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Effects of a minimal-guided on-line intervention for alcohol misuse in Estonia: a randomized controlled trial

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ABSTRACT

Background and Aims Estonia has one of the highest alcohol-attributable mortality rates within the European Union. The aim of this study was to estimate the efficacy of an on-line self-help intervention to reduce problem drinking at the population level. **Design** On-line open randomized controlled trial with an 8-week intervention and an active control group (intervention n = 303, control n = 286). Assessments took place at baseline and at 6 months follow-up. **Setting** On- and offline channels were used for population-based recruitment within a nation-wide prevention campaign in Estonia. **Participants** Inclusion criteria were age ≥ 18 years, heavy drinking [Alcohol Use Disorders Identification (AUDIT) test score ≥ 8], literacy in Estonian and at least weekly access to the internet; n = 589 participants were randomized (50% male, 1% other; mean age 37.86 years; 45% with higher level of education). **Intervention and comparator** The intervention consisted of 10 modules based on principles of cognitive–behavioral therapy and motivational interviewing. The active control group received access to a website with a self-test including personalized normative feedback and information for standard alcohol treatment. **Measurements** The primary outcome was AUDIT scores at 6 months follow-up adjusted for baseline scores. **Findings** Intention-to-treat analyses were applied. Missing data were addressed by using baseline observation carried forward (BOCF) and multiple imputation by chained equations (MI); 175 completed follow-up in the intervention group and 209 in the control group. AUDIT score at follow-up was significantly smaller in the intervention [BOCF mean = 13.91, standard deviation (SD) = 7.61, MI mean = 11.03, SD = 6.55] than control group (BOCF mean = 15.30, SD = 7.31; MI mean = 14.30, SD = 7.21), with a group difference of −1.38 [95% confidence interval (CI) = –2.58, –0.18], P = 0.02 for BOCF and −3.26 (95% CI = –2.01, –4.51), $P < 0.001$ for MI. **Conclusions** A randomized controlled trial has found that an on-line self-help intervention with minimal guidance was effective at reducing problem drinking in Estonia.

Keywords Alcohol, AUDIT, drinking, e-intervention, Estonia, minimal guidance, RCT, self-help.

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INTRODUCTION

Alcohol is one of the leading factors for the global burden of disease world-wide [1] and accounts for 8.3% of years of life lost in the European Union [2]. Among its Member States, the burden is particularly evident in Estonia, with the third-highest alcohol-attributable mortality rate [2]. Thus, there is an urgent need to reduce alcohol misuse at the population-level. Hazardous drinking in Estonia was defined at the time of the study as more than four standard drinks per day for men or more than two drinks per day for women with fewer than 3 days of abstinence in a week [3]. A recent Estonian survey indicated that only 2% of adult hazardous drinkers are receiving treatment, thus resulting in a great demand for professional health services [4]. Social isolation and increased stress due to the COVID-19

pandemic further aggravate this situation and may increase susceptibility to problem drinking in vulnerable populations [5]. On-line-based interventions, in particular, have the potential to address this problem due to their scalability, low barriers to access and higher acceptance than face-to-face treatment [6,7] and with proven evidence for high-income countries [7–10].

Regarding the effectiveness of specific treatment principles, a meta-analysis indicated that integrated therapeutic approaches [e.g. including elements of cognitive–behavioral therapy (CBT), motivational interviewing, personalized normative feedback (PNF) or behavioral self-control] yield better results than interventions based on PNF alone [7]. However, most studies employed designs with non-active control conditions, thus leaving a significant gap regarding superiority of interventions over active control groups [11]. To our knowledge, only one study has directly confirmed effects of an unguided high-intensity intervention based on integrated CBT and brief supportive counseling compared to a PNF/information booklet control condition in the general population, despite severe attrition [12].

Furthermore, a recent meta-analysis concluded that guided interventions are more effective than fully automated ones, which aligns with the importance of social support for increasing adherence in on-line interventions [7,13]. However, studies with guided interventions are still scarce [11]. Investigations into characteristics of a social presence factor compared to an active control group are warranted to further strengthen evidence. Specifically concerning Estonia, evidence-based on-line interventions are non-existent. To address these evident gaps, we conducted a randomized-controlled trial (RCT) to reduce problem drinking. Initially developed in 2018, RCTs with variants of the same intervention are currently taking place in several countries [14,15].

The current study aims to test the efficacy of the intervention to determine its potential as an evidence-based treatment that can be implemented within the country's official public health strategy. We hypothesized that the study intervention would lead to a greater reduction in alcohol misuse at follow-up compared to the control condition.

METHODS

Design

The study was an on-line open RCT conducted in Estonia. An integrated minimal-guidance on-line intervention (SELGE: sober and clear in Estonian) was compared to an active control condition. SELGE consists of an 8-week program with 10 treatment modules integrating CBT and motivational interviewing. Assessments took place at baseline, at the end of the intervention (8 weeks) and at 6 months follow-up.

The study follows the Consolidated Standards of Reporting Trials (CONSORT) guidelines with published trial protocol [16]. The Tallinn Medical Research Ethics Committee, Estonia approved the study.

Recruitment and procedures

Recruitment of participants took place as a nation-wide campaign between March and April 2019. Potential participants were contacted through various on- and offline channels nation-wide, including advertisement banners on social media platforms (Facebook, Instagram) and Google search, printed flyers placed at general practitioners' locations and press releases in local and country-wide newspapers. All releases led to the institutional webpage with further information and a link to the study. On the landing page of the study, site visitors were informed about the study, risk and benefits, inclusion/exclusion criteria and their rights, such as voluntary participation and withdrawal. They had to provide informed consent by checking respective boxes in the consent form. Subsequently, participants could set up their personal account with username, password and e-mail address and provided telephone numbers for follow-up interviews in case they could not be reached by standard reminder e-mails. After having confirmed study eligibility during the baseline assessment, participants were randomly assigned to the intervention or control group. Non-eligible users were excluded from the study, but continued to have access to the program. Participants were invited to take part in a raffle of one of 10 smartphones when they had completed the trial follow-up measures. There was no other compensation for participation.

Participants

Inclusion criteria were age $\geq$ 18 years, at least current at-risk alcohol use [score $\geq$ 8 in the Alcohol Use Disorders Identification Test (AUDIT)] [17], regular access to the internet and good command of Estonian. Participants were excluded if they participated in other treatment for substance use disorders at baseline, if they reported consumption of opioids, stimulants or cannabis more than four times in the preceding 30 days, if they were in previous treatment for cardiovascular problems or reported current pregnancy or breast-feeding due to a requirement outlined by the responsible ethics committee. Participants were also excluded if suicidal ideation had been present within the last year using the P4 Suicidality Screener [18].

Randomization

Participants were randomly assigned by the software using server-based simple randomization to either the intervention or the control group at a 1:1 ratio. This was not

executed according to a pre-defined random number list (allocation sequence), but at runtime after an applicant had submitted the baseline questionnaire using the PHP-function rand [1,2]. Therefore, no allocation concealment mechanism was needed. As an open trial, participants were aware of the study condition they were assigned to.

Intervention

The content of the treatment modules was as followed: motivational enhancement and self-monitoring (module 1), skills for meeting set goals (module 2), drinking-refusal skills (module 3), high-risk situations (module 4), problem-solving (module 5), dealing with craving (module 6), dealing with slips (module 7), sleep hygiene, rumination and worries (module 8), relaxation exercises (module 9) and long-term relapse prevention (module 10). The order of modules was fixed. Participants worked through these sections at their own pace and were free to repeat and/or skip modules. A graphical consumption diary was implemented for tracking weekly alcohol consumption and daily goals measured in Estonian standard drinks. As guidance, a virtual automated e-coach was present during the program to motivate and send reminders. Furthermore, the e-coach was represented by a real study team member who could be contacted via e-mail to provide personal guidance. The e-coach was also visible in introductory videos at the beginning of each module. A second social element was implemented by selecting a fictional companion with similar personal characteristics out of six different options. The companion provided further guidance and examples in specific modules.

Control group

In the active control group, participants had access to a help-page with a link to an external website, where they received PNF on a self-test for alcohol use and further information together with contact details for treatment options. The intervention content was made available for all participants after the end of the study duration.

Participant assessment

Automatic e-mail prompts were sent at each assessment point and participants received up to two additional reminders. Finally, they were contacted via telephone by the study coordinator if they had not started the assessment after the two reminders were sent.

Measures

At baseline, the following socio-demographic variables were assessed: Age, gender, level of education, employment, and living place. The primary outcome was the AUDIT at follow-up with a time frame of the past six months [17]. Secondary outcomes were: Changes in the weekly number of Estonian standard drinks (10 g of ethanol) and days without alcohol consumption over the past 6 months. Both were assessed by one question about alcohol use in standard drinks on each day of a typical week [15]. Further outcomes were drinking motives using the Drinking Motives Questionnaire (DMQ-R-5) [19], motivation for change assessed by one item each for importance ("How important is it for you to change your alcohol consumption?"), confidence ("How confident are you that you can change your alcohol consumption if you want to?") and readiness ("To what extent are you ready to contribute to changing your alcohol consumption?"). Self-reported emotional functioning and general distress was assessed with the Mental Health Inventory (MHI-5) [20]. Further illicit drug use was measured with an adapted version of the NIDA-Modified ASSIST V2, part 2 [21]. Measures for intervention acceptance were the Client Satisfaction Questionnaire for internet interventions (iCSQ-8), adapted for the Estonian context [22], hours of usage of external material and hours of usage of other external help. Treatment retention was measured *via* the fill-out rate of the weekly alcohol consumption diary implemented in the intervention. In addition, time spent with the intervention and number of modules completed was recorded.

Sample size

Sample size was calculated to be 298 per group to find an effect of Cohen's $d = 0.23$ with 80% power. This effect size was based a previous study investigating an unguided self-help intervention, which came closest to the intervention in the current study and reported a Cohen's $d = 0.20$ [12]. As our intervention was minimally guided, a slightly higher effect size was expected due to the general superiority of guided approaches [7].

Statistical analysis

Data were analyzed based on the intention-to-treat (ITT) principle. Missing data was imputed using baseline observation carried forward (BOCF). Multiple imputation (MI) by chained equations was performed as sensitivity analyses (Supporting information, S1). Fifteen sets of imputations were conducted, as imputations numbers between 10 and 20 are probably sufficient [23].

For investigating treatment effects, multivariable linear regression models were calculated. Follow-up scores for the outcomes served as dependent variables, with study condition as the independent variable; all controlled for the baseline value of the respective outcome variable. Mean difference as well as Cohen's *d* and associated 95% confidence intervals (CI) were calculated as effect size, with higher

absolute values indicating a greater difference between the intervention and control group. Bayes factors were calculated to assess strength of evidence.

Individuals lost to follow-up were compared to completers regarding baseline characteristics across study conditions. Interaction effects between study arm (intervention versus control) and drop-out status (non-completers versus completers) were additionally calculated. All tests were two-sided with $P < 0.05$. R version 4.0.0 was used [24].

RESULTS

Sample characteristics

Between 13 March and 15 April 2019, 589 individuals participated; 303 were randomly assigned to the intervention group and 286 to the control group (Table 1). All drug consumption items presented severe bottom effects.

A total of 384 (65%) took part in the 6-month follow-up. Significantly fewer participants in the intervention than the control group participated at follow-up ($P < 0.001$) (Fig. 1).

Among study conditions, participants lost to follow-up revealed a significant baseline difference for education compared with study completers. Individuals with primary school as the highest level of education and higher levels of baseline cocaine use dropped out more frequently, and individuals with higher education were more likely to complete follow-up. Interaction effects revealed that individuals in the intervention group lost to follow-up were younger, were living in the capital city and had lower levels of education. There were no other significant differences (Supporting information, Table S1).

Participants' socio-demographic characteristics were mainly comparable with problem drinkers in the general population. There was an over-representation of students and un-employed individuals living in the capital city but not in rural areas (Supporting information, Table S2).

Intervention effects: primary outcome

Participants in the intervention group reported a significantly reduced AUDIT score at follow-up compared to the control group with an effect size in the small range (Table 2). The Bayes factor for the overall model was > 300, thus indicating strong evidence for the alternative hypothesis.

Intervention effects: exploratory secondary outcomes

Due to the bottom effects found for baseline drug consumption, these variables had to be skipped. Individuals in the intervention group reported a greater number of days without alcohol consumption at follow-up compared to the control group. They also exhibited fewer motives to drink. Based on the MI approach, the intervention group also had a significantly smaller consumption of standard drinks, greater confidence regarding motivation to change and better emotional functioning compared to the control condition.

Findings were non-significant regarding importance of and readiness in motivation to change. In general, differences and associated effect sizes were smaller for the BOCF compared to the MI approach (Table 3).

Treatment acceptance, satisfaction and retention

Individuals in the intervention group with follow-up spent a mean of 3 hours with the program during the 8-week period and completed seven modules, with 63 (36%) completing all modules. Satisfaction with and usefulness of the program was rated as moderate (Table 4).

Mean time invested in external resources other than the study material was considerably low with less than 1 hour on average, and did not differ between study conditions within both the program period and at follow-up. Concerning the use of professional assistance, a similar pattern emerged (Supporting information, Table S3).

DISCUSSION

To our knowledge, this is the first study investigating an on-line intervention to reduce problem drinking by comparing a minimal-guided program based on CBT/motivational interviewing with an active PNF/information dissemination control group. It is also the first study that recruited within a nation-wide campaign in a country where no other internet-based alcohol intervention had been available. The study exhibits first evidence for the effectiveness of SELGE, which is reflected in a significantly smaller AUDIT score at follow-up in the intervention group compared to the control group. Secondary outcomes indicated a greater number of weekly alcohol-free days and fewer drinking motives.

The study supports the evidence that integrated CBT/motivational interviewing approaches are particularly important in addressing problem drinking [7]. In contrast to most of the previous RCTs, the study employed an active control group. It has been argued that effects in non-waiting-list control RCTs are deflated, because individuals in the control conditions present a higher likability of having received alternative support during the study phase [25]. However, there was no group difference in time invested outside the study resources, which further underlines the effectiveness of SELGE.

Elaborating on the superiority of guided versus unguided interventions [7,10], the study indicates that minimal guidance based on a mainly automated e-coach might

Table 1 Sample characteristics at baseline.

	Intervention (n = 303)	*Control (n = 286)*	*Total (N = 589)*
Socio-demographics			
Gender, no. (%)			
Female	133 (44)	155 (54)	288 (49)
Male	167 (55)	129 (45)	296 (50)
Other	3 (1)	2 (1)	5 (1)
Age in years, mean (SD)	37.95 (11.38)	37.76 (10.94)	37.86 (11.16)
Level of education, no. (%)[a]			
Primary school	33 (11)	28 (10)	61 (10)
Secondary school	75 (25)	70 (25)	145 (25)
Vocational training	63 (21)	56 (20)	119 (20)
Higher education	132 (44)	132 (46)	264 (45)
Employment, no. (%)[a]			
Self-employed	44 (15)	52 (18)	96 (16)
Employed	209 (69)	189 (66)	398 (68)
Student	16 (5)	17 (6)	33 (6)
Unemployed	18 (6)	16 (6)	34 (6)
Retired	16 (5)	11 (4)	27 (5)
Living place, no. (%)[a]			
Tallinn	126 (42)	119 (42)	245 (42)
Other major city	66 (22)	76 (27)	142 (24)
Other city	58 (19)	44 (15)	102 (17)
Rural area	53 (17)	47 (16)	100 (17)
Primary outcome			
AUDIT, mean (SD)[b]	18.03 (6.18)	18.38 (6.43)	18.2 (6.3)
Exploratory secondary outcomes			
Alcohol-free days, mean (SD)	2.97 (2.09)	3.02 (2.01)	2.99 (2.05)
Standard drinks, mean (SD)[c]	27.8 (26.7)	27.08 (24.45)	27.45 (25.61)
DMQ-R-5, mean (SD)[d]	11.94 (4.41)	12.17 (4.64)	12.05 (4.52)
Motivation for change, mean (SD)[e]			
Importance	8.22 (2.01)	8.15 (2.05)	8.19 (2.03)
Confidence	7.01 (2.25)	6.8 (2.25)	6.91 (2.25)
Readiness	7.82 (1.92)	7.71 (1.97)	7.76 (1.94)
NIDA-ASSIST, median (range)[f]			
Cannabis	0 (0–4)	0 (0–6)	0 (0–6)
Cocaine	0 (0–3)	0 (0–4)	0 (0–4)
Methamphetamines	0 (0–4)	0 (0–4)	0 (0–4)
Ecstasy	0 (0–3)	0 (0–3)	0 (0–3)
Prescription opioids	0 (0–2)	0 (0–4)	0 (0–4)
Street opioids	0 (0–2)	0 (0)	0 (0–2)
Sedatives	0 (0–6)	0 (0–4)	0 (0–6)
GHB/GBL	0 (0–3)	0 (0–3)	0 (0–3)
Mushrooms	0 (0–2)	0 (0–2)	0 (0–2)
Inhalants	0 (0)	0 (0–2)	0 (0–2)
Other	0 (0–6)	0 (0–6)	0 (0–6)
MHI-5, mean (SD)[g]	62.92 (19.01)	63.50 (19.54)	63.20 (19.26)

[a]Sum of percentage may exceed 100% due to rounding. [b]AUDIT = Alcohol Use Disorders Identification Test, time-frame = past 6 months, scoring from 0 to 40. [c]Mean number of standard drinks/alcohol-free days on a typical week in the past 6 months. [d]DMQ-R-5 = Revised Drinking Motives Questionnaire, five items, scoring from 5 to 25. [e]MHI-5 = short version of the Mental Health Inventory. Scoring from 0 to 100. Higher scores indicate better mental health. [f]Scales ranging from 1 = not at all to 10 = completely. [g]NIDA-ASSIST = National Institute on Drug Abuse, Alcohol, Smoking and Substance Involvement Screening Test. Scoring for each category 0 = never, 2 = once or twice, 4 = monthly, 6 = daily or almost daily. GHB/GBL = gamma hydroxybutyrate/gamma butyrolactone; SD = standard deviation.

be a useful opportunity to account for social presence and increase adherence [13] and similarly to exploit the maximum potential of automated treatment components. This approach reduces the need for constant availability of a real person and thus results in greater scalability and cost efficiency. Program satisfaction was good and treatment retention high. Thus, there seems to be a broad acceptance in the general population.

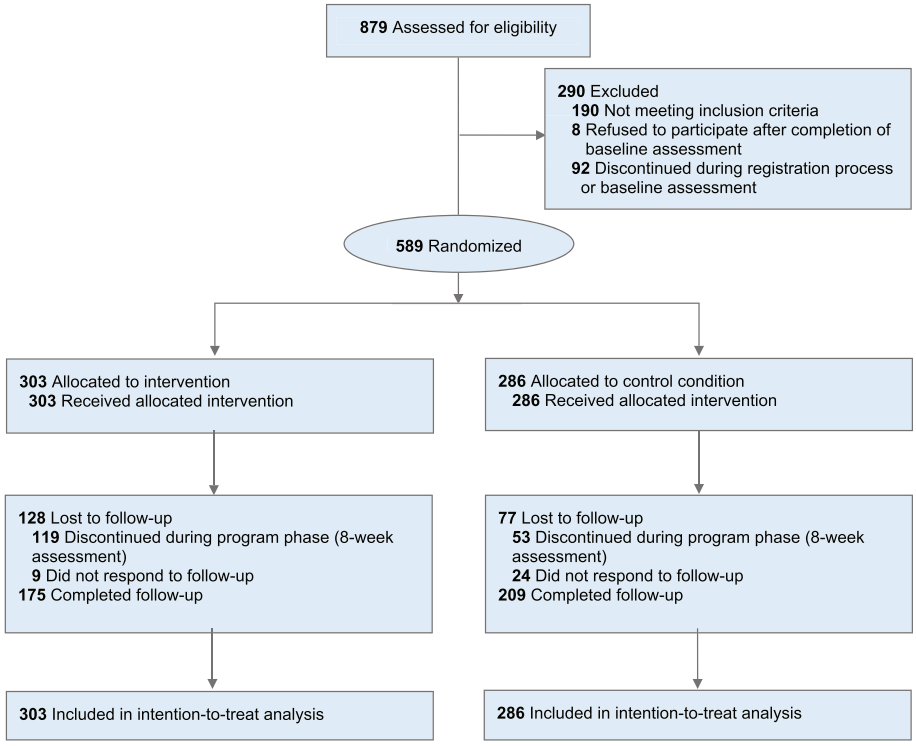

Figure 1 Participant flow-chart [Colour figure can be viewed at wileyonlinelibrary.com]

Table 2 Effects of the intervention for the primary outcome intent-to-treat analyses with two approaches to account for missing data.

	AUDIT intervention, mean (SD)	*AUDIT control, mean (SD)*	*Difference*[a] *(95% CI)*	*Beta (SE)*[b]	*P-value*	*Cohen's d (95% CI)*
Baseline observation carried forward	13.91 (7.61)	15.30 (7.31)	−1.38 (−2.59, –0.18)	1.09 (0-.44)	**0.02**	0.21 (0.04, 0.37)
Multiple imputation	11.03 (6.55)	14.30 (7.21)	−3.26 (−4.51, –2.01)	3.04 (0.54)	< **0.001**	0.46 (0.30–.063)

Note: *P*-values below 0.05 are printed in bold. AUDIT = Alcohol Use Disorder Identification Test; SD = standard difference; SE = standard error; CI = confidence interval. [a]Difference intervention group minus control group. [b]Multivariable linear regression models with study arm (reference: control group) as independent and follow-up score as dependent variables, with adjustment for respective baseline variables. Parameters of the baseline variable and intercept were removed due to better readability.

Except for illicit drugs, non-significant outcomes were motivation for change regarding readiness and importance. An explanation could be a lack of change sensitivity, in the sense that users would not have been chosen for an intervention if they had not already been willing to participate and considered change as important. In the sensitivity, but not the main analyses, participants in the intervention group additionally exhibited less consumption of standard drinks, more confidence in change and higher emotional functioning compared to the control condition. Furthermore, effects of all outcomes were generally larger in the multiple imputation models. A potential explanation is selective attrition, especially in the intervention group that might have flawed the missing at random assumption inherent to multiple imputation. Revisions of SELGE should focus upon increasing adherence of younger individuals with lower levels of education living in the capital in order to prevent dropouts in these particular groups, although the conservative approach of the main analyses might have underestimated the true effect. Future research is needed to address these divergent findings.

The intervention effect size found for the primary outcome was of a similar magnitude to primary studies of the meta-analysis that had also integrated principles of CBT and motivational interviewing [26,27] and for which highest values were reported compared to other approaches [7]. Although the effect size was in the small range, the benefit for public health is promising. There is evidence that even a smaller reduction in risk drinking levels is associated with a significantly reduced mortality and improved mental health [28,29]. Moreover, in light of lower costs, the reduced need for involvement of mental health professionals due to the minimal-guidance approach and thus potential scalability, the impact for public

Table 3 Effects of the intervention for explanatory secondary outcomes intent-to-treat analyses with two approaches to account for missing data.

	Intervention, mean (SD)	*Control, mean (SD)*	*Difference (95% CI)*[a]	*Beta (SE)*[b]	*P-value*	*Cohen's d (95% CI)*
No. alcohol-free days						
Baseline observation carried forward	3.78 (2.28)	3.52 (2.23)	0.26 (−0.10, 0.63)	−0.30 (0.15)	**0.045**	−0.17 (−0.33, 0.0)
Multiple imputation	4.32 (2.24)	3.70 (2.21)	0.63 (0.17, 1.08)	−0.64 (0.22)	**0.003**	−0.25 (−0.41, −0.08)
No. standard drinks						
Baseline observation carried forward	19.77 (27.01)	21.53 (22.91)	−1.74 (−5.81, 2.30)	2.24 (1.51)	0.14	0.12 (−0.04, 0.28)
Multiple imputation	14.80 (22.02)	19.67 (20.54)	−4.87 (−9.49, 0.25)	5.1 (2.23)	**0.02**	0.19 (0.03, 0.35)
DMQ-R-5						
Baseline observation carried forward	10.57 (4.27)	11.36 (4.65)	−0.79 (−1.52, –0.07)	0.63 (0.26)	**0.02**	0.20 (0.03, 0.36)
Multiple imputation	9.40 (3.58)	11.31 (4.67)	−1.73 (−2.49, –0.96)	1.62 (0.36)	< **0.001**	0.38 (0.21, 0.54)
MOT importance						
Baseline observation carried forward	7.97 (2.23)	7.84 (2.32)	0.13 (−0.24, 0.50)	−0.07 (0.14)	0.59	−0.04 (−0.21, 0.12)
Multiple imputation	7.59 (2.37)	7.70 (2.40)	0.10 (−0.40, 0.61)	0.15 (0.24)	0.54	0.05 (−0.11, 0.21)
MOT confidence						
Baseline observation carried forward	7.46 (2.10)	7.06 (2.30)	0.39 (0.04, 0.75)	−0.27 (0.14)	0.05	−0.16 (−0.32, 0.00)
Multiple imputation	7.81 (2.03)	7.08 (2.39)	0.73 (0.30, 1.16)	−0.65 (0.21)	**0.002**	−0.26 (−0.42, −0.10)
MOT readiness						
Baseline observation carried forward	7.70 (2.05)	7.64 (2.02)	0.07 (−0.26, 0.40)	0.01 (0.13)	0.95	0.0 (−0.16, 0.17)
Multiple imputation	7.56 (2.14)	7.49 (2.06)	0.07 (−0.49, 0.35)	−0.02 (0.20)	0.60	−0.01 (−0.17, 0.15)
MHI-5						
Baseline observation carried forward	68.40 (18.91)	67.06 (19.02)	1.33 (−1.74, 4.40)	−1.7 (1.18)	0.15	−0.12 (−0.28, 0.04)
Multiple imputation	72.61 (17.69)	67.51 (19.07)	5.10 (1.42, 8.77)	−5.54 (0.04)	< **0.001**	−0.25 (−0.41, −0.09)

Note: *P*-values below 0.05 are printed in bold. No. = number; SD = standard difference; SE = standard error; CI = confidence interval; DMQ-R-5 = revised Drinking Motives Questionnaire; MOT = motivation for change; MHI-5 = Mental Health Index 5. [a]Difference intervention group minus control group. A positive value indicates a greater score and a negative value a smaller score in the intervention group, respectively. [b]Multivariable linear regression models with study arm as independent and follow-up score as dependent variables, each model controlled for respective outcome baseline variable. Parameters of the baseline variable and intercept were removed due to better readability.

Table 4 Treatment retention and satisfaction.

	Intervention all (n = 303)	*Intervention completers (N = 175)*
Hours spent with program, median (range)	3 (0–20)	3 (0–20)
Number of completed modules, median (range)	3 (0–10)	7 (0–10)
Consumption diary fill out rate, median (range)	50% (0–100)	100 (0–100)
0%	70 (23)	17 (10)
1–50%	88 (29)	34 (19)
51–99%	33 (11)	19 (11)
100%	112 (37)	105 (60)
Program satisfaction, mean (SD)[a]	17.95 (3.43)	18 (2.97)

[a]Scale ranges from 8 to 32.

health might be substantial in order to reach individuals with problem drinking beyond the primary health-care system [10]. Altogether, the study provides the first evidence for the effectiveness of SELGE to reduce problem drinking in Estonia. The Bayes factor also strongly indicated an effect. Research concerning long-term effects beyond the follow-up period is warranted, as vulnerability to relapse in substance use problems is high (e.g. [30]).

The strengths of the study lie in the nation-wide recruitment, the low threshold for participation, no regular compensation for study participation except the smartphone raffle and an approach that combines automated treatment components with minimal guidance. Socio-demographic profiles of participants were mainly representative of the population, with a few exceptions regarding living place and employment status. SELGE seems to be particularly attractive for low-income populations such as students or unemployed individuals. Therefore, it might bring important public health benefit to the Estonian general population at relatively low costs and especially target populations with otherwise limited access to mental health services.

Further limitations in addition to the selective attrition are the reliance on self-report and thus potential dependency on the respondents' personal perception and ability to memorize. The assessment of other illicit drugs revealed significant bottom effects that made it impossible to test associations with treatment effects. Moreover, the study did not include women who were either pregnant or breast-feeding, and therefore results cannot be generalized to these populations. Finally, potential negative effects of the intervention were not explicitly taken into account.

CONCLUSIONS

Despite a small effect size, results are promising regarding the effectiveness of SELGE. Thus, after careful replication of results, SELGE could be implemented as a public health strategy to reduce problem drinking in Estonia. If its effectiveness is to be replicated, the intervention has the potential to significantly increase access to and availability of treatment. The on-line approach is particularly relevant for public health during the COVID-19 pandemic to reach vulnerable populations. Enlarging the study towards neglected populations is an important avenue for future research.

Trial registration

ISRCTN trial registry ID 48753339, www.isrctn.org.

Declaration of interests

D.D.E. has served as a consultant to/on the scientific advisory boards of Sanofi, Novartis, Minddistrict, Lantern, Schoen Kliniken, Ideamed and German health insurance companies (Barmer, Techniker Krankenkasse) and a number of federal chambers for psychotherapy. He is also stakeholder of the Institute for health training on-line (GET.ON/HelloBetter), which aims to implement scientific findings related to digital health interventions into routine care. The other authors declare no conflicts of interest.

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Author contributions

Mareike Augsburger: Data curation; formal analysis; visualization. **Esta Kaal:** Conceptualization; data curation; formal analysis; investigation; methodology; project administration; resources; visualization. **Trin Ülesoo:** Conceptualization; investigation; methodology; project

administration; resources. **Andreas Wenger:** Conceptualization; data curation; formal analysis; methodology; project administration; software; validation. **Matthijs Blankers:** Conceptualization; methodology. **Severin Haug:** Formal analysis; methodology; supervision; validation. **David Ebert:** Conceptualization; methodology. **Heleen Riper:** Conceptualization; methodology. **Matthew Keough:** Conceptualization; methodology. **Helen Noormets:** Conceptualization; data curation; investigation; project administration; resources. **Michael Schaub:** Conceptualization; funding acquisition; investigation; methodology; resources; software; supervision; validation. **Karin Kilp:** Conceptualization; data curation; funding acquisition; investigation; methodology; project administration; resources; supervision.

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Data S1 Multiple imputations were conducted separately for the two conditions but with the same set of variables. This has been shown to result in correct treatment effect estimates in RCTs [1]. All socio-demographic as well as primary and secondary outcome variables that had been assessed in both groups were included in the imputation model with the exception of some NIDA-modified ASSIST items (consumption of prescription opioids, street opioids, gamma-hydroxybutyrate, mushrooms, and inhalants) due to collinearity and (near) zero variance that had led to errors during imputation procedures and were subsequently removed. Including as many variables as possible results in a more plausible assumption of data missing at random [2].
Table S1 Drop-out analyses of baseline variables.
Table S2 Representativeness of the sample population.
Table S3 Group comparison for the use of other resources at both the end of the program period and at follow-up.

