The implementation and (cost)effectiveness analysis of the "BeweegKuur" Depressive Symptoms in primary care

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This study investigates if the BeweegKuur Depressive Symptoms is more (cost-)effective in comparison with "watchful waiting". Complementary, success factors and barriers of the implementation of the BeweegKuur Depressive Symptoms in...

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

Summary

ID

NL-OMON39552

Source
ToetsingOnline

Brief title
Effectiveness of the BeweegKuur Depressive Symptoms

Condition

- Mood disorders and disturbances NEC

Synonym
depressed, gloom

Research involving
Human

Sponsors and support

Primary sponsor: Trimbos-instituut

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Depressive symptoms, Exercise, Prevention, Primary Care

Outcome measures

Primary outcome

The primary outcome measure is the difference between "BeweegKuur Depressive Symptoms" and "watchful waiting" in terms of change in depressive symptoms, which will be measured with the CES-D.

Secondary outcome

Other outcomes include level of physical activity (frequency and duration), psychological wellbeing, self efficacy, degree of self management and quality of life. Measures will be conducted at baseline, and after three, six and twelve months. To gain insight in the cost-effectiveness of the intervention, the direct and indirect costs of the BeweegKuur Depressive Symptoms will be collected (productivity losses, medicine.)

Study description

Background summary

The Netherlands Intstitute for Sports and Exercise developed the intervention "BeweegKuur". This is a lifestyle program for people with (a high risk on) overweight or diabetes type 2. The BeweegKuur will be adapted for people with depressive symptoms. This study evaluates if the BeweegKuur Depressive Symptoms is (cost)effective and identifies success factors and barriers in the implementation of the BeweegKuur Depressive Symptoms.

Study objective

This study investigates if the BeweegKuur Depressive Symptoms is more

(cost-)effective in comparison with "watchful waiting". Complementary, success factors and barriers of the implementation of the BeweegKuur Depressive Symptoms in primary care are identified, to maximize participation of the target group including people with a low socioeconomic status.

Study design

Pragmatic multicenter randomized controlled trial with a costeffective analysis.

Intervention

Ten Primary care clinics will offer the BeweegKuur Depressive Symptoms (experimental condition), and ten clinics will use the watchful waiting method (control condition) as is prescribed in the Multidisciplinary Guideline Depression. The BeweegKuur Depressive Symptoms consists of a tailored exersice program of 3-6 months either independently or under supervision of the physiotherapist, an suitable and desirable evidence-based psychological intervention offered by the physician assistant-mental health, and for one's under- or overweight consultation with a dietician. A life style advisor or physician assistant-mental health supports the participant during one year.

Study burden and risks

After inclusion the participants of the study conduct four measurements. Every measurement will take about 20 till 30 minutes to fill in different questionnaires. The measurements do not lead to any risks.

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

Participants are men and women, and are included in the study if they
(a) are at least 18 years of age,
(b) have a CES-D score of 6-46 (6-15 indicating some depressive symptoms, 16-46 indicating probably depression)
(c) do not have suicide ideation or concrete suicidal plans,
(d) currently fail to meet the Dutch norm for healthy physical activity (30 minutes of moderate to vigorous physical activity on at least 5 days per week) and are sufficiently motivated to change their physical activity level (to be judged subjectively by the primary care providers during intake), (e) do not have any psychological or psychiatric disorder or severe physical problems and other issues that will hinder participation in the BeweegKuur Depressive Symptoms,
(f) mastered the Dutch language sufficiently to fill in questionnaires
(g) gives written informed consent, and
(h) complete the t0 questionnaire.

Exclusion criteria

The General Practitioner decides whether a patient should be excluded from the study, for other (medical) reasons than stated in D4, main inclusioncriteria.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-11-2013
Enrollment:	322
Type:	Actual

Ethics review

Approved WMO Date:	19-08-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	31-10-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-01-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-04-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL41705.041.12