

Cost-effectiveness of a stepped-care program for depression among primary care patients with type 2 diabetes mellitus and/or coronary heart disease and subthreshold depression.

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To evaluate the cost-effectiveness of a nurse-led stepped-care program for depression among primary care patients with type 2 diabetes mellitus and/or coronary heart disease and subthreshold depression in comparison with usual care.

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

Summary

ID

NL-OMON39877

Source

ToetsingOnline

Brief title

Step-Dep

Condition

- Mood disorders and disturbances NEC

Synonym

depressive complaints, subthreshold depressive disorder

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Cost- effectiveness, Depression, Primary care, Stepped-care

Outcome measures

Primary outcome

The cumulative incidence of depression after 12 months according to an independent Mini International Neuropsychiatric Interview (MINI)

Severity of depression symptoms

Quality of life

Secondary outcome

HbA1C

bloodpressure

LDL cholesterol

Study description

Background summary

Co-morbid depressive symptoms constitute a significant health problem among patients with type 2 diabetes mellitus (DM2) and/or coronary heart disease (CHD). Depressive symptoms increase the risk for major depression and are associated with poor compliance to treatment, adverse health outcomes and lower overall quality of life. Prevention of the development of major depression in high risk patients is expected to reduce the burden of depression for individuals and society.

Study objective

To evaluate the cost-effectiveness of a nurse-led stepped-care program for

depression among primary care patients with type 2 diabetes mellitus and/or coronary heart disease and subthreshold depression in comparison with usual care.

Study design

Economic evaluation alongside a cluster randomized trial.

Intervention

The stepped-care program with a central role for patients consists of sequentially watchful waiting, bibliotherapy, problem solving treatment (PST), medication and referral to secondary care/psychiatrist if necessary.

Study burden and risks

Participating in this study will mean that patients have to fill in web-based questionnaires at baseline and at 3, 6, 9 and 12 months. Patients in the experimental condition will be offered a maximum of four sequential evidence based treatment steps. Patients in the control condition will be offered care as usual. No treatment will be denied to any participants nor will it be postponed. There is no additional medical risk present for any participants in this study. The experimental group will potentially have better treatment options for their depressive symptoms.

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

- 18 years and older
- diagnosis of diabetes mellitus type 2 and/or coronary heart disease
- in primary care
- subthreshold depression (scoring 6 points or more on PHQ-9 in combination with the absence of a diagnosis on the Mini International Neuropsychiatric Interview (MINI))

Exclusion criteria

- bipolar disorder
- cognitive impairment or dementia
- psychotic illness
- terminal illness
- currently taking antidepressant medication
- a history of suicide attempts
- insufficient Dutch language skills
- visual impairments or illiteracy
- loss of significant other < previous six months
- pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Other
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):	30-07-2013
Enrollment:	236
Type:	Actual

Ethics review

Approved WMO	
Date:	05-11-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	18-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	03-04-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	17-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	11-11-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	01-04-2014

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	07-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	19-06-2014
Application type:	Amendment
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	NL39261.029.12