U@Uni LifeGuide: Trial of an online health behaviour intervention to promote healthy lifestyle habits in new university students

Submission date 19/08/2013	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 03/09/2013	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 30/08/2016	Condition category Other	[_] Individual participant data

Plain English summary of protocol

Background and study aims

Healthy eating, being physically active, drinking sensibly and not smoking are known to reduce the risk of developing serious diseases and conditions such as cancer, heart and circulatory disease, obesity and type 2 diabetes. However, few young people engage in these behaviours. The transition from school to university provides an ideal opportunity to try to promote healthy lifestyle habits, as this is a time when young peoples health beliefs and behaviours are likely to be in a state of flux and therefore more open to change. The aim of the current study is to find out whether the online resource promotes healthier behaviour among new university students.

Who can participate?

All incoming undergraduate students (in 2013) to the University of Sheffield, UK are eligible to take part in the study.

What does the study involve?

Students who decide to take part will be asked to complete a questionnaire on their health behaviour about one month before starting university. They will then be randomly assigned to either the intervention group (an online health behaviour intervention) or the control group. The intervention is an online resource (website) that students can use before they come to university and when they are at university to help them make healthier lifestyle choices. The resource will be available to the intervention group for the duration of the study. This uses a number of evidence-based techniques from health psychology to ensure that students engage with the resource material, receive messages that target key beliefs to promote each health behaviour and make specific plans to be more healthy. All participants will be asked to complete further questionnaires 1 and 6 months after starting university. In addition, 200 participants (100 each from the intervention and control groups) will be recruited to provide a small sample of cut hair that can be analysed for biochemical markers of various health behaviours (e.g., smoking, drinking).

What are the possible benefits and risks of participating? Engaging in various health behaviours can reduce the risk of long-term health complications. We hope that the intervention will help students to make healthier lifestyle choices when at university. In order to encourage participation, participants will have the opportunity to be entered into a £100 prize draw after completing each questionnaire. Participants completing all three questionnaires will also receive a £10 gift voucher and be entered into an additional prize draw for an iPad mini. Participants who provide a hair sample will receive a gift voucher for £10 for each hair sample. No major risks or discomfort are anticipated.

Where is the study run from? The study is conducted online and is managed by researchers at the University of Sheffield, UK

When is the study starting and how long is it expected to run for? September 2013 to December 2014

Who is funding the study? The study is funded by the National Prevention Research Initiative (NPRI) in the UK

Who is the main contact? Prof. Paul Norman p.norman@sheffield.ac.uk

Study website http://www.sheffield.ac.uk/psychology/research/groups/uatuni

Contact information

Type(s) Scientific

Contact name Prof Paul Norman

ORCID ID http://orcid.org/0000-0002-5892-0470

Contact details Department of Psychology University of Sheffield Sheffield United Kingdom S10 2TP

p.norman@sheffield.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Sponsor Ref: 129941

Study information

Scientific Title

U@Uni LifeGuide: Using the transition from school to university to promote healthy lifestyle habits in young people

Acronym

U@Uni LifeGuide

Study objectives

The primary research question is whether an online intervention delivered during the transition from school to university produces significant improvements in the health behaviours of young people (i.e., fruit and vegetable intake, physical activity, alcohol consumption, smoking) six months after starting university.

Additional research questions that will be addressed include whether the intervention: (i) changes health beliefs (and whether these changes mediate the effect of the intervention on health behaviour), (ii) enhances health status, (iii) reduces health service usage, (iv) reduces recreational drug use, (v) enables young people to achieve a healthy BMI, and (vi) is cost-effective.

The study is a two-arm randomised controlled trial, with participants randomised to (i) an online health behaviour intervention or (ii) a control (measurement only) condition.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Sheffield, Department of Psychology Research Ethics Committee, 05/07/2013, number: 2013-665,

Study design

Two-arm randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Other

Study type(s) Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request patient information sheet

Health condition(s) or problem(s) studied

Health behaviour (fruit and vegetable intake, physical activity, alcohol consumption, smoking).

Interventions

After completion of an online baseline questionnaire (approximately one month before entering university), participants will be randomised to the intervention or control conditions and followed-up one and six months after starting university.

On their first approach to the intervention (following study enrolment information, consent and completion of the baseline questionnaire), participants will complete a self-affirmation task in which they select their most important personal value and provide a reason why the value is important to them. This will form part of the users profile which will be displayed every time that the user logs on to the intervention (to serve as a self-affirmation booster).

Next, participants will be directed to messages based on the theory of planned behaviour that target the key beliefs underlying each of the focal health behaviours. These messages will include a mixture of text and videos, as well as links to other relevant material. The messages were developed on the basis of formative work that identified the key behavioural, normative and control beliefs underlying new students intentions and behaviour for each of the four health behaviours.

Finally, the messages will be followed by implementation intention exercises to ensure that good intentions are supplemented by specific plans for acting on these intentions. For each health behaviour, participants will be provided with an example of an appropriate implementation intention and then instructed to generate their own if-then plan which will be saved and emailed to them as a reminder.

Intervention Type

Behavioural

Primary outcome measure

The intervention and control groups will be compared on the following primary outcome measures at six-month follow-up (controlling for baseline measures):

1. Number of portions of fruit and vegetables consumed per day assessed with a two-item food frequency questionnaire.

Total physical activity as assessed by the International Physical Activity Questionnaire (IPAQ).
 Number of units of alcohol consumed in the past week assessed with a retrospective alcohol diary.

4. Smoking status assessed with HSE items.

Secondary outcome measures

The intervention and control groups will also be compared on the following secondary outcome measures:

- 1. Frequency of binge drinking in the past week.
- 2. AUDIT scores (6 month follow-up).
- 3. Number of cigarettes smoked.

4. Social cognitive variables for each health behaviour intention (all times points), attitude, subjective norms, descriptive norms, self-efficacy, perceived control and planning (1 and 6 month follow-up).

5. Health status EQ-5D.

6. Recreational drug use (indirect measure).

7. BMI calculated from self-reported height and weight.

8. Health services usage. Self-report data on the use of the health service (e.g., GP visits, hospitalisations) (6 month follow-up).

9. Engagement with the online intervention including number of pages visited, the number of activities completed, etc. (1 and 6 month follow-up).

10. Hair analysis to provide biochemical markers of various health behaviours related to alcohol consumption, cigarette smoking, diet and recreational drug use. Participants who provide hair samples will also have their height and weight measured to calculate BMI. (Intro week and 6 month follow-up).

Unless otherwise indicated, the primary and secondary outcome measures will be assessed at all three time points (baseline and 1 and 6 month follow-up).

Overall study start date

02/09/2013

Completion date 31/12/2014

Eligibility

Key inclusion criteria

All incoming undergraduate students (in 2013) to the University of Sheffield

Participant type(s) Patient

Age group Adult

Sex Both

Target number of participants

At least 1200 (600 per arm) at 6 month follow-up + at least 200 (100 per arm) for an additional study on bio-chemical markers of health behaviour.

Key exclusion criteria Does not meet inclusion criteria

Date of first enrolment 02/09/2013

Date of final enrolment 30/09/2013

Locations

Countries of recruitment England

United Kingdom

Study participating centre University of Sheffield Sheffield United Kingdom S10 2TP

Sponsor information

Organisation University of Sheffield (UK)

Sponsor details Research & Innovation Services New Spring House 231 Glossop Road Sheffield England United Kingdom S10 2GW

Sponsor type University/education

Website http://www.shef.ac.uk/ris/index

ROR https://ror.org/05krs5044

Funder(s)

Funder type Research council

Funder Name

Medical Research Council (MRC) (UK) - National Prevention Research Initiative (NPRI) Phase 4 (UK). Ref: MR/J000450/1

Results and Publications

Publication and dissemination plan

Papers reporting the main results and the health economic analysis have been submitted and are under review.

Intention to publish date

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?
<u>Results article</u>	results	07/12/2015		Yes	No