HELP-COPD

HELPing older people with very severe chronic obstructive pulmonary disease (COPD) towards the end of their lives: a systematic review of holistic interventions

Systematic review protocol

Research team

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Summary

Building on earlier qualitative work, and set within the preliminary phases of the Medical Research Council's (MRC) framework for the design and evaluation of complex interventions, this systematic review forms essential background work underpinning a programme of research to develop, refine and pilot a novel intervention to address the holistic care needs of people with very severe chronic obstructive pulmonary disease (COPD) towards the end of their lives.

We will identify and critically review the published and unpublished evidence for interventions designed to deliver or enhance holistic care for people with very severe COPD.

Introduction

Globally, long-term conditions such as COPD are responsible for an increasing proportion of deaths.[1] People with very severe COPD have a well recognised burden of disabling physical symptoms (especially breathlessness), compounded by co-morbidity, psychological distress and social isolation.[2-6] Despite this, the needs of these patients are typically poorly addressed with limited access to palliative care.[2 3] Echoing government calls for equity of access to palliative care services,[7] the Consultation on a Strategy for Services for COPD in England,[8] and the Standards of Care document in Scotland for COPD[9] have prioritised the improved provision of supportive and palliative care towards the end of life.

Limitations of existing palliative care service models

The current approach is to build on existing cancer-based palliative care services,[10 11] which are predicated on an ability to recognise a terminal phase.[12 13] Prognostic indicators are described to aid identification of people 'at risk of dying' whose physical, psychological, social and spiritual needs can then be assessed and their care planned.[13 14] About half of patients discharged after a hospital admission for COPD will die within two years,[15 16] and markers such as severity of disease, poor nutritional status, co-morbid heart disease, depression, impaired quality of life, and older age have all been shown to be associated with poor prognosis.[15 16] Accurate prognostication for individuals with COPD, however, remains extremely difficult,[14 17] compounded by a tendency for doctors who are familiar with patients to over-estimate survival.[18] The only condition where prognosis is less accurate is dementia.[17] There is widespread concern that this approach may lead to 'prognostic paralysis' in the context of a condition characterised by slow physical decline punctuated by potentially serious, but unpredictable disease exacerbations.[19]

A further challenge to providing appropriate care is the recognised tendency for people with COPD to remain 'silent' about their (often very considerable) physical and social disabilities.[20] People with end-stage COPD tend to 'normalise' their limitations as the result of 'old age',[21] about which 'nothing can be done'.[20] 'Weary resignation' after years of futile attempts to improve their circumstances,[22] and/or a 'recalibration' of expectations[23] as an adaptive coping strategy may contribute to an undemanding acceptance of their circumstances.

The findings of our recent multi-perspective longitudinal qualitative study[24] have allowed us to offer a theoretical explanation for this difficulty (discussed below), challenge the assumptions underpinning current palliative care provision for people with COPD, and suggest a more appropriate approach which forms the basis for our proposed intervention.

Insights from our recent longitudinal qualitative study

Twenty-one patients (11 of whom died during the study), 13 carers and 18 professionals provided a total of 92 interviews at four time-points during our 18 month study. In contrast to the clearly defined stories of people with, for example, cancer and heart failure,[25] patients with COPD told a 'chaos narrative' (i.e. a narrative that appears as a disjointed series of events, within which neither the narrator who is living within the story, nor the listener can discern a clear purpose or direction[26]). These individual stories of living with COPD typically had no clear beginning, a directionless narrative indistinguishable from their life story, and an unpredictable and unanticipated end. Severe symptoms causing major disruption to normal life were described, but often in terms implying acceptance of the situation as a 'way of life' rather than an 'illness'.[27]

This work suggests that in contrast to the more typical disruptive experience of developing a chronic illness, and the consequent rethinking of a person's biography and perception of self,[28-30] people with COPD gradually adjust their sense of self over the years to fit within the limitations imposed by their condition. This lack of biographical disruption may underpin an acceptance of and adaptation to increasing disability and major health and social needs, in a lifestyle which has become familiar over many years to patients, carers and professionals.

Significantly for the development of models of care towards the end of life, our data suggested that a 'point of transition' to palliative care is meaningless in a condition with no coherent story and an unanticipated end. Instead, we concluded that physical, psychological, social and spiritual needs should be proactively sought, and palliation of symptoms and supportive care intensified according to need, without any formal requirement to identify end-stage disease.

Our programme of work and this systematic review

Our programme of work (see Appendix 2: HELP-COPD flow diagram) builds on this underpinning work to develop, refine and formally pilot the HELP-COPD intervention.

In line with the preliminary phases of the MRC framework for the design and evaluation of complex interventions,[31] our programme aims to:

- develop a prototype intervention by identifying the evidence base, identifying and developing the theoretical underpinning, and scoping/modelling key aspects of the intervention.
- identify and develop the underpinning theory, model the process and outcome, undertake an iterative process of refining the prototype intervention ready for piloting

- pilot the HELP-COPD intervention in a Phase II randomised controlled trial (RCT) using quantitative and qualitative methods to assess feasibility, acceptability and potential impact.

A core component of the preliminary tasks is systematically to scope the literature for interventions designed to deliver/enhance holistic care for people with severe/very severe COPD.

Aim of the systematic review

We aim to identify and critically review the published and unpublished evidence for interventions designed to deliver/enhance holistic care for patients with severe COPD towards the end of their lives.

Research questions

What is the impact of a holistic intervention designed to address physical, psychological, social and/or spiritual needs of patients with severe/very severe COPD towards the end of their lives on:

- quality of life?
- physical, psychological, spiritual and/or social well-being?
- health and/or social service resource use?

Plan of investigation

We will follow the procedures described in the Cochrane Handbook for Systematic Reviews of Interventions.[32]

Identification of studies

We will search databases, scan reference lists, identify unpublished studies using a PICOS search strategy.

Table 1: PICOS search strategy

		Definitions
Population	People with severe/very severe COPD.[13 33]	Severe COPD may be defined: • as an FEV1 <50%.[13 33] • as an MRC Dyspnoea score of 4 or 5.[34 35] • as having had an admission with an exacerbation of COPD. [15 16] • identified by a clinician as being 'at risk of dying' from COPD.[19]
Intervention	Any holistic intervention designed to address physical, psychological, social and/or spiritual needs either with or without formal palliative care input	We define a 'holistic intervention' as comprising at least three of the four components (physical, psychological, social and spiritual).[36] The intervention may be part of a wider intervention (e.g. pulmonary rehabilitation) if it satisfies this definition of holistic intervention and measures an outcome of interest.
Context	Any healthcare setting	
Outcomes	<u>Primary outcome</u>: health-related quality of life <u>Secondary outcomes</u> Measures of: • proportion of eligible patients who were referred for, and who accepted the intervention • physical, psychological, spiritual and social well-being, • health and/or social service resource use	Health related quality of life may be disease-specific or generic
Study design	Randomised controlled trials (RCTs), quasi-RCTs and controlled clinical trials (CCT).	

In addition we will search for any qualitative studies associated with included trials to add context to our interpretation of trial data.

Search strategy

<u>i. Published studies:</u> We will search the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, CINAHL, PsycINFO, AMED, LILACS, British Nursing Index (BNI), ZETOC, Database of Abstracts of Reviews for Effectiveness (DARE), ISI Web of Science. Search dates will be from 1990 (the provision of palliative and supportive care for people with non-malignant disease is a relatively recent concern:[7] one of the earliest papers in COPD was published in 2000[2]) to February 2012. Our search terms are detailed in the Appendix.

ii. References from published studies: The bibliographies of all eligible studies will be scrutinised to identify additional possible studies.

iii. Unpublished and in progress studies: Unpublished and ongoing work and research in progress by searching key Internet-based relevant databases – UK Clinical Research Network Study Portfolio and the meta Register of Controlled Trials, www.clinicaltrials.gov; www.controlledtrials.com. In addition, to extend our search for published, unpublished and on-going studies, we will contact an international panel of experts in this field.

iv. Language: No language restrictions will be imposed; translations will be undertaken where necessary.

Selection of studies

Titles and abstracts of trials identified from the searches will be checked by two investigators. In order to ensure that we do not overlook potentially eligible trials we will consider any trial in which at least two of the components of a holistic intervention (physical, psychological, social and spiritual) are explicitly mentioned in the abstract.

The full text of all potentially eligible studies will be retrieved and independently assessed against the inclusion criteria (see above) by two reviewers. The reviewers will decide which of the studies fit the inclusion criteria: any disagreements will be resolved by discussion, with a third researcher brought in to arbitrate if needed.

To ensure transparency, the process of selection will be summarised using a PRISMA flow diagram.[37]

Dealing with lack of information

If after the full text assessment it is still unclear whether a study fulfills the inclusion criteria, or if we require clarification of any details relating to the intervention or data we will attempt to contact authors by email for further relevant information. If we fail to make contact/retrieve this, we will list the respective study as "potentially relevant study".

Dealing with duplication

Multiple papers may be published for a number of reasons including translations, results at different follow-up period or reporting of different outcomes. We will treat a study with multiple reports as a single study, but draw on and make reference to all the relevant publications.

Assessment of methodological quality

We will assess and document the methodological quality of included controlled trials following the Cochrane approach using the methods detailed in section six of the Cochrane Handbook for Systematic Reviews of Interventions.[32] Intervention studies will be assessed using the Cochrane Effectiveness and Practice Organisation of Care (EPOC) guidelines. We propose to concentrate on using the following seven domain-based parameters to assess quality: adequate sequence generation, allocation concealment; blinding of participants and personnel, blinding of outcomes, incomplete outcome data addressed, free of selective reporting and free of other bias. We will grade each parameter of trial quality: A - low risk of bias; B - moderate risk of bias; C - high risk of bias and an overall assessment for each controlled trial using the same three criteria will be made. Reviewers will not be masked to study details. We will assess the agreement of reviewers on methodological quality assessment and resolve disagreements by discussion, with a third researcher brought in to arbitrate if needed.

Data extraction

Quantitative data: Two reviewers will extract data using a customised data extraction form which will initially be piloted to ensure the form is easily and consistently interpreted and captures all relevant information. We will resolve any disagreements by discussion between reviewers; in the case of consensus not being reached, a third reviewer will become involved and, if necessary, arbitrate.

For the narrative synthesis: In order to compile a detailed descriptive summary, two reviewers will independently extract data, using the headings 'setting', 'mode of delivery', 'aspects of holistic care addressed', 'duration and intensity of components'. If descriptions are inadequate we will contact authors and may undertake some short qualitative interviews with authors in order to get detailed descriptions of the interventions.

Data synthesis

Based on our preliminary scoping work, we anticipate that we will identify a limited number of eligible trials with substantial heterogeneity so that meta-analysis will not be appropriate.[32] We therefore plan to undertake a narrative synthesis by developing a matrix of what has been shown to be effective or ineffective and the elements of the interventions under the headings of setting, mode of delivery, aspects of holistic care addressed, duration and intensity of components.

In the (unlikely) event of identifying sufficient trials suitable for inclusion in a meta-analysis we will follow the standard procedures described in the Cochrane handbook.[32]

Project management

Research environment and project management

Within the Centre for Population Health Sciences of The University of Edinburgh Centre there is an on-going programme of qualitative and quantitative work underway involving social scientists, clinicians, epidemiologists, trialists and statisticians providing access to in-house methodological expertise.

Dr Pinnock will lead the research team and oversee the conduct of the study with the support of the grant-holders.

Grant holders

Dr Hilary Pinnock is a GP with an interest in respiratory care and experience of developing and evaluating complex interventions. She led the study which underpins the HELP-COPD intervention. She contributed to the Department of Health COPD National Strategy and is a member of the British Thoracic Society (BTS) COPD Specialist Advisory Group

Dr Marilyn Kendall is a medical sociologist, with expertise in qualitative research methods, and in research with people with life limiting illnesses. She is also the User Involvement lead for a large supportive and palliative care research collaborative.

Professor Scott Murray brings conceptual understanding of the multi-dimensional distress suffered by such patients and carers, and support in testing interventions in the community

Dr Allison Worth is a community nurse by background and has long-standing qualitative research interests in patients and families affected by long-term conditions, and the professionals who provide care for them.

Dr Kirsty Boyd is a Consultant in Palliative Medicine, Palliative Care Team, Royal Infirmary of Edinburgh and Honorary Clinical Senior Lecturer, University of Edinburgh.

Professor Bill MacNee is Professor of Respiratory and Environmental Medicine at the University of Edinburgh and a Consultant Respiratory Physician with a long-standing clinical and research interest in COPD.

Professor Aziz Sheikh is a GP, epidemiologist and trialist with an interest in respiratory and allergic disorders. He has considerable experience of undertaking RCTs of complex interventions and systematic reviews, and has recently chaired the BTS's Science and Research Committee.

Dr Patrick White is an academic GP whose main research interests are in the impact of advanced COPD and in service delivery for COPD in primary care. He has particular expertise in recruiting and assessing patients with advanced COPD.

Dr Roberto Rabinovich is a clinical research fellow with a particular interest in the muscle wasting and pulmonary rehabilitation of COPD patients. He has extensive experience of clinical investigations in patients with COPD.

Dr Ellen Drost is a post-doctoral research fellow with considerable experience of clinical research relating to COPD and recently undertook qualitative research in a European Funded Innovative Medicine's Initiative project with COPD patients.

Research team

The research team who will actively work on the review are:

- Dr Ulugbek Nurmatov (systematic reviewer),
- Dr Hilary Pinnock (Principal Investigator)
- Dr Marilyn Kendall (senior qualitative researcher),
- Susan Buckingham (research assistant),

They will be supported by:

- Cristina Matthews (study secretary),
- Susie Ferguson, (research nurse)

Library facilities will be provided by Marshall Dozier

Statistical advice will be provided by Dr Rob Elton

Lay Advisory Group

In a model of patient involvement which we have used successfully in previous work[24] we will establish a Lay Advisory Group facilitated by Dr Kendall who will meet approximately quarterly to review findings and offer advice.

Timetable

January – February 2012	• Develop and agree search strategy • Database searching • Data collection from all sources • Preliminary data analysis
March – April 2012	• Selection of papers • Contact authors/experts

May 2012	• Data extraction • Quality assessment
June 2012	• Final data analysis • Write report • Prepare abstracts and write papers

Implementation potential

The underlying purpose of the study is to establish essential background work for the development, piloting and evaluation of a holistic intervention to address physical, psychological, social and/or spiritual needs of patients with severe COPD towards the end of their lives. This systematic review will clarify the evidence base underpinning the intervention.

Dissemination

We will share our findings with fellow investigators planning intervention studies, present abstracts at international conferences, disseminate findings within our professional spheres of influence. A paper will be published in a peer reviewed journal.

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Appendix 1: Search strategy

Search terms for Cochrane library, CINAHL, LILACS, British Nursing Index (BNI), ZETOC, ISI Web of Science (1990-2012)

("severe chronic obstructive pulmonary disease" or "severe COPD" or advanced chronic obstructive pulmonary disease or end-stage chronic obstructive pulmonary disease or obstructive lung disease* or obstructive pulmonary disease* or pulmonary emphysema or chronic bronchitis)
AND
(intervention stud* or experimental stud* or clinical trial or controlled clinical trial or randomised controlled trial or quasi-randomised clinical trial)
AND
("holistic health" or "palliative care" or "long-term care" or "quality of life" or "health related quality of life")

Search terms for MEDLINE, EMBASE, AMED, PsycINFO (1990-2012)

1. exp Intervention Studies/
2. intervention studies.mp.
3. experimental stud*.mp.
4. exp Clinical Trial/
5. clinical trial.mp.
6. exp Controlled Clinical Trial/
7. controlled clinical trial.mp.
8. exp Randomized Controlled Trial/
9. randomized controlled trial.mp.
10. randomi* controlled trial.mp.
11. quasi-randomi* controlled trial.mp.
12. non-randomi* trial.mp.
13. exp Placebos/
14. placebos.mp.
15. exp Random Allocation/
16. random allocation.mp.
17. exp Double-Blind Method/
18. double-blind method.mp.
19. double-blind design.mp.
20. exp Single-Blind Method/
21. single-blind method.mp.
22. random*.mp.
23. **or/1-22**

24. exp Holistic Health/
25. holistic.mp.
26. exp Palliative Care/

27. palliative care.mp.
28. exp "Quality of Life"/
29. quality of life.mp.
30. health related quality of life.mp.
31. physical well-being.mp.
32. psychological well-being.mp.
33. spiritual well-being.mp.
34. exp "Quality of Health Care"/
35. exp Quality Assurance, Health Care/
36. exp Quality Indicators, Health Care/
37. exp Long-Term Care/
38. quality of care.mp.
39. (Social and Healthcare Support).mp.
40. or/24-39

41. "severe chronic obstructive pulmonary disease".mp.
42. severe COPD.mp.
43. “end-stage chronic obstructive pulmonary disease”.mp.
44. “end-stage COPD”.mp.
45. “advanced chronic obstructive pulmonary disease”.mp.
46. “advanced COPD”.mp.
47. or/41-47
48. 23 AND 40 AND 47
49. limit 48 to yr="1990 - Current"

Appendix 2: HELP-COPD flow diagram