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everyBody – Tailored online health promotion and eating disorder prevention for women at different risk stages

Submission date
25/02/2016

Recruitment status
No longer recruiting

Registration date
26/02/2016

Overall study status
Completed

Last Edited
19/12/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Eating disorders are a group of common conditions which are defined by an abnormal attitude towards food. Anyone can develop an eating disorder although they are far more common in women, particularly between the ages of 12 and 20. Dietary restriction (avoiding certain foods) and body dissatisfaction (poor body image) are well-known risk factors for developing eating disorders as well as eating-related health problems such as obesity. Studies have shown that prevention programs for those at risk of developing an eating disorder can be very effective. The programs mainly focus on changing attitudes and behaviors in order to encourage a healthier lifestyle and attitude towards food. “everyBody” s an internet-based program which aims to encourage healthy behavior and eating disorder prevention. There are various variations of the program, in order to provide tailored help to women with different risk factors, such as those with poor body image, those who binge and purge (overeat and then intentionally get rid of the food, such as by vomiting) or those who restrict what they eat. The aim of this study is to find out whether women who take part in the “everyBody” program is an effective way to help women improve their body confidence and encourage healthier eating behaviors.

Who can participate?
Healthy women over 18 years of age.

What does the study involve?
At the start of the study, participants are individually screened for eating disorders. The participants are then allocated to one of five groups based on their respective needs and conditions. Each of the groups takes part in variations of the “everyBody” program, which involves internet-based sessions including discussion groups and education. The first group is for women with a BMI between 21 and 25 who have concerns about their weight and body shape. These women take part in eight weekly sessions in which the aim is to improve their body image. The second group is for women with a BMI greater than 18.5 who occasionally binge eat and/or purging (i.e. making themselves sick or using laxatives). These women take part in eight weekly sessions which aim to reduce binge eating and/or purging, along with improving body image, as well as receiving personal feedback. The third group is for women with a BMI of 18.5 to 21 who

have concerns about their weight and body shape. These women take part in 10 weekly sessions which aim to stop cutting things out of their diet (dietary restriction) and improve body image, as well as receiving personal feedback. The fourth group is for women with a BMI of 18.5 to 25 who show no signs relating to eating disorders. These women attend four weekly sessions without any additional guidance. The fifth group is for women with a BMI of over 25 (overweight). These women take part in 12 weekly sessions which promote healthy weight regulation, healthy eating and exercise habits. Participants in all groups complete a number of questionnaires at the start of the study, at the end of the “everyBody” program, and then again 6 and 12 weeks later, in order to assess the effectiveness of the different variations of the program.

What are the possible benefits and risks of participating?
Participants may benefit from receiving bonus money or prizes from their health insurance provider upon completion of the program. There are no notable risks involved in taking part in this study.

Where is the study run from?
Technical University Dresden (Germany)

When is the study starting and how long is it expected to run for?
September 2015 to August 2018

Who is funding the study?
European Union's Horizon 2020 Framework Programme for Research and Innovation (Belgium)

Who is the main contact?
Prof. Corinna Jacobi (scientific)
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Study website
https://www.icare-online.eu/de/everybody.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Tailored online health promotion and eating disorder prevention for women at different risk stages aiming to reduce weight and shape concerns

Study objectives
Women who participate in the "everyBody" tailored online intervention for health promotion and eating disorder prevention will show statistically significant lower weight and shape concerns at post intervention compared to baseline.

Ethics approval required
Old ethics approval format

Ethics approval(s)
TU Dresden Ethics Committee, 23/02/2016, ref: EK83032016

Study design
Single centre non-randomized parallel group interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Internet/virtual

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Eating disorders

Interventions
Based on the individual screening result, participants will be allocated to one of the five parallel intervention groups. Women with full-syndrome eating disorders will be excluded from participation and receive a treatment referral. Following informed consent and baseline assessment of primary and secondary outcomes each group obtains access to an evidence-based online prevention program tailored to their respective needs and conditions: everyBody Original, everyBody Basic, everyBody Plus, everyBody AN and everyBody Fit. All programs offer psychoeducation and behavioral exercises aiming to promote or establish healthy eating and exercise habits as well as improve self-esteem.

EveryBody Original targets women with a BMI from 21 to 25 who report elevated weight and shape concerns, but no other symptoms of an eating disorder. Participants from this group receive 8 weekly intervention sessions and get access to a moderated group discussion board. An additional aim in this group is the improvement of body image.

EveryBody Plus targets women with a BMI greater than 18.5 who report occasional binge eating and/or compensatory behaviors. Participants from this group receive 8 weekly intervention sessions, get access to a moderated group discussion board and receive weekly personal feedback. Additional aims in this group are the reduction of binge eating and/or purging and improvement of body image.

EveryBody AN targets women with a BMI ranging from 18.5 to 21 who report elevated weight and shape concerns but no other eating disorder symptoms. Participants from this group receive 10 weekly intervention sessions, get access to a moderated group discussion board and receive weekly personal feedback. Additional aims in this group are the reduction of dietary restraints and improvement of body image.

EveryBody Basic targets women with a BMI from 18.5 to 25 without elevated weight and shape concerns or other symptoms of an eating disorder. Participants from this group receive 4 weekly intervention sessions without guidance.

EveryBody Fit targets women with a BMI greater than 25 and promotes healthy weight regulation, healthy eating and exercise habits. Participants from this group receive 12 weekly intervention sessions and get access to a moderated group discussion board.

Participants are followed up post-intervention and at 6 and 12 months follow-up in all groups.

Intervention Type
Behavioural

Primary outcome measure
Weight and shape concerns (measured with Weight Concerns Scale) at baseline and post-intervention

Secondary outcome measures
1. Weight and shape concerns are measured using the Weight Concerns Scale at baseline, 6 and 12 months follow up (effectiveness)
2. Core eating disorder symptoms (binge eating, compensatory behaviors are measured by self-

report (questionnaire) at baseline, post-intervention, 6 and 12 months follow up (effectiveness)
3. Self-esteem is measured using the Rosenberg Self Esteem-Scale at baseline, post intervention, 6 and 12 months follow up
4. Quality of life is measured using the Assessment of Quality of Life-8D questionnaire at baseline, post intervention, 6 and 12 months follow up
5. The reach of the program is measured using sociodemographic variables (questionnaire) of participants at baseline
6. The adoption of the program is measured qualitatively by analyzing communication with stakeholders pre-intervention
7. The implementation of the program is measured by analyzing access paths, cost per recruit and participants adherence to the program before, during and post intervention
8. The maintenance of the program on a participant level is measured by assessing primary and secondary effectiveness outcomes
9. The maintenance of the program on a setting level is qualitatively assessed by analyzing stakeholder attempts to deliver the intervention at their own expense after recruitment for the study is completed

Overall study start date
01/09/2015

Completion date
15/06/2019

Eligibility

Key inclusion criteria
1. Age 18 or older
2. Female
3. Access to Internet
4. Informed consent (online)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
4160

Key exclusion criteria
1. Individuals reporting binge eating and/or compensatory behaviours more than once a week
2. Underweight individuals (BMI less than 18.5)

Date of first enrolment
16/11/2016

Date of final enrolment
06/05/2019

Locations

Countries of recruitment
Austria

Germany

Luxembourg

Switzerland

Study participating centre
Technical University Dresden (Technische Universität Dresden)
Institute of Clinical Psychology and Psychotherapy
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Sponsor information

Organisation
Technical University Dresden (Technische Universität Dresden)

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Sponsor type
University/education

ROR
https://ror.org/042aqky30

Funder(s)

Funder type
Government

Funder Name
European Union's Horizon 2020 Framework Programme for Research and Innovation

Results and Publications

Publication and dissemination plan
1. The study protocol, as well as at least one paper on results, will be submitted to an international peer-reviewed scientific journal by September 2019 at the latest
2. Current status of the trial is published on the project website: https://www.icare-online.eu/de/everybody.html

Intention to publish date
31/08/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/02/2018	05/06/2019	Yes	No
Other publications	Estimation of minimal data sets sizes for machine learning predictions in digital mental health interventions	18/12/2024	19/12/2024	Yes	No