[Environmental Health and Preventive Medicine 9, 152–160, July 2004]

Special Issue

Original Article

Effects of Stage-matched Repeated Individual Counseling on Smoking Cessation: A Randomized Controlled Trial for the High-risk Strategy by Lifestyle Modification (HISLIM) Study

Masakazu NAKAMURA[1], Shizuko MASUI[1], Akira OSHIMA[2], Akira OKAYAMA[3], Hirotsugu UESHIMA[4] and the HISLIM Research Group[5]

[1]*Department of Health Promotion and Education, Osaka Medical Center for Health Science and Promotion, Osaka, Japan*
[2]*Department of Cancer Control and Statistics, Osaka Medical Center for Cancer and Cardiovascular Disease, Osaka, Japan*
[3]*Department of Preventive Cardiology, National Cardiovascular Center, Osaka, Japan*
[4]*Department of Health Science, Shiga University of Medical Science, Shiga, Japan*
[5]*Investigators of the research group are listed in the final report of the Research on Long-Term Chronic Disease "Seikatsu Syukanbyo han" 1998, granted from the Ministry of Health and Welfare, Japan*

Abstract

Objective: The purpose of this study was to evaluate the effects of stage-matched repeated individual behavioral counseling as an intervention for the cessation of smoking.

Methods: We conducted a multisite randomized controlled trial that enrolled smokers unselected for their readiness to quit. There were 979 smokers with hypertension or hypercholesterolemia recruited from 72 study sites and randomly allocated to the intervention or control group. Smokers in the intervention group received stage-matched individual counseling consisting of a 40 minute initial session and four 20–30 minute follow-up sessions. Smokers in the control group received individual behavioral counseling for hypertension or hypercholesterolemia.

Results: The point prevalence abstinence rate at 6 months, validated by carbon monoxide testing, in the intervention group (13.6%) was 5.4 times higher ($p<0.001$) than that in the control group (2.5%). When the data were analyzed based on the baseline stage of change, there were significant differences in the abstinence rates at 6 months in smokers versus controls with each stage of change except in immotives. The odds ratio was 6.4 ($p<0.001$) in precontemplators, 6.7 ($p<0.001$) in contemplators, and 6.2 ($p<0.01$) in preparators. There was a positive, consistent effect of the intervention regardless of study site (worksite or community) or the presence of hypertension or hypercholesterolemia.

Conclusions: We showed the effects of an intervention with repeated individual behavioral counseling on the cessation of smoking in smokers unselected for their readiness to quit. This result suggests that stage-matched individual counseling, based on the transtheoretical model, is effective in smokers with a lower motivation to quit as well as those ready to quit.

Key words: smoking cessation, individual counseling, stage of change, intervention study, effect, randomized ontrolled trial

Introduction

Tobacco use is the single most important preventable health risk in developed countries, and a major cause of premature death and disability worldwide (1, 2). In 2000, tobacco smoking accounted for an estimated 113,000 of the total 962,000 deaths in Japan (3). Thus, tobacco smoking is responsible for approximately one in every eight to nine deaths in Japan. Although the prevalence of smoking among men has gradually decreased to 45.9% in 2000 (4), the absolute number of annual tobacco-attributed deaths among men in Japan is still increasing as a consequence of high-level tobacco consumption over several decades (3). Smoking is uncommon among Japanese women, with only about 10% currently smoking; however, smoking is increasing among younger women (4).

Received Feb. 12 2004/Accepted May 19 2004
Reprint requests to: Masakazu NAKAMURA
Department of Health Promotion and Education, Osaka Medical Center for Health Science and Promotion, 1-3-2 Nakamichi, Higashinari-ku, Osaka, 537-0025, Japan
TEL: +81(6)6973-5531, FAX: +81(6)6973-3574
E-mail: nakamura@kenkoukagaku.jp

Therefore, it is easy to predict that the health burden caused by tobacco use will become a more serious social problem in the future. The burden of tobacco-caused diseases in the first half of the 21st century occurred mainly in those who were current smokers (5). Thus, comprehensive tobacco control measures to reduce smoking prevalence are urgently needed.

The essence of tobacco use is nicotine dependence (6). Nicotine dependence is a chronic disease that often requires repeated intervention (7). Environmental change strategies for tobacco control, such as tobacco taxation and smoking restriction in public places, can be effective in reducing tobacco use (8, 9), but smokers often find it difficult to overcome their dependence without help (10). Effective treatments to promote smoking cessation need to be implemented in various health care settings as part of a comprehensive tobacco control measure.

There is clear evidence that various interventions for the treatment of tobacco dependence are both effective and cost-effective compared to other medical and disease prevention interventions (11–13). In Western countries, evidence-based guidelines for treating tobacco dependence were developed for health professionals as well as health commissioners and managers (7, 12), and many efforts have been made to implement these guidelines into health care settings.

However, in Japan, there have been a limited number of studies on smoking intervention. Seven intervention studies with a controlled trial design examined the effects of individual counseling or a combined intervention format including individual counseling (14–20). Although some have shown the intervention to be effective (14–17), others failed to show a significant difference, mainly due to a small sample size (18) or a small effect of the intervention (19, 20). These previous studies had limitations in that only a few used a biochemical test to validate self-reports of smoking status (17, 18) and only three assigned the subjects to study groups by random allocation (17–19).

From a theoretical perspective, most previous studies did not include a description of the theoretical background of behavioral science for the design of the smoking intervention. The transtheoretical model (stages-of-change model) (21, 22) proposes that interventions should take into account the current stage (readiness) of the individual to change. We have developed a smoking cessation intervention that utilizes repeated individual counseling based on the transtheoretical model. We have also developed a training program to teach health care providers a behavioral approach to use in counseling smokers. The purpose of this study was to perform a multisite, randomized, controlled trial to examine the effects of a smoking intervention with repeated individual counseling by trained health care providers.

Methods

Overview

A multisite randomized controlled trial (the High-risk Strategy by Lifestyle Modification, HISLIM study) was organized to examine the effects of individual counseling for behavior change among high-risk subjects aged 20 to 69 who had two of three risk factors: hypertension (systolic BP of 135 to 179 or diastolic BP of 85 to 104), hypercholesterolemia (total cholesterol of 220 to 300 mg/dl), and smoking. To be eligible for enrollment, subjects were required to have smoked for at least 1 year before recruitment. Pipe or cigar smokers were excluded from the study.

Study subjects consisted of three subgroups: the smoking and hypertension group (SHT), the smoking and hypercholesterolemia group (SHC), and the hypertension and hypercholesterolemia group (HTHC). Subjects of each subgroup (SHT, SHC, HTHC) were individually assigned at random to the two intervention groups within each study center. Subjects assigned to the intervention A or B group received a behavioral intervention for risk factor A or B, respectively. In evaluating the effect of the behavioral intervention for risk factor A, the intervention B group was treated as a control group ("positive control group"). The main outcome criteria of the trial were changes in the risk factors at 6 months.

The original sample size estimate of 220 in each group provided the study with 80% power to detect a 4 mmHg decrease in systolic BP in the intervention group compared with the control group. This power analysis was calculated using a 2-sided test with the probability level (α) being set at 0.05 and standard deviations of 15.0 for SBP. The number of participants in our study was also considered to be sufficient for detecting differences between the two groups for both total cholesterol reduction (8 mg/dl) and the abstinence rate (10%).

All of the survey and intervention procedures were examined and approved by the Medical Science Ethics Review Board of Shiga University of Medical Science.

Recruitment of the study site

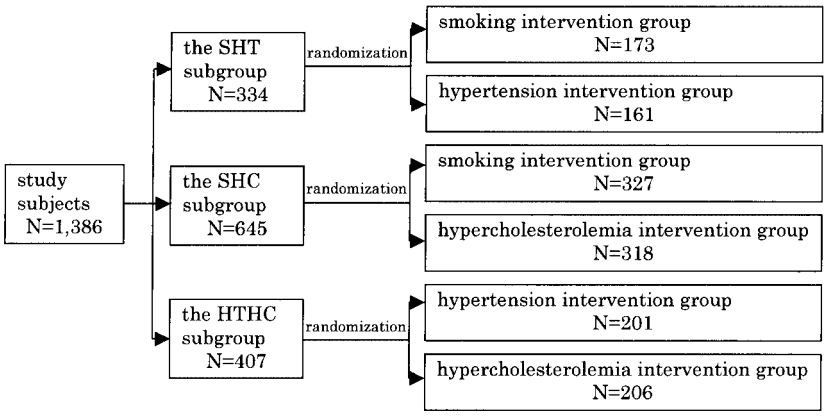
Two-day research workshops were held in the Kanto and Kansai districts for over 200 health care providers working for communities or worksites that were interested in participating in the study. In the workshops, the study purpose and protocols were explained.

As a result, 72 sites participated in the study. The 72 study sites consisted of 26 communities and 46 worksites. Among the 26 communities, there were 7 prefectural health centers and 19 municipal health centers or offices. Among 46 worksites, there were 28 private companies, 4 public worksites, and 14 medical facilities providing worksites with health check-up services.

Subject recruitment and randomization

Study subjects were recruited from the 72 sites. Each study site was requested to select one of three risk-factor subgroups (SHT, SHC, HTHC) and recruit 20 subjects who met the inclusion criteria. All subjects were informed of the study and gave their written consent.

A total of 1,386 subjects were recruited by the study sites: 334 subjects in the SHT subgroup, 645 in the SHC subgroup, and 407 in the HTHC subgroup (Fig. 1). The subjects were stratified by study site and randomly assigned to either one of the two intervention groups in each subgroup. As a result of randomization, 173 of 334 subjects in the SHT subgroup were assigned to the smoking intervention group and 161 subjects were assigned to the hypertension intervention subgroup. Among



Note. SHT: smoking and hypertension group, SHC: smoking and hypercholesterolemia group, HTHC: hypertension and hypercholesterolemia group.

Fig. 1 Outline of randomization assignment of study subjects

the 645 subjects in the SHC subgroup, 327 and 318 subjects were assigned to the smoking and hypercholesterolemia interventions, respectively. Among the 407 subjects in the HTHC subgroup, 201 and 206 subjects were assigned to the hypertension and hypercholesterolemia interventions, respectively.

Among the 1,386 subjects, 399 subjects (28.8%) had all three risk factors (hypertension, hypercholesterolemia, and smoking). The percentage of those who had all three risk factors was 27.2% in the SHT subgroup, 42.6% in the SHC subgroup, and 8.6% in the HTHC subgroup. There were no statistical differences in the percentage of those who had all three risk factors among intervention groups in the SHT, SHC, and HTHC subgroups. A total of 979 smokers (334 in SHT, 645 in SHC) were selected for the present study to examine the effects of stage-matched smoking intervention. Among 334 subjects in the SHT subgroup, two subjects proved to be ex-smokers at randomization and were excluded from the analysis. Thus, 977 subjects (332 in SHT, 645 in SHC) were included in the final analysis. There were 500 subjects in the smoking intervention group (173 in SHT, 327 in SHC) and 477 in the control group (159 in SHT, 318 in SHC).

Health care provider training

One-day and consecutive two-day training seminars were provided for health care providers who participated in the study. To standardize our intervention protocol and method, the study sites were requested to send two staff members to participate in these seminars. The purpose of the seminars was to make participants understand the significance of risk factor interventions by behavioral counseling, and to demonstrate and practice the counseling. The participants received lectures on smoking intervention in the first seminar. The contents of the lectures were the health effects of smoking, the significance of smoking cessation, and the smoking intervention protocol of the study. In the second seminar, conducted 5 to 6 months after the first, the instructor presented the method used to counsel smokers according to their stage of change for smoking cessation and showed a videotape demonstrating successful stage-matched counseling interactions. The participants used role-playing to rehearse smoking cessation counseling.

Smoking intervention protocol

Based on a smoking cessation program for health check-up settings that we developed (23), standardized intervention protocols and manuals were arranged to guide health care providers in delivering smoking cessation counseling. The smoking intervention consisted of a 40 minute initial counseling session and four 20–30 minute follow-up counseling sessions at 1, 2, 4, and 6 months after the initial session. These sessions were conducted face-to-face by individual counselors. If a smoker established a quit date, there was an additional follow-up 1 week after the initial session by telephone call or letter. The initial session consisted of stage-matched individual counseling with the feedback of expired carbon monoxide (CO) testing (24) and provision of a self-help guide that described the stages of change for smoking cessation (25). The stage-matched individual counseling included: 1) assessing the smoker's stage of change, 2) providing counseling about smoking cessation that differed according to the smoker's stage of change, 3) recommending that smokers willing to quit smoking set a quit date. A smoker's stage of change was categorized into four categories: the immotive stage (not interested in quitting smoking and not thinking about quitting in the next 6 months), the precontemplation stage (interested in quitting smoking but not thinking about quitting in the next 6 months), the contemplation stage (planning to quit within the next 6 months), and the preparation stage (planning to quit in the next month) (22, 26, 27).

With smokers in the immotive stage (immotives), the immediate goal of smoking intervention is to help them begin to think about quitting (28). The counselor's task is to raise the client's awareness of risks and problems with smoking behavior. With smokers in the precontemplation stage (precontemplators) and the contemplation stage (contemplators) who are ambivalent about changing their smoking behavior, the counselor's task is to help them make the decision to quit smoking by providing individualized information on the potential risks of smoking, and by identifying the barriers to quitting and offering potential solutions. With smokers in the preparation stage (preparators), who are ready to quit smoking and seeking cues for action, the counselor's task is to help them plan the quit

attempt by setting a quit date and providing individualized information on cognitive and behavioral strategies for quitting.

At follow-up counseling sessions, if smokers succeeded in quitting smoking, the counselor first congratulated them on their efforts to quit, then talked with them about the withdrawal symptoms and the urge to smoke, and provided information on solutions to prevent relapse. At the latter part of the follow-up sessions, if quitters experienced weight gain, the counselor advised them on methods of weight control. If smokers failed to quit smoking or relapsed, the counselor discussed with them the reasons for their behavior, and encouraged them to try to quit smoking again if they were willing.

The smoking intervention in our study was conducted by health care providers including public health nurses, nurses, physicians, nutritionists, and medical technologists. In the intervention at worksites, the number of public health nurses and nurses was the largest, about 80% of the total number. In the intervention at communities, the largest number of health care providers consisted of public health nurses, at about 70% of the total, followed by nutritionists at about 20% of the total.

Nicotine replacement therapy was not used in this study as clearly stated in the intervention protocols. Health care providers were also informed about not using nicotine replacement therapy at the training seminars.

Baseline assessment and outcome measures

A baseline assessment was scheduled in each subject 3 weeks before the initial intervention session. The subjects who attended the baseline assessment session received: 1) a screening test including systolic and diastolic blood pressure, serum cholesterol, and expired CO concentration; 2) a food survey for dietary assessment; and 3) a self-administered questionnaire survey on lifestyle and medical history, followed by an interview with the study providers. After baseline assessment, the same assessments were also conducted at the initial intervention session and the follow-up intervention sessions at 1, 2, 4, and 6 months.

In the self-administered questionnaire surveys at the baseline session, questions on smoking were asked concerning daily cigarette consumption, age at start of smoking, stage of change, Fagerstrom Test for Nicotine Dependence (FTND) score, number of quit attempts, and confidence in quitting. Questions on smoking status, daily cigarette consumption, and stage of change were also asked at the five consecutive intervention sessions.

Smoking status was validated by measurement of the expired CO concentration with a Micro Smokerlyzer (29). If the concentration of CO in expiratory air exceeded 8 ppm, the subject was classified as a smoker (30).

The main outcome measure was the CO-validated abstinence rate at 6 months. We defined smoking cessation in three different ways. Our primary definition of smoking cessation was the CO-validated point prevalence abstinence rate at 6 months. The other two outcome measures with more stringent criteria were the CO-validated two-point consecutive abstinence rate at 2 and 6 months and the four-point consecutive abstinence rate at all four follow-up sessions (at 1, 2, 4, and

Table 1 Comparison of the baseline characteristics of male and female smokers aged 20–69 years old between the intervention and the control groups

	Intervention group (N=500)	Control group (N=477)	p-value
Age (years)	44.5	44.8	0.616
Sex (%)			
Male	98.6	98.1	0.549
Female	1.4	1.9	
Stage of change (%)			
Immotive	27.3	26.9	0.828
Precontemplation	53.0	51.9	
Contemplation	12.0	14.0	
Preparation	7.7	7.1	
Age at the start of smoking (years)	20.4	20.4	0.837
Daily cigarette consumption	25.2	24.9	0.682
FTND score	4.6	4.7	0.528
Expired carbon monoxide (ppm)	26.0	25.6	0.607
Number of attempts to quit (%)			
Never quit	46.8	52.4	0.115
Quit once	20.2	20.6	
Quit 2 ~ 3 times	26.0	19.5	
Quit 4+ times	7.1	7.5	
Confidence in quitting (%)			
Almost none	55.2	58.4	0.364
Some	31.0	30.8	
A lot	13.8	10.8	

Note. FTND: Fagerstrom Test for Nicotine Dependence

Table 2 CO-validated abstinence rates at 6 months according to three different criteria

	Intervention group (N=500)	Control group (N=477)	Odds ratio	Test for significance
Abstinent at 6 months	13.6%	2.5%	5.4	p<0.001
Abstinent at both 4 months and 6 months	10.0%	1.9%	5.3	p<0.001
Abstinent at all four points (1, 2, 4, and 6 months) after initial intervention	3.6%	0.8%	4.5	p<0.005

6 months).

Subjects lost to follow-up and those whose report of cessation could not be confirmed biochemically were classified as current smokers. The percentages of those lost to follow-up at the initial intervention and the four follow-up sessions were 2.2%, 1.4%, 2.4%, 4.0%, and 4.8% in the smoking intervention group and 6.7%, 5.9%, 5.9%, 4.4%, and 6.3% in the control group, respectively. The percentage of those whose report of cessation could not be confirmed biochemically at the five consecutive sessions were 1.0%, 2.8%, 4.6%, 3.4%, and 4.6% in the smoking intervention group and 0.0%, 0.2%, 0.2%, 0.2%, and 0.6% in the control group, respectively.

Statistical analysis

Baseline characteristics by study groups were examined using chi-square for categorical variables and Student's t test for continuous variables. Associations of smoking intervention with outcome measures were examined through the use of chi-square tests. In cases in which the number of samples in a cell was small (less than 5) in 2 x n contingency tables to compare the categorical data, Fisher's exact test was used. All statistical analyses were performed using SPSS 10.0.

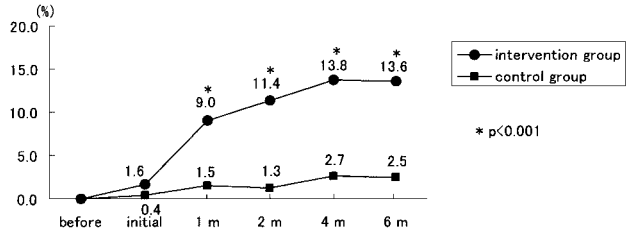
Results

Baseline characteristics of study groups

There were no differences between the intervention and control groups in baseline characteristics, including age, sex, stage of change, age at the start of smoking, daily cigarette consumption, FTND score, expired CO, number of attempts to quit, and confidence in quitting (Table 1).

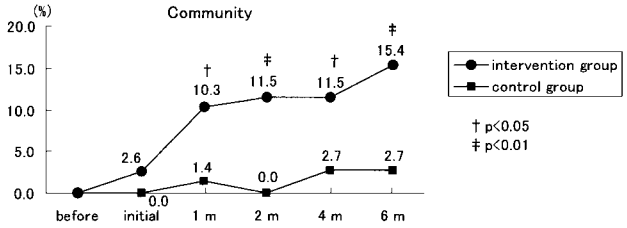
Smoking status outcomes

The point prevalence abstinence rate at 6 months in the intervention group (13.6%) was 5.4 times higher (p<0.001) than that in the control group (2.5%) (Table 2). When more stringent criteria of abstinence were applied in calculating the abstinence rate at 6 months, the differences were also significant, with odds ratios that remained almost constant as the stringency of abstinence increased.

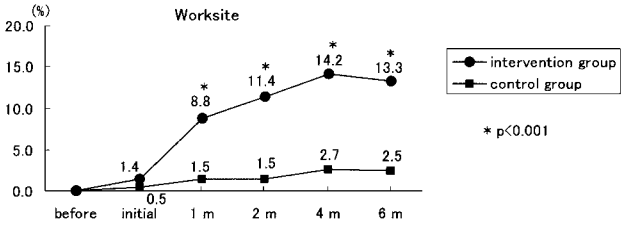


Note. Odds ratios of the abstinence rates were 6.0, 8.8, 5.1, and 5.4 at the four points from 1 to 6 months after the initial intervention, respectively.

Fig. 2 CO-validated abstinence rates by time from start of the intervention (n=500 for the intervention group, n=477 for the control group) in 72 study cites.

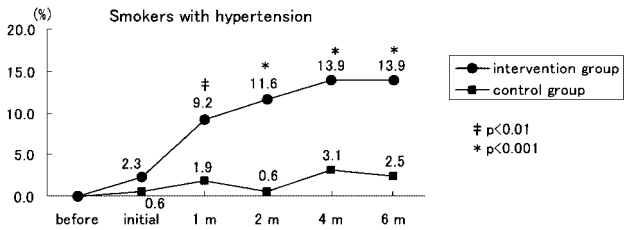


Note. Odds ratios of the abstinence rates were 7.4, ∞, 4.3, and 5.7 at the four points from 1 to 6 months after the initial intervention, respectively.

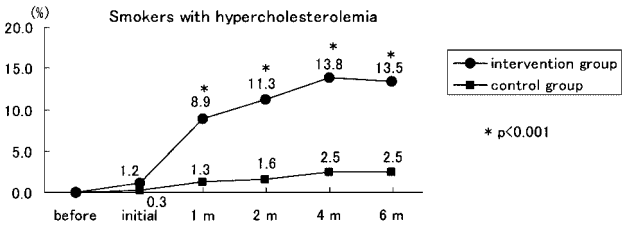


Note. Odds ratios of the abstinence rates were 5.9, 7.6, 5.3, and 5.3 at the four points from 1 to 6 months after the initial intervention, respectively.

Fig. 3 CO-validated abstinence rates by study site

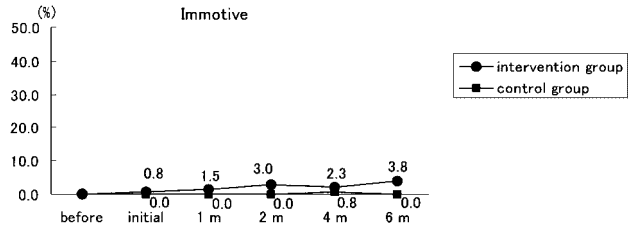


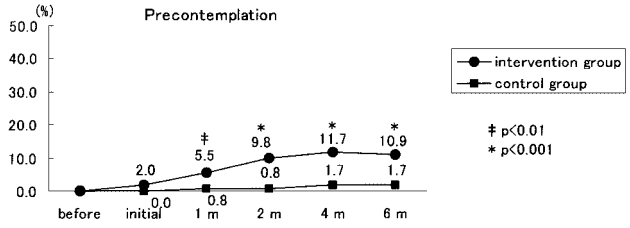
Note. Odds ratios of the abstinence rates were 4.8, 19.3, 4.5, and 5.6 at the four points from 1 to 6 months after the initial intervention, respectively.



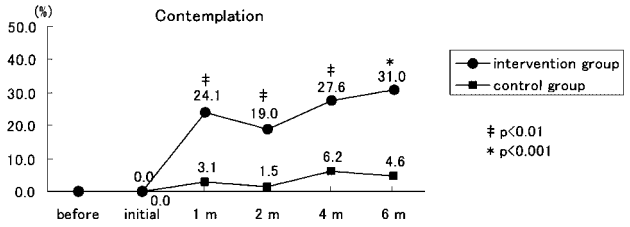
Note. Odds ratios of the abstinence rates were 6.8, 7.1, 5.5, and 5.4 at the four points from 1 to 6 months after the initial intervention, respectively.

Fig. 4 CO-validated abstinence rates by study subgroup

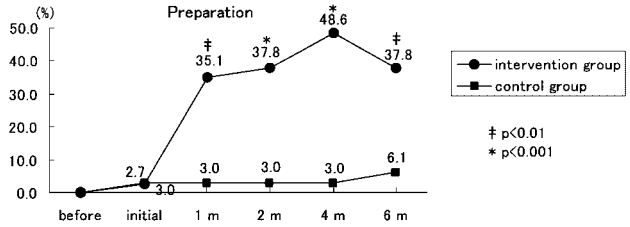




Note. Odds ratios of the abstinence rates were 6.9, 12.3, 6.9, and 6.4 at the four points from 1 to 6 months after the initial intervention, respectively.



Note. Odds ratios of the abstinence rates were 7.8, 12.7, 4.5, and 6.7 at the four points from 1 to 6 months after the initial intervention, respectively.



Note. Odds ratios of the abstinence rates were 11.7, 12.6, 16.2, and 6.2 at the four points from 1 to 6 months after the initial intervention, respectively.

Fig. 5 CO- validated abstinence rates by stage of change

The point prevalence CO-validated abstinence rates at each period from 1 month to 6 months in the intervention group were 5.1–8.8 times higher than those in the control group (Fig. 2). All the differences were significant.

The smoking outcomes at 6 months did not differ by study site (community, worksite) or by study subgroup (smokers with hypertension, smokers with hypercholesterolemia) (Figs. 3, 4). The odds ratios of point prevalence CO-validated abstinence rates at 6 months by study site were 5.7 at community ($p<0.01$) and 5.3 at worksite settings ($p<0.001$). The odds ratios were 5.6 among smokers with hypertension ($p<0.001$) and 5.4 among smokers with hypercholesterolemia ($p<0.001$).

The point prevalence CO-validated abstinence rates by stage of change at each period from 1 to 6 months in the intervention group were significantly higher than those in the control group among all stages of change except immotives, with the abstinence rates in both groups increasing as the stage of change shifted towards smoking cessation (Fig. 5). The odds ratios of the point prevalence abstinence rates at 6 months among smokers in precontemplation, contemplation, and preparation were 6.4 ($p<0.001$), 6.7 ($p<0.001$), and 6.2 ($p<0.01$), respectively.

Discussion

This is the first multisite randomized controlled study in Japan that has demonstrated the effects of a moderately intensive smoking intervention based on the transtheoretical model and implemented by trained health care providers. This study showed that repeated individual counseling to smokers unselected for their readiness to quit significantly increased by 5.4 times the point prevalence abstinence rate at 6 months. The intervention was effective despite stringent evaluation criteria at 6 months. There was a positive, consistent effect regardless of study site or subgroup. Therefore, these effects appear to be directly attributable to the intervention. Our intervention also succeeded in increasing the abstinence rates during the study period among smokers with a lower motivation to quit (precontemplators and contemplators) as well as those ready to quit (preparators). From the viewpoint of public health, this is significant because most existing smoking-cessation interventions target only motivated smokers, with few interventions having a positive effect in smokers with a lower motivation to quit.

There was no statistical difference in the abstinence rates among immotives between the intervention and control groups during the study period. This may be related to the characteristics of the immotives, who have decided to keep on smoking (26) and do not recognize smoking as a problem.

The odds ratio for smoking cessation in our study was higher compared to that in the two previous studies (11, 31), although nicotine replacement therapy was not used as part of the protocol in this study and the distribution of Japanese smokers by stage of change was shifted to a lower stage compared to smokers in the United States and other developed countries (32, 33). According to a recent meta-analysis of 18 randomized or quasi-randomized trials of the effects of individual behavioral counseling by the Cochrane Review (31), the odds ratio for smoking cessation was 1.62, which was significant (95% CI 1.35 to 1.94). This result was consistent with the review undertaken for the updated United States clinical practice guideline for treating tobacco use and dependence (11). The US review included an analysis of 58 trials and estimated the odds ratio to be 1.7 (95% CI 1.4 to 2.0) for smoking cessation with individual counseling compared to that with no intervention.

The impact of our intervention may be related to four factors. First, the intensity of our intervention was classified as moderately intensive, since it consisted of five sessions and an additional telephone follow-up contact to smokers who set a quit date (31). The intensity of the smoking intervention in previous studies varied and included a single session intervention (11, 31). In the Cochrane Review, 7 of the 18 studies used a brief

intervention with only a single session (31). There is a dose-response relationship between the intensity of the smoking intervention (e.g., number of intervention sessions and session lengths) and successful intervention outcome (11). Thus, the difference in the intensity of the interventions may account for the difference in the abstinence rates between our study and the results of the meta-analysis. Second, the duration of follow-up in our study was 6 months, which was shorter than that in previous studies. The previous studies provided outcome data with follow-up for at least 6 months or more after the initial intervention (31) or at least 5 months or more after the designated quit date (11). The shorter periods of our follow-up could yield higher abstinence rates. Since smokers are likely to relapse during follow-up periods, a short length of follow-up period is usually related to high abstinence rates. Third, the smokers in the control group had little chance to receive even a minimum smoking intervention or to quit voluntarily, because we used a "positive control group" as our control group. They, therefore, concentrated on other lifestyle changes for reducing hypertension or hypercholesterolemia. Studies designed with a "positive control" group may decrease the point prevalence abstinence rate in the control group to 2.5% at 6 months. Furthermore, in the studies included in the Cochrane Review (31), most control groups received the usual care or minimal intervention for smoking cessation by brief advice or self-help materials. This may account for the difference in results between our study and previous studies. Fourth, as the smoking prevalence in Japanese men is still higher than that in populations in other developed countries (4, 34), Japanese smokers may be more likely to quit smoking than those in other developed countries, although the level of motivation to quit smoking in Japanese smokers was lower compared to that in other developed countries (32, 33). Successful tobacco control is thought to result in a higher dependence among the remaining smokers due to selective quitting by low-dependent smokers (35). At the level of countries, the degree of nicotine dependence was negatively correlated with the prevalence of smoking (35). In addition to the level of nicotine dependence, the relative proportion of other types of "hard-core smokers" with comorbid psychological or psychiatric conditions among the total smoking population may increase with the success of tobacco control at a national level (36). Therefore, these differences in the characteristics of smokers between our study and the previous studies may extend to differences in the odds ratios.

Our study had methodological strengths. First, it was performed in a population recruited from smokers who received health check-ups in communities or worksites. Therefore, the study subjects did not actively volunteer to take part in the smoking intervention and had no special motivation to quit smoking. Second, a randomized controlled study design was used. The study groups were well matched at baseline, and follow-up rates were quite high and similar in the study groups. Fairly good adherence with the intervention was also obtained. Therefore, we consider that we could evaluate the effects of repeated individual counseling in an ideal setting. Third, we used an intention-to-treat analysis, except for two subjects who did not satisfy the inclusion criteria, with all subjects lost to follow-up being classified as smokers. As a result, a modest abstinence rate was estimated. Fourth, self-reports of smoking status were biochemically validated using expired CO. Biochemical markers for smoking are used to validate self-reports of smoking cessation in intervention studies. CO and cotinine are popular markers. Although cotinine has a higher sensitivity and specificity than CO, CO is more convenient to measure and is only modestly less useful (37, 38).

Our study also had some limitations. First, the duration of the follow-up was relatively short and limited to the treatment period. Most relapses take place within 3 months of cessation (6, 39). A point prevalence measure taken at 6 months would certainly capture the great majority of those relapse events (11). However, it is desirable to conduct a follow-up survey after an intervention-free period. Second, there were few female subjects in our study. It is uncertain whether the study results would be applicable to a female smoking population. Further research is needed to clarify the intervention effect on female smokers. Third, our smoking cessation program was effective, but moderately intensive. Considering its dissemination into health care settings, it will be difficult for health care providers to use it in routine health services such as at an outpatient clinic or health check-up setting, because the time allotted for behavioral counseling in these settings is limited. From a public health perspective, health care settings have an excellent potential to yield many quitters if effective programs are successively combined into routine health services. Therefore, further research is needed on the development of a brief smoking intervention program tailored for use in an outpatient clinic or health check-up setting, and the development of a training program for health care providers. Intervention studies are also needed to examine the effects of the programs.

In conclusion, we showed the effects of repeated individual behavioral counseling to smokers unselected for their readiness to quit. This result suggests that stage-matched individual counseling based on the transtheoretical model is effective in smokers with a lower motivation to quit, as well as in those ready to quit.

Acknowledgements

This study is a part of the cooperative study for " High-risk Strategy by Lifestyle Modification (HISLIM) study" supported by Funds for Comprehensive Research on Long-Term Chronic Disease 1995–1997 from the Ministry of Health and Welfare, Japan.

The authors thank Minoru Ida, Yukinori Kusaka, Hideaki Nakagawa, and Yasuyuki Nakamura for their efforts conducting this research. The authors are also thankful to the staff of the study sites that participated in this study.

References

(1) Fagerstrom K. The epidemiology of smoking. Health consequences and benefits of cessation. Drugs 2002; 62 suppl. 2: 1–19.

(2) Kuper H, Adami HO, Boffetta P. Tobacco use, cancer causa-

tion and public health impact. J. Intern. Med. 2002; 251: 455–466.
(3) Peto R, Lopez AD, Boreham J, Thun M. Mortality from smoking in developed countries 1950–2000 (2nd edition). http://www.ctsu.ox.ac.uk/~tobacco/.
(4) Ministry of Health, Labour and Welfare: The National Nutrition Survey in Japan, 2001. Tokyo: Daiichi Shupan (in Japanese).
(5) Nakamura M. Effective intervention for smoking cessation. Practical guidance for medical facilities including smoking cessation clinics. JMAJ 47: 97-104, 2004.
(6) US Department of Health and Human Services: The Health and Consequences of Smoking. Nicotine Addiction: a report of the Surgeon General. US Department of Health and Human Services, DHHS Publication No. (CDC) 88-8406, Washington DC, 1988.
(7) The Tobacco Use and Dependence Clinical Practice Panel, Staff, and Consortium Representatives. A Clinical Practice Guideline for Treating Tobacco Use and Dependence. A US Public Health Service Report. JAMA 2000; 283: 3244–3254.
(8) The World Bank. Curbing the epidemic. Governments and the economics of tobacco control. Washington DC: The International Bank for Reconstruction and Development, 1999.
(9) Department of Health. Smoking Kills. A white paper on tobacco. London: Stationary Office, 1998.
(10) Department of Health. Report of the scientific committee on tobacco and health. London: Stationary Office, 1998.
(11) US Department of Health and Human Services: Clinical Practice Guideline: Treating Tobacco Use And Dependence. US Department of Health and Human Services, Washington DC, 2000.
(12) Raw M, McNeill A, West R. Smoking cessation guidelines for health professionals. A guide to effective smoking cessation interventions for the health care system. Thorax 1998; 53 (Suppl 5, Part 1).
(13) Parrot S, Godfrey C, Raw M, West R, McNeill A. Guidance for commissioners on the cost-effectiveness of smoking cessation interventions. Thorax 1998; 53 (Suppl 5, Part 2)
(14) Akahane K, Anada K, Arino M, Ono A, Tomonaga M, Nakabayashi M, Nishida M, Yamakawa N, Yoshitsugu M, Shimo T, Ohi T, Tokudome O, Minowa M, Mori H, Tango T, Fujita T, Uehata T. Efficacy of individual smoking cessation instructions for general smokers among clients of a health center. Nippon-Koshu-Eisei-Zasshi 1992; 39: 199–204 (in Japanese).
(15) Higashi A, Ozasa K., Watanabe Y, Hayashi K, Aoike A, Kawai K, Nakazawa A, Takahara S, Nishimura S. Efficasy of smoking cessation instruction for general smokers at an annual physical examination. Nippon-Koshu-Eisei-Zasshi 1995; 42: 313–321 (in Japanese).
(16) Ogawa H. Smoking cessation at a specialized hospital for cancer treatment center. Journal of Japan Medical Association. 1996; 116: 365–368 (in Japanese).
(17) Kadowaki T, Watanabe M, Okayama A, Hishida K, Ueshima H. Effectiveness of smoking-cessation intervention in all of the smokers at a worksite in Japan. Ind. Health. 2000; 38: 396–403.
(18) Shimizu J, Kita Y, Kai K, Okayama A, Choudhury SR, Kawashima J, Ueshima H. Randomized controlled trial for smoking cessation among city office employees. Nippon-Koshu-Eisei-Zasshi 1999; 46: 3–13 (in Japanese).
(19) Shimizu H, Fukao A, Hisamichi S, Sugahara N. A study of the effect of individual anti-smoking advice by physicians. Nippon-Koshu-Eisei-Zasshi 1985; 32: 698–702 (in Japanese).
(20) Ozasa K, Higashi A, Shiroeda O, Watanabe Y, Aoike A, Kawai K, Nishimura S. A study of smoking cessation education in a human dock setting. Nippon-Koshu-Eisei-Zasshi 1991; 38: 45–51 (in Japanese).
(21) Prochaska JO, Clemente CC, Norcross JC. In search of how people change. Applications to addictive behaviors. Am. Psychol. 1992; 47: 1102–1114.
(22) Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. Am. J. Health. Promot. 1997; 12: 38–48.
(23) Nakamura M, Oshima A. An instructor manual for smoking cessation counseling. (Kinen—shido—puroguramu—shidosha—yo—manuaru), Tokyo: Houken, 1995 (in Japanese).
(24) Jarvis M, Belcher M, Versey C, Hutchison D. Low cost carbon monoxide monitors in smoking assessment. Thorax 1986; 41: 886–888.
(25) Nakamura M, Oshima A. Smoking cessation self help guide. (Kinen—serufu—herupu—gaido), Tokyo: Houken, 1995 (in Japanese).
(26) Dijkstra A, Roijackers J, Vries HD. Smokers in four stages of readiness to change. Addict. Behav. 1998; 20: 339–350.
(27) Dijkstra A, De Vries H. Subtypes of precontemplating smokers defined by different long-term plans to change their smoking behavior. Health. Educ. Res. 2000; 15: 423–434.
(28) Prochaska JO, Goldstein MG. Process of smoking cessation. Implications for clinicians. In: Samet JM, Coultas DB, editors. Clinics in chest medicine. Smoking cessation. Philadelphia: W.B. Saunders company Harcourt Brace Jovanovich, Inc., 1991; 12: 727–735.
(29) Micro Smokerlyzer. Bedfont Scientific Ltd., UK.
(30) Irving JM, Phil M, Clark EC, Crombie IK, Smith WCS. Evaluation of a portable measure of expired-air carbon monoxide. Prev. Med. 1988; 17: 109–115.
(31) Lancaster T, Stead LF. Individual behavioral counseling for smoking cessation (Cochrane Review). In: The Cochrane Library, Issue 4, 2003. Chichester: John Wiley & Sons, Ltd.
(32) Osaka Prefectural Government Bureau of Health and Hygiene: Survey on Health and Lifestyle of Residents in Osaka: a report of the Survey. Osaka Prefectural Government Bureau of Health and Hygiene, Osaka, 1998 (in Japanese).
(33) Etter JF, Perneger TV, Ronchi A, Sociol D. Distributions of smokers by stage: international comparison and association with smoking prevalence. Prev. Med. 1997; 26: 580–585.
(34) Forey B, Hamling J, Lee P, Wald N. International smoking statistics. A collection of historical data from 30 economically developed countries, second edition. New York: Oxford University Press Inc., 2002.
(35) Fagerstrom KO, Kunze M, Schoberberger R, Breslau N, Hughes JR, Hurt RD, Puska P, Ramstrom L, Zatonski W. Nicotine dependence versus smoking prevalence: comparisons among countries and categories of smokers. Tob. Control. 1996; 5: 52–56.
(36) Seidman, DF, Covey LS. Helping the hard-core smoker. A clinician's guide. New Jersey: Lawrence Erlbaum Associates, Inc., 1999.

(37) Jarvis MJ, Tunstall-Pedoe H, Feyerabend C, Vesey C, Saloojee Y. Comparison of tests used to distinguish smokers from non-smokers. Am. J. Public Health. 1987; 77: 1435–1438.
(38) Murray RP, Connett JE, Lauger GG, Voelker HT. Error in smoking measures: effects of intervention on relations of cotinine and carbon monoxide to self-reported smoking. Am. J. Public Health. 1993; 83: 1251–1257.
(39) Abrams DB, Emmons KM, Niaura R, Goldstein MG, Sherman CB. Tobacco dependence: an integration of individual and public health perspectives. Annual Review of Addictions Research and Treatment. 1991: 391–436.