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Does an adapted cardiac rehabilitation programme delivered in a hospice for patients with advanced chronic heart failure have an impact on quality of life?

Submission date
22/04/2014

Recruitment status
No longer recruiting

Registration date
15/05/2014

Overall study status
Completed

Last Edited
29/11/2017

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic heart failure, where the heart is unable to pump enough blood around the body to meet requirements, can be a common problem especially in older people with other conditions. It is estimated a third of people diagnosed die within the first year. However, people are often not referred to specialist palliative care (specialists in end of life care). A collaboration between heart and end of life specialists has been found to have a positive impact on patients and carers. We are proposing to adapt a heart education and exercise programme for patients with advanced chronic heart failure, to be delivered in the day centre of a hospice. We want to see if this collaboration affects patients' quality of life, feelings of distress and choices made about the end of their life.

Who can participate?
Participants diagnosed with chronic heart failure and with a life expectancy greater than 10 weeks at the start of the programme.

What does the study involve?
The study involves you meeting with the researcher at your home to ask any questions you may have about the study and sign a consent form. Once this has been done, you will be asked to fill in three short questionnaires about you and your heart failure. This will take a maximum of 30 minutes. Once this is done, you and other heart failure patients will join start a programme for 2 hours a week for 8 weeks in the local hospice. A driver will come and collect you and take you home again. The programme will let you meet other heart failure patients and work through some exercises done in a chair that will help your joints move better and keep you circulation going. After the exercises, each week there will be a talk to you as a group about your heart failure and how to manage things for you at home. Once the 8 weeks have finished, the researcher will come and visit you at home again and you will be asked to fill in the same three questionnaires and then be asked about your views and opinions of the 8 week programme. This will end your involvement in the study.

What are the possible benefits and risks of participating?
We hope the study will help you meet people and gain support and knowledge about how to access information and services about end of life care when you or your family need them. The exercise programme will hopefully make daily activities more comfortable for you. The intervention does involve gentle seated exercises which may be uncomfortable. A participant can choose not to participate and the decision will be accepted. During the programme sessions, the participant may feel distressed by the nature of the topics. The sessions are delivered by specialist palliative care nurses who deal with this potential daily and will be able to offer support . During the interview, the participant may become upset while discussing the implications of the programme on their life and the progression of chronic heart failure. If this occurs, the interview will be stopped until the participant is ready to continue, or chooses to end the interview. With permission, any concerns may be passed on to the heart failure nurse specialist.

Where is the study run from?
Katharine House Hospice, Adderbury, Oxfordshire (UK)

When is the study starting and how long is it expected to run for?
April 2014 to December 2014.

Who is funding the study?
Oxford Brookes University (UK)

Who is the main contact?
Dr Helen Walthall

Contact information

Type(s)
Scientific

Contact name
Dr Helen Walthall

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Does an adapted cardiac rehabilitation programme delivered in a hospice for patients with advanced chronic heart failure have an impact on quality of life? A non-randomised study

Study objectives
The aim of this study is to inform the development of services provided by the Local Strategic Clinical Network for Heart Failure by examining benefits and drawbacks of an adapted cardiac rehabilitation programme delivered in a hospice environment for heart failure patients with advanced disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Berkshire B; 17/02/2014; ref. 14/SC/0006

Study design
Clinical trial of a novel intervention of an 8 week programme delivered in a single centre hospice to patients who have advanced chronic heart failure. There is no randomisation or blinding

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Advanced Chronic Heart Failure

Interventions
The measurements before and after the intervention are :
1. Minnesota Living with Heart Failure Questionnaire (Rector et al, 1993)
2. Emotion Thermometer (Gessler et al, 2008).
3. Foot in the door assessment tool (Stananought et al 2011).

Intervention:
It is an 8 week adapted cardiac rehabilitation programme for 2 hours per week delivered to a group of CHF patients in the day hospice. The first part of the intervention is an exercise programme that has been adapted to the profile of the patients undertaking the programme. It has been taken from the British Heart Foundation's DVD 'Active heart, healthy heart' which offers a progressive exercise regime for people who have a diagnosis incorporating heart failure. The programme on the DVD begins with a fully seated programme aimed at people who are diagnosed with heart failure and only includes the seated exercises. It is these exercises that are used in the intervention.

The second hour of the intervention includes education and support sessions which are relevant to the profile of the participants undertaking the programme. The 8 weekly structure will follow the outline below:
Sharing of information, advice and support in living with heart failure at the end of life, exploring topics such as breathing and relaxation techniques, nutrition advice, diversion and distraction, sleep and fatigue, incorporating energy conservation/lifestyle adjustment, medication review, advanced care planning and what this means (covering pacemakers and Implantable Cardiac Defibrillators) and who's who when you need help which includes a closer look at accessing hospice services.

After the intervention participants will be interviewed for their views and experiences of the intervention

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The primary quantitative outcome of the study are changes to in quality of life, emotional state and confidence in future planning.
2. The primary qualitative outcome measure is satisfaction of the 8 week adapted cardiac rehabilitation programme and the environment in which it was delivered.

The measures are taken at baseline and post intervention (Intervention is 8 weeks) so within 1 week of the completion of the intervention.

The measures are all questionnaires with likert scales.

Secondary outcome measures
Not provided at time of registration

Overall study start date
15/04/2014

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Diagnosed with Chronic Heart Failure and assessed as New York Heart Association (NYHA) class III/IV
2. Assessed as meeting Strategic Network's criteria defining End of Life by the Consultant Cardiologist (Heart Failure Lead) and community Heart Failure Nurse Specialist. The significant criteria for advanced disease, is that no further treatment options are available for the patient, and so treatment options are symptom management and palliative support.
3. Survival has been assessed as being greater than 10 weeks from the start of the programme by the Community Heart Failure Nurse Specialist who is the primary health professional carer.
4. Cognitively intact

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Unable to read (or have translated) English
2. Inability to undertake the level of exercise within the intervention

Date of first enrolment
15/04/2014

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford Brookes University
Oxford
United Kingdom
OX3 0FL

Sponsor information

Organisation
Oxford Brookes University (UK)

Sponsor details
c/o Mrs Hazel Abbott
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Sponsor type
University/education

ROR
https://ror.org/04v2twj65

Funder(s)

Funder type
University/education

Funder Name
Oxford Brookes University (UK)

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