

# 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

<b>Submission date</b> 25/04/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/04/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/05/2020	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Richella Ryan

**Contact details**  
Palliative Care Team  
Addenbrookes Hospital  
Hills Road  
Cambridge  
United Kingdom  
CB2 0QQ  
-  
rcr41@medschl.cam.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

ClinicalTrials.gov number

Secondary identifying numbers

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

### Secondary study design

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Treatment

**Participant information sheet**

**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 measure**

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

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

11/03/2013

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

UK Sample Size: 72; Description: The sample will consist of 36 patient-carer dyads, resulting in a total of 72 participants.

**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**

England

United Kingdom

**Study participating centre**

**Palliative Care Team**

Cambridge

United Kingdom

CB2 0QQ

## **Sponsor information**

**Organisation**

Cambridge University Hospitals NHS Foundation Trust (UK)

**Sponsor details**

Palliative Care Team

Addenbrookes Hospital

Hills Road

Cambridge

England

United Kingdom

CB2 0QQ

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.cuh.org.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

Publication and dissemination plan  
Not provided at time of registration

Intention to publish date

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?
<a href="#">HRA research summary</a>			28/06/2023	No	No