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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
https://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

### Protocol serial number
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

### Study type(s)
Treatment

### 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(s)
Change in scores on the Health Anxiety Inventory between baseline assessment and 6 months

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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**
United Kingdom

England

**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

**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

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