasibility of the methods and procedures of the RCT.
3. To evaluate the preliminary effectiveness of the Frailty+ intervention in frail older people, with and without cancer, and their family carers.

METHODS AND ANALYSES

In describing the study protocol, we followed the Standard Protocol Items of the Recommendations for Interventional Trials (SPIRIT) 2013 Checklist (27) and the Consolidated Standards of Reporting Trials (CONSORT) 2010 checklist (28).

Study design

We will conduct a pilot RCT with two parallel groups (38:38 patients) and an embedded process evaluation. The intervention group will receive the Frailty+ intervention in addition to standard care. The control group will receive standard care. Patients who consent will be randomly assigned to one of the study arms after baseline assessment. The assessments will be conducted at baseline and eight weeks after the baseline measurement. Data will be collected from patients and their family carers.

Study setting

In Belgium, multidisciplinary and trained teams of health care professionals are the main providers of specialized palliative care at home. Their main goal is to advise general practitioners (GPs), health professionals, counsellors, informal carers and volunteers involved in the provision of palliative home care of a patient and to organize and coordinate the provision of palliative care at home between different care providers (29). The GP's approval is required to initiate this service (29), usually consisting of nurses, a psychologist and a palliative care physician and covering a geographical region. The intervention in this study will be conducted in Flanders, the Dutch-speaking region of Belgium, in cooperation with two specialized palliative home care services. Recruitment of patients will be done via three hospitals in Flanders, one of which is a university hospital.

Eligibility criteria

Patients will be recruited upon discharge from a hospital admission. The inclusion and exclusion criteria for patients are provided in Table 1. For the specific recruitment of frail older people with cancer (as specified above), we will apply an additional criterion based on a previous study of early palliative care in oncology (30). Additionally, patients will be asked to indicate their most important family carer. The inclusion and exclusion criteria for family carers are provided in Table 2.

Table 1. Inclusion and exclusion criteria for patients

Inclusion criteria *All connected by 'AND'*	1. aged 70 years or over 2. have a Clinical Frailty Scale (CFS) score (31) between 5 and 7 i.e. mild to severe frailty, as judged by the treating physician in the hospital[a] 3. have one or more unresolved or complex symptoms or problems, as judged by the treating physician in the hospital[b] 4. are in a hospital and referred to return to their home in the regions covered by the participating specialized palliative home care services 5. are able to speak and understand Dutch, and provide informed consent to participate in the study. If a person lacks capacity to consent the representative specified in the Belgian law for patient rights will be approached (32) 6. have a family carer who is eligible and willing to participate (see Table 2) OR do not have a family carer corresponding to the inclusion criteria
Inclusion criterium for frail older people with cancer	7. have advanced-stage solid tumor or hematologic malignancy
Exclusion criteria *All connected by 'OR'*	1. have had one or more palliative care consultations (i.e. specialized palliative home care service and/or palliative care unit) in the 6 months prior to inclusion in the study 2. have taken/are taking part in another research study that evaluates a palliative care intervention 3. have urgent palliative care needs and/or are deteriorating rapidly (and should therefore be referred to specialized palliative care)

a The CSF is a scale based on activities of daily living which categorizes frailty on a scale of 0 - 9, with higher scores indicating greater frailty (31).

b Unresolved or complex symptoms or problems can include situations such as, but not limited to (13,33): complex needs of patient and/or family in the physical, psychological, social and/or spiritual domain; 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; 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 (for example, dissonance or conflicts, older patients who refuse care etc.)

Table 2. Inclusion and exclusion criteria for family carers

Inclusion criteria *All connected by 'AND'*	1. Person for whom the patient (or representative if patient does not have cognitive capacity) indicated that they are the most important family carer or representative 2. Person lives with the patient or has in-person contact with him or her at least twice a week
Exclusion criteria *All connected by 'OR'*	1. Person has taken or is taking part in another research study that evaluates a palliative care intervention 2. Person does not speak or understand Dutch

Treatment arms

Standard care (control) group

Patients in the control group will receive standard care from primary care providers (e.g. GP, district nurses) and any specialists. If a patient is referred to a specialized palliative home care service as part of standard care within their follow-up period (eight weeks), we will exclude them from the study.

Intervention group

We have developed and modelled the Frailty+ intervention, using a theory-based development approach (Theory of Change) integrated with the UK Medical Research Council (MRC) framework for developing and evaluating complex interventions (34–37). As part of this, we integrated the evidence of a previously conducted systematic literature review of specialized palliative care services for older people in primary care (20) with qualitative research, including qualitative interviews and group discussions with older people and family carers, Theory of Change workshops with professional stakeholders (i.e. bringing together key professional stakeholders to develop a Theory of Change map and to encourage stakeholder buy-in (34)), and research group meetings.

The Frailty+ intervention will be provided alongside any standard care. The core components of the Frailty+ intervention are the provision of timely short-term specialized palliative care, facilitated by a nurse from the specialized palliative home care service over a period of eight weeks; care should be holistic and based on needs as well as capacities; it should be person-centred and family-focused as well as goal-oriented and pro-active; collaboration and integration with other health professionals is essential (see box 1 for more information on each component). Additional implementation components are added to this to ensure optimal implementation. They include informing, engaging and training of professionals involved in primary and secondary care in the intervention region and identification and referral of frail older people with complex unresolved symptoms who have been hospitalised and are referred home, and of their family carers.

Box 1. Description of the core components of the Frailty+ intervention

Timely integration of short-term specialized palliative care service: 1 – 4 home visits with, if needed, additional phone follow-up, over a period of 8 weeks.
Holistic needs- and capacity-based care: identifying and managing support needs in the four palliative care domains i.e. physical, psychological, social and existential/spiritual, and focusing on disabilities as well as functioning and capacities (strengths and deficits).
Person-centered and family focused, viewing family as both care recipients and care providers.
Goal-oriented and pro-active care: focus on the patient's individual health and care goals across several health, life and care domains; supporting the patient in defining and meeting realistic or attainable goals and determining how well these goals are being met. This also includes the initiation of advance care planning conversations and drafting an emergency response plan and out-of-hours plan.
Collaborative- and integrative working: focus on multiprofessional and multidisciplinary collaboration, coordination and continuity of care from the perspective of the patient and family. This includes the organization of at least one multidisciplinary face-to-face meeting with health care professionals involved in the patient's care and appointing a key health professional for the patient and family within the primary care team who coordinates care within the multidisciplinary team.

Timing of intervention

The first home visit will take place within five working days after discharge from the hospital. The additional visits and the multidisciplinary meetings will be planned by the nurses from the specialized palliative home care service with each patient and family individually. We foresee at least one and on average three to four home visits per patient and additional telephone calls, if needed, over a period of eight weeks. An overview of the participant flow through the pilot RCT is displayed in Figure 1.

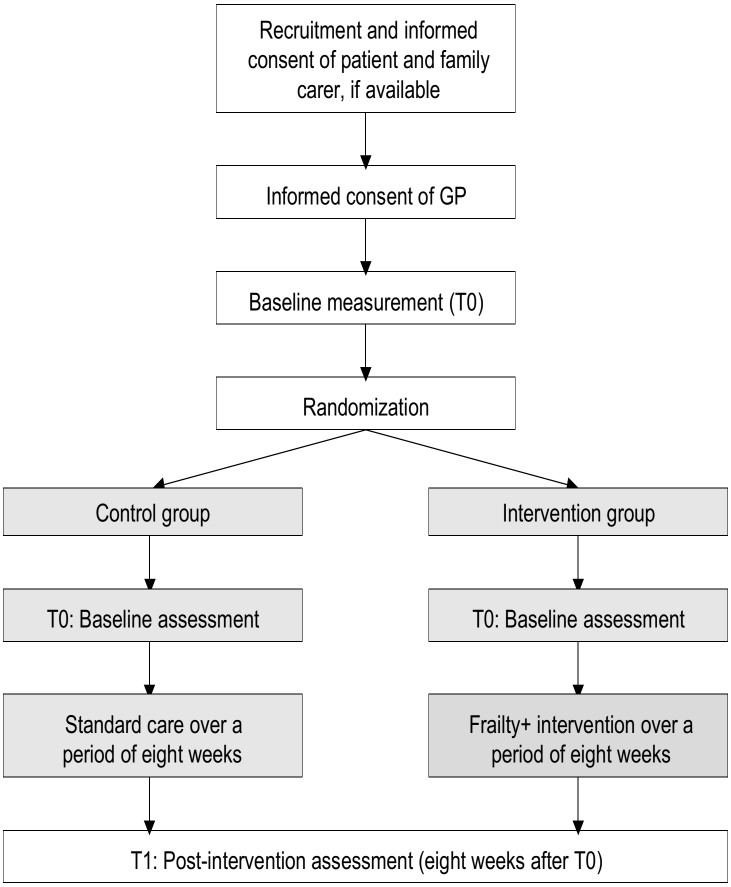

Figure 1. Flow chart of participant flow through pilot RCT. GP, general practitioner; RCT, randomized controlled trial

Outcomes and data collection

Objective 1: pilot the Frailty+ intervention and evaluate its implementation, mechanisms of change and contextual factors affecting implementation and outcomes

To address objective 1, we will conduct a process evaluation, guided by the MRC process evaluation framework (38), to evaluate the following:

1) components and activities that were delivered as part of the Frailty+ intervention, their ‘dose’ or ‘quantity’, and the adaptations that were made to the initial intervention description;
2) views of and experiences with the timely short-term specialized palliative care service intervention, according to healthcare professionals (palliative home care services, GPs, geriatric liaison teams, geriatricians), patients and family carers;
3) occurrence and type of unexpected or adverse effects, according to healthcare professionals (palliative home care services, GPs, geriatric liaison teams, geriatricians), patients and family carers;
4) which external factors, if any, influenced the implementation and outcomes of the Frailty+ intervention according to healthcare professionals (palliative home care services, GPs, geriatric liaison teams, geriatricians), patients and family carers.

The process evaluation focuses on the intervention so will be carried out in the intervention group only. We will use a mixed methods approach, integrating quantitative and qualitative data. The data will be collected by the researcher and the data manager prior to recruitment and eight to eleven weeks after baseline (i.e. at T1). The quantitative data will be collected through registrations in standardized documents developed by the researchers and by the use of a structured data extraction form to scan electronic patient records. The qualitative data will be collected through semi-structured qualitative interviews and focus groups. The interviews and focus groups will be audio recorded and transcribed verbatim by the researcher. An overview of the data that will be collected and the methods and timing of data collection is given in Table 3.

Table 3 Process evaluation: data collected, methods and timing

Data collected	**Methods of data collection**	**Timing of data collection/extraction**
1) Components and activities that were delivered as part of the Frailty+ intervention, "dose" or "quantity" and the adaptations that were made compared to the initial intervention description		
Meetings and training sessions with healthcare professionals; information brochures distributed to primary care providers Number of meetings, number of training sessions, number of information brochures distributed to primary care providers Persons who attended the meetings and training sessions Topics discussed during the meetings and training sessions	Registration by researcher in standardized document developed by the researchers	Prior to patient recruitment
Home visits Number and duration of home visits per patient Topics discussed during home visits	Data extraction from electronic patient records completed by nurses of the specialized palliative home care service using a structured data extraction form	T1: 8 weeks
Multidisciplinary face-to-face meetings and other collaboration/communication between healthcare professionals Number and timing of multidisciplinary meetings per patient Persons who attended the multidisciplinary meetings Topics discussed during the multidisciplinary meetings Number of consultations between nurses of the palliative home care services and the advising geriatrician Number of contacts and topics discussed among palliative home care services, GPs, district nurses, hospital staff	Data extraction from electronic patient records completed by nurses of the specialized palliative home care service using a structured data extraction form	T1: 8 weeks
2) Views of and experiences with the timely short-term specialized palliative service care intervention, according to the healthcare professionals (palliative home care services, GPs, geriatric liaison teams, geriatricians), patients and family carers		
Patients and family carers Experiences with home visits and multidisciplinary meetings, including perceived barriers and facilitators	Semi-structured qualitative interviews with patients and family carers	T1: 8 – 11 weeks
Specialized palliative home care services, GPs and geriatric liaison teams in hospitals and hospital geriatricians Views and experiences with the home visits, the collaboration with other healthcare professionals (including multidisciplinary meetings and geriatric advice), and the use of the semi-structured guidance documents, including perceived barriers and facilitators	Focus groups with specialized palliative home care services Semi-structured qualitative phone interviews with GPs Focus groups with geriatric liaison teams and geriatricians	T1: 8 – 11 weeks
3) Occurrence and type of unexpected or adverse effects, according to the healthcare professionals (palliative home care services, GPs, geriatric liaison teams, geriatricians), patients and family carers		
Number of activations of distress protocol including reason for activation	Registration by researcher in standardized document developed by the researchers	Throughout the study period, as applicable
4) Which external factors, if any, influenced the implementation and the outcomes of the Frailty+ intervention according to the healthcare professionals (palliative home care services, GPs, geriatric liaison teams, geriatricians), patients and family carers.		

Views and experiences of healthcare professionals (palliative home care services, GPs, geriatric liaison teams, geriatricians), patients and family carers on external factors that influenced implementation and outcomes	Semi-structured qualitative interviews with patients and family carers Focus groups with specialized palliative home care services Semi-structured qualitative telephone interviews with GPs Focus groups with geriatric liaison teams and geriatricians	T1: 8 – 11 weeks

Evaluation of care delivered in control group

In order to evaluate and explore care in the control group, the researchers will conduct telephone interviews with the GP eight weeks after the baseline measurement (after post-intervention assessment) to obtain the following information: which care providers delivered care and where (e.g. home, hospital); number of visits or consultations (by GP and other healthcare professionals), topics discussed, if any multidisciplinary meetings were organized (and if so, who attended and which topics were discussed).

Objective 2: To test the feasibility of the methods and procedures of the RCT

The feasibility of the RCT methods and procedures will be tested in the intervention and control group using a mixed methods approach, integrating quantitative and qualitative data (see Table 4 for detailed information). The data will be collected by the researcher, the data manager and the hospital staff involved in patient recruitment. The quantitative data will be collected through registrations in standardized forms developed by the researchers. The qualitative data will be collected through semi-structured qualitative interviews and focus groups.

Table 4. Feasibility of the methods and procedures: operationalizations and data collection methods

Data collected	Methods of data collection	Timing of data collection/extraction
<u>Recruitment procedure</u> 1) Number of eligible patients and family carers approached 2) Number and characteristics of eligible patients and family carers who were not approached and reasons for not approaching them 3) Number of approached patients, family carers and GPs who provided informed consent 4) Number and characteristics of patients and family carers who refused to participate and reasons for refusal (if stated) 5) Views of and experiences with the information letter and informed consent procedure of patients, family carers and GPs 6) Views of and experiences with the inclusion criteria and their application, and the introduction of the study to patients and family carers of the geriatric liaison team and geriatricians.	1) and 2) Registration on standardized form developed by researchers and completed by the hospital staff involved in recruitment 3) and 4) Registration by researchers in standardized document developed by the researchers 5) Semi-structured qualitative interviews with patients and family carers and semi-structured qualitative telephone interviews with GPs 6) Focus groups with geriatric liaison teams and geriatricians	1 – 4) Throughout the study period 5, 6) T1: 8 weeks
<u>Randomisation procedure</u> 1) Number of patients who gave informed consent and who started their randomly allocated treatment 2) Views of and experiences with the randomisation procedure of patients, family carers and GPs	1) Registration by researchers in standardized document developed by the researchers 2) Semi-structured qualitative interviews with patients and family carers and semi-structured qualitative phone interviews with GPs	1) Throughout the study period 2) T1: 8 weeks
<u>Retention in the study</u> Number of patients, family carers and GPs who dropped out of the study and reasons for dropping out (if stated)	Registration by researcher in standardized document developed by the researchers	Throughout the study period
<u>Data collection completion</u> 1) Number of patients and family carers who completed baseline measurements 2) Number of patients and family carers who completed follow-up assessment (T1) and reasons for not completing the baseline measurements or follow-up measurements (if stated) 3) Patients' and family carers' views of and experiences with the baseline measurement and the follow-up assessments	1) and 2) Registration by researcher in standardized document developed by the researchers 3) Semi-structured qualitative interviews with patients and family carers	1, 2) Throughout the study period 3) T1: 8 weeks

Objective 3: To evaluate the preliminary effectiveness of the Frailty+ intervention in frail older people

The evaluation of preliminary effectiveness will be carried out by comparing the intervention and control groups (see Table 5 for details). We will measure the primary and secondary outcomes using structured questionnaires (administered in interview format). The data will be collected by the researcher and data manager at T0 and T1 from patients and family carers at a place and time of their preference. Respondents will be interviewed separately (or together, if they prefer). The primary outcome is the mean score across five key symptoms that are amenable to change (i.e. breathlessness, pain, anxiety, constipation, fatigue) as measured using the integrated Palliative care Outcome Scale (iPOS). The iPOS is a validated questionnaire with good psychometric properties (39,40).

Table 5. Primary and secondary outcomes and respective measures to pilot the RCT and assess preliminary effectiveness

Outcome	Scale/instrument	Respondent	Number of items	Timing
Primary outcome				
Five key symptoms amenable to change in the past week (mean score across the items)	Integrated Palliative care Outcome Scale (iPOS) (40)	Patients	5	T0: 0 weeks T1: 8 weeks
Secondary outcomes				
Most distressing symptom in the past week	Extra question added to the Integrated Palliative care Outcome Scale (iPOS) (40)	Patients	1	T0: 0 weeks
Palliative care needs	Integrated Palliative care Outcome Scale (iPOS) (40)	Patients	17	T0: 0 weeks T1: 8 weeks
Well-being	ICECAP Supportive Care Measure (ICECAP-SCM) (42)	Patients	7	
Sense of security in care	Sense of Security in Care – Patients (SEC-P) (43)	Patients	15	
Continuity of care[a]	Nijmegen Continuity of Care (NCQ) (44)	Patients	16	
Views on care[a]	Palliative care Outcome Scale – Views on Care (POS-VoC) (45)	Patients	1	
Sense of security in care	Sense of Security in Care – Relatives (SEC-R) (46)	Family carers	17	
Family carers' support needs	Family Appraisal of Caregiving Questionnaire for Palliative Care (FACQ-PC) (47)	Family carers	14	
Exploratory outcomes				
Healthcare utilization (number and length of hospital admissions, including to intensive care unit and emergency department, number of GP visits and days spent in hospital or elsewhere	Structured phone interviews	GPs	n/a	T1: 8 weeks
Patient's and family carer's perspective on the extent to which their self-identified goals and wishes are respected	Semi-structured qualitative interviews	Patients and family carers		
Attitudes towards and feelings of team collaboration among healthcare professionals	1) Semi-structured qualitative interviews 2) Focus groups	1) GPs 2) Specialized palliative home care services, and separately with geriatric liaison teams and geriatricians		

a: measured by subscales of the indicated questionnaire.

In addition, we will measure exploratory outcomes (i.e. outcomes that are used to frame future research questions or explore new hypotheses (41)) using a mixed methods approach, integrating quantitative and qualitative data (see Table 6). These data will be collected by the researcher and the data manager at T1 only. The quantitative data will be collected through structured phone interviews and the qualitative data through semi-structured qualitative interviews and focus groups. The qualitative interviews and focus groups will be audio recorded and transcribed verbatim by the researcher.

For all participating patients, we will register basic sociodemographic data (i.e. gender, age, educational attainment, current or previous professions) and aspects of their social situation (i.e. living situation, marital status, number of children, geographic proximity and contact frequency with family and friends). Age at baseline, gender and medical diagnosis data will be taken from the patient medical file by hospital staff, other sociodemographic data at the T0 interview. We will also collect basic sociodemographic data of the family carer (i.e. gender, age, relation to the patient) during the interview at T0.

Pre-testing of questionnaires

The questionnaires to assess the primary and secondary outcomes from patients and family carers will be translated from English into Dutch, where necessary, using forward-backward procedures and pre-tested with five patients and five family carers (or until data saturation is reached). Participants for pre-testing will be identified according to inclusion and exclusion criteria as described in Tables 1 and 2 and will be recruited at one of the participating hospitals.

Capacity and proxy measurements

If a patient does not have the capacity to consent to participation (according to the clinical judgment of the treating physician, see recruitment section for evaluation of cognitive capacity) at T0 and/or at T1, a proxy respondent will be identified following stipulations of Belgian law concerning representatives of people lacking cognitive capacity (32). The first choice is the patient’s legal representative; if none has been assigned, this will be the person named in the will as executor (32). Only when there is no person named as executor, the representative is the spouse or any other beneficiary (32). For data collection with proxy respondents, a proxy version of the patient questionnaire will be used..

Sample size

The main objective of this pilot RCT is to assess feasibility and acceptability of the intervention, and of the RCT methods and procedures. As determining effectiveness is not the main objective, sample size calculations seem of less importance (48,49). Nevertheless, we have conducted a provisional sample size calculation to allow the reader to interpret our analysis of preliminary effectiveness of the Frailty+ intervention based on the only similar RCT available at time of development (follow-up periods and the patient population differ to some extent) (50). The intervention will be evaluated in two groups: frail older people and frail older people specifically with a cancer diagnosis. We aim to include 50 eligible patients, 25 in each study arm; it is estimated that this will allow us to detect differences of >1.6 on the Palliative Outcome Scale (for individual items) at $\alpha=0.05$ and power $1-\beta=0.80$ (50). After the target sample has been reached, we will sample an additional 25 frail older people who have a cancer diagnosis in order to achieve a sample of N=50 frail older people with cancer (based on the estimate that around half of those included will have a cancer diagnosis; clinical estimate based on patient numbers at the participating university hospital). The total sample will therefore be N=76 (rounded up to an even number). To allow for an expected attrition of 45%, we plan to recruit at least 139 patients.

Recruitment

Patients will be recruited at the acute geriatric department and through the geriatric liaison teams of several hospitals in Flanders. Each hospital will assign one staff member as contact person; the treating physician will judge if a patient meets the inclusion criteria and will ask them if they will agree to a researcher visiting them to introduce the study; if so, the treating physician or contact person will inform the research team. Once every three weeks the researcher or data manager will attend the multidisciplinary meeting at the acute geriatric department in each hospital to ensure that all eligible patients are offered the opportunity to participate in the study.

On their initial visit, the researcher will inform the patient about the details of the study and what participation entails. They will explain the term ‘specialized palliative care service’ (i.e. an additional service that is often provided at the end of life for people with advanced serious illnesses but may be beneficial also at earlier stages of illness), and that this study aims to test whether timely provision would be feasible and acceptable and beneficial for older people discharged from the hospital. If the patient agrees to participate, the researcher will ask them to provide written informed consent and indicate their most important family carer (if they have one and conforming to inclusion and exclusion criteria) and whether they can be contacted for participation in the study. They will then visit the family carer to inform them about the study and obtain written informed consent. They will also ask the patient for permission to contact their GP to introduce the study and obtain their written informed consent to participate in the study.

If the patient does not have cognitive capacity (according to the clinical judgment of the treating physician) a proxy respondent will be approached (for details on this procedure, see outcomes and data collection section). It is important to test the Frailty+ intervention in those without cognitive capacity too as they form a large proportion of the older population (51) ensuring that the conclusions apply to this population as well.

Patients randomized to the intervention group will be referred to the specialized palliative home care service by the researcher which will then obtain a formal referral from the GP, as required in the Belgian health care system. In case the patient is randomized to the control group, the GP will be informed and will provide standard care.

Patient recruitment started in January 2020 and is expected to end in December 2020 (last patient follow-up ends in February 2021). Due to COVID-19, recruitment was suspended between March 13 – June 9, 2020. We will adapt the timing should the crisis cause further delays.

Randomisation and blinding

Patients will be randomized in a 1:1 ratio to receive either the Frailty+ intervention or standard care. We will use a block randomization technique with a variety in blocks, in order to reduce potential bias (i.e. the variety in blocks prevents the researcher being able to predict which group the patient will be referred to) and achieve balance in allocation of patients to the intervention and control arm which will be done randomly by an external researcher independent of the research team for this study. This is an unmasked trial. The researchers involved in data collection cannot be blinded in this pilot RCT as the process evaluation is conducted in the intervention group only.

Analysis

Process evaluation and feasibility

The data collected via the standardized documents and the structured data extraction form developed by the researcher will be described using descriptive summary statistics (mean, standard deviation, percentages). All qualitative data will be analysed by using thematic content analysis (i.e. inductive coding into themes) (52). One researcher will read the transcripts carefully several times to have a sense of the data, with a sample checked by another researcher. Both researchers will independently conduct the preliminary analysis by generating initial codes and converting them into categories that represent the main themes and categories arising from the data. The identified themes and categories will be compared, and in case of disagreement, a third reviewer will reconcile any discrepancies. Subsequently, meetings with the research team will enable consensus to be reached on the themes and categories. The analysis will be conducted in the original Dutch language, and final themes and categories (as well as selected quotes) will be translated to English by one researcher in cooperation with a professional translator.

Preliminary effectiveness

We will calculate summative scale scores for the primary and secondary outcomes. The resulting scale score for an individual is the sum of the individual item scores. If more than 25% of the items per scale were not answered (i.e. missing), no sum score will be calculated for that scale and will be defined as missing. The pilot RCT data will be analysed on 'intention-to-treat' principle. This means that all patients who were enrolled and randomized will be accounted for in the main analysis, regardless whether they completed the Frailty+ intervention or not. The characteristics of patients in the intervention and control group will be described using descriptive summary statistics. We will test for differences in the primary and secondary outcomes between the groups at baseline and eight weeks later (i.e. T1). Linear mixed model analyses will be used with treatment, time and treatment-by-time interaction as independent variables and with two random factors, one for clustering of patients within hospitals and one for clustering of the two measures within patients. Linear mixed models handle missing data through maximum likelihood estimation, so no missing data imputation method will be applied. All significance tests will be two-tailed and assessed at the 5% significance level. The quantitative exploratory data will be described using descriptive summary statistics and the qualitative data using thematic content analysis. All analyses will be conducted in IBM SPSS and R.

Patient and public involvement

Patients and family carers were involved in the design of the study.

ETHICS AND DISSEMINATION

Ethics approval and consent to participate

The study has been approved by the ethics committee of the University Hospital Ghent. In line with GDPR guidelines of May 2018, an internal register will provide all required information on e.g. the purposes of all processing operations; a description of the categories of data subjects and the recipients or categories of recipients to whom the data are disclosed; the legal basis of the processing operation for which the data are intended (the detailed internal register of all procession operations will also be sent to the Data Protection Officer of the University Hospital Ghent). In order to protect participants' rights, information materials and informed consent forms are carefully formulated and structured to ensure that participants know exactly what participation in the study entails.

Distress Protocol

The contact details of the researchers are mentioned on all information letters, consent forms and questionnaires. This allows the participants to contact the research team in case they feel the need to do so. In case a specific concern arises, the researcher will examine, together with the patient and family carer, which of their regular health care professionals is available to provide professional help and/or support. In addition, a psychologist from our research group (external to this project) will be available to provide support during the study period.

Confidentiality

The collected and transferred data will be pseudonymised to ensure that participants' privacy and personal information are protected (e.g. all personal information that can lead to identification of the patient or the family carers is changed into a code by those that perform the data entry, e.g. the researchers). We will use sufficient safety measures to protect the data, e.g. virtual server firewall, and back-up systems and sufficient access controls (i.e. ID and ultra-high password regulator and frequent password changes).

Availability of data and material

The final data set will be available to all researchers involved in this study. After reporting of the results, the data will be stored safely for 25 years, with Prof. Dr. Lieve Van den Block being responsible for their storage. The audio files will be deleted immediately after transcription. Following the publication of the main results of the pilot RCT, the respective data will be made available for non-commercial research purposes upon a reasonable request made to the researchers.

Dissemination

The results of this study (feasibility of the methods and evaluation of the intervention) will be submitted for publication in peer-reviewed journals and will be presented at national and international conferences. Participants and health care professionals involved in the study will be informed about the results in a leaflet. The results of this study will be used to adapt the theoretical model of the intervention and inform the design of a subsequent full-scale effectiveness trial.

Contributors: Conception and design of the work: KdN, LP, NVDN, PP, LVdB; Ethics committee application: KdN, LP, NVDN, PP, LVdB; Study registration: KdN, LP, LVdB; Drafting of the article: KdN, LP, LVdB; Critical revision for important intellectual content: NVDN, PP, LVdB; All authors read and approved the final manuscript.

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CHAPTER 6

Timely short-term specialised palliative care services for older people with frailty and their family in primary care: easier said than done

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Submitted

ABSTRACT

Background: There is insufficient evidence on the feasibility and effects of short-term palliative care interventions for older people. We developed Frailty+ in a theory-guided process based on stakeholder input.

Aim: To pilot Frailty+ and evaluate its implementation, assess feasibility of the trial design, and test for intervention effects.

Design: Pilot randomised controlled trial and process evaluation (ISRCTN39282347). Patients were assigned to standard care and Frailty+ (timely palliative home care over eight weeks by specialised palliative care nurses) or to standard care. We assessed Frailty+ implementation and feasibility of the trial design during and post-intervention. The primary outcome for intervention effects was mean change on a sum score consisting of five palliative care symptoms from baseline to eight weeks.

Setting/participants: Older patients with frailty and complex needs and their families were recruited from two Belgian hospitals upon discharge.

Results: We recruited a smaller sample (N=37) than planned (N=50). We randomised patients to Frailty+ (N=19) or standard care (N=18), and included 26 family carers. Participants generally valued Frailty+. Most patients were visited only once over the eight-week period. Nurses did not organise multidisciplinary meetings as foreseen, deeming them unnecessary for patients they judged to have no urgent needs. The trial methods were largely feasible. We found no intervention effects on the primary outcome.

Conclusions: Although Frailty+ was well-received, it was not entirely implemented as intended. This is likely due to difficulties implementing palliative care services in an earlier phase of illness. Prior to conducting a full-scale RCT, intervention modifications are required.

INTRODUCTION

Many older people with frailty are affected by multiple complex and fluctuating care needs in the last years of life (1,2). Palliative care is indicated to address these needs (3). The World Health Organisation describes palliative care as an approach that aims to improve the quality of life of patients and their families facing the problems associated with life-threatening illness, through the early identification, assessment and treatment of physical, psychosocial, and spiritual problems (3). There is an accepted differentiation in palliative care provision between *generalist* palliative care provided by health and social care providers who have good basic palliative care skills and knowledge, and *specialised* palliative care provided by multidisciplinary services or clinicians whose main activity and tasks are the provision of palliative care and who are specifically trained in this (4–6). For those who require it, it is advised that specialised palliative care services are delivered timely in a patient's illness trajectory, that is, when needs are too complex to be met by generalist palliative care providers alone, regardless of expected survival (4,6). However, in practice, palliative care services are generally involved very late in the disease trajectory (7–10), and older people with non-cancer conditions are less likely to access them (11). This underscores the need to develop and evaluate palliative care services that can be initiated in a timely way and address the complex needs of older people with frailty in the last years of life. This is particularly required in the setting where they most often reside, i.e. at home (12).

A model of community-based short-term palliative care has recently been developed with the aim to reduce the serious health-related suffering of older people with serious non-cancer conditions (13). This model foresees service delivery during episodes of complex symptom presentation integrated within existing primary care services (13,14). It also foresees short-term delivery, i.e. one to three visits over a period of three months (13). This intervention was tested in southern England in a pilot randomised controlled trial (RCT) and improvements in the primary outcome i.e. patient symptom burden were observed (14). While this is the first valuable evidence, it remains unclear which intervention components and processes have led to changes in outcomes for older people. Moreover, it is currently not known how or under which conditions such services should be implemented in practice for older people with frailty and their family. Without specifying these aspects of the specialised palliative care intervention, this existing model cannot be directly translated to other healthcare contexts.

We have developed and modelled a theory-based timely short-term specialised palliative care intervention for older patients with frailty and complex care needs and their family carer in primary care (i.e. Frailty+) (15). The underlying Theory of Change of Frailty+, visualised in a map, specifies how and under which circumstances the intervention is expected to work (15). In this paper, we address the following three objectives:

1) To pilot the Frailty+ intervention and evaluate its implementation, the underlying mechanisms of change, and the contextual factors potentially affecting implementation and outcomes.
2) To assess the feasibility of the methods and procedures of the RCT, specifically the recruitment and randomisation procedure, retention and data collection completion.
3) To test the preliminary effectiveness of the Frailty+ intervention in older people with frailty and their family carers.

METHODS

Study design

We conducted a non-blinded pilot RCT with a two-arm parallel design and an embedded process-evaluation. The feasibility and process evaluation employed convergent mixed methods; quantitative and qualitative data were collected in parallel and then analysed separately (16). The process evaluation design was informed by the Theory of Change map underpinning Frailty+ (15), the UK Medical Research Council (MRC) guidance for process evaluations of complex interventions (17) and the Normalisation Process Theory (18). To test the preliminary effectiveness of Frailty+, we used quantitative data. Data were collected from February 2020 (start of patient recruitment) until March 2021 (data collection completion). Reporting of this pilot RCT followed the Consolidated Standards of Reporting Trials extension to randomised pilot and feasibility trials statement (19). The trial protocol has been published (20) and was registered at ISRCTN (identifier: ISRCTN39282347).

Study setting

Frailty+ is situated in the home setting. Two specialised palliative home care services, each covering a geographical region in Flanders (Belgium), facilitated the provision of Frailty+. These specialised palliative care services are delivered by a multidisciplinary team comprising nurses, psychologists, and palliative care physicians. In Belgium, these services are generally involved in the last days or weeks of the disease trajectory of terminally ill patients with serious symptoms or problems (7,8,10). Patients were recruited upon discharge from the acute geriatrics department and via the multidisciplinary mobile geriatric teams of two hospitals. These teams deliver care to patients with a geriatric profile admitted to a non-geriatric unit and advise other hospital care staff according to geriatric concepts and principles (21).

Participants and recruitment process

Older patients and family carers

The data collectors (KE, AJ) attended weekly staff meetings in one hospital and identified potentially eligible patients for the study. In the other hospital, researchers were not allowed to attend the meetings and the geriatricians and mobile geriatric staff identified patients.

Patient inclusion criteria were:

- ≥ 70 years of age;
- Clinical Frailty Scale score (CSF) between 5 and 7 (22);
- one or more unresolved or complex symptoms or problems in the physical, psychological, social and/or spiritual domain as judged by their treating physician in the hospital (23,24);
- admitted to a hospital and about to be discharged home in the region covered by the participating specialised palliative home care service and;
- Dutch-speaking.

Exclusion criteria were:

- had one or more palliative care consultations in the six months prior to study inclusion;
- had taken part in another research study that evaluated a palliative care intervention;
- had urgent palliative care needs and/or rapidly deteriorating health (and should therefore be referred to specialised palliative care) or;
- the family carer declined to participate in the study.

Family carers of eligible patients were those the included patient indicated were their most important carer or representative. Inclusion criteria were that they lived with the patient or had in-person contact with him/her at least twice a week. Exclusion criteria were that had taken part in another study that evaluated palliative care or were not Dutch-speaking.

The data collectors/researcher informed eligible patients and their families about the study. They introduced the term specialised palliative care as ‘an additional service that is often provided at the end of life for people with serious chronic conditions but may be beneficial at earlier stages’. Eligible patients and families were asked to provide written informed consent. Where a person lacked capacity to consent, we approached the appropriate representative as specified in the Belgian law for patient rights (25).

Healthcare professionals

The data collectors/researcher contacted general practitioners (GPs) of patients who agreed to participate. They introduced the study to them and obtained their written informed consent. This is required in Belgium to initiate specialised palliative care services (26). The process evaluation included as respondents the specialised palliative care teams, the included patients’

GPs and the recruiting geriatricians and mobile geriatric teams. The researcher invited the two specialised palliative care teams, separately, for 60-minute online focus groups. The GPs were each invited for a 15-minute structured phone interview. We invited recruiting geriatricians and mobile geriatric staff of the two hospitals, separately, for a 60-minute online focus group.

Randomisation and masking

We randomised patients after the baseline measurement. Patients were randomised (1:1) to Frailty+ in addition to standard care (intervention group) or to standard care alone (control group). We used a permuted block randomisation technique with a variety in block sizes, to reduce potential allocation prediction and to achieve balance in allocations of patients to the two arms. The statistician (SDB) created computer-generated sequences. An external researcher (RM) was the only person able to access the sequences. This was an unmasked trial.

The Frailty+ intervention

Both the intervention and the control group received standard care. Patients assigned to the intervention group received standard care plus Frailty+. Should a patient in the control group be referred to a specialised palliative care service as part of standard care, the participant would remain in the control group. Development of Frailty+ was informed by the UK MRC guidance for complex interventions (27) and the Theory of Change approach (28). We used the Template for Intervention Description and Replication (TIDieR) to describe Frailty+ (29). We described development and content of the intervention elsewhere (15). In summary, Frailty+ consists of seven implementation components and a core component. The implementation components were based on informing and engaging generalists and specialists in the study regions and selection and referral of older people with frailty and complex care needs upon hospital discharge, and their families. Moreover, we educated palliative care nurses on topics related to the specific problems of older people with frailty and on the need for needs- and capacity-based and pro-active care, and how to work with the semi-structured guides for the home visits and multidisciplinary meetings. The core comprised five sub-components, namely:

- Short-term delivery of the specialised palliative care service: the service is initiated timely i.e. when the patient’s complex care needs cannot be addressed by generalist providers alone. The service is delivered on a short-term basis: it was estimated to involve at least one and probably no more than four home visits by the palliative care nurse with additional phone follow-up, according to needs.
- Collaborative and integrative working: nurses were encouraged to organise at least one multidisciplinary primary care meeting on palliative care per patient.

- Holistic needs- and capacity-based care: nurses were encouraged to identify and manage patients' palliative care needs, as well as their strengths and capacities.
- Person-centred as well as family-focused care: nurses were encouraged to view family as both care recipients and care providers.
- Goal-oriented and pro-active care: nurses were encouraged to support patients to define and meet their health and care goals across various health, care, and life domains.

The specialised palliative care services received financial support from the researchers to provide Frailty+ for older people with complex needs.

Data collection and outcomes

Sociodemographic and clinical characteristics

The data collectors/researcher collected patients' and family carers' sociodemographic characteristics using a questionnaire administered in a structured interview format. Information about the patient's medical diagnosis was collected from the patient medical file (via the treating hospital physician).

Implementation, mechanisms of change and contextual factors (Objective 1)

We collected quantitative and qualitative data in the intervention group only. The quantitative data, e.g. the number of activations of the distress protocol, were collected during the intervention period through registration in standardised documents developed by the researchers. We also conducted semi-structured qualitative interviews with patients and their families, focus groups with specialised palliative care teams and with the mobile geriatric teams and geriatricians, and structured phone interviews with GPs. Topic guides for the interviews and focus groups explored implementation, mechanisms of change and contextual factors of Frailty+ (17). For the focus groups with the specialised palliative care teams we used additional questions of the Normalisation MeAsure Development (NoMAD) tool (30), which is informed by the Normalisation Process Theory (18). This theory is based on four key constructs, namely coherence i.e. sense-making, cognitive participation i.e. engagement, collective action i.e. work done to enable the intervention to happen, and reflexive monitoring i.e. appraisal of benefits and costs of intervention (18). The NoMAD tool measures implementation from the perspectives of those delivering the intervention (30). We adapted these questions according to Frailty+. An overview of the collected data, methods and timing of data collection is given in Table 1.

Table 1. Process evaluation: Data collected, methods and timing of data collection

Data collected	Methods of data collection	Timing of data collection/extraction
Implementation i.e. the components and activities that were delivered as part of the Frailty+ intervention, their 'dose', and the adaptations that were made to the initial intervention description		
1. Number of information brochures distributed to primary care providers 2. Number of meetings and training sessions with healthcare professionals, who attended, and topics discussed 3. Number and duration of home visits and topics discussed 4. Number and timing of multidisciplinary meetings, who attended, and topics discussed 5. Number of consultations between nurses of the palliative home care services and the advising geriatrician, and topics discussed 6. Number of contacts between palliative home care services, GPs, districts nurses and hospital staff, and topics discussed	1. and 2. Registration by researcher in standardised document developed by the researchers. 3 – 6. Data extraction from electronic patient records completed by specialised palliative care nurses using a structured data extraction form.	1. and 2. Prior to patient recruitment 3 – 6. Post-intervention
Mechanisms of change i.e. healthcare professionals', patients' and family carers' responses to and interactions with the Frailty+ intervention, and whether there were any unexpected events		
1. Patients' and family carers' views of and experiences with the home visits and multidisciplinary meetings, including perceived barriers and facilitators 2. GPs' views of and experiences with the home visits, collaboration with other health care professionals (including the multidisciplinary meetings), including perceived barriers and facilitators 3. Geriatricians' and mobile geriatric teams' views of and experiences with the training sessions, meetings, home visits, collaboration with other health care professionals (including the multidisciplinary meetings), including perceived barriers and facilitators 4. Specialised palliative care teams' views of and experiences with the training sessions, meetings, home visits, collaboration with other health care professionals (including multidisciplinary meetings and geriatric advice), the use of the semi-structured guidance documents, including perceived barriers and facilitators to introducing, implementing, and embedding the new service model 5. Number of activations of distress protocol including reason for activation	1. Semi-structured qualitative interviews 2. Structured phone interviews 3. and 4. Focus groups 5. Registration by researcher in standardised document developed by the researchers.	1. and 2. 8 – 11 weeks post-baseline 3. and 4. post-intervention 5. Throughout the study period, as applicable
Contextual factors i.e. factors, external to the intervention, that influenced the implementation and outcomes of the Frailty+ intervention according to healthcare professionals, patients, and family		
Specialised palliative care nurses', mobile geriatric staff', geriatricians', GPs', patients', and family carers' views of and experiences with external factors that influenced implementation and outcomes.	Focus groups with specialised palliative care nurses, and with geriatricians and mobile geriatric staff Semi-structured qualitative interviews with patients and family Structured phone interviews with GPs	Focus groups: post-intervention Interviews: 8 – 11 weeks post-baseline

Feasibility of the RCT methods (Objective 2)

During the intervention period, the researcher, data collectors and recruiting hospital staff collected quantitative feasibility data through registration in standardised documents. The researcher also conducted semi-structured qualitative interviews with patients and family and structured phone interviews with GPs 8-weeks post-baseline, and focus groups with recruiting hospital staff post-intervention, assessing:

- <u>Recruitment procedure, comprising:</u>
    - Number of eligible, approached, and enrolled patients and family carers
    - Number and characteristics of eligible patients and family carers not approached or not enrolled, and reasons for not approaching them or for patients' or family carers' refusal to participate
    - Patients', families' and GPs' views of the information letter and informed consent procedure
    - Mobile geriatric teams' and geriatricians' views of and experiences with the inclusion criteria and their application, and the procedure of introducing the study to patients
- <u>Randomisation procedure, comprising:</u>
    - Number of patients randomised to allocated treatment
    - Patients', family carers' and GPs' views of and experiences with randomisation procedure
- <u>Retention in the study, comprising</u>:
    - Number of patients, family carers and GPs who dropped out of the study, and reasons for dropping out (if stated)
- <u>Data collection completion, comprising</u>:
    - Number of patients and family carers who completed the baseline assessment or reasons for not completing it (if stated)
    - Number of patients and family carers who completed follow-up assessment or reasons for not completing it (if stated)
    - Patients' and family carers' views of and experiences with completing both the baseline assessment and follow-up assessment

Preliminary effectiveness of the Frailty+ intervention (Objective 3)

We used structured interviews for patients and family carers at baseline, i.e. T0, and 8-weeks post-intervention, i.e. T1. We assessed primary, secondary, and exploratory outcomes. The secondary outcomes were used to investigate additional effects of Frailty+, while the exploratory outcomes were used to explore new research hypotheses (31). The primary outcome was mean change on a sum score based on five key palliative care symptoms (i.e.

breathlessness, pain, anxiety, constipation, drowsiness) from baseline to 8-weeks, measured by the Integrated Palliative Care Outcome Scale (IPOS) (32). The secondary outcomes for patients were 1) palliative care needs (IPOS) (13), 2) well-being (ICECAP Supportive Care Measure) (33) and 3) sense of security in care (Sense of Security in Care – Patients) (34). The secondary outcomes for family carers were sense of security in care (Sense of Security in Care – Relatives) (35) and family carers' support needs (Family Appraisal of Caregiving Questionnaire for Palliative Care) (36). The exploratory outcomes for patients and family carers included the three subscales of the IPOS (32), the three subscales of the Sense of Security in Care – Patients (34), the three subscales of the Nijmegen Continuity Questionnaire (37), one item, i.e. overall quality of life today, of the IPOS - Views on Care (38), the three subscales of the Sense of Security in Care – Relatives (35) and the four subscales of the Family Appraisal of Caregiving Questionnaire for Palliative Care (36). We also collected exploratory information regarding the patient's healthcare utilisation (i.e. number and length of hospital admissions and number of GP visits) through phone interviews with their GP 8-weeks post-baseline.

Data analysis

Process evaluation and feasibility

The quantitative process evaluation and feasibility data were analysed using descriptive statistics. The first author transcribed all qualitative data from the interviews and focus groups verbatim. The transcripts were then deductively coded into themes according to the coding framework developed by the research team that focused on the study objectives and the three key process evaluation topics (17). A random 20% of the transcripts were independently coded by another researcher (RM) using the same analytical process. We then inductively formed subthemes within the deductive themes. The two independent coders met regularly to compare the results and discuss the coding structures. Analyses were conducted in NVIVO version 12.

Preliminary effectiveness

We aimed to include a total sample of 50 patients (25 in each study arm). However, the final sample size was 37. As the foreseen sample size was only an estimate and we aimed to test the preliminary effects in this pilot study, we decided to perform the data analyses as planned with 37 patients.

Characteristics of the intervention and control group were analysed using descriptive statistics. Differences in mean change from baseline to follow up at 8-weeks between the intervention and control group were tested using a generalised linear mixed model where the baseline value is also used as outcome measure. The fixed effects were treatment, time, and a treatment-by-time interaction. The random effects part included one random intercept for patient to account for the two measures within a patient. A negative binomial distribution with log link was used. Estimated marginal means at baseline and follow-up with corresponding 95% CI were reported, both for the intervention and control group. Moreover, we reported the estimated interaction effect which is the ratio of the mean ratio of Frailty+ over standard care post-intervention over the mean ratio of Frailty+ over standard care at baseline. Where the variance for the random intercept was estimated to be zero, the 95% CI for the interaction effect was calculated manually based on a normal z-distribution. Data analysis was based on the 'intention-to-treat' principle, where all patients randomised are analysed according to their allocated arm. All recorded observations were used for the analysis; the missing value mechanism behind missing outcome data is ignorable under missingness at random with likelihood inference. We used IBM SPSS version 26 to perform the analyses.

Ethical considerations

The study was approved by the commission of Medical Ethics of the University Hospital Ghent (B.U.N. B670201941807, date: January 22, 2020) and the local research committees of the other hospital. Older people, family carers and GPs (their approval is needed to initiate the service (26)), gave written informed consent for participation in the pilot RCT. Healthcare professionals involved in the focus groups and interviews gave verbal informed consent.

RESULTS

Participant flow and recruitment

Trial recruitment started in February 2020 and the last patient was recruited in December 2020 (last patient follow-up in February 2021). In total, 229 patients were eligible of whom 151 were approached. Of these, 37 (25%) were randomised to standard care plus Frailty+ (19 patients) or standard care alone (18 patients). Ultimately, 28 patients were assessed after eight weeks (intervention n=16 and control n=12). We included 26 family carers in the trial (intervention n=15 and control n=11). Figure 1 shows the CONSORT diagram of participant flow.

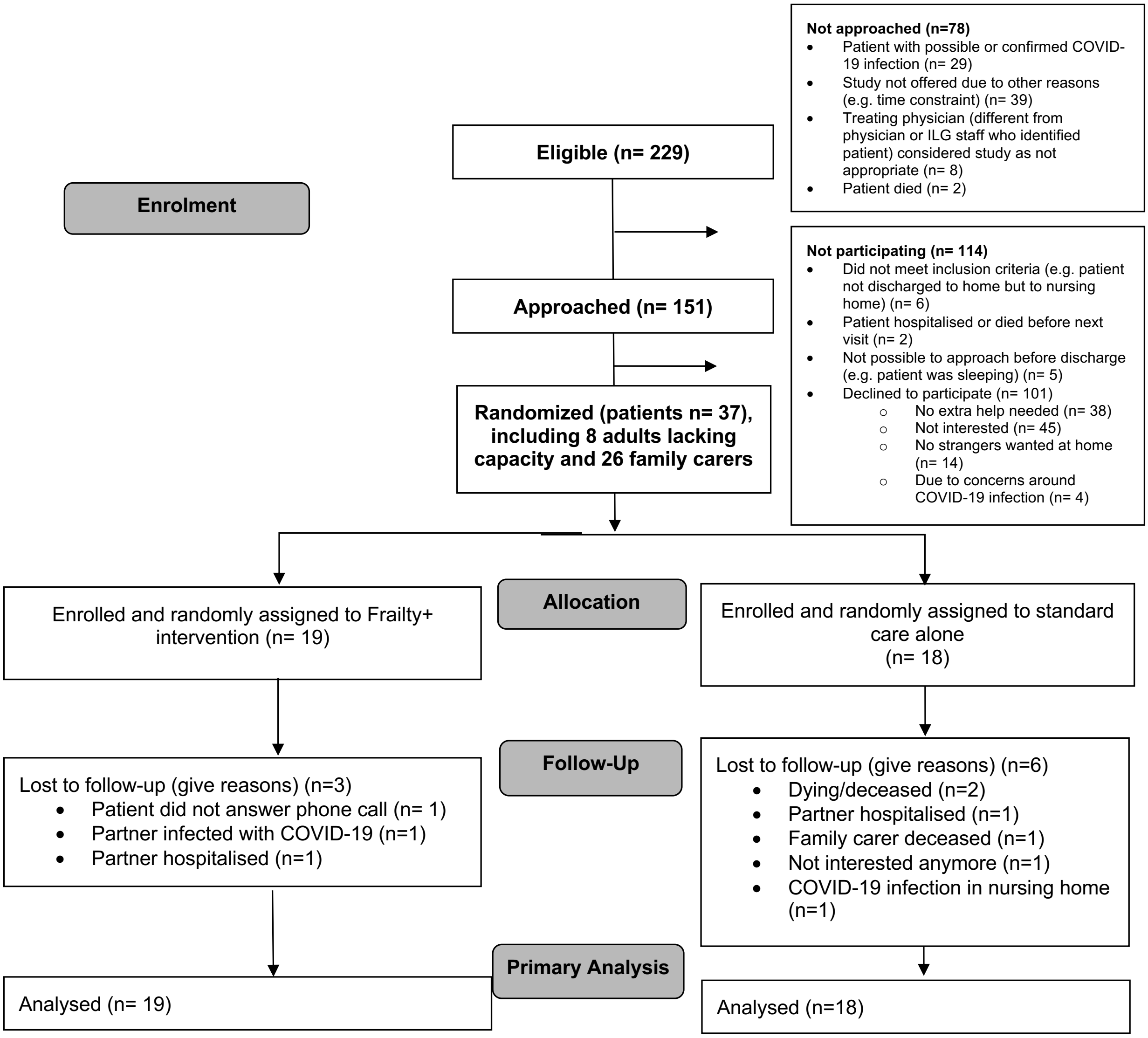

Figure 1. Consort flow diagram of recruitment and retention.

Participant characteristics

Older patients and family

Baseline patient characteristics are described by group in Table 2. The mean age of family carers in the intervention group was 68.8 years (SD 14.5) and in the control group 71.5 years (SD 12.2). Most family carers were women (intervention group 81.8% and control group

66.7%) and were the partner/spouse of the patient (intervention group 63.6% and control group 66.7%).

Table 2. Patient characteristics at baseline (n=37)

Characteristics	**Frailty+ intervention (n=19)**	**Control group (n=18)**
Age (years)		
Mean age (SD)	83.7 (5.3)	84.0 (7.0)
Age range	75 – 91	74 – 98
Gender		
Female (%)	10 (52.6)	8 (44.4)
Male (%)	9 (47.4)	10 (55.6)
Living situation		
Home, alone	6 (31.6)	7 (38.9)
Home, with partner/children/other	13 (68.4)	11 (61.1)
Clinical Frailty Score (CFS)[a,b,±]		
5 (%)	9 (52.9%)	6 (33.3%)
6 (%)	6 (35.3%)	5 (27.8%)
7 (%)	2 (11.8%)	7 (38.9%)
Medical diagnosis[b,c,±]		
Cancer (%)	4 (21.1)	7 (41.2)
Cardiovascular disease (%)	2 (10.5)	5 (29.4)
Nervous system disease (%)	3 (15.8)	4 (23.5)
Respiratory disease (%)	2 (10.5)	3 (17.6)
Liver disease (%)	2 (10.5)	0
Renal disease (%)	4 (21.1)	2 (11.8)
Gastrointestinal disease (%)	3 (15.8)	1 (5.9)
Psychological disease (%)	2 (10.5)	1 (5.9)
Recurrent falls (%)	3 (15.8)	0
Bone fracture (%)	0	2 (11.8)
Other (%)	4 (21.1)	2 (11.8)
Educational level[d]		
No education (%)	2 (10.5)	0
Primary education (%)	2 (10.5)	2 (11.1)
Lower secondary education (%)	7 (36.8)	5 (27.8)
Upper secondary education (%)	6 (31.6)	7 (38.9)
Higher education (%)	2 (10.5)	4 (22.2)
How many people outside the household have given any kind of personal care or practical help (i.e. informal carers)?		
0	7 (36.8)	4 (22.2)
1	4 (21.5)	6 (33.3)
2	0	3 (16.7)
3	2 (10.5)	5 (27.8)
> 3	6 (31.6)	0
Which types of professional health and social care providers provided care at home[a,b]		
Family care and additional home care	3 (15.8)	3 (16.7)
Homemaker or basic assistance care	4 (21.1)	5 (27.8)
Nursing care	15 (78.9)	12 (66.7)
Local service centre care	1 (5.3)	2 (11.1)
Social work services of the health insurance	1 (5.3)	0
Other	2 (10.5)	4 (22.2)

SD standard deviation

± Missing data standard care group: medical diagnosis (n= 1), missing data intervention group: CSF (n= 2).

A The CFS is scored from 0 to 9, with higher scores representing increasing frailty. We recruited patients scoring 5 to 7, corresponding to 'mildly to severely frail'.

B Reported by the treating physician in the hospital.

C More than one diagnosis per patient is possible. Intervention group: 5 patients had 2 diagnoses (26.3%) and 2 patients had 3 diagnoses (10.5%); Control group: 11 patients had 2 diagnoses (64.7%) and 0 patients had 3 diagnoses.

D Reported by the general practitioner.

E More than one provider per patient is possible.

Healthcare professionals

We conducted focus groups with participating healthcare professionals from January to March 2021. Two online focus groups with the specialised palliative care services (one each) were conducted, both together consisting of eight nurses and one coordinator (75% were female), and one online focus group with the recruiting staff of one hospital, including a nurse and an occupational therapist of the mobile geriatric team and a geriatrician (all female). In the other hospital, there was a preference for individual interviews. We performed online interviews with a psychologist from the mobile geriatric team and a geriatrician (both female). We conducted structured phone interviews (N=31) with GPs of patients included in the study (35% female). We could not reach six GPs for interviews (covering six patients, four from the intervention group and two from the control group).

Feasibility of the RCT design

Informed consent procedure, randomisation, and measurements

Most patients, family, and GPs indicated in the interviews that they had received sufficient information from the data collectors in the consent procedure to decide whether to participate. Some patients reported that they did not know what to expect from the home visits and they suggested we provide a clearer explanation of the different roles of the researchers and palliative care nurses in the consent procedure. Nine GPs could not remember exactly which information was given in the consent procedure. They felt that they were given enough time to think about participation.

Regarding the randomisation, two patients randomised to the control group mentioned that they preferred to be in the intervention group and to receive the palliative care service. Illustrative quotes for these results are presented in Table 3.

Identification, eligibility criteria, and introduction of the study

Hospital care staff mentioned in the focus groups that most patients were identified during the multidisciplinary meetings and that the attendance of the data collectors was necessary to remind them about the study. They described the need to ‘protect’ the patients for the study. Mobile geriatric staff of one hospital mentioned that they often forgot to focus on the complex needs criterion in the identification process (see Table 3 for illustrative quotes). The other hospital care staff highlighted that the inclusion criteria were rather broad since according to them almost all patients admitted to the acute geriatrics department had complex care needs and a CSF score between 5 – 7. Palliative care nurses also reported that the inclusion criteria were too broad, and many patients met those criteria. Three nurses suggested adding a criterion around patients having questions about end-of-life issues and to change the criterion around complex needs into those having more than one complex need.

In one hospital, the recruiting care staff first provided a short introduction about the study to the patient, as intended. They felt that this approach was important because they already knew the patient. In the other hospital, the care staff permitted the data collectors to approach the patient after identification. All recruiting hospital staff were concerned about how the researchers would explain palliative care and study processes to participants.

Table 3. Themes related to feasibility of RCT design identified through qualitative analysis of the interviews and focus groups split up by respondent groups

Themes	**Respondent group**	**Illustrative quotes**
Informed consent procedure, randomisation, and measurements		
Mixed views on information received in consent procedure	Patients and family carers, GPs	*It wasn't discussed very clearly how many times these people would come or what they were going to do. (Family carer)* *Very well described. You know what you are taking part in (GP)*
Preference to be in the intervention group	Patients and family carers in control group	*But I would actually do that directly because palliative care could be good for X (patient). But we were in the control group, so yes, unfortunately.* (Family carer)
Identification, eligibility criteria and introduction of the study		
No attention given to complex needs criterion	Mobile geriatric staff of one hospital	*The complex problems, well we didn't really pay so much attention to them in the identification process.* (Mobile geriatric staff member)
Need to "protect" patients for the study	Hospital care staff	*We want to protect these patients because we have seen them, oh, this is a weak one, no, this is not yet the moment to approach them whereas in fact that could be a patient who could have fitted in the study.* (Mobile geriatric staff member)
Too broad inclusion criteria	Hospital care staff, specialised palliative care teams	*Too broad, in my opinion, simply because this group is so wide, people are then obviously, if they have a frailty score between five and seven and one complex care need, then yes, obviously people have that very quickly.* (Specialised palliative care nurse)
Concerns about how researchers introduced the study to potential participants	Hospital care staff	*Let alone that you won't get the intervention. I think it's extremely difficult for patients to understand this.* (Mobile geriatric staff member) *The word palliative care makes it so negative for people, for many people of that generation it is a very tough word.* (Mobile geriatric staff member)
Suggestions for improvement		
Clear information, different roles of researcher and palliative care nurses	Patients and family carers	*Describe the task of researchers and palliative care team more clearly in the explanation and the information form. (*Family carer)
Add more specific inclusion criteria	Specialised palliative care teams	*Then I think that there should have been more unresolved needs as an inclusion criterion, because, for example if you go to someone who only has a physical symptom and otherwise everything is going well, then I think that you are not going to be able to help much there, are you? (*Specialised palliative care nurse)

Implementation of Frailty+

The intervention components and activities that were delivered are reported in Appendix, Table 1. All patients in the intervention group received at least one home visit from a palliative care nurse (N=19 patients), seven received a second and one a third (mean visits per patient: 1.4; mean duration 77 minutes). None of the patients in the control group received specialised palliative care in the intervention period. Nurses reported having provided psychosocial support during the first home visit for 16 of the 19 patients, introduction/information for 15/19, coordination/practical help for 12/19, pain control, symptom control and comfort care for 10/19 and life and existential questions support for 6/19. Details of the care provided during the second home visit are reported in Appendix, Table 1. Twelve patients received at least one phone call from the palliative care nurse (mean phone calls per patient: 1.3; mean duration 7 minutes). The nurses reported that they did not organise multidisciplinary meetings as was foreseen.

Mechanisms of Change

We present the responses of participants to the intervention in general and to the intervention components separately. The distress protocol was not activated during the study period. Themes and illustrative quotes are presented in Table 4.

Intervention in general

Palliative care nurses appreciated that the intervention was well planned, clear and they were regularly supported by the researchers. When we asked them about the differences between the population they usually care for and the study population, they mentioned that study patients seem to have a longer life expectancy and fewer care needs. This was also mentioned as a reason why home visits were often restricted to one only, as the nurses did not always perceive needs they would label as complex or urgent. Some reported that this earlier involvement could be beneficial to patients as they would already be involved in the care before their health deteriorated which could make it possible to build a trusting relationship before the deterioration. However, nurses also indicated that the downside of this approach is that they would need to take care of a lot more patients than they currently do.

Training sessions and meetings prior to patient recruitment

Palliative care nurses mentioned that the number of sessions and meetings were sufficient, the topics discussed were helpful to understand the study, and teams could discuss with each other. Nurses appreciated that they were asked for feedback in the development of the semi-structured guides. According to some of them, the topics listed in the home visit guides differed little from the topics they usually address during visits. Others felt that the topics presented in the guides expanded their knowledge, such as the topics on goal-oriented care.

Home visits and phone calls

Patients and family who received Frailty+ valued the home visits of the nurses. Palliative care nurses reported that patients often did not know them before the first visit. Patients, family, and nurses mentioned that often care was arranged well at the first home visit. However, three patients and families who received one visit mentioned that they would have liked to have received a follow-up visit. Nurses felt that the topics of the guides were not always applicable to the study patients (for example developing an emergency response plan, because this was already arranged). Nurses who planned more follow-up visits felt that the first visit was like an introduction, and the subsequent visits involved more in-depth conversations in which their expertise was more valuable. Some doubted whether their expertise was already needed in the first visits for patients perceived as not having complex needs. However, they also thought that they would not have reached the same level of conversation without those introductory visits. When we asked for views on the intervention duration, they mentioned that it depends on a patient's health status. Eight weeks might be too long if a patient has no urgent needs. Others said that follow-up time should be longer than eight weeks to ensure that the nurses are involved in care when the patient's health deteriorates.

Collaboration with other healthcare professionals

Palliative care nurses reported that the multidisciplinary primary care meetings were often not organised because the patient's health was judged stable, and care was arranged well. They also mentioned that they had limited contacts with other healthcare professionals.

Impact of Frailty+

When we asked the palliative care nurses what the outcomes of the intervention were for participants, they reported that the intervention lowered the threshold for patients to contact the service again in case their health deteriorated. One nurse mentioned that it changed patients' views on palliative care; they became more 'positive' about palliative care, they gained more insight into their own health and end-of-life preferences, and some wanted to continue palliative care follow-up after the intervention period. Several nurses emphasised that a trusting relationship with the patient is needed to achieve this impact.

Table 4. Mechanisms of change based on interviews and focus groups, split up by respondent groups

Themes	Respondent group	Illustrative quotes
Intervention in general		
Difference between population the nurses usually see and the study population	Specialised palliative care teams	*In the study, we come earlier, and the patient gets, after a number of visits, complex care needs, while usually, the patient would be referred to us at the moment he/she has the complex care needs, or even later* (Specialised palliative care coordinator)
Timely involvement of services is needed to build a trusting relationship	Specialised palliative care teams	*The complex needs occur when you are already involved in patient's care, so trust has already been established, so yes, that is an added value, of course, at the same time, what is the starting point, because we have to follow up so many patients then.* (Specialist palliative care coordinator)
Training sessions and meetings prior to patient recruitment		
Added value of the training sessions and meetings prior to patient recruitment	Specialised palliative care teams	*Bringing together all the teams, so you heard other opinions on how they approach it, how they look at it, that yes, I think that personally we do that rather too little, teams coming together, to discuss.* (Specialised palliative care nurse)
Home visits and phone calls		
Positive views on home visits	Patients and family carers	*We positively experienced the home visit, very friendly nurse and very clear communication.* (Family carer)
Patients not always aware of who the nurse was and what the study was about	Specialised palliative care teams	*But the patient didn't know which organisation I was from and that didn't become clear during the conversation, either.* (Specialised palliative care nurse)
Mixed views on need for follow-up home visits	Patients and family carers, Specialised palliative care teams	*A bit more follow-up, because one moment everything is going well but the next you can feel helpless.* (Family carer) *There wasn't that much to arrange, as I'm a nurse myself so I am familiar with it, so there was no need for follow-up visits.* (Family carer) *These people thought that everything was arranged well, so I don't think that is a good option to keep pushing for a follow-up visit* (Specialist palliative care nurse)
Topics of semi-structured guidance often not relevant	Specialised palliative care teams	*I think there are a lot of things in the guide that were not relevant or already arranged well, such as the emergency response plan, the patient knew who to call and when* (Specialised palliative care nurse)
First home visits more introduction, follow-up visits more in-depth conversations where expertise of nurses is valuable	Specialised palliative care teams	*The first conversations are more 'get-to-know-you conversations' where we really work through the things, so that you see, everything is fairly ok, and naturally, owing to the amount of work, we wondered whether that is part of it as well, but we now see, after a time, that we can support the patient and family.* (Specialised palliative care nurse)
Doubts whether expertise of the nurses is needed in first visits for patients perceived as not having complex needs	Specialised palliative care teams	*We asked the question at the beginning; does it have to be people with our competence. Because we had the idea at the start that these were patients with very complex care needs, where we can still deal with a lot of things at home, but in fact everything was already arranged well.* (Specialised palliative care nurse) *Then I wonder, do you have the same conversations, if you have not had this get-to-know-you conversation, you sometimes have to build up to that more in-depth conversation with these people.* (Specialised palliative care coordinator)

Mixed views on duration of the intervention (i.e. 8 weeks)	Specialised palliative care teams	*I actually think that eight weeks is good in itself. But of course, if you then find yourself in situations where after the first visit people clearly indicate that there is not a lot you can do there, that is perhaps a lot, eight weeks. (*Specialised palliative care nurse) *With a longer intervention period, you have a point where the patients' health deteriorates, and I think with a shorter intervention period, we would have missed that. (*Specialised palliative care nurse)
Collaboration with other healthcare professionals		
Less collaboration because there were no needs	Specialised palliative care teams	*And this multidisciplinary consultation, I've discussed that as well with the patient. Do you think it's needed? But yes, that was never. So yes, we have mentioned these meetings, but it was not needed. (*Specialised palliative care nurse)
Impact of Frailty+ intervention		
Intervention lowered the threshold for patients to contact the service again	Specialised palliative care teams	*I tell a patient that I am going to stop, but then I get the reaction from them, but if it's not going well, can I please call you again.* (Specialised palliative care nurse)
Patients prefer to continue specialised palliative care after intervention	Specialised palliative care nurse	*Once they get to know us, yesterday I got the signal that they wanted to continue receiving specialised palliative care (*Specialised palliative care nurse)
Patients gain more insight into own situation and end-of-life preferences	Specialised palliative care teams	*I think the patient has become more aware of their situation and what their preferences are for the end of their life. (*Specialised palliative care nurse)

Contextual factors

We identified several contextual factors that influenced the implementation and outcomes of Frailty+. Themes and illustrative quotes are presented in the Appendix, Table 2. All participants mentioned the COVID-19 crisis. Palliative care nurses mentioned that it was a busy period for them due to the pandemic, and therefore they sometimes forgot about the study or prioritised patients with more urgent needs. Some also mentioned that there was little contact between nurses about the study because they mainly worked from home. This regular contact helped them in a previous study to solve study issues earlier on and to motivate each other. The recruiting hospital staff experienced less continuity of care, for instance some of them worked on COVID-19 departments and had less time to approach patients. Patients and families mentioned that due to the crisis, they had fewer social contacts than before and this negatively impacted them. Next to factors related to the pandemic, recruiting staff of one hospital felt little involvement in the study due to many ongoing studies.

Preliminary effects of Frailty+

The estimated mean sum score on the primary outcome (five key IPOS palliative care symptoms; range 0 – 20) was 6.0 in the intervention group and 5.6 in the control group at baseline, and 4.5 in the intervention group and 4.1 in the control group 8-weeks post-baseline (adjusted ratio 1.0, i.e. no effect of Frailty+ over time on the mean sum score compared to standard care alone) (Table 5). The well-being score of patients in the intervention group was 23.1 and in the control group 22.8 at baseline, and 23.4 in the intervention group and 23.3 in the control group 8-weeks post-baseline (adjusted ratio 1.0) (ICECAP-SCM, range 0 – 28). Of 31 out of 37 included patients, we included information regarding their healthcare utilisation through their GP. Eight patients (intervention group n=2, control group n=6) were admitted to the hospital at least once. One patient of the control group was admitted twice and another patient of the control group three times. Of the 31 patients for whom we have data on healthcare utilisation, 27 visited their GP at least once during the study period (four patients in the control group had no contact with their GP). Results of the other explorative outcomes are presented in the Appendix, Table 3.

Table 5. Estimated mean changes in primary and secondary outcomes from baseline to 8-weeks.

	Baseline (T0)		8-weeks post-baseline (T1)		
Patient primary and secondary outcomes	Intervention group N=19 Estimated mean (95% CI)	Control group N=18 Estimated Mean (95% CI)	Intervention group N=19 Estimated Mean (95% CI)	Control group N=18 Estimated Mean (95% CI)	Adjusted ratio[a] (95% CI)
Primary outcome					
Five key palliative care symptoms (IPOS, range 0-20)	6.00 (4.17 – 8.64)	5.62 (3.93 – 8.05)	4.48 (2.99 – 6.72)	4.12 (2.55 – 6.66)	1.02 (0.48 – 2.16)
Secondary outcomes					
Palliative care symptoms (IPOS, range 0-68)	19.87 (14.86 – 25.56)	21.88 (16.53 – 28.98)	18.07 (13.26 – 24.65)	17.98 (12.35 – 26.16)	1.11 (0.62 – 1.98)
Well-being (ICECAP-SCM, range 0 – 28)	23.06 (20.90 – 25.44)	22.80 (20.71 – 25.10)	23.40 (21.03 – 26.04)	23.27 (20.54 – 26.37)	0.99 (0.80 – 1.23)
Sense of security in care (SEC-P, 15 – 90)	72.83 (68.89 – 77.01)	77.11 (73.04 – 81.41)	78.25 (73.75 – 83.02)	78.32 (73.29 – 83.69)	1.06 (0.94 – 1.19)
	Baseline (T0)		8-weeks post-baseline (T1)		
Family carer secondary outcomes	Intervention group (N=15) Estimated Mean (95% CI)	Control group (N=11) Estimated Mean (95% CI)	Intervention group (N=15) Estimated Mean (95% CI)	Control group (N=11) Estimated Mean (95% CI)	Adjusted ratio[a] (95% CI)
Sense of security in care (SEC-R, 17 - 102)	79.29 (73.74 – 85.26)	87.57 (81.01 – 94.66)	78.50 (72.11 – 85.45)	93.26 (85.30 – 101.96)	0.93 (0.80 – 1.08)
Family carers' support needs (FACQ-PC, 25 - 125)	80.11 (75.15 – 85.40)	77.43 (71.79 – 83.52)	79.82 (74.05 – 86.03)	80.78 (74.04 – 88.14)	0.96 (0.83 – 1.10)

[a] Adjusted ratio is calculated as the ratio of the ratio of Frailty+ over control at 8-weeks post-baseline over the ratio of Frailty+ over control at baseline (interaction).

DISCUSSION

Main findings

While Frailty+ was well-received by participants, not all intervention components were implemented as intended. More specifically, nurses visited most patients only once while more visits would have been possible over the 8-week intervention period. They also did not initiate the multidisciplinary primary care meetings as foreseen. Nurses judged this as not necessary because they perceived the patients as having a relatively stable health status. Nevertheless, the palliative care nurses also reported that Frailty+ had the potential to benefit patients and family and identified several factors as potentially important mechanisms, such as building a trusting relationship with patients. Several contextual factors were identified that were likely to have influenced the implementation and outcomes of the study, the COVID-19 crisis being one. The RCT methods such as randomisation were feasible, but participant recruitment was challenging. We found no intervention effects on the primary outcome in our sample of older patients.

Strengths and limitations

This pilot RCT had several strengths; we adopted a rather pragmatic approach allowing some tailoring of intervention components, incorporating broad eligibility criteria, involving primary, secondary and, exploratory outcomes relevant to participants, and implemented the intervention in daily practice (40). The trial provided multifaceted and in-depth data on feasibility and implementation processes reported by various professional stakeholders and patients and families. This can inform subsequent trials evaluating palliative care interventions for older people with frailty, multimorbidity and complex needs. This study also has several limitations. We recruited fewer participants than planned; this hindered us in estimating the effect of Frailty+ on the patient and family outcomes in a more precise way. In addition, there is a possibility of selection bias. It is possible that patients and family who were interested in research and/or palliative care took part in the study. Lastly, we conducted the online interviews and focus groups with healthcare professionals after completion of participant recruitment, which might have introduced recall bias.

What this study adds

Patients and families in the study generally valued the specialised palliative home care service. Several indicated that they would have liked to have continued the service after the intervention period. Additionally, healthcare professionals mentioned that timely palliative care had the potential to improve patient and family outcomes, for instance by lowering the threshold for patients to contact the service again if their health deteriorated. A recent study among generalist and specialised palliative care providers also showed that the majority of them valued timely palliative care for this population (41). According to the nurses in our study, building a trusting relationship with the patient and family is particularly important to achieving beneficial outcomes. Establishing such a relationship is also identified in the literature as pivotal for effective home-based palliative care services (42,43). However, our study did not find improvements on the primary effects outcome in the expected direction. We believe that this was mainly because the core of Frailty+ was not entirely implemented as foreseen.

There were several issues regarding implementation and context that need to be resolved. Nurses reported in the focus groups that when they first visited the patient at home, they often perceived them as having a relatively stable health status without urgent needs. They therefore visited most patients only once and did not organise the multidisciplinary meetings as intended. This is surprising because the baseline data showed high levels of need and comorbidities, and these were comparable to the data of a previous short-term palliative care intervention for older people in England (14). In routine practice, patient referral to these services is often in the terminal phase or happens as a direct response to a crisis situation (7–10) and care is typically focused on end-of-life symptom control (44). A possible explanation is therefore that specialised palliative care nurses perceived their relatively earlier involvement in the care of older people, in which care was mainly focused on psychosocial support, as less central to their tasks, especially in COVID-19 times. These results highlight that implementation of timely palliative care services for older people may require more profound changes in the daily practices and habits of professionals delivering the intervention than we had initially foreseen. In our study, nurses reported having valued the training sessions and supporting the concept of timely palliative care for older people. On this basis, the NPT construct of coherence was likely to be reached (18). However, it is possible that the training sessions were not sufficient to reach cognitive participation with nurses. In retrospect, these sessions were more based on encouraging them to provide needs- and capacity-based care rather than training them how to work with Frailty+ and how to integrate it into daily practice. We might have allowed more time and used better techniques to ensure actual buy-in, and full engagement with the required practice change. Only a few nurses of the teams that delivered the intervention participated in the Theory of Change workshops to develop Frailty+, hence co-production of the intervention with the services might have improved implementation. Another important issue is the COVID-19 crisis. Nurses reported that they already needed to change their usual ways of working, and they may have prioritised caring for patients with more urgent needs. They therefore may have had less time and opportunity to fully adopt Frailty+.

It is striking that our study produced different results from the original UK short-term palliative care intervention for community-dwelling older people (14). The latter was effective in reducing symptom distress of older people and high levels of interprofessional collaboration were reported (14). One possible reason for this is that both interventions were implemented in considerably different contexts. Several factors in the UK healthcare context or in the local context where the intervention was implemented in the UK might have facilitated implementation of timely palliative care interventions in primary care better than in Belgium. For instance, researchers and clinicians might have a longer tradition of collaboration in the UK which would increase buy-in and engagement in a pilot trial (45,46). In future research, it might be interesting to explore and compare in greater detail the development and implementation processes of such complex interventions, which then could lead to a better description of the mechanisms essential to bringing about change in practice.

Lastly, our feasibility findings have shown that a randomised design is feasible in this population. All randomised participants were able to complete the baseline measures in interview format. In addition, missing data levels were generally low for all outcomes, even with us having to adapt the data collection methods from face-to-face interviews to interviews over the phone or questionnaires sent by regular mail due to measures related to the COVID-19 crisis.

The most difficult part of this RCT was participant recruitment. The final sample size was smaller than planned for two main reasons. Firstly, the COVID-19 crisis considerably hindered recruitment, for instance recruitment in the hospitals was suspended for four months. Secondly, recruiting hospital staff experienced difficulties in the selection of potential participants. They reported that they felt the need to ‘protect’ patients from the study. Clinicians are often reluctant to refer patients to palliative care, and may be concerned about causing distress to the patient (47,48). However, patients and families in the study expressed no reluctance about the timely introduction of palliative care. For the future, we need to ensure more frequent researcher attendance at all recruitment sites to motivate and support recruiting hospital staff.

Recommendations

Timely and short-term palliative care services have the potential to lead to beneficial patient and family outcomes. However, Frailty+ is not yet ready for wide implementation and evaluation in a full-scale RCT. We need to better prepare and support specialised palliative care nurses to adopt the necessary practice change towards timely involvement of specialised palliative care services for older people. We therefore recommend striving for more co-production of intervention content with professionals delivering the intervention (49). In addition, we recommend the use of implementation and behavioural science theories, such as NPT (18) and Theoretical Domains Framework (50), early on in the intervention development phase. The NPT for example could be used as a guiding framework to investigate, in co-production with professionals, how the four key constructs of NPT can be best reached. Additionally, we advise incorporating more frequent meetings with professionals delivering the intervention throughout the implementation period. This could provide opportunities to pro-actively discuss implementation issues. If specialised palliative care services were to move upstream to work with patients earlier in the trajectory, this will imply a larger case load and a different way of working. Financing and regulatory mechanisms should then be put in place to support this new way of working.

Conclusions

The timely and short-term specialised palliative home care intervention for older people and their families is promising. However, no intervention effects were found on the primary outcome. This was probably because Frailty+ was not implemented in practice as we had initially foreseen. Suboptimal implementation is probably due to contextual factors such as the COVID-19 crisis, and to issues in adapting current practices and habits, as implementing Frailty+ requires changing ways of working. RCT methods were largely feasible in this population, but recruitment needs improvement. Based on these results, we conclude that several modifications to the current intervention and evaluation method are needed before it can be evaluated in a full-scale RCT. We recommend further improving the intervention together with professionals in the regions and with patients and families.

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1a) Study conception and design: de Nooijer, Pivodic, Van Den Noortgate, Pype, Van den Block;
1b) Acquisition of data: de Nooijer;
1c) Analysis and interpretation of data: de Nooijer, Pivodic, Van Den Noortgate, Pype, Van den Block;
2) Drafting the manuscript: de Nooijer;
3) Critical revision: de Nooijer, Pivodic, Van Den Noortgate, Pype, Van den Block.
All authors have approved the final manuscript and agree to be accountable for all aspects of the work. Questions related to the accuracy or integrity of any part of the work will be appropriately investigated and resolved.

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Supplementary table 1. Intervention components and their dose according to palliative care nurses

Implementation components	**Dose**	**Who attended**
Meetings and training sessions with specialised palliative care teams	Total number of meetings: 4 (2 per specialised palliative care team) Total number of training sessions: 3 (specialised palliative care teams followed the sessions together)	Nurses and coordinators of two specialised palliative home care teams
Information brochures distributed to primary care providers	None	-
Meetings with hospital staff	Total number: 4 (2 per hospital)	Geriatricians, geriatric nurses, and geriatric liaison staff
Core components *(Intervention group only N=19 patients)*	**Dose**	**Topics discussed**
Home visits by specialised palliative care nurse	Total number: 27 (19 patients received 1 home visit, 7 patients 2 home visits, 1 patient 3 home visits) Mean number per patient: 1.4 Mean duration per patient: 77 minutes	First home visit (N=19): Psychosocial support (16/19), Introduction/information (15/19), Coordination/practical help (12/19), Pain and symptom control, comfort care (10/19), Life-and existential questions support (6/19) Second home visit (N=7) Psychosocial support (5/7), Pain and symptom control, comfort care (4/7), Introduction/information (3/7), Coordination/practical help (2/7), Life-and existential questions and support (2/7)
Phone calls between specialised palliative care nurse and the patient and/or family	Total number: 24 (7 patients had no phone calls, 7 patients had one phone call, 2 patients had 2 phone calls, 2 patients had 3 phone calls, 1 patient had 7 phone calls) Mean number per patient: 1.3 Mean duration per patient: 7 minutes	First phone call (N=7) Introduction/information (5/7), Psychosocial support (4/7), Pain and symptom control, comfort care (4/7) Second phone call (N=7) Pain and symptom control, comfort care (4/7), Psychosocial support (3/7), Introduction/information (1/7)
Multidisciplinary meetings on palliative care and consultations between palliative care nurses and advising geriatrician	None held	-
Phone contacts between nurses of the palliative home care services and other healthcare professionals (excluding contact for referral to specialised palliative care service).	Total number: 6 (2 with GPs, 4 with community nurses)	Explanation of intervention and providing support regarding medication and psychological needs.

Supplementary Table 2. Contextual factors identified through interviews and focus groups split up by respondent groups

Themes	Respondent group	Illustrative quotes
COVID-19 crisis	Patients and family carers, Specialised palliative care nurses, Hospital care staff	*We weren't allowed to go to any department for a number of weeks and therefore could not recruit patients (*Geriatric liaison staff member) *Coronavirus, no visits from children and grandchildren as usual, I really missed that. (*Patient) *Before the COVID-19 crisis we met more and discussed more. Whereas now, for me, I had the feeling that you only discussed the patient afterwards, when it actually was too late (*Specialised palliative care nurse)
Felt little involvement in the study due to many ongoing studies	Hospital care staff of one hospital	*There are lots of studies going on in hospital, and we feel little involvement. (*Geriatric liaison staff member)

Supplementary Table 3. Estimated mean changes exploratory endpoints from baseline to 8-weeks.

	Baseline (T0)		8-weeks post-baseline (T1)		
Patient exploratory outcomes	Intervention group N=19 Estimated mean (95% CI)	Control group N=18 Estimated Mean (95% CI)	Intervention group N=19 Estimated Mean (95% CI)	Control group N=18 Estimated Mean (95% CI)	Adjusted ratio[a] (95% CI)
Physical symptoms (subscale IPOS, range 0 to 40)	10.51 (7.45 – 14.82)	13.25 (9.55 – 18.40)	9.49 (6.57 – 13.72)	8.64 (5.61 – 13.32)	1.39 (0.69 - 2.78)
Emotional symptoms (subscale IPOS, range 0 to 16)	5.68 (4.03 – 8.00)	6.24 (4.49 – 8.67)	5.14 (3.55 – 7.44)	5.16 (3.29 – 8.08)	1.09 (0.55 – 2.16)
Communication/practical symptoms (subscale IPOS, range 0 to 12)	4.17 (2.86 – 6.09)	2.61 (1.79 – 3.81)	3.65 (2.50 – 5.32)	3.00 (1.77 – 5.10)	0.76 (0.33 – 1.76)
Care Interaction Scale (subscale SEC-P, range 8 – 48)	41.33 (38.41 – 44.48)	43.83 (40.82 – 47.07)	44.27 (40.96 – 47.84)	43.67 (40.01 – 47.66)	1.075 (0.92 – 1.25)[b]
Identity Scale (subscale SEC-P, range 4 to 24)	20.67 (18.63 – 22.93)	20.83 (18.79 – 23.10)	20.94 (18.77 – 23.37)	21.08 (18.59 – 23.91)	1.00 (0.81 – 1.24)[b]
Mastery Scale (subscale SEC-P, range 3 to 18)	10.92 (9.35 – 12.74)	12.54 (10.70 – 14.71)	13.05 (11.16 – 15.27)	13.48 (11.24 – 16.16)	1.11 (0.82 – 1.51)
Personal continuity, care provider knows me (subscale NCC, range 5 to 25)	21.50 (19.30 – 23.95)	21.67 (19.58 – 23.98)	22.53 (20.21 – 25.13)	21.42 (18.91 – 24.27)	1.06 (0.85 – 1.32)[b]
Personal continuity, care provider shows commitment (subscale NCC, range 3 to 15)	11.52 (9.39 – 14.13)	10.51 (8.87 – 12.45)	11.00 (9.37 – 12.91)	11.65 (9.62 – 14.12)	0.86 (0.60 – 1.23)
Team/cross boundary continuity (subscale NCC, range 8 to 40)	32.67 (25.73 – 41.48)	32.00 (25.14 – 40.74)	40.00 (30.71 – 52.11)	36.33 (28.97 – 45.57)	1.08 (0.72 – 1.61)[b]
Overall quality of life today (item POS-VoC, range 1 to 7)	4.62 (3.71 – 5.75)	4.33 (3.47 – 5.40)	4.32 (3.39 – 5.49)	4.43 (3.37 – 5.83)	0.91 (0.57 – 1.46)[b]
	Baseline (T0)		8-weeks post-baseline (T1)		
Family carer exploratory outcomes	Intervention group (N=15) Estimated Mean (95% CI)	Control group (N=11) Estimated Mean (95% CI)	Intervention group (N=15) Estimated Mean (95% CI)	Control group (N=11) Estimated Mean (95% CI)	Adjusted ratio[a] (95% CI)
Care Interaction Scale (subscale SEC-R, range 7 – 42)	33.07 (30.20 – 36.21)	37.73 (34.17 – 41.66)	32.93 (29.46 – 36.81)	39.50 (35.26 – 44.26)	0.95 (0.78 – 1.16)[b]
Patient Situation Scale (subscale SEC-R, range 5 – 30)	24.93 (22.38 – 27.78)	25.82 (22.90 – 29.11)	24.55 (21.71 – 27.76)	27.13 (23.65 – 31.11)	0.94 (0.73 – 1.20)
Mastery Scale (subscale SEC-R, range 5 – 30)	21.40 (19.12 – 23.96)	24.18 (21.37 – 27.37)	21.28 (18.65 – 24.28)	27.13 (23.65 – 31.11)	0.89 (0.69 – 1.13)[b]
Caregiver Strain (subscale FACQ-PC, range 8 – 40)	18.82 (15.52 – 22.83)	16.48 (13.06 – 20.78)	21.95 (17.65 – 27.31)	18.91 (14.53 – 24.60)	1.03 (0.69 – 1.53)
Positive caregiving appraisal (subscale FACQ-PC, range 7 – 35)	28.27 (25.58 – 31.24)	29.18 (26.02 – 32.73)	27.58 (24.35 – 31.24)	28.99 (25.30 – 33.21)	0.98 (0.78 – 1.24)
Caregiver stress (subscale FACQ-PC, range 4 - 20)	10.06 (8.10 – 12.48)	8.44 (6.47 – 11.01)	8.83 (6.79 – 11.48)	8.62 (6.33 – 11.75)	0.85 (0.53 – 1.38)
Family well-being (subscale FACQ-PC, range 6 – 30)	22.60 (20.25 – 25.23)	24.23 (21.12 – 27.79)	21.20 (18.45 – 24.37)	25.71 (22.11 – 29.91)	0.88 (0.68 – 1.15)[b]

[a] Adjusted ratio is calculated as ratio of Frailty+ over control at 8-weeks post-baseline over ratio of Frailty+ over control at baseline (interaction). [b] The variance for the random intercept was estimated to be zero, the 95% CI for the interaction effect was calculated manually based on a normal z-distribution.

GENERAL DISCUSSION

GENERAL DISCUSSION

This part of the dissertation discusses the main findings of the six studies aiming to describe current palliative care provision for and palliative care needs and well-being of older people in Belgium and internationally (Research aim 1) and the development and pilot evaluation of a timely short-term specialised palliative care service intervention for older people in primary care (Research aim 2). To realise research aim 1, we examined the quality of primary palliative care for older people in three European countries, described the palliative care needs and well-being of older people upon hospital discharge and systematically reviewed the evidence on specialised palliative care services for older people in primary care **(Part 1 of this dissertation).** To realise research aim 2, we described the Theory of Change of a timely short-term specialised palliative care intervention for older people with frailty in primary care, as well as the study protocol of a pilot randomised controlled trial to test this intervention. Moreover, we evaluated the feasibility of the trial methods, as well as and the implementation and preliminary effectiveness of the intervention **(Part 2 of this dissertation).** The main findings are summarised, followed by methodological considerations and a discussion of the findings in relation to current evidence. Finally, recommendations and implications for clinical practice, research, and policy are provided.

1. SUMMARY OF THE MAIN FINDINGS

The first three chapters focused on palliative care services for older people in primary care and their palliative care needs and well-being upon hospital discharge (Research aim 1).
We studied the use and quality of palliative care in primary care for older people in Belgium, Italy, and Spain in Chapter 1. We included deaths of patients who were 65 years or older which were non-sudden as judged by the general practitioner. We calculated the differences between countries in characteristics and quality indicator scores of those aged 65-84 years and those aged 85 years or older. We identified, in both groups, considerable between-country differences in quality indicator scores, such as regular pain measurement by the general practitioner in the last three months of life, communication between the general practitioner and patient about illness-related topics, and involvement of specialised palliative care services in the last three months of life. We identified for almost all quality indicators higher scores for Belgium than Italy, but fewer consistent differences between Belgium and Spain. Nevertheless, in Belgium, Italy, and Spain, more than half of the general practitioners reported not having measured patients' pain regularly, not having communicated with the patient regarding illness-related topics, and not being aware of their patients' medical preferences. In the three countries, general practitioners reported relatively high quality indicator scores regarding family discussions on illness-related topics and bereavement counselling.

In Chapter 2, we explored the palliative care needs and well-being of those older people with complex care needs upon hospital discharge. We surveyed 37 older people who were identified as having frailty and complex care needs upon hospital discharge to their home. The data showed heterogeneity in experienced symptom burden; although most patients were severely affected by multiple symptoms and concerns some were not. Symptoms and concerns that were frequently rated as causing severe/overwhelming problems were weakness (46%) and poor mobility (40%). Thirty-nine percent of patients reported that their family experienced anxiety most of the time/always. Of the 17 IPOS items, 86% of the patients rated at least one concern or symptom as causing severe/overwhelming problems. More than half of the patients reported feeling supported, being able to maintain their dignity, being able to be with people who care about them, and having a say about their life and care. Lastly, we found that greater palliative care needs were moderately correlated with a lower well-being.

In Chapter 3, we systematically reviewed the international evidence on specialised palliative care services for older people in primary care. We searched seven databases (until June 2019) and included ten publications with heterogeneous study designs: three qualitative, three quantitative, three mixed-method, and one narrative review, mostly with a low to moderate methodological quality score. We identified that referral criteria for older people for specialised palliative care services in primary care were mainly focused on patient characteristics, such as age, prognosis, and diagnosis, and less on their palliative care needs. We also identified that the services provided multidisciplinary holistic care and that outcomes were mainly related to patients and families, such as symptom management. Most of the included articles did not provide a full description of the population studied, nor of the intervention activities and procedures, which hindered full understanding and identification of successful specialised palliative care components.

In Chapter 4 – 6, we focused on the development and pilot evaluation of the timely short-term specialised palliative care service intervention for older people with frailty and complex care needs in primary care, i.e. Frailty+ intervention (Research Aim 2). We described the hypothesised causal pathway of Frailty+ in Chapter 4, using the structured participatory Theory of Change approach. The theoretical model was visualised through a Theory of Change map that specified through which changes and processes the intervention's long-term outcomes and impact can be achieved. To do so, we synthesised evidence of the systematic review (Chapter 3) with findings from qualitative interviews and group discussions with patients and family carers (n=22), and with the Theory of Change workshops with 45 professional stakeholders, including healthcare professionals, policy makers and researchers. We identified long-term outcomes of the intervention related to the person with frailty (e.g. fewer unmet symptoms and concerns), and the family carer (e.g. increased sense of security in care). The identified preconditions (or intermediate outcomes) that need to be fulfilled to achieve the long-term outcomes and impact were put in chronological order in the Theory of Change map. We presented all the preconditions and long-term outcomes related to the level to which they applied, i.e. level of older people and family, healthcare professionals and healthcare system. Preconditions included: specialised palliative care services in the region being willing and available to work with the intervention, and patients and family being identified and informed about the intervention. Consequently, patients and families need to receive the intervention facilitated by the palliative home care nurse. The Frailty+ intervention consisted of several components to achieve each of the preconditions. We divided these components into implementation components, e.g. training for specialised palliative care teams and meetings with recruiting hospital staff, and a core component. The latter includes five sub-components: timely and short-term delivery of the specialised palliative care service; collaborative and integrative working within primary care; delivery of holistic needs- and capacity-based; person-centred and family-focused; and goal-oriented and pro-active care.

In Chapter 5, we present the study protocol of a non-blinded pilot RCT with two parallel groups and an in-depth process evaluation to study the feasibility of RCT methods and implementation and preliminary effectiveness of Frailty+. Hospital geriatricians and geriatric liaison staff identified potential participants. Eligible patients were 70 years or older, had a Clinical Frailty Scale score 5 – 7 (i.e. mild to severe frailty) (1), unresolved complex care needs in one of the four palliative care domains, and in the hospital and referred to return to their home. Patients were randomised (1:1) to receive standard care (control group) or the Frailty+ intervention in addition to standard care (intervention group). At the core of Frailty+ is the provision of timely short-term specialised palliative home care service over a period of 8 weeks, facilitated by a specialised palliative care nurse. Nurses were encouraged to use semi-structured guides for the home visits and the multidisciplinary meetings on palliative care. Feasibility was assessed in terms of recruitment, randomisation, acceptability of the intervention and retention in the programme and data completion. The primary outcome for assessing preliminary effectiveness was a mean sum score across five key palliative care symptoms (breathlessness, pain, anxiety, constipation, drowsiness) measured at baseline and eight-weeks post-baseline (with higher score meaning greater symptom burden). Implementation, mechanisms, and contextual factors were assessed in the intervention group only, with measurements throughout and post- intervention, using mixed methods.

In Chapter 6, we reported the feasibility of RCT methods and the implementation and preliminary effectiveness of the Frailty+ intervention for older people and their family carers in primary care. In total, 37 patients with frailty and complex care needs were randomised to the Frailty+ intervention (n=19) or standard care (n=18), and 26 family carers. Frailty+ was well received by participants. However, we identified suboptimal implementation in routine clinical practice. Nurses reported in the focus groups that they visited most patients only once, while it was planned that the intervention could run for 8 weeks. They also did not organise face-to-face multidisciplinary meetings on palliative care with all primary care providers, as intended. Nurses judged this as not needed because, according to them, patients had a relatively stable health status without urgent care needs. We identified important contextual factors that likely influenced optimal implementation in practice, such as the current COVID-19 crisis. Nurses reported important mechanisms of change, such as building a trusting relationship with patients and families. RCT methods were largely feasible. However, participant recruitment issues were identified. The estimated mean sum score on the five key palliative care symptoms (IPOS) at baseline was 6.0 in the Frailty+ group and 5.6 in the control group. At 8-weeks, the mean sum score was 4.5 in the Frailty+ group and 4.1 in the control group (adjusted ratio 1.0, that is, no effect of Frailty+ over time on the IPOS mean sum score compared to standard care alone).

2. STRENGTHS AND LIMITATIONS

To describe current palliative care provision for and palliative care needs of older people in Belgium and internationally (research aim 1), we used a population-based mortality follow-back study using existing general practitioner sentinel networks (EUROSENTIMELC), a cross-sectional survey study and a systematic literature review with narrative synthesis of specialised palliative care services. As the cross-sectional survey study was part of the pilot RCT, we describe its methodological considerations as part of the pilot RCT.

To realise research aim 2, we developed a hypothesised causal pathway of Frailty+, and conducted a pilot RCT and process evaluation to evaluate feasibility of RCT methods and implementation and preliminary effectiveness of Frailty+. The development and evaluation were informed by the UK Medical Research Council (MRC) framework for developing and evaluating complex interventions (2) integrated with the Theory of Change approach (3). Each study had strengths and limitations that merit consideration.

A mortality follow-back study

We conducted an in-depth analysis of the use and quality of primary palliative care for people aged 65 years and older in Belgium, compared to Spain and Italy (Chapter 1), using a validated minimum set of nine quality indicators. We used data of the large cross-national population-based EUROSENTIMELC study 2013 – 2015 (4). A clear strength is that this study used existing sentinel networks (i.e. epidemiological surveillance networks) of general practitioners. We were therefore able to obtain samples of deaths representative for the whole population of people in Belgium, Italy and Spain (in Spain from Valencian Community and Castile and Leon) (4). General practitioners were asked to categorise deaths as either sudden and totally unexpected or as non-sudden. This is a frequently used method in palliative care research for retrospectively selecting people for whom palliative care and end-of-life care were relevant considerations (5,6). However, this study also has limitations. Patient's perspective has not been used to evaluate the use and quality of primary palliative care. However, it has been shown that proxy respondents, such as general practitioners or family carers, can accurately report on care needs and quality of care (7). In addition, there might have been recall bias in this study. This was likely limited because general practitioners registered deaths of patients on a weekly basis (4). Lastly, the general practitioners completed registration forms that provided information on the quality of primary palliative care, such as prevalence of patients who expressed a preference regarding a medical treatment. However, the forms do not provide in-depth insights on, for instance, what the preference entailed and how the general practitioner dealt with this. This was beyond the scope of this population-based epidemiological study, but it could be a focal point for further in-depth qualitative research on communication processes towards the end of life.

Systematic literature review

We conducted a systematic review with narrative synthesis of research reporting on specialised palliative care services for older people in primary care (Chapter 3). A strength of the review was that we conducted a comprehensive search in seven databases, such as Embase and Medline. By using a broad search string, we were able to maximise the chance that we included all articles involving specialised palliative care, even those that did not use this term. However, this study has limitations. There might have been subjectivity in evaluating criteria. Nevertheless, this process involved two independent reviewers, regular discussions with the research team and use of existing tools for methodological quality assessment. In addition, we included studies with different designs, and therefore assessed their quality using different scales (e.g. for primary studies we used the qualitative and quantitative scales developed by Gomes et al. (8), and the AMSTAR tool for review articles (9)). Several of the ten included studies were of a low/medium standard. Still, all studies provided important information on delivery of specialised palliative home care services for older people.

Theory of Change approach to develop the theoretical model of Frailty+

Although the UK MRC guidance for developing and evaluating complex interventions highlights the use of theory in intervention research (2), there is no specific guidance on which theory to use (e.g. mid-range, grand or programme theories). In this dissertation, we have used the structured and participatory Theory of Change approach (3) to develop and model the theory underlying Frailty+ (Chapter 4). We followed 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'* (3,10). This thorough Theory of Change approach following established guidance has rarely been used in palliative care and end-of-life care research (11). One of the major strengths is that the Theory of Change approach enabled us to identify and visualise all intervention components, preconditions, and long-term outcomes in the causal pathway. This can aid other researchers (in other settings and countries) in assessing whether the elements in the Theory of Change map are applicable to their healthcare contexts and systems, and whether they need further adaptation or can be directly transferred. Another strength of this participatory approach is that implementation issues are already identified in the intervention development phase, and professionals stakeholders then directly suggest solutions to ensure that the long-term outcomes and impact can be achieved in routine practice (3). In addition, developing an intervention with a wide range of professionals might have contributed to more willingness and engagement of them in the integration of the intervention in practice (12). Finally, we used the Template for Intervention Description and Replication (TIDieR) to rigorously report the intervention and implementation components of Frailty+ (13). This study also holds some limitations. Patients and family were not involved in the workshops, as we perceived this method as too challenging. We therefore conducted additional interviews and focus groups with patients and their family to ensure that their input was also included in the Theory of Change map. The resulting Theory of Change is a relatively simple representation of a highly complex intervention in a highly complex context. Since a map that is highly detailed is perceived as too complex and too time-consuming to evaluate, we have chosen to only select the key components and processes that potentially lead to the desired outcomes and impact (14). Lastly, although the Theory of Change method, and other theoretical methods, have received increased scientific attention in intervention development and evaluation (15), it has not yet been proven that interventions that were guided by this theoretical approach lead to more effective interventions.

Pilot randomised controlled trial

In Chapter 5 we reported the study protocol of the pilot RCT of the Frailty+ intervention. The baseline survey data of the pilot RCT were analysed in Chapter 2, and we evaluated the feasibility of the intervention and RCT methods in Chapter 6. One of the major strengths is that we aimed to implement the intervention in routine clinical practice, i.e., we used a more pragmatic approach to conducting clinical trials (16). In contrast to the explanatory trial approach, this trial incorporated broad eligibility criteria, allowed tailoring of intervention components according to patients' and family carers' needs, and selected outcomes that were relevant to and valued by various stakeholders, including patients and family. This pragmatic approach has the potential to increase the generalisability and applicability of the findings of this study (17–19). We aimed to include a diverse population of older people with frailty and multidimensional complex care needs, including older patients with cognitive impairments who are often under-represented in clinical research (20). We also used an existing tool to select and identify older people with frailty in the hospitals, namely the Clinical Frailty Scale (1). This is an often-used tool in research and practice because of its efficiency and simplicity (21). However, this tool also has limitations. For instance, there might be some subjectivity because it is based on the judgement of the treating healthcare providers. In addition, it is an unidimensional scale mainly focused on the physical domain of frailty and might therefore not be able to capture the multidimensional and comprehensive aspects of frailty (22). We also used outcome measures that were translated from English to Dutch through forward-backward translation procedures and were thus not formally validated in Dutch (all except the Nijmegen Continuity of Care Questionnaire). We could not blind participants and the data collectors/researcher. In addition, there might have been selection bias in the study, which is a frequent issue in prospective health and health services research (23). It is possible that patients and families interested in research/studies in general or palliative care were more likely to take part in the study. Lastly, we recruited a smaller final sample size than planned, and could therefore not accurately estimate the effect of Frailty+ on the outcomes. However, we recruited sufficient participants to provide information on the main aims of this study: assessing the feasibility of RCT methods and implementation of the intervention in routine clinical practice.

Mixed-methods process evaluation

We conducted an in-depth process evaluation studying implementation of the intervention, mechanisms of change, and context (Chapter 6), following the UK MRC framework guidance for process evaluations of complex interventions and the Normalisation Process Theory (14,24). It was a strength that we adopted qualitative and quantitative methods to the process evaluation, as this provides multifaceted and comprehensive information that is crucial in the evaluation and implementation of interventions (14,25,26). We used convergent mixed methods, that is, we collected data in parallel and then analysed the data separately, and findings were then triangulated in the interpretation phase (25,27). This enabled us to provide in-depth information on which intervention components and processes were implemented well and which were not implemented as planned. Nevertheless, our process evaluation has some limitations. There might have been recall bias, as healthcare professionals involved in delivery of Frailty+ and participant recruitment were interviewed after completion of participant recruitment. When developing the Theory of Change (Chapter 4), we did not specify the indicators for success because there is limited evidence available to determine cut-offs for these indicators. Indicators in a Theory of Change enable researchers to evaluate whether each of the preconditions (or intermediate outcomes) in the pathway to change has been reached (3). In the evaluation of the intervention, this hindered us in determining which intervention components were most (or least) important to achieving the patient and family outcomes.

3. DISCUSSION OF THE MAIN FINDINGS

This section is divided into three sections, namely palliative care provision for and needs of older people living at home (3.1); the hypothesised causal pathway of timely short-term palliative care for older people in primary care (3.2); and the implementation of the Frailty+ intervention – outcomes of the pilot RCT (3.3).

3.1 PALLIATIVE CARE PROVISION FOR AND NEEDS OF OLDER PEOPLE LIVING AT HOME

Primary palliative care for older people in three European countries

This thesis provides insights into primary palliative care provision for older people in Belgium compared to Italy and Spain. We identified in Chapter 1 that there were differences between the countries in the use and quality of primary palliative care, which are probably due to differences in the healthcare organisations and structures, and in cultures around palliative care and end-of-life care (28–30). The three studied countries have palliative care strategies as well as plans and policies regulating the provision, organisation, and aims of palliative care (30), yet, this might not be enough to ensure a high-quality palliative care response for all older people living at home. Previous studies also identified suboptimal primary palliative care for other populations, such as those with dementia and organ failure (31,32). In our study, quality indicator scores in Belgium were relatively higher than in Italy. This might be related to the fact that in Italy provision of primary palliative care for older people with serious non-cancer conditions may be still inadequate (33). In addition, we identified fewer consistent differences in quality indicator scores between Belgium and Spain. For instance, we found relatively higher quality indicator scores on involvement of specialised palliative care services in the last months of life in Spain than in Belgium (Spain, people aged 65 – 84 years: 88.9%; people aged 85 years and older: 77.3% vs Belgium, people aged 65 – 84 years: 62.3%; people aged 85 years and older: 60.5%). Recently in Spain, increased attention has been paid towards palliative care provision for patients with serious non-cancer conditions, including older people with frailty, multimorbidity and palliative care needs, through a coordinated care response of generalist and specialised palliative care services (34). On the other hand, there are also well-established regional palliative care networks and services in Belgium (35,36). These differences in the involvement of services are not immediately concerning; general practitioners are often the main generalist palliative care providers for older people. However, further work is required, as it can be expected that they experience multidimensional complex care needs towards the end of life which require joint working between generalist and specialised palliative care services.

We identified that all three countries scored relatively high on the quality indicators of bereavement counselling and general practitioner communication with the family carer. However, there were particularly low quality indicator scores on regular pain measurement by the general practitioner, and on communication with the older patient on illness-related topics and patient medical preferences in the last months of life.

First, we identified that for most of the older people in the three European countries, pain was not measured regularly by the general practitioner in the last three months of life (ranged from 35.1% in those aged 65 – 84 years in Spain to 85.2% in those aged 85 years and older in Italy). This is concerning, because inadequate pain assessment is identified as a barrier for high-quality pain treatment for older people (37,38). Undertreatment may have considerable multidimensional (e.g. physical and psychological) consequences, such as sleep disturbances and depression (39,40), and may even lead to a lower quality of life and well-being (40). In the baseline survey study of the pilot RCT (Chapter 2), we identified that pain is a frequent symptom among older people with complex care needs upon hospital discharge: 54% were at least slightly/moderately affected by pain. These results are in line with a previous review reporting that pain is frequently experienced among older people with frailty and multimorbidity across all care settings; prevalence estimates ranged between 10% - 52% (41). Although these estimates largely differed between studies (41), often due to the differences in populations studied, the settings, methods, definitions and intensity reported (38), the findings underscore the importance of timely and frequent proactive assessment of pain in older people across all settings, including primary care settings.

Second, we identified in the three European countries that most of the general practitioners did not communicate about illness-related topics, such as treatment options, with the older person (ranged from 39.2% in those aged 64-84 years in Belgium to 90.6% in those aged 85 years and older in Italy). General practitioners were also often not aware of the person's medical and health preferences (ranged from 56.5% in those aged 65-84 years in Belgium to 88.4% in those aged 85 years and older in Italy) (Chapter 1). In clinical practice, a complex interplay of factors and reasons form a barrier for older people to participate in clinical conversations with their treating health and social care providers. This could be related to changes due to the ageing process that hinder optimal patient-physician communication. For instance, older people with frailty and multimorbidity often have an uncertain and unpredictable clinical trajectory, might experience functional decline such as hearing loss, and might have cognitive decline (42–48). In addition, these low scores might reflect the perception of healthcare professionals that the older person prefers not to be involved in the medical decision-making. This might have hindered their access to the discussion. On the other hand, some older people have stated the preference to leave the clinical decision-making and communication up to their treating healthcare professional and/or family carers (49). Additionally, other cultural factors and aspects may have played a role. In several countries including Italy, full information on diagnosis, prognosis and medical treatments in serious chronic conditions is not always the case (29). Lastly, often multiple health and social care providers across settings are involved in the care for older people, possibly hindering optimal communication processes (48). We showed in Chapter 1 that family carers were often involved in communication with the general practitioner. It may be the case that the general practitioner finds it easier to communicate with them rather than with the patient. Despite suboptimal communication, there might be a trend in the preference of older people towards more active involvement in their health and care, including clinical decision-making and communication. Older people may want to receive full medical information and prefer to self-manage their health and care (if possible) (47,48,50,51). Moreover, systematic reviews identified that, to reach successful communication between older patients, their family carers, and all involved health and social care providers, trust and respect between involved parties is required. The older person needs to have the feeling of having 'permission' to participate in communication and decision-making (48,52).

Inter-individual variation in symptoms and diseases of older people

Findings of Chapter 2 shed light on the palliative care needs and well-being of older people who were judged by their hospital physician as having complex care needs upon hospital discharge. We showed that most older people experienced a high symptom burden. This is in line with recent cross-sectional studies in the UK and Sweden reporting high levels of symptoms and concerns among home-dwelling older people with multimorbidity (53,54). However, our data showed important heterogeneity in the experienced symptom burden. While most of the patients were severely affected by multiple and multidimensional (i.e. physical, psychological, social and spiritual) symptoms and concerns, some were not (14% of the patients reported that they were not severely affected by any IPOS symptom or concern). These findings support previous research stating that there is large variation among those with frailty and multimorbidity in terms of their needs and comorbidities (55). We also reported in Chapter 2 that half of the patients who were judged as frail according to their treating physician had at least two additional medical diagnoses, such as cancer, cardiovascular and nervous system disease. These people might be affected by cumulative and interacting effects as a result of the multiple diseases and health problems they simultaneously experience (56). Based on these findings, we need to carefully consider in the care response for older people this inter-individual variation in health status, symptoms, and concerns.

Being old and experiencing symptoms does not mean one has a low well-being

Our findings in Chapter 2 showed that greater palliative care symptoms and concerns were correlated with a lower well-being. Recent research among older people with frailty and multimorbidity in the Netherlands also showed that higher symptom burden was correlated with a lower quality of life (57). Importantly, only modest correlations were identified between needs and well-being and quality of life. In other words, these findings underscore that older people with high levels of symptoms and concerns do not necessarily have low well-being or quality of life. A recent mixed-method study in Belgium also reported that older people with frailty had a relatively good quality of life (58). These findings are particularly relevant in the light of the current plan of action of the United Nations (UN) for the decade of healthy ageing (2020 – 2030) (59). The UN states that it is necessary to maintain and strengthen physical and mental capacities that enable well-being and quality of life in older age (59). Older people with frailty reported that main contributors to their quality of life and well-being were social contacts, their ability to adapt to challenges, and positive and negative life events (58,60).

Based on these findings, and aligned with the recommendations of the UN healthy ageing action plan (59), healthcare professionals caring for older people with frailty, multimorbidity and complex care needs are encouraged to focus on the identification and management of their symptoms and concerns, as well as on maintaining and strengthening their abilities, resources and capacities (58). Moreover, important to note for those caring for older people who have symptoms or problems that might be classified as frail, is that these older people do not use the term 'frail' or 'frailty' to describe themselves. Instead, they prefer to describe themselves as resilient or independent (for as long as possible) (61).

Existing evidence on specialised palliative care for older people in primary care

It is widely advocated that when patients' symptoms and concerns are too complex to be managed by generalist palliative care providers alone, referral to specialised palliative care services is needed (62,63). This is also advocated for older people with serious chronic conditions (64). In Chapter 3, we studied current evidence on referral criteria, activities and the frequency with which activities were delivered, and outcomes of specialised palliative care services for older people with serious chronic conditions living at home. We found ten articles that showed several activities through which specialised palliative home care was delivered for older people, such as holistic needs- and capacity-based care, comprehensive assessment, goal-based care, and coordination and collaboration between generalists and specialised palliative care providers. We identified that most activities were similar as those classified as essential elements of quality home-based palliative care for all patients with life-limiting illnesses (65,66). However, elements such as goal-oriented care and capacity-based care were not identified in these reviews and might be more specific in the care for older people with serious chronic conditions (67).

Moreover, we identified in Chapter 3 that the frequency in which specialised palliative care was provided for older people differed between services, ranging from ongoing care over long periods of time and timely short-term care provision only in periods of deteriorating health. If we compare this to other patient groups, for instance people with advanced cancer, the advocacy for timely specialised palliative care in cancer care might be better established and defined. It is proposed that patients with advanced cancer are referred to specialised palliative care services timely in the illness trajectory, that is often described as at the time of the diagnosis of advanced cancer, with frequent service follow-up until death (68). While it is also accepted that palliative care should be provided in a timely manner for older people with multimorbidity, frailty and complex care needs (69), there is currently no consensus on what timely provision of specialised palliative care entails or how it should be organised. This might be particularly difficult to define, as older people often experience multiple and multidimensional complex care needs towards the end of life (41), as indicated by our findings in Chapter 2, which might fluctuate over time (70). As older people may experience these care needs over the span of several years, it might not be feasible nor clinically relevant to provide ongoing specialised palliative care to them (70). Further research is needed to investigate which specialised palliative care service models and structures are best in addressing the complex palliative care needs of older people in the last years of life.

3.2 HYPOTHESISED CAUSAL PATHWAY OF TIMELY SHORT-TERM PALLIATIVE CARE FOR OLDER PEOPLE IN PRIMARY CARE

Building on the evidence from Chapter 3 and the participatory Theory of Change workshops, we described the development of a hypothetical causal pathway of a timely short-term specialised palliative care service intervention for older people with frailty and complex care needs and their family living at home, i.e. Frailty+ (Chapter 4). The participatory Theory of Change approach enabled us to identify and visualise important intervention components and preconditions that need to be in place to achieve the desired long-term outcomes. Below, several crucial elements of our first Theory of Change and Frailty+ intervention are described (before its evaluation in the pilot RCT, discussed under section 3.3).

Need for integration of care approaches and principles as the core of Frailty+

We identified and incorporated palliative care and geriatric care principles and elements in the core component of the Frailty+ intervention. The core was driven by person-centred care: a care response according to patient's needs, preferences, and goals (71). It has been recognised that such an integrated care approach is particularly relevant in the care for older people with serious chronic conditions (67,72). Specialised palliative care nurses in Frailty+ were therefore encouraged to identify and manage palliative care needs and disabilities as well as to focus on functioning and strengths (i.e. deficits and strengths).

In addition, we integrated proactive goal-oriented care with advance care planning as core foci of the intervention. Both concepts have been widely studied, and there is an overlap between the two. Advance care planning has recently been defined as *'the process that includes identification of values and defining goals and preferences for future medical treatment and care and discussion of these factors with the patient's family and healthcare providers'* (73). Goal-oriented care has been established as 'opposite' of the so-called problem-oriented care (74), and recently defined as '*the overarching aims of medical care for a patient that are informed by patients' underlying values and priorities, established within the existing clinical context, and used to guide decisions about the use of or limitation on specific medical interventions'* (75). The most important difference is that patient's self-defined goals of care do not only involve medical and clinical goals, but also social, ethical, family, financial, psychosocial, and any other goals important to the patient (76). We therefore incorporated both concepts in Frailty+. Specialised palliative care nurses were encouraged to support patients in eliciting realistic and attainable goals in a broad way and in different health, life and care domains, and to determine how well these goals were met (74,76). This also included the initiation of advance care planning conversations and drafting an emergency response and out-of-hours plan.

The importance of training and engagement of professional stakeholders

Focusing on optimal implementation strategies or processes of complex interventions in routine care has received increased research attention in previous years (77–80). In the development of the theoretical model, we identified several components which aimed to improve implementation of Frailty+ in routine clinical practice (Chapter 4; these were made explicit and presented in the Theory of Change map). They included, among others, the need to create engagement with those delivering the intervention and training for specialised palliative care services. Regarding the training, we organised three half-day sessions in which we focused on topics such as clinical concepts of frailty and multi-morbidity and their specific problems, symptoms and concerns; insights into differences and similarities between palliative care and geriatric service models, including needs- and capacity-based care; and how to deliver and work with the intervention materials, such as the semi-structured guides for the home visits and multidisciplinary meetings, of Frailty+. As family carers often play an important role in the care for the older person living at home (70), training sessions were also focused on identification and management of multidimensional family carer support needs (81). Training on these topics might be particularly relevant for them, as the patients included in

Frailty+ may require different care activities, and coordination, and collaboration with other healthcare professionals than the patients they 'usually' care for (82). That is, patients often receive specialised palliative care services in the terminal phase (82–85), and practice is primarily focused on pain and symptom control (83) of patients with cancer (84).

Development of complex care needs criterion for referral of older people to specialised palliative care services

It is recognised that patient referral to specialised palliative care services should be based on the level, intensity and complexity of their palliative care needs rather than on clinical and medical characteristics such as prognosis/diagnosis (85,86), while taking into account the environmental and social/supportive networks around the patient (85,86). However, there are currently no consensus-based complex care needs criteria for referral of older people with frailty to specialised palliative care services. We therefore developed, based on stakeholders' input and the evidence of the systematic literature review (Chapter 3), a complex needs criterion for timely identification of older people to specialised palliative care services in primary care. We identified that involvement of these services could be based on unresolved or complex needs in one of the four palliative care domains. These include, for example, complex end-of-life issues such as being 'tired of living', complex mental health needs, or difficult interactions between the patient, family and/or healthcare professionals, such as patients who refuse care (63,85).

Feelings of security important outcome of timely palliative care

We identified in Chapter 3 that most outcomes used to evaluate specialised palliative care services were related to the patient and family carer. This is supported by the findings of our development work of the theoretical model of the Frailty+ intervention in Chapter 4: all long-term outcomes of the intervention were related to older people with frailty and their family carers. We identified, through qualitative research with stakeholders, next to the more often used outcomes to evaluate the effectiveness of palliative care interventions, such as palliative care symptoms and family carer support needs, also the outcome 'increased sense of security'. This outcome stands next to outcomes more commonly used to evaluate the effectiveness of palliative care interventions, such as palliative care symptoms and family carer support needs. There is a growing body of literature recognising that an increased sense of security is particularly relevant to and valued by patients with serious chronic conditions and their families receiving palliative care at home (87–89), including the recent timely and short-term palliative care intervention in England (90). Even though it is recognised as an important element of high-quality home-based palliative care, there are no studies which captured this outcome to assess the effectiveness of the specialised palliative care intervention for the older person and family (only one geriatric care RCT (91)).

3.3 IMPLEMENTATION OF THE FRAILTY+ INTERVENTION – OUTCOMES OF THE PILOT RCT

We conducted a pilot RCT and an embedded process evaluation of Frailty+ from February 2020 (start of patient recruitment) to March 2021 (data collection completed) (Chapter 5 and 6). We recruited a smaller sample (N=37) than planned (N=50). Although we had some promising results, we also found suboptimal implementation of the Frailty+ intervention in routine clinical practice compared to what we intended. We hypothesised this could be explained by multiple factors, including important contextual factors, such as the current COVID-19 crisis, and due to challenges in implementing specialised palliative care services in an earlier phase of illness. The trial methods were largely feasible, such as randomisation and repeated data collection. However, challenges with recruitment were evident. We found no intervention effects on the primary outcome in our sample of older people. We believe that this was mainly because the core of Frailty+ was not implemented as we initially had foreseen. Based on these findings, we have concluded that several modifications to the current intervention, its underlying theory of change, and RCT procedures are needed before it can be widely implemented and evaluated in a full-scale RCT.

3.3.1 The Frailty+ intervention and its underlying theory of change

Promising service model according to stakeholders

Frailty+ was well-received by patients and families. Moreover, some even wished to continue care follow-up after the intervention period. Specialised palliative care nurses also reported supporting Frailty+. A recent study also found that most generalist and specialised palliative care providers strongly favoured timely palliative care for this population (92). Moreover, nurses mentioned that Frailty+ has the potential to improve patient and family carer outcomes. The intervention can lower the threshold for patients and families to contact the service again in case their health deteriorates, or in periods of complex palliative care needs. Nurses also mentioned that patients may have gained more insight into their own situation and end-of-life preferences. Important to note, these outcomes were not identified in the original Theory of Change of the Frailty+ intervention (Chapter 4). Further research is therefore required to better understand which outcomes match best with Frailty+ and should be measured to assess its effectiveness.

In addition, nurses reported that it is important to build a trusting relationship with patients and their family to reach beneficial outcomes. Research has shown that such a relationship can facilitate conversations about medical treatments, illness progression and clinical uncertainty, and goals of care discussions (88,89). In addition, several studies have identified that building a trusting relationship is crucial for patients and families to feel safe at home (88,93). A qualitative study also showed that patients' feel safe when they feel that health and social care providers have the skills and knowledge to do their work, sufficient time, and the ability to create a positive relationship (94). However, in our study, most patients received only one home visit by the specialised palliative care nurse. It might therefore be particularly difficult to build such a relationship. Generally, this might be an issue in short-term palliative care interventions, establishing such relationships requires time. It is therefore recommended for those developing and evaluating timely short-term palliative care interventions to take this into consideration.

Suboptimal implementation of Frailty+ in routine clinical practice

As part of the original Theory of Change which we developed in this project, we identified a number of intervention components which were needed to achieve the desired long-term outcomes related to patients (i.e. fewer unmet needs, increased well-being, increased sense of security in care, increased continuity of care, fewer unnecessary hospital admissions and longer stay at home) and to family carers (i.e. increased sense of security in care and fewer family support needs). At the core of the Frailty+ intervention was the involvement of timely short-term specialised palliative care nurses over a period of 8 weeks. We judged this component as not well-implemented, as the results of the pilot trial showed that most patients in the intervention group only received one home visit by the nurses and no follow-up (face-to face or telephone) visit. Additionally, the specialised palliative care nurses reported that, although multidisciplinary meetings on palliative care in primary care were also a core intervention component, no such meetings were organised. As a main reason, nurses reported that patients seemed to have a stable health status without urgent complex care needs, so multidisciplinary communication/collaboration or organisation of follow-up visits were not required. One possible explanation for this it that, in routine clinical practice, specialised palliative home care nurses are usually involved very late in the disease trajectory of patients and consequently focus on complex pain and symptom management (83,95–97). It might therefore be the case that nurses perceived their timely involvement in the care for older people, which primarily concerned psychosocial support and provision of information/introduction, as less central to their practices and tasks.

These findings underscore that implementation and integration of such timely palliative care interventions often involve changes/adaptations in daily practices, habits, skills, and/or perceptions of those delivering the intervention (98,99). The Normalisation Process Theory (NPT) describes four key constructs that facilitate in-depth evaluation of implementation processes. These involve coherence (i.e. sense-making), cognitive participation (i.e.

engagement), collective action (i.e. work done to enable intervention to happen), and reflexive monitoring (i.e. appraisal and benefits of the intervention) (24). In our study, nurses highly valued the training sessions and meetings, and reported favouring timely palliative care for older people with complex care needs living at home. Based on this, the NPT construct of coherence, or sense-making, was likely to be reached. Yet, our training sessions and meetings may not have been sufficient to reach cognitive participation with the nurses. In retrospect, the sessions were based on encouraging nurses to provide needs- and capacity-based care and proactive care rather than training them in how to work with Frailty+ and how to implement the intervention within their daily practices (100). Moreover, the number of sessions might also not have been adequate to fully acquaint them with Frailty+. In addition, only a few nurses of the teams that delivered the intervention participated in the Theory of Change workshops to develop Frailty+, hence co-creation of the intervention with the services might have improved implementation. Another important issue is the COVID-19 crisis. The nurses reported that they already needed to change their usual ways of working (e.g. mainly working from home, using face masks), and they might have prioritised caring for patients with more urgent care needs. They therefore may have had less time, abilities, and opportunities to become acquainted with and adopt the Frailty+ intervention. Implementation of complex palliative care interventions is often hindered by time constraints or a high work-load of healthcare providers (101,102). These effects might have been intensified in Frailty+ due to the current pandemic.

Poor integration between generalist and specialised palliative care providers

Within the Frailty+ intervention, collaborative and integrative working was highlighted as important ensuring coordination and continuity of care. This is particularly necessary given that high-quality integrated care is often lacking for older people at the end of life (103). Therefore, palliative care nurses were asked to plan a multidisciplinary meeting with health and social care professionals surrounding patients and families, and to identify a key health provider who coordinates care within the multidisciplinary team. However, the process evaluation showed that these meetings were never organised. Moreover, there was limited collaboration and communication between the specialised palliative care services and other healthcare providers. This shows that implementing such meetings proactively in the care for older people does not seem to fit with routine clinical practices. A recent UK research report stated that, to improve integration of health and social care services, it is particularly important to strength the relational integration rather than only the organisational or structural integration (104). It is interesting to see that the previous short-term palliative care intervention in England was effective in reducing symptom distress of older people, and that high levels of collaboration and communication between generalists and specialised palliative care providers were reported (90). Several factors in the UK healthcare system might have facilitated implementation of the timely palliative care intervention in primary care better than in Belgium. For instance, the collaborative partnerships between the specialised palliative care services and the primary care providers might have been better established in the UK. It might be particularly interesting to further study the development and implementation processes and strategies of such complex palliative care interventions, which then could lead to a better description of the mechanisms essential to bring about change in practice. In addition, further efforts are required to improve the relational integration of services in the shared care for older people, for instance through the organisation of joint training sessions for generalists and specialised palliative care providers (104). In addition, other service-level components, such as implementation of shared electronic health records across professions and settings, may further facilitate the collaboration and communication between health and social care providers (105).

3.3.2 RCT methods and procedures

RCT methods largely feasible in this population

In palliative care research, patients and families often report concerns around the randomisation process and may even refuse participation because of these concerns (106,107). In our study, we identified that it was feasible to randomise older people and their families to the intervention group or the control group. None of the patients declined participation based on issues around randomisation procedures. This might have been influenced by the trained data collectors and researcher who carefully explained randomisation and study procedures to potential participants. Related to this, the data collectors/researcher collected the primary, secondary and exploratory outcomes using structured questionnaires (via interviews) from patients and family carers. We identified that patients and family carers were able to complete the baseline measures at a place or time of their preference (most often in the hospital), and we identified relatively low levels of missing data 8-weeks post-baseline. This data collection method needed to be adapted during the intervention period due to the measures related to the current COVID-19 crisis. The adapted methods of data collection, i.e. questionnaires sent via post and/or assessed via phone calls, were also feasible and acceptable for older people and their family carers, and in case the patient had cognitive impairments, their representatives.

Need to optimise participant recruitment

On the other hand, we also identified threats to feasibility of the RCT design. One of the main difficulties was related to participant recruitment in the hospitals. Although this is a common problem in palliative care and end-of-life care research (108,109), in our study it was largely impacted by an external factor, namely the current COVID-19 crisis. Participant recruitment was suspended for four months, as researchers were prohibited from visiting the hospitals. In addition, recruiting hospital staff reported that they had less time to approach potential participants because they were working in COVID-19 departments. However, important to note is that, even under these circumstances, we were still able to recruit 37 patients and 26 family carers (planned sample size: 50 patients). Next to these external factors, recruiting hospital staff experienced difficulties in identification of potential participants using the prespecified eligibility criteria. For instance, in one hospital, some of the recruiting staff highlighted they did not specifically discuss whether patients had complex care needs. They mainly selected patients based on their frailty score and whether they were referred to return to their home. In addition, we identified that recruiting hospital staff felt the need "to protect" some patients for the study and therefore they did not always approach them, and/or prevented that the researcher would approach them. In the focus groups, they mentioned that they were concerned about how the researchers would explain study processes and the term palliative care. This so-called gatekeeping by carers or healthcare professionals has been identified as an important factor that may hinder optimal participant recruitment in palliative care and end-of-life care research (110–112). Most often, healthcare professionals reported fear of burdening potential patients and families, and experienced issues with disclosure of the health status or palliative care study, as the patient may become too distressed (23). In our study, data collectors/researcher explained the study to patients and family carers, while using the term 'palliative care' and not any alternative to this term (such as supportive care). They introduced this term as an additional approach that is usually initiated late in the illness trajectory but may be beneficial for patients and families at an earlier stage of illness. We found that none of the patients and family carers expressed any concerns about palliative care and/or study procedures (in case they refused participation, they mentioned other reasons for refusal).

4. CONCLUSION

Community-dwelling older people often face multiple and multidimensional complex care needs towards the end of life. These care needs are not always met in a timely and adequate manner by palliative care providers. There is still very limited evidence on which palliative care service models and interventions are best suited for identifying and managing the complex care needs of this population. We therefore developed and modelled a theory-based intervention of timely and short-term specialised palliative home care for older people with frailty and complex care needs and their family. This service was well-received by older patients and their families. In addition, healthcare professionals highly valued the concept of timely palliative care for this population. However, we identified that implementation of such an intervention in routine clinical practice is very complex and difficult. This is primarily because it is challenging to integrate specialised palliative care services in an earlier phase of illness as it requires changes in often well-established ways of working of specialised palliative care nurses that are more suited for people in a later or terminal phase of illness. We should therefore further improve and adapt the Frailty+ intervention and its underlying theoretical model in co-production with professional stakeholders in the regions and with older people and families.

5. RECOMMENDATIONS FOR FUTURE RESEARCH, POLICY, AND CLINICAL PRACTICE

5.1 RECOMMENDATIONS FOR CLINICAL PRACTICE

Provide high-quality generalist and specialised palliative home care for older people

It is widely accepted that high-quality palliative care is crucial in the care approach for older people with serious chronic conditions and complex care needs (69). However, we identified in this dissertation that there is room for improvement in primary palliative care provision for older people in Belgium and internationally. For instance, throughout this dissertation we have underscored the need for more frequent comprehensive needs assessment and enhanced interdisciplinary collaboration and communication between all healthcare providers involved in the older person's primary care. In addition, we identified in Chapter 1 that there was limited communication between the general practitioner and the older person regarding illness-related topics. Communication and decision-making with older persons in clinical practice has been identified as a crucial element of optimal palliative care provision (113). However, adequate communication between patients and their treating health and social care providers is often hindered by multi-faceted factors that can relate to the patient, family, healthcare professional, organisation or system, or even wider cultural factors and aspects. Several key elements can facilitate the communication with the older person and his/her family, such as empathic behaviour and communication of the treating healthcare professional, which is crucial to create a trusting relationship (the importance of such relationships was also mentioned by professionals in Frailty+). The older persons' information needs should then be assessed, before judging whether they prefer full and detailed medical and disease information or not. Based on their needs, tailored and flexible information can be provided (44,47).

Further, involvement of specialised palliative care services should then be initiated in a timely manner, based on older patients' complex palliative care symptoms, concerns and problems. These specialised palliative care services should be integrated with their existing health and social care providers, such as general practitioners and district nurses. Although healthcare professionals, including those involved in the development and implementation of Frailty+, valued timely palliative care for older people with serious chronic conditions (92), it is currently not fully part of their routine practices. The model should be further adapted and improved with professionals to ensure that the intervention better fits with routine practices.

Provide care that is focused on both needs as well as capacities

Generally, it is stated that palliative care provision for people with serious chronic conditions is not a one-size-fits-all approach. Rather, care provision is highly dependent on the functional status, diseases and multidimensional needs of the patient (114,115). We identified a large heterogeneity in the symptom burden and health problems within the population of older people with complex care needs (Chapter 2). This heterogeneity for older people can result in some persons remaining in relatively good health, with steady functional deterioration towards the end of life, while others may be affected by multiple diseases and/or experience several physical, psychological, social, and spiritual needs over long periods of time (41). Taking this into account, it is recommended that those caring for older people with frailty in the last years of life frequently assess their needs and functional status. Tailored and flexible interventions and treatments should be provided aligned to assessment (56).

Moreover, we identified that even those patients affected by multiple diseases and palliative care needs can have a relatively good quality of life and well-being (Chapter 2). In line with the plan of action of the decade on healthy ageing by the UN, it is recommended that those caring for older people should also focus on developing and strengthening their intrinsic capacities and abilities, even for those at the end of life (59). According to a recent developed framework, the intrinsic capacity consists of five domains, namely sensory, locomotion, cognition, psychological and vitality, which are all related to each other and the environment (116). Thus, next to the management of their needs, healthcare professionals are encouraged to generate relationships based on respect with older people and to identify and enhance the different intrinsic capacities domains towards a better quality of life and well-being (59,117).

Enhance professional relationships between generalist and specialised palliative care providers

Various health and social care providers across settings are often involved in the care for older people towards the end of life (e.g. hospital geriatricians, district nurses), making optimal interdisciplinary collaboration difficult. In Chapter 6, we also identified that there was very limited communication and collaboration between specialists and generalists, potentially hindering optimal coordination and continuity of care. A recent UK research report showed that to enhance partnerships between health and social care services, better relational integration is needed rather than solely organisational or structural integration (104). Thus, only implementing multidisciplinary meetings proactively in the care for older people might not be sufficient in improving integrative working between services. It is suggested to support skills and capacities of professionals in integrative and collaborative relationships (104). It could therefore be an important starting point to let generalists and specialised palliative care providers get to know each other better, for instance through joint training sessions on interdisciplinary palliative care for older people, and to leave room to clarify current roles and (shared) responsibilities of the different care providers (118,119). This may help to ensure that every professional knows what is expected from them in the interdisciplinary relationship. Moreover, such sessions and meetings can also be organised online. This makes meetings more accessible for healthcare professionals as it requires less time and efforts (120,121).

Improve understanding and knowledge of palliative care

Palliative care can have a negative connotation for patients, families and healthcare professionals (122–124). In a previous study, medical oncologists reported that the term 'palliative care' hinders effective patient referral to such services, especially for patients who need to be referred early to the service (122). In Chapter 6, we indeed identified that recruiting hospital geriatricians and geriatric liaison staff expressed concerns around the researchers using the term 'palliative care' to potential study participants because, according to them, it might distress patients and families. In the literature, there is much debate about whether palliative care should be rebranded into an alternative, and potentially less loaded term such as 'supportive care' or 'continuing care' to increase referral to palliative care services (125–127). In our study, we informed patients and families about timely palliative care by emphasising that the potential benefits of end-of-life care are not limited to the end of life but might also apply to people in earlier stages of illness. We identified that none of the patients declined participation based on concerns around the term palliative care. Based on these findings, and aligned with previous studies (123,124), we believe that using the term 'palliative care' is possible for timely introduction of the service given careful explanation and education of healthcare professionals as well as the general public about the meaning and purpose of palliative care.

5.2 RECOMMENDATIONS FOR FUTURE RESEARCH

Understand (variation in) complex needs and well-being of older people

In this dissertation, we provided insights into the variation in multidimensional symptoms and concerns and well-being among older people with complex care needs upon hospital discharge. However, this involved a descriptive cross-sectional study design. This underscores the need for more larger-scale studies of the prevalence, interactions and evolution of the multidimensional needs and well-being of older people with complex care needs. This could be, for instance, through population-based and longitudinal studies. Such studies have the potential to provide extensive information, and to enable us to better understand inter-individual variation in and evolution of needs and well-being over time. In addition, network analysis methods could be used to investigate in-depth the clusters of symptoms, concerns, and well-being, as well as associations within and between these clusters (128). This in-depth knowledge would help to develop interventions and services which are better tailored to the individual palliative care needs and well-being of older people over the last years of life.

Further, we still lack consensus-based complex needs criteria for referring older people with frailty and multimorbidity living at home to specialised palliative home care services. In this thesis (Chapter 4), we therefore developed a complex needs criterion based on evidence and stakeholders' input. Recruiting hospital staff and specialised palliative care nurses in this study reported that the current criteria might be too broad, as most older people admitted to the hospital have at least one complex care need in one of the four palliative care domains. We therefore recommend to further evaluate whether this is an appropriate criterion to identify older people with complex care needs. For instance, those developing and evaluating timely palliative care interventions for the population of older people, could then collect comprehensive information of those who are referred to the specialised palliative care service (and those who are not), in terms of their complex multidimensional symptoms and concerns, but also on the comorbidities, physical and cognitive functioning. In addition, several existing tools, based on needs rather than diagnosis/prognosis, might facilitate referral procedures to palliative home care services. These tools include the comprehensive geriatric assessment (CGA) (129) and the recently developed and validated ID-PALL (i.e. IDentification of Patients in need of PALLiative care tool (130).

Improve the theoretical model of timely and short-term palliative care for older people

In this thesis, we applied a Theory of Change approach to the development, implementation, and evaluation of the Frailty+ intervention. Moreover, we provided an in-depth description of the intervention, for instance we reported information on who provided care, when, with which frequency and for whom (13). We therefore advise researchers to also provide comprehensive theoretical understanding, information on the intervention content and implementation processes and strategies. This enables others to better understand how the intervention can be implemented and embedded in practice, or transferred and tailored to other healthcare settings or countries (2). The fact that we made Frailty+ and its Theory of Change explicit, enabled us to clearly identify and show in the evaluation which intervention components and processes were implemented well and which were not implemented as planned.

As recommended by De Silva et al. 2014 (3), the original Theory of Change should be adapted based on new evidence. The findings of Chapter 6 showed that implementation of Frailty+ in routine practice needs to be improved. The researchers need to better prepare and support specialised palliative care nurses to adopt the practice change towards timely palliative care for older people with complex care needs. We therefore advise striving for more co-production and co-creation of intervention content with professionals delivering the complex intervention or practice change (131–133). In addition, in this study we used the NPT to enhance evaluation of the implementation processes (24), but we would recommend incorporating such implementation theories and other behavioural theories as early as the intervention development and implementation phase. Such theories could, for instance, be used as a guiding framework in intervention development to investigate, in co-creation with professionals, how the four key constructs of NPT can best be achieved. This then has the potential to improve the implementation and integration of the practice change in routine clinical practice (24,134).

Further, we identified the important concept of ‘building a trusting relationship’ between specialised palliative care nurses and older people and their families (Chapter 6). A growing body of literature has shown that establishing such a relationship is pivotal for effective home-based palliative care. Further research should investigate whether and how such relationships can be established in short-term palliative care models. In addition, we identified several outcomes in Chapter 6 that were not reported in our original Theory of Change map (Chapter 4). We should further investigate which long-term outcomes fit best with the specialised palliative care service and should be incorporated in the theoretical model.

Improve methodological procedures of palliative care trials

Although we identified that the RCT procedures and methods were feasible in this population (Chapter 6), recruiting hospital staff experienced challenges in recruitment of potential participants. We therefore recommend conducting more frequent meetings with recruiting staff prior and throughout the intervention period to ensure that problems are solved earlier. Moreover, we identified that there is generally very limited guidance on best methodological practices for palliative care trialists. Research shows that palliative care trials often have difficulties in reaching and retaining the planned number of participants in the time specified (108,135). Moreover, articles often lack a full description of the strategies used for optimising recruitment and retention, or the factors that hindered or facilitated recruitment and retention (135). There is considerable experience among researchers in trial methods and procedures. However, this has until now not been brought together in a way that it can benefit the whole palliative care research community. We should therefore start exchange our experiences in RCT methods and procedures, and conduct more consensus-building exercises on best recruitment and retention practices, for example through Delphi studies or consensus development conference methods (136). Although both methods considerably differ from each other, at their core both methods are based on reaching consensus among a group of experts (136).

Next to this, we identified that trials that measured the effectiveness of timely short-term palliative care trials based their evaluation on different outcomes. Moreover, we may wonder whether outcomes are always important and meaningful to patients and family carers. For instance, we identified that feelings of security were highly important for patients, yet there are no timely palliative care studies who measured this outcome to evaluate the effectiveness of their intervention. It might therefore be particularly important to develop an international core outcome set in timely short-term palliative care trials, including outcomes that are relevant to all stakeholders, to generate better evidence regarding the effectiveness of these interventions. A core outcome set represents *'the minimum of outcomes that should be measured and reported in all trials in a particular setting or condition'* according to the Core Outcome Measures in Effectiveness Trials (COMET) Initiative (137). There are for instance already such sets under development for interventions on best care for the dying person (138). Research on timely short-term palliative care interventions would thus largely benefit from a core outcome set that ensures alignment in outcomes measured, that takes better into account the importance of outcomes to all stakeholders and the methodological appropriateness and robustness.

5.3 POLICY RECOMMENDATIONS

Integrate palliative care for older people in healthcare policies

The findings of this thesis showed that there is much room for improvement in the provision of palliative care for home-dwelling older people with serious chronic conditions in Belgium and internationally. This is particularly necessary as the number of older people with serious chronic conditions and complex care needs is expected to grow in the near future (139). To advance its use and quality for the population of older people, it is crucial that palliative care and end-of-life care are integrated into healthcare policies on ageing (140,141). A recent policy-analysis on palliative care for older people showed that several essential palliative care aspects were mentioned in policy documents in most countries. However, care at the end of life, including death and dying, were often not addressed in these documents (142). This underscores that first pivotal policy efforts are needed to ensure that all holistic elements of palliative care and end-of-life care are part of national healthcare policies, plans, and other regulations for older people (142,143).

Train healthcare professionals on timely palliative care for older people

The findings of this thesis underscore the need for policy action towards more and better training on aspects related to provision of timely palliative care for older people with serious chronic conditions, such as frailty and multimorbidity. As identified in Chapter 4, these aspects include specific multidimensional health and care needs, principles of palliative care and geriatric care models, needs- as well as capacity-based care, goal-oriented and proactive care, and patient/family-focused care. In addition, training courses proposing skills, knowledge, and insights to improve professional collaboration and communication across settings in the shared care for older people are strongly recommended. Lastly, topics focused on improving and supporting end-of-life care communication with and information provision for older patients and families might also be relevant. This may be accomplished through courses on for instance "Breaking Bad News". These efforts have the potential to improve interdisciplinary palliative care for home-dwelling older people with serious chronic conditions and their family carers in the last years of life.

Provide sufficient resources for high-quality timely palliative care for older people

Current healthcare systems are moving towards more timely initiation of palliative care for people with serious chronic health conditions. However, to provide high-quality timely palliative care, sufficient resources in terms of time, staff, and financial support are needed. Recent research shows that generalist and specialised palliative care providers currently lack adequate resources to provide timely palliative care (92). We also identified in the focus groups that specialised palliative care nurses doubted whether they have sufficient time and staff to provide timely short-term palliative care for older people with frailty and complex care needs (Chapter 6). These findings show that current systems might not yet have sufficient resources available to be ready to deliver timely palliative care. If specialised palliative care services would move upstream to work with patients earlier in the trajectory, this will imply a larger case load and different ways of working. Financing and regulatory mechanisms should then be in place to support this practice change. For instance, to optimise timely integration between generalist and specialised palliative care providers in the shared care for older people, it is pivotal to invest in relational integration (104) and service-level components such as implementation of shared electronic health records across professions and settings (105).

Reflect on public attitudes and behaviours towards age, ageing and older people

Many people show negative behaviours, attitudes, and feelings towards ageing and older people (59). According to the WHO, ageism is described as 'how we think (i.e. stereotypes), how we feel (i.e. prejudice), and how we act (i.e. discriminate) towards others or oneself based on age' (144). This can have a strong impact on the functioning, health and quality of life of older people, and on their access to healthcare services (144). For instance, palliative care researchers have shown that older people with frailty and multimorbidity often have lower access to generalist and specialised palliative care services than middle-aged and younger people (145). On the one hand, this may be explained by their often-unpredictable course of disease, on the other hand, this might reflect ageism in current healthcare systems. This points towards the need to create more age-friendly healthcare systems and societies. In line with the policy action plan of the United Nations decade of Healthy Ageing (59), we need to ensure that palliative care policies, frameworks, practices, and laws are without any form of discrimination on the basis of age. In addition, it is important to invest in media awareness campaigns on ageing, ageism, palliative care and end-of-life care for older people to improve public understanding of these concepts.

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ENGLISH SUMMARY

INTRODUCTION

We live longer, but not always in good health. Many older persons experience long periods of illness, multimorbidity, disabilities or frailty. Frailty is a common condition in old age. In medical literature, it is defined by a decline in the physiological capacity of several organ systems that cause an increased susceptibility to stressors. When older people with serious chronic conditions approach the end of life, they often experience multiple and multidimensional symptoms, concerns and problems that transcend physical, psychosocial, and spiritual domains. While we should acknowledge that many of them spend a large proportion of their life in relatively good health, and not all of them approaching the end of life have these needs, the complex care needs of those who do experience them are not always adequately met.

It is stated that palliative care should be integrated in the care response for older people with serious chronic conditions. It has been recommended by the World Health Organisation as an approach to address problems associated with life-threatening illness by means of early identification, assessment, and treatment of physical, psychosocial, and spiritual problems. Two complementary palliative care service models have been advocated, namely generalist palliative care provided by healthcare providers with good basic palliative care knowledge and skills, and specialised palliative care provided by clinicians and multidisciplinary services who are specially trained in palliative care delivery. Specialised palliative care services are recommended at times when patient's needs become too complex to be addressed by generalist palliative care providers alone.

In the literature, older people with frailty and multimorbidity are frequently called the 'disadvantaged dying'. This refers to their often low and late access to palliative care services, that is, often in the terminal phase or reactively in a crisis. Several reasons have been identified that might explain the inequality in palliative care for them. For instance, their disease trajectory is often described as clinically uncertain, meaning it might be particularly difficult for healthcare professionals to prognosticate death and dying. Currently, there is limited evidence on which palliative care service models are best in addressing the often-complex care needs of older people towards the end of life. Developing and evaluating such services for older people is particularly important in primary care settings as most of them prefer to remain in their usual residence as long as possible (e.g. home).

Recently, new models of timely short-term palliative care have been developed for older people with serious non-cancer conditions. These models comprised involvement of specialised palliative care services during episodes of complex needs and integration of services with the existing primary care providers. The service model was tested in England in a small-scale randomised controlled trial (RCT) and showed to be effective in reducing symptom distress for older people in a pilot study. While this is first important evidence, it remains unclear which intervention components have led to beneficial patient outcomes. In addition, it is not known how such interventions can best be implemented in routine clinical practice. Lastly, this type of intervention has only been tested in a small region; it should be further investigated whether this type of intervention can also lead to beneficial outcomes for older people elsewhere.

A major reason for the lack of clarity in intervention components and implementation, is the difficulty of describing and evaluating such complex interventions comprehensively. According to the UK Medical Research Council (MRC) guidance for developing and evaluating complex interventions, such interventions often consist of several interacting components situated at different levels and interacting with contextual barriers and facilitators. The UK MRC recommends researchers to provide understanding of components and processes that potentially lead to the desired outcomes, and how the intervention should be implemented in practice. To facilitate this understanding, the framework recommends incorporating a theory in the design and evaluation, conducting a process evaluation alongside the outcome evaluation, and assessing feasibility of the intervention and pilot methods prior testing the intervention in a full-scale RCT. In the domain of palliative care, such theories are usually not developed. This project aimed to changed that tradition.

RESEARCH AIMS

Hence, we aim to provide an overview of current palliative care provision for and palliative care needs and well-being of older people nationally and internationally (Part 1 of this thesis). To realise **research aim 1**, we examined the quality of primary palliative care for older people in three European countries, described the palliative care needs and well-being of older people upon hospital discharge and systematically reviewed the evidence on specialised palliative home care services for older people. In addition, we also aim to develop, implement, and pilot a timely short-term specialised palliative care service intervention for older people with frailty and complex care needs and their family in primary care (i.e. the Frailty+ intervention) (Part 2). To realise **research aim 2**, we described the Theory of Change of the timely short-term specialised palliative care service intervention and the study protocol of a pilot randomised controlled trial to test this intervention. Moreover, we evaluated the feasibility of the RCT methods and the implementation and preliminary effectiveness of Frailty+.

METHODS

We used different research methods to realise the research aims of this thesis. **Research aim 1** was addressed using a population-based mortality follow-back study using existing sentinel networks of general practitioners in Belgium, Italy and Spain, a cross-sectional study using the baseline survey of the pilot RCT, and a systematic literature review. **Research aim 2** was addressed through the development and pilot evaluation of a timely and short-term specialised palliative care service intervention for older people with frailty and complex care needs in primary care and their family, following the established UK MRC guidance for developing and evaluating complex interventions integrated with a Theory of Change approach.

MAIN FINDINGS

In Chapter 1, we assessed the use and quality of primary palliative care for people aged 65 years or older in Belgium compared to Italy and Spain. We used a validated set of nine quality indicators. For almost all quality indicators, we found higher scores for Belgium than Italy, but fewer consistent differences between Belgium and Spain. General practitioners in the three countries reported relatively high quality indicator scores regarding general practitioner and family communication and bereavement counselling. However, across the three countries, there is common room for improvement, in particular in regular pain measurement of the general practitioner in the last months of life and general practitioner and patient communication about illness-related topics. In Chapter 2, we found heterogeneity in experienced symptom burden of older people who were identified as having frailty and complex needs upon hospital discharge. Most patients were affected by multiple symptoms and concerns, while some were not. The most frequently reported symptoms that cause severe problems included weakness, poor mobility, sore mouth, pain, and family anxiety. Close to three-quarters or more of the patients reported feeling supported, being able to maintain their dignity and to be able to be with people who care about them. We found that greater palliative care symptoms and concerns were moderately correlated with lower well-being. In Chapter 3, we identified that referral criteria to specialised palliative care services were mainly focused on patient characteristics, such as prognosis and to a lesser extent on needs. We also identified that services provided multidisciplinary holistic care and outcomes were related to patients and families, such as symptom control. Most articles did not provide complete descriptions of the services which hindered full understanding of essential components.

We used the Theory of Change approach to develop the hypothesised causal pathway of Frailty+ (Chapter 4). The Theory of Change specified through which changes the intervention's long-term outcomes can be reached. To do so, we synthesized evidence from the systematic review (Chapter 3) and qualitative research. Long-term outcomes were identified, such as increased well-being, and preconditions to achieve them, for instance, palliative care nurses need to be willing to deliver Frailty+. The intervention consisted of several intervention components, including implementation components and a core component. The latter includes five sub-components: timely and short-term service delivery; collaborative and integrative working within primary care; delivery of holistic needs- and capacity-based; person-centred as well as family-focused; and goal-oriented and pro-active care. In Chapter 5, we presented the study protocol of a pilot RCT and a process evaluation to study feasibility of trial methods and implementation and preliminary effects of Frailty+. Eligible patients were aged 70 years or older, with mild to severe frailty, and complex care needs and about to be discharged to home from the hospital. Patients were randomly assigned either to receive standard care (control group) or Frailty+ in addition to standard care (intervention group). Those randomised to Frailty+ received timely short-term specialised palliative care facilitated by a palliative home care nurse over a period of 8-weeks. We assessed implementation of Frailty+ and feasibility of trial methods during and post-intervention using mixed methods. The primary outcome for evaluating preliminary effects was a mean sum score across five key palliative care symptoms measured at baseline and 8-weeks post-baseline. In Chapter 6, we reported the results of the pilot RCT. We recruited a smaller sample than planned (n=50). In total, 37 patients were randomised (intervention group: n=19; control group: n=18), and 26 family carers. Frailty+ was generally well-received by patients and families. However, we identified that the core of Frailty+ was not entirely implemented as foreseen. Nurses visited most intervention patients only once at home while it was foreseen that the intervention could run for 8 weeks. They also did not plan multidisciplinary primary care meetings on palliative care, as intended. Nurses perceived this as not necessary because according to them patients had a relatively stable health status. Contextual factors likely influenced implementation in practice, such as the COVID-19 crisis. RCT methods were feasible in this population, however, recruitment difficulties were identified. We found no intervention effects on the primary outcome in our sample of patients.

DISCUSSION OF MAIN FINDINGS

Palliative care provision for and needs of older people living at home

Findings of this dissertation shed light on current palliative care services for and needs of home-dwelling older people. First, we identified that there is substantial room for improvement in palliative care for older people in primary care. More specifically, most of the older people their pain was not regularly measured by their general practitioner. Also, general practitioners did often not communicate with the patient about illness related topics and were not aware of the person's medical preferences. In clinical practice, often a complex interplay of factors related to different levels, such as the patient, family, healthcare professional and even the wider organisation or system, form a barrier to optimal patient-physician clinical communication and decision-making. Second, findings from the review showed several activities through which specialised palliative home care was delivered for older people such as holistic needs- and capacity-based care, goal-based care, comprehensive assessment and coordination and collaboration between generalists and specialised palliative care providers. In addition, it is accepted that palliative care should be provided timely for older people with chronic conditions, the findings of our review showed that there is currently no consensus of what timely specialised palliative care provision for older people entails or how it should be organised in primary care. Lastly, our baseline survey data showed important heterogeneity in the experienced symptom burden and health status of older people towards the end of life. Moreover, our data showed that older people with high symptom burden do not necessarily have low well-being. Based on these findings, and aligned with the action plan of the United Nations on Healthy Ageing, it may be particularly appropriate that palliative care providers caring for older people towards the end of life focus on the management of symptoms and concerns and on supporting existing abilities and capacities.

Hypothesised causal pathway of timely short-term palliative care for older people

Through the participatory Theory of Change approach, we identified and visualised important components and processes that need to be in place to achieve the desired long-term outcomes. We identified and incorporated care principles from different disciplines such as palliative care and geriatric/rehabilitative care, and integrated pro-active and goal-oriented care with advance care planning as core foci of the intervention. In addition, we made components explicit that aimed to improve implementation of Frailty+, such as meetings to ensure engagement and buy-in, and training sessions for those delivering Frailty+. Several long-term outcomes were identified, of which some were also measured in previous studies, such as fewer unmet palliative care needs, but others were less often used to evaluate the effects of palliative care interventions, such as increased sense of security.

Implementation of the Frailty+ intervention – outcomes of the pilot RCT

Patients and families generally valued Frailty+. Palliative care nurses also reported that the intervention has the potential to achieve beneficial outcomes for participants. While these are promising results, several aspects of the intervention model and RCT methods need to be improved before it can be evaluated in a full-scale RCT. First, the core of Frailty+ was not implemented as foreseen in practice. A possible reason for this is that palliative care nurses are usually involved late in the disease trajectory of patients and consequently primarily focus on complex pain and symptom management. It might therefore be that nurses perceived their timely involvement in the care for older people, as less central to their practices. This underscores that implementation of such timely palliative care interventions requires more changes in practices and habits of nurses than we had foreseen. In retrospect, the training sessions were more based on encouraging nurses to provide needs- and capacity-based care rather than how to work with Frailty+ and how to implement it within their daily practices. Another important issue is the COVID-19 crisis. Nurses may have prioritised patients with more urgent needs. Therefore, they may have had less time and opportunities to fully adopt Frailty+. Second, we aimed to improve collaboration between generalists and specialised palliative care services through the organisation of multidisciplinary meetings in primary care. However, these meetings were never organised. Recent research stated that, to improve integration of health and social care services, it is particularly important to strength the relational integration rather than only the organisational integration. Further efforts are needed to improve the relational integration of palliative care services in the joint care for older people, for instance through the organisation of shared training sessions. Lastly, we identified that while most RCT methods were feasible in this population, our participant recruitment was hampered, primarily for two reasons, namely the current COVID-19 crisis considerably hindered recruitment (e.g. participant recruitment in the hospitals was suspended for four months) and recruiting hospital staff experienced issues in the selection of potential participants. This resulted in a smaller sample size than planned.

CONCLUSION

We identified that older people towards the end of life often experience multiple and multidimensional complex care needs. Frailty+, the timely short-term specialised palliative care intervention, has the potential to benefit older people and their families. However, we identified that implementation of timely palliative care services for older people in primary care is highly complex and difficult. This is primarily because implementation of such services often requires changes in current ways of working of specialised palliative care services. Based on these results, we conclude that several modifications to the current intervention are needed before it can be evaluated in a full-scale RCT. This should be conducted in co-production with professionals, patients, and families.

IMPLICATIONS

This thesis provides important recommendations for clinical practice, including: 1) provide high-quality generalist and specialised palliative home care for older people; 2) provide care that is focused on both palliative care needs as well as capacities of older people; 3) enhance professional relationships between generalist and specialised palliative care providers and 4) improve understanding and knowledge of palliative care.

There are also recommendations and suggestions for future research, including: 1) understand (variation in) multidimensional complex palliative care needs and well-being of older people;

2) improve the theoretical model of timely and short-term specialised palliative home care for older people and 3) improve methodological procedures of palliative care trials.

Lastly, the thesis gives policy recommendations: 1) integrate palliative care for older people in healthcare policies; 2) train healthcare professionals on timely palliative care for older people; 3) provide sufficient resources for high-quality timely palliative care for older people and 4) reflect on public attitudes and behaviours towards age, ageing and older people.

NEDERLANDSE SAMENVATTING

INLEIDING

Het aantal mensen dat oud wordt, neemt toe. Dat is een positieve evolutie en veel ouderen kunnen op deze wijze nog lange tijd in goede gezondheid leven. Echter, voor veel ouderen worden de laatste levensjaren niet altijd in goede gezondheid doorgebracht. Veel ouderen worden geconfronteerd met lange perioden van ziekte, multimorbiditeit, of kwetsbaarheid. 'Frailty' is een veelvoorkomende aandoening bij mensen met een oudere leeftijd. Vanuit de medische literatuur wordt frailty gedefinieerd als een afname van de fysiologische capaciteit van verschillende orgaansystemen, waardoor een verhoogde gevoeligheid voor stressfactoren ontstaat.

Wanneer ouderen met ernstige chronische aandoeningen het einde van hun leven naderen, worden zij vaak getroffen door meerdere symptomen, zorgen en/of problemen, zowel fysieke, als psychosociale of spirituele. Veel ouderen brengen een groot deel van hun leven in relatief goede gezondheid door, en niet iedereen die het levenseinde nadert, wordt met deze problemen geconfronteerd. Voor diegenen die wel complexe problemen ervaren, wordt er echter niet altijd adequaat aan de zorgbehoeften voldaan.

Palliatieve zorg is een belangrijk element van de zorg voor ouderen met ernstige chronische aandoeningen. Het wordt door de Wereldgezondheidsorganisatie omschreven als een benadering om problemen aan te pakken die gepaard gaan met levensbedreigende ziekte door middel van vroegtijdige identificatie, beoordeling en behandeling van lichamelijke, psychosociale en spirituele problemen. Palliatieve zorg omvat twee complementaire dienstverleningsmodellen, namelijk generalistische palliatieve zorg die wordt verleend door zorgverleners met goede basiskennis en -vaardigheden op het gebied van palliatieve zorg, en gespecialiseerde palliatieve zorg die wordt verleend door clinici en multidisciplinaire diensten die speciaal zijn opgeleid voor het verlenen van palliatieve zorg. Inschakeling van deze gespecialiseerde palliatieve zorgdiensten wordt aanbevolen op momenten dat de behoeften van patiënten te complex zijn om door generalistische palliatieve zorgverleners alleen te kunnen worden aangepakt.

In de literatuur worden ouderen met ernstige chronische aandoeningen, zoals frailty, vaak de 'disadvantaged dying' genoemd. Dit verwijst naar de vaak late toegang tot palliatieve zorg voor deze groep ouderen, wat veelal pas plaats vindt in de terminale fase. Er zijn verschillende redenen die de ongelijkheid in palliatieve zorg voor hen zou kunnen verklaren, bijvoorbeeld dat hun ziektetraject vaak wordt beschreven als klinisch onvoorspelbaar. Het kan voor zorgverleners hierdoor moeilijk zijn om het verloop van de ziekte en het einde van het leven in te schatten. Momenteel is er beperkt bewijs over welke modellen van palliatieve zorg het beste tegemoet komen aan de vaak complexe zorgbehoeften van ouderen tegen het einde van hun leven. Het ontwikkelen en evalueren van dergelijke zorgmodellen voor ouderen is met name van belang in de eerstelijnszorg, aangezien de meeste ouderen er de voorkeur aan geven zo lang mogelijk in hun gebruikelijke verblijfplaats (hun thuis) te blijven.

Recentelijk zijn nieuwe zorgmodellen van tijdige en kortdurende palliatieve zorg ontwikkeld voor ouderen met ernstige complexe aandoeningen. Deze modellen omvatten de inzet van gespecialiseerde palliatieve zorgdiensten tijdens perioden van complexe zorgbehoeften en integratie van de diensten met de bestaande eerstelijnszorgverleners, zoals de huisarts. Het zorgmodel werd in Engeland getest in een kleinschalige gerandomiseerde klinische trial en bleek in een pilootstudie effectief te zijn in het verminderen van symptoomlast bij ouderen. Dit is het eerste belangrijke bewijs van de mogelijke effecten van een tijdig en kortdurend palliatief zorgmodel voor ouderen. Het blijft echter onduidelijk welke componenten tot gunstige resultaten voor de patiënt hebben geleid. Bovendien is niet bekend hoe dergelijke interventies in de praktijk het beste kunnen worden geïmplementeerd. Ten slotte is dit type interventie slechts in een kleine regio in Engeland getest; er moet verder worden onderzocht of dit type interventie ook elders tot gunstige uitkomsten voor ouderen kan leiden.

Een belangrijke reden voor het gebrek aan duidelijkheid omtrent de werking en implementatie van deze nieuwe zorgmodellen is de moeilijkheid om dergelijke complexe interventies in detail te beschrijven en te evalueren. Volgens de UK Medical Research Council (MRC) richtlijn voor het ontwikkelen en evalueren van complexe interventies, bestaan zulke interventies vaak uit meerdere componenten die zich op verschillende niveaus bevinden en die worden beïnvloed door de context waarin zij worden geïmplementeerd. De UK MRC raadt onderzoekers aan om inzicht te verschaffen in de interventiecomponenten en processen die mogelijk tot de gewenste uitkomsten leiden, en hoe de interventie in de praktijk moet worden geïmplementeerd. Om dit inzicht te bevorderen, raden zij aan om theorie in de ontwikkeling en de evaluatie van de interventie te gebruiken, een procesevaluatie naast de uitkomstenevaluatie uit te voeren en de haalbaarheid van de interventie en methoden te testen alvorens de interventie in een grootschalige trial te evalueren. In het domein van de palliatieve zorg worden dergelijke theorieën echter amper ontwikkeld. Daar wil dit onderzoek verandering in brengen.

ONDERZOEKSDOELEN

Het eerste deel van dit proefschrift geeft een overzicht van de huidige palliatieve zorgverlening aan en de zorgbehoeften en het welzijn van ouderen op Belgisch en internationaal niveau. Om **onderzoeksdoel 1** te verwezenlijken hebben we de kwaliteit van de eerstelijns palliatieve zorg voor ouderen in België, Italië en Spanje onderzocht, de zorgbehoeften en het welzijn van ouderen na ontslag uit het ziekenhuis beschreven en de wetenschappelijke literatuur over gespecialiseerde palliatieve thuiszorg voor ouderen systematisch geëvalueerd. Het tweede deel van dit proefschrift heeft als doel het ontwikkelen, implementeren en testen van een tijdige en kortdurende gespecialiseerde palliatieve zorg interventie voor ouderen met frailty en complexe zorgbehoeften en hun familie in de eerstelijnszorg (de Frailty+ interventie). Om **onderzoeksdoel 2** te realiseren, beschreven wij de Theory of Change van de tijdige kortdurende gespecialiseerde palliatieve zorg interventie en het studieprotocol van een piloot-gerandomiseerde klinische trial om deze interventie te testen. Bovendien evalueerden wij de haalbaarheid van de trialmethoden en de implementatie en voorlopige effectiviteit van Frailty+.

<u>METHODEN</u>

We gebruikten verschillende onderzoeksmethoden om de onderzoeksdoelen van dit proefschrift te realiseren. **Onderzoeksdoel 1** werd bereikt door middel van een mortaliteitsopvolgingsstudie gebruikmakend van bestaande epidemiologische onderzoek systemen (Sentinel netwerk van huisartsen in België, Italië en Spanje), een cross-sectionele studie gebruikmakend van de baseline survey van de piloot-trial, en een systematisch literatuuronderzoek. **Onderzoeksdoel 2** werd bereikt door de ontwikkeling en piloot-testen van een tijdige en kortdurende gespecialiseerde palliatieve zorginterventie voor ouderen met frailty en complexe zorgbehoeften in de eerstelijnszorg en hun familie, waarbij we de UK MRC richtlijnen voor het ontwikkelen en evalueren van complexe interventies geïntegreerd met een Theory of Change benadering hebben gevolgd.

<u>BELANGRIJKSTE BEVINDINGEN</u>

We hebben het gebruik en de kwaliteit van palliatieve zorg in de eerste lijn voor mensen van 65 jaar of ouder in België, Italië en Spanje onderzocht (<u>hoofdstuk 1</u>). We hebben gebruik gemaakt van een gevalideerde set van negen kwaliteitsindicatoren. Voor bijna alle kwaliteitsindicatoren werden hogere scores gevonden voor België dan voor Italië, maar niet significant hoger dan in Spanje. Huisartsen in de drie landen rapporteerden relatief hoge scores met betrekking tot de communicatie met de familie en rouwbegeleiding. Desondanks is er in de drie landen ruimte voor verbetering, zoals regelmatige pijnbeoordeling door de huisarts en communicatie met de patiënt. In <u>hoofdstuk 2</u> onderzochten we de zorgbehoeften en het welzijn van ouderen waarvan was vastgesteld bij ontslag uit het ziekenhuis dat zij frailty en complexe zorgbehoeften hadden. De gegevens toonden heterogeniteit in de ervaren symptoomlast; hoewel de meeste patiënten last hadden van meerdere symptomen, hadden anderen dat niet. Symptomen die het vaakst werden gerapporteerd als veroorzakers van ernstige problemen waren: zich zwak voelen, verminderde mobiliteit, pijnlijke of droge mond, pijn, en familie die zich angstig voelt. Bijna driekwart of meer van de patiënten gaf aan zich gesteund te voelen, in staat te zijn hun waardigheid te behouden en bij mensen te kunnen zijn die om hen geven. We ontdekten dat een toename van zorgbehoeften matig gecorreleerd was met een lager welzijn. In hoofdstuk 3 hebben we systematisch de internationale wetenschappelijke literatuur over gespecialiseerde palliatieve thuiszorg voor ouderen onderzocht. Criteria voor verwijzing naar de gespecialiseerde palliatieve thuiszorg waren vooral gericht op prognose en in mindere mate op zorgbehoeften. We stelden ook vast dat de gespecialiseerde palliatieve thuiszorg diensten vaak multidisciplinaire holistische zorg boden, en dat de uitkomsten van studies vaak gericht waren op patiënten en families, zoals symptoomcontrole. Artikels gaven vaak geen volledige beschrijvingen van de zorgactiviteiten en procedures, wat ervoor zorgt dat we geen volledig inzicht hebben in essentiële interventie componenten.

Wij gebruikten de Theory of Change benadering om het theoretisch model van Frailty+ te ontwikkelen (hoofdstuk 4). Een Theory of Change is een visuele voorstelling van hoe een interventie kan werken; ze laat zien via welke veranderingen de uitkomsten van de interventie bereikt kunnen worden. Om de Theory of Change te maken, hebben we het bewijs uit het systematische literatuuronderzoek (hoofdstuk 3) en kwalitatief onderzoek samengevoegd. We hebben uitkomsten geïdentificeerd, zoals toegenomen welzijn, en veranderingen die nodig zijn om deze te bereiken, zoals gespecialiseerde palliatieve zorg verpleegkundigen die bereid moeten zijn om tijdige en kortdurende palliatieve zorg aan ouderen te verlenen.

De uiteindelijk ontwikkelde Frailty+ interventie bestond uit verschillende interventiecomponenten, waaronder implementatiecomponenten en een kerncomponent. Deze laatste omvat vijf subcomponenten: tijdige en kortdurende dienstverlening; samenwerking en integratie binnen de eerstelijnszorg; zorg gericht op zorgbehoeften alsook capaciteiten; zorg gericht op de persoon alsook op de familie; en doelgerichte en proactieve zorg. In hoofdstuk 5 presenteerden wij het studieprotocol van een piloot-trial en een procesevaluatie om de haalbaarheid van de trial methoden en implementatie en de voorlopige effecten van Frailty+ te onderzoeken. Patiënten die in aanmerking kwamen waren 70 jaar of ouder, hadden 'mild to severe frailty' én complexe zorgbehoeften en waren op het punt om vanuit het ziekenhuis naar huis ontslagen te worden. Patiënten werden willekeurig toegewezen aan ofwel de standaardzorg (controlegroep) ofwel Frailty+ in aanvulling op de standaardzorg (interventiegroep). De patiënten die werden gerandomiseerd naar Frailty+ kregen gedurende 8 weken tijdige en kortdurende gespecialiseerde palliatieve zorg verleend door een gespecialiseerd verpleegkundige palliatieve zorg. Wij evalueerden de implementatie van Frailty+ en de haalbaarheid van de trial methoden tijdens en na de interventie met behulp van kwalitatieve en kwantitatieve methoden. De primaire uitkomst voor het evalueren van de voorlopige effecten was een gemiddelde somscore over vijf belangrijke palliatieve zorg symptomen gemeten op baseline en 8 weken na de baselinemeting. In hoofdstuk 6 laten we de resultaten van de piloot-trial zien. We hebben een kleinere steekproef geworven dan gepland (n=50). In totaal werden 37 patiënten gerandomiseerd (interventiegroep: n=19; controlegroep: n=18), en 26 mantelzorgers. Frailty+ werd over het algemeen goed ontvangen door de deelnemers. We stelden echter vast dat Frailty+ niet volledig werd geïmplementeerd zoals we hadden voorzien. Verpleegkundigen bezochten de meeste interventiepatiënten slechts één keer thuis, terwijl was voorzien dat de interventie 8 weken zou kunnen duren. Ook werden er geen multidisciplinaire bijeenkomsten in de eerste lijn gepland, zoals de bedoeling was. Verpleegkundigen vonden dit niet nodig omdat de patiënten volgens hen een relatief stabiele gezondheidstoestand hadden. Contextuele factoren beïnvloedden waarschijnlijk de implementatie in de praktijk, zoals de COVID-19 crisis. Trialmethoden waren haalbaar in deze populatie, maar er werden problemen in het rekruteren van deelnemers vastgesteld. We vonden geen interventie-effecten op de primaire uitkomst in patiënten.

BESPREKING VAN DE BELANGRIJKSTE BEVINDINGEN

Palliatieve zorg voor en zorgbehoeften van thuiswonende ouderen

De bevindingen van dit proefschrift werpen licht op de huidige palliatieve zorgverlening voor en de zorgbehoeften van thuiswonende ouderen. Ten eerste stelden we vast dat er een duidelijk ruimte is voor verbetering van palliatieve zorg voor ouderen in de eerstelijnszorg. We vonden namelijk dat er bij het merendeel van de ouderen hun pijn niet regelmatig gemeten werd door de huisarts. Ook communiceerden huisartsen vaak niet met de patiënt over ziekte gerelateerde onderwerpen en waren ze niet op de hoogte van de medische voorkeuren van de patiënt. In de klinische praktijk vormt vaak een complex samenspel van factoren op verschillende niveaus, zoals het niveau van de patiënt, de familie, de zorgverlener en zelfs de bredere gezondheidsorganisatie, een belemmering voor optimale communicatie en besluitvorming tussen patiënt en arts. Ten tweede toonden de bevindingen van het literatuuronderzoek aan dat gespecialiseerde palliatieve thuiszorg werd verleend aan ouderen door middel van verschillende zorgactiviteiten, zoals holistische zorg gebaseerd op behoeften en capaciteiten, doelgerichte zorg, en coördinatie en samenwerking tussen generalistische en gespecialiseerde palliatieve zorgverleners. Alhoewel het algemeen aanvaard is dat palliatieve zorg tijdig moet worden verleend aan ouderen, toonden de bevindingen van ons onderzoek aan dat er momenteel geen consensus bestaat over wat tijdige gespecialiseerde palliatieve zorgverlening aan ouderen precies inhoudt of hoe deze in de eerstelijnszorg georganiseerd zou moeten worden. Ten slotte toonden onze baseline survey gegevens belangrijke heterogeniteit aan in de ervaren symptoomlast en gezondheidsstatus van ouderen. Bovendien toonden onze gegevens aan dat ouderen met een hoge symptoomlast niet noodzakelijk een laag welzijn hebben. Gebaseerd op deze bevindingen, en in lijn met het actieplan van de

Verenigde Naties over gezond ouder worden, is het aangeraden dat palliatieve zorgverleners zich niet alleen richten op het aanpakken van de symptomen en zorgen van ouderen, maar zich ook richten op het versterken van de capaciteiten van ouderen.

Causale mechanismen van tijdige en kortdurende palliatieve zorg voor ouderen

Via de Theory of Change aanpak hebben we belangrijke interventiecomponenten geïdentificeerd en zichtbaar gemaakt die nodig zijn om de gewenste uitkomsten van tijdige en kortdurende palliatieve zorg te bereiken. We identificeerden en voegden zorgprincipes uit verschillende disciplines samen zoals palliatieve zorg en geriatrische zorg, en integreerden proactieve en doelgerichte zorg met voorafgaande zorgplanning als kernpunten van de interventie. Daarnaast hebben we componenten expliciet gemaakt die gericht waren op het verbeteren van de implementatie van Frailty+, zoals afspraken met de palliatieve thuiszorg teams om hun betrokkenheid in de interventie te garanderen, en trainingssessies voor de teams. Verschillende uitkomsten werden geïdentificeerd, waarvan sommige ook in eerdere studies werden gemeten, zoals minder zorgbehoeften, maar ook uitkomsten die minder vaak in andere studies worden gebruikt om de effecten van de interventie te evalueren, zoals een toegenomen gevoel van veiligheid.

Implementatie van de Frailty+ interventie - uitkomsten van de piloot-trial

Patiënten en hun mantelzorgers waren over het algemeen positief over Frailty+. Ook de verpleegkundigen gaven aan dat de interventie mogelijkheid biedt om tot gunstige uitkomsten te leiden. Hoewel dit veelbelovende resultaten zijn, moeten verschillende aspecten van het interventiemodel en de trialmethoden worden verbeterd voordat de interventie in een grootschalige trial kan worden geëvalueerd. Ten eerste werd Frailty+ niet volledig geïmplementeerd zoals voorzien. Een mogelijke reden hiervoor is dat verpleegkundigen meestal pas laat in het ziektetraject van patiënten worden betrokken en zich daardoor vooral richten op complexe pijn- en symptoombestrijding. Het is daarom mogelijk dat verpleegkundigen hun tijdige betrokkenheid bij de zorg voor ouderen als minder centraal of noodzakelijk zagen in hun taken. Dit benadrukt dat de implementatie van dergelijke tijdige palliatieve zorg interventies vaak veranderingen vereist in de huidige taken en gewoonten van verpleegkundigen. Achteraf gezien waren de trainingen ook meer gebaseerd op het aanmoedigen van verpleegkundigen om zorg te verlenen op basis van zorgbehoeften en capaciteiten dan op hoe te werken met Frailty+ en hoe dit te implementeren binnen hun dagelijkse praktijk. Een andere belangrijke kwestie is de COVID-19-crisis. Verpleegkundigen hebben wellicht voorrang gegeven aan patiënten met meer urgente zorgbehoeften; daarom hadden zij misschien niet de mogelijkheid en de tijd om Frailty+ volledig eigen te maken. Ten tweede wilden wij de samenwerking tussen generalistische en gespecialiseerde palliatieve zorgverleners verbeteren door multidisciplinaire bijeenkomsten in de eerstelijnszorg te organiseren. Deze bijeenkomsten werden echter nooit georganiseerd. Recent onderzoek toonde aan dat wie professionele samenwerkingsverbanden wil verbeteren, zich moet richten op het versterken van de relationele integratie en niet alleen op organisatorische integratie. Verdere inspanningen zijn daarom nodig om de relationele integratie van palliatieve zorgverleners te verbeteren, bijvoorbeeld door het organiseren van gezamenlijke opleidingssessies. Ten slotte stelden we vast dat de meeste trial methoden haalbaar waren in deze populatie. De rekrutering van deelnemers werd echter bemoeilijkt. Dit had twee redenen, namelijk de huidige COVID-19 crisis belemmerde de rekrutering aanzienlijk (de rekrutering van deelnemers in de ziekenhuizen werd vier maanden stopgezet) en het ziekenhuispersoneel die betrokken waren bij de rekrutering, ondervonden problemen bij de selectie van potentiële deelnemers. Dit resulteerde in een kleinere steekproef dan gepland.

CONCLUSIE

We hebben vastgesteld dat ouderen aan het einde van hun leven vaak meerdere complexe zorgbehoeften hebben. Frailty+, de tijdige kortdurende gespecialiseerde palliatieve zorginterventie, kan hier antwoorden bieden. Wij hebben echter vastgesteld dat de implementatie van tijdige palliatieve zorg voor ouderen in de eerste lijn zeer complex en moeilijk is. Dit komt vooral omdat de implementatie van dergelijke innovaties vaak veranderingen vereist in de huidige manier van werken van gespecialiseerde palliatieve zorgdiensten. Op basis van deze resultaten concluderen wij dat de huidige interventie op een aantal punten moet worden aangepast voordat deze kan worden geëvalueerd in een grootschalige RCT. Dit zou moeten gebeuren in samenwerking met professionals, patiënten en families.

IMPLICATIES VAN DIT PROEFSCHRIFT

Op basis van de bevindingen van dit proefschrift zijn er belangrijke aanbevelingen voor de klinische praktijk, waaronder: 1) verbeter de generalistische en gespecialiseerde palliatieve zorg voor thuiswonende ouderen; 2) richt de zorg op zowel de palliatieve zorgbehoeften als de capaciteiten van ouderen; 3) verbeter de professionele samenwerking tussen generalistische en gespecialiseerde palliatieve zorgverleners en 4) verbeter het inzicht in en de kennis van palliatieve zorg.

Dit proefschrift geeft ook aanbevelingen en suggesties voor toekomstig onderzoek, waaronder: 1) begrijp (variatie in) palliatieve zorgbehoeften en welzijn van ouderen; 2) verbeter het theoretische model van tijdige en kortdurende gespecialiseerde palliatieve thuiszorg voor ouderen en 3) verbeter methodologische procedures van palliatieve zorg trials. Ten slotte worden beleidsaanbevelingen gedaan: 1) integreer palliatieve zorg voor ouderen in het gezondheidszorgbeleid; 2) train zorgverleners in het verlenen van tijdige palliatieve zorg voor ouderen; 3) zorg voor voldoende middelen voor implementatie van tijdige palliatieve zorg voor ouderen en 4) geef het publiek meer inzicht in ouder worden, ouderen en palliatieve zorg voor ouderen.

CURRICULUM VITAE

Kim de Nooijer was born on 1 March 1993 in Vlissingen, the Netherlands. She obtained her Bachelor's degree in Health Sciences in 2015 at the Maastricht University, the Netherlands, where she was also selected for the Honours Programme of her Bachelor's degree. In 2017, she obtained her Research Master's degree in Health Sciences, with a specialisation in Clinical Epidemiology, at the Erasmus University Medical Center Rotterdam, the Netherlands. During her Bachelor's degree, she went on an Erasmus Exchange Semester at the University of Helsinki (Finland) and during her Master's degree on a Research Internship Abroad at the University of Bologna (Italy).

After obtaining her Research Master's degree, Kim started in September 2017 as a Doctoral Researcher at the End-of-Life Care Research Group at the Vrije Universiteit Brussel (VUB) in Belgium. Kim worked on a Research Foundation Flanders (FWO) funded research project under the supervision of Prof. Dr. Lieve Van den Block and Prof. Dr. Lara Pivodic. This project entailed the development, implementation, and evaluation (pilot RCT) of a theory-based timely and short-term specialised palliative care intervention for older people with frailty and their family carers in primary care. The findings of this research project have been published in international high-impact peer-reviewed journals. Furthermore, Kim has disseminated her research through presentations at national and international conferences and scientific workshops. Kim's aim is to further contribute to the development of effective palliative care interventions for older people, and to improve methodological procedures for palliative care trials.

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ACADEMIC PRESENTATIONS

2022

'Timely short-term specialized palliative care for older people with frailty and their family in primary care: easier said than done'. 12th World Research Congress of the European Association for Palliative Care. Interactive online sessions. Poster presentation.

'Palliatieve zorg symptomen, zorgen en welzijn van ouderen met kwetsbaarheid met complexe zorgbehoeften die van ziekenhuis naar huis worden ontslagen'. Nederlands-Vlaamse Wetenschapsdagen Palliatieve Zorg, Tiel, the Netherlands. Oral presentation.

2021

'What are the palliative care symptoms, concerns and wellbeing of older people with frailty with complex care needs who are discharged from hospital to home?'. 17th World Congress of the European Association for Palliative Care. Interactive online sessions. Poster presentation.

'Timely short-term specialized palliative care service intervention for frail older people and their family carers in primary care: development of the theoretical model of the Frailty+ intervention'. 17th World Congress of the European Association for Palliative Care. Interactive online sessions. Poster presentation.

2020

'Timely short-term specialized palliative care service intervention for frail older people and their family carers in primary care: intervention development and modelling. International Research Seminar of the EAPC Research Network Public Health Research in Palliative Care: Towards Solutions for Global Challenges. Interactive online sessions. Oral presentation

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2019

'Gespecialiseerde palliatieve thuiszorgservices voor ouderen: een systematisch literatuuronderzoek'. Nederlands – Vlaamse Wetenschapsdagen Palliatieve Zorg, Antwerpen, Belgium. Poster presentation.

‘Specialised palliative care for older people in primary care: findings of a systematic review using a narrative synthesis’. 16th World conference of the European Association of Palliative Care EAPC, Berlin, Germany. <u>Poster presentation.</u>

2018

‘The quality of primary palliative care for the oldest-old in Belgium, Italy and Spain: a mortality follow-back study’. Public Health Research Palliative Care Conference, Brussels, Belgium. <u>Oral presentation.</u>

Self-management of patients with advanced cancer: a systematic review of experiences and attitudes’. Public Health Research Palliative Care Conference, Brussels, Belgium. <u>Oral presentation.</u>

The quality of primary palliative care for older people in Belgium, Italy, and Spain: a mortality follow-back study’. 10th World Research Congress of the European Association for Palliative Care, Bern, Switzerland. <u>Oral presentation.</u>

‘In-depth theory-guided process evaluation of complex palliative care interventions’. European Association for Palliative Care RN&PACE seminar, Bern, Switzerland. <u>Oral presentation.</u>