

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

Submission date 12/02/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 18/02/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/07/2019	Condition category 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

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

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 measure

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

Secondary outcome measures

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

Overall study start date

01/09/2015

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

5550

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

Austria

England

United Kingdom

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

Sponsor details

Strand

London

England

United Kingdom

WC2R 2LS

Sponsor type

University/education

Website

www.kcl.ac.uk

ROR

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

Funder(s)**Funder type**

Not defined

Funder Name

European Commission

Alternative Name(s)

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκή Επιτροπή, Европейская комиссия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottság, 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 will be submitted to an international peer-reviewed scientific journal by December 2016 at the latest. Study results will be disseminated through different channels including scientific publications, publications in popular and medical magazines, flyers and posters, newsletters, educational activities for mental health professionals and students, and posting on the dedicated project website and periodical social media posts. Dissemination is expected Q1-Q2 2018.

Intention to publish date

31/08/2019

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	15/03/2018		Yes	No