

Official Title of the Study:

REM Enhancement Sleep Technology for Well-being, Emotion, and Life Lift

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Study Protocol and Statistical Analysis Plan

Official Study Title:

REM Enhancement Sleep Technology for Well-being, Emotion, and Life Lift

Official Abbreviation/ Protocol ID:

RESTWELL2026

Brief Summary:

This study aims to explore the efficiency of a digital, Smartphone-delivered intervention for improving the quality of REM sleep on the mental health, emotion regulation and overall life quality of users.

Detailed Description:

Building upon previous research regarding the use of digital solutions to enhance sleep quality, the primary objective of this study is to test the impact of using the REST-WELL application over a 60-day period within an adult sample.

The total sample will consist of 360 adult participants, students at the George Emil Palade University of Medicine, Pharmacy, Science and Technology, who will be randomly assigned to two groups: an experimental group of 180 participants, and a control group of 180 participants. Inclusion criteria involve a minimum age of 18 and the absence of diagnoses within the spectrum of neurocognitive, learning, or severe psychiatric disorders.

The present study will be conducted as part of the research project entitled "REM Sleep Augmentation Technology for Wellbeing, Affectivity, and Quality of Life Improvement" (unique registration code PN-IV-P7-7.1-PTE-2024-0844). Consequently, the group composition is based on the project proposal (300 participants, of whom 180 in the target group and 180 in the control group), based on the "matching groups" principle, requiring uniform distribution across groups in clinical trials. Participants in the experimental group will use the REST-WELL application via a smartwatch device for 60 nights. The data collection instruments will include:

- The Kessler Psychological Distress Scale (K10), administered on days 0 and 60, to measure adjustment difficulties;
- The World Health Organization Quality of Life Scale – Abbreviated Form (WHOQOL-Bref), administered on days 0, 30, and 60, to assess general perceived wellbeing across various areas of functioning;
- The PROMIS Scale, administered bi-weekly, to measure sleep quality;
- The Difficulties in Emotion Regulation Scale (DERS), administered bi-weekly;
- The PERMA Profiler (Positive Emotions, Engagement, Relationships, Meaning, and Accomplishment), administered on days 0, 30, and 60.

Additionally, the analysis will include an evaluation of the students' academic performance in both groups, conducted on days 0 and 60, using the most recent exam session as a reference point.

An integrated system will be utilized, consisting of a mobile and Apple Watch application available in TestFlight (Apple's testing framework), comprising several components: the Sleep Data Collection Module, the Sleep Data Analysis Module, the Specific Sleep Cycle Detection Module, the Integration Module between sleep analysis and the haptic engine of the wearable device used, the Software Module for controlling the haptic engine and generating vibrations, and the Post-Haptic Intervention (vibration-based) Sleep Data Analysis Module.

Study Design

Type: Experimental

Model: Between-Subjects & Within-Subjects Design

Time Perspective: Prospective

Sample Size: 360 participants

Eligibility Criteria

Inclusion criteria: age at least 18, the ability to provide consent, the absence of neurocognitive and severe psychiatric disorders

Exclusion criteria: the presence of severe cognitive impairment, psychosis, inability to understand the informed consent and complete questionnaires

Outcome Measures

Primary:

The Kessler Psychological Distress Scale (K10) measure adjustment difficulties, including 10 items. In the present study, it will be used as a screening tool, higher levels indicating elevated distress, as follows: scores between 20-24 indicate the likelihood to present a mild disorder, scores between 25 and 29 indicate the likelihood to present a moderate disorder, while scores above 30 mean the possibility of a severe disorder.

The World Health Organization Quality of Life Scale – Abbreviated Form (WHOQOL-Bref) is a measure of life quality, comprising multiple subscales like physical health, psychological health, social relationships and environment. The raw scores ranges are the following: between 7 and 35 for Physical Health, between 6 and 30 for Psychological Health, between 3 and 15 for Social relationships, along with 8 and 40 for Environment. Also, a transformed score involves a wide range between 0 and 100. Higher scores represent a higher quality of life for the specific evaluated field.

The PROMIS Scale is a measure of the degree to which responders present sleeping difficulties. The total scores ranges between 8 and 40, higher scores indicating the increased severity of sleep disturbances. The raw scores are then converted to T scores, which can be interpreted as follows: final T score between 55 and 59 indicates mild intensity, between 60 and 69 moderate intensity, while T scores over 70 are equivalent to high severity.

Secondary:

The Difficulties in Emotion Regulation Scale (DERS) constitutes a measure of various aspects of one's ability to modulate emotions, specifically emotional awareness and acceptance. Raw scores range from 36 to 180, higher scores suggesting increased emotion regulation difficulties. Severity categories are based on percentiles, responders presenting levels that correspond to the 96th percentile or above indicating very high emotion regulation difficulties.

The PERMA Profiler is a measure of well-being, involving six subscales, as follows: positive and negative emotions, engagement, relationships, meaning, accomplishment, as well as health. Each item is rated using a scale from 0 to 10, the subscale scores being calculated as the mean of individual items. A total score of minimum 9 is considered an indicator of very good functioning, while a score below 5 is thought to be a hallmark of malfunctioning.

Statistical Analysis Plan

Preliminary Analysis:

Before testing the primary hypotheses, the following analyses perform:

Descriptive Statistics:

Means and standard deviations for all scales (K10, WHOQOL, PROMIS, DERS, PERMA) will be computed at each time point.

Baseline Characteristics:

Independent t-tests on Day 0 scores will be performed to ensure there are no significant differences between the Experimental and Control groups before the intervention.

Assumption Testing:

Normality (Shapiro-Wilk) and homogeneity of variance (Levene's test) will be checked.

Primary Analysis: The Mixed-Design ANOVA:

The Mixed-Design ANOVA will be used to test the group and time effects, as follows:

Between-Subjects Factor: Group (Experimental vs. Control).

Within-Subjects Factor: Time (the change of scores over time).

The Interaction Effect (Group \times Time): Comparison between the target and the control group in terms of changes in sleep quality over the 60 days.

Secondary Analysis: ANCOVA (Analysis of Covariance)

The impact on academic performance will be assessed using the ANCOVA, with the academic performance assessed in Day 60 as the dependent variable, and the Day 0 academic performance as a covariate, controlling for the students' initial academic standing.

Ethical Considerations

The study will be conducted in accordance with the principles stated within the Declaration of Helsinki.

Ethical approval for the present study was issued by the Scientific Ethics Committee of the George Emil Palade University of Medicine, Pharmacy, Science and Technology of Targu Mures. Informed consent is mandatory. Data will be anonymized and securely stored.

References:

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