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Timely short-term specialised palliative home care for older people with frailty and their family: a mixed-methods pilot randomised controlled trial and process evaluation

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ABSTRACT

Objective The primary study aims were to evaluate the implementation, mechanisms and context of a timely short-term specialised palliative care intervention for older people with frailty (Frailty+ intervention) as well as to assess the feasibility of a randomised controlled trial to evaluate Frailty+. Our secondary aim was to describe any preliminary effects of Frailty+.

Design Pilot randomised controlled trial with process evaluation.

Setting/Participants We aimed to recruit 50 adults (≥70 years) with Clinical Frailty Scale score 5–7, and complex care needs and their main family carer, if available, from two Belgian hospitals on discharge.

Interventions Patients were randomised to the Frailty+ intervention alongside standard care or standard care alone.

Outcome measures Implementation and trial feasibility were assessed through interviews, focus groups and quantitative data. The primary outcome to be used in a potential full-scale trial if the study is feasible and implementable was mean change in five palliative care symptoms over 8 weeks.

Results We enrolled 37 patients (19 intervention, 18 control) and 26 family carers (15 intervention, 11 control). Patients and family carers valued the home visits from palliative care nurses, and nurses saw value in Frailty+. But most patients received only one visit over 8 weeks, and nurses did not organise foreseen multidisciplinary meetings, referring to absence of urgent needs. Many aspects of the trial methods were feasible, but recruitment was challenging. The baseline mean score on the five palliative care symptoms was 6.0 and 5.6 in intervention and control group, respectively; and 4.5 and 4.1 at 8 weeks (adjusted ratio 1.0, ie, no effects on symptoms).

Conclusions While Frailty+ was generally welcomed by older people with frailty, families and palliative care nurses, our process evaluation uncovered multiple barriers, mostly rooted in the current organisation of specialised palliative care that is tailored to advanced stages of illness. Ensuring timely access requires efforts beyond timely referral alone, and implies profound organisational and cultural change.

Trial registration number ISRCTN39282347.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The combination of a pilot randomised controlled trial and a process evaluation allowed us to evaluate the feasibility, implementation and preliminary effects of the timely short-term specialised palliative home care intervention.
⇒ Our research design included mixed methods, such as interviews, focus groups and registrations, which provided in-depth qualitative and quantitative data reported by various stakeholders.
⇒ We included older people with frailty and complex care needs, including those who lacked the cognitive capacity to provide informed consent, as we wanted to ensure that the results of the trial and process evaluation also apply to them.
⇒ Study data were collected in a specific healthcare context; however, we could assume that the main findings generalise to other specialised palliative care systems that are primarily provided to people with advanced illness.
⇒ Detection bias cannot be excluded in this study, as data managers and researcher involved in outcome assessment were not blinded.

INTRODUCTION

Frailty is a common condition in older people. Following the definition by Clegg *et al*,[1] frailty is defined as 'a health state of increased vulnerability to poor resolution of homoeostasis after a stressor event, which increases the risk of adverse outcomes, including falls, delirium and disability'.[1] An estimated 12% of people living in the community are frail.[2] Many older people with frailty experience complex care needs in the physical, psychosocial and/or spiritual domains as their illness progresses and towards the end of life.[3 4] Palliative care is indicated for managing these problems and symptoms.[5] WHO defines 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'.[5] Palliative care provision distinguishes *generalist* palliative care that can, in principle, be provided by all healthcare providers and requires basic palliative care skills and knowledge, and *specialised* palliative care, that is provided by multidisciplinary services or clinicians who are specifically trained in and whose main activity is palliative care provision.[6–8] For those who require it, specialised palliative care should be delivered in a *timely* manner, that is, not restricted to the last weeks and months of life only but whenever needs are too complex to be met by generalist palliative care alone.[6 8] However, in practice, palliative care services are generally involved late in the illness trajectory,[9–12] when needs can become difficult to manage. Furthermore, older people, and particularly those with non-cancer conditions, are less likely to receive palliative care.[9 13–15] This underscores the need to develop, implement and evaluate palliative care services that are initiated in a timely manner to address the complex care needs of older people with frailty. This is particularly relevant at their home, as this is the setting where most of them live.[16]

A model of community-based short-term specialised palliative care has been developed with the aim to manage the complex care needs of older people with non-cancer conditions.[17] This model foresees service delivery during periods of complex symptom presentation integrated within primary care services.[17 18] It also foresees short-term delivery, that is, one to three visits over a period of 3 months.[17] That intervention model was tested in a randomised controlled trial (RCT), and improvements in the primary outcome, that is, patient symptom burden were observed.[18] While this is valuable preliminary evidence, it does not provide more specific and deeper insight into intervention components, their implementation and interaction with existing healthcare context—information that is necessary to translate the intervention to and test its effectiveness in healthcare contexts beyond the one in which it was developed and first studied. This is particularly relevant for complex interventions such as specialised palliative care, where multiple intervention components interact with a given context to produce the desired outcomes.[19] To inform a potential scale-up and international application of short-term specialised palliative care for older people, considerably more information is needed on how the various intervention components are applied within the existing healthcare context and organisation and through which mechanisms they effect change.

Using a theory-of-change approach and through extensive involvement of stakeholders (ie, patients and family carers, healthcare professionals and policy makers concerned with healthcare for older people), we developed an intervention based on timely and short-term involvement of a specialised palliative care service for older people with frailty and complex care needs and their main family carer (ie, the Frailty+ intervention).[20] The theory of change of Frailty+ has been published separately; it specifies how and under which circumstances the intervention can lead to the desired changes for patients and family carers.[20] Healthcare interventions, including specialised palliative care, can be tested in RCTs. In-depth process evaluation alongside such trials are recommended to gain understanding of the manner in which an intervention was implemented, through which mechanisms it interacted with measured outcomes and the contextual factors influencing its implementation and outcomes.[21] However, trials are challenging to conduct among older people in deteriorating health.[22] Recruitment and retention are among the main difficulties. Several initiatives, such as The Methods of Researching End of life Care (MORECare), provide guidance on how to improve research methods and procedures in palliative care.[22] In line with recommendations from the UK Medical Research Guidance (MRC),[19] they suggest that a pilot RCT should precede a full-scale RCT with the primary aim to assess the feasibility of the intervention and the trial design. We conducted a pilot RCT with an embedded process evaluation with the primary aims to:

1. evaluate the implementation, underlying mechanisms of change and the contextual factors potentially affecting implementation and outcomes of the Frailty+ intervention;
2. assess the feasibility of the methods and procedures of the pilot RCT, specifically recruitment and randomisation procedures, retention and missing data.

The secondary aim was to:

3. test the preliminary effects 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 pilot RCT and process evaluation employed a convergent mixed-methods design in which quantitative and qualitative data were collected in parallel, analysed separately and then integrated at the interpretation stage.[23] The intervention design and process evaluation design were informed by the theory of change map underpinning Frailty+[20] and guided by the UK MRC guidance for process evaluations of complex interventions[21] and Normalisation Process Theory.[24] The process evaluation examined the implementation of Frailty+ and the feasibility of the trial methods using semi-structured interviews, focus groups and registration of trial and intervention procedures on structured forms. To test the preliminary effects of Frailty+, we used quantitative data collected through structured measures (the measures are described in the section 'Data collection and outcomes'). Data were collected from February 2020 (start of patient recruitment) until March 2021 (data collection completion). We

followed the Consolidated Standards of Reporting Trials extension to randomised pilot and feasibility trials statement[25] for reporting of this pilot RCT. The trial protocol has been published.[26] We registered the study at ISRCTN (identifier: ISRCTN39282347). Changes have been made to the described methods in the register. We changed some of the secondary outcome measures (ie, the brief Coping Orientation to Problems Experienced questionnaire and Carer Support Needs Assessment Tool were not used; instead, we used the Family Appraisal of Caregiving Questionnaire for Palliative Care) because this outcome better fits the intervention being studied. In addition, we changed the planned sample size because the current one is based on a more appropriate calculation for pilot RCTs.

Study setting

The Frailty+ intervention is delivered in the older person's home setting. Two specialised palliative home care services, each covering one geographical region in Flanders (Belgium), facilitated the provision of Frailty+. These services consist of multidisciplinary teams comprising nurses, psychologists and palliative care physicians. In Belgium, these services are typically involved in the last days or weeks of life of patients with serious symptoms or problems.[9 10 12] Next to the provision of specialised palliative care, generalist palliative care is, for most patients, provided by their general practitioner (GP). According to Belgian law, the GP needs to initiate the involvement of the specialised palliative care service. Regarding the recruitment of the participants for our study, patients were recruited on discharge from the acute geriatrics department and via the multidisciplinary mobile geriatric teams of two public hospitals. These teams deliver care to patients with a geriatric profile admitted to non-geriatric units and provide advice to staff in these units.[27] We recruited participants on discharge from hospital to home, as many older people with frailty and complex needs are hospitalised towards the end of life, and because close collaboration with local clinical settings is needed to include participants who are in deteriorating health into research.

Participants and recruitment process

Older patients and family carers

Participants were recruited and data were collected by one researcher (KDN) and two data collectors/research assistants. In one hospital, the data collectors attended weekly staff meetings, where they identified potentially eligible patients for the study and obtained permission from their treating physicians to approach them for participation in the study. In the other hospital, researchers were not allowed to attend the meetings. Instead, the geriatricians and mobile geriatric teams identified patients and asked them whether the researchers could come to introduce the study. Patient and family inclusion and exclusion criteria were developed based on stakeholder input and evidence from a previous systematic review.[28] Using that evidence base, we decided on rather broad inclusion criteria in terms of diagnosis. Due to the nature of frailty and multimorbidity in older age, a selection based on one specific condition would be arguably 'artificial' as in this group, it is often the interaction of multiple chronic conditions that create illness, disability and complex care needs. Therefore, rather than focusing on a specific diagnosis or prognosis, we included those with frailty and complex or unresolved care needs. This is in line with currently widely accepted views that specialised palliative care should be offered based on the complexity of care needs, rather than diagnosis or life expectancy.[29 30] We also chose not to exclude any specific diagnoses or conditions as this is a frequent pitfall in health research in older populations, leading to findings that are difficult to generalise.[31]

The inclusion criteria for patients were:

- Aged 70 years or older.
- Clinical Frailty Scale score (CSF) between 5 and 7.[32] This scale is often used by healthcare professionals in clinical practice.[33]
- One or more unresolved or complex symptoms or problems in the physical, psychological social and/or spiritual domain as judged by the patient's hospital physician.[6 34]
- Admitted to a hospital and about to be discharged home in the region covered by the participating specialised palliative home care service.
- Able to participate in data collection in Dutch.

Exclusion criteria were:

- Had one or more palliative care consultations in the 6 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).
- Had a family carer declined to participate in the study (but patients who did not have a family carer were still eligible to participate).

As family carers of eligible patients, we included those whom the patient referred to as their most important carer or representative. They were included if they lived with the patient or had in-person contact with him/her at least twice a week. They were excluded if they had taken part in another study that evaluated palliative care or if they were not able to participate in data collection in Dutch.

We also included older people who lacked the cognitive capacity to provide informed consent, according to their treating physician. We decided to include them because they form a large proportion of older people in primary care settings,[35] and we wanted to ensure an inclusive trial with findings that also apply to this group. Where a person lacked capacity to consent, we approached the appropriate representative as specified in the Belgian law for patient rights.[36] Most often, this was a close family member.

The researcher or data collector informed eligible patients and their families, or their legal representatives,

about the study and about what participation would entail. 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'.

Healthcare professionals

The researcher or data collectors contacted the GPs of patients who agreed to participate (which included agreeing that their GP be contacted). They introduced the study to them and obtained their written informed consent for the patient to participate. This was a necessary step because in Belgium, the specialised palliative care service needs to be formally requested by a person's GP.[37] Additionally, members of the specialised palliative care teams, the included patients' GPs and the recruiting geriatricians and mobile geriatric teams participated as respondents in the process evaluation of the Frailty+ intervention.

Randomisation and masking

We randomised patients (1:1) after the baseline measurement 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. A statistician (SDB) created computer-generated sequences for randomisation which were accessible to an external researcher only. If patients in the control group were referred to a specialised palliative care service as part of standard best practice care, they would remain in the control group, in accordance with intention-to-treat principles. Masking of study group assignment was not feasible for the study investigators or participants because of the nature of the intervention.

The Frailty+ intervention

Frailty+ consists of one core component and seven implementation components, delivered by nurses of the specialised palliative home care team. The core comprised five subcomponents, namely:

- Short-term delivery of a specialised palliative care service: the service is initiated in a timely manner, that is, when the patient's complex care needs cannot be addressed by generalist providers alone. The service is also delivered on a short-term basis. We expected it would involve at least one and likely no more than four home visits by the palliative care nurse. Additional follow-up by telephone was possible, based on needs.
- Collaborative and integrative working: palliative care nurses are encouraged to organise at least one multidisciplinary primary care meeting per patient, to discuss palliative care.
- Holistic, needs-based and capacity-based care: palliative care nurses are encouraged to identify and manage patients' palliative care needs, as well as their resources and capacities.
- Person-centred as well as family focused care: palliative care nurses are encouraged to view and support family in their role as both care providers and care recipients.
- Goal-oriented and pro-active care: palliative care nurses are encouraged to support patients to define and meet their health and care goals across various health, care and life domains.

The implementation components include strategies to inform and engage primary and secondary care providers in the study regions as well as procedures to select and refer older people with frailty and complex care needs and their families to Frailty+. One implementation component was training of specialised palliative care nurses on topics related to the earlier-than-usual provision of palliative care to older people with frailty, which is a different population from the one predominantly served by these teams, namely people at later stages of illness predominantly with cancer diagnoses.[9] The training covered the specific health problems of this population and how to work with the semi-structured guides for the home visits and multidisciplinary meetings that were part of the Frailty+ intervention. The specialised palliative care teams were paid from the research project for their participation in the study next to their usual tasks, as they needed to hire additional staff. Both existing staff members and new staff members delivered Frailty+.

Data collection and outcomes

Sociodemographic and clinical characteristics

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

Implementation, mechanisms of change and contextual factors (primary aim)

The primary outcomes of this study included the 'dose' of the intervention components that were delivered as well as the adaptations that were made to the initial intervention description, the experiences with the intervention of the stakeholders, including the unexpected events and the factors that influenced the outcomes and implementation of the intervention according to the stakeholders. An overview of the collected data, methods and timing of data collection is given in table 1. These data were collected in the intervention group only. The quantitative data were collected throughout the intervention period through registration in standardised documents prepared by the researchers. We conducted semi-structured qualitative face-to-face interviews with patients and family carers and structured phone interviews with GPs 8–11 weeks postbaseline. We also conducted online focus groups with specialised palliative care teams, geriatricians

Table 1 Process evaluation: data collected, methods and timing of data collection (primary aim)

Data collected	Methods of data collection	Timing of data collection/extraction
Implementation, that is, 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. Postintervention
Mechanisms of change, that is, 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 healthcare 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 healthcare 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 healthcare 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 postbaseline 3. and 4. Postintervention 5. Throughout the study period, as applicable

Continued

Table 1 Continued

Data collected	Methods of data collection	Timing of data collection/extraction
Contextual factors, that is, 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 teams', 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 families Structured phone interviews with GPs	Focus groups: postintervention Interviews: 8–11 weeks postbaseline

GP, general practitioner

and mobile geriatric teams postintervention. The topic guides for the interviews and focus groups covered implementation, mechanisms of change and contextual factors of Frailty+.[21] For the focus groups with the specialised palliative care teams, we additionally used adapted questions of the Normalisation MeAsure Development (NoMAD) tool,[38] which is informed by the Normalisation Process Theory.[24] This theory is based on four key constructs, namely coherence (ie, sense-making), cognitive participation (ie, engagement), collective action (ie, work done to enable the intervention to happen) and reflexive monitoring (ie, appraisal of benefits and costs of intervention).[24]

Feasibility of the RCT methods (primary aim)

The other primary outcomes of this study were related to the feasibility of the RCT methods. More specifically, we assessed the recruitment and randomisation procedures by reporting: (1) the number of eligible, approached, enrolled and randomised patients and family carers; (2) the 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; (3) patients', families' and GPs' views of the information letter and informed consent procedure; (4) mobile geriatric teams' and geriatricians' views of and experiences with the inclusion criteria and their application, and with the procedure of introducing the study to patients and (5) patients', family carers' and GPs' views of and experiences with the randomisation procedure. The recruitment rate was calculated as the number of participants randomised divided by the number of approached participants. We also evaluated the study retention and data collection procedures by reporting the following: (1) number of patients, family carers and GPs who dropped out of the study and reasons for dropping out (if stated); (2) number of patients and family carers who completed the baseline/follow-up assessment or reasons for not completing it (if stated) and (3) patients' and family carers' views of and experiences with completing baseline and follow-up assessments. We calculated the retention rate as the number of participants who completed the follow-up assessment divided by the number of randomised participants.

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 carers and structured phone interviews with GPs (8–11 weeks postbaseline) and focus groups with recruiting hospital staff (4–8 weeks after completion of recruitment).

Preliminary effects of the Frailty+ intervention (secondary aim)

The secondary aim of this pilot RCT was to evaluate preliminary effects of the Frailty+ intervention. This is considered a preliminary effects study, as this pilot RCT is not statistically powered to determine the effectiveness of Frailty+. All secondary outcomes related to the preliminary effects evaluation were identified through stakeholder input and previous literature.[20] The research team then classified them as primary, secondary or exploratory outcomes for potential use in a future full-scale RCT if the study is considered as feasible and implementable (outcomes are described in table 2). The primary outcome served as the most relevant outcome to evaluate the effect of Frailty+. This was mean change on a sum score based on five key palliative care symptoms experienced by the older person (ie, breathlessness, pain, anxiety, constipation, drowsiness) from baseline to 8 weeks, measured by the Integrated Palliative Care Outcome Scale (IPOS).[39] We used secondary outcomes to investigate additional effects of Frailty+, and exploratory outcomes to explore new research hypotheses.[40] Outcome classification was based on the availability of validated questionnaires that could be used to measure the outcomes, and on the primary outcomes assessed in previous evaluations of short-term specialised palliative care interventions, with a view to obtain comparable results.[18]

The outcomes were measured using validated questionnaires in a structured interview format, as self-completion would have been too difficult for many older people in poor health. We collected data at baseline (T0) and 8 weeks after baseline (T1). One exploratory outcome, namely patient's healthcare utilisation (ie, number and length of hospital admissions and number of GP visits), was assessed only at 8 weeks postbaseline through telephone interviews with the patient's GP.

Table 2 Preliminary effects evaluation: outcomes, measures and respondents (secondary aim)

Outcome	Outcome measure	Respondent
Primary outcome potentially to be used in a full-scale RCT		
Mean change on a sum score based on five key palliative care symptoms (ie, breathlessness, pain, anxiety, constipation, drowsiness)	IPOS[39]	Patients
Secondary outcomes potentially to be used in a full-scale RCT		
Palliative care needs	IPOS[39]	Patients
Well-being	ICECAP-SCM[49]	Patients
Sense of security in care	Sense of security in care—patients[50]	Patients
Sense of security in care	Sense of security in care—relatives[51]	Family carers
Support needs	Family Appraisal of Caregiving Questionnaire for Palliative Care[52]	Family carers
Exploratory outcomes potentially to be used in a full-scale RCT		
Physical symptoms, emotional symptoms and communication/practical symptoms	IPOS subscales[39]	Patients
Care interaction, identity and mastery	Sense of security in care—patients subscales[50]	Patients
Personal continuity and team/cross boundary continuity	Nijmegen Continuity Questionnaire subscales[53]	Patients
Overall quality of life today	One item of the IPOS—views on care[54]	Patients
Care interaction, patient situation and mastery	Sense of security in care—relatives subscales[51]	Family carers
Caregiver strain, positive caregiving appraisal, caregiver stress and family well-being	Family Appraisal of Caregiving Questionnaire for Palliative Care subscales[52]	Family carers
Patient's healthcare utilisation, that is, number and length of hospital admissions and number of GP visits	Telephone interview	GP

GP, general practitioner; ICECAP-SCM, ICEpop CAPability measure for supportive care; IPOS, Integrated Palliative Care Outcome Scale; RCT, randomised controlled trial.

Data analysis

The quantitative process evaluation and feasibility data were analysed using descriptive statistics. KDN transcribed the qualitative data from the interviews and focus groups verbatim. Subsequently, the transcripts were deductively coded into prespecified themes, namely feasibility of trial methods and procedures, implementation, contextual factors and mechanisms of change.[21] A random 20% of the transcripts were independently coded by another researcher using the same analytical process to examine potential disagreements. We then inductively formed subthemes within the prespecified themes. The two independent coders met regularly to compare the results and discuss the codes, themes and subthemes. If disagreements arose, solutions were sought through discussions with the research team. Qualitative analyses were conducted in NVIVO V.12.

Regarding the sample size, we aimed to include a total sample of 50 patients (25 in each study arm). Characteristics of the two study arms were described using descriptive statistics. Differences in mean change from baseline to follow-up at 8 weeks between the intervention and control groups were tested using a generalised linear mixed model analysis where the baseline value is also used as outcome measure. The fixed effects were treatment, time and treatment-by-time interaction. The random effects part included one random intercept for patient to account for the two measures within a patient. Depending on the end point, a normal distribution with identity link or 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 groups. Moreover, we reported the estimated interaction effect, which is the ratio of the mean ratio of Frailty+ to standard care postintervention, divided by the mean ratio of Frailty+ to 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 V.26 to perform the analyses.

The research team discussed the qualitative and quantitative findings during several research meetings to come to an integrated understanding and decision about whether, and how, to continue with a full-scale RCT.

Patient and public involvement

Patients and family carers were involved in the development and design of the Frailty+ study. More specifically, we conducted qualitative interviews with them to better understand what is important to them regarding timely and short-term specialised palliative care at home. Their views were then used, together with the insights of other stakeholders, as input for the development and design of Frailty+.

RESULTS

Participant flow, recruitment and retention

The recruitment for this pilot RCT and process evaluation 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 (76%) completed measurements after 8 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 Consolidated Standards of Reporting Trials diagram of the participant flow. The final sample size was smaller than planned. However, since the foreseen sample size for this pilot RCT, whose main aim was to test the feasibility of the trial methods and assess the implementation of the intervention in practice, was not based on a statistical power calculation, we performed the data analyses as planned with 37 patients. We were convinced that this number would allow us to determine the main strengths, issues and challenges in feasibility and implementation, as well as to describe any preliminary intervention effects.

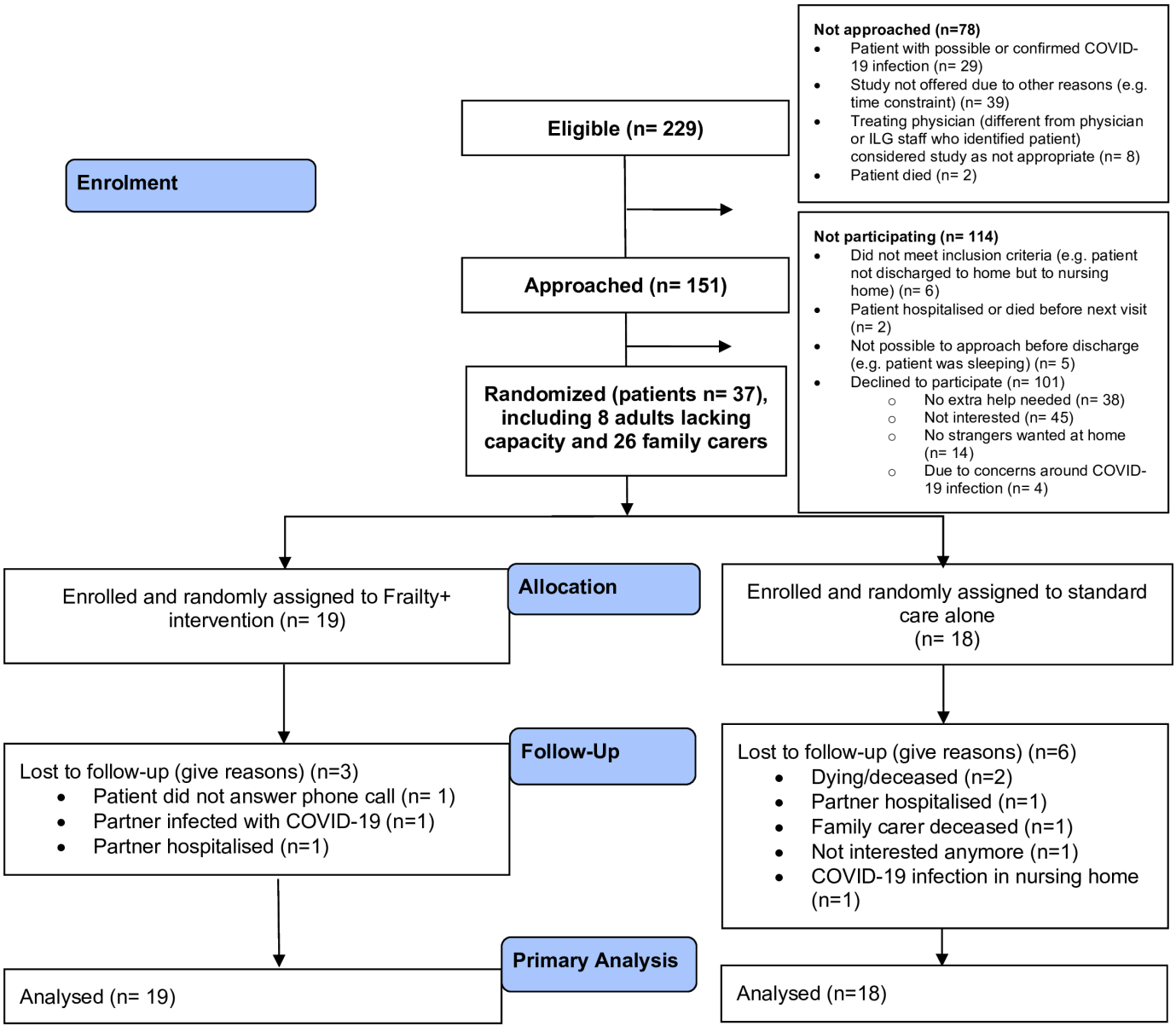

Figure 1 Consolidated Standards of Reporting Trials flow diagram of recruitment and retention.

Table 3 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)
CFS*†‡		
5 (%)	9 (52.9%)	6 (33.3%)
6 (%)	6 (35.3%)	5 (27.8%)
7 (%)	2 (11.8%)	7 (38.9%)
Medical diagnosis†§‡		
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		
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 (ie, informal carers)?		
0	7 (36.8)	4 (22.2)
1	4 (21.1)	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¶**		
Family care and additional home care		
Homemaker or basic assistance care	3 (15.8)	3 (16.7)
Nursing care	4 (21.1)	5 (27.8)
Local service centre care	15 (78.9)	12 (66.7)
Social work services of the health	1 (5.3)	2 (11.1)
insurance	1 (5.3)	0
Other	2 (10.5)	4 (22.2)

*The CFS is scored from 0 to 9, with higher scores representing increasing frailty. Patients were included with a frailty score 5–7, in other words mildly to severely frail.
†Reported by the treating physician in the hospital.
‡Missing data standard care group: medical diagnosis (n=1), missing data intervention group: CSF (n=2).
§ More than one diagnosis per patient is possible. Intervention group: five patients had two diagnoses (26.3%) and two patients had three diagnoses (10.5%). Control group: 11 patients had two diagnoses (64.7%) and 0 patients had three diagnoses.
¶Reported by the general practitioner.
** More than one provider per patient is possible.
CFS, Clinical Frailty Scale; SD, Standard deviation.

Participant characteristics

Older patients and family

Baseline patient characteristics are described by study group in table 3. 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 the partner/spouse of the patient (intervention group 63.6% and control group 66.7%).

Healthcare professionals

We conducted two online focus groups with the specialised palliative care services between January and March 2021. Participants were eight specialised palliative care nurses and one coordinator (75% female). We also conducted 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 (both female). In the other hospital, there was a preference for individual interviews over focus groups. We performed online interviews with a psychologist from the mobile geriatric team and a geriatrician (both female). We conducted structured phone interviews with 31 GPs of patients included in the study (35% female). We could not reach six GPs for interviews (covering six patients, four in the intervention group and two in the control group).

Feasibility of the RCT design

Identification, eligibility criteria and introduction of the study

Hospital geriatricians and mobile geriatric team members stated that most patients were identified during the multidisciplinary meetings and that the attendance of the researcher/data collectors was crucial to reminding the professionals of the study. They mentioned that they did not approach some patients for study participation because they felt the need to 'protect' them:

> We want to protect these patients because we have seen them, oh, this is a weak person, no, this is not yet the moment to approach them whereas in fact this could be a patient who could have fit in the study. (Mobile geriatric team member)

Members of the mobile geriatric team at one hospital pointed out that they often forgot to focus on the complex needs criterion during the identification process:

> The complex problems, well we didn't really pay so much attention to them in the identification process. (Mobile geriatric team member)

Several hospital geriatricians and mobile geriatric team members highlighted that the inclusion criteria were rather broad since according to them almost all patients admitted to the acute geriatrics unit had complex care needs and a CFS score between 5 and 7. Specialised palliative care nurses also reported that the inclusion criteria were too broad, and many patients met those criteria:

> 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)

Three specialised palliative care nurses therefore 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.

As for introducing the study to potential participants, in one hospital, the recruiting hospital geriatricians and mobile geriatric team members 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 hospital geriatricians and mobile geriatric team members permitted the data collectors and researcher to approach the patient directly after identification, without the physician first introducing the study. All of them expressed concern about how the researchers would explain palliative care and study processes to participants because, according to them, this might cause distress to patients:

> The word palliative care makes it so negative for people, for many people of that generation it is a very tough word. (Mobile geriatric team member)

Informed consent procedure and randomisation

Most patients, families and GPs indicated in the interviews that they had received sufficient information from the data collectors or researcher to decide whether to participate. Some patients and family carers reported that they did not know what to expect from the home visits:

> It wasn't discussed very clearly how many times these people would come or what they were going to do. (Family carer)

Patients and families suggested we provide a clearer explanation in the consent procedure of the different roles of the researchers and palliative care nurses. 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 would have preferred to be in the intervention group and receive the palliative care service.

Implementation of the Frailty+ intervention

The intervention components and activities that were delivered are reported in table 4. All 19 patients in the intervention group received at least one home visit from a palliative care nurse, seven received a second and one patient received a third visit (mean visits per patient: 1.4; mean duration 77 min). 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 in the intervention group, introduction/information concerning the specialised palliative home care service 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 table 4. Twelve patients received at least one phone call from the palliative care nurse (mean phone calls per patient: 1.3; mean duration 7 min). The nurses reported that they did not organise the multidisciplinary meetings on palliative care that were foreseen by the intervention.

Mechanisms of change

We present the responses of participants to the intervention in general and to the different intervention components specifically. The distress protocol was not activated during the study period (more information about the distress protocol can be found in the study protocol of Frailty+).[26]

Intervention in general

The specialised palliative care nurses appreciated that the intervention was well planned, clear and that they were regularly supported by the researchers in intervention delivery. Nurses stated that study patients seemed to have a longer life expectancy and fewer care needs compared with the population they usually care for. This was also brought up 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 would enable them 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 many more patients than they currently do.

> The complex care 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. (Specialised palliative care coordinator)

Training sessions and meetings prior to patient recruitment

Nurses of the specialised palliative care teams mentioned that the number of training sessions and meetings with researchers were sufficient, the topics discussed were helpful to understand the study. Moreover, they appreciated that the members of the two participating specialised palliative care teams could exchange about the study with each other. Nurses appreciated that they were asked for feedback in the development of the semi-structured guides for the home visits that were part of the intervention. According to some of them, the topics listed in the 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 concerning goal-oriented care.

Home visits and phone calls

Patients and family carers who received the Frailty+ intervention stated that they valued the home visits of the

Table 4 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 (two 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 (two 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 one home visit, seven patients two home visits, one patient three home visits) *Mean number per patient:* 1.4 *Mean duration per patient:* 77 min	*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 (seven patients had no phone calls, seven patients had one phone call, two patients had two phone calls, two patients had three phone calls, one patient had seven phone calls) *Mean number per patient:* 1.3 *Mean duration per patient:* 7 min	*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 (two with GPs, four with community nurses)	Explanation of intervention and providing support regarding medication and psychological needs

GP, general practitioner

specialised palliative care nurses. Several patients, family carers and specialised palliative care nurses pointed out that patients' care was already well arranged prior to the first home visit. However, three patients and family carers who received one visit only stated that they would have liked to have received a follow-up visit, for instance, because of the uncertainty of how their situation would evolve.

> More follow-up visits, because one moment everything is going well but the next you can feel helpless. (Family carer)

Following their use of the guides for home visits, nurses stated that the topics in the guides were not always applicable to the study patients:

> 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)

Nurses who planned more follow-up visits felt that the first visit constituted an introduction, and the subsequent visits involved more in-depth conversations in which their expertise was more valuable compared with the first visits. Some therefore doubted whether their expertise was really needed in those first visits for patients whom they perceived as not having urgent needs:

> We asked the question at the beginning: does it have to be people with our skills. Because we had the idea at the start of the study 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 arranged well. (Specialised palliative care nurse)

However, they also thought that they would not have reached the same depth of conversation with patients and their family carers in the follow-up visits without having done those introductory visits:

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 patients. (Specialised palliative care coordinator)

Specialised palliative care nurses suggested that the duration of the period during which home visits take place (ie, 8 weeks) should depend on a patient's health status. Eight weeks might be too long if a patient has no urgent needs, but others said that it may need to be longer than 8 weeks for patients in deteriorating health, to ensure that the nurses are involved then.

Collaboration with other healthcare professionals

The specialised palliative care nurses reported that they did not organise the multidisciplinary meetings on palliative care in primary care because they judged the patient's health as stable, and found that their care was arranged well prior to the first home visit. They also brought up that they had limited contacts with other healthcare professionals involved in the respective patients' care.

Impact of the Frailty+ intervention

The specialised palliative care nurses reported that the intervention lowered the threshold for patients to contact the service again in case their health deteriorated. One nurse stated 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.

Contextual factors

We identified several contextual factors that likely influenced the implementation and outcomes of Frailty+. All participants mentioned the COVID-19 crisis. Palliative care nurses said 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 stated that there was little contact between nurses about the study because they mainly worked from home, when not conducting visits to patients. They found that such 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 in COVID-19 departments and had less time to approach patients. Next to factors related to the pandemic, the recruiting staff at one hospital felt minimally involved in the study due to the many other studies that were ongoing at the same time.

Preliminary effects of Frailty+

As this was a pilot RCT, we evaluated preliminary effects of the Frailty+ intervention. The estimated mean sum score on the primary outcome to be used in a potential full-scale RCT if the study proves to be feasible and implementable (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 postbaseline (adjusted ratio 1.0, ie, no effect of Frailty+ over time on the mean sum score compared with standard care alone) (table 5). 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 during the study period. 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 online supplemental table 1.

DISCUSSION

The results of this pilot RCT and process evaluation of the Frailty+ intervention revealed that patients and family carers valued the home visits offered by the specialised palliative care nurses, and that the nurses recognised this group's need for an additional layer of support and timely referral. Many trial procedures seemed feasible, for example, informed consent procedure. Attrition and missing data were minimal. However, we encountered some difficulties in patient identification and recruitment and the intervention was not entirely implemented as planned (eg, fewer home visits than expected, no multidisciplinary meetings organised). Both the implementation and recruitment challenges appear to be linked to specialised palliative care nurses perceiving patients as being in relatively stable health condition without urgent care needs, and hence different from those usually referred to the service, who are at later or terminal stages in the disease trajectory. Our findings bring forward important questions and first answers about what 'timely' short-term specialised palliative care for older people with frailty must entail beyond timely referral.

Our study confirms previous findings indicating widespread recognition of the need and considerable fertile ground for timely referral of older people with frailty to specialised palliative care services, based on the complexity of their needs rather than prognosis.[29] However, our analysis of the mixed-methods data of this pilot RCT revealed important complexities and tensions

Table 5 Estimated mean changes in primary and secondary outcomes potentially to be used in a full-scale RCT from baseline to 8 weeks

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

*The adjusted ratio is calculated as the ratio of the ratio of Frailty+ over control at 8 weeks postbaseline over the ratio of Frailty+ over control at baseline (interaction).
FACQ-PC, Family Appraisal of Caregiving Questionnaire for Palliative Care; ICECAP-SCM, ICEpop CAPability measure for supportive care; IPOS, Integrated Palliative Care Outcome Scale; RCT, randomised controlled trial; SEC-P, sense of security in care—patients; SEC-R, sense of security in care—relatives.

that limit the readiness for implementation of timely initiated and short-term specialised palliative care services in this group. These barriers concern the target group and potential value of such service models for them, and the fit of these new models with existing palliative care provision models and specialised palliative care nurses' perceptions of their own role. These complexities and tensions were apparent both in the findings concerning implementation of the Frailty+ intervention and the feasibility of trial procedures, two aspects that cannot be fully disentangled. We highlight two particular areas of tension revealed by this study.

The first area of tension is between nurses' recognition of the importance of timely specialised palliative care for older people with frailty and complex care needs and their concurrent perception that this group has less urgent care needs than the population they usually care for. This reveals a key problem to be solved on the road to timely integration of specialised palliative care for older people. While nurses as well as patients and family carers recognised the need for an additional layer of support, the nurses' predominant impression appeared to be concerned whether their particular service and their expertise were appropriate for the needs of older people with frailty identified in this study. This seemed to primarily result from their perception of these patients being in stable health, not having urgent care needs and good care arrangements being in place. This is also what nurses indicated as the reason for having provided only one home visit to most patients and for not having organised the multidisciplinary meetings that were foreseen as part of Frailty+. Nurses therefore expressed doubts that a relevant population was included into this pilot RCT. However, a separate and in-depth analysis of our baseline data of patients' symptoms and concerns showed that we have succeeded in capturing a patient group beyond those in very late stages of illness who at the same time had an important symptom burden.[41] Moreover, we found that nurses did address relevant needs in their first home visits. For instance, nurses indicated that for the vast majority (16/19) of patients they provided psychosocial support. It has been recognised that timely involvement of specialised palliative care, that is, prior to the terminal phase, would necessarily involve a greater focus on care organisation, planning and preparedness and less on management of complex physical symptoms that are more linked to rapid deterioration and the very last phase of life.[30] This was also recognised by the participants of our theory of change workshops where we developed the Frailty+ intervention.[20] Furthermore, some patients and families would have preferred more follow-up visits, which was related to their uncertainty about changes in health that might come about quickly. This wish may be a reflection of a need for security in care that is not met by standard care, which was also emphasised by older patients and family carers who contributed to the development of Frailty+.[20] A preference for more home visits is especially noteworthy considering that this group is generally reluctant to have yet another healthcare professional visit them at home. It also echoes findings from a meta-ethnography that found that a key role of home palliative care is supporting patients' feelings of security.[42] Nurses seemed to agree with this, as several saw benefits in already having visited a patient and family before deterioration, and hence knowing them prior to the onset of urgent needs. It hence appears that for timely integration, timely *referral* alone is not enough. It also takes a reappraisal of what complex care needs entail prior to the terminal phase of life, and for non-cancer trajectories. This is also closely linked to the question how long the short-term involvement of these services should be, that is, when 'discharge' from the specialised palliative care service to primary care is possible. This requires certainly a better understanding of end-of-life trajectories and the nature of changing care needs in older people,[43] and an even closer collaboration among researchers and healthcare professionals in developing timely initiated specialised palliative care interventions and related referral criteria. Our theory of change process was likely a good first step, as it allowed us to anticipate that specialised palliative care at earlier stages of illness will involve different components and a stronger focus on psychosocial care, care planning and coordination. Still, we recommend for future research even more intensive processes of co-design and co-creation of the intervention with patients, families and stakeholders in primary and secondary care.

A second area of tension concerns the recognition of specialised palliative care nurses that all who need an additional layer of support should have access to it yet that this would have the inevitable consequence that they would have to care for many more patients than they currently do. The hospital geriatricians, mobile geriatric team members and specialised palliative care nurses interviewed in our study expressed concerns that many older patients on hospital discharge fulfilled the criteria of a frailty score between 5 and 7 and at least one complex care need. Some of them suggested that the service should therefore be restricted to patients with more than one complex care need and patients having questions about end-of-life issues. The latter may be perceived as running counter to the widely accepted position that specialised palliative care referral should be needs-based rather than tied to a prognosis[29 30] as it would tie access to specialised palliative care to the 'end of life', and hence again a limited life expectancy criterion. Previous trials of early palliative care interventions were mostly conducted with people with advanced cancer,[44] where cancer staging provides a delineation of sorts of what can be considered a phase relevant for specialised palliative care. As we seek to implement these services for older people with non-cancer disease, such as frailty or organ failure, that do not have similarly recognised staging criteria, we face an important challenge in defining eligibility based on the level and complexity of their needs alone. However, we need to take seriously the concerns of specialised palliative care teams that they would not be able to care for the

additional number of patients that would be referred to them using our criteria. This needs to be a key consideration on policy and regulatory levels when thinking about strategies to advance timely specialised palliative care.

Based on this study, timely short-term specialised palliative care services in primary care may be a promising way to support older people with frailty at times when complex care needs arise. However, several important questions remain to be answered prior to a larger-scale implementation and evaluation of such an intervention. Our work showed that timely access to specialised palliative care takes more than just timely *referral*, and that additional organisational enablers must be in place. A key barrier is achieving agreement on relevant referral criteria in older people with frailty. As we seek to expand timely specialised palliative care to non-cancer conditions, known for their hard-to-predict fluctuations, it is critical that we resolve this question soon. The complex needs criterion in this study emerged from our theory of change workshops.[20] But it appears that even closer processes of co-creation between research, clinical and policy sectors are needed to achieve broader agreement on which complex needs warrant specialised palliative care services, who should assess and communicate these needs, who should refer patients to specialised palliative care and how and which services need to deliver which type of care to address these complex care needs. This work could then help resolve a key question that emerged from this study, namely to what extent short-term provision of mainly psychosocial care and care coordination, in the absence of complex physical symptoms, is a central part of specialised palliative care teams' role. For about half of patients in our study, the specialised palliative care nurses indicated that the topics they discussed in the home visit were not focused on the management of physical symptoms, and that may have contributed to them not perceiving complex or urgent needs. Such co-creation processes will also have to address the necessary organisational and culture change in current approaches to specialised palliative care for older people, including changes in staff training, if this service is to become more inclusive towards older people with frailty.

Further development of these services should be followed by robust evaluations. This pilot RCT showed that we can confidently conduct RCTs with older people with frailty and their family carers, given careful preparation and execution of the trial. However, recruitment procedures require improvement before a full-scale RCT is attempted, and recruitment feasibility is closely linked with intervention feasibility. The problems around identifying patients eligible for specialised palliative care have impacted recruitment, as well as hospital staff's concerns about how the term 'palliative care' would be introduced to patients by the researchers and whether this would cause distress for them. However, reluctance at hearing the term 'palliative care' was not given as a reason by any patient who declined to participate which is a promising finding that can counter this concern. However, not all patients stated reasons and perhaps some were reluctant to voice worry about a palliative care nurse visiting them. While improvements in recruitment are clearly needed, we believe that having recruited 37 out of the 50 foreseen patients of a vulnerable group in poor health, and during the first wave of the COVID-19 pandemic, holds promise for a future full-scale trial.

Our analysis of preliminary effects of Frailty+ showed no effects on primary or secondary outcomes potentially to be used in a full-scale trial. This preliminary analysis is limited by the sample size of this pilot RCT, but the lack of effects is also likely a consequence of the implementation problems we encountered. A future large-scale trial therefore needs to pay particular attention to implementation to ensure that useful effectiveness data are obtained. Another possible explanation for the small differences in primary and secondary outcomes is that the needs of the patients in the control group could have been addressed by their GP. Our process evaluation showed that almost all patients had contact with their GP during the study at least once. However, we do not exactly know which care was delivered during these consultations. For future studies, we would advise to also carefully describe and evaluate care as usual in the control group. Given the main topics covered in the home visits (eg, psychosocial support and care coordination), we also need to reconsider the choice of physical symptoms as a relevant primary outcome for Frailty+ and consider alternative quantifiable outcomes, for instance, those mentioned in our theory of change.[20]

Comparing our results with a previously conducted short-term specialised palliative care intervention for older people in the UK, we identified considerably different findings. For instance, the UK intervention was effective in reducing symptom distress in older people.[18] A possible explanation for this difference might be the different healthcare contexts in which the intervention was implemented, which might have influenced the implementation of the intervention. For instance, there might be closer existing collaborations and co-creation between the researchers and the professional stakeholders in the UK enabling a stronger engagement in the study.[45] To further our understanding of the mechanisms essential to bringing about change in clinical practice, a comparative case study focusing on commonalities and differences in the implementation strategies and processes of both studies could be useful.

This study demonstrated the value and benefits of taking a prudent approach to evaluating a timely short-term specialised palliative care service by undertaking a pilot RCT and in-depth mixed-methods process evaluation prior to investing resources and patients', families' and healthcare professionals' time in a full-scale trial. Limitations of this study include that it was conducted during the COVID-19 pandemic and that it is difficult to say whether some of the conclusions we draw are tied to the ongoing public health emergency at the time. Moreover, these study data were obtained in a specific context and healthcare system. We acknowledge that some of

the challenges of implementation may be linked to the Flemish palliative care and primary care organisation and landscape. However, we can still assume that the principal findings—for example, the need for clearer eligibility criteria and contextual changes beyond earlier referral—generalise to other systems of specialised palliative care primarily provided to people in late stages of illness, particularly those modelled on end-of-life care in cancer care.[9] This is the case in numerous countries beyond Belgium.[9 46 47] We have also described this analysis in much detail to show which questions need to be asked and which research data collected in different contexts where efforts are ongoing to implement timely short-term specialised palliative care for older people with frailty. Also important to note, we recruited patients who were specifically admitted to the hospital and about to be discharged home, therefore the included population might not be representative for the wider population of older people with frailty and complex care needs in the community. We cannot exclude recall bias, as the process evaluation data from healthcare professionals were collected after recruitment was completed. There might also be detection bias, as the data managers and researcher were not blinded. A Cochrane review showed that there might be an overestimation of the effects of the intervention in non-blinded trials.[48] Finally, there could be selection bias, because in one hospital, researchers were not allowed to attend the staff meetings and hospital care staff were gatekeepers in the recruitment of potential participants. They might have selected patients that were in better health considering this was a trial in timely short-term specialised palliative care. Hence, our sample might represent a group with a lower symptom burden compared with the wider population.

CONCLUSION

We showed that timely initiated and short-term specialised palliative care in primary care was generally welcomed by older people with frailty, family carers and specialised palliative care nurses. RCT methods were largely feasible in this population, even during the COVID-19 crisis. However, recruitment was challenging and our mixed-methods data identified important implementation barriers and complexities that should be addressed prior to a full-scale implementation and evaluation. These barriers were mainly related to current organisation of specialised palliative care services and definitions of complex care needs, which are mostly tailored to patients at advanced stages of disease. Our findings highlight that considerable organisational and cultural changes are required to ensure timely initiated and short-term specialised palliative care for older people. Furthermore, we recommend striving for more co-creation between researchers, practitioners and policymakers in the development and implementation of such complex interventions, in which we need to establish agreement on complex needs-based referral criteria for older people and to define roles and tasks of specialised palliative care nurses in addressing these complex needs.

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Contributors KDN, LP and LVdB designed the study. KDN acquired the study data, along with data collectors Eecloo and Joos (see 'Acknowledgements' section). KDN conducted the analyses, and KDN, NVDN, PP, LP and LVdB contributed to the interpretation of the findings. KDN drafted the article and LP made substantial contributions to the interpretation of findings and the drafting of the 'Discussion' section. All authors critically reviewed the article and gave final approval of the version to be published. They all take responsibility for the integrity of the data and the accuracy of the data analysis. LVdB is the guarantor. LP and LVdB are joint last authors.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the 'Methods' section for further details.

Patient consent for publication Not applicable.

Ethics approval The study was approved by the ethics committee of Ghent University Hospital (B.U.N. B670201941807, 22 January 2020) and the ethics committee of the other hospital involved in patient recruitment. Older adults, family caregivers and general practitioners provided written informed consent to participate. Verbal informed consent was obtained from professionals involved in the focus groups and interviews

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