

An internet-based intervention for the prevention and early intervention of eating disorders: A randomized controlled trial investigating the effectiveness and cost-effectiveness of automatic feedback on self-monitored eating behaviour with or without weekly support from an expert patient.

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

Summary

ID

NL-OMON46645

Source

ToetsingOnline

Brief title

An RCT of an internet-based intervention for eating disorders.

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: ZonMW subsidie

Intervention

Keyword: Eating disorders, Internet, Intervention

Outcome measures**Primary outcome**

The primary outcome measure will be eating disorder psychopathology (as measured by the Eating Disorder Examination Questionnaire: EDE-Q).

Secondary outcome

Secondary outcome measures will be experienced social support, self-efficacy, symptoms of anxiety and depression, motivation to change, user satisfaction, compliance and help-seeking attitudes and behaviors.

Study description**Background summary**

Many individuals with eating disorder (ED) symptoms do not receive appropriate mental health care. E-health may help to decrease the time between onset of symptoms and seeking help. Featback, an internet-based self-help program, offers a personalized intervention and exist of psycho-education, an automated monitoring and feedback system, and digital support. In the current study, support will be executed by expert patients. Peer support by expert patients (or *experts by experience*; in Dutch: *ervaringsdeskundigen*), who have a self-evident credibility, may improve the self-efficacy of individuals with EDs and improve outcomes in terms of eating disorder psychopathology and

experienced social support. Earlier research indicates Featback to be effective in reducing ED symptomatology and suggests that Featback can help with early detection and intervention for individuals with eating problems.

Study objective

The current study has two aims. Firstly, to investigate the effectiveness and cost-effectiveness of 8 weeks of the E-health program, Featback, in comparison to Featback with online support from an expert patient, online support from an expert patient without Featback, and a waiting list control condition.

Secondly, to investigate moderators of intervention response to explore what intervention works for which individuals.

Study design

This study will be a randomized controlled trial with a two-by-two factorial design with repeated measures. The four conditions will be 1) E-health program Featback, 2) weekly support by an expert patient, 3) Featback with weekly support by an expert patient, and 4) a waiting list. Condition 1 comprises of self-guided psychoeducation and a fully automated self-monitoring and feedback system. Four important dimensions of EDs are assessed weekly, namely excessive concerns with body weight and shape, unbalanced nutrition and dieting, binge eating, and compensatory behaviors. After completion, a supportive feedback message will be automatically generated, which addresses their reported status (healthy or unhealthy range) and patterns of change (improved, deteriorated or unchanged) on each of the above-mentioned dimensions. In condition 2 participants can schedule a weekly appointment with an expert patient. For each session, participants can choose to receive support via chat or e-mail. Participants in condition 3 will receive the Featback intervention and the weekly individual support by an expert patient as described above. In condition 4 participants will be placed on a waiting list for 14 months, after which they will be offered 8 weeks of Featback with support by an expert patient. Participants will be assessed at pre-intervention (T0), post-intervention (T1) and at 3 (T2), 6 (T3), 9 (T4) and 12 month follow-up (T5).

Intervention

N.a.

Study burden and risks

Participants do not have to disclose any personal information to participate in the study, which guarantees confidentiality and anonymity. Participants are asked to complete questionnaires at baseline, a weekly monitoring questionnaire during the intervention and a three-monthly questionnaire during the follow-up phase, which has been found to be an acceptable burden by the client panel.

Earlier research with a similar design showed no adverse effects of Feedback and participants in all conditions, including the waiting list, are allowed to seek treatment outside the study.

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

- 1) 16 years or above
- 2) Access to the internet
- 3) At least mild self-reported eating problems as indicated by
 - Score 52 or higher on the Weight Concern Scale, or...
 - One or more of the following symptoms as assessed by the Short Evaluation of Eating Disorders: i) a BMI lower than or equal to 18.5, ii) one or more binge eating episodes a week over the past four weeks, iii) one or more compensatory behaviors a week over the past four

weeks

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:	Completed
Start date (anticipated):	09-10-2018
Enrollment:	348
Type:	Actual

Ethics review

Approved WMO	
Date:	01-10-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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: 23136

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL64553.058.18

Study results

Date completed: 08-01-2021

Results posted: 23-12-2021

Actual enrolment: 355

First publication

23-12-2021