Abstract

Background: The literature shows that computer-delivered interventions with personalized normative feedback reduce alcohol consumption among risky drinkers for up to 6 months in the West. Meanwhile, no studies have been conducted to examine the effects of such interventions among Japanese risky drinkers. Possible moderators associated with effectiveness of the intervention need to be also explored.

Objective: The purpose of this study is to develop a web-based intervention targeted to reduce risky drinking. A second aim of this study is to conduct a trial and examine the efficacy of this intervention on several measures of alcohol consumption among Japanese risky drinkers. Additionally, this study will examine whether the level of alcohol use disorder and beliefs about the physical and psychological outcomes of drinking moderate the effect of the intervention on outcome measures.

Methods: The authors have developed a website that includes personal normative feedback and psychoeducation. This study will then conduct a single-blind, 2-armed randomized controlled trial. Japanese adults with an AUDIT score of 8 or higher will be enrolled in the trial. Participants allocated to the intervention group will receive the intervention immediately after the baseline measurements, and participants allocated to the waitlist group will receive the intervention at the end of the trial. Outcome measures include drinking quantity, drinking frequency, and alcohol-related consequences. Follow-up assessment will take place at 1 month, 2 months, and 6 months after the baseline measurement is taken. The authors will not know the group allocation during trial.

Results: Enrollment began on January 6, 2018. Data are expected to be available by August 2018.

Conclusion: This study will contribute to the literature by demonstrating the efficacy of the intervention among Japanese risky drinkers and indicating several possible moderators between the intervention and outcomes. This type of web-based brief intervention has the possibility of being implemented in Japanese school and workplace settings as a prevention tool.

Trial Registration: UMIN Clinical Trials Registry R000034388; https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000034388 (Archived by WebCite at http://www.webcitation.org/6xmOoTfTI)

Keywords: risky drinking, web-based interventions, personalized normative feedback, Japanese drinkers, randomized controlled trial
A Web-based Screening and Brief Intervention for Risky Drinking among Japanese
Risky Drinkers: Intervention Development and Protocol of a Single-blind Randomized
Controlled Trial

Introduction

Alcohol use disorder is a common problem globally. The World Health Organization reports that harmful use of alcohol is among the top five risk factors for disease, disability, and injury [1]. Harmful use of alcohol also results in 5.9% of all deaths [2]. However, the rate of individuals seeking and receiving professional help with alcohol-related problems is low. Studies have shown that only one in three individuals with alcohol abuse or dependence have ever received treatment in Canada [3]. Among individuals who needed alcohol use treatment, only 0.8% of them made an effort to receive treatment in the US [4].

Computer-delivered Interventions

One recent approach for treating alcohol-related problems is using information computer technology. Computer-delivered interventions have several advantages as compared to face-to-face interventions when intervening to reduce alcohol-related problems. First, computer-delivered interventions have advantages with user accessibility and can reach a wide population via the Internet. Second, computer-delivered interventions can minimize financial costs. Although evidence is limited for alcohol-related problems, computer-delivered interventions are relatively cost effective for other mental health problems such as depression [5]. This approach can also reduce the burden on professionals. Also, it reduces stigma associated with treatments as some users prefer to receive interventions anonymously [6].

Recent studies have shown that Internet interventions for alcohol-related problems can be beneficial [7,8]. However, the effects of computer-delivered interventions are relatively limited. For example, several systematic reviews and meta-analyses show that computer-delivered screenings and brief interventions reduce alcohol consumption for up to 6 months, but the effects do not last longer than 12 months [9,10]. A meta-analysis shows multi-session interventions have sustained effects compared with single-session interventions [11], although one study reports no difference between the two types of intervention [12]. When compared to face-to-face interventions, computer-delivered interventions appear to be inferior [13].

Many interventions that have shown the efficacy to reduce alcohol consumption include personalized normative feedback [14,15]. In personalized normative feedback, after users enter information about their demographics and alcohol
consumption, they can compare their levels of drinking with the average levels of their age and sex. Personalized normative feedback thus corrects user’s misperception of drinking. Internet-based brief interventions with personalized normative feedback have shown to reduce harmful alcohol use among Canadians [15], indigenous people in New Zealand [16], and young Swiss men [17]. Although effect sizes of these studies are between small and medium [15-17], a meta-analysis supports that personalized normative feedback is effective in reducing alcohol consumption [18].

Psychoeducation is generally included along with personalized normative feedback to inform risks of heavy drinking. Some individuals do not perceive their drinking as problematic despite their high consumption. One study shows that participants who overestimated their drinking reported greater reduction in alcohol consumption compared to the overestimated control group [14]. At the same time, those who underestimated their alcohol consumption did not show greater reduction compared to the underestimated control group [14].

Because personalized normative feedback and psychoeducation involve cognitive restructuring regarding drinking patterns, further studies are needed to identify cognitive variables that increase or decrease effectiveness of the interventions. Alcohol expectancies are one variable to theoretically explain one’s drinking behavior. According to social learning theory, alcohol expectancies are individual beliefs about effects of drinking on affect and behavior [19]. Alcohol expectancies are associated with frequency and quantity of alcohol consumption [20]. However, the current literature is limited in demonstrating whether effectiveness of brief Internet interventions differs according to the levels of alcohol expectancies.

Alcohol-related Problems in Japan

According to a recent survey in Japan, alcohol abuse/dependence ranked the most common individual disorder with 7.4% lifetime prevalence, followed by major depressive disorder [21]. Although the Japanese government reports that average alcohol consumption has been decreasing since 1992 [22], the amount of alcohol consumption still remains high in Japan [23]. Furthermore, alcohol consumption by women has been significantly increasing, and men and women aged 40 to 59 are particularly vulnerable to risky drinking [24]. Statistics show that only 1 in 50 people with alcohol use disorders actually seek professional help [25]. To overcome this low rate, computer-delivered interventions can be an effective way to approach this problem in Japan. One study found that a psychoeducational video in a classroom setting increased knowledge about alcohol-related problems but did not reduce alcohol-
related problems among Japanese students in junior college at the 2-month follow up [26]. To our knowledge no prior studies have examined effects of Internet-delivered interventions using personal normative feedback among Japanese with risky drinking.

**5 Purpose of This Study**

The first purpose of this study is to develop a web-based screening and brief intervention utilizing personalized normative feedback and psychoeducation for Japanese drinkers. The second purpose is to examine the efficacy of the web-based intervention on reducing risky drinking among Japanese adults with problematic drinking by conducting a pilot trial. To better understand the effects of the intervention, this study will also explore moderators between the intervention and outcome variables such as the degree of alcohol-related problems and the beliefs about the effects of alcohol consumption (ie, alcohol expectancies). The authors hypothesize that a web-based intervention will reduce the quantity and frequency of alcohol consumption among Japanese risky drinkers. The authors also hypothesize that the degree of alcohol-related problems and alcohol expectancies will moderate the effects of the intervention on outcome measures of alcohol consumption. Among individuals with some of alcohol-related problems, those with stronger negative beliefs about the effects of drinking, or those with weaker positive beliefs about the effects of drinking, will experience a greater reduction of alcohol consumption after receiving the intervention.

**22 Methods**

**23 Development of the Screening and Brief Intervention (Your Health and Alcohol)**

The authors have developed a web-based screening and brief intervention in Japanese based on Cunningham et al’s work [15]. The development of the intervention took place between May 2017 and December 2018. This intervention consists of three parts: assessment, personalized normative feedback, and psycho-education. The assessment part asks users to enter their demographic information such as age, sex, height, and weight, as well as average spending in one standard drink (see Multimedia Appendix 1). Users then enter their frequency of typical and risky alcohol consumption, the quantity of typical and heaviest alcohol consumption, and different areas of life affected by risky drinking in the past 12 months. These measures are partly taken from the Alcohol Use Disorder Identification Test (AUDIT) [27] and the Daily Drinking Questionnaire (DDQ) [28].

The personal normative feedback part shows user’s reported drinking on a
1typical week, drinking in which they drank the most, frequency of risky drinking (5 or
2more drinks in a day), and AUDIT score. Pie charts and bar graphs are used to compare
3their levels of alcohol consumption with other individuals of their age and sex (see
4Multimedia Appendix 2). Estimated annual drinks, the cost of drinking, caloric intake,
5and areas affected by drinking are also provided. All these results are based on the
6assessment taken in the first part of the intervention. The reports of other individuals’
7drinking patterns that users compare with their own were obtained from a previous
8survey collected from the community using a research marketing company.
9The last part of the intervention is psychoeducation about consequences of
10risky drinking. This section aims to educate users regarding the recommended amount
11of drinks according to a report from the Japanese government published by the Ministry
12of Health, Labor and Welfare [29]. It also explains the process of digesting alcohol and
13the time it takes to break down alcohol. Based on the weight reported in the assessment
14part, the website calculates the estimated time the user needs to break down consumed
15alcohol in the body. The website also informs about possible physical consequences of
16risky drinking (ie, damage to the liver, stomach, pancreas, circulatory system, hormone,
17and brain), psychological consequences (ie, aggression) and social consequences (ie,
18increased risk of domestic violence). Users also learn ways to prevent and reduce risky
19drinking. Finally, this section includes multiple-choice questions to check how well
20users understand the psychoeducation materials (see Multimedia Appendix 3).

22Trial Setting, Recruitment, and Eligibility Criteria
23All participation during trial occurs online. Recruitment will take place through two
24crowdsourcing websites and one research marketing company. Individuals registered on
25the systems will be asked to participate in the study through the posted URL. The URL
26will direct participants to a website created specifically for this trial. The inclusion
27criteria for participation is scoring 8 or higher on AUDIT [27] and being age 20 or older.
28
29Procedure and Allocation
30Once participants are directed to the trial website, they will first take the
31screening measures (ie, AUDIT), and only those who meet the eligibility criteria will be
32invited to formally participate in this trial. After participants fully read and understand
33the nature of this study and consent to participate in the trial, they will be asked to enter
34their email address or their account name on the crowdsourcing site to receive
35notification for subsequent follow-ups. They will then provide their demographic
36information and complete measures of alcohol expectancies.
This study will be a 2-armed randomized controlled trial. Participants will be randomly allocated to either the intervention group or the control group. The control group is the waitlist group in which participants will receive the intervention at the end of the participation. The website created for this trial automatically allocates participants to either group using computer-generated numbers.

Figure 1 shows the flow of the trial. Participants will complete outcome measures at baseline, 1 month, 2 months, and 6 months. At each follow-up, participants will be asked to enter information about their drinking patterns since their last assessment. Specifically, they will be asked about their drinking pattern during the past 10 months at the 1-month and 2-month follow-ups or about the past 4 months at the 6-11 months follow-up because the previous assessment will be one month and four months apart respectively. At the end of the participation, they will be debriefed thoroughly about the nature of the study. Participants registered in the research marketing company will be compensated with ¥120 and 1000 credits. Participants on the crowdsourcing website will receive ¥1200 as work compensation after completing all the follow-up measures.

Figure 1. A CONSORT flowchart of the trial.

Interventions
This study will use the web-based intervention (Your Health and Alcohol) developed prior to the trial (see above for the description of the intervention).

**Measures**

Primary outcomes are quantity of weekly alcohol consumption, quantity of largest alcohol consumption on one occasion, and frequency of drinking. The secondary outcome is the different areas of life which risky drinking has affected. These measures are partly taken from AUDIT [27,30] and DDQ [28]. They have been used in other trials previously [15-17].

To investigate possible moderators between the intervention and outcome measures, participant’s levels of alcohol-related problems will be categorized as hazardous, harmful, and dependent according to their levels of AUDIT score [31,32].

Another measure is alcohol expectancies. In this measure, alcohol expectancies are defined as beliefs about physical and psychological effects of alcohol consumption [33]. Positive aspects of alcohol expectancies are mood enhancement and stress coping, and negative aspects of alcohol expectancies are physical ailments and dysphoria.

**Participant timeline**

Enrolment began on January 6, 2018.

**Blinding**

At the beginning of the study, participants are informed that they will receive the intervention either immediately after the baseline or at the end of the trial. Meanwhile, all instructions to participants are uniform, and the authors will not know the participants’ allocation during trial.

**Ethical procedures and possible harm**

The research ethics board at the first author’s university approved the current study (approval #17-174). All procedures are according to the UMIN Clinical Trial Registry (R000034388) and follow the guidelines of Standard Protocol Items: Recommendation for Intervventional Trials [34]. All personal information will be stored in a secure database. Once data collection is complete, all identifying information will be deleted. Only the authors and developers of the website will have access to the data.

This study includes participants at risk of substance use disorder. The authors think possible harm of this intervention are minimal because participants simply receive information related to alcohol consumption. However, harm of receiving the
interventions include experiencing negative feelings from thinking about their drinking patterns and reading the intervention materials. If participants experience distress and require professional assistance during the trial, the authors will refer them to appropriate treatment. The contact information of the first author will be provided to participants at the beginning of the study.

Power Analysis

Previous studies have suggested small effect size for Internet-based interventions for drinking consumption (1 drink less per week) [9]. Power analysis was conducted in R and found that to obtain statistically significant results a total sample of 393 is necessary for 80% statistical power at \( P < .05 \) for significance level. Because high attrition is expected in Internet-based research, the authors will collect a larger sample. One trial conducted in Japan reported a 65% dropout rate [35].

Data Monitoring and Auditing

Since the intervention is a single session immediately subsequent to the baseline, the authors have determined that monitoring of participants’ reporting or interim analyses to continue or discontinue with the trial is not necessary. The authors do not plan to ask a third-party to audit the trial.

Data Management

All data will be stored on first author’s computer which is secured with passwords in a locked office. All consent forms and private or identifying information will be separated during data analyses to protect anonymity. To ensure quality of the data, the authors will check the raw data to identify incorrect entries. Data will be deleted 5 years after the study approval by first author’s university.

Statistical Analyses

To evaluate the feasibility of the website intervention, the authors will review participants’ comments about the intervention. Also, the authors will calculate the attrition rate from the enrollment to the final assessment. All data analysis will be performed in R [36]. First, descriptive statistics will be calculated to show the mean and standard deviation of measured variables. Data will be screened for missingness, outliers, linearity, normality, and homoscedasticity. Appropriate data transformation will be used for subsequent data analyses. Intention-to-treat analyses will be conducted to examine the efficacy of the intervention on all outcome measures. Missing data will be
replaced with multiple imputations. If a substantial portion of the sample drops out of the trial, per-protocol analyses will be conducted by removing participants lost at follow-ups.

Linear mixed-effect model analyses of variance (ANOVA) will be used to examine the main effects of condition, the main effects of time, and the condition × time interaction effects of the intervention on outcome measures. To examine moderating variables between the intervention and outcome measures, alcohol expectancies and levels of AUDIT will be separately added into the model. Interactions of alcohol expectancies or AUDIT with condition, time, and condition × time will be analyzed. An R package called “nlme” will be used for these analyses [37].

Results
Recruitment began on January 6, 2018, and data are expected to be available for analyses by August 2018.

Discussion
The first purpose of this study is to develop a website that provides personalized normative feedback as a form of screening and brief intervention for Japanese individuals with risky drinking. The second purpose of this study is to conduct a single-blind 2-armed pilot randomized controlled trial to examine the efficacy of the website intervention for 6 months. This study will collect data using two different crowdsourcing websites and one research marketing company. Participants in the intervention group will receive the intervention after completing the baseline measure, and the control (waitlist) group will receive the intervention at the end of the participation. Both participants are asked to complete follow-up measures at 1 month, 2 months, and 6 months. Instructions are uniformly given throughout the trial, and thus the authors will not know the allocation of the participants. The outcome variables are the quantity and frequency of typical drinking and heavy drinking, as well as the consequences of problematic drinking. Additionally, this study will examine whether alcohol expectancies and levels of AUDIT will moderate the effects of the intervention on the outcome measures. Data collection is expected to end in mid-2018.

The authors hypothesize that the intervention will have significant effects with a medium or small effect size consistent with a similar previous study [15-17]. The effect size will likely decrease over time but may last up to 6 months, since the literature shows that the effects of computer-delivered interventions do not last for longer than 6 months [9,10,38]. The authors also hypothesize that alcohol expectancies will moderate
the effects of the intervention on the outcome measures. Participants with higher negative alcohol expectancies or lower positive alcohol expectancies will show a larger reduction in alcohol consumption after receiving the intervention. Additionally, the authors expect that the levels of the AUDIT scores will moderate the effects of the intervention on the outcomes. Participants at the harmful or hazardous level of the AUDIT score will show larger effects from the intervention than those at the dependent level. The authors predict that participants at the hazardous and dependent levels will generally be alarmed with the feedback report in the intervention. However, this screening and brief intervention is likely not sufficient to treat individuals with relatively heavy symptoms of the alcohol use disorder, as the literature suggests its limited effectiveness [9]. These individuals will require more extended Internet or face-to-face interventions.

Limitations

This study comes with several limitations. First, a sampling bias may exist because this study will recruit only individuals who are registered in a specific research marketing company or participating crowdsourcing websites. This sample may have different characteristics from those in the general population in Japan such as a familiarity with Internet technology or a particular job status. The second limitation is the accuracy of item responses. Converting alcohol consumption to a standard measure of drink will be an unfamiliar task for many Japanese individuals, and they may not report their AUDIT or the screening items accurately. Literature shows that Internet-based studies commonly encounter high drop-out rates and inattentive responses during trial [35,39]. Per-protocol analyses will be performed by removing participants who provide inattentive responses and/or lost at follow-ups, but this will lower the sample size and statistical power.

Implications of the study

As previous studies have revealed that seeking alcohol treatment is unpopular in the West and Japan [4,22], computer-delivered interventions will play an important role for reducing risky drinking. To our knowledge this is the first study to examine the efficacy of an Internet intervention with personalized normative feedback among Japanese risky drinkers. The authors argue that a web-based screening and brief intervention can be useful to implement in various settings such as university or workforce. Since the legal drinking age is 20 in Japan, many university students are at risk of underage drinking and thus alcohol-related problems. One study reports more
1 than half of the students engaging in underage drinking [40]. Also, statistics show that 2 in Japan men aged between 40 and 60 have the highest alcohol consumption compared 3 to men in other ages or women [24]. Interventions with personalized normative 4 feedback and psychoeducation can be used as a preventative tool before students 5 develop serious problems.

The literature shows ample evidence that alcohol expectancies are associated 7 with drinking behavior [41]. Generally positive alcohol expectancies predict increased 8 alcohol use, but how these cognitive variables are associated with outcomes of 9 interventions is not well understood in the literature. Examining alcohol expectancies as 10 possible moderators between effects of interventions and drinking behavior can 11 contribute to the literature by applying theoretical understanding of drinking patterns 12 into clinical settings.

The literature indicates that single-session interventions have limited effects on 14 alcohol-related problems [42]. Future studies need to develop more rigorous 15 interventions which improve the magnitude and duration of the effects. Previous studies 16 have shown that extended multiple interventions have sustained effect sizes compared 17 with single-session interventions [11]. Although this study offers only a brief single- 18 session intervention, extended and theory-based computer-delivered interventions 19 would provide added benefits for reducing alcohol-related problems.

21 Dissemination policy
22 Once data collection and analysis are completed, the authors will prepare a manuscript 23 to publish the results in an academic journal. The authors plan to disclose the protocol 24 or the results in first author’s academic thesis, academic conferences, and the journal in 25 which the manuscript will be published.

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31 Conflicts of interest
32 None declared
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35 References


