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Web-based self-help for problem drinkers: a pragmatic randomized trial

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ABSTRACT

Aims Self-help interventions for adult problem drinkers in the general population have proved effective. The question is whether this also holds for self-help interventions delivered over the internet. **Design** We conducted a pragmatic randomized trial with two parallel groups, using block randomization stratified for gender and with follow-up at 6 months. **Setting** The intervention and trial were conducted online in the Netherlands in 2003–2004. **Participants** We selected 261 adult problem drinkers from the general population with a weekly alcohol consumption above 210 g of ethanol for men or 140 g for women, or consuming at least 60 g (men) or 40 g (women) at least 1 day a week over the past 3 months. Participants were randomized to either the experimental drinking less (DL) condition or to the control condition (PBA). **Intervention** DL is a web-based, multi-component, interactive self-help intervention for problem drinkers without therapist guidance. The recommended treatment period is 6 weeks. The intervention is based on cognitive-behavioural and self-control principles. The control group received access to an online psychoeducational brochure on alcohol use (PBA). **Outcome measures** We assessed the following outcome measures at 6-month follow-up: (i) the percentage of participants who had reduced their drinking levels to within the normative limits of the Dutch guideline for low-risk drinking; and (ii) the reduction in mean weekly alcohol consumption. **Findings** At follow-up, 17.2% of the intervention group participants had reduced their drinking successfully to within the guideline norms; in the control group this was 5.4% [odds ratio (OR) = 3.66; 95% confidence interval (CI) 1.3–10.8; $P = 0.006$; number needed to treat (NNT) = 8.5]. The intervention subjects decreased their mean weekly alcohol consumption significantly more than control subjects, with a difference of 12.0 standardized units (95% CI 5.9–18.1; $P < 0.001$; standardized mean difference 0.40). **Conclusions** To our knowledge this is one of the first randomized controlled trials on a web-based self-help intervention without therapist guidance for self-referred problem drinkers among the adult general population. The intervention showed itself to be effective in reducing problem drinking in the community.

Keywords General population, internet, pragmatic randomized controlled trial, problem drinking, self-help.

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INTRODUCTION

Problem drinking is a widely prevalent condition accompanied by high morbidity and mortality [1,2]. It has formidable economic repercussions in the form of higher health care and criminal justice costs and reduced productivity [3–5].

Active screening and brief intervention in primary care have been proposed as a good way to improve the low service uptake by problem drinkers; several meta-analyses have shown that approach to be effective [6–8].

However, many problem drinkers do not even use primary care, or they are not recognized by primary care services as problem drinkers [9–11]. Alternative ways of reaching out to problem drinkers in the general public are therefore needed to tackle this major public health problem [12]. Community-based self-help interventions are one such alternative. They appear to be effective, but they have been assessed less thoroughly than brief interventions in primary care [13,14].

These types of structured, potentially effective and low-cost self-help interventions can also be provided

Trial registration ISRCTN47285230: <http://www.controlled-trials.com/isrctn47285230>.

online. The internet makes it feasible to increase tremendously the number of people reached by health-related interventions, thus delivering substantial health gains both among underserved populations and among the general public [15,16]. Clients may apply these interventions in the privacy of their homes and at the times they find convenient. Randomized controlled trials and a meta-analysis have shown online interventions, mainly with therapeutic guidance, to be effective for common mental health disorders such as depression [17–20] and anxiety [21–23]. Such web-based self-help interventions have also been developed for problem drinkers [24,25], and although studies of an evaluative nature have shown promising results [26–28] only a few randomized controlled trials of such interventions are now available. Most of these have involved student populations [29–32] or youth in the work-place [33], and they have supported the effectiveness of the web-based interventions in the targeted groups of problem drinkers. The effectiveness of online interventions without therapeutic guidance for self-referred adult problem drinkers in the community has not yet been examined [27,34], and this paper is one of the first to report on a randomized controlled trial among adult problem drinkers in the general population. We hypothesized that an online self-help intervention without therapeutic guidance would be more effective than an online psychoeducational brochure in reducing drinking levels to below the normative limits set by the Dutch guideline for low-risk drinking [35], and that it would also have a greater beneficial impact in terms of decreased weekly alcohol consumption.

METHOD

Participants and procedure

As our study was designed as a pragmatic randomized controlled trial focusing on problem drinkers in the general population rather than those in clinical settings [36], we recruited participants through advertisements in national newspapers and health-related websites. Responders were referred to a research website for additional information about the study. The study and intervention were conducted entirely via the internet with the exception of the informed consent form, which had to be sent to us by post to ensure written and signed consent. Those who returned consent forms were invited to complete a brief web-based screening questionnaire. Participants were selected for the trial whose alcohol consumption exceeded the limits specified by the pertinent Dutch guideline for low-risk drinking [35]. The online screening test was a measure of alcohol consumption patterns consisting of weekly recall and a quantity–

frequency variability index of alcohol intake [37–39]. Different cut-off points for problem drinking were applied for men and for women. Men were selected who were drinking either (i-a) more than 21 units per week (excessive drinking) or (i-b) 6 or more units at least 1 day per week for the past 3 months (hazardous drinking). Women were included if they drank (i-a) over 14 units a week or (i-b) 4 or more units at least 1 day a week for the past 3 months. One unit represents 10 g of ethanol. Additional inclusion criteria were: (ii) age 18–65; (iii) access to the internet; (iv) not receiving professional help for problem drinking at the start of the study; and (v) informed consent. Participants satisfying all inclusion criteria were invited by e-mail to complete an online baseline questionnaire (t_0). They were then randomized to either the web-based drinking less (DL) self-help intervention (the experimental condition) or to the six-page web-based psychoeducational brochure on alcohol (PBA, the control condition). Six months after the start of the intervention, participants received automated online follow-up questionnaires, and a reminder 2 weeks later if necessary. Figure 1 shows the flow of participants through the trial. Ethical approval was granted by an independent medical ethics committee (ref. no. 3.12.2002).

Randomization

Randomization was stratified for gender, as the guideline for low-risk drinking differs for men and for women. It was performed in blocks of two to ensure equal numbers of participants in each condition.

Interventions

Participants in the experimental condition received access to the DL intervention (<http://www.minderdrinken.nl>). DL is a free-access web-based self-help intervention without therapist guidance for problem drinkers who want to reduce their alcohol consumption, preferably to within the recommended limits for low-risk drinking. The intervention is based on cognitive-behavioural and self-control principles [40–44], which are highly suitable for web-based implementation due to their standardized nature and systematic approach. DL consists of a home page giving information on alcohol and treatment services and offering access to the self-help programme via an automated sign-up procedure, with a description indicating for whom the intervention is suitable. The self-help programme proceeds in four successive stages: (i) preparing for action; (ii) goal setting; (iii) behavioural change; and (iv) maintenance of gains and relapse prevention. These stages contain elements known to be effective, such as goal setting and analysis of drinking

Figure 1 Flow of participants through the trial

behaviour [42,45]. The self-help programme also includes access to a moderated peer-to-peer discussion forum. The recommended treatment period is 6 weeks, which should give a reduction in alcohol consumption enough time to take hold [41]; trial participants were allowed to use the intervention as long as they felt necessary. Control subjects received access to a web-based psychoeducational brochure on the effects of alcohol use [46], which described the impact of alcohol use on physical and social functioning in a factual manner. The brochure could be read in 10 minutes. Access to both interventions proceeded through a unique login and security identification code and was available on a 24-hour, 7-day basis.

Primary outcome

The primary outcome measure was problem drinking, defined as alcohol consumption exceeding the guideline—an average of more than 21 or 14 standard units [male/female (m/f)] per week or 6 or 4 units or more (m/f) at least 1 day per week over the previous 3 months. Mean weekly alcohol consumption was assessed with the Dutch version of weekly recall (WR [37,38]); it records the number of units consumed in the 7 days preceding the assessment. Units per day per week were assessed with the Dutch version of the Quantity–Frequency Variability Index (QFV; 39).

Table 1 Baseline characteristics. Values are numbers (percentages) of participants, unless indicated otherwise.

	Condition*	
	Intervention (n = 130)	Control (n = 131)
Female gender	64 (49.2)	64 (48.9)
Age (mean, SD)	45.9 (8.9)	46.2 (9.2)
Education		
Unskilled	41 (31.5)	38 (29.0)
Vocational	52 (40.0)	55 (42.0)
Academic	37 (28.5)	38 (29.0)
Living with a partner	75 (57.7)	71 (54.2)
Paid employment	94 (72.3)	96 (73.3)
No prior alcohol treatment	116 (89.2)	115 (87.8)
Contemplation stage†	116 (89.2)	115 (87.8)
≥3 alcohol-related problems‡	114 (87.8)	118 (90.1)
Problem drinking§	130 (100)	131 (100)
Excessive drinking	125 (96.2)	128 (97.7)
Hazardous drinking	121 (93.1)	121 (93.1)
Weekly alcohol intake in standard units (mean, SD)¶	43.7 (21.0)	43.5 (22.3)

*All differences between conditions were non-significant (tested at $P < 0.10$). †Assessed with the validated Dutch version [50] of the Readiness to Change Questionnaire [49]. ‡Assessed with a validated Dutch questionnaire for problem drinking [48]. §Drinking >21 or 14 units [male/female (m/f)] average per week over previous 3 months (excessive drinking) and/or drinking ≥6 or 4 units (m/f) at least 1 day per week over previous 3 months (hazardous drinking). ¶Standard unit contains 10 g of ethanol.

Secondary outcome

Mean weekly alcohol consumption as a continuous measure was assessed with WR [37,38].

Baseline measures

Alcohol-related problems were assessed using the validated six-item version of the Dutch 18-item alcohol problem questionnaire developed by Cornel and colleagues [47]. A score of 3 or more reflects alcohol-related problems. The scale has shown good psychometric properties [48].

The extent to which participants were willing to alter their alcohol consumption was measured with the validated Dutch version of the Readiness to Change Questionnaire (RCQ-D [49,50]). This 12-item questionnaire assesses the stage of change that respondents are currently experiencing. The three possible stages are precontemplation, contemplation or action.

Power

Originally the trial was powered to detect clinically significant health gains expressed as a standardized effect size ($d > 0.45$) in a one-sided test and at a power of $(1 - \beta) = 0.80$. The results reported in this paper, however, are based on two-tailed tests. From a clinical perspective, standardized effect sizes of 0.45 are considered to be of medium size [51].

Analysis

We began by using t -tests, χ^2 tests and logistic regression to assess whether the randomization had resulted in two comparable groups at baseline (see Table 1) and whether any differential loss to follow-up had occurred. We then performed intention-to-treat (ITT) analysis, using multiple imputation (MI [52]) to deal with loss to follow-up. Multiple imputation has the advantage that each missing observation at follow-up is replaced by a series of plausible values (we created 10 imputed data sets), rather than by a single value. This captures more effectively the stochastic uncertainty inherent, but often ignored, in other imputation techniques [53]. The following procedure was used. Missing values were replaced by values that were drawn randomly from 'donor' cases with complete data. This was performed on condition that the 'donor' cases were from the same gender and age group and had similar baseline scores on the WR and the QFV (i.e. falling in the same quartile). The hypotheses were then tested using regression analysis of the outcome in the treatment dummy within the multiple imputation framework.

Logistic regression was performed to derive odds ratios (OR). A linear risk model was used to obtain the risk difference (RD). The number needed to treat (NNT) was calculated as the inverse of the RD. Confidence intervals (CI) were based on multiple imputation. We report 95% CIs throughout, and tests were conducted at $\alpha = 0.05$ (two-sided). Additionally, we conducted completers-only

Table 2 Success rates of adherence to the low-risk drinking guideline at 6-month follow up: intention-to-treat (multiple imputation) and completers-only analyses.

	<i>Experimental condition (DL)</i>		<i>Control condition (PBA)</i>		OR	95% CI	NNT	Test result	P
	<i>n</i>	% success	<i>n</i>	% success					
Intention-to-treat	130	17.2	131	5.4	3.66	1.3–10.8	8.5	$t_{2105,5} = 2.69$	0.006
Completers-only	70	18.5	81	4.9	4.39	1.4–13.4	7.3	$\chi^2_1 = 6.99$	0.008

DL = drinking less, web-based self-help intervention (experimental condition); PBA = web-based psychoeducational brochure on alcohol use (control condition); OR = odds ratio; CI = confidence interval; NNT = numbers needed to treat.

analyses using logistic regression without imputation on the participants that completed the follow-up questionnaire at 6 months ($n = 151$). All analyses were carried out independently by two researchers to cross-check outcomes. Data were analysed with Stata/SE versions 8.1 and 9.2 [54].

RESULTS

Sample

The demographic and clinical characteristics of the participants at baseline are shown in Table 1. No statistically significant differences emerged between groups on any of these variables at baseline (tested at $P < 0.10$).

At baseline, all 261 participants (100%) were exceeding one or both criteria for problem drinking. Mean weekly alcohol intake was 43.6 standard units [standard deviation (SD) = 21.6]. Most participants ($n = 231$; 88.5%) were in the contemplation stage of change, meaning that they wanted to decrease their alcohol consumption in the near future [49,55]. Most (243; 93%) aimed for moderation rather than abstinence. The large majority (228; 88%) had never received professional help for their problem drinking.

Loss to follow-up

Loss to follow-up at 6 months was 42.1% ($n = 110$) and was distributed evenly across the two conditions ($n = 60$ for the intervention and $n = 50$ for the control condition; $\chi^2_1 = 1.71$; $P = 0.19$). Participants who did not return the questionnaire 6 months after baseline did not differ from follow-up responders in terms of the characteristics assessed at baseline ($P > 0.10$; Table 1).

Effect of the intervention

Table 2 shows the effect of the intervention on the primary outcome—the percentage of problem drinkers now adhering to the guideline. Six months after the baseline assessment, significantly more participants in the intervention condition were drinking within the guide-

line than those in the control condition. Based on the ITT analysis, 17.2% of the experimental subjects were now drinking successfully within the limits of the guideline compared to 5.4% of the control subjects (OR = 3.66; CI 1.3–10.8; NNT 8.5; $P = 0.006$). The significant difference was maintained in the completers-only (CO) analysis.

The intervention was also effective in decreasing the mean weekly alcohol intake in the experimental condition relative to the control group. Table 3 shows that, based on the ITT analysis with multiple imputation, the experimental group decreased its mean weekly alcohol consumption by 15 units compared to 2.9 units in the control group, a difference in means of 12 units on a weekly basis (95% CI 5.86–18.10; $P < 0.001$). This corresponds to a medium standardized effect of $d = 0.40$. The significant difference was sustained in the CO analyses (see Table 3).

Intervention uptake

On the basis of the non-imputed data, 59 (45.4%) of the baseline participants in the experimental condition actually made use of the DL intervention. In the control condition, 67 (51.1%) of the baseline participants actually used the psychoeducational brochure. Those who did use DL rated the self-help programme with a mean score of 7.2 (SD = 1.4) on a scale from 1 (very poor) to 10 (very good); the psychoeducational brochure users rated it at 6.3 (SD = 1.8).

DISCUSSION

Main findings

This study lends support to the hypothesis that the DL intervention is successful in curbing alcohol intake. Although both the experimental and control groups achieved a decrease in alcohol consumption, it was significantly stronger in the experimental DL condition in terms of both the outcome measures assessed here. Some 17.2% of the DL group and 5.4% of the controls succeeded in drinking within the normative Dutch guideline

Table 3 Mean weekly alcohol consumption (WR) at 6-month follow-up: intention-to-treat (multiple imputation) and completers-only analysis.

	Experimental condition (DL)		Control condition (PBA)		Comparisons between conditions			
	n	M	n	M	dif	95% CI	SE dif	T(d.f.)
Intention-to-treat	130	28.7	131	40.6	12.0	5.86–18.10	2.72	T(570.5) = 4.40
Completers-only	70	28.7	81	39.2	10.6	4.33–16.94	3.19	T(149) = 3.33
								P
								<0.001
								0.001
								d
								0.40
								0.38

DL = drinking less, web-based self-help intervention (experimental condition); PBA = web-based psychoeducational brochure on alcohol use (control condition); WR = weekly recall; dif = difference in means; SE dif = standard error of difference in means; d = differential effect size.

for low-risk drinking. DL subjects also reduced their mean weekly alcohol consumption by a significantly greater amount than the controls. The medium standardized effect size ($d = 0.40$) observed here is comparable to the effects found in the meta-analyses by Moyer *et al.* [6] and Apodaca & Miller [14] for brief and self-help interventions. This is an important finding from a clinical point of view, as drinking within the guidelines and lower weekly consumption imply lower risks for the morbidity and mortality associated with problem drinking [2,4,7]. Although our results also show that not all problem drinkers did succeed in reducing their alcohol intake or in adhering to the limits, a small-to-moderate effect size can nevertheless translate into considerable health and social gains at a population level [56].

These results thus support the propositions that self-help interventions without therapeutic guidance can be effective in reducing problem drinking in self-referred adults from the general population [6,14] and that the internet offers an appealing and viable delivery format for this type of intervention [25–28,57]. This is underscored further by the estimated number needed to be treated (NNT) of 8.5 found in our study, which is comparable to the NNT figures of seven [58] to eight [9] obtained by delivering brief face-to-face advice in primary care for reducing problem drinking. Replication of our study is still necessary to establish the robustness of the results we have obtained and to assess how the observed effectiveness is maintained over time. In addition, research on the generalizability of the DL intervention in terms of implementation for routine, non-controlled public access is required, and is currently being conducted by our research group.

Limitations and strengths

These findings should be seen in light of the limitations and strengths of this study. The loss to follow-up was substantial (42.1%), although high dropout rates are characteristic for brief and self-help interventions for problem drinking [13,59]. Attrition rates appear to be even higher for interventions delivered over the internet, as easy accessibility may also mean easy dropout [60]. In this study, we handled dropout data analytically as rigorously as possible by conducting ITT analyses that used multiple imputation to estimate missing end-points. Moreover, our findings are robust in that a re-analysis without any imputation produced near-identical outcomes.

We kept our exclusion criteria to a minimum, in keeping with the nature of community-based self-help interventions. Consequently, we did not conduct diagnostic interviews, and it is therefore unknown what percentage of the sample would have met the diagnostic criteria

for alcohol abuse or dependence. However, given the high level of mean weekly alcohol consumption at baseline (43.6 standard units, $SD = 21.6$) we appear to have reached a high-risk group, as the probability of abuse and dependence is known to increase linearly with the average number of drinks consumed per day [61–63].

The few available evaluation studies of web-based interventions for problem drinking, most of which involved student populations, have reported promising results [29–32]. Adult problem drinkers differ from students, of course, in terms of age and other socio-demographic factors, but also in their drinking patterns, with students exhibiting mainly binge drinking [64].

The DL intervention proved to reach out effectively to these adult problem drinkers. The vast majority ($n = 231$; 88%) had never had any professional help for their alcohol use, yet they did show a willingness to take part in the self-help intervention. It is also worth noting that we recruited the required number of 261 participants in the rather short period of 3 months. These observations thus indicate that internet-based self-help interventions may be suitable for problem drinkers who do not take up traditional alcohol treatment services. This is consistent with findings from other studies, which have reported the 50–80% of participants had never had professional help for their problem drinking before the study assessment [10,24,65]. Women also had a high, one-to-one level of representation in our study, which is in striking contrast with the reported male-to-female ratio of 4 : 1 among problem drinkers in the general population [66]. A similarly high gender ratio has been reported in other studies of internet interventions [27]. Online self-help therefore appears well suited for adult female problem drinkers in the general population, and it may help to overcome the under-representation of women in many brief intervention trials [8].

CONCLUSIONS

The high prevalence of adult problem drinkers in the general population, in combination with their low rate of health service utilization, underlines the need for low-threshold self-help interventions. Such interventions need to be evidence-based and suitable for a broad range of users. Our findings point to a sizeable population of problem drinkers who are willing to seek self-help via the internet and who do so effectively. From a public health perspective, the challenge now is to make such self-help interventions widely available to the community. By virtue of its increasing level of penetration world-wide [58], the internet has the potential to reach out to problem drinkers on a large scale. Significantly, searches for health information rate among the top 10 reasons for internet use [67–69], and web-based self-help that is low-

threshold, anonymous and free of charge appears to hold some appeal to problem drinkers [70–72]. Moreover, web-based interventions are economic to run and maintain.

We therefore recommend that online self-help for problem drinking be further explored. It has an apparent potential to reduce problem drinking in terms of different outcome measures, and it seems suitable for use in different settings. Given the heterogeneity of the problem-drinking population, it could, as part of a public health promotion strategy, help to increase the numbers of people in the community who adhere to the guidelines for low-risk drinking. It also has a potential for use in a stepped-care approach. Future research could identify which groups could benefit most from online self-help and which may not. What also remains to be investigated is whether minimal contact with a professional might improve online outcomes and whether that might serve as a second step in treatment delivery to those who do not succeed with the lowest-threshold interventions. Other directions for research involve the potential of this type of intervention to give preliminary help to people who are currently wait-listed for more intensive treatments. It might also have possibilities for use as an adjunct to primary care or out-patient treatments. That would allow therapists to delegate some of their routine work to the computer by 'prescribing' certain modules of web-based self-help interventions to their patients. The efficiency gain thus achieved could also benefit patients who still clearly need face-to-face therapeutic contact. In this regard, the cost-effectiveness of this type of population-based interventions needs to be evaluated in terms of the population-level consequences and health gains in terms of disability adjusted life years and in terms of the maintenance of health gains over time.

There is ample evidence that brief interventions in primary care are effective in curbing problem drinking. The findings of this randomized controlled trial are among the first to be published on the effectiveness of web-based self-help interventions for self-referred adult problem drinkers in the general population. This study shows that drinking less, a low-threshold online self-help intervention without therapist guidance, can be effective in helping problem drinkers who want to reduce their alcohol consumption to within the guidelines for low-risk drinking. Our findings may also support the feasibility of online stepped care for adult problem drinkers.

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