

An internet-based intervention for the prevention and (early) intervention of eating disorders: A randomized controlled trial investigating the (cost-) effectiveness of computer-tailored feedback with or without supplemented frequent or infrequent e-mail, chat, or Skype support from a coach.

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

Summary

ID

NL-OMON37391

Source

ToetsingOnline

Brief title

The (cost-) effectiveness of an internet intervention for eating problems.

Condition

- Eating disorders and disturbances

Synonym

Eating disorder, eating problems

Research involving

Human

Sponsors and support

Primary sponsor: Stichting Rivierduinen

Source(s) of monetary or material Support: Stichting GGZ Rivierduinen

Intervention

Keyword: Eating disorders, Internet, Intervention

Outcome measures

Primary outcome

Primary outcome measures are ED-related behaviors and attitudes.

Secondary outcome

Secondary outcome measures contain eating disorder-related quality of life, self-stigma of seeking help, self-esteem, mastery and support, symptoms of depression and anxiety, repetitive negative thinking, motivation to change, user satisfaction, compliance, help-seeking attitudes and behaviors and medical and societal costs.

Study description

Background summary

New technologies may be able to bridge the gap between the need and actual treatment received, providing opportunities to reach individuals who would otherwise be hard to reach. In the treatment and (preventive) intervention of

eating disorders, several internet-based interventions have shown (at least some) effectiveness. Still, there is a need to refine the internet-based interventions for eating disorders, given that most existing programs seem to be limited by their static 'one size fits all' approach. 'Featback', an internet-based program that has been developed for the prevention and (early) intervention of eating disorders, provides a more individualized approach. It consists of several support components (psycho education, a fully automated monitoring and feedback system, support from a coach), which can be matched according to participants' needs and preferences.

Study objective

The primary objective is to examine the effectiveness of (the different components of) Featback with regard to the primary and secondary outcome measures. The secondary objective is to examine predictors, moderators and mediators of intervention responses. The third objective is to report on practical experiences with Featback, such as the user satisfaction and the (intensity of) use of the different components. The fourth objective is to examine the cost-effectiveness of Featback.

Study design

Participants will be randomized to one of the four intervention conditions. In condition one, participants will receive the basic version of Featback, which consists of psycho education and the fully automated monitoring and feedback system. In condition two, participants will receive the basic version of Featback supplemented with the possibility of infrequent (once a week) e-mail, chat, or Skype support from a coach. In condition three, participants will receive the basic version of Featback supplemented with the possibility of frequent (three-weekly) e-mail, chat, or Skype support from a coach. Participants in one of these active intervention conditions will be assessed prior to the intervention (T0), post-intervention (T1), and at 3- (T2) and 6-month follow-up (T3). The fourth condition is a waiting list control (WLC). Participants will undergo a 5-month waiting period, and will be measured at T0 (week 0), T1 (week 8) and T2 (week 20), after which they will be offered the intervention of condition two.

Intervention

See study design.

Study burden and risks

There are no anticipated risks for taking part in this study. The burden is kept to a minimum: a screening questionnaire (+/- 5 minutes) and four assessments (40 minutes each), (baseline, post-intervention, 3-months follow-up

and 6-months follow-up).

For the intervention itself the participants have to fill out a weekly questionnaire which takes them 5 minutes. Depending on the condition participants are allowed to receive 0, 20 or 60 minutes of support by a coach via e-mail, Skype or chat

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 need to:

- be 16 years or older
- report at least some (mild) forms of eating disorder symptoms AND/OR at least some risk for the development of an eating disorder

- have access to a computer, iPhone, Ipad, Smartphone or laptop with an internet connection

Exclusion criteria

none

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2012
Enrollment:	344
Type:	Actual

Ethics review

Approved WMO	
Date:	06-11-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL40085.058.12