Original Article

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A Pilot Randomized Controlled Trial of a Non-pharmacological Smoking Cessation Program for Males with Chronic Obstructive Pulmonary Disease in Japan

Takeo Yamamura, Ph.D. candidate (M.A.)[1,2], Katsuyoshi Mizukami, M.D., Ph.D.[2]

[1]Faculty of Human Sciences, Sophia University, Shimoochiai 4-16-11, Shinjyuku Ku, Tokyo, Japan.

[2]Graduate School of Comprehensive Human Sciences, University of Tsukuba, Tennodai 1-1-1, Tsukuba, Ibaraki, Japan.

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Abstract:

Objective: Smoking cessation is considered the most reliable approach for preventing the worsening of chronic obstructive pulmonary disease (COPD). However, the majority of the previous studies on the effectiveness of non-pharmacologic smoking cessation support methods for people with COPD have been conducted in European and North American populations. This study aimed to fill a gap in the knowledge by focusing on the Japanese population.

Material and Methods: This pilot randomized controlled trial included Japanese male participants aged above 50 years, diagnosed with COPD. Participants were allocated equally to the intervention group and the control group. The intervention group received a non-pharmacological cessation program developed in this study (twice online) in addition to outpatient smoking cessation at the collaborating institutions (5 visits in 12 weeks). The control group received only outpatient smoking cessation treatment at the collaborating medical institutions.

Results: In total, 12 males (6 each in both groups) participated. No participants in the intervention group reported a tendency to smoke unconsciously, and none had resumed smoking. This suggests that the program was effective in helping participants maintain their motivation to quit smoking after the end of smoking cessation visits. Because of the small sample size, no statistically significant difference was observed in the smoking cessation rates between the 2 groups. However, the effect size between the 2 groups was large (Φ=0.517).

Conclusion: The non-pharmacological cessation program developed in this study may be effective for males aged over 50 years with COPD in Japan.

Keywords: chronic obstructive pulmonary disease, COPD, Japan, males, non-pharmacological, smoking cessation

Contact: Takeo Yamamura, Ph.D. candidate (M.A.)
Faculty of Human Sciences, Sophia University, Shimoochiai 4-16-11, Shinjyuku Ku, Tokyo, Japan.
E-mail: t-yamamura@eagle.sophia.ac.jp

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Introduction

Chronic obstructive pulmonary disease (COPD) is an inflammatory disease of the lungs caused by the long-term inhalation of toxic substances, mainly tobacco smoke; the incidence and mortality rates of COPD are increasing worldwide. Smoking cessation is the most reliable approach to prevent the aggravation of COPD[1]. However, people with COPD are generally more dependent on nicotine than people without COPD, and they may need smoking cessation support measures that are different from those intended for general smokers[2-4]. Drugs such as varenicline are sometimes used to help people quit smoking; however, varenicline causes psychiatric symptoms, including suicidal thoughts, as a side effect[5]. Furthermore, varenicline production has been suspended since 2021 owing to above-threshold carcinogen levels being detected. These circumstances have resulted in many medical institutions suspending their smoking cessation clinics. Therefore, effective non-pharmacological smoking cessation support methods are needed for patients with COPD.

Most previous studies on the effectiveness of non-pharmacological smoking cessation support methods for people with COPD have involved European and North American populations[6,7]. To the best of our knowledge, no such study has included Japanese patients. According to a study involving older males with COPD in Japan, people with COPD in Japan have different social environments and psychological conditions than their counterparts in Western countries[8]. Therefore, methods that are effective for patients with COPD in other countries may not be effective if applied directly to such patients in Japan. Although numerous randomized controlled trials on smoking cessation programs for people with COPD have been published in various countries, few have clarified the details of these programs[7].

Published studies have revealed effective non-pharmacological smoking cessation support methods, with methodology based on findings reported in systematic reviews and meta-analyses of previous studies, for people with COPD[7], and the reasons why middle-aged and older (aged 50 years or older) males with COPD in Japan have been able to stop smoking[9]. In this study, we examined the effectiveness of a pilot non-pharmacological smoking cessation program for Japanese males of middle age and older with COPD, based on the results of these studies. In addition, this study describes the program in detail in order to serve as a reference for future researchers implementing similar programs in other countries, including Japan.

Material and Methods

Participants

The participants were males aged 50 years or older who had been diagnosed with COPD, who had received (or were scheduled to receive) smoking cessation treatment covered by medical insurance at multiple cooperating medical institutions in Japan, and who were referred by the cooperating medical institutions after having granted consent to participate in the study. The participants were referred in cooperation with medical institutions. Those diagnosed with dementia or severe mental illness were considered ineligible for participation. In Japan, the following 4 conditions must be met in order to receive outpatient smoking cessation treatment covered by medical insurance[10]:

(1) Diagnosis of nicotine dependence by a screening test for nicotine dependence.

(2) Patients aged 35 years or older with a Brinkman index of 200 or higher.

(3) The patient has the desire to quit smoking immediately.

(4) The patient has received an explanation of the smoking cessation treatment by the Standard Procedures for Smoking Cessation Treatment[11] and has granted written consent to undergo such treatment.

Under the Japanese health insurance program, smoking cessation treatment consists of 5 visits over a

12-week period along with counseling and pharmacology; nicotine patches are also provided by physicians.

Research method and program content details

All participants were randomly assigned to either the intervention or control group in the order in which they agreed to participate in the study at each medical institution. The assignment was performed using computer-generated random numbers with block randomization for each two-person group. Neither the participants, intervention providers, nor outcome assessors were blinded to the intervention, as the intervention was delivered only to the intervention group; the authors were involved in conducting the intervention and evaluating the intervention outcomes.

In addition to the outpatient smoking cessation treatment provided by the collaborating medical institutions (5 visits in 12 weeks), the program developed in this study was administered to the intervention group, twice online (via Zoom ver.5.12.6), during the 12 weeks following their first visit to the smoking cessation clinic. The participants received the program at home, while the intervention provider conducted the program and collected data in the laboratory. The contents of the program, provided only to the participants in the intervention group, are listed in the upper half of Table 1. The contents of the program have been thought to be effective by previous studies[7-9]. The maximum program length was 30 minutes per session, and participants were asked the questions in Table 2 at the first session. In contrast, the control group received only the outpatient smoking cessation treatment provided by the collaborating medical institutions. Therefore, in the intervention group, all items in Table 1 were implemented, whereas in the control group, only the items in the lower half of Table 1 (i.e., the Standard Procedures for Smoking

Table 1 the content of the program provided to the intervention group only and the standard procedures for smoking cessation treatment administered to both groups

The content of program added only for participants in the intervention group	
1.	Conduct motivational interviews.
2.	Encourage participants to become aware of smoking to smoking without conscious thought.
3.	Emphasize that the threat to life and health from diseases other than COPD* diminishes with smoking cessation (although COPD may be emphasized in home oxygen therapy users because they are likely to be aware of COPD).
4.	Explain the anticipated consequences of quitting smoking (or encourage participants to verbalize the anticipated consequences of quitting smoking).
5.	Emphasize the financial burden for those who do not have employment or who are retired.
6.	If family members do not want participants to smoke, get the family members to be actively involved in the smoking cessation process.
7.	Urge older participants to take care of their health because of their advanced age.
The content of the standard procedures for smoking cessation treatment	
8.	For those who have once quit smoking but have resumed smoking, elicit reasons, duration of smoking cessation, and reasons for resuming smoking.
9.	Advise those who are not confident in their ability to quit smoking to become confident in their abilities.
10.	Seek support from family, friends, colleagues, and other familiar people.
11.	Discuss weight gain (especially in the latter half of the treatment period).
12.	Praise the patient when he has been able to quit smoking.
13.	If the patient is unable to quit smoking, discuss the situation and consider means of relieving anxiety (If the patient's motivation to quit smoking de-creases, reiterating the need to quit smoking).
14.	Keep daily records.

COPD=chronic obstructive pulmonary disease

Cessation Treatment) were implemented. The sale of varenicline, a commonly used smoking cessation drug in Japan, was suspended throughout the study period; therefore, varenicline was not used for smoking cessation treatment at any of the collaborating medical institutions.

All participants were administered smoking cessation questionnaires (Table 3) 12 and 24 weeks after their first outpatient smoking cessation visit at the collaborating institution. The primary outcome of the study was the smoking cessation rate 24 weeks after the first outpatient visit to the collaborating institutions. The participants in the intervention group who participated in both sessions of the online program and responded to both questionnaires at 12 and 24 weeks after their first visit to the smoking cessation outpatient clinic received a 500 Japanese yen voucher as a reward, regardless of whether they had completed the smoking cessation treatment at the collaborating medical institution. Participants in the control group were given a 500 Japanese yen voucher as a reward if they responded to both questionnaires at 12 and 24 weeks after their first visit to the smoking cessation clinic, regardless of whether they had completed smoking cessation treatment at the participating medical institution.

This study was conducted in accordance with the CONSORT statement[12]. This study was registered as a clinical trial in the UMIN Clinical Trials Registry System (UMIN ID: UMIN000048212).

Table 2 Contents of the pre-intervention questionnaire

- Age and occupation.
- Whether they were living with family members. If the participant was living with family members, they were asked to describe their family members' attitude toward smoking using a five-point Likert scale.
- Currently receiving home-based oxygen therapy or not.
- Select the reasons for smoking tobacco: It is fun, for socializing, somewhat habitual, to relieve stress, or they feel uncomfortable if they did not smoke
- For how many years had they smoked cigarettes, and how many cigarettes did they smoke per day on average. (The Brinkman index was then calculated.)
- Have they tried to quit smoking but failed? If they had unsuccessful experiences, they were asked to explain why they were unsuccessful.
- Select the symptoms that were frequently experienced: Shortness of breath, cough, sputum, heart palpitations, wheezing, or no specific symptoms.
- Mention the diseases, other than COPD, that they have been diagnosed with.

COPD=chronic obstructive pulmonary disease

Table 3 Contents of the post-intervention questionnaires

- Age (years). (12 weeks after only)
- How many times did you visit a smoking cessation clinic? (12 weeks after only)
- Has the smoking cessation continued?
- Have your thoughts or perceptions of smoking changed after participating in this smoking cessation program (answer using the three-point Likert-type scale: changed considerably, changed slightly, and did not change)? If yes, describe how they changed.
- Have your thoughts or perceptions of COPD changed after participating in this smoking cessation program (answer using the three-point Likert-type scale: changed considerably, changed slightly, and did not change)? If yes, describe how they changed.

COPD=chronic obstructive pulmonary disease

Survey Items

In addition to whether participants had quit smoking at the time of the 2 follow-up visits (12 and 24 weeks after the first visit to the smoking cessation clinic), the survey also included questions on the number of times they had attended smoking cessation clinics at the collaborating institutions and whether their thoughts on smoking or smoking cessation had changed due to their visits to the smoking cessation clinics and or participation in the study program. The participants responded using a three-point Likert-type scale, a 'Yes' or 'No' response, or free text (including numerical entries).

Duration

November 2022 to April 2024.

Statistical analysis

The data were compared between the intervention and control groups. Fisher's exact probability test or t-test was used to test for differences between the 2 groups. R (ver. 4.3.2) was used for the statistical analysis. The two-sided significance level was set at 5%.

Ethical considerations

This study was conducted in compliance with the principles of the Declaration of Helsinki. This study was approved by the Ethics Committee of the Sophia University (Approval No. 2022-049). In addition to oral and written explanations by the attending physician, the participants were given a written statement explaining that their cooperation in the research was not obligatory, that their medical treatment at the collaborating medical institution would not be affected if they refused to cooperate, and that they could withdraw their consent at any time, even after providing their consent to cooperate with the research. Written informed consent was obtained from all the participants. When implementing the program for the participants in the intervention group, we always paid attention to their health conditions, including respiratory status.

Results

Twelve participants, 6 each in the intervention and control groups, were included. A flowchart detailing participant selection is shown in Figure 1. One participant in the control group did not respond to the second questionnaire, indicating that he had not quit smoking at the time of the first questionnaire. Table 4 shows the mean age of participants in the intervention and control groups, and the results 12 and 24 weeks after initiation of treatment.

Table 5 summarizes the results of the pre-intervention questionnaire administered to the intervention group. Table 6 shows a summary of the responses to questions in the post-intervention questionnaire, other than whether the participants had quit smoking. None of the participants reported any significant adverse events associated with the program.

Owing to the small sample size, no significant difference was observed in the smoking cessation rates between the intervention and control groups at any time point. However, in terms of effect size, a difference of Φ (effect size between binary variables)=0.517 was observed between the 2 groups after 24 weeks from the first visit to the smoking cessation clinics. If both the intervention and control groups had had 6 participants, the difference in effect size between the 2 groups would have been Φ=0.577. The lower limit of the 95% confidence interval was 0.012.

In the intervention group, all the participants had been able to quit smoking at both 12 and 24 weeks after their first visit to the smoking cessation clinics. However, some variations in the characteristics of each participant, such as occupation, Brinkman index, and medical history, were observed. In the control group, one participant had resumed smoking at 12 weeks and 2 participants had resumed smoking at 24 weeks.

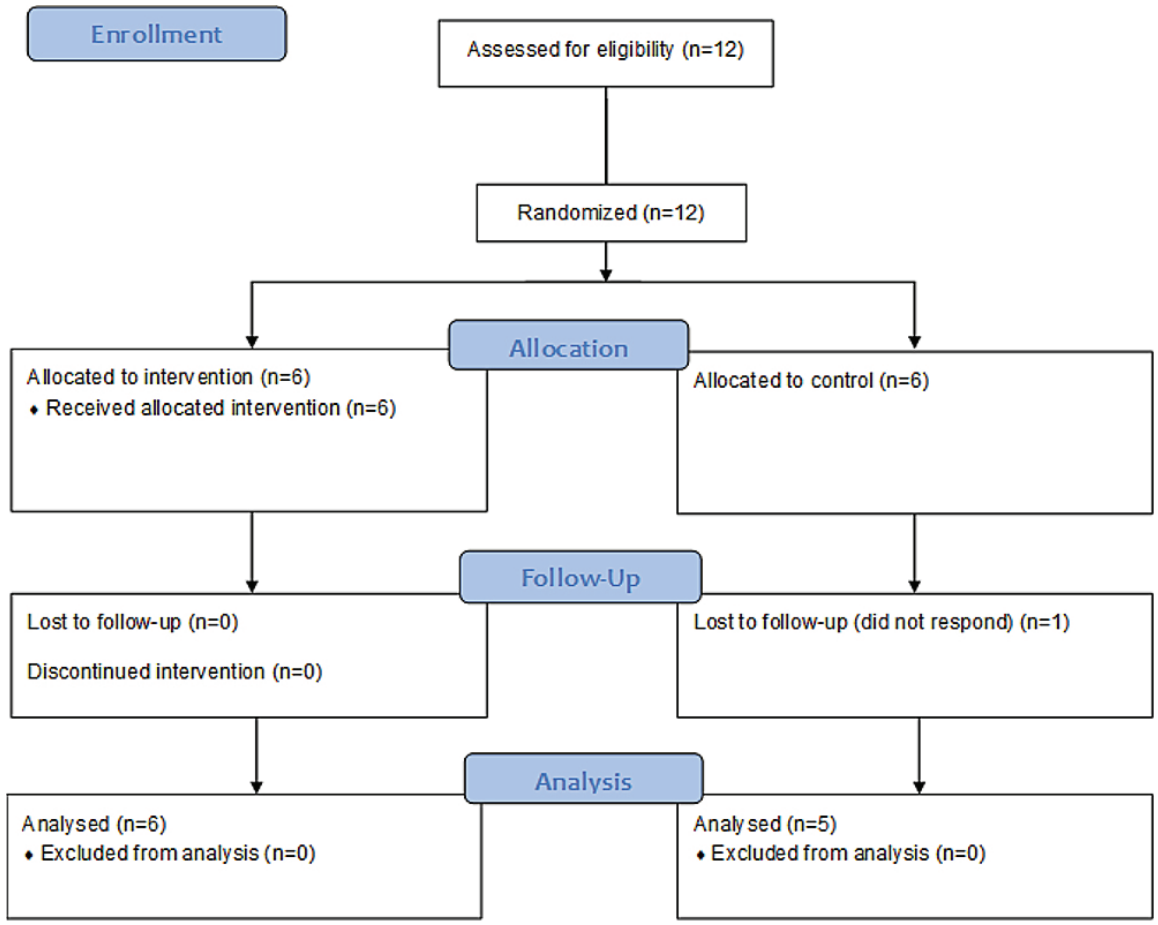

Figure 1 Participant selection flowchart

Table 4 Summary of results

	Intervention group (n=6)	Control group (n=6*)	p-value	effect size (Φ)
Age (years, S.D.)	63.50±4.04	64.00±5.97	0.882	
No. of quitters after 12 weeks	6	5	1.000	
No. of quitters after 24 weeks	6	3	0.182	0.517

*Five participants were analyzed after 24 weeks in the control group, The p-value for age was calculated using a t-test, and the p-values for the number of quitters after 12 and 24 weeks were calculated using Fisher's exact probability test. S.D.=standard deviation

Table 5 Pre-intervention questionnaire results for the intervention group

Question	Answer	Number of respondents
Job	Full-time	3
	Part-time	1
	Unemployed	2
Have family member living with	Yes	4
	No	2
Family member's attitude toward smoking (those living with family member only)	Dislike strongly	1
	Dislike	2
	Neutral	0
	Not dislike so much	0
	Not dislike at all	1
Receiving home oxygen therapy	Yes	0
	No	6
Reasons for smoking (multiple responses allowed)	It is fun	0
	For socializing	1
	Somewhat habitual	6
	To relieve stress	3
	Uncomfortable if do not smoke	2
Smoking cessation failure experience	Yes	5
	No	1
Reasons for smoking cessation failure (free answer, those have smoking cessation failure experience only)	Work-related stress	2
	Encouraged to smoke around people when drinking	1
	People around were smoking	1
	Smoking unconsciously	1
Number of years smoking	35 to 39 years	2
	40 to 44 years	1
	45 to 49 years	2
	50 to 54 years	1
Average number of cigarettes smoking per day	10 to 19 cigarettes	3
	20 to 29 cigarettes	1
	30 to 39 cigarettes	1
	40 to 49 cigarettes	1
Brinkman Index (the number of cigarettes smoked per day multiplied by the number of years of smoking)	401 to 500	2
	601 to 700	1
	1001 to 1100	1
	1201 to 1300	1
	1501 to 1600	1
Diseases have been diagnosed with other than COPD (free answer, multiple answers allowed)	Hypertension	3
	Lung cancer	2
	Interstitial pneumonia	2
	Depression	1
	Reflux esophagitis	1
	Gallbladder polyps	1
	Angina pectoris	1
	Prostate enlargement	1
	Dyslipidemia	1
	Diabetes mellitus	1

COPD=chronic obstructive pulmonary disease

Table 6 Results of the post-intervention questionnaires for both groups

Question	Answer	Intervention group	Control group*
Number of visits to outpatient smoking cessation clinics	5 times (completed)	6	5
	3 times	0	1
Change in perception of smoking after participating in this smoking cessation program (as of 12 weeks after)	Changed considerably	2	2
	Changed slightly	4	3
	Not changed	0	1
Change in perception of COPD* after participating in this smoking cessation program (as of 12 weeks after)	Changed considerably	1	0
	Changed slightly	0	1
	Not changed	5	5
Change in perception of smoking after answering the first post-intervention questionnaire (as of 24 weeks after)	Changed considerably	0	0
	Changed slightly	1	2
	Not changed	5	3
Change in perception of COPD† after answering the first post-intervention questionnaire (as of 24 weeks after)	Changed considerably	0	0
	Changed slightly	0	0
	Not changed	6	5

*One of the participants in the control group did not respond to the second post-intervention questionnaire (24 weeks after), COPD=chronic obstructive pulmonary disease

In the first post-intervention questionnaire, all 6 participants in the intervention group and 5 in the control group answered 'No' to the question of whether their perception of smoking had changed, whereas only one participant in both the intervention and control groups answered 'No' to the question of whether their perception of COPD had changed. In the second post-intervention questionnaire, one participant each in the intervention and control groups answered something other than 'No' to the question of whether their perception of smoking had changed. In the second post-intervention questionnaire, one participant in the intervention group and 2 in the control group answered 'No' to the question on whether their perceptions of smoking had changed. The free-response statements of these participants indicated that the negative image of cigarettes and smoking was further reinforced in the intervention group ("breathing is easier than before I quit smoking and I've realized that smoking is bad for my health"), whereas the participants in the control group seemed to have smoked without conscious thought ("I know it is bad for my health, but I find myself smoking"; "I tend to smoke in my spare time"). The control group participants were more likely to smoke without conscious thought.

Discussion

According to data from Japan's Ministry of Health, Labour and Welfare, approximately 30% of patients, including those who have not been diagnosed with COPD, visit smoking cessation outpatient clinics until the fifth (final) visit[13]. In contrast, in our study, 100% of the participants in the intervention group and 83% of the participants in the control group attended outpatient smoking cessation clinics until their last visit.

In Japan, the quitting rate at 12 weeks after the first visit to an outpatient smoking cessation clinic for males who do not use varenicline in an outpatient smoking cessation clinic is approximately 60%[14]. In the present study, both the intervention and control groups had higher cessation rates of 100% and 83%, respectively, at 12 weeks after the first visit to the smoking cessation outpatient clinics. The high

proportion of participants who had visited smoking cessation outpatient clinics for up to 5 visits suggests that many participants in both groups had a relatively high motivation to quit smoking until the last of the outpatient clinic visits. In contrast, none of the participants in the intervention group resumed smoking during the 12 weeks after the final visit, whereas 2 of the 5 participants in the control group resumed smoking, indicating a widening gap between the 2 groups during the 12 weeks.

A study by Higashiura et al.[15] analyzed the status of smoking resumption since the end of smoking cessation visits in Japan: approximately 20% of male participants, including those without a diagnosis of COPD, who visited a smoking cessation clinic for up to 12 weeks (i.e., from the first visit to after 24 weeks) resumed smoking. In addition, van Eerd et al.[3] suggested that smokers with COPD may have higher nicotine dependence than nonsmokers, making it more difficult for them to maintain their smoking cessation status. In the present study, a higher percentage of participants in the control group than in the intervention group resumed smoking in the 12 weeks after completing the program; participants who resumed smoking answered that they tended to smoke without consciously thinking about it. This confirms the suggestion of van Eerd et al.[3] that smokers with COPD are more dependent on nicotine than general smokers and have difficulty continuing to abstain from smoking. However, no participants in the intervention group responded that they unconsciously tended to smoke and none of the participants had resumed smoking, suggesting that the program was effective in helping the participants maintain the motivation to quit smoking after the smoking cessation visits.

Owing to the small sample size, no significant difference in smoking cessation rates was observed between the 2 groups. However, a difference of Φ=0.517 was found between the 2 groups, where 0.1 indicates a small effect, 0.3 a moderate effect, and 0.5 a large effect[16]. Therefore, the intervention effect was large. The fact that the lower limit of the 95% confidence interval for Φ was 0.012, which is greater than 0, when the effect size was calculated assuming that the one dropout case in the control group had also resumed smoking at 24 weeks after their first visit to the smoking cessation clinic, supports the large effect of this intervention program.

Only a small number of participants in both groups reported that their perception of COPD had changed, and all the participants in the intervention group had successfully quit smoking. This means that although the intervention did not change the participants' perceptions of COPD to any significant degree, it did lead to quitting attempts that were more successful than those in the control group. Awareness of COPD is not strongly linked to smoking cessation[8,9], that is, placing emphasis on the link between COPD and smoking habits does not lead to smoking cessation in middle-aged and older Japanese males.

This study had 5 limitations. First, during the study period, most smoking cessation clinics in Japan were closed, making it extremely difficult to find participants. As a result, the number of participants became small. Because of the small sample size, the data collected may have been biased. Second, owing to the nature of the research program, the intervention provider and outcome evaluator (both of whom were also investigators in the study), as well as the participants, were not blinded; therefore, the possibility of bias in their evaluation cannot be ruled out. Third, because intending to quit smoking immediately is a condition for smoking cessation insurance coverage in Japan, all participants in this study were in the preparation stage of the stages of change model (or the transtheoretical model)[17] when they started the smoking cessation visits; if the smokers had continued to quit by the time they completed the second post-intervention questionnaire 24 weeks after their first visit, they would have entered the maintenance stage and have been likely to continue the cessation. However, the possibility of the results being different at later time points cannot be ruled out. Fourth,

due to Coronavirus disease 2019 (COVID-19) infection prevention measures, most medical institutions did not conduct pulmonary function tests or cotinine level tests during the study period in Japan[18]. In particular, none of the participants in this study received these tests. Therefore, objective evidence such as carbon monoxide levels in breath or cotinine levels before and after treatment were not recorded for both the intervention and the control groups. Fifth, this study relies on self-reported data regarding smoking habits and cessation, which can be subject to bias. Participants may underreport smoking behavior due to social desirability or recall bias. However, this bias likely applies not only to the intervention group but also to the control group, and therefore, it is unlikely to have led to an overestimation of the intervention effects in this study.

Conclusion

This randomized controlled trial piloted a non-pharmacological smoking cessation support program for males aged over 50 years with COPD. Although no statistically significant difference was observed in smoking cessation rates between the intervention and control groups 24 weeks after the first visit to the smoking cessation clinic, possibly owing to the small sample size, the effect size was significant. These results suggest that the program may be effective for males with COPD who are 50 years and older in Japan, even if conducted online, and it also indicates that this program may be effective for those living in remote areas.

Conflict of interest

There are no potential conflicts of interest to declare.

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