Report – NanoVi Exo® Wellness Pilot Study

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Methods

This study aimed to evaluate the wellness benefits of the NanoVi Exo® device in adults aged 60 and over, specifically examining its effects on heart rate variability and self-reported outcomes. A total of six adults (3 males, 3 females; mean age 69.17 years) participated.

After providing informed consent, participants completed baseline assessments using the PSQI, DASS-21, FSS, and PROMIS-29 questionnaires, along with physiological evaluation using the PPG Stress Flow device (Biotekna, Italy). Following these assessments, participants underwent a 15-minute NanoVi Exo® session. Immediately after the session, the PPG Stress Flow device was used again to measure acute physiological changes.

At 15 days, participants repeated all questionnaires as a midpoint evaluation, and at 30 days they completed the same questionnaires again for the final evaluation.

Statistical analyses were performed using GraphPad Prism® (v. 8.0). Outliers were identified and excluded when appropriate. Data normality was assessed with the Shapiro–Wilk test. For questionnaire data, Friedman's test was used to evaluate changes across pre-, midpoint, and post-evaluations, with Dunn's multiple comparisons test for pairwise comparisons. For physiological parameters, paired t-tests compared pre- and post-session data, while non-parametric distributions were analyzed with Wilcoxon or Mann–Whitney tests. Results were presented as mean ± standard deviation (SD) and considered statistically significant at $p < 0.05$. Percentage changes were calculated relative to baseline values, and delta values were computed by subtracting post-intervention from pre-intervention values to determine mean differences.

Results

1. Physiological Acute effects

1.1 PPG Stress Flow – Mean Heart Rate

Mean heart rate (HR) represents the average number of heartbeats per minute, serving as a baseline measure of cardiovascular function. It provides insights into the activity of the autonomic nervous system (ANS) and overall cardiovascular health. An optimal heart rate reflects a balanced autonomic response, with normative values ranging between 46.9 and 84.8 beats per minute.

Although no statistically significant differences were observed, an 11% decrease in mean HR was noted immediately after the session (Figure 1-A).

1.2 PPG Stress Flow – Standard Deviation of NN intervals (SDNN)

SDNN is a key clinical index of heart rate variability (HRV), reflecting the overall health and adaptability of the autonomic nervous system. It represents the standard deviation of beat-to-beat intervals (NN intervals) over a 5-minute period, with a minimum normal value of 50 ms.

Although no statistically significant differences were observed, SDNN values increased by 16% immediately after the session, moving closer to normal values (Figure 1-B).

1.3 PPG Stress Flow - Root Mean Square of Successive Differences (RMSSD)

RMSSD is a measure of the vagal (parasympathetic) component of heart rate variability, reflecting the heart's capacity to respond to vagal modulation. It serves as an indicator of parasympathetic nervous system function and emotional resilience. The minimum normal value is 30 ms.

Although no statistically significant differences were observed, RMSSD values increased by 21% immediately after the session, moving closer to normal values (Figure 1-C).

1.4 PPG Stress Flow – Total Power

Total power represents the overall activity of the autonomic nervous system, encompassing both sympathetic and parasympathetic components. It provides a comprehensive measure of autonomic balance, with a minimum normal value of 8.

Although no statistically significant differences were observed, Total Power values increased by 1% immediately after the session, moving closer to normal values (Figure 1-D).

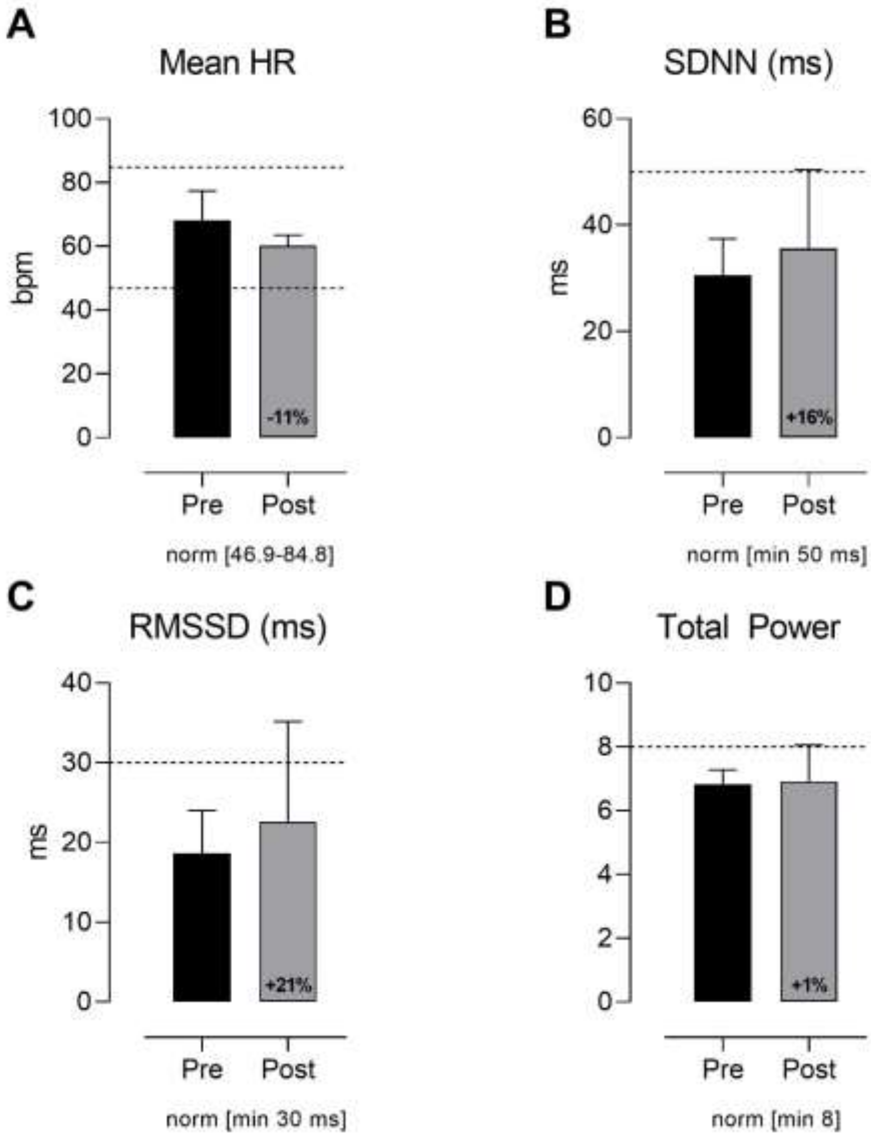

Figure 1. Mean Heart rate, SDNN, RMSSD and Total Power parameters before and immediately after the NanoVi Exo® session.

1.5 PPG Stress Flow – LF/VLF

This ratio compares the power in the low-frequency (LF) band to the very low-frequency (VLF) band, offering insights into the balance between short-term autonomic modulation and long-term regulatory influences. The minimum normal value is 1.

Although no statistically significant differences were observed, LF/VLF values decreased by 5% immediately after the session (Figure 2-A). Values below the norm suggest an increased influence of long-term regulatory mechanisms over short-term modulation, which may indicate chronic stress or reduced adaptability to environmental changes.

1.6 PPG Stress Flow – VLF Power

Very Low Frequency (VLF) power is associated with the cholinergic anti-inflammatory pathway and reflects the body's ability to manage inflammation and emotional stress. This component represents slower regulatory mechanisms of the autonomic nervous system, with a maximum normal value of 6.7.

Although no statistically significant differences were observed, VLF Power values increased by 2% immediately after the session. However, the values remained below the maximum threshold (Figure 2-B). Values within the norm suggest balanced functionality of the cholinergic anti-inflammatory pathway, indicating appropriate regulation of emotional states and inflammatory processes.

1.7 PPG Stress Flow – LF Power

Low-Frequency (LF) power measures sympathetic nervous system dominance, offering insights into stress response and sympathetic activity. The minimum normal value is 6.7.

Although no statistically significant differences were observed, LF Power values decreased by 2% immediately after the session (Figure 2-C). Values remaining below the norm suggest reduced sympathetic dominance, which may be associated with fatigue, autonomic dysfunction, or overactive parasympathetic activity.

1.8 PPG Stress Flow – HF Power

High-Frequency (HF) power reflects parasympathetic (vagal) activity and is associated with relaxation, emotional regulation, and the body's ability to rest and digest. The minimum normal value is 6.5.

Although no statistically significant differences were observed, HF Power values decreased by 1% immediately after the session (Figure 2-D). Values remaining below the norm suggest poor vagal activity, which is often correlated with stress, anxiety, or impaired recovery.

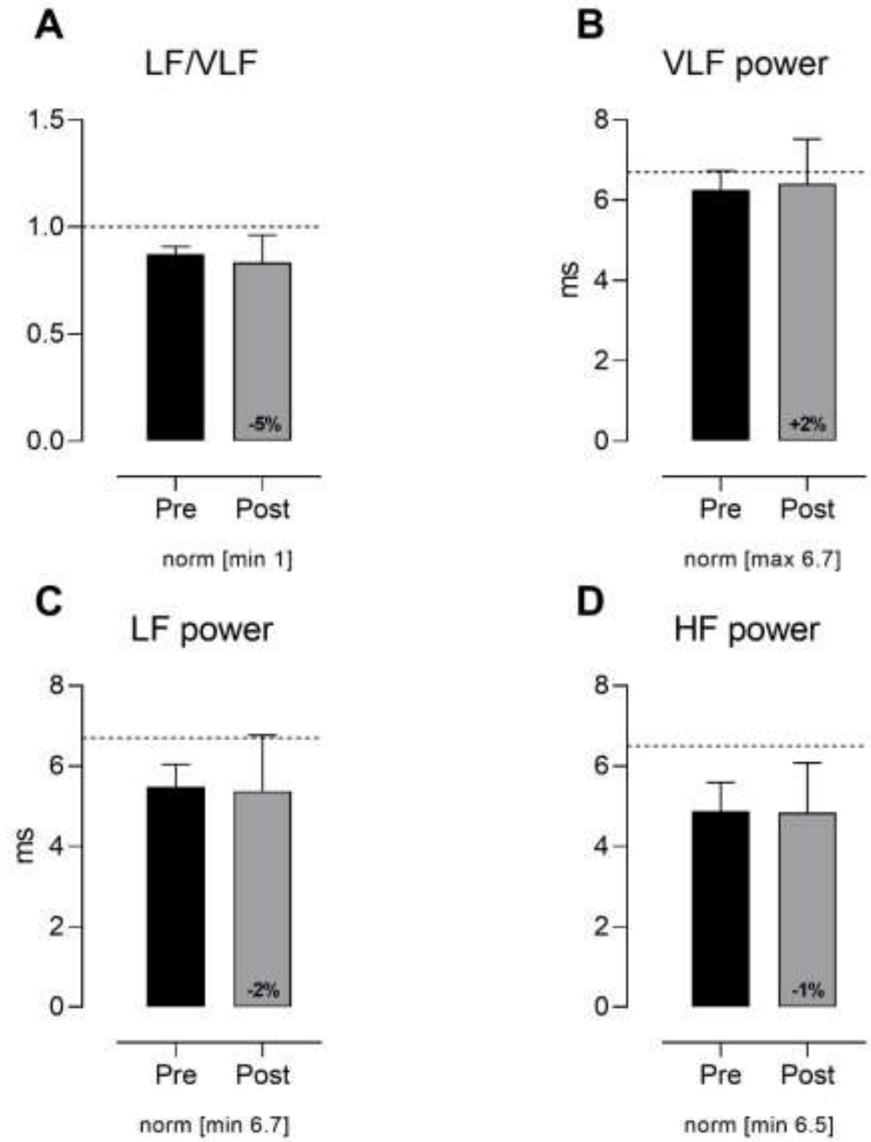

Figure 2. LF/VLF ratio, VLF power, LF power and HF power parameters before and immediately after the NanoVi Exo® session.

1.9 PPG Stress Flow - SNS LF% and PNS HF%

These percentages represent the relative dominance of the sympathetic (SNS LF%) and parasympathetic (PNS HF%) nervous systems, with their sum equaling 100%. The minimum normal value for SNS LF% is 70%, and the maximum normal value for PNS HF% is 30%.

No statistically significant differences were observed. However, there was a 3% reduction in SNS LF% values (mean: 60.68) and a 5% increase in PNS HF% values (mean: 39.32) immediately after the session, resulting in a corresponding mean delta change of 1.86. Although PNS HF% exceeded 30%, the values together totaled 100%, reflecting a balanced autonomic system. This balance supports effective stress response and recovery.

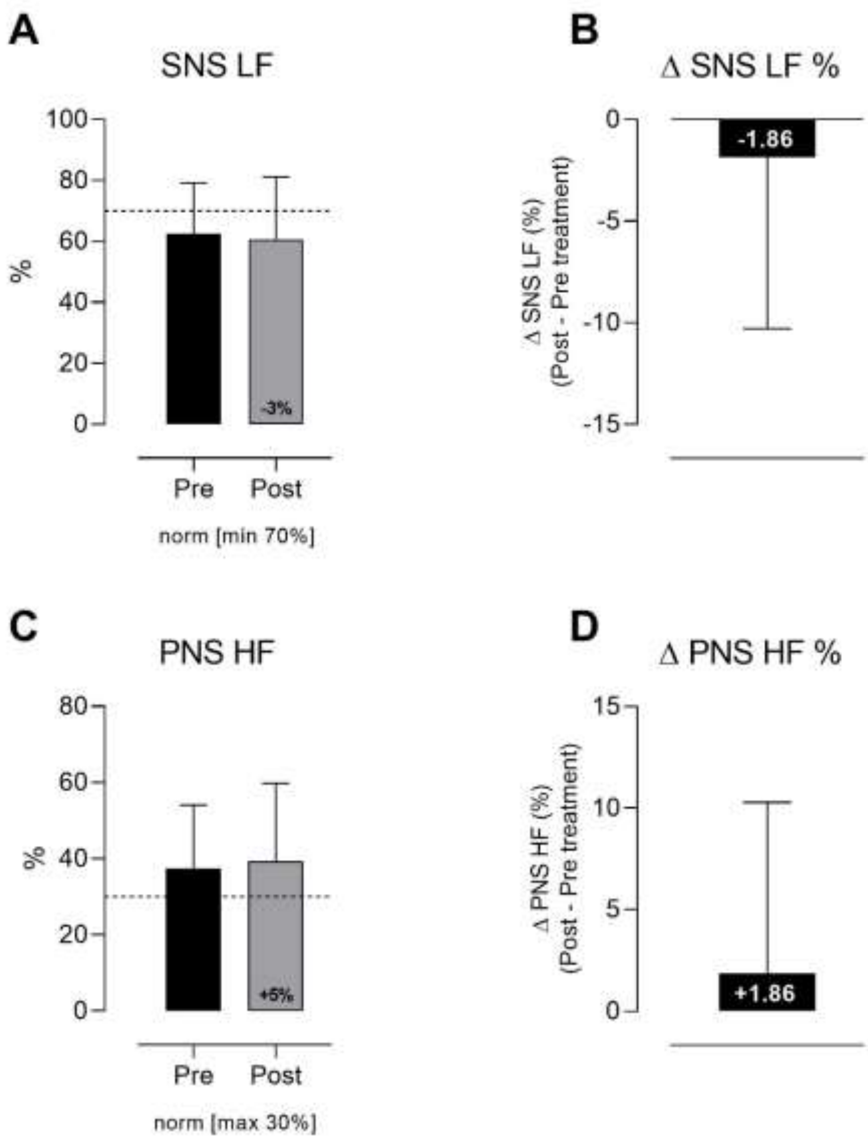

Figure 3. SNS LF (%) and PNS (%) before and immediately after the NanoVi Exo® session.

2. Questionnaires

2.1 Pittsburgh Sleep Quality Index

The Pittsburgh Sleep Quality Index (PSQI) assesses various aspects of sleep quality across seven components, each scored from 0 (no difficulty) to 3 (severe difficulty). These scores are summed to generate a global score ranging from 0 to 21, with higher scores indicating poorer sleep quality.

After 15 and 30 days of daily NanoVi Exo® sessions, there was a 50% improvement in Subjective Sleep Quality (Figure 4-A). Sleep Latency improved by 100% after 15 days, with scores remaining 50% lower after 30 days (Figure 4-B). A 100% improvement in Sleep Duration was observed by the end of the study (Figure 4-C). However, no changes (0%) were noted in Sleep Efficiency (Figure 4-D), Sleep Disturbances (Figure 5-A), or the Use of Sleep Medication (Figure 5-B). Daytime Dysfunction improved by 67% after 15 days, and this improvement was sustained after 30 days (Figure 5-C). The Global PSQI Score showed a 36% improvement after 15 days, which was maintained at 30 days (Figure 5-D).

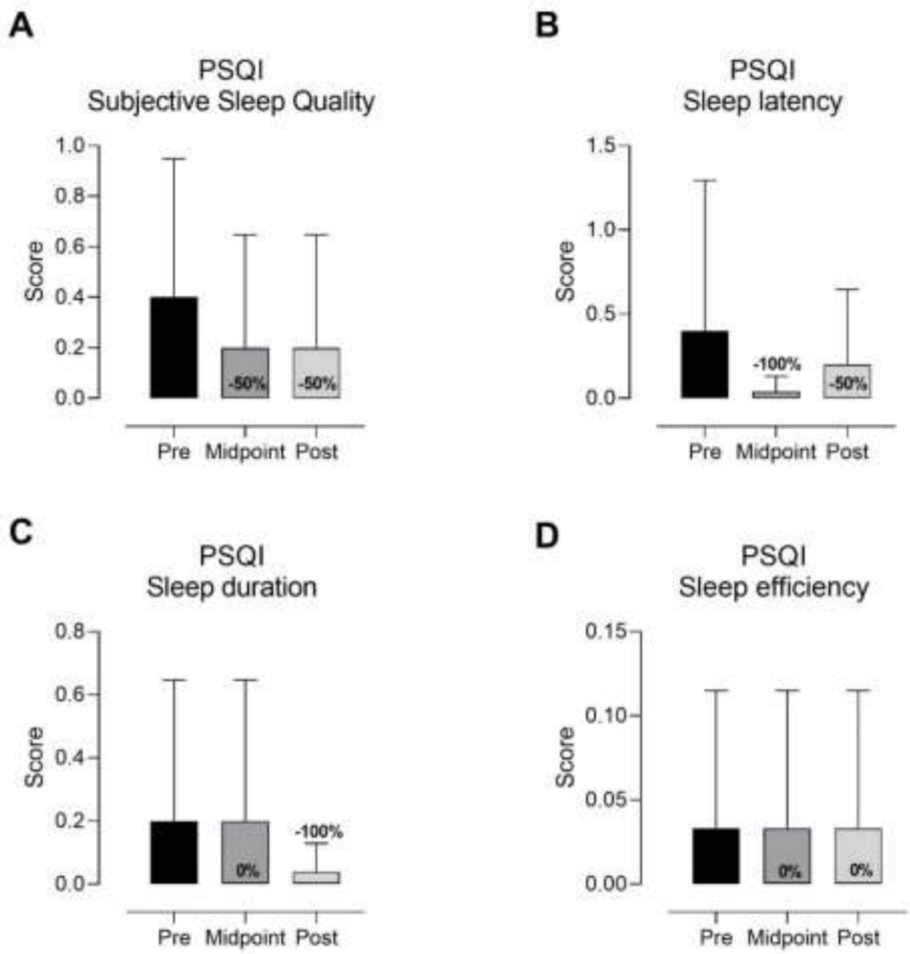

Figure 4. Pittsburgh Sleep Quality Index components 1 to 4 before, at midpoint, and after 30 days of daily NanoVi Exo® sessions.

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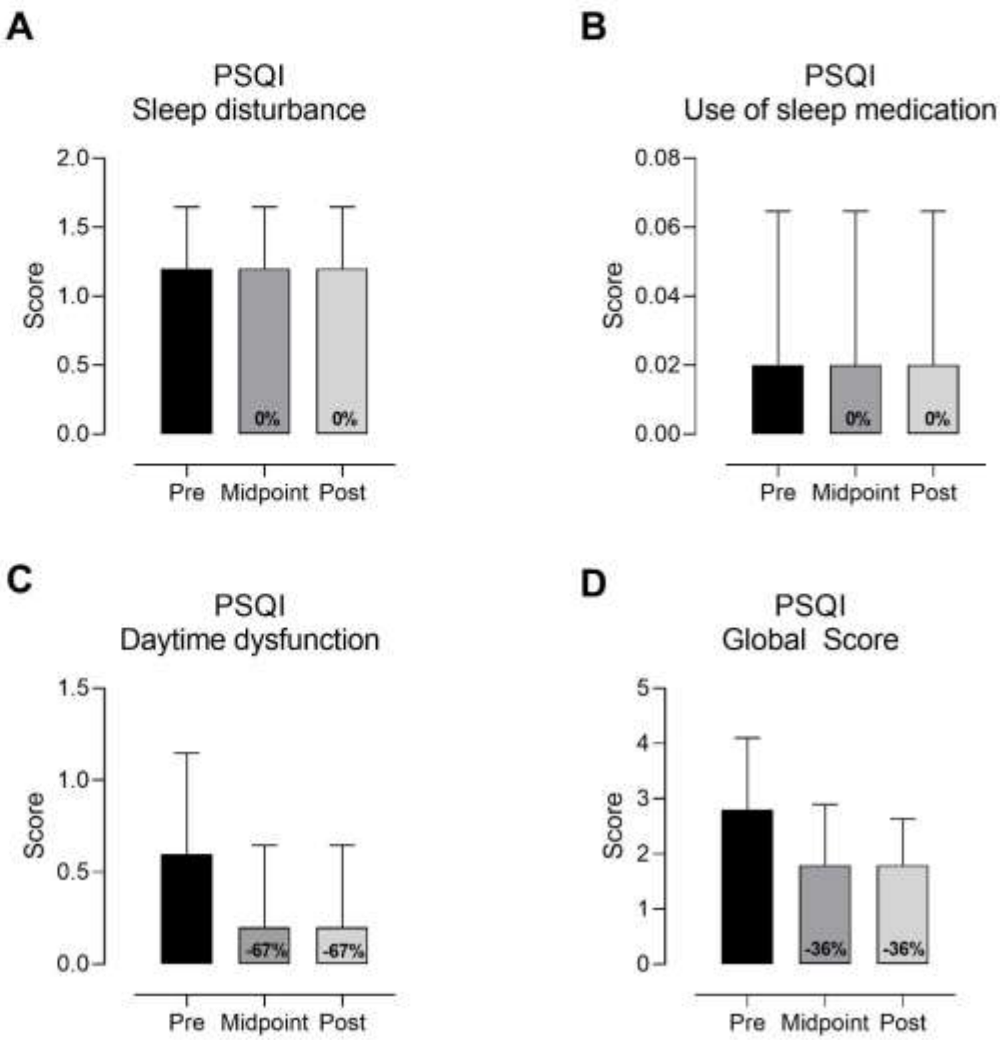

Figure 5. Pittsburgh Sleep Quality Index components 5 to 7 before, at midpoint, and after 30 days of daily NanoVi Exo® sessions.

2.2 DASS21

The DASS-21 questionnaire evaluates self-reported levels of Depression, Anxiety, and Stress, with higher scores indicating more severe outcomes. After 15 days of daily NanoVi Exo® sessions, participants reported a 50% reduction in Depression scores, which further decreased to 100% after 30 days, indicating complete resolution (Figure 6-A). Anxiety scores showed a 25% reduction after 15 days; however, by 30 days, there was a 25% increase compared to baseline levels (Figure 6-B). Stress scores remained unchanged at the 15-day midpoint but demonstrated a significant 67% reduction by the end of the 30-day period (Figure 6-C).

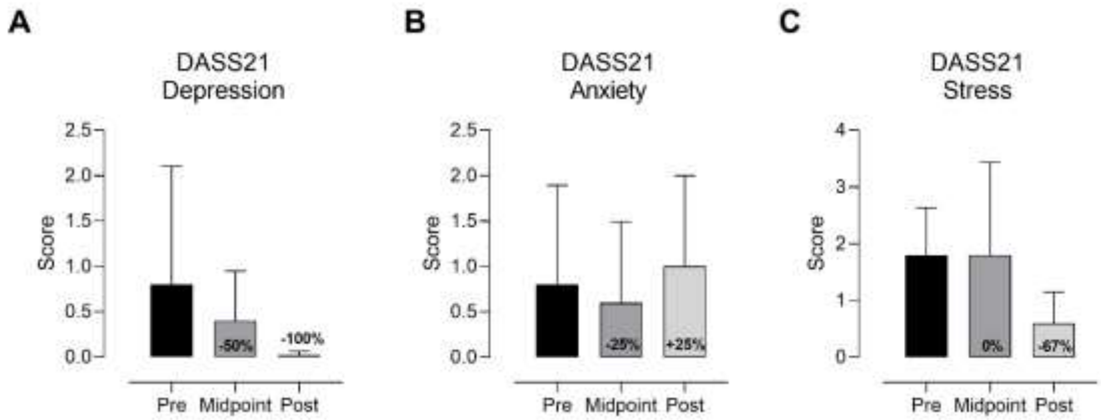

Figure 6. Depression, Anxiety and Stress scores before, at midpoint, and after 30 days of daily NanoVi Exo® sessions.

2.3 Fatigue Severity Scale

The Fatigue Severity Scale (FSS) measures the impact of fatigue on daily life. Scores below 36 indicate an absence of clinically significant fatigue, while scores of 36 or higher may warrant further medical evaluation.

After 15 days of daily NanoVi Exo® sessions, participants reported a 9% reduction in fatigue severity, which further decreased by 38% after 30 days (Figure 7). Although this change was not statistically significant, scores at both time points remained below the threshold of 36, suggesting no clinically significant fatigue was present throughout the study.

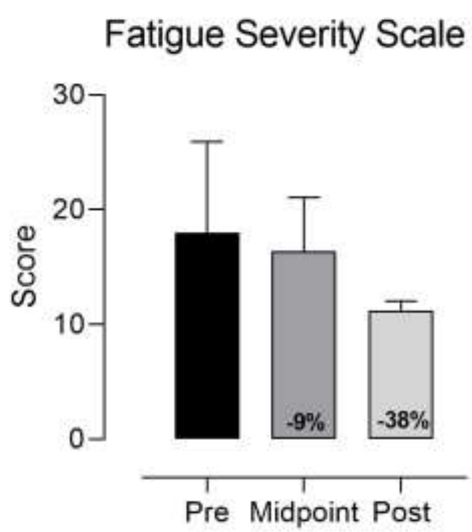

Figure 7. Fatigue Severity Scale score before, at midpoint, and after 30 days of daily NanoVi Exo® sessions.

2.4 PROMIS-29 V2.0

The PROMIS-29 v2.0 profile assesses pain intensity on a 0–10 numeric scale and evaluates seven health domains—Physical Function, Fatigue, Pain Interference, Depressive Symptoms, Anxiety, Ability to Participate in Social Roles and Activities, and Sleep Disturbance—using four items per domain. Scores were summed, and T-scores were calculated for analysis (standard error not included).

After 15 days of daily NanoVi Exo® sessions, participants reported a 3% improvement in Physical Function, increasing to 7% after 30 days (Figure 8-A). Anxiety scores showed no change at 15 days but improved by 20% at 30 days (Figure 8-B). Depression worsened by 4% at 15 days but returned to baseline by 30 days (Figure 8-C). Fatigue levels decreased by 9% at 15 days and 14% at 30 days (Figure 8-D). Sleep Disturbance improved by 7% at 15 days and 10% at 30 days (Figure 9-A), while the Ability to Participate in Social Roles and Activities improved by 9% at 15 days, with this improvement sustained at 30 days (Figure 9-B). Pain Interference decreased by 2% at 15 days and 9% at 30 days (Figure 9-C). Additionally, participants reported a 50% reduction in average pain scores at 15 days, which further improved to a 69% reduction by 30 days (Figure 9-D).

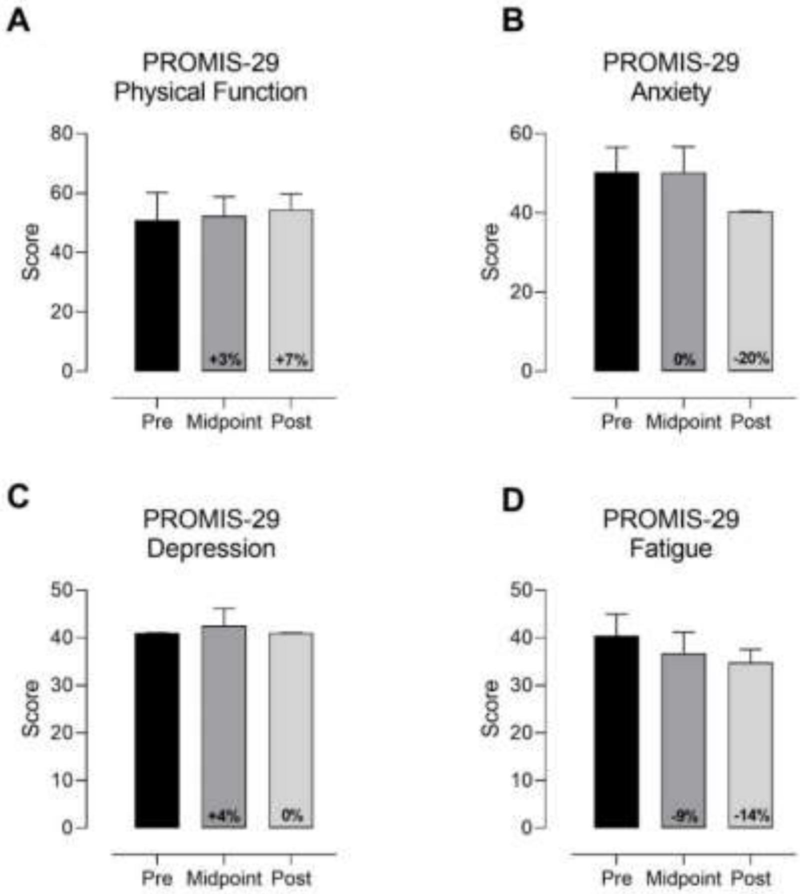

Figure 8. PROMIS-29 scores before, at midpoint, and after 30 days of daily NanoVi Exo® sessions.

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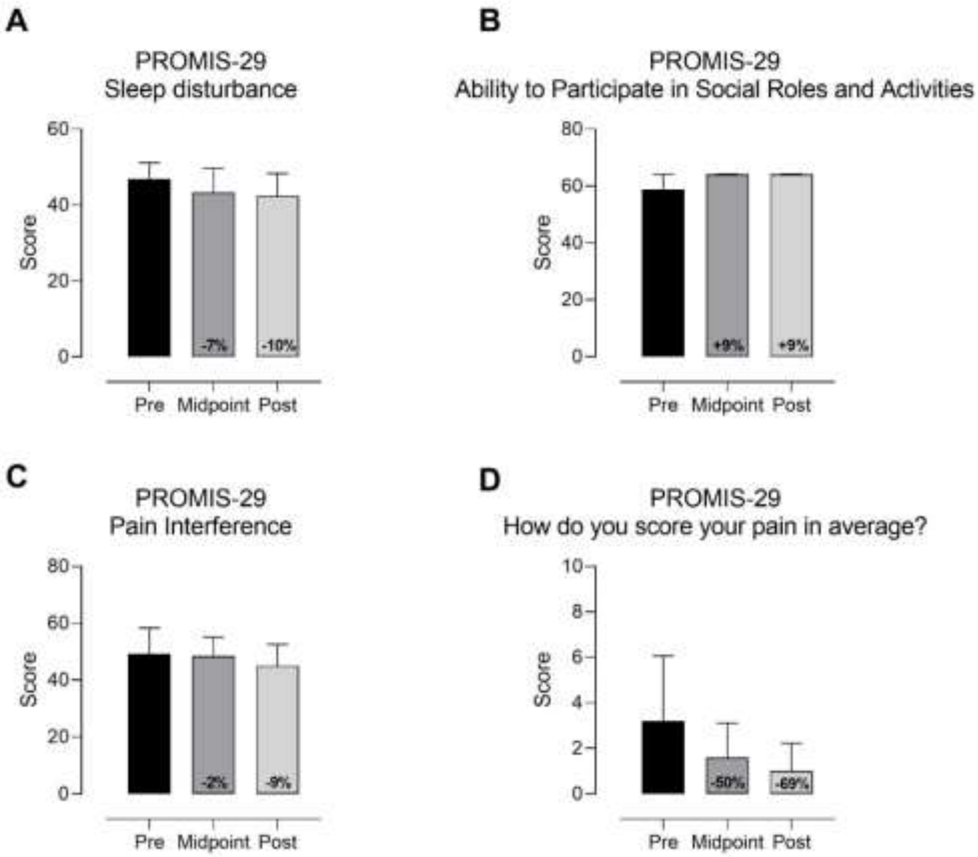

Figure 9. PROMIS-29 scores before, at midpoint, and after 30 days of daily NanoVi Exo® sessions.

Conclusion

This pilot study suggests that daily NanoVi Exo® sessions may support both immediate physiological changes and longer-term improvements in self-reported well-being among older adults. Acute analysis of heart rate variability indicated a shift toward parasympathetic activity and reduced sympathetic dominance, consistent with potential relaxation and recovery benefits.

After 15 and 30 days, questionnaire data demonstrated meaningful improvements in sleep quality, mood, fatigue, and pain. Participants reported better sleep latency and duration, reduced depressive symptoms and stress, lower fatigue severity, and less interference from pain. Improvements were also noted in domains of physical function and emotional well-being. The temporary increase in self-reported anxiety observed during the study period may have been influenced by seasonal factors.

Overall, these findings indicate that NanoVi Exo® sessions may help promote relaxation, sleep quality, and overall well-being in healthy or mildly symptomatic older adults. However, given the small sample size and absence of a control group, results should be interpreted with caution. Replication of the study with a larger cohort, controlled conditions, and across different time periods is warranted to confirm these preliminary outcomes and better understand the long-term impact of NanoVi Exo® on physiological and psychological health.

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ABSTRACT

Immediate and Short-Term Effects of NanoVi Exo® on Heart Rate Variability and Self-Reported Wellness in Older Adults: A Pilot Study

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Purpose: This study aimed to evaluate the wellness benefits of the NanoVi Exo® device in adults aged 60 and over, focusing on its immediate effects on heart rate variability (HRV) and the longer-term impact on self-reported outcomes of sleep, mood, fatigue, and well-being.
Methods: Six adults (3 males, 3 females; mean age 69.17 years) participated. Baseline assessments included the Pittsburgh Sleep Quality Index (PSQI), DASS-21, Fatigue Severity Scale (FSS), and PROMIS-29 questionnaires, along with HRV measurement using the PPG Stress Flow device (Biotekna, Italy). Participants completed a 15-minute NanoVi Exo® session, after which HRV was reassessed to determine acute effects. Questionnaires were repeated at 15 and 30 days. Statistical analysis included paired t-tests for HRV and Friedman's test with Dunn's multiple comparisons for questionnaire data, with significance set at $p < 0.05$.
Results: Immediately after a single session, participants showed increased HRV (SDNN and RMSSD) and a shift toward parasympathetic activity, suggesting enhanced autonomic balance. At 15 and 30 days, questionnaire results indicated improvements in sleep quality and duration (PSQI), reduced fatigue (FSS), and decreased depression and stress scores (DASS-21). PROMIS-29 results also showed improvements in physical function, anxiety, and pain by day 30.
Conclusion: Daily NanoVi Exo® sessions may support short-term autonomic balance and contribute to improved self-reported sleep, mood, fatigue, and overall well-being over 15 to 30 days in older adults.

ABOUT US

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†Disclaimer

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