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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

Registration date
26/04/2013

Overall study status
Completed

Last Edited
29/05/2020

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
HRA research summary			28/06/2023	No	No