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

Submission date
12/02/2016

Recruitment status
No longer recruiting

Registration date
18/02/2016

Overall study status
Completed

Last Edited
09/07/2019

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
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
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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

Primary study design
Interventional

Study design
Multi-centre two arm prospective parallel group randomised controlled trial

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, 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

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