Finding the optimal treatment of severe panic symptoms in patients presenting at the emergency department with non-cardiac chest pain or palpitations.

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The objective is to compare the reduction of panic symptoms and use of health care bewteen a single session cognitive behavioural therapy based intervention to providing an information leaflet directly at the ER, in patients suffering from non-...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20389

Bron
Nationaal Trial Register

Verkorte titel
NOCIE

Aandoening

Non cardiac chest pain. Niet cardiale pijn op de borst. Palpitations. Hartkloppingen. Anxiety disorder. Angststoornis. Panic disorder. Paniekstoornis. Panic attack. Paniekaanval.

Ondersteuning

Primaire sponsor: Performer: OLVG Hospital
Overige ondersteuning: No external funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: A large proportion of patients presenting with cardiac chest pain or palpitations at an emergency room are suffering form severe panic symptoms. Previous studies have shown that a single cognitive behavioural therapy session or an information sheet can reduce these symptoms. No study has compared these interventions directly
Objective: To compare the reduction of panic symptoms after one month of a single session cognitive behavioural therapy based intervention to providing an information leaflet directly at the ER, in patients suffering from non-cardiac chest pain with comorbid panic symptoms.

Study design: Single centre, single-blinded, randomized controlled trial

Study population: Patients older than18 years, presenting at the emergency department of the Onze Lieve Vrouwe Gasthuis in Amsterdam with acute chest pain or palpitations and have negative test results for acute coronary syndrome and have no life threatening non-cardiac disease.

Methods: Patients are included at the emergency room if they are likely to suffer from panic symptoms, by scoring an eight or higher at the HADS-anxiety score. After randomization, one group receives a single cognitive behavioural group session, developed for panic symptoms. The other group receives an information sheet about non-cardiac chest pain after assessment in the emergency room. The day after presentation, participants are interviewed with a MINI, CGI and HADS-A. Use of health care, CGI and HADS-A are evaluated after one month. A second HADS will be performed after two months.

Main study parameters/endpoints:
The reduction in panic symptoms measured by the anxiety score of the HADS after four weeks compared to baseline. Secondary outcome measures are the use of health care with the TIC-P questionnaire and the Global Cognitive Impression (CGI) scale.

Doel van het onderzoek

The objective is to compare the reduction of panic symptoms and use of health care bewteen a single session cognitive behavioural therapy based intervention to providing an information leaflet directly at the ER, in patients suffering from non-cardiac chest pain with comorbid

panic symptoms.

Onderzoeksopzet

Inclusion will start at the emergency department where they will as described in the study design. All patients are called the next day by one of the research assistants for the subset of the MINI, which 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 psychiatric disorders in this population. Is will also filter out the seriously ill patients who need immediate psychiatric treatment. If necessary, they will be leaded to care as is usual in our region. One month after the intervention, a second, blinded research assistant will call all enrolled participants to obtain the second HADS-anxiety score, the TIC-P questionnaire and the Global Cognitive Impression (CGI) scale. After two months a third HADS-A will be obtained by a short telephone interview

Onderzoeksproduct en/of interventie

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 information leaflet contains psycho-educational elements about non-cardiac chest pain. It explains the pathway in which anxiety causes somatic symptoms and how this can mimic a heart attack. Is also gives information about epidemiology, symptoms and treatment of panic symptoms.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 an age of 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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. Substance abuse can cause panic-like symptoms on a physical level. Psychological treatment might interfere with our test results.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	100

Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-10-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41156
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4778
NTR-old	NTR4917
CCMO	NL48093.100.14
OMON	NL-OMON41156

Resultaten

Samenvatting resultaten
None