BLENDING: BLENded care for Depressive symptoms IN General practice: a randomised non-inferiority trial

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Objective: Primary objective is to demonstrate non-inferiority of the e-prescription to the use of antidepressants on the short term. Secondary objectives are to assess its effect on long term outcomes, antidepressant use, and to assess its...

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

Summary

ID

NL-OMON40697

Source
ToetsingOnline

Brief title
BLENDING

Condition

- Mood disorders and disturbances NEC

Synonym
depressive disorder, depressive symptoms

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Blended_care, Depressive_symptoms, General_practice, Randomised_Controlled_Trial

Outcome measures

Primary outcome

Main study parameters/endpoints:

Main endpoint is the reduction in depressive symptoms as assessed by the Hamilton Depression Rating Scale-17 (HRSD-17) from baseline to three months after intervention.

Secondary outcome

Secondary endpoints are the reduction on depressive symptoms using the HRSD-17 at 12 months, percentage response (50% reduction in symptoms on HRSD-17), remission (HRSD-17 score below 7) at three and twelve months of follow-up, antidepressant use, effect on general health status, functional impairment, treatment satisfaction and cost-effectiveness.

Study description

Background summary

Rationale: Depression is a common mental disorder that has a high burden of disease and high economic burden. The majority of patients with mental health problems are treated by general practitioners (GPs). Guidelines recommend a stepped care approach for the treatment of these patients. This means that structured non-pharmacological interventions of low-intensity (e.g. short psychological treatments) are recommended before starting antidepressants. However the use of this approach is limited and it has been estimated that 70% of the cases are primarily treated with antidepressants. Time constraints and lack of familiarity with psychological treatments are probably key to this problem. In this randomized controlled trial we will study the effectiveness of an e-prescription for a blended care approach in the psychological treatment of

participants with depression or depressive symptoms in the general practice. The e-prescription will be a prescription to an online self-management program based on the principles of behavioural activation and problem-solving treatment, blended with a few telephonic or face-to-face contacts with a GP or POH-GGZ.

Study objective

Objective:
Primary objective is to demonstrate non-inferiority of the e-prescription to the use of antidepressants on the short term. Secondary objectives are to assess its effect on long term outcomes, antidepressant use, and to assess its effectiveness on percentage response, remission, functional impairment, treatment satisfaction and general health status.

Study design

Study design: Pragmatic investigator blinded monocentre 1:1 randomized controlled non-inferiority trial

Intervention

Intervention:
E-prescription to an online self-management program (1-2 sessions per week spread over 5-10 weeks), blended with a few telephonic or face-to-face contacts with the GP or POH-GGZ.

Study burden and risks

There are minimal risks associated with this trial, as the intervention is non-invasive. A potential but likely neglegible risk is violation of privacy. However the e-prescription will be designed to be as non-intrusive and secure as possible according to the quality criteria of the NEN7510.

Major depressive disorder comes with a risk of suicide. This is intrinsic to this disorder and not related to the intervention. In this study we will monitor depressive symptoms en suicidality during the intervention (as previously mentioned). See also the protocol pages 28 and 32.

There is some degree of burden; participants will follow their e-prescription or prescription of antidepressants. They will be interviewed four times during this study, during the inclusion, at baseline and also after three and twelve months follow-up by the researcher or the research assistant. At baseline and at follow-up questionnaires will be administrated through the internet. These research data will be coded. During the intervention there will be three consultations with their GP in either group to discuss any problems occurring

in the course of treatment in both groups. Participants will receive reminders through e-mail to fill in questionnaires for the monitoring. The estimated time investment is around 10 hours in one year for patients who have been randomized to the e-prescription. This includes two hours for filling in questionnaires and two hours for participating in the interviews.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
Adult patients, i.e. aged 18 or over;
Patients presenting to the GP with a depressive disorder or depressive symptoms;
Patients for whom GP considers prescribing an antidepressant.

Exclusion criteria

Patients will excluded if they:
- are unwilling to accept randomization to either a psychological (e-prescription) or care as usual.
- have an anxiety disorder or obsessive compulsive disorder as primary diagnosis
- have current substance abuse (alcohol, drugs)
- receive currently treatment for depression (i.e. medication or e-mental health intervention)
- have an insufficient command of the Dutch language
- have not given an informed consent
- No internet available or grossly insufficient computer skills

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2016
Enrollment:	302
Type:	Actual

Ethics review

Approved WMO

Date:	11-02-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO Date:	07-11-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL49952.042.14