

# Treating affective disorders in patients with non-cardiac chest pain

<b>Submission date</b> 19/09/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 10/10/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/10/2015	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Non-cardiac chest pain is chest pain that resembles heart pain in patients who do not have heart disease. Most patients with non-cardiac chest pain experience anxiety and depressive symptoms. Commonly they receive reassurance and are referred back to primary care, leaving the psychiatric symptoms undiagnosed and untreated. A few small studies have suggested the effectiveness of 12 sessions of cognitive behavioral therapy (CBT), a talking therapy that can help you manage your problems by changing the way you think and behave. The aim of this study is to examine the effectiveness of a brief CBT treatment (six sessions) in reducing anxiety and depressive symptoms in patients with non-cardiac chest pain and panic and/or depressive disorders.

### Who can participate?

Patients aged 18 or older with non-cardiac chest pain and panic disorder and/or depressive disorder.

### What does the study involve?

Participants are randomly allocated to be treated with either brief cognitive behavioral therapy (CBT) or treatment as usual (TAU). CBT consists of a total of six 45-minute individual sessions and is tailored to the individual needs of the patients. Patients allocated to TAU are reassured by the cardiologist that their complaints were not caused by heart disease. TAU is tailored to the individual needs of the patients but does not include psychotherapy, including CBT, or antidepressants. At the start of the study and after 24 weeks the patients' anxiety and depressive symptoms are assessed using questionnaires.

### What are the possible benefits and risks of participating?

Participants receive either treatment as usual (no benefit, no risk) or a psychological treatment for their diagnosed psychiatric complaints (possible benefit when effective). No side effects are expected beforehand. After the study the general practitioner receives the psychiatric diagnosis and, when needed, subjects are referred for (follow up) psychiatric treatment (possible benefit).

### Where is the study run from?

VU University Medical Center, Amsterdam, the Netherlands.

When is the study starting and how long is it expected to run for?  
February 2001 to March 2003.

Who is funding the study?  
College voor Zorgverzekeringen/Doelmatigheidsproject00152, Amsterdam, Department of Psychiatry and EMGO Institute, VU University Medical Center, and GGZinGeest, Amsterdam, The Netherlands.

Who is the main contact?  
Dr Maria van Beek  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Anton van Balkom

**Contact details**  
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Netherlands  
1081 HL

## Additional identifiers

**Protocol serial number**  
Doelmatigheidsproject00152

## Study information

**Scientific Title**  
A brief cognitive-behavioural intervention for treating affective disorders in patients with non-cardiac chest pain: a 24-week randomized controlled trial

**Study objectives**  
After 24 weeks a brief CBT treatment (6 sessions) is more effective in reducing anxiety and depressive symptoms in patients with non-cardiac chest pain and comorbid panic and/or depressive disorders than treatment as usual.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
VU University Medical Center Ethical Review Committee, 24/01/2011, ref: TJFS/bz 2000-2338a

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Non-cardiac chest pain patients with a diagnosed panic and/or depressive disorder

**Interventions**

Patients randomized to TAU are reassured by the cardiologist that their complaints were not caused by cardiac disease. TAU is tailored to the individual needs of the patients. However, TAU does not include psychotherapy, including CBT, or antidepressants.

CBT consists of a total of six individual sessions with a duration of 45 minutes. The CBT protocol consists of a combination of psychoeducation, cognitive restructuring and influencing behavior, according to the basic concept of CBT that physical complaints can be cognitively mediated. The treatment is matched to the subject's diagnosis, so that, if needed, more attention is given to psychoeducation on the physical symptoms of anxiety or physical symptoms associated with depressed mood.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Disease severity with the Clinical Global Inventory (CGI) by a blinded independent rater.

**Key secondary outcome(s)**

Anxiety and depressive symptoms as assessed with the State-Trait Anxiety Inventory, the Fear Questionnaire, the Hospital Anxiety and Depression Scale and the Hamilton Depression Rating Scale. Furthermore, in the completer sample, at 24 weeks the assessor-rated Clinical Global Impression-Improvement Scale (CGI-Improvement) is administered.

**Completion date**

01/04/2003

**Eligibility****Key inclusion criteria**

1. All subjects aged 18 years or older who present themselves at the cardiac emergency unit of the VU University Medical Center with chest pain and are convinced they are experiencing a heart attack.
2. Full medical examination reveals no cardiopulmonary, gastrointestinal or endocrinal explanation for their complaints (and thus were diagnosed with 'non-cardiac chest pain')

3. Score 8 or higher on either or both subscales of the Hospital Anxiety and Depression Scale (HADS).
4. Meeting the DSM-IV criteria for panic disorder and/or depressive disorder
5. Providing signed informed consent after an oral and written explanation of the procedures and purpose of the study

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Those with insufficient knowledge of the Dutch language
2. Those who, in the month before screening, received systematic psychotherapy or used antidepressants. Benzodiazepine usage is allowed during the trial, up to a maximum of 50 mg of oxazepam or equivalent doses of other medications.

**Date of first enrolment**

01/02/2001

**Date of final enrolment**

01/04/2003

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

VUmc en GGZ inGeest

Amsterdam

Netherlands

1081 HL

**Sponsor information**

**Organisation**

VU University Medical Center (Netherlands)

**ROR**

<https://ror.org/00q6h8f30>

**Funder(s)****Funder type**

University/education

**Funder Name**

College voor Zorgverzekeringen (Netherlands)

**Alternative Name(s)**

Health Care Insurance Board, Netherlands, CVZ

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Netherlands

**Funder Name**

VU University Medical Center (Netherlands)

**Funder Name**

GGZinGeest (Netherlands)

**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?
<a href="#">Results article</a>	results	01/07/2013		Yes	No