

# A randomized controlled trial of an internet-based intervention for eating disorders

No registrations found.

|                              |                     |
|------------------------------|---------------------|
| <b>Ethical review</b>        | Positive opinion    |
| <b>Status</b>                | Recruitment stopped |
| <b>Health condition type</b> | -                   |
| <b>Study type</b>            | Interventional      |

## Summary

### ID

NL-OMON23136

### Source

Nationaal Trial Register

### Health condition

English

Eating disorder, internet, intervention, E-health, expert patient, peer support

Nederlands

Eetstoornis, internet, interventie, E-health, ervaringsdeskundige

## Sponsors and support

**Primary sponsor:** GGZ Rivierduinen Eetstoornissen Ursula

**Source(s) of monetary or material Support:** Subsidising party: ZonMW

## Intervention

## Outcome measures

### Primary outcome

ED symptomatology as measured by the Eating Disorder Examination Questionnaire (EDE-Q).

## Secondary outcome

Experienced Social Support (SSL-12)

Self-Efficacy (GSES)

Anxiety and Depression (PHQ-4)

Motivation to change

Satisfaction with intervention

Compliance

Help seeking attitudes and behaviors

## Study description

### Background summary

Country of recruitment: Netherlands

The study sample will be recruited via the Dutch e-community 'Proud2Bme'

(<http://www.proud2bme.nl>), via the Featback website and the network of the patient organization WEET. Proud2Bme is an interactive website that is designed for young people or adolescents (mainly girls) with eating problems or an ED. It is a healthy alternative to many pro-anorexia websites and promotes a healthy lifestyle and positive self-image. One can find information on EDs, beauty, fashion and health, as well as personal stories of individuals with a history of an ED. The site also offers the possibility to engage in a forum or (thematic) group chats with a psychologist, dietician or a trained expert. Monthly, Proud2Bme is visited by approximately 75.000 unique visitors, most of whom experience ED(-related) symptoms. We therefore consider it possible to recruit the planned number of individuals for our study.

### Study objective

It is hypothesized that the online intervention Featback without expert patient support, Featback with expert patient support, and expert patient support without Featback will be more (cost-) effective in reducing ED psychopathology compared to a waiting list

## **Study design**

Screening

Baseline (T0; week 1)

Intervention Period (week 1-8; 8 weeks)

Measurement 1 (T1; week 8)

Measurement 2 (T2; 3 month FU)

Measurement 3 (T3; 6 month FU)

Measurement 4 (T4; 9 month FU)

Measurement 5 (T5; 12 month FU)

## **Intervention**

### **1) Feedback**

All participants in the Feedback conditions will have access to the Feedback website where comprehensive and general information on EDs can be found (i.e., psychoeducation). The psychoeducation will be purely self-guided, meaning that participants are free to choose what to read and when. The monitoring and feedback system includes a weekly invitation by email to complete a monitoring questionnaire. This questionnaire consists of eight 4-point Likert items assessing cognitive and behavioral correlates of the following four dimensions: 1) excessive concerns with body weight and shape, 2) unbalanced nutrition and dieting, 3) binge eating, and 4) compensatory behaviors. After completion, a supportive feedback message will be automatically generated according to a pre-defined algorithm, which addresses their reported status (healthy or unhealthy range) and patterns of change (improved, deteriorated or unchanged) on each of the above-mentioned dimensions. The messages contain a summary of self-reported eating problems, psychoeducation and advice on how to counteract ED-related symptoms, which are conveyed in a supportive and reinforcing way.

### **2) Support from an expert patient**

Expert patients (in Dutch 'ervaringsdeskundigen') are individuals with a lived ED experience, who have recovered completely and who, following recruitment and selection, have undergone specialized training to be able to use their knowledge and skills to help and support others understand and manage their ED symptoms. Participants can schedule a weekly appointment

with an expert patient. For each session, participants can choose to receive support via chat or e-mail. Chat sessions have a duration of 20 minutes and for e-mail support participants are required to send an email before the scheduled appointment to which an expert patient will reply at the time of the appointment. All expert patients will undergo an intensive day of training. The first part of the training comprises how to use the experience of having had and overcoming an ED to help others struggling with ED-related problems.

The second part contains an elaborate explanation of the research and the Featback program. Subsequently, a training specifically focused on the delivery of online support via chat and e-mail will be delivered. An intervention protocol that includes guidelines for the provision of support will be handed out and explained to the expert patient support team, so that all expert patients will work from a similar perspective and with similar methods. The methodology of the chat is based on a 5-phase model, containing 1) warm welcome, 2) clarifying the question, 3) determining the goal of the conversation, 4) concrete elaboration of the goal of the conversation, and 5) closing the circle. E-mail support is based on the following phases: 1) extracting the question, 2) formulating an answer, and 3) checking the message and sending it. More detailed information on the models for e-mail and chat support can be found in the handbook written by Schalken et al. (2010). The expert patient supporters will practice with offering chat and email support during and after the training, and feedback on their practice sessions will be provided by an expert patient and experienced psychologist. Participating expert patients will receive monthly supervision during the study by an experienced expert patient and clinical psychologist, as a matter of routine professional and ethical care.

### 3) Featback and support from an expert patient

Participants in this condition will receive both interventions as described above.

### 4) Waiting list control

Participants will be placed on a waiting list for 14 months (8 weeks intervention period + 1-year followup), after which they will be offered 8 weeks of Featback with support by an expert patient.

## Contacts

### **Public**

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## **Eligibility criteria**

### **Inclusion criteria**

Eligible participants are aged 16 years or above, have access to the internet, have self-reported ED symptoms as defined as scoring 52 or higher on the Weight Concern Scale (Killen et al., 1993) or report one or more of the following ED symptoms assessed by the Short Evaluation of Eating Disorders (SEED; Bauer, Winn, Schmidt & Kordy, 2005): a body mass index lower than or equal to 18.5, one or more binge eating episodes a week over the past four weeks, or one or more compensatory behaviors a week over the past four weeks.

### **Exclusion criteria**

For the current study there are no predefined exclusion criteria. Participants who indicate a BMI lower than 15 or report to be engaged in self-induced vomiting, binge eating or use of laxatives at least once a day over the past four weeks will be send an e-mail with the message that their test scores indicate severe ED symptoms and that we strongly recommend seeking professional help if they are not yet in treatment. However, these individuals will not be excluded from the study, as there is no reason to

withhold Featback or expert patient support. It could well be that these individuals are reluctant to seek (face-to-face) treatment or that they are not fully aware of the severity of their symptoms.

Accordingly, Featback may serve as an important first step to regular health care, because it could help individuals with the process of recognition and acknowledgement of the severity of their ED symptoms and the need to seek professional help. Moreover, Featback and/or the individualized support from expert patients may serve as an important and unique source of

support that could help individuals deal with their (eating) problems more effectively.

## Study design

### Design

|                     |                               |
|---------------------|-------------------------------|
| Study type:         | Interventional                |
| Intervention model: | Parallel                      |
| Allocation:         | Randomized controlled trial   |
| Masking:            | Single blinded (masking used) |
| Control:            | N/A , unknown                 |

### Recruitment

|                           |                     |
|---------------------------|---------------------|
| NL                        |                     |
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 01-09-2018          |
| Enrollment:               | 352                 |
| Type:                     | Actual              |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

|                   |                  |
|-------------------|------------------|
| Positive opinion  |                  |
| Date:             | 07-06-2018       |
| Application type: | First submission |

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 46645  
Bron: ToetsingOnline

Titel:

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

No registrations found.

## In other registers

| Register | ID             |
|----------|----------------|
| NTR-new  | NL7065         |
| NTR-old  | NTR7263        |
| CCMO     | NL64553.058.18 |
| OMON     | NL-OMON46645   |

## Study results

### Summary results

Rohrbach, P. J., Dingemans, A. E., Spinhoven, P., Van den Akker-Van Marle, E., Van Ginkel, J. R., Fokkema, M., Moessner, M., Bauer, S., & Van Furth, E. F. (2019). A randomized controlled trial of an Internet-based intervention for eating disorders and the added value of expert-patient support: study protocol. *Trials*, 20(1), 1-17.

The current study builds on results from a previous study on Feedback from the same research group (trial registration: NTR3646).

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References earlier research regarding Feedback of this research group:

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Aardoom, J. J., Dingemans, A. E., Spinhoven, P., Hakkaart-van Roijen, L., & Van Furth, E. F. (2013). An internet-based intervention for eating disorders consisting of automated computer-tailored feedback with or without supplemented frequent or infrequent support from a coach: study protocol for a randomized controlled trial. *Trials*, 14, 340.

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Aardoom, J. J., Dingemans, A. E., Spinhoven, P., Van Ginkel, J. R., De Rooij, M., & Van Furth, E. F. (2016). Web-based fully automated self-help with different levels of therapist support for individuals with eating disorder symptoms: a randomized controlled trial. *Journal of Medical Internet Research*, 18, e159.

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Aardoom, J. J., Dingemans, A. E., Van Ginkel, J. R., Spinhoven, P., Van Furth, E. F., & Van den Akker-van Marle, M. E. (2016). Cost-utility of an internet-based intervention with or without therapist support in comparison with a waiting list for individuals with eating disorder symptoms: a randomized controlled trial. *International Journal of Eating Disorders*, 49, 1068-1076.

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Aardoom, J. J., Dingemans, A. E., Fokkema, M., Spinhoven, P., & Van Furth, E. F. (2016). Moderators of change in an internet-based intervention for eating disorders with different levels of therapist support: what works for whom? *Behaviour Research and Therapy*, 89, 66-74.