

Effects of a Revised Moderate Drinking Program for Enhancing Behavior Modification in the Workplace for Heavy Drinkers: A Randomized Controlled Trial in Japan

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Abstract

This study examined the effects of the Hizen Alcoholism Prevention Program (HAPPY) and the revised version of HAPPY (HAPPY Plus), and also compared the two programs to determine whether the HAPPY Plus achieved better outcomes for heavy drinkers in the workplace. The HAPPY Plus designed to strengthen participants' recruitment, perception of threat, stress management, behavior modification by self-monitoring using a calendar-based diary, and to prevent dropout by telephone and e-mail follow-up by a trained nurse. Participants were men and women who consumed at least 20 g and 10 g of alcohol daily, respectively, and had not been diagnosed with alcohol dependence. A group intervention, 3-month randomized controlled trial was conducted. The control and intervention groups received the HAPPY and HAPPY Plus, respectively. The primary endpoint was average daily alcohol consumption. The Alcohol Use Disorders Identification Test (AUDIT), weight, body mass index, blood pressure, liver function, goal achievement rate, self-efficacy, and self-esteem were also measured. Out of 88 recruited employees, 83 (intervention group: 40; control group: 43) completed the study (completion rates were 100% and 93.4% respectively). As a result, average daily alcohol consumption decreased significantly in both groups ($p < 0.001$), but did not differ between groups. Even though behavior change rate was higher, and self-efficacy and confidence increased in the intervention group, AUDIT decreased in both groups but was significant only in the control group. Physiological indicators in the intervention group improved, but were not significant between the groups. Against the program revision, this study did not prove

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superiority of HAPPY Plus to the HAPPY regarding the indicators. However, better behavior modification and lower dropout were observed in the HAPPY Plus. Therefore, after further improvement is made, this group intervention program is applied to the workplace.

Keywords

Heavy Drinkers, Harmful Use of Alcohol, Moderate Drinking Program, Behavior Modification, Workplace

1. Introduction

Harmful alcohol use is a risk factor affecting not only drinkers' health but also the risk of traffic accidents, violence, suicide, and injury, which leads to premature death or disability. Despite the fact that these events could be avoided via interventional strategies designed to prevent or reduce harmful alcohol use, global provision of such strategies is inadequate, and there is a need for the involvement of several fields such as primary care, workplace, and school settings [1].

According to the International Classification of Diseases-10 [2], alcohol-related disorders are divided into two categories, for which treatment responses differ. Alcohol dependence is treated as a psychiatric condition, with treatment based on abstinence and rehabilitation, while treatments for harmful use are based on improving health behaviors (e.g., drinking moderation). The World Health Organization (WHO) reported that harmful alcohol use is an important risk factor for noncommunicable diseases such as mental and neurological disorders, cardiovascular disease, cirrhosis of the liver, and various types of cancer. Despite the possibility of risk prevention, there were approximately 2.5 million alcohol-related deaths globally in 2004 [1].

In Japan, drinking has been strongly implicated in the incidence of lifestyle-related diseases [3]-[5], depression and other mental and neurological disorders [6], many types of accidents and injuries, and death due to hypothermia [7]. In addition, companies incur rising medical costs due to increases in lifestyle-related diseases involving drinking, absenteeism, and presenteeism [8].

These alcohol related problems are considered to be caused by consumption of 6 or more alcoholic drinks (60 g of alcohol) per day. The amount of alcohol consumed in Japan represents the consumption by an estimated 8% of the adult population: 2.4 million extremely heavy drinkers and 8.6 million heavy drinkers with average daily pure alcohol intake of at least 120 g and 60 g, respectively [9] [10]. Despite implementation of the 10-year "Health Japan 21" project, which was initiated in 2000 to extend the nation's healthy life expectancy, to reduce the supply of alcohol, increase knowledge, and limit the hours during which alcohol could be sold, the numbers of male and female heavy drinkers increased from 4.1% to 4.8% and 0.3% to 0.4%, respectively [11].

A brief intervention (BI) was developed in the 1980s, and a cross-national collaborative research project driven by WHO had been underway, mainly in Europe, to reduce the number of alcohol-related deaths [12]. The probability that alcohol consumption would decline over a 6 - 12 months period had been found to double in drinkers who received the BI [13]. Some studies have demonstrated the effectiveness of the BI in reducing alcohol consumption, and its use has been recommended in diagnosis and treatment guidelines for harmful drinking in various countries [12] [14]-[16]. On the other hand, other studies have shown that one of the limitations of BI is that the intervention period is short, preventing the provision of evidence of long-term effectiveness [16] [17].

The BI is used mainly in primary care [12] and designed to encourage intrinsic motivation centered on 2 - 3 counseling sessions, each lasting 10 - 15 minutes and including feedback, advice, and goal setting, provided by trained medical and counseling staff. From medical viewpoint, Yuzuriha developed the Hizen Alcoholism Prevention Program (HAPPY) in Japan in 2001, which included feedback, responsibility, advice, a menu, empathy, and self-esteem [18]. In addition, 1) the inclusion of an educational video to present medical information (the effects of drinking on the body) was considered a BI weakness; 2) to amplify the perception of threat, the Japanese version of the Alcohol Use Disorders Identification Test (AUDIT) [19] was administered, with information regarding risk, based on score results, provided for participants as a first assessment; 3) to reinforce self-determined behavior modification [20], a "drinking diary" was included to provide feedback to ensure that

participants could view a record of their day-to-day behavior changes and review them with their medical staff; and 4) these diaries were integrated into the program to ensure that it could be implemented consistently. Moreover, in contrast to the BI, which mainly consisted of individual counseling in a primary care setting, the HAPPY was developed to allow implementation for groups in the workplace.

One study showed that the HAPPY significantly reduced the number of days on which heavy drinking occurred and significantly increased the number of alcohol-free days [21]; in addition, it significantly reduced γ -glutamyltranspeptidase (γ -GT) in another study [22]. The first study, however, did not include a control group, and small sample size was an issue for both studies.

Japan does not have a general practitioner system, and the implementation of BIs is not common practice. Because of the low take-up rate (46.2%) in those eligible for specific lifestyle-related disease checkups in their communities [23], it is extremely difficult to use the regional healthcare system framework to identify people whose drinking could be considered harmful. In addition, amid the opportunistic drinking that is customary in the workplace, many employees could be considered to engage in harmful alcohol use. Further, because workplace health checkup take-up rates are high, and the workplace has been linked to the primary prevention of alcohol abuse [24], inclusion of these programs in company-provided health services is considered as both necessary and effective.

Therefore, an improved version of the HAPPY, the HAPPY Plus, was developed, and the purpose of this study was to measure its effectiveness and compare it with that of the HAPPY in employees in the workplace whose drinking qualified as harmful use.

In companies that aim to reduce their healthcare costs, resolving the issue of heavy drinking contributes to this management via primary prevention of alcohol related lifestyle diseases; ultimately controls healthcare costs related to chronic diseases [25]. It is a preventative measure for psychological problems such as depression, insomnia, and social problems, which include absenteeism, presenteeism, and drunken driving; and is connected to controlling the progression of drinking toward alcohol dependence.

2. Methods

2.1. Study Design and Sample

A randomized controlled trial was conducted, with the HAPPY and HAPPY Plus provided for the control and intervention groups, respectively.

Participants were selected from employees of 10 companies that had agreed to collaborate in the study, who provided informed consent and fulfilled the following eligibility criteria: (1) aged over 20 years, (2) average daily alcohol intake of 2 drinks (20 g) for men and 1 drink (10 g) for women, and (3) no diagnosis of alcohol dependence.

Regarding the sample size, given an effect size of 0.33 for the BI [26], a significance level of 5%, and calculation of significant differences with statistical power of 80%, the number of participants required for within-group measures and interactions in a two-way repeated measures ANOVA was 58 for each group. Using the same method and effect size, the required number of participants for between-subjects measures was 28 for each group. Assuming an attrition rate of 10% at 3 months, the target sample size was set at 128 (64 for each group) to produce the required sample size of 58 for each group.

2.2. Sampling and Randomization

Employees who, according to the results of workplace-provided health checkups required by the Industrial Safety and Health Act, were classified as people whose alcohol intake was at the heavy drinking level (540 ml or more per day) or people who already have a health disorder of γ -GT > 50 U/l were selected for participation. Recruitment was made through the companies by distributing flyers to each individual. After providing informed consent, participants were randomly assigned to the two groups.

2.3. Development of the HAPPY Plus and Training

Referring to the results of a recent field study that used focus group methodology to interview 12 male heavy drinkers [27], the following revisions were made to the HAPPY:

- 1) A program title was created to improve recruitment. "Learning How to Have a Long-Term Relationship

with Alcohol” was used as the title for the drinking moderation program, because 2 points had become clear. First, there was a strong resistance to reducing drinking (drinking provides an opportunity to socialize and build collegiality, and “being able to hold one’s liquor” is tied to the meaning of one’s existence, while drinking in moderation is believed to be connected to the disavowal of drinkers’ values). Second, there was a lack of foresight regarding long-term health (people do not think about being unable to drink because of health problems; it does not occur to them that their very existence could be threatened if they develop a health problem that makes it physically impossible to drink).

2) Changes were made to amplify participants’ perception of the threat to their health in order to increase behavior change rate. The absence of the perception of a threat to health results from a paucity of information and knowledge concerning alcohol-related health problems, with the benefits of drinking emphasized. Therefore, we revised the way in which information was provided, using the Health Belief Model [28] [29], and improved the provision of medical information by instructing the therapist to present the information to participants interactively.

3) Stress management education was added. Because one of the reasons that participants drank alcohol to relieve stress, stress management education was integrated into the program to ensure that participants could learn to cope with stress via alternative means.

4) Measures were added to prevent dropout. We implemented interactive e-mail and telephone follow up between sessions, and integrated motivational interviewing skills into the program presentation, to strengthen communication regarding approval, encouragement, motivation, and sympathy.

5) The self-monitoring method was improved in order for participants to evaluate their drinking behavior objectively. We strengthened participants to set their goals on drinking behaviors and alcohol consumption and to monitor these achievements used a calendar-based diary.

6) Group dynamics were applied. Because customary drinking with work colleagues strengthens collegiality and provides a means via which to be oneself with others, we included group discussions regarding successful drinking (modeling), to increase self-efficacy.

A nurse facilitated this process. To assure the quality of this program, prior to the study, the nurse attended HAPPY training sessions and followed the manual prepared for this program.

2.4. Procedures

As shown in **Figure 1**, participants were assigned to the control (HAPPY) or intervention (HAPPY Plus) group. The trained nurse was assigned as a facilitator for sessions 1 - 3 and follow up for both groups. One group consisted of about six participants. The durations of the sessions and between-session intervals were the same for both groups, with a period of one month between sessions 1 and 2 and two months between sessions 2 and 3 (**Figure 1**).

Session 1 consisted mainly of 1) an explanation regarding the fundamental volume of the workbook, alcohol consumption assessment, and setting moderate-drinking goals; 2) amplification of participants’ perception of the threat of alcohol-related health problems; and 3) participants’ recording of their alcohol consumption. To amplify the perception of threat, medical information presentation was interactive, and group discussion was included in the intervention group. Session 2 consisted mainly of 1) an explanation regarding the exercise volume of the workbook, alcohol consumption assessment (progress of implementation), and goal resetting; and 2) amplification of participants’ perception of the threat of alcohol-related health problems. Session 3 consisted of alcohol consumption assessment (progress of implementation), goal resetting, and a blood test.

2.5. Outcome Evaluation

2.5.1. Primary Endpoint

The primary endpoint was average daily alcohol consumption (number of drinks), which was assessed preintervention and at 1 and 3 months postintervention. Sensible drinking was defined as 2 regular alcohol-free days per week [30]. Sensible drinking recommended by Ministry of Health in Japan includes drinking up to 2 drinks per day for men and 1 drink per day for women [11].

2.5.2. Secondary Endpoints

- 1) AUDIT scores [19];

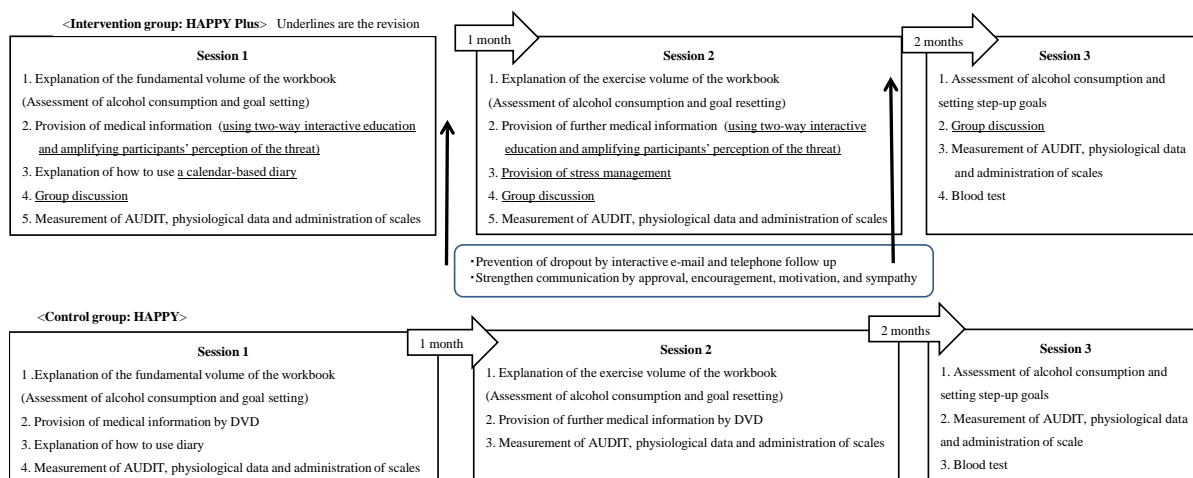


Figure 1. Contents of programs and the process.

2) Physiological indicators: weight, body mass index (BMI), systolic blood pressure, diastolic blood pressure, aspartate transaminase (AST), alanine transaminase (ALT), γ -GT, non-high-density lipoprotein cholesterol (non-HDL), and fasting glucose;

3) Psychological indicators: The General Self-Efficacy [31] [32] and Self-Esteem Scales [33] [34];

4) Achievement of moderate-drinking goals and importance and confidence ratings.

Weight, BMI, and blood pressure were measured by a nurse at each session. Other physiological indicators were measured preintervention and postintervention. The AUDIT and the General Self-Efficacy and Self-Esteem Scales were completed by participants and collected at every session. Blood samples were collected by the nurse at the session site and sent to a laboratory for analysis. Regarding the process indicators, at 1 and 3 months postintervention, participants completed a self-evaluation form concerning goal fulfillment and moderate drinking, with responses chosen from “goal almost achieved”, “goal partially achieved”, and “goal not achieved”. In addition, participants performed self-evaluation during every session, rating the importance of preventing alcohol-related health problems and their confidence in their ability to control alcohol consumption.

The observation period was set at 3 months, because behavioral change could be measured by goal achievement rate and self-efficacy score [35]; we used these measurements as surrogate indicators.

2.6. Statistical Analysis

First, to examine the effects of the HAPPY, a Friedman test was performed to determine the change in overall results over time for both groups, with the items measured at 3 time points for each group. A paired t test was performed to compare items measured at 2 time points (pre- and postintervention). To determine whether the HAPPY Plus yielded superior outcomes, a two-way repeated measures ANOVA or an unpaired t test was performed after determining normality. Participants' achievement of moderate-drinking goals was expressed in terms of proportions of the participant group. A Friedman test was also used to examine changes in importance and confidence ratings over time for each group.

2.7. Study Period

Because the study was performed office by office, participant recruitment and the study procedures were conducted between September 2012 and March 2015.

2.8. Ethical Considerations

Ethical approval for the study was obtained from the Epidemiology Research Ethics Committee at the institution with where the authors were affiliated, and each office of the companies that collaborated in the study. The participants provided written informed consent to participation and the study was performed according to the Declaration of Helsinki.

3. Results

Eighty-eight people agreed to participate in the study. Of these, two withdrew from the study prior to randomization, and three of the control group withdrew prior to initiation of the intervention; all five withdrawals occurred because of business duty burden. Data for 40 participants in the intervention group and 43 in the control group were included in the analysis. Completion rates were 100% and 93.4% for the intervention and control groups, respectively (Figure 2).

3.1. Comparison of Demographic and Baseline Data

Participants' mean age was 46.1 ± 8.6 years (range: 25 - 60 years). Their mean alcohol consumption was 5.25 ± 3.23 drinks, and their mean AUDIT score was 14.0 ± 5.53 (Table 1). Statistically significant differences were not confirmed for control comparison.

3.2. Effectiveness of the Programs

Table 2 shows the changes in alcohol consumption over time and the physiological and psychological indicators for both groups combined and individually.

Daily alcohol consumption decreased significantly over time in the intervention and control groups and both groups combined (all, $p < 0.001$). However, according to the results of the two-way repeated measures ANOVA, consumption did not differ significantly between groups. Superior outcomes, therefore, were not observed for the HAPPY Plus with respect to the primary endpoint. AUDIT scores decreased significantly over time in the control group ($p < 0.05$) and both groups combined ($p < 0.01$), while scores did not change in the intervention group.

Regarding physiological indicators, BMI decreased significantly in the intervention group ($p < 0.01$) and both groups combined ($p < 0.05$). Systolic blood pressure also decreased significantly in the intervention group and both groups combined (all, $p < 0.05$). However, BMI and systolic blood pressure did not differ significantly between groups.

With respect to liver function, AST and ALT did not change subsequently to the intervention in both groups combined and individually (Table 3). However, γ -GT decreased significantly in the control group ($p < 0.05$) and both groups combined ($p < 0.01$), but did not change in the intervention group. In addition, γ -GT did not differ significantly between groups. Non-HDL and fasting glucose decreased very little; therefore, values did not differ significantly between or within groups.

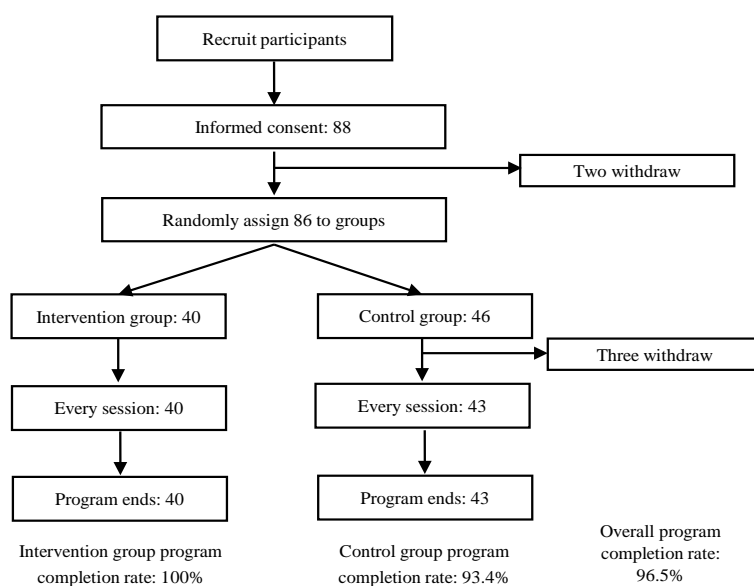


Figure 2. Participation and program completion rates.

Table 1. Baseline characteristics.

Items	Intervention group (n = 40)	Control group (n = 43)	<i>p</i> value
Base characteristics			
Sex (male/female)	30/10	34/9	0.795 n.s.
Age (year), mean \pm SD	46.4 \pm 9.3	45.7 \pm 8.0	0.722 n.s.
Alcohol consumption/day (drinks)	5.27 \pm 3.8	5.22 \pm 2.7	0.951 n.s.
AUDIT score	13.3 \pm 5.9	14.7 \pm 5.1	0.244 n.s.
Physiological indicators (mean \pm SD)			
Weight (kg)	68.9 \pm 13.1	68.7 \pm 13.3	0.959 n.s.
Body mass index	23.9 \pm 3.5	24.2 \pm 3.5	0.697 n.s.
Systolic blood pressure (mmHg)	132.1 \pm 19.6	130.5 \pm 18.8	0.707 n.s.
Diastolic blood pressure (mmHg)	85.4 \pm 15.3	82.9 \pm 13.6	0.423 n.s.
AST (U/l)	25.6 \pm 9.8	27.4 \pm 14.7	0.512 n.s.
ALT (U/l)	28.4 \pm 19.0	28.4 \pm 21.7	0.997 n.s.
γ -GT (U/l)	68.5 \pm 75.4	90.1 \pm 109.7	0.304 n.s.
Non-HDL (mg/dl)	135.4 \pm 41.1	141.7 \pm 41.6	0.626 n.s.
Fasting glucose (mg/dl)	99.8 \pm 13.2	96.1 \pm 16.5	0.266 n.s.
Psychological indicators			
Self-efficacy score	9.9 \pm 4.1	9.1 \pm 4.3	0.450 n.s.
Self-esteem score	22.7 \pm 3.7	22.3 \pm 3.3	0.583 n.s.

Sex: chi-squared test; Psychological indicators: Mann-Whitney U test; Other: unpaired t test Abbreviations: γ -GT: γ -glutamyltranspeptidase; ALT: alanine transaminase; AST: aspartate transaminase; AUDIT: Alcohol Use Disorders Identification Test; non-HDL: non-high-density lipoprotein cholesterol; SD: standard deviation; n.s.: No Significant

Regarding γ -GT, a pre/postintervention comparison was performed for participants with baseline values exceeding the reference value (>50 U/l; **Table 4**). Large reductions, all of which were statistically significant, were observed in the intervention and control groups (all, $p < 0.05$) and both groups combined ($p < 0.01$). However, no significant difference was observed between groups.

Self-efficacy increased significantly in the control group ($p < 0.05$) and both groups combined ($p < 0.01$). However, scores in the intervention group did not change and did not differ significantly between groups. Scores in self-esteem were observed unchanged in both groups combined and individually (**Table 2**).

Participants' goal achievement levels are shown in **Table 5**, and changes in their confidence levels over time and ratings for perception of the importance of preventing alcohol-related health problems are shown in **Table 6**. At both 1 and 3 months postintervention, relative to that of the control group, a higher proportion (60%) of participants in the intervention group had chosen the "goal almost achieved" response. Preintervention perception of the importance of preventing alcohol-related health problems was high in both groups, but no postintervention increases were observed. Confidence levels increased significantly in the intervention and control groups (all, $p < 0.05$). In addition, slight changes in goal achievement levels were observed in the intervention and control groups over time.

3.3. Participant Evaluations of Program Improvements

Table 7 shows the results of participants' evaluations of the programs. The HAPPY Plus evaluation included the improvements applied to address the weak points of the HAPPY. Approximately 80% of participants rated the improvements as good or very good. In contrast, 32.5% rated the provision of information concerning stress

Table 2. Changes in alcohol consumption and physiological and psychological indicators over time.

	Both Groups (n = 83)				Intervention Group (n = 40)				Control Group (n = 43)				Two-way repeated measures ANOVA (upper: F value; lower: p value)		
	Preintervention	After 1 month	After 3 months	p value	Preintervention	After 1 month	After 3 months	p value	Preintervention	After 1 month	After 3 months	p value	Interaction	Between groups	Within groups
Alcohol consumption day	5.25 ± 3.23	4.10 ± 2.71	3.76 ± 2.65	<0.001	5.27 ± 3.77	4.25 ± 3.12	3.82 ± 2.87	<0.001	5.22 ± 2.68	3.96 ± 2.30	3.70 ± 2.46	<0.001	0.272	0.062	41.931
AUDIT score	14.0 ± 5.53	12.9 ± 5.39	12.5 ± 5.51	0.004	13.3 ± 5.92	12.4 ± 5.65	12.2 ± 5.45	0.136	14.7 ± 5.12	13.4 ± 5.16	12.7 ± 5.63	0.022	0.689	0.744	8.025
Weight (kg)	68.8 ± 13.1	68.8 ± 13.0	68.5 ± 12.9	0.151	68.9 ± 13.1	68.9 ± 13.1	68.5 ± 13.1	0.015	68.7 ± 13.3	68.7 ± 13.0	68.5 ± 12.8	0.925	0.171	0.002	1.205
Body Mass Index	24.1 ± 3.5	23.9 ± 3.5	23.8 ± 3.4	0.048	23.9 ± 3.5	23.6 ± 3.5	23.5 ± 3.5	0.005	24.2 ± 3.5	24.1 ± 3.4	24.0 ± 3.4	0.974	0.793	0.964	0.296
Systolic blood pressure (mmHg)	131.3 ± 19.1	128.5 ± 16.2	127.1 ± 18.1	0.032	132.1 ± 19.6	126.9 ± 16.9	125.9 ± 20.8	0.019	130.5 ± 18.8	129.9 ± 15.5	128.3 ± 15.3	0.572	1.710	0.116	5.302
Diastolic blood pressure (mmHg)	84.1 ± 14.5	84.8 ± 13.0	82.6 ± 15.2	0.818	85.4 ± 15.3	85.3 ± 13.5	81.5 ± 17.6	0.337	82.9 ± 13.6	84.3 ± 12.8	83.6 ± 12.7	0.742	1.949	0.027	1.835
Self-efficacy	9.5 ± 4.2	10.0 ± 4.5	10.4 ± 4.5	0.002	9.9 ± 4.1	10.5 ± 4.3	10.9 ± 4.4	0.055	9.1 ± 4.3	9.5 ± 4.7	9.9 ± 4.6	0.040	0.146	0.870	0.163
Self-esteem	22.5 ± 3.5	22.7 ± 3.8	23.3 ± 4.0	0.055	22.7 ± 3.7	23.0 ± 4.0	23.6 ± 4.3	0.129	22.3 ± 3.3	22.5 ± 3.6	23.0 ± 3.6	0.333	0.136	0.435	6.762
													0.854	0.511	0.002

Abbreviations: AUDIT: Alcohol Use Disorders Identification Test.

Table 3. Changes in blood test data over time.

	Both Groups (n = 83)			Intervention Group (n = 43)			Control Group (n = 43)			Unpaired t test p value	
	Preintervention	Postintervention	p value	Preintervention	Postintervention	p value	Preintervention	Postintervention	p value	Preintervention	Postintervention
AST (U/l)	26.6 ± 12.7	24.5 ± 9.4	0.060	25.6 ± 9.8	25.0 ± 10.7	0.647	27.7 ± 15.0	24.0 ± 7.9	0.055	0.512	0.627
ALT (U/l)	28.5 ± 20.5	27.1 ± 16.6	0.331	28.4 ± 19.0	27.6 ± 19.1	0.663	28.5 ± 22.2	26.5 ± 13.8	0.377	0.997	0.769
γ-GT (U/l)	80.5 ± 95.6	64.3 ± 65.2	0.009	68.5 ± 75.4	59.7 ± 70.2	0.114	92.6 ± 111.8	69.0 ± 60.3	0.033	0.304	0.529
Non-HDL L (mg/dl)	138.3 ± 41.0	141.6 ± 41.9	0.400	135.4 ± 41.1	138.8 ± 45.7	0.486	141.7 ± 41.6	144.9 ± 37.6	0.629	0.626	0.631
Fasting glucose (mg/dl)	98.1 ± 15.1	98.9 ± 20.5	0.647	99.8 ± 13.2	98.5 ± 14.0	0.644	96.2 ± 16.8	99.3 ± 25.8	0.179	0.266	0.828

Abbreviations: γ-GT: γ-glutamyltranspeptidase; ALT: alanine transaminase; AST: aspartate transaminase; non-HDL: non-high-density lipoprotein cholesterol.

Table 4. Participants' γ-GT values exceeding the reference value.

	n	Wilcoxon rank sum test			Mann-Whitney U test p value	
		Preintervention	Postintervention	p value	Preintervention	Postintervention
Both groups	32	151.8 ± 118.9	108.1 ± 81.5	0.001	0.459	0.352
Intervention group	14	132.6 ± 98.6	103.0 ± 100.3	0.041		
Control group	18	166.8 ± 133.4	112.0 ± 66.2	0.014		

Abbreviations: γ-GT: γ-glutamyltranspeptidase.

Table 5. Change in participants' goal achievement over time.

	Intervention group (n = 40)		Control group (n = 43)	
	After 1 month	After 3 months	After 1 month	After 3 months
Goal almost achieved, n (%)	24 (60.0)	24 (60.0)	16 (37.2)	18 (41.9)
Goal partially achieved, n (%)	14 (35.0)	13 (32.5)	17 (39.5)	18 (41.9)
Goal not achieved, n (%)	2 (5.0)	3 (7.5)	10 (23.3)	7 (16.3)
Total	40 (100.0)	40 (100.0)	43 (100.0)	43 (100.0)

Table 6. Changes in ratings for importance and confidence related to drinking in moderation over time.

	Intervention Group (n = 40)				Control group (n = 43)			
	Preintervention	After 1 month	After 3 months	p value	Preintervention	After 1 month	After 3 months	p value
Importance rating	7.15 ± 2.21	7.33 ± 1.73	7.53 ± 2.00	0.911	7.14 ± 2.57	7.26 ± 2.28	7.28 ± 2.15	0.940
Confidence rating	5.43 ± 2.07	5.78 ± 2.28	6.23 ± 1.90	0.020	5.05 ± 1.98	5.81 ± 1.93	5.93 ± 2.28	0.041

Table 7. Overall program evaluations.

	n	Very good (Long)	Good (A little long)	Neither	Bad (A little short)	Very bad (Short)	No response
HAPPY Plus							
Alcohol-related health problem slides	40	8 (20.0%)	25 (62.5%)	6 (15.0%)	0 (0.0%)	0 (0.0%)	1
Alcohol-related health problem explanations	40	9 (22.5%)	26 (65.0%)	4 (10.0%)	0 (0.0%)	0 (0.0%)	1
Support via telephone and e-mail	40	8 (20.0%)	22 (55.0%)	9 (22.5%)	0 (0.0%)	0 (0.0%)	1
Group discussions	40	9 (22.5%)	23 (57.5%)	7 (17.5%)	0 (0.0%)	0 (0.0%)	1
Learning materials for stress management	40	6 (15.0%)	20 (50.0%)	13 (32.5%)	0 (0.0%)	0 (0.0%)	1
Alcohol consumption diary: frequency of use	40	29 (72.5%)	6 (15.0%)	4 (10.0%)	1 (2.5%)	0 (0.0%)	0
Alcohol consumption diary: ease of use	40	7 (17.5%)	21 (52.5%)	11 (27.5%)	1 (2.5%)	0 (0.0%)	0
Information included with the alcohol consumption diary	40	7 (17.5%)	30 (75.0%)	3 (7.5%)	0 (0.0%)	0 (0.0%)	0
HAPPY							
Alcohol consumption diary: frequency of use	43	21 (48.8%)	14 (32.6%)	4 (9.3%)	2 (4.7%)	1 (2.3%)	1
Alcohol consumption diary: ease of use	43	3 (7.0%)	24 (55.8%)	10 (23.3%)	5 (11.6%)	0 (0.0%)	1
Information included with the alcohol consumption diary	43	1 (2.3%)	36 (83.7%)	5 (11.6%)	0 (0.0%)	0 (0.0%)	1

management as “neither”. The HAPPY Plus revised alcohol consumption diary received a number of positive reviews.

4. Discussion

4.1. Study Participation

As the participants’ baseline daily alcohol consumption and AUDIT scores indicated harmful use but did not fall within the alcohol dependence range; in addition, almost 40% of the participants already caused alcoholic liver disease, the study appears to have been successful in recruiting a sample in need of lifestyle modification. Collaborating with companies and the change in the program title facilitated the engagement process. These improvements appeared effective. In addition, the efforts to retain participants by e-mail and telephone follow up in the HAPPY Plus appeared successful, as 100% of the participants completed the study.

4.2. Effects of the HAPPY and HAPPY Plus

Since HAPPY Plus is a revision of the HAPPY, we examined effectiveness of both groups combined first. While significant changes occurred in the primary endpoint, average daily alcohol consumption, and secondary endpoints, AUDIT scores, BMI, systolic blood pressure, and γ -GT, were observed with both programs. The HAPPY, which provides feedback via the use of AUDIT scores to give participants with a clear understanding of their current alcohol use, relevant medical knowledge, and a tool of self-monitoring their consumption using diaries, exerted a direct effect on the reduction of alcohol consumption, showed the similar effect to that exerted by the BI [36]. As a secondary effect, the results confirmed a decrease in blood pressure, which was also suggested in the positive relationships between alcohol intake and hypertension shown in other studies [37]-[39].

On the other hand, although alcohol intake is related to risk of glucose intolerance [40] and elevated fatty acid levels [41], there were no improvements in these indicators. This may have occurred because there were only three participants whose results exceeded the reference values for diabetes. More important reason is that the program did not include diet and exercise education. This is explained in comparison with disease management programs which include comprehensive health risk behavior modification [35] and the metabolic syndrome lifestyle change education [42], which proved improvement in indicators for not only alcohol consumption but also blood glucose, blood pressure, and lipids. Especially, Iyatomi *et al.* showed significant improvement for targeting high-risk drinkers whose AUDIT scores of at least 10 or consumed at least 21 drinks per week [42]. Therefore, we need to improve the programs; once the effects of moderate alcohol consumption have increased, the next step is to guide participants into programs including disease prevention programs that provide good dietary and exercise guidance or those that aim to improve overall health behavior.

In addition, scores for self-efficacy and self-esteem improved over time. This suggests that the intervention elements included in the HAPPY, such as empathy, goal setting and evaluation, could have been effective in providing a successful experience in drinking moderation.

4.3. Effects of the HAPPY Plus vs. the HAPPY

Goal achievement was considerably higher in the HAPPY Plus, as further information concerning alcohol-related health problems was provided, presentation was interactive, group dynamics were introduced, and telephone and e-mail follow up were added. Aside from this finding, the HAPPY Plus was not shown to be superior to the HAPPY.

A considerable reason is that there were control group participants whose data values were extreme, and improvements in these participants' data exerted a strong influence on the results. Moreover, even in the HAPPY Plus, with behavior modification enhancement, the goal achievement rate was only 60%; notwithstanding the finding that there was a significant decrease in AUDIT scores in both groups combined. The average score did not fall below the dangerous consumption level. Further, despite a large and statistically significant reduction in γ -GT values in both groups combined, the average value did not decrease sufficiently to reach the normal range.

Another explanation for this could be that, even though the medium and method were altered, feedback, advice, goal setting, self-monitoring, and acquisition of medical knowledge were included in both programs. Moreover, as company employees, participants could be assumed to possess sufficient cognitive ability to adapt an approach to suit their needs and use the Internet and other resources to obtain information as required. In fact, some participants stated that the alcohol consumption diary required improvement and created their own spreadsheet programs. However, the diary used in the HAPPY Plus demonstrated some strengths. The calendar style exerted a self-monitoring effect, as participants were able to grasp the relationship between changes in their behavior and alcohol consumption, such as "the relationship between weekend dinner parties and alcohol consumption" and "setting alcohol-free days and its effects", at a glance. While the introduction of a drinking diary was not shown to exert a significant effect in one study [43], Hara *et al.* [44] described the effectiveness of moderate-drinking goals and a drinking diary. Nevertheless, with the finding that levels of achievement of behavioral goals were high in the HAPPY Plus, using a longer measurement period, it is conceivable that results could be reflected in improved physiological indicators and AUDIT scores.

In addition, participants' evaluations of the stress management section of the program were low, and it did not exert a direct effect on controlling drinking behavior. Although entirely within the realm of conjecture, because this was a group intervention implemented in the workplace, it is possible that participants felt unable to discuss stress. Even though some studies have indicated that drinking behavior was associated with stress coping in men [45], rather than drinking serving as a means of relieving stress, it could simply reflect a daily habit, as some participants value drinking for its own sake, and their drinking is not related to stress relief [27]. Therefore, stress management could be deleted for the group intervention.

Regarding the use of group interventions in the workplace, in recent years, Internet-based programs designed to assist individuals in reducing their drinking have multiplied in other countries, and there is evidence to support their effectiveness [46]. In particular, because such programs are easily accessible, they are useful for minors engaging in drinking illegally [47]. However, given that the development of web-based programs to reduce drinking has just begun in Japan, the use of group interventions should not be underestimated for several reasons. The biggest reason is that in Japan, drinking is often work related, and peer effect should not be underestimated.

The results of this study suggested that convincing heavy drinkers to participate in and complete such programs requires an enforcement mechanism.

4.4. Summary and Future Improvements

Both the HAPPY and HAPPY Plus were found to reduce daily alcohol consumption. In addition, to support participants with metabolic syndrome and respect to their dietary problems, the revised version of HAPPY that includes improvement of overall health behaviors is required. To improve program participation and completion rates, it was important to direct appeal for participation to companies, establish work-based groups, and conduct e-mail and telephone follow-up between sessions. Finally, since goal achievement rate was high in HAPPY Plus, it might be necessary to observe changes in drinking behavior over a period of at least a year rather than relying on surrogate indicators.

Conflicts of Interest

The authors declare that there are no conflicts of interest associated with this manuscript.

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Access to Study Data

All authors had access to the study data.

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