Collaborative Care in the Treatment of Depressive Disorder Containing an Antidepressant Algorithm and PST; a Multicentre Cluster Randomized Trial in Primary Care

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric disorders
Study type	Interventional

Summary

ID

NL-OMON29861

Source
ToetsingOnline

Brief title
CC:DIP

Condition

- Psychiatric disorders

Synonym
Depression, Major Depressive Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: RVVZ (Reserves Voormalige Vrijwillige Ziekenfonds Verzekeringen)

Intervention

Keyword: Collaborative care, Major Depressive Disorder, Primary Care, PST

Outcome measures

Primary outcome

Reduction of depressive symptoms remission.

The severity of the symptoms is measured by the Inventory for Depressive Symptomatology-Self Report (IDS-SR) and the Patient Health Questionnaire depression subscale (PHQ9). The IDS-SR can be used for a global assessment of depressive symptoms. The instrument consists of 30 questions on a *0-3 scale*. The PHQ9 is a brief but valid instrument that scores each of the DSM-IV criteria from *0* (not at all) to *3* (nearly every day).

Remission -reduction of DSM-IV criteria below threshold for a depressive disorder diagnosis [ref APA]- is measured by the MINI interview at the end of the intervention period (T1) and 12 months (T3), and with the PHQ9 -cut-off score below 15-.

Secondary outcome

Cost utility, next to the improvement of severity of symptoms, the cost utility of collaborative care compared to CAU is assessed in this design. Therefore, an estimation of the direct medical costs and the costs due to production losses (productivity costs) is made. Data for estimating the costs are collected by using the Trimbos/iMTA questionnaire for Costs associated with Psychiatric

Illness (TiC-P). Quality of life is assessed by using the EQ-5D and the SF-36, which are validated tools for measuring general health*related quality of life.

The cost utility is evaluated by relating the difference in direct medical costs per patient receiving collaborative care or CAU to the difference in terms of Quality Adjusted Life Years gained (QALY), which yields a cost per QALY estimate. Furthermore, we also estimate the cost per QALY including the productivity costs.

*Additional outcome measures and effectmodifcators:

1. Physical illness, as measured by the CBS-list, a questionnaire by the Central Bureau of Statistics (CBS) in the Netherlands containing 28 chronic conditions ranging from diabetes type II to Multiple Sclerosis.
2. Disability caused by the disorder, evaluated with the World Health Organization Disability Assessment Survey II (WHO-DAS-II). WHO-DAS-II is developed to assess the activity limitations and participation restrictions actually experienced by an individual, irrespective of diagnosis. It has six major domains: understanding and communicating with the world, moving and getting around, self-care, getting along with people, life activities, and participation in society. The instrument consists of 32 questions.
3. Adherence and compliance, assessed by the number of drop outs in the intervention group compared to the CAU group.

Possible preferences of the patient, assessed by the choices of patients within the intervention group.

4. Attitude of the GP towards the treatment of depressive disorder, measured with the Depression Attitude Questionnaire (DAQ).

5. The patient-doctor working relationship, measuring this variable The Patient Doctor Relationship Questionnaire (PDRQ-9) is included.

6. Treatment in the CAU group, assessed in patients and GPs with the Scale Assessing Medical Utilization of Health Services.

7. Somatisation, the number and intensity of functional somatic complaints a patient is experiencing is assessed with the LKV (Lichamelijke Klachten Vragenlijst; Bodily Complaints Questionnaire). The LKV consists of 55 functional somatic complaints, ranging from headaches to fatigue on a scale from *0 tot 3*.

8. Somatosensory amplification, the Whitely Index is the first questionnaire specifically designed to assess hypochondriasis. It is also used for this purpose in this study. The Whitely Index consists of 14 yes/no questions.

9. Life-events, to assess whether or not life-events can be seen as an effectmodifier in this study, the Social Readjustment Rating Scale is also included. The Social Readjustment Rating Scale consists of items that indicate the amount of change in daily life; for example marriage scores 50 points on the list. Taken together these items form the *Life change unit* that can be used to quantify the stress of life-events, independently of the desirability of those life-events.

10. Personality, is measured with the NEO-FFI. This is the short version of the

NEO, measuring the big five personality traits. It consists of 60 items on a five point likert scale. There has been a debate whether or not the NEO remains a valid instrument if someone is suffering from major depressive disorder, but in a study by Duggan et al. (1995) current depressive symptoms did not explain all the group differences in neuroticism after the effect of depression (measured by the BDI) was partialled out. Therefore personality traits (to be more specific neuroticism and introversion) are included in this study as possible effectmodifiers.

11. Social support, will be assessed with the SOS (Social Support Scale, Dutch version) This instrument consists of five items that measure the extent of social support a patient receives.

Study description

Background summary

Depressive disorder is today one of the two most common national disorders. Evidence-based treatments of depressive disorder are already available, but are used insufficiently and with less results than possible. Prior research in the USA has shown good results in the treatment of depressive disorder by using a collaborative care approach and an antidepressant algorithm, and prior research in the UK has shown good results with Problem Solving Treatment (PST). These treatment strategies may very well also work in the Netherlands, even though health care systems in these countries show differences.

Study objective

The primary aim of the study is to test the effectiveness of a collaborative care model for major depressive disorder in primary care. Secondary aims are 1) to test whether the effects are generic for patients with or without chronic physical illness and 2) the cost-effectiveness of each treatment involved.

Study design

The study comprises a two armed cluster-randomized clinical trial, with randomization between general practitioner (GP) practices. The aim of the trial is an evaluation of the treatment of depressive disorder in primary care in the Netherlands by means of a collaborative care model including contracting, compliance and adherence improving strategies, PST and an antidepressant algorithm. 40 GP practices will be randomized between the intervention group or control group, the control group performing Care as Usual (CAU). Patients are then included who are diagnosed with moderate to severe depression based on DSM-IV criteria. The intervention group receives treatment based on the collaborative care approach, the control group receives CAU. Baseline measures and follow up measures (3, 6 and 12 months) are done by means of questionnaires. Primary outcome measure is the reduction of depressive symptoms as measured with de IDS-SR. The Secondary outcome measure is the cost-effectiveness as measured with the TIC-P. Adherence and compliance, (possible) preferences of the patient, attitude towards treatment options of the GP, effects of life events, patient satisfaction and the Patient-Doctor Relationship Questionnaire (PDRQ-9) are additional outcome measures.

Intervention

A collaborative care framework is used with the following elements:

-Problem Solving Treatment (PST)
-An antidepressant Algorithm
-Contracting
-Techniques enhancing adherence and complience
-Casemanagement

Study burden and risks

We believe there are no special risks related to the study. No physiological parameters will be assessed. The patients in the control group receive care as usual. The intervention group will receive only evidence-based forms of treatment. These forms of treatment have been implemented within a collaborative care framework with good results abroad.

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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 15 or higher on the PHQ9, a short questionnaire that screens for Major Depressive Episode. The symptoms have to be present for at least six weeks, or have to cause marked dysfunctioning (for instance problems at work or sleeping problems).

Exclusion criteria

Patients with high suicidal risk, those currently experiencing a psychotic episode, those who have dementia or those who are addicted to alcohol or narcotics are excluded from the study (they are however referred to the general practitioner in case of high suicide risk or a suggestion is given for another form of help).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2007
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL13756.029.06