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ICARE-PREVENT: Effectiveness of an Internet based intervention for eating disorders and obesity for adolescents in school setting

Submission date
28/01/2016

Recruitment status
No longer recruiting

Registration date
05/02/2016

Overall study status
Completed

Last Edited
04/10/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Body image concerns and chaotic eating behaviors such as unhealthy dieting and binge eating are becoming increasingly common in teenagers. These problems are common at both ends of the spectrum, with both eating disorders (such as anorexia and bulimia) and obesity. Adolescence is a particularly turbulent time, and studies have shown that being very overweight or underweight can dramatically lower self-esteem and mood. It is therefore very important to promote healthy eating and exercise habits to young people in order to prevent these conditions and their consequences. This study will test a new internet program which is geared towards promoting healthy eating and exercise, as well information about improving body image and to learning how to deal with difficult emotions. The aim of this study is to test the effectiveness of this program at preventing eating disorders and obesity in school age adolescents.

Who can participate?
All students aged 14 to 19 years old who attend participating Austrian and Spanish schools.

What does the study involve?
Schools that agree to participate in this study are assigned to one of two groups. All participants taking part complete an online questionnaire, which includes about eating and physical activity habits, attitudes towards weight and shape, feelings, self-esteem and quality of life. Students attending schools in the first group take part in the internet-based prevention program “Staying Fit”. Based on the results of the initial online-questionnaire, participants are allocated to one of two tracks to fit their specific needs (overweight students take part in a program geared towards weight management and healthy weight student take part in a program about healthy habits). Both tracks consist of eight modules where the participants learn how to build healthy eating and exercise habits, to improve their body image and to learn how to deal with difficult emotions. The participants are able to work on these modules (one 30 minute module per week) during school hours and/or at home. Following completion of the initial questionnaires, participants in the second group continue as normal and are not given access to the Staying Fit program for the 12 month study. After the end of the program as well as 6 and 12 months later,

participants in both groups complete the online questionnaires again to see if there has been any change to their eating and exercise habits, diet, self-esteem and mood. At the end of the 12 month study, participants in the second group are given access to the “Staying Fit” program.

What are the possible benefits and risks of participating?
Participants who take part in the Staying Fit program may learn to better cope it difficult situations and learn to respect themselves as they are, helping them to feel better. The study could also lead to improved eating and exercise habits, which is beneficial for their health. There are no real risks of taking part however some participants may feel uncomfortable or embarrassing when answering certain questions in the questionnaires, although they are given the opportunity to talk about this with the team anonymously at any time.

Where is the study run from?
1. Medical University of Vienna (Austria)
2. Ferdinand-Porsche FernFH (Austria)
3. Jaume I University (Spain)
4. University of Valencia (Spain)

When is the study starting and how long is it expected to run for?
September 2015 August 2019

Who is funding the study?
European Commission (Belgium)

Who is the main contact?
1. Dr Megan Jones (scientific)
2. Professor Andreas Karwautz (scientific)
3. Professor Rosa Maria Banos Rivera (scientific)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
No. 634757

Study information

Scientific Title
Evaluating and disseminating transdiagnostic preventive interventions for eating disorders and obesity for adolescents in school settings (ICare-Prevent)

Acronym
ICare-Prevent

Study objectives

The internet-based prevention program reduces eating disorder and obesity risk for adolescents in the intervention groups compared to a control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Commission of the Medical University of Vienna, 28/01/0216, ref: 2209/2015

Study design
Multi-centre international randomised controlled trial to test

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
1. Eating Disorders
2. Obesity

Interventions
Schools (upper secondary level) in Austria and Spain are approached and asked for participation in the study. Participating schools are randomly assigned to either the intervention or the control condition. All students of a school assigned to the intervention group will receive the “Staying Fit” prevention program. All students of a school assigned to the control group will do the assessments only.

Control group: Participants will complete online-questionnaires at four different time points (baseline, 9 weeks, 6 months, 12 months) assessing eating and physical activity habits, body image concerns, weight and height, food intake, depression, anxiety, self-esteem and health related quality of life. Completing the questionnaires take about 30 minutes. After the end of the study (after 12 months) participants of the control group receive access to the prevention program “Staying Fit”.

Intervention group: Participants will complete the same online-questionnaires as the control group. Based on the baseline assessment, participants will be assigned to one of two available tracks of the “Staying Fit” prevention program which will be provided via an online-platform. Overweight adolescents will be assigned to the “Staying Fit – Weight management” track.

Normal weight adolescents will receive the “Staying Fit – Health Habits” track. Both tracks consist of 8 modules which take about 30 minutes to complete. The participants will work on these modules during school lessons and/or at home and they are asked to complete one module per week. In both program tracks, the participants will learn about healthy eating and physical activity habits, how to deal with difficult emotions and situations, how to build a healthy body image and how to critically analyse contents from media (like internet and TV). The participants will also be encouraged to do some little practical exercises concerning these topics (e.g. completing food and physical activity diaries, setting specific goals they would like to work on).

Differences between the “Staying Fit – Weight Management” and “Staying Fit – Healthy Habits” track are primarily in the language used to describe the content and exercises, rather than the content itself. In the Staying Fit-Weight management” track there is a bit more emphasize on the topics eating and physical activity whereas in the “Staying Fit-Health Habits” track there is a bit more emphasize on the topics dealing with difficult emotions and media literacy.

After completing the 8 program modules (that means after 9 weeks) as well as after 6 and 12 months the participants are invited to complete a follow-up online-questionnaire which contains mainly the same questions as in the baseline assessment.

Intervention Type
Behavioural

Primary outcome measure
Intuitive Eating measured by Intuitive Eating Scale (IES) at baseline, 9 weeks, 6 and 12 months.

Secondary outcome measures
1. Eating disorder psychopathology is measured using the Eating Disorder Examination Questionnaire at baseline, 9 weeks, 6 and 12 months
2. Body image concerns are measured using the Weight Shape Concerns Scale (questionnaire for females) and the Male Body Image Concerns scale (questionnaire for males) at baseline, 9 weeks, 6 and 12 months
3. BMI is determined from height and weight measurements (self-rating) at baseline, 9 weeks, 6 months and 12 months
4. Food intake is measured using the Food Frequency Questionnaire at baseline, 9 weeks, 6 and 12 months
5. Physical Activity is measured using the International Physical Activity Questionnaire at baseline, 9 weeks, 6 and 12 months
6. Depression is measured using the Child Depression Inventory at baseline, 9 weeks, 6 and 12 months
7. Anxiety is measured using the State/Trait Anxiety Inventory at baseline, 9 weeks, 6 and 12 months
8. Self-Esteem is measured using the Rosenberg Self-Esteem Scale at baseline, 9 weeks, 6 and 12 months
9. Health Related Quality of Life is measured using Inventory of Life Quality of Children and Youth at baseline, 9 weeks, 6 months and 12 months

Overall study start date
01/09/2015

Completion date

31/08/2019

Eligibility

Key inclusion criteria
1. Students aged 14-19 years in Austrian and Spanish schools
2. Access to and ability to use a computer with Internet
3. Adolescents' as well as parental informed consents are available

Participant type(s)
Healthy volunteer

Age group
Mixed

Sex
Both

Target number of participants
430

Key exclusion criteria
1. Adolescents with a current diagnosed mental disorder and/or currently in treatment due to a mental disorder
2. Adolescents below a healthy body weight, as defined by BMI <18,5 or Ideal Body Weight (IBW) below 75% or with pronounced eating disorder symptoms

Date of first enrolment
01/09/2016

Date of final enrolment
31/05/2018

Locations

Countries of recruitment
Austria

Spain

Study participating centre
Medical University of Vienna
Spitalgasse 23
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1090

Study participating centre
Ferdinand-Porsche FernFH
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Study participating centre
Universitat Jaume I de Castellon
Avenida de Vicent Sos Baynat s/n
12071 Castellón
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Spain
12071

Study participating centre
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Sponsor information

Organisation
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Spitalgasse 23
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Sponsor type
University/education

Website
http://www.meduniwien.ac.at/homepage/1/homepage/

ROR
https://ror.org/05n3x4p02

Organisation
University of Valencia

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Sponsor type
University/education

Funder(s)

Funder type
Government

Funder Name
European Commission

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
A study protocol for this study should be submitted to an international peer-reviewed scientific journal by December 2016 at the latest. A final results report will be posted to the trial registry by August 2019. Further publications in scientific peer-reviewed journals will be prepared as soon as data collection and analyses is completed.

Intention to publish date
31/08/2019

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		27/02/2018	04/10/2022	Yes	No