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Student Life @ Manchester: Evaluating a brief well-being planning intervention

Submission date	Recruitment status	[ ] Prospectively registered
11/08/2014	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/09/2014	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/05/2015	Other	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Starting university is a major life change. It can involve moving away from home, taking the first steps in training for a new career or studying a completely new subject. Major life changes such as this can have a negative effect on well-being. This study (SL@M - Student life at Manchester) will test how well a brief planning intervention, or treatment based on making positive statements about yourself (self-affirmation) designed to reduce feelings of threat and anxiety, does in improving well-being and health. This study will also find out if using the same intervention (as a booster) at a later date will further improve well-being.

Who can participate?
Students who are starting a course at the University of Manchester in 2014.

What does the study involve?
Before starting university, participants are asked to complete a questionnaire about their lifestyle (i.e., details on how much fruit and vegetables they eat, how much alcohol they drink , how much they exercise, whether they smoke or take recreational drugs) and well-being (e.g., details about sleep, depression, anxiety). After completing the questionnaire participants are randomised to one of two groups. Those in group 1 receive the intervention. Those in group 2 act as controls. The intervention involves the student completing a self-affirmation task on an if-then basis to deal with threat and anxiety when it is encountered (e.g., If I am feeling threatened or anxious then I will think about the things that I value). Halfway through their university course, participants are randomised again either the intervention or control group. Lifestyle and well-being questionnaires are completed by all students every 6 months while at university and then every year for the next 20 years.

What are the possible benefits and risks of participating?
Participants who complete the self-affirmation implementation intention may experience an improvement in their well-being. There are no risks to taking part.

Where is the study run from?
University of Manchester (UK)

When is study starting and how long is it expected to run for?
The study will be started in September 2014 prior to the first semester of university. Recruitment will stop when university semester starts in October 2015. Follow-up questionnaires will be given for up to 20 years after the start of the study.

Who is funding the study?
University of Manchester (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
A randomised controlled trial to evaluate a self-affirmation implementation intention to target health and well-being in new university students

Acronym
SL@M

Study objectives
The main hypotheses are:
1. Halfway through their university course, group I (completed the self-affirmation implementation intention before starting university and halfway through their course) and group II (completed the self-affirmation before starting university only) will have greater health and well-being than the other two groups.
2. After finishing their course, group I will have greater health and well-being than the other three groups.
3. After finishing their course, group II and group III (completed self-affirmation implementation

halfway through their course only) will have greater health and well-being than group IV (the control group did not complete self-affirmation implementation intention at either stage).

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Manchester Committee on the ethics of research on human beings; 24/06/2014; reference ethics/14204

Primary study design
Interventional

Study design
Randomised controlled trial with the between-persons factor of condition with four levels

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
A psychological health intervention on a population of university students

Interventions
Participants will be randomised to two groups: self-affirmation implementation intention condition and a comparison group (control group who do not complete this task). Halfway through their course, participants will again be randomised to the above two groups. The four study arms are:
1. Self-affirmation implementation intention at the start and halfway through the university course
2. Self-affirmation implementation intention at the start of the university course and control group halfway through the university course
3. Control group at the start of the university course and self-affirmation implementation intention halfway through the university course
4. Control group at the start and halfway through the university course (control)

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Perception of threatening life events
2. Depression
3. Anxiety
4. Well-being
Measured by questionnaire at baseline, 1, 6, 12, 18, 24, & 36 months after starting university and annually thereafter.

Key secondary outcome(s)

1. Fruit and vegetable consumption
2. Physical activity
3. Smoking status
4. Alcohol consumption
5. Recreational drug use
6. Sleep quality
7. Self-integrity
Measured by questionnaire at baseline, 1, 6, 12, 18, 24, & 36 months after starting university and annually thereafter.

Completion date
15/09/2034

Eligibility

Key inclusion criteria
Student at the University of Manchester starting in 2014

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Not a student at the University of Manchester starting in 2014

Date of first enrolment
15/09/2014

Date of final enrolment
01/10/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Manchester Centre for Health Psychology
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
University of Manchester (UK)

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
University/education

Funder Name
University of Manchester (UK) - Manchester Centre for Health Psychology

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration