



(RESEARCH ARTICLE)



# A new dawn: The next frontier in AI-driven sleep enhancement through gradual awakening

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## Abstract

**Background:** Given the prevalence of sleep issues, their impact on overall health and the potential of gradual awakening in mitigating part of the negative effects, innovative solutions can be leveraged to facilitate this awakening process.

**Objectives:** The current study aims to present in detail and validate a novel system that utilizes advanced AI algorithms for sleep tracking, sleep stage prediction, and a "smart alarm" component for optimal gradual awakening.

**Methods:** A clinical trial was conducted to assess the system's effectiveness, namely its influence on several key daily aspects. Participants wearing consumer wearable devices in their sleep were required to self-assess their quality of life, sleep quality and perception of their own waking process through several questionnaires.

**Results:** The integrated system is developed and works as intended. The clinical study findings demonstrate statistically significant benefits in quality of life, sleep quality, user satisfaction with the waking process and mental status upon awakening. On average, an increase in WHOQOL-BREF score from 88.44 to 94.75, a decrease in Sleep Quality Scale scores from 65.66 to 58.19 and in awakening scores from 10.81 to 8.95 (the latter two scores decrease as outcome improves) were observed.

**Conclusion:** Our system shows promise for enhancing individual well-being and productivity by detecting the optimal sleep stage for awakening and providing a more natural waking experience, indicating a valuable direction for future sleep health technologies. Research should be directed at expanding the search for more potential uses, optimizing algorithms and improving user experience.

**Keywords:** Integrated system; Sleep tracking; Haptic feedback; Gradual awakening; Quality of life

## 1. Introduction

Sleep serves as a foundational element for our mental and physical health, playing a pivotal role in enhancing our life's quality. It's during sleep that our bodies engage in repair and growth processes, which are crucial for maintaining health and supporting development, especially among children[1,2]. This restorative period significantly impacts our alertness and performance in our waking hours, underlining the necessity of aligning our sleep patterns with our natural circadian rhythms for optimal health[3,4].

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Yet, in stark contrast to its critical importance, the phenomenon of sleep deprivation has escalated to what the Centers for Disease Control and Prevention (CDC) identify as a "public health emergency"[5]. Modern lifestyles, characterized by poor sleep habits, high levels of stress and inadequate diets and exercise, have precipitated a global epidemic of sleep issues. A significant segment of the population worldwide reports experiencing various sleep problems, such as not getting enough hours of sleep, poor sleep quality, waking up frequently during the night or not being able to fall back asleep.

The ripple effects of sleep deficiency span far and wide, from decreased productivity, elevated daily stress and bad mood to psychological conditions like anxiety and depression or even increased susceptibility to severe chronic illnesses. All cognitive functions are impaired by the lack of quality sleep, including memory, decision-making and problem-solving, crucial for most lines of work, impairment which could in turn lead to decreased productivity in the workplace. Countries like the UK, Germany and the US incur significant losses due to low productivity, accounting for billions USD annually and contributing to an important economic toll. Even though the socio-economic and health risks are very much apparent, society tends to underestimate the harmful potential of sleep disruption on a large scale, treating it more like a temporary matter, one that may even solve itself, eventually. The critical role of sleep in health and well-being is severely misjudged and undermined.

In the quest for better sleep, technology has frequently been employed to optimize the complex elements that make up our nightly routine. Sleep tracking is one of them: an innovative approach to monitor and enhance sleep quality and, consequently, overall quality of life. Sleep tracking technology, predominantly through wearable devices and mobile applications, has undergone significant advancements, moving from basic wrist-worn devices that monitor sleep duration to sophisticated gadgets capable of analyzing sleep stages and quality. These technologies primarily employ accelerometers to detect movement and algorithms to infer sleep patterns. For instance, certain devices utilize heart rate variability, body temperature, and respiratory rates to provide a comprehensive analysis of sleep stages, including light, deep, and REM sleep[6].

Sleep tracking technologies are categorized based on the methodology and type of sensors used for monitoring sleep patterns. These methodologies include wearable devices, non-wearable devices, and smart bedding technologies. Each type leverages different sensors and markers to analyze sleep quality, duration, stages, and disturbances. Wearable devices, such as fitness trackers and smartwatches, are the most common tools for sleep tracking. They primarily use accelerometers and heart rate sensors to monitor movements and physiological signals during sleep. For instance, accelerometers detect the user's movement to infer sleep stages, while heart rate sensors measure variations in heart rate, contributing to sleep quality analysis[6].

The primary allure of sleep tracking lies in its potential to enhance self-awareness regarding sleep habits, thereby empowering individuals to make informed adjustments to their sleep hygiene. Studies have shown that users of sleep tracking technology report improvements in lifestyle choices that positively impact sleep quality. For instance, insights into the effects of caffeine intake, exercise, and screen time before bedtime can lead to behavior modifications that promote better sleep health[7]. Moreover, the data collected by sleep trackers can serve as valuable feedback for healthcare professionals, aiding in the diagnosis and management of sleep disorders. Wearable sleep trackers have been found to accurately estimate sleep parameters, such as sleep onset and wake times, and have been proposed as potential tools for preliminary sleep disorder screening[8].

Despite their benefits, sleep tracking technologies are not without challenges. A primary concern is the accuracy and reliability of sleep tracking technologies. Many consumer-grade devices rely on proprietary algorithms whose details are not publicly disclosed, making it difficult to assess their accuracy against gold-standard methods like polysomnography (PSG). Research indicates that these devices might not always accurately track sleep patterns, often underreporting sleep disruptions while overstating total sleep duration and effectiveness. This underscores the importance of implementing standardized validation procedures and ensuring transparency in how their algorithms operate[6]. Long-term adherence to using sleep tracking devices is another challenge. The decrease in comfort associated with prolonged use of wearable devices or the effort required to set up non-wearable trackers nightly can deter continuous use. Furthermore, the impact of long-term tracking on sleep behavior and its potential to induce anxiety or obsessive behavior over sleep metrics has been noted as a concern that requires careful design considerations to ensure that devices support, rather than undermine, sleep health[9]. The complexity of sleep data interpretation poses a significant challenge for users. Without proper context or guidance, users may misinterpret the data, leading to incorrect conclusions about their sleep health. Bridging the gap between the data collected by sleep trackers and actionable insights that users can understand and apply is crucial for the effective use of this technology[10].

Besides passive sleep tracking, there are several options offered to users in order to empower them to actively take control of their sleep. One of the most common options is gradual awakening. Gradual awakening, as opposed to abrupt waking, plays a significant role in influencing sleep quality, daytime productivity, and overall quality of life. The manner in which we transition from sleep to wakefulness can significantly impact our cognitive functions, emotional well-being, and physiological health. Gradual awakening is associated with improved sleep quality by mitigating “sleep inertia”, which is the grogginess and impaired alertness subjectively experienced immediately after waking. Studies indicate that individuals experiencing gradual awakenings report feeling more refreshed and perform better in cognitive tasks upon waking compared to those who are abruptly awakened. This smoother transition from sleep to wake state leads to more favorable reports of thinking rather than dreaming, suggesting a more natural progression of sleep stages[11]. The quality of morning awakenings can significantly influence an individual's quality of life. Gradual awakenings are linked to enhanced mood and reduced stress levels upon waking, attributable to a gentle transition allowing for a natural progression through sleep stages, especially from REM sleep, crucial for emotional regulation. Furthermore, gradual awakenings positively affect subjective sleep quality, leading to more restorative sleep and better overall well-being, as self-perceived. The mode of awakening also has a direct correlation with productivity levels. Individuals who wake up gradually exhibit higher levels of alertness and cognitive function in the morning and throughout the day, even after partial sleep deprivation. This contrasts with forced awakenings, associated with prolonged reaction times and discomfort upon waking. Improved alertness and comfort following self-awakening contribute to better work performance and decreased daytime sleepiness, enhancing overall productivity[12]. Research also highlights the physiological underpinnings of gradual awakenings, such as the modulation of stress hormone levels and the activation of certain brain regions that facilitate a smooth transition to wakefulness. These processes are crucial for re-establishing alertness and consciousness efficiently without the abrupt stress responses associated with forced awakenings[13].

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## 2. Materials and Methods

Current hardware and software solutions that deal with gradual awakening have various limitations and challenges to be overcome. The consumer-level industry standard for sleep tracking and stage prediction in wearable devices is the Apple Watch, which runs a proprietary system developed in-house. The system employed by Apple in their wearable device is a very performant one. It has received FDA approval as a Class II medical device, proving that its systems and hardware support are reliable and trustworthy in regard to tracking of body functions. At the moment, prediction of sleep stages is limited in its nature, but nevertheless, Apple's proprietary sleep analysis system is considered state-of-the-art (SOTA), achieving 76.6% accuracy in REM sleep stage prediction when compared to an EEG device in similar conditions[8,14]. However, Apple's own system has its shortcomings and the closed nature of the environment has its disadvantages. Its purely observational nature limits the potential of interventions such as applied patterns of haptic feedback for gradual awakening. In turn, we have developed and validated our own proprietary real-time sleep tracking and intervention system, composed of several modules:

- Data and sleep metadata collection module
- Sleep data analysis module
- Specific sleep cycle detection module
- Integration module between sleep analysis and wearable device's haptic engine
- Haptic motor control and vibration module
- Post-intervention sleep data analysis module

The system effectively functions as a “smart alarm” application. It accurately detects and predicts the sleep stage the user is currently in, and delivers haptic feedback to the user's wrist via Apple Watch as an “alarm” to gradually wake the user up, according to the optimal sleep stage as detected by the system, as close to the alarm time as possible.

The system is in active development, with components being continuously improved through internal and user feedback. The system has passed several technology readiness levels (TRLs) thus far. In order to improve our technology readiness level from TRL 3 to 4, our team completed the development of the hardware-software interface, and to reach TRL 5, the team assembled all the completed components into one functional system. The scope of the current article is a detailed description of the process of advancing the current project from TRL 3 to 5: completion of the hardware-software interface, integration of all separate components into a working system and validation of said system in a relevant environment.

## 2.1. Technical description of the hardware-software interface - reaching TRL 4

### 2.1.1. Main Functions

The primary function of the developed smart alarm application is data collection and gradual awakening through haptic interventions applied to the wrist:

- Heart rate
- Users movement during sleep - acceleration on the three axes (x y z)
- Waking the user through feedback generated by the device's haptic motor
- Haptic intervention during sleep so that the user transitions from one sleep stage to another

Collecting this data is necessary to train a Multi-Layer Perceptron neural model that predicts the sleep stages the user is in, in real-time, such as: REM, non-REM, deep sleep, or awake (in-bed). The task of analyzing sleep data and detecting a specific cycle during sleep is performed by the sleep prediction server-side system, while the companion app on the Apple Watch merely aids the collection of the necessary data for sleep prediction. The sleep prediction server represents an extension of a system responsible for data management and storage.

### 2.1.2. Data flow and sleep analysis experience

The user-facing system consists of two separate applications: a smartphone application which manages authentication, alarms, and other important profiling functionality (such as weight, typical bedtime, typical wake time, etc), and a companion smartwatch application which ensures that data is being passed to our systems and can be correctly interpreted. The smartwatch application is also responsible for haptic interventions.

We interact constantly with two different sleep stage prediction systems

- Apple's post-session (after wake time) proprietary sleep stage prediction system
- Our proprietary real-time sleep stage prediction system

While we need real-time analysis, we rely on Apple's proprietary system for fine-tuning purposes. Our team is committed to improving the accuracy of our sleep stage prediction systems, aiming for 90%+ accuracy. We are refining models, exploring new datasets, and incorporating modern AI architectures. Therefore, we continuously improve our proprietary system, by training against Apple's proprietary system and an additional proprietary PSG dataset.

When the user first initiates the usage of the smart alarm app on their wearable device, multiple permissions are requested to access the device's sensors, to access past sleep data, and access the HealthKit system which allows us to initiate sleep sessions using the user's Apple Watch.

Each time the user reaches the companion app's home page, past Apple-analyzed sleep data is queried and stored securely through the HealthKit library. This data is processed, normalized, and prepared for future re-training sessions of our system. This is the first step we take to support our efforts of achieving SOTA. All other actions the user completes on the smart watch application interact directly with our proprietary systems. Emphasizing on the fact that it is our system that is solely used for real-time sleep pattern prediction during night-time.

To reliably use our sleep & smart alarm systems, the user must follow these steps

- The user must have an account i.e., be registered and then authenticated in the application
- Authentication is done using the Auth0 authentication service in a secure manner. Each user has a name, an email and a password.
- Auth0 authentication ensures security standards over each user's data and reduces the complexity of managing the authentication process.
- Using the smartphone application, the user sets an alarm, using the usual morning rise time as the trigger time
- The alarms are registered in our database for each user individually. Users can activate/deactivate and configure them by assigning specific days when these are triggered.

Since our technical research focuses on gradual awakening, a smart alarm application is the best possible experience. Focusing on familiar interactions (setting alarms, clocks, and such), we offer a software-hardware-powered experience that solves all steps behind the scenes.

### *2.1.3. Collecting Motion and Heart Rate Data*

Through the data collection module, the user's biometric data is obtained using the device's sensors. The collection of data is performed every 5 seconds, and stored every 30 seconds.

Data is collected through the HealthKit library, which has extensive documentation and implementation details available online[15]. HKHealthStore is a class from the HealthKit framework offered by Apple, providing an interface for managing and requesting access to the user's health data. Applications can use HKHealthStore to read and write a variety of health and fitness data types, with the user's permission. First, health data for which permission has been requested from the user are collected, then this data is processed and subsequently transmitted to the database to be saved and used in predictions. This data is collected each time the user reaches the initial page of the smart alarm application. If the user has allowed access to sensors and is authenticated, the data will be collected.

### *2.1.4. Sleep Stage Predictions*

Sagemaker, an AWS service, has been integrated into a sleep data analysis module to analyze sleep data, make predictions about sleep stage, and calculate average sleep duration. Sleep Stage Predictions are stored in a database and sleep data is collected from the Apple Watch's sensors. Based on these predictions, statistics can be made that include the user's average sleep, as well as the average time the user was in REM, Core, Deep sleep, and the average time the user was awake. This average is configurable and can be calculated for the last n nights slept with the smartwatch and the application started accordingly by the user.

### *2.1.5. Interaction*

On the smartwatch companion app, the user is presented with a "Hack your sleep" button to initiate a sleep session. Upon pressing this button communication is established between the mobile app and the watch to request the user's authentication token. Communication between the phone and the watch is facilitated through the WCSSessionDelegate protocol which defines methods for sending and receiving messages using the WCSSession object. Session objects are used to communicate between the iOS app on an iPhone associated with a companion device like the Apple Watch. Privacy and security is at the forefront of our software systems, and this is not an exception. Authentication systems are described below.

### *2.1.6. Setting and Activating the Alarm*

Users are able to easily create and store alarm objects directly in the smartphone application by pressing the "sleep button" at the bottom of the footer-placed navigation menu. The alarm must always be set between 15 minutes and a maximum of 24 hours. If the alarm is set for less than 15 minutes a warning message will appear on the user's screen urging them to set a different alarm. If the alarm is correctly set in the mobile app a timer is set on the watch indicating when the alarm should start. Through the argument 'triggerInSeconds' of the 'setAlarm' function the next alarm is set in the specified seconds. When this is called any vibration intervention or previously set alarm is canceled. Each intervention alarm or vibration has a specific haptic template.

Each alarm intervention or vibration uses a haptic template to provide haptic feedback. In the case of the alarm notification-type feedback is used. This is rendered every 2 seconds so the device will vibrate every 2 seconds. The software mode for controlling the haptic motor and generating vibrations is done through the WKInterfaceDevice object which by definition is an object that provides information about the user's Apple Watch. When an alarm is activated a button appears on the screen to stop it. The alarm will continue to sound until the user stops it. After stopping the alarm, while still in an active sleep session, the process of collecting sleep data continues as before except that no vibrations are set to bring the user into a light sleep stage assuming the user is already in this stage.

### *2.1.7. Setting Vibrations*

Alongside this process, a series of vibrations are set with the purpose of bringing the user into a light sleep state from which they can be easily awakened. These haptic interventions are triggered 15 minutes before the alarm, then 5 minutes before. Each intervention consists of 5 seconds of short pulses. These vibrations should not wake the user, thus the lightest vibration templates are used. Before each vibration of this type, any previously set interventions or vibrations are canceled, if any exist.

### *2.1.8. Sleep Sessions*

Sleep Sessions are required to ensure appropriate data grouping and relevancy throughout the many nights of sleep a user might use the app to improve wake-up experience.

A sleep session is initiated when the user activates the smart alarm functionality on their smartwatch. The session concludes when the user stops the alarm the next morning.

#### 2.1.9. Security and data privacy

The authentication process is carried out with the help of auth0, which is an authentication and authorization platform. Auth0 is often used to reduce the complexity of managing authentication and authorization and to quickly implement robust security standards in applications. For registering a new user, an endpoint has been created that collects the user's entered data (email, password, name), creates the corresponding object, and then adds it to the special database provided by auth0. For user authentication, an endpoint has been created that collects the data entered by the user (email, password), which is transmitted to auth0 through an authentication.GetToken object. Following authentication, a refresh token and a JWT (JSON Web Token) are obtained, which is a secure method of authentication often used in web applications.

A typical JWT consists of three parts

- Header: Contains metadata about the token type (usually JWT) and the signing algorithm used (such as HS256, RS256, etc.). It is encoded in Base64URL.
- Payload: Contains so-called "claims" which declare the entity (usually the user) and additional information or rights (for example, access rights). "Claims" are of three types: registered, public, and private. It is also encoded in Base64URL.
- Signature: Created by signing the header and payload with a secret key or a public/private key pair. It is used to verify that the message has not been altered along the way.

Thus, a token can be obtained which, after decoding, would look like this: [image] To call any endpoint, the access token received after authentication is transmitted and verified through the jwt library. Since an access token expires in 3 days, we use the refresh token (which expires in 30 days) obtained after authentication, which can be used to refresh the access token. We value privacy, therefore the user has the option to delete their account from the app's settings.

#### 2.1.10. Requesting and Receiving JWT

The watch requests the user's JWT (JSON Web Token) which contains the user's ID and the tokens expiration date serving as the method by which each user is identified. Each time the JWT is sent to the watch app it is validated then sent to the watch as illustrated in the diagram below. The JWT is obtained after the user authenticates with their email and password thus this information needs to be sent to the watch each time. After the mobile app sends the JWT to the watch app the user is alerted through a dialog window with an OK button regarding the following aspects:

- The device should be charged 100% before use
- Silent mode should be turned on
- Sleep mode should be turned on
- The always-on screen mode should be turned off

## 2.2. The Future State of the Developed Technology

Although a fair amount of complex and robust technology has been built, our roadmap does not end here. The technical team actively explores new AI architectures, adding the capabilities of including more datasets, considering more data points (such as daily activity which has a direct correlation to the quality of sleep and specific sleep stage length), and ensuring an ever-increasing level of privacy and security for our users. Therefore, we expect SOTA accuracy of sleep stage prediction will be reached and surpassed.

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## 3. System validation - reaching TRL 5. Clinical study

All separated components of the newly-established system have previously been validated separately, but in order for the system to acquire TRL 5, the process of validation in a relevant environment must be properly conducted. This is most accurately and rigorously done through a clinical study, designed specifically with the new system in mind.

### 3.1. Study methodology

In order to validate our newly-established system, we designed a study to quantify the beneficial effects of subliminal, haptic feedback in the form of vibrations applied through an Apple Watch, for individual patterns of sleep. The positive

effects were assessed in the form of self-perceived sleep quality (a “total sleep score”, as inferred from the Sleep Quality Scale[16].) and self-perceived quality of life (as inferred from the WHOQOL-BREF scale[17]). The Sleep Quality Scale (SQS) is a comprehensive instrument designed to quantitatively evaluate an individual's sleep quality over a specific time period, usually the preceding month. It comprises a total number of 28 items that participants respond to, which collectively cover various dimensions of sleep such as duration, efficiency, disturbances, latency, use of sleeping medication, and daytime dysfunction. Each item on the SQS is scored on a Likert-type scale of 1 to 5, and these individual scores are then aggregated to produce a total score. This total score is interpreted to assess overall sleep quality, with lower scores indicating higher sleep quality[16]. The WHOQOL-BREF is an abbreviated version of the WHOQOL-100 quality of life assessment, developed by the World Health Organization. It is designed to provide a quick, comprehensive evaluation of an individual's perceived quality of life across four broad domains: physical health, psychological health, social relationships, and environment. The WHOQOL-BREF contains a total of 26 items, with two items assessing overall quality of life and general health, and the remaining 24 items distributed across the four domains. Each item is rated on a five-point Likert scale, contributing to domain-specific scores as well as an overall quality of life score. The WHOQOL-BREF's concise format makes it a practical tool for both research and clinical settings, offering valuable insights into the impact of health conditions, interventions, and social circumstances on an individual's quality of life[17]. In addition, part of the Sleep Quality Scale was processed to calculate an “awakening” score. 4 items, “I feel refreshed after sleep”, “I feel vigorous after sleep”, “My fatigue is relieved after sleep” and “I have a clear head after sleep” were also scored and summed up separately to infer this new score, in order to assess the system's beneficial effect on the perceived quality of the awakening process in the morning.

A total of 100 healthy volunteers were included in our study. Inclusion criteria were: the ability to speak English, age between 18 and 65 years old, possession of an Apple Watch and an iPhone. Exclusion criteria were inability to provide informed consent, sufferer of any chronic sleep disease (such as narcolepsy or chronic insomnia) or any other debilitating chronic disease. Upon inclusion in the study, informed consent was given by all participants in the study and demographic data was collected. The participants were asked to sleep for 30 nights wearing the Apple Watch, running the proprietary system designed for this study. Every night, as an intervention, personalized vibrations were applied to each participant, according to our proprietary algorithm and design, in order to assess its beneficial effects. The study design involved the following information to be collected at various points in the study:

- Sleep Quality Scale - day 0 (study inclusion), day 15 and day 30 (final day of the study)
- WHOQOL-BREF - day 0 (study inclusion), day 15 and day 30 (final day of the study)

Both scales were automatically sent to participants on the respective days of the study to be completed inside the proprietary mobile application, which also automatically collected sleep data.

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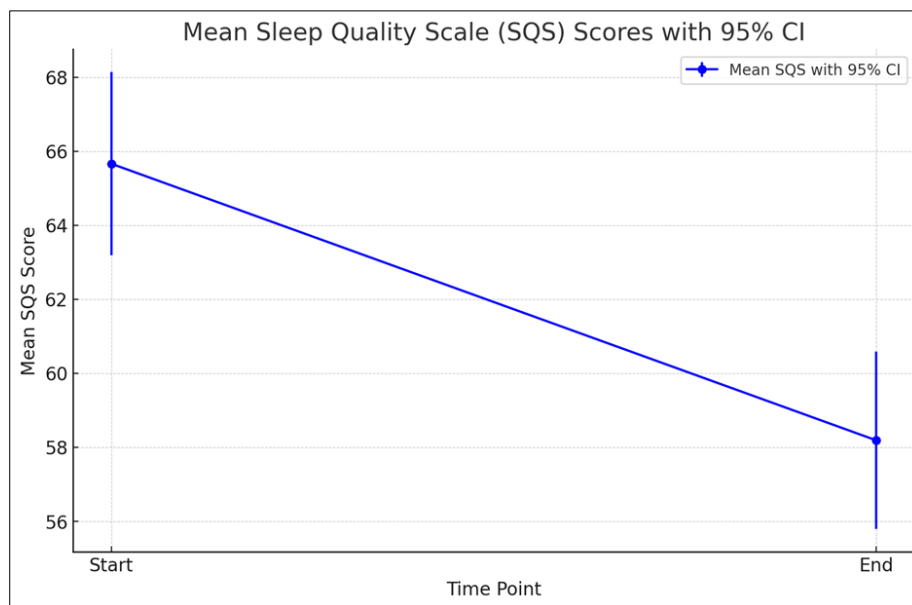
## 4. Results

All collected survey data has been compiled in a database in order to be processed. Variables were defined for the purpose of this study:

- Sleep Quality Scale: “SQS\_0” - score at the beginning of the study, “SQS\_1” - score on day 15, “SQS\_2” - score at the end of the study.
- WHOQOL\_BREF: “QOL\_0” - score at the beginning of the study, “QOL\_1” - score on day 15, “QOL\_2” - score at the end of the study.
- Awakening score - “awakening\_0” - score at the beginning of the study, “awakening\_1” - score on day 15, “awakening\_2” - score at the end of the study.

### 4.1. Statistical analysis - Sleep Quality Scale (SQS)

The primary objective was to determine whether there was a statistically significant improvement in self-perceived sleep quality, as shown by sleep scores, from the onset to the end of the study period. To assess the distribution of SQS scores, we conducted normality tests. The Shapiro-Wilk test, selected for its appropriateness for small sample sizes and its power to detect deviations from normality, yielded p-values of 0.6501 for SQS\_0 and 0.1068 for SQS\_2. These results suggest that both initial and final SQS scores follow a normal distribution, as p-values exceeded the conventional alpha level of 0.05, indicating no significant deviation from normality. Given the normal distribution of our data, we proceeded with a parametric test to compare the means of the two related groups. The Paired Samples t-test, an appropriate choice for comparing means from the same participants under two different conditions, was employed. The analysis revealed a significant difference in sleep quality scores from the beginning to the end of the study period ( $p < 0.001$ ), indicating a substantial improvement in sleep quality over the 30 days (Figure 1).

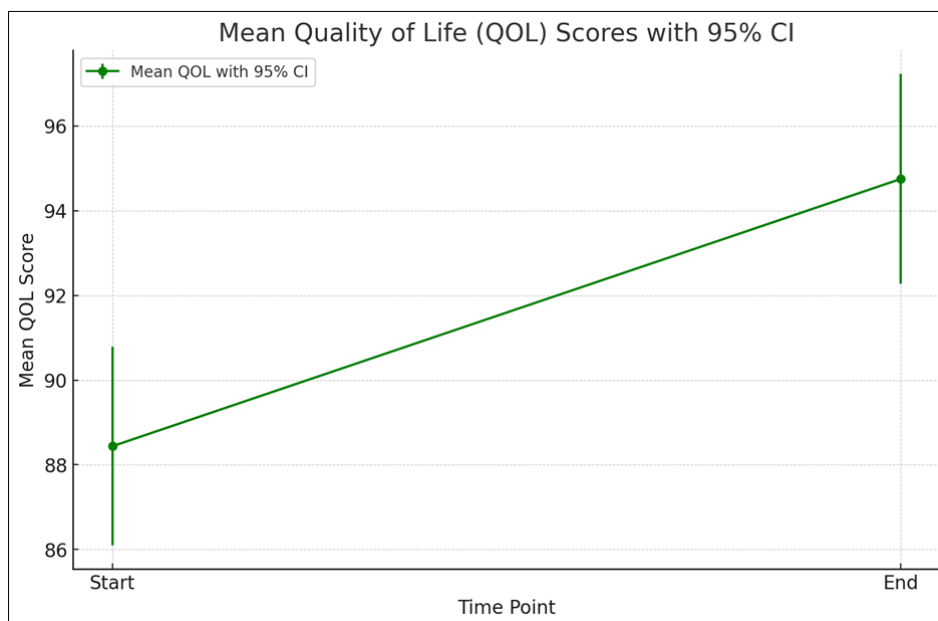


**Figure 1** Mean Sleep Quality Scale scores with 95% CI

The mean SQS score at the onset of the study was 65.66 [95% CI 63.18-68.14], which decreased to 58.19 [95% CI 55.79-60.59] by the study's conclusion (lower scores are associated with better sleep). The median scores followed a similar trend, moving from 67 to 60, further substantiating the improvement in sleep quality among participants. In summary, the statistical analysis conducted as part of this investigation indicates a significant improvement in sleep quality, as measured by the Sleep Quality Scale, over the 30-day period. These findings underscore the potential effectiveness of the interventions or conditions being assessed in enhancing sleep quality among the study participants.

#### 4.2. Statistical analysis - Quality of Life (WHOQOL-BREF)

The primary objective was to discern any statistically significant enhancement in the QOL scores from the onset to the end of the study period.



**Figure 2** Mean quality of life scores with 95% CI

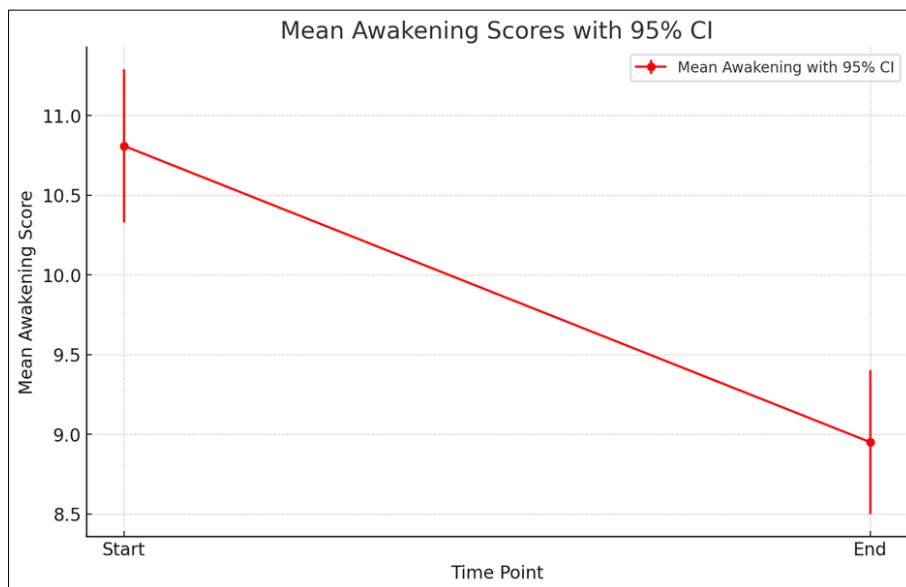
The mean QOL score (Figure 2) at the onset of the study was 88.44 [95% CI 86.10 - 90.78], which notably increased to 94.75 [95% CI 92.27 - 97.23] by the study's conclusion (higher scores are associated with higher quality of life). This



change is further reflected in the median scores, which rose from 90 at the beginning to 92.5 at the end of the study period. These descriptive statistics highlight a clear trend of improvement in the participants' perceived quality of life. In order to highlight the statistical significance of our findings, we proceeded with further analysis. We conducted normality tests to determine the appropriateness of subsequent analyses. The Shapiro-Wilk test was chosen for its efficacy in handling small sample sizes and its capacity to detect departures from normality. The test results for QOL\_0 indicated a deviation from normal distribution ( $p = 0.0188$ ), suggesting the need for non-parametric methods for further analyses due to the significant deviation from normality at the study's onset. Conversely, the QOL\_2 scores did not significantly deviate from normality ( $p = 0.0858$ ), indicating a borderline normal distribution at the study's conclusion. The statistical significance of the improvement in quality of life scores was confirmed through a Paired Samples t-test, yielding a  $p$ -value  $< 0.001$ . The statistical analysis conducted within this investigation highlights a significant enhancement in the quality of life, as measured by the WHOQOL-BREF form, over the 30-day study period. These findings emphasize the potential benefits of the interventions or conditions under assessment in improving the quality of life for the study participants.

#### 4.3. Statistical analysis - Awakening score

The Shapiro-Wilk normality test was employed to evaluate the distribution of awakening scores at both time points. This test was chosen due to its effectiveness in assessing normality in small sample sizes. The results indicated that the awakening scores at both the beginning ( $p$ -value = 0.0633) and the end of the study ( $p$ -value = 0.0529) did not significantly deviate from a normal distribution. Given these findings, it was appropriate to proceed with parametric testing to compare the awakening scores between the two time points. A Paired Samples t-test was conducted to compare the mean awakening scores from the onset to the conclusion of the study. This test is suitable for comparing means from the same participants under two different conditions. The analysis revealed a statistically significant change in awakening scores over the study period, with a  $p$ -value  $< 0.001$ . This indicates a significant difference in the awakening scores from the beginning to the end of the study, suggesting an improvement or alteration in the participants' awakening states over the 30-day period.



**Figure 3** Mean awakening scores with 95% CI

The mean awakening score (Figure 3) at the onset of the study was approximately 10.81 [95% CI 10.33 - 11.29], which decreased to about 8.95 [95% CI 8.50 - 9.40] by the study's conclusion (similar to Sleep Quality Scale, lower scores reflect better outcomes). The median scores also reflected a similar trend, moving from 11 to 9. This trend substantiates the notion that there was a significant positive change in the self-perceived states of participants upon awakening over the course of the study.

## 5. Discussions

In our study, we introduced a sleep tracking system with a smart alarm designed to enhance the awakening process through personalized haptic feedback on an Apple Watch. This innovation aims to improve upon existing sleep

technologies, particularly in their capacity to accurately monitor sleep stages and offer a more natural waking experience in the form of gradual awakening. As mentioned in the introduction of the current article, previous research highlights certain limitations in consumer-grade sleep trackers, especially their challenges in accurately detecting sleep stages[6]. Furthermore, sleep trackers have a tendency to overestimate sleep duration and efficiency. Our system leverages consumer-grade sensors and technology with advanced, AI-powered analysis to offer nuanced insights into sleep architecture and offer custom, personalized haptic feedback in an attempt at an innovative approach to awakening. Thus, our system is not only an important advancement in sleep technology but also enhances user comfort and overall sleep experience, signaling a promising direction for future developments in sleep health management.

The potential of our smart alarm system for mental health benefits stands as a notable advancement, suggesting its broader application beyond individual use to a clinical setting. The system's capability to enhance sleep quality and facilitate more natural awakenings presents a valuable tool for healthcare professionals in managing sleep-related issues. This aligns with emerging research emphasizing the integration of technology-assisted sleep interventions within healthcare practices to provide comprehensive patient care[9]. The personalized and non-intrusive nature of our system, combined with its validated effectiveness, underscores its potential as a pivotal component in the toolkit of sleep medicine, offering a promising avenue for the future of sleep health management. Furthermore, the system's capacity to gently modulate sleep-wake transitions may offer insights into non-pharmaceutical interventions for mental health issues such as anxiety or depression. This connection is made particularly relevant in light of findings from Crisan et al. in a review that elucidates the complex role of REM sleep in affective disorders[18]. By potentially affecting REM sleep patterns through tailored awakening processes, our system might not only enhance morning alertness but also contribute to broader mental health benefits. Given the critical role of sleep in both physiological well-being and psychological resilience, insights into coping mechanisms during significant stressors, as presented in studies on the effects of the war in Ukraine[19] and the COVID-19 pandemic on Romanian populations[20], highlight the diverse strategies individuals employ to manage stress and maintain mental health in challenging times. Integrating our system's potential to improve sleep quality and facilitate smoother awakenings could significantly contribute to better coping mechanisms in stressful situations by enhancing sleep quality, thereby supporting overall mental health and resilience.

The development of our smart alarm system represents a significant innovation in alarm technology, as we've crafted a solution that not only wakes users more effectively but does so in a manner that reduces the grogginess often associated with traditional alarms. Other technologies and avenues currently explore the same approach: the advancement of this field of science is mirrored in the work of Kwansomkid et al., who explored the use of IoT technology to create an alarm clock designed to wake individuals gently, minimizing the risk of sleep-related diseases by avoiding the need for snoozing. Their findings, showing an 86% system accuracy rate in waking individuals effectively, underscore the potential of such innovations to enhance the waking process[21]. Our system rides the wave of the same innovative approach of gradual awakening, offering a tool that could seamlessly integrate into its users' lives.

The study also reinforced the critical role of sleep stage prediction in enhancing the effectiveness of alarm systems. By focusing on the optimal timing for awakening—preferentially during lighter sleep stages—our smart alarm minimizes sleep inertia, ensuring users start their day feeling more refreshed and mentally alert. This approach significantly improves upon traditional alarm methods by aligning wake-up times with the body's natural sleep cycles, a concept supported by Slyusarenko and Fedorin in their work on smartwatch alarm systems. Their findings demonstrate that predicting sleep stages to schedule alarms can greatly reduce sleep inertia effects, offering a more personalized and efficient way to transition from sleep to wakefulness. This innovation represents a leap forward in smart alarm technology, promising to enhance morning productivity and overall well-being[22].

The integration of our smart alarm system emphasizes the crucial role of ambient conditions in enhancing sleep quality. Our findings demonstrate that by tailoring the sleep setting, namely the awakening process, to individual needs, our system promotes a more conducive environment for restful sleep. This approach is similarly echoed in the work by Han et al., who explored the impact of custom ambient conditions, through IoT bed sensors and IoT LED lighting on sleep induction and awakening[23]. Their research supports our system's premise that manipulating environmental factors can lead to substantial improvements in sleep quality, ultimately contributing to better health and well-being.

To the best of our knowledge, this is the first study establishing the potential of a sleep tracking and gradual awakening system to offer positive benefits in the self-perceived quality of life and subjective perception of waking. Further studies could explore the broader implications of this technology in clinical settings, particularly its potential mental health benefits, such as in the treatment of anxiety or depression through the modulation of REM sleep patterns. Additionally, investigating the system's long-term effects on sleep behavior, adherence rates, and its integration with other health management tools could provide deeper insights into optimizing sleep health and well-being. Expanding the dataset to

include diverse populations and environmental conditions may also yield valuable information on customizing interventions for varied sleep profiles, thereby enhancing the system's applicability and effectiveness.

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## 6. Conclusion

In conclusion, the current article presents a comprehensive description of the process undertaken for technology advancement from TRL 3 to 5. An integrated system designed for advanced sleep tracking, sleep stage prediction and facilitation of gradual awakening through a "smart alarm" system has been developed and validated in the course of this project. This system was validated in a relevant environment through a clinical study designed around its functionalities. By leveraging cutting-edge AI technologies alongside robust clinical methodologies, the system aims to significantly enhance quality of life and productivity by offering a more natural and health-conscious approach to waking. Our findings indicate promising directions for future research and potential clinical applications, highlighting the system's capacity to blend seamlessly into users' lives while providing tangible benefits to their sleep health and overall well-being.

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## Compliance with ethical standards

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### *Disclosure of Conflict of interest*

Mr. Fintinari (CEO of SC STEEPSOFT AI SRL) was involved in providing proprietary software used in the study, developed by the company SC STEEPSOFT AI SRL. No interpretation of data or formulation of conclusions was done by Mr Fintinari. The other authors declare no conflicts of interest.

### *Statement of Informed consent*

All clinical study participants agreed to the terms set by the research team and signed an informed consent form, prior to their inclusion in the study. A copy of the template of the informed consent form (Google Forms document) is available upon request.

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