Psyfit, an internet-based intervention in order to promote well-being.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20459

Source
NTR

Health condition

Wellbeing, depressieve symptoms

Sponsors and support

Primary sponsor: Trimbos Institute
Source(s) of monetary or material Support: Ministry of Health, Welfare and Sports

Intervention

Outcome measures

Primary outcome

Well-being (WHO-5 and Mental Health Continuum-Short Form) and depressive symptoms (CES-D).

Secondary outcome

General health and vitality (subscales in MOS-SF36), economic costs (care consumption; TIC-P / work productivity, absenteeism, inefficient job performance; PRODISQ).

Study description

Background summary

The aim of the study is to evaluate the (cost-)effectiveness of Psyfit, an online mental fitness self help program, on well-being and depressive symptoms. The study design is a two-armed pragmatic randomised controlled trial:

1. 2-month access to Psyfit (experimental condition);

2. Waiting list for 6 months (control condition).
Measurements will be made prior to inclusion and randomisation (t0), 2 months after starting the intervention (t1), 6 months after starting the intervention (t2).

Study objective

The internet-based self-help intervention is effective in the enhancement of well-being, the reduction of depressive symptoms and in terms of economic costs in comparison to a waiting list control group.

Study design

1. t0: baseline;

2. t1: post test, 2 months after t0;

3. t2: follow-up, 6 months after t0.

Intervention

The intervention concerns a multiple internet-based self-help intervention (‘Psyfit’) aimed at the promotion of well-being en the reduction of depressive symptoms. Based on their needs and current level of well-being they can choose one out of six modules. Each module consists of a four-week program with theoretical information, short films and assignments. Participants can monitor their progress in a personal plan and a mood meter. For sharing experiences and peer-to-peer support an online community is available. Participants are randomized to the intervention of a waitinglist control group. Participants in the watinglist control group are able to attend the intervention 6 months after T0.

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Eligibility criteria

Inclusion criteria

Subjects:

1. Are 25 years or older;

2. Have very mild to moderate depressive symptoms as measured by the Center for Epidemiological Studies Depression Scale (CES-D) in a score 10 or higher ànd moderate or low well-being as measured by the cut-off points in the Mental Health Continuum (Keyes, Keyes and Westerhoff);

3. Have access to a computer and a good internet connection;

4. Have sufficient knowledge of the Dutch language.

Exclusion criteria

1. Serious depressive complaints (score CES-D >=25);

2. Suicideal ideation (active suicidal thoughts or plans, score Web Screening Questionnaire 2 or 3).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	414
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-11-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33265
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2009

Register	ID
NTR-old	NTR2126
CCMO	NL28769.097.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33265

Study results

Summary results
N/A