Brief Intervention in the Workplace for Heavy Drinkers: A Randomized Clinical Trial in Japan

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Abstract — Aims: To investigate the effectiveness of brief intervention (BI) conducted in the workplace for heavy drinkers. Methods: A randomized controlled trial was conducted at six companies in Japan. Participants were heavy drinkers who met the inclusion criteria and were randomized into three groups: the BI group, BI with diary group and a control group. Outcomes (total drinks, binge drinking episodes and alcohol-free days) were evaluated at 3 and 12 months. Results: The 304 participants recruited were allocated to the three groups and 277 participated in all follow-up evaluations. Dropout rates in the respective groups were 7.0, 14.9 and 5.5%. Some improvements were observed in all the groups. In particular, alcohol-free days in the BI group were significantly increased by 93.0% at 12 months. Total drinks at 12 months were reduced by 41 g per week in the BI group compared with the control group, although the intergroup difference was not significant. Conclusion: BI in the workplace is effective for increasing the number of alcohol-free days. However, the effectiveness on decreasing alcohol consumption was unclear, which could be explained by alcohol screening itself causing a reduction in drinking.

INTRODUCTION

Alcohol-related disorders are a serious public health problem worldwide (World Health Organization, 2011). The effectiveness of brief intervention (BI) with heavy drinkers is widely recognized in primary care settings (Bien et al., 1993; Fleming et al., 1997, 2002; Evelyn et al., 2004; Bertholet et al., 2005; Kaner et al., 2007) and in heavy drinkers among many other populations, including patients on general hospital wards (Emmen et al., 2004; McQueen et al., 2011), patients in emergency departments (Robert, 2010) and students (Carey et al., 2011). Its effectiveness has also been reported with heavy drinkers in non-Western countries (Tsai et al., 2009; Sairat et al., 2010; Liu et al., 2011).

In Japan, alcohol-related disorders are perceived as a serious social problem that adversely affects health. According to a 2003 nationwide survey on drinking, some 8,600,000 people consumed >60 g of alcohol per day and an estimated 800,000 had alcohol dependence (Osaki et al., 2005), of which around 50,000 are actually receiving treatment (Higuchi and Saito, 2013). This is largely because the treatment of alcohol dependence in Japan focuses solely on abstinence from drinking, and medical treatment is undertaken in psychiatric hospitals (Higuchi and Saito, 2013). In Japan, men who are able to consume large quantities of alcohol are often regarded as masculine and especially capable in the workplace, and such irrational belief has hindered the development of treatments for binge drinking until recently (Shimizu, 2003); while treatments in Japan have tended to focus on treating alcohol dependence, a recent trend focuses on secondary prevention also, such as the provision of alcohol consumption guidance to those at potential risk of alcohol abuse. The background to this trend is growing social awareness of the importance of primary prevention of lifestyle-related diseases, drink-driving accidents and depression. However, since few studies have been conducted on the efficacy of BI in Japan, insufficient data have been accumulated to adequately demonstrate its effectiveness, which has thus precluded diffusion of BIs. Previous studies of binge drinking in Japan have been conducted primarily in workplace settings, and to our knowledge, no studies in primary healthcare settings have been published in Japan. The main reason for this is that large companies in Japan are often highly oriented toward preventive medicine and have improved their occupational healthcare systems. However, there are few studies that investigate and demonstrate the effectiveness of BI in Japan, which hinders the wider adoption of BI practices (Hara et al., 2011; Iyadomi et al., 2013).

Studies are increasingly reporting the effects of BI in occupational settings in the West, where BI is being investigated in a wide range of fields (Richmond et al., 2000; Anderson and Larimer, 2002; Bennett et al., 2004; McPherson et al., 2009; Hermansson et al., 2010; Ames and Bennett, 2011). Japanese law (Industrial Safety and Health Act) stipulates that companies with >50 employees provide the services of an occupational physician to protect workers’ health, which helps with the earlier implementation of many types of health interventions. It also helps with the provision of BI in the workplace as part of employee health care programs by, for example, helping to schedule participation and enabling long-term follow-up of participants’ drinking habits. Accordingly, the workplace is expected to be an important venue for BI in Japan, even though only a very limited number of studies on workplace BI have been conducted to date.

This study, the first randomized controlled trial (RCT) to be conducted in the workplace for heavy drinkers in Japan, investigates the effectiveness of BI with heavy drinkers, particularly with respect to reduction in alcohol consumption.

METHODS

Study design

This RCT was administered by the Interventions for Heavy Drinkers Methods Development and Effectiveness Evaluation Research Team, affiliated with the National Hospital Organization...
Kurihama Medical and Addiction Center, Kanagawa, Japan. The fieldwork took place at six companies in Japan from April 2008 through December 2009.

Participants
The occupational health departments of each company in this study recruited participants from among employees in the period April–November 2008. The workplace sites in this study were all large companies with >1000 employees each, and they all had well-organized occupational health care systems. Among the participants, blue-collar workers were the largest group. We advertised with posters at each site to recruit participants, and applicants were asked to submit self-administered screening questionnaires, which included items covering the amount of alcohol consumption per week and the numbers of binge drinking episodes in the previous 28 days. Inclusion criteria were (1) older than 19 and younger than 60 years of age and (2) consuming >210 g (men) or 140 g (women) of pure alcohol per week or >60 g per day more than once a week. In this study, we considered the person who met the criteria of (2) as a ‘heavy drinker.’ As Rehm et al. pointed out, it would be arbitrary to define thresholds and cut-points for heavy use (Rehm et al., 2013). Also, as Kaner et al. noted, there is variability in the definitions of ‘heavy drinking’ used in previous studies on alcohol (Kaner et al., 2007). The titer used here is larger than that in many previous studies; however, it was based on the amount of alcohol in a 1.8-l bottle of Japanese sake, which was a familiar unit of measure for Japanese people. Exclusion criteria were (1) an intermediate period of alcohol withdrawal syndrome in the past, (2) previous diagnosis of alcohol dependence, (3) drinking >600 g per week, (4) told to reduce alcohol consumption by a physician or public health nurse in the past year, (5) history of moderate to severe depression, (6) previous- or decrease alcohol consumption.

Training and BI manual
All participating companies had a fulltime occupational physician and health nurse available to provide employees with services concerning health and safety conditions. In this study they were in charge of implementing the BI. Prior to the study, they attended BI training sessions or received similar training by attendees of these sessions using the same materials. The 10-h training program was composed of lectures and role play based on an original BI manual we developed for this study. During the sessions, we taught the basic techniques of BI and provided pointers about how to give advice to individuals with alcohol problems (Saizt, 2005). We also explained about the stage model of change (DiClemente, 1999) and techniques of motivational interviewing (Hettema et al., 2005), emphasizing in particular the six important core concepts of FRAMES (feedback responsibility, menu, empathy and self-efficacy) (Bien et al., 1993) model. During the study period, we supervised the occupational health nurses and physicians who implemented the BI.

Intervention
In this RCT, participants who met the inclusion criteria were randomized by the sealed envelope method into three groups:

the BI group, BI with diary group and a control group. We conducted an initial alcohol evaluation, which was followed by BI. In the initial evaluation of alcohol use, a survey of alcohol consumption in the previous 4 weeks was conducted based on the Timeline Followback (TLFB) method (Sobell and Sobell, 1992). The TLFB was administered by occupational health physicians and nurses through the research organization. The BI group received two 15-min BI sessions, the second of which took place 4 (±2) weeks after the first. In each BI session, a one-on-one interview was conducted by one of the trained occupational health care providers based on workbooks completed by the subjects before the session. The workbooks were developed based on principles of cognitive behavioral therapy, and included evaluation using the Alcohol Use Disorders Identification Test (AUDIT), feedback of results, a balance sheet of merits and demerits of drinking, setting of goals about drinking, and coping methods to deal with risky situations associated with binge drinking. The BI with diary group received the same interventions as in the BI group, but after the first BI session they were asked to complete a ‘drinking diary’ every day for the next 3 months. This is because diaries are widely considered to be a good self-monitoring tool for changes in lifestyle behaviors such as dieting, and they were also already being used at the study workplace sites. In their diaries subjects reported the type and amount of alcohol consumed and the situation in which they consumed it, to encourage them to self-analyze their alcohol consumption in the context of varying situations. The control group did not receive any BI but at the baseline interview received a booklet described the association between binge drinking and lifestyle-related diseases or depression and the importance of reducing alcohol consumption in general. The booklet was also distributed to in the BI and BI with diary groups.

Outcome evaluation
Using the TLFB technique, we surveyed subjects’ alcohol consumption in the previous 28 days on three occasions: at the start of the study (baseline); 3 (±0.5) months after the second BI session; and 12 (±1) months after the second BI session. Occupational health care providers such as nurses and physicians administered the TLFB. We conducted interviews to collect data included the following: (1) total drinks in the previous 7 days; (2) number of binge drinking episodes in the previous 28 days; and (c) number of alcohol-free days in the previous 28 days. ‘Binge drinking’ was defined as drinking >60 g of pure alcohol per day. The AUDIT assessment was not used, because we wanted to avoid any feedback effects that could be caused by AUDIT use. In addition, the AUDIT was included in the workbook, which meant that the intervention groups (BI and BI with diary) received the AUDIT evaluations. For those not available for interview we mailed a survey questionnaire, and for those who did not respond to the survey we attempted a phone interview. We offered a gift card worth 5000 JPY (equivalent to around 50 USD) as a token of appreciation to those who participated in all aspects of the study.

Statistical analysis
Differences among the three groups in alcohol consumption at baseline were examined using one-way analysis of variance for continuous level variables and Chi-square tests for categorical
variables. Chronological change in alcohol consumption within each group from baseline was examined using paired t-tests. To examine differences in BI effects among the three groups, change in alcohol consumption from baseline was compared using one-way analysis of variance, and Turkey’s method was used for multiple comparisons. All statistical analysis was conducted according to the intention-to-treat principle, using JMP software (Version 8; SAS Institute, Cary, NC, USA). Differences were considered significant at the \( P < 0.05 \) level.

Ethical approval

After obtaining approval from the Ethics Review Board of Kurihama Medical and Addiction Center, we verbally explained the study to the participants and obtained their written informed consent. All data were anonymized for analysis.

RESULTS

Participant flow and follow-up

The flow of participants through the study is shown in Fig. 1. The 304 participants recruited were allocated to one of the three: 100 to the BI group, 94 to the BI with diary group and 110 to the control group. From those groups, eight individuals withdrew for personal reasons before the initial alcohol evaluation and intervention (four in the BI group, two in the BI with diary group, and two in the control group). Thus, the baseline sample comprised 296 persons (96 in the BI group, 92 in the BI with diary group and 108 in the control group) who took part in the initial alcohol evaluation. Of those, 282 persons (94 in the BI group, 84 in the BI with diary group and 104 in the control group) participated in the follow-up evaluation held 3 months after the second BI session and responded to the question items. In total, 277 persons (93 in the BI group, 80 in the BI with diary group and 104 in the control group) participated in all follow-up evaluations and completed the question items. Dropout rates were 7.0, 14.9, and 5.5%, respectively.

Baseline data

Participant demographics are shown in Table 1. Mean age ranged from 46.0 to 47.4 years, and participants were predominantly male. No significant differences were observed between the study groups for any of the demographic variables.

Outcomes

Changes in the three outcomes over time for each group are shown in Table 2. Within all three groups, the three main outcomes of total drinks in the previous 7 days, number of binge drinking episodes, and number of alcohol-free days in the previous 28 days appeared to steadily improve relative to baseline levels, except for the number of binge drinking episodes in the previous 28 days in the control group. In particular, total drinks in the previous 7 days at 12 months dropped dramatically to 31.6, 21.6, and 21.6% in the BI, BI with diary and control groups, respectively.

While improvements in all outcomes were observed in both the intervention groups compared with the control group, levels of improvement varied depending on outcome. For the total drinks consumed at 12 months into the intervention, the control group showed a 7.01 drinks/week reduction (21.6%, from 32.5 to 25.5 drinks/week) and the BI group showed an 11.2 drinks/week reduction (31.6%, from 35.2 to 24.1 drink/week). The difference in improvement between the groups (10.1%) was not statistically significant. For the number of binge drinking episodes, the differences between the intervention and control groups were largest at 3 months; differences in improvement rates between the intervention and control groups were 26.2% (−31.8 vs. −5.6%) for the BI group, and 26.1% (−31.7 vs −5.6%) for the BI with diary group. At 12 months, the difference in improvement rate between the intervention groups was ~20% (not significant). For the number of alcohol-free days, the BI group showed substantial improvement. Statistically significant differences in improvement relative to the control group were observed: 46.9% (71.9 vs 25.0%) at 3 months and 61.5% (93.0 vs. 31.5%) at 12 months. Lastly, the BI and BI with diary groups showed no significant differences in improvement in total drinks, number of binge drinking episodes or number of alcohol-free days.

DISCUSSION

This study is the first Japanese RCT to investigate the effectiveness of BI conducted in the workplace for heavy drinkers. Since even in the control group the total drinks consumed measure was lower at 12 months follow-up, no significant difference was seen between the two BI groups and the control group, although number of binge drinking episodes and number of alcohol-free days were reduced compared with the control group.

Previous studies of the effectiveness of BI in primary health care settings reported reduced alcohol consumption at 12-month follow-up evaluations among participants in intervention groups compared with controls: reductions of 2.9–8.7 drinks per week (Evelyn et al., 2004) and 38 g per week (Bertholet et al., 2005; Kaner et al., 2007). Similarly, in the present study, the BI group had reduced alcohol consumption by 4.1 drinks (41 g/week) at the 12-month evaluation compared with controls, whereas the BI with diary group reported a comparative reduction of only 0.55 drinks (5.5 g per week). Although another study reported reductions of 7.6 drinks per week in BI groups and 3.4 in controls (Fleming et al., 1997), our results of a 7-drink per week reduction in controls are almost the improvement as previously reported for the BI groups (Fleming et al., 1997). It was this reduction in our control group that led to less marked differences with the BI groups.

In relation to the number of binge drinking episodes in the previous 1 month, Fleming et al. (1997) reported a 2.6-day reduction in BI groups and a 1.1-day reduction in controls, which are similar to our findings of a 3.11-day reduction in the two BI groups and a 1.45-day reduction in the control group. Fleming and colleagues (Fleming et al., 1997, 2002) have also reported the effects lasted more than a year; likewise, the present study observed effects at 12 months after intervention far beyond those seen after 3 months.

Several studies have investigated BI in the workplace (Hermansson et al., 1998, 2010; Richmond et al., 2000; Anderson and Larimer, 2002; Bennett et al., 2004), but only Richmond et al. (2000) reported the number of total drinks as a direct outcome. They reported a reduction of 4.3 drinks per
week in their BI groups and 0.6 drinks in their controls, whereas we observed a greater reduction in the present study. This may be because our participants were relatively heavier drinkers from the outset, which meant the intervention effects were clearly apparent.

Despite our finding that, compared with the controls, both BI groups showed greater trends toward improvement for all outcomes, a significant difference was observed only in the number of alcohol-free days in the previous 28 days (BI group vs. controls). Because this study compared three not just two groups, each group’s sample size was accordingly smaller, which usually reduces statistical power for detecting differences between them. When we conducted two-group comparisons (both BI groups vs. controls), we obtained significant differences in the number of binge drinking episodes ($P = 0.012$ and $P = 0.058$ at 3 and 12 months, respectively) and in the number of alcohol-free days ($P = 0.039$ and $P = 0.007$, respectively).

In this study, all three groups demonstrated improvements (i.e. reductions) in drinking behavior across all outcomes. Many of the occupational health care providers who implemented the BI in this study, with public health nurses at the core, already knew some of the participants well and provided them with support in health management and lifestyle improvement. Possible reasons for observing large improvements in the control group include regression to the mean and the research goal of reducing drinking being told to the participants.
when they joined the study. In addition, the detailed drinking survey feedback based on the TLFB with an interview method was administered by occupational health care providers, who had already been engaged in providing support for other lifestyle-related improvements. This could be regarded as a BI element that facilitated empathy and self-efficacy. Indeed, previous studies have reported the effectiveness of self-evaluation questionnaires alone and feedback-centered information provision alone for reducing drinking (McCormack and Kypri, 2011; Kaner et al., 2013). These factors may have helped participants have a common understanding and a greater sense of self-efficacy, which could be interpreted as a type or corollary of BI. In addition, because subjects applied for participation in this study after seeing a flyer with a clear description of the research purpose to reduce alcohol consumption, they were already motivated to some degree. These factors might have affected the results such that even those in the control group demonstrated relatively marked reductions. Notably, similar effects of the relationships between occupational health care staff and participants have been reported (Hermansson et al., 2010), which suggests a possible favorable effect of contact with health care professionals regardless of the BI content.

Among the three outcomes, the number of alcohol-free days showed the greatest differences across groups, and the number of drinks per week showed the least differences. In Japan, people often call alcohol-free days ‘liver rest days,’ and the habit to try to recover liver function by periodic abstinence is widespread. Despite traditional beliefs that connect a high tolerance for alcohol with masculinity, heavy drinkers appear to have little resistance to the ‘liver rest day’ concept. In this study, we asked subjects in the intervention groups to set goals related to their drinking: the most commonly stated goal was increasing the number of ‘liver rest days.’ These factors suggest that increasing the number of alcohol-free days might be the most achievable among the three outcomes. The number of alcohol-free days is a metric equivalent to the number of drinking days, but is a more easily understandable expression in Japanese culture.

We found no difference in effects between the BI and BI with diary groups. In a similar study administered in a different workplace setting (Hara et al., 2011), we observed that the drinking diary was very helpful for over half the participants, mainly because in the middle of the study we encouraged counselors to add the intervention of writing compassionate comments, encouragement and advice in the participants’ diaries. However, in the present study counselors did not provide these extra interventions, which might be why we observed such minimal effects in the BI with diary group. In a previous study, a self-monitoring approach that included a drinking diary was reported to be one of the only effective strategies among >40 BI approaches (Michie et al., 2012). For this reason, a drinking diary is thought to facilitate an additional impact if it is properly designed to suit the subject.

The Industrial Safety and Health Act requires companies to take action to maintain employees’ health and to keep records of their health conditions. Further, occupational health

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<tr>
<th>Total drinks in previous 7 days</th>
<th>BI group (n = 93)</th>
<th>BI with diary group (n = 80)</th>
<th>Control group (n = 104)</th>
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<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
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<tr>
<td>Baseline</td>
<td>35.2 (18.0)</td>
<td>Reference</td>
<td>32.5 (17.5)</td>
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<tr>
<td>3 months</td>
<td>29.0 (15.2)</td>
<td>P = 0.001</td>
<td>29.1 (16.4)</td>
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<tr>
<td>12 months</td>
<td>24.1 (14.9)</td>
<td>P &lt; 0.0001</td>
<td>25.5 (14.1)</td>
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<td>% Change</td>
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<tr>
<td>Baseline to 3 months</td>
<td>−17.6</td>
<td>−17.6</td>
<td>−10.4</td>
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<td>Baseline to 12 months</td>
<td>−31.6</td>
<td>−21.6</td>
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<table>
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<tr>
<th>No. of binge drinking episodes in previous 28 days</th>
<th>Baseline</th>
<th>BI group (n = 93)</th>
<th>BI with diary group (n = 80)</th>
<th>Control group (n = 104)</th>
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<tr>
<td>Mean (SD)</td>
<td>7.55 (8.34)</td>
<td>8.33 (7.53)</td>
<td>6.72 (7.70)</td>
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<td>3 months</td>
<td>5.15 (4.81)</td>
<td>5.69 (5.81)</td>
<td>6.35 (6.62)</td>
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<td>12 months</td>
<td>4.44 (5.91)</td>
<td>4.68 (4.81)</td>
<td>5.27 (6.09)</td>
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<tr>
<td>% Change</td>
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<tr>
<td>Baseline to 3 months</td>
<td>−31.8</td>
<td>−31.7*</td>
<td>−5.6</td>
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<tr>
<td>Baseline to 12 months</td>
<td>−41.2</td>
<td>−43.8</td>
<td>−21.6</td>
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<table>
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<tr>
<th>No. of alcohol-free days in previous 28 days</th>
<th>Baseline</th>
<th>BI group (n = 93)</th>
<th>BI with diary group (n = 80)</th>
<th>Control group (n = 104)</th>
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<tr>
<td>Mean (SD)</td>
<td>4.63 (5.71)</td>
<td>4.11 (5.60)</td>
<td>5.00 (6.58)</td>
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<td>3 months</td>
<td>7.97 (7.38)</td>
<td>5.78 (6.11)</td>
<td>6.25 (6.79)</td>
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<td>12 months</td>
<td>8.95 (7.93)</td>
<td>7.46 (7.39)</td>
<td>6.58 (7.41)</td>
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<td>% Change</td>
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<tr>
<td>Baseline to 3 months</td>
<td>71.9**</td>
<td>40.4</td>
<td>25.0</td>
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<tr>
<td>Baseline to 12 months</td>
<td>93.0**</td>
<td>81.5</td>
<td>31.5</td>
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P-values are derived from paired t-tests within each group, otherwise indicated.

*One-way ANOVA across the three groups.

*P < 0.1, **P < 0.05: Post hoc Tukey tests for comparisons with the control group.
physicians and nurses are obligated to keep health information confidential. Therefore, even though they are part of a company, they cannot provide their human resource department with employees’ health-related information, which facilitates occupational health physicians and nurses playing important roles in improving the health of the employees under their care. Indeed, in this study, occupational health physicians and nurses did not share participants’ health data with their companies, a practice that participants understood would also continue during the study period.

However, regarding the confidentiality of employee’s health information, we are moving to an era where company professionals’ duty of confidentiality might not suffice. Some pioneering studies of BI have used an Internet method (Murray et al., 2013) that helps minimize potential sampling bias due to recruitment of only health-seeking subjects. In addition, this type of Internet method may help make it easier to ensure subject confidentiality and anonymity, so researchers may wish to consider Internet use in future studies. This method would allow anonymous participation via the Internet, where participants could receive BI from external staff without face-to-face interviews.

Although there are still technical issues to be addressed, this study demonstrated an improvement in drinking patterns and sustained progress over a 1-year period, its most important finding. Even in Japanese society, where people have generally tolerant attitudes toward drinking, BI demonstrated positive effects in the workplace. In addition, we have reported in previous work that BI for drinkers improved their physiological and biochemical parameters, including body weight and blood pressure, lipid, and blood sugar levels (Iyadomi et al., 2013).

There are several limitations to this study. First, there were no records about the number of individuals approached for recruitment versus those who actually enrolled. We know only that the recruiters were colleagues in the various occupational health provider offices and that very few recruits declined to enroll. Second, we were unable to determine the specific reasons for dropout mid-study. This may be due in part to the research design that allowed withdrawal at any time without giving a concrete reason. Third, group allocation was somewhat uneven. While no significant differences were observed in basic attributes across groups, we cannot deny a potential impact of an absence of randomized blocking at the time of allocation. Fourth, because participants in this study were already concerned about their drinking behaviors and spontaneously participated in the study, we should be cautious about generalizing the study results. Fifth, because the BI in this study was administered by the companies’ internal professionals, there might be some risk of a breach in confidentiality. For future studies, confidentiality could be kept more secure by using the above-mentioned BI through Internet methods.

In conclusion, this study is the first Japanese RCT of the effectiveness of workplace BI with heavy drinkers in Japan. We observed positive BI effects in this setting despite the generally positive cultural attitude toward drinking, and tailoring BI to account for Japanese culture, values, and drinking customs may allow for even greater effectiveness. We believe that BI conducted in the workplace is beneficial for both employees and employers and that BI can also play an important role in primary health care settings.

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Conflict of interest statement. None declared.

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