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Developing a support needs approach for patients (SNAP2)

Submission date
07/06/2017

Recruitment status
No longer recruiting

Registration date
08/06/2017

Overall study status
Completed

Last Edited
22/10/2021

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic Obstructive Pulmonary Disease (COPD) is a long-term lung condition that shortens people's lives. People with advanced COPD have severe breathlessness and face difficulties in daily living. Patients with COPD have unmet care and support needs. This is usually due to patients' contacts with the health care professionals (HCPs) are often brief and are only about responding to problems such as lung infections. They rarely provide opportunities for patients to identify and discuss their support needs. Even when there is time patients are uncertain what they can ask about. HCPs cannot rely on patients telling them their concerns unless it is a time of crisis. Providing appropriate care is therefore difficult. If HCPs gave patients a brief tool to complete (a set of questions to consider), it might act as a prompt to patients to help them identify and express their support needs. The patient-completed tool could then be used by HCPs to start a conversation with the patient about their needs, and how they might be met. This new approach to identifying and addressing patient support needs is called the "Support Needs Approach for Patients" (SNAP). A similar approach, using a tool, has been developed for carers and is being successfully used in clinical practice nationally and internationally. The aim of this study is to enable person-centred care in patients with advanced COPD by developing and exploring the feasibility and acceptability of the Support Needs Approach for Patients (SNAP).

Who can participate?
Adults aged 18 and older who have COPD and health care professionals/patients who will deliver /receive the SNAP interventions.

What does the study involve?
This study includes two stages. The first stage checks the validity and content of the sNAP tool by running two focus groups involving participants with advanced COPD and their carers. These take around two hours and ask participants and carers about their views on the SNAP tool. Then another group of 200 participants are invited to take part in a postal survey which includes the SNAP tool alongside frequently used questionnaires in order to measure the disease impact and compare those results with the SNAP tool results. The second phase of the study evaluates how SNAP works in the clinical setting and how to train HCPs to use it. This is done by first developing a training package for HCPs in how to use SNAP. Then workshops are held with HCPs to deliver the training before the SNAP-trained HCPs try out SNAP with patients over a four

month period. During that time the HCPs report on (either face to face or by telephone) how often they are using SNAP and things which prevent them from using SNAP. Some of the patients who have experienced SNAP are invited to take part in an interview about their experience of SNAP (i.e. what was the tool like to complete, any missing items, how did HCPs use and respond to the tool, and how was this different to usual care they receive). At the end of the four months the HCPs who used SNAP are invited to focus groups to tell us about their experiences of SNAP. The findings of Stage 2 are used to improve the training package and to design a larger study to formally test SNAP in clinical practice.

What are the possible benefits and risks of participating?
There are no direct benefits with participating, however participants may benefit from the opportunity to share experiences within focus groups. This study potentially deals with sensitive issues in relation to support needs in advanced COPD. Participants and carers are directed to sources of support if required.

Where is the study run from?
This study is being run by the University of East Anglia (UK) and will take place in hospital and community/primary health centres in the UK.

When is the study starting and how long is it expected to run for?
March 2017 to August 2019

Who is funding the study?
Marie Curie Cancer Care (UK)

Who is the main contact?
Dr Morag Farquhar

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
34247

Study information

Scientific Title
Accessing and delivering person-centred care in advanced non-cancer conditions: Developing and piloting a Support Needs Approach for Patients (SNAP) with advanced COPD

Acronym
SNAP2

Study objectives
The aim of this study is to enable person-centred care in patients with advanced COPD by developing and exploring the feasibility and acceptability of a new intervention: the Support Needs Approach for Patients (SNAP).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Stage 1: East of England – NHS Essex Research Ethics Committee, 17/05/2017, ref: 17/EE/0192
Stage 2: Not provided at time of registration.

Study design
Stage 1: Observational validation of outcome measures
Stage 2: Interventional feasibility study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied

Specialty: Primary Care, Primary sub-specialty: Respiratory disorders; UKCRC code/ Disease: Respiratory/ Chronic lower respiratory diseases

Interventions

Stage 1: SNAP Tool Validation

The first stage involves two tasks. The first task is the initial validation of the SNAP tool. As a patient-completed tool, face validity is essential. As a holistic tool, content validity ensures breadth of coverage. Face and initial content validity are assessed through two focus groups (around six to eight participants each) involving participants with advanced COPD and their informal carers recruited via primary care practices, supplemented via secondary care (e.g. respiratory clinics) and relevant support groups if required. Focus groups last about two hours, and are conducted in accessible, attractive local venues with easy parking. Written informed consent is taken from both patients and carers. Focus groups consider the appropriateness, relevance and completeness of the tool, and will be audio-recorded with permission.

The second task is the main validation evaluation. Both content and criterion validation are assessed through patient self-completion of a postal survey including the SNAP tool alongside established measures of disease impact (outlined below). Content validity establishes relevance and comprehensiveness of tool items. Criterion validity establishes whether the tool identifies meaningful and relevant needs within the context of living with advanced COPD; the tool should be significantly related to how the patient feels and underlying illness burden (impact). Patients are recruited from primary care. The survey booklet contains the SNAP tool, standard measures of disease impact, demographic and basic health questions (to assess sample representativeness). Standard measures of disease impact include Chronic Respiratory Questionnaire (CRQ), COPD Assessment Test (CAT), and Hospital Depression and Anxiety Scale (HADS). The CRQ measures quality of life in chronic lung disease: the self-report version (CRQ-SR) comprises 20 questions covering dyspnoea, fatigue, emotional-functioning and mastery. CAT assesses COPD impact: eight questions e.g. shortness of breath, ease of living at home. HADS detects presence of depression and anxiety: 14 questions. Analyses report the summary statistics for content validity (e.g. percentages of patients indicating need for more support with each tool item and identification of redundant items) and correlations between tool items and impact measures for criterion validity i.e. the tool should be significantly related to how the patient feels and underlying illness burden (impact).

Stage 2 SNAP Feasibility Study:

SNAP's feasibility and acceptability is explored in primary, community and secondary care settings. Up to two primary care practices, a community respiratory team and a hospital respiratory department are purposively recruited to a four-month feasibility study to explore barriers and facilitators to SNAP-adoption in these varying clinical contexts. Normalisation Process Theory (NPT) provides a framework for collection and analysis of Stage 2 data. NPT is a theory of social action addressing the gap between research and adoption into clinical practice, providing a structure to investigate implementation processes. Its upstream use in this MRC Phase I study will pre-empt downstream (MRC Phase II-IV) implementation barriers e.g. major components of NPT (coherence, cognitive participation, collective action and reflexive monitoring) will inform topic guides for qualitative data collection and analysis.

The first task in this stage if the development of SNAP Training and Support Package. As this is a new approach to care, a SNAP Training and Support package is required for HCPs. This includes: brief training package for primary/community/secondary care HCPs, recommendations for organisational adaptions potentially required (e.g. SNAP's fit with existing recording systems), and a support package to facilitate SNAP in clinical practice.

The second task in this stage involves workshops with pilot sites. SNAP is introduced to the three recruited clinical settings in workshops (one per setting) with targeted HCPs. Each workshop delivers the SNAP Training and Support package. HCPs then be asked to discuss how and when they might use the approach. Workshop discussions are audio-recorded with permission.

The third task is a four-month pilot implementation. SNAP-trained HCPs implement SNAP with patients in the three recruited clinical settings over a four month period. Participating HCPs are interviewed by telephone monthly to monitor tool use and identify immediate barriers to SNAP delivery (and site visits will be made). Interviews are audio-recorded with permission.

The fourth task in this stage is the patient interviews. This involves a purposive sample of patients who have experienced SNAP in the feasibility study that are invited to participate in an interview about their experience of SNAP (i.e. what was the tool like to complete, any missing items, how did HCPs use and respond to the tool, and how was this different to usual care). Interviews are audio-recorded with permission.

The fifth task is the HCP focus groups. On completion of the feasibility study HCPs are invited to focus groups within their clinical setting to explore experiences of SNAP, including working with the tool, and barriers/facilitators to SNAP implementation. Focus groups are audio-recorded with permission.

The last task involves the refinement of SNAP Training and Support Package. This includes the Stage 2 findings, including identified barriers/facilitators to delivering SNAP in clinical practice, to inform refinement of the training and support package to enable SNAP implementation in primary, community and secondary care within a future MRC Phase II study.

Intervention Type
Other

Primary outcome measure
Stage 1:
1. Face validity and initial content validity of the SNAP tool is assessed using patient and carer focus groups.
2. Content and criterion validity of the SNAP tool (includes SNAP tool plus quality of life, COPD impact and anxiety and depression measures) is assessed through patient self-completion of the postal survey
3. Quality of life in chronic lung disease is measured using the Chronic Respiratory Questionnaire (CRQ) at time of the survey
4. COPD impact is measured using the COPD Assessment Test (CAT) at time of the survey
5. Presence of depression and anxiety is measured using the Hospital Depression and Anxiety Scale (HADS) at time of survey

Stage 2:
1. HCP SNAP tool use and barriers to SNAP implementation are assessed using semi-structured telephone interviews at month one, two, three and four
2. Patient experiences of SNAP (i.e. what was the tool like to complete, any missing items, how did HCPs use and respond to the tool, and how was this different to usual care) are assessed using face to face semi-structured interviews at month one to four
3. HCP experiences of SNAP (including working with the tool, and barriers/facilitators to SNAP implementation) are assessed using focus groups following month four

Secondary outcome measures
There are no secondary outcome measures for both stage one and two.

Overall study start date
01/03/2017

Completion date
31/08/2019

Eligibility

Key inclusion criteria
Stage 1:
Adult patients with COPD who meet two or more of these inclusion criteria:
1. FEV1< 30%
2. 2+ exacerbations requiring prednisolone and antibiotics in previous year
3. Admission for COPD in previous 2 years
4. Long-term oxygen therapy
5. Cor pulmonale
6. MRC dyspnea scale 4+

Stage 2:
1. Healthcare professionals working at pilot study clinical sites who deliver (or facilitate delivery of) the SNAP intervention
2. Patients with COPD registered with pilot study clinical sites and who receive the SNAP intervention
3. Aged 18 and older

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Stage 1: Planned Sample Size: 216; UK Sample Size: 216. Stage 2 includes four sites (8 per site around 24-32 in total)

Total final enrolment
256

Key exclusion criteria

For both Stage 1 and 2:
1. Serious mental health problem
2. Serious learning difficulty
3. Unable to give informed consent

Date of first enrolment
12/06/2017

Date of final enrolment
31/01/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of East Anglia
Norwich Research Park
Norwich
United Kingdom
NR4 7TJ

Sponsor information

Organisation
University of East Anglia

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Charity

Funder Name
Marie Curie Cancer Care

Alternative Name(s)
Marie Curie Cancer Care

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Study results are planned to be shared through a multi-faceted dissemination strategy including open access peer-reviewed publications, presentations to local stakeholders and at conferences, and funder and governance reports, as well as costed-in interactive dissemination event, organisation targeting (national organisations), and engagement through social media.

Intention to publish date
30/07/2021

Individual participant data (IPD) sharing plan
The current 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/10/2021	22/10/2021	Yes	No
HRA research summary			28/06/2023	No	No