Effectiveness of Screening and Brief Alcohol Intervention at the Workplace: A Study Protocol for a Randomized Controlled Trial at Five Japan-Based Companies

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ABSTRACT

Background  Despite evidence regarding the effectiveness of screening and brief interventions for excessive alcohol use in primary care, these tools are not a part of routine practice. It has been suggested that using these tools at the workplace may be critical to alcohol-associated harm; however, evidence for this claim is unclear. The aim of this article is to develop a study protocol which evaluates the effect of brief alcohol intervention at the workplace to reduce harmful alcohol drinking.

Methods  A randomized controlled trial involving employees (aged 20–74 years) of five Japan-based companies who were screened “positive” by Alcohol Use Disorder Identification Test (AUDIT) is ongoing. Participants were randomized into “Patient Information Leaflet” (control group), “Brief Advice and Counselling,” and “Five-minute Brief Advice” groups. A self-administered questionnaire was used to assess alcohol consumption, lifestyle behavior, health status, work performance, and consequences of alcohol use. Data of laboratory markers were collected from routine health checkups.

Results  A total of 351 participants were randomized into Patient Information Leaflet (n = 111), Brief Advice and Counselling (n = 128), and Five-minute Brief Advice (n = 112) groups. Participants were mostly men with a median age of 49 years. Median AUDIT score and weekly alcohol consumption were 11 points and 238 g/week, respectively. Two-thirds of the participants were manufacturing workers.

Conclusion  This study protocol developed the first trial in Japan to investigate the effect of brief alcohol intervention combined with a recommended screening tool at the workplace. Our findings can provide evidence on the effectiveness and relevance of these tools to occupational health.

Key words  brief intervention; excessive alcohol drinking; prevention; workplace

Excess alcohol use is a public health threat worldwide. It is a leading cause of global morbidity and premature mortality, associated with violence, risk of injuries, various social harms, and substantial economic losses. In Japan, excess alcohol use (defined as > 40 g/day for men and > 20 g/day for women) is a critical public health issue.

The effectiveness of screening and brief interventions (SBIs) for harmful alcohol use in primary healthcare (PHC) settings has been established. However, SBIs are not currently part of routine PHC practice, despite evidence in their favor. Previous reports have indicated that this issue is due to the limited time allocated to prevent harmful alcohol use over other potential targets for prevention such as poor diet, too little exercise, or smoking. Moreover, workload pressure, anxiety due to offending clients, and difficulty in getting past an addictive preoccupation with alcoholism are explained as the reasons for the limited implementation. SBIs should be accessible to the public to reduce alcohol-associated harm. Studies have evaluated the effect of SBI use outside of PHC settings, including at accident and emergency departments, and non-healthcare settings.

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Abbreviations: ANOVA, a one-way analysis of variance; AUDIT, alcohol use disorder identification test; IPAQ, International Physical Activity Questionnaire; JPY, Japanese Yen; K6, K6 Distress Scale; MCS, Mental Component Summary; PCS, Physical Component Summary; PHC, primary healthcare; PIL, patient information leaflet; QOL, Quality of Life; SBIs, screening and brief interventions; SF-8, SF-8 health survey; UMIN-CTR, university hospital medical information network clinical trials registry

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settings such as the workplaces.\textsuperscript{16, 17}

Insufficient implementation of SBI in PHC settings leads to the necessity to implement alcohol-related interventions within the workplaces.\textsuperscript{18} Interventions delivered at the workplaces have potential advantages, including reaching populations that tend to be missed by healthcare systems. Additionally, they might be able to address alcohol-related harm other than that related to health.\textsuperscript{11} Excess alcohol use can cause economic loss due to accidents or low performance. A study on SBI efficacy at the workplace reported a positive effect on alcohol consumption reduction,\textsuperscript{19} suggesting it could be an important strategy to alleviate alcohol-associated harms. However, other studies on its effectiveness have delivered inconsistent results.\textsuperscript{20–22} Previous reports have indicated that the results may be due to bias in the selection of study participants. These studies also targeted relatively heavier drinkers from the onset, which meant the intervention effects were not apparent. It is worth mentioning that effective use of SBI at the workplace requires screening to identify drinkers who are rarely reached by the PHC system. Moreover, considering the time-constraint in daily clinical practice that we have described above, there may be certain advantages in the implementation of SBI if short intervention shows sufficient effect.

The aim of this article is to develop a study protocol which evaluates the effectiveness of SBIs using the Alcohol Use Disorder Identification Test (AUDIT)\textsuperscript{23} screened participants using two types of interventions aimed at reducing excessive alcohol consumption, delivered in the workplace setting.

MATERIALS AND METHODS

Study setting
Employees from five companies (35–910 employees) in two western Japanese regions were recruited for this study. Four of these companies had well-organized occupational health departments.

Participant recruitment and screening
Specific health checkups and health guidance is a feature of Japan’s public health system.\textsuperscript{24} National law stipulates that medical insurers and employers are obliged to provide health checkups and guidance regarding visceral fat obesity for every person insured over 40 years of age and their dependents.\textsuperscript{25} Health checkup guidelines recommend AUDIT screening.\textsuperscript{23} We contacted companies that had incorporated self-reported AUDIT screening into their routine health checkups; thereafter, a site visit was arranged for research staff to explain trial protocols and acquire employer and occupational health care worker consent to participate in this study.

Inclusion criteria
Employees were eligible for inclusion in this study if they were aged 20-years or older, and their AUDIT score was \( \geq 8 \) points. Staff from the occupational health department judged that they were alert and orientated enough to participate in the study. Screening cut-off points were based on the values reported in the literature.\textsuperscript{26}

Exclusion criteria
Employees were excluded from participation if they were aged \( \geq 75 \) years, involved in an alcohol treatment program in the previous year, reported symptoms of alcohol withdrawal in the last 12-months, received advice from their physician in the previous three months to change their pattern of alcohol consumption, were pregnant, or reported suicidal tendencies.

The occupational health department of each company that accepted our invitation to participate recruited participants from among their employees during January–December 2019.

Randomization
An individual participant was the unit of randomization. Unrestricted simple randomization was used. The intervenent was informed of the group allocation of each participant, by letter. Participants who met the inclusion criteria were enrolled and randomized into three groups by researchers using a computer-generated allocation method.

Consent
Consent to participate was obtained in a two-stage process. Staff from the occupational health department at each site screened employees for eligibility. No identifiable information was collected at this stage. Employees who met the inclusion criteria received information about the study from the research team. Written informed consent was obtained at this stage including permission to allow the research staff access to participant personal and contact details and routine health checkup records. Participants agreed to be followed up after six and 12-months. After providing consent, participants filled out the baseline questionnaire; once the external staff confirmed that the questionnaire was completed, participants received their allocated intervention.
Training and brief intervention manual
External health professionals with nursing qualifications conducted the brief intervention. Before the study, each participating nurse received training on alcohol SBIs. The training program consisted of e-learning and role playing using an SBI manual developed specifically for this study. The program conveyed basic details about the AUDIT program and relevant techniques and tips for giving advice to individuals with alcohol-related problems. Training material included the stages of change model and techniques of motivational interviewing. After the training, the participating nurses were provided the opportunity to observe an actual brief alcohol intervention which was implemented by well-trained physicians.

Interventions
Our trial aimed to examine whether standard brief alcohol intervention is effective for reducing alcohol consumption. Internationally, a 15-minute brief advice and counselling is within the standard time length. Moreover, we aimed to investigate the effectiveness of short intervention. If short intervention shows sufficient effect, there may be certain advantages in the implementation of SBI under the time-constraint in daily clinical practice. Therefore, we set up three groups: Patient information leaflet group, Brief advice and counseling group, and Five-minute brief advice group.

Participants were randomized into three groups and external health professionals randomly took charge the company’s employees, randomly. The interventions were provided at the time of recruitment at their the workplaces. Every participant was requested to use the original smartphone application which contained a drinking diary and self-study tools. The application contained functions that allowed users to create a diary on how much they drink in a day, week, or month. It also had an educational function as it contained materials that provided users with information on the consequences of drinking and how to reduce alcohol consumption. All intervention tools and protocols are available from our university website. At the beginning stage of the study, we prioritized and conducted sessions with the participants who were allocated to the Brief Advice and Counseling group. Well-trained physicians demonstrated the intervention and checked whether the trained nurse provided appropriate intervention to the participants. Therefore, the number of participants in the Brief Advice and Counselling group was larger than the other two groups.

Patient information leaflet
Participants in the control group completed baseline questionnaires and were provided their AUDIT score together with a patient information leaflet (PIL). The PIL used in this trial was adapted from the Kurihama National Hospital’s leaflet, “Getting on well with alcohol.”

Brief advice and counseling
Participants in the brief advice and counseling group completed the baseline questionnaires and received 15-minute SBI sessions, including a one-on-one interview with trained health staff and an original worksheet. The sessions aimed to have the participants complete six tasks from a worksheet. The worksheet was based on the principles of cognitive-behavioral therapy and included an AUDIT evaluation, feedback on results, a balance sheet for considering of pros and cons of drinking, drinking-related goal-setting, and a list of coping methods for dealing with risky situations associated with binge drinking.

Five-minute brief advice
Participants in the five-minute brief advice group completed the baseline questionnaire and received up to five minutes of a simple structured brief intervention from a trained professional. The worksheet used with the brief advice and counseling group was also used with the five-minute group. The SBI session aimed to complete three tasks from the worksheet i.e. AUDIT evaluation, feedback on results, and drinking-related goal-setting.

Follow-up and outcomes
The primary outcome was a change in alcohol consumption amount per week (gram of pure alcohol per week). By using a self-administered questionnaire, we assessed the frequency of drinking alcohol, binge drinking in the previous 30-days, and the amount of alcohol usually consumed at baseline, 6 (±1) months, and 12 (±1) months. These three questions were the same as those asked in the AUDIT-C. The research member calculated the alcohol consumption per week by assessing the frequency of alcohol use and the type of alcohol and the amount of drinking on a daily and monthly basis. “Binge drinking” was defined as drinking > 60 g of pure alcohol per occasion.

In addition, a self-administered questionnaire at baseline, 6-months, and 12-months assessed health service use, laboratory markers, health-related quality of life (SF-8), sleep disorders, mental health status, physical activity, selected eating behavior, smoking, and work performance.
Each participant received a JPY 1000 (USD 10) voucher from the interviewer after completing the baseline questionnaire. Another JPY 1000 voucher was posted after the completion of the six and 12-month follow-up questionnaires.

Sample size calculation
Sample size was calculated to account for participant-level outcomes. Change in weekly alcohol consumption at 6-months was the primary outcome of interest. Based on a previous study, we expected a 40 g/week consumption reduction in the brief intervention group compared to the control group. The standard deviation in 7-day alcohol use: 100 g/week was estimated based on a previous study. Given a 5% significance level, 80% statistical power of a two-sided test, the number of participants per group is 100, yielding a total sample of 300 participants. Our experience with other trials of SBIs at their workplaces suggested a potential 10% loss at follow-up across groups, resulting in a final sample of 110 participants per group (a total of 330).

Blinding
The present study did not involve the blinding of participants due to the nature of the intervention. Nevertheless, blinding was performed for the outcome assessment.

Planned analysis
The planned analysis was by intention-to-treat. The primary outcome (changes in alcohol consumption per week) was continuous and was analyzed using a one-way analysis of variance (ANOVA). Dunnett’s tests were used to determine the differences between the intervention groups against the control group in the case of statistical significance being detected using ANOVA. In addition, a logistic regression model was used to examine the independent effect of the interventions on alcohol use after adjusting for covariates. Secondary analyses were undertaken using the method appropriate for each outcome, adjusting where appropriate for intake values and other known prognostic variables in the analysis of covariance. Intervention efficacy was examined with a secondary analysis, following a per-protocol approach; a sub-sample of participants who engaged with their allocated treatment were used in this analysis. Here, the definition of the per-protocol group is the group that contained participants who responded to both six months and 12-months of intervention. Finally, sub-group analysis was conducted to explore intervention effectiveness stratified by age into the under 49-years old and over 50-years old groups and occupational status groups into manufacturing workers and office workers.

Ethical and research governance approval
This trial protocol was reviewed and approved by the Ethics Review Committee of Faculty of Medicine, Tottori University, at the time of the survey (Reference No. 18B002).

The current trial was registered at the University Hospital Medical Information Network (UMIN) Clinical Trials Registry (UMIN-CTR) (unique ID UMIN000036244). In addition, research governance approval was granted by the Ministry of Health and Welfare Health Science Research Fund in Japan (Grant No. 29060801).

Project timescales
The trial commenced in January 2019 and will continue until March 2025.

RESULTS
Participant recruitment process is shown in Fig. 1. A total of 2,276 employees from five companies completed the AUDIT screening. Among them, 505 participants scored > 8 points on AUDIT and were invited to participate. Finally, based on inclusion/exclusion criteria, verbal consent was requested and obtained from 351 participants who were randomized into the PIL ($n = 111$), Brief Advice and Counselling ($n = 128$), and Five-minute Brief Advice ($n = 112$) groups.

Baseline descriptive statistics
Participant characteristics are shown in Table 1. Participants were predominantly men with a median age of 49-years. Median AUDIT score and number of weekly alcohol consumption was 11-points and 238.0 g/week, respectively. The proportion of participants who drank > 3 days/week, who binge drank in the previous 30-days, and who currently smoke was 84.9%, 73.5%, and 39.3%, respectively. Most participants had completed 12-years of education (graduated from high school) and were within the 6–8 million yen household income bracket. Moreover, 71.2% of participants were married, and approximately two-thirds were engaged in a manufacturing occupation. No significant differences were observed between study groups on any of the baseline variables except for marital status.

DISCUSSION
One main strength of this study is that it is the first randomized controlled trial in Japan to investigate the impact of SBIs in the workplace combined with a recommended screening tool at the workplace. Despite
the evidence in other countries, no trial in Japan showed the effectiveness of brief alcohol intervention at the workplace. Screening by AUDIT enabled us to select the study participants who are more suitable to examine the effectiveness of brief alcohol intervention. The intervention tools in our study were originally developed and simple to use for any health professionals. In the previous studies from other countries, most interventions were provided multiple times by doctors in a healthcare setting. However, in this study, trained nurses provided a single-time intervention at the workplace. If the novel intervention shows sufficient effect, our findings can provide evidence which recommends the occupational health staff to use the implementable SBI in daily practice. Moreover, we aimed to examine the effectiveness of 5-minute brief advice. Conducting a study in the workplace has the advantage of being able to follow-up the participants and would provide the data with a minimum drop-out rate. In addition, the use of routine annual checkup database provided access to data on among others, laboratory markers. Moreover, using laboratory markers and self-reported information allows us to cross-check and validate participant responses. The analyses accounted for a wide-range of patient-level variables such as screening test results, weekly alcohol consumption, alcohol-related problems, public service use, and quality of life. Self-administered questionnaires can be more robust than face-to-face interviews when collecting sensitive information. Nevertheless, this protocol has some weaknesses, including a measurement of weekly alcohol consumption that was different from that commonly used method. In addition, although blinding was performed for outcome assessment, in line with previous studies, the present study did not involve blinding of participants due to the nature of the intervention. Furthermore, selection bias may have been present in this study, precluding meaningful discussions about generalizability, which require larger studies. Finally, this study presented significant ethical challenges, due to research staff gaining access to sensitive employee information; hence, appropriate data management was required to protect the participants from any occupational disadvantages.

In conclusion, this study protocol developed the first trial in Japan to investigate the effect of brief alcohol intervention combined with a recommended screening tool at the workplace. The findings from this study protocol can provide the first evidence that SBI at the workplace is effective on reducing harmful alcohol use.

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Table 1. Baseline characteristics of participants and variables for randomization

|                       | All participants | Information leaflet | Brief advice/counselling | 5-min brief advice | P-value $^a$ |
|-----------------------|------------------|---------------------|--------------------------|-------------------|-------------|
| **Age (years)**       | 49 (IQR: 42, 55) | 49 (IQR: 40, 54)   | 49 (IQR: 41, 55)         | 49 (IQR: 43, 56)  | 0.536       |
| **Sex**               |                  |                     |                          |                   |             |
| Male                  | n (%) 345 (98.3) | n (%) 108 (97.3)    | n (%) 125 (97.7)         | n (%) 112 (100.0) | 0.234       |
| Female                | n (%) 6 (1.7)    | n (%) 3 (2.7)       | n (%) 3 (2.3)            | n (%) 0 (0.0)     |             |
| **AUDIT score**       | 11 (IQR: 9, 15)  | 10 (IQR: 9, 14)     | 12 (IQR: 9, 15)          | 12 (IQR: 9, 15)   | 0.098       |
| **Weekly alcohol consumption (gram/week)** | 238 (IQR: 121, 392) | 231 (IQR: 98, 394) | 247.1 (IQR: 126, 420) | 248.5 (IQR: 137, 352) | 0.719 |
| **Frequency of drinking > 3 days/week** | n (%) 298 (84.9) | n (%) 90 (81.1)     | n (%) 108 (84.4)         | n (%) 100 (89.3)  | 0.226       |
| **Binge drinking in previous 30 days** | n (%) 258 (73.5) | n (%) 80 (72.1)     | n (%) 99 (77.3)          | n (%) 79 (70.5)   | 0.451       |
| **Current smoker**    | n (%) 138 (39.3) | n (%) 48 (32.2)     | n (%) 47 (36.7)          | n (%) 43 (38.4)   | 0.571       |
| **Subjective sleep quality** | | | | | |
| Very good             | n (%) 26 (7.4)   | n (%) 10 (9.0)      | n (%) 8 (6.3)            | n (%) 8 (7.1)     | 0.308       |
| Good                  | n (%) 192 (54.7) | n (%) 66 (59.5)     | n (%) 69 (53.9)          | n (%) 57 (50.9)   |             |
| Bad                   | n (%) 127 (36.2) | n (%) 33 (29.7)     | n (%) 47 (36.7)          | n (%) 47 (42.0)   |             |
| Very bad              | n (%) 6 (1.7)    | n (%) 2 (1.8)       | n (%) 4 (3.1)            | n (%) 0 (0.0)     |             |
| **Health-related QOL: SF-8 score** | | | | | |
| PCS                   | 50.6 (IQR: 46.5, 53.6) | 50.9 (IQR: 48.0, 54.3) | 49.8 (IQR: 45.3, 53.0) | 50.8 (IQR: 45.9, 53.6) | 0.119       |
| MCS                   | 52.3 (IQR: 47.5, 54.9) | 51.3 (IQR: 47.1, 55.0) | 52.7 (IQR: 47.5, 54.9) | 52.6 (IQR: 47.8, 54.8) | 0.522       |
| **Mental health status: K6 score** | | | | | |
| Well: K6 ≤ 4          | n (%) 135 (38.5) | n (%) 35 (31.5)     | n (%) 49 (38.3)          | n (%) 51 (45.5)   | 0.241       |
| Moderate depression: K6 = 5–12 | n (%) 184 (52.4) | n (%) 67 (60.4)     | n (%) 66 (51.6)          | n (%) 51 (45.5)   |             |
| Serious depression: K6 ≥ 13 | n (%) 32 (9.1)  | n (%) 9 (8.1)       | n (%) 13 (10.2)          | n (%) 10 (8.9)    |             |
| **Physical activity: IPAQ score** | | | | | |
| Low                   | n (%) 186 (53.0) | n (%) 61 (55.0)     | n (%) 69 (53.9)          | n (%) 56 (50.0)   | 0.39        |
| Moderate              | n (%) 108 (30.8) | n (%) 31 (27.9)     | n (%) 44 (34.4)          | n (%) 33 (29.5)   |             |
| High                  | n (%) 57 (16.2)  | n (%) 19 (17.1)     | n (%) 15 (11.7)          | n (%) 23 (20.5)   |             |
| **Educated years**    | 12 (IQR: 12, 14) | 12 (IQR: 12, 14)    | 12 (IQR: 12, 14)         | 12 (IQR: 12, 14)  | 0.256       |
| **Marital status**    |                  |                     |                          |                   |             |
| Married and living with spouse | n (%) 238 (67.8) | n (%) 68 (61.3)     | n (%) 86 (67.2)          | n (%) 84 (75.0)   | 0.027       |
| Married and separated from spouse | n (%) 12 (3.4)  | n (%) 2 (1.8)       | n (%) 7 (5.5)            | n (%) 3 (2.7)     |             |
| Never married         | n (%) 74 (21.1)  | n (%) 35 (31.5)     | n (%) 23 (18.0)          | n (%) 16 (14.3)   |             |
| Divorced/widowed      | n (%) 27 (7.7)   | n (%) 6 (5.4)       | n (%) 12 (9.4)           | n (%) 9 (8.0)     |             |
| **Equivalent household income** | | | | | |
| < 6 million JPY       | n (%) 103 (29.3) | n (%) 33 (29.7)     | n (%) 41 (32.0)          | n (%) 29 (25.9)   | 0.704       |
| 6–8 million JPY       | n (%) 83 (23.6)  | n (%) 26 (23.4)     | n (%) 27 (21.1)          | n (%) 30 (26.8)   |             |
| > 8 million JPY       | n (%) 86 (24.5)  | n (%) 23 (20.7)     | n (%) 32 (25.0)          | n (%) 31 (27.7)   |             |
| I cannot answer       | n (%) 79 (22.5)  | n (%) 29 (26.1)     | n (%) 28 (21.9)          | n (%) 22 (19.7)   |             |
Table 1. Baseline characteristics of participants and variables for randomization (Continued)

| Occupational status                        | All participants | Information leaflet | Brief advice/counselling | 5-min brief advice | P-value \(a\) |
|--------------------------------------------|------------------|---------------------|--------------------------|-------------------|---------------|
| n = 351                                    | n = 111          | n = 128             | n = 112                  |                   |               |
| Professional/technical occupation          | n (\%)           | 51 (14.5)           | 17 (15.3)                | 23 (18.0)         | 11 (9.8)      | 0.488         |
| Managers                                   | n (\%)           | 34 (9.7)            | 13 (11.7)                | 11 (8.6)          | 10 (8.9)      |               |
| Office work                                | n (\%)           | 38 (10.8)           | 15 (13.5)                | 10 (7.8)          | 13 (11.6)     |               |
| Production site/manufacturing occupation  | n (\%)           | 225 (64.1)          | 65 (58.6)                | 84 (65.6)         | 76 (67.9)     |               |
| Transport service                          | n (\%)           | 2 (0.6)             | 1 (0.9)                  | 0 (0.0)           | 1 (0.9)       |               |
| I cannot answer                            | n (\%)           | 1 (0.3)             | 0 (0.0)                  | 0 (0.0)           | 1 (0.9)       |               |

\(a\) Kruskal-Wallis analysis or chi-square test was used for between-group comparisons. AUDIT, Alcohol Use Disorders Identification Test; IPAQ, International Physical Activity Questionnaire; IQR, Interquartile Range; JPY, Japanese Yen; K6, K6 Distress Scale; MCS, Mental Component Summary; PCS, Physical Component Summary; QOL, Quality of Life; SF-8, SF-8 health survey.

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