Psyfit: a randomised controlled trial to study the effectiveness of an online mental fitness program

Published: 04-09-2009
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The aim of the study is to evaluate the effectiveness of Psyfit, an online mental fitness program.

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

Summary

ID

NL-OMON33265

Source
ToetsingOnline

Brief title
Psyfit: a randomised controlled trial

Condition

- Mood disorders and disturbances NEC

Synonym
down, well-being

Research involving
Human

Sponsors and support

Primary sponsor: Trimbos-instituut
Source(s) of monetary or material Support: Ministerie van VWS

Intervention

Keyword: e-health, mental health, self-management, well-being

Outcome measures

Primary outcome

Well-being and depressive symptoms

Secondary outcome

Quality of Life, care consumption, productivity, absenteeism

Study description

Background summary

The investment in a positive mental health is an important addition to current mental health policy in which reduction and prevention of mental disorders are central elements. Everyone can work on his mental fitness, the same as you can work on a physical condition. The Trimbos institute developed an online zelf help intervention, Psyfit, which aims to improve well-being and to reduce depressive symptoms. The effectiveness of Psyfit will be examined in a randomized controlled trial.

Study objective

The aim of the study is to evaluate the effectiveness of Psyfit, an online mental fitness program.

Study design

The study design is a randomised controlled trial with two conditions: 1) 2-month access to Psyfit (experimental condition), 2) waiting list 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).

Intervention

Psyfit (*mental fitness*) is an online intervention to support a positive

mental health in people in general en to reduce depressive symptoms by addressing issues like stress management, foster positive emotions, investment in relationships and living in the here and now. It is a pure self help intervention which means there is no support from a professional. Participants tailor their personal program and their progress is measured by several self tests. Furthermore they can exchange their experiences, pains and successes in an online community which is built in the intervention. During the trial people in the experimental group receive two-month access to Psyfit.

Study burden and risks

For the study participants will be asked to complete 3 questionnaires (experimental group and control group): before the intervention starts, 2 months after starting and 6 months after starting. In total it will take 90 minutes at the maximum. How burdensome the intervention will be depends on the extent to which the participant wishes to make use of it. The participant will tailor the intervention on his own needs. Ideally it will take on average 20 minutes each day to practice the exercises (but it depends on the week and the exercise you are doing).

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

• Age from 25 to 70 years old;
• Very mild to moderate depressive symptoms (CES-D score >=10), and moderate or low well-being (Mental Health Continuum score)
• Acces to the internet and computer

Exclusion criteria

• Major depressive symptoms as measured with the CES-D (score >=25)
• Suicidal tendencies(operationalised by section E18-E21 of the Composite International Diagnostic Interview (CIDI)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2009
Enrollment:	414
Type:	Anticipated

Ethics review

Approved WMO Date:	04-09-2009
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (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

ID: 20459
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL28769.097.09
OMON	NL-OMON20459