

Defining the palliative care patient: A systematic review

Palliative Medicine
27(3) 197–208
© The Author(s) 2012
Reprints and permission:
sagepub.co.uk/journalsPermissions.nav
DOI: 10.1177/0269216311435268
pmj.sagepub.com


Wouter Van Mechelen *Academic Center for General Practice, K.U.Leuven, Belgium*

Bert Aertgeerts *Academic Center for General Practice, K.U.Leuven, Belgium*

Karolien De Ceulaer *Academic Center for General Practice, K.U.Leuven, Belgium*

Bregje Thoonsen *Radboud University Nijmegen, the Netherlands*

Mieke Vermandere *Academic Center for General Practice, K.U.Leuven, Belgium*

Franca Warmenhoven *Radboud University Nijmegen, the Netherlands*

Eric Van Rijswijk *Radboud University Nijmegen, the Netherlands*

Jan De Lepeleire *Academic Center for General Practice, K.U.Leuven, Belgium*

Abstract

Background: The lack of a clear definition of the palliative care patient hampers the comparison of results across different studies and impedes implementation of research findings in everyday practice.

Aim: The aim of this article is to propose minimum characteristics that define a palliative care patient.

Design: The design involved a systematic review of medical literature searching randomised controlled trials (RCTs) in palliative care for clear descriptions of their palliative care patients. We systematically describe relevant characteristics of the study populations of 60 eligible RCTs.

Data sources: The data sources used were MEDLINE, EMBASE, CINAHL, and PSYCHINFO, including all non-cancer RCTs (1 January 1995–4 March 2010) and an equivalent number of the most recent cancer RCTs (1 January 2003–4 March 2010).

Results: Half of the non-cancer studies were excluded because they did not relate to palliative care. We conclude that published RCTs have no clear definitions of their palliative care patients and illustrate the diversity of this patient, the lack of consensus concerning the attributes of illnesses needing palliation and the ambiguous use of the adjective 'palliative'.

Conclusions: We propose elements of the patients' health status (e.g. a progressive, life-threatening disease with no possibility of obtaining remission or stabilisation, or modifying the course of the illness) and the care delivered to them (e.g. a holistic interdisciplinary approach that focuses on supporting the quality of the end of life) to be included in the definition of a palliative care patient. We also suggest considering the patients' readiness to accept palliative care and a vision of palliative care shared by the patient and all caregivers involved as potentially important elements in this definition.

Keywords

Palliative care patient, terminal care patient, definition

Introduction

Research in the domain of palliative care has grown significantly in recent decades. Nevertheless, the description of this patient population remains vague. In the WHO definitions of palliative care, the patient is only defined as having a disease that is not responsive to curative treatment

(WHO 1990) or a disease that is life-threatening (WHO 2002).¹ In palliative care research, different studies have different criteria for including patients in their study population,^{2–4} and in clinical practice and health policy palliative care patients have also been defined in many different ways.⁴

The lack of consensus among health care professionals about the stage of life addressed by palliative care is a

Corresponding author:

Wouter Van Mechelen, Kapucijnenvoer 33 blok J bus 7001, 3000 Leuven.
Email: Wouter.VanMechelen@med.kuleuven.be

plausible explanation for this vague description.⁵ Moreover, in a concept analysis Meghani articulate that palliative care, as a dynamic concept, has gained new meaning and significance over time, which has resulted in new models and related concepts such as preterminal care, terminal care and end-of-life care.⁶ Nevertheless, in everyday practice, palliative care is frequently introduced at a later stage in a life-threatening disease, thereby defining itself as care given to a terminally ill patient.⁴ The use of palliative care as being synonymous with end-of-life care or terminal care has, however, created confusion regarding the exact content of the various concepts, the stage of life to which these concepts refer and the patients for whom they may be appropriate.

Secondly, there have been important changes in the patient population receiving palliative care. Whereas two decades ago palliative care was mainly confined to the treatment of pain and other symptoms caused by cancer, patients with deteriorating chronic diseases such as chronic heart failure, chronic obstructive pulmonary disease and cognitive impairment, now receive more attention.^{1,4}

Many authors define their study populations differently, giving rise to this heterogeneous view of palliative care as a concept and its target population.^{2,3,7-10} Inclusion criteria often refer to characteristics of the patients' disease (e.g. a progressive, life-threatening illness) or clinical indicators of advanced disease, such as weight loss or oxygen dependency. Other commonly used inclusion criteria are the patients' choice of non-curative treatment, indicators of an increased need for palliative care such as multiple hospital admissions, or a high level of dependency. In addition, authors frequently combine previous criteria with the 'surprise question': 'Would you be surprised if the patient were to die during the next year?', which integrates co-morbidity, social and other factors into prognostication.^{9,11,12} However, Borgsteede et al. highlight the limitations of using varying inclusion criteria in palliative care research by showing substantial differences in palliative care patient populations selected according to these different inclusion criteria.¹³ The potential bias imposed by chosen inclusion criteria on population characteristics, and therefore on outcomes, confirms the need for internationally agreed criteria to define the palliative and terminal care patient. This would reduce heterogeneity between different studies and facilitate comparison of results across studies.

A recent report by the Belgian Health Care Knowledge Center concerning the organisation of palliative care in Belgium confirms the absence of a consensus on the definition of a palliative care patient. Keirse et al. concluded that while palliative care is extensively described, the palliative care patient is not, and the definitions used vary depending on their purpose,⁴ as confirmed in a recent discourse analysis of palliative care definitions by Pastrana et al.³

Since a systematic review of the literature on the definition of a palliative care patient is non-existent, we formulated

the assumption that peer-reviewed randomised controlled trials (RCTs) in palliative care research would have clear descriptions of their palliative care patient populations. The aim of the study was to systematically search for relevant characteristics of the study population in these RCTs as a starting point for proposing minimal criteria for a definition of a palliative and terminal care patient. We differentiated between palliative care and terminal care populations and we paid attention to the growing proportion of non-cancer patients receiving palliative care.

Methods

Literature search

We conducted a search in four databases: MEDLINE (1947+), EMBASE (1947+), CINAHL (1937+) and PSYCINFO (1806+), using the search terms ('palliative care', 'palliative therapy', 'terminal care', 'terminally ill', 'terminally ill patients', 'death and dying') as illustrated in Table 1. All search terms were specified as major topics and the searches were restricted to randomised controlled trials and adult study populations (18 years or older).

For two reasons we divided the literature search into two arms: one dealing with palliative care RCTs and a second focusing on terminal care RCTs. The first reason is the frequent use of the concept 'terminal care' in daily practice and its potential confusion with the concept 'palliative care'. The second reason is the importance of recognising a transition from palliative care to terminal care. Using this search strategy we hope to find characteristics other than 'evident' prognostic ones to describe a palliative or a terminal care patient, since it is well known that physicians are not good at prognostication.^{4,14}

Our search was updated to 4 March 2010. All studies were inserted in Reference Manager 12 and duplicate studies were excluded. Duplicate studies in different study arms of our literature search were allocated to the appropriate study arm by two independent reviewers (WVM and KDC), defining terminal care as the comprehensive care during the last days of illness. A third reviewer (BA) made the decision in cases of unresolved disagreement.

The RCTs included had to focus on interventions and/or outcomes for the palliative or terminal care patient or his family, and were rejected if they did not focus on palliative or terminal care. Other exclusion criteria were non-human research, a non-Western language, a missing abstract or a missing study design.

Selection by title and abstract

An early evaluation of the literature revealed the clear predominance of cancer-related trials in both study arms. We therefore made a selection of the RCTs to obtain a more representative view of the different research populations. Also, since the shift in the WHO definition of palliative care

Table 1. Search strategy.

Date	Database	Search strategy	Notes
4 March 2010	MEDLINE	Palliative care RCTs: "palliative care" [Majr] AND "humans" [MeSH Terms] AND "adult" [MeSH Terms] Terminal care RCTs: ("terminal care" [Majr] OR 'terminally ill' [Majr]) AND "humans" [MeSH Terms] AND "adult" [MeSH Terms]	
4 March 2010	EMBASE	Palliative care RCTs: 'palliative therapy'/exp/mj AND ([adult]/lim OR [aged]/lim) AND [humans]/lim AND [embase]/lim Terminal care RCTs: (terminal care'/exp/mj OR 'terminally ill patient'/exp/ mj) AND ([adult]/lim OR [aged]/lim) AND [humans]/ lim AND [embase]/lim	
4 March 2010	CINAHL	Palliative care RCTs: MM 'palliative care' Terminal care RCTs: MM 'terminal care' OR MM 'terminally ill patient'	Exclude MEDLINE records; Age Groups: "all adult"
4 March 2010	PSYCINFO	Palliative care RCTs: exp *Palliative Care/ Terminal care RCTs: exp *Terminally Ill Patients/ OR exp *"death and dying"/	Limit search to (human and abstracts and "adulthood <age 18 yrs and older">" and human)

in 2002, we assumed that most adapted definitions of a palliative care patient would be found in most of the recent literature.¹ Consequently, after reading the title and abstract, all non-cancer trials and an equivalent number of the most recent cancer trials were selected in each study arm, resulting in four different groups: group A (palliative care, non-cancer), group B (palliative care, cancer), group C (terminal care, non-cancer) and group D (terminal care, cancer).

All articles selected for inclusion were screened by reading their full text version, and a second selection was made based on the inclusion and exclusion criteria as described above. Duplicate studies in the same part of our literature search were excluded.

Data analysis

In order to choose relevant characteristics to define a palliative care patient, we focused on key features that occur in different types of definitions of a palliative care patient or palliative care.^{1-4,6-10} We selected six important characteristics: diagnosis, disease progression, life expectancy of the study population and clinical setting, intervention and outcome of the studies included. Based on a discussion with co-authors on 10 randomly chosen RCTs (cancer and non-cancer), we listed the most relevant descriptions for each characteristic selected and added an identification number (see Appendix 1 in the supplementary material).

Using this framework, all the included studies were read carefully by two independent reviewers (WVM and KDC), focusing on the description of the study population and the

inclusion and exclusion criteria used. For each RCT the six characteristics were identified and given the corresponding identification number as determined in the framework (for a quantitative description of these patient-related characteristics in the four groups of RCTs see Appendix 2 in the supplementary material). Finally, we analysed the distribution of the identification numbers for each characteristic. All operations were performed in Microsoft Excel.

Fisher's exact tests and the exact Mann-Whitney *U*-test were used, respectively, to compare proportions and continuous variables between the four trial groups. Analyses were performed using the statistical package StatXact-9.

Results

Literature search

In MEDLINE we identified 333 palliative care trials and 75 terminal care trials. In EMBASE we found 112 and 16 studies, respectively. No appropriate palliative care studies were found in CINAHL and PSYCINFO. We did, however, identify one and two terminal care studies, respectively, resulting in a total of 445 potentially relevant palliative care trials and 94 potentially terminal care trials.

Selection by title and abstract

Figure 1 shows a flow diagram of the literature selection as described above. Ultimately, 60 RCTs were included in this review (for a qualitative description of

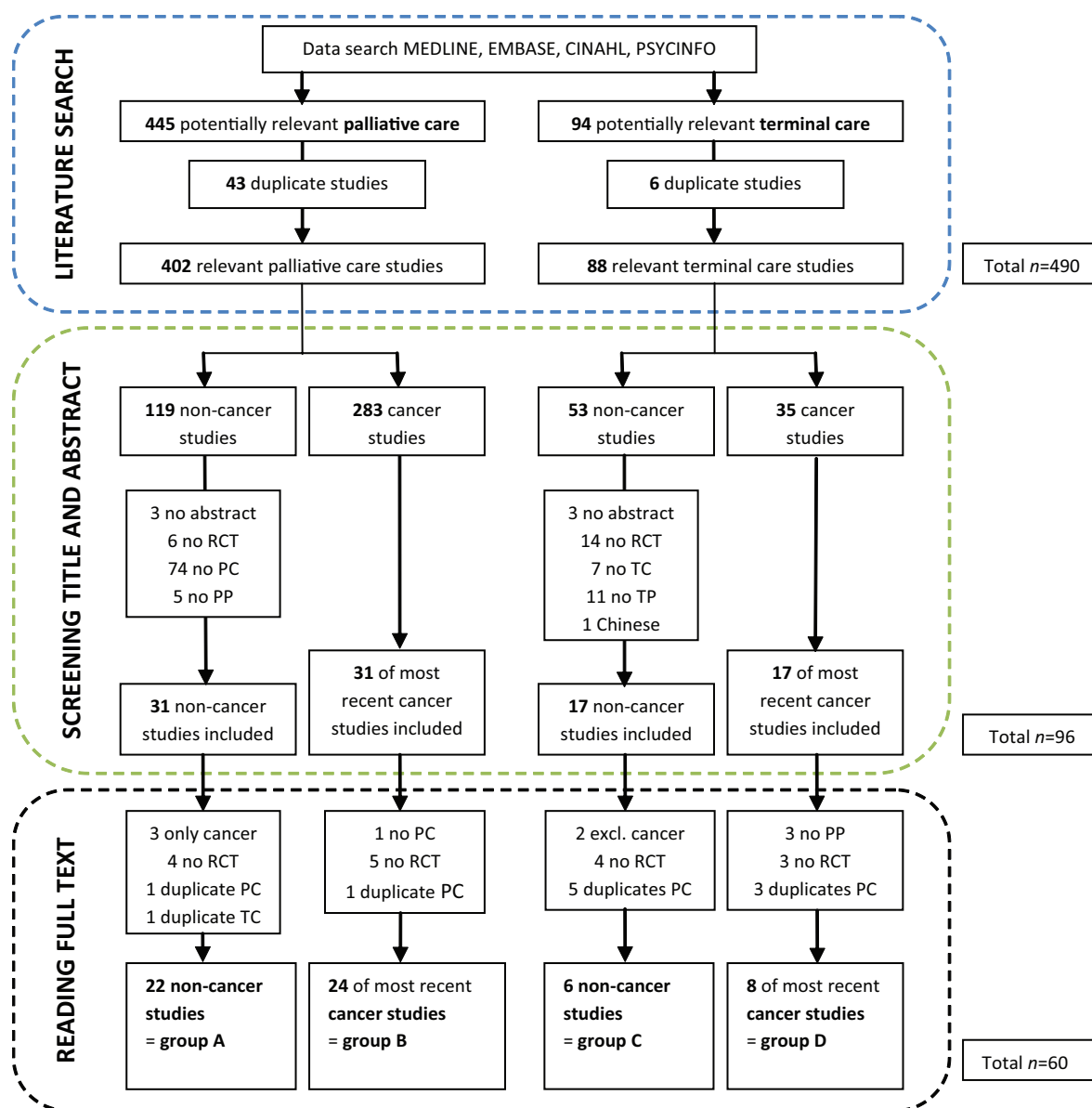


Figure 1. Flow chart. After reading title and abstract we included all non-cancer studies and an equivalent number of the most recent cancer studies. After reading the full text version of the articles, a total of 60 randomized controlled trials were included in this review. 46 palliative care trials (22 non-cancer trials and 24 of the most recent cancer trials) and 14 terminal care trials (6 non-cancer trials and 8 of the most recent cancer trials). RCT: randomised controlled trial; PC: palliative care; PP: palliative patient; TC: terminal care; TP: terminal patient.

the included RCTs see Appendix 3 in the supplementary material). Over 80% of the RCTs included were published in the last five years. All cancer trials were published after 2002.

Almost half (49%) of the non-cancer studies ($n = 172$, palliative care and terminal care arms combined) were excluded because the trials did not refer to palliative or terminal care. The study populations suffered from endometriosis, osteoarthritis, bullous keratopathy, HIV, lower back

pain, diabetic polyneuropathy, and so on; essentially pathologies with no curative treatment options.

Nine duplicate studies were noted between the palliative care and the terminal care arm. Three duplicate cancer studies were allocated to the palliative care arm (group B). Five duplicate non-cancer studies were allocated to the palliative care arm (group A). Only one duplicate non-cancer study was allocated to the terminal care arm (group C).

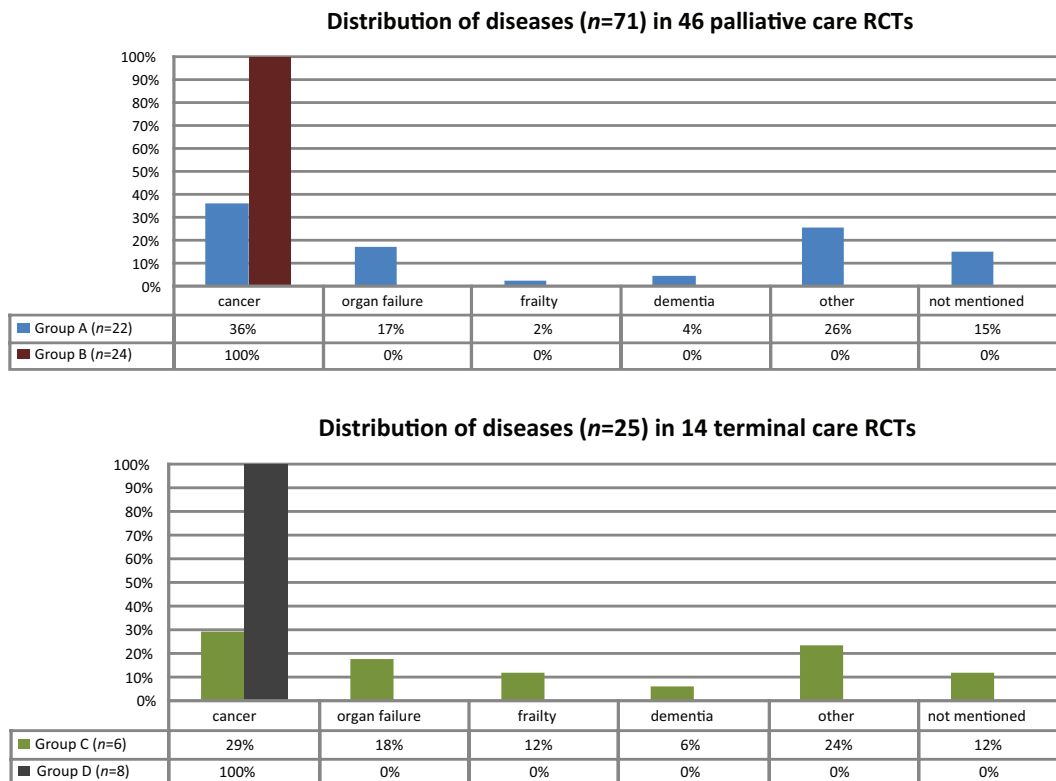


Figure 2. Distribution of diseases in 46 palliative care RCTs and 14 terminal care RCTs. The numbers in the table represent the percentage of patient populations with the corresponding disease in non-cancer RCTs (group A and C) and in cancer RCTs (group B and D). No significant differences between palliative care and terminal care patients were found (all *p*-values of Fisher’s Exact Probability Test exceed 0.1).

Data analysis

Patients’ disease. We identified 12 different pathologies in our selected studies (*n* = 60), of which cancer, organ failure, dementia and frailty were most commonly represented (see Figure 2). When analysing by patients’ disease we frequently found more than one population per RCT. As a consequence we identified a total of 96 populations. A total of 54 populations (56.3%) were diagnosed with cancer, 11 populations (11.5%) with organ failure, three with frailty (3.1%) and an equal number with dementia (3.1%). We identified 16 populations (16.7%) with other pathologies (multiple sclerosis and other neurodegenerative disorders, amyloidosis, AIDS and stroke). In nine RCTs (15.0%) the disease was not mentioned. No significant differences between palliative care and terminal care populations were found concerning the distribution by patients’ disease (all *p*-values of Fisher’s Exact Probability Test exceed 0.1).

Disease progression. The progressive aspect of the disease in a palliative or terminal care patient was not mentioned in 95% of the RCTs included. Disease progression was not mentioned in all terminal care RCTs.

Patients’ prognosis. The patients’ prognosis was not mentioned in 56.7% (*n* = 34) of the RCTs included. If the patients’ prognosis was described, their life expectancy was expressed as ‘more than *n* days’ in 16 RCTs. Only 10 RCTs described prognosis as ‘less than *n* days’ and there was significant variability. No significant difference in the patients’ life expectancy was found when comparing the distribution by stated prognosis (less than *n* days) in palliative care RCTs (14, 180, 180, 180, 180, 365, 365 days) with that in terminal care RCTs (3, 180, 180, 365 days) (*p* = 0.86, calculated using exact Mann–Whitney *U*-test).

Setting. Most of the interventions in our selected studies occurred in a hospital setting (41.7%) (see Figure 3). Only one RCT took place in a nursing home, while 17 RCTs (30%) occurred in the home care setting. 15.0% were performed in a palliative care unit or hospice, and 10.1% used multiple settings. We identified no terminal care RCTs in hospice settings. No significant differences were found between settings for palliative care and terminal care RCTs (all values of Fisher’s Exact Probability Test exceed 0.1).

Interventions. Complex interventions, defined as multiple and often diverse interventions delivered by different

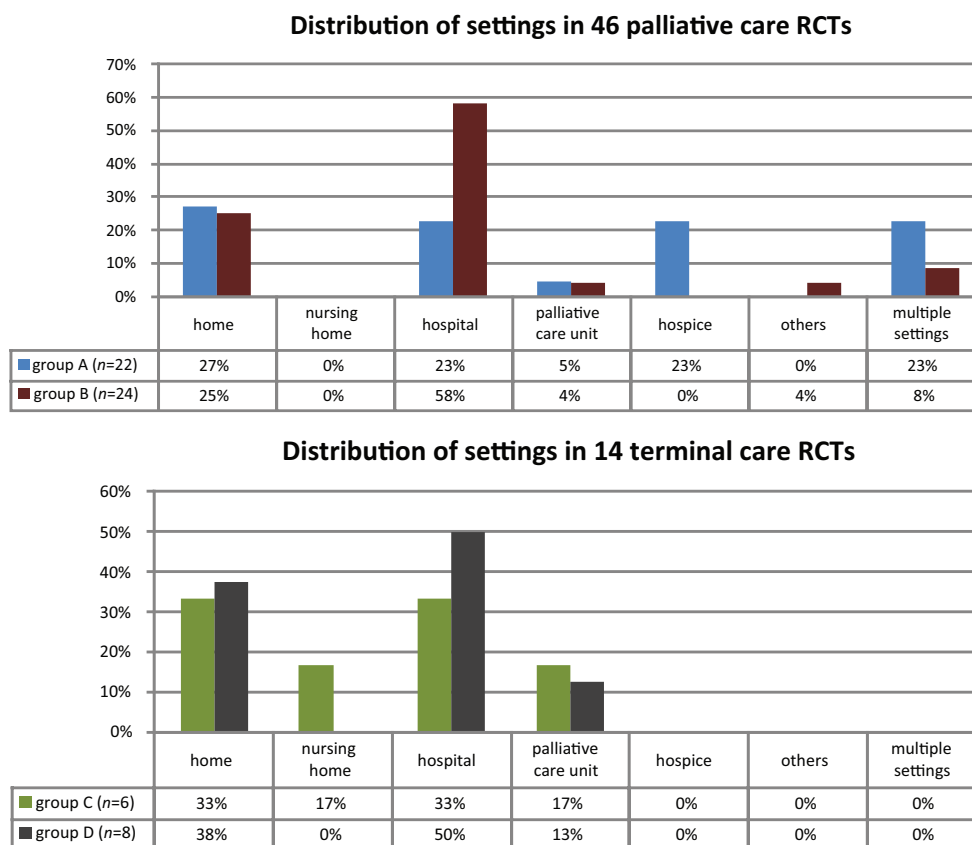


Figure 3. Distribution of settings in 46 palliative care RCTs and 14 terminal care RCTs. The numbers in the table represent the percentage of RCTs in the corresponding setting. Group A and C are non-cancer RCTs, group B and D are cancer RCTs. No significant differences between palliative care and terminal care patients were found (all p -values of Fisher's Exact Probability Test exceed 0.1).

caregivers (e.g. care programs), were performed in 30.0% of the selected studies ($n = 18$) (see Figure 4). Symptom relief through drug administration was the major intervention strategy in 23.3% of RCTs ($n = 14$). Other interventions included symptom control through surgery ($n = 6$), promoting communication ($n = 5$), alternative therapies ($n = 5$), advance care planning ($n = 3$), psychiatric care ($n = 3$), symptom control through radiotherapy ($n = 2$), disease control through radiotherapy ($n = 1$), disease control through drug administration ($n = 1$) and patient and caregiver education ($n = 1$).

We noticed a greater variety of interventions (11 versus 5) in palliative care RCTs compared to those in terminal care ($p = 0.01$). More terminal care RCTs included a psychiatric intervention than palliative care RCTs ($p = 0.04$), and more non-cancer palliative care RCTs performed complex interventions compared with cancer palliative care RCTs ($p = 0.004$).

Primary outcomes. We identified 23 different primary outcome measures in the 60 selected RCTs. When analysing by study outcome we found a total of 118 primary

outcomes. Half (50.9%) of primary outcomes dealt with pain or symptom control (34.8%), or quality of life (16.1%) (see Figure 5). Other outcome measures included economic outcomes (11.0%), mortality or survival rate (7.6%) and technical outcomes (4.2%). Only one RCT (0.8%) chose disease control as the primary outcome. The remaining outcome measures (25.4%) form a heterogeneous group of 17 outcomes dealing with patient uncertainty, patient satisfaction, patients' needs, patients' worries, patients' wishes about end-of-life care, patients' self-care, prevalence and timing of Do Not Attempt Resuscitation (DNAR) codes, patients' functional status, patients' hope, place of death, caregiver well-being, communication, complication rate, case conference features, toxicity, morbidity and the ability to forgive.

More outcomes dealt with pain or symptom control (50.0% versus 30.0%) and quality of life (25.0% versus 13.3%) when comparing terminal care RCTs to those in palliative care, although these findings are not statistically significant (all p -values using the chi-square test exceed 0.1).

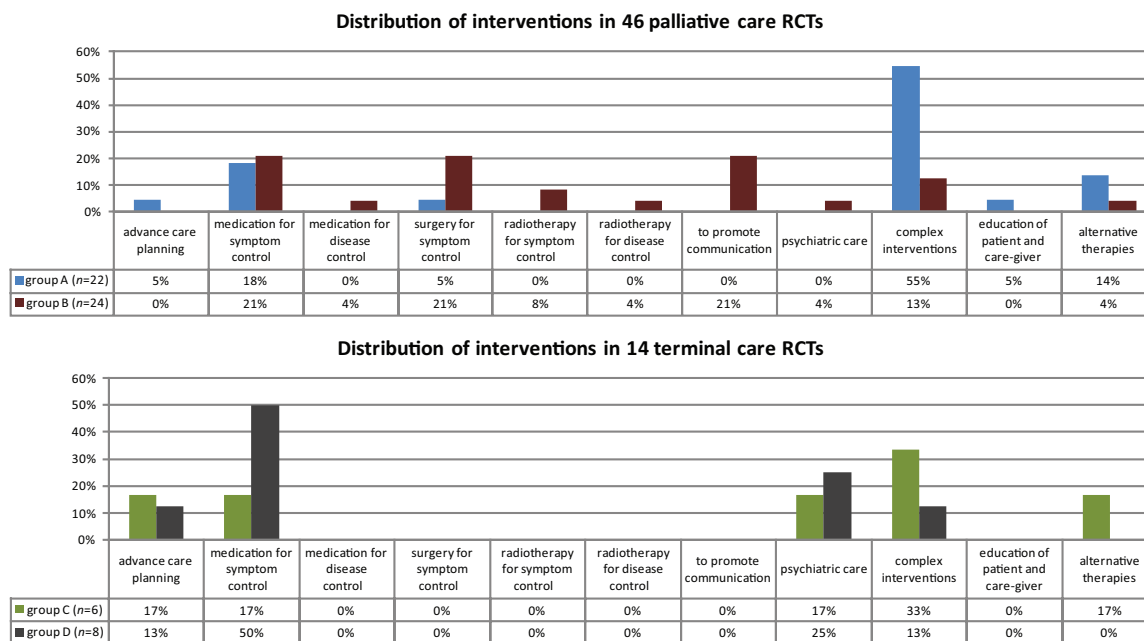


Figure 4. Distribution of interventions in 46 palliative care RCTs and 14 terminal care RCTs. The numbers in the table represent the percentage of RCTs with the corresponding intervention. Group A and C are non-cancer RCTs and group B and D are cancer RCTs. We noticed a greater variety of interventions in palliative care RCTs compared to those in terminal care ($p=0.01$). More terminal care RCTs concerned a psychiatric intervention than palliative care RCTs ($p=0.04$) and more palliative care non-cancer RCTs performed complex interventions compared to palliative care cancer RCTs ($p=0.004$).

Discussion

The assumption that peer-reviewed RCTs use clear definitions or descriptions of palliative or terminal care patients was incorrect. This highlights the lack of clear population criteria. The *diversity* within the palliative and terminal care patient populations, as illustrated in this review, complicates the search for clear population definitions and can lead to ambiguity and misunderstandings as illustrated by some remarkable findings. This will limit the comparison of results across different studies, as previously shown by Borgsteede et al., and impede implementation of research findings in everyday practice.^{1,3}

Patients' disease

49% of the non-cancer studies were excluded because they concerned not palliative care but rather care for chronic non-life-threatening conditions without a curative treatment option (e.g. osteoarthritis, endometriosis, diabetic polyneuropathy). This finding illustrates the narrow interpretation of the adjective 'palliative' as 'non-curative' in the context of a transitional model of palliative care where palliative care and curative care are each other's opponents.¹⁵ Furthermore, the definition of palliative care used in the databases might facilitate our finding since MEDLINE defines palliative care as 'care

alleviating symptoms without curing the underlying disease'. We argue for the use of a trajectory model of palliative care with a gradual transition from curative to palliative care as described by Lynn et al.¹² Questions arise concerning the reliability of allocating MeSH terms like 'palliative care' and 'terminal care' to research articles. Even the publication by Polinder et al., who studied the effect of surgery with curative intent in patients with oesophageal cancer, is classified as a palliative care study.¹⁶

Disease progression

The absence of clearly defined disease progression was obvious in 95% of RCTs. Progressive decline in patients' health care status does, however, seem to be significant when defining a palliative care patient, since many palliative care definitions include progress of the disease as an essential feature.^{3,4} We can only assume that this time dimension is intrinsically present in the diseases as described in the trials included.

Patients' prognosis

We observed no significant difference between the prognosis for palliative care patients and terminal care patients, although a difference was expected. An excessively small sample may

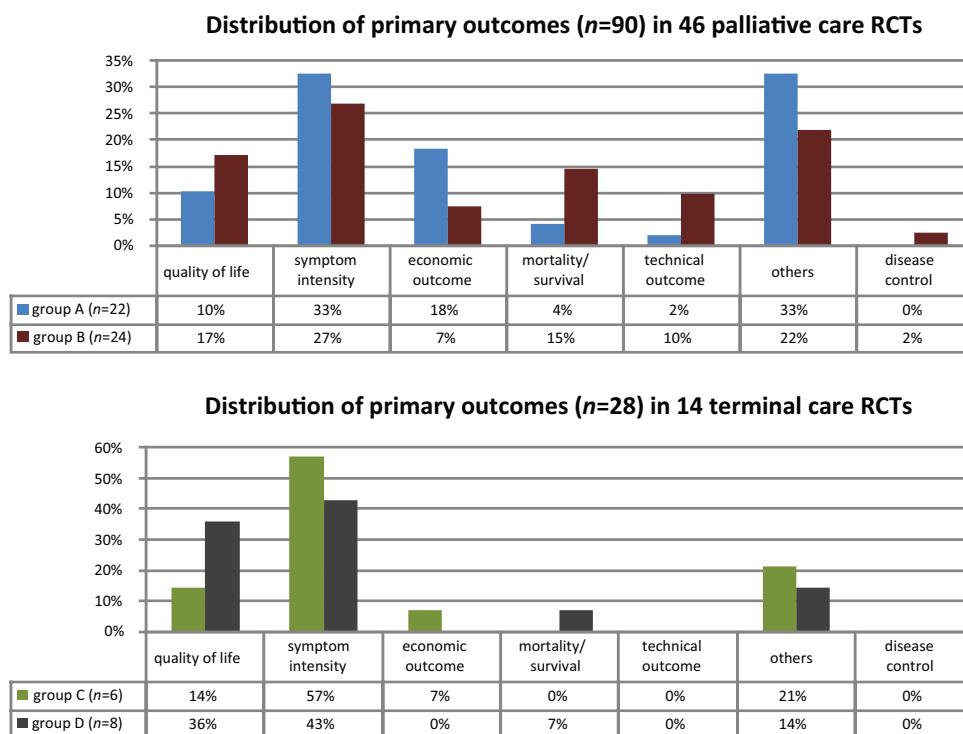


Figure 5. Distribution of primary outcomes in 46 palliative care RCTs and 14 terminal care RCTs. The numbers in the table represent the percentage of primary outcomes in non-cancer RCTs (group A and C) and in cancer RCTs (group B and D). More outcomes dealt with pain or symptom control and quality of life when comparing terminal care RCTs to those in palliative care, although these findings are not statistically significant (all p -values using a Chi-Square test exceed 0.1).

be partially responsible for this. This finding also illustrates the ambiguity of defining and distinguishing these two patient populations. Moreover, the patients' prognostic characteristics were not mentioned in 57% of the RCTs included, and where present they were mostly expressed as 'more than n days', indicating that patients were selected to survive the study programme rather than indicating an essential characteristic of a palliative or terminal care patient.

Patients' setting

Since the majority of patients would like to be cared for and die at home^{4,17} and since the preferred place of death is often seen as an important end point in palliative care, a relatively small proportion of the included RCTs (30%) took place in the home care setting. Surprisingly, only one RCT was performed in a nursing home, although we expected a significant number of palliative and terminal care patients in nursing homes as 25% of the Belgian population dies in this setting.⁴

In this review, terminal care patients received significantly more psychiatric interventions than palliative care patients. The practical significance of this finding is unclear since there is a lack of clear criteria to differentiate palliative and terminal care patients, and results comparing palliative and terminal care populations need

to be interpreted with caution, given the small sample sizes.

Suggestions for key elements in a definition

Although this review describes important characteristics of palliative and terminal care patients and the types of care delivered to them, it does not allow us to formulate an operational definition of a palliative or terminal care patient, nor to discriminate between them. Nevertheless, we propose that the following key elements should be integrated in definitions of a palliative care or terminal care patient.

Disease trajectory. Most palliative care patients are suffering from an irreversible disease that is reinforcing the normal decline of their health status and will ultimately lead to death. Similar disease trajectories of a palliative care patient are described in the definition of palliative care used by the Société Française d'Accompagnement et de soins Palliatifs (SFAP): 'a patient in an advanced or terminal stage of a severe, progressive and life-threatening disease without cutoff of prognosis' (translation by Keirse et al.) and the derived research definition of a palliative care patient used in the epidemiological survey of the Belgian Federal Knowledge Center: 'a patient suffering from an incurable,

progressive, life-threatening disease with no possibility of obtaining remission or stabilization or restraining of the illness'.⁴ As mentioned earlier, the WHO definition of palliative care describes palliative care patients only on the basis of diseases that are life-threatening (WHO 2002).¹ In the literature, however, as shown by Pastrana et al., no consensus exists about the attributes of palliative care patients' illness (progressive, incurable, far-advanced or just advanced, life-threatening and/or active).³

The type of disease and its progression. Not only cancer, but also other pathologies are described in this review, e.g. organ failure, dementia, neurodegenerative disorders, AIDS and stroke. The Worldwide Palliative Care Alliance (WPCA) lists similar conditions, other than cancer, requiring palliative care.¹⁸ Not every patient suffering from one of these diseases would, however, be referred to as a palliative care patient. Factors such as an *advanced* disease,^{3,9} the *rate of disease progression*, whether we can *slow progression*³ and the *absence of therapies with a curative intent*³ would also play an important role as features to describe the course of disease progression in a palliative care patient.

Approach and outcome. Complex interventions are performed in one-third of the selected trials. This complexity reflects *the holistic and multidisciplinary approach* to the palliative care patient. Symptom relief through the administration of drugs is the second major intervention strategy. These two characteristics are present in almost all palliative care definitions.^{3,4} Outcome measures are extremely diverse with an emphasis on *pain and symptom control* and *quality of life*. These are well-known goals of palliative care and are clearly mentioned in the WHO definition of palliative care.^{1,3}

Other elements. No specific pathology is mentioned in 9% of all patient groups, indicating that features other than disease-related characteristics may be important in the description of the palliative care patient. The Belgian Federal Knowledge Center places a strong emphasis on 'the need for extra care' as an important characteristic to describe the palliative care patient⁴ and, as described in the Introduction, the patient's choice or readiness to accept a palliative approach and the subjective appreciation of the palliative status by a physician or a palliative care team using the surprise question could also be important elements.^{9,11,12} Based on the results of a nominal group technique (results not published), the patient's readiness to accept palliative care and a vision of palliative care shared by the patient and all caregivers involved, should also be considered as potentially important elements in a definition of a palliative care patient.

Strengths and weaknesses

This review is the first step in a mental exercise towards defining the palliative and terminal care patient. As far as

we know this has never been approached in such a systematic way.

The studies in this review represent the most recent research into palliative care interventions, since over 80% of the randomised trials included have been published in the last five years.

We estimate the chance of a selection bias omitting papers with clear definitions to be extremely small or almost negligible. Due to our selection, we included all RCTs in palliative care over a recent time span of seven years (2003–2010) and all non-cancer RCTs ever published (1995–2010). Since we included all non-cancer RCTs, missing RCTs could be described as cancer RCTs with a publication date before 2003. We assume that it is very unlikely to find clear definitions of a palliative care patient in RCTs dealing only with cancer patients published before 2003. We performed an additional search in this group of missing RCTs which confirmed our hypothesis.

As well as the inappropriate use of the adjective 'palliative' as 'non-curative', we must also consider the subjective use of the MeSH term 'terminal care' allocated to palliative care RCTs, since only one out of nine duplicate studies between the palliative and terminal care data was allocated to the terminal care arm. The question arises as to whether to revise all 14 terminal care RCTs and reconsider their allocation to palliative or terminal care. This would, however, result in a subjective appraisal since it is hard to distinguish between palliative care and terminal care due to a lack of clear criteria. Consequently, the results comparing palliative and terminal care populations need to be interpreted with caution. Moreover, this differentiation is complicated by the use of heterogeneous definitions of palliative and terminal care by the different databases.

We are aware of the potential loss of information due to categorising a complex description of a palliative or terminal care patient into predetermined characteristics. This is a reference to patient descriptions in two trials that were included but were not fully covered by our key characteristics. In the study by Miller et al., eligible patients were those with 'serious medical conditions that would probably not cause their death within six months but were severe enough to create a limited life expectancy, and therefore warranted consideration of end-of-life issues (as determined by their primary physicians)'.¹⁹ Higginson et al. included 'patients living with MS and deemed (by staff – MS nurses, neurologists, rehabilitation staff, primary care staff, social workers – and in a few instances via voluntary groups and self-referrals) – to have specialist palliative care needs'.²⁰

Research agenda

After 30 years of palliative care research, the need for a clear and useful definition of a palliative care patient persists. More intervention studies in palliative care research

should focus on home care and nursing home settings since a relatively small proportion of the included RCTs took place in a home care setting and only one RCT was identified in the nursing home setting.²¹ More attention should be given to intervention studies with non-cancer patients since only six RCTs include only non-cancer patients and the majority of non-cancer studies (79%) did contain some cancer patients.

Conclusions

In RCTs of palliative and terminal care no clear-cut definitions are used. The diversity of the palliative and terminal care patient population makes it difficult to describe these patients clearly. The resulting ambiguity is illustrated by some remarkable findings. Firstly, the misinterpretation of the adjective 'palliative' as 'non-curative', since half of the non-cancer studies were excluded because they concerned not palliative or terminal care but conditions without a curative treatment option. Secondly, although disease progression should be an essential element in the definition of a palliative care patient, most RCTs did not mention it explicitly. Thirdly, life expectancy (expressed as 'less than *n* days') was similar in palliative care and terminal care RCTs, demonstrating the difficulty of differentiating between these two patient groups.

We propose integrating the above-mentioned elements of patients' health status (type of disease and *disease trajectory*) and the types of care delivered to them (*holistic, multidisciplinary approach focusing on pain and symptom control and quality of life*) into the definitions of a palliative care patient and a terminal care patient. Nevertheless, we need a more qualitative approach to identify other key elements that are important in defining the palliative care patient and differentiating them from a terminal care patient. Based on results from a nominal group technique we suggest considering *patients' readiness* and a *vision of palliative care shared by the patient and all caregivers involved* to be potential important elements in the definitions of a palliative care patient and a terminal care patient.

Acknowledgements

Our thanks go to the members of the Steering Committee of the Chair Constant Van de Wiel (J. Menten, E. Keirse, M. Desmet, C. Gastmans, J. Lisaerde, C. Aubry, K. Struys, J. Coppens, A. Beyen and K. Cornette) for their guidance; we are also grateful to S. Fieuws for his statistical support and to S. Iliffe for his comment on the final draft of the manuscript.

Funding statement

This work was supported by the Chair for General Practice Constant Van de Wiel.

References

1. Sepulveda C, Marlin A, et al. Palliative Care: the World Health Organization's global perspective. *J Pain Symptom Manage* 2002; 24: 91–96.
2. George LK. Research design in end-of-life research: state of science. *Gerontologist* 2002; 42: 86–98.
3. Pastrana T, Junger S, Ostgathe C, et al. A matter of definition—key elements identified in a discourse analysis of definitions of palliative care. *Palliat Med* 2008; 22: 222–232.
4. Keirse E, Beguin C, Desmedt M, et al. Organisation of palliative care in Belgium Health Services Research (HSR). Brussel: Federaal Kenniscentrum voor de Gezondheidszorg (KCE). KCE reports 115A (D/2009/10.273/40). October 2009.
5. Shipman C, Gysels M, White P, et al. Improving generalist end of life care: national consultation with practitioners, commissioners, academics, and service user groups. *BMJ* 2008; 337: a1720.
6. Meghani SH. A concept analysis of palliative care in the United States. *J Adv Nurs* 2004; 46: 152–161.
7. Yurk R, Morgan D, Franey S, et al. Understanding the continuum of palliative care for patients and their caregivers. *J Pain Symptom Manage* 2002; 24: 459–470.
8. Rainone F, Blank A and Selwyn PA. The early identification of palliative care patients: preliminary processes and estimates from urban, family medicine practices. *Am J Hosp Palliat Care* 2007; 24: 137–140.
9. National Gold Standards Framework Centre. England. *Prognostic Indicator Guidance Paper*, <http://www.goldstandards-framework.nhs.uk> (2008, accessed February 2009).
10. Marshall D, Howell D, Brazil K, et al. Enhancing family physician capacity to deliver quality palliative home care: an end-of-life, shared-care model. *Can Fam Physician* 2008; 54: 1703.e1-7.
11. Pattison M and Romer AL. Improving care through the end of life: launching a primary care clinic-based program. *J Palliat Med* 2001; 4: 249–254.
12. Lynn J, Schuster JL and Kabacene A. *Improving Care for the End of Life: A Sourcebook for Health Care Managers and Clinicians*. Oxford: Oxford University Press, 2000.
13. Borgsteede SD, Deliens L, Francke AL, et al. Defining the patient population: one of the problems for palliative care research. *Palliat Med* 2006; 20: 63–68.
14. Lorenz K, Lynn J, Morton SC, et al. End-of-life care and outcomes. *Evid Rep Technol Assess (Summ)* 2004; 110: 1–6.
15. Lynn J. and Adamson DL. *Living Well at the End of Life: Adapting Health Care to Serious Chronic Illness in Old Age*, http://www.rand.org/pubs/white_papers/WP137.html. (2003, accessed February 2010).
16. Polinder S, Verschuur EM, Siersema PD, et al. Cost comparison study of two different follow-up protocols after surgery for oesophageal cancer. *Eur J Cancer* 2009; 45: 2110–2115.
17. Neergaard MA, Jensen AB, Sondergaard J, et al. Preference for place-of-death among terminally ill cancer patients in

- Denmark. *Scand J Caring Sci*. Epub ahead of print 1 March 2011. DOI: 10.1111/j.1471-6712.2011.00870.x.
18. Worldwide Palliative Care Alliance (WPCA). *WPCA Policy statement on defining palliative care*, <http://www.thewpca.org/about-hospice-and-palliative-care>. (2009, accessed September 2010).
 19. Miller DK, Chibnall JT, et al. Supportive-affective group experience for persons with life-threatening illness: reducing spiritual, psychological, and death-related distress in dying patients. *J Palliat Med* 2005; 8: 333–343.
 20. Higginson IJ, Hart S, Burman R, et al. Randomised controlled trial of a new palliative care service: compliance, recruitment and completeness of follow-up. *BMC Palliative Care*. Epub ahead of print May 2008; 7: 7. DOI: 10.1186/1472-684X-7-7.
 21. Chapman DG and Toseland RW. Effectiveness of advanced illness care teams for nursing home residents with dementia. *Soc Work* 2007; 52: 321–329.
 22. Molassiotis A, Brearley S, Saunders M, et al. Effectiveness of a home care nursing program in the symptom management of patients with colorectal and breast cancer receiving oral chemotherapy: a randomized, controlled trial. *J Clin Oncol* 2009; 27: 6191–6198.
 23. Loew BJ, Howell DA, Sanders MK, et al. Comparative performance of uncoated, self-expanding metal biliary stents of different designs in 2 diameters: final results of an international multicenter, randomized, controlled trial. *Gastrointest Endosc* 2009; 70: 445–453.
 24. Curran D, Pozzo C, Zaluski J, et al. Quality of life of palliative chemotherapy naive patients with advanced adenocarcinoma of the stomach or esophagogastric junction treated with irinotecan combined with 5-fluorouracil and folinic acid: results of a randomised phase III trial. *Qual Life Res* 2009; 18: 853–861.
 25. Bakitas M, Lyons KD, Hegel MT, et al. Effects of a palliative care intervention on clinical outcomes in patients with advanced cancer: the Project ENABLE II randomized controlled trial. *JAMA* 2009; 302: 741–749.
 26. Shenfine J, McNamee P, Steen N, et al. A randomized controlled clinical trial of palliative therapies for patients with inoperable esophageal cancer. *Am J Gastroenterol* 2009; 104: 1674–1685.
 27. Moorey S, Cort E, Kapari M, et al. A cluster randomized controlled trial of cognitive behaviour therapy for common mental disorders in patients with advanced cancer. *Psychol Med* 2009; 39: 713–723.
 28. Hansen MJ, Enright RD, et al. A palliative care intervention in forgiveness therapy for elderly terminally ill cancer patients. *J Palliat Care* 2009; 25: 51–60.
 29. Kim ES, Jeon SW, Park SY, et al. Comparison of double-layered and covered Niti-S stents for palliation of malignant dysphagia. *J Gastroenterol Hepatol* 2009; 24: 114–119.
 30. Foro AP, Fontanals AV, Galceran JC, et al. Randomized clinical trial with two palliative radiotherapy regimens in painful bone metastases: 30 Gy in 10 fractions compared with 8 Gy in single fraction. *Radiother Oncol* 2008; 89: 150–155.
 31. Xinopoulos D, Dimitroulopoulos D, Karanikas I, et al. Gemcitabine as palliative treatment in patients with unresectable pancreatic cancer previously treated with placement of a covered metal stent. A randomized controlled trial. *J Buon* 2008; 13: 341–347.
 32. Weber C, Merminod T, et al. Prophylactic anti-coagulation in cancer palliative care: a prospective randomised study. *Support Care Cancer* 2008; 16: 847–852.
 33. Katsinelos P, Kountouras J, Paroutoglou G, et al. Uncovered Hanaro Versus Luminex metal stents for palliation of malignant biliary strictures. *J Clin Gastroenterol* 2008; 42: 539–545.
 34. Lissoni P, Brivio F, Fumagalli L, et al. Neuroimmunomodulation in medical oncology: application of psychoneuroimmunology with subcutaneous low-dose IL-2 and the pineal hormone melatonin in patients with untreatable metastatic solid tumors. *Anticancer Res* 2008; 28: 1377–1381.
 35. Laval G and Paris A. Methylphenidate in palliative care in cancer patient: a double-blind randomised trial versus placebo. *Bull Cancer* 2008; 95: 241–246.
 36. Wu TH, Chiu TY, Tsai JS, et al. Effectiveness of Taiwanese traditional herbal diet for pain management in terminal cancer patients. *Asia Pac J Clin Nutr* 2008; 17: 17–22.
 37. Bruera E, Willey J, et al. Expressive writing in patients receiving palliative care: a feasibility study. *J Palliat Med* 2008; 11: 15–19.
 38. Conio M, Repici A, Battaglia G, et al. A randomized prospective comparison of self-expandable plastic stents and partially covered self-expandable metal stents in the palliation of malignant esophageal dysphagia. *Am J Gastroenterol* 2007; 102: 2667–2677.
 39. Beijer S, Gielisse EA, Hupperets PS, et al. Intravenous ATP infusions can be safely administered in the home setting: a study in pre-terminal cancer patients. *Invest New Drugs* 2007; 25: 571–579.
 40. Duggleby WD, Degner L, Williams A, et al. Living with hope: initial evaluation of a psychosocial hope intervention for older palliative home care patients. *J Pain Symptom Manage* 2007; 33: 247–257.
 41. Clayton JM, Butow PN, Tattersall MH, et al. Randomized controlled trial of a prompt list to help advanced cancer patients and their caregivers to ask questions about prognosis and end-of-life care. *J Clin Oncol* 2007; 25: 715–723.
 42. Amouzegar-Hashemi F, Behrouzi H, Kazemian A, et al. Single versus multiple fractions of palliative radiotherapy for bone metastases: a randomized clinical trial in Iranian patients. *Curr Oncol* 2008; 15: 36–39.
 43. Mills ME, Murray LJ, Johnston BT, et al. Does a patient-held quality-of-life diary benefit patients with inoperable lung cancer? *J Clin Oncol* 2009; 27: 70–77.
 44. Murthy V, Thomas K, Foo K, et al. Efficacy of palliative low-dose involved-field radiation therapy in advanced lymphoma: a phase II study. *Clin Lymphoma Myeloma* 2008; 8: 241–245.
 45. Higginson IJ, McCrone P, Hart SR, et al. Is short-term palliative care cost-effective in multiple sclerosis? A randomized phase II trial. *J Pain Symptom Manage* 2009; 38: 816–826.

46. Benzo R, Farrell MH, Chang CC, et al. Integrating health status and survival data: the palliative effect of lung volume reduction surgery. *Am J Respir Crit Care Med* 2009; 180: 239–246.
47. Steinhauser KE, Alexander SC, Byock IR, et al. Do preparation and life completion discussions improve functioning and quality of life in seriously ill patients? Pilot randomized control trial. *J Palliat Med* 2008; 11: 1234–1240.
48. Horne-Thompson A and Grocke D. The effect of music therapy on anxiety in patients who are terminally ill. *J Palliat Med* 2008; 11: 582–590.
49. Gade G, Venohr I, Conner D, et al. Impact of an inpatient palliative care team: a randomized control trial. *J Palliat Med* 2008; 11: 180–190.
50. Shelby-James TM, Currow DC, Phillips PA, et al. Promoting patient centred palliative care through case conferencing. *Aust Fam Physician* 2007; 36: 961–964.
51. Brumley R, Enguidanos S, Jamison P, et al. Increased satisfaction with care and lower costs: results of a randomized trial of in-home palliative care. *J Am Geriatr Soc* 2007; 55: 993–1000.
52. Kyle G. Evaluating the effectiveness of aromatherapy in reducing levels of anxiety in palliative care patients: results of a pilot study. *Complement Ther Clin Pract* 2006; 12: 148–155.
53. Abernethy AP, Currow DC, Hunt R, et al. A pragmatic 2 x 2 x 2 factorial cluster randomized controlled trial of educational outreach visiting and case conferencing in palliative care—methodology of the Palliative Care Trial [ISRCTN 81117481]. *Contemp Clin Trials* 2006; 27: 83–100.
54. Aiken LS, Butner J, Lockhart CA, et al. Outcome evaluation of a randomized trial of the PhoenixCare intervention: program of case management and coordinated care for the seriously chronically ill. *J Palliat Med* 2006; 9: 111–126.
55. Prentice WM, Roth LJ and Kelly P. Topical benzydamine cream and the relief of pressure pain. *Palliat Med* 2004; 18: 520–524.
56. Meier DE, Thar W, Jordan A, et al. Integrating case management and palliative care. *J Palliat Med* 2004; 7: 119–134.
57. Reymond L, Charles MA, et al. The effect of dexamethasone on the longevity of syringe driver subcutaneous sites in palliative care patients. *Med J Aust* 2003; 178: 486–489.
58. Schofield P and Payne S. A pilot study into the use of a multi-sensory environment (Snoezelen) within a palliative day-care setting. *Int J Palliat Nurs* 2003; 9: 124–130.
59. Hanks GW, Robbins M, Sharp D, et al. The imPaCT study: a randomised controlled trial to evaluate a hospital palliative care team. *Br J Cancer* 2002; 87: 733–739.
60. Latimer EJ, Crabb MR, Roberts JG, et al. The Patient Care Travelling Record in palliative care: effectiveness and efficiency. *J Pain Symptom Manage* 1998; 16: 41–51.
61. Sweeney MP, Bagg J, et al. Clinical trial of a mucin-containing oral spray for treatment of xerostomia in hospice patients. *Palliat Med* 1997; 11: 225–232.
62. Ahronheim JC, Morrison RS, Morris J, et al. Palliative care in advanced dementia: a randomized controlled trial and descriptive analysis. *J Palliative Med* 2000; 3: 265–273.
63. Grande GE, Todd CJ, et al. Does hospital at home for palliative care facilitate death at home? Randomised controlled trial. *Br Med J* 1999; 319: 1472–1475.
64. Kamboj SK, Tookman A, et al. The effects of immediate-release morphine on cognitive functioning in patients receiving chronic opioid therapy in palliative care. *Pain* 2005; 117: 388–395.
65. El-Jawahri A, Podgurski LM, Eichler AF, et al. Use of video to facilitate end-of-life discussions with patients with cancer: a randomized controlled trial. *J Clin Oncol* 2010; 28: 305–310.
66. McMillan SC and Small BJ. Using the COPE intervention for family caregivers to improve symptoms of hospice homecare patients: a clinical trial. *Oncol Nurs Forum* 2007; 34: 313–321.
67. Philip J, Gold M, Milner A, et al. A randomized, double-blind, crossover trial of the effect of oxygen on dyspnea in patients with advanced cancer. *J Pain Symptom Manage* 2006; 32: 541–550.
68. Bruera E, Sala R, Rico MA, et al. Effects of parenteral hydration in terminally ill cancer patients: a preliminary study. *J Clin Oncol* 2005; 23: 2366–2371.
69. Keefe FJ, Ahles TA, Sutton L, et al. Partner-guided cancer pain management at the end of life: a preliminary study. *J Pain Symptom Manage* 2005; 29: 263–272.
70. Bruera E, Moyano JR, Sala R, et al. Dexamethasone in addition to metoclopramide for chronic nausea in patients with advanced cancer: a randomized controlled trial. *J Pain Symptom Manage* 2004; 28: 381–388.
71. Hilliard RE. The effects of music therapy on the quality and length of life of people diagnosed with terminal cancer. *J Music Ther* 2003; 40: 113–137.
72. Clark K, Currow DC, Agar M, et al. A pilot phase II randomized, cross-over, double-blinded, controlled efficacy study of octreotide versus hyoscine hydrobromide for control of noisy breathing at the end-of-life. *J Pain Palliative Care Pharmacother* 2008; 22: 131–138.
73. Wildiers H, Dhaenekint C, Demeulenaere P, et al. Atropine, hyoscine butylbromide, or scopolamine are equally effective for the treatment of death rattle in terminal care. *J Pain Symptom Manage* 2009; 38: 124–133.
74. Downey L, Diehr P, Standish LJ, et al. Might massage or guided meditation provide “means to a better end”? Primary outcomes from an efficacy trial with patients at the end of life. *J Palliat Care* 2009; 25: 100–108.
75. Allen RS, Hilgeman MM, Ege MA, et al. Legacy activities as interventions approaching the end of life. *J Palliat Med* 2008; 11: 1029–1038.
76. Connors J, Dawson NV, Desbiens NA, et al. A controlled trial to improve care for seriously ill hospitalized patients: the study to understand prognoses and preferences for outcomes and risks of treatments (SUPPORT). *J Am Med Assoc* 1995; 274: 1591–1598.