

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

<b>Submission date</b> 28/01/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/02/2016	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 04/10/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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## **Additional identifiers**

**Protocol serial number**

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)**

## **Study design**

Multi-centre international randomised controlled trial to test

## **Primary study design**

Interventional

## **Study type(s)**

Prevention

## **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(s)**

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

## **Key secondary outcome(s)**

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

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

**Sex**

All

**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**

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## Sponsor information

**Organisation**  
Medical University of Vienna

**ROR**  
<https://ror.org/05n3x4p02>

**Organisation**  
University of Valencia

## Funder(s)

**Funder type**  
Government

**Funder Name**  
European Commission

**Alternative Name(s)**  
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**

## Results and Publications

## 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?
<a href="#">Protocol article</a>		27/02/2018	04/10/2022	Yes	No