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Is it possible to introduce a palliative care approach to primary care clinics to improve the quality of life of patients with chronic lung disease in South Africa?

Submission date 16/03/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 27/03/2020	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/04/2021	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic (long-lasting) lung disease is one of the main causes of death in South Africa. It is associated with a high burden of symptoms, such as shortness of breath, lack of sleep, pain, fatigue, and concerns, such as worry, depression, frequent hospital admission and frequent attendance to the emergency department, along with poor quality of life. Palliative care is a medical approach that aims to improve the quality of life of a person with a serious illness by relieving their pain, anxiety and other symptoms or concerns, but without treating the underlying illness. There is no guidance in South Africa on palliative care interventions that improve the quality of life of patients with chronic lung disease. The study aims to assess whether it is possible to incorporate a palliative care approach into primary care (for example, GP clinics) for chronic lung disease in Western Cape.

Who can participate?
The study aims to recruit 105 people with chronic lung disease and their family caregivers. Both patient and family caregivers need to be aged 18 years or over, able to communicate in English, Afrikaans or Xhosa, able to give informed consent.

What does the study involve?
The study involves training, providing mentorship and support to health care professionals (working at three facilities in Western Cape: False Bay Hospital, Delft Community Health Centre and Heideveld Community Day Centre) to provide person-centred care to patients with chronic lung disease and their family caregivers.
Facility staff will be trained in three clinics. The research team will start the new training one clinic at a time. The order in which they get trained is determined by a computer (which has no information about facilities and participants). For the first three months, the researchers will observe clinics working as normal, then they will start the training. At 3 months, healthcare professionals will be trained to provide person-centred palliative care at the first site. At six months, healthcare professionals will be trained to provide person-centred care at a second

facility. At 9 months, healthcare professionals will also receive training as above at a third site. The training at each site will last one month. Patients and their family caregivers who are attending primary care at these three clinics will be recruited for the first two months. They will be invited to complete a questionnaire to be administered by the researcher at each of the three sites. Patients will be followed up for 12 months, each month they will be requested to complete the questionnaire with the researcher.

What are the possible benefits and risks of participating?
There are no direct benefits for those taking part in the study. However, this may be an opportunity for patients and family caregivers to learn ways of managing symptoms and concerns experienced due to chronic lung disease. There are no risks involved to those taking part in the study and every effort will be made not to inconvenience patients or their family carers.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
February 2020 to January 2022 (updated 20/04/2021, previously: April 2021)

Who is funding the study?
The National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Professor Richard Harding, richard.harding@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Richard Harding

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A novel integrated person-centred palliative care intervention in primary care for patients with chronic lung disease and their families: a cluster stepped wedge feasibility hybrid type 2 RCT

Study objectives
Objectives:
1. To develop a training support and implementation programme for healthcare professionals (HCPs) in primary health care (PHC) for patients with chronic obstructive pulmonary disease (COPD) and chronic lung disease (CLD) at the three sites
2. To recruit patients with CLD and COPD and their caregivers at three primary care sites to a feasibility hybrid stepped-wedge trial
3. To randomly introduce the intervention stepwise at the three sites and providing training and mentorship to HCPs at each facility
4. To measure completion of patients and caregivers outcomes and staff costs data
5. To assess fidelity to the standardised intervention manual
6. To assess views of HCPs, patients and their caregivers following delivery and recipient of the intervention
7. To assess implementation mechanisms and sustained fidelity of the intervention within primary care at the three sites

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 20/12/2019, King's College London PNM Research Ethics Subcommittee (Frankin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Rd, London SE1 9NH; +44 (0)207 848 4020; rec@kcl.ac.uk), ref: HR-19/20-14450
2. Approved 12/12/2019, University of Cape Town Faculty of Health Sciences Human Research Ethics Committee (Room E53, 46 Old Main Building, Groote Schuur Hospital, Cape Town, South Africa; +27 (0)21 406 6492; hrec-enquiries@uct.ac.za), ref: 756/2019

Study design
Cluster-randomized stepped-wedge hybrid type two feasibility randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet.

Health condition(s) or problem(s) studied
Chronic lung disease

Interventions
Face-to-face training to be delivered by palliative care physicians from University of Cape Town using the curriculum used to train palliative care professionals at the University of Cape Town

Training will cover the following modules:
1. Healthcare workers (HCW, including community care workers in the area) training and mentoring on:
1.1. Review of PACK (Practical Approach to Care Kit) training on CLD/COPD diagnosis, management and prognosis. PACK is a health systems strategy comprising of a guide, training strategy, health systems strengthening interventions and monitoring and evaluation component.
1.2. Smoking cessation
1.3. Communication skills and teamwork
1.4. Patient-centred care including care planning
1.5. Specific symptom control management – pharmacological and non-pharmacological, including self-management techniques
1.6. Psycho-Social distress recognition and management
1.7. Referral to community based services (CBS) for patient and family support
1.8. Breathlessness intervention pack (crisis plan, handheld fan)
2. Health care workers (including community care workers in the area) training on patient education topics around the following:
2.1. Respiratory rehabilitation including exercise
2.2. Self-management techniques for breathlessness
2.3. Inhaler technique

After training health care professionals are expected to implement what they covered during training. They are also expected to train patients on inhaler techniques and smoking cessation. The training is for 1 month. After training there will be mentorship and support.

The material for the patient education topics will include posters and patient leaflets. The leaflets have been adapted (with permission) from the Kings College London Breathlessness Support Service and the University of Cape Town smoking cessation programme. Posters will be developed based on the leaflets and in collaboration with the intervention sites. As part of the intervention, video clips will be developed that can be used for patient education at clinics.

The duration of the intervention is 9 months for site 1, 6 months for site 2 and 3 months for site 3. Randomisation is computer-generated.

Intervention Type
Behavioural

Primary outcome measure
1. Number of patients who meet inclusion criteria recorded using study records during the recruitment period
2. Number of patients approached recorded using study records during the recruitment period
3. Number of patients who consent to study entry and data collection recorded using study records during the recruitment period
4. Time taken to recruit planned feasibility sample recorded using study records during the recruitment period
5. Number of recruited patients who have a family member who consents to data collection recorded using study records during the recruitment period
6. Number of patients able to self-report at each time point recorded using study records during the data collection period
7. Reasons for loss to follow-up recorded using study records during the data collection period
8. Number of patients who die within data collection period recorded using study records during the data collection period
9. Place of death recorded using study records during the data collection period
10. Number of participants who complete each data point recorded using study records during the data collection period
11. Unrelieved patient symptoms assessed using a subscale of the Integrated Palliative Care Outcome Scale (IPOS) at monthly intervals during the data collection period
10. Patient depression risk assessed using the Centre for Epidemiologic Studies Depression Scale (CES-D) at monthly intervals during the data collection period
11. Emergency hospital or clinic visits for dyspnoea relief recorded using the Client Services Receipt Inventory (CSRI) and patient diaries at monthly intervals

Secondary outcome measures
1. Time to complete person-reported outcome measures (researcher read aloud and record response) recorded using study records during the data collection period
2. Number of measures completed at each data point recorded using study records during the recruitment period
3. Number of patient records/files with person-centred care plans recorded using patient medical records during the data collection period
4. Number of observations made recorded using study records during the data collection period
5. Number of health care professionals delivering care in line with the training received assessed by comparing names of care providers in patient medical records with recorded documentation on person-centred care plans. The research team will also engage a mentor who will provide mentorship and support to all health care professionals. The mentor will also observe and record the care delivered by health care professionals throughout the study period.
6. Number who received patient-centred care or care in line with the intervention or training provided to clinicians recorded using patient medical records during the data collection period
7. Multidimensional problems and concerns of the patients and families over the previous 3 days assessed using the 10-item African Palliative Care Association (APCA) African Palliative Outcome Scale (APOS) at each monthly visit during the intervention and control periods
8. Patient depression assessed using the Center for Epidemiologic Studies Depression Scale (CES-

D) at the first assessment during the control period and 6-8 weeks after the start of the intervention
9. Health status assessed using the COPD Assessment Test (CAT)
10. Patient's assessment of their condition and healthcare experience assessed using the Picker Patient Experience questionnaire (PPE-15) at monthly intervals throughout their participation
11. Patient's perceptions of relational empathy with healthcare worker assessed using the Consultation and Relational Empathy (CARE) measure at monthly intervals throughout their participation
12. Health service and informal care usage assessed using the Client Services Receipt Inventory (CSRI) at monthly intervals throughout their participation

Overall study start date
08/08/2019

Completion date
15/01/2022

Eligibility

Key inclusion criteria
Patients:
1. Adults (aged at least 18 years) attending primary care with diagnosed COPD or chronic lung disease (CLD) on the basis of the likely aetiological determinants in South Africa, namely cigarette or other smoking history, biomass fuel smoke exposure, history of previous pulmonary tuberculosis or other respiratory infections and occupational dust exposure
2. Eligible for palliative care on the basis of disease severity, with at least one of the following:
2.1.Breathless at rest or on minimal exertion
2.2. On home oxygen
2.3. Three or more hospital admissions in the last year
2.4. More than three emergency centre (EC) visits in the last month
2.5. Karnofsky Performance Status of 50 or less
2.6. Dependence on others for activities of daily living (ADLs)
3. Able to communicate in English, Afrikaans or Xhosa
4. Able to give informed consent

Family members/caregivers:
1. Primary caregiver to be identified by the patient, in line with the definition of caregiver: "Unpaid, informal providers of one or more physical, social, practical and emotional tasks. In terms of their relationship to the patient, they may be a friend, partner, ex-partner, sibling, parent, child or other blood or non-blood relative."
2. Adult aged at least 18 years
3. Able to communicate in English, Afrikaans or Xhosa
4. Able to give informed consent

Participant type(s)
Mixed

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
n=105 (n=35 per site), we are recruiting at three sites

Key exclusion criteria
Patients:
1. Housebound and unable to attend primary care
2. Unable to give informed consent due to loss of capacity
3. Unable to communicate in English, Afrikaans or Xhosa
4. Asthma

Caregivers:
1. Paid caregivers such as nurses or social workers
2. Aged under 18 years
3. Not involved in day-to-day care for the COPD or CLD patient

Date of first enrolment
15/03/2021

Date of final enrolment
15/01/2022

Locations

Countries of recruitment
South Africa

Study participating centre
False Bay Hospital
17th Avenue
Fish Hoek
Cape Town
South Africa
7975

Study participating centre
Delft Community Health Centre
Corner of Main Rd and Voorbrug Rd
Cape Town
South Africa
8001

Study participating centre
Heideveld Community Day Centre
Heideveld Rd
Heideveld
Cape Town
South Africa
7764

Sponsor information

Organisation
National Institute for Health Research

Sponsor details
NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC)
University of Southampton
Alpha House
Enterprise Road
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SO16 7NS
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Sponsor type
Government

Website
https://

ROR
https://ror.org/0187kwz08

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. The results are also planned to be presented at the APCA and EAPC conferences in 2022.

Intention to publish date
30/05/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date