Finding the optimal treatment of severe panic symptoms in patients presenting at the emergency department with non-cardiac chest pain or palpitations. A cognitive behavioural therapy based intervention versus an information sheet. A randomized controlled trial.

Published: 27-05-2014
Last updated: 19-03-2025

The objective of our study is to examine the effectiveness of a cognitive behavioural therapy based intervention compared to an information leaflet on anxiety symptoms after one month, in patients presenting at the emergency unit with non-cardiac...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON41156

Source
ToetsingOnline

Brief title
Non Cardiac Chestpain or palpitations in the ER (NOCIE).

Condition

- Cardiac disorders, signs and symptoms NEC
- Anxiety disorders and symptoms

Synonym

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atypical chest pain, panic attack, unexplained chest pain

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chest Pain, Emergency service, Hospital, Panic

Outcome measures

Primary outcome

The main parameter is the (equality in the) decrease of the score on the anxiety part of the hospital depression and anxiety score (HADS-A).

Secondary outcome

Secondary outcome measures are the use of health care with the TIC-P questionnaire and the Global Cognitive Impression (CGI) scale. A cost minimisation calculation will be performed.

The economic evaluation reflects the time window between randomization and 30 days after primary ED visit. Costs of distributing a leaflet are compared with those of the single session CGT. The cost analysis will include all real costs for primary visit and visits of health care providers within 30 days. The cumulative costs during this period will be estimated according to registration of volumes and calculation of prices by the Dutch costing guidelines. Direct medical costs and non medical costs will be included in the analysis. All prices will be defined by the year 2014.

Study description

Background summary

Non cardiac chest pain (NCCP) is a common diagnosis among patients visiting an emergency department. In 50-90% of cases, patients presenting to the emergency department with a chief complaint of chest pain are diagnosed with non-cardiac chest pain (1, 2). After exclusion a cardiac cause of the symptoms, patients with chest pain are usually reassured and discharged from the emergency department. More than half of these patients continue to report chest pain and remain concerned about having a serious heart disease (3, 4) resulting in high medical care utilization (5). One of the causes or precipitating factors of NCCP may be an underlying psychiatric illness such as an anxiety disorder or mood disorder.
High prevalence rates of psychiatric symptoms have been reported in patients with chest pain or palpitations (6, 7, 8, 2, 9). These symptoms are most frequently caused by a panic disorder (PD). This can be due to the tendency of individuals with PD to focus on the physical symptoms, which they interpret as dangerous and needing immediate medical care. A panic disorder is rarely diagnosed after medical evaluation by emergency physicians (9, 6). Without timely treatment, PD tends to have a chronic course (10, 11), leading to repeated utilization of emergency departments (12, 13, 14), and high medical and societal costs (15). This highlights the importance of rapid intervention.
Few studies have described a cognitive behavioural intervention in this patient group. In Canada, a three-arm randomized controlled trial was performed among 58 NCCP patients presenting at the emergency department. Seven sessions of cognitive behavioural therapy (CBT) were compared to a short panic management intervention and treatment as usual (12, 16). The primary outcome was a reduction in panic symptoms. Both interventions led to greater improvements panic disorder severity compared to treatment as usual. There was no significant difference between the seven sessions CBT and the one-session management intervention.
In the Netherlands, a study compared six sessions of CBT with treatment as usual (to be reassured by their cardiologist that their complaints were not caused by cardiac disease). in 113 NCCP patients presenting at the cardiac emergency unit (17). The primary outcome measure was the clinical global inventory (CGI). They concluded that CBT was superior to treatment as usual. Similar results were reported in a study in the Unites States (18). Another study examined the effect of providing an information leaflet compared to standard verbal advice in a randomized clinical trial with 700 NCCP patients (19). Outcome measures were the HADS and SF-36. Providing the leaflet resulted in significant improvement in anxiety and depressive symptoms.
In summary, several interventions have proven to be effective for treating panic symptoms in patients with NCCP. The advantage of a leaflet over a short cognitive behavioural intervention is that it does not require any specialized

training or extra personnel and is less time consuming However no trial has compared the difference in efficacy of these two interventions. The objective of our study is to examine the effectiveness of CBT compared to providing an information leaflet on anxiety and depressive symptoms after four weeks in patients presenting at an emergency unit with non cardiac chest pain with comorbid panic symptoms.

Study objective

The objective of our study is to examine the effectiveness of a cognitive behavioural therapy based intervention compared to an information leaflet on anxiety symptoms after one month, in patients presenting at the emergency unit with non-cardiac chest pain.

Study design

This study is a single-center randomized clinical trial. All adult (>=18 years) patients presenting at the emergency department of the Onze Lieve Vrouwe Gasthuis with non-cardiac chest pain during a 3-month period (April 2014 to August 2014) are eligible to enrol. An emergency physician must have excluded clear somatic causes of the chest symptoms. All patients will complete a Hospital Anxiety and Depression Rating Scale (HADS) during consultation. This questionnaire will be administered as part of standard care. The nurse practitioner will be present and can be contacted by the patient during the stay at the ED for further information and help. The HADS is frequently used in consultation and liaison psychiatry in similar studies. Patients who score above the cut-off score of 8 in the anxiety part of the questionnaire will be eligible for the study.
Eligible patients will be asked to enroll and handed over the informed consent letter by their treating emergency physician. Participating patients are randomized with an off site computer program during their stay at the emergency room after written informed consent. Usual care has traditionally consisted of reassurance that the patient has no cardiac disease causing the chest pain and discharge to care as needed through the patient*s primary care physician (PCP). Because previous studies show significant effects of both our interventions [ref], we decided not to develop a control group with treatment as usual. Patients are randomised for either the leaflet group, or the cognitive based therapy intervention group. The patients who are randomised for the leaflet-group, receive the leaflet with an explanation of the treating nurse at the emergency room. Patients who are randomised for the cognitive therapy based intervention will be scheduled the next day for the cognitive based intervention within two weeks after their emergency visit. This intervention will be performed by one of the hospital psychologists within two weeks of the emergency room visit. All participating patients will be contacted by telephone the next weekday by one of the research assistants. During this phone call participants will be screened with a subset of the MINI. This is a short

diagnostic structured interview for classifying ICD-10 and DSM -IV psychiatric disorders. It focuses on current disorders and will be used to measure the prevalence of mood and anxiety disorders in this population. One month after the emergency department visit, an independent research assistant (not informed about randomisation, patient characteristics and previous score) will call all enrolled participants to collect data for the HADS-anxiety score, their health care use by the TIC-P and the clinical global inventory.

Intervention

3.1 Cognitive therapy based intervention
The cognitive therapy based intervention will consist of a single group session of one and a half hour within two weeks of presentation. This session consist of education on the relation of panic complaints and somatic symptoms and includes a short exposure exercise. The session is described in detail in attachment A

3.2 Leaflet
The information leaflet contains psycho-educational elements. It explains the pathway in which anxiety causes somatic symptoms: how this can mimic a heart attack and gives information about epidemiology, symptoms and treatment of a panic disorder. The content of this leaflet is based on a previous study (19), the Dutch guideline for panic disorder, the patient information folder of the Dutch Psychiatric Association and several informative websites (see attachment B).

Study burden and risks

Not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients are included if they present with chest pain or palpitations of possible cardiac origin, and have negative test results for acute coronary syndrome and have no life threatening non-cardiac disease (eg pnemothorax, pneumonia, or cardiac arrhythmia) or traumatic injuries (rib fracture). Other inclusion criteria are 18 years or older and scoring an 8 or higher on the HADS-A, being able to speak the Dutch language and being reachable by telephone. Patients can only be included once during the study period.

Exclusion criteria

Patients will be excluded from the study if they are already receiving psychiatric or psychological treatment, have current substance dependence or abuse, or suffer from psychosis or severe cognitive dysfunction. Patients who are not able to speak the Dutch language will also be excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-09-2014
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	27-05-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20389
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL48093.100.14
OMON	NL-OMON20389