Study Protocol

Date: 7/20/2023

IRB Approval date:

NCT05952297

A randomized pilot study of a wearable device using variable complex weak magnetic fields (VCMFs) among participant with poor sleep quality

Daniel J. Anderson[1], Wendy M. Troxel[2], Joshua Landvatter,[1] and Kelly Glazer Baron[1]

[1] Department of Family and Preventive Medicine, University of Utah, Salt Lake City, UT

[2] Rand Corporation, Santa Monica, CA

Ver 7/20/2023

INTRODUCTION

Poor sleep quality is a prevalent and global health problem. Roughly one-third of the world's population reports insufficient sleep duration and as much 70% report poor quality or non-restorative sleep[1] which can have cascading impacts on an individual's health and wellbeing, including increased risk for cardiovascular morbidity and mortality, depression, and accidents.[2-4] Beyond these individual health consequences, there are also substantial societal implications of poor sleep quality. Insomnia is associated with reduced productivity in the workplace due to absenteeism and presenteeism, resulting in the loss of an average of 44–54 working days per year.[5] A recent RAND report estimated the economic losses associated with insomnia in several of the world's largest economies, including an estimated $207.5 billion dollar loss annually.[6]

Given the profound consequences to public health and the economy, it is important to identify novel and scalable treatment options to aid the millions of individuals worldwide experiencing poor sleep quality. Importantly, the front-line treatment for insomnia is cognitive-behavioral therapy for insomnia.[7] However, this treatment remains underutilized due to a combination of factors, including a lack of specialty trained providers and lack of time and resources by both providers and patients.[8] Furthermore, the typical course of behavioral treatment for insomnia is 6 to 8 sessions, which may be a time burden for many patients, especially for in-person treatment. Moreover, from a prevention perspective, there is an acute need to identify safe, effective, and non-invasive treatments to improve sleep quality, in those experiencing poor sleep quality though not necessarily meeting diagnostic criteria for clinical insomnia. This perspective is also consistent with current recommendations to consider sleep health on a continuum, as opposed to discrete clinical disorders only, and to promote sleep health across the continuum.[9]

Recognizing this need, the current study investigates a novel device (Evolv28) designed to improve sleep through the application of variable weak magnetic frequencies. Evolv28 is a wearable sleep wellness device that contains coils that emits variable complex weak magnetic fields (VCMFs) through a neckband. The device is classified as a low-risk wellness device that does not require FDA approval.

Variable weak magnetic frequencies are proposed to interact with neural activity by subtly altering the brain's electromagnetic environment. Results of a pilot study testing Evolv28 suggest that device users may experience reductions in perceived stress and anxiety. Given strong associations between stress, anxiety, and poor sleep quality,[10] the application of variable weak magnetic fields may also have benefits for sleep quality. Preliminary studies have indicated that these frequencies can influence brainwave patterns associated with different sleep stages, suggesting their potential to enhance the restorative aspects of sleep.[11-13] By targeting specific frequencies, it may be possible to facilitate transitions between sleep stages, potentially helping to consolidate sleep (i.e., improve sleep efficiency) and improve sleep quality.

The goal of the current study was to conduct a randomized pilot study to evaluate the efficacy of the Evolv28 device for improving sleep quality among individuals reporting poor sleep quality. If successful, this intervention could represent a novel and scalable solution to the widespread global problem of poor sleep quality and its downstream consequences.

METHOD

Study Design

The study was a randomized, double blinded, placebo-controlled trial with 4-week intervention followed by a two-month open label follow-up period. This study was approved by the University of Utah Institutional Review Board (IRB_00165943) and registered on clinicaltrials.gov (https://clinicaltrials.gov/study/NCT05952297).

Participants

Participants were recruited from the United States via social media advertising and the University of Utah research study locator portal. Inclusion criteria included the following: age 18-65, read and write in English, smartphone user and reporting moderate to severe insomnia symptoms, defined as an

Insomnia Severity Index score of ≥15. Participants were excluded if they had diagnosed sleep disorders other than insomnia (e.g., sleep apnea or restless legs syndrome) or were currently receiving additional treatment for insomnia (e.g., hypnotic medication, cognitive behavioral therapy, etc.). Further exclusion criteria include a history of serious mental health conditions (e.g., Patient Health Questionnaire 8 score of >15, psychosis, Bipolar I or the use of antipsychotic or mood stabilizing drugs), serious physical conditions (e.g., current cancer treatment, neurological illness), drug use (as defined by >14 alcoholic beverages per week, the use of cannabis >3 times in the past month, any use of illicit street drugs), caffeine intake of >400mg per day, overnight work more than once a month, frequent moderate to severe migraine attacks or headaches, pregnancy, and traveling across time zones >3 times throughout the study period.

Procedure

All study procedures were performed remotely. Interested participants completed a screening survey, then if eligible, a study coordinator contacted the participant via email to review study information and schedule a time to complete informed consent. Upon completion of informed consent, study materials were sent to the participant that consisted of the Evolv28 device (inactive), a Fitbit and device instructions. Upon receipt of the study materials, participants completed an instructional meeting with study staff, where they reviewed baseline procedures and Fitbit setup. Participants then completed online surveys, 7 days of daily electronic sleep diary surveys (SurveySignal) and wore the Fitbit for 7 days.

After participants completed their baseline week, a staff member, who was not associated with the study, determined each participant's group assignment and then sent that participant's device serial number to programmers. Participants were randomized 1:1 between intervention and control groups. The randomization table was generated using a random number table stratified by gender using permuted blocks of 4 to 6 participants. Study staff and participants were both blinded to treatment group assignment. To begin the 4-week trial period, the study coordinator met with each participant to ensure the device was activated and confirmed the participant's understanding of how to use it. The intervention

group received the active program, and the control group received an inactive program. In both conditions, the device and application appeared to be active. Participants were asked to wear the device for at least 3 hours per day. If any technical issues occurred, the intervention time was extended to allow for at least four weeks of use before the post-intervention assessment. Participant adherence to the Fitbit and Evolv28 were monitored by the study statistician throughout the trial and reminders were sent to participants who were non-adherent in wearing either device for more than 2 days.

For the follow-up assessment, participants wore the Fitbit again for 7 days and completed electronic sleep diaries for 7 days. Upon completion of the 4-week trial, participants completed a set of follow-up surveys to assess changes in sleep and mood. After the post-trial assessment, all Evolv28 were transitioned to run the active treatment program between week 4 and 3 months. At the end of 3 months, participants completed online questionnaires. Participants were compensated with $100 via an Amazon.com gift card and kept the study Fitbit and Evolv28 device.

Measures

Demographics: Participants filled out a brief demographic measure that contained questions on age, sex, gender, race/ethnicity, marital status, education level, household income level, and employment status.

Insomnia Severity Index (ISI): The ISI is a widely used tool that assesses the severity of insomnia.[14] It consists of questions that evaluate various aspects of insomnia, including difficulty sleeping, staying asleep, waking up too early, and the impact of these on daily functioning. Each question is scored 0-4 and summed, allowing for a total range of 0 to 28. Higher scores indicate a greater severity of insomnia, with 15-21 interpreted as moderate insomnia and 22-28 interpreted as severe insomnia.

Sleep Disturbance and Sleep-Related Impairment: Participants completed PROMIS sleep disturbance and sleep-related impairment,[15] which are both 8-question adaptive measures that assess the degree to which participants have difficulty sleeping and the degree to which it impacts their lives, respectively. Raw

scores are converted to a standardized *t* score that has a mean of 50 and SD of 10. Higher scores indicate worse sleeping or impact of sleep, with scores greater than 60 considered elevated.

Functional Outcomes of Sleep Questionnaire 10-item (FOSQ-10): The FOSQ-10[16] is a 10-item assessment that assesses the impact of sleep on daily functioning, such as driving and working. Each item was scored on a 4-point Likert scale and summed. Lower scores suggest greater impairment due to sleep-related issues.

General Anxiety Disorder 7 (GAD-7): The GAD-7[17] is a 7-item questionnaire designed to assess the severity of generalized anxiety disorder symptoms. Each item is scored on a 4-point Likert scale. Questions indicating negative affect were coded and summed. Questions indicating positive affect were reverse scored, then summed for a total score. Higher scores indicate more severe general anxiety.

Perceived Stress Scale (PSS): The PSS[18] is a 10-item questionnaire that measures the degree to which individuals are stressed in the past month. Each item is scored on a 5-point Likert scale. Questions indicating negative affect were coded and summed. Questions indicating positive affect were reverse scored. Higher scores indicate a greater amount of perceived stress.

Patient Health Questionnaire 8: The Patient Health Questionnaire 8[19] is an 8-item assessment to determine the degree to which a respondent experiences depressive symptoms. Each item corresponds to diagnostic criteria for major depressive disorder, such as little interest in doing things, or trouble concentrating. Each question is scored and added together on a 4-point Likert scale. Higher scores indicate a greater severity of depressive symptoms. Scores $\geq$ 10 indicate the presence of depressive symptoms.

Sleep Diary: Participants completed items from the Consensus Sleep diary.[20] Items include bedtime, sleep latency, number of awakenings, total duration of awakenings, final wake time and rise time. It also

provided the opportunity to comment on any unusual event that may have occurred. Using these diaries, we calculated sleep latency, sleep duration, wake after sleep onset, and sleep efficiency. Sleep diary data was cleaned (e.g., reviewed for AM/PM errors, negative sleep efficiencies and sleep efficiencies >1) diaries were considered valid if participants had at least 4 valid days completed.

Objective sleep/wake estimation: Sleep-wake data was estimated using a Charge 5 Fitbit that was worn during the baseline week, the first week of the trial, and the last week of the trial. Fitbits are comparable to research-grade actigraphy for estimating sleep duration.[21] Fitbit data was collected and aggregated using the Fitabase platform. Fitbit-derived sleep variables included total sleep time, wake after sleep onset (WASO) and sleep efficiency (percent asleep divided by the sleep period time). Sleep periods were auto-scored, and therefore the sleep latency variable was not valid. The sleep variables were scored by the Fitbit algorithm, using the stages algorithm (with heart rate data) when possible, and if not available using the classic (movement only) algorithm. Most days both pre and post for each group were scored using the stages algorithm (>90%) and therefore all valid days were used in the analysis. To determine a valid day, we first identified the primary sleep period. Primary sleep periods <2 h were excluded if the sleep diary did not corroborate the very short sleep period. Fitbit data were considered valid if participants had at least 4 nights of valid data.

Evolv28 adherence: Evolv28 adherence was collected via the company's dashboard. The dashboard was password protected and only study staff not associated with screening and assessments had access to this data. The dashboard contained participant ID, group assignment (intervention or control) and device usage (average and total).

Adverse events: At 4-weeks and 3-months, participants completed a measure that asked if they experienced any symptoms while wearing the sleep device, when they developed, and their degree of

severity. In addition, if participants reported to study staff any effects of the device, these were recorded in an adverse event log and if necessary, reported to the IRB.

Data analysis

Data were analyzed using R version 4.2.2. We utilized descriptive statistics to describe the sample statistics at baseline. Then, we conducted linear mixed models to the effect for time and time x group interaction. The primary outcome was defined as change in ISI at 1-month. We also conducted linear mixed models to examine change over time and time x group changes from baseline to 3-months. Analyses were conducted as intention to treat and all participants who completed baseline data and were randomized were included in the mixed models. We utilized chi-square tests to evaluate percentage with a response to the intervention (decrease of 6 points or more on the ISI) and remission (ISI post-intervention score $\leq$7). An a-priori power analysis, assuming a medium-to-large effect size of d = 0.74, indicated that a total sample size of 60 participants (30 per group) would provide a power of 80% to detect significant differences with a two-sided alpha level of 0.05.

REFERENCES

1. Robbins R, Quan SF, Buysse DJ, et al. A nationally representative survey assessing restorative sleep in US adults. Frontiers in Sleep. 2022;1. doi:10.3389/frsle.2022.935228
2. Chattu VK, Manzar MdD, Kumary S, Burman D, Spence DW, Pandi-Perumal SR. The global problem of insufficient sleep and its serious public health implications. Healthcare. 2018;7(1):1. doi:10.3390/healthcare7010001
3. The Lancet Diabetes & Endocrinology. Sleep: A neglected public health issue. The Lancet Diabetes & Endocrinology. 2024;12(6):365. doi:10.1016/s2213-8587(24)00132-3

4. Gottlieb DJ, Ellenbogen JM, Bianchi MT, Czeisler CA. Sleep deficiency and motor vehicle crash risk in the general population: A prospective cohort study. BMC Medicine. 2018;16(1). doi:10.1186/s12916-018-1025-7
5. Hafner M, Romanelli R, Yerushalmi E, Troxel W. The societal and economic burden of insomnia in adults: An international study. RAND Corporation. 2023. doi:10.7249/rra2166-1
6. Hafner M, Stepanek M, Taylor J, Troxel W, Stolk C. Why sleep matters: The economic costs of insufficient sleep. RAND Corporation. 2016. doi:10.7249/rb9962
7. Edinger JD, Arnedt JT, Bertisch SM, et al. Behavioral and psychological treatments for chronic insomnia disorder in adults: An American Academy of Sleep Medicine Clinical Practice guideline. Journal of Clinical Sleep Medicine. 2021;17(2):255-262. doi:10.5664/jcsm.8986
8. Thomas A, Grandner M, Nowakowski S, Nesom G, Corbitt C, Perlis ML. Where are the behavioral sleep medicine providers and where are they needed? A geographic assessment. Behavioral Sleep Medicine. 2016;14(6):687-698. doi:10.1080/15402002.2016.1173551
9. Hale L, Troxel W, Buysse DJ. Sleep health: An opportunity for public health to address health equity. Annual Review of Public Health. 2020;41(1):81-99. doi:10.1146/annurev-publhealth-040119-094412
10. Riemann D, Benz F, Dressle RJ, et al. Insomnia disorder: State of the Science and challenges for the future. Journal of Sleep Research. 2022;31(4). doi:10.1111/jsr.13604
11. Dorokhov VB, Taranov AI, Narbut AM, et al. Effects of exposure to a weak extremely low frequency electromagnetic field on daytime sleep architecture and length. Sleep Medicine Research. 2019;10(2):97-102. doi:10.17241/smr.2019.00486
12. Tworoger SS. Effect of a nighttime magnetic field exposure on sleep patterns in young women. American Journal of Epidemiology. 2004;160(3):224-229. doi:10.1093/aje/kwh215
13. Herrero Babiloni A, Bellemare A, Beetz G, et al. The effects of non-invasive brain stimulation on sleep disturbances among different neurological and neuropsychiatric conditions: A systematic review. Sleep Medicine Reviews. 2021;55:101381. doi:10.1016/j.smrv.2020.101381

14. Bastien C. Validation of the insomnia severity index as an outcome measure for insomnia research. Sleep Medicine. 2001;2(4):297-307. doi:10.1016/s1389-9457(00)00065-4
15. Buysse DJ, Yu L, Moul DE, et al. Development and validation of patient-reported outcome measures for sleep disturbance and sleep-related impairments. Sleep. 2010;33(6):781-792. doi:10.1093/sleep/33.6.781
16. Chasens ER, Ratcliffe SJ, Weaver TE. Development of the FOSQ-10: A short version of the functional outcomes of sleep questionnaire. Sleep. 2009;32(7):915-919. doi:10.1093/sleep/32.7.915
17. Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder. Archives of Internal Medicine. 2006;166(10):1092. doi:10.1001/archinte.166.10.1092
18. Cohen S, Williamson G. Perceived stress in a probability sample of the United States. In: Spacapan S, Oskamp S, eds. The Social Psychology of Health. Newbury Park, CA: Sage Publications; 1988:31-67.
19. Kroenke K, Strine TW, Spitzer RL, Williams JBW, Berry JT, Mokdad AH. The PHQ-8 as a measure of current depression in the general population. Journal of Affective Disorders. 2009;114(1-3):163-173. doi:10.1016/j.jad.2008.06.026
20. Carney CE, Buysse DJ, Ancoli-Israel S, et al. The consensus sleep diary: Standardizing prospective sleep self-monitoring. Sleep. 2012;35(2):287-302. doi:10.5665/sleep.1642
21. Willoughby AR, Golkashani HA, Ghorbani S, et al. Performance of wearable sleep trackers during nocturnal sleep and periods of simulated real-world smartphone use. Sleep Health. Published online April 2024. doi:10.1016/j.sleh.2024.02.007
22. Perlis ML, Jungquist C, Smith MT, Posner D. Cognitive Behavioral Treatment of Insomnia: A Session-by-Session Guide. Springer; 2005.
23. Hasan F, Tu Y-K, Yang C-M, et al. Comparative efficacy of digital cognitive behavioral therapy for insomnia: A systematic review and network meta-analysis. Sleep Medicine Reviews. 2022;61:101567. doi:10.1016/j.smrv.2021.101567

24. van Straten A, van der Zweerde T, Kleiboer A, Cuijpers P, Morin CM, Lancee J. Cognitive and behavioral therapies in the treatment of insomnia: A meta-analysis. Sleep Medicine Reviews. 2018;38:3-16. doi:10.1016/j.smrv.2017.02.001
25. Yeung V, Sharpe L, Glozier N, Hackett ML, Colagiuri B. A systematic review and meta-analysis of placebo versus no treatment for insomnia symptoms. Sleep Medicine Reviews. 2018;38:17-27. doi:10.1016/j.smrv.2017.03.006
26. Winkler A, Rief W. Effect of placebo conditions on polysomnographic parameters in primary insomnia: A meta-analysis. SLEEP. Published online June 1, 2015. doi:10.5665/sleep.4742
27. Jiang B, He D, Guo Z, Mu Q, Zhang L. Efficacy and placebo response of repetitive transcranial magnetic stimulation for primary insomnia. Sleep Medicine. 2019;63:9-13. doi:10.1016/j.sleep.2019.05.008
28. Schabus M, Griessenberger H, Gnjezda M-T, Heib DP, Wislowska M, Hoedlmoser K. Better than sham? A double-blind placebo-controlled neurofeedback study in primary insomnia. Brain. 2017;140(4):1041-1052. doi:10.1093/brain/awx011

Figure Captions

Figure 1

CONSORT Flowchart of Participants

Figure 2

Response and Remission

Note. Response and remission scores of participants are shown for control and intervention groups. Response is a clinically meaningful reduction in Insomnia Severity Index score (change of 6 or more) from screening to end of the 1-month trial. Remission is an Insomnia Severity Index score of 7 or below at the end of the 1-month trial.

Table 1

Baseline characteristics	Intervention M, SD or N, %		Control M, SD or N, %		Full sample M, SD or N, %	
Age (years)	38.9	12.5	41.6	11.8	40.4	12.1
Sex						
Female	19	68	20	65	39	66
Male	9	32	11	35	20	34
Race						
White	20	71	22	71	42	71
Asian	6	21	4	13	10	17
Black/African American	2	7	4	13	6	10
Native Hawaiian or other Pacific Islander	0	0	1	3	1	2
Ethnicity						
Hispanic/Latino	1	4	4	13	5	8
Non-Hispanic/Latino	27	96	27	87	54	92
Employment Status						
Full-time[a]	13	46	18	58	31	53
Part-time[a]	5	18	6	18	11	19
Student	3	11	3	11	6	10
Not employed	5	18	3	10	8	14
Retired	2	7	1	4	3	5
Highest level of education						
Completed high school or some high school	5	18	5	16	10	17
Associate degree or trade school	8	29	6	19	14	24
Bachelor's degree	8	29	9	29	17	29
Graduate degree	7	25	11	35	18	31

Combined yearly household income						
$25,000 or below	3	11	6	19	9	15
$26,000-$50,000	6	21	4	13	10	17
$51,000-$75,000	8	29	6	19	14	24
$76,000-$100,000	4	14	6	19	10	17
>$101,000	6	21	6	19	12	20
Prefer not to say	1	4	3	10	4	7

Sociodemographic Characteristics of Participants at Baseline

Note. N = 59 (*n* = 28 for intervention and n = 31 for control). Participants were on average 40.4 years old (*SD* = 12.1), and participant age did not differ by condition. [a] Full-time reflects 32 hours or more of work per week. Part-time reflects less than 32 hours of work per week.

Table 2. Self-Reported Outcomes at 1 Month

Assessment	Intervention						Control						$p_{between}$	p_{within}
	Baseline		1-month		Change		Baseline		1-month		Change			
	M	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*		
Insomnia Severity Index	19.1	3.3	11.8	5.2	-7.34 [a]	1.87	18.6	3.2	11.0	4.0	-7.58 [a]	.84	0.88	0.001
PROMIS Sleep Disturbance	60.6	5.9	7.9	7.9	-6.80 [a]	2.02	60.8	4.9	53.5	4.9	-7.28 [a]	.05	0.98	0.001
PROMIS Sleep-Related Impairment	61.0	6.1	56.0	8.0	-4.97 [a]	1.85	60.4	6.2	53.4	8.1	-7.02 [a]	1.97	0.37	0.001
General Anxiety Disorder	7.00	4.9	5.72	4.6	-1.28 [a]	-0.27	6.71	4.2	4.90	3.5	-1.81 [a]	-0.65	0.53	0.005
Perceived Stress Scale	16.9	6.4	15.8	7.6	-1.13	1.19	16.4	6.7	15.7	6.2	-0.76	-.49	0.87	0.44
Functional Outcomes of Sleep	32.8	3.9	35.8	4.9	+3.05 [a]	1.00	31.8	5.6	35.2	4.7	+3.44 [a]	-0.90	0.81	0.002
Patient Health Questionnaire	7.40	3.6	5.4	3.6	-2.00 [a]	-0.07	7.7	3.6	4.7	3.4	-2.99 [a]	-0.23	0.39	0.001

Note. Missing questionnaire data $N = 3$ in the intervention group and $N = 2$ for the control group. $P_{between} = p$ value for the time x condition effect, $p_{within} = p$ value for the time effect.

Table 3. Fitbit and Sleep Diary Outcomes at 1 Month

Assessment	Intervention						Control						$p_{between}$	p_{within}
	Baseline		1-month		Change		Baseline		1-month		Change			
	M	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*		
Sleep diary														
Sleep duration (h)	6.36	1.77	6.89	2.08	+0.53 [a]	+0.30	6.36	1.5	6.64	1.86	+.28 [a]	+0.34	0.25	0.046
Wakefulness after sleep onset (m)	34.8	53.4	28.8	49.8	-6.0	-3.39	29.3	44.4	31.8	42.0	+2.4	-2.67	0.37	0.73
Efficiency (%)	75.0	0.16	79	0.15	+0.04	-0.01	78.0	0.14	77.0	0.16	-0.01	+0.02	0.03	0.90
Sleep latency (m)	43.2	46.2	39	42.0	-4.2	-4.69	41.4	41.4	43.2	52.2	+1.8	+10.70	0.07	0.63
Fitbit														
Sleep Duration (h)	6.28	0.58	6.47	1.02	+0.19	+0.43	6.37	0.88	6.47	1.45	+0.1	+0.57	0.80	0.70
Wake after sleep onset (m)	48.8	8.1	51.4	17.7	+2.6	+9.60	50.9	17.2	49.8	16.9	-0.9	-0.33	0.46	0.74
Efficiency (%)	93.6	2.6	92.9	5.8	-0.7	+3.22	93.9	2.4	94.1	2.80	+0.2	+0.34	0.55	0.81

Note. Missing data for actigraphy (n=23), missing data for sleep diaries (n=). $p = p_{between} = p$ value for the time x condition effect, $p_{within} = p$ value for the time effect.

Table 4. Results of Self-Reported Outcomes at 3-Months

Assessment	Intervention						Control						$p_{between}$	p_{within}
	Baseline		3-month		Change		Baseline		3-month		Change			
	M	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*		
Insomnia Severity Index	19.1	3.3	11.2	4.7	-7.98 [a]	+1.36	18.6	3.2	9.3	4.5	-9.31 [a]	+1.29	0.360	0.001
PROMIS Sleep Disturbance	60.6	5.9	53.7	8.0	-6.84 [a]	+2.16	60.8	4.9	52.4	6.5	-8.37 [a]	+1.67	0.478	0.001
PROMIS Sleep-Related Impairment	61.0	6.1	56.2	9.4	-4.81 [a]	+3.30	60.4	6.2	52.6	9.1	-7.84 [a]	+2.94	0.246	0.001
General Anxiety Disorder	7.0	4.85	7.24	5.6	+0.24	+5.06	6.71	4.2	5.13	5.4	-1.58	+5.83	0.284	0.338
Perceived Stress Scale	16.9	6.37	17.5	7.6	+0.6	+1.23	16.4	6.7	15.0	7.8	-1.4	+1.10	0.254	0.227
Functional Outcomes of Sleep	32.8	3.85	34.6	5.9	+1.8 [a]	+2.07	31.8	5.6	35.2	5.4	+3.4 [a]	-0.13	0.319	0.004
Patient Health Questionnaire	7.4	3.64	7.1	4.8	-0.3 [a]	+1.20	7.6	3.6	5.4	4.7	-2.2 [a]	+1.09	0.111	0.007

Note. Missing data n=1 at the 3-month assessment. $P_{between}$= p value for the time x condition effect, p_{within}= p value for the time effect.