

# Study on the efficacy of an Internet self-help program for binge eating disorder, used with the guidance of a coach

<b>Submission date</b> 20/08/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/09/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 23/06/2011	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www2.salut-ed.org/step>

## Contact information

### Type(s)

Scientific

### Contact name

Prof Alain Golay

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

Guided self-help treatment on the Internet for binge eating disorder: A randomised controlled trial

## Study objectives

The Internet program group will report improvements of eating behaviour, psychological health and quality of life compared to a control group after 6 months of intervention.

These improvements will be sustained after a 6-month follow-up

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The ethical committee of the University Hospitals of Geneva, Department of Community Medicine, approved on 19/11/2007 (protocol no: 07-167, ref: Med 07-045)

## Study design

Single centre interventional randomised controlled study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Binge eating disorder

## Interventions

Participants used an Internet self-help treatment program for binge eating disorder and benefited of a weekly e-mail contact with a psychologist during the time of intervention. First group received a 6-month Internet intervention and then a 6-month follow-up. Second group had a 6-month waiting period before receiving the 6-month Internet intervention. Assessors were not blinded to controlled conditions but assessments were conducted with self-report questionnaires, limiting biases.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Eating Disorder Inventory (EDI-2) Bulimia subscale (Garner, Olmsted, & Polivy, 1983). Self reporting questionnaire which was chosen because it was sensitive to participants progress in previous studies using the Internet program.

Assessments were carried out at baseline, after 6-month intervention/waiting-list, after 6-month follow-up/intervention (= 0-6-12 months)

**Secondary outcome measures**

Self-report questionnaires:

1. EDI-2 subscales (Garner, Olmsted, & Polivy, 1983)
2. Eating Disorder Examination-Questionnaire (EDE-Q) (Fairburn & Beglin, 1994)
  - 2.1. total score
  - 2.2. number of objective binge episodes
3. Proportion of patients abstinent from bingeing (=0 binge episodes in the last 28 days)
4. Three-Factor Eating Questionnaire (TFEQ) scales (Stunkard & Messick, 1985)
5. Beck Depression Inventory-II (BDI-II) score (Beck, Steer, & Brown, 1996)
6. Symptom Check-List (SCL-90R) global severity index (Derogatis, 1977)
7. Impact of Weight on Quality of Life (IWQOL-Lite) total score (Kolotkin, Crosby, Kosloski, & Williams, 2001)
8. Rosenberg self-esteem scale (RSES) score (Rosenberg, 1965)
9. BMI (body mass index, taken out of the EDE-Q)

Assessments were carried out at baseline, after 6-month intervention/waiting-list, after 6-month follow-up/intervention (= 0-6-12 months)

**Overall study start date**

08/01/2008

**Completion date**

18/02/2010

**Eligibility****Key inclusion criteria**

1. Women, age  $\geq 18$  years
2. Binge eating disorders and related eating disorders
3.  $20 < \text{BMI} < 50$

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

74

**Key exclusion criteria**

1. Drug or alcohol dependence
2. Suicide attempt during the last year
3. Unmanaged severe psychiatric disorder
4. Gastric bypass
5. Current cognitive and behavioural therapy

**Date of first enrolment**

08/01/2008

**Date of final enrolment**

18/02/2010

## **Locations**

**Countries of recruitment**

Switzerland

**Study participating centre**

**Geneva University Hospitals**

Geneva

Switzerland

1211 Geneva 14

## **Sponsor information**

**Organisation**

University Hospitals of Geneva (Switzerland)

**Sponsor details**

c/o Prof Alain Golay

Service of Therapeutic Education for Chronic Diseases

Gabrielle-Perret-Gentil 4

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Switzerland

1211 Geneva 14

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/01m1pv723>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Hans Wilsdorf Foundation (Switzerland)

**Funder Name**

Marie Curie Research Training Network (Europe) - Individually tailored stepped care for women with eating disorders (INTACT) (MRTN-CT-2006-035988)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/08/2011		Yes	No