ISRCTN67858971 https://doi.org/10.1186/ISRCTN67858971

Treating affective disorders in patients with non-cardiac chest pain

Submission date
19/09/2012

Recruitment status
No longer recruiting

Registration date
10/10/2012

Overall study status
Completed

Last Edited
29/10/2015

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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-minutes 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
M.H.C.vanBeek@psy.umcn.nl

Contact information

Type(s)
Scientific

Contact name
Prof Anton van Balkom

Contact details
VUmc en GGZ inGeest
A.J.Ernststraat 1187
Amsterdam
Netherlands
1081 HL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Secondary outcome measures
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.

Overall study start date
01/02/2001

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Sample size of 45 subjects per condition. Assuming a dropout rate of 30% (n=27), a total of 117 persons are to be included

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)

Sponsor details
Department of Psychiatry
EMGO Institute
A.J.Ernststraat 1187
Amsterdam
Netherlands
1081 HL

Sponsor type
Hospital/treatment centre

Website
http://www.ggzingeest.nl/zorg/

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

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?
Results article	results	01/07/2013		Yes	No