

# Indicated web-based prevention of mental disorders in undergraduate university students

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		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/02/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 09/07/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The transition from school to university or from undergraduate to postgraduate study can often worsen mental health problems, or make them more likely to develop, due to the stresses involved. This study is looking at whether a website created for undergraduate students can improve their well-being and reduce the risk of suffering from common mental health problems. The study aims to provide students with helpful information to support them during their first year at university and address factors which have been identified to contribute to the development of mental health problems such as substance or alcohol misuse, depression, eating disorders, and anxiety.

### Who can participate?

Any student enrolled at a university in the UK or Austria is eligible to take part in this study. (updated 09/07/2019, previously: Any first-year student enrolled at a university in the UK or Austria is eligible to take part in this study.)

### What does the study involve?

Students are first assessed on a range of personality and mental health questionnaires. The results from these questionnaires are used to determine whether a student is more or less likely to develop a mental health problem. Students identified as being of high risk are then randomly allocated to one of two groups. Those in group 1 are given access to a website containing helpful information on studying (e.g. money-saving tips, how to find accommodation in London, etc). Those in group 2 are given access to a website that has modules that help to improve well-being and reduce the risk of becoming mentally unwell. All participants are asked to fill in the questionnaires again after 3 months, 6 months and then 12 months later.

### What are the possible benefits and risks of participating?

The questionnaires cover a variety of different topics, some of which might be embarrassing or difficult. However, there is no risk anticipated with regard to completing the online modules.

### Where is the study run from?

This study is run by King's College London (lead centre) and the Medical University of Vienna.

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 Commission (Belgium)

Who is the main contact?  
Dr Peter Musiat

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Peter Musiat

**ORCID ID**  
<https://orcid.org/0000-0001-7439-0441>

**Contact details**  
King's College London,  
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London  
United Kingdom  
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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Indicated web-based prevention of mental disorders in undergraduate university students: randomised controlled trial of a web-based cognitive behavioural intervention and a web-based active control intervention for the reduction of depression and anxiety

**Acronym**  
ICARE-PLUS

**Study objectives**  
Compared to individuals receiving an active control intervention, individuals at high risk for developing mental disorders will show reduced depression and anxiety after receiving a cognitive behavioural intervention

**Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

1. King's College London Psychiatry, Nursing and Midwifery Research Ethics Sub-Committee, ref: PNM/14/15-130
2. Researcher Ethics Committee of the Medical University Vienna, ref: 2208/2015

### **Study design**

Multi-centre two arm prospective parallel group randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Prevention

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

Depression, anxiety, substance use disorders and eating disorders.

### **Interventions**

Participants are randomly allocated to one of two groups:

1. Intervention group: PLUS (Personality and Living of University Students) is a web-based intervention for the prevention of depression, anxiety, substance use disorders and eating disorders in university students. It is based on the intervention investigated in a previous RCT (Musiat et al., 2014). It follows a cognitive-behavioural approach and consists of seven modules. The modules target personality risk factors for common mental health problems in students i.e. low self-esteem, high perfectionism and anxiety; and how to deal with difficult emotions. They were designed to help students with identifying cycles of unhelpful behaviour and breaking such cycles. Students in the prevention group can optionally download the content of the modules as PDF for offline use. During the intervention stage, students of both groups will receive an email reminder to invite them to visit the site regularly (maximum number of emails over study duration: 10). The modules are designed to be completed by students independently and without personal support.
2. Active control: The active control condition is a web-based intervention, which consists of several modules addressing issues commonly experienced by undergraduate students. They provide information on finding accommodation when studying away from home, tips for saving money and managing finances at university, and tips on time management and how to work effectively with academic texts. These modules have been developed in collaboration with undergraduate students.

All participants can access their web-based intervention for a period of 12 weeks post randomisation.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

1. Severity of depression, as assessed by the Patient Health Questionnaire (PHQ-9)
2. Severity of anxiety, as assessed by the Generalised Anxiety Disorder Assessment (GAD-7)

Assessment points: baseline, 3 months, 6 months and 12 months post randomisation

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

1. Alcohol consumption, assessed by the AUDIT (Alcohol Use Disorders Identification Test)
2. Drug use, assessed by the DUDIT (Drug Use Disorders Identification Test)
3. Severity of eating disorders, assessed by the EDDE (Eating Disorders Diagnostics Scale)
4. Quality of life, assessed by the WHOQOL-bref (WHO Quality of Life)
5. Self-esteem, assessed using the RSE (Rosenberg Self-Esteem scale)
6. Costs of care, assessed by the CSRI (Client Service Receipt Inventory)

Assessment points: baseline, 3 months, 6 months and 12 months post randomisation

### **Completion date**

31/08/2018

## **Eligibility**

### **Key inclusion criteria**

Current participant inclusion criteria as of 09/07/2019:

1. Students at any UK or Austrian University
2. Age at least 18 years

Previous participant inclusion criteria:

1. First-year students at any UK or Austrian University
2. Age at least 18 years

### **Participant type(s)**

Other

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Any current common diagnosed mental disorder or history of a common mental health disorder in the past 12 months
2. Have received psychotherapeutic treatment for any common mental disorder in the past 12 months
3. Current acutely suicidality (as assessed with question 9 of the PHQ9, score > 1)

### **Date of first enrolment**

01/09/2016

### **Date of final enrolment**

31/08/2017

## Locations

### Countries of recruitment

United Kingdom

England

Austria

### Study participating centre

**King's College London**

London

United Kingdom

WC2R 2LS

### Study participating centre

**Medical University of Vienna (Medizinische Universität Wien)**

Vienna

Austria

1090

## Sponsor information

### Organisation

King's College London

### ROR

<https://ror.org/0220mzb33>

## Funder(s)

### Funder type

Not defined

### Funder Name

European Commission

### Alternative Name(s)

European Union, Comisi3n Europea, Europaische 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

#### 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>	protocol	15/03/2018		Yes	No