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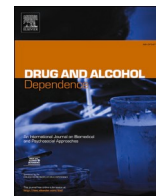
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Mediators of effects of a digital alcohol intervention for online help-seekers: Findings from an effectiveness trial

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ABSTRACT

Background: Digital alcohol interventions have been shown to exert effects in helping individuals reduce their drinking. However, little is known about the mechanisms which mediate such effects. The objective of this study was to estimate natural direct and indirect effects of a digital alcohol intervention.

Methods: This secondary analysis of mediated effects used data from a randomised controlled trial which included individuals with unhealthy alcohol use with access to a mobile phone aged 18 years or older in Sweden. The comparator was basic alcohol and health information. The digital intervention was centrally designed around weekly monitoring of consumption followed by feedback and tools to support behaviour change. Mediated effects were estimated using measures from 1-, 2-, and 4-months post-randomisation. Primary outcomes were total weekly consumption (TWC) and frequency of heavy episodic drinking (HED). A counterfactual framework was used to estimate three hypothesised mediators: importance, knowledge of how to change (know-how), and confidence.

Results: Between 25/04/2019 and 26/11/2020, 2129 participants were randomised. The intervention improved know-how and confidence, which in turn mediated the effects on TWC and HED at 2- and 4-months. Analyses with imputed data were not markedly different.

Conclusions: A digital alcohol intervention was found to exert effects in reducing consumption by means of improving individuals' knowledge of how to reduce their consumption and confidence in their ability to reduce. The use of face-valid single item measures is a study limitation notwithstanding observed findings, as is attrition and lack of blinding of participants.

1. Introduction

Delivering support to those who wish to reduce their alcohol consumption via digital means has gained increased attention over the past decade (Bendtsen et al., 2021a; Hoogendoorn et al., 2018; Kaner et al., 2017). Commonly known as *digital alcohol interventions*, these interventions include the use of web pages, text messages, and mobile phone apps to deliver support for behaviour change. The reported effects of digital alcohol interventions are on par with brief face-to-face interventions with respect to effects on behaviour (Hoogendoorn et al., 2018; Kaner et al., 2017), and they have the capacity to scale to large populations.

In response to continued high prevalence of drinking in Sweden, with more than 30% of the adult population drinking at levels which are

considered hazardous and harmful (Guttormsson, 2021), we investigated if a digital alcohol intervention targeting those seeking help online should be part of the societal response to reducing drinking. In a randomised controlled trial, (Bendtsen et al., 2022; Bendtsen and McCambridge, 2019), we found that those who were given access to the intervention consumed less alcohol after 4-months access, in comparison to those who were given access to alcohol and health material that is generally available online. The posterior median incidence rate ratio (IRR) for weekly consumption was 0.77 (probability of effect > 99.9%), and the posterior median IRR for frequency of heavy episodic drinking was 0.71 (probability of effect > 99.9%).

The intervention, which was fully automated, consisted of weekly self-assessments initiated via text messages, followed by web-based feedback and advice for change. The content of the advice was

List of abbreviations: RCT, Randomised controlled trial; IRR, Incidence rate ratio; CI, Compatibility interval.

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designed to influence three factors which have been proposed to be necessary for producing behaviour (Fishbein et al., 2001): increasing intention to perform the behaviour, addressing environmental constraints, and enhancing skills necessary to perform the behaviour. These factors are common to social cognitive theories of behaviour (Conner, 2009), which have played a central role in health behaviour research over the past 70 years. Actions which have shown to be promising to promote in order to manipulate these factors with respect to alcohol consumption include those that focus on behaviour substitution, problem solving, goal setting, review of behavioural goals, self-monitoring, and normative feedback (Garnett et al., 2015, 2018). We therefore designed modules of the digital intervention that revolved around these activities. Based on the behaviour change domains underlying the design of the intervention, and the corresponding intervention modules, we hypothesized that by promoting such actions we could influence three mediators of change: (1) the degree to which participants found it was important to make this change (Ajzen, 1991; Bandura, 1997; Becker et al., 1977; Rogers et al., 1983); (2) participants' knowledge of how to implement actions aimed at an alcohol reduction goal (know-how) (Conner, 2009; Fishbein et al., 2001); and (3) participants' confidence in being able to make a change they specified in reducing alcohol consumption (Bandura, 1997). In Table 1, we have described the intervention's modules and how the behavioural factors, intervention modules, and mediators of change were hypothesised to relate to one another.

Dismantling observed effects in trials in order to understand the mechanisms by which the change was induced can aid the development of more effective interventions (Gaume et al., 2014). Therefore, the objective of this study was to estimate to what degree importance, know-how, and confidence mediated the causal relationship between the digital alcohol intervention and alcohol consumption. This study was nested within a trial which primary objective was to estimate the total effect of the intervention on alcohol consumption (Bendtsen et al., 2022; Bendtsen and McCambridge, 2019), and which facilitated the estimation of natural direct and natural indirect effects by including measures of potential mediating factors at multiple follow-up intervals. The trial design was informed by extensive experience of conducting similar evaluation studies of digital alcohol interventions (Bendtsen et al., 2015; Kypri et al., 2014; McCambridge et al., 2013; Thomas et al., 2018).

2. Methods

This study of mediated effects was nested in, and used data from, a two-arm, parallel groups, randomised controlled trial (RCT) (Bendtsen et al., 2022). The trial was registered prospectively in the ISRCTN database (ISRCTN48317451) and received ethical approval on 2019-11-06 by the Regional Ethical Committee in Linköping, Sweden (Dnr 2018/417-31). A SPIRIT study protocol (Chan et al., 2013), including a statistical analysis plan for the mediator analyses, was published prior to recruitment (Bendtsen and McCambridge, 2019). There were no deviations from the study protocol. This report has been constructed following the guidelines set out for mediator analysis reporting in the AGRReMA statement (Lee et al., 2021).

2.1. Participants, recruitment, randomisation, and blinding

The target population was Swedish adults seeking help online to reduce their alcohol consumption. Individuals were required to be at least 18 years of age, have access to a mobile phone, and have unhealthy alcohol use according to Swedish guidelines. This is defined as either drinking 9 (women) / 14 (men) or more standard drinks of alcohol per week (total weekly consumption) or drinking 4 (women) / 5 (men) or more standard drinks on a single occasion at least once a month (heavy episodic drinking). A standard drink is in Sweden defined as 12 g of alcohol.

Table 1

Description of the digital intervention's modules and their respective behavioural factors and mediators.

Intervention module	Behaviour change domain	Mediators
Information about some of the risks from drinking alcohol, including risk of disease, how it may affect children in proximity, driving, and other negative consequences. This module also allows individuals to simulate how different levels of consumption affected risk of cardiovascular disease.	Intentions	Importance
Normative comparison of the individual's current consumption compared with others of the same age group and gender (based on data from Sweden), and classification as harmful or hazardous drinking.	Intentions	Importance
The individuals' consumption over time plotted in a chart (with data from the weekly assessments). Individuals can set a goal for their consumption, which will then show graphically in the chart. This allows individuals to set and review their own goals while also visualising the discrepancy between their current consumption and their goals.	Intentions	Confidence
Creation of a plan which could be used when facing an environmental or behavioural trigger (e.g., going to the pub). This module asks individuals to write a text message to themselves and pick a time and date for when they want to receive this message in the coming week (up to 3 times).	Skills and environment	Know-how and confidence
General tips to strengthen know-how on how to reduce consumption. The tips include suggestions to create prompts or cues as reminders of the commitment to reduce drinking, as well as suggestions to practice a new behaviour and substitute current behaviour with a different one (e.g., replacing at least two alcoholic beverages with non-alcoholic beverages each week). The tips also concern identification of relapse triggers and barriers, avoiding social cues for drinking, and environmental restructuring (e.g., avoid keeping alcohol at home).	Skills and environment (& maintenance of intention)	Know-how and confidence
On Wednesdays, Fridays, and Saturdays, individuals receive additional text messages with content aimed to increase motivation and skills. It is also possible to opt-in for additional text messages to be sent on the Mondays, Tuesdays, and Thursdays. The messages sent are a refinement of a previously developed set that was created through formative development (Thomas et al., 2016).	Skills and environment (& maintenance of intention)	Importance, know-how, and confidence

Recruitment began on 25/04/2019 and ended on 26/11/2020, at which time 2129 participants had been randomised. Participants were recruited to the trial using web search engine advertisements (Google, Yahoo, Bing) and Facebook. Individuals interested in the study sent a text message to a dedicated phone number. Within 10 minutes, a response was sent back with a hyperlink to a web page which presented the informed consent material. Those who consented were asked to respond to a baseline questionnaire (which also assessed eligibility). Please see Appendix A for all questions asked at baseline.

Immediately after completing the baseline questionnaire, participants were randomised to either immediate or delayed access to the digital intervention. Simple randomisation was used which was fully computerised. Neither research personnel nor participants were able to discover or in any way manipulate the randomisation sequence. Research personnel were blinded before and after allocation, and all study procedures were fully automated, except for phone calls to collect follow-up data from participants who had not responded to initial attempts. Participants were aware of their allocation status (see Interventions).

2.2. Sample size

There was no power calculation done specifically for the mediation analyses. The power calculation for the primary objective was done using a Monte Carlo study, the details of which can be found in the study protocol (Bendtsen and McCambridge, 2019). In brief, we assumed that the intervention group would be drinking 15% less alcohol than the control group at the four-month follow-up. We aimed for an expected power of 80% at the 0.05 significance level. Based on our previous studies of digital interventions, we anticipated an attrition rate between 5% and 25%. The simulations suggested an expected sample size of 2126 individuals (inter quartile range = 2031;2198).

2.3. Interventions

Participants allocated to the control group were advised via a text message that they would receive information designed to motivate them to think more about reducing their alcohol consumption, and that after four months they would receive additional support delivered to their mobile phone. A link to a national website with alcohol and health information was provided (<https://www.iq.se>). Participants in the intervention group were given information about the same website but also immediate access to the digital intervention for four months. Access to the intervention was restricted to four months, however, it should be noted that this restriction was purely for research purposes. In a non-research setting, individuals would be able to engage with this intervention for as long as they found it helpful.

2.4. Outcomes and measures

2.4.1. Mediators

Three potential mediating factors were assessed: importance, know-how, and confidence. Importance or outcome-efficacy is an aspect of motivation and readiness to change and speaks to the extent that the goal is valued. These are closely related factors in modern theory, for example, protection motivation theory (Rogers et al., 1983), social cognitive theory (Bandura, 1997), and theory of planned behaviour (Ajzen, 1991) (and has been retrospectively added to the health belief model (Becker et al., 1977)). Having knowledge of the means of how to change (know-how), connects with several factors in theoretical models, for example, to behavioural control in the theory of planned behaviour, and has been proposed as a necessary factor for behaviour change (Conner, 2009; Fishbein et al., 2001). Note this formulation of knowledge is distinct from possessing information about alcohol consumption and its consequences (importance), and is instead about being aware of how to implement actions aimed at an alcohol reduction goal.

Confidence is a shorthand for self-efficacy, a cornerstone of modern theoretical models of behaviour change, prominently in social cognitive theory (Bandura, 1997).

All three mediators were measured at baseline and 1-, 2-, and 4-months post randomisation. To reduce participant burden across the entire trial period, we decided against using multi-item questionnaires to measure these factors, instead relying on face valid single-item measures. We based these items on importance and confidence rulers (Harris et al., 2008), which are typically used without a fixed time interval, asking about the individuals' general assessment rather than specifically about the coming week or month. The items used are presented in Text Box 1.

2.4.2. Outcomes

There were two alcohol consumption outcomes, which were co-primary in the parent trial: total weekly alcohol consumption measured by asking participants the number of standard drinks consumed in the past week; and frequency of heavy episodic drinking assessed by asking participants how many times they consumed 4 (women) / 5 (men) or more standard drinks on one occasion the past month. Both were measured at baseline and 2-, and 4-months post randomisation. Both outcomes are part of the core outcome set for brief alcohol interventions (Shorter et al., 2021).

2.4.3. Follow-up procedures

All follow-ups were initiated by sending text messages to participants with hyperlinks to web questionnaires. A total of two reminders were sent two days apart to those who had not responded. If no response was collected after the second reminder, a fourth text message was sent to participants asking them to respond to the questions by responding directly with a text. We called participants to collect responses if there was no response to the fourth text message (maximum of five calls).

2.5. Effects of interest

The effects of interest were natural direct and natural indirect effects following the definitions of Pearl (Pearl, 2012). The natural direct effect is interpreted as the expected change in response induced by moving from the control group to the intervention group while keeping the mediating factor constant at the value it would have taken if this move had not been made. Conversely, the natural indirect effect is interpreted as the expected change in response induced by staying in the control group but changing the mediating factor to the value it would have taken if a move had been made from the control group to the intervention group. Using these definitions, the study aimed to estimate:

- the natural direct effect of treatment allocation on alcohol consumption outcomes at 2- and 4-months post randomisation,
- the natural indirect effect of treatment allocation through mediating factors at 1-month post randomisation on alcohol consumption outcomes at 2-months post randomisation,
- the natural indirect effect of treatment allocation through mediating factors at 2-months post randomisation on alcohol consumption outcomes at 4-months post randomisation.

Estimation of these effects were pre-specified in the trial protocol as the second objective of the trial, following the primary total effects of intervention on alcohol consumption (Bendtsen and McCambridge, 2019). Causal models were used for estimation, including each mediating factor individually (Fig. 1), and a single model with all three mediating factors (same as Fig. 1 with three mediators). The causal models were constructed based on the assumption that accounting for baseline characteristics removes any confounding among mediators and outcomes, an assumption which cannot be tested and should be borne in mind when interpreting findings.

Box 1

Items used to assess mediators.

- **Importance:** How important is it for you to reduce your alcohol consumption? (10-point scale ranging from 1 = “Not important” to 10 = “Very important”)
- **Know-how:** How well do you know how to reduce your alcohol consumption? (10-point scale ranging from 1 = “Not well at all” to 10 = “Very well”)
- **Confidence:** How confident are you that you will be able to reduce your alcohol consumption? (10-point scale ranging from 1 = “Not at all” to 10 = “Very confident”)

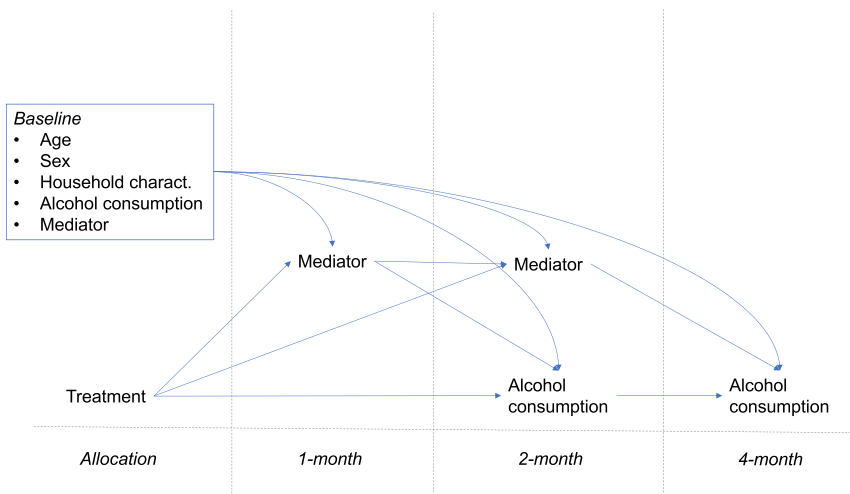


Fig. 1. Causal model representing baseline characteristics, treatment, mediators, and outcomes at allocation and follow-up interval.

2.6. Statistical methods

Participants were analysed in the groups to which they were randomised (intention-to-treat). Missing data was initially handled by available data analysis, complemented with sensitivity analyses where missing data was imputed using multiple imputation with chained equations (White et al., 2011), please see Appendix C for details. Analyses were done using R version 4.05 with packages rstan version 2.21.2, mice version 3.13.0, and cmdstan version 2.30.1. Source code for the Stan models can be found as [supplementary materials](#).

The analyses were conducted using a counterfactual framework following Pearl's mediation formulas (Pearl, 2012). Negative binomial regression was used to model alcohol consumption measures (total weekly consumption and frequency of heavy episodic drinking), and linear regression to model mediator variables (which were standardised). Treatment-mediator and treatment-mediator-outcome models were adjusted for sex, age, household characteristics, and baseline values for each respective mediator and alcohol outcome. Models were estimated using Bayesian inference (Bendtsen, 2018), with standard normal priors for all coefficients representing effects. When reporting requires, the medians of posterior distributions are used as point estimates, which will be presented with 95% compatibility intervals (CI) defined by the 2.5% and 97.5% percentiles of the posterior distribution.

2.7. Attrition analyses

Attrition analyses investigated if responders and non-responders differed systematically with respect to baseline characteristics and among study groups. We used logistic regression with and without an interaction for group allocation and estimated the models with Bayesian inference (Bendtsen, 2018). We used Cauchy priors for coefficients with a normal hyperprior for the scale parameter (Piironen and Vehtari,

2017) to account for the excessive number of covariates.

The total effect of intervention on alcohol consumption outcomes were estimated using data from participants for which mediation data was available. These estimates were compared to estimates of total effect from the primary analyses of the trial which have already been reported (Bendtsen et al., 2022). Marked differences between estimates may be indicative of systematic differences between participants with mediation data available and those without.

3. Results

From 25/04/2019–26/11/2020, a total of 2437 individuals signed up for the trial of which 90.2% (n = 2199) consented to participate. There were 36 consenting participants who did not complete the baseline questionnaire, and 34 who were excluded due to not fulfilling the inclusion criteria. The remaining 2129 participants were randomised: 1063 to the intervention group and 1066 to the control group. Baseline characteristics of randomised participants are presented in Table 2 (see parent trial report for full CONSORT flowchart (Bendtsen et al., 2022)).

3.1. Outcomes and estimates

At the 1-month follow-up interval, mediator measures were collected from 80% (n = 1699) of participants. At the 2-month follow-up interval, mediator measures were collected from 53% (n = 1130) of participants and alcohol consumption measures were collected from 73% (n = 1557 for weekly consumption, n = 1548 for heavy episodic drinking) of participants. At the 4-month follow-up interval, mediator measures were collected from 50% (n = 1073) of participants and alcohol consumption measures were collected from 67% (n = 1429 for weekly consumption, n = 1424 for heavy episodic drinking) of participants. As reported alongside the primary findings of the trial (Bendtsen et al., 2022), there

Table 2
Participants' baseline characteristics.

	Total (n = 2129)	Intervention (n = 1063)	Control (n = 1066)
Total weekly alcohol consumption (standard drinks), median (quartiles)	17 (10;25)	17 (10;25)	16 (10;25)
Frequency of heavy episodic drinking (per month), median (quartiles)	6 (4;11)	6 (4;10)	6 (4;12)
Age, median years (quartiles)	45 (36;54)	45 (35;55)	46 (36;54)
Sex, n (%)			
Women	1237 (58%)	612 (58%)	625 (59%)
Men	892 (42%)	451 (42%)	441 (41%)
Household characteristics, n (%)			
Living alone without kids at home	443 (21%)	219 (21%)	224 (21%)
Living alone with kids at home	215 (10%)	114 (11%)	101 (9%)
Living with somebody without kids	544 (26%)	267 (25%)	277 (26%)
Living with somebody with kids	756 (36%)	383 (36%)	373 (35%)
Have a partner but not living together	171 (8%)	80 (8%)	91 (9%)
Importance, median score (quartiles)	10 (9;10)	10 (9;10)	10 (9;10)
Know-how, median score (quartiles)	5 (2;7)	5 (2;7)	5 (2;6)
Confidence, median score (quartiles)	6 (5;8)	6 (5;8)	6 (5;8)

was evidence that older individuals and individuals with less frequent episodes of heavy drinking at baseline were more likely to have reported both 2- and 4-month alcohol consumption data. Group allocation was not observed to be strongly associated with missingness of alcohol outcome measures at either follow-up interval. A similar pattern was evident for mediator measures, with older individuals and individuals with less frequent episodes of heavy drinking at baseline being more likely to respond to mediator follow-up. In addition, those with higher motivation at baseline were more likely to respond to mediator follow-up. There was no marked association between group allocation and missingness of mediator data, however, there was some evidence that group allocation moderated the confidence and age relationships between baseline characteristics and missingness. However, this

interaction was not consistent over time and was found to be weak. Please see Appendix B for full details of the attrition analyses. Estimates of total effect using data available for the mediation analyses were comparable to those estimated in the primary findings, details of which can also be found in Appendix B.

3.1.1. Effects of intervention on mediator outcomes

Fig. 2 presents mean and standard errors for mediator measures for each group at baseline and each follow-up interval. Table 3 presents adjusted standardised effect estimates of treatment on mediators. There was strong evidence of an observed effect on know-how and confidence. Importance was already high in both groups at baseline, and the evidence suggested that there was no observed effect of intervention on importance.

3.1.2. Natural direct and natural indirect effects

Estimates of natural direct and natural indirect effects of treatment allocation on total weekly alcohol consumption, expressed as IRRs, are presented in Table 4. Equally so for heavy episodic drinking in Table 5. Findings were no different using available data versus imputed data, therefore, available data analyses are presented here with imputed analyses available in Appendix C.

3.1.2.1. Total weekly consumption. Estimates of natural direct and indirect effects on weekly alcohol consumption are presented in Table 4. The model including all three mediators showed that the effect of the intervention on 2-month weekly consumption was entirely explained through the mediators measured at 1-month. However, while the magnitude of the indirect effect remained when considering 2-month mediators on 4-month consumption outcomes, the direct effect had increased. Table 4 also shows that this pattern holds for models including single mediators, with know-how and confidence explaining almost entirely the effects of the intervention at the 2-month interval, but not at the 4-month interval. Importance did not explain any of the effect, which is consistent with it being already very high in both groups at study entry.

3.1.2.2. Heavy episodic drinking. Estimates of natural direct and indirect effects on heavy episodic drinking are presented in Table 5. The model including all three mediators showed that the effect of the intervention

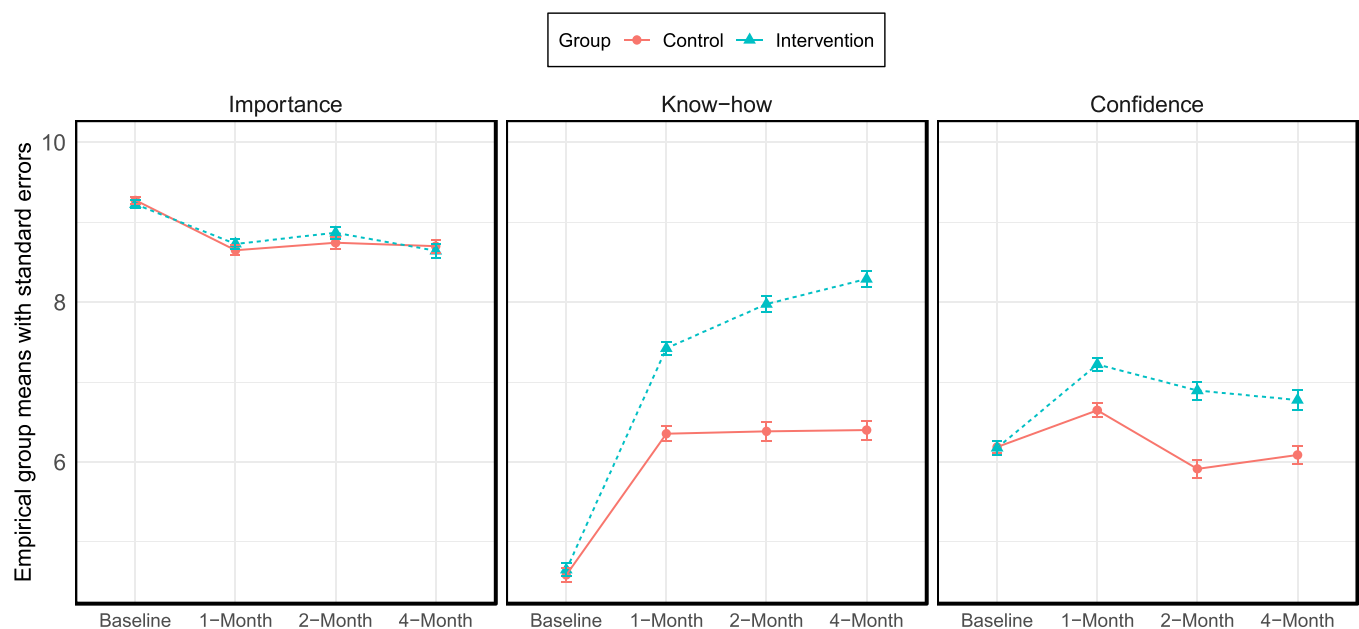


Fig. 2. Empirical means and standard errors of mediator measures at baseline and 1-, 2- and 4-months.

Table 3
Estimate of adjusted standardised effects of treatment on mediator factors at 1-, 2- and 4-months.

	1-Month		2-Month		4-Month	
	Est. 95% CI	Pr. (Est. > 0)	Est. 95% CI	Pr. (Est. > 0)	Est. 95% CI	Pr. (Est. > 0)
Importance						
Intervention vs. Control (standardised)	0.05 (-0.04; 0.13)	86.1%	0.04 (-0.07; 0.15)	77.8%	-0.05 (-0.17; 0.06)	16.4%
Know-how						
Intervention vs. Control (standardised)	0.41 (0.32; 0.49)	> 99.9%	0.58 (0.48; 0.69)	> 99.9%	0.70 (0.59; 0.80)	> 99.9%
Confidence						
Intervention vs. Control (standardised)	0.21 (0.13; 0.30)	> 99.9%	0.34 (0.23; 0.44)	> 99.9%	0.24 (0.13; 0.35)	> 99.9%

Abbreviations:

Est. – Median of the marginal posterior distribution of adjusted standardised effects.
CI – Compatibility interval (defined by the 2.5% and 97.5% percentiles of the posterior distribution).
Pr. – Posterior probability.

Table 4
Natural indirect and natural direct effects of treatment on total weekly alcohol consumption estimated under each of the causal models.

	1-month mediator -> 2-month total weekly alcohol consumption		2-month mediator -> 4-month total weekly alcohol consumption	
	IRR 95% CI	Pr. (IRR < 1)	IRR 95% CI	Pr. (IRR < 1)
Full model (All three mediators)				
Natural indirect effect	0.93 (0.90; 0.96)	> 99.9%	0.93 (0.89; 0.97)	> 99.9%
Natural direct effect	1.00 (0.90; 1.11)	51.7%	0.79 (0.70; 0.90)	> 99.9%
Importance				
Natural indirect effect	1.00 (0.99; 1.00)	56.2%	1.00 (0.99; 1.00)	72.2%
Natural direct effect	0.91 (0.82; 1.02)	95.2%	0.75 (0.66; 0.85)	> 99.9%
Know-how				
Natural indirect effect	0.94 (0.91; 0.96)	> 99.9%	0.94 (0.90; 0.98)	99.8%
Natural direct effect	0.99 (0.89; 1.11)	54.8%	0.79 (0.70; 0.90)	> 99.9%
Confidence				
Natural indirect effect	0.95 (0.92; 0.97)	> 99.9%	0.94 (0.91; 0.97)	> 99.9%
Natural direct effect	0.97 (0.88; 1.08)	71.2%	0.78 (0.69; 0.88)	> 99.9%

Abbreviations:

IRR – Median of the marginal posterior distribution of adjusted incidence rate ratios (IRRs).
CI – Compatibility interval (defined by the 2.5% and 97.5% percentiles of the posterior distribution).
Pr. – Posterior probability.

on 2-month heavy episodic drinking was partially explained through mediators at 1-month. The indirect effect remained when considering 2-month mediators on 4-month consumption outcomes, while the direct effect had increased in magnitude. This pattern replicated what was observed for total weekly consumption, with indirect effects being persistent over time, giving strong evidence of confirmation in this population.

4. Discussion

In an effectiveness trial, we found evidence of indirect effects of a digital intervention on alcohol consumption mediated through knowing how to reduce one’s drinking and confidence in being able to reduce one’s drinking. Indirect effects fully explained the total effect on weekly consumption at two months post randomisation, with evidence of additional direct effect at four months post randomisation. For heavy

Table 5
Natural indirect and natural direct effects of treatment on frequency of heavy episodic drinking estimated under each of the causal models.

	1-Month mediator -> 2-Month heavy episodic drinking		2-Month mediator -> 4-Month heavy episodic drinking	
	IRR 95% CI	Pr. (IRR < 1)	IRR 95% CI	Pr. (IRR < 1)
Full model (All three mediators)				
Natural indirect effect	0.92 (0.88; 0.95)	> 99.9%	0.94 (0.89; 0.99)	99.0%
Natural direct effect	0.92 (0.82; 1.03)	92.1%	0.71 (0.61; 0.81)	> 99.9%
Importance				
Natural indirect effect	1.00 (0.99; 1.00)	63.6%	1.00 (0.99; 1.00)	72.1%
Natural direct effect	0.87 (0.77; 0.97)	99.3%	0.67 (0.58; 0.76)	> 99.9%
Know-how				
Natural indirect effect	0.94 (0.91; 0.96)	> 99.9%	0.96 (0.92; 1.00)	96.6%
Natural direct effect	0.94 (0.84; 1.06)	83.9%	0.69 (0.60; 0.80)	> 99.9%
Confidence				
Natural indirect effect	0.94 (0.91; 0.96)	> 99.9%	0.93 (0.89; 0.96)	> 99.9%
Natural direct effect	0.90 (0.81; 1.01)	96.8%	0.71 (0.62; 0.81)	> 99.9%

Abbreviations:

IRR – Median of the marginal posterior distribution of adjusted incidence rate ratios (IRRs).
CI – Compatibility interval (defined by the 2.5% and 97.5% percentiles of the posterior distribution).
Pr. – Posterior probability.

episodic drinking, indirect effects partially explained the total effect at both two- and four months post randomisation. No indirect effects were observed mediated through importance of reducing one’s drinking. This suggests that the initial decrease in consumption can be explained by the mediators, however, not the decrease that occurred later. This is consistent with the estimates of effect of intervention on mediators, where it was evident that groups diverged with respect to know-how and confidence already after one month, after which the difference remained similar over time for confidence but grew slightly for know-how. Importance was rated as very high for both groups at baseline, and no differences between groups over time were observed. The findings are coherent with the underpinning logic of the intervention, helping participants build know-how and confidence in their own ability to reduce their drinking, by giving advice on specific actions to take. This implies that those who are seeking digital help to reduce their drinking need, among other things, content of this type.

Our know-how measure is novel. Knowledge of how to reduce one's drinking or its consequences has been previously studied as a mediator most closely in the form of protective behavioural strategies (Braitman and Lau-Barraco, 2020; Lau-Barraco et al., 2018; Walters et al., 2009), without finding evidence of mediation. In contrast, knowledge of how to reduce one's drinking was the strongest mediator in the current study, which intriguingly suggests that the specific content of the relevant behaviour change strategies we used, and the encouragement of their adoption, may be an active ingredient in how brief interventions can work. Caution is appropriate, however, as this is one study of a digital alcohol intervention, whose findings need further testing and replication in other contexts. It could be that brief interventions with such contents are more likely to be effective than those without, thus potentially contributing to explanations of the conflicting evidence on brief interventions more broadly (McCambridge, 2021; McCambridge and Saitz, 2017). Note also, the present study presents the first evidence of which we are aware that confidence is a demonstrated mediator of digital or in-person brief interventions, and thus a mechanism by which brief interventions may function.

Our findings indicate that the total observed effect of the digital alcohol intervention is not fully explained by the mediators measured in this study. While this is likely due to limitations inherent in the ability to capture know-how and confidence using single face-valid items in a digital effectiveness trial, and ceiling effects on the importance measure, there are also other possible mediators that were not studied here. Perceived norms (Bedendo et al., 2020; Braitman and Lau-Barraco, 2020; Gersh et al., 2019; Neighbors et al., 2006; Pedersen et al., 2017; Williams et al., 2009) is one such candidate, though findings have been generally disappointing, as has been true also of other studied candidates (Barnett et al., 2010; Byregowda et al., 2022; Gex et al., 2022; Pedersen et al., 2017). Advances remain needed in the study of mediators of brief interventions, including digital interventions (Gaume et al., 2014).

4.1. Limitations

Considering minimal barriers to effectiveness trial participation, it is not surprising that attrition subsequently proved to be a prominent study limitation (Murray et al., 2013). While the response rate to the mediator questionnaire at the 1-month interval was 80% ($n = 1699$), rates dropped at the 2- and 4-month intervals to 53% ($n = 1130$) and 50% ($n = 1073$) respectively. The analyses of baseline characteristics presented in Appendix B revealed that older participants, participants who had fewer episodes of heavy drinking, and participants who rated their confidence higher, were more likely to respond to follow-up. Group allocation on its own was not observed to be strongly associated with missingness, however, there was some evidence indicating moderation between group allocation and age and confidence at baseline. These moderated associations were, however, weak and inconsistent over time. Analyses with missing data imputed did not reveal differential findings, however, this only offers evidence of robustness of findings under the assumption of data missing at random.

Anticipating high attrition and balancing considerations of participant burden, we decided against using empirically supported multi-item questionnaires to measure importance, know-how, and confidence. This means we should be cautious in our interpretation of findings because the measures have limited evidence of construct validity. Note, however, that both the importance and confidence rulers have been found to correlate with readiness to change among individuals with harmful alcohol use (Harris et al., 2008).

Since the data for the mediation analyses came from an RCT, and since measures of mediators and outcomes were lagged, treatment to mediator and treatment to outcome relationships can be considered unconfounded. This is however not the case for the mediator to outcome relationships. While lagged data ensures directionality, the relationship can still be confounded by measured and unmeasured variables post-

randomisation. In our analyses, we adjusted for baseline characteristics, so note there could be residual confounding from unmeasured baseline and time varying variables, meaning that findings may not fully represent demonstrated causal influence of mediator on outcomes but in part an association caused by confounding. This means that estimates of effects may be biased both towards and away from the null, and we suggest that our stringent approach to interpretation is particularly appropriate given the nature of the mediator data.

Finally, participants in the control group were informed that they were being given information about alcohol and health as motivation to think more about their alcohol consumption and what they could do to reduce it, and that later they would be given additional support. The material was constructed to inform control group participants that this was one way in which the support was intended to work, attempting to avoid explicitly saying that they had to wait for support. It is unavoidable that this was understood by some as being asked to wait, as participants were looking online for help and were likely to have already come across the general alcohol and health information offered. We therefore cannot disregard concerns about potential bias arising from disappointment in waiting list designs (Bendtsen et al., 2021b; Cunningham et al., 2013; Müssener et al., 2019), as well as biases related to the lack of blinding of participants that may arise from social desirability (Davis et al., 2010). The identification of mediators in this study does, however, provide evidence that trial findings may not be entirely due to social desirability bias (Kypri et al., 2016; McCambridge, 2021; McCambridge and Saitz, 2017). The intended change in participants' confidence and know-how was observed and this in turn partially explained differences in outcomes between groups. However, if social desirability also affected reports on mediators, the same pattern would emerge; these data are therefore relevant to interpretation of risk of social desirability bias but are not conclusive. Biological verification may become practical in large-scale effectiveness studies—conditional on their own inherent limitations, including ascertainment bias—though that prospect seems more distant for online studies.

5. Conclusions

A digital alcohol intervention was reported by participants to be effective in reducing alcohol consumption by means of improving their know-how and confidence in their ability to reduce their drinking. Total effects were not fully explained, thus, there are unknown mechanisms at work which require further study. The use of face-valid single item measures limits findings, as does attrition and lack of blinding.

Author disclosures

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Declaration of Competing Interest

MB owns a private company (Alexit AB) that maintains and distributes evidence-based lifestyle interventions to be used by the public and in health care settings. Alexit AB played no role in developing the intervention, study design, data analysis, data interpretation, or writing of this report. Services developed and maintained by Alexit AB were used for sending text messages and data collection. KÅ and JM declare no competing interests.

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Contributions

MB and JM designed the study. MB did the statistical analysis. KÅ was responsible for follow-up data collection. MB and KÅ accessed and verified the data. MB wrote the first draft of the report, with input from both JM and KÅ. All authors had access to all the data in the study and had final responsibility for the decision to submit for publication. The corresponding author, who is also the guarantor, attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.drugalcdep.2023.110957](https://doi.org/10.1016/j.drugalcdep.2023.110957).

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