Effects and costs of a combined screening and treatment program for elderly (aged 75 years and over) with depressive symptoms in general practice

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To study the effects and costs of a screening and treatment program for elderly with depressive symptoms in general practice.

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

Summary

ID

NL-OMON30250

Source
ToetsingOnline

Brief title
Proactive management of depression in the elderly/PROMODE

Condition

- Mood disorders and disturbances NEC

Synonym
depressed mood, depression, depressive symptoms

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZONMw;programma Doelmatigheid

Intervention

Keyword: Depression, elderly (75 years and over), screening, stepped care

Outcome measures

Primary outcome

The primary outcome is the difference in severity of depressive symptoms as measured with the Montgomery-Asberg Depression Rating Scale (MADRS) between 0 and 6 months in patients in the intervention arm versus usual care patients.

Secondary outcome

Secondary outcome measures (at 6 and 12 months) are differences in percentage of responders, quality of life, use of (in)formal home care, medical consumption, mortality and costs per quality adjusted life years (QALYs).

Study description

Background summary

Although depressive symptoms in the elderly have serious negative influences and effective treatment is available, elderly with depressive symptoms are often untreated. Under-recognition is an important reason; depressive symptoms seem to be accepted as an unavoidable part of 'normal' aging. In general, combined screening and treatment programs are advocated to treat depressive symptoms more adequately. However, the effects and costs of such programs in elder elderly in general practice are unknown.

Study objective

To study the effects and costs of a screening and treatment program for elderly with depressive symptoms in general practice.

Study design

Pragmatic cluster randomised controlled trial with the general practice as the unit of randomisation. Elderly aged 75 years and over enlisted in general practices will be screened at baseline for depressive symptoms, measured by Geriatric Depression Scale (GDS-15). If GDS-15 score is > 4 points intervention or usual care will be offered according to the allocated treatment to their general practice.

Intervention

In the intervention practices elderly with depressive symptoms will be offered a stepped care treatment program, including 1) individual counselling by a community psychiatric nurse 2) psycho-education by a Coping with Depression group course or a similar therapy on individual basis, and 3) pharmacological treatment and/or referral for patients with persistence of depressive symptoms after step 1 and 2.

Study burden and risks

After agreement to participate in the study, the first part of baseline measurement will take approximately 50 minutes, to administer the screening questionnaires by a research nurse. In elderly who screen positive for depression (GDS-15 > 4) and have no severe cognitive impairment an extension of the baseline measurement is needed, mainly for measurement of severity of depressive symptoms by the MADRS; this part will take approximately another 50 minutes. In those elderly who screen positive for depression and a sample of elderly who screen negative for depression, outcome measurements will be repeated at 6 months and 12 months.
Patients with severe depressive symptoms at baseline (MADRS >30 points) and/or suicidal risk (according to the MADRS) will be referred to the GP, both in the intervention and the control group, to discuss and provide appropriate treatment.

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

Inclusion criteria for screening: elderly aged 75 years and over enlisted in general practices.
Inclusion criteria for treatment-offer: screen positive for depression (GDS-15 > 4).

Exclusion criteria

Exclusion criteria for screening: terminal illness (life expectancy < 3 months), current treatment for depression, loss of partner/important relative < 3 months ago and MMSE < 19 (confirmed in secondary care).
Exclusion criteria for treatment-offer: severe cognitive impairment (MMSE < 19).

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	4000
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
Other	kandidaatnummer NTR (Nederlands Trial Register): 2363
CCMO	NL15665.058.06