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Effect of a smartphone intervention as a secondary prevention for university students with unhealthy alcohol use: randomised controlled trial

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ABSTRACT

OBJECTIVE
To estimate the effects of providing access to an alcohol intervention based on a smartphone.

DESIGN
Randomised controlled trial.

SETTING
Four higher education institutions in Switzerland.

PARTICIPANTS
1770 students (≥18 years) who screened positive for unhealthy alcohol use (ie, a score on the alcohol use disorders identification test-consumption (AUDIT-C) of ≥4 for men and ≥3 for women) were randomly assigned by 1:1 allocation ratio in blocks of 10.

INTERVENTION
Providing access to a brief, smartphone based alcohol intervention.

OUTCOME MEASURES
The primary outcome studied was number of standard drinks per week at six months and the secondary outcome was number of heavy drinking days (past 30 days). Additional outcomes were maximum number of drinks consumed on one occasion, alcohol related consequences, and academic performance. Follow-up assessments occurred at months three, six, and 12. Data were analysed by intention to treat and by using generalised linear mixed models with random intercepts for the recruitment site and participants nested within the recruitment site, and with intervention (*v* control), time (three months *v* six months; 12 months *v* six months), and baseline outcome values as fixed effects.

RESULTS
The study was conducted between 26 April 2021 and 30 May 2022, and 1770 participants (intervention group (n=884); control group (n=886)) were included. Mean age was 22.4 years (standard deviation 3.07); 958 (54.1%) were women; and 1169 (66.0%) were undergraduate students, 533 (30.1%) were studying for a master's degree, 43 (2.4%) were studying for a doctorate, and 25 (1.4%) were students of other higher education programme. The baseline mean number of standard drinks per week was 8.59 (standard deviation 8.18); the baseline number of heavy drinking days was 3.53 (4.02). Of 1770 participants, follow-up rates were 1706 (96.4%) at three months, 1697 (95.9%) at six months, and 1660 (93.8%) at 12 months. Of 884 students randomly assigned to the intervention group, 738 (83.5%) downloaded the smartphone application. The intervention had a significant overall effect on the number of standard drinks per week (incidence rate ratio 0.90 (95% confidence interval 0.85 to 0.96)), heavy drinking days (0.89 (0.83 to 0.96)), and the maximum number of drinks consumed on one occasion (0.96 (0.93 to 1.00), P=0.029), indicating significantly lower drinking outcomes in the intervention group than in the control group during the follow-up period. The intervention did not affect alcohol related consequences or academic performance.

CONCLUSION
Providing access to the smartphone application throughout the 12 month follow-up was effective at reducing the average drinking volume of university students who had self-reported unhealthy alcohol use at baseline.

TRIAL REGISTRATION
ISRCTN 10007691.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Among young adults, and especially among students, unhealthy alcohol use is a leading cause of morbidity and mortality

Screening and brief intervention is an early public health approach, recommended by the World Health Organization, for people with unhealthy alcohol use

Evidence of efficacy of smartphone interventions for unhealthy alcohol use is inconclusive

WHAT THIS STUDY ADDS

The impact of providing access to a smartphone application for students who had unhealthy alcohol use was estimated

Our study indicates that providing access to the app was associated with lower drinking volume and fewer heavy drinking days at follow-up

Among students, smartphones can be used to deliver brief interventions for unhealthy alcohol use

Introduction

Unhealthy alcohol use (ie, consumption increasing the risks of health consequences, including alcohol use disorder)[1] is an important public health problem, a leading cause of morbidity and mortality, and the leading health risk factor among people aged 15-49 years worldwide.[2-5] Students' social lives and academic demands can favour unhealthy behaviours, including alcohol use[6]; they tend to drink more alcohol than similarly aged people who are not students.[7] The 2019 US National Survey on Drug Use and Health reported prevalence among students of heavy episodic drinking at 33.0% and of regular heavy alcohol use 8.2% (*v* 27.7% and 6.4% for people who are not students, respectively).[8] In Europe, prevalence of unhealthy

alcohol use among students varied from 30% to 60%.[9-11] The Monitoring the Future study indicated that 50.3% of students aged 19-20 years who drunk alcohol had experienced adverse consequences related to alcohol in the past 12 months.[12] Students' alcohol use is associated with physical, behavioural, emotional, and relational consequences, academic impairment, and institutional costs.[12-15] Students are thus an appropriate target for selective prevention interventions.[16 17]

Screening and a brief intervention form a public health approach (recommended by the US Preventive Services Task Force and World Health Organization) for delivering prompt interventions for people with unhealthy alcohol use.[18 19] The systematic identification of unhealthy use via a validated screening tool is combined with a brief intervention for those identified. Addressing unhealthy alcohol use is challenging and only limited numbers of people will actively seek treatment.[20 21] Interventions using information technology can be used to address this challenge because they have greater reach, are more easily implemented, and are more consistent than traditional face-to-face interventions.[22-24]

Smartphones are increasingly used in healthcare, with studies highlighting their potential usefulness and patients' interest in applications (apps) for managing chronic conditions, physical activity, and mental health.[25-31] Apps offer rapid adoption, especially among younger individuals, enabling multiple contact, proactivity, or just-in-time interventions, and providing links to additional services for those requiring more intensive interventions and support.[32] Although internet interventions and apps share similarities, proven, effective internet interventions can not be assumed to be transferred to apps without formal testing. Evidence on the efficacy of smartphone based interventions is inconclusive.[33-35] Rigorous evaluations of the efficacy of apps targeting unhealthy alcohol use are necessary,[36 37] especially because these apps will likely pull users away from internet based interventions with shown efficacy. Evaluation will inform public health agencies and the general public on whether app use and development are recommendable alongside existing internet interventions.

We aimed to assess the impact of providing students at four higher education institutions in Switzerland and reporting unhealthy alcohol use with a smartphone based intervention (ie, an app).

Methods

Study design

The protocol for this secondary prevention, parallel group, randomised controlled trial was registered and published before the trial began.[38] Secondary prevention is directed at preventing a progression to more use or problems, in individuals with unhealthy alcohol use, identified by screening. The trial was monitored independently by Lausanne University Hospital's Clinical Trial Unit. No deviations were made from the protocol. The published protocol's analytical approach was modified during this paper's review process to provide more easily interpretable results. The analyses described in the protocol are available as supplementary material (appendix 1). Results remained consistent across the alternative re-analyses.

Recruitment

Participants were recruited from 26-28 April 2021 at the University of Lausanne (UNIL), the Swiss Federal Institute of Technology Lausanne (EPFL), the Ecole Hôtelière de Lausanne (EHL), and the University of Applied Sciences and Arts Western Switzerland's School of Health (HESAV). UNIL has more than 16 000 students in seven faculties: Theology and Sciences of Religions; Law, Criminal Justice and Public Administration; Arts; Social and Political Sciences; Business and Economics; Biology and Medicine; and

Table 1 | Description of the study app's six modules

Module	Description
1) Personalised feedback on self-reported alcohol consumption	This module includes normative feedback and feedback on the calorific content of reported consumption and on health risks. The user's reported alcohol consumption is compared with that of people of the same sex and age in Switzerland, with an emphasis on the percentage of people drinking less than the user. The user also receives an indication of the risks associated with their drinking. The calorific content of the reported alcohol use is indicated (in kcal) and presented in terms that are equivalent to hamburgers. At the end of the module, users can choose to set themselves drinking limits with a link to the goal setting tool (module 4).
2) Blood alcohol content computation tool	This module estimates the blood alcohol content that users reach with a particular reported consumption and indicates the risks associated with different levels of blood alcohol content. The module also computes how long before the alcohol is eliminated.
3) Self-monitoring tool	When this module is activated, users are invited to report their drinking daily. Drinking patterns are then presented to users on graphs indicating recommended drinking limits.
4) Goal setting tool	This module enables users to set themselves drinking limitations for one, two, seven, or 30 days. Users are then invited to report their drinking daily. Users receive virtual badges when they drink at or below their self-determined drinking limits.
5) Designated driver tool	This module allows users to take pictures of themselves and their friends. The app then randomly picks the picture of the designated sober driver.
6) Fact sheets	This module presents fact sheets on alcohol and health (ie, effects of alcohol on the human body, diseases caused by alcohol, acute and long term effects of alcohol use on health, addiction, and resources (available treatment options and contacts)).

The intervention content was based on existing literature, previous research involving online digital interventions conducted by our group,[43-53] and input from members of the target population. Product design quality is a major predictor of user engagement and was central to the intervention's development,[51] with particular attention given to usability, visual design, user engagement, persuasive design (ie, call to action, ongoing feedback and monitoring, data-driven content, rewards), a non-judgmental environment, acceptance, and credibility.

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Geosciences and Environment. EPFL has more than 12 000 students in five schools and two colleges: Architecture, Civil and Environmental Engineering; Computer and Communication Sciences; Basic Sciences; Engineering; Life Sciences; Management of Technology; and Humanities. EHL has more than 4000 students at its Lausanne Campus studying degrees in hospitality management. HESAV has over 1000 students studying four programmes: Nursing; Physiotherapy; Midwifery; and Medical Radiology Technique. Institutions promoted the study via their official communication channels, as did their student associations on their websites and social media (with the study logo and text). The EHL and HESAV displayed study information on information screens, and the EPFL and University of Lausanne used hallway posters. Students registered at the EPFL and University of Lausanne also received an email describing the study and inviting them to participate. All these media presented the same information and invited students to visit the study's specially developed website. Study materials (including the app) were provided in French and English because Switzerland's higher education institutions host numerous international students.

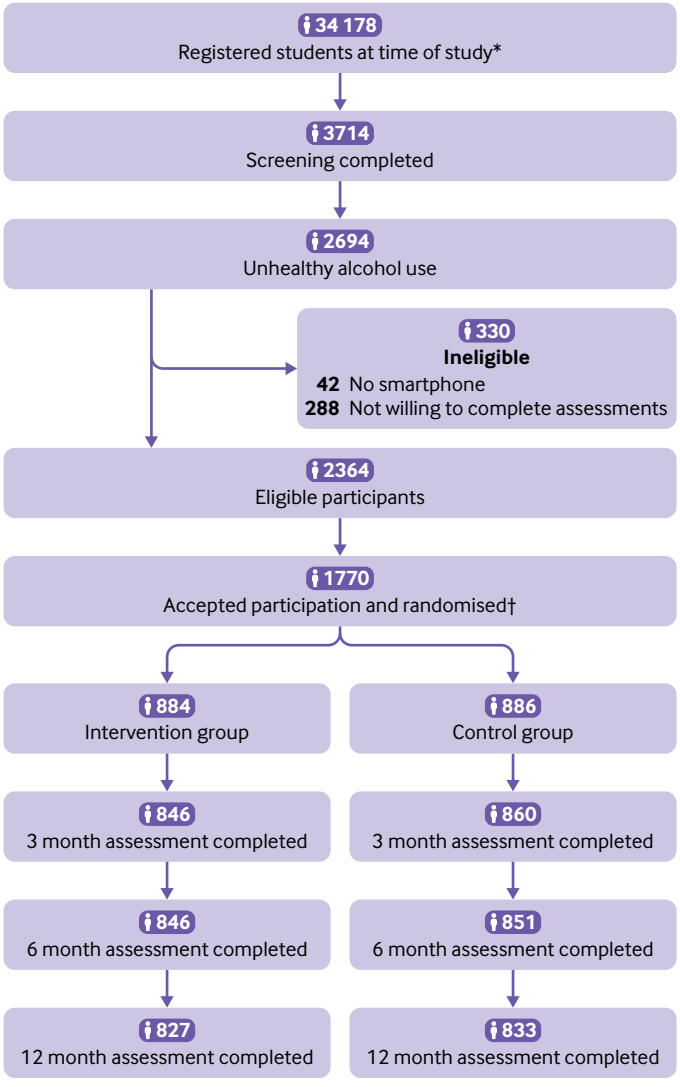

Fig 1 | CONSORT flow diagram. *Participants were students registered at one of four higher education institutions in Switzerland: the University of Lausanne, the Swiss Federal Institute of Technology Lausanne (EPFL), the Ecole Hôtelière de Lausanne (EHL), and the University of Applied Sciences and Arts Western Switzerland's School of Health (HESAV). †Most participants came from the two largest schools: University of Lausanne (n=843) and EPFL (n=806); and then EHL (n=108) and HESAV (n=13)

Participants

Interested students accessed the study website and completed an anonymous questionnaire assessing the inclusion criteria. Eligibility criteria were: student status at recruitment, aged 18 years or older, positive result from screening for unhealthy alcohol use (defined as an alcohol use disorders identification test-consumption score of 4 or higher for men and 3 or higher for women),[39-41] ownership of a smartphone, and willing to complete the follow-up questionnaires. Individuals who participated in the app's development were ineligible for the trial.

Eligible participants were presented with the informed consent procedure. Those giving informed consent received a copy of their consent form via email and a personalised link to the study's baseline assessment. Once the baseline assessment was completed, participants were included in the study, randomly assigned to a group, and presented with the information relevant to their study group.

Presenting study objectives to participants

Our research was presented as a study on alcohol use involving four consecutive online questionnaires for students who regularly consumed alcohol and for whom this behaviour might negatively impact their health. The study's objective that was provided to participants was to test "a new method of monitoring and electronic prevention of alcohol consumption among students". Participants were informed that some individuals would be "randomly asked to consult prevention materials on their smartphones". Although participants were not given precise details about the intervention's objectives, they knew that the study options would be different.

Randomisation, concealed allocation, and blinding

After completing the baseline assessment on the study website, participants were randomly assigned using a 1:1 allocation ratio in blocks of 10. Participants were unaware of when randomisation happened to mitigate bias by partially masking them to the study's nature. The website programmers implemented the randomisation sequence independently of the study researchers so that they were completely masked to which participants were allocated to which group until the study's completion. All subsequent assessments were also conducted online, ensuring that blinding was maintained.

Intervention group

Participants randomly assigned to the intervention group were presented with a screen thanking them for completing the baseline questionnaire and

Table 2 | Participants' characteristics

Characteristics	Full sample (n=1770)	Intervention group (n=884)	Control group (n=886)
Age, mean (SD)	22.35 (3.07)	22.24 (2.85)	22.45 (3.27)
Sex, no (%):			
Female	958 (54.1)	465 (52.6)	493 (55.6)
Male	812 (45.9)	419 (47.4)	393 (44.4)
Higher education programme, no (%):			
Bachelor	1169 (66.0)	598 (67.6)	571 (64.4)
Master	533 (30.1)	253 (28.6)	280 (31.6)
Doctorate	43 (2.4)	20 (2.3)	23 (2.6)
Other	25 (1.4)	13 (1.5)	12 (1.4)
AUDIT score with optimal sensitivity and specificity for AUD (men >10; women >6), no (%)	955 (53.9)	476 (53.8)	479 (54.1)
AUDIT score with specificity prioritised (men >13; women >11), no (%)	394 (22.2)	199 (22.5)	195 (22.0)
No of standard drinks per week (%)	8.59 (8.18)	8.93 (8.66)	8.25 (7.65)
No of heavy drinking days (past 30 days), mean (SD)	3.53 (4.02)	3.58 (4.19)	3.48 (3.83)
Maximum no of drinks on one occasion (past 30 days), mean (SD)	7.40 (4.13)	7.41 (4.16)	7.39 (4.10)
Alcohol related consequences, mean (SD)*	3.83 (3.96)	3.82 (4.05)	3.84 (3.88)
Academic performance, mean (SD)†	3.18 (0.79)	3.18 (0.80)	3.19 (0.78)

AUD=alcohol use disorder; AUDIT=alcohol use disorders identification test; SD=standard deviation.
*Alcohol related consequences in the past three months were measured using the short inventory of problems[59]; minimum possible score=0 and maximum=45.
†Academic performance was measured on a scale of 1-5 using the following question: "how do you rate your performance in comparison with your fellow students?" (response options: much worse, worse, similar, better, much better).

encouraging them to download the app. Concurrently, they were emailed a CHF5 coupon for a large Swiss retail company (roughly £4; $5; €4.5 at study commencement) and a personal code to unlock the app. The code was only valid once, preventing multiple participation or app usage by individuals outside of the study or in the control group. Those unlocking the app received an additional CHF5 coupon.

The theoretical bases for the app involved norms perception and risk perception.[38] The app's development, content, and theoretical underpinnings have been presented in detail elsewhere.[38 42] The app comprised six modules (table 1).

Control group

Participants randomly assigned to the control group were presented with a screen thanking them for completing the baseline questionnaire. They were also emailed a CHF5 coupon but did not receive access to the app because the control condition had no intervention. To mimic the intervention group procedure, ensuring equal incentives across groups, we used an attention control procedure involving participants receiving a personal code by email and a request to log on to a specific webpage and enter the code to unlock an additional CHF5 coupon.

Follow-up assessments

At the appropriate follow-up times, participants received an email containing a personalised link to their follow-up online questionnaire assessments, compatible with computers, smartphones, and tablets. Individuals who had not completed their assessment within three days were sent an email reminder, with a second reminder sent three days after that. Research assistants contacted participants who had not responded by telephone (up to five unanswered calls) and text message (up to three messages), encouraging them to complete the questionnaire. Participants received additional coupons for each completed questionnaire (CHF10 for the three month questionnaire and additional CHF15 for the six and 12 month questionnaires). Participants completing every assessment could thus earn CHF50. Participants in the intervention and control groups received the same monetary incentives. Each questionnaire required an estimated 5-10 min to complete. All measures were self-reported.

Outcomes

The primary and secondary outcomes were prespecified.[38] The primary outcome was weekly drinking volume in standard alcoholic drinks, reported as the mean number of standard drinks per week over the past 30 days and assessed using a validated quantity per frequency measure.[54] In Switzerland, a standard alcoholic drink is defined as containing about 10-12 g of ethanol.[55] Standard UK drinks contain 8 g of ethanol and standard US drinks contain 14 g of ethanol. Participants were provided with visual aids for recognising standard drinks. The secondary outcome was the number of heavy drinking days (ie, days with ≥5 drinks for men and ≥4 drinks for women) over the past 30 days. These outcomes were chosen based on the recommendations of the International Network on Brief Interventions for Alcohol and Other Drugs, an organisation that has established a core set of outcomes for alcohol related brief intervention studies.[56-58] Additional outcomes were: maximum number of drinks on any day over the past 30 days; alcohol related adverse consequences (measured using the short inventory of problems)[59]; and academic performance (measured using the question: "how do you rate your performance in comparison with your fellow students?"). The baseline questionnaire also included the full alcohol use disorders identification test questionnaire.[40]

Sample size

The study was designed to estimate a potential intervention effect at six months; measures were also collected at 12 months to estimate its potential

Table 3 | Outcome measures and estimated intervention effects

	Outcome, mean (SD)*			Intervention effect, IRR/b (95% CI)			
Outcome or intervention	Three months	Six months	12 months	Overall effect†	Three months‡	Six months‡	12 months‡
No of standard drinks per week:							
Control	10.80 (11.33)	7.68 (8.11)	7.59 (7.88)	Ref	Ref	Ref	Ref
Intervention	10.07 (10.33)	7.11 (6.29)	7.04 (6.25)	0.90 (0.85 to 0.96)	0.91 (0.84 to 0.98)	0.90 (0.83 to 0.97)	0.91 (0.8 to 0.98)
No of heavy drinking days (past 30 days):							
Control	4.54 (5.13)	3.39 (3.65)	3.26 (3.47)	Ref	Ref	Ref	Ref
Intervention	4.15 (4.71)	3.02 (3.18)	3.07 (3.45)	0.89 (0.83 to 0.96)	0.89 (0.82 to 0.98)	0.88 (0.80 to 0.97)	0.91 (0.83 to 1.00)§
Maximum no of drinks on one occasion (past 30 days):							
Control	7.59 (4.83)	7.25 (4.41)	7.05 (4.49)	Ref	Ref	Ref	Ref
Intervention	7.09 (4.04)	6.93 (4.14)	6.90 (4.02)	0.96 (0.93 to 1.00)¶	0.94 (0.90 to 0.98)	0.96 (0.92 to 1.01)	0.98 (0.94 to 1.03)
Alcohol related consequences**:							
Control	3.37 (3.73)	3.62 (3.92)	3.46 (3.85)	Ref	Ref	Ref	Ref
Intervention	3.26 (3.84)	3.67 (4.33)	3.20 (3.67)	0.93 (0.86 to 1.00)‡‡	0.93 (0.85 to 1.01)	0.97 (0.89 to 1.06)	0.89 (0.81 to 0.97)
Academic performance††:							
Control	3.25 (0.79)	3.19 (0.74)	3.21 (0.72)	Ref	Ref	Ref	Ref
Intervention	3.25 (0.78)	3.21 (0.73)	3.21 (0.73)	0.02 (−0.03 to 0.06)	0.01 (−0.04 to 0.06)	0.04 (−0.02 to 0.09)	0.00 (−0.05 to 0.06)

CI=confidence interval; IRR=incidence rate ratio; SD=standard deviation. Due to a configuration problem, the question about academic performance was missing from the 12 month online questionnaire. It was sent separately to participants two weeks later. This question's response rate was lower than for the rest of the questionnaire (n=1375 (77.7%) of 1770), control group (n=690/886), intervention group (n=685/884).

*At three months, n=1706 (n=860 for control, n=846 for intervention). At six months, n=1697 (n=851 for control, n=846 for intervention). At 12 months, n=1660 (n=833 for control, n=827 for intervention).

†Intervention main effects from model 1 were obtained by including variables coding the intervention (yes/no), three months (*v* six months), 12 months (*v* six months), and baseline values of the outcome as fixed effects.

‡Effects of intervention from model 2, with the references for time set at three, six, and 12 months, respectively. For estimations of the intervention's effects at three months, the fixed effects of model 2 used variables coding the intervention (yes/no), six months (*v* three months), 12 months (*v* three months), intervention-by six months and intervention-by 12 months interactions, and baseline values of the outcome. For estimations of the intervention's effects at six months, the fixed effects of model 2 used variables coding the intervention (yes/no), three months (*v* six months), 12 months (*v* six months), intervention-by three months and intervention-by-12 months interactions, and baseline value of the outcome. For estimations of the intervention's effects at 12 months, the fixed effects of model 2 used variables coding intervention (yes/no), three months (*v* 12 months), six months (*v* 12 months), intervention-by-three months and intervention-by-six months interactions, and baseline value of the outcome.

§P=0.059.

¶P=0.029.

**Alcohol related consequences were measured using the short inventory of problems measure[59]; minimum possible score=0, maximum=45; in the past three months.

††Academic performance was measured on a scale of 1-5 using the following question: "How do you rate your performance in comparison with your fellow students?" (response options: much worse, worse, similar, better, much better).

‡‡P=0.064.

longer term effects. The sample size was computed to estimate the intervention's effect on drinks consumed per week (past 30 days). We anticipated reductions of two drinks per week in the intervention group and 0.39 drinks per week in the control group.[45] We considered the potential need to adjust for clustering (recruitment from four sites but with two sites predominating). We hypothesised a low intraclass correlation (rho=0.001) and did not expect substantial differences in drinking between schools. Notably, the two larger institutions where we recruited participants have adjacent campuses, where students live in the same area, have similar access to alcohol, and attend the same parties. All four participating schools were in the greater Lausanne area. The design effect due to clustering was calculated as 1.399, which was slightly larger than the assessments of the Health Behaviour in School-Aged Children study and the European School Survey Project on Alcohol and Other Drugs, which focused on younger participants.[60 61] The sample size required to detect a significant difference, with an expected attrition rate of 10%, a power of 90%, and an α type 1 error of 5%, was 848 participants per group. The minimum total targeted sample size was 1696 individuals.

Statistical analyses

The primary analysis used an intention-to-treat method, including all participants according to their randomly assigned group. We estimated the effect of providing access to the app on drinking outcomes. Participants in the intervention group who did not download the app were nevertheless included in that group's analysis (as would be done in a randomised clinical trial where participants who did not take the intervention medication are analysed according to their randomisation status).

The intervention's effects on outcomes were estimated using generalised linear mixed models. To account for the data's nested structure, two random effects were put into the model: one random intercept for the recruitment site and another for participants nested within that recruitment site. Two models were fitted. Model 1 included the fixed effects of the intervention (*v* control), time (three months *v* six months; 12 months *v* six months), and the baseline values of the outcome. In model 1, the estimate of the intervention variable reflects the intervention's main effect during the follow-up period, independent of time. Two additional intervention-by-time interactions (ie, intervention-by-three months; intervention-by-12 months) were added to model 2. These two interaction terms estimated how much the intervention effects at three and 12 months differed from those at six months. To test whether intervention effects differed significantly between follow-ups, the overall effect of the two interaction terms was estimated using a likelihood ratio test comparing models 1 and 2. In model 2, the intervention's estimated main effect corresponds to

Table 4 | Subgroup analyses, by AUDIT score, with estimated intervention effects. Data are incidence rate ratio (95% confidence interval (CI)), unless otherwise specified

	Subgroup 1: Men (AUDIT score >10); women (AUDIT score >6)					Subgroup 2: Men (AUDIT score >13); women (AUDIT score >11))				
Intervention effect	Standard drinks per week	Heavy drinking days (past 30 days)	Maximum no of drinks (past 30 days)	Alcohol related consequences*	Academic performance†, b (95% CI)	Standard drinks per week	Heavy drinking days (past 30 days)	Maximum no of drinks (past 30 days)	Alcohol related consequences*	Academic performance†, b (95% CI)
Main effect‡	0.89 (0.83 to 0.97)	0.89 (0.82 to 0.97)	0.94 (0.90 to 0.99)	0.96 (0.88 to 1.04)	0.01 (−0.05 to 0.06)	0.90 (0.81 to 1.01)	0.86 (0.76 to 0.97)	0.93 (0.87 to 0.99)	1.01 (0.91 to 1.13)	0.01 (−0.09 to 0.10)
Three months§	0.88 (0.80 to 0.97)	0.89 (0.80 to 0.99)	0.91 (0.86 to 0.97)	0.97 (0.88 to 1.07)	0.00 (−0.07 to 0.07)	0.84 (0.73 to 0.97)	0.83 (0.71 to 0.97)	0.86 (0.79 to 0.94)	0.97 (0.85 to 1.10)	−0.03 (−0.14 to 0.09)
Six months§	0.89 (0.80 to 0.98)	0.88 (0.78 to 0.99)	0.96 (0.90 to 1.02)	1.00 (0.91 to 1.10)	0.02 (−0.06 to 0.09)	0.93 (0.81 to 1.08)	0.85 (0.72 to 1.00)¶	0.96 (0.88 to 1.04)	1.07 (0.94 to 1.21)	0.03 (−0.09 to 0.15)
12 months§	0.91 (0.83 to 1.01)	0.92 (0.82 to 1.03)	0.96 (0.90 to 1.02)	0.91 (0.82 to 1.00)¶	0.00 (−0.08 to 0.08)	0.94 (0.81 to 1.08)	0.91 (0.77 to 1.07)	0.98 (0.90 to 1.07)	1.01 (0.89 to 1.15)	0.02 (−0.11 to 0.14)

AUDIT=alcohol use disorders identification test; CI=confidence interval.
*Measured using the short inventory of problems measure[59]; minimum possible score=0, maximum=45; in the past 3 months.
†Measured on a scale of 1-5 using the following question: "How do you rate your performance in comparison with your fellow students?" (response options: much worse, worse, similar, better, much better).
‡Intervention main effects from model 1 were obtained by including variables coding the intervention (yes/no), three months (*v* six months), 12 months (*v* six months), and baseline values of the outcome as fixed effects.
§Effects of the intervention using model 2, with the references for time set at three, six and 12 months, respectively. For estimations of the intervention's effects at three months, fixed effects of model 2 used variables coding intervention (yes/no), six months (*v* three months), 12 months (*v* three months), intervention-by-six months and intervention-by-12 months interactions, and baseline values of the outcome. For estimations of the intervention's effects at six months, fixed effects of model 2 used variables coding the intervention (yes/no), three months (*v* six months), 12 months (*v* six months), intervention-by-three months and intervention-by-12 months interactions, and baseline value of the outcome. For estimations of the intervention's effects at 12 months, fixed effects of model 2 used variables coding intervention (yes/no), three months (*v* 12 months), six months (*v* 12 months), intervention-by-three months and intervention-by-six months interactions, and baseline value of the outcome.
¶P=0.051.

the intervention effect (*v* control) conditional to the time, coded 0, namely, the intervention effect at the set reference time point. By changing the reference group for the two dummy variables of time, the intervention effects at three months and 12 months could also be estimated.

Count models were used for standard drinks per week, heavy drinking days, maximum number of drinks, and consequences related to alcohol because these variables were not normally distributed. We used tests for Poisson overdispersion to determine whether a Poisson or negative binomial distribution best fitted the data. Overdispersion tests were significant for standard drinks per week and heavy drinking days but not significant for maximum number of drinks and alcohol related consequences. Thus, a negative binomial distribution was used to model standard drinks per week and heavy drinking days, whereas the Poisson distribution was used to model maximum number of drinks and consequences related to alcohol. The distribution for academic performance was approximately normal, and a Gaussian distribution was used. Missing data were handled using multiple imputation. Technical details of our analyses and multiple imputation are reported in appendix 2.

We conducted preregistered secondary subgroup analyses using scores from the alcohol use disorders identification test (known as AUDIT) to estimate the intervention effect among students reporting a potential alcohol use disorder (the full test questionnaire was completed as part of the baseline questionnaire). Two subgroups were used: men with scores of more than10 or women with scores of more than 6 (cut-off points with optimal sensitivity and specificity for alcohol use disorder); and men with scores of more than 13 or women with scores of more than 11 (cut-off points prioritising specificity).[62]

Patient and public involvement

Students with unhealthy alcohol use were involved in developing the app[42] and reviewed the study questionnaire. The app was updated from a previous version.[43 44]

Results

The study was carried out between 26 April 2021 and 30 May 2022. Of 3714 students who complete anonymous screening, 2694 (72.5%) screened positive for unhealthy alcohol use. Of those, 2364 (87.8%) were eligible to participate, and 1770 (65.7%) completed the baseline assessment and were included in the study (fig 1). Overall follow-up rates were 96.4% (n=1706/1770) at three months, 95.9% (n=1697/1770) at six months, and 93.8% (n=1660/1770) at 12 months. Four participants officially withdrew during the study (ie, requested to leave the study and no longer receive study questionnaires). Reasons given for withdrawal were no longer being interested in the study (one intervention group and two control group participants) and having moved abroad (one control group participant).

Mean age was 22.4 years (standard deviation 3.07), 958 (54.1%) of 1770 participants were women, and most participants were bachelor's degree students (1169 (66.0%) of 1770). The baseline mean for number of drinks per week was 8.59 (standard deviation 8.18) and the baseline mean heavy drinking days over the past 30 days was 3.53 (standard deviation 4.02) (table 2).

Among participants who were randomly assigned to receive the app, 738 (83.5%) of 884 downloaded the app. Among the control group, 846 (95.5%) of 886 completed the corresponding procedure. Throughout the study, participants who downloaded the app used a mean of 2.0 (standard deviation 1.5) of its modules (range 0-6; median 2.00 (interquartile range 1-3)) and used the app a mean of 21.2 times (standard deviation 61.9; range 0-403; median (interquartile range 1-8)).

Estimation of intervention effects

Means and standard deviations for all the assessment outcomes, for the intervention and control groups, are reported in table 3, along with summarised results from the generalised linear mixed models estimating the intervention's effects on outcomes. Full results for models 1 and 2 are reported in appendix 3.

For the primary outcome of the number of standard alcoholic drinks per week (drinking volume), analyses showed a significant main effect for the intervention in model 1 (incidence rate ratio 0.90 (95% confidence interval 0.85 to 0.96)), indicating significantly lower drinking volumes in the intervention group than in the control group during the follow-up period. The intervention-by-time interaction in model 2 was not significant, indicating that the intervention effects did not significantly differ between follow-ups (incidence rate ratio 0.91 (0.84 to 0.98) at three months; 0.90 (0.83 to 0.97) at six months; 0.91 (0.84 to 0.98) at 12 months). Of note, drinking volumes increased at three months in both groups and then decreased (below baseline levels) in both groups at six months and 12 months.

For the secondary outcome of heavy drinking days, analyses showed a significant main effect of the intervention in model 1 (incidence rate ratio 0.89 (95% confidence interval 0.83 to 0.96)). The intervention-by-time interaction in model 2 was not significant. The intervention's conditional effect was significant at three months (incidence rate ratio 0.89 (0.82 to 0.98)) and six months (0.88 (0.80 to 0.97)); at 12 months, the results were of approximately the same size but not statistically significant (0.91 (0.83 to 1.00), P=0.059). Similarly to drinking volume, the number of heavy drinking days in both groups was higher at three months and lower at six months and 12 months.

For the additional outcome of the maximum number of drinks consumed on one occasion, the main effect of the intervention in model 1 was significant (incidence rate ratio 0.96 (95% confidence interval 0.93 to 1.00), P=0.029). The intervention-by-time interaction in model 2 was not significant. The conditional effect at three months was significant (0.94 (0.90 to 0.98)), but the findings did not remain significant at six months (0.96 (0.92 to 1.01)) or 12 months (0.98 (0.94 to 1.03)). The intervention had no significant main effect on consequences related to alcohol or academic performance.

Per protocol analyses testing the intervention's effects on outcomes among participants who downloaded the app (738 (83.4%) of 884) or completed the attention control procedure (846 (95.4%) of 886) are reported in appendix 4. The results were similar to the intention-to-treat analyses but with slightly increased intervention effects.

Subgroup analyses

Results from the subgroup analyses are summarised in table 4. Full results for models 1 and 2 are reported in appendices 5 and 6. Subgroup analyses showed intervention effects of similar magnitudes among students reporting a potential alcohol use disorder.

Analyses of the original dataset (ie, before imputation, see appendices 7 and 8) yielded similar patterns of associations. Results remained consistent across the alternative re-analyses.

Discussion

Principal findings

Adaption of interventions to the latest multimedia trends is important to reach younger populations and of particular importance are interventions that are assessed by smartphone. Our study is one of only a few to have shown the beneficial effects of an app aimed at decreasing alcohol consumption.[33] This study identified university students reporting unhealthy alcohol use and showed that providing them access to a specially designed app was associated with drinking fewer drinks per week and fewer heavy drinking days over the 12 months of follow-up. No overall intervention effect was observed for alcohol related consequences or self-reported academic performance. No major differences were reported in the estimations of the intervention's effects on the subgroups with alcohol use disorders identification test scores indicating an alcohol use disorder: intervention effects were similar to the full sample analyses. Nonetheless, the intervention did not result in significant main effects on numbers of standard drinks per week in the second subgroup analysis (ie, alcohol use disorders identification test score >13 for men and >11 for women), which might be explained by a lack of statistical power related to the limited sample size.

These results were observed in a population whose overall alcohol use was unhealthy but not excessively high (ie, fewer than nine drinks per week at baseline, with an average of between three and four heavy drinking days per month), but they revealed the app's impact on reducing drinking.

Comparison with other studies

The effects were similar to those reported by other digital interventions: a Cochrane review published in 2017, with analyses restricted to studies with a low risk of bias (11 trials, 10 272 participants), reported that intervention groups consumed 10.5 g per week of ethanol less (95% confidence interval −13.7 to −7.4) than did control groups,[46] the equivalent of one Swiss standard drink. Observed decreases in drinking in this study were similar, with a decrease of 1.82 standard drinks (18-22 g per week) in the intervention group and a reduction of 0.57 standard drinks (6-7 g per week) in the control group at six months. A meta-analysis from 2018 estimated the effects of internet interventions: in randomised trials,[63] the effect of unguided interventions (such as the present study's app) was a mean reduction of 22.4 g per week. This meta-analysis also showed a greater treatment response among people older than 55 years than those who were younger. Thus, our results are similar to the effects of unguided internet interventions, considering that younger individuals seem to be less responsive than older individuals. On the basis of 15 randomised

trials, the 2017 Cochrane review estimated a reduction of 0.24 heavy drinking episodes per month.[46 64] Our study showed a reduction of 0.56 heavy drinking days per month in the intervention group and 0.09 in the control group. While heavy drinking episodes and heavy drinking days are not similar, they can be considered heavy drinking patterns. Our study showed an effect on a heavy drinking pattern (heavy drinking days), similarly to what has been reported for other digital interventions.

One interesting finding was that drinking increased at three months in both the intervention and control groups, and we postulate two main explanations for this. The study was conducted during the covid-19 pandemic (although not at peak incidence), and recruitment started when students were returning to their campuses after a lockdown period, with covid-19 restrictions being partially lifted. Students may have been eager to take advantage of more easily available alcohol and softer social distancing rules allowing more opportunities to drink than previously.[65] The three month follow-up also coincided with summer, when students are typically on holiday, which may explain the general increases in drinking observed at three months in both groups.

Strength and limitations

This study had some notable strengths. Participants came from four different higher education institutions, covering a breadth of the student population. We maintained a high follow-up rate, which was a challenge in previous studies of digital interventions.[66] We feel that limiting the length of the questionnaires reduced the risk of assessment reactivity, and because the entire study was conducted online, the risk of social desirability bias and the Hawthorne effect was kept to a minimum.[67 68] The observation of generally increased drinking at three months, followed by decreases at six months and 12 months, provides some reassurance that the reported reductions were not entirely driven by assessment effects or social desirability.

The study also had some limitations, however, notably its use of self-reported measures that were potentially subject to under-reporting. We chose not to collect biological samples because of the impractical logistics involved with a large trial and the potential to lower the participation rate. Nevertheless, we observed consistent effects across all the measures of drinking, and the measures of effect were aligned with other studies involving online digital interventions. The question on academic performance was missing from the 12 month questionnaire because of a configuration problem; the question had to be sent separately two weeks later, when this problem was identified. The attrition rate for this question was higher than the rest of the questionnaire, with 1375 (77.7%) of 1770 responses. Allocations could have been revealed if control group participants had shared their experiences with intervention group participants, and control group participants could have accessed the app on the telephone of a friend allocated to the intervention group. These events would have biased the results towards the null. Finally, we did not measure or assess any potential harms related to study participation, or attempt to assess cost-effectiveness.

Implications

The importance of the reductions in drinking observed in our study must be considered from the viewpoint of the public health risks associated with alcohol use. The Organisation for Economic Co-operation and Development estimated that approximately 80% of individuals drinking alcohol could lower their risk of premature death from all causes by drinking 10 g of ethanol less per week.[69] In the European Union, alcohol consumption of less than 20 g of ethanol per day accounts for 13% of all alcohol attributable cancers, with more than a third of these cancer cases being associated with drinking less than 10 g of ethanol per day.[70] Furthermore, heavy drinking episodes are associated with increased risks of intentional and non-intentional injuries, violence, and suicide. Notably, any heavy drinking increases mortality risk[71]; thus, any decrease in the number of heavy drinking days (−0.56 heavy drinking days per month in the present study) can be considered potentially important. Thus, we think that the reductions in drinking observed in the present study are relevant from a public health viewpoint and that the types of intervention investigated could partly lower the risks associated with drinking in large parts of the population.

Conclusions

Compared with the group who were not given the intervention, providing access to the app for 12 months was effective at reducing the average drinking volume of university students who had self-reported unhealthy alcohol use at baseline. The intervention required fewer resources than face-to-face interventions (with no need to hire and train specialist healthcare professionals to perform screening), brief interventions (with no need for a dedicated space on campus), and use of existing communication channels to reach large groups of people (eg, email and social media). Our study also resulted in good adoption rates. Although these findings point to a potential intervention dissemination strategy for the future, follow-up research should investigate whether widespread implementation is possible through similar channels outside of a research setting and whether this approach could be adapted to other settings (including in other countries).

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of any portion of the work are appropriately investigated and resolved. All authors approved the final version of the report. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Ethical approval: The trial was approved by the Human Research Ethics Committee of the Canton of Vaud (2018-00560).

Data sharing: The technical appendix, statistical code, and dataset are available from the corresponding author at Nicolas.Bertholet@chuv.ch (data transfer agreement requested).

The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Dissemination to participants and related patient and public communities: The Lausanne University Hospital communication team will help coordinate the communication of the study results to the press. The results have been presented at two scientific conferences (oral presentations at the International Network on Brief Interventions for Alcohol and other drugs (INEBRIA, Edinburgh, UK, 2022) and The Association for Multidisciplinary Education and Research in Substance use and Addiction conference (AMERSA, Boston, USA, 2022). The same will be done for the exploratory analyses regarding the impact of the various components of the app. The published results will be added to the ISRCTN profile and will be announced to the Swiss National Science Foundation. Per the Swiss National Science Foundation guidelines, all articles related to the project have to be available to the public. Given the study results, the app is freely available. The app is available via Apple's app store (https://apps.apple.com/ch/app/smaart/id1494678022?l=fr) and Google play store (https://play.google.com/store/apps/details?id=com.netinfluence.smaart&hl=fr&pli=1). All study participants have been notified of the study results and of the availability of the study app. The student associations involved in the study recruitment phase and the participating schools and universities have been informed of the study preliminary results and will be involved in the dissemination of the app when the study results are published.

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Web appendix: Supplementary material