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Research Article

Effectiveness of a Telemedicine-Based Intervention for Sleep Disturbances: A Randomized Trial with Actigraphy Monitoring in Adults from the General Population

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Abstract

Objectives

Telemedicine offers an effective and cost-eficient approach to support sleep health, but its impact in non-clinical populations with self-reported sleep disturbances remains underexplored. The objective of this study was to evaluate whether a sleep tracker combined with optional telemedicine support could improve sleep duration and quality compared to a sleep tracker alone in in adults with poor sleep but without a diagnosed sleep disorder.

Methods

This was an eight-month randomized clinical trial that included participants aged 18-65 years with a Pittsburgh Sleep Quality Index score > 5 and no prior sleep disorder diagnosis. Participants (N=206) were randomly assigned to either a control group using a wrist-worn sleep tracker or an intervention group with a sleep tracker and access to an online platform that included optional expert consultations and educational sleep resources. Actigraphy data were collected throughout the study.

Results

The primary outcome was the average total sleep time (TST) measured via actigraphy across the 8-month period. Both groups showed significant within-group increases in weekday TST and time in bed (TIB) from the first to the final fortnight (intervention: TIB +0.3 h, p=0.001; TST +15.2 min, p=0.0016; control: TIB +0.3 h, p<0.0001; TST +13.1 min, p=0.0028). However, changes between groups were not statistically significant. Sex differences were observed in both groups, with women consistently sleeping longer than men. No significant changes were found in subjective sleep quality, sleep hygiene, or daytime sleepiness.

Conclusions

Wearable self-monitoring was associated with modest improvements in sleep duration but optional telemedicine support did not yield significant added benefit. This may reflect increased awareness and behavioral adjustments prompted by long-term sleep tracking. Future research should examine whether more structured telemedicine interventions with standardized expert involvement can more effectively support sleep health in non-clinical populations.

Keywords: Sleep hygiene; Actigraphy; Sleep tracker; Wearable; Telemedicine; Total sleep time; Time in bed

Statement of significance

This randomized clinical trial demonstrates that wearable sleep trackers can modestly improve sleep duration in adults with self-reported poor sleep, even without formal diagnosis. The addition of optional, real-time expert consultations did not yield additional benefits, suggesting that self-tracking alone may promote behavioral change. This study is among the first to evaluate telemedicine-supported sleep interventions in a non-clinical population over a long-term period, offering important insights for scalable, preventive strategies in sleep health.

Introduction

Sleep is essential for physical and mental well-being, and its deficiency is linked to negative health consequences and reduced quality of life [1,2]. Even a single night of poor sleep can cause drowsiness and impair cognitive and psychomotor performance, increasing the risk of traffic and occupational accidents [3]. Sleep deficiency also reduces work performance and productivity [4]. Chronic sleep deficiency is associated with increased risk of cardiovascular disease, obesity, depression and impaired immune response [5-9]. These adverse effects are thought to result from dysregulation of the autonomic nervous system, inflammatory pathways, and hormonal systems, including insulin sensitivity and the leptin-ghrelin axis involved in appetite regulation [10]. Accordingly, experts recommend that adults sleep between 7 and 9 hours per night [11,12]. Despite this, about 20% of the adult population does not achieve this recommended sleep duration, representing a significant public health challenge [13].

Sleep disorders, such as insomnia or sleep apnea, are typically managed through in-person evaluations [14]. However, many individuals experience persistent sleep difficulties, such as short sleep duration, irregular sleep timing, or poor subjective sleep quality, without meeting criteria for formal sleep disorders like insomnia [15-17]. This preclinical population is often overlooked in research and clinical practice, even though their symptoms may significantly impair daily functioning. Early identification and intervention in this group could help prevent the development of chronic sleep disorders and associated health conditions.

Telemedicine has emerged as an alternative approach to the traditional in-person consultations. It has revolutionized healthcare by enabling physicians to provide high-quality, personalized care to patients remotely via video calls, messaging platforms, or specialized applications in a cost-effective manner [18-21]. Telemedicine-delivered cognitive behavioral therapy for insomnia (CBT-I) has demonstrated efficacy comparable to face-to-face interventions [22] with additional benefits when expert human support is provided [23,24]. Despite this promising evidence, the potential of telemedicine to support adults with self-reported poor sleep who do not qualify for formal diagnosis remains largely unexplored [25].

Nonetheless, digital and telemedicine-based approaches to sleep intervention are rapidly evolving [26]. Several recent studies have examined broader telemedicine strategies beyond CBT-I, including mobile-based coaching, automated feedback platforms, and hybrid models combining wearable devices with clinician oversight. These approaches have shown benefits in improving sleep outcomes in both clinical and community settings, including older adults and patients with comorbid conditions (see for example [27-29]). Nevertheless, most of these studies have focused on diagnosed insomnia or clinical populations, leaving a gap in understanding their applicability to adults experiencing suboptimal sleep without meeting diagnostic criteria.

In parallel, interest has grown in wearable sleep-tracking devices for objectively monitoring sleep in real-world settings [30]. These

technologies can detect early patterns indicative of insufficient sleep but the data they produce are often difficult to interpret or act on without expert guidance. Integrating wearable sleep tracking with telemedicine-based expert support could bridge this gap, promoting healthy sleep behaviors in adults experiencing suboptimal sleep duration. This study aimed to evaluate whether using a wearable sleep tracker combined with optional telemedicine consultations could effectively increase total sleep time (TST) in adults reporting poor sleep quality without formally diagnosed sleep disorders. We hypothesized that personalized recommendations from a sleep physician, in combination with wearable sleep tracking, would yield greater improvements in sleep duration compared to tracking alone. We conducted a randomized clinical trial comparing this approach to a control condition utilizing sleep tracking alone over an 8-month period. Additionally, we assessed the intervention's effects on secondary sleep parameters (time in bed, sleep onset latency, wake after sleep onset, and sleep efficiency) and subjective outcomes (sleep hygiene behaviors, daytime sleepiness, and health-related quality of life). Exploratory analyses examined potential sex differences and the influence of specific calendar periods, such as holidays, on sleep outcomes.

Material and methods

Study design and Participants

A randomized, open-label, parallel-group, cluster-controlled trial was conducted to assess the effectiveness of an eight-month sleep monitoring intervention. Eligible subjects for the study were employees of the Vitoria-Gasteiz City Council in the Basque Country. Recruitment was conducted remotely via an e-mail, which included a link to study information and the electronic informed consent form. Interested individuals completed an online survey and provided baseline data, including age, sex, comorbidities, history of diagnosed sleep disorders and anthropometrics (height and weight for BMI calculation). Additional information was collected on education, work schedule, marital status and caregiving responsibilities. All participants completed the Pittsburgh Sleep Quality Index (PSQI) to assess self-reported sleep quality [31,32].

Inclusion criteria were adults between 18 to 65 years old with a PSQI score >5 points, indicating poor sleep. Exclusion criteria included prior diagnosis or treatment for sleep disorders (e.g., insomnia, obstructive sleep apnea, restless legs syndrome, narcolepsy, parasomnia), serious psychiatric conditions, inability to use mobile technology, or unwillingness to actively participate or follow digital sleep recommendations. Electronic informed consent was obtained from all participants before their inclusion in the study.

Participants were randomized in clusters (i.e. different centres of the City Council) in a 1:1 ratio to intervention or control group. Allocation concealment was ensured by performing the randomization only after clusters were formed. Neither participants nor researchers knew group assignments prior to randomization. An independent statistician, with no contact with participants and no role in data collection or analysis performed the randomization. The identity of both clusters and individual participants was only known to the principal investigator.

The trial was registered retrospectively at ClinicalTrials.gov (identifier NCT05066581). Participant recruitment and study activities began in late May 2021, with the first participant enrolled on June 21, 2021. The study protocol was approved by the institutional ethics committee prior to enrolment and followed throughout the study without changes to the pre-specified primary or secondary outcomes. Due to administrative delays during the early stages of implementation, registration was completed in September 2021 and publicly posted on October 4, 2021. Despite the delayed registration, all study procedures and outcome measures were predefined and documented in the approved protocol. The study was approved by an independent Research Ethics Committee (The Basque Country Ethics Committee CEIm-E, Spain (code PS2021015) and adhered to the Declaration of Helsinki and applicable national guidelines.

The intervention

- **Control group**

Participants in the control group wore a Philips® Health Band (PHB) to continuously monitor sleep, heart rate, respiratory rate and physical activity. They were instructed to wear the PHB 24 hours a day and to install a mobile app on their smartphone that synchronized data from the device via Bluetooth. Actigraphy data were collected continuously throughout the 8-month study.

- **Intervention group**

Participants in the intervention group followed the same monitoring procedures as the control group. Additionally, they had access to an online survey in which they reported mood, sleep perception, daily activities and sleep habits. Participants were encouraged but not required to complete the survey regularly, reflecting real-world use. The final item of the survey provided optional access to a virtual live-chat platform, where participants could consult with sleep specialists if they felt their sleep was insuficient. Specialists provided personalized sleep hygiene recommendations based on participants' survey responses and concerns. Representative examples of these recommendations are included in the Supplementary Material. Seventy-eight participants (78 % of the intervention group) used this feature at least once, with a median of nine interactions (IQR: 2-39.5).

Outcomes

Primary Outcome

The primary outcome was TST measured using wrist actigraphy over the 8-month intervention period. The primary objective was to determine whether participants' average daily TST fell within the recommended range of 7 to 9 hours. Actigraphy data were collected daily and individual-level averages were calculated across the full study duration. Both participants and investigators had access to raw actigraphy data, but only investigators accessed and analyzed the aggregated results.

Secondary Outcomes

The secondary objectives were to assess whether the intervention influenced additional sleep-related parameters beyond TST. Specifically, we evaluated the effects on actigraphy-derived measures including time in bed *(TIB), sleep onset latency (SOL), wake after sleep onset (WASO) and sleep eficiency (SE). Objective sleep parameters were analyzed as weekly averages, stratified by day type (weekday vs weekend) and changes from the first to the final fortnight of the intervention period were also assessed.*

Wealso investigated changes in subjective outcomes, including sleep hygiene behavior, daytime sleepiness and health-related quality of life, measured through validated questionnaires completed at baseline and on the final fortnight. The Sleep Hygiene Index (SHI) is a 13 item self-administered questionnaire to assess behaviours related to sleep hygiene. The SHI total score varies between 13 and 65, where higher scores indicate poor sleep hygiene [33,34]. Daytime somnolence was estimated using the Epworth Sleepiness Scale (ESS) with a total score ranging from 0 to 24, with higher scores indicating higher levels of daytime sleepiness [35]. Health- related quality of life (HRQOL) was evaluated using the EuroQoL five-dimensional three-level instrument (EQ-5D-3L), which includes a descriptive system and a visual analogue scale (VAS) [36,37]. EQ VAS scores range from 0 (worst imaginable health) to 100 (best imaginable health). The descriptive system comprises five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression, each with three levels of severity (e.g., no problems, some problems, extreme problems). The proportion of participants selecting each response level was calculated for each domain. Comparisons were made by group and time point within each domain. The EQ VAS was analyzed separately, with scores ranging from 0 (worst imaginable health) to 100 (best imaginable health*).*

Exploratory Analyses

Exploratory analyses examined additional sleep patterns and subgroup differences. The distribution *of TST was analyzed by sex, day type (weekday vs weekend) and study group, using aggregated* data across the entire 8-month period. We also conducted sex-stratified analyses for TIB, SOL and WASO.

Additionally, we explored the impact of specific calendar periods, such as Christmas holidays, summer holidays and long weekends, on sleep parameters. Holiday periods were identified a priori and included in multivariate mixed-effects regression models.

Statistical analysis

The required sample size was estimated at 202 participants (101 per group). The calculation was based on data from the 2018 Basque Country Health Survey (https://www.euskadi.eus/encuesta-salud/inicio/), assuming a standardized mean difference of 0.417 (0.5/1.2), a 1:1 allocation ratio, 95% confidence level, 80% statistical power and a 10% expected dropout rate. The lack of independence among subjects within the clusters was accounted for in the statistical analysis by calculating the intraclass correlation coefficient (ICC) and adjusting the results accordingly. However, as this was a pilot study, the ICC was not considered in the sample size calculation. Data analysis adhered to an intention-to-treat approach, including all randomized participants unless they withdrew after baseline but before initiating sleep monitoring.

Sample sizes reported for each outcome reflect the number of participants with complete data for the relevant time points. Analyses used a complete-case approach, whereby only participants with valid data for both the first and final fortnights were included in longitudinal comparisons. Missing actigraphy data were due to device non-wear, syncing errors, or non-compliance. Missing questionnaire data were due to partial or missed follow-up assessments. Sample sizes for each analysis are reported in the corresponding tables.

Descriptive statistics (means ± SDs and proportions) were used to summarize baseline characteristics and outcome measures. Between-group comparisons were performed using parametric (Student's t-test) or non-parametric (Mann-Whitney U) tests for continuous variables and Chi-square or Fisher's exact test for categorical variables.

We used multivariable mixed-effects models to identify predictors of continuous sleep outcomes (TST, TIB, WASO, SOL) and categorized models to examine predictors of TST across sex and day type. Subgroup analyses by sex and weekday/weekend were pre-specified as exploratory, based on prior literature. Statistical significance was set at $p < 0.05$. All analyses were conducted using IBM SPSS Statistics (v29.0) and R (v4.3.2, 2023-10-31 ucrt).

Results

Participants

Figure 1 shows the participant flow through the study. A total of

279 individuals were screened between May and June 2021. Of these, 44 were excluded for not meeting eligibility criteria (n=40), declining participation (n=3), or unwillingness to be randomized (n=1). Consequently, 235 participants were randomized: 117 to the intervention group and 118 to the control group. Among them, 206 (87.7%) completed the 8-month study: 100 in the intervention group and 106 in the control group. Twenty-nine participants withdrew during the study. Sample sizes varied slightly across outcomes due to missing actigraphy data (e.g., device non-use or sync errors) and incomplete questionnaire responses. These variations are reported in the corresponding tables.

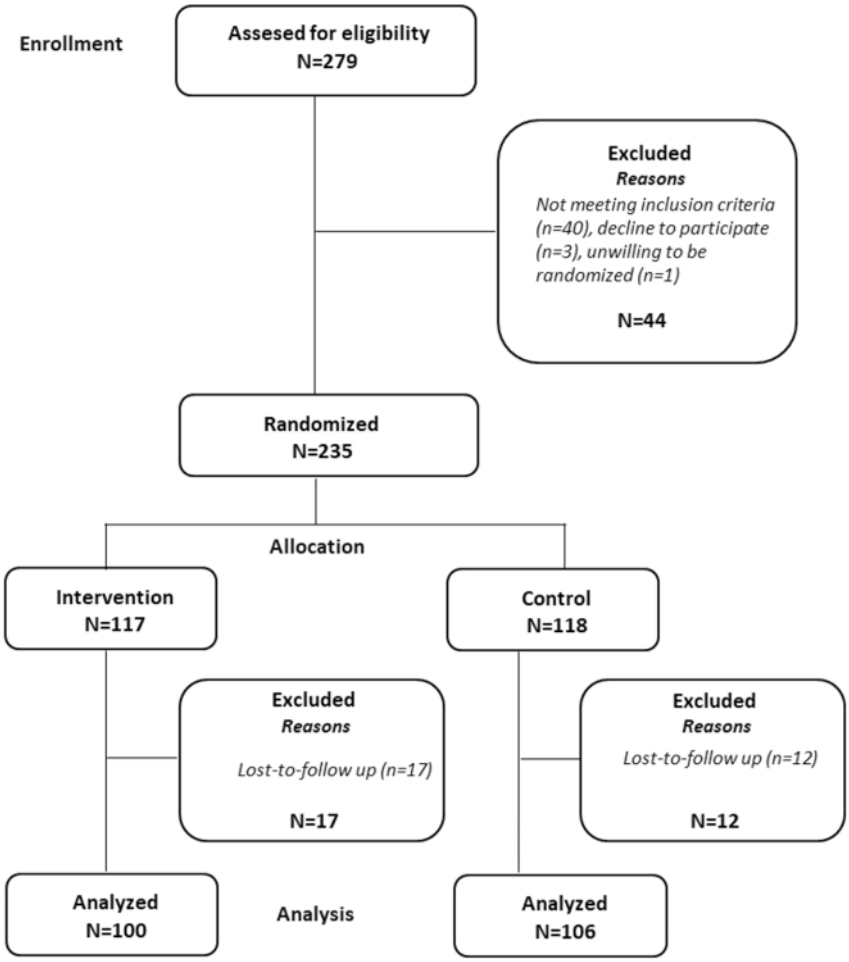

Figure 1: Flow chart of patients through the study.

Table 1 shows the baseline sociodemographic, anthropometric and clinical characteristics of both groups. The groups were well balanced in terms of age, sex distribution, BMI, education level, working schedule, marital status and comorbidities. The only statistically significant difference was alcohol consumption, which was higher in the control group ($p < 0.01$).

	Study group		
Characteristics	**Intervention**	**Control**	**p-value**
No. (%)	100	106	
Age (years), mean (SD)	51.2 (8.4)	50.1 (7.5)	0.1971 [a]
Gender, male, n (%)	26 (26.0)	34 (32.1)	0.3606 [b]
Educational level, n (%)			
Primary education	5 (5.7)	1 (1.0)	0.4778 [c]
Secondary education	20 (20.7)	37 (37.8)	
University or higher	63 (71.6)	60 (61.2)	
Working schedule, n (%)			
Morning	58 (79.5)	50 (61.7)	0.1990 [d]
Rotating shifts (morning and afternoon)	8 (11.0)	17 (21.0)	
Half-time	2 (2.7)	8 (9.9)	
Unspecified	2 (2.7)	3 (3.7)	
Afternoon	1 (1.4)	1 (1.2)	
Night	0 (0.0)	1 (1.2)	
Not applicable	2 (2.7)	1 (1.2)	
Marital status, n (%)			
Married	63 (74.1)	56 (58.9)	0.2008 [d]
Single	15 (17.6)	27 (28.4)	
Divorce	6 (7.1)	10 (10.5)	
Widower	1 (1.2)	2 (2.1)	
People in charge (yes), n (%)	56 (69.1)	58 (63.7)	0.5191 [b]
Comorbidity, n (%)			
At least one comorbidity, n (%)	14 (18.2)	16 (18.0)	1.0000 [e]
Comorbidities, n (%)			
Endocrine disease	6 (7.9)	8 (9.1)	1.0000 [e]
Rheumatic disease	1 (1.3)	4 (4.5)	0.3741 [e]
Cardiovascular disease	5 (6.6)	5 (5.7)	1.0000 [e]
Digestive/hepatic disease	0 (0.0)	4 (4.5)	0.1244 [e]
Respiratory disorder	0 (0.0)	2 (2.3)	0.4996 [e]
Psychiatric condition	1 (1.3)	1 (1.1)	1.0000 [e]
BMI (Kg/m^2), mean (SD)	24.6 (4.0)	24.8 (3.9)	0.5691 [a]

Toxic habits			
Smoking, n (%)	10 (11.9)	9 (9.9)	0.8088 [e]
Packs/year, mean (SD)	86.4 (92.5)	173.6 (126.0)	0.1409 [a]
Alcohol, n (%)	26 (31.0)	21 (24.1)	0.3920 [e]
Amount (g/day), mean (SD)	9.4 (11.9)	22.1 (13.9)	**0.0061 [a]**
Key: BMI: body mass index; SD: standard deviation. (a) Mann-Whitney test; (b) Fisher's exact test; (c) Linear-by-linear association test; (d) Pearson chi-squared test; (e) Fisher's exact test.			

Table 1: Participant´s sociodemographic, anthropometric and clinical characteristics in the intervention and the control groups at baseline.

Actigraphy outcomes

Primary Outcome: Total Sleep Time (TST)

Table 2 summarizes TST during the first and final fortnights of the study, stratified by weekday and weekend. On weekdays, TST increased significantly in both groups: from 386.5 (52.2) to 399.2 (48.0) minutes in the intervention group and from 392.3 (42.4) to 404.8 (54.5) minutes in the control group. These changes correspond to mean increases of 15.2 (44.9) and 13.1 (42.1) minutes, respectively. However, the difference in change between groups was not statistically significant (p=0.3738). Weekend TST showed no significant within-group changes, but was consistently longer than weekday TST. In the first fortnight, mean TST was 386.5 (52.2) minutes on weekdays and 432.5 (63.3) minutes on weekends in the intervention group (p<0.0001) and 392.3 (42.4) vs 440.3 (56.4) minutes in the control group (p<0.0001). This pattern continued in the last fortnight, with TST of 399.2 (48.0) minutes on weekdays and 438.9 (70.2) minutes on weekends in the intervention group (p<0.0001) and 404.8 (54.5) vs 430.4 (75.5) minutes in the control group (p=0.0020).

To further characterize TST patterns, we conducted a multivariable regression analysis to identify independent predictors (Table 3). Sex and holiday periods were the strongest predictors of TST. Compared to weekdays, weekends were associated with an average increase of β=39.2 minutes (p<0.0001). Additional holiday periods were also associated with longer TST: Christmas holidays (β = 20.5 minutes), summer holidays (β = 3.4 minutes) and long weekends (β=17.2 minutes) (all p< 0.0001). Men slept on average β=31.7 minutes less than women (p<0.0001) and although participants in the intervention group slept β=9.6 minutes less than those in the control group, this difference was not statistically significant (p=0.0745).

Variables	Weekdays			Weekends			Weekdays vs weekends p-value	
	Intervention N=98	**Control N=102**	**Intervention vs control p-value**	**Intervention N=99**	**Control N=99**	**Intervention vs control p-value**	**Intervention N=99**	**Control N=99**
TST (min), mean (SD)								
First fortnight	386.5 (52.2)	392.3 (42.4)	0.5228 [a]	432.5 (63.3)	440.3 (56.4)	0.6660 [a]	**<0.0001[c]**	**<0.0001[c]**
Last fortnight	399.2 (48.0)	404.8 (54.5)	0.5261 [a]	438.9 (70.2)	430.4 (75.5)	0.4343 [b]	**<0.0001[c]**	**0.0020[c]**
Change	15.2 (44.9)	13.1 (42.1)	0.3738 [a]	9.0 (62.1)	-7.1 (75.7)	0.1211 [b]	0.3106[c]	0.0617[c]
First vs Last fortnight p-value [c]	**0.0016**	**0.0028**		0.1758	0.3727			
TIB (hours), mean(SD)								

First fortnight	7.1 (0.9)	7.2 (0.8)	0.5774 [a]	8.0 (1.2)	8.1 (1.0)	0.9101 [a]	**<0.0001[c]**	**<0.0001[c]**
Last fortnight	7.4 (0.9)	7.5 (1.0)	0.4273 [b]	8.2 (1.3)	7.9 (1.3)	0.1582 [b]	**<0.0001[c]**	**0.0044[c]**
Change	0.3 (0.8)	0.3 (0.8)	0.7157 [a]	0.2 (1.2)	-0.1 (1.3)	0.0651 [b]	0.3966[c]	**0.0212[c]**
First vs Last fortnight p-value [c]	**0.001**	**<0.0001**		0.1006	0.3134			
SE (%), mean (SD)								
First fortnight	90.7 (1.8)	90.9 (1.8)	0.3924 [a]	90.3 (2.2)	91.1 (1.8)	**0.0221 [a]**	0.3597[d]	0.4649[c]
Last fortnight	90.4 (2.1)	90.5 (1.9)	0.9524 [a]	90.2 (2.3)	90.9 (2.4)	**0.0394 [b]**	0.1852[c]	0.2982[d]
Change	-0.2 (1.6)	-0.4 (1.9)	0.5867 [a]	-0.1 (2.5)	-0.1 (2.5)	0.9600 [b]	0.9579[c]	0.5154[d]
First vs Last fortnight p-value [c]	0.3029	0.0553		0.7746	0.8284			
WASO (min), mean (SD)								
First fortnight	28.1 (8.0)	26.4 (7.6)	0.1910 [a]	33.7 (10.5)	31.4 (9.4)	0.1552 [a]	**<0.0001[d]**	**<0.0001[c]**
Last fortnight	28.7 (8.1)	30.1 (11.4)	0.6738 [a]	34.0 (12.0)	31.5 (11.5)	0.1481 [b]	**<0.0001[c]**	0.1470[d]
Change	0.5 (8.4)	3.6 (10.5)	0.0544 [a]	0.1 (13.2)	-0.4 (12.9)	0.7794 [b]	0.7330 [c]	**0.0258[d]**
First vs Last fortnight p-value [c]	0.5962	**<0.0001**		0.9273	0.7588			
SOL (min), mean (SD)								
First fortnight	9.5 (3.4)	10.0 (3.0)	0.0698 [a]	10.0 (3.3)	9.1 (3.6)	**0.0079 [a]**	0.1848[c]	**0.0078[d]**
Last fortnight	10.7 (3.8)	10.1 (3.5)	0.4863 [a]	10.0 (4.6)	9.0 (4.5)	0.1232 [a]	0.2685[c]	**0.0254[d]**
Change	1.1 (3.9)	-0.1 (4.4)	0.0762 [b]	-0.1 (5.4)	-0.1(5.3)	0.9264 [a]	0.0883[c]	0.9511[d]
First vs Last fortnight p-value [c]	**0.0078**	0.9444		0.9100	0.9368			

Table 2: *Actimeter sleep parameters compared between the first and the last fortnights in weekdays and weekends in the intervention and the control groups.*

Key: TST-total sleep time; TIB-time in bed; SE(%)-sleep eficiency ()%; WASO-wake after sleep onset; SOL-sleep onset latency. SD: standard deviation. (a)Mann-Whitney test; (b) t test independent data; (c) t test paired data; (d) Wilcoxon signed rank test (paired). Significant p values are highlighted in bold. Sample size reflects participants with complete actigraphy data for the respective time period.

Secondary Actigraphy Outcomes

Time in Bed (TIB)

Table 2 shows that weekday TIB increased significantly over time in both groups: from 7.1 (0.9) to 7.4 (0.9) hours in the intervention group ($p = 0.001$) and from 7.2 (0.8) to 7.5 (1.0) hours in the control group ($p<0.0001$). However, the between-group difference in change from the first to the last fortnight was not statistically significant. Weekend TIB did not change significantly in either group. Weekday–weekend differences were significant in both groups at both time points, with participants consistently spending longer TIB on weekends. In the first fortnight, weekday vs weekend TIB was 7.1 (0.9) vs 8.0 (1.2) hours in the intervention group ($p<0.0001$) and 7.2 (0.8) vs 8.1 (1.0) hours in the control group ($p<0.0001$). This pattern remained in the last fortnight (intervention: 7.4 (0.9) vs 8.2 (1.3) hours, $p<0.0001$; control: 7.5 (1.0) vs 7.9 (1.3) hours, $p=0.0044$).

Multivariate mixed-effects modelling (Table 3) confirmed that TIB was significantly longer on weekends compared to weekdays ($\beta=0.72$ hours, $p<0.0001$) and significantly shorter in men than in women ($\beta=–0.55$ hours, $p<0.0001$). Holiday periods were also associated with increased TIB, with Christmas holidays showing the strongest effect ($\beta=0.43$ hours, $p<0.0001$), followed by long weekends ($\beta=0.33$ hours, $p<0.0001$) and summer holidays ($\beta=0.06$ hours, $p<0.0001$). The intervention group showed a non-significant reduction in TIB compared to the control group ($\beta=–0.14$ hours, $p=0.1494$).

Variables			Weekends	Intervention group	Sex (masculine)	Christmas holidays	Summer holidays	Long weekends
TST (min)	Coefficient		39.176	-9.595	-31.744	20.505	3.445	17.202
	CI95%	Inferior	39.153	-20.139	-43.324	20.463	3.420	17.158
		Superior	39.199	0.948	-20.164	20.547	3.470	17.245
	P value		**p < 0.0001**	p = 0.0745	**p < 0.0001**	**p < 0.0001**	**p < 0.0001**	**p < 0.0001**
TIB (h)	Coefficient		0.720	-0.138	-0.547	-0.425	-0.062	-0.333
	CI95%	Inferior	0.697	-0.327	-0.754	0.383	0.038	0.290
		Superior	0.743	0.049	-0.341	0.467	0.087	0.377
	P value		**p < 0.0001**	p = 0.1494	**p < 0.0001**	**p < 0.0001**	**p < 0.0001**	**p < 0.0001**
SOL (min)	Coefficient		-0.507	0.004	-0.227	0.146	-0.009	0.000
	CI95%	Inferior	-0.529	NA	-0.811	0.104	-0.034	NA
		Superior	-0.484	NA	0.356	0.188	0.015	NA
	P value		**p < 0.0001**	p ≈ 1.0000	p = 0.4449	**p < 0.0001**	p = 0.4449	p ≈ 1.0000
WASO (min)	Coefficient		4.342	0.777	-1.281	3.957	0.699	2.166
	CI95%	Inferior	4.318	-0.976	-3.208	3.915	0.674	2.122
		Superior	4.365	2.531	0.645	3.999	0.724	2.209
	P value		**p < 0.0001**	p = 0.3851	p = 0.1923	**p < 0.0001**	**p < 0.0001**	**p < 0.0001**

Table 3: *Multivariable linear regression analysis of predictors of actigraphy-derived sleep parameters throughout the 8-month study. Each column reports the estimated effect (coeficient), 95% confidence interval and p-value for total sleep time (TST, in minutes), time in bed (TIB, in hours), sleep onset latency (SOL, in minutes) and wake after sleep onset (WASO, in minutes). Reference categories were weekdays (for weekend effects), control group (for intervention effect) and female sex. Significant p-values are shown in bold.*

Sleep Onset Latency (SOL)

SOL remained stable across time in both groups. On weekdays, SOL increased slightly in the intervention group from 9.5 (3.4) to 10.7 (3.8) minutes (p=0.0078) and it remained unchanged in the control group (10.0 (3.0) to 10.1 (3.5) minutes, p=0.9444). On weekends, SOL values ranged from 9.0 to 10.0 minutes and did not show significant within- or between-group changes (Table 2).

Multivariate analysis revealed that SOL was significantly longer on weekends than weekdays (β=0.51 minutes, p<0.0001) and during Christmas holidays compared to non-holiday periods (β=0.15 minutes, p<0.0001). No significant effects were found for sex, intervention group, or other holiday periods (Table 3).

Wake After Sleep Onset (WASO)

Table 2 shows that WASO increased in the control group on weekdays from 26.4 (7.6) to 30.1 (11.4) minutes (p<0.0001) and remained stable in the intervention group (28.1 (8.0) to 28.7 (8.1) minutes, p=0.5962). On weekends, WASO values were higher than on weekdays in both groups, but within-group changes from the first to last fortnight were not significant (intervention: 33.7 (10.5) to 34.0 (12.0) minutes, p=0.9273; control: 31.4 (9.4) to 31.5 (11.5) minutes, p = 0.7588).

In the multivariate model, weekends were associated with significantly higher WASO compared to weekdays (β=4.34 minutes, p<0.0001). Similarly, Christmas holidays (β=3.96 minutes, p<0.0001), summer holidays (β=0.70 minutes, p<0.0001) and long weekends (β=2.17 minutes, p<0.0001) were linked to increased WASO. The effects of sex and intervention group on WASO were not statistically significant (Table 3).

Sleep Efficiency (SE)

Sleep eficiency remained high and stable over time. On weekdays, SE decreased slightly in the intervention group from 90.7 (1.8)% to 90.4 (2.1)% and in the control group from 90.9 (1.8)% to 90.5 (1.9)%; these changes were not statistically significant. On weekends, SE showed minor fluctuations: in the intervention group, SE decreased from 90.3 (2.2)% to 90.2 (2.3)% and in the control group from 91.1 (1.8)% to 90.9 (2.4)% (Table 2). No significant between-group differences were observed. SE remained consistently high across all conditions thus it was not included in the multivariate regression analyses.

Sex Differences

Sex-related differences in sleep parameters were examined using two complementary approaches: longitudinal averages over the 8-month period (first row in each section of Table Supplementary S1) and fortnight-specific comparisons at the beginning and end of the study.

Across the full study period, women consistently exhibited significantly longer TST and TIB than men on both weekdays and weekends. For example, in the intervention group, average weekday TST was 6.79 (1.27) hours in women versus 6.25 (1.39) hours in men (p<0.001) and average weekend TST was 7.53 (1.50) vs 6.99 (1.51) hours, respectively (p<0.001). Similar sex differences were observed in the control group (weekdays: 6.92 (1.29) vs 6.40 (1.30), p<0.001; weekends: 7.53 (1.51) vs 7.18 (1.44), p<0.001).

TIB followed the same pattern, with women spending significantly longer TIB than men across all day types and groups (all p<0.001). SOL was also longer in women compared to men throughout the 8-month period (e.g., intervention weekdays: 11.37 (11.30) vs 10.26 (7.11) minutes, p<0.001). Women had higher WASO values as well, particularly on weekdays (e.g., control group: 29.60 (15.46) vs 29.13 (16.21) minutes, p<0.001), although absolute differences in WASO were modest.

When focusing on the first and last fortnights, sex differences in TST and TIB were still observed, but with more variation in statistical significance. For example, during the last fortnight, weekday TST remained significantly longer in women than men in both groups (intervention: 6.65 (1.13) vs 6.38 (1.05), p=0.044; control: 6.83 (1.33)vs 6.44(1.31), p=0.005). However, on weekends, sex differences in TST and TIB were no longer statistically significant in several comparisons.

These fortnight-specific data show that the overall pattern of longer sleep in women is robust but short-term comparisons can vary based on timing and day type. This variability may reflect contextual influences, such as calendar effects (e.g., holiday periods), which are evident in the seasonal trends displayed in Figure 2.

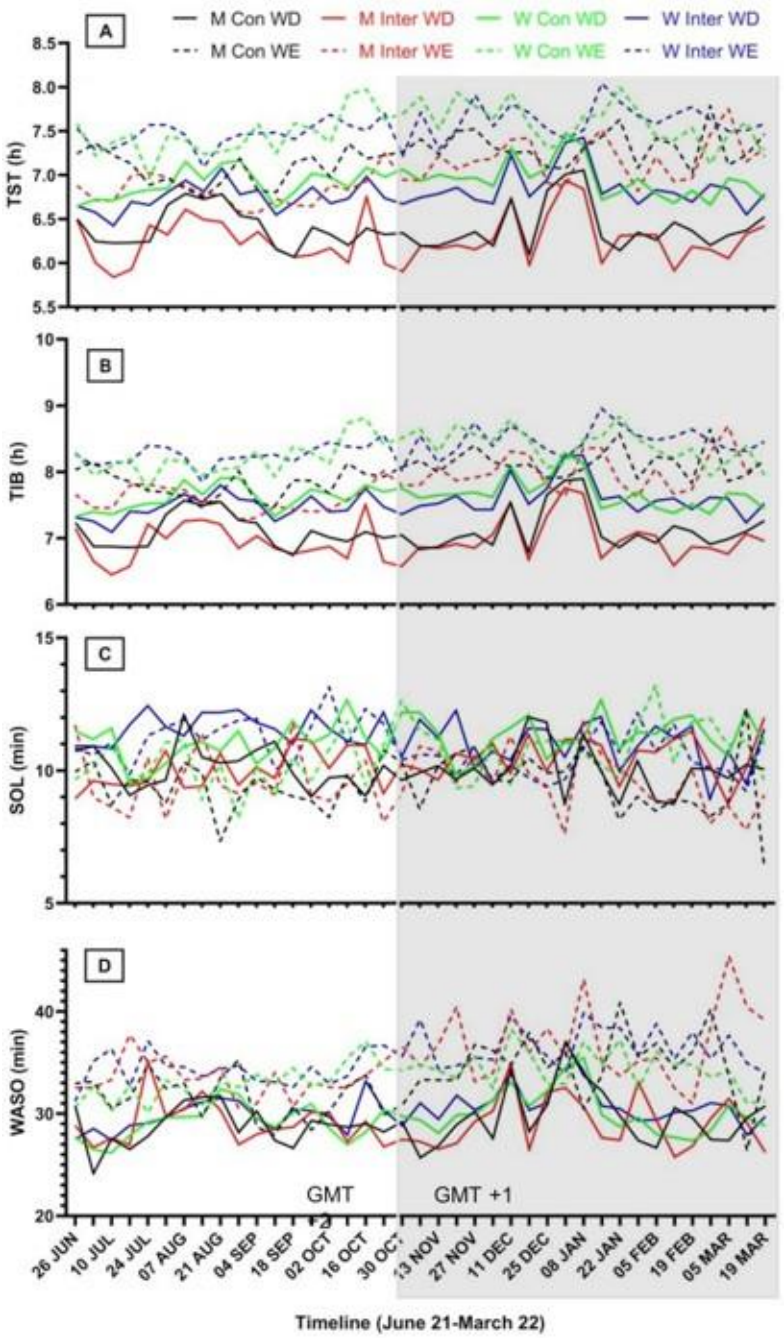

Figure 2: Longitudinal analysis of the averaged sleep parameters measured by actigraphy from June 2021 to March 2022. Sleep data are categorized by intervention group (control [Con] and intervention [Inter]), sex (men [M] and women [W]) and day type (weekdays [WD] vs weekends [WE]). The parameters include: (a) Total Sleep Time (TST); (b) Time in Bed (TIB); (c) Sleep Onset Latency (SOL); (d) Wake After Sleep Onset (WASO). Lines represent different groups: men and women in control (black and green, respectively) and intervention groups (red and blue, respectively), for both weekdays (solid lines) and weekends (dashed lines). The white background represents the period when Vitoria-Gasteiz was on GMT+2 and the grey background represents the period when the region was on GMT+1.

Subjective sleep outcomes and health related quality of life

Subjective sleep outcomes are summarized in Table 4. Sleep hygiene, assessed by SHI scores, indicate that both groups had good sleep hygiene at baseline, with no significant changes observed by the end of the study. There was no significant difference in SHI scores between the groups neither at baseline (intervention: 13.3 (5.6); control: 14.1 (5.4); p=0.375) nor after at the end of the study (intervention: 13.0 (5.3); control: 14.2 (5.3); p =0.166).

Variables	**Study group**		
	Intervention	**Control**	**p-value**
Self-reported sleep quality			
Sleep Hygiene Index (SHI), n	86	94	
Baseline, mean (SD)	13.3 (5.6)	14.1 (5.4)	0.3752 [(a)]
8 months, mean (SD)	13.0 (5.3)	14.2 (5.3)	0.1657 [(a)]
Change from baseline, mean (SD)	-0.2 (3.3)	-0.4 (3.8)	0.7069 [(b)]
p-value [(c)]	0.5788	0.3465	
Daytime sleepiness			
Epworth Sleepiness Scale, n	86	94	
Baseline, mean (SD)	9.0 (3.7)	10.1 (4.3)	0.1410 [(b)]
8 months, mean (SD)	9.2 (4.0)	9.8 (3.9)	0.3234 [(a)]
Change from baseline, mean (SD)	0.2 (2.1)	-0.2 (2.8)	0.2848 [(a)]
p-value [(c)]	0.4229	0. 4585	
Quality of life			
EQ-VAS, n	81	83	
Baseline, mean (SD)	69.7 (18.0)	69.8 (14.6)	0.6704 [(b)]
8 months, mean (SD)	73.1 (15.5)	71.0 (15.4)	0.2953 [(b)]
Change from baseline, mean (SD)	2.9 (15.4)	0.7 (12.1)	0.6171 [(b)]
p-value [(c)]	0.1200	0.6377	

Table 4. Subjective data on self-reported sleep quality, daytime sleepiness and quality of life at baseline and 8-month follow-up. **Key:** SD: standard deviation(a) t test independent data; (b) Mann-Whitney test; (c) t test paired data. Responses were only included from participants who completed both baseline and follow-up questionnaires.

Daytime sleepiness, measured by the ESS, indicates that the scores of both groups are within the normal range with no significant differences within the groups when comparing baseline and end of the study. The mean ESS scores were not significantly different between groups at baseline (intervention: 9.0 (3.7); control: 10.1 (4.3); p =0.141) or at the end of the study (intervention: 9.2 (4.0); control 9.8 (3.9); p =0.3234). There were no significant differences in the ESS results when stratifying the data by sex.

Regarding HRQOL measured by the EQ-5D 3L questionnaire, we found that there were no significant differences between the intervention and the control group in any of the dimensions of the questionnaire. The mean self-rated EQ-5D VAS scores were not significantly different between groups at baseline (intervention: 69.7 (18.0); control: 69.8 (14.6); p<0.6704) or at the end of the study (intervention: 73.1 (15.5); control: 71.0 (15.4); p<0.2953) with no significant changes within groups.

Discussion

This randomized controlled trial investigated whether combining wearable sleep tracking with optional personalized recommendations from a sleep physician, could improve

objectively measured TST in adults reporting poor sleep but without diagnosed sleep disorders. Although both the intervention and control groups showed modest weekday increases in TST over the 8-month period, there were no significant differences between groups. These findings suggest that long-term self-monitoring may be sufficient to encourage slight improvements in sleep duration, potentially by increasing users´ awareness of their sleep patterns. Contrary to our hypothesis, the addition of optional expert guidance did not yield added benefits, highlighting the limited incremental value of low-intensity telemedicine in this context [38,39].

The small effect of the intervention could be due to several factors. First, self-monitoring alone may be sufficient to promote behavior change leading to healthier sleep habits. It has been previously shown that self-monitoring leads individuals to take greater responsibility for their health and care and thus modifying their habits [30,40,41] . In our study, both groups had access to their sleep data throughout the clinical trial which may have led to lifestyle changes regardless of their group assignment. Second, the specific telemedicine modality chosen for this trial, chat-based interaction, may not have been optimal for promoting behavioral change. Telemedicine formats involving richer interpersonal communication, such as video or phone calls, may yield better therapeutic outcomes. Third, sleep habits are often deeply integrated and resistant to change, particularly when they are shaped by long-standing routines. In the Spanish context, late-night cultural norms, such as delayed meal times, social activities, and late-evening television, narrow the window of opportunity for sleep. In addition, Spain's use of Central European Time (CET), despite its geographical alignment with Greenwich Mean Time (GMT), is believed to contribute to delayed daily schedules [42,43]. These structural and cultural factors may have limited participants' ability to implement sleep habit adjustments, even with expert guidance. Finally, because participants in this study were not formally diagnosed with a sleep disorder and reported only modest impairments in quality of life, their motivation to engage with recommendations and pursue substantial changes in sleep may have been limited.

Sex differences in objective sleep measures were found in both groups with women having longer TIB and TST than men. These findings align with prior research showing that women generally sleep longer than men despite experiencing more fragmented sleep and reporting poorer sleep quality [44-51]. Interestingly, no sex differences were observed in subjective daytime sleepiness (ESS), SOL, or WASO in our population. One common explanation for sex-based differences in TST is the differential type of work men and women perform and the different amount of time they dedicate to their jobs [52]. Also higher education levels and socioeconomic factors are related to longer sleep duration [44,53]. These factors may play a role in some populations. However, in our study population, comprising municipal employees with similar work schedules and responsibilities, these factors are unlikely to explain the observed differences. Instead, biological factors may play a role. Prior studies have shown that women tend to have earlier chronotype and circadian phase markers, such as melatonin onset and core body temperature rhythms, which could contribute to earlier sleep timing and longer sleep duration [54-58]. Furthermore, some studies have proposed that women prioritize sleep more than men for well-being and health reason and consequently go to bed earlier than men, regardless of their occupational demands [59].

Strengths and limitations

To our knowledge, this is the first long-term randomized trial to evaluate the effect of a wearable-based intervention with telemedicine on sleep in a working population without diagnosed sleep disorders. The 8-month duration allowed for the assessment of sleep patterns across seasons and holidays, providing valuable insights into real-world variability. Additionally, the study incorporated both objective and subjective sleep outcomes, as well as detailed subgroup analyses by sex, day type and holiday periods.

Despite the strengths of the study, several limitations should be noted. First, the study population consisted of municipal employees from a single employer, limiting generalizability to other occupational or demographic groups. The sample was predominantly female, middle-aged and highly educated with relatively stable work schedules and no night shifts. Engagement with the telemedicine component was voluntary and variable, making it difficult to assess its true impact. Additionally, the remote nature of the intervention prevented verification of whether recommended habit changes were implemented. This variability in exposure to the intervention may have contributed to the lack of significant differences in sleep outcomes between the groups. Nevertheless, this is a common limitation of remote studies using digitally delivered interventions. Not all participants wore the actigraphy device consistently over the entire 8-month period, leading to missing data for some timepoints and a reduced sample size in certain analyses. Similarly, all participants completed the baseline questionnaires but a subset did not complete follow-up assessments, limiting the completeness of self-reported outcomes. These patterns of missingness were expected in a long-term, real-world digital study and are transparently reported in the tables. We also acknowledge potential biases in self-reported questionnaire data, such as recall errors or social desirability effects, which may have affected subjective outcomes on sleep hygiene, sleepiness, and quality-of-life measures. We also must take into account that this study recruited healthy subjects that were considered bad sleepers based on the baseline PSQI score. Thus, it is unknown whether the effects of the intervention would be different in subjects with diagnosed sleep disorders. Finally, this study targeted healthy adults

with self-reported poor sleep (PSQI >5), rather than individuals with clinically diagnosed sleep disorders. Therefore, the effects of the intervention may differ in clinical populations. Future research should explore more structured telemedicine interventions with standardized expert involvement, such as scheduled video calls, interactive behaviour-change tools or algorithm- or AI-driven feedback tailored to actigraphy data [60,61]. These formats may increase engagement and improve sleep outcomes in preclinical populations reporting poor sleep. Additionally, longer follow-up periods may be needed to assess whether observed improvements are sustained over time.

Conclusion

This randomized controlled trial found that both the intervention and control groups experienced modest increases in sleep duration during weekdays, as measured by actigraphy. However, the addition of optional personalized recommendations from a sleep physician did not result in a statistically significant improvement over sleep tracking alone. These findings suggest that wearable-based self-tracking may be sufficient to promote small behavioral changes in adults reporting poor sleep but without diagnosed sleep disorders. However, given the characteristics of the sample, findings should be interpreted with caution when extrapolating to other populations.

Cultural habits and structural factors, such as late bedtimes in Spain or work schedules may reduce sleep opportunity and could have contributed to the observed modest effects of the intervention. This suggests that individuals are "time-poor" and tend to prioritize work, household chores and leisure activities over sleep. In addition, we observed consistent sex differences in sleep duration, with women sleeping longer than men, independent of group allocation. Despite its limitations, this study provides valuable long-term data on the feasibility of telemedicine-supported self-monitoring in a real-world, working population. Future research should investigate whether systematic telemedicine interventions, with standardized expert involvement, can produce stronger effects in preclinical populations and help prevent the escalation of subclinical sleep complaints into chronic sleep disorders

Data availability statement: The raw data supporting the conclusions of this article will be made available by the authors on reasonable request, following de-identification and in accordance with ethical approvals.

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