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Review

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EEG-based headset sleep wearable devices

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The rise of wearable technology has led to EEG-based sleep monitoring devices that use electrodes placed on the forehead, ear, or neck. These devices offer promising applications in clinical and healthy populations by comparing sleep patterns, monitoring intervention responses, and examining the relationship between sleep and lifestyle factors. Despite their potential, challenges like validation against polysomnography, regulatory hurdles, data privacy, and usability hinder clinical adoption. This review explores these devices, their applications, and integration challenges in clinical practice.

Sleep plays a crucial role in overall health and well-being, and its quality is strongly linked to numerous health issues, as well as mental health and cognitive performance[1,2]. Polysomnography (PSG) has been the gold standard for clinical sleep monitoring and diagnostics, capturing a variety of physiological responses, including electroencephalogram (EEG), electro-oculogram (EOG), and electromyogram (EMG) activity, as well as breathing effort, airflow, pulse, and blood oxygen saturation[3]. Despite PSG's reliability in recording sleep patterns, it has several limitations. PSG studies are expensive and time-consuming, requiring trained professionals for setup and data scoring. Sleep stages (wake, sleep stages 1 (N1), 2 (N2), 3 (N3), and rapid eye movement (REM) sleep) are manually annotated by experts in 30-second epochs according to the American Academy of Sleep Medicine's guidelines[3]. N1 and N2 stages are often combined as light sleep, and N3 is referred to as deep sleep. This manual scoring suffers from low inter-rater reliability, with an average agreement of 82.6%[4] or $\kappa = 0.76$[5], decreasing even further in patients with sleep pathologies[4]. The stage-specific agreement has shown to be even lower, with N1 demonstrating only fair agreement between scorers ($\kappa = 0.24$)[5]. Furthermore, PSG may not accurately represent a patient's typical sleep. The unfamiliar clinical settings can cause stress, and one-night recordings do not account for intra-individual night-to-night variabilities.

Wearables and nearables are increasingly being used for sleep monitoring[6–11]. While nearables offer non-contact methods to monitor sleep, wearables provide more detailed and accurate sleep data[12]. Unlike other sleep-monitoring wearbles, EEG-based devices closely mimic the EEG component of PSG, making them highly relevant for precise sleep monitoring. In the past decade, advancements in wearable technologies have given rise to new types of sleep staging devices that use forehead, ear, or neck electrodes to acquire EEG data. These user-friendly and cost-effective devices can potentially offer a viable alternative to PSG, facilitating long-term, home-based sleep monitoring without the need for expert oversight. However, their integration into clinical practice is still in its infancy, largely due to the limited evidence of validations against PSG, regulatory constraints, data privacy and security concerns, and usability and availability issues.

While previous reviews[6–11] have provided comprehensive overviews of wearable sensors in sleep monitoring, they typically cover a broad range of devices, including wrist-worn, ring-based, and other non-EEG-based wearables. However, these reviews often only touch upon EEG-based devices as part of a larger discussion. This review differentiates itself by specifically focusing on EEG-based wearable sleep monitoring devices, delving deeper into their unique challenges and advantages. We provide a detailed examination of validation studies, regulatory considerations, and specific applications of EEG-based devices in both clinical and healthy populations. Additionally, this review highlights distinct issues related to data privacy and security, usability, and the challenges hindering their wide adoption in clinical practice, along with potential strategies to mitigate these obstacles. By narrowing our focus to EEG-based devices, we aim to provide a more targeted analysis that can better inform the development, adoption, and future direction of these specific technologies in sleep monitoring.

EEG-based wearable sleep tracking devices

The performance of EEG-based sleep tracking devices is often evaluated using Cohen's kappa (κ) values, which measure the agreement between two hypnograms (e.g., specialist vs. device) while accounting for agreements that occur by chance. It is calculated as $\kappa = (p_j\text{-}p_e)/(1\text{-}p_e)$, where p_j is the scorer accuracy, and p_e is the baseline accuracy. Kappa values less than 0.00 indicate poor agreement, 0.00–0.20 slight agreement, 0.21–0.40 fair agreement, 0.41–0.60 moderate agreement, 0.61–0.80 substantial agreement, and over 0.80 excellent agreement[13]. While devices' overall performance and agreement with the gold standard are often reported using Cohen's kappa and/or accuracies, the evaluation of sleep-stage-specific performance frequently relies on sensitivity and specificity metrics, as they provide a clearer understanding of the device's ability to detect specific sleep stages[14].

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Forehead

Wearable EEG-based devices utilizing forehead electrodes have demonstrated varying degrees of success in sleep staging and monitoring. A common type of wearable EEG measurement device is a headband, with which electrodes are primarily placed on hair-free facial locations to ensure optimal contact and signal quality. Headbands such as Zeo have shown moderate agreement with PSG ($\kappa = 0.56$) but face challenges in detecting wakefulness and have lower performance in low sleep efficiency sleep[15–17]. The Dreem headband has shown good similarity with PSG ($\kappa = 0.75$)[18]. In addition to sleep staging, the Dreem headband has been used to measure sleep position[19] and apnea events[20], expanding its utility in sleep monitoring. Sleep Profiler ($\kappa = 0.63$ to 0.65) and Cognionics (accuracy = 74%) headbands have also demonstrated moderate agreement with PSG but had low agreement ($\kappa = 0.07$) and sensitivities for the N1 stage (sensitivity = 0.27–0.32)[21–24]. Sleep Profiler is also used to measure arousals[25], sleep position[26] and sleep spindles[27]. Other types of devices utilizing forehead and EOG electrodes include sleep masks, which have demonstrated substantial agreement with PSG ($\kappa = 0.77$ and $\kappa = 0.79$) but also face limitations in accurately measuring N1[28,29]. The Sleepscope device has been utilized not only for sleep staging, where it demonstrated a substantial agreement with PSG ($\kappa = 0.75$), but also for measuring arousals[30]. Neury, a prototype bipolar EEG device, has been used for spike quantification, providing insights into sleep microstructure[31]. Devices using thin, comfortable, cost-effective electrode sheets while ensuring data quality can offer a comfortable alternative to the existing headband and sleep-mask-type devices. Such devices have shown substantial agreement with PSG ($\kappa = 0.72$ and $\kappa = 0.70$)[32,33]. Another type of device, the SOMNOwatch Plus EEG, combines actigraphy with EEG. In healthy adults, the device showed a high agreement ($\kappa = 0.78$) with PSG when using semiautomatic sleep analysis (Somnolyzer 24x7), while its software DOMINO Light only showed fair agreement with PSG ($\kappa = 0.37$)[34]. In sleep apnea patients, SOMNOwatch Plus EEG showed high agreement with PSG (agreement = 74.2%), and combining EEG with EOG/EMG improved the results (agreement = 75.5%)[35].

Ear

Ear EEG devices have emerged as a promising alternative for sleep monitoring, demonstrating good agreement with PSG and potential applications in various settings. Both in-lab and home monitoring studies have consistently shown that such devices can be used for automatic sleep staging (substantial agreement with PSG, $\kappa = 0.61$–0.74)[36–42], longitudinal monitoring[39], sleep spindle detection[43], muscle activity detection[44], and drowsiness monitoring[45,46]. Devices using around-the-ear electrodes, like the cEEGrid, have shown moderate to substantial agreement with PSG ($\kappa = 0.42$ to 0.67)[47–49], which increased with the addition of EOG and EMG electrodes ($\kappa = 0.70$)[50]. Self-application of these devices has been proven feasible for healthy participants, enabling self-recording of EEG at home[50,51]. However, like devices utilizing forehead electrodes, ear EEG devices face challenges in detecting the N1 stage[36–42,47–50].

Neck

The Zmachine Insight+ sleep monitoring system uses electrodes placed on the neck and derives data from the differential mastoids (A1-A2). The system has demonstrated excellent agreement with PSG ($\kappa = 0.85$)[52] for sleep-wake detection and substantial agreement ($\kappa = 0.72$) for staging wake, light, deep, and REM sleep[53].

In this review, we examine 32 studies utilizing EEG-based wearable sleep monitoring devices in clinical ($n = 20$) and healthy populations ($n = 12$). Most of these studies ($n = 21$) used forehead devices. Overall, Sleep Profiler, Zmachine Insight+, and Dreem were the most used devices in the analyzed studies. An overview of the devices is provided in Table 1.

Wearable EEG-based sleep-tracking devices in clinical and healthy populations

This section explores the applications of wearable EEG-based sleep-tracking devices in both clinical and healthy populations. The studies include comparisons of sleep patterns between healthy individuals and those with clinical conditions, analyses of intervention effects on sleep, performance comparisons with gold-standard methods, and investigations of the relationships between sleep and various aspects of daily life. Tables 2 and 3 summarize these applications, highlighting the effectiveness and potential benefits of these devices in diverse settings.

Clinical populations

Neurodegenerative diseases. EEG-based wearables have provided valuable insights into critical sleep differences between neurodegenerative disease (NDD) patients and healthy controls, such as reduced slow wave sleep in Alzheimer's disease (AD) patients[54] and NREM (non-REM) slow wave activity as an early biomarker for identifying individuals at risk for AD[25]. Additionally, these devices highlighted that agreement levels between Zmachine Insight+, actigraphy, and sleep diaries were shown to decrease in AD patients, highlighting that sleep diaries may capture different aspects of sleep compared to wearable EEG devices[55]. For Parkinsonian spectrum disorder (PSD) patients, EEG wearables have shown comparable results to PSG[56], suggesting their potential in tracking disease progression through biomarkers like NREM sleep with hypertonia[27]. In multiple sclerosis (MS) patients, a correlation between physical activity and increased deep sleep was revealed[57]. Furthermore, supine sleep was found to be more prevalent in NDD patients than in healthy controls[26]. These findings align with broader research indicating that sleep disorders are observed in over 60% of patients with NDDs like PSD, AD, and MS[58–63]. Addressing sleep disorders could potentially delay or prevent the development of cognitive impairments, yet the relationship between sleep disturbances and NDDs remains unclear[64]. Overall, EEG-based wearables can provide critical insights into this relationship and guide the development of targeted interventions for NDD patients.

Neurological and psychiatric disorders. Wearable EEG-based devices have shown promising results in monitoring sleep and responses to therapy in epilepsy patients. Ear EEG has demonstrated effectiveness in detecting seizures in temporal lobe epilepsy patients and provided moderately high agreement with scalp EEG for sleep staging[38,65]. In pediatric epilepsy patients with continuous spike-wave of sleep, these devices can provide accurate quantification of spike activity and have been used to monitor responses to corticosteroids, sulthiame, and ketogenic diets[31]. These findings are consistent with broader research indicating that sleep and epilepsy share a complex bidirectional relationship, where on one hand, seizures and anti-epileptic drugs have found to impact sleep, and on the other hand, sleep pattern changes, such as increased wake after sleep onset, decreased REM, disruptions in the stability of NREM sleep, and sleep oscillations, have been linked to epilepsy[66]. Sleep disturbances, such as insomnia, poor sleep quality and nightmares, are also prevalent in psychiatric disorders and are associated with the severity of psychiatric symptoms[67–69]. Monitoring sleep in this patient group using Zmachine Insight+ showed fair to good agreement with PSG for most sleep metrics[70], suggesting that wearable EEG-based devices could be effectively used for longitudinal monitoring. This could facilitate the development of targeted interventions to improve sleep quality and overall well-being in psychiatric patients.

Chronic pain. EEG-based wearables like the Dreem headband have shown potential for monitoring sleep in chronic pain patients, as preliminary findings indicate patient satisfaction with the device, suggesting its future utility in clinical practice[71]. Despite the prevalence of sleep problems among this population and their role in developing and maintaining chronic pain, they are often overlooked in routine care[72,73].

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Table 1 | Overview of devices used in the application studiess

Device/study	Medical Certificate	Integrated Sensors	Wet/Dry	# of EEG electrodes	EEG Electrode Placement	Validation Results (average)	Compliance with Menghini et al[14]. Guidelines[a]
Forehead							
Dreem[19]	FDA-registered	EEG, 3D accelerometer, pulse oximeter	Dry	5	O1, O2, Fpz, F7, F8	$\kappa = 0.75$[18]	Yes
Sleep Profiler[149]	MDSAP ISO 13485, EN ISO 13485, EC	EEG, EOG, EMG, ECG, accelerometer, PPG, nasal pressure transducer (optional), pulse oximeter (optional)	Dry	3	AF7, AF8, Fpz	$\kappa = 0.67$[21]	Yes
						$\kappa = 0.07–0.62$[22]	Mostly yes (no B-A plots or CIs)
						$\kappa = 0.63$[23]	Mostly yes (no CIs)
Cognionics headband[150]	N/R	EEG	Dry	4	F3, A1, F4, A2	*Accuracy* = 74%[24]	Mostly yes (no B-A plots or CIs)
Sleepgraph[151]	Japanese Medical Device Certification 231AHBZX00001000	EEG, EMG, EOG	Wet	2	(Fp1, M2) + 2 EOGs	$\kappa = 0.80$[152]	Mostly yes (no CIs)
Somnowatch plus EEG[153]	DIN EN ISO 13485 and 93/42/EEC	EEG, EOG, EMG, ECG, actigraphy	Wet	2 or 6	Fp2, A1[57]/ F3, F4, A1, A2, AFz, FCz[154]	$\kappa = 0.78$ (*using 6 EEG electrodes*)[34]	Mostly yes (no CIs)
iSleep[115]	No certificate (prototype)	EEG	Dry	1	Fp1[115]	*Accuracy* = 87.5% (for sleep onset detection)[155]	No
Sleepscope[156]	Japanese Medical Device Certification: 225ADBZX00020000	EEG	Wet	2	Fpz, M1[157]	$\kappa = 0.75$[157]	Mostly yes (no CIs)
Prototype bipolar EEG (Neury)[31]	No certificate (prototype)	EEG	Wet	4	Subject specific	N/R[31]	No
Ear							
Individualized 6-electrode silicone ear-EEG[158]	No certificate (prototype)	Ear-EEG	Dry	6 per ear	ELA, ELB, ELE, ELI, ELG, ELK, ERA, ERB, ERE, ERI, ERG, ERK	$\kappa \approx 0.61$[36]	Partially yes (no B-A plots, CIs, discrepancy analysis, outlier handling)
						$\kappa = 0.73$[37]	Yes
						$\kappa \approx 0.74$[38]	Partially yes (no B-A plots, CIs, discrepancy analysis, outlier handling)
						$\kappa = 0.72$[39]	Partially yes (no B-A plots, CIs, discrepancy analysis)
Neck							
Zmachine Insight+[159]	FDA-cleared	EEG	Wet	2	A1, A2	$\kappa = 0.72$[53]	Mostly yes (no CIs)
						$\kappa = 0.85$[52]	Mostly yes (no CIs)

The symbol "≈" is used to represent the average κ value which is calculated based on the confusion matrix provided in the original study.

A1 and A2 are synonymous with M1 and M2, respectively.

B-A Bland-Altman, *CI* confidence interval, *ECG* electrocardiography, *EEG* electroencephalography, *EMG* electromyography, *EOG* electrooculography, *PPG* photoplethysmography.

[a]The guideline by Menghini et al for evaluating the performance of sleep trackers against gold-standard PSG included epoch-by-epoch analysis, standard accuracy metrics (sensitivity, specificity, F1 score, accuracy, Cohen's Kappa), stage-specific sensitivity and specificity, Bland-Altman plots, discrepancy analysis (bias and limits of agreement), confidence intervals for accuracy metrics and biases, handling outliers, and a standardized analytical framework involving multiple sleep experts[14].

Table 2 | Summary of clinical applications of EEG-based wearable sleep monitoring devices

Clinical Application	Wearable device	Measurement	Duration	Participants	Summary
Neuro-degenerative diseases	Cognionics	Wake, N1, N2, N3 (deep sleep) and REM stages	≤ 3 nights	AD (n = 26) HC (n = 24)	Home EEG sleep assessments are feasible in patients with mild-moderate AD. AD patients have significantly ↓ SWS (3.4% of TST compared to 10.8% in HCs)[54].
	Sleep Profiler	TST, SE, SOL, REM onset latency, WASO, N1, N2, N3 (deep sleep), REM, arousals, time spent napping per day	≤ 6 consecutive nights	AD (n = 119)	NREM SWA inversely related to AD pathology, particularly tauopathy. Participants with ↑ tauopathy experienced daytime sleepiness despite ↑ TST[25].
	Sleep Profiler	TST, SE, SOL, WASO	≤ 6 consecutive nights	n = 293	TST has the highest agreement across Sleep Profiler, actigraphy, sleep diary. Agreement levels ↓ in mildly impaired and AD, especially for TST. Sleep diaries may capture different aspects of sleep compared to EEG and actigraphy[55].
	Sleepgraph	N1, N2, N3 (deep sleep), REM, TST, TIB, SPT, WASO, SE, RWA	1 night	PSD (n = 8, 2 excluded)	Sleepgraph is comparable to PSG in detecting sleep parameters in PSD patients, apart from N3 where a significant difference was found[56].
	Sleep Profiler	N1, N2, N3 (deep sleep), REM, NRH, WASO, SE, AI, SOL, arousals, spindle duration	≥ 2 nights	PSD (n = 45) HC (n = 120)	PSD group has ↑ NRH, ↓ TST, ↓ SE, ↑ awakenings, and ↓ REM sleep compared to the non-PSD group[27].
	Somno-watch + 1-channel EEG	TST, SE, SOL, WASO, REM, NREM, light sleep, deep sleep	1 night	MS (n = 16)	↑ moderate physical activity levels associated with ↑ deep sleep in MS patients. Better objective sleep patterns associated with ↓ symptoms of restless legs syndrome[57].
	Sleep Profiler	Sleep position	2 nights	NDD (n = 45) HC (n = 120)	Frequency of supine sleep for > 2h/night was significantly ↑ in the NDD group[26].
	Sleep Profiler	Wake, N1, N2, N3 (deep sleep), REM, sleep position, SWA	3 nights	PD (n = 20)	PD patients often sleep supine with more SWA and N3. N3 and REM in supine correlate with motor impairment and disease duration. Sleep architecture stable across nights, suggesting glympathic system malfunction risk[160].
	Sleep Profiler	NRH, sleep spindles, AAI, PR-CV		LBD (n = 16), PD (n = 14), iRBD (n = 12), AD (n = 26), MCI (n = 34), controls (n = 54)	AAI and PR-CV identify ANS dysfunction in α-synucleinopathies. AAI decreased in LBD and PD vs. controls and MCI. Weak negative correlation between AAI and NRH. Supports use of AAI in classifying neurodegenerative disorders[161].
Neurological and Psychiatric disorders	Ear-EEG	Seizure detection	1-5 nights	Epilepsy (n = 13)	Ear-EEG can be used instead of scalp-EEG in detecting seizures in patients with suspected temporal lobe epilepsy[65].
	Ear-EEG	Wake, N1, N2, N3 (deep sleep), REM	1-5 nights	Epilepsy (n = 13)	Ear-EEG moderately high in agreement with scalp-EEG for sleep staging in patients with epilepsy (k = 0 .74)[38].
	Prototype bipolar EEG (Neury)	Spike quantification	24h	CSWS (n = 38)	Wearable EEG device can be used to monitor responses to therapy in patients with CSWS. Corticosteroids found to produce the most reduction in spike activity compared to other therapies[31].
	Zmachine Insight+ device	TST, SE, WASO, REM, NREM, light sleep, deep sleep	1 night	Psychiatric disorders (n = 103)	Fair to good agreement between PSG and Zmachine for TST, SE, WASO, REM and NREM. Zmachine could be a useful tool for monitoring sleep in psychiatric patients[70].
Chronic Pain	Dreem	SOL, WASO, sleep duration, SE, REM, NREM	≥ 2 consecutive nights	Chronic pain (n = 21)	Most participants (76%) were satisfied with the study, were willing to wear Dreem for more than required (86%) and found it to be comfortable during sleep (57%)[71].

Table 2 (continued) | Summary of clinical applications of EEG-based wearable sleep monitoring devices

Clinical Application	Wearable device	Measurement	Duration	Participants	Summary
PTSD	Cognionics	Wake, REM, Light, Hi Deep, Lo Deep	3 nights over 2 weeks	PTSD (*n* = 60) HC (*n* = 70)	PTSD patients had ↓ REM, ↓ Lo Deep sleep, and ↑ Hi Deep sleep. Medications such as SSRIs, SNRIs, and antipsychotics, as well as depression and anxiety negatively impacted sleep efficiency and fragmentation[74].
	Cognionics	Wake, REM, Light, Hi Deep, Lo Deep	≥ 1 night over 3 consecutive nights	PTSD (*n* = 69)	Melatonin and busiprone linked to ↑ Lo Deep, prazosin and sertraline to ↓ REM sleep. Higher caffeine intake linked to ↓ Lo Deep and ↑ Hi Deep sleep[75].
Diabetes	Zmachine Insight+ device	TST, SE, SOL, WASO, light sleep, deep sleep, REM	2 weeks	Diabetes (*n* = 20)	Poor sleep quality associated with ↑ glycaemic variability in Type I Diabetes patients[79].
ICU or surgical patients	Dreem	Wake, N1, N2, N3 (deep sleep), REM	2 nights (1 pre, 1 post)	Pre (*n* = 74) Post (*n* = 83)	One night of recording sufficient for determining perioperative sleep structure and sleep marker acquisition. ↑ N1 and N2 and ↓ N3 and REM in postoperative patients[87].
	Sleep Profiler	TST, SE, N1, N2, N3 (deep sleep), REM, arousals	1 night	DEX (*n* = 36) No-DEX (*n* = 36)	DEX infusion improved sleep duration and quality in ICU patients, indicated by ↑ N2, ↑ N3, ↑ TST, and ↑ SE, ↓ N1, and ↓ cortical arousals[86].
	Sleep Profiler	TST, REM, N1, N2, N3 (deep sleep), SWS, SE, number of cortical, sympathetic, and behavioral arousals	2 nights (before and after)	Critically ill patients (*n* = 50)	Intubated patients had ↑ SE and ↑ NREM sleep compared to extubated patients. Sedation type influenced sleep duration and architecture, with propofol demonstrating better outcomes than fentanyl, propofol and fentanyl, or no sedation[82].
Opioid and Alcohol Use Disorder	Sleep Profiler	SOL, WASO, TST, SE, sleep quality, N1, N2, N3 (deep sleep), REM	7 consecutive nights	Methadone (*n* = 23 EEG; *n* = 24 diary) Buprenorphine (*n* = 26 EEG; *n* = 29 diary)	No significant differences between treatment groups. Women exhibited ↑ TST, ↓ N2 and ↑ N3. EEG showed ↓ TST and ↓ SE, and ↑ WASO compared to self-reported sleep[88].
	Sleep Profiler	TST, N1, N2, N3 (deep sleep), REM, Wake	Multiple nights	OUD (*n* = 8)	↑ withdrawal severity was associated with ↓ SE, ↓ REM, ↓ N1 and ↓ N2[89].
	Sleep Profiler	N2, N3 (deep sleep), REM, TST	2 nights	AUD (*n* = 36) HC (*n* = 26)	Sleep disturbances in AUD associated with GM reductions. ↓ CT in right hemisphere associated with↓ N3, ↓ CT in left hemisphere with ↓ REM sleep. ↑ GMD associated with ↑ N3 and ↑ REM in AUD, but with ↓ REM in HC[90].
Sleep Disorders	Sleep Profiler	Wake, N1, N2, N3 (deep sleep), REM, REM without atonia (RSWA), NRH	1 night	iRBD (*n* = 26)	Sleep Profiler accurately detected REM and differentiated between N2 and N3 in iRBD patients when compared to PSG and manual scoring. NRH corresponded with physicians' iRBD diagnoses based on RSWA[93].
	Sleep Profiler	Wake, N1, N2, N3 (deep sleep), REM, SB episodes, episode index, burst index	1 night	SB (*n* = 10), Healthy (*n* = 10)	Sleep Profiler demonstrated high sensitivity and specificity for diagnosing SB when using optimized cutoff values. However, there was a risk of overestimating SB episodes compared to PSG[92].
	Dreem 2	AHI, breathing frequency	1 night	OSA (*n* = 41)	The Dreem 2 demonstrated high accuracy in detecting OSA, with sensitivity and specificity similar to expert PSG scoring. Correlation between DH and PSG scorers was significant (r=0.79, p<0.001)[20].

AAI autonomic activation index, *AD* Alzheimer's disease, *AI* arousal index, *ANS* autonomic nervous system, *CSWS* continuous spike-wave of sleep, *CT* cortical thickness, *DEX* dexmedetomidine, *EEG* electroencephalography, *GM* gray matter, *GMD* gray matter density, *HC* healthy controls, *ICU* intensive care unit, *iRBD* isolated REM sleep behavior disorder, *LBD* Lewy Body dementia, *MCI* mild cognitive impairment, *MS* multiple sclerosis, *NDD* neurodegenerative disease, *NRH* NREM with hypertonia, *NREM* non-REM, *OUD* opioid use disorder, *PR-CV* pulse rate coefficient of variation, *PSG* polysomnography, *PSD* Parkinsonian spectrum disorders, *PTSD* post-traumatic stress disorder, *REM* rapid eye movement, *RWA* REM sleep without atonia, *SB* sleep bruxism, *SE* sleep efficiency, *SNRI* serotonin and norepinephrine reuptake inhibitor, *SOL* sleep onset latency, *SSRI* selective serotonin reuptake inhibitor, *SWA* slow wave activity, *SWS* slow wave sleep, *TIB* time in bed, *TST* total sleep time, *SPT* sleep period time, *WASO* wake after sleep onset, ↑ increase, ↓ decrease.

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Table 3 | Summary of the applications of wearable EEG-based sleep monitoring devices in healthy populations

Clinical Application	Wearable device	Measurement	Duration	Participants	Summary
Diet, Stress, Chemosensory function	Zmachine Insight+ device	TST, SWS, REM	2 consecutive nights	$n = 56$	↓ Sweet taste preference correlated with ↑ TST and the sum of REM and SWS duration in non-obese females[97].
	Zmachine Insight+ device	TIB, TST, REM, SWS, NREM, REM + SWS	2 consecutive nights	$n = 51$	Sweet taste preference negatively associated with TST, REM sleep and REM+SWS in non-obese males. Odor identification ability was not associated with TST and REM duration[98].
	Zmachine Insight+ device	TIB, TST, SWS, REM	2 nights at least 2 weeks apart	$n = 24$ (for 2 participants, self-reported TIB was used)	The nigh with 33% less TIB as confirmed by Zmachine in non-obese women was associated with self-reported ↑ hunger, tiredness, sleepiness, consuming more chocolate, larger portion sizes[99].
	Sleepscope	TST, SE, SOL, arousals	7 nights	$n = 18$	↑ TST and ↓ SOL significantly associated with ↑ Δvitality[30].
	Zmachine Insight+ device	TST, SOL, WASO, SE, SWS, REM	14 consecutive nights	$n = 98$	↓ TST, ↓ SE, ↓ SWS and ↓ REM sleep significantly predict ↑ next-day stress levels in undergraduate students[102].
Sports & Exercise	Sleep Profiler	Light sleep, deep sleep, REM	2 nights (before and after)	$n = 5$	12-week aerobic exercise intervention significantly associated with ↑ deep sleep, ↓ REM sleep[106].
	Somnowatch + 6-channel EEG	N1, N2, N3 (deep sleep), REM SOL, WASO, TWT, TST, SE	2 consecutive nights	$n = 25$	No significant differences between the self-applied EEG-based method and PSG in SOL, N1, N2, N3 and REM[154].
Changes in Daily Routine	Dreem	Sleep onset duration, TST, N2, N3 (deep sleep), REM, sleep continuity	≥ 1 non-consecutive nights over 5 weeks	$n = 599$	↑ sleep duration, ↓ deep sleep, ↑ light sleep, and ↑ REM, less weekend-specific changes in sleep patterns during COVID-19 lockdown[111].
	Zmachine Insight+ device	TST, light sleep, deep sleep, REM, SE, LPS, WASO	12 nights: baseline (3 nights), night float (6 nights), recovery (3 nights)	$n = 29$ (one subject stopped at day 8)	6 consecutive night shifts had significantly ↓ TST, ↓ light, ↓ deep and ↓ REM sleep. 3-day recovery period is insufficient for restoring REM and deep sleep levels, even though TST similar to baseline[112].
Improving Sleep	iSleep	Time-to-sleep	2 naps	$n = 28$	Audio stimulation significantly speeds up the time-to-sleep in the slow sleep onset group[115].
	Dreem	N1, N2, N3 (deep sleep), REM, Wake, sleep apnea events	1 night	Obstructive sleep apnea ($n = 8$)	Bone-conducted acoustic stimulation significantly associated with ↓ apnea event duration by 21.4%[114].
	Dreem	N1, N2, N3 (deep sleep), REM, Wake	≥ 2 nights over 10 consecutive nights	$n = 90$	Auditory closed-loop stimulation of SSO led to 43.9% ↑ in delta power of N3. The increase of SSO response was consistent after 10 nights[113].

COVID-19 coronavirus disease 2019, *EEG* electroencephalography, *LS* light sleep, *LPS* latency to persistent sleep, *REM* rapid eye movement, *SE* sleep efficiency, *SOL* sleep onset latency, *SSO* sleep slow oscillation, *SWS* slow wave sleep, *TIB* time in bed, *TST* total sleep time, *TWT* total wake time, *WASO* wake after sleep onset, ↑ increase, ↓ decrease.

Integrating wearable EEG-based devices could help better understand and address sleep-related issues in chronic pain management.

Post-traumatic stress disorder (PTSD). Wearable EEG devices have provided valuable insights into sleep disturbances experienced by individuals with PTSD. For instance, data collected using the Cognionics device revealed that PTSD patients have less REM and Lo Deep sleep (0.1–1 Hz) and more Hi Deep sleep (1–3 Hz) compared to controls[74]. Additionally, the impact of medications on sleep efficiency and fragmentation was demonstrated in another study using the Cognionics device, with melatonin being associated with more Lo Deep sleep, indicating its potential effectiveness in treating PTSD-related sleep problems[75]. These findings align with broader research indicating that over 92% of individuals with PTSD report sleep disturbances, including insomnia and nightmares, which significantly impact their overall functioning and quality of life[76–78].

Diabetes. Wearable EEG-based devices have highlighted significant associations between sleep quality and glycemic variability in diabetes patients. For instance, a study using Zmachine Insight+ showed that poor sleep quality was associated with increased glycemic variability in type 1 diabetes patients, emphasizing the need to consider sleep quality in personalized diabetes management plans[79]. This aligns with broader research demonstrating sleep disturbances in this population and the relationship between poor sleep quality and lowered glycemic control in both, type 1 and 2 diabetes patients[80,81]. Using wearable EEG-based devices for home monitoring may provide a feasible way to optimize blood glucose control in diabetes patients.

Intensive Care Unit (ICU) and surgical patients. EEG-based wearables have provided critical insights into sleep disturbances in ICU and surgical patients, highlighting the impact of these disturbances on patient outcomes. Using the Sleep Profiler, Jean et al. examined sleep architecture in critically ill patients, demonstrating how intubation and sedation methods affect sleep quality[82]. This aligns with broader research indicating that sleep deprivation in ICU patients is linked to delirium, prolonged mechanical ventilation, increased mortality, and extended ICU stays[83–85]. Another study found the potential benefits of dexmedetomidine sedation on sleep duration in non-intubated ICU patients[86]. In geriatric cardiac surgical patients, the Dreem headband was utilized for peri- and postoperative sleep analysis, revealing increased light sleep and decreased deep sleep in the postoperative phase[87]. Overall, using EEG-based devices can enhance the management of sleep disturbances and improve outcomes in ICU and surgical settings.

Opioid Use Disorder (OUD) and Alcohol Use Disorder (AUD). Wearable EEG-based sleep trackers have facilitated the investigation of sleep impairments in both OUD and AUD patients. For instance, gender-based differences and discrepancies between objective and self-reported sleep metrics were noted in individuals with OUD undergoing methadone vs. buprenorphine treatment, while no differences between the treatment groups were found[88]. In another study, further discrepancies between EEG-based and self-reported sleep metrics, along with associations between withdrawal severity and alterations in sleep metrics, were found[89]. A study in individuals with AUD found lower cortical thickness in the right and left hemispheres to be associated with shorter N3 and REM sleep stage durations, respectively, indicating that addressing brain structural changes could positively impact sleep and vice versa[90]. These findings are consistent with broader research showing that sleep impairments are a common comorbidity in OUD and AUD patients[91], underscoring the potential of wearable EEG-based devices to improve the management of sleep disturbances in these populations.

Sleep disorders. EEG-based sleep wearables have demonstrated potential in detecting and monitoring sleep disorders. The Dreem2 headband accurately detects OSA with performance comparable to expert PSG scorers, making it suitable for at-home monitoring[20]. The Sleep Profiler is effective in diagnosing sleep bruxism[92] and identifying biomarkers for non-REM hypertonia and REM sleep behavior disorder (RBD), aiding early diagnosis of neurodegenerative conditions[93]. These findings are particularly relevant given the established links between sleep disturbances, including OSA and central sleep apnea, and severe cardiovascular issues such as hypertension, stroke, arrhythmias, coronary artery disease, and heart failure[94–96]. The relationship between sleep disturbances and cardiovascular diseases highlights the potential of sleep monitoring wearables to provide critical insights and enable timely, effective interventions.

Healthy populations

Diet, stress, and chemosensory function. Wearable EEG-based sleep monitoring devices have demonstrated the short-term impacts of sleep fluctuations on daily life and well-being. Studies in non-obese participants revealed associations between sleep duration and chemosensory function, with longer sleep being correlated with lower sweet taste preference and better odor identification[97,98]. Additionally, one night of reduced sleep in non-obese women was linked to increased hunger, tiredness, sleepiness, and food cravings[99]. These findings align with broader research indicating that poor sleep quality is associated with poor dietary habits, including higher intake of fats and carbohydrates, which can exacerbate sleep disturbances[100,101]. Furthermore, the EEG-based wearables have shown that changes in sleep measurements can predict next-day stress levels[102] and changes in emotional status[30], supporting the connection between poor sleep quality and heightened stress levels highlighted in the broader literature[103–105]. Overall, these insights underscore the potential of wearable EEG-based devices to enhance our understanding of the interplay between sleep, diet, and stress, suggesting that improving sleep quality could positively impact dietary habits and stress levels.

Sports and exercise. EEG-based sleep monitoring devices have shown promise in sports science research, providing valuable insights into the relationship between exercise, sleep, and neurocognitive health. Although such devices cannot fully replace PSG, they can be feasible for monitoring and detecting sleep disorders in athletes[42]. A study investigating the effects of exercise on sleep in older adults found increased deep sleep, decreased REM sleep, and increased total EEG power in light and deep sleep following a 12-week aerobic exercise intervention[106]. These findings support broader research indicating that good sleep quality, which can be enhanced by moderate-intensity aerobic exercise, particularly in older adults[107], is crucial for overall health and athletic performance[108–110].

Changes in daily routine. Wearable EEG-based sleep monitoring devices have been used to study the effects of changes in daily routines and work schedules on sleep. For instance, data collected using the Dreem headband demonstrated alterations in objective sleep measures during COVID-19 lockdowns in France. The largest changes were found in "night owls" whose REM sleep had significantly increased[111]. Another study used Zmachine Insight+ to monitor night shifts' effects on anesthesia residents' sleep and demonstrated that a three-day recovery period is not sufficient for restoring sleep levels after night shifts[112].

Improving sleep. EEG-based wearable devices have demonstrated potential in improving sleep quality and reducing sleep disturbances. For example, the Dreem headband has been shown to be feasible for delivering auditory stimulation during N3 sleep to enhance slow oscillations and improve sleep quality[113]. Additionally, it has been used

to administer acoustic simulations during sleep apnea events to reduce apnea event duration and oxygen desaturation amplitude and duration[114]. iSleep, an EEG- and audio-based sleep enhancement device, significantly reduced time-to-sleep for individuals with difficulty falling asleep[115]. Furthermore, a randomized controlled trial demonstrated that providing feedback and guidance on sleep perceptions using wearable devices like Fitbit and EEG headbands can reduce insomnia severity and sleep disturbance, though it did not alter sleep-wake state discrepancies significantly[116].

Discussion

Challenges

Wearable EEG-based devices for sleep staging have emerged as a promising solution to enable data-driven approaches in healthcare, promoting personalized and preventive medicine. However, their widespread adoption in clinical practice faces several technical and ethical challenges. Collaboration between various stakeholders, including technology experts, medical professionals, and regulatory bodies, is essential to overcome these barriers.

Accuracy and validation. Demonstrating clinical validity is crucial for the adoption of wearable EEG-based devices. Recent guidelines by Menghini et al. emphasize the importance of epoch-by-epoch evaluation when validating sleep trackers against gold standard PSG, which should be considered for accurate validation of new devices[14]. Even studies achieving the highest accuracies[18,38,53] have exhibited lower agreeability measures with PSG than inter-scorer reliability in PSG-based approaches (κ = 0.76)[117], likely due to a lower signal-to-noise ratio in wearables. Manual scoring can improve agreement with PSG data; for instance, Sleep Profiler's agreement increased from 71.3% (κ = 0.63) to 73.9% (κ = 0.67) after manual review, demonstrating that current automatic staging of these devices is still not as accurate as human expert analysis[23]. Several disorders can impact sleep structure, possibly affecting the performance of automatic staging, yet most devices have only been validated against PSG in healthy populations. Evidence in clinical populations is limited (Table 2). Accuracy can also be affected by inter-user variabilities, such as age and sleep hygiene and structure[118], as well as intra-user variability and first-night bias. For example, sleep spindles, autonomic activation, and N3 stage have shown the least between-night variability and strongest stability in users, while sleep time duration, REM stage, and sleep efficiency show the lowest stability, suggesting that two-night studies may be necessary for accurate profiling of these metrics[23].

Improving automatic scoring is crucial for establishing the clinical validity of these devices. However, this task is complicated by the significant variability in interscorer agreement. While the overall interrater reliability of manual PSG scoring indicates substantial agreement (κ = 0.76), the agreement for specific sleep stages varies considerably: fair for N1 (κ = 0.24), moderate for N2 and N3 (κ = 0.57 for both), substantial for REM (κ = 0.69), and substantial for Wake (κ = 0.70)[5]. This variability complicates the validation of automatic scoring systems against PSG standards. Furthermore, this subjectivity inherent in manual scoring can be transferred to trained models when they rely on single-scorer annotations[4,117]. Interscorer agreeability has also been shown to be lower for scoring the data from EEG-based wearable devices, e.g., κ = 0. 66 for a wearable device vs. κ = 0. 76 for PSG in one study[32] and κ = 0.94 vs. κ = 0.97 in another[21]. Ensuring the accuracy and validity of these devices requires the development of evaluation frameworks, collaboration between stakeholders, and further research to improve device performance across various populations.

Regulatory issues. Challenges related to regulatory issues for EEG-based wearable sleep-tracking devices are multifaceted, requiring a delicate balance between ensuring quality and safety and fostering innovation. Most wearable devices are classified as lifestyle and fitness products and are often not subject to the same level of regulatory scrutiny as medical devices. The absence of clear regulatory oversight policies governing these devices can lead to the emergence of products with unknown safety and accuracy, posing risks to consumers and undermining trust in wearable health technologies.

Integration into clinical practice requires devices to be regulated, providing credibility and reliability for medical professionals and patients. However, current regulatory pathways can create market barriers, particularly for small companies and start-ups. In the European Union (EU), manufacturers must comply with the Medical Device Regulation (MDR) 2017/745 put in place in 2021, leading to additional requirements for software products, including wearables[119]. However, with no centralized regulatory body, the process is complicated, and time-to-certification can take 13–18 months[120]. In the United States (US), the Food and Drug Administration (FDA) regulates medical devices. Its 510(k) process allows for an accelerated clearance, allowing wearable devices to be marketed upon demonstrating substantial equivalence to an existing medical device[121–123]. Furthermore, with the increasing use of artificial intelligence (AI), new regulatory frameworks are being developed, such as the European Commission's AI Act, which aims to harmonize rules for AI systems and promote development while addressing possible risks[124–126]. These regulations can be especially challenging for small- and medium-sized enterprises or academic researchers developing new devices, often hindering the availability of innovative devices for medical use. In navigating these multifaceted regulatory landscapes, the role of ethical design standards like IEEE Std 7000™-2021[127] becomes crucial. This standard offers a methodology to integrate ethical considerations into system design, emphasizing communication with stakeholders and ensuring their ethical values are traceable throughout the design and implementation. By leveraging such ethical design, developers can navigate regulatory challenges more effectively, ensuring the alignment of their products with ethical considerations and contributing to the attainment of regulatory approvals. To support innovation, efforts have been made to accelerate the development and adoption of new devices, such as the FDA's real-world evidence program in the United States[128] and the DiGA Fast-Track in Germany[129].

Data privacy and security. EEG-based wearable sleep-tracking devices pose distinct data security risks, as brain wave data can reveal various personal details such as potential predispositions to certain diseases or disorders, as well as age and sex assigned at birth[130]. Ensuring data privacy and security is crucial to protect users from potential abuses of their data. In the EU, the key framework for protecting personal data is the European General Data Protection Regulation ((EU) 2016/679, GDPR) which grants individuals the right to access, alter, or delete their personal data and restrict its processing[131]. The EU's MDR also requires adherence to the GDPR. Additionally, the EU has introduced a Directive on Security of Network and Information Systems to harmonize cybersecurity regulations[132]. In the US, data privacy regulations are less strict compared to the EU. Nonetheless, specific rules apply to healthcare data, particularly the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA establishes relatively broad permissions for the use of protected health information, often making individual consent unnecessary, and devices not intended for use within the healthcare context of HIPAA-covered entities are not subject to these regulations[133].

To mitigate data privacy and security risks linked to wearable devices, strategies such as using advanced cybersecurity tools like blockchain, developing transparent data user agreements, updating outdated regulations, and raising individual awareness of security risks could be employed. Furthermore, following standards like IEEE Std 7000™-2021[127] reinforce ethical considerations and values in system design, enhancing the overall trust of these devices. Implementing robust data privacy and security measures will foster users and healthcare professionals' trust, facilitating the integration of these devices into clinical practice.

Availability. One of the main challenges with integrating EEG-based wearable devices into clinical practice is addressing availability concerns and ensuring equal access to these technologies. Users with higher digital literacy and socioeconomic resources are more likely to

benefit from wearable devices, which in turn can exacerbate disparities in healthcare access. Public health policies and reimbursement strategies should be designed to promote equal access to these devices and cover the costs associated with wearable data reviews and prescribing. This would encourage healthcare providers to adopt wearables in clinical practice.

In the US, the Center for Medicare[134] and Medicaid Services has established new reimbursement codes for remote patient monitoring. In Germany, a fast-track process for low-risk medical devices, including wearables, was introduced in the Digital Health Care Act. These digital health applications, referred to as DiGA, are intended for direct patient use and can be prescribed by physicians or psychotherapists in primary care settings[129].

Behavioral change in clinicians. Maintaining behavioral change in clinicians is crucial for the successful integration of EEG-based wearable devices in clinical practice. Clinicians are often hesitant to adopt new technologies for various reasons, such as unfamiliarity, concerns about data privacy, and compatibility with existing clinical systems. Addressing these concerns requires a comprehensive approach that focuses on easing the transition for clinicians. First, seamless interoperability between wearables and existing hospital systems must be ensured without compromising patient privacy or data accessibility. Second, a strong body of clinical evidence demonstrating the benefits and safety of wearable EEG-based devices is needed to increase patient and clinician trust. Finally, comprehensive training and ongoing support must be provided for clinicians, incorporating structured learning modules about wearables and their clinical applications.

Usability. Usability remains a significant challenge for wearable EEG-based devices, particularly in terms of comfort and impact on perceived sleep quality. A study by Mikkelsen et al. (2019)[37] that utilized in-ear EEG devices revealed that 85% of participants rated their sleep quality as bad or bearable on the first night, and 75% of participants reported the comfort of the earplugs as bad or bearable on the first night. Only 10% of participants indicated that the earplugs did not negatively impact their sleep at all during the first night of recording[18]. To ensure wider uptake and consistent usage of these devices, it is vital to address issues related to user experience. Manufacturers should prioritize improving designs by, for example, making them lighter, incorporating soft, breathable textiles in headbands, and utilizing ergonomic designs that better conform to users' head and ear shapes. Additionally, ensuring that devices are easy to apply correctly, as well as offering clear instructions and support, can further enhance the user experience. By focusing on improving usability, manufacturers can make wearable EEG-based devices more appealing to users, ultimately leading to better patient adherence and more high-quality data collection.

Subjectivity. Subjective sleep assessments are essential for a comprehensive understanding of sleep health, especially in at-home monitoring. These assessments provide insights into perceived sleep quality, complementing objective measures from wearable devices. Common methods include sleep diaries, the Pittsburgh Sleep Quality Index (PSQI)[135], and the Epworth Sleepiness Scale (ESS)[136]. For example, a study comparing single-channel EEG, actigraphy, and sleep diaries in older adults found that while total sleep time agreement was high, it decreased in participants with mild impairment and Alzheimer's, showing that sleep diaries capture different sleep aspects. Integrating subjective assessments with wearable EEG data can provide a more comprehensive view of sleep health, identifying issues that objective measures alone may miss[55]. Including these assessments in studies and at-home monitoring enhances sleep health understanding and helps tailor interventions. More studies should combine both methods to better capture different aspects of sleep.

Clinical practice. As sleep monitoring devices gain traction, healthcare professionals and policymakers face numerous challenges when integrating these technologies into clinical practice.

There are various types of wearables and nearable devices available for sleep monitoring, each offering different advantages and levels of accuracy. Wearable nasal flow devices have proven to be particularly useful for diagnosing disordered breathing-related sleep disorders like OSA, offering diagnostic accuracy comparable to PSG with less invasiveness[137–140]. Nearable devices, such as an audio-based system has achieved 87.00% agreement with PSG in sleep stage classification[141], and a contactless breathing monitor has shown high sensitivity for deep and REM sleep (75.00% and 74.80%, respectively), but lower sensitivities for light sleep and wake (59.90% and 57.10%, respectively), outperforming some wrist-worn devices[142]. Wrist and finger-based wearables, including devices like Fitbit, Apple Watch, Garmin, Polar, Oura Ring, WHOOP, and Somfit, are popular for home-based sleep monitoring due to their non-invasiveness. These devices are effective in detecting sleep versus wake states but struggle with specific sleep stage detection ($\kappa = 0.20–0.65$)[143–146].

Overall, EEG-based wearables provide superior accuracy compared to wrist-based devices, which, while offering greater user-friendliness and cost-effectiveness, have lower accuracy in clinical populations. For example, EEG headbands have shown higher accuracy compared to actigraphy for sleep quality parameters[147], and the Zmachine has shown higher agreement with PSG compared to Fitbit in psychiatric patients[148]. Integrating EEG-based wearables into clinical practice is crucial for precise sleep monitoring, especially in clinical populations where accuracy is paramount. However, the choice of sleep monitoring technology should be tailored to the specific needs of the patient. For instance, patients with suspected sleep-related breathing disorders may benefit more from nasal wearables, while wrist-based wearables might be more suitable for healthy populations requiring long-term monitoring due to their comfort and ease of use.

To assist clinicians in evaluating and incorporating wearable sleep-tracking devices into their daily practice, we present a comprehensive list of topics to consider (Table 4). This list covers devices' available data, validation against PSG, regulatory status, evidence for specific clinical populations and applications, and fair availability. It also addresses the potential benefits for patients and clinicians, such as cost-effectiveness, and the challenges of workflow integration, including electronic health record integration, staff training, billing, and data review. Finally, the list highlights the crucial aspects of data rights, governance, storage, and privacy. By carefully considering these factors, clinicians can potentially adopt wearable sleep monitoring devices effectively, paving the way for a new era of connected remote patient care in sleep monitoring. To further illustrate the proposed integration process, Fig. 1 outlines the steps for integrating EEG-based wearable devices into clinical practice, from data collection to clinician review and patient counseling, highlighting key considerations at each step.

EEG-based wearable sleep monitoring devices hold great potential for transforming the field of sleep medicine by offering a more accessible, cost-effective, and patient-centric approach to sleep assessment. This paper has delved into the current state and applications of these devices, exploring their role in understanding sleep in various clinical populations, the effect of interventions on sleep patterns, and daily aspects of sleep. For instance, these devices have provided insights into sleep alterations in patients with NDDs and the effects of lifestyle factors such as diet and stress on sleep patterns, and vice versa.

However, the integration of these technologies into clinical practice presents several challenges, such as validation against PSG, regulatory compliance, data privacy and security, and patient and clinician benefits, which must be addressed. This paper has provided a comprehensive list of factors to consider to effectively adopt wearable sleep monitoring devices in clinical settings. Clinicians should carefully evaluate the available data, validation results, regulatory status, evidence for specific clinical populations and applications, and fair availability. The potential benefits and challenges for both patients and clinicians should be weighed, including the improvement of clinical workflows, cost-effectiveness, remote patient care,

Table 4 | Summary of the considerations for integrating wearable EEG-based devices into clinical practice

Topics	Questions	Possible Answers and Considerations
Available Data	What data is available? Is raw data available? What is the quality of the data?	Wearable EEG-based devices generate sleep stage data classified into four (wake, light, deep and REM sleep, e.g., Zmachine Insight+) or five classes (wake, N1, N2, N3, REM, e.g., Dreem and Sleep Profiler). Additionally, further metrics, e.g., SE, TST, SOL, WASO are provided. In most cases, raw data is available for visual interpretation.
Validation against PSG	Has the device been validated against PSG? What are the validation results? What validation metrics are provided? How do the validation results compare to the interrater agreement (κ = 0.76)?	Wearable EEG-based devices vary in the availability of validation results and agreements with PSG, e.g., Dreem κ = 0.75 with high *sensitivities* for REM and N3 (0.87), but low for N1 (0.48)[18], Sleep profiler κ = 0.63-0.67 with poor *sensitivities* for N1, ranging from 0.21 to 0.44[21–23], Zmachine Insight+ κ = 0.72[53].
Medical Device Regulations (MDR) and Ethical Considerations	Does the device comply with MDR? Is the device FDA approved or does it have other regulatory approvals? Does the device comply with ethical design standards like IEEE Std 7000™-2021, in addition to MDR?	Some devices are FDA approved (Zmachine Insight+ and Dreem 3), Sleep Profiler has MDSAP ISO 13485, EN ISO 13485 and EC certificates. Other devices, particularly those in the prototype stage, likely do not have regulatory approvals. It is important to verify the regulatory status of the device before applying it for clinical monitoring or research. Furthermore, reviewing compliance with ethical design standards, such as IEEE Std 7000™-2021, can provide insights into the ethical considerations that were taken into account during the design and development phase.
Evidence for specific clinical populations	Is there evidence supporting the use of wearable devices in specific clinical populations? Are there studies comparing the performance of wearable devices with PSG in these populations?	There is a growing body of literature on using wearable devices in diverse clinical populations (Table 2). However, only a few studies compared the performance of wearable devices with gold standard to validate the use in the population[38,56,65,70]. More research is needed to validate the use of wearable EEG-based devices in specific clinical populations.
Evidence for specific applications	Is there evidence supporting the use of wearable devices for the specific application?	There is a growing body of literature on using wearable devices for various applications in both clinical and healthy populations (Tables 2 and 3), with some studies comparing sleep metrics in patients and healthy controls[26,27,54,74,90], some studies looking at intervention results[31,57,86,88], some studies assessing the relationship between sleep and daily aspects[30,102,106].
Fair availability	How readily available is the device to patients? How can fair availability be ensured?	Most EEG-based wearable sleep staging devices are not yet readily available to consumers due to price or other constraints. It is important to ensure fair availability to enable the integration of these devices into clinical practice. Reimbursement policies should cover both, prescribing devices to the patients as well as data review by clinicians.
Clinical Workflow Integration	What are the logistical concerns related to integrating this device into clinical workflows? How can these challenges be addressed? Who will train the health-care staff and patients to use the devices? What are the billing codes for device set up and data review?	Implementing wearable EEG-based devices into clinical practice requires addressing several logistical concerns. Clinicians must establish patient consent and determine who will train patients and healthcare staff to use the device. Integration with existing systems, e.g., electronic health records, is also required. Billing processes and codes for using the devices in clinical practice must be defined. As there are currently no best practice guidelines for using wearable EEG-based devices for sleep staging in clinical practice, it is essential to address the above-mentioned challenges and consider the device's validation data, regulatory status, and specific applications when incorporating it into clinical practice.
Clinician Benefits	What potential benefits does the device offer to you? How can the deivce improve clinical workflow and patient care?	Wearable EEG-based devices for sleep staging can potentially improve clinical workflow by providing a convenient, cost-effective alternative to in-lab sleep studies. This may allow clinicians to manage more patients remotely, reduce wait times for sleep studies, and provide timely interventions for sleep disorders. However, it is essential to consider the specific device, its accuracy, and the clinical context. Devices with regulatory approvals may offer more reliable data for clinical decision-making.
Patient Benefits	What benefits does this device provide for remote monitoring? Does integrating the device improve patient outcomes?	Wearable EEG-based devices for sleep staging can potentially improve patient care by facilitating remote monitoring to detect sleep disorders or to better understand the role of sleep in various clinical populations, e.g., in NDD patients. In addition to avoiding the inconvenience and expense of in-lab sleep studies, these devices can also enable longitudinal sleep monitoring and provide a more comprehensive overview of sleep patterns. However, it is important to consider the specific device, its accuracy, and the patient population.
Data Rights, Governance, Storage and Privacy	Who owns the rights to the data? Where are these data being stored? How can I ensure compliance with relevant privacy regulations? How does the device adhere to ethical design standards like IEEE Std 7000™-2021, ensuring the protection of user data and rights?	Clinicians must ensure that patients have consented to the use of their data for clinical care and, if applicable, research purposes. Data storage and sharing practices must comply with relevant privacy regulations (e.g., HIPAA or GDPR) to maintain patient trust. Devices with regulatory approvals may have more established data storage and privacy practices, while devices in the prototype stage or those not classified as medical devices may require additional efforts to ensure appropriate data storage and privacy measures are in place. Additionally, assessing the adherence to ethical design standards like IEEE Std 7000™-2021 can provide a comprehensive overview of the ethical considerations in place related to data rights, governance, and privacy. It can reflect the manufacturers' commitment to ensuring data protection and user rights.

EC European Conformity, *EEG* electroencephalogram, *EN* European Standard, *FDA* Food and Drug Administration, *GDPR* General Data Protection Regulation, *HIPAA* Health Insurance Portability and Accountability Act, *ISO* International Organization for Standardization, *MDSAP* Medical Device Single Audit Program, *MDR* medical device regulation, *NDD* neurodegenerative disease, *PSG* polysomnography, *REM* rapid eye movement, *SE* sleep efficiency, *SOL* sleep onset latency, *TST* total sleep time, *WASO* wake after sleep onset.

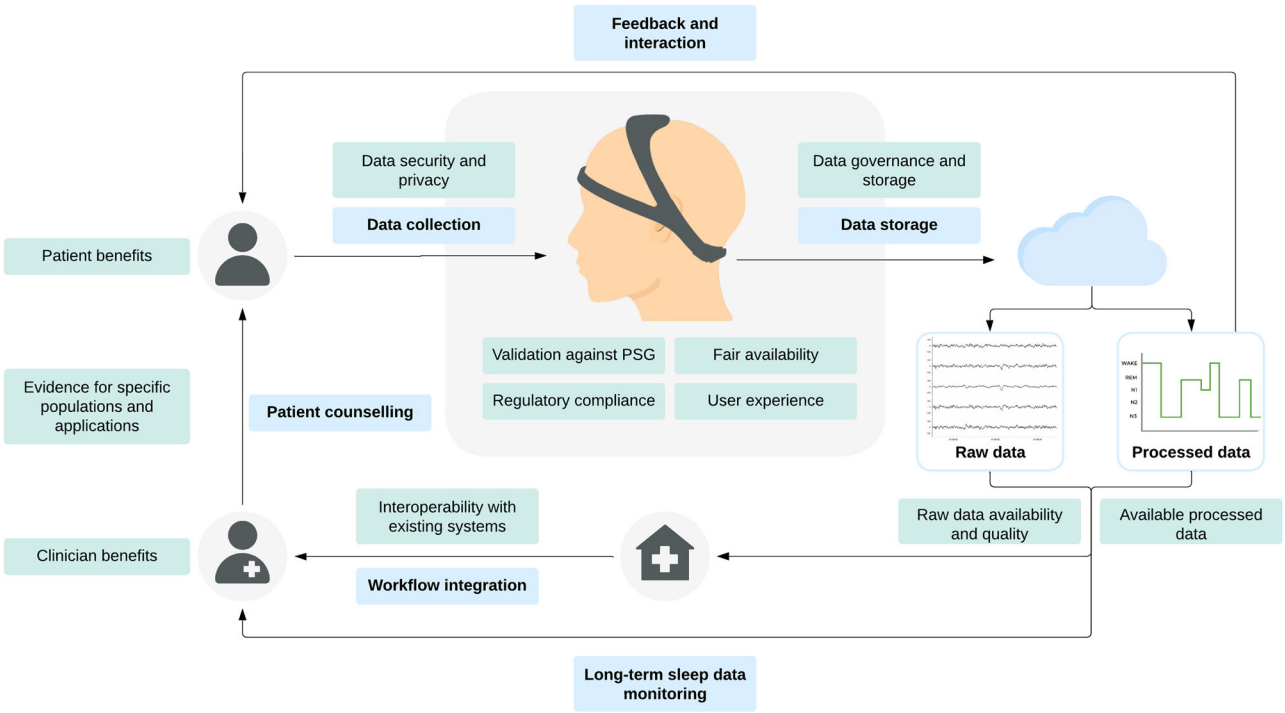

Fig. 1 | Proposed Clinical Integration of EEG-Based Wearable Devices for Sleep Monitoring. This figure outlines the steps (blue) of data collection from users via wearable devices, followed by data storage and data processing to yield both raw and processed data. Processed data is supplied back to the user for feedback and interaction, while both raw and procsessed data are provided to the clinician for review, enabling long-term sleep data monitoring. The clinician then utilizes this data for patient counseling. The figure emphasizes key considerations (green) at each step, such as the validation results and user experience of the device, data privacy, data availability and quality, interoperability with existing systems, integration into the clinicians' workflow, and benefits for clinicians and patients. PSG: polysomnography.

and the complexities of integrating these devices into existing systems. Moreover, addressing the critical aspects of data rights is crucial to maintain patient and clinician trust.

As we look toward the future, the continued exploration of wearable sleep monitoring devices in specific clinical populations and applications will be crucial. Future research should focus on furthering the devices' validation and establishing best practice guidelines for their use, ultimately aiming to seamlessly integrate them into clinical practice. Sleep monitoring devices may pave the way for a new era of connected remote patient care in sleep monitoring, enabling personalized and effective sleep disorder management. However, this requires a collaborative effort between researchers, healthcare professionals, device manufacturers, and policymakers to ensure that these technologies are responsibly and ethically integrated into the clinical landscape.

Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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Author contributions

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Competing interests

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Additional information

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