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General Study Information

Principal Investigator: Roberto P Benzo, MD

Study Title: A Lifestyle Program for Severe Comorbid Obstructive Sleep Apnea with Severe Obesity

Research Question and Aims

Hypothesis: Patients with Obstructive Sleep Apnea (OSA) and obesity will have positive behavior changes as the result of participating in a remote monitoring and health coaching program. The positive behavior changes include improved control of their OSA via adherence to prescribed medical devices, reductions in obesity and improved quality of life.

Aims, purpose, or objectives: Mayo Clinic in collaboration with Minnesota Health Solutions (MHS) will develop a data driven system for persons with severe obesity sleep apnea that utilizes remote monitoring with health coaching to create behavior changes aimed at improving health and quality of life. In previous NIH funding, Mayo and MHS have previously developed a home-based monitoring system with health coaching for COPD patients (IRB's 14-009016, 17-009449, 18-002453). MHS will modify the system for patients with severe obesity sleep apnea. Mayo Clinic will conduct the at-home feasibility testing and qualitative interviews.

Background: Obstructive sleep apnea (OSA) is a disorder characterized by episodic cessation of breathing during sleep with intermittent hypoxemia and sleep fragmentation. Its effects go far beyond sleep and it is associated with decreased neurocognitive function, reduced quality of life and increases in hypertension, insulin resistance and cardiovascular disease.[3,7,23] The prevalence of clinically significant OSA has been estimated at 7% for adult males and 5% for adult females.[1–3] Researchers have found though that OSA likely has a higher undiagnosed prevalence, up to 21% in the general population[3], and that prevalence increases with age.[7,24] The strongest risk factor for developing OSA is obesity and it is estimated that more than half of the prevalence of OSA is attributable to excess body weight.[7,25]

First line therapy for OSA has been positive airway pressure (PAP); however, despite many technological advances in PAP therapy, adherence to use, a behavior, remains a problem. Using best current practices, acceptable PAP adherence at 31-90 days is seen in only 75% of patients[21] and only 65% will be adherent at one-year[22]. Although PAP is considered the best single therapy for OSA, this is only applied during sleep and only addresses airway patency with no direct impact on obesity or the many comorbidities that contribute to and perpetuate OSA. Most of the chronic conditions associated with sleep apnea are related to behavior. Hence, there is a need for interventions that promote compliance with PAP and promote behavior change to improve obesity and other comorbidities. We propose to develop a remote system that utilizes effective digital intervention techniques in combination with data monitoring and health coaching to create behavior change. Health coaching informed by biomonitoring can create the conditions for behavioral change by providing motivation and feedback, which support the development of self-efficacy to create change.

Health coaching has been shown to improve outcomes in the most prevalent chronic conditions including COPD, diabetes and heart failure. Health coaching via telehealth provides a unique engagement that supports behavior change through the theory of planned behavior. Through coaching, patients have the opportunity to develop the motivation to change. Remote monitoring provides patients and the health coach direct feedback that can bring awareness of measures, such as activity level, weight, sleep quality and PAP adherence. Properly presented and used these data become a unique tool to inform the dialogue for behavior change. Patients are able to develop the self-efficacy to support behavior change. Best practices in digital intervention are well-suited to health coaching and support the development of a system that is scalable, accessible, and billable.

Multiple studies have shown that the annual health care costs of OSA patients are double the costs for age and sex matched controls.[26–30] These additional costs are due to hospitalizations, physician fees, specialist fees, and prescriptions.[7] Additionally, researchers have shown that effectively treated patients show a gradual decrease in healthcare costs while matched controls continue to show an in increase in healthcare costs.[31,32]
Obesity is also associated with increased health expenditures compared to people with a normal body weight and it is estimated that 9% of annual health expenditures are due to obesity.[33] Most of this extra cost is due to health care conditions associated with obesity, including diabetes and cardiovascular disease.[17–20] However, it is difficult to separate the contributions of OSA and obesity from the costs of treating common comorbidites.[5]

There are multiple bi-directional relationships between a wide range of comorbidities and OSA[7,34] and there is substantial sharing of genetic polymorphisms between OSA and obesity. OSA influences hormonal regulation of appetite and metabolism via intermediaries such as leptin and grehlin, and treatment with PAP tends to influence these factors in favor of weight loss.[35] However, without changes in activity and diet, most studies demonstrate ongoing weight gain in newly treated obese OSA patients. Both obesity and OSA have independent contributions to cardiovascular risk. While PAP therapy remains an essential part of OSA treatment,[25,26,36,37] its use does not directly impact obesity or all of the comorbidities associated with severe OSA syndrome. Most of the chronic conditions associated with OSA are related to behavior. Additionally, PAP has significant problems with adherence, a behavior.

There is a need for interventions that lead to behavior change, resulting in weight loss and reduced risk of cardiovascular events, and these should be recommended to all patients with OSA.[25] A consistent finding in clinical studies is that weight reductions result in improvement in OSA symptoms. In a group of patients with obesity, diabetes and OSA, an intensive lifestyle intervention led to more weight loss and more than three times the rate of remission from OSA than the controls receiving standard diabetes support and education.[38]

Health coaching has demonstrated effectiveness for behavior change and chronic disease management. While still limited, there is growing evidence that health coaching can be used for weight management, physical activity promotion, and medication adherence.[39–41] A recently completed meta-analysis that included 15 randomized trials found that health coaching could easily be delivered and provided motivation strategies for behavior change (physical activity, dietary behavior, health responsibility and stress management) among patients with cardiovascular risk factors.[42] A previous study by PI Benzo that utilized health coaching for patients with severe COPD after hospitalization showed decreased readmission and sustainable improvements in quality of life.[43] In another study by Benzo of severe obesity in patients with chronic lung disease, an eight week intervention with weekly health coaching calls resulted in weight loss and improvements in body composition, walking tests, mindful eating behavior and quality of life.[44] Additionally, this study incorporated the Weight Watchers app for recording food and an activity monitor to capture daily steps.

The use of remote monitoring devices offers an additional opportunity to enhance health coaching. A pilot study that combined wearable devices with health coaching to promote healthy lifestyle changes in overweight patients resulted in clinically significant weight loss over 16 weeks.[45] Participants had good adherence to wearing their devices and lost more weight as time went along. The researchers hypothesize that effectiveness was increased by participants completing questions in advance of health coaching sessions, which allowed the focus in sessions to be on relationship building and problem solving. In another recently completed study that used health coaching and remote monitoring for weight loss in obese patients, participants who received health coaching had increased compliance with device adherence and higher rates of weight loss than participants who did not receive the health coaching.[46] Health coaching combined with remote monitoring offers the possibility of a relatively inexpensive intervention that is scalable, billable and able to be delivered remotely. Patients who have difficulty accessing a facility, for any reason, may be more likely and able to participate.

Engaging digital intervention techniques are well-suited to health coaching as many of the effective strategies are common to both. While there is no single strategy that is effective for engagement for everyone, there are proven strategies to increase the likelihood of engagement and success. Specific strategies that the system will incorporate to increase engagement that work well with health coaching are goal setting, self-monitoring, interactivity, accountability and personalization. Goal Setting, which will be facilitated through health coaching, is most effective when it is used together with self-monitoring and accountability which increases engagement through enhanced motivation.[47] Self-monitoring involves participants monitoring their own behavior in regard to a goal.[48] In the proposed system, self-monitoring will be supported by providing data and feedback to the participants. Accountability will be facilitated by providing participant data to the health coaches who can help clarify the participant's goals, monitor progress, and reflect on their progress.[49] The system will be interactive through the use of the health coaches, which has been found to be more engaging and more persuasive for digital health interventions.[50] Finally, the system will support personalization and will be adaptive to individual's needs with the goal of behavior change.[51] Other strategies may be incorporated as they are deemed effective in development and testing (e.g., reminders). The proposed system will be built for usability and with high quality visual design. While usability itself does not increase engagement, a system that is not usable will be a barrier to the program and technology use.[47] A high quality visual design supports usability and it can directly impact engagement.[47] We propose a user-centered design process to ensure the usability and appeal of the visual design of the system.

Preliminary evidence shows that an effective digital health intervention that utilizes remote monitoring and health coaching to address obesity may be as effective as an in-person program, in addition to having benefits in accessibility and scalability.[52] Recent preliminary research also shows that this type of intervention is feasible, acceptable, and effective for older adults living in rural areas to address obesity.[53] This is particularly important as there has been limited study of older adults participation in digital health interventions.[53]

Scientific Premise : Severe OSA associated with obesity and other comorbidities is highly influenced by behavior. Early evidence suggests that health coaching is effective at supporting patients with behavior changes and chronic disease management. Health coaching associated with remote monitoring has been tested and offers promise to address behavior, including PAP use, physical activity, and mindful eating. Based on our previous NIH funded work in other chronic conditions, we hypothesize that a remote monitoring system with health coaching for severe OSA with obesity and comorbidity is feasible and may improve quality of life. Additionally, it may create conditions for behavior change resulting in increased adherence to PAP use as well as addressing obesity and other comorbid conditions. If effective these findings are extremely important to

addressing a critical health problem through a solution that is relatively inexpensive, scalable, billable, and accessible.

We propose to develop a home-based system for obese patients with OSA. The proposed system will provide patients with remote guidance, personalized reports, and monitoring integrated with health coaching. Health coaches will also receive individualized patient information, formatted in accessible and usable way. Monitoring will include key indicators: PAP use, sleep quality, physical activity, weight and symptom days (self-reported well-being, fatigue, sleepiness, and daily activity). The system is compliant to bill for remote patient monitoring through existing Medicare and private insurance billing codes.

Study Design and Methods

Methods: *Describe in lay terms, completely detailing the research activities that will be conducted by Mayo Clinic staff under this protocol*.

The proposed system (see Figure 1) will use technology to facilitate remote health coaching for people with severe comorbid OSA with the goal of encouraging behavior change. The system will be built upon the existing home-based pulmonary rehabilitation (PR) system that was jointly developed by Mayo and MHS. The PR system was well-received and has proven effective, reliable, and easy to use. The overall architecture will be reused for the OSA coaching system, but a new set of sensors, cloud services, and data reporting capabilities will need to be integrated and developed.

The system will be designed so that a newly-diagnosed patient can immediately benefit from health coaching, including equipment setup, goal setting, and trend monitoring in all pertinent aspects of care: PAP management, sleep scheduling, sleep duration, diet, exercise, medications and more. When they register for the program, patients will be provided with a set of pre-configured sensors and a dedicated Android tablet. The tablet will exclusively run a custom-built Android application that graphs patient progress, asks periodic self-report questions, sends secure text messages between the health coach and patient, displays timely reminders, and plays helpful videos to assist with sensor use. The tablet and sensors upload the patient's activities, physiological data, and answers to the daily self-report questions to a secure website. This website also allows health coaches to view patient data via overview, weekly, daily, and trend reports. Health coaches call patients regularly to celebrate progress, assist with any issues, and set new goals.

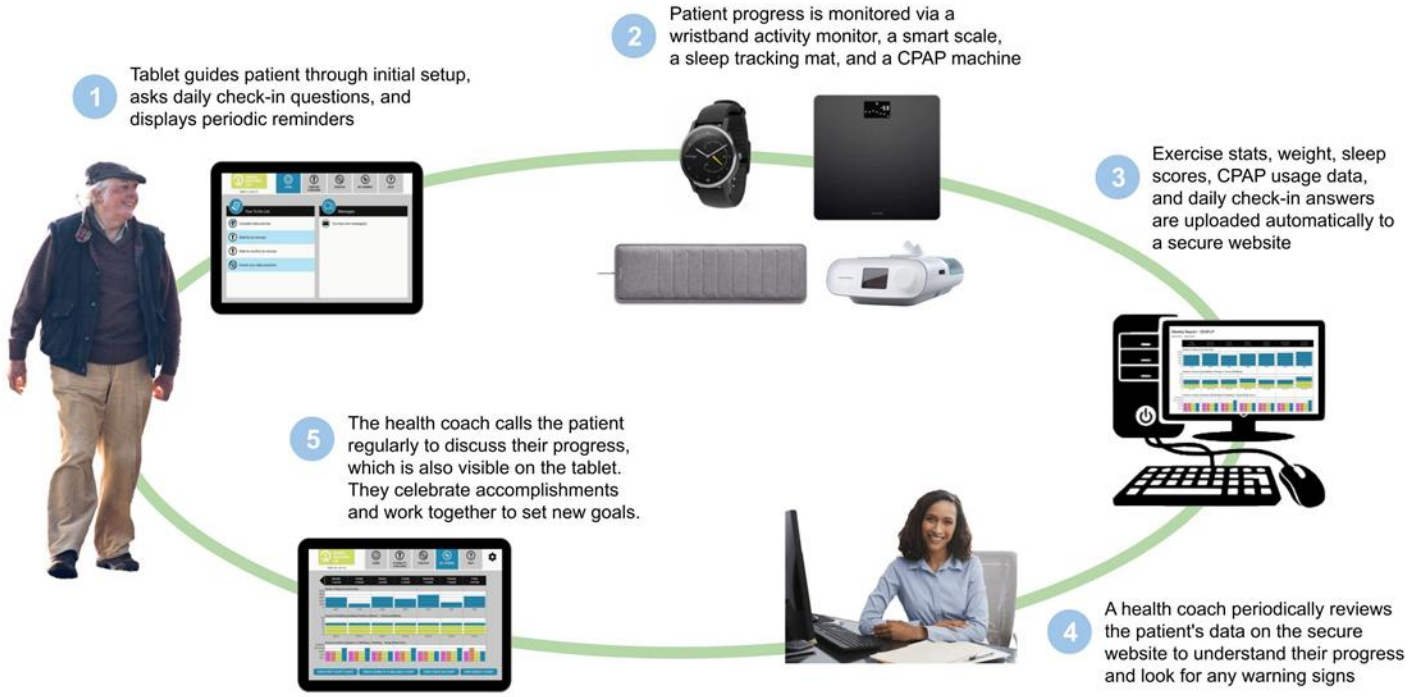


Figure 1. A diagram of the proposed health coaching system.

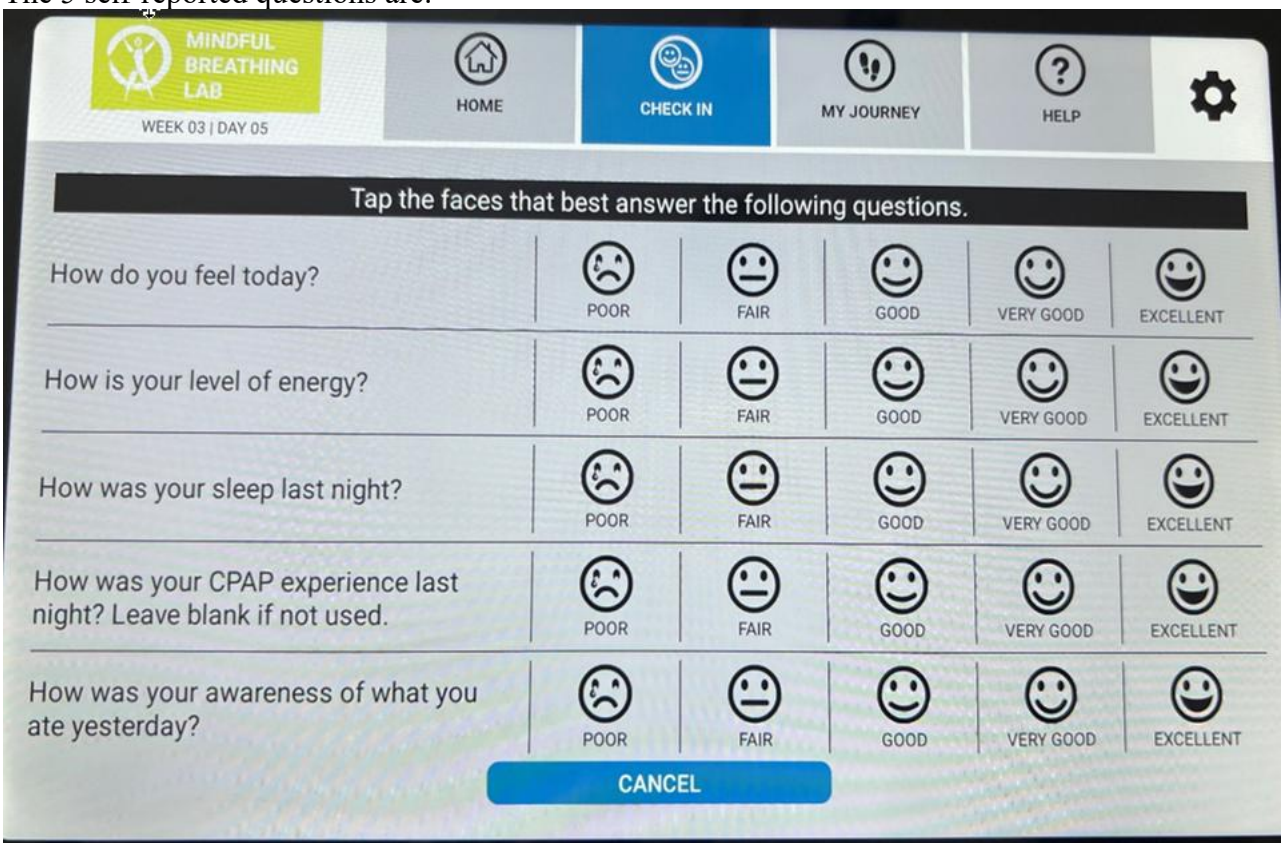
In the past, MHS and Mayo jointly developed an in-home PR system that was well-received and is being widely deployed. Patients receive an Android tablet running an app that plays exercise videos, graphs patient progress, asks periodic self-report questions, sends text messages between the health coach and patient, displays timely reminders, and shows instructional videos to assist with sensor use. The app runs in "kiosk" mode, ensuring that the patient cannot close the app, accidentally misconfigure the tablet, or use the tablet for other purposes (e.g., web browsing, watching movies). Each tablet has a unique API key that allows it to sync the patient's activities, physiological data, and daily self-report answers to a secure website. Health coaches can login to this website to review the data for each of their patients.

MHS engineers will provision a web server and database for the OSA coaching system. The web server will be an AWS EC2 t2.micro instance running Ubuntu Linux 18.04 with an .NET Core 3.1 application (or newer). The database will be an AWS RDS db.t2.micro instance running MariaDB 10.3.23 (or newer).
Software development best practices will be used throughout development. All source code will be versioned using Git and backed up GitHub.com.

Patients will be provided with a system (Android tablet linked to a Withings Body Smart scale, Withings Sleep Tracking Mat, and a Withings Move Activity and Sleep Watch, see Appendix 1 for Withings device information) to take home and instructions to use it for two weeks along with their newly prescribed PAP machine. Patients will be asked to weigh themselves at least once a week, to use the PAP machine and sleep mat daily, and to monitor their steps. Patients will also be asked to complete self-report questions at least 6 of the seven days and to complete a health coaching call twice per week. The activity monitor watch is to be worn

at all times. The participant tablet home screen display will have a simple To-Do list. To initiate an activity, the user selects the corresponding activity from the "To-Do" column. When the participant finishes the selected activity, it appears in the "Done" column. The application provides instructions before and between each activity. Participants will also be able to see limited reports of their activity as will the health coach. In phase II, this reporting capability will be flushed out. The health coaches are an established part of Dr. Benzo's laboratory and have been trained to support participants in the behavior change process.[55]

The 5 self-reported questions are:



Following the 2 week testing period , participants will be interviewed by the Research Coordinator to provide qualitative feedback on the acceptability and usability of the system, including what they liked and did not like about the app interface, the concept of home-based system, and the health coaching. Participants will be asked to describe any struggles with using the system or past efforts in behavior change. Participants will also complete a brief socio-demographic survey. Additionally, the system securely collects and stores the following patient data: timestamped interactions with the Android app, answers to the daily questionnaire, physiological and activity data collected by the scale, sleep mat and activity monitor. All data will be reviewed and visualized to understand patient usage, identify potential barriers, and to plan further developments to the system.

The interviews will be recorded for subsequent transcription of the interactions. The transcribed interviews will be examined for common themes. Each interview will vary between 20 and 30 minutes and will be performed by a member of the Mindful Breathing Laboratory who is trained in Motivational Interviewing and Qualitative Interviewing. Additional members from the Lab will assist in the transcription of the interviews as well as theme identification. Data collection and analysis will be overseen by Dr. Benzo. (A guided interview script will be used.)

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Subject Information

Target accrual: 15

Adult patients who are newly diagnosed with severe OSA and severe obesity (BMI>35) will be recruited from the Mayo Clinic Center for Sleep Medicine. A Research Study Coordinator will contact qualified patients prior to their follow-up appointment in the Sleep Center. This appointment typically takes place 2 or 3 months after the initial consultation with a sleep provider. This window will give the patient time to adjust to using their new sleep apnea machine. The study team will use Epic's Slicer Dicer feature to search the appointment return type and add the required BMI and age requirement. A member of the study team will contact via telephone eligible patients using an approved phone script. If interested, the patient will have the option of receiving the consent form electronically through Ptrax or a paper copy through the US Mail. A member of the study team is available if the patient would like to meet in person during their follow up visit with their provider. Patients may also be referred at the time of their return visit.

Inclusion Criteria:

- 18 years of age or older
- Diagnosis of OSA
- BMI > or = to 35

Exclusion Criteria:

- Patients with an inability to provide good data or follow commands (patients who are disoriented, have a severe neurologic or psychiatric condition).

Review of medical records, images, specimens

The study involves data that exist at the time of IRB submission **and** data that will be generated after IRB submission. Include this activity in the Methods section.

To determine eligibility and obtain contact information, a study team member may review the participant's medical record.

Qualitative Data Analysis

Power Statement: This is a feasibility study, no sample size is required.

Data Analysis Plan:

A qualitative analysis , in the way of likert-scale questions, will be completed when the participant has completed the intervention. The qualitative approach will provide a framework for which detailed information about the participants experience is collected and eventually analyzed.

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Bibliography & References Cited

1. Bixler EO, Vgontzas AN, Lin H-M, et al. Prevalence of Sleep-disordered Breathing in Women. *Am J Respir Crit Care Med*. 2001;163(3):608-613. doi:10.1164/ajrccm.163.3.9911064
2. Young T, Palta M, Dempsey J, Skatrud J, Weber S, Badr S. The occurrence of sleep-disordered breathing among middle-aged adults. *N Engl J Med*. 1993;328(17):1230-1235. doi:10.1056/NEJM199304293281704
3. Young T, Peppard PE, Gottlieb DJ. Epidemiology of obstructive sleep apnea: a population health perspective. *Am J Respir Crit Care Med*. 2002;165(9):1217-1239. doi:10.1164/rccm.2109080
4. Kushida CA, Efron B, Guilleminault C. A predictive morphometric model for the obstructive sleep apnea syndrome. *Ann Intern Med*. 1997;127(8 Pt 1):581-587. doi:10.7326/0003-4819-127-8_part_1-199710150-00001
5. Ronksley PE, Hemmelgarn BR, Tsai WH. Comorbidity and healthcare costs in patients with obstructive sleep apnoea. *Breathe*. 2011;8(2):95-104. doi:10.1183/20734735.011311
6. Logan AG, Perlikowski SM, Mente A, et al. High prevalence of unrecognized sleep apnoea in drug-resistant hypertension. *J Hypertens*. 2001;19(12):2271-2277. doi:10.1097/00004872-200112000-00022
7. Lee W, Nagubadi S, Kryger MH, Mokhlesi B. Epidemiology of obstructive sleep apnea: a population-based perspective. *Expert Review of Respiratory Medicine*. 2008;2(3):349-364. doi:10.1586/17476348.2.3.349
8. West SD, Nicoll DJ, Stradling JR. Prevalence of obstructive sleep apnoea in men with type 2 diabetes. *Thorax*. 2006;61(11):945-950. doi:10.1136/thx.2005.057745
9. Mooe T, Rabben T, Wiklund U, Franklin KA, Eriksson P. Sleep-disordered breathing in men with coronary artery disease. *Chest*. 1996;109(3):659-663. doi:10.1378/chest.109.3.659
10. Y P, H K, J H, S L, A J, M B. An independent association between obstructive sleep apnoea and coronary artery disease. *Eur Respir J*. 1999;14(1):179-184. doi:10.1034/j.1399-3003.1999.14a30.x
11. Javaheri S. Sleep disorders in systolic heart failure: a prospective study of 100 male patients. The final report. *Int J Cardiol*. 2006;106(1):21-28. doi:10.1016/j.ijcard.2004.12.068
12. Oldenburg O, Lamp B, Faber L, Teschler H, Horstkotte D, Töpfer V. Sleep-disordered breathing in patients with symptomatic heart failure: a contemporary study of prevalence in and characteristics of 700 patients. *Eur J Heart Fail*. 2007;9(3):251-257. doi:10.1016/j.ejheart.2006.08.003
13. Sin DD, Fitzgerald F, Parker JD, Newton G, Floras JS, Bradley TD. Risk Factors for Central and Obstructive Sleep Apnea in 450 Men And Women with Congestive Heart Failure. *Am J Respir Crit Care Med*. 1999;160(4):1101-1106. doi:10.1164/ajrccm.160.4.9903020
14. Parra O, Arboix A, Bechich S, et al. Time course of sleep-related breathing disorders in first-ever stroke or transient ischemic attack. *Am J Respir Crit Care Med*. 2000;161(2 Pt 1):375-380. doi:10.1164/ajrccm.161.2.9903139
15. Bassetti CL, Milanova M, Gugger M. Sleep-disordered breathing and acute ischemic stroke: diagnosis, risk factors, treatment, evolution, and long-term clinical outcome. *Stroke*. 2006;37(4):967-972. doi:10.1161/01.STR.0000208215.49243.c3

16. Hui DSC, Choy DKL, Wong LKS, et al. Prevalence of Sleep-Disordered Breathing and Continuous Positive Airway Pressure Compliance: Results in Chinese Patients With First-Ever Ischemic Stroke. *Chest*. 2002;122(3):852-860. doi:10.1378/chest.122.3.852
17. Marin JM, Carrizo SJ, Vicente E, Agusti AGN. Long-term cardiovascular outcomes in men with obstructive sleep apnoea-hypopnoea with or without treatment with continuous positive airway pressure: an observational study. *Lancet*. 2005;365(9464):1046-1053. doi:10.1016/S0140-6736(05)71141-7
18. Nieto FJ, Young TB, Lind BK, et al. Association of sleep-disordered breathing, sleep apnea, and hypertension in a large community-based study. Sleep Heart Health Study. *JAMA*. 2000;283(14):1829-1836. doi:10.1001/jama.283.14.1829
19. Reichmuth KJ, Austin D, Skatrud JB, Young T. Association of Sleep Apnea and Type II Diabetes. *Am J Respir Crit Care Med*. 2005;172(12):1590-1595. doi:10.1164/rccm.200504-637OC
20. Yaggi HK, Concato J, Kernan WN, Lichtman JH, Brass LM, Mohsenin V. Obstructive Sleep Apnea as a Risk Factor for Stroke and Death. *New England Journal of Medicine*. 2005;353(19):2034-2041. doi:10.1056/NEJMoa043104
21. Cistulli PA, Armitstead J, Pepin J-L, et al. Short-term CPAP adherence in obstructive sleep apnea: a big data analysis using real world data. *Sleep Med*. 2019;59:114-116. doi:10.1016/j.sleep.2019.01.004
22. Morrone E, Giordano A, Carli S, et al. Something is changing in adherence to CPAP therapy: real world data after 1 year of treatment in patients with obstructive sleep apnoea. *Eur Respir J*. 2020;55(3). doi:10.1183/13993003.01419-2019
23. Young T, Skatrud J, Peppard PE. Risk factors for obstructive sleep apnea in adults. *JAMA*. 2004;291(16):2013-2016. doi:10.1001/jama.291.16.2013
24. Fietze I, Laharnar N, Obst A, et al. Prevalence and association analysis of obstructive sleep apnea with gender and age differences – Results of SHIP-Trend. *Journal of Sleep Research*. 2019;28(5):e12770. doi:https://doi.org/10.1111/jsr.12770
25. Pleava R, Mihaicuta S, Serban CL, et al. Long-Term Effects of Continuous Positive Airway Pressure (CPAP) Therapy on Obesity and Cardiovascular Comorbidities in Patients with Obstructive Sleep Apnea and Resistant Hypertension—An Observational Study. *Journal of Clinical Medicine*. 2020;9(9):2802. doi:10.3390/jcm9092802
26. Kim J, Tran K, Seal K, et al. *Interventions for the Treatment of Obstructive Sleep Apnea in Adults a Health Technology Assessment*. CADTH Optimal Use Report; 2017.
27. Smith R, Ronald J, Delaive K, Walld R, Manfreda J, Kryger MH. What are obstructive sleep apnea patients being treated for prior to this diagnosis? *Chest*. 2002;121(1):164-172. doi:10.1378/chest.121.1.164
28. Tarasiuk A, Greenberg-Dotan S, Brin YS, Simon T, Tal A, Reuveni H. Determinants affecting health-care utilization in obstructive sleep apnea syndrome patients. *Chest*. 2005;128(3):1310-1314. doi:10.1378/chest.128.3.1310
29. Tarasiuk A, Greenberg-Dotan S, Simon-Tuval T, Oksenberg A, Reuveni H. The effect of obstructive sleep apnea on morbidity and health care utilization of middle-aged and older adults. *J Am Geriatr Soc*. 2008;56(2):247-254. doi:10.1111/j.1532-5415.2007.01544.x
30. Greenberg-Dotan S, Reuveni H, Simon-Tuval T, Oksenberg A, Tarasiuk A. Gender differences in morbidity and health care utilization among adult obstructive sleep apnea patients. *Sleep*. 2007;30(9):1173-1180. doi:10.1093/sleep/30.9.1173
31. Albarrak M, Banno K, Sabbagh AAl, et al. Utilization of Healthcare Resources in Obstructive Sleep Apnea Syndrome: a 5-Year Follow-Up Study in Men Using CPAP. *Sleep*. 2005;28(10):1306-1311. doi:10.1093/sleep/28.10.1306

32. Banno K, Manfreda J, Walld R, Delaive K, Kryger MH. Healthcare utilization in women with obstructive sleep apnea syndrome 2 years after diagnosis and treatment. *Sleep*. 2006;29(10):1307-1311. doi:10.1093/sleep/29.10.1307
33. Finkelstein EA, Trogdon JG, Cohen JW, Dietz W. Annual medical spending attributable to obesity: payer-and service-specific estimates. *Health Aff (Millwood)*. 2009;28(5):w822-831. doi:10.1377/hlthaff.28.5.w822
34. Kuvat N, Tanriverdi H, Armutcu F. The relationship between obstructive sleep apnea syndrome and obesity: A new perspective on the pathogenesis in terms of organ crosstalk. *The Clinical Respiratory Journal*. 2020;14(7):595-604. doi:https://doi.org/10.1111/crj.13175
35. Romero-Corral A, Caples SM, Lopez-Jimenez F, Somers VK. Interactions between obesity and obstructive sleep apnea: implications for treatment. *Chest*. 2010;137(3):711-719. doi:10.1378/chest.09-0360
36. Wozniak DR, Lasserson TJ, Smith I. Educational, supportive and behavioural interventions to improve usage of continuous positive airway pressure machines in adults with obstructive sleep apnoea. *Cochrane Database Syst Rev*. 2014;(1):CD007736. doi:10.1002/14651858.CD007736.pub2
37. Rotenberg BW, Murariu D, Pang KP. Trends in CPAP adherence over twenty years of data collection: a flattened curve. *J Otolaryngol Head Neck Surg*. 2016;45(1):43. doi:10.1186/s40463-016-0156-0
38. Foster GD, Borradaile KE, Sanders MH, et al. A Randomized Study on the Effect of Weight Loss on Obstructive Sleep Apnea Among Obese Patients With Type 2 Diabetes: The Sleep AHEAD Study. *Archives of Internal Medicine*. 2009;169(17):1619-1626. doi:10.1001/archinternmed.2009.266
39. Butterworth S, Linden A, McClay W, Leo MC. Effect of motivational interviewing-based health coaching on employees' physical and mental health status. *J Occup Health Psychol*. 2006;11(4):358-365. doi:10.1037/1076-8998.11.4.358
40. Olsen JM, Nesbitt BJ. Health coaching to improve healthy lifestyle behaviors: an integrative review. *Am J Health Promot*. 2010;25(1):e1-e12. doi:10.4278/ajhp.090313-LIT-101
41. Mao A, Chen C, Magana C, Caballero B, Olayiwola J. A Mobile Phone-Based Health Coaching Intervention for Weight Loss and Blood Pressure Reduction in a National Payer Population: A Retrospective Study. - Abstract - Europe PMC. *JMIR Mhealth and Uhealth*. 2017;5(6):e80. doi:10.2196/mhealth.7591
42. An S, Song R. Effects of health coaching on behavioral modification among adults with cardiovascular risk factors: Systematic review and meta-analysis. *Patient Education and Counseling*. 2020;103(10):2029-2038. doi:10.1016/j.pec.2020.04.029
43. Benzo RP, Kirsch JL, Hathaway JC, McEvoy CE, Vickers KS. Health Coaching in Severe COPD After a Hospitalization: A Qualitative Analysis of a Large Randomized Study. *Respir Care*. 2017;62(11):1403-1411. doi:10.4187/respcare.05574
44. Dupuy-McCauley KL, Novotny PJ, Benzo RP. Treating Severe Obesity to Reduce Dyspnea in Patients With Chronic Lung Disease: A Pilot Mixed Methods Study. *CHEST*. 2020;158(3):1128-1131. doi:10.1016/j.chest.2020.02.032
45. Hurst I, Bixenstine PJ, Casillas C, et al. A telehealth intervention to promote weight loss and physical activity in overweight primary care patients. *Healthcare*. 2021;9(1):100509. doi:10.1016/j.hjdsi.2020.100509
46. Alencar M, Johnson K, Gray V, Mullur R, Gutierrez E, Dionico P. Telehealth-Based Health Coaching Increases m-Health Device Adherence and Rate of Weight Loss in Obese Participants. *Telemed J E Health*. 2020;26(3):365-368. doi:10.1089/tmj.2019.0017
47. Strauss G. Engagement techniques for digital health interventions. Limbix. Published January 19, 2021. Accessed February 8, 2021. https://blog.limbix.com/engagement-techniques-for-digital-health-interventions-b14e4128993b

48. Crane D, Garnett C, Michie S, West R, Brown J. A smartphone app to reduce excessive alcohol consumption: Identifying the effectiveness of intervention components in a factorial randomised control trial. *Scientific Reports*. 2018;8(1). doi:10.1038/s41598-018-22420-8
49. Pratap A, Grant D, Vegesna A, et al. Evaluating the Utility of Smartphone-Based Sensor Assessments in Persons With Multiple Sclerosis in the Real-World Using an App (elevateMS): Observational, Prospective Pilot Digital Health Study. *JMIR mHealth and uHealth*. 2020;8(10):e22108. doi:10.2196/22108
50. Oh J, Sundar SS. How Does Interactivity Persuade? An Experimental Test of Interactivity on Cognitive Absorption, Elaboration, and Attitudes. *Journal of Communication*. 2015;65(2):213-236. doi:10.1111/jcom.12147
51. Lustria MLA, Noar SM, Cortese J, Stee SKV, Glueckauf RL, Lee J. A Meta-Analysis of Web-Delivered Tailored Health Behavior Change Interventions. *Journal of Health Communication*. 2013;18(9):1039-1069. doi:10.1080/10810730.2013.768727
52. Silberman JM, Kaur M, Sletteland J, Venkatesan A. Outcomes in a digital weight management intervention with one-on-one health coaching. *PLOS ONE*. 2020;15(4):e0232221. doi:10.1371/journal.pone.0232221
53. Batsis JA, Petersen CL, Clark MM, et al. Feasibility and acceptability of a technology-based, rural weight management intervention in older adults with obesity. *BMC Geriatrics*. 2021;21(1):44. doi:10.1186/s12877-020-01978-x
54. Benzo RP, Kramer KM, Hoult JP, Anderson PM, Begue IM, Seifert SJ. Development and Feasibility of a Home Pulmonary Rehabilitation Program With Health Coaching. *Respiratory Care*. 2018;63(2):131-140. doi:10.4187/respcare.05690
55. Benzo R, Vickers K, Ernst D, Tucker S, McEvoy C, Lorig K. Development and feasibility of a self-management intervention for chronic obstructive pulmonary disease delivered with motivational interviewing strategies. *Journal of cardiopulmonary rehabilitation and prevention*. 2013;33(2):113-122. doi:10.1097/HCR.0b013e318284ec67

Appendix 1:

Withings Sleep Mat

Device

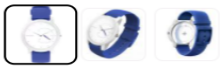
Outer material	Premium fabric
Dimensions and weight	Length: 637mm (25") Width: 190mm (7.5") Thickness: 5mm (0.2") Weight: 350 g (1.13 oz)
Sensors	Pneumatic sensor: measures respiratory rate, heart beats via ballistocardiography and body movements across the mattress. Sound sensor: identifies audio signals specific to snoring & cessation of breathing episodes.
Data storage & sync	Free and unlimited online data storage with a Withings account. Local storage of data between syncs.
Power supply	Power supply 5V 1A USB power adapter included

Withings Smart Scale

Device

Four weight sensors	Weighing range: 5 -> 180kg (9 -> 396lb) 100g (0.2lb) graduation Units: kg, lb, st lb
Patented body position detector	Highly-accurate weighing via Position Control™ technology
Scale	Large, high-strength tempered glass platform Paint-free satin white casing Ultra slim design Dimensions: 12.8 x 12.8 x 0.9 in. / 327x327x23mm
Display	Large, easy-on-the-eye graphical display (2.4"x1.6"), 128x64 pixels High-contrast lighting
Storage and memory	Free and unlimited online storage of weight readings Stores up to 16 readings if scale cannot sync wirelessly
Power supply	4x 1.5V Alkaline cells (AAA) Average battery lifetime of 18 months

Withings Move Activity and Sleep Watch



Device

Materials	Withings Move comes with a plastic case and a stainless steel bottom case with a silicone wristband. Withings Move Timeless Chic features a stainless steel case with a brushed dial, mineral glass, chrome indexes and metal hands. Timeless Chic Blue & Rose Gold comes with a leather band and an extra silicone band.
Single battery charge lasts	Up to 18 months (CR2430)
Storage & memory	Free and unlimited online data storage with a Withings account 5 days of local storage of data between syncs
Usage instruction	Workout mode: Launch workout mode with a long press on the watch button. It will activate a timer directly on the watch, and it will activate the connected GPS feature.

Metrics tracked

Metrics	Walking and running: Steps, distance, calories Swimming: Session duration, calories Sleep: Deep and light sleep phases, sleep interruptions Automatic detection of activities, no need for user's action Connected GPS: distance, pace & elevation