Transmural Collaborative Care: Depression and Anxiety disorders with concomitant physical symptoms.

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

Samenvatting

ID

NL-OMON23655

Bron
Nationaal Trial Register

Verkorte titel
TCC:DAPS

Aandoening

Physical symptoms, major depressive disorder, generalized anxiety disorder, panic disorder. Lichamelijke klachten, depressie, gegeneraliseerde angststoornis, paniekstoornis.

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Baseline measurements:
The PHQ9, the GAD7 and the LKV. The Mini International Neuropsychiatric Interview (MINI) for classification of symptoms.
Primary outcome measure is reduction of physical symptoms as measured by the LKV, as this is considered crucial to attain improvement on the concomitant common mental disorder as well.
The CBS questionnaire will be used to distinguish between medically explained and medically unexplained physical symptoms.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Concomitant physical symptoms frequently complicate the treatment of common mental disorders. The objective of this study is to investigate effects and costs of a Transmural Collaborative stepped Care model with Consultation Letter (TCCCL) to the General Practitioner (GP), versus Care As Usual (CAU), for patients with concomitant physical symptoms in Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD) and Panic Disorder (PD) who are referred by GPs to the mental health outpatient clinic.

Methods/design:

Study design: Two armed cluster randomized controlled trial with randomization between referring GP practices. Follow up at 3, 6, 9 and 12 months.

Study population: Patients referred to the mental health outpatient clinic who at baseline screening fulfil criteria for 5 or more concomitant physical symptoms in MDD/GAD/PD.

Intervention:

The TCCCL model combines several modules that were proven effective separately in patients with physical symptoms and in patients with MDD/GAD/PD, in a stepped care model:

1. Cognitive Behavioural Treatment (CBT) with self help manual for physical symptoms;

2. Problem Solving Treatment (PST) for MDD/GAD/PD;

3. Graded activity guided by a physiotherapist;

4. Antidepressant medication;

5. Consultation Letter with diagnosis and treatment advice to the GP.

Sample size calculation/data analysis:

In order to be able to detect a clinical relevant difference of 1/2 SD with the CAU on the continuous measure of the 'Lichamelijke Klachten Vragenlijst' (LKV), considering that we want to perform multilevel analysis and estimating 30% loss to follow up, we must include 2 x 87 patients to attain 2 x 67 completers (alpha 0,5; power 0,90). Multilevel analysis will be performed with the GPs in the first and the patient outcomes in the second hierarchical level. Intention to treat analysis will be performed with multilevel analysis and imputation for missing data.

Outcome measures:

Primary outcome measure is reduction of physical symptoms as measured in the LKV and MDD/GAD/PD symptoms as measured in the PHQ9 and GAD7.

Economic evaluation:

The aim of this economic evaluation is to assess the cost effectiveness of TCCCL in a transmural model of treatment in mental health outpatient clinic and primary care of MDD, GAD or PD with 5 or more concomitant physical symptoms. The economic evaluation will be undertaken from a societal perspective. Hence, all relevant effects and costs due to resource

utilisation within the healthcare (direct medical costs) and costs due to production losses (productivity costs) will be included.

Time schedule:

Preparation: 6 months. Inclusion and intervention phase: 24 months. Follow up: 12 months. Data analysis and writing: 6 months. The study will last 4 years.

Discussion:

In this study, the transmural collaborative stepped care intervention for MDD/GAD/PD with concomitant physical symptoms will be evaluated for (cost-)effectiveness in comparison with care as usual. Patients start treatment in the mental health outpatient setting, and receive good follow up when they are referred back to the GP care, with a consultation letter, in the primary care setting. Results of this study will contribute to treatment options for a complex group of patients. Results are expected in 2015. We hypothesize that the transmural collaborative stepped care intervention will be more cost-effective than care as usual.

Doel van het onderzoek

Concomitant physical symptoms frequently complicate the treatment of common mental disorders. The objective of this study is to investigate effects and costs of a Transmural Collaborative stepped Care model with Consultation Letter (TCCCL) to the General Practitioner (GP), versus Care As Usual (CAU), for patients with concomitant physical symptoms in Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD) and Panic Disorder (PD) who are referred by GPs to the mental health outpatient clinic. We hypothesize that the transmural collaborative stepped care intervention will be more cost-effective than care as usual.

Onderzoeksopzet

Baseline measurements take place before inclusion (T0), follow up at 3 months (T1), 6 months (T2), 9 months (T3) and 12 months (T4).

Onderzoeksproduct en/of interventie

The TCCCL model combines several modules that were proven effective separately in patients with physical symptoms and in patients with MDD/GAD/PD, in a stepped care model:

1. Cognitive Behavioural Treatment (CBT) with self help manual for physical symptoms;

2. Problem Solving Treatment (PST) for MDD/GAD/PD;

3. Graded activity guided by a physiotherapist;

4. Antidepressant medication;

5. Consultation Letter with diagnosis and treatment advice to the GP.

Patients will visit the mental health outpatient clinic twice a week and the physiotherapist once a week. Each visit will last a half hour up to an hour. The minimal duration of the treatment is 6 weeks, the maximal duration is 24 weeks.

Controls will receive care as usual.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

Of the referred patients, all patients that present with both five physical symptoms and a common mental disorder, namely MDD, GAD or PD, are eligible for the study. MDD is operationalized as a score of 10 or more on the Patients Health Questionnaire depression subscale (PHQ9) on the ROM; GAD and PD are operationalized as a score of 10 or more on the GAD7, and we speak of increased physical symptoms when the patient reports five or more physical symptoms on a validated self-report questionnaire (Physical Symptoms Questionnaire, in Dutch 'Lichamelijke Klachten Vragenlijst'; LKV) as that number of symptoms was found to be associated with poor functioning by Escobar e.a. The diagnosis of MDD, GAD or PD should be confirmed in the clinical interview that follows the ROM. If the diagnosis is not confirmed in the clinical interview, but the patient does have a score of 10 or more on the PHQ9 or GAD7, the patient will also be included. The data of these patients will form a subgroup in the analysis. All the described patients are asked informed consent and if they agree, are enrolled in the study. Although women suffer from (medically unexplained) physical symptoms, MDD and anxiety disorders more often than men, both sexes will be sufficiently represented in the sample to consider gender as a variable in the analysis. The same holds for age and cultural background.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients are excluded from the study if they are less than 18 years old, have insufficient knowledge of Dutch to fill in the questionnaires, or are suicidal, psychotic or suffering from dementia.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-10-2011
Aantal proefpersonen:	174
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	12-08-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35190
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2878
NTR-old	NTR3023
CCMO	NL37505.097.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35190

Resultaten

Samenvatting resultaten
N/A