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Cognitive therapy for pain in the chest

Submission date
04/03/2015

Recruitment status
No longer recruiting

Registration date
05/03/2015

Overall study status
Completed

Last Edited
05/07/2017

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Chest pain is one of the most common reasons for attending an Accident & Emergency Department. Heart conditions often present with chest pain and many sufferers require emergency treatment to save their life. Most people who experience pain in the chest do not have any serious illness, but because of the potential fatal consequence of untreated heart disease, they are encouraged by medical professionals and publicly displayed advertisements, to seek help. Unfortunately there are very few services to deal with psychological causes of chest pain. Such patients are often inadequately managed, receiving a combination of support and reassurance that may reinforce rather than resolve the problem. A modification of cognitive behaviour therapy for chest pain (CBT-CP) has been developed. It is administered mainly by trained general nurses and preliminary results have shown it to work well. The aim of this study is to test its value formally.

Who can participate?
Patients aged between 16 and 75 with significant chest pain for which no significant disease explaining the condition has been found.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention) are given between 4 and 10 sessions of CBT-CP treatment over a three month period. The treatment involves an initial assessment with a trained therapist followed by 3 to 9 further sessions of treatment each lasing about an hour, the number depending on the complexity and speed of response to treatment. Those in group 2 (control) are given the standard care offered by cardiology and other hospital clinics by general practitioners. Each patient is followed over a one year period and in which they undergo assessments of their anxiety levels, depression, amount of pain and discomfort experienced and general quality of life.

What are the possible benefits and risks of participating?
No adverse effects have been noted to date.

Where is the study run from?
Royal Berkshire Hospital, Kings Mill Hospital and the Hillingdon Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2012 to March 2016.

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
1. Mrs Sylvia Cooper (public)
s.cooper@imperial.ac.uk
2. Professor Peter Tyrer (scientific)
p.tyrer@imperial.ac.uk

Contact information

Type(s)
Public

Contact name
Mrs Sylvia Cooper

Contact details
Centre for Mental Health
Imperial College
7th Floor
Commonwealth Building
Hammersmith Hospital
London
United Kingdom
W12 0NN
+44 (0)207 386 1237
s.cooper@imperial.ac.uk

Type(s)
Scientific

Contact name
Dr Peter Tyrer

ORCID ID
http://orcid.org/0000-0002-0358-1459

Contact details
Centre for Mental Health
Imperial College
7th Floor
Commonwealth Building
Hammersmith Hospital
London
United Kingdom

W12 0NN
+44 (0)208 383 4161
p.tyrer@imperial.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11424

Study information

Scientific Title
Randomised controlled trial of modified cognitive behaviour therapy for non-cardiac chest pain

Acronym
COPIC

Study objectives
Does an adapted form of cognitive behaviour therapy for non-cardiac chest pain lead to reduced anxiety over health and lower health service costs than standard care over 6 months and one year.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands - Northampton, 22/11/2011, ref: 11/EM/0376

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied
Topic: Mental Health; Subtopic: Anxiety, Stress-related and somatoform; Disease: Anxiety, Stress-related and somatoform disorders

Interventions
Equal (randomised) allocation of patients to:
1. Cognitive behaviour therapy arm, in which between 4 and 10 sessions of treatment are given by a supervised trained therapist over a three month period
2. Standard care given in cardiology and other hospital clinics, and by general practitioners

Follow Up Length: 12 month(s)

Intervention Type
Behavioural

Primary outcome measure
Change in scores on the Health Anxiety Inventory between baseline assessment and 6 months

Secondary outcome measures
1. Change in scores on the Health Anxiety Inventory between baseline assessment and 12 months
2. Change in scores on the Lucock Health Anxiety Questionnaire-Chest Pain version between baseline assessment and 6 months
3. Visual analogue scales for pain and discomfort between baseline assessment and 6 months
4. Schedule for Evaluating Persistent Symptoms (SEPS) between baseline assessment and 6 months
5. Hospital Anxiety and Depression Scale - Anxiety and Depression components between baseline assessment and 6 months
6. Quality of life (EQ-5D) between baseline assessment and 6 months
7. Social functioning (SFQ) between baseline assessment and 6 months
8. Costs using the Adult Service Use Schedule (AD-SUS) between baseline assessment and 6 months

Overall study start date
10/07/2012

Completion date
31/03/2016

Eligibility

Key inclusion criteria
1. Significant chest pain on at least two separate occasions in the past year in which no significant pathology explaining the symptoms was found
2. Signed consent to take part in the study
3. Aged between 16 and 75

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 68; UK Sample Size: 68; Description: study team confirmed sample size is 120. 31/5/12Study team advised sample size 100. 12/7/12Study team advised 'the final total will be enough for research purposes as the drop-out rate is less than we originally expected.' 4/12/14

Key exclusion criteria
Patients who are:
1. Under active psychiatric care
2. Have had a new prescription of a psychoactive drug within the previous two months
3. Receiving, or on waiting list for, a psychological treatment. Those who are currently stable and on regular psychoactive medication (for more than 2 months) are eligible for the study.

Date of first enrolment
10/07/2012

Date of final enrolment
31/01/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
Kings Mill Hospital
Mansfield Road
Sutton-in-Ashfield

Nottinghamshire
United Kingdom
NG17 4JL

Study participating centre
The Hillingdon Hospital
Pield Heath Road
Uxbridge
United Kingdom
UB8 3NN

Sponsor information

Organisation
Imperial College of Science, Technology and Medicine

Sponsor details
Du Cane Road
London
England
United Kingdom
W12 0NN

Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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
Protocol paper in preparation to be submitted in September 2015. Main results to be published in both psychiatric and medical journals.

Intention to publish date
30/09/2015

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?
Protocol article	protocol	24/11/2015		Yes	No
Results article	results	16/05/2017		Yes	No