HELP-COPD

HELPing older people with very severe chronic obstructive pulmonary disease (COPD) towards the end of their lives: developing, piloting and refining a practical intervention (HELP-COPD)

Protocol

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Summary

Based 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,[1] this study will develop, refine and pilot a new intervention to address the holistic care needs of people with very severe chronic obstructive pulmonary disease (COPD) towards the end of their lives.

Introduction

Globally, long-term conditions such as COPD are responsible for an increasing proportion of deaths.[2] 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.[3-7] Despite this, the needs of these patients are typically poorly addressed with limited access to palliative care.[3,4] Echoing government calls for equity of access to palliative care services,[8] the Consultation on a Strategy for Services for COPD in England,[9] and the Standards of Care document in Scotland for COPD[10] 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,[11,12] which are predicated on an ability to recognise a terminal phase.[13,14] 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.[14,15] About half of patients discharged after a hospital admission for COPD will die within two years,[16,17] 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.[16,17] Accurate prognostication for individuals with COPD, however, remains extremely difficult,[15,18] compounded by a tendency for doctors who are familiar with patients to over-estimate survival.[19] The only condition where prognosis is less accurate is dementia.[18] 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.[20]

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.[21] People with end-stage COPD tend to 'normalise' their limitations as the result of 'old age',[22] about which 'nothing can be done'.[21] 'Weary resignation' after years of futile attempts to improve their circumstances,[23] and/or a 'recalibration' of expectations[24] as an adaptive coping strategy may contribute to an undemanding acceptance of their circumstances.

The findings of our recent multi-perspective longitudinal qualitative study[25] 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 [25]

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,[26] 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[27]). These individual stories of

their 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'.[28]

This work suggests that in contrast to the disruptive experience of developing a chronic illness, and the consequent rethinking of a person's biography and perception of self,[29-31] people with COPD gradually adjust their sense of self over the years to fit within the limitations imposed by the 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 proposed HELP-COPD intervention: initial ideas

We held a multidisciplinary two-day meeting to brainstorm an intervention that would invoke the palliative care principles of systematically addressing holistic needs (physical, psychological, social and spiritual needs as appropriate to the individual) of people with COPD. We agreed that the intervention should be triggered at a significant milestone in the patient's life and importantly without any assumptions about prognosis or formal consideration of suitability for 'palliative care'. Admission with an exacerbation of COPD is one such milestone. It is a marker of severity, has prognostic significance,[16,17] is disruptive for patients, and is a highly 'visible' event for professionals which can then trigger action. We considered that the HELP-COPD intervention, probably administered by a nurse with respiratory and palliative care training either during or shortly after an admission, is likely to consist of a series of prompts intended to facilitate a holistic assessment and record the intended actions (if any) in a short paper-based format to be held by the patient and copied to any relevant referral agencies (discussed further below; see also appendix 1 for the initial draft of the action plan). We envisaged that the palliative care approach will thus become progressively integrated with good care of a life-long progressive disabling condition, with palliative care generalists and specialists available to advise on management of intractable symptoms. This proposal seeks to build on this underpinning work and further develop, refine and formally pilot the HELP-COPD intervention. We intend to submit an application for funding a definitive randomised controlled trial within six months of completing this preliminary work.

Aim

To develop, refine and pilot a novel complex (HELP-COPD) assessment, undertaken during or immediately after a hospital admission, which addresses the holistic care needs of people with severe COPD.

Objectives

1. To develop a prototype intervention by identifying the evidence base, identifying and developing the theoretical underpinning, and scoping/modelling key aspects.
2. To undertake an iterative process of refining the prototype intervention in preparation for formal piloting.
3. To pilot the intervention in a Phase II randomised controlled trial (RCT) using quantitative and qualitative methods to assess feasibility, acceptability and potential impact.

Research plans

Objective 1: To develop a prototype intervention by identifying the evidence base, identifying and developing the theoretical underpinning, and scoping/modelling key aspects

The MRC framework describes three core tasks in developing a prototype intervention:[1]

1.1 Identifying the existing evidence base.

We will systematically scope the literature for interventions designed to deliver/enhance holistic care for people with severe/very severe COPD. Preliminary searches have identified some potentially eligible trials.[32-35] We will follow standard systematic review methodology detailed in the guidance from the Centre for Reviews and Dissemination (York, UK).[36]

Search and selection strategy

We will search databases, scan reference lists, identify unpublished studies using a PICOS search strategy:[36]

Population: People with severe/very severe COPD.[37,38]

Intervention: Any holistic intervention designed to address physical, psychological, social and/or spiritual needs either with or without formal palliative care input (including pulmonary rehabilitation only if it includes a significant focus on holistic/palliative care and measures an outcome of interest).

Context: All healthcare settings.

Outcomes: Our primary outcome is quality of life (disease-specific or generic). Other outcomes of interest are measures of physical, psychological, spiritual and social well-being, health and/or social service resource use and proportion of eligible patients who were referred for, and who accepted the intervention.

Study design: RCTs; we will search for any qualitative studies associated with included trials to add context to our interpretation of trial data.

We will search the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE (1990 onwards), EMBASE (1990 onwards), CINAHL (1990 onwards), PsycINFO, AMED (1990 onwards), LILACS, British Nursing Index (BNI), ZETOC, Database of Abstracts of Reviews for Effectiveness (DARE), ISI Web of

Science, UK Clinical Research Network Study Portfolio and the meta Register of Controlled Trials. In addition we will search trial registers for on-going trials, reference lists of included studies, and contact international experts known to us from our previous work or as authors of studies included in the review.

Following standardisation of the process, one reviewer (with at least 10% examined by a second reviewer) will review titles and abstracts and select possibly relevant studies. The full texts of all potentially eligible papers will be assessed against our inclusion criteria: we will contact authors if eligibility is unclear. The process will be summarised using a PRISMA flow diagram[39] and a third reviewer brought in to arbitrate disputes if needed. Studies with multiple reports will be treated as a single study.

Assessment of methodological quality

One reviewer (with at least 10% examined by a second reviewer, and a third reviewer to arbitrate disputes) will assess and document the methodological quality of intervention studies following the Cochrane approach using the methods detailed in the Cochrane Handbook for Systematic Reviews of Interventions.[40]

Data extraction and analysis

One reviewer (with at least 10% examined by a second reviewer) will extract data using a customised, piloted data extraction form. We will develop 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. If descriptions are inadequate, we may undertake some short qualitative interviews with authors in order to get detailed descriptions of the interventions.

1.2 Identifying/developing theory.

Our qualitative work suggests that sociological theories of 'health problems that are not illnesses' and life-long conditions that lack a sense of biographical disruption are important in understanding the key barriers to the provision of holistic supportive care in people with very severe COPD. We will continue to read and further our understanding of relevant theories: in particular, we will consider interventions designed to meet the needs of frail elderly people as our work suggests that end-of-life trajectory of COPD may, in some important respects, most closely resemble the slow decline of old age. Other relevant literature will relate to quasi-experimental studies and interventions that address specific symptoms (e.g. breathlessness[41]), or approaches to care (e.g. dignity,[42] communication[43]).

1.3 Modelling process and outcomes.

The HELP-COPD intervention is likely to be implemented by a specialist respiratory nurse who will see the patient during or immediately after an admission with an exacerbation of COPD and act as a facilitator of care provision. Specifically we expect this to involve identification of physical, psychological, social and spiritual needs (if any), devise an individually-tailored plan of action with the patient, arrange referrals to professionals and agencies able to address identified needs, and follow up progress over the subsequent month(s). Our initial draft of the HELP-COPD assessment action plan is

attached in appendix 1. We will need to scope and model key points in this process (e.g. feasibility of seeing patients before or shortly after discharge, link with post-discharge pulmonary rehabilitation, capacity of relevant agencies, efficiency of referral processes, timescales) in order to understand the practicalities of delivering the intervention. The knowledge, skills and training required by the specialist nurse in order to deliver the intervention will need to be defined.

Recruitment

We will recruit stakeholders for interviews in which we will explore their perception of the proposed intervention, and any practical barriers to implementation.

- A broad range of professional stakeholders will be approached by the researcher in order to enable us to understand the context and how the HELP-COPD intervention might be best delivered. This will include ward staff (clinical and administrative), primary care (GPs and practice nurses), community specialist teams (clinicians and administrators), other agencies to which referrals may be made (including social services, chaplaincy, specialist palliative care).
- Patients meeting the eligibility criteria admitted to the Royal Infirmary of Edinburgh (RIE) with an acute exacerbation of COPD will be approached with information about the study by the specialist nurse as soon as their clinical condition allows. Contact details of those willing to consider participating will be given to the qualitative researcher who will arrange to meet them at a convenient time to gain consent and undertake an interview (either on the ward before discharge or at home/GP surgery/University shortly after discharge). For this phase of the study when we are seeking to understand the context in order to inform the development of the prototype HELP-COPD intervention we will purposely sample patients with a range of demography, social background, disease severity, number of previous admissions, co-morbidity.

Interviews, which we anticipate will take about 30 minutes, will take place at a venue and time convenient to the participant (e.g. place of work, hospital ward, GP surgery or home visits for patients), with the option of telephone interviews. We expect to undertake up to 20 interviews in order to obtain a picture of the organisational context.

Topic guide

The aim of this interview is to obtain data to aid in modelling key points in the process. It is likely to cover areas such as:

- Where patients would like the intervention to be delivered (hospital ward, quiet room, GP surgery, at home etc)
- When patients would like the intervention to be delivered (whilst on the ward, after discharge home)
- Who they would like to be present (family, friends, carers)
- Which issues they think should be included, and which should not
- The language, format and layout

- How the nurse might best approach the task; any barriers they foresee

Data handling and analysis

Interviews will be transcribed verbatim, coded and themes identified which will inform the development of the prototype HELP-COPD intervention.

Objective 2: To undertake an iterative process of refining the prototype intervention ready for piloting

2.1 Refining the HELP-COPD intervention.

We will undertake an iterative process of piloting the HELP-COPD action plan and seeking feedback from all relevant stakeholders (patients, family carers, primary, secondary and intermediate care professionals, social services and other referral agencies). The respiratory nurse will use the prototype HELP-COPD action plan, identifying any needs and making referrals as appropriate. The researcher will subsequently interview the patient (with their carer if the patients' wishes), asking about their perception of the action plan and how it may be improved. We will also explore the impact of using the action plan from the perspective of the ward staff, discharge processes, GP and community respiratory staff, and any other medical or social professionals to whom a referral is made. We anticipate several 'cycles' each with up to three or four patients as the intervention is refined, the processes understood and the possible impact assessed in preparation for piloting.

Recruitment

We will recruit patients during, or immediately after a hospital admission with an acute exacerbation of COPD.

- Patients meeting the eligibility criteria admitted to the RIE with an acute exacerbation of COPD will be approached with information about the study by the specialist nurse as soon as their clinical condition allows. We will purposely sample patients with a range of demography, social background, disease severity, number of previous admissions, co-morbidity. The specialist nurse will explain the nature of the intervention and (if the patient consents) undertake the HELP-COPD assessment (see below).
- Contact details of participants will be given to the qualitative researcher who will arrange to meet them at a convenient time for an interview about a week after the delivery of the HELP-COPD intervention and if appropriate a second interview about a month later.
- With the patients' consent, we will approach professionals/organisations involved as a result of the HELP–COPD assessment action plan. This may include family carers, primary, secondary and intermediate care professionals, social services and other referral agencies. We will conduct semi-structured qualitative interviews in order to understand acceptability of the HELP-COPD action plan, impact (both positive and negative) on workload and working practices, effectiveness of referrals in stimulating action and the need for follow-up contact.

Interviews, which we anticipate will take about 30 minutes, will take place at a venue and time convenient to the participant (e.g. place of work, hospital ward, GP surgery or home visits for patients), with the option of telephone interviews.

The HELP-COPD intervention

The specialist respiratory nurse trained in palliative aspects of respiratory care will arrange a meeting to suit the patient's clinical condition and convenience (before discharge, or in their home/GP surgery after discharge). During the meeting the HELP-COPD action plan will be worked through by the respiratory specialist nurse with the patient (and carer if the patient wishes) and any areas of concern will be identified. Based on the findings of the assessment, a range of actions points may be generated. Examples include optimising treatment, recommending pulmonary rehabilitation to address functional disability, highlighting low mood to the primary care team, providing information about local support groups, referring to social services or occupational therapy, seeking specialist palliative care advice for intractable symptoms. All referrals will be made through the usual channels.

The completed HELP-COPD action plan will be given to the patient, a copy will be sent to the patient's GP, and a further copy retained in the hospital records. Agencies and individuals receiving referrals as a result of the assessment will also be sent a copy of the HELP-COPD action plan and action points. Issues that have arisen from the assessment will be clearly recorded on the HELP-COPD action plan and by ensuring that all agencies (and importantly the patient) have copies of the plan it is hoped that the planned action points will be reviewed and implementation facilitated. The action plan will be reviewed by the respiratory nurse who will contact (normally by phone) the patient at 1, 3 and 6 months to check progress with any action points.

Topic guide

The aim of this interview is to obtain data to aid in an iterative process of refining the prototype intervention ready for piloting. Important questions to be answered in this phase will be:

- The format of the (probably) paper-based HELP-COPD action plan (e.g. suitability of 'prompt questions', the 'one-page' design, e-versions)
- The feasibility of delivery (timing during/immediately after admission/during post-discharge pulmonary rehabilitation, time taken to administer, updating during subsequent admissions)
- Acceptability to patients (timing, duration and content of the interview, preferences for patient-held copies)
- Acceptability to other ward staff and integration into ward processes, process of facilitating action (e.g. assimilation into existing referral processes, acceptability to referral agencies such as social services, pulmonary rehabilitation, general practice, community respiratory teams, chaplaincy)
- Effectiveness of referrals in stimulating action and the need for follow-up contact.

Data handling and analysis

Interviews will be transcribed verbatim, coded and themes identified which will inform the development of the HELP-COPD intervention ready for piloting.

Objective 3: To pilot the HELP-COPD intervention in a Phase II RCT using quantitative and qualitative methods to assess feasibility, acceptability and potential impact.

Appendix 2 tabulates key questions for the pilot trial and how the pilot study will help us answer these.

3.1 Outcome measures

Primary outcome measure

The Functional Assessment of Chronic Illness Therapy (FACIT) measurement system has a core of 27 validated questions in four domains: Physical, Social/Family, Emotional, and Functional well-being.[44] Scores range from 0 (worst quality of life) to 108, and are responsive to change with a minimum clinically important difference for improvement of 5.5.[45,46] A sub-scale of 10 questions for use in lung cancer is considered to be appropriate in other respiratory conditions.[47]

Secondary outcome measures

- *Health-related quality of life:* The St George Respiratory Questionnaire (SGRQ) is a validated and widely used instrument which measures health impairment (symptoms, activities and impacts) in patients with COPD on a scale: 100 (greatest impairment) to 0; it is responsive to change,[48,49] with a minimum important difference (MID) of 4.[50]
- *Physical well-being:* MRC Dyspnoea score,[51] Dyspnoea 12,[52] COPD Assessment Test (CAT),[53,54] Number of exacerbations and hospital admissions (including bed days) in the six months of the pilot trial. The cause and place of any deaths will be noted.
- *Psychological well-being:* The Hospital Anxiety and Depression Scale (HADS) is a validated questionnaire with independent scales for anxiety and for depression.[55]
- *Spiritual well-being:* The FACIT Spiritual Well-Being sub-scale (FACIT-Sp) measures spiritual well-being, and has been validated in the cancer populations.[56]
- *Quality of care:* Palliative care Outcome Scale (POS) is a validated questionnaire which measures quality of care, psychological status, family anxiety, symptoms, and pain control.[57,58] It has been widely used to evaluate interventions,[59] and a modified version including a question on breathlessness has been used in people with COPD.[60]
- *Social and healthcare support:* The number and outcome of referrals to other agencies (e.g. social services, specialist palliative care, pulmonary rehabilitation, community respiratory team) during the six month trial period.
- *Health economic analysis:* We will administer the EQ-5D.[61] and pilot the collection of data about use of healthcare resources (including consultations and prescriptions) comparing the feasibility of

collecting data from primary care records with accuracy of patient recall using a questionnaire at the 3 and six month data collection points.

3.2 Methods

Design

A six-month, phase II pilot RCT.

Setting

Primary and secondary care in Edinburgh

Participants

Inclusion criteria: People registered with Lothian general practices admitted with an exacerbation of COPD as the primary diagnosis under the care of the respiratory unit at the RIE. It is anticipated that this group will have severe or very severe COPD (post-bronchodilator FEV_1 < 50% predicted, FEV_1/ FVC <70% predicted). We anticipate significant co-morbidity.

Exclusion criteria: We will exclude patients with other significant lung disease, and those unable to give informed consent (e.g. because of severe dementia) or complete the supervised questionnaires in English.

Sample size

No formal sample size calculations have been undertaken for this preliminary work. We will aim to recruit 40 patients (30 in the intervention group: 10 in the control group) into the pilot trial, this being both sufficient to enable us to answer the key questions and feasible within the timescale of this proposal.

Recruitment

Patients meeting the eligibility criteria admitted to the RIE with acute exacerbation of COPD will be approached with information about the pilot trial by the specialist nurse as soon as their clinical condition allows. Contract details of those willing to consider participating will be given to the research team.

Confirmation of eligibility and consent

The trial researcher will arrange to meet the patient at a convenient time to confirm eligibility, to discuss the trial and obtain informed consent.

Baseline measurements

The trial researcher will undertake a baseline assessment including current smoking status, presence of co-morbidity and baseline questionnaires (FACIT-L,[44] SGRQ,[48] MRC Dyspnoea score,[51] Dyspnoea 12,[52] CAT,[54] HADS,[55] POS,[57] EQ-5D[61]).

Randomisation

Patients will be centrally randomised (using a computer generated random sequence) to either the HELP-COPD or usual care group in the ratio of 3:1 intervention:usual care. Randomisation will be done by the specialist nurse or the qualitative researcher.

Protection against bias

Concealment: Baseline data and optimisation of care will take place prior to randomisation and allocation which will be carried out remotely to ensure adequate concealment.

Blinding: It is not possible to blind clinicians or patients to allocation thus potentially introducing bias in subsequent care. However, all trial data collection will be undertaken by the trial researcher, blinded to allocation. Patients will be requested not to reveal their allocation, although we recognise that inadvertent references by the patients or in their primary care record may reveal allocation. The use of objective outcomes (validated questionnaires, admissions) will also reduce the possibility of bias.

Trial interventions

HELP-COPD intervention: [The following describes our initial plans for the HELP-COPD intervention, but the exact nature of the action plan and its implementation will be refined during the earlier developmental phases.] The trial specialist nurse trained in palliative aspects of respiratory care will arrange a meeting to suit the patients' clinical condition and convenience (before discharge, or in their home/GP surgery after discharge). During the meeting the HELP-COPD action plan will be worked through by the patient (and carer if the patient wishes) and study nurse, and any areas of concern will be identified. Based on the findings of the assessment, a range of actions points may be generated. Examples include optimising treatment, recommending pulmonary rehabilitation to address functional disability, highlighting low mood to the primary care team, providing information about local support groups, referring to social services or occupational therapy, seeking specialist palliative care advice for intractable symptoms. All referrals will be made through the usual channels.

The completed HELP-COPD action plan will be given to the patient, a copy will be sent to the patient's GP, and a further copy retained in the hospital records. Agencies and individuals receiving referrals as a result of the assessment will also be sent a copy of the HELP-COPD action plan. Issues that have arisen from the assessment will be clearly recorded on the HELP-COPD action plan and by ensuring that all agencies (and importantly the patient) have copies of the plan it is hoped that the planned action points will be reviewed and implementation facilitated. The action plan will be reviewed by the study nurse who will contact the patient at 1, 3 and 6 months to check progress with action points.

Usual care: Patients in the usual care group will receive all usual care on discharge (including referral to pulmonary rehabilitation and the community respiratory team if appropriate).

Clinical care: Throughout the trial, patients in both groups will be reviewed according to clinical need by their normal clinical advisors in accordance with existing agreed local protocols, based on the recommendations of national and international guidelines.[37,38]

Duration of intervention

The duration of the intervention is six months.

Quantitative data collection and management

- Study questionnaires (FACIT,[44] SGRQ,[48] MRC Dyspnoea score, [51] Dyspnoea 12,[52] CAT,[54] HADS,[55] POS,[57] EQ-5D[61] plus a one page questionnaire about use of healthcare resources) will be posted to the patient to complete at 3 months, and administered by the trial researcher (blinded to allocation) at 6 months. Arrangements will be made for completion at the patient's surgery, home or other suitable location convenient to the patient.
- The number and outcome of referrals to other agencies (e.g. social services, specialist palliative care, pulmonary rehabilitation, community respiratory team) during the six month trial period will be recorded from the patients' medical record.
- Adverse events will be recorded from the patients' primary care records at the end of the trial
- Use of healthcare resources for the health economic analysis (including number and duration of admissions, exacerbations treated with antibiotics and/or oral steroids, practice and out-of-hours consultations for COPD, routine reviews for COPD, prescriptions for respiratory drugs,) will be collected from the primary care records

Data will be entered from questionnaires and paper records by the trial researcher, with 10% checked for accuracy. If we detect systematic errors we will re-enter all the data.

Statistical analysis

All patients who are randomised will be followed up and included in the analysis in their allocated treatment groups regardless of the treatment actually received. Parametric (independent sample t-tests to compare mean questionnaire scores, and Chi^2 for categorical data) and non-parametric tests will be appropriately employed, depending on the distribution of data.

Missing data: We will use an intention to treat analysis and carry forward the last observation and assume no change, but will also carry out sensitivity analyses using only patients with complete follow-up data

Health economic analyses

Cost data will be calculated as means and compared with independent sample t-tests.[62] The perspective will be the NHS.

3.3 Nested qualitative study

Design

Semi-structured interviews with patients, carers and professionals involved in their care.

The nested qualitative study aims to follow and understand the process by which the intervention facilitates (or not) supportive care. To achieve this, interviews will be scheduled:

- Within a week after provision of the HELP-COPD intervention to capture the reflections of the patient (and carer if appropriate) on the acceptability and experience of completing the HELP-COPD action plan.
- After 4 to 6 weeks, to explore whether any/all of the action points have been implemented, what pro-active action (if any) the patient has taken to encourage implementation and whether the patient-held HELP-COPD action plan has facilitated this. With the patients' consent, parallel interviews with any agencies to whom a referral was made will track the impact of the action plan and progress from a professional perspective
- In the final month of the trial, to explore any benefit or detriment of using the HELP-COPD action plan, whether any action points are still outstanding and why.

Participants

We will select up to 10 patients from the intervention group with diverse demography, co-morbidity, family and social circumstances and arrange to conduct interviews with them (and their family carer if the patient wishes). We will ensure that we undertake interviews in situations where the HELP-COPD action plan appears to have been particularly effective as well cases where problems have arisen or the intervention has been ineffective.

Topic guide

Participants will be encouraged to give their views on the usefulness of the HELP-COPD action plan in general and the impact of the intervention on their care. Interviews with professionals will seek to investigate perceptions of the benefits (or otherwise) of the intervention, experiences of implementing it and the barriers and facilitators they have experienced.

A more detailed topic guide will be developed in the light of the findings of the preliminary phases and refined iteratively as data are gathered and analysed and new themes arise.

Analysis

The interviews will be fully transcribed and coded by the qualitative researcher using NVivo. Thematic analysis will be carried out and reviewed by the wider research team to aid interpretation.

Exit strategy

The HELP-COPD assessment is intended to be delivered at the time of an admission, triggering additional care if required, and with two or three brief follow-up contacts to establish if any referrals made have occurred. Unless the patient had a subsequent admission, no further assessment/intervention is planned.

There is no anticipation that the HELP-COPD intervention will continue to be provided for people with very severe COPD who have a hospital admission. If our pilot work proves promising, we will be seeking funding for a major RCT to establish in a properly powered trial the efficacy (or not) of the intervention. At that stage it will be appropriate for NHS trusts to consider whether such an intervention should be implemented.

Publication strategy

The systematic scoping, review and the pilot trial will be published in peer-reviewed journals, presented as abstracts at national and international conferences and disseminated via the co-applicants' contacts with professional and policy bodies and lay groups and organisations.

Risk Management Strategy

Identification of unmet need

It is possible that unmet clinical, social or spiritual need may be identified during an interview. Researchers will be alert to this possibility and, if necessary, encourage patients to seek help from their usual advisors. With the patient's explicit consent important health concerns or unmet needs may be drawn to the attention of the patient's professional advisors.

Workload

Our previous qualitative work showed us that people with very severe COPD often have significant unmet (often social) needs. An admission with an exacerbation of COPD is a marker of more severe disease, and our intervention, therefore, aims to adopt a supportive and palliative care approach to systematically asking about physical, psychological, social and spiritual needs. If any unmet needs are identified, a referral will be made through normal channels to the appropriate agency. The biggest risk is that cash strapped health and social care services may struggle to provide the necessary care: though that is an existing problem and not one created by this study.

Data security

Research data will be stored on secure, password-protected university computers with access limited to the named research team

Project team and task allocation

- Dr Hilary Pinnock is the principal investigator. She 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.
- The grantholders who will support the project are:
  - 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 Pam Levack is a consultant in palliative care with an interest in acute palliative medicine and establishing a palliative care service in all acute hospitals to ensure the palliative care needs of patients admitted to hospital are identified and addressed.
- 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 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.
- Mr John Stewart is a lay person with COPD. Mr Stewart has experience of involvement in research as he was a member of the Lay Advisory Group for our previous COPD study. He also acts as co-ordinator for a large Breathe Easy group in Scotland.

In addition, Dr Kirsty Boyd, Consultant in Palliative Medicine, Palliative Care Team, Royal Infirmary of Edinburgh and Honorary Clinical Senior Lecturer, University of Edinburgh has indicated her willingness to act as a collaborator on the project

- The research team are:
  - Dr Marilyn Kendall will be the senior researcher, and will undertake the qualitative work.
  - Susan Buckingham will act as the trial researcher and undertake the quantitative data collection.
  - Ulugbek Nurmatov will undertake the systematic review.
- A specialist respiratory nurse will be appointed as an NHS appointment to provide the HELP-COPD intervention.
- Dr Rob Elton will provide statistical advice.
- Dr Marshall Dozier will provide library services.

Project Management and Quality Assurance

- The project team, consisting of grantholders and research staff, will meet two monthly.
- There will be a weekly management meeting between the Dr Pinnock and the research team.
- The study will be carried out to Good Clinical Practice standards and managed within the Research Governance Framework. Ethical approval will be sought via the National Research Ethics Service and management approval from NHS Lothian.
- Research governance approval will be sought from NHS Lothian Research Governance Committee
- The trial will be co-sponsored by NHS Lothian and the University of Edinburgh.

- Indemnity will be provided by the NHS indemnity scheme, the University of Edinburgh.

Lay Advisory Group (LAG)

In a model of patient involvement which we have used successfully in previous work[25] we will establish a LAG who will meet approximately quarterly to review findings and offer advice. The LAG will be facilitated by Dr Kendall who, with Mr Stewart, will act as a liaison between the project team and the LAG.

Timetable

(Planned start date 1st January 2012)

Months	1-3			4-6			7-9			10-11			13-15			16-18			19-21			22-24		
Ethics and R&D approvals																								
1a Systematic literature scope																								
1b Developing theory																								
1c Modelling																								
2 Refining intervention																								
3 Pilot trial																								
Report and publications																								

Finance

Existing resources

Resources will be provided by the Centre for Population Health Sciences of The University of Edinburgh, including the full range of support services (library facilities (Marshall Dozier), statistical (Dr Rob Elton) and computing support), as well as office space. Within the Centre there is an on-going programme of qualitative and quantitative work underway involving social scientists, clinicians, epidemiologists, trialists and statisticians providing excellent access to in-house methodological expertise. The applicants on this proposal encompass expertise in the fields of general practice, palliative care, respiratory medicine, nursing, development and evaluation of complex interventions, social sciences and user involvement.

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Appendices

Appendix 1. The prototype HELP-COPD action plan

This is the sheet to be used by a specialist nurse with a patient shortly after an admission for an exacerbation of COPD. The questions in the first column are designed as prompts. The second column is space for recording any identified needs or concerns and the final column is the agency or person to any referrals have been made. The completed HELP-COPD action plan will be given to the patient, a copy will be sent to the patient's GP, and a further copy retained in the hospital records. Agencies and individuals receiving referrals as a result of the assessment will also be sent a copy of the HELP-COPD action plan and action points.

Appendix 2. Key questions, and how the pilot trial will answer them

Appendix 1. The prototype HELP-COPD action plan

Domain	**Priorities** (possible actions/referral routes)	**Responsibility**
Physical symptoms *What symptoms are a particular bother at the moment, either from your COPD or any other illnesses?*	Eg. Pulmonary rehabilitation, discussion with medical team to optimise medicines, referral to or discussion with specialist palliative care	
Psychological symptoms *What if anything are you worried or anxious about?* *Do you often find yourself feeling down?*	Eg. HAD score, relaxation or anxiety management, drug treatments, pulmonary rehabilitation	
Social needs *How you are managing at home? Are there any particular problems at the moment for you and/or your carer?*	Eg. Referral to social work, occupation therapy, district nurses, day hospitals, carer support groups	
Spiritual *How do you see the future? Do you have any particular concerns?* *Who do you get your support from during tough times?*	Eg. Support groups, befriending services, chaplaincy	
Is there anything important that we have not talked about? (E.g the presence of a family carer who may have needs)		

Appendix 2: Key questions for the pilot trial

Questions to refine the intervention	How the pilot study will answer them
Where will initial HELP-COPD consultations take place?	Records will be kept of arrangements made for identification, recruitment and the HELP-COPD consultations (before discharge, in the patients home or GP surgery) and why (timing of discharge, patients' clinical condition and/or patient preference)
In what proportion of patients was an action point identified?	We will keep a record of the needs identified and actions recommended a result of the HELP-COPD assessment
What actions were triggered by the HELP-COPD assessment?	We will keep detailed records of the actions and referrals made as a result of the HELP-COPD assessment
What follow-up will be needed to ensure that referrals to appropriate agencies occur in a timely manner?	The specialist nurse will review pilot patients at 1, 3 and 6 months to see if referrals and other arrangements have been implemented. As appropriate, brief phone calls will be scheduled at 2, 4 and 5 months to determine progress with any outstanding actions. Detailed records will be kept of the progress of referrals and other actions and of any reminders or re-referrals made.
What are the barriers to implementation of action points?	Qualitative interviews with stakeholders to identify reasons for observed delays.
How acceptable is the intervention? How may it be improved?	Qualitative interviews with all stakeholders (patients, carers, professionals and referral agencies?)
Questions to inform the planned RCT	How the pilot trial will answer them
What proportion of eligible patients will agree to participate?	Records of numbers of patients identified as eligible and proportion who agreed to participate.
What factors encouraged (or discouraged) participation?	Qualitative interviews with participants, and records of the characteristics of those who decline to participate and any reasons proffered for not participating.
What is the likely attrition rate?	We will monitor withdrawals (with reasons where proffered) and loss to follow-up (e.g. because death, moving, incapacity)
What is the most appropriate duration for the RCT and when should interim assessments be undertaken?	To determine the most appropriate timescale for measuring outcomes in the main trial, in the pilot we will measure this at baseline, 3 and 6 months.
How feasible/practical are the proposed outcome measures?	We will note problems with questionnaire completion, and the burden on the patient. We will note any difficulties extracting data from records and if necessary explore alternative strategies.
What outcomes are most important to patients and carers?	Qualitative interviews with patients about their perception of the relevance of the outcome measures. We will also discuss this with the lay advisory group.
What is the best way to collect data about use of healthcare resources	We will compare the practicality and accuracy of collecting data about use of healthcare resources from the patients' primary care records and from a self-completed questionnaire at 3 and 6 months
Is there any evidence of contamination?	We will include questions about the possibility of contamination in interviews of the specialist trial nurse (who will be delivering the intervention) and also when interviewing other members of the clinical team who may have been influenced by the trial.
What is the expected change in the primary outcome measure?	We will compare FACIT at 3 and 6 months.