STUDY PROTOCOL

A personalised active self-management of sleep apnea program (PASS) to improve positive airway pressure treatment uptake and adherence: A pilot randomized controlled trial

A. BACKGROUND

1. Obstructive sleep apnea (OSA) needs patient-centred chronic disease management.

OSA is a prevalent chronic disease associated with increasing obesity, affecting 12-24% of adults in Hong Kong and China(1). The chronic intermittent hypoxia and sleep fragmentation of OSA can lead to cardiometabolic and neurocognitive sequelae, including hypertension, diabetes, daytime sleepiness, and depression. Long-term, multidisciplinary management that engages patients in deciding their treatment strategies is essential to address OSA and prevent complications effectively(2).

2. Cardiovascular management and treatment adherence in OSA subjects

Obese or overweight OSA subjects stands a high risk of adverse cardio-metabolic outcomes (2). Weight control is a critical aspect of managing sleep apnea; however, achieving and maintaining weight loss is challenging. Many patients struggle with lifestyle changes, lack of access to resources, and maintaining long-term motivation. Positive airway pressure (PAP) is the first-line OSA treatment. Consistent use of PAP therapy can alleviate sleep apnea symptoms, reduce daytime sleepiness, improve quality of life, and lower the risk of cardiovascular events. However, studies have shown that adherence rates can be as low as 50% after the first year of therapy. Still, adherence remains a significant challenge and limits its effectiveness. Many patients struggle with adherence due to discomfort, inconvenience, side effects, or lack of perceived benefit (3).

3. Underdevelopment of self-management programmes and the underutilisation of digital technology

Self-management programmes are perceived to be cost-effective in long-term OSA patient care, but their development is limited. While digital self-management interventions are still in their infancy, the potential for improving self-efficacy and clinical outcomes in patients with chronic diseases, including OSA, is a cause for optimism. Digital self-management interventions were reported improved self-efficacy and clinical outcomes in patients with chronic diseases(4). We only found one mobile health application to support CPAP therapy for OSA (5). Digital technology is underutilized in patient-centred self-management programmes to improve PAP treatment and lifestyle modifications in OSA.

4. Previous work done by us

Previous work done by us: In 2012-2013, we conducted a RCT on a self-management support program to enhance self-efficacy and treatment adherence on 100 sleep apnea subjects at the 3-month and 1-year follow-up (6, 7). The RCT was awarded the 2017 Excellent Research Award from Food and Health Bureau, Hong Kong, and the intervention has been routinely conducted in real-world clinical practice with positive effects (8). Since 2014, we have led a series of lifestyle modification programs through instant messaging and chat-based support. Our 6 RCTs/cluster RCTs of Zero-time exercise (lifestyle-integrated exercise, using a foot-in-the-door approach to empower people to start simple exercises) programs involving 5600 subjects (including elderly and patients with heart disease) showed improved QOL, emotion, and physical activity and/or fitness (9-13). No discomfort or adverse

effects from performing Zero-time exercise were reported. Our 4 cRCTs of healthy eating programs involving 1550 subjects reduced dietary sugar consumption (10, 13, 14). Consistent evidence of effectiveness was found and shared in an invited presentation in the Lancet Symposium 2019 (15). We have also developed online workshops and web-based game involving 400 community participants for stress reduction and positive process and outcome evaluation findings were reported (16-18). In 2020, we conducted 2 pilot trials of smartphone-based self-management support programs for patients with chronic illness, including sleep apnea (n=10) and advanced lung cancer (n=20), and positive feedback on useability and acceptability were reported (19, 20).

5. The gap

Firstly, OSA is a common chronic condition imposing a large disease burden. The current services are providing fragmented patient care and PAP device-focused management. Existing OSA education programmes are conducted via face-to-face sessions focusing either on CPAP adherence or lifestyle modification, but not both. Besides, there are know-do gaps in cardiovascular management and treatment adherence in OSA subjects. **Secondly**, the WHO recommended empowering patients to engage and collaborate in self-management to build capacity for managing chronic illness. Despite the consensus on the benefits of self-management programmes, they are limited in their use in OSA. **Thirdly**, Hong Kong has extensive smartphone penetration (90% in 2024), and strong evidence supports the value of mobile text messaging in managing chronic illness. Despite the potential positive effects of information communication technology (ICT) integration, ICT development in OSA has focused on downloading and retrieving PAP adherence records but not on self-care management.

6. The proposed work

We conducted a pilot study to

- assess the feasibility and acceptability of the PASS in OSA patients
- examine the effectiveness of improving PAP uptake and adherence, self-efficacy in self-care, the change of health-related living habits, and health outcomes.
- assess facilitators and barriers to implementing the PASS

The proposed research will address the question: Can OSA patients accept an app-based program? Can the content be integrated with lifestyle habits and accepted by OSA subjects? Can the PASS improve self-efficacy in OSA self-management and treatment-related health cognition, behaviours, and outcomes?

B. OBJECTIVES AND HYPOTHESES

Our objectives of the proposed project are to:

1. Assess the feasibility and acceptability of PASS in OSA patients
2. Examine the effects on PAP uptake and adherence, self-efficacy in self-care, the change of health-related living habits, quality of life, and health outcomes.
3. Assess facilitators and barriers to implementing PASS

We expect that OSA subjects will accept the digital PASS program. Participants in the intervention group will have greater increases in PAP uptake and adherence, self-efficacy for sleep apnea

management, physical activity levels and weight control, compared with those in the control group at 4-month follow-up.

C. STUDY DESIGN

1. Design

This is a two-group pilot randomised control trial with a 4-month follow-up.

2. Intervention

Intervention group: Subjects will receive a 4-month Personalized and Adaptive Sleep Support program (PASS), a digital platform-based intervention. The PASS will be guided by social cognitive theory and use brief motivational interviewing (brief MI) to enhance subjects' psychological capacity and motivation, feel confident in managing chronic situations, and provide continuous individual support. **The PASS** is a 4-month program that employs a multimodal approach incorporating the following three main components:

(i) **A *20-Minute Brief Motivational Interviewing Session***: These sessions utilize Motivational Interviewing (MI) techniques to engage and motivate participants in managing their OSA.

(ii) ***A Digital Platform:*** This platform serves multiple functions for OSA subjects, including:

- Self-selection of personalised OSA health-related videos and information
  - Users can choose resources that are most relevant to their needs.
- Recording of Positive airway pressure treatment adherence
  - Users can track their adherence to prescribed treatment.
- Recording of physical activity levels, diet, sleep habits, body weight, blood pressure
  - Participants can log their daily activities and dietary intake.
- Self-monitoring and goal setting
  - The platform allows individuals to monitor their progress and set personal health goals.

(iii) ***Continuous Personalized Chat-Based Messaging and Phone Call Support:*** This component provides ongoing, tailored support and encouragement through messaging, helping to engage and adhere to the program. Participants receive additional support through regular phone calls, offering a more personal touch and the opportunity to address any specific concerns or challenges they may be facing. Please see Appendix A1-A3 for examples of the intervention package.

Control Group: Participants will receive a 4-month general hygiene program, including (i) A 20-minute session, (ii) messaging, and (iii) phone call support.

The content focuses on: Hand hygiene and Food hygiene

- Discuss how washing hands regularly (before eating, after using the restroom, etc.).
- Demonstrate proper handwashing technique (use soap, scrub for 20 seconds, rinse thoroughly).
- Discuss using hand sanitizers when soap and water aren't available.
- Wash fruits and vegetables before eating.
- Store food properly to prevent contamination.
- Avoid sharing utensils or cups.

3. Selection and withdrawal of subjects

Inclusion criteria:

- Aged 18 years and above
- Newly diagnosed with OSA (diagnosis made within the past year)
- Newly started or not yet started Positive Airway Pressure (PAP) treatment, with a treatment duration of less than 6 months
- Physically inactive (self-reported moderate physical activity per week of <150 minutes)
- Overweight (BMI≥23 kg/m2)
- Mentally, cognitively, and physically fit to join the trial as determined by the doctor in charge and responsible clinical investigators
- Able to speak, read, and write Chinese
- Willing to complete the questionnaires and assessments
- Has a smartphone

Exclusion criteria

- Clinically significant psychiatric disorder
- Use of prescription drugs or clinically significant drugs affecting sleep.

All subjects have the right to withdraw during the sessions if they wish not to continue. Subjects withdrawn from the study will not be replaced by other subjects. Participation in the study is entirely voluntary. The subjects will be required to sign a consent form before participating in the study component of the project and questionnaire surveys. All subjects will be provided with a contact telephone number in case they have any queries about the project, and reassured that they have the right to withdraw at any time point without any consequences.

4. Sample Size calculation

This pilot trial is a new intervention for OSA patients. A sample of at least 12 per group can provide sufficient methodological experience to conduct a fully powered study. With an assumption of a 60 % drop-off rate, the study requires 30 subjects per group. Sixty subjects (30 for the intervention group and 30 for the control group) will be recruited with a 4-month follow-up.

5. Assessment

Program feasibility and acceptability

Participants' engagement and satisfaction with the PASS will be evaluated via semi-structured interviews at the 4-month follow-up

Outcomes to be measured at baseline and 4 month

5.1. Primary Outcome

PAP uptake: whether the patient start to use the PAP therapy.

5.2. Secondary Outcome

PAP adherence: Adherence information will be retrieved from the PAP machine.

- Mean daily usage: the total number of hours of mask on divided by the total number of study days, which was downloaded with software.
- Intention to use***:*** the percentage of days on which CPAP has been switched on (ie, total number of switch-on days divided by the total number of study days).
- Usage index***:*** the percentage of days using CPAP for at least 4 h/d (ie, total number of such CPAP days divided by the total number of study days).

Self-efficacy in self-management and treatment adherence:

- Treatment adherence-related cognitions measured by a 26-item Self-efficacy Measure for Sleep Apnea

Health-related living habits

- Dietary habits measured by a 10-item dietary intake and practice questionnaire;
- Physical activity level measured by a 4-item International Physical Assessment Questionnaire – short version

Health-related quality of life:

- Daytime sleepiness is measured by an 8-item Epworth Sleepiness Scale;
- Sleep quality is measured by a 7-item Insomnia Severity Index; and
- Quality of life is measured by a 10-item Functional Outcomes of Sleep Questionnaire

Clinical outcomes: (Baseline and 4 months only)

- Waist circumference, body mass index, body fat composition
- Severity of sleep apnoea measured by a Home-sleep test.

Technology acceptance (4 months only)

- Measured by modified 7-item Technology Acceptance Model questionnaire.

6. Data Collection

Quantitative data collection

Self-administered questionnaires will be used at baseline and 4 months, and objective assessment tools (such as sleep tests) will be used at baseline and 4-month follow-up. PAP adherence will be downloaded from PAP machines (if available) for all subjects in both groups at baseline and month 4.

Qualitative data collection

Individual interviews will be conducted after a 4-month program. The aims are to (i) explore subjects' perception and satisfaction with the programme, (ii) understand the impacts and extent to which the changes have sustained and integrated into their daily life; and (iii) identify elements of the programme they view as helpful/unhelpful in supporting them to increase self-management ability, (iv) explore the facilitators and barriers for exercise adherence. If subjects withdraw from the assessment or drop

out of the programme, they will not be asked for the reasons, and it will not affect the current treatment and follow-up.

7. Assessment of safety

The Physical Activity Readiness Questionnaire (Appendix B), adopted by the Canadian Health Department, will be used to screen and alert those with elevated risk for cardiovascular diseases and bone and joint problems. Simple physical fitness assessments impose little risk to the subjects, and if any subjects feel distressed and discomfort arises, the fitness assessments will be terminated immediately. A contact card states the joined study and the responsible person's contact information that will be given to the participants (Appendix C) for enquiry, if needed.

8. Incentives

Both groups will receive the same amount of incentives after completing the study. Participants in the intervention group will receive a smartwatch after completing the baseline assessment and HKD 200 upon completing the 4th-month follow-up. Participants in the control group will receive a smartwatch and HKD 200 upon completing the 4th-month follow-up assessments. Apart from the standard medical fees, no additional costs will be required from participants.

9. Statistics

Quantitative*:* Quantitative data will be analyzed using IBM SPSS Statistics 24.0. All significance tests were 2-sided with a 5% level of significance. The demographic characteristics of the subjects will be described using frequencies and percentages, and the baseline scores of outcome variables will be described using means and standard deviations. Pearson's chi-square test and a Wilcon rank test will be conducted. The predefined primary outcome was the interventional effect on daily usage of CPAP and the consistency of the interventional effect over time. The interventional effects on CPAP adherence, symptoms of daytime sleepiness, health-related quality of life, and adherence-related cognitions were examined by a linear mixed-effects model, and the interventional effect on the proportion of adherent users was examined by generalized estimating equations. The methods took into account the extra covariance between repeated measurements taken at baseline and 4 months, and the potential confounding factors as covariates.

Qualitative: The in-depth interviews will be recorded and transcribed verbatim. Transcripts will be analyzed by thematic content analysis, following the guidelines recommended by Morse & Field (1995). Each transcript will be analyzed sentence by sentence and coded for the respondents' meanings. Initial open coding of the data used differing codes, which will then be organized into categories. Categories will be then integrated into themes within and across groups. Once the categories and themes are identified, the transcripts will be reviewed again to validate the thematic analysis and to ensure that all meaningful interview data have been analyzed. Data comparisons within and between groups will also be conducted. Field notes will be reviewed with the transcripts during the process. The software NVivo 9.0 (QSR International; Melbourne, VIC, Australia) will be employed to assist with qualitative data administration, including creating codes, organizing and summarizing data, searching for interrelationships between codes, and suggesting themes.

10. Direct Access to Source Data/Documents

The investigators permit study-related monitoring, audits, IRB/IEC review, and regulatory inspection(s), and provide direct access to the source of data/documents.

11. Data Handling and Record Keeping

Raw data will be kept in a locked cabinet in a locked room with restricted access by our team members and designated staff from our project team will be responsible for safekeeping. Data will be entered into a password-protected computer, which can only be accessed by members of our team. Designated team members from our team will have access to the raw data or study record during and after the study.

The raw data will be kept for five years after the completion of the study, and destroyed afterwards unless an application to the IRB for further retention is approved. Personal identifying information will be removed before statistical analyses. To protect participants' privacy, all research data would be handled in line with the HA / Hospital's policy on handling/storage/destruction of patients' medical records.

12. Compliance with ICH-GCP

The study will be conducted in compliance with the guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use - Good Clinical Practice (ICH-GCP)

13. Funding

This study was conducted without any external funding support.

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