Cost-effectiveness of collaborative care for chronic medically ill patients with comorbid depressive disorder in the general hospital setting

Published: 21-12-2006
Last updated: 20-05-2024

The primary aim of the study is to test the effectiveness of a collaborative care model for major depressive disorder for patients with DM, CVD, COPD, and HIV in the general hospital outpatient setting. Secondary aim is to estimate the cost-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON33947

Source
ToetsingOnline

Brief title
CC: DIM

Condition

- Mood disorders and disturbances NEC

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) en het Onze Lieve Vrouwe Gasthuis (OLVG).

Intervention

Keyword: Collaborative Care, General Hospital, Major Depressive Disorder, Problem Solving Treatment

Outcome measures

Primary outcome

Primary outcome measure is remission of depressive symptoms (i.e. reduction of DSM-IV criteria below threshold for a depressive disorder diagnosis) as measured by the Dutch version of the depression subscale of the *Patient Health Questionnaire* (PHQ-9). The PHQ-9 is a brief but valid instrument that scores each DSM-IV criterion of a major depressive disorder.

Secondary outcome

As secondary outcome measure, the cost-utility of collaborative care compared to CAU is assessed in this study. Therefore, an estimation of the direct medical costs and the costs due to production losses (productivity costs) is made. To estimate the costs, the *Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness* (TiC-P) is used. Quality of life is assessed by the the *EuroQol* (EQ-5D) and the *Medical Outcomes Study Short Form Health Survey - 36* (SF-36).

Additional outcome measures and effect modifiers:

-Physical illness is measured by the CBS-list, a questionnaire by the Central Bureau for Statistics (CBS) in the Netherlands. The CBS-list contains 28 chronic conditions ranging from diabetes type II to multiple sclerosis.

-Disability caused by disorder is evaluated with the *World Health Organization-Disability Assessment Survey-II* (WHO-DAS-II). The WHO-DAS-II is developed to assess the limitations in activity and participation restrictions actually experienced by an individual irrespective of diagnosis and contains six major domains: understanding and communicating, getting around, self-care, getting along with people, life activities, and participation in society.

-Depressive symptoms is measured by the Inventory for Depressive Symptomatology-Self Report (IDS-SR).

-Patient and provider adherence is assessed by a qualitative questionnaire.

-Adverse effects of medication are measured with the 'Discontinuation Emergent Signs and Symptoms' checklist (DESS).

-Preferences of the patient (PST and/or antidepressant medication) are assessed by the choices of patients within the intervention group.

-Attitude of the medical specialists and nurses towards the treatment of depressive disorder is measured with the 'Depression Attitude Questionnaire' (DAQ).

-Somatisation is assessed as the number and intensity of functional somatic complaints a patient experiences by using the *Lichamelijke Klachten Vragenlijst* (LKV; Bodily Complaints Questionnaire).

-Hypochondria is measured by the *Whitley Index*.

-Health anxiety and illness behaviour is measured with the Illness Attitude Scale (IAS).

-Comorbid somatoform disorder is measured by the SOMS-7.

-The working relationship between the patient and the care manager is measured

by the *Helping Alliance Questionnaire* (HAQ-II) as the care manager will provide PST.

-Treatment in the CAU group is assessed in patients, general practitioners, and other treating physicians with the *Scale assessing medical utilization of health services*. Given that this trial is considered an effectiveness trial, the content of usual care is not known yet. It is expected however, that a lot of variation will be seen concerning treatment of the usual care group.

-Life-events are assessed by the *Social Readjustment Rating Scale* to indicate the amount of change in daily life, which form the *Life Change Unit* (LCU). These can be used to quantify the stress of life-events irrespective of the desirability of those events.

-Pain is measured by the *McGill Pain Questionnaire - Dutch Language Version* (MPQ-DLV).

-Fatigue is assessed by the Dutch version of the *Multidimensional Fatigue Inventory* (*Multidimensionele Vermoeidheids Index*).

-Personality traits are measured by two scales of the *NEO Five-Factor Inventory* (NEO-FFI), the abbreviated version of the NEO personality inventory which measures the big five personality traits: extraversion, openness, agreeableness, conscientiousness, and neuroticism. In this study, only neuroticism and extraversion scales are used.

- The 'Preceived need for care' will be used to assess the perceived need for care of diabetes patients in the OLVG.

-

Study description

Background summary

Depressive disorder is one of the two most common disorders and is even more prevalent in chronic medically ill patients. The presence of comorbid depression has a negative influence on quality of life, costs, morbidity, and mortality of chronic medically ill patients. However, early diagnosis with subsequent well-organized treatments of depression showed to have a positive influence on these aspects. Evidence-based treatments of depressive disorder are already available, but are used insufficiently and with less result than possible. In the general hospital setting, recognition and treatment remains unsatisfactory. Prior research in the US has shown good results regarding the treatment of depressive disorder using a collaborative care approach and an antidepressant algorithm. In the UK *Problem Solving Treatment* has proved to be feasible to use. However, in the general hospital setting, this approach has not yet been evaluated. These treatment strategies may also be effective in the Netherlands even though the health care systems differ.

Study objective

The primary aim of the study is to test the effectiveness of a collaborative care model for major depressive disorder for patients with DM, CVD, COPD, and HIV in the general hospital outpatient setting. Secondary aim is to estimate the cost-effectiveness of each treatment involved.

Study design

The study consists of a two-armed randomized clinical trial, with randomization between patients. The aim of the trial is an evaluation of the treatment of depressive disorder in the general hospital setting in the Netherlands by means of a collaborative care model including contracting, PST, an antidepressant algorithm, een zelfhulp werkboek voor depressie bij chronisch zieke patienten, and compliance and adherence improving strategies. 126 outpatients will be randomised between the intervention group and control group. Patients are included who are diagnosed with moderate to severe depression based on DSM-IV criteria and measured by the M.I.N.I. The intervention group receives treatment based on the collaborative care approach; the control group receives *Care As Usual* (CAU). Baseline measures and follow up measures (after 3, 6, 9, and 12 months) are done by means of questionnaires.
Primary outcome measure is the severity of depressive symptoms as measured with the PHQ-9. Secondary outcome measure is the cost-utility as measured with the TiQ-P, the EQ-5D and the SF-36. Further outcome measures are remission of depressive symptoms, pain, patient and provider adherence, (possible) preferences of the patient, fatigue, somatisation, hypochondrias, effects of

life events, patient satisfaction, and the working relationship between the care manager and the patient.

Intervention

A treatment of depression fit in the collaborative care model with problem solving treatment, an antidepressant algorithm, contracting, care management, and a manual guided self-help depression for chronically ill patients.

Study burden and risks

The expected risk are very little. No physiological parameters will be assessed. The control group receives care as usual. The intervention group receives only evidence-based treatment techniques. We expect that these are a supplement to care as usual. Furthermore, good results are found using the collaborative care model abroad.

Contacts

Public
Trimbos-instituut

AJ Ernststraat 887
1081 HL Amsterdam
NL
Scientific
Trimbos-instituut

AJ Ernststraat 887
1081 HL Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients of the OLVG visiting the participating outpatient clinics (diabetes, cardiology, HIV, and part of lung medicine [patients with chronic obstructive pulmonary disease (COPD)]) and who already have a diagnosis specified in their file. Patients are included in the study if a cut off score of 15 (moderate to severe depressive disorder) is reached on the PHQ-9. The symptoms have to be present for at least six weeks or have to cause marked dysfunctioning (e.g. problems at work, housekeeping).

Exclusion criteria

-Suicidal (in case of a high risk for suicide, patients will be referred.);(Concerning the following criteria a suggestion is given to the patients concerning a different kind of help:)
-Psychotic
-Suffering from dementia or delirium
-Insufficient knowledge of the Dutch language to fill in questionnaires
-Serious mental impairment
-Alcohol or drug addiction
-Already receiving psychiatric treatment
-Pregnancy
-Bipolar disorder;Concerning HIV patients:
-Organic psychosyndrome
-Personality change
-In terminal phase

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2007
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	21-12-2006
Application type:	First submission
Review commission:	METC Onze Lieve Vrouwe Gasthuis (Amsterdam)
Approved WMO Date:	17-04-2008
Application type:	Amendment
Review commission:	METC Onze Lieve Vrouwe Gasthuis (Amsterdam)
Approved WMO Date:	30-10-2008
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-02-2009
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-06-2009
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ISRCTN	ISRCTN95575369
CCMO	NL13965.067.06