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Calming Hand And Fan Feasibility study

Submission date
20/09/2012

Recruitment status
No longer recruiting

Registration date
30/10/2012

Overall study status
Completed

Last Edited
23/01/2019

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Many people live with continuing distress and difficulties arising from breathlessness despite treatment given to the underlying disease which causes it. Exercise is known to be important and helpful for breathlessness. But, people with breathing difficulties are unwilling to exercise as any exertion triggers the breathlessness. Simple measures may be useful. Two options are the hand held battery operated fan designed to give cool airflow to the face, or the Calming hand, a simple breathing strategy that could help reduce anxiety that often occurs with breathlessness. Both are cheap, easy to use and portable providing something that the patient and their carer can use in any circumstances and may form part of a crisis self-management plan. But will such simple interventions provide relief and enable people who are breathless from exercise to recover faster and have more confidence in managing activity in their daily routine. The first stage, therefore, is a initial investigation called to see how we should set up such a study with regard to the following: Will patient participants and carers find the study we propose acceptable and practical? What number of participants and carers would we need to make a subsequent full scale study able to answer our research question and is it possible to recruit sufficient numbers?

Who can participate?
People with refractory breathlessness from any cause and their carer's will be eligible. The study aims to recruit 40 adult, male/female participants from the respiratory and oncology out-patient clinics, Castle Hill hospital, Cottingham, Hull.

What does the study involve?
There will be four different groups and you will be allocated to one of these by a process called "randomisation" like the toss of a coin. You will be given and taught how to use a hand held fan, or the Calming hand diagram and procedure, both of these, and/or instructed in the usual breathlessness care. You will be asked to walk up and down a corridor externally paced by an audio signal that gradually increases in pace, using a walking aid if normally required, until you feel your worst or maximal breathlessness tolerance from exercise. When you do not wish to continue walking, you will be instructed to sit down and use either the hand held fan and usual breathlessness care, or the Calming hand and usual breathlessness care, both the fan and the Calming hand and the usual breathlessness care, or the usual breathlessness care only. You will record your breathlessness scores before exercise, immediately after the exercise at maximal breathlessness and then every minute whilst sitting down during 10 minutes recovery. You will

be given the Numerical Rating Scale for scoring your breathlessness (a 0 10 scale where 0 = no breathlessness, 10 = worst possible breathlessness). You will have the scale explained to you before taking part and you will have help to practise using it.
Information leaflets about the hand held fan, the Calming hand or the usual breathlessness care, including guidance about exercise will be available for you to take home afterwards and you will be asked to continue using the treatments(s) and /or usual breathlessness care for the next 28 days, whenever you are feeling breathless from activity or anxiety. The study will last for 28 days and you will be followed up on Day 14 with a telephone call, and then with a second appointment on Day 28 in the Breathlessness Clinic or alternatively a home visit will be offered at your request. You will be asked to score your severity and distress from breathlessness at the start, on Day 14 via the telephone call, and again at the end of the study on Day 28. You will perform the walking test on Day 1 and Day 28 and score your breathlessness in relation to recovery from exercise. You will also be asked to complete some questionnaires at the start and the finish about how you feel you are coping with the breathlessness, and how the symptoms are affecting your quality of life and daily activities. Your carer will also be invited to take part in the study with your permission. If they agree they will be asked to complete some questionnaires at the start on Day 1, and at the end of the study on Day 28 about their quality of life and the strain they may experience in their role as the carer.

What are the possible benefits and risks of participating?
This study is aimed at determining if the use of simple options such as the hand held battery operated fan or the Calming hand have any benefit for the symptoms and consequences of breathlessness. There may be potential benefit for the participant and their family. However, this is a initial study and is not designed to specifically provide such benefit. It forms a vital and key stage to the development and design of a subsequent study which will provide benefit to future clinical decision making and care. This is a low risk study, and in previous studies and in clinical practice of over 7 years use in over 600 patients from one clinical centre of one study (Addenbrookes Hospital) there has not been one serious adverse reaction related to the use of the fan. This is in keeping with a device that is in widespread community use, available for unmonitored purchase by the lay population including many elderly people. There are no known risks or harm associated with or without the use of the "Calming hand".

Where is the study run from?
Castle Hill Hospital (UK)

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start in December 2012 and that the study will run for approximately 16 months.

Who is funding the study?
Hull York Medical School, Centre for Health and Population Studies (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R&D No: R1369

Study information

Scientific Title
Effectiveness of the "Calming Hand" and the hand held fan for the relief of refractory breathlessness from exercise in palliative patients and the self-efficacy of the interventions in a "ritual for crisis" plan for the patient and carer: a feasibility study using a 2x2 factorial randomised controlled trial design

Acronym
CHAFF

Study objectives
This is a feasibility study which intends to generate essential information for a larger scale study therefore a study hypothesis is not specified.

1. To test the feasibility of conducting an adequately powered large, multi-centre study comparing the effectiveness of the following treatments at relieving breathlessness from exercise:
1.1. Fan and usual breathlessness care
1.2. Calming hand and usual breathlessness care
1.3. Both, fan and Calming hand and usual breathlessness care
1.4. Usual breathlessness care only
2. To explore the feasibility of the study design in relation to:
2.1. Recruitment rates
2.2. Acceptability of study protocol to participants and carers

2.3. The views of participants and carers with regard to the use of the interventions and the most useful outcomes
2.4. The variability of the outcome measures

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & the Humber - Leeds East, 04/09/2012, ref: 12/YH/0410

Study design
2x2 factorial un-blinded single-site randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Breathlessness/palliative medicine

Interventions
1. Fan and usual breathlessness care
2. Calming hand and usual breathlessness care
3. Both, fan and Calming hand and usual breathlessness care
4. Usual breathlessness care only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
This is a pilot study that aims to establish feasibility, therefore the primary outcome is not specified or decided. The objective will be to assess the variability of the outcome measures (breathlessness intensity, distress and unpleasantness; activity; recovery time from breathlessness; self management; carer burden) to inform the choice of a primary end-point and to enable a sample size calculation for a subsequent larger future study.

At this stage the proposed primary outcome measure will be the Numerical Rating Scale (NRS) of breathlessness intensity.

Secondary outcome measures
This is a feasibility study therefore, the secondary outcome measures are also not specified or decided. The objective will be to assess the variability of these outcome measures to inform the choice for a larger future study.

Overall study start date
01/12/2012

Completion date
01/03/2015

Eligibility

Key inclusion criteria
1. Over 18
2. Able to provide verbal or written consent to take part in the study
3. Living in the community with or without a carer
4. Intractable breathlessness from all causes, for whom all reversible components of breathlessness have been addressed
5. Level 3 on the Medical Research Council (MRC) Dyspnoea scale
6. Have not used the hand held fan or "Calming hand" for breathlessness for 2 weeks
7. Willingness to engage with breathlessness training and study measures

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Too breathless to participate in study as assessed by the opinion of investigator and/or patient
2. Cognitively impaired and unable to understand the study
3. Trigeminal nerve damage/disease

Date of first enrolment
01/12/2012

Date of final enrolment

01/12/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Castle Hill Hospital
Hull
United Kingdom
HU16 5JQ

Sponsor information

Organisation
Hull and East Yorkshire (HEY) NHS Trust (UK)

Sponsor details
Castle Hill Hospital
Castle Road
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Sponsor type
Hospital/treatment centre

Website
http://www.hey.nhs.uk/content/corporate/default.aspx

ROR
https://ror.org/01b11x021

Funder(s)

Funder type

University/education

Funder Name
Hull York Medical School, Centre for Health and Population Studies (UK) - PhD Studentship

Results and Publications

Publication and dissemination plan
1. Intention to publish results from feasibility trial and the data from follow up participant interviews as a mixed method paper - now in preparation
2. Future dissemination plan - conference presentation to be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are available from Dr Flavia Swan (Flavia.Swan@hyms.ac.uk) on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/12/2017	23/01/2019	Yes	No