A Theory-Based Online Health Behavior Intervention for New University Students: Study Protocol for a Repeat Trial

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Background

As detailed in the accompanying paper [1], the U@Uni intervention was initially trialled with the 2012 cohort of incoming undergraduate students to the University of Sheffield. The results of the trial indicated that the U@Uni intervention had a significant effect on smoking status at six-month follow-up, although the intervention did not significantly effect the other primary outcome variables (i.e., portions of fruit and vegetables, physical activity, units of alcohol).

Unfortunately, the original trial was compromised by a number of limitations that resulted in recruitment into the trial and engagement with the intervention being lower than expected; indeed, just 1% of the participants completed all three components of the intervention. This may have been due to four issues. First, the bespoke software platform that was developed to deliver the U@Uni intervention had a number of technical glitches. As a result, participants' experience of completing the baseline questionnaire and being directed to the intervention was less than optimal. What was intended to be a seamless process was experienced as a series of discreet steps with subsequent drop-out at each step. For example, after completing the baseline questionnaire, participants in the intervention arm were directed to the U@Uni login page where they had to enter some registration details before completing the self-affirmation manipulation. After completing self-affirmation manipulation, participants had to login a second time in order to access the intervention material. Second, as a result of efforts to try to correct the technical glitches, the recruitment emails were sent a week later than intended, which meant that potential participants received the initial recruitment emails only two weeks before the start of the first semester (i.e., only one week before "Freshers' Week"). This may have coincided with a particularly busy period of time for many potential participants which may have dampened recruitment. Third, the baseline questionnaire was time-consuming to complete (approximately 20 minutes) due to the large number of items needed to assess the primary and secondary outcomes variables. Indeed,

approximately 9% of those who started the questionnaire failed to complete it. Fourth, intervention participants had complete control over the extent and type of intervention material that they viewed. For example, intervention participants could choose which health behaviours and which belief-based messages to view and whether or not to make plans. However, this may also have reduced engagement as intervention participants could choose not to view any messages or make any plans.

With these limitations in mind, a number of changes will be made to the study protocol and a repeat trial will be conducted. First, the intervention will be delivered using the LifeGuide open-source software platform [2]. LifeGuide has been specifically designed for researchers to develop, deliver and evaluate online health behaviour interventions. It allows participants to complete baseline measures, be randomly allocated to arms, and access intervention material all within the same website. As a result, transitions between the various tasks are experienced by participants as seamless with reduced opportunity to exit (e.g., by having to re-login). Second, the initial recruitment emails will be sent to potential participants four weeks before the start of the first semester (i.e., three weeks before "Freshers' Week"). This will extend the recruitment period and ensure that potential participants are able to complete the baseline questionnaire well before starting university. Third, the baseline questionnaire will be shortened, where possible, through the use of brief measures of the primary outcome variables and removing measures of some of the secondary outcome variables. This will help to reduce questionnaire fatigue before participants are directed to the intervention material. Fourth, when visiting the intervention website, participants will be required to work through four short modules that will require them to choose at least one belief-based message to read and to make at least one plan for each health behaviour, before gaining access to the full intervention website. It is hoped that these changes will mean that the repeat trial is able to provide more accurate data on the efficacy of the intervention by ensuring that more participants are recruited into the trial and that intervention participants

view (i.e., engage with) the intervention material. This, in turn, should provide more precise estimates of the intervention effects and reduce decision uncertainty in the health economic modelling.

Principal Research Questions

The primary research question is whether, compared to a measurement only control arm, an online digital intervention ("U@Uni LifeGuide") delivered during the transition from school to university produces significant changes in the health behaviours (i.e., fruit and vegetable intake, physical activity, alcohol consumption, smoking) of young people 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 the health behaviours), (ii) enhances health status, (iii) reduces health service usage, (iv) reduces recreational drug use, and (v) reduces BMI.

Method

Ethical Approval

The study was approved by the Department of Psychology Research Ethics Committee at the University of Sheffield (no. 2013-665).

Trial Registration

Current Controlled Trials, ISRCTN07407344.

Design

Randomised controlled trial with 2 arms: (i) an online intervention targeting four health behaviours during the transition from school to university and (ii) measurement only control.

Recruitment, Randomization and Allocation

Incoming undergraduate students to the University of Sheffield ($N \approx 5000$) will be sent an email one month before the start of semester 1 with information about the study and a link to the baseline questionnaire. On completion of the baseline questionnaire participants will

be randomly allocated to one of two arms using a random number generator (as part of the LifeGuide software). Participants in both arms of the trial will be sent emails with links to the follow-up questionnaires using SurveyGizmo one and six months after starting university. All participants will receive three automatic reminders to complete the questionnaires at each time point. Participants in the intervention arm will also be sent automatic email prompts to use the intervention website after initially accessing the intervention website and shortly before the start of their second semester at university. Participants will receive incentives to complete the questionnaires by being entered into £100 prize draws at each time point. Participants who complete all three questionnaires will receive a £10 gift voucher and will be entered into a further prize draw for an iPad mini.

Intervention

After completing the baseline questionnaire, participants in the intervention arm will be directed to the online intervention that will combine three techniques from health psychology (self-affirmation, theory-based messages, and implementation intentions) to support the adoption of healthy behaviours at university. The intervention will be delivered using the open-access LifeGuide software platform.

Participants allocated to the intervention arm will first complete a self-affirmation task. They will be asked to provide details of their name, course, home town and main interests/hobbies before being asked to select their most important personal value from a list of 8 commonly held personal values (e.g., sense of humour, academic achievement; adapted from [3]) in a drop-down menu (or provide their own). Participants will also be asked to briefly provide one reason why the value is important to them. The resultant information will form part of the user's "profile" that will be displayed in the banner at the top of all pages of the intervention website. The profile will include the participant's name as well as the value they chose and the reason why it is important to them ("I value "X" because "Y") and will serve as a self-affirmation "booster" (i.e., to reaffirm participants whenever the website is

accessed). Participants will then be directed to complete four short modules on each of the four targeted health behaviours before gaining access to the full U@Uni website.

Module 1 will focus on exercising regularly at university. Participants will be presented with a list of the topic headings that contain the belief-based messages developed via formative research [4] and instructed to choose one topic (e.g., "Exercise improves your fitness"). They will then be directed to the intervention page containing the theory-based message that will include a mixture of text, videos of students talking about the targeted belief, and links to other related material. After viewing the page, participants will have the opportunity to either view another topic/message or proceed to the planner. On the planner page, participants will be presented with a brief video and text explaining the purpose and format of the planning exercise. They will be presented with an example of an implementation intention in an if-then format (e.g., "IF I am tempted to skip exercising, THEN I will tell myself no excuses and remind myself I will feel great after exercising") and asked to make their own plans using the if-then format. Participants will then be presented with their plan and asked to repeat it to themselves several times. A record of the plan will be automatically emailed to the participant and saved in their plan repository. When participants have finished Module 1, they will be presented with the first page of Module 2 ("Eating fruit and vegetables), and instructed to work through the module in the same way as with Module 1 (i.e., they read theory-based messages before being asked to form a plan). Participants will then be invited to complete Modules 3 ("Avoiding binge drinking") and 4 ("Avoiding smoking").

When all four modules have been completed, participants will be given access to the full U@Uni website. The home page will contain an introductory video and text on how to use the website. Tabs will direct participants to the messages and information on each of the four health behaviours as well as links to the planner, their saved plans, and general health information. Participants will have full control over which parts of the intervention website they access and the website will be available during the full duration of the trial.

Biochemical Analyses

200 participants (100 from each arm of the trial) will be recruited into a further study on the biochemical markers of health-related behaviour. All participants will be sent an email at the start of "Freshers' Week" inviting them to participate in the study in which they will be required to provide two hair samples that can be analysed for biochemical markers of health-related behaviour. The first hair sample (baseline) will be taken during "Freshers' Week" and the second (follow-up) taken six months after starting university.

Measures

Primary outcome measures: Self-reported health behaviour will be measured using a mixture of reliable and validated measures as well items from the Health Survey for England (HSE) [5]. (i) *Fruit and Vegetable Consumption*. Fruit and vegetable consumption (portions per day) will be assessed using a two-item dietary questionnaire [6] which has been validated against bio-chemical markers (e.g., potassium excretion, urinary potassium/creatinine ratio and plasma vitamin C). (ii) *Physical Activity*. The International Physical Activity Questionnaire (IPAQ) will be used to assess levels of physical activity. Respondents indicate how many times, and for how long, they have engaged in vigorous exercise, moderate exercise and walking in the past 7 days. These values are then comverted into METs (metabolic equivalent of task) to provide a total score. The IPAQ has undergone extensive reliability and validity testing across 12 countries [7]. The IPAQ items will be supplemented by more detailed questions on walking from the HSE. (iii) *Alcohol*. Alcohol consumption will be assessed using a retrospective seven-day diary in which participants are asked to report the amount of alcohol consumed on each of the past 7 days [8]. The total number of units of alcohol consumed in the past week (and the number of binge sessions) will be calculated. (iv) *Smoking*. Items based on the HSE [5] will be used to assess participants' current smoking status (and the typical number of cigarettes/amount of tobacco smoked).

Secondary outcome measures: (i) *Social cognitive variables*. Brief measures of social cognitive variables for each behaviour will be constructed in line with current recommendations [9]. These will include measures of attitude (e.g., "Engaging in binge drinking at university would be… good/bad"), norms (e.g., "Most people who are important to be think I should/should not engage in binge drinking at university"), self-efficacy (e.g., "If I wanted, I could easily engage in binge drinking at university"), perceived control (e.g., "Whether or not I engage in binge drinking at university is under my control"), intention (e.g., "I intend to engage in binge drinking at university") and planning (e.g., "To what extent do you have a detailed plan about how to avoid binge drinking at university?"). (ii) *Health status* will be assessed using the EQ-5D-3L [10]. The EQ-5D-3L is a short, standardised measure of health status that assesses levels of severity (no problems/some or moderate problems/extreme problems) in five dimensions: mobility, self-care, usual activities, pain/discomfort, anxiety/ depression. The measure provides a descriptive profile and a single index of health status. (iii) *Recreational drug use*. An indirect method of assessing recreational drug use will be used that maintains respondent anonymity [11]. Respondents will be asked to indicate the number of yes answers (0 or 5, 1, 2, 3, 4) to 5 questions – 4 of which have 50% population prevalence (e.g., odd or even date of birth) and 1 of which is on their use of recreational drugs. (iv) The Alcohol Use Disorders Identification Test (AUDIT) [12] will also be used to assess hazardous and harmful patterns of alcohol use. (v) *BMI*. Participants will record their height and weight to calculate BMI. (vi) *Health services usage*. Participants will be asked to report their use of health services (e.g., GP visits, hospitalisations). (vii) *Engagement with the digital intervention*. Various measures of engagement with the intervention will be recorded including the number of pages visited, the number of activities completed, etc.

Hair analysis: For participants who participate in the additional study of biochemical markers of health behaviour, the hair samples will be liquefied and analysed for biochemical markers of various health behaviours related to alcohol consumption, cigarette smoking, diet

and recreational drug use. The participants will also have their height and weight measured to calculate BMI.

Sample Size Calculations

The original trial of the U@Uni intervention achieved an initial response rate of 31.34% to the recruitment emails and was able to obtain at least one follow-up data point from 76.60% of respondents. Assuming the same response and retention rates for the repeat trial, this would produce a total sample size of 5000 x .3134 x .7660 = 1200 (i.e., 600 per arm of the trial). This sample will be sufficient to detect a standardised effect size of d = 0.20 at a two sided significance level of .0127 (the p value has been adjusted to allow for multiplicity in the co-primary endpoints) with 80% power. Webb et al. [13] reported that the overall effect size of internet-based health behaviour interventions was d = 0.16, although this increased for interventions based on the TPB (d = 0.36) and those using implementation intentions (d = 0.25). Given that the proposed intervention incorporates these additional features, we anticipate sufficient power to detect differences between the intervention and control arms in outcomes. For the hair analysis, a sample size of 100 participants will be sufficient to detect a medium effect size of d=0.40 (alpha=.05, power=.80).

Analyses

Both the data and the health economic analyses will follow the same procedure as outlined in the study protocol paper for the original U@Uni trial [14] and reported in the accompanying papers [1, 5]. Thus, multivariate analysis will be conducted to assess the impact of the intervention on each of the four targeted health behaviours at six-month follow-up, controlling for age, gender, nationality and baseline scores.

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Table 1. *Summary of Primary and Secondary Outcome Measures*

Measure	Baseline	One-month follow-up	Six-month follow-up
Primary Outcome Measures:			
Fruit and Vegetable Intake	x	x	x
IPAQ (Physical Activity)	x	x	x
Alcohol Use (Units)	x	x	x
Smoking Status	x	x	x
Secondary Outcome Measures:			
Number of binge sessions	x	x	x
Number of cigarettes	x	x	x
Intention (all HBs)	x	x	x
EQ-5D-3L (Heath status)	x	x	x
BMI	x	x	x
Drug use	x	x	x
TPB variables/planning		x	x
AUDIT			x
Health services usage			x
Hair samples	x		x

Figure 1. *Flowchart of the Randomised Controlled Trial*