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The Effectiveness of a Smart Sleep Apnea Self-Management Support (4S) Program to Improve Apnea Severity and Cardiovascular Health Risk: A Pragmatic Randomized Controlled Trial

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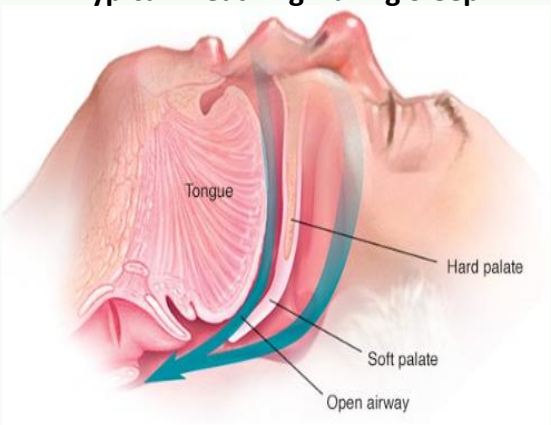
Background: Sleep Apnea is a Chronic Disease

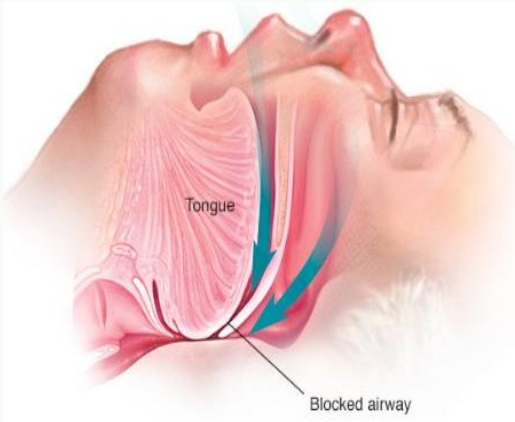
Pathophysiology

- Fat deposits around the upper airway that promote airway obstruction during sleep causing intermittent hypoxia and sleep fragmentation.
- This leads to increased cardiovascular risk and reduced quality of life.

Typical Breathing During Sleep



Obstructive Sleep Apnea



OSA and Obesity

- The rising obesity rates parallel the increasing prevalence of OSA. A 10% increase in body weight associated with 32% rise apnea hypopnea index (AHI).[1]

Common Interventions

- Positive airway pressure therapy (PAP) is the first-line treatment, but adherence is low. [2]
- Lifestyle measures: weight control, physical activity, and healthy diet.

The Gaps in OSA Management

Challenges

- Emphasis on **PAP device management** rather than holistic treatment.
- Programs typically target **either PAP adherence or lifestyle change**, rarely both.
- Poor support for **OSA** self-management despite WHO recommendations for chronic illness

Opportunities

- Widely used, **low-cost platforms** (e.g., WhatsApp, WeChat) support interactive messaging.
- Mobile interventions have **proven benefits for chronic disease management**

Proposed Solutions

Shifting from **PAP device-focused care** to a **patient-centered chronic care model**

A RCT of Smart Sleep Apnea Self-Management Support (4S) Program

Aims

- To evaluate whether 4S improves apnea severity, cardiovascular health, and quality of life compared with GH.

Hypothesis

- The 4S group will show greater improvement in apnea severity, measured by a larger decrease in apnea-hypopnea index (AHI), than the GH group at 4 months.
- The 4S group will also have better secondary outcomes, including improved apnea severity, reductions in waist circumference, body weight, and daytime sleepiness, as well as improvements in mood, quality of life, sleep quality, dietary habits, physical activity and fitness at 4 and 12 months.

Study Design

- Two-armed parallel 1:1 ratio pragmatic RCT with 12–month FU
- Specialist outpatient clinics of two hospitals (Queen Mary Hospital and Queen Elizabeth Hospital)
- Recruitment period: Sept 2022 to March 2024
- IRB was approved by Hospital Authority (UW21-135 and KC/KE-23-0071/ER-2)
- RCT was registered at the National Institutes of Health (US Clinical Trial Registry ID: NCT05390138).

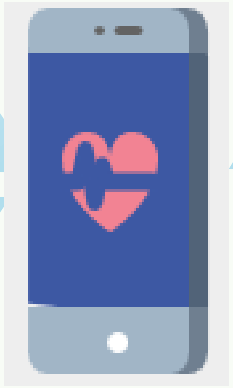
A RCT of Smart Sleep Apnea Self-Management Support (4S) Program

Inclusion Criteria

- Aged 18 years and above
- Diagnosis of moderate to severe OSA
- Physically inactive (<150 minutes of moderate PA per week)
- Over-weight (BMI≥23 kg/m^2)
- Mentally, cognitively and physically
- Able to speak and read Chinese;
- Has a smartphone with instant messaging function.

Exclusion Criteria

- Clinically significant psychiatric, neurological, or serious medical disorders other than OSA
- Use of prescription drugs or other clinically significant drugs that affect sleep



Sample Size Calculation

- Based on two meta-analyses [3,4], 92 participants (46 per group) provide 80% power to detect a 7 events/hour difference in change in AHI between 2 groups at 4 months, assuming a standard deviation of 12 and an effect size of 0.58.
- Allowing for a 30% dropout rate, 120 participants (60 per group) are needed.

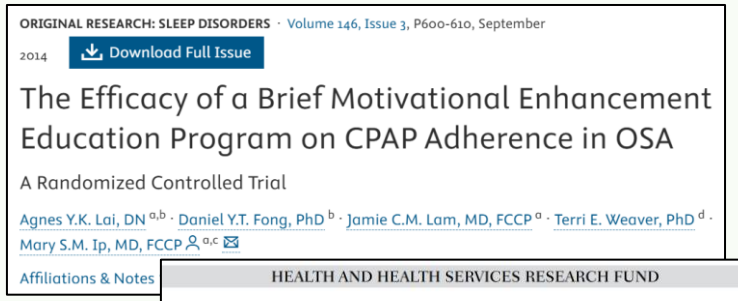
Randomisation and Concealment

- Stratified by PAP use status (including newly diagnosed OSA - PAP naïve, experienced PAP users and non-PAP users)
- 1:1 allocation with a block size from 4 to 6.
- Assessor-blinded

Groundwork

1 Foundation:

Established a brief motivational interviewing education model for PAP adherence



ORIGINAL RESEARCH: SLEEP DISORDERS · Volume 146, Issue 3, P600-610, September 2014

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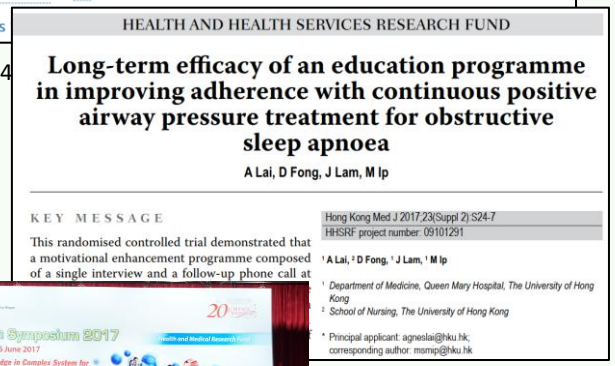
The Efficacy of a Brief Motivational Enhancement Education Program on CPAP Adherence in OSA

A Randomized Controlled Trial

Agnes Y.K. Lai, DN [a,b] · Daniel Y.T. Fong, PhD [b] · Jamie C.M. Lam, MD, FCCP [a] · Terri E. Weaver, PhD [d] · Mary S.M. Ip, MD, FCCP [a,c]

Affiliations & Notes



HEALTH AND HEALTH SERVICES RESEARCH FUND

Long-term efficacy of an education programme in improving adherence with continuous positive airway pressure treatment for obstructive sleep apnoea

A Lai, D Fong, J Lam, M Ip

KEY MESSAGE

This randomised controlled trial demonstrated that a motivational enhancement programme composed of a single interview and a follow-up phone call at

Hong Kong Med J 2017;23(Suppl 2):S24-7

HHSRF project number: 09101291

Lai et al., 2014

2 Needs assessment:

Identified the information needs and preferences of instant messaging to facilitate the design of patient-centred intervention

Original Article

Page 1 of 12

Exploring health literacy, perceived needs, information preferences and acceptability of smartphone-based messaging interventions among individuals with obstructive sleep apnoea in Hong Kong: a mixed-method approach

Agnes Yuen-Kwan Lai[1^], Asa Ching-Man Choi[2^], Macy Mei-Sze Lui[1], Hannah Wing-Hang Tsoi[1^], Tyrone Tai-On Kwok[1^], Yuying Sun[1^], Mary Sau-Man Ip[1^]

Lai et al., 2025

3 Pilot Study:

Tested and demonstrated the feasibility of instant messaging self-management intervention.

4 Collect Feedback for Program Refinement:

Conducted focus group interviews with OSA subjects and interdisciplinary healthcare meetings enhanced the 4S intervention for the main study

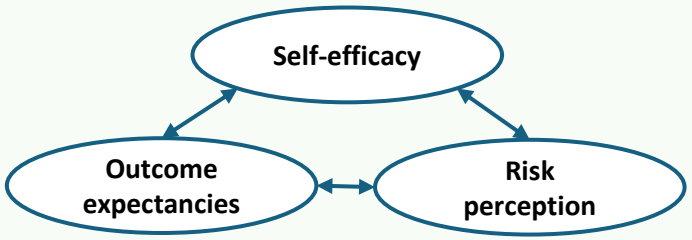
Smart Sleep Apnea Self-Management Support (4S) Program

The 4S Program: Framework with 4 key concepts

Brief Motivational Interviewing

- Enhance intrinsic motivation, and confidence to act as their own therapists in managing their OSA and related conditions.

Treatment-related Cognitions



- **Tx adherence-related cognitions**

Social Cognitive Theory

- Focus on cognitive factors driving behavior change.

Foot-in-the-door approach

- Kickstart health behavior change by simple steps, and integrate easy-to-do exercises into daily life.

Health-related behaviors

Living habits

- PA and dietary habits

PAP use

- Intention to use, daily usage

Continuous personalized support

- Send 2-min videos for knowledge enhancement and encouragement for the positive behaviors change in PA, diet and PAP use.
- Offer actionable suggestions, chat-based ongoing support tailored to individual needs.

Health Outcomes

Apnea severity:

AHI, MinO2, ODI

Cardiovascular health:

- Neck & waist circumference, trunk fat, body weight
- Blood pressure
- Fasting blood glucose and lipid

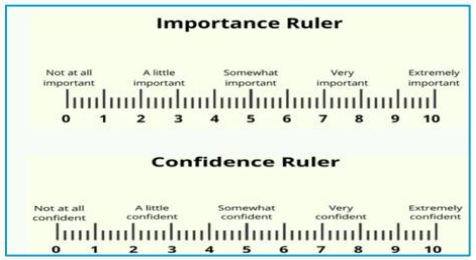
Physical fitness performance:

- Hand grip strength,
- Lower limb flexibility
- Balance

Health-related quality of life:

- Daytime sleepiness,
- Sleep quality
- Functional outcomes

The 4S Program (4S for intervention group)



Part I. Brief motivational interviewing

- baseline and 4 months
- assess self-efficacy and readiness
- explore benefits of CPAP and weight reduction

Part II. Theory- and theme-based video messages and calls

- intensive phase month 1–4
- moderate phase month 5–12

Part III. Personalised chat-based support

- messaging, phone calls, and hotline support

Part IV. E-platform for goal setting

- goal setting and self-monitoring

The General hygiene information (GH for control group)

- The GH mirrors the 4S structure, comprising four parts with the same format and duration.
- It includes (i) two GH sessions, (ii) a series of GH-related instant messages and phone calls, (iii) personalized support and hotline services, and (iv) an e-platform.

Outcomes Evaluation (at baseline, 4 months & 12 months)

Objective measurements

Outcomes		Measurement tools
Apnea severity	• Apnea hypopnea index (primary), • Duration of <90% oxygen desaturation, • Oxygen desaturation index, Minimum O2	○ Home Sleep Apnea Test [5]
Cardiovascular risks	• Body weight, body height and waist circumference • Blood pressure • Lipid	○ Stadiometer ○ Dinamap ○ Fasting blood
Physical activity levels	• Step count and physical activity levels	○ Actigraphy
Physical fitness performance	• Hand grip strength • Balance • Lower limb strength • Flexibility	○ A Jamar dynamometer [6] ○ A single-leg-stance test [7] ○ A 30-second chair stand test [8] ○ A sit and reach test [9]
Positive airway pressure therapy (PAP) adherence	• PAP use • Daily usage	○ Downloaded data from PAP machine

Outcomes Evaluation (at baseline, 4 months & 12 months)

Subjective measurements

Outcomes		Measurement tools
Treatment adherence-related cognitions	• Risk perception, outcome expectancies, and treatment self-efficacy	○ Self-efficacy Measure for Sleep Apnea [10,]
Physical activity habits	• Moderate physical activity • Vigorous physical activity	○ International Physical Activity Questionnaire—(IPAQ-C) [12]
Dietary habits	• Eating habits	○ Outcome –based questionnaire
Mood	• Depression • Anxiety	○ Patient Health Questionnaire [13] ○ Generalized Anxiety Disorders [14]
Health-related quality of life	• Sleep quality • Daytime sleepiness • Impact of daytime sleepiness on activities of daily living	○ Insomnia Severity Index [15] ○ Epworth Sleepiness Scales [16] ○ Functional Outcomes of Sleep Questionnaire [17]

Process Evaluation (at month 4 & month 12)

- ***Process evaluation*** will be conducted during and after the 12-month intervention, including three essential features of **context**, **implementation** and **mechanism of impact**, via
  - Exploring participants' perceptions of and satisfaction with the programme;
  - Identifying facilitators and barriers for improving physical activity and dietary habits, and PAP adherence,.
- Participants who withdraw or drop out will be asked their reasons.

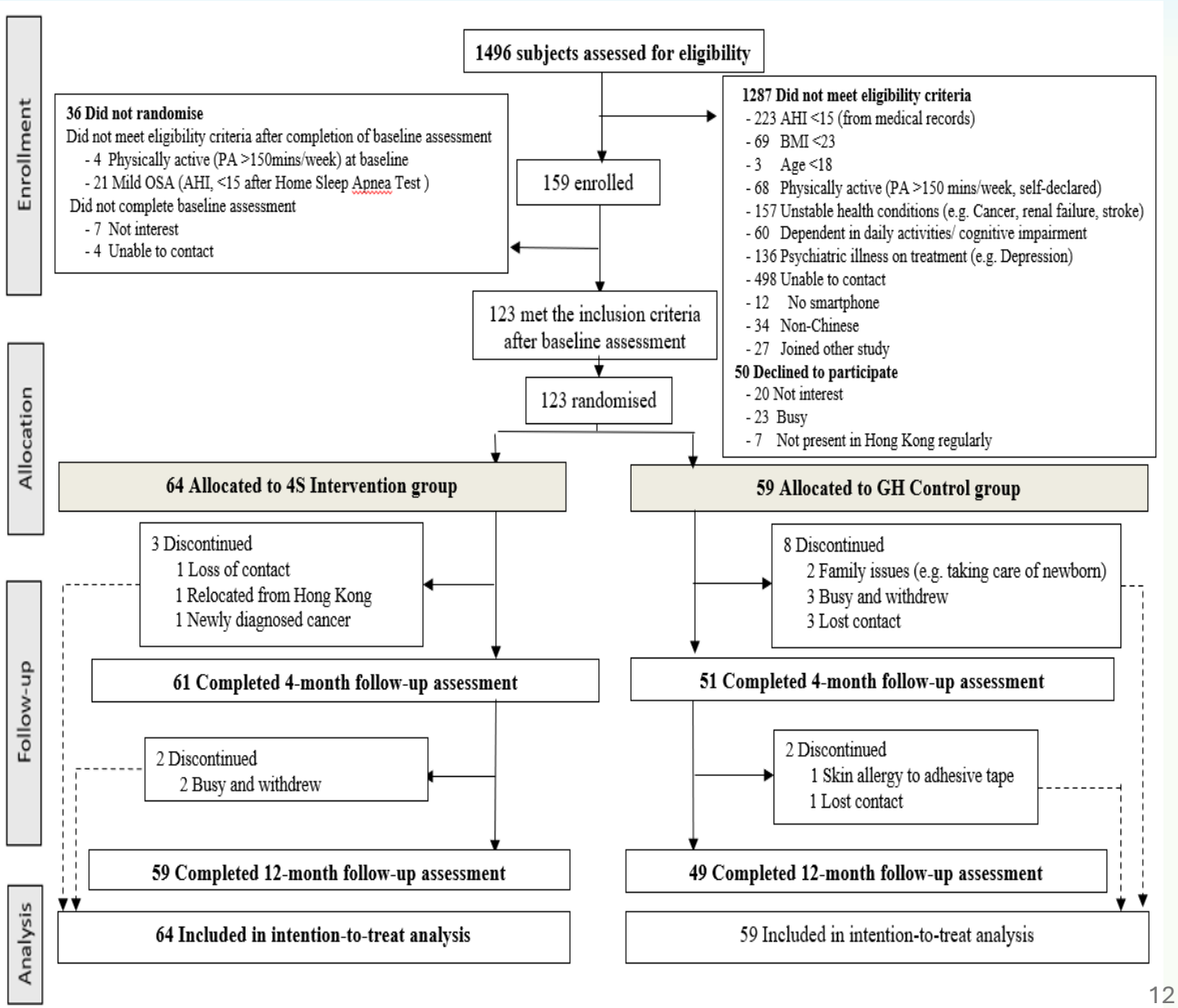
Statistic analysis

- Mixed-methods approach with outcome and process evaluation.
- **Linear mixed-effects model** to compare differences in parameters and scores between groups at different time points.
- **Generalized estimating equations** were applied for binary variables (e.g., proportion of adherent users),
- The consistency of the intervention effect over time will be assessed using **group-by-time interaction** terms.

Results: The Recruitment

- 1,496 subjects with OSA were screened; 1,287 were ineligible, and 50 declined participation.
- 159 entered baseline assessment; 36 were later excluded (11 incomplete assessment, 21 mild OSA, 4 already highly active).
- 123 subjects were finally recruited.
- 11 subjects dropped out. 112 subjects completed the 4-month follow-up, giving a retention rate of 92%.
- A further 4 subjects withdrew between 4 months and 12 months, 108 subjects completed the 12-month follow-up, giving a retention rate of 83%.

The Flow Chat



Results:

Participants

- 123 subjects with moderate to severe OSA (73.2% male, mean age: 60 years, mean BMI 30 kg/m$^{2.}$
- No difference in patients' characteristics between 2 groups

Table 1 Baseline characteristics of the two groups

	Intervention N = 64	Control N = 59	P Value
Age[1]	61.6 ± 8.9	58.7 ± 10.9	0.11
Men[2]	49 (76.6)	41 (69.5)	0.38
BMI, kg/m² [1]	29.8 ± 3.9	31.0 ± 5.0	0.12
Marital status[2]			0.42
Single	13 (20.3)	10 (16.9)	
Married	49 (76.6)	44 (74.6)	
Separated/divorced/widowed	2 (3.1)	5 (8.5)	
Education[2]			0.92
Primary or below	8 (12.5)	6 (10.2)	
Secondary	30 (46.9)	28 (47.5)	
Tertiary	26 (40.6)	25 (42.4)	
History of comorbid diseases[2]			
Diabetes mellitus	21 (32.8)	18 (30.5)	0.78
Hyperlipidemia	43 (67.2)	32 (54.2)	0.14
Cardiovascular disease	12 (18.8)	12 (20.3)	0.82
Hypertension	49 (76.6)	42 (71.2)	0.50
Employment status[2]			0.48
Unemployed/Retired/Homemaker	29 (45.3)	23 (39)	
Employed full-time/part-time	35 (54.7)	36 (61)	
Apnea severity			
Moderate (Apnea Hypopnea Index ≥ 15 - <30)	22 (34.4)	25 (42.4)	0.36
Severe (Apnea Hypopnea Index ≥ 30)	42 (65.6)	34 (57.6%)	
Sleep parameters			
Apnea Hyponea Index, events/h[3]	43.5 (26.6, 51.9)	39.5 (28.2, 52.1)	0.79
Duration of oxygen saturation, <90%, min[3]	20.3 (6.80, 51.7)	12.4 (2.6, 52.3)	0.60
Minimum oxygen, %[3]	75.0 (67.3, 82.8)	76.0 (69.0, 83.0)	0.67
Oxygen desaturation index, events/h[3]	30.8 (19.0, 52.1)	32.7 (19.9, 38.4)	0.89
Titrated Pressure[3]	10.8 (9.0, 12.6)	11.0 (10.0, 13.0)	0.21
Number of months since diagnosis[2]			0.79
6 months or below	25 (39.1)	26 (44.1)	
6 - 24 months	16 (25)	12 (20.3)	
24 months or above	23 (35.9)	21 (35.6)	

Results:

Improved Apnea Severity

- The intervention group showed significant improved apnea severity at both 4- and 12-month follow-up.
- However, the intervention shows significantly greater improved apnea severity than control group in newly diagnosed OSA subjects only, including
  - **Apnea-hyopnea Index:** -5.97 events/hour
  - **Oxygen desaturation index**: -9.61 events/hour
  - **Duration with oxygen saturation below 90%:** -0.5 min
  - **Minimum oxygen saturation**: +3.4%

Table 2 Sleep parameters of all subjects and newly diagnosed OSA subjects across time for both groups

	Intervention Group N = 64 Mean ± SD	*P* Value[1]	Control Group N = 59 Mean ± SD	*P* Value[1]	Between-group difference Estimates (95%CI)	*P* Value[2]
All subjects						
Apnea Hyponea Index, events/hour					0.14 (-3.34, 3.61)	0.94
Baseline	40.41 ± 18.1		39.42 ± 19.59			
4 months	37.49 ± 21.16	0.14	36.8 ± 18.11	0.11		
12 months	37.86 ± 21.24	0.20	36.72 ± 19.53	0.13		
Oxygen Desaturation Index, events/hour					-2.12 (-5.35, 1.12)	0.20
Baseline	36.28 ± 19.43		35.54 ± 19.6			
4 months	32.06 ± 19.7	**0.03***	33.83 ± 19.08	0.26		
12 months	33.14 ± 19.63	0.11	34.47 ± 19.54	0.50		
Minimum oxygen saturation, %					0.62 (-1.2, 2.44)	0.50
Baseline	73.94 ± 10.64		74.75 ± 10.01			
4 months	75.56 ± 9.61	0.14	76.22 ± 10.38	0.11		
12 months	76.69 ± 10.14	**0.04***	75.8 ± 9.26	0.14		
Duration of oxygen saturation < 90 %, minutes [1]					-0.03 (-0.28, 0.21)	0.792
Baseline	20.29 (6.8, 51.65)		12.43 (2.57, 52.27)			
4 months	19.78 (3.58, 43.34)	0.164	12.5 (2.32, 38.23)	0.101		
12 months	11.09 (3.35, 37.93)	**0.031***	12.78 (4.33, 36.13)	0.297		
Newly diagnosed OSA subjects						
	Intervention Group N = 27 Mean ± SD	*P* Value[1]	Intervention Group N = 21 Mean ± SD	*P* Value[1]	Between-group difference Estimates (95%CI)	*P* Value[2]
Apnea Hyponea Index, events/hour						
Baseline	37.56 ± 16.28		39.22 ± 17.27		**-5.97 (-11.54, -0.41)**	**0.036***
4 months	32.9 ± 17.98	0.134	37.73 ± 17.47	0.576		
12 months	29.58 ± 14.83	**0.013***	39 ± 19.18	0.948		
Oxygen Desaturation Index, events/hour					**-9.61 (-14.74, -4.47)**	**<0.001*****
Baseline	32.17 ± 16.43		38.33 ± 18.94			
4 months	25.63 ± 15.63	**0.031***	36.71 ± 17.8	0.541		
12 months	23.69 ± 11.99	**0.012***	39.07 ± 18.88	0.797		
Minimum oxygen saturation, %					**3.39 (0.48, 6.29)**	**0.023***
Baseline	72.26 ± 12.76		71.38 ± 9.59			
4 months	77.52 ± 7.58	**0.007****	73.62 ± 10.72	0.200		
12 months	77.85 ± 7.83	**0.029***	74.24 ± 8.67	0.090		
Duration of oxygen saturation < 90 %, minutes [3]					**-0.5 (-0.94, -0.05)[3]**	**0.029***
Baseline	28.13 (6.72, 53.75)		32.95 (5.39, 84.81)			
4 months	8.78 (2.33, 31.25)	**0.030***	20.58 (5.24, 50.68)	0.177		
12 months	8.78 (2.73, 20.87)	**0.009****	18.27 (7.21, 50.37)	0.278		

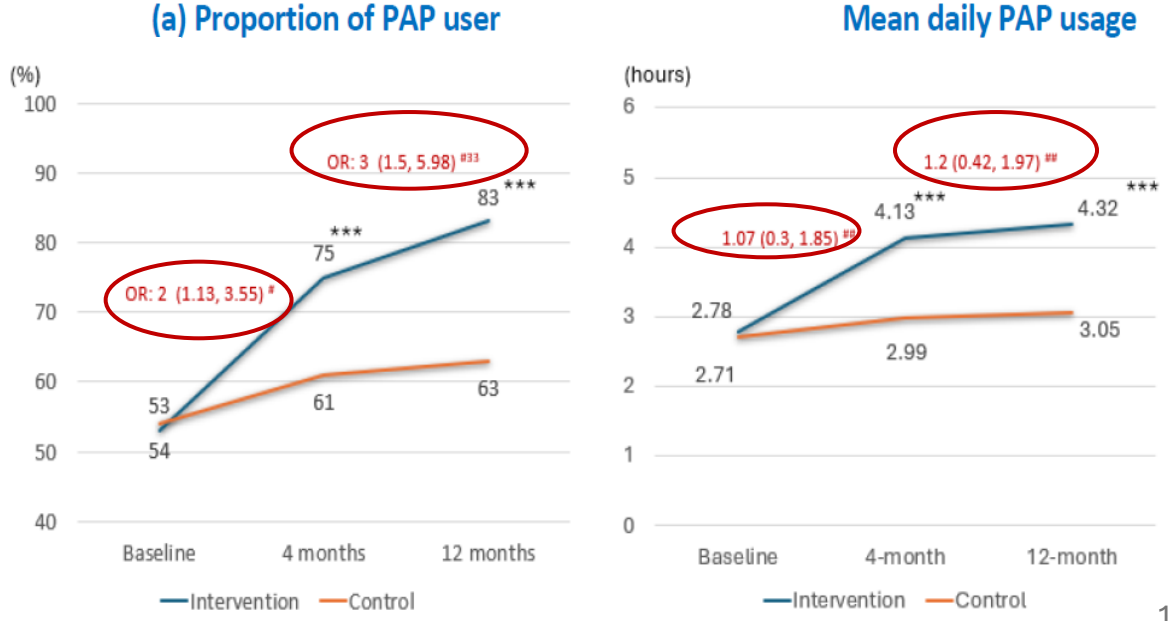
[1]Within-group changes were analyzed using paired sample t-test
[2]Between-group differences were analyzed using linear mixed model with baseline adjustment

Results:

Enhanced PAP-related Cognitions and PAP Uptake

- Significantly greater enhanced outcome expectancies, treatment self-efficacy and PAP uptake in the intervention group than in the control group.
  - **Outcome expectancies**: + 0.21 scores during 12-month study period
  - **Treatment self-efficacy**: + 0.23 scores during 12-month study period
  - **PAP users**: 2-fold higher at 4 months; 3-fold higher at 12 months.
  - **Daily PAP use**: +1.1 h/day at 4 months; +1.2 h/day at 12 months.

	Intervention Group N = 64		Control Group N =59		Between-group difference	
	Mean ± SD	*P* Value[1]	Mean ± SD	*P* Value[1]	Estimate (95% CI)	*P* Value[2]
SEMSA-Perceived Risks					0.01 (-0.12, 0.14)	0.85
Baseline	2.25 ± 0.55		2.27 ± 0.58			
4 months	2.26 ± 0.64	0.81	2.23 ± 0.68	0.57		
12 months	2.26 ± 0.63	0.86	2.30 ± 0.65	0.62		
Outcome Expectancies					0.21 (0.05, 0.37)	0.01##
Baseline	2.52 ± 0.73		2.3 ± 0.8			
4 months	2.7 ± 0.82	0.06	2.33 ± 0.81	0.68		
12 months	2.78 ± 0.79	<0.001***	2.41 ± 0.92	0.17		
Treatment Self-efficacy					0.23 (0.05, 0.41)	0.01##
Baseline	2.28 ± 0.65		2.16 ± 0.8			
4 months	2.46 ± 0.77	0.04*	2.10 ± 0.89	0.49		
12 months	2.47 ± 0.83	0.08	2.24 ± 0.89	0.43		

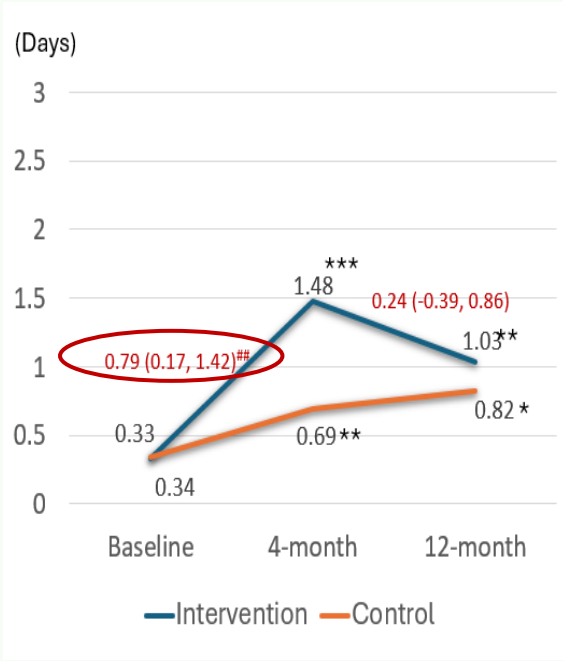


Results:

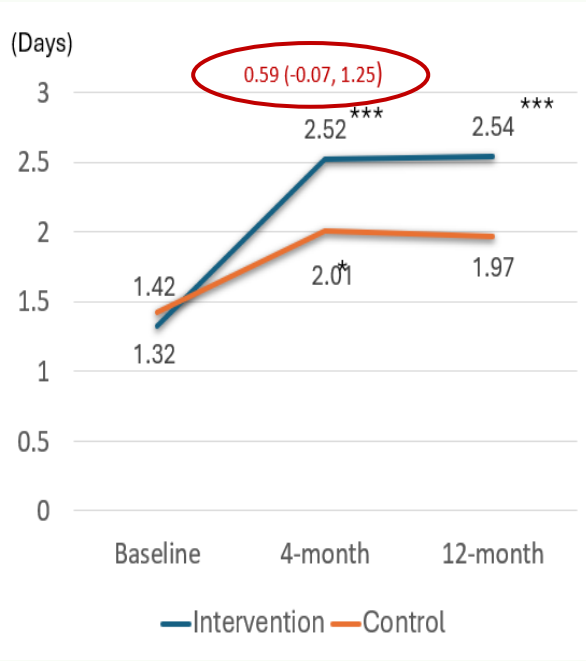
Improved Physical Activity and Dietary Habits

- Significantly greater improved physical activity and dietary habits in the intervention group than in the control group.
  - **Vigorous PA**: + 0.79 days/week at 4 months, but not at 12 months
  - **Moderate PA**: + 0.59 days/ week during 12-month study period
  - **Frequency of eating fried food**: - 0.4 units at 12 months, but not at 4 months

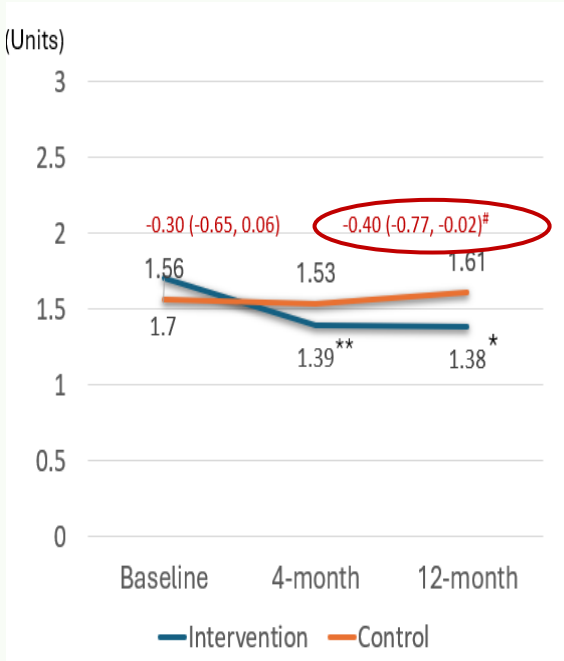
Vigorous physical activity



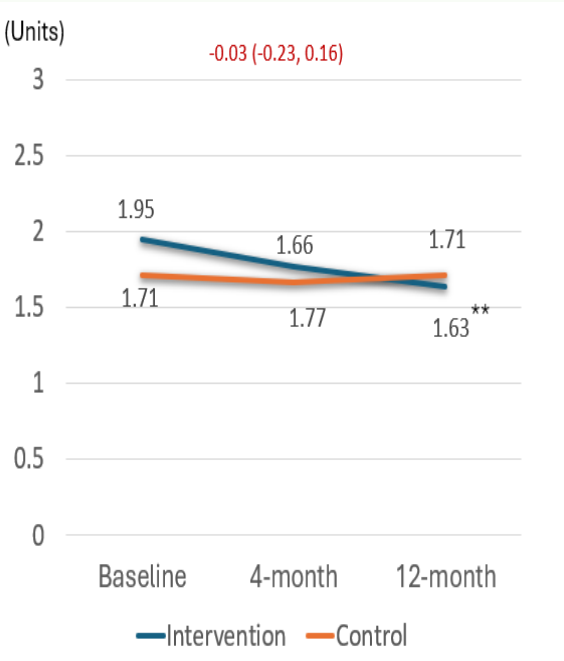
Moderate physical activity



Frequency of eating fried food



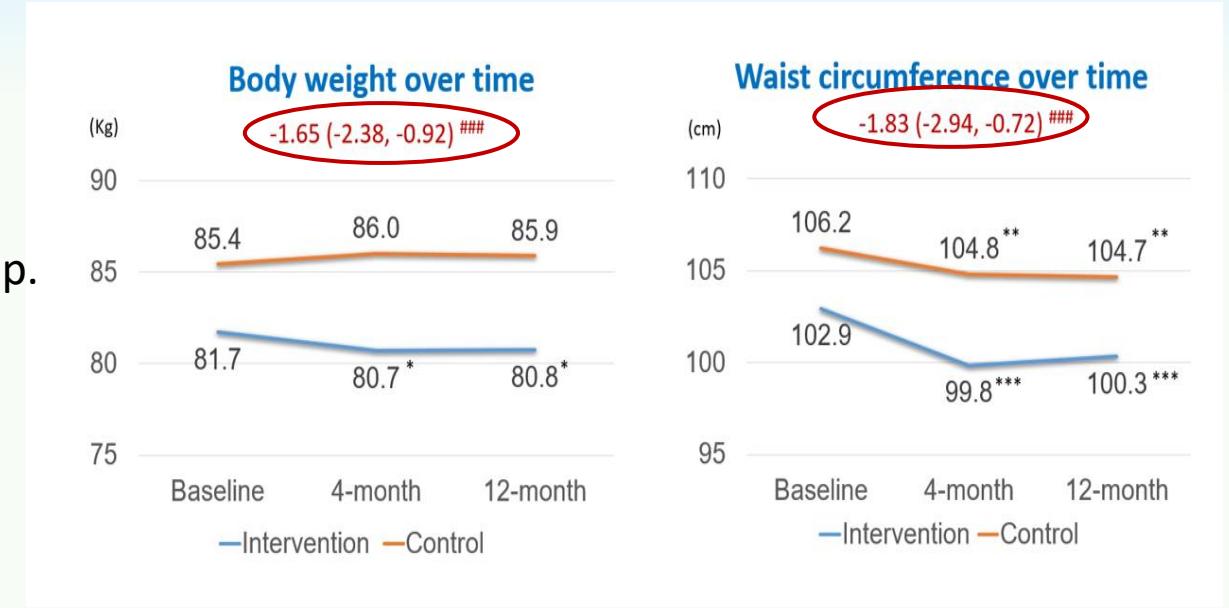
Frequency of taking sugary drinks

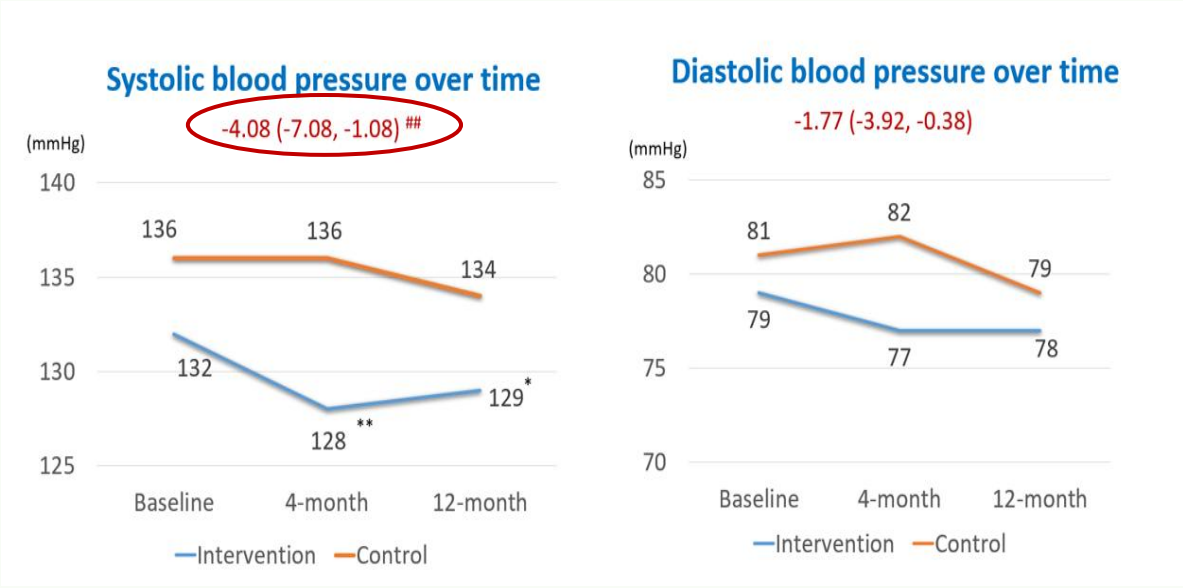


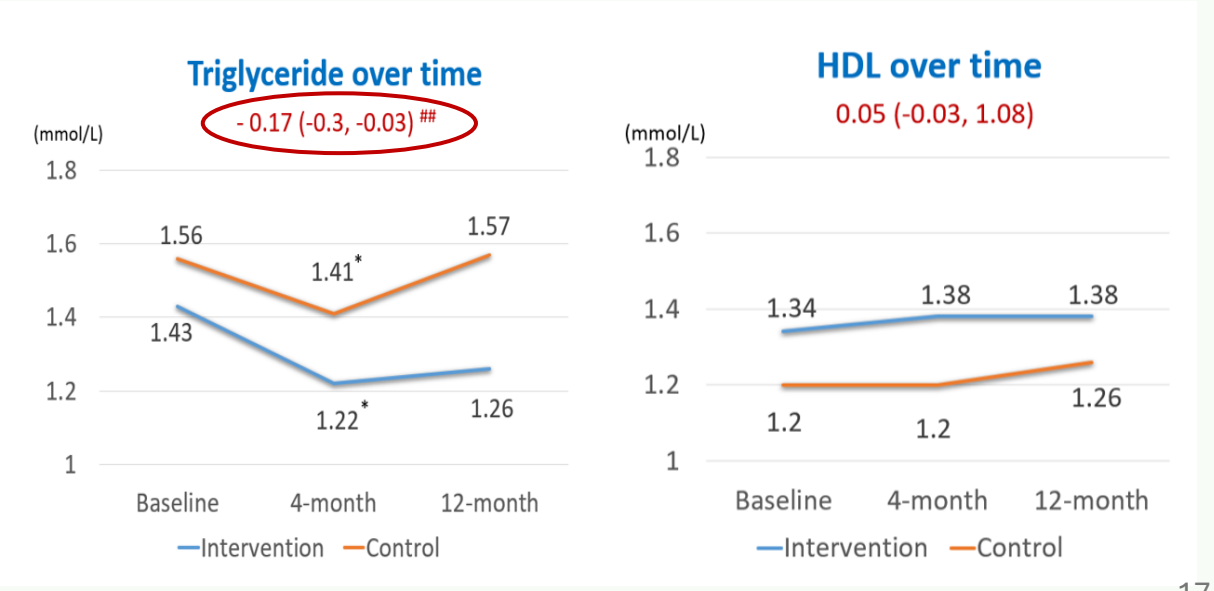
Results:

Improved Cardiovascular Health

- Significantly greater improved cardiovascular health indicators in the intervention group than the control group.
  - **BW**: -1.7 kg;
  - **waist circumference**: -1.83 cm
  - **Systolic BP**: - 4.1 mmHg
  - **Triglycerides**: - 0.2 mmol/L

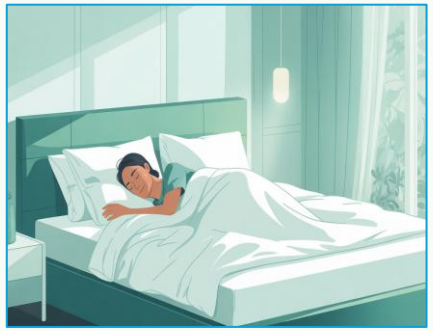






Results:

Better Health-related Quality of Life



- Greater benefits in the intervention group vs control group.
  - **Insomnia symptoms:** - 0.9 units during 12-month study period
  - **Functional outcomes:** + 0.46 units during 12-month study period

	Intervention Group N = 64		Control Group N = 59		Between-group difference	
	Mean ± SD	*P* Value[1]	Mean ± SD	*P* Value[1]	Estimates (95%CI)	*P* Value[2]
Insomnia Severity Index						
Baseline	8.28 ± 4.29		7.97 ± 4.51		-0.9 (-1.76, -0.04)	**0.04** #
4 months	7.19 ± 3.89	**0.03***	7.81 ± 4.82	0.78		
12 months	6.7 ± 3.75	**< 0.00*****	7.51 ± 4.39	0.36		
Epworth Sleepiness Scale					-0.69 (-1.46, 0.09)	**0.08**
Baseline	7.8 ± 3.32		7.73 ± 4.59			
4 months	7.05 ± 3.65	0.06	7.47 ± 4.37	0.52		
12 months	7.14 ± 4.14	0.18	8.07 ± 4.01	0.45		
Functional Outcomes of Sleep Questionnaire					0.46 (0.07, 0.85)	**0.02** #
Baseline	17.39 ± 1.93		17.29 ± 2.26			
4 months	17.77 ± 1.81	0.09	17.59 ± 2.22	0.31		
12 months	17.94 ± 1.89	**0.02***	17.73 ± 1.91	0.11		

Others: No significant difference in changes in mood and physical fitness performance between 2 groups.

Conclusion

Impact

Clinically meaningful improvement

The 4S program significantly improved apnea severity, PAP adherence, cardiovascular risk, sleep quality, and functional outcomes in overweight, inactive adults with moderate-to-severe OSA.

Reframing

OSA needs patient engagement

The findings support reframing OSA as a chronic condition requiring long-term patient engagement and chronic care model rather than a narrow device-based approach.

Model

Patient-centered self-management

By combining patient-centered self-management, personalized behavioral support, and digital communication, the 4S model strengthens OSA management.

Future Directions

The next phase of the 4S program focuses on **scaling** across sleep clinics, **disseminating** video-based education across hospitals, and **adapting** the smartphone-based, patient-centred model for other chronic disease management.

Scale Across sleep clinics

Use implementation science approaches to support wider uptake, consistent delivery, and long-term integration.

Disseminate Across hospitals

Expand 4S video messages to strengthen patient education, reinforce behaviour change, and support self-management.

Adapt For other chronic disease management

Extend the smartphone-enabled, patient-centred framework to other chronic disease management (e.g. COPD)

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Thank You