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Feasibility, Acceptability, and Preliminary Effectiveness of a Sleep Intervention in Adults at Risk for Metabolic Syndrome With Short Sleep Duration

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Abstract

Background: The prevalence of short sleep duration is rising and is linked to chronic comorbidities, such as metabolic syndrome (MetS). Sleep extension interventions in adults with MetS comorbidities and short sleep duration are limited and vary widely in terms of approach and duration.

Objectives: This pilot study aimed to test the feasibility and acceptability of a personalized 12-week systematic sleep time extension intervention on post-intervention sleep outcomes in middle-aged adults at risk for MetS with actigraphy-estimated short sleep duration.

Methods: A single-arm, 12-week, 12-session systematic sleep time extension intervention was delivered weekly via videoconferencing. Feasibility and acceptability were assessed using retention rates and mean sleep diary completions. Sleep was estimated for 14 consecutive days prior to and immediately following the 12-week intervention using wrist actigraphy. Daytime sleepiness was assessed using the Epworth Sleepiness Scale. Paired sample t-tests modeled changes in study outcomes.

***Results*:** Study participants (N = 41) had a mean age of 52, were mostly female and White; 86% attended > 80% of sessions, and mean sleep diary completion was 6.7 diaries/week. Significant improvements in sleep from pre- to post-intervention included increased total sleep time, earlier sleep onsets, more regular sleep onsets, a higher sleep regularity index, and reduced daytime sleepiness. Extending sleep, as well as improving sleep timing and regularity in middle-aged adults with actigraphy-estimated short sleep duration and at risk for MetS, is feasible and acceptable.

***Discussion*:** Behavioral sleep characteristics may be modifiable and present a novel behavioral paradigm for mitigating MetS risk. This pilot study provides a proof of concept for the

feasibility, acceptability, and preliminary effectiveness of a systematic sleep time extension for middle-aged adults at risk for MetS with actigraphy-estimated short sleep duration.

Keywords: metabolic syndrome, middle aged, sleep deprivation, sleep extension, sleep initiation and maintenance disorders

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Feasibility, Acceptability, and Preliminary Effectiveness of a Sleep Intervention in Adults at Risk for Metabolic Syndrome With Short Sleep Duration

Metabolic syndrome (MetS) is a clustering of comorbidities, including abdominal obesity, hypertension, hyperglycemia, and dyslipidemia, that underlie leading causes of death worldwide (Mozaffarian et al., 2015). Lifestyle modifications are the first line of prevention and treatment for MetS and often target physical inactivity and unhealthy eating habits (Magkos et al., 2009). Lifestyle modifications effectively reduce MetS risk, yet 35% to 86% of the U.S. population fails to meet the recommended guidelines for these lifestyle behaviors (Elgaddal et al., 2022; Lee et al., 2022). Improving sleep is one approach that may enhance progress towards mitigating MetS risk because inadequate sleep (e.g., sleeping < 7 hr/night) is linked to MetS directly (Dettoni et al., 2012; van Leeuwen et al., 2009) and indirectly through increased MetS risk behaviors (St-Onge et al., 2016), and greater barriers to adopting and maintaining lifestyle modifications (e.g., depressive symptoms; Lin et al., 2021). Indeed, greater depressive symptoms at baseline predict poorer lifestyle behaviors 5 years later (Sin et al., 2016), and a causal link between depression and MetS has been reported (Zhai et al., 2021). Recognizing sleep as a potential upstream factor for MetS risk has fueled interest in improving sleep in adults with short sleep duration (self-reported < 7 hr/night or actigraphy-estimated ≤ 6.5 hr/night).

Sleep extension studies have produced promising results for extending sleep in short-sleeping adults (N = 7 studies; Zhu et al., 2022), but these studies are limited to healthy adults with few, if any, MetS comorbidities (Al Khatib et al., 2018; Baron et al., 2019; Haack et al., 2013; Leproult et al., 2015; So-Ngern et al., 2019; Tasali et al., 2014). Additionally, sleep extension interventions vary widely in terms of approach and duration (Al Khatib et al., 2018;

Baron et al., 2019; Haack et al., 2013; Kubo et al., 2011; Leproult et al., 2015; So-Ngern et al., 2019; Tasali et al., 2014). Rising prevalence of short sleepers underscores the urgency for determining *whether* sleep extension interventions are effective for adults at risk for MetS with short sleep duration (Jean-Louis et al., 2014), as well as how to design sleep extension interventions for maximal impact.

Systematic sleep time extension is a personalized data-driven approach grounded primarily in sleep restriction therapy (SRT) the principles in Cognitive Behavioral Therapy for Insomnia (CBT–I; Kyle et al., 2015; Spielman et al., 2011). The parameters for SRT used to guide the systematic sleep time extension employed in the current study included: (a) calculating total sleep time and time-in-bed from 1 to 2 weeks of sleep diaries, (b) setting a minimum time-in-bed for 5.5 hr—if sleep restriction was needed, (c) using the following sleep efficiency criteria: (i) extend time-in-bed for sleep efficiency > 90%, (ii) maintain time-in-bed for sleep efficiency 85%–90%, or (iii) decrease time-in-bed for sleep efficiency < 85%, (d) modifying the magnitude of the sleep window by 15 min, and (e) positioning time-in-bed by advancing the bedtime, but participant preference was taken into consideration. Daytime napping instructions were provided to participants for weekly Epworth Sleepiness Scale > 10, including a nap time duration of < 60 min and a 4 p.m. wake-up time at the latest. It is unknown whether this systematic sleep time extension intervention grounded in SRT principles can change actigraphy-estimated sleep parameters in adults who are not diagnosed with insomnia but who present with short sleep duration.

Novel behavioral paradigms are needed for chronic disease prevention. Sleep extension may be a feasible and efficacious behavioral approach to mitigate MetS risk. This pilot study tested the feasibility and acceptability of a personalized data-driven sleep intervention in adults at risk for MetS with actigraphy-estimated short sleep duration. Secondary aims were to assess the preliminary efficacy of the intervention on sleep health (duration, timing, regularity, daytime sleepiness). Exploratory analyses examined whether the sleep intervention reduced depressive symptoms and fatigue levels, as well as improved quality of life.

Methods

Sample

Participants were recruited between April 2019 and March 2020 and provided written informed consent prior to any study procedures. Inclusion criteria were 30–60 years of age, ≤ 6.5 hours/night actigraphy-estimated sleep, ≥ 1 objectively confirmed MetS risk factor (waist circumference > 120cm [men], > 88cm [women]; blood pressure ≥ 135/85mm/Hg; fasting glucose ≥ 110 mg/dL; serum triglycerides ≥ 150 mg/dL; or HDL-c < 50 mg/dL [men] < 40 mg/dL [women] measured from blood samples. Exclusion criteria were pregnancy/lactation, current chemotherapy treatments, alcohol abuse, moderate–severe depression, shift work, transmeridian travel (previous 4 weeks or during intervention period), habitual napping (≥ 2 naps/week for ≥ 90 min/each), untreated and diagnosed obstructive sleep apnea, and chronic use of sleep-promoting medications (≥ 3 times/week).

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Measures

Primary Outcomes

Feasibility was estimated by study adherence (≥ 80% sleep diary completion; ≥ 80% intervention attendance). Acceptability was assessed using a pre- and post-15-question survey that estimated acceptability, feasibility, perceived benefit, satisfaction, and an overall evaluation.

Secondary Outcomes

Sleep–wake habits were inferred from wrist actigraphy data (ActiGraph WGT3X-BT, (ActiGraph Inc.) worn at least 7 nights pre- and post-intervention. Actigraphy data were processed using Actilife software, version 6.13. Algorithm-detected sleep periods were checked and cleaned manually (SKM). Actigraphy-derived variables used in these analyses included total time-in-bed (hours), total sleep time (hours), sleep onset time (hours: minutes), sleep onset latency (minutes), wake after sleep onset (minutes), number of nocturnal awakenings, awakening length (minutes), movement index, fragmentation index, sleep fragmentation index, and sleep efficiency. These variables provided data to calculate estimates of sleep timing and sleep regularity indexes (SRIs; Phillips et al., 2017). Sleep midpoints were estimated as the clock time halfway between sleep onset and the out-of-bed time. Daytime sleepiness was assessed weekly using the eight-item Epworth Sleepiness Scale (minimum–maximum = 0–24).

Exploratory Outcomes

Exploratory outcomes included depression, fatigue, quality of life/affective well-being, and self-regulation measured pre- and post-intervention. Depression was measured using the 6-item PROMIS depression short-form scale. Higher scores indicate greater depressive symptoms

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(minimum–maximum = 6–30). Fatigue was measured using the 6-item PROMIS fatigue short-form scale, modified to be completed in the morning and the evening. The quality of life/affective well-being construct was measured with the Short-Form 36v2 (SF–36v2). The SF–36v2 comprises 36 items grouped into eight subscales, each examining a different dimension of health, including physical function, role limitations for physical problems, bodily pain, general health perception, vitality, social functioning, role limitations for emotional problems, and general mental health. Higher scores indicate better quality of life and effective well-being (minimum–maximum = 0–100). Self-regulation was measured using the 9-item NINR Index of Self-Regulation. Higher scores indicate greater self-regulation (minimum–maximum = 6–54).

Sociodemographic Characteristics

Demographic data were self-reported at baseline and categorized as follows: age (years), sex (male, female), race (Black/African American, White, other/not reported), ethnicity (Hispanic, non-Hispanic, other/not reported), education (< high school, high school ≥, bachelor's degree, not reported), employment status (employed, unemployed, retired/disabled, other), and marital status (currently married/partnered, not currently married/partnered).

Intervention

The systematic sleep time extension intervention is a personalized data-driven approach. Each week, participant sleep diaries were used to calculate average sleep efficiency (SE) and time-in-bed prescriptions (see above). Twelve individual weekly sessions delivered by a cognitive behavioral therapy for insomnia (CBT-I) trained study team member (SKM) via a videoconferencing platform. The first three sessions lasted 45–60 min and included sleep

assessment, stimulus control, and sleep hygiene modules. Systematic sleep time extension was initiated during the second intervention session. Subsequent sessions lasted 15–30 min. The final session focused on maintaining sleep improvements. The treatment fidelity plan included audiotaping each intervention session and reviewing content against an a priori performance checklist to ensure consistency in the systematic sleep time extension intervention.

Statistical Analysis

Descriptive statistics for all study variables were generated. Paired sample t-tests were used to compare means within-subject pre- and post-intervention study variable changes. Cohen's *d* effect sizes were used to estimate the pre- to post-intervention magnitude of change (≥ 0.2 small, ≥ 0.5 medium, ≥ 0.8 large).

Results

Eighty-one adults completed the in-person screening interview; 44 were enrolled. Three participants withdrew, yielding an analytic sample of N = 41 (Figure 1). No age, race, gender, or ethnicity differences were seen between participants who completed versus those who withdrew from the study. The mean age of participants was 52.2 (6.3). The mean number of MetS comorbidities was 2.7 (1.2). For other sociodemographic and clinical characteristics (see Table 1). For Aim 1, participants' average attendance was 10.9 (*SD* = 2.8) out of 12 sessions, with 86.4% (*SD* = 38.0) attending ≥ 80% of the intervention sessions. Participants completed an average of 6.2 (*SD* = 1.4) weekly daily sleep diaries. Intervention acceptability, perceived benefit, satisfaction, and overall evaluation increased from pre- to post-intervention (see Table 2). For Aim 2, most actigraphy-estimated sleep metrics improved from pre- to post-intervention.

Time-in-bed increased, total sleep time increased, sleep onset advanced earlier, and the sleep regularity index was greater from pre- to post-intervention (see Table 3). On the other hand, sleep onset latency increased, and sleep efficiency decreased from pre- to post-intervention (see Table 3). For Aim 3, depressive symptoms, as well as morning and evening fatigue, declined from pre- to post-intervention. All quality of life and affective metrics significantly improved (see Table 4).

Discussion

This pilot study tested the feasibility and acceptability of a personalized data-driven approach to increase sleep duration for adults at risk for MetS with actigraphy-estimated short sleep duration. Secondary aims were to assess the preliminary efficacy of the intervention on actigraphy-estimated dimensions of sleep. Previous studies have been limited by small sleep extension sample sizes (Al Khatib et al., 2018; Baron et al., 2019; Haack et al., 2013; Leproult et al., 2015; So-Ngern et al., 2019; Tasali et al., 2014), few racial minorities (Al Khatib et al., 2018; Baron et al., 2019; Haack et al., 2013; Leproult et al., 2015; So-Ngern et al., 2019; Tasali et al., 2014), few participants with chronic comorbidities (Al Khatib et al., 2018; Leproult et al., 2015; So-Ngern et al., 2019; Tasali et al., 2014), limited sleep health measures, and short intervention periods (Al Khatib et al., 2018; Baron et al., 2019; Haack et al., 2013; Leproult et al., 2015; So-Ngern et al., 2019; Tasali et al., 2014). This pilot study extends previous findings by demonstrating a sleep extension intervention's feasibility, acceptability, and preliminary effectiveness by improving multiple dimensions of sleep and reducing depressive symptoms and fatigue in actigraphy-estimated short-sleeping middle-aged adults at risk for MetS.

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Sleep duration, timing, regularity, and daytime sleepiness significantly improved following the intervention. The sleep duration increase in the current study is similar to the actigraphy-estimated sleep duration increase reported by others in short sleepers (1.1 hr in the current study versus 0.9 hr in a pooled analysis; Zhu et al., 2022). Others have reported that increasing sleep duration by 35 min reduced blood pressure in adults with pre-hypertension/stage 1 hypertension (Haack et al., 2013); increasing sleep duration by 45 min improved insulin sensitivity in healthy young adults (Leproult et al., 2015); and increasing sleep duration by 21 minutes and 1.4 hr reduced unhealthy food cravings in healthy young adults and overweight young adults, respectively (Al Khatib et al., 2018; Tasali et al., 2014). Furthermore, it has been reported that insulin sensitivity improvements hinged on healthy adults achieving ≥ 6 hr/night (So-Ngern et al., 2019). Although the current study increased sleep duration from 5.16 to 6.26 hr/night, its effect on mitigating MetS comorbidities is uncertain.

Sleep intervention studies have primarily focused on sleep duration. Links between later sleep timing and sleep irregularity with MetS risk suggest that sleep interventions should also shift sleep times earlier and promote greater sleep regularity (Fritz et al., 2021; Nikbakhtian et al., 2021). Few sleep extension studies have reported changes in these sleep dimensions. In the current study, sleep onset advanced by 37 min. These findings mirror limited reports of changes in sleep onset (Baron et al., 2019; Tasali et al., 2014). Others have reported sleep onset advances ranging from 12 to 76 min following a sleep intervention (Baron et al., 2019; Tasali et al., 2014). Nikbakhtian et al. (2021) found that sleep onsets ≥ 00:00 are linked to a greater cardiovascular disease incidence independent of sleep duration. Although the current study advanced sleep onset by 37 min, its effect on mitigating MetS comorbidities is unsure.

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Sleep regularity improved in the current study. Lower versus higher SRIs correlate with a greater risk of MetS comorbidity and depression in adults ≥ 45 years of age (Fritz et al., 2021; Lunsford-Avery et al., 2018). Despite improvements in sleep regularity, the mean post-intervention SRIs are lower than those reported by others. Lower SRIs have been associated with minoritized races, later sleep timing, physical inactivity, less daytime light exposure, overweight/obesity, and high glucose levels (Fritz et al., 2021; Lunsford-Avery et al., 2018). Whether these factors contributed to the lower SRIs reported in this study is uncertain. Nonetheless, findings from the current study suggest that sleep regularity is a modifiable behavioral factor.

High levels of fatigue and depression are common (> 50%) in adults with MetS comorbidities (Jain et al., 2015). Extending sleep and achieving adequate sleep duration have been shown to reduce fatigue (Mantua et al., 2019) and depressive symptoms (Li et al., 2017). Meta-analytic data have shown a significant mean reduction in depressive symptoms following non-pharmacological treatment for sleep problems in adults (Gee et al., 2019). The results of the current study suggest that participation in a sleep extension intervention has the potential to reduce depression and fatigue in adults at risk for MetS, although the underlying mechanisms through which improved sleep reduced depressive symptoms and fatigue were not identified in this exploratory aim. Given that higher levels of fatigue and depression impede compliance with health care recommendations, including medication compliance, self-care activities, and health care appointment attendance (DiMatteo et al., 2000; Heckman et al., 2018; Sumlin et al., 2014), reducing depression and fatigue symptoms through sleep extension may improve compliance to health care recommendations among short sleepers.

Limitations

The single-arm design with no control group and small sample size are limitations of the current study. Additionally, all participants were from the greater New York City area and were highly educated. Although the 12-week intervention supports the ability of actigraphy-estimated short sleepers to extend sleep longer than previously supported by 6-week interventions, habit formation may take up to 36 weeks (Lally et al., 2010). The current study was not developed to identify the underlying mechanisms linking improved sleep with reduced depressive symptoms. Nor was the current study designed to determine whether this systematic sleep extension intervention directly reduced depressive symptoms.

Conclusion

Behavioral patterns are the largest domain influencing health and well-being; the current pilot study suggests that behavioral sleep characteristics may be modifiable. This pilot study provides proof of concept for the feasibility, acceptability, and preliminary effectiveness of a systematic sleep time extension.

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Figure Legend

Figure 1: CONSORT flow diagram showing participant flow through each stage of the pilot study (recruitment, multi-stage screening, enrollment, completion).

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Figure 1: CONSORT DIAGRAM

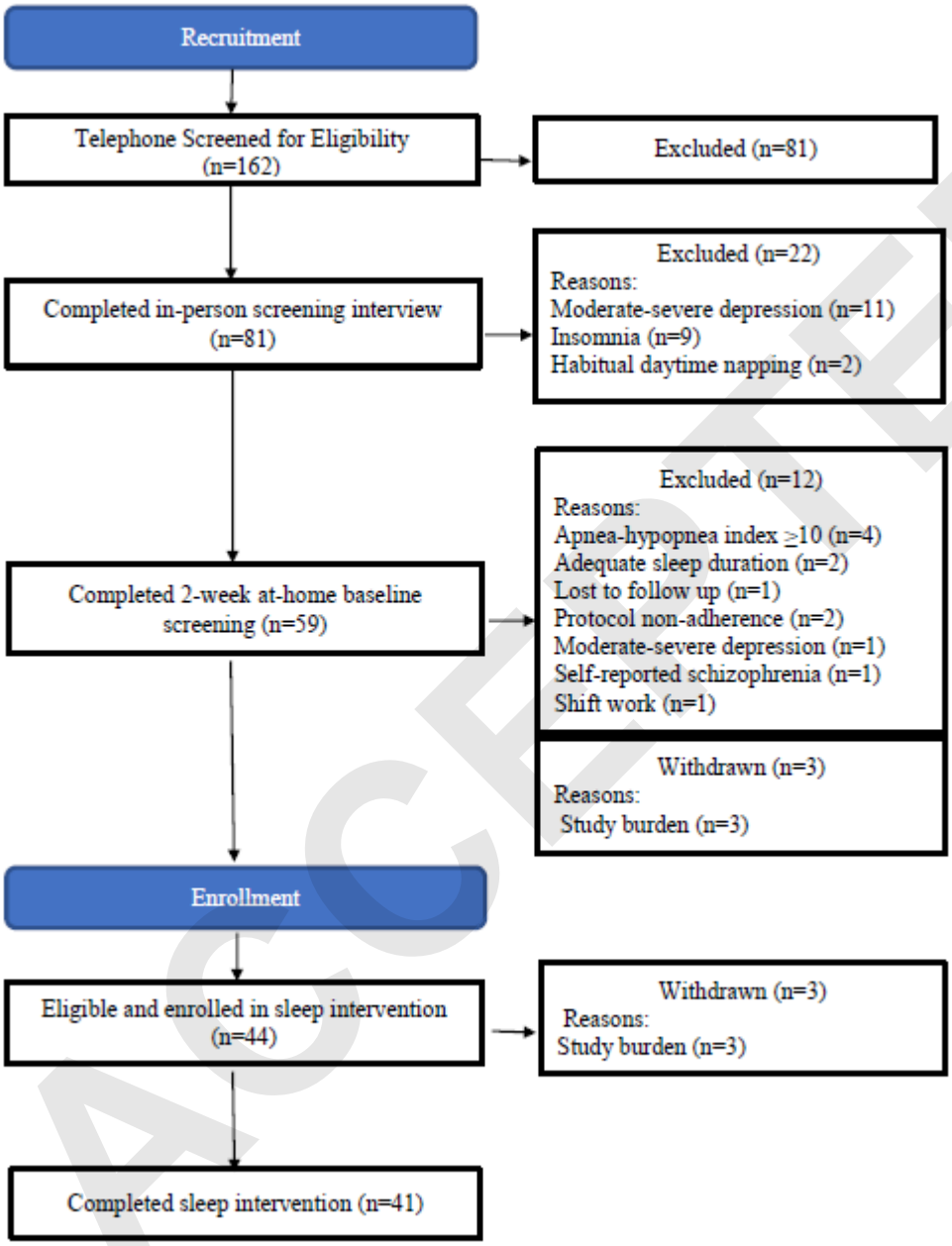

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Table 1

Sociodemographic and Metabolic Syndrome Characteristics of Participants (N=41)

Characteristic	*n* (%)
Sex	
Male	18 (43.9)
Female	23 (56.1)
Race	
Black/African American	15 (36.6)
White	21 (51.2)
Other/not reported	5 (12.2)
Ethnicity	
Hispanic	3 (7.3)
Not Hispanic	33 (80.5)
Other/Not reported	5 (12.2)
Education	
High school	11 (26.8)
≥ Bachelor's degree	30 (73.2)
Employment	
Employed	31 (75.6)
Unemployed	2 (4.8)
Retired/Disability	4 (9.8)
Other	4 (9.8)
Marital/partnership status	
Currently married/partnered	17 (41.5)
Not currently married/partnered	24 (58.5)
Metabolic Syndrome Factors	
Abdominal obesity	32 (78.1)
High blood pressure	29 (70.7)
High blood glucose	14 (42.4)
High triglycerides	18 (43.9)
Low HDL-c	12 (29.7)
Metabolic syndrome (>=3 factors)	21 (51.2)

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Table 2

Prospective Descriptive Statistics for Sleep Intervention Acceptability: Aim1

Domain	Pre-intervention		Post-intervention		*t*-test	Effect size
	n (%)	Minimum-maximum of Values (lowest, highest)	*n* (%)	Minimum-maximum of Values (lowest, highest)	*t* (df)	Cohen's *d*
Acceptability	4.03 (0.40)	3.33 – 5.00	4.52 (0.45)	3.17 – 5.00	-6.43*** (40)	1.00
Feasibility	3.66 (0.47)	3.00 – 5.00	3.35 (0.78)	1.00 – 5.00	1.94 (40)	0.30
Perceived benefit	4.08 (0.55)	3.00 – 5.00	4.53 (0.52)	3.25 – 5.00	-4.44*** (40)	0.69
Satisfaction	4.06 (0.56)	3.00 – 5.00	4.48 (0.52)	3.00 – 5.00	-4.42*** (40)	0.69
Overall evaluation	3.73 (0.67)	3.00 – 5.00	4.70 (0.53)	3.00 – 5.00	-8.14*** (32)	1.42

Note: *df*=degrees of freedom
*p<0.05
**p<0.01
***p<0.001

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Table 3

Prospective Descriptive Statistics for Actigraphy-estimated Sleep Intervention Preliminary Effectiveness: Aim 2

Actigraphy-estimated Sleep Characteristic	Pre-intervention		Post-intervention		*t*-test	Effect size
	M (SD)	Minimum-maximum of Values (lowest, highest)	*M (SD)*	Minimum-maximum of Values (lowest, highest)	*t* (df)	Cohen's *d*
Total time in bed (hours)	6.00 (0.68)	4.17 – 7.26	7.48 (1.21)	5.10 – 11.37	-8.03*** (36)	1.32
Total sleep time (hours)	5.16 (0.63)	3.71 – 6.56	6.26 (1.23)	2.52 – 9.90	-6.13*** (36)	1.01
Intraindividual variability	1.25 (0.39)	0.52 – 2.60	1.06 (0.67)	0.36 – 4.52	1.83 (36)	0.30
Sleep onset latency (minutes)	2.47 (1.12)	0.30 – 5.07	3.07 (0.84)	1.50 – 5.06	-2.71* (36)	0.45
Sleep onset (hours:minutes)	00:26 (0.05)	22:12 – 3:31	23:53 (0.06)	21:13 – 3:23	-2.51* (36)	0.41
Sleep onset regularity	0.06 (0.04)	0.02 – 0.20	0.04 (0.02)	0.01 – 0.14	3.15** (36)	0.52
Out of bed time (hours:minutes)	6:29 (0.06)	3.34 –10:12	7:12 (0.12)	7:13 –14:42	-0.13 (36)	0.04
Sleep midpoint (hours:minutes)	3:19 (0.05)	00:19 – 5:40	3:17 (0.05)	00:29– 5:37	0.21 (36)	0.03
Sleep midpoint regularity	0.05 (0.04)	0.02 – 0.19	0.07 (0.18)	0.01 – 1.09	-0.45 (36)	0.07
Wake after sleep onset (minutes)	48.41 (18.69)	18.33 – 125.00	69.68 (32.11)	2.25 – 152.00	-4.64*** (36)	0.76
Number of nocturnal awakenings	16.14 (5.85)	5.62 – 32.00	20.10 (7.92)	1.58 – 49.38	-3.58** (36)	0.59
Awakening length (minutes)	3.09 (0.80)	1.72 – 8.25	3.54 (1.58)	1.15 – 11.19	-1.73 (36)	0.28
Movement index	12.87 (3.71)	7.80 – 32.90	15.27 (8.41)	0.92 – 57.08	-2.25* (36)	0.37
Fragmentation index	11.77 (2.72)	7.28 – 20.64	12.87 (4.30)	6.79 – 25.93	-1.63 (36)	0.27
Sleep fragmentation index	24.64 (5.80)	15.08 – 47.59	28.13 (11.73)	7.87 – 83.01	-2.22* (36)	0.36

Sleep efficiency	86.08 (4.61)	71.63 – 93.74	83.63 (7.88)	49.61 – 99.10	2.05* (36)	0.34
Sleep Regularity Index	44.02 (17.25)	9.87 – 82.69	55.88 (12.82)	29.29 – 80.06	-3.41** (36)	0.56

Note: M=mean; SD=standard deviation; df=degrees of freedom
*p<0.05
**p<0.01
***p<0.001

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Table 4

Prospective Descriptive Statistics for Intervention Depressive Symptoms, Self-regulation, Fatigue, Daytime Sleepiness, and Quality of Life/Affective Well-being Preliminary Effectiveness: Aim 3

	Pre-intervention		Post-intervention		t-test	Effect size
	M (SD)	Minimum-maximum of Values (lowest, highest)	*M (SD)*	Minimum-maximum of Values (lowest, highest)	*t* (df)	Cohen's *d*
Depressive symptoms	10.03 (4.26)	6 - 22	8.55 (4.56)	6 - 24	2.74* (32)	0.48
Self-regulation	4.01 (0.66)	2.33 - 5	4.18 (0.72)	1.44 - 5	-1.72 (40)	0.27
Fatigue						
morning	14.27 (6.00)	6 - 28	9.32 (3.20)[a]	6 - 20	5.67 (36)	0.93
evening	14.73 (4.74)	0 - 30	9.36 (3.30)[-a]	5 - 19	6.26 (36)	1.03
Daytime Sleepiness	7.26 (4.30)	0 - 19	2.86 (2.07)[a]	0 - 9	6.63 (38)	1.06
Quality of life/Affective well-being for:						
Physical functioning	81.84 (20.32)	10 - 100	84.88 (20.63)	5 - 100	-2.18* (40)	0.34
Role limitations due to physical health	68.29 (38.74)	0 - 100	79.27 (34.42)	0 - 100	-2.46* (40)	0.38
Role limitations due to emotional health	67.48 (40.47)	0 - 100	79.67 (35.65)	0 - 100	-2.73** (40)	0.43
Energy	50.61 (21.94)	10 - 90	65.12 (18.15)	25 - 90	-4.71*** (40)	0.74
Emotional well-being	75.32 (16.05)	40 - 100	80.98 (14.08)	40 - 100	-3.35** (40)	0.52
Social functioning	80.79 (21.30)	25 - 100	88.72 (18.92)	37.5 - 100	-3.13** (40)	0.49
Pain	72.87 (22.02)	0 - 100	80.24 (21.42)	12.5 - 100	-2.41* (40)	0.38

General health	63.90 (21.43)	25 - 100	70.24 (21.00)	30 - 100	-3.65*** (40)	0.57

Note: M=mean; S*D*=standard deviation; *df*=degrees of freedom
*p<0.05
**p<0.01
***p<0.001
[a]end of treatment=week 12