

**Randomized controlled trial of a web-based primary care intervention for multiple  
health risk behaviors**

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## **Abstract**

**Background:** Physical inactivity, low fruit and vegetable intake, hazardous drinking, and smoking are leading risk factors for disease and injury. The aim of this study was to obtain estimates of efficacy in reducing the first three of these behaviors.

**Method:** The design was a randomized controlled trial: 218 patients (17-24 years) attending a student health service at a New Zealand university in 2003 were assigned to: (A) web-based assessment and personalized feedback (n=72); or (B) assessment only (n=74); or (C) minimal contact (n=72). Outcome measures were the proportion meeting recommendations for fruit and vegetable consumption, physical activity, and alcohol consumption six weeks later.

**Results:** Follow-up assessments were attained for 86% of participants, with no evidence of differential attrition. There were significant differences in the proportion meeting recommendations for fruit and vegetable consumption and physical activity in group A relative to C. Hazardous drinking prevalence did not vary significantly by group.

**Conclusions:** Differences appear attributable to the intervention. The intervention could be routinely provided in primary care, and its efficacy could be assessed in a large randomized controlled trial.

**Keywords:** web, brief intervention, student, fruit, vegetable, physical activity, alcohol

Physical inactivity, low fruit and vegetable intake, hazardous alcohol consumption, and smoking are leading behavioral risk factors for disease and injury [1]. Their importance is acknowledged by the WHO [2], in the policy documents of most governments, and there is a vast research literature on the epidemiology of these behaviors and on means of modifying them [3-6].

A promising line of inquiry is the development of interventions delivered in the context of primary care, i.e., general practice settings, hospitals, and emergency departments. For example, meta-analytic reviews of randomized controlled trials for brief intervention in hazardous drinking, reveal benefits of a 5-15 minute intervention enduring for 12 months or more [7, 8].

Research is emerging on the use of computers to deliver such interventions. A recent review paper [9] concluded that “the evaluation of innovative interventions for alcohol problems is still at a fledgling stage. Existing studies need replication, and effort must be made to conduct controlled trials in naturalistic conditions to ensure generalisability of the findings to routine healthcare delivery” (p233). It was noted that normative feedback is typically a key ingredient and several studies show a benefit of personalized normative feedback on drinking, even if many were laboratory-based rather than studies conducted in primary care settings [9].

In a trial at the student health service of a New Zealand university, reductions in hazardous drinking of 20-30% lasting six months were observed in persons exposed to a 15-minute computerized intervention relative to controls [10]. The supposed mechanism was to encourage individuals to moderate their drinking by creating dissonance between their behavior and actual peer drinking norms, which are typically overestimated [11].

This mechanism is probably common to other health risk behaviors: individuals may overestimate their compliance with norms for physical activity and fruit intake. It is also likely that many underestimate the extent to which they fall short of health recommendations for these behaviors.

An intervention that is deliverable within the current infrastructural constraints of primary care, that is appealing to users, and effective in reducing risk behavior, could produce health benefits for the population. Few trials of such multiple behavioral risk factor interventions have been reported [12]. Accordingly, the aim of this study was to examine the efficacy of a brief web-based intervention for multiple risk behaviors in a primary care setting for young people.

## **Method**

### *Study design*

The study was a three-arm, parallel group, randomized controlled trial. Participants were assigned to receive (A) computerized assessment, feedback and advice on their fruit and vegetable consumption, physical activity, alcohol consumption, and smoking; (B) computerized assessment only, or (C) minimal contact at baseline. Ethical approval was granted by the University of Otago Ethics Committee in February 2003. A two-arm trial (A versus B) would ordinarily be sufficient to examine the efficacy of such an intervention. However, given the similar nature of the assessment required to measure outcome, and the intervention itself (described below), which might induce a Hawthorne Effect [13], thereby reducing the experimental contrast, a third group (C) which was not assessed at baseline was included. We did not expect to be able to assess the effects on smoking, given its low prevalence in this population group [14].

### *Sample size estimation*

There have been no similar trials on which to base sample size estimates. Our previous trial of electronic screening and brief intervention was for hazardous drinking only and it relied on more extensive outcome measures than could be used here [10]. In that trial, effect sizes in the range 0.40-0.45 standard deviation units were observed. For this study we sought to examine intervention effects in terms of the prevalence of individuals meeting health recommendations post intervention. Given there were three outcomes measured, i.e., compliance with recommendations for (1) fruit and vegetable consumption, (2) alcohol consumption, and (3) physical activity, we produced a range of sample size estimates based on 25% differences between groups A and C. It was assumed that post intervention compliance with fruit and vegetable guidelines would be 55% (group A) versus 30% (group C). For physical activity we assumed 70% versus 45% compliance. For alcohol consumption we assumed that binge drinking would be reported by 40% of group A versus 65% of group C. Using the procedure described by Sokel and Rolf [15], and assuming Type I error of .05, power of 0.80, and loss-to-follow-up of 15%, the number of persons required per group was 71.

### *Recruitment*

Patients attending the student health service of the University of Otago were invited to complete a confidential computerized survey as part of the *Tertiary Student Health Project*. The survey was to be completed in the waiting area, followed by a web-based survey six weeks later. In accordance with ethical approval, the study was not described as a randomized controlled trial. In addition, participants were invited to have their blood pressure measured with an electronic sphygmomanometer, in order to test the feasibility

of measuring blood pressure for a larger trial. Blood pressure data are not presented in this paper.

### *Randomization*

Participants were assigned by a computerized random number generator in blocks of 15 (five per trial arm), to ensure approximately equal group sizes in a short recruitment period. Allocation concealment was achieved by not informing participants that they were participating in an intervention trial, in accordance with ethical approval.

Additionally, the research assistant recruiting participants was not informed of group allocation, which was done by computer. Recruitment was conducted separately by sex, to ensure approximately equal numbers of men and women in the trial as a whole.

### *Assessment*

Participants completed a web-based questionnaire in the waiting area. Groups A, B and C entered demographic details and had their blood pressure measured. At this point Group C participants were thanked and reminded that they would be contacted by e-mail in six weeks to complete a web-based follow-up assessment. Participants in groups A and B continued, completing assessments as follows:

*Fruit and vegetable consumption.* Two questions from a national survey [16] were used to assess (1) daily fruit intake (from 0 to >2 pieces), and (2) daily vegetable intake (from 0 to >3 servings).

*Alcohol consumption.* Participants were asked to indicate (1) the age they first had a drink (10g ethanol), (2) whether they had alcohol in the last year, (3) the largest amount

consumed in the previous four weeks and the duration of the episode, and (4) their responses to the Alcohol Use Disorders Identification Test (AUDIT) [17].

*Smoking.* Participants were asked to indicate their smoking status: (1) ‘never smoked’, (2) ‘ex-smoker’, (3) ‘occasional smoker’ defined as on average <1 cigarette per day, and (4) ‘regular smoker’ defined as on average  $\geq 1$  cigarettes per day. Occasional and regular smokers completed the Fagerström Test [18].

*Physical activity.* Participants were presented with a list of 30 common activities and asked how often in the past week they had engaged in each, the duration of each episode, and their level of exertion (vigorous or non-vigorous).

Participants then completed the mental health subscale of the SF-36 [19]. Members of group B were thanked and reminded that they would be contacted by e-mail in six weeks to complete web-based follow-up.

### *Feedback*

Participants in group A were then presented with feedback. For each behavior, feedback was presented in terms of (1) health authority recommendations followed by (2) social norms and self-comparison, e.g., recommendations to eat at least two servings of fruit and three servings of vegetables per day, that adherence to these guidelines reduces the risk of heart disease, some cancers and type II diabetes; the percentage of the population of the same age and gender adhering to these recommendations, directly compared to the participant’s level of fruit and vegetable intake. The assessment and feedback can be viewed at <http://ipru.otago.ac.nz/heartdemo/index.html>. Group A participants were thanked

and were reminded that they would be contacted by e-mail in six weeks for follow-up assessment.

#### *Follow-up assessment*

Six weeks after intervention, all participants were invited by letter to complete a follow-up questionnaire by clicking a hyperlink to the study website, sent to their e-mail address. Embedded in the hyperlink was a unique identifier which allowed the participants' record to be matched to their baseline data. Included with the letter was a pen (value US\$0.50) as a token of appreciation for participating. A reminder e-mail was sent to participants who did not respond, followed by a reminder telephone call.

#### *Outcome measures*

*Fruit and vegetable consumption* was dichotomized as meeting or exceeding the recommendation of two servings of fruit and three servings of vegetables per day (code=1) versus not meeting the recommendation (code=0).

*Physical activity* was dichotomized from the five levels of activity used in the 1996/97 *New Zealand Health Survey* [20]. Participants were categorized as follows: *sedentary* = no activity in the previous seven days, *relatively inactive* < 2.5 hours, *relatively active* ≥ 2.5 hours, *highly active* >5 hours, while *vigorous activity* was defined as ≥1 hour in a single session, of sufficient intensity to cause sweating. Endorsements of the latter three categories were coded as *active* (code=1) while the first two were coded as *inactive* (code=0).



*Alcohol consumption* measures were based on a four-week report of the maximum drinks consumed in a single episode and the episode's duration. Participants reported their weight in kilograms for the purpose of computing an estimated blood alcohol concentration (EBAC) [21]. We computed a continuous measure of the peak EBAC, and a dichotomous classification of binge drinking representing consumption of more than four/six (women/men) standard drinks in a single episode in the preceding four weeks.

### *Analysis*

Dichotomous variables were analyzed using Pearson's Chi-squared test with one degree of freedom for the following pairwise comparisons: A vs C, A vs B, and B vs C. Mean peak EBACs and 95% confidence intervals were computed for each experimental group using the method described by Armitage and Berry [22]. Mean differences were analyzed using analysis of variance.

## **Results**

A schema of the trial design is presented in Figure 1. Of 277 eligible students invited to participate, 43 refused (16%), five were too sick (2%), two could not complete in the time available (1%), six did not consent to follow-up (2%), and four experienced technical problems (1%). This left 218 participants in the trial (78% of those eligible). Table 1 presents the demographic characteristics and baseline compliance levels of the three experimental groups.

<Table 1>

We attained six-week follow-up assessment data for 61, 65, and 61 students in groups A, B, and C respectively, a follow-up rate of 86% overall, and with no evidence of

differential attrition by experimental group ( $\chi^2=0.389$ ,  $p=0.823$ ). Six participants (two from each group) did not complete all of the physical activity assessment items at follow-up, such that the number of participants included in these analyses was 59, 63, and 59 in groups A, B, and C respectively.

*Assessment of bias attributable to loss to follow-up*

Table 2 presents baseline summary data for participants in groups A and B (C was not assessed at baseline) as a function of whether they completed the six-week assessment. Participants lost to follow-up had a significantly greater prevalence of smoking than did those who completed follow-up assessments. Differences for other health behaviors were non-significant.

<Table 2>

*Fruit and vegetable consumption*

Table 3 illustrates differences in compliance with recommendations for fruit and vegetable consumption as a function of group membership. Group A had significantly greater compliance with recommendations than did group C. Differences between A and B, and B versus C were non-significant.

*Physical activity*

Table 3 also presents differences in compliance with recommendations for physical activity as a function of group membership. Group A had significantly greater compliance with recommendations than did group C, while other pairwise comparisons were non-significant.

*Alcohol consumption per occasion*

None of the groups differed significantly in their compliance with recommended limits for episodic alcohol consumption (based on binge criteria). The mean (95% confidence interval) peak EBACs in groups A, B, and C were 0.11 (0.08, 0.14), 0.12 (0.09, 0.15), and 0.13 (0.10, 0.15),  $F=0.208$ ,  $p=0.813$ .

<Table 3>

## **Discussion**

In summary, six weeks after a brief computerized intervention in a primary care setting, there was significantly higher compliance with guidelines for fruit and vegetable consumption and physical activity in individuals receiving assessment and personalized feedback (group A), relative to those exposed to minimal contact at baseline (group C). Differences in drinking levels were non-significant, and given the small number of smokers at baseline, it was not possible to assess the effect of the intervention on smoking.

Strengths of the study include the standardized implementation of randomization, baseline assessment, intervention, and follow-up assessment, made possible by the computer format. Attrition was low (14%) for a trial of this nature. These features protect against various threats to internal validity. In addition, the trial was conducted in a naturalistic setting rather than a laboratory, such that results should generalize to implementation with young people in primary care settings. The use of dichotomous outcome variables reduces statistical power relative to continuous measures. However, given the preliminary nature of the study, these were preferable to continuous measures which require more sophisticated analysis. The measures used give conservative

estimates of effects for the purpose of designing a more comprehensive trial, and are readily interpretable in relation to epidemiologically-derived public health advice.

Given the promising findings from an earlier trial of a similar web-based intervention for hazardous drinking in the same setting [10], the lack of effect for alcohol in this trial is surprising. A major difference between the studies is that 25% of those included in the present trial were non-drinkers or light drinkers, while all were hazardous drinkers in the previous work. The presence of non-drinkers and light drinkers will have diluted the intervention effects.

There are some limitations, including the reliance on self-report of outcomes. Measuring saliva cotinine is an alternative to self-report for smoking [23], but no objective measures exist for fruit and vegetable consumption or physical activity. For alcohol, blood markers are insensitive for use with young people [24]. Assuming that a social desirability bias [25] might affect responses at follow-up, some participants may have over-reported their fruit and vegetable consumption and physical activity, the socially desirable behaviors, while under-reporting their drinking and smoking. If this occurred it may have exaggerated the apparent efficacy of the intervention.

A second limitation is the potential ceiling effect for physical activity. University students are relatively active, with around three in four meeting recommendations at baseline, leaving little room for improvement in the intervention group relative to controls. This would cause a tendency to the null hypothesis.

A challenge for brief intervention research is measuring modest effects and to create experimental contrasts which minimize (or allow measurement of) Hawthorne effects [13]. The non-significance of differences between the contiguous experimental groups (A vs B and B vs C) may be due to individuals who received assessment, reducing their risk behavior to a small extent. A future trial should include a sample large enough to assess effects on smoking. In addition, follow-up assessments at six and twelve months should be used to examine the longevity of effects, a control group not assessed at baseline should be employed.

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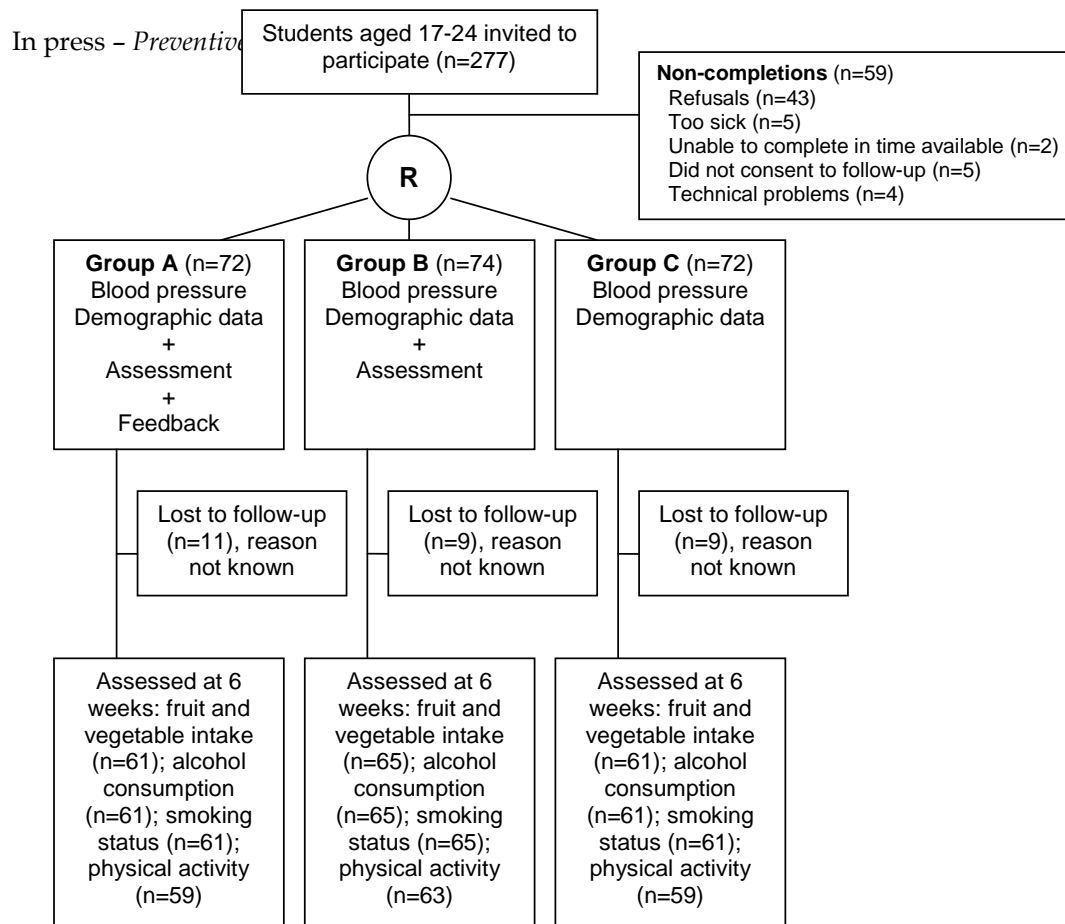


Figure 1. Flow of participants through the trial



Table 1. Demographic characteristics of trial participants at baseline

	A	B	C	All
<i>Gender</i>				
Women - n (%)	32 (44)	43 (58)	32 (44)	107 (49)
Mean age (SD) in years	20.3 (1.6)	19.9 (1.5)	20.5 (1.5)	20.2 (1.5)
<i>Ethnicity<sup>a</sup> - n (%)</i>				
Maori	7 (10)	5 (7)	5 (7)	17 (8)
European	54 (75)	55 (74)	54 (75)	163 (75)
other <sup>b</sup>	11 (16)	14 (19)	13 (19)	38 (17)
<i>Percentage compliance</i>				
<i>with recommendations</i>				
Fruit and vegetables	24	21	– <sup>c</sup>	23
Binge drinking	24	28	– <sup>c</sup>	26
Physical activity	81	76	– <sup>c</sup>	78

<sup>a</sup> Based on the Statistics New Zealand coding system<sup>b</sup> Includes the categories: Asian, Pacific People, and ‘Other’<sup>c</sup> Not assessed at baseline

Table 2. Health behaviour measures of participants lost to follow-up versus those followed-up<sup>a</sup>

	Followed-up	Lost to follow-up	p-value*
Ate at least two servings of fruit and three servings of vegetables per day	91%	85%	0.38
Completed $\geq 2.5$ hours of moderate or $\geq 1$ hour of vigorous activity per week	87%	84%	0.72
Drank $> 4/6$ drinks (women/men) in an episode in the last 4 weeks	72%	85%	0.23
Smokes cigarettes	9%	23%	0.03

<sup>a</sup> Includes only members of groups A (n=72) and B (n=72). C was not assessed at baseline.

\* For  $\chi^2$  statistic

Table 3. Compliance levels by experimental group six weeks after intervention

<i>Percentage</i>	A	B	C	All	p-value*		
<i>compliance with</i>					A versus C	A versus B	B versus C
<i>recommendations</i>							
Fruit and vegetables	33	26	13	24	0.02	0.44	0.08
Alcohol consumed per occasion	26	34	30	30	0.84	0.44	0.70
Physical activity	90	83	71	81	0.01	0.30	0.14

\* For  $\chi^2$  statistic