ORIGINAL INVESTIGATION

Randomized Controlled Trial of Web-Based Alcohol Screening and Brief Intervention in Primary Care

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Background: There is compelling evidence supporting screening and brief intervention (SBI) for hazardous drinking, yet it remains underused in primary health care. Electronic (computer or Web-based) SBI (e-SBI) offers the prospects of ease and economy of access. We sought to determine whether e-SBI reduces hazardous drinking.

Methods: We conducted a randomized controlled trial in a university primary health care service. Participants were 975 students (age range, 17-29 years) screened using the Alcohol Use Disorders Identification Test (AUDIT). Of 599 students who scored in the hazardous or harmful range, 576 (300 of whom were women) consented to the trial and were randomized to receive an information pamphlet (control group), a Web-based motivational intervention (single-dose e-SBI group), or a Web-based motivational intervention with further interventions 1 and 6 months later (multidose e-SBI group).

Results: Relative to the control group, the single-dose e-SBI group at 6 months reported a lower frequency of drinking (rate ratio [RR], 0.79; 95% confidence interval [CI], 0.68-0.94), less total consumption (RR, 0.77; 95% CI, 0.63-0.95), and fewer academic problems (RR, 0.76; 95% CI, 0.64-0.91). At 12 months, statistically significant differences in total consumption (RR, 0.77; 95% CI, 0.63-0.95 [equivalent to 3.5 standard drinks per week]) and in academic problems (RR, 0.80; 95% CI, 0.66-0.97) remained, and the AUDIT scores were 2.17 (95% CI, –1.10 to –3.24) points lower. Relative to the control group, the multidose e-SBI group at 6 months reported a lower frequency of drinking (RR, 0.85; 95% CI, 0.73-0.98), less total consumption (RR, 0.79; 95% CI, 0.64-0.97 [equivalent to 3.0 standard drinks per week]), reduced episodic heavy drinking (RR, 0.65; 95% CI, 0.45-0.93), and fewer academic problems (RR, 0.78; 95% CI, 0.65-0.93). At 12 months, statistically significant differences in academic problems remained (RR, 0.75; 95% CI, 0.62-0.90), while the AUDIT scores were 2.02 (95% CI, –0.97 to –3.10) points lower.

Conclusions: Single-dose e-SBI reduces hazardous drinking, and the effect lasts 12 months. Additional sessions seem not to enhance the effect.

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SCREENING AND BRIEF INTERvention (SBI) represents a considerable advance in the treatment of hazardous drinking and the prevention of alcohol-related harm. Such screening typically involves opportunistic administration by a physician or nurse of a brief screening questionnaire such as the Alcohol Use Disorders Identification Test (AUDIT)[1] and, for those who screen positive, provision of 5 to 10 minutes of advice or motivational therapy.[2] For people with severe problems or alcohol dependence, a referral may be made for further assessment and specialist treatment.[3]

A review of 36 randomized controlled trials showed that SBI typically reduces hazardous drinking for 12 months or longer.[4] The US Preventive Services Task Force[5] recommends its implementation in primary health care, and SBI is a central element in the treatment manual of the National Institute on Alcohol Abuse and Alcoholism.[6] Obstacles to widespread implementation include the scarcity of practitioner time and a reluctance of physicians[7] and patients[8] to discuss alcohol use in the context of a general medical consultation.

Computerized methods may help overcome these obstacles. Electronic (computer or Web-based) SBI (e-SBI) was developed for use in primary care and is available free to anyone using it for not-for-profit purposes.[9] It involves 2 to 3 minutes of screening and 10 to 15 minutes of assessment and personalized feedback according to the principles of motivational interviewing.[2] Assessment includes a retrospective drinking diary and questions about perceptions of drinking norms of peers.[10] Feedback consists of risk status, a summary of recent consumption, a com-

parison with recommended upper limits, and an estimate of blood alcohol concentration for the heaviest drinking occasion in the preceding month (criterion feedback). This is followed by a comparison of the user's consumption with national and local norms (normative feedback) and by correction of misperceptions of norms.

A pilot randomized controlled trial of e-SBI conducted at a New Zealand university student health service showed reductions of 20% to 30% in hazardous drinking, with attenuation of differences between the control and intervention groups between the 6-week and 6-month follow-up assessments.[11] A process evaluation[12] suggested 2 explanations for this attenuation. First, control subjects said that the 6-week assessment had a moderating effect on them. It is possible that the reduction in effect sizes at 6 months was partly a result of exposing control subjects to aspects of the intervention at 6 weeks. The possibility was raised that there may have been an assessment effect given the control subjects' comments that completing a drinking diary brought excessive consumption to their attention. The assessment effect hypothesis was tested experimentally by the inclusion of 2 control arms in a 4-arm randomized controlled trial at a primary health care service for university students.[13] The first control arm (A) received a 3-minute screen at baseline, while the second control arm (B) received a 3-minute screen at baseline and a 10-minute assessment 4 weeks later. Twelve months later, group B reported less total consumption and fewer problems than group A. Some of the differences were statistically significant, and the results support the assessment effect hypothesis.[13]

A second explanation for the convergence in drinking between the intervention and control groups in the pilot trial is that the intervention lost effectiveness over time. McKay et al[14] argue that researchers have unreasonably high expectations of psychological interventions when one considers that pharmacological interventions for mental disorders require ongoing administration of the active agent and that no one expects long-term change after a single dose. They question the wisdom of evaluating the efficacy of a single dose of psychological intervention. In the same vein, others call for successive minimal interventions, as opposed to an intensive episode treatment, for excessive drinkers.[15]

Interviews conducted after the pilot trial[11] suggested that participants wanted to receive periodic assessment and feedback, giving them the opportunity to monitor their progress over time. The technology required to do this is straightforward, with e-SBI being presented in a series of Web pages linked to a relational database. Users can be recruited using an e-mail message containing a hyperlink. When clicked, the hyperlink takes the user to the Web site, where the user provides information about his or her drinking. Pages can be written to allow users to revisit the site and to compare their recent drinking with what they recorded in previous assessment sessions. Additional sessions may serve to augment the initial intervention by reinforcing gains or by focusing attention on continued risk. The objective of this study was to test the hypothesis that single-dose and multidose e-SBI would reduce hazardous drinking.

METHODS

STUDY DESIGN

The study was a 4-arm randomized controlled trial, of which 3 arms were analyzed herein (**Figure**). Students attending a university health care service who screened positive for hazardous drinking were assigned to 1 of 2 groups that received Web-based assessment and personalized feedback on their drinking (e-SBI) or to 1 of 2 control groups that received a pamphlet on the health effects of alcohol consumption. Screening and intervention were conducted on desktop computers in semiprivate cubicles in the waiting room. An earlier study[11] of assessment effects comparing the 2 control groups showed that patients who received screening plus assessment reported less total consumption and fewer problems 6 to 12 months later than control subjects who received screening only. For this study, we used as control subjects the group that had the least exposure to assessment (ie, those who received screening only).

SAMPLE SIZE ESTIMATES

Sample size estimates for the trial were based on an effect size of 0.37, the mean that was observed in the pilot trial.[11] Assuming power of 0.80 with $\alpha = .05$, 114 individuals per group were required for analysis. With allowance for 20% attrition at 12 months, 143 individuals per group were required at baseline.

SAMPLING OF SERVICE USERS

We selected a random sample of patients presenting for care, with stratification by sex. Each week of the sampling period was divided into 10 sessions. Research assistants (M.L.C.-S. and others) were trained in the application of a study protocol that stipulated that they should invite the next patient leaving the reception desk (awaiting a medical consultation) to participate in the study, obtain informed consent, log the participant on a computer for screening, and return to the reception desk to recruit the next patient. Instances in which a patient seemed too sick or whose English was insufficient to participate were recorded, as were refusals (Figure).

The research assistants were informed that random covert compliance checks would be conducted by a principal investigator (K.K.). These occurred on 2 occasions in each of the 3 weeks of enrollment (total, 6 checks) by observing assistants (M.L.C.-S. and others) for 15 minutes from a concealed vantage point. Observed compliance with the protocol was 100%.

INFORMED CONSENT

A 2-stage recruitment procedure was used whereby patients were first invited to complete a computerized survey (stage 1 [screening]). Patients eligible for the study on the basis of screening were asked for consent to be contacted for follow-up surveys (stage 2 [assessment and intervention]). The study was presented to potential participants as a series of surveys on alcohol use, not as a randomized controlled trial. Randomization was effected by computer on completion of screening. This approach was approved by the human research ethics committee at the University of Otago, Dunedin, New Zeland.

BLINDING

Research staff were not informed of participants' group allocations during intervention or follow-up. The generation of the sequence and the loading of it into the server database were

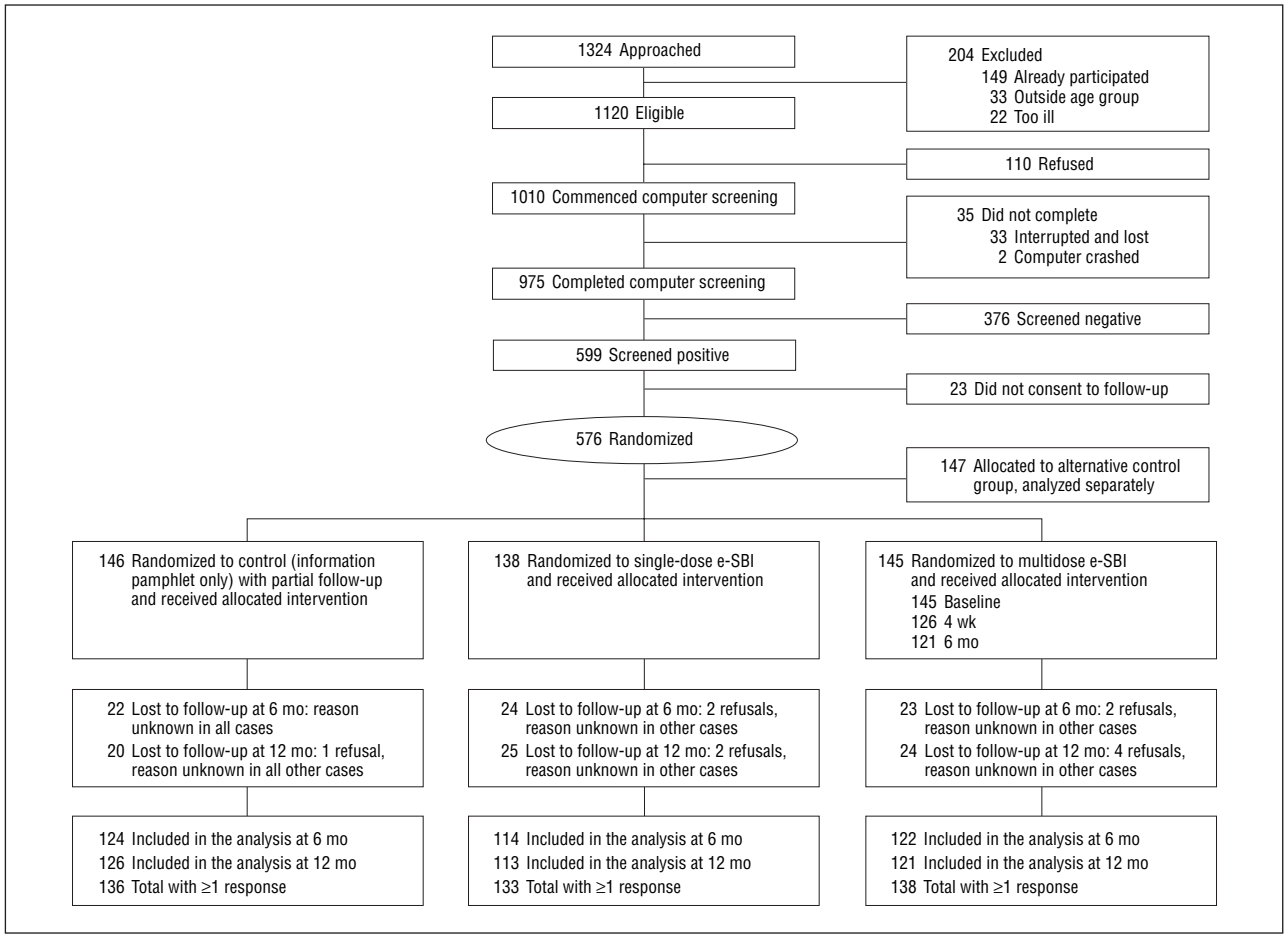

Figure. Trial schema. e-SBI indicates electronic screening and brief intervention.

conducted by off-site staff who never came into contact with study participants.

RECRUITMENT

Participants assigned to the control conditions were directed to a Web page thanking them for their involvement, whereas participants assigned to e-SBI conditions were presented with further assessment items and then personalized feedback. The research assistant then gave all participants a pamphlet on alcohol facts and effects and initiated second-stage consent by asking for contact details for follow-up surveys. On completion, participants were thanked and resumed their wait for medical care. The median completion time for the intervention groups was 9.3 minutes, while for controls (ie, for screening alone) it was 3.3 minutes.

The second-stage consent procedure was conducted after patients had completed the Web pages used in the intervention or control condition. Patients were asked whether they were willing to complete Web-based follow-up assessments up to 12 months later and were directed to provide contact details for this purpose. If they did not provide contact details, they were considered to have declined consent and were excluded from the trial. We used their baseline data (eg, the AUDIT score) to examine differences between consenters and nonconsenters.

SCREENING AND RANDOMIZATION

AUDIT is a validated 10-item screening questionnaire, and a cutoff of 8 points or higher has optimal sensitivity and specificity for identifying persons with hazardous drinking habits.[1] Participants scoring 8 or higher on the AUDIT were randomly assigned by computer to 1 of the following experimental groups before second-stage consent: control group (information pamphlet only), single-dose e-SBI group (Web-based brief motivational intervention), or multidose e-SBI group (Web-based brief motivational intervention with booster sessions after 1 and 6 months). Recruitment was stratified by sex to ensure approximately equal numbers of men and women. The random sequence was generated using the RAND function (Excel; Microsoft Corporation, Redmond, Washington).

INTERVENTION

Those assigned to single-dose and multidose e-SBI were presented with assessment questions and then personalized feedback, which together comprised the intervention. Assessment included self-reported weight, a 14-day retrospective drinking diary, and perceptions of drinking norms of peers.[10] Feedback consisted of their risk status, a summary of recent consumption, a comparison of their consumption with recommended limits, and an estimate of blood alcohol concentration for their heaviest drinking occasion in the preceding 4 weeks (criterion feedback), as well as a comparison of their consumption with that of national and university norms (normative feedback) and correction of misperceptions of norms. Multidose e-SBI involved repetition of the assessment and feedback, with the participant's drinking at 6 months compared against that at baseline and at 1 month in a series of bar charts.

FOLLOW-UP ASSESSMENT

Participants were invited by posted letter to complete 6-month and 12-month follow-up surveys by clicking on a hyperlink to the Web site that was sent to their e-mail address. Included with each letter was a lunch voucher valued at NZ$4.95. Reminder e-mails were sent to nonrespondents, followed by a reminder telephone call. The 6-month and 12-month follow-up phases were completed by October 24, 2003, and by June 25, 2004, respectively.

OUTCOME MEASURES

The following 7 outcome measures were selected: (1) frequency of drinking (number of drinking days in the preceding 2 weeks); (2) typical occasion quantity (standard drinks [10 g of alcohol] consumed per typical drinking occasion in the preceding 4 weeks); (3) total volume (standard drinks consumed in the preceding 2 weeks); (4) frequency of very heavy episodes (number of occasions in the preceding 2 weeks on which a threshold of 80 g of alcohol for women or 120 g of alcohol for men was breached); (5) personal, social, sexual, and legal consequences of episodic heavy drinking (items endorsed on the Alcohol Problems Scale [score range, 0-14])[16]; (6) consequences related to academic performance (score on the Academic Role Expectations and Alcohol Scale [score range, 0-35])[16]; and (7) the AUDIT score at 12 months.

Outcomes 1, 3, and 4 were measured using a retrospective diary in which the number of standard drinks was recorded for each of the preceding 14 days. Outcome 2 was measured using the question: "How many drinks containing alcohol did you have on a typical day when you were drinking in the last 4 weeks?" The Alcohol Problems Scale consists of 14 items with yes or no answers, encompassing a range of problems arising from heavy drinking, with a 4-week reference period.[16] The Academic Role Expectations and Alcohol Scale consists of 5 items examining the effect of drinking on academic behavior.[16]

STATISTICAL ANALYSIS

Intent-to-treat analyses are reported consisting of comparisons of single-dose e-SBI participants vs control subjects and of multidose e-SBI participants vs control subjects. Outcomes 1 through 5 were analyzed by negative binomial regression for panel data using the xtnbreg procedure (Intercooled STATA 9; StataCorp LP, College Station, Texas) accounting for overdispersion in the data. For outcome 6, which is a scale, we used linear regression analysis for panel data after log transformation. For outcome 7, we used linear regression analysis for panel data without log transformation. Models included terms for the group, follow-up assessment, and their interaction.[17] The interaction term tested for differences in the intervention effects between follow-up assessments. The results of the negative binomial regression analyses are presented as rate ratios (RRs) (ie, the ratio of the geometric mean for the intervention group to that of the control group at each follow-up assessment).[17] The analytic methods conform with current expert advice on the analysis of alcohol outcomes in clinical trials.[18]

RESULTS

Of 1324 patients assessed for eligibility from March 3, 2003, to March 25, 2003, 1120 were invited to participate, and 975 (87.1%) (age range, 17-29 years) completed the screening. Of these, 599 (61.4%) screened positive for hazardous drinking, a proportion similar to that (65%) among University of Otago students aged 17 to 24 years.[19] Twenty-three patients declined further involvement (second-stage consent), leaving 576 (300 of whom were women) in the trial, of whom 429 were included in the 3 arms analyzed in this study (Figure).

The mean AUDIT score of 23 individuals who did not give second-stage consent was 15.3 (95% confidence interval [CI], 13.0-17.6), while that of 576 individuals who gave second-stage consent was 14.9 (95% CI, 14.5-15.3). **Table 1** summarizes the data for the study groups.

Table 1. Sex, Age, and Alcohol Use Disorders Identification Test (AUDIT) Scores of the Study Groups at Baseline

Variable	Control Group (n = 146)	Single-Dose e-SBI Group (n = 138)	Multidose e-SBI Group (n = 145)
Female sex, No. (%)	76 (52.1)	71 (51.4)	76 (52.4)
Age, mean (SD), y	20.1 (2.2)	20.1 (1.9)	20.1 (1.9)
AUDIT score, mean (SD)	15.1 (5.5)	14.9 (5.1)	14.7 (4.7)

Abbreviation: e-SBI, electronic screening and brief intervention.

PARTICIPANT FLOW AND FOLLOW-UP

At 6 months, data were obtained from 124, 114, and 122 participants in the control, single-dose e-SBI, and multidose e-SBI groups, respectively (Figure); at 12 months, data were obtained from 126, 113, and 121 participants, respectively, in the 3 groups. The baseline AUDIT scores were statistically significantly lower for those who did not complete the follow-up assessment at 12 months (mean, –1.64; 95% CI, –2.92 to –0.37) but not at 6 months (mean, –0.80; 95% CI, –2.00 to 0.40). The proportion of participants lost to follow-up did not differ by treatment group at 6 months (χ^2=0.42, P=.94) or at 12 months (χ^2=0.77, P=.68). **Table 2** summarizes the data for the outcomes at the 6-month and 12-month follow-ups in each study group.

SINGLE-DOSE e-SBI GROUP VS CONTROL GROUP

Table 3 gives the treatment effect ratios for outcomes 1 through 6 at 6 and 12 months, as well as a regression coefficient for the AUDIT score, administered at 12 months. Relative to controls, the single-dose e-SBI group at 6 months reported a lower frequency of drinking (RR, 0.79; 95% CI, 0.68-0.94), less total consumption (RR, 0.77; 95% CI, 0.63-0.95), and fewer academic problems (RR, 0.76; 95% CI, 0.64-0.91). At 12 months, statistically significant differences in total consumption (RR, 0.77; 95% CI, 0.63-0.95 [equivalent to 3.5 standard drinks per week]) and in academic problems (RR, 0.80; 95% CI, 0.66-0.97) remained, and the AUDIT scores were 2.17 (95% CI, –1.10 to –3.24) points lower. The other differences favored intervention (ie, RRs were <1) but were statistically nonsignificant.

MULTIDOSE e-SBI GROUP VS CONTROL GROUP

Table 3 also gives the treatment effect ratios for outcomes 1 through 6 at 6 and 12 months, as well as a re-

Table 2. Summary Outcome Data at 6 Months and at 12 Months After the Intervention

Outcome	Median (Range)		
	Control Group	Single-Dose e-SBI Group	Multidose e-SBI Group
Frequency of Drinking			
1. No. of drinking days in the past 2 wk			
6 mo	4 (0-11)	3 (0-10)	3 (0-11)
12 mo	4 (0-14)	4 (0-14)	4 (0-10)
Typical Occasion Quantity			
2. No. of drinks per typical drinking occasion in the past 4 wk			
6 mo	8 (0-25)	7.5 (0-25)	6.5 (0-24)
12 mo	8.5 (1-24)	8 (1-25)	7 (1-22)
Total Consumption			
3. Total drinks in the past 2 wk			
6 mo	28.5 (0-143)	21 (0-124)	22 (0-106)
12 mo	30 (0-175)	26 (0-165)	21 (0-136)
Frequency of Episodic Heavy Drinking			
4. No. of episodes of episodic heavy drinking in the past 2 wk			
6 mo	1 (0-8)	1 (0-6)	0 (0-6)
12 mo	1 (0-8)	0 (0-10)	0 (0-7)
Personal, Social, Sexual, and Legal Consequences of Episodic Heavy Drinking			
5. No. of problems on the Alcohol Problems Scale			
6 mo	2 (0-12)	2 (0-8)	2 (0-7)
12 mo	3 (0-11)	2 (0-10)	2 (0-8)
Consequences Related to Academic Role Expectations			
6. Score on the Academic Role Expectations and Alcohol Scale			
6 mo	2 (0-14)	1 (0-16)	1 (0-10)
12 mo	1 (0-10)	0 (0-11)	1 (0-9)
AUDIT Score			
7. AUDIT score[a]			
12 mo	14 (2-30)	12 (2-27)	12 (4-28)

Abbreviations: AUDIT, Alcohol Use Disorders Identification Test; e-SBI, electronic screening and brief intervention.
[a]Measure has a 12-month reference period; therefore, it was not assessed at 6 months as per the trial protocol.

gression coefficient for the AUDIT score. Relative to controls, the multidose e-SBI group at 6 months reported a lower frequency of drinking (RR, 0.85; 95% CI, 0.73-0.98), less total consumption (RR, 0.79; 95% CI, 0.64-0.97 [equivalent to 3.0 standard drinks per week]), reduced episodic heavy drinking (RR, 0.65; 95% CI, 0.45-0.93), and fewer academic problems (RR, 0.78; 95% CI, 0.65-0.93). At 12 months, statistically significant differences in academic problems remained (RR, 0.75; 95% CI, 0.62-0.90), while the AUDIT scores were 2.02 (95% CI, –0.97 to –3.10) points lower. The other differences favored intervention (ie, RRs were <1) but were statistically nonsignificant.

COMMENT

The results were consistent with the hypothesis, namely, that patients who received e-SBI reported statistically significantly less alcohol consumption and fewer problems at 6 and 12 months after baseline on some measures (in particular, AUDIT scores, total volume consumed, and consequences related to academic role expectations). Differences on other measures were in the hypothesized direction but were not statistically significant. The similarity in the differences across a range of measures suggests that the provision of up to 2 additional sessions (ie, multidose e-SBI) did not increase the efficacy of e-SBI. The treatment effects were of modest size but were of the same order as those for SBI delivered by a health professional.[4]

The blinding of participants and research assistants to group allocation minimized the potential of demand characteristics or assessors' expectations biasing the results. The high participation rate at baseline and the naturalistic setting of the intervention permit strong inferences to be made about likely effectiveness in real-world conditions.

Attrition did not seem to bias the results. Participants who were lost to follow-up tended to drink less heavily than those who remained in the trial, but the proportions lost to follow-up did not differ statistically significantly by experimental group, such that the group comparisons are unlikely to be biased.

This trial was based on self-report data, which have generally been found to be reliable.[20,21] It might be thought that blood markers (eg, γ-glutamyltransferase level) would be preferable for measuring treatment outcomes; however, they are insufficiently sensitive to patterns of episodic heavy drinking to be useful in a trial such as this.[22] There remains a potential for social desirability bias to have exaggerated the treatment effects. There may be value

Table 3. Treatment Effects Based on Random-Effects Models Without Imputation for Missing Values[a]

Outcome	Treatment Effect, Ratio Rate (95% Confidence Interval)	*P* Value
Single-Dose e-SBI Group vs Control Group		
1. Frequency of drinking		
6 mo	0.79 (0.68 to 0.94)	.008
12 mo	0.86 (0.74 to 1.01)	.07
2. Typical occasion quantity		
6 mo	0.93 (0.80 to 1.08)	.33
12 mo	0.95 (0.82 to 1.09)	.47
3. Total consumption		
6 mo	0.77 (0.63 to 0.95)	.02
12 mo	0.77 (0.63 to 0.95)	.01
4. Frequency of episodic heavy drinking		
6 mo	0.78 (0.55 to 1.12)	.18
12 mo	0.75 (0.53 to 1.07)	.12
5. Personal, social, sexual, and legal consequences of episodic heavy drinking		
6 mo	0.86 (0.70 to 1.06)	.17
12 mo	0.82 (0.67 to 1.01)	.07
6. Consequences related to academic role expectations		
6 mo	0.76 (0.64 to 0.91)	.003
12 mo	0.80 (0.66 to 0.97)	.02
7. AUDIT score[a]		
12 mo	−2.17 (−3.24 to −1.10)	<.001
Multidose e-SBI Group vs Control Group		
1. Frequency of drinking		
6 mo	0.85 (0.73 to 1.00)	.05
12 mo	0.92 (0.79 to 1.07)	.28
2. Typical occasion quantity		
6 mo	0.85 (0.73 to 0.98)	.02
12 mo	0.87 (0.75 to 1.01)	.06
3. Total consumption		
6 mo	0.79 (0.64 to 0.97)	.02
12 mo	0.87 (0.71 to 1.06)	.16
4. Frequency of episodic heavy drinking		
6 mo	0.65 (0.45 to 0.93)	.02
12 mo	0.71 (0.51 to 1.01)	.06
5. Personal, social, sexual, and legal consequences of episodic heavy drinking		
6 mo	0.87 (0.71 to 1.07)	.20
12 mo	0.81 (0.66 to 1.00)	.05
6. Consequences related to academic role expectations		
6 mo	0.78 (0.65 to 0.93)	.005
12 mo	0.75 (0.62 to 0.90)	.002
7. AUDIT score[a]		
12 mo	−2.02 (−3.10 to −0.97)	<.001

Abbreviations: AUDIT, Alcohol Use Disorders Identification Test; e-SBI, electronic screening and brief intervention.
[a]Linear regression coefficient.

in attempting to measure and control for the tendency toward socially desirable response[23]; however, the literature is equivocal on the validity of existing social desirability measures.[24]

The size of the CIs for the outcomes of interest reveals the difficulty in measuring modest effects. The study was powered to detect an effect size of 0.37 in single-dose e-SBI participants vs a control group. Even with initial sample sizes of 146, 138, and 145, CIs spanned 30 to 50 percentage points in a mean ratio and more than 2 points on the AUDIT score. This occurred despite the retention of 83.9% of participants at the 12-month follow-up assessment, an attrition level that is rare in brief intervention efficacy trials.[25] Considerably larger trials may be required to study the modest individual effects expected from such population interventions.

Contamination may have biased the results toward the null. There are approximately 18 000 university students in Dunedin, New Zealand (population, 120 000), where the trial occurred. It is likely that some patients shared accommodations or classes with others who were in the trial. If members of either e-SBI group discussed the intervention with control subjects, the experimental contrast may have been weakened such that e-SBI effects will have been underestimated.

Reductions of 5% to 35% in alcohol consumption, 13% to 25% in the incidence of problems, and 2 points on the AUDIT score, lasting 6 to 12 months, are sufficient to warrant implementing e-SBI in student health care settings given its nonreliance on costly practitioner time, its acceptability to users, and the capability to reach large numbers of patients. Further research is required to es-

timate the effectiveness of e-SBI when delivered under conditions of normal health care delivery and its efficacy in other settings and populations.

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Author Contributions: Dr Kypri had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Kypri, Langley, and Saunders. *Acquisition of data:* Kypri and Cashell-Smith. *Analysis and interpretation of data:* Kypri, Langley, Saunders, and Herbison. *Drafting of the manuscript:* Kypri, Langley, and Saunders. *Critical revision of the manuscript for important intellectual content:* Kypri, Langley, Saunders, and Herbison. *Statistical analysis:* Herbison. *Obtained funding:* Kypri, Langley, and Saunders. *Administrative, technical, and material support:* Kypri, Langley, Saunders, and Cashell-Smith. *Study supervision:* Kypri and Saunders.
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