

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Other condition
<b>Study type</b>	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 exercises guided by a physiotherapist, medication and referral back to the general practitioner with a consultation letter that contains instructions for further 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**

### **Public**

GGZ Breburg Groep (Rijen)

Lage Witsiebaan 4  
5042DA Tilburg  
NL

### **Scientific**

GGZ Breburg Groep (Rijen)

Lage Witsiebaan 4  
5042DA Tilburg  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

A score of  $\geq 10$  on the Patients Health Questionnaire-9 (PHQ-9) and  $\geq 5$  physical symptoms,

or:

A score of  $\geq 10$  on the Generalised Anxiety Disorder Assessment (GAD-7) and  $\geq 5$  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: NTR  
Title:

### In other registers

Register	ID
CCMO	NL37505.097.11
OMON	NL-OMON23655