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Phase III randomised controlled trial of a breathlessness intervention service for intractable breathlessness

Submission date 30/10/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 18/12/2008	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 24/01/2022	**Condition category** Respiratory	[_] Individual participant data

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-a-service-for-people-who-have-problems-with-breathlessness

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00678405

Secondary identifying numbers
v2 09/09/08

Study information

Scientific Title
Phase III randomised controlled trial of a breathlessness intervention service for intractable breathlessness

Acronym
Phase III RCT BIS

Study objectives
The aim of this study is to evaluate the impact of the Breathlessness Intervention Service (BIS) on the quality of life of patients and families affected by intractable breathlessness. The questions to be addressed by the research are:
1. Is BIS more effective than standard care for patients with intractable breathlessness from advanced malignant or non-malignant disease?
2. Does it reduce patient and carer distress due to breathlessness, and increase patients' sense of mastery of the symptom?
3. What are the experiences and views of those who use BIS, their informal carers and the clinicians who refer to it?
4. Is BIS cost-effective?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 2 Research Ethics Committee, July 2008. Substantial amendment submitted in September 2008 and approved October 2008.

Study design

Randomised controlled phase III (MRC's framework for complex interventions) parallel-assignment single-blind (investigator) trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information material can be found at: http://www.cancerhelp.org.uk/trials/trials/trial.asp?=&trialno=15866

Health condition(s) or problem(s) studied
Intractable breathlessness, malignant and non-malignant conditions

Interventions
Active comparator:
Waiting list groups (malignant and non-malignant) - best supportive care (standard care). Standard care entails specialist outpatient appointments in secondary care (e.g. respiratory, cardiology, neurology or oncology), which may include specialist nurse input, and primary care services.

Experimental:
Fast-track (malignant and non-malignant) Breathlessness Intervention Service. The Breathlessness Intervention Service consists of a clinical specialist physiotherapist and palliative care consultant. It aims to manage the symptom of breathlessness in patients with any disease using a rehabilitative approach. Interventions include: evidence based non-pharmacological interventions (psychological, social and physical); palliative care input (e.g. end of life issues, psychosocial issues, family concerns) and pharmacological review. BIS seeks to enhance the self-management of breathlessness. The treatment is holistic in nature in that it is located in clinic or in patient's home as appropriate. Referrals come from medical specialists, GPs and allied health professionals.

The two broad disease courses, malignant and non-malignant, will be considered separately due to their different trajectories and needs, and resultant different service models. The intervention model for patients with non-malignant disease consists of two - three visits and three telephone contacts (to patient and/or primary care staff) over a four-week period with a 16 week (from first assessment) follow-up, whereas the model for patients with malignant disease consists of one visit in conjunction with a primary care professional/key worker and two telephone contacts (to patient and/or primary care staff/key worker) over a two-week period, with a six week (from first assessment) follow-up. Thus, the measurement points for the disease groups will differ.

Timepoints for non-malignant group:
Fast-track group: after baseline interview (t1), the fast-track group will receive BIS for four weeks. The next measurement (nmFTt2) will be conducted midway through the intervention (2 weeks post-commencing BIS), then again after discharge from BIS (nmFTt3) and finally 4 weeks after discharge from BIS (nmFTt5).
Waiting list group: after baseline interview (t1), the waiting list group will receive standard care for four weeks, then will receive the BIS intervention for another four weeks. Interviews will be held 2 weeks from entering the waiting list group (nmCCt2), prior to commencing BIS (nmCCt3), during BIS (two weeks post-commencing BIS; nmCCt4) and then again after discharge from BIS (four weeks post-commencing BIS (nmCCt5).

Timepoints for malignant group:
Fast-track group: after baseline interview (t1), the fast-track group will receive BIS for two weeks. The measures will be repeated after discharge from BIS (two weeks post-commencement of BIS; mFTt3) and then again two weeks after discharge (mFTt5).
Waiting list group: after baseline interview (t1), the waiting list group will receive standard care for two weeks, then will receive the BIS intervention for another two weeks. Measures will be repeated just prior to commencing BIS (mCCt3) and then again after discharge on from BIS (two weeks post-commencing BIS, mCCt5).

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Numerical Rating Scale (NRS) distress due to breathlessness.

Time Frame:
Malignant group: 2 weeks after baseline
Non-malignant group: 4 weeks after baseline

Secondary outcome measures
1. Modified Borg
2. NRS breathlessness at best/worst/average
3. Dyspnoea descriptors (patients only)
4. A wellbeing measure
5. Chronic Respiratory Questionnaire (CRQ - patients only)
6. EQ-5D (EuroQoL)
7. Hospital Anxiety Depression Scale
8. Client Service Receipt Inventory
9. Charlton Co-morbidity Index
10. Social functioning item
11. Karnofsky Performance Scale
12. Burden Interview and Caregiver appraisal scale (carer only)
13. Experience of breathlessness and expectations of/views/satisfaction with BIS (qualitative)

Time Frame:
Malignant group: 2 weeks after baseline
Non-malignant group: 4 weeks after baseline

Overall study start date
01/08/2008

Completion date
30/04/2011

Eligibility

Key inclusion criteria
For patients:
1. Appropriate referral to BIS
2. Aged 18 years or older, either sex
3. Any patient not meeting any exclusion criteria

For carers:
1. Informal carers (significant others, relatives, friends or neighbours) of phase III recruits
2. Aged 18 years or older, either sex
3. Any carer not meeting any exclusion criteria

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120 patients and their carers (60 per group)

Key exclusion criteria
Patients/carers:
1. Unable to give informed consent
2. Previously used BIS
3. Demented/confused
4. Learning difficulties
5. Other vulnerable groups for example head injury, severe trauma, mental illness
6. Not meeting all inclusion criteria

Date of first enrolment
01/08/2008

Date of final enrolment
30/04/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/research/research_index.html

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Government

Funder Name

National Institute for Health Research- Research for Patient Benefit (RfPB) programme (ref: PB-PG-0107-11134)

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
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/05/2011		Yes	No
Results article	results	31/10/2014		Yes	No
Results article	results	04/04/2016		Yes	No
Plain English results			24/01/2022	No	Yes