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Does a breathlessness intervention service ('CBIS') reduce stress significantly more than usual care in breathless patients with advanced non-malignant disease and their carers? A phase II feasibility study

Submission date 25/04/2013	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 26/04/2013	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 29/05/2020	**Condition category** Respiratory	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
14073

Study information

Scientific Title
Does a breathlessness intervention service ('CBIS') reduce stress significantly more than usual care in breathless patients with advanced non-malignant disease and their carers? A phase II feasibility study

Acronym
BISCORT

Study objectives
Background: Breathlessness is common in people with serious heart and lung disease. Experts agree that using a number of treatments together (e.g. exercise, relaxation, medication) brings the greatest improvement. The Cambridge Breathlessness-Intervention Service (CBIS) uses this approach in patients and their carers. We think that 'CBIS' works by reducing stress. Stress levels in the body can be assessed by measuring the amount of a hormone called cortisol in saliva.

Aim: We want to know whether CBIS reduces stress. We can only answer this question accurately by doing a large study. This is a small study testing our methods before doing the large study.

Methods: We plan to recruit 36 patients along with their carers. Half of the participants will receive 'CBIS' and half of them will not. We will measure salivary cortisol levels before and after study entry (at 0 and 8 weeks) in both the participants receiving the service and in those who do not receive the service. In addition, participants will be asked to complete questionnaires about their level of breathlessness and stress. We will also measure sleep and inflammation as these phenomena are related to chronic stress. At 8 weeks, we will compare the results between the two groups. Those who receive CBIS will have further measurements taken at 12 and 20 weeks to establish whether there is a long-term change in the measures. All participants will be invited to take part in an interview about their experience of the study at 20 weeks.

More details can be found at: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=14073

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 21/02/2013, ref: 13/EE/0021

Study design
Randomised interventional trial; Design type: Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Cardiovascular, Respiratory; Subtopic: Cardiovascular (all Subtopics), Respiratory (all Subtopics); Disease: Cardiovascular, Respiratory

Interventions
CBIS, The Cambridge Breathlessness Intervention Service (CBIS) is a multidisciplinary service consisting of a medical consultant, an occupational therapist and a physiotherapist. It uses a psychologically-informed and rehabilitative approach to address the multi-dimensional nature of breathlessness. The intervention consists of multiple interacting components which are delivered in a flexible manner.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Diurnal Salivary Coritsol Profile; Timepoints: For parallel study: week 0 and 8, For longitudinal study (intervention arm only): week 0, 8,12, 20

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/01/2015

Eligibility

Key inclusion criteria
Patients:
Any patient referred to CBIS with non-malignant disease who:
1. Has a diagnosed and investigated cause for breathlessness
2. Is troubled by breathlessness despite optimal medical therapy
3. May benefit from a self-management programme
4. Has an informal live-in carer

Carers:
1. Is an informal carer (i.e not employed or paid as a carer) of the referred patient
2. Lives with the referred patient
3. Has some involvement in the patients day-to-day activities or care
4. Male & Female; lower age limit 18 years, upper age limit 100 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Patients:
1. Active cancer
2. Rapidly progressing disease-course (CBIS cannot be delayed in this situation)
3. On corticosteroids at the time of screening or within the preceding month
4. Unable to provide informed consent
5. Has a baseline perceived stress scale (PSS) score of <12 (PSS is a scale for measuring subjective stress. The maximum score is 40 and a score of 12/40 is the average score for a normal population)
6. Does not fulfil the inclusion criteria

Carers:
1. On corticosteroids at the time of screening or within the preceding month
2. Suffers from breathlessness
3. Has a baseline PSS<12
4. Unable to provide informed consent
5. Works regular night shifts
6. Does not fulfil the inclusion criteria

Date of first enrolment
11/03/2013

Date of final enrolment
31/01/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Palliative Care Team
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Government

Funder Name
NIHR (UK) - Doctoral Research Fellowship; Grant Codes: NIHR-DRF-2012-05-702

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No