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A study on improving sleep quality in COPD patients through inhalation management education by nurses using video conferencing tools

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Ⅰ. Background and Significance of the Study

COPD is associated with sleep-disordered breathing (SDB) due to multiple factors, including airflow obstruction and lung hyperinflation in the emphysematous type [Know et al, 2009], hypercapnia caused by reduced ventilation during sleep [Lee et al, 2019] and nocturnal SaO2 levels below 90%[Czerwaty et al, 2022]. Many patients with COPD have been reported to exhibit a tendency toward impaired sleep quality [Azuma, 2014. Climaco, 2022].

In Japan as well, it has been demonstrated that reduced sleep quality among male urban workers with COPD is significantly associated with sleep-disordered breathing (SDB) [Azuma, 2014]. Poor sleep quality in patients with COPD is associated with worsening health status [Lin, 2023. Shorofsky, 2019], increases the risk of exacerbations, and hampers symptomatic improvement [Lin, 2023]. Although appropriate interventions to improve sleep quality are warranted, healthcare providers have relatively few opportunities to address sleep status or the daytime consequences of poor sleep in this patient population.

Bronchodilators, the mainstay of COPD treatment, are predominantly administered via inhalation, allowing direct delivery to the lungs and thereby ensuring therapeutic efficacy while minimizing systemic side effects. Bronchodilators, such as β2-agonists and anticholinergic agents, have been reported to increase FEV_1 and improve average nocturnal SaO_2. However, incorrect inhalation technique may reduce their efficacy, leading to insufficient therapeutic effects [Sulaiman, 2016] . Furthermore, some studies have reported that improvements in sleep quality, respiratory symptoms, and quality of life (QOL) were not achieved [Krachman, 2021. Bouloukaki, 2015]. In recent years, with the diversification of inhalation devices and the increasing use of multiple inhaled medications, the prevalence of inhaler misuse has been reported to range between 37% to 75% [Lindh, 2022. Ahn, 2020. Ngo, 2019. Muller, 2017]. Furthermore, even after receiving education on inhalation techniques, 63.6% of patients continued to misuse inhalers [sauriasari, 2021], highlighting the importance of repeated instruction, particularly for elderly patients and those with COPD receiving multiple medications. Inhaler technique education is a crucial component of COPD management, and it should be delivered not only by pharmacists but also by nurses.

Previous studies [Sauriasari, 2021. Al-Kalaldeh, 2016] have primarily focused on the technical aspects of inhalation techniques. However, in nurse-led disease management education—which encompasses a wide range of topics such as disease education, nutritional management, and responses to exacerbations [Moriyama, 2010] —it cannot

be said that sufficient education is being provided regarding the appropriate use and administration of inhaled medications. Furthermore, patient education and guidance, which were traditionally delivered face-to-face, have increasingly incorporated information and communication technologies (ICT), such as telephone consultations, online videos, and mobile applications, particularly since the COVID-19 pandemic. Nevertheless, there are no existing reports evaluating the effectiveness of video conferencing for inhalation management education.

Based on the above, the central academic question of this study is whether inhalation management education provided by nurses via video conferencing can improve sleep quality in patients with COPD. By clarifying this relationship and examining the impact of inhalation management education, we aim to develop an effective educational program tailored to the specific characteristics of COPD patients. We believe that conducting this study will help maximize the therapeutic benefits of current treatments, thereby contributing to improved sleep quality, symptom alleviation, and enhanced quality of life (QOL), even among individuals with this chronic progressive disease.

Furthermore, since many COPD patients are elderly and may experience difficulty accessing medical facilities due to transportation challenges, this study may offer insights into enabling continuous care, regular technical assessments, and appropriate treatment even during outbreaks of emerging infectious diseases such as COVID-19.

Ⅱ. Objective

To investigate whether providing two sessions of patient education on inhalation technique and self-management via video conferencing, in addition to continuous inhalation therapy, improves sleep quality and quality of life in COPD patients compared to standard self-care support.

Ⅲ. Methods

1. Study Design

A multicenter, block-randomized controlled trial involving patients with COPD.

2. Study Participants and Eligibility Criteria

Patients in the stable phase of chronic obstructive pulmonary disease (COPD) who regularly attend Kumamoto University Hospital, Konan Hospital, or Iwakuni Municipal Nishiki Central Hospital, all of which provide internal medicine and respiratory care, will be eligible for participation in this study. Eligible participants must meet all of the inclusion criteria and none of the exclusion criteria listed below.

(1) Inclusion Criteria

1. Individuals aged 20 years or older at the time of obtaining informed consent.
2. Individuals who have been prescribed and continuously using inhaled medications for more than one month.
3. No restrictions regarding previous experience with inhalation instruction.
4. No hospitalizations due to COPD exacerbation within one month prior to study participation.
5. Individuals with coexisting obstructive sleep apnea syndrome (OSAS) and undergoing treatment with continuous positive airway pressure (CPAP) may be included, provided their symptoms are stable following CPAP initiation.
6. Individuals capable of operating a device such as an Android tablet, iPad, or personal computer. However, participants may still be eligible if a caregiver can operate the device on their behalf.
7. Individuals who have received approval from their attending physician.

[Justification for Inclusion Criteria]

1. The minimum age for participants to make an informed decision about joining this study was set at 20 years old.

2. 3. Based on prior research, participants were defined as those receiving continuous inhaled medication therapy for at least one month, not new patients.

4. In cases of hospitalization due to COPD exacerbation, the first month post-discharge is difficult to assess whether symptoms like dyspnea or bronchodilator effects stem from the recovery process or inhaler management education. Therefore, the one-month mark, when symptoms are considered stable, was set as the starting point.
5. If symptoms are stable (fixed) after OVS diagnosis and CPAP initiation, the bronchodilator effect from proper inhaler use is considered independent of OVS presence and thus acceptable. If OSAS suspicion arises during pre-enrollment screening and is subsequently diagnosed, treatment takes priority. After consultation with the primary physician, the study will commence 3-6 months after CPAP initiation.
6. This requirement was established because the intervention in this study utilizes video conferencing. Participants unable to operate devices for video conferencing (e.g., Skype, Zoom) would necessitate unnecessary contact, potentially increasing participant burden and introducing bias.
7. This was established as a necessary requirement for conducting this study.

(2) Exclusion Criteria

Participants will be excluded if they meet any of the following criteria:

1. Presence of other respiratory diseases such as asthma or interstitial pneumonia.
2. Diagnosis of advanced cancer, including lung cancer.
3. Restricted thoracic mobility due to thoracic deformities or trauma.
4. Presence of diseases that cause dyspnea, such as cardiac disorders.
5. Sleep-disordered breathing in which central apnea–hypopnea index (AHI) accounts for the majority of events.
6. Diagnosis of dementia or psychiatric disorders.

[Justification for Exclusion Criteria]

1. This criterion is intended to ensure accurate assessment of the effects of the educational intervention specific to COPD patients. Asthma will be definitively excluded through a fractional exhaled nitric oxide (FeNO) test at the time of study enrollment.
2. Advanced cancer may affect sleep quality due to psychological stress or disease burden, which could confound the study results.
3. In cases where thoracic movement is restricted, dyspnea may not respond to bronchodilation from inhaled medications, limiting the ability to assess intervention effectiveness.

4–5. Symptoms such as breathlessness caused by cardiac disease or central sleep apnea are unlikely to improve through the pharmacological effects of inhaled bronchodilators, making it difficult to evaluate the intervention's effectiveness.

6. Exclusion of participants with psychiatric or cognitive disorders is necessary to avoid potential confounding effects on sleep quality and to ensure participants can make autonomous decisions regarding study participation.

3. Subject Registration

After approval by the Kumamoto University Ethics Committee, the principal investigator or co-investigator/collaborator will receive referrals of patients meeting the eligibility criteria from the attending physicians at the collaborating research institutions. The principal investigator or co-investigator/collaborator will then provide an explanation of the study at the date, time, and location specified by the patient. The purpose, significance, methods, and ethical considerations of the study will be explained verbally and in writing, and written informed consent will be obtained. After obtaining consent, contact the Principal Investigator to obtain a subject identification code and register the subject in the study.

4. Allocation Method

Stratified block allocation will be used, with gender (male, female) and severity classification (Grade 1, 2, 3, 4) as allocation factors. Allocation of subjects to each treatment group will be performed by Makiko Yamamoto at the Department of Basic Nursing Science, Kumamoto University Graduate School.

Following a pre-generated random allocation table, subjects will be sequentially assigned to treatment groups in the order of case registration. A registration confirmation document listing the subject registration number and group name will be issued. The allocation table will be retained by the person responsible for allocation and will not be disclosed to the Principal Investigator or Co-Investigators.

5. Target Sample Size and Rationale

Target Sample Size:

- Intervention group: 30 participants
- Control group: 40 participants
- **Total:** 60 participants

Rationale for Sample Size:

There are no previous studies that have specifically examined the impact of inhalation management education on sleep quality. In prior studies, the mean PSQI (Pittsburgh Sleep Quality Index) scores among patients with COPD ranged from 8.3 to 11.5, with a commonly used cutoff score of 5.5 to indicate poor sleep quality. Based on this, we assumed a mean reduction of 5.0 points in the PSQI-J score at 3 months in the intervention group.

Using a two-tailed test with a significance level of 5% ($\alpha = 0.05$) and a power of 80% ($\beta = 0.20$), the required sample size was calculated to be 17 participants per group.

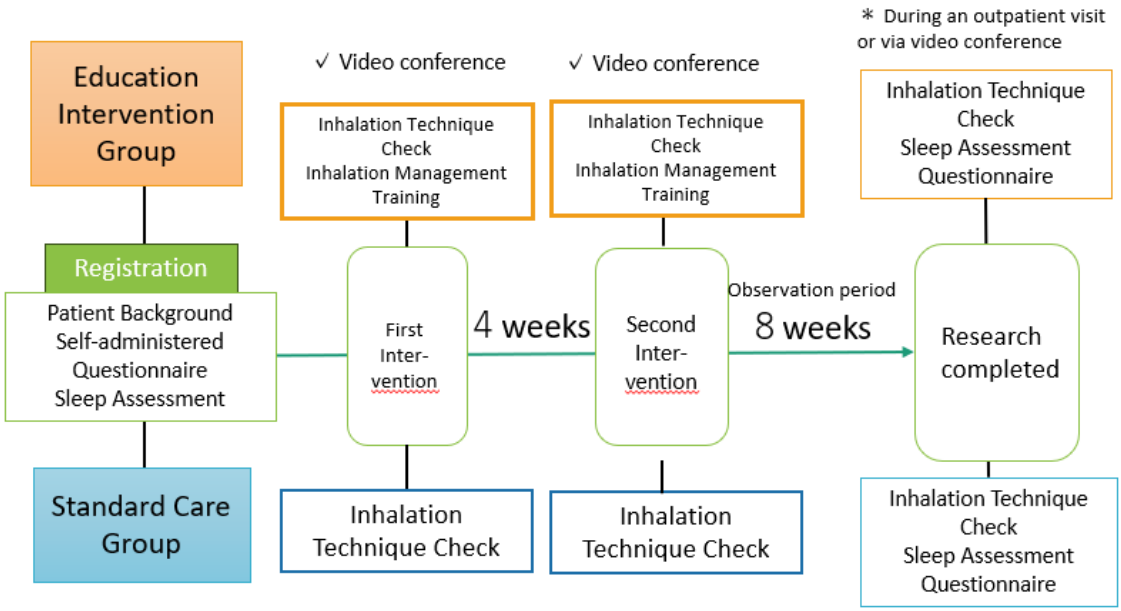
However, considering that many participants are older adults who may face challenges in consistently using personal computers or video conferencing tools, a higher dropout rate than usual is expected. Therefore, we increased the target enrollment to 30 participants per group, for a total of 60 participants.

6. Research Outline

After obtaining research consent, baseline attributes, inhalation technique checks, and pre-intervention sleep assessments are conducted. For the pre-intervention assessment, a Watch Pad 200U or 300 is loaned to participants, who wear it overnight at home to record sleep onset.

After random assignment, the intervention group undergoes two inhalation technique

checks and inhalation management education sessions during an 8-week follow-up period. At the study's conclusion, participants undergo an inhalation technique check, sleep assessment, and questionnaire survey. If inhalation technique errors persist after training completion and the participant requests it, inhalation management education will be provided post-study. For the control group, these technique checks and education involve sending a pamphlet on using the same device as their prescribed inhaled medication at enrollment or approximately one week after enrollment, followed by an inhalation technique check via video conference. After a 12-week observation period, the study concludes with an inhalation technique check, sleep assessment, and questionnaire completion at the study end. Additionally, inhalation management education will be provided after the study concludes if the participant requests it.



7. Intervention

The intervention content for the education intervention group is described below. The usual care group will receive only the same pamphlet as the intervention group, without any explanation or instruction on inhalation techniques.

First Intervention Session (within one month of participant enrollment):

1) During a video conference, the participant will be asked to use their prescribed inhaled medication while the study staff (applicant) observes their inhalation technique. The staff will assess the technique using a standardized technical checklist. Feedback will be provided based on the assessment, and any technical errors will be corrected through demonstration of the correct inhalation method.

2) Education will be provided on self-management, including how to use inhaled medications in response to symptoms such as dyspnea and cough perceived in daily life, appropriate timing of inhalation, and self-monitoring strategies.

Second Intervention Session (four weeks after the first session):

1) During a video conference, the participant will again demonstrate inhalation using their prescribed inhaler, observed by the study staff who will assess technique with the checklist. Feedback will be given, and any technical errors will be addressed through correct method demonstration.
2) The staff will inquire about any difficulties or symptoms experienced by the participant since the previous intervention, and discuss inhaler use and management strategies together with the participant.

8. Evaluation Items

(1) Primary Evaluation Item

Improvement in the Japanese version of the Pittsburgh Sleep Quality Index (PSQI-J)

[Rationale]

The PSQI (Pittsburgh Sleep Quality Index) is a scale for evaluating sleep quality. It is the most widely used and standardized measure globally, employed in numerous clinical trials. A Japanese version, PSQI-J, has also been developed. Since this study aims to examine sleep quality improvement as an effect of inhalation management education, this scale was selected as the primary outcome measure.

The PSQI-J is a questionnaire assessing sleep status over the past month. It consists of 19 self-reported items and seven subscales: Sleep Quality, Sleep Onset, Sleep Duration, Sleep Efficiency, Sleep Difficulty, Sleep Medication Use, and Daytime Sleepiness. A total score ranging from 0 to 3 points (0–21 points total) is calculated, with higher scores indicating greater sleep impairment.

Assessment timepoints were at participant registration, the second intervention session, and study completion.

(2) Secondary Evaluation Items

1) Sleep Quality

① Japanese Version of Epworth Sleepiness Scale (JESS)

[Rationale]

JESS is a scale used to assess subjective daytime sleepiness and diagnose sleep disorders. It has been modified with items tailored to Japanese lifestyles, and its reliability and validity in the Japanese population have been verified. Similar to PSQI-

J, since nighttime sleep conditions are thought to influence daytime sleepiness and related states, we will evaluate improvements in subjective symptoms using JESS. Assessment points are set at: before the first intervention, during the second intervention, and at the end of the observation period.

Respondents answer eight questions using a 4-point scale: “0 points” for “Very unlikely to doze off” and “3 points” for “Very likely to doze off.” A total score of 11 points or higher indicates a high likelihood of sleep apnea syndrome.

②Nighttime Sleep Assessment (AHI, ODI3%, ODI4%, average nighttime SpO2, time with nighttime SpO2 <90%, arousal status)

【Rationale】

Bronchodilator effects of β2 agonists, anticholinergic agents, and inhaled corticosteroids, along with improvements in nighttime SaO2 and AHI, have been reported. In this study, it is presumed that correct inhalation implementation enhances drug efficacy and further improves nocturnal sleep status. Therefore, these parameters were set as secondary endpoints for objective evaluation.

Watch PAT continuously measures peripheral arterial blood flow throughout the night and calculates AHI, ODI, nocturnal hypoxia, arousals, and REM sleep depth. In studies comparing Watch PAT to PSG, strong correlations were confirmed for AHI and RDI measurements (r=0.889 [95% CI; 0.862-0.911]; P<0.001). Watch PAT enables objective sleep assessment without requiring measurements in non-routine settings like hospitals and without burdening subjects. Assessment points are at participant enrollment and at the end of the observation period.

③Japanese Version of CAT (COPD Assessment Test)

【Rationale】

The St George's Respiratory Questionnaire (SGRQ) is a respiratory disease-specific QOL measure developed for COPD patients. However, it contains 80 items and takes approximately 20 minutes to complete. In contrast, the CAT was developed as a shorter, simpler questionnaire to assess the impact of COPD on patients' lives. It shows good correlation with the SGRQ (r=0.80, p<0.0001). Furthermore, the Japanese version of the CAT, adapted to the Japanese lifestyle, also demonstrated high internal consistency (Cronbach's alpha: 0.891), a high correlation with the SGRQ (r ≈ 0.82, p<0.001), and showed a correlation with the general health-related QOL questionnaire (SF-12v2). Therefore, this study will use the Japanese version of the CAT to assess patient QOL. The assessment points were set at the time of participant registration and at the end of the observation period, in accordance with the CAT Policy Committee and the GOLD Strategy Document.

The assessment uses an 8-item scale (cough, sputum production, breathlessness, dyspnea on exertion, daily activities, confidence in going out, sleep, and energy) rated on a 6-point scale from 0 to 5, with a total score out of 40. A higher total score indicates a worsening health status.

2) Items related to inhalation technique

① Number and content of technical errors assessed using the inhalation technique checklist

[Rationale]

To evaluate whether the intervention enabled patients to perform inhalation correctly using device-specific checklists. The inhalation technique checklists were developed based on prior research. Evaluation points are after the first intervention, before and after the second intervention, and at the end of the observation period.

9. Observation and Examination Items and Schedule

In this study, the following information will be collected from the participant at the time of enrollment, at the time of intervention, and at the end of the study, either through direct interview with the participant or by retrieving it from medical records with the participant's permission. Sleep evaluation will be measured for research purposes (research funding).

At the time of enrollment

[Patient Basic Information]

Patient Background: Age, Gender, Smoking History, BMI, Disease Duration, Alcohol Consumption (presence/absence and frequency), Use of Sleep Medications, Hospitalization within the Past 6 Months, Presence of Comorbidities (e.g., Diabetes, Heart Disease, Stroke, Hypertension, Depression, Cognitive Impairment), mMRC, Types and Number of Inhaled Medications

Respiratory Function: FVC (ml), FEV1 (ml), FEV1/FVC (%), %FEV1 (%) measured between 6 months prior to enrollment and the first intervention

Sleep assessment: AHI, ODI, snoring level, wakefulness/sleep depth, REM sleep structure, oxygen saturation (mean minimum oxygen saturation, frequency of oxygen saturation drops, heart rate during sleep) using Watch Pad 200U or 300

Inhalation therapy experience: Presence/absence of inhalation therapy instruction and details (providing profession, time since last instruction, past instruction method [demonstration, video, pamphlet, verbal])

[Self-Administered Questionnaire I]

Anxiety/Depression Tendencies: Japanese Version of the Hospital Anxiety and Depression Scale (HADS)

QOL: Japanese Version of the CAT

Sleep Quality: PSQI-J, JESS

Initial Intervention: Within one month of participant registration

Inhalation Technique: Assessment using the Inhalation Technique Checklist

・Presence of technical errors

Second Intervention: Approximately 4 weeks after initial intervention

Inhalation Technique: Assessment using Inhalation Technique Checklist

・Presence of technical errors

・Changes to device, medication content, or frequency and reasons

［Self-Report Questionnaire II］

Sleep Quality: PSQI-J, JESS

Anxiety/Depression Tendencies: HADS

Study Completion (Approximately 8 weeks after second intervention)

Inhalation Technique: Assessment using Inhalation Technique Checklist

・Presence of technical errors

・Changes in device, medication type, or dosage frequency and their reasons

Sleep Assessment: AHI, ODI, snoring level, arousal/sleep depth, body position, REM sleep structure, oxygen saturation statistics (mean minimum oxygen saturation, frequency of oxygen saturation drops, heart rate during sleep) using Watch　Pad 200U or 300

[Self-Report Questionnaire III]

Sleep Quality: PSQI-J, JESS

QOL: Japanese CAT

Anxiety/Depression Tendencies: HADS

Presence of unscheduled visits or hospitalizations from enrollment to study completion

[Brochure]

Self-assessment of inhaler usage, inhalation log (symptoms of breathlessness, cough/phlegm, self-rated sleep)

Table1. Inspection Schedule

	within 6weeks	registration	Initial intervention	Second intervention	At the completion of the research	Cancellation
Pulmonary Function Test	○					
Patient Basic Attributes		○				
QOL（Quality of life）		○		○	○	△
PSQI・JESS （Sleep quality）		○		○	○	△
Sleep Assessment （Sleep study）		○			○	△
Check of inhalation technique		○※	○※	○	○	△
HADS (Anxiety and Depressive Tendencies)		○		○	○	△
Unplanned medical visits or hospitalizations					○	△
Observation of adverse events			◄———	———	———►	△
Inhalation Management Log					○	△

"○" indicates required items; "△" indicates optional items;
"※" indicates items to be completed during registration or around the time of the first intervention.

10. Analysis Methods

1) Analysis of Primary Endpoint

Primary Endpoint: PSQI-J at 3 months post-educational intervention

Analysis of the primary endpoint will be performed using the Full Analysis Set (FAS). The change in PSQI-J for each group will be calculated, and between-group comparisons will be performed at a 5% significance level (two-tailed) using covariance analysis adjusted for the background factors of age and disease stage classification. A similar analysis will be performed secondarily using PPS as the analysis population.

2) Secondary Outcome Measure Analysis

Outcome Measures: Using the FAS as the analysis population, comparisons of the mean change in JESS, nocturnal sleep assessments (AHI, ODI, nocturnal hypoxia, arousal status, etc.), and Japanese CAT scores between groups will be tested at a 5% significance level. A similar analysis will be performed secondarily using PPS as the analysis population.

Safety Assessment: Not applicable

11. Study Period

Registration Period: Study Approval Date ~ June 30, 2026
(Last Observation Date for Last Patient: ~ December 31, 2026)
Implementation Period (Total Study Period): Study Approval Date ~ March 31, 2030

12. Informed Consent Documents and Methods for Obtaining Subject Consent

The Principal Investigator or Co-Investigator shall provide the research subject with the informed consent document approved by the Kumamoto University Clinical Research Ethics Review Committee (hereinafter referred to as the Ethics Review Committee) and authorized by the head of the research institution. They shall provide a thorough explanation both verbally and in writing and obtain the research subject's written informed consent freely given. Furthermore, when information regarding efficacy, safety, or other factors that could influence the research subject's consent is obtained, or when changes to the implementation plan or other aspects that could affect the research subject's consent are made, the research team shall promptly provide this information to the research subject. The research team shall confirm the research subject's intention regarding participation in the research in advance. The research team shall also revise the explanatory document, etc., after obtaining prior approval from the Ethics Review Committee and permission from the head of the research institution, and obtain renewed consent from the research subject.

13. Ethical Considerations

1) Applicable Regulations

This study complies with the World Medical Association's “Declaration of Helsinki (latest version)” and the “Ethical Guidelines for Life Science and Medical Research Involving Human Subjects (Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labor and Welfare, Ministry of Economy, Trade and Industry Notice No. 1 of 2021)” issued by the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labor and Welfare, and the Ministry of Economy, Trade and Industry.

2) Handling of Personal Information

To protect the personal information of research subjects, utmost care will be exercised in its handling. All case reports, documents, correspondence, specimens, etc.,

will have names and medical record numbers removed. For questionnaires and survey forms, a reference table will be created, and research subjects will be assigned unique identification codes for handling. Only data in a state where individuals cannot be identified will be collected for this research.

Furthermore, any attempt to identify specific individuals from processed samples or information that has been rendered non-identifiable without reasonable justification is prohibited. Data containing assigned identification codes shall be managed and analyzed on a PC located in a strictly secured room (Room 405, Building E, Department of Health Sciences, Kumamoto University School of Medicine). Access shall be restricted by password, and measures against unauthorized software shall be implemented to prevent unauthorized external access.

Documents that are not anonymized, such as consent forms, shall be stored in a lockable cabinet in Room 405, Building E, Department of Health Sciences, Kumamoto University School of Medicine.

Furthermore, information that could identify individuals shall not be disclosed in reports or presentations of research results.

14. Research Funding and Conflict of Interest

1) Funding Sources

This research is conducted using funding from the Kumamoto University Diversity Project (Collaborative Research Project) for fiscal years 2023 and 2025, Grants-in-Aid for Scientific Research (Grant Number 24K14058), and the Mitsubishi Foundation Grant for Social Welfare Research.

2) Researchers' Conflict of Interest

No researcher has received financial benefits or other related benefits from companies or organizations with potential conflicts of interest in this research. Conflict of interest matters are managed by the Kumamoto University Clinical Research Conflict of Interest Management Committee.

3) Cost Burden for Research Participants

For standard self-care support in this study, no fees related to medical treatment will be charged. Costs for examinations and other procedures related to conducting the research will be covered by the research funds.

Both the intervention and control groups will receive inhalation technique checks via video call, incurring communication fees for the video conferencing. Video calls are estimated to last approximately 30 minutes for the control group and 60 minutes for the intervention group receiving inhalation management education. We plan to use

Zoom or Skype for video calls. Data usage is estimated at approximately 300MB for 30 minutes and 600MB for 60 minutes. Although video conferences occur only once per month, since most carriers charge ¥1,100 (tax included) for each 1GB of additional data, we consider it appropriate for the researcher to cover these costs.

Therefore, we will pay compensation that includes these communication fees as part of the honorarium for participating in this study.

4) Compensation

Participants who assist with the research will receive compensation in the form of a Quo Card or Amazon gift card worth 10,000 yen. Payment will be made by mail or handed directly by the researcher after the 3-month study period ends, with a receipt obtained. Compensation will not be requested back if participation is withdrawn after the study concludes.

15. Methods for Storing and Disposing of Samples and Information, and Secondary Use

1) Methods for Storing and Disposing of Samples and Information

(1) Sample Storage

Samples obtained during the research period (including subjects' medical information) shall be stored in a lockable cabinet in Room 405, Building E, Kumamoto University. The storage period shall be the later of: 5 years from the date the completion of the research was reported, or 3 years from the date the final publication of the research results was reported. After the storage period ends, the samples shall be disposed of anonymously using appropriate methods.

Samples obtained during the research will be stored as anonymized processed information, making it impossible to identify the source, for potential future research. When utilizing this information for future research, it will be disclosed in a manner allowing research subjects to opt out, following approval by the Ethics Review Committee.

(2) Information Storage

Information obtained during the research period shall be stored on the principal investigator's personal computer and in a locked room in Room 405, Building E, Kumamoto University. The retention period shall be the later of either: five years from the date the completion of the research is reported, or three years from the date the final publication of the research results is reported. After the retention period ends, the information shall be disposed of appropriately while maintaining its anonymized state.

(3) Storage of Records and Documents

Documents related to the implementation of this research (copies of application documents, notification documents, copies of various application forms and reports, research subject identification code lists, consent forms, copies of case report forms, and other documents or records necessary to ensure data reliability) shall be retained for a period ending on the later of either five years after the date the completion of the research was reported or three years after the date the final publication of the research results was reported. After the retention period ends, the documents shall be anonymized and disposed of by appropriate means.

16. Secondary Use of Samples and Information

Samples and information obtained from research subjects in this study may potentially be used in research on sleep quality in patients with COPD and OSA overlap syndrome, or in studies investigating the effects of long-term inhalation management education. In such cases, a new research protocol will be prepared, reviewed by the Ethics Review Committee, and implemented only upon approval.

When providing samples or information to other research institutions, the head of the institution will be notified, and the materials will be provided only after anonymization.

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