# Trial of an online health behaviour intervention to promote healthy lifestyle habits in new university students

Submission date 30/08/2012	Recruitment status No longer recruiting Overall study status	Prospectively registered		
		[X] Protocol		
<b>Registration date</b>		Statistical analysis plan		
09/10/2012	Completed	[X] Results		
Last Edited 15/09/2015	<b>Condition category</b> Mental and Behavioural Disorders	Individual participant data		

#### Plain English summary of protocol

Background and study aims:

Eating healthily, 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 health behaviours. The transition from school to university provides an ideal opportunity to try to promote healthy lifestyle habits, as this is a time when students' health beliefs and behaviours are likely to be in a state of flux and therefore more open to change. The programme is an online resource that students can use before they come to university and when they are at university to help them make healthier lifestyle choices. The online resource will be accessible from computers as well as other digital devices such as smart phones and tablets, and will be linked to a Facebook and Twitter account. The resources will be available for the duration of the study. The programme uses a number of techniques from health psychology to ensure that students 1. engage with the material

- 2. receive messages that target key beliefs to promote each health behaviour
- 3. make specific plans to be more healthy

The aim of the current study is to evaluate whether the online programme promotes healthier behaviours among new university students.

Who can participate?

All incoming undergraduate students (in 2012) to the University of Sheffield.

#### What does the study involve?

Students who decide to take part will be asked to complete a questionnaire on their health behaviour approximately one month before starting university. They will then be randomly assigned to receive an online resource to help them to make healthy choices at university or a control condition. All participants will be asked to complete further questionnaires, 1 and 6 months after starting university. Participants will receive a gift voucher for £10 for completing all three questionnaires as well as the opportunity to win a gift voucher for £100 in a prize draw after completing each questionnaire. In addition, a random sample of 200 participants (100 from each of the groups) will be asked to provide a small sample of cut hair that can be analysed for

bio-chemical markers of various health behaviours (e.g. smoking, drinking). Participants asked to provide a hair sample will receive a gift voucher for £10 for each hair sample.

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 programme will help students to make healthier lifestyle choices when at university. No major risks or discomfort are anticipated.

Where is the study conducted?

The study is conducted online and is managed by researchers at the University of Sheffield.

When is the study starting and how long is it expected to run for? September 2012 to August 2013.

Who is funding the study?

National Prevention Research Initiative (NPRI), UK. This is a national initiative made up of government departments, research councils and major medical charities that are working together to encourage and support research into chronic disease prevention.

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

## **Contact information**

**Type(s)** Scientific

**Contact name** Dr Paul Norman

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## Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers 129941

## Study information

#### Scientific Title

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

#### Acronym

U@Uni

#### **Study objectives**

The primary research question is whether a multi-device digital 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:

1. Changes health beliefs (and whether these changes mediate the effect of the intervention on health behaviour)

- 2. Enhances health status
- 3. Reduces health service usage
- 4. Reduces recreational drug use
- 5. Enables young people to achieve a healthy BMI
- 6. Improves academic performance
- 7. Is cost-effective

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

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

University of Sheffield, Department of Psychology Research Ethics Committee, 13/08/2012, ref: 2012-436

#### Study design

Two-arm randomised controlled trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

Study setting(s) Hospital

**Study type(s)** Quality of life

#### Participant information sheet

Not available in web format. Please use the contact details below to request patient information material.

#### 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 user's 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. Participants will be able to tag the material that they find interesting so that it is highlighted on their profile page. Participants will also be able to upload other relevant information from the web and share this with other users.

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. Each planning exercise will involve participants using a series of dynamic boxes to identify a good opportunity to act on their intentions (e.g., 'If I am in the supermarket', 'If I am offered a drink') and a suitable response to that opportunity (e.g., 'then I will buy at least three fruits!', 'then I will say that I need to get up early in the morning!'). Suggestions will be provided of the most common opportunities and responses (based on formative research with current students and exemplars from the implementation intention literature) to aid this process, although participants will also be able to generate their own opportunities and responses. Participants will be prompted to make a plan when they exit a section of the intervention. The plans that participants make will be stored in a 'plan repository' that can be reviewed at any time with a direct link from the participant's profile page. Participants can also opt to receive reminders of their plans.

Participants in the control group will be directed to the University of Sheffield home page after completing baseline questionnaire.

All participants will complete online questionnaires approximately one month before starting university (baseline) and at one and six months after starting university.

**Intervention Type** Other

**Phase** Not Applicable

#### Primary outcome measure

The following will be measured at six-month follow-up (controlling for baseline measures): 1. Number of portions of fruit and vegetables consumed per day assessed with items from the Health Survey for England (HSE)

2. Total physical activity as assessed by the International Physical Activity Questionnaire (IPAQ)

3. Number of units of alcohol consumed in the past week assessed with HSE items (retrospective alcohol diary)

4. Smoking status assessed with HSE items

#### Secondary outcome measures

1. Sedentary behaviour (sitting) as assessed by the IPAQ.

2. Frequency of binge drinking in the past week.

3. AUDIT scores (6 month follow-up).

4. Number of cigarettes smoked.

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

6. Health status - EQ-5D.

7. Recreational drug use (estimated across sample using an indirect measure, rather than reported by participant).

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

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

10. Academic performance. Average exam marks and registration status (i.e., registered, transferred, withdrawn, leave of absence) at the end of Semester 1 and 2.

11. Usage of university sports facilities - self-reported and usage data from university sports facilities (6 month follow-up).

12. Engagement with the digital intervention including number of pages visited, the number of activities completed, etc.

13. 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.

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

03/09/2012

# **Completion date** 31/08/2013

## Eligibility

#### Key inclusion criteria

All incoming undergraduate students (in 2012) 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 03/09/2012

Date of final enrolment 31/08/2013

## 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 n.donkin@sheffield.ac.uk

**Sponsor type** University/education

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

ROR https://ror.org/05krs5044

## Funder(s)

Funder type Government

**Funder Name** National Prevention Research Initiative - Phase 4 (UK) ref: MR/J000450/1

## **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?
Protocol article	protocol	05/02/2013		Yes	No
Results article	results	05/06/2014		Yes	No
<u>Results article</u>	results	27/09/2014		Yes	No