


# BMJ Open Non-pharmacological interventions in primary care to improve the quality of life of older patients with palliative care needs: a systematic review protocol

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## ABSTRACT

**Introduction** In the last decades, the number of older people living with chronic diseases has rapidly increased. The prevalence of palliative care needs in this population can reach 17%, making the general practitioner a cornerstone in the identification and first medical intervention delivery. Therefore, knowing the primary care interventions that effectively improve the quality of life of these patients can play an important role in the delivery of healthcare.

**Methods and analysis** We will systematically review randomised controlled trials evaluating the effect of non-pharmacologic primary care interventions on the quality of life of older patients (≥65 years) with palliative care needs. PsycINFO, EMBASE, MEDLINE, Cochrane and CINAHL will be searched until December 2021. Screening, data extraction and quality evaluation (using the Cochrane RoB 2.0 tool) will be done by independently by two reviewers, with disagreements solved by a third reviewer. We will conduct meta-analysis if appropriate. In case of high heterogeneity, findings will be analysed by subgroup according to intervention type, main disease/symptoms and care context. Evidence will be graded using the Grading of Recommendations Assessment, Development and Evaluation approach. We will perform a sensitivity analysis based on study quality. Publication bias will be assessed using funnel plots.

**Ethics and dissemination** Formal ethical approval is not required as primary data will not be collected. The results will be disseminated through a peer-reviewed publication, conference presentation and the press.

**PROSPERO registration number** CRD42020154216.

## INTRODUCTION

In the last decades, the number of people living with chronic diseases has rapidly increased, mainly due to the ageing of the population, leading to a rise in dependency status and entailing important social costs.<sup>1</sup> These chronic, progressive, life-threatening and burdensome diseases play an important role in this new era of the palliative care approach. The prevalence of palliative care needs in older people ranges from 8% to

## Strengths and limitations of this study

- ⇒ This protocol describes a comprehensive systematic review of randomised controlled trials, prospectively registered in PROSPERO and guided by Preferred Reporting Items for Systematic Reviews and Meta-Analyses and Cochrane recommendations.
- ⇒ Subgroup analyses can help with the expected heterogeneity and identify groups for whom the interventions have greater effectiveness.
- ⇒ The data summarised can be valuable to develop primary palliative care.

17%, depending on the population studied and the tools used to identify needs.<sup>2,3</sup>

Palliative care is a philosophy of care focused on improving the quality of life (QoL) of patients and their family members in the process of coping with death through early identification, prevention and relief of suffering, evaluation of treatment appropriate to physical, psychosocial and spiritual problems.<sup>4</sup> The evaluation of QoL of patients in palliative care is an important procedure in the identification of a patient's overall condition as well as in the evaluation of the quality of service provided.<sup>5</sup>

The occurrence of incurable diseases can cause an enormous challenge to the patient, his/her family as well as medical professionals, affecting the patient's QoL in many ways.<sup>6</sup> This holistic paradigm calls for new measures to reduce suffering and provide comfort, which is the key goal of medicine, particularly in palliative care.<sup>7</sup>

Pharmacological techniques have improved and are now more capable of managing physical pain. However, palliative care extends beyond the relief of physical symptoms as it seeks to strengthen the psychological, spiritual and social domains to provide greater comfort to patients.<sup>8,9</sup> Therefore,

non-pharmacological interventions had been increasingly used in palliative care to promote comfort and improve patients' satisfaction with end-of-life care.<sup>10-12</sup>

Primary care professionals promote a community-based care delivery and a long-lasting follow-up of their patients. These professionals are in a good position to contribute to the early identification of patients with chronic, progressive, life-threatening and burdensome diseases and to intervene in the delivery of palliative and end-of-life care. Some evidence supports that when general practitioners are involved in care, palliative care seems to improve, with benefits for the patient and his/her family.<sup>13 14</sup> However, no systematic review has been conducted on this topic, identifying the most effective interventions and therefore helping in choosing the best ones to use in the primary care setting. Thus, we aim to determine the effectiveness of the non-pharmacological interventions used in the primary care setting, in improving the QoL of older patients with palliative care needs.

## METHODS AND DESIGN

Reporting complies with Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidance 2020.<sup>15</sup>

### Eligibility criteria

This systematic review will include randomised controlled trials (study design) conducted with adults aged  $\geq 65$  years with palliative care needs (population). Both patient-randomised trials and cluster-randomised trials will be included. Quasi-randomised trials will be excluded.

For a study to be included, the majority of patients will have palliative care needs, defined as having a chronic, progressive and potentially fatal illness in an advanced or severe stage (malignant or non-malignant), no longer responding to curative/maintenance treatment or symptomatic, or both (eg, lung/brain tumours or metastatic cancers, chronic obstructive pulmonary disease).

We will evaluate interventions that are applicable in primary healthcare setting. Thus, interventions that require hospital multidisciplinary teams, devices only available in hospital care or that require hospitalisation will be excluded.

QoL (primary outcome) will be assessed according to the score results of standardised and validated tools used to evaluate these domains (eg, World Health Organization Quality of Life (WHOQOL),<sup>16</sup> the Quality of Life Scale (QOLS),<sup>17</sup> EuroQol instrument (EQ-5D),<sup>18</sup> the 36 or the 12-item Short Form Survey (SF-36,<sup>19</sup> SF-12<sup>19</sup>).

As secondary outcomes, we will consider patients' symptoms relief (namely, pain, dyspnoea, constipation, distress, depression and other important symptoms presented) and other patients' well-being measurements.

### Search strategy

The search will be conducted in PsycINFO, EMBASE, MEDLINE, Cochrane and CINAHL from the start of indexing until December 2021. To identify ongoing

clinical trials, we will also search in [clinicaltrials.gov](http://clinicaltrials.gov). No restriction on the language of publication will apply. See online supplemental file 1 for the search strategy in Medline. Searches in the other databases will be adapted accordingly.

The search will be complemented by a manual search of abstract books of relevant congresses and scientific meetings in the last 5 years, namely the World Congress of the European Association for Palliative Care, International Congress on Palliative Care, WONCA Europe Conference. Grey literature will also be accessed via Google Scholar search. Experts in this area will also be contacted to identify pertinent articles that may have not been identified by our query. Authors of retrieved articles will be contacted in case additional clarification is required.

When analysing the search results, we will first screen the titles and abstracts of the articles found in the search. Then, all potential candidates will be selected by reading their full text. Both phases will be independently carried out by two reviewers. Reasons for exclusion will be recorded. Disagreements will be solved by a third reviewer. Reviewer agreement in the selection process will be evaluated using agreement proportion and kappa statistics.

### Data extraction

The extraction of data from the studies will be independently carried out by two reviewers, with disagreements solved by a third reviewer. Customised data extraction tables will be created, piloted with five of the included studies and used to collect relevant data from all.

To conduct data extraction, it will be used a standard data extraction form.

The following data will be extracted: general characteristics of the study (study design, sample size and setting), sociodemographic sample characteristics (gender, age and care context, eg, home, care home, hospice, palliative care unit), main disease, main symptoms, the description of the intervention and comparator, methods of QoL assessment and other reported outcomes such as symptom relief or other measures of well-being.

Whenever possible, raw data will be extracted, allowing the calculation of the effect measure (such as QoL, symptom relief or other well-being measures). When data are ambiguous or missing from the published study, the corresponding author will be contacted.

### Methodological quality assessment

We will evaluate the quality of the studies using the Cochrane risk-of-bias (RoB) 2.0 tool.<sup>20</sup> Two reviewers will independently apply the tool to each study, with disagreements solved by a third reviewer. The grade of the evidence will be assessed using the Grading of Recommendations Assessment, Development and Evaluation<sup>21</sup> approach.

## DATA SYNTHESIS

We will undertake a narrative synthesis of the findings from the included studies, structured around the type of interventions and target population characteristics. Each intervention will be summarised in terms of its care context, content, and format, and resulting effects.

The primary outcome (QoL) will be described using standardised mean differences (SMD). Secondary outcomes will be described using SMD for continuous outcomes and risk ratio for categorical outcomes. The SMD will be categorised as small, medium and large based on the thresholds 0.2, 0.5 and 0.8, respectively, as suggested by Cohen.<sup>22</sup>

In case of high heterogeneity (expected), subgroup analyses will be performed according to the type of intervention, main disease/main symptoms and care context.

Using the RevMan V.5.1 software, we will extract the data from the primary studies and analyse to decide whether it makes sense, according to heterogeneity and number of comparable studies, to perform a quantitative synthesis through meta-analysis to obtain an aggregate measure of QoL. Heterogeneity will be evaluated using the Cochran Q test (for a significance level of 0.05) and the  $I^2$  statistic. In the absence of heterogeneity, we will use the model of fixed effects. In the presence of slight to moderate heterogeneity ( $I^2 < 40\%$ – $50\%$ ), we will use the random effects model. In case of severe heterogeneity ( $I^2 > 40\%$ – $50\%$ ), even in subgroup analyses, which impedes the accomplishment of an adequate quantitative synthesis, we will attempt to explain the existing variability.

If meta-analysis is performed, the pooled effect on QoL will be expressed as SMD. A p value of 0.05 will be used as the cut-off value to determine statistical significance and data will be presented as the estimated effect with 95% CIs.

We will conduct a sensitivity analysis based on study quality and publication bias will be assessed by visual inspections of funnel plots.

We plan to start this review, by searching the databases, on 1 April and plan to have it completed for publication by 31 August.

## Patient and public involvement

Patients were not involved.

## DISCUSSION

This review will search, critically appraise and summarise the existing evidence on the effectiveness of non-pharmacological interventions applicable in primary care settings in improving the QoL of older adults with palliative care needs.

There are some studies assessing non-pharmacological interventions to improve the QoL of patients with palliative care needs.<sup>20–22</sup> However, as far as we are aware, none summarises the interventions that can be performed in primary care. Considering a holistic definition of palliative care, the involvement of primary care is essential,

and its professionals need to be empowered with the best scientific evidence to deliver good quality care to their patients. By publishing the research protocol, we reinforce the clarity of the strategy and minimise the risk of bias, namely on selective outcome reporting.

Potential limitations of the review include the expected heterogeneity in terms of populations, interventions, care contexts and outcome measurement between the studies.

However, despite limitations, the review findings can be valuable and will be disseminated to help inform policy, service developments and professional training, with a view to improve care and thus the QoL of the patients and their families.

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1 **Supplementary file 1**

2

3 **MEDLINE Query**

4

5 **Group 1**

6 1. exp Terminal care/

7 2. exp Palliative care/

8 3. exp Terminally ill /

9 4. exp Hospices/

10 5. exp Death/

11 6. Palliat\*.mp

12 7. Hospice\*.mp

13 8. End of life.mp

14 9. Advanced or end stage or terminal adj4 disease\* or illness\*.mp

15 10. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9

16

17 **Group 2**

18 11. exp Aged/

19 12. exp Old Age Assistance/

20 13. Old or aged or elderly.mp

21 14. 11 or 12 or 13

22

23 **Group 3**

24 15. exp Primary Health Care

25 16. exp General Practice

26 17. exp Family Practice

27 18. exp Community Health Centers

28 19. exp General Practitioners

29 20. exp Physicians, Family

30 21. exp Physicians, Primary Care

31 22. Primary care or family practice\* or health center\* or health centre\*.mp

32 23. General practitioner\* or GP\* or family doctor\*.mp

33 24. 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24

34

35 **Group 4**

36 25. randomized controlled trial.pt

37 26. controlled clinical trial.pt

38 27. randomized.ti or randomized.ab

39 28. placebo.ti or placebo.ab

40 29. clinical trials as topic/

41 30. randomly.ti or randomly.ab

42 31. trial.ti

43 32. 25 or 26 or 27 or 28 or 29 or 30 or 31

44 33. animals.sh NOT humans.sh

45 34. 32 not 33

46

47

48 **Group 5**

49

50 35. Exp "Quality of life"/

51 36. Quality of life.mp

52 37. 35 or 36

53

54 38. 10 and 14 and 24 and 34 and 37

55

56 To adapt to PsycInfo, EMBASE, Medline, Cochrane and Cinahl search.

57