Trial Description

Title

Internet-based relapse prevention for eating disorders following inpatient treatment: randomised controlled trial for anorexia nervosa

Trial Acronym

EDNET 3 AN VIA

URL of the trial

[---]*

Brief Summary in Lay Language

Anorexia nervosa is a potentially life threatening disease with a high rate of chronicity which is found primarily in women. This study evaluates a 9-month self-help relapse prevention program which is offered via internet to female patients after in-patient treatment. The program is attended by psychotherapists. A total of 258 patients were randomized to the program or a control condition with treatment as usual. Course and outcome of eating disorder and other symptoms (including body weight which is especially important in anorexia nervosa) will be assessed during and at the end of the program as well as at a 9 months follow-up.

Brief Summary in Scientific Language

Randomized Controlled Trial evaluating an internet-based relapse prevention program in anorexia nervosa with two conditions: 1. Self-help relapse prevention program over 9 months. 2. Controls: Treatment as usual. A total of 258 in-patients was randomized to the study conditions. Instruments include expert- (e.g. SIAB-EX) and self-ratings assessing eating disorder and general psychopathology at the beginning and the end of intervention (smaller assessments during the program) and at a 9-month follow-up. Primary outcome will be body weight.

Organizational Data

- DRKS-ID: DRKS00000081
- Date of Registration in DRKS: 2009/02/13
- Date of Registration in Partner Registry or other Primary Registry: 2007/01/04
- Investigator Sponsored/Initiated Trial (IST/IIT): yes
- Ethics Approval/Approval of the Ethics Committee: Approved
- (leading) Ethics Committee Nr.: 06034, Ethik-Kommission der Bayerischen Landesärztekammer
Secondary IDs

- Primary Registry-ID: 20173615 (ISRCTN)
- Sponsor-ID: 01GV0604 (BMBF)

Health condition or Problem studied

- Free text: Anorectic eating disorder
- ICD10: F50.0 - Anorexia nervosa
- ICD10: F50.1 - Atypical anorexia nervosa

Interventions/Observational Groups

- Arm 1: Internet-based relapse prevention self-help program over 9 months
- Arm 2: Control condition treatment as usual

Characteristics

- Study Type: Interventional
- Study Type Non-Interventional: [---]*
- Allocation: Randomized controlled trial
- Blinding: [---]*
- Who is blinded: assessor
- Control: [---]*
- Purpose: Treatment
- Assignment: Parallel
- Phase: N/A
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

Body weight (Body Mass Index BMI): Difference of BMI at randomization and end of intervention (9 months)

Secondary Outcome

Descriptive assessment of the course and outcome to support the study hypothesis. Main assessment points: 1. Randomization (end of inpatient treatment); 2. end of intervention (9 months); 3. follow-up (additional 9 months).
Assessments by expert-rating (SIAB-EX, PSR, Morgan-Russell Scale) and self-rating (SIAB-S, EDI, BSI).

Countries of recruitment

- DE Germany

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2007/04/05**
- Target Sample Size: **258**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **16 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Written informed consent including legal representative where appropriate
- Access to the internet by the patient
- Successful in-patient treatment for anorexia nervosa (DSM-IV)

Exclusion criteria

- Mental or somatic disability prohibiting participation in study
- acute or chronic organic or schizophrenic psychosis, severe suicidal ideation/behaviour

Addresses

- **Primary Sponsor**
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Sources of Monetary or Material Support

- Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)

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Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2013/03/31

Trial Publications, Results and other documents

- Paper Does internet-based prevention reduce the risk of relapse for anorexia nervosa? Behaviour Research and Therapy
- Paper Internet-based relapse prevention for anorexia nervosa: Nine-month follow-up
- Paper Rückfallprophylaxe auf Internetbasis bei Anorexia nervosa - Längerfristiger Verlauf in einer „Intent-To-Treat“-Stichprobe
- Paper Internetbasierte Ansätze in der Therapie von Essstörungen

* This entry means the parameter is not applicable or has not been set.
*** This entry means that data is not displayed due to insufficient data privacy clearing.