Transmural Collaborative Care: Depression and Anxiety Disorders with concomitant physical symptoms

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To compare transmurale collaborative stepped care with care as usual for patients with a depression or anxiety disorder with five or more concomitant physical symptoms.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35190

Source
ToetsingOnline

Brief title
TCC: DAPS

Condition

- Other condition
- Somatic symptom and related disorders

Synonym
depression and anxiety symptoms, Physical symptoms

Health condition

Depressie, gegeneraliseerde angststoornis, paniekstoornis

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Breburg Groep (Rijen)
Source(s) of monetary or material Support: GGz Breburg

Intervention

Keyword: Anxiety Disorder, Collaborative Care, Depression, Physical symptoms

Outcome measures

Primary outcome

PHQ-9, GAD-7 and the Dutch version of the Physical Symptoms Questionnaire, in

Dutch *Lichamelijke Klachten Vragenlijst* (LKV).

Secondary outcome

Short Form 36 Health Survey (SF36), EuroQol-D5 (EQ-D5), Nederlandse versie van

de Coping Inventory for Stressful Situations (CISS-NL), Patient-Doctor

Relationship Questionnaire (PDRQ9), Brief Pain Inventory (BPI), Scale for

Medical Utilisation of Health Services, CBS-vragenlijst and Trimbos/iMTA

questionnaire for Costs associated with Psychiatric Illness (TiC-P).

Study description

Background summary

Concomitant physical symptoms frequently complicate the treatment of common mental disorders. At this time, usual care for this highly prevalent patient group is insufficient. 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, versus care as usual, for patients with concomitant physical symptoms in Major Depressive Disorder, Generalized Anxiety Disorder and Panic Disorder who are referred by general practitioners to the mental health outpatient clinic. Patients start treatment in the mental health outpatient setting, and receive good follow up when they are referred back to the general practitioner 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.

Study objective

To compare transmurale collaborative stepped care with care as usual for patients with a depression or anxiety disorder with five or more concomitant physical symptoms.

Study design

Two armed randomized clinical trial.

Intervention

Patients in the intervention-arm will receive care following a collaborative stepped care protocol with Problem Solving Treatment, en selfhelp manual guided by a psychologist, graded activity excerices guided by a physiotherapist, medication and reverral back to the general practitioner with a consultation letter that contains instructions for futher guidance.
The control group will receive care as usual.

Study burden and risks

Both groups (intervention and care as usual) will receive evidence based treatment, so there is no risk in participation.

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

A score of >= 10 on the Patients Health Questionnaire-9 (PHQ-9) and >= 5 physical symptoms,
or:
A score of >= 10 on the Generalised Anxiety Disorder Assessment (GAD-7) and >= 5 physical symptoms

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-10-2011
Enrollment:	174
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-01-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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: 23655
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL37505.097.11
OMON	NL-OMON23655