

PLUS (Personality and Living of University Students): A web-based intervention to reduce common mental health problems in university students

Submission date 30/04/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/05/2013	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/01/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

This study investigates whether an internet website can help students reduce symptoms of common mental health problems, such as low mood, anxiety, drug and alcohol use and eating disorders. Although other websites of this kind already exist, they usually focus on symptoms of one disorder and are not targeted at students. In university students, however, symptoms of different mental health problems often go hand in hand. Our aim is to determine whether students will use this website and whether their low mood, anxiety and self-esteem problems decrease. In addition, we are interested in how much students like the website and to get feedback from them on how to improve it.

Who can participate?

All university students aged 18 or older and studying at a university in the UK were eligible to take part in this study.

What does the study involve?

Students visit the study website and after giving consent complete a set of baseline questionnaires. They receive automated feedback on these questionnaires and are randomised into the intervention or control group. Student in the intervention get access to a series of intervention modules, whereas the control group get access to general information relevant to students. These modules can be completed in any order and speed.

After 6 weeks and 12 weeks, students are asked to complete a series of questionnaires again. The questionnaires assess symptoms of mental health problems (low mood, anxiety, drug and alcohol use and eating disorders), self esteem and personality.

What are the possible benefits and risks of participating?

To compensate students for their time and as an incentive to participate in the study, participants are offered a £15 shopping voucher for completing all three assessments. Participation in this study is not associated with any risk for physical harm. It is possible that

some students find it difficult or upsetting to answer questions on their mental health. However, students do not have to answer all questions unless they want to and they can withdraw from the study at any time by leaving the website. In addition, students contact details of the primary investigator as well as telephone numbers for national helplines are provided on the website.

Where is the study run from?

The study was run from the Section of Eating Disorders, Institute of Psychiatry, Kings College London.

When is the study starting and how long is it expected to run for?

The study started in September 2011 and ran for 6 months. Each participants involvement in the study lasted approximately 12 weeks, beginning with registering on the website and ending with completion of the final set of questionnaire. Students registered at different times during this period.

Who is funding the study?

The study has been funded by the National Institute for Health Research (NIHR).

Who is the main contact?

Dr. Peter Musiat (peter.musiat@kcl.ac.uk)

Prof Ulrike Schmidt, Ulrike.schmidt@kcl.ac.uk (Supervisor)

Study website

<http://www.plusonline.org.uk>

Contact information

Type(s)

Scientific

Contact name

Dr Peter Musiat

Contact details

PO-Box 077
Institute Of Psychiatry
De Crespigny Park
London
United Kingdom
SE5 8AF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Web-based trait-focused prevention of common mental disorders in university students

Acronym

PLUS

Study objectives

Main hypothesis:

Students at high risk for common mental disorders (depression, anxiety, substance misuse, eating disorders) receiving the intervention will show significantly reduced levels of depression, anxiety and increased self-esteem compared to students at low risk and students in the control group at post-intervention (12 weeks).

Subsidiary hypotheses:

Students will find the personalized feedback and intervention content helpful and acceptable.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval provided by Kings College London Research Ethics Committee, Psychiatry, Nursing & Midwifery Research Ethics Subcommittee (REF PNM 10/11-101) on May 16 2011

Study design

Multi centre 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Depression, anxiety, substance use, eating disorders

Interventions

Students allocated to the intervention group were given access to 5 intervention modules on the PLUS website (Personality and Living of University Students). The modules are online self-help resources and focus on perfectionism, how to improve self-esteem, dealing with difficult emotions and anxiety and worry. Students could also download a text version of each module. Copies of the interventions modules can be obtained from the contact above.

Students in the control group were given access to 3 online modules with general information for students. These modules cover how to find accommodation as a student, money saving tips as well as general study tips, such as time management.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Participant self-reported depression and anxiety assessed with the Patient Health Questionnaire (9 items) and the Generalised Anxiety Disorder Scale (7 items).
Questionnaires were administered at baseline, 6 weeks after randomisation and 12 weeks after randomisation.

Secondary outcome measures

1. Participant self-reported questionnaires assessing:
 - 1.1. Self-esteem (Rosenberg Self-Esteem Scale, 10 items)
 - 1.2. Perfectionism (Frost Multidimensional Perfectionism Scale, 36 items)
 - 1.3. Personality (NEO-Five Factor inventory, 60 items)
 - 1.4. Substance Use Risk Profile, 23 items)
 - 1.5. Eating behaviour (Eating Disorder Diagnostics Scale, 22 items)
 - 1.6. Drinking behaviour (Alcohol Use Disorder Identification Test, 10 items)
 - 1.7. Quality of life (WHO quality of life questionnaire, 26 items)
2. In addition, students could indicate how much they liked the website, how helpful they found the modules and the personalised feedback, how they found the design and usability of the website, as well as whether they had criticism or positive remarks.
3. Attrition and feasibility was assessed by electronically logging which modules students had started and completed.

Overall study start date

01/09/2011

Completion date

31/03/2012

Eligibility

Key inclusion criteria

1. University student (male or female) aged 18 or older
2. Currently enrolled in a UK Higher Education Institution

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

1500

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/09/2011

Date of final enrolment

31/03/2012

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

PO-Box 077

London

United Kingdom

SE5 8AF

Sponsor information**Organisation**

King's College London (UK)

Sponsor details

Institute of Psychiatry

Section of Eating Disorders

PO-Box 059
De Crespigny Park
London
England
United Kingdom
SE5 8AF

Sponsor type

University/education

Website

<http://www.kcl.ac.uk/iop/index.aspx>

ROR

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

Funder(s)

Funder type

Government

Funder Name

NIHR Biomedical Research Centre for Mental Health (UK)

Funder Name

South London and Maudsley NHS Foundation Trust (UK)

Funder Name

Institute of Psychiatry, Kings College London (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/04/2014		Yes	No