ICare Prevent * an Internet -and Mobile based Self-help Intervention for the Indicated Prevention of Depression and Anxiety

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47514

Source
ToetsingOnline

Brief title
ICare Prevent

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
anxiety, Depression

Health condition

angstsymptomen

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: European Commission

Intervention

Keyword: Anxiety, Depression, Internet intervention, Prevention

Outcome measures

Primary outcome

The primary ouctome is disorder specific symptom severity at post-intervention.

This will be assessed by the QIDS for depression and the HAM-A for anxiety.

Secondary outcome

Secondary endpoints include:

* CMHD onset within 6 and 12 months follow-up (outcome)

* CMHD free days (outcome)

* Costs (outcome)

* Health related quality of life (outcome)

* Self-esteem (moderator)

* Motivation (mediator)

* Program evaluation (mediator)

* Wellbeing (outcome)

* Alcohol use (outcome)

* Socioeconomic/demographic characteristics (moderators)

* Risk factors (optional, moderators)

* Negative effects of treatment (outcome)

* Sleep quality (outcome)

* Worry (outcome)

* Emotion regulation (outcome)

* Incongruence (outcome)

* Personality (moderator)

* Supporting accountability (mediator)

* Resilience (moderator)

* Treatment satisfaction (mediator)

* Behavioural activation (outcome)

Study description

Background summary

Depression and anxiety are common mental health disorders. Interventions that target mild complaints could treat and prevent the development of these conditions. The internet offers the possibility of following such an intervention independently with minimal guidance. ICare Prevent is a transdiagnostic Internet intervention that aims at the treatment and prevention of anxiety and depression. Research indicates that anxiety and depression share common underlying factors, a transdiagnostic approach is therefore particularly appropriate in this context. Since there is still insufficient evidence on the additional value of support by means of a coach, and on the cost-effectiveness of Internet interventions, these factors will be investigated more closely in this study.

Study objective

The objective is to investigate the effectiveness of an Internet-based self-help intervention for people with mild symptoms of anxiety and/or depression. This intervention will be offered with and without guidance and will be compared to usual care (treatment as usual: TAU). Moreover, the cost-effectiveness of the intervention will be determined. In addition,

moderators and mediators of adherence and effectiveness will be investigated.

Study design

This study is a randomized controlled trial with three arms: 1) unguided intervention group, 2) (minimally) guided intervention group, 3) control group (TAU). Treatment allocation is blinded. It is not possible to blind either participants or eCoaches. Outcome assessors who will conduct the interviews will be blinded. Participants have a 1:1:1 chance to be randomized into either one of the three conditions.

Intervention

ICare Prevent is an Internet-based intervention using evidence-based cognitive behavioral therapy (CBT) principles. The intervention consists of 7 main sessions and 1 booster session (activated 4 weeks after session 7). In sessions 5 and 6 participants choose whether they would like to learn more problem-solving techniques (for more prominent depressive complaints) or engage in exposure (for more prominent anxiety complaints). In sessions 2-7 participants can decide to add either one of 9 choice modules (sleep, perfectionism, self-esteem, alcohol consumption, gratitude/appreciation, acceptance, rumination, relaxation, worry confrontation). Participants in the guided intervention group receive support by an eCoach. This coach provides feedback on the exercises. Participants in the unguided intervention group receive short motivational messages.

Study burden and risks

No known risks. Participants may expierence answering the questionnaires and interviews as a burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) age * 16 years
2) experience mild self-reported symptoms of depression (CES-D between 16 and 28) and/or anxiety (GAD-7 between 5 and 14)

Exclusion criteria

1) being on a waitlist for, currently receiving, or having received psychotherapy within the past 12 months for any mental health condition
2) having a lifetime bipolar or psychotic disorder (assessed by M.I.N.I.)
3) being at moderate-high suicide risk (M.I.N.I.)
4) self-reported inability to read or write Dutch or English
5) No access to the Internet
6) no informed consent
7) participation in similar studies at time of inclusion

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-11-2017
Enrollment:	252
Type:	Actual

Medical products/devices used

Generic name:	Minddistrict
Registration:	No

Ethics review

Approved WMO Date:	01-06-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-07-2018
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

ID: 27825
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL60705.029.17
OMON	NL-OMON27825