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TRIALS

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Effects of Study Design and Allocation on participant behaviour-ESDA: study protocol for a randomized controlled trial

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Abstract

Background: What study participants think about the nature of a study has been hypothesised to affect subsequent behaviour and to potentially bias study findings. In this trial we examine the impact of awareness of study design and allocation on participant drinking behaviour.

Methods/Design: A three-arm parallel group randomised controlled trial design will be used. All recruitment, screening, randomisation, and follow-up will be conducted on-line among university students. Participants who indicate a hazardous level of alcohol consumption will be randomly assigned to one of three groups. Group A will be informed their drinking will be assessed at baseline and again in one month (as in a cohort study design). Group B will be told the study is an intervention trial and they are in the control group. Group C will be told the study is an intervention trial and they are in the intervention group. All will receive exactly the same brief educational material to read. After one month, alcohol intake for the past 4 weeks will be assessed.

Discussion: The experimental manipulations address subtle and previously unexplored ways in which participant behaviour may be unwittingly influenced by standard practice in trials. Given the necessity of relying on self-reported outcome, it will not be possible to distinguish true behaviour change from reporting artefact. This does not matter in the present study, as any effects of awareness of study design or allocation involve bias that is not well understood. There has been little research on awareness effects, and our outcomes will provide an indication of the possible value of further studies of this type and inform hypothesis generation.

Trial Registration: Australia and New Zealand Clinical Trials Register (ANZCTR): ACTRN12610000846022

Background

The "Hawthorne effect", also known as *reactivity*, refers to the possibility that people may change their behaviour simply because they know they are participating in a study [1]. The name derives from studies done in the workplace at the Western Electric Plant in Hawthorne, Illinois from 1924-32. It is well accepted that there is unintended reactivity by participants in randomised controlled trials [2-4]. Placebo control conditions have been developed in pharmacological trials and elsewhere to control for the effects of disappointment at allocation outcome as well as for the placebo effect itself [5,6]. Despite longstanding awareness of reactivity [1], we are aware of only one experimental study measuring the size of the aggregate effect. This study found the effect to be large: approximately 1.5 standard deviations maintained for six months on an objectively ascertained outcome without scope for information bias [7]. However, this dental experiment compared one group, led to believe both that they were in a trial and in receipt of experimental toothpaste, with a second group from whom consent was not obtained and who were unaware of research participation. This design means that the specific effects of trial participation cannot be separated from the broader effects of research participation. There are also many possible explanations for the observed differences including research recruitment, research assessment, randomisation and placebo effects. Of these, assessment reactivity or mere measurement effects have attracted considerable recent attention [8-11] and there

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is an extensive and advanced literature on placebo effects [6,12,13].

In addition to possible effects in the recruitment phase of a randomised controlled trial (RCT), the process of randomisation itself may be perceived by participants as odd or confusing [2,14]. This uncertainty about how participants view the process of taking part in RCTs leads logically to the question of whether participation in these studies generates sufficient reflection upon behaviour to impact upon the outcomes of interest. An experimental contrast with participation in a non-randomised study is needed to evaluate this possibility.

This study, funded via a project grant from the Australian Research Council, will examine the effects of participants' knowledge of research design, comparing the effects of participation in a cohort study, with participation in a RCT. The behavioural focus of the study will be alcohol consumption. Participant awareness of study design and random allocation will be experimentally manipulated. Two hypotheses will be tested: (1) that knowledge of participation in a randomised study in comparison to a cohort (i.e., a non-experimental) study alone will reduce participants' alcohol consumption; and (2) that knowledge of allocation to an intervention condition in comparison to a control condition in a randomised trial will reduce participants' alcohol consumption. This latter hypothesis investigates whether placebo effects are influenced by expectancies generated as a result of the trial process rather than solely deriving from the perceived properties of the intervention.

Methods

Design

The study design is a multi-centre three-arm parallel group randomised controlled trial (Figure 1). Ethical approval to conduct the study was granted by the University of Otago Ethics Committee (Protocol number: 10/148).

Setting

The setting is large public universities in New Zealand and Australia and recruitment and randomisation will be undertaken in waves, one university at a time, with adjustment to sample size estimates after preliminary analyses at each stage. This design is not to be confused with the stepped wedge design, as participants are randomised to the three experimental conditions as they are recruited.

Procedure

All students will be invited by e-mail to participate in an on-line "Research project on student drinking". Students will be informed that "The study involves the completion of two short web surveys each one month apart" and asked to click on a hyperlink which takes them to the study website (URL) and information form (http://www.behaviourscience.net/InformedConsent.pdf). Clicking on a link to complete the first survey will be taken as consent. A reminder message will be sent two weeks later.

Screening

The baseline survey will be comprised of questions about alcohol intake and other behaviour (available at http://behaviourscience.net/). Any participant whose answers indicate a moderate to high level of alcohol intake (indicated by a score of 4 or more on the AUDIT-C [15]) will be randomised to one of three conditions. Those who score less than 4 on the AUDIT-C will be thanked for participating and provided with a link to *Alcohol: The Basics*, a page containing information about effects of alcohol, safe drinking levels and problems associated with drinking, such as drink-driving (Figure 2).

Randomisation

Following screening, participants will be randomised without their knowledge to one of three conditions (A-C). Randomisation will be effected by computer using a random number generator. Participants will not be informed that they are participating in a randomised study and given the computerised randomisation, the research team will not know which group each participant is assigned to until after outcomes are assessed. There is thus no opportunity for randomisation to be subverted.

Interventions

Participants in the three experimental groups will also be presented with the opportunity to access the *Alcohol: The Basics* material via a hyperlink. This material was selected *not* to be effective in promoting behaviour change, and there will be identical levels of encouragement to actually read the alcohol health information in each condition. The differences between groups exist solely in the way the study is described to participants (see Figure 1), namely, in what students are told is the design of the study (cohort or trial), along with their allocation status if randomised to the trial. It should be noted that Figure 1 includes the exact text presented to participants with the differences between conditions B and C emboldened here.

Outcome measurement

At baseline each participant will be advised they will be sent another survey by email in a month's time. The second survey (which can be viewed at http://behaviourscience.net/) contains eight questions about

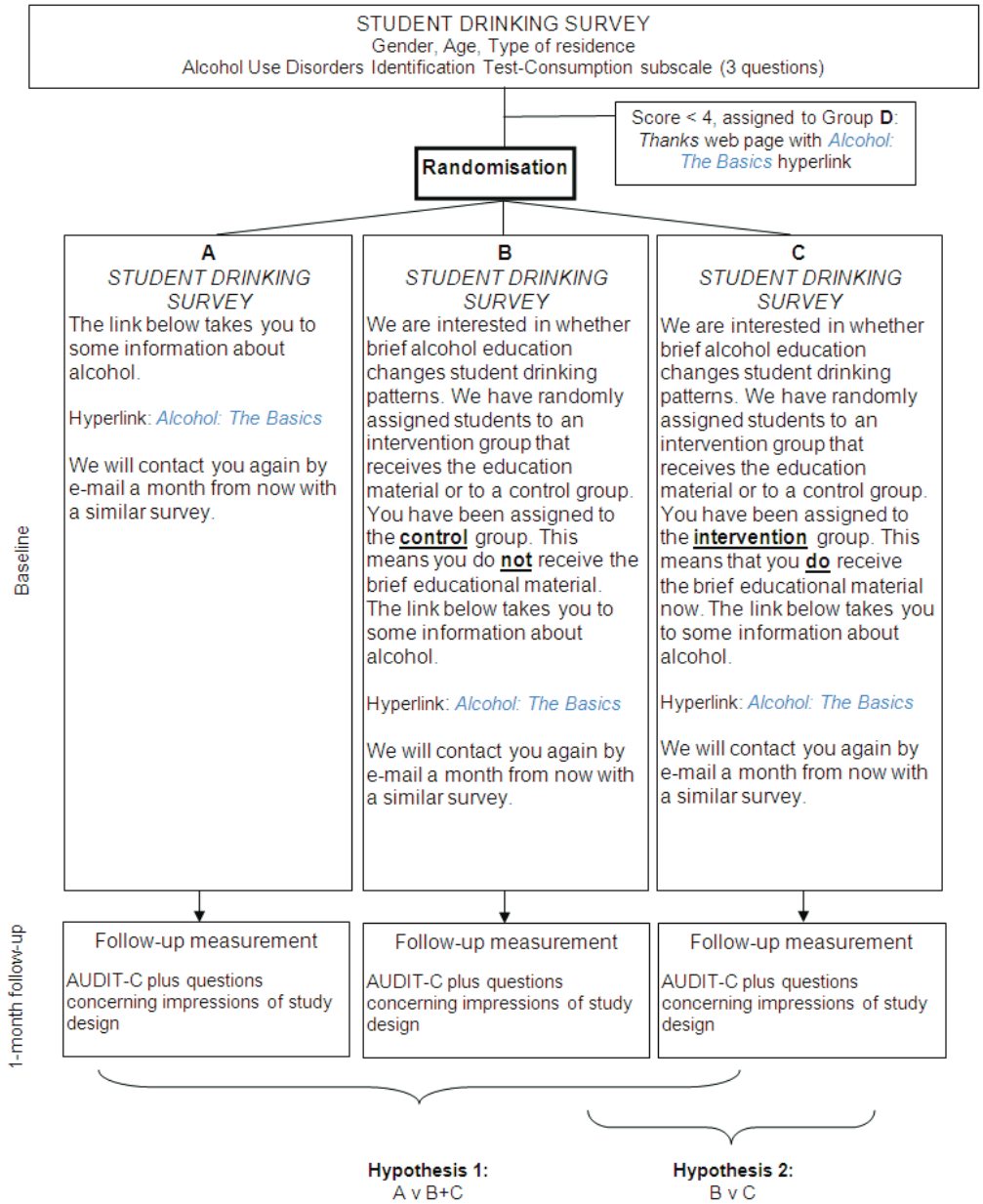

Figure 1 Study design.

drinking patterns over the past month and participants' impressions of the study. The primary outcome measures will be the frequency, quantity of alcohol consumption per typical drinking occasion (in standard drinks; 10 g ethanol), volume of alcohol consumed in the preceding four weeks and the incidence of hangover in the same period.

Sample size estimation

There is no previous research on which to base an expected effect size for this study. Assuming power of 0.80, alpha 0.05, dispersion of 0.2, and a 2-sided test, we would need to analyse 1,946 cases per group at 1 month (i.e., a total N of 5838) we could detect a group difference of 5.5% for comparisons of B v C (Hypothesis 2). This sample size provides additional power to detect an effect of similar size for A v B and C (Hypothesis 1). If the dispersion is greater than anticipated at 0.4, with 5,838 participants at follow-up we will still be able to detect a 7% difference. Accordingly, we will invite all students at the University of Otago (approximately 20,000 individuals), with the expectation of recruiting approximately a third