



Catalyzing Success Through Scientific Strategy

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CONTENTS

1. About Us.....	02
2. Disclaimer.....	03
3. Report	04

1. ABOUT US

At Scientifica Consulting, we ignite innovation and power success in health and wellness. With over a decade of experience, we blend science with strategy to help companies excel, ensuring FDA and FTC compliance every step of the way. Our team of experts—professors, scientists, and researchers—guides you from idea to market, turning possibilities into breakthrough products. Let's shape the future together!



2. DISCLAIMER

This report was prepared by Scientifica Consulting based on a study conducted by Scientifica Consulting, including study implementation, data collection, analysis, and interpretation. The findings reflect an exploratory pilot study and should be considered preliminary; they do not establish causation, long-term effects, clinical efficacy, or expected outcomes for individual users.

While reasonable scientific methods and care were applied throughout the study and analysis, Scientifica Consulting makes no warranties regarding the generalizability or future applicability of the findings and assumes no responsibility or liability for claims, marketing materials, regulatory representations, commercial decisions, or other uses of these findings by third parties. Any subsequent use or communication of the study results remains the responsibility of the party making such use or communication.

Preliminary Report

Short-Term Wellness-Related Effects of a Single 20-Minute AVACEN Session: Findings from a Pilot Study

This pilot study was conducted to explore short-term, wellness-related changes that may occur during a single 20-minute session with the AVACEN device. The study used a pre- and post-session design and included non-invasive assessments performed immediately before and after the session. The purpose was to observe whether a single session was associated with measurable changes in physiological and self-reported wellness-related outcomes.

The assessment protocol included PPG Stress Flow and HEG measurements obtained with Bioteckna devices, together with an online questionnaire completed by participants before and after the session. The questionnaire consisted of 10 outcome-related terms. Five represented positive wellness-related states and were scored on a scale from 0 to 5, with higher scores indicating a better perceived state. The other five represented negative wellness-related states and were also scored from 0 to 5, but in this case higher scores indicated a worse perceived state. A total wellness score was then calculated based on all 10 questionnaire items, with higher final scores reflecting a better overall wellness state.

All data were analyzed using GraphPad Prism 8.0. Outliers were screened using the ROUT method and removed when appropriate. Data distribution was assessed using the Shapiro-Wilk normality test. Based on the results of the normality analysis, paired or unpaired statistical tests were applied as appropriate, using parametric or non-parametric methods according to the characteristics of the data. Statistical significance was set at $p < 0.05$. In addition to statistical testing, percentage changes were calculated in relation to baseline values to help illustrate the magnitude and direction of observed changes following the session.

The sample included 24 participants ranging in age from 52 to 81 years. The mean age was 65.5 years. Most participants were female, with 17 women (70.8%) and 7 men (29.2%). Overall, the group was composed primarily of older adult women.

Results

Heart Rate and Heart Rate Variability

Following the single 20-minute AVACEN session, the PPG Stress Flow assessment showed a 3% reduction in mean heart rate, which reached statistical significance ($p = 0.0481$). Heart rate variability-related parameters showed a mixed response. SDNN decreased by 15%, RMSSD increased by 22%, and total power decreased by 3%. The LF/VLF ratio increased by 10%, which was also statistically significant ($p = 0.0022$). VLF power decreased by 6%, while HF power and LF power increased by 3% and 2%, respectively. Sympathetic activity, represented by SNS LF, decreased slightly by 1%, corresponding to a delta change of -0.76. In contrast, parasympathetic activity, represented by PNS HF, increased by 2%, corresponding to a delta change of +0.76.

Additional PPG-derived perfusion-related measures also changed after the session. The perfusion index increased by 18%, while remaining within the optimal range. Perfusion transit time increased by 6%, reaching statistical significance ($p = 0.0459$), and also remained within the optimal range.

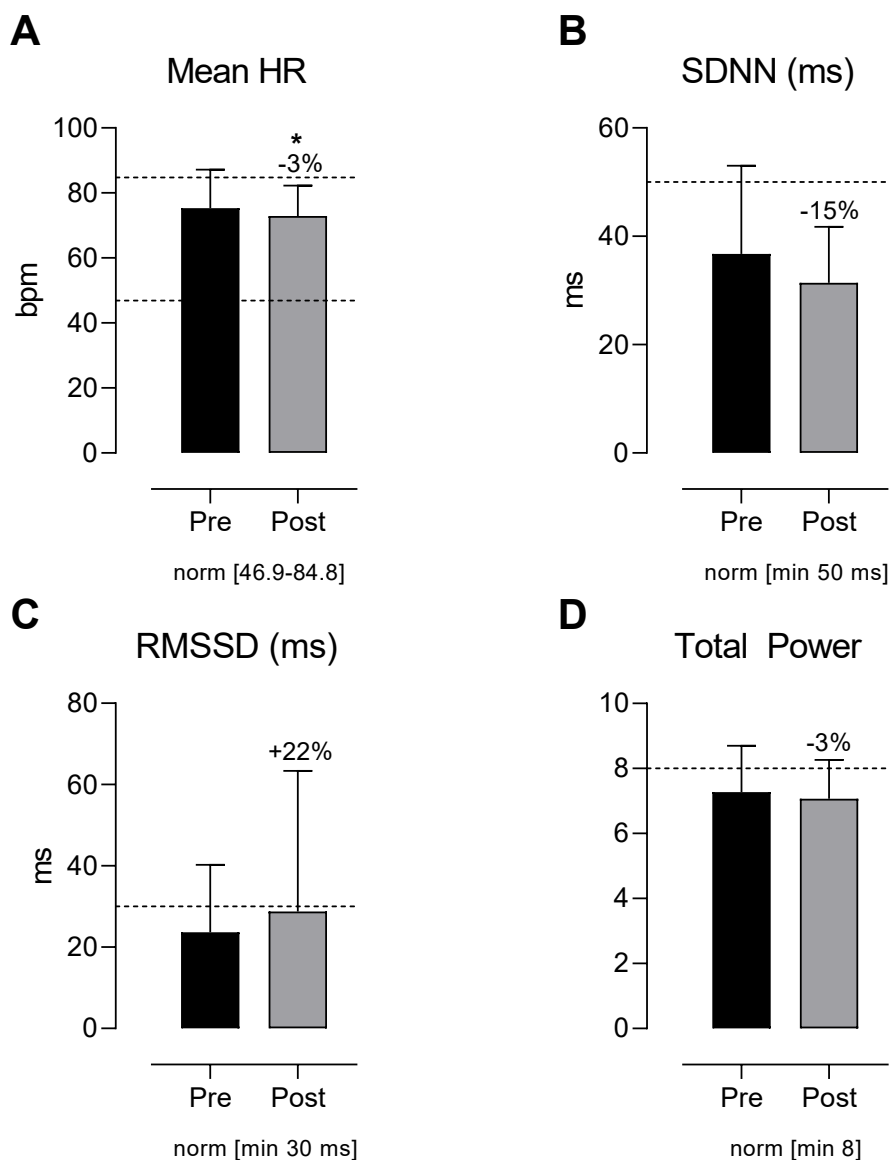


Figure 1. Heart Rate and HRV Outcomes

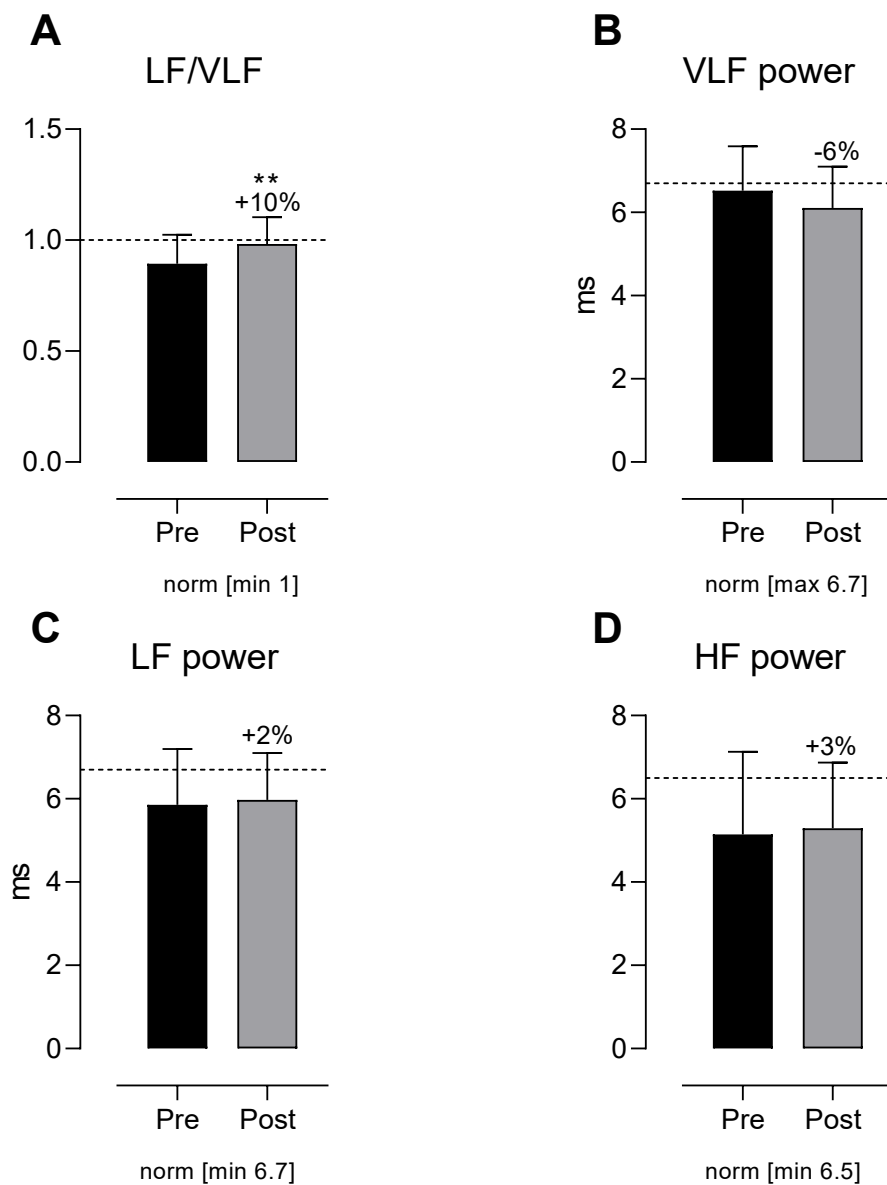


Figure 2. Frequency-Domain HRV Outcomes

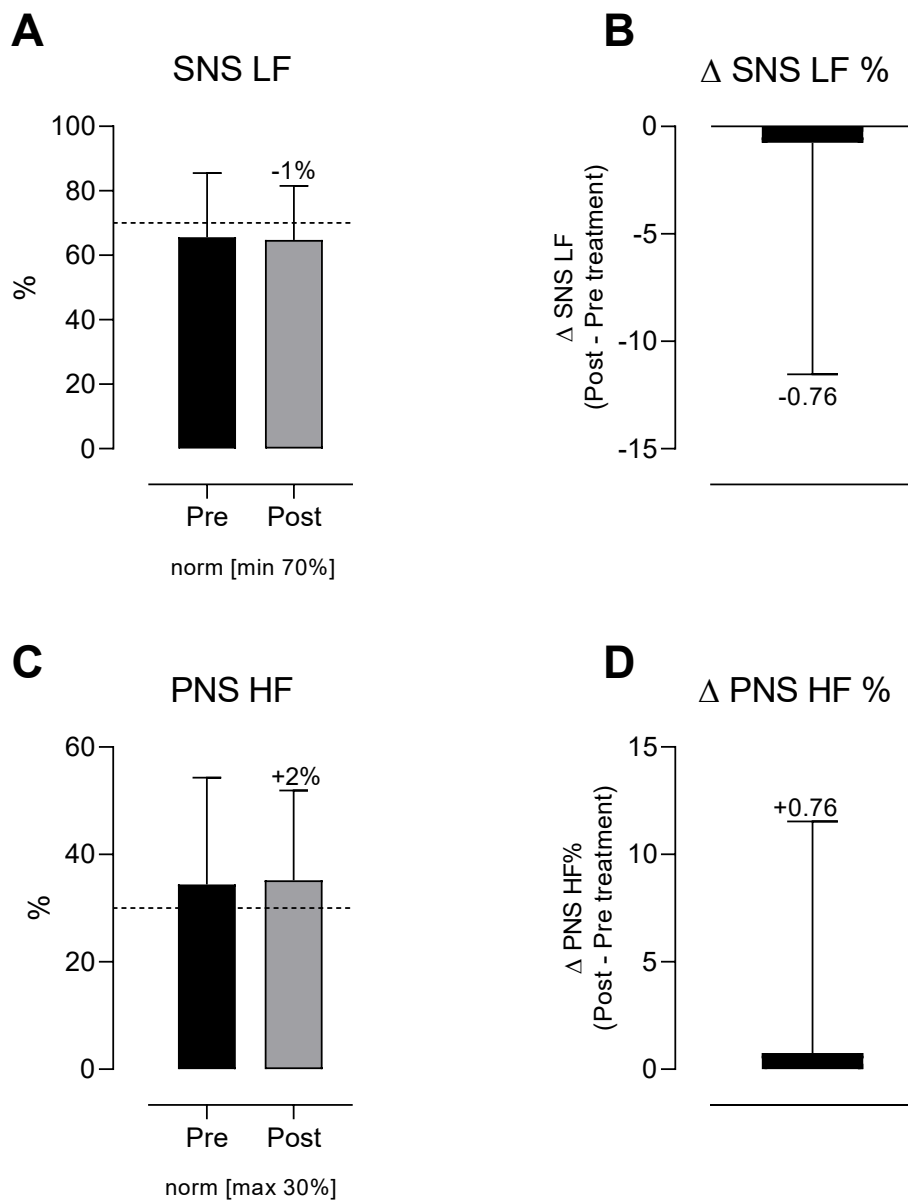


Figure 3. Sympathetic and Parasympathetic Balance

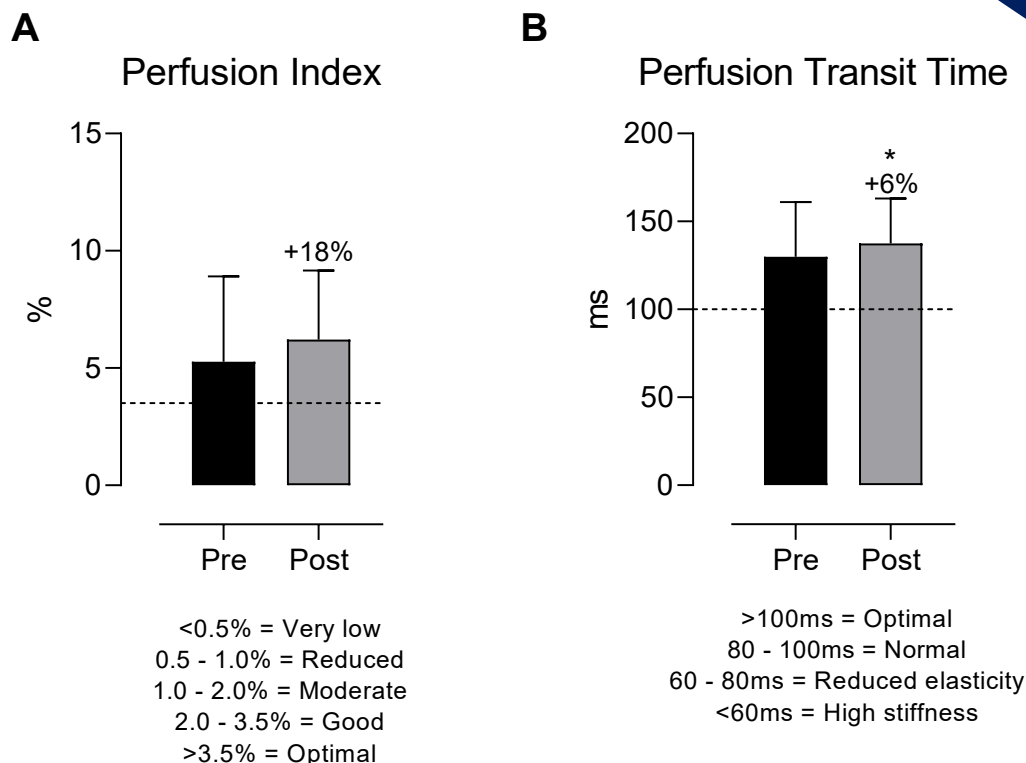


Figure 4. Perfusion Measures

Bilateral Flow Gain

Peripheral circulation-related changes were also observed after the session. Bilateral Flow Gain increased in both hands, even though the AVACEN device was applied to only one hand. Left BFG increased by 25%, corresponding to a delta change of +127.98, while right BFG increased by 30%, reaching statistical significance ($p = 0.0134$) and corresponding to a delta change of +104.77. These bilateral findings may be particularly noteworthy given the unilateral application of the device.

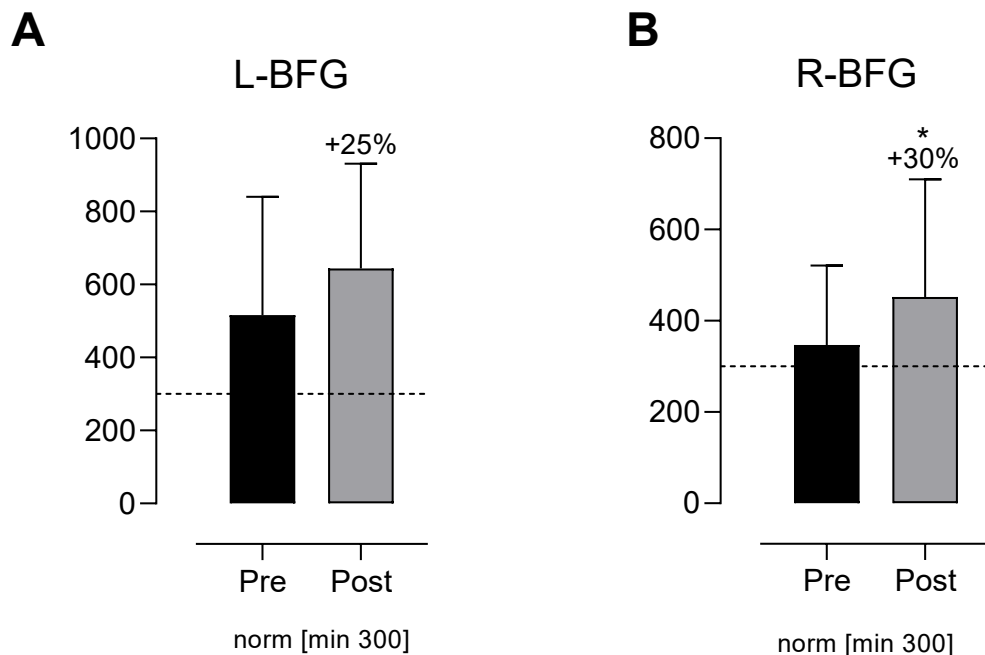


Figure 5. Bilateral Flow Gain

HEG Results

In the HEG assessment, overall rCBO2 decreased by 2%, while CBF increased by 3% after the session. However, when the results were examined according to baseline values, a normalization pattern was observed. Among participants with baseline rCBO2 values below 50, rCBO2 increased by 19%, whereas among those with baseline values above 50, rCBO2 decreased by 18%. A similar pattern was observed for CBF. When baseline CBF was below 300, values increased by 7% after the session, whereas in those with baseline values above 300, CBF decreased by 6%. These findings may suggest a tendency toward adjustment in the direction of a more balanced physiological state following the AVACEN session.

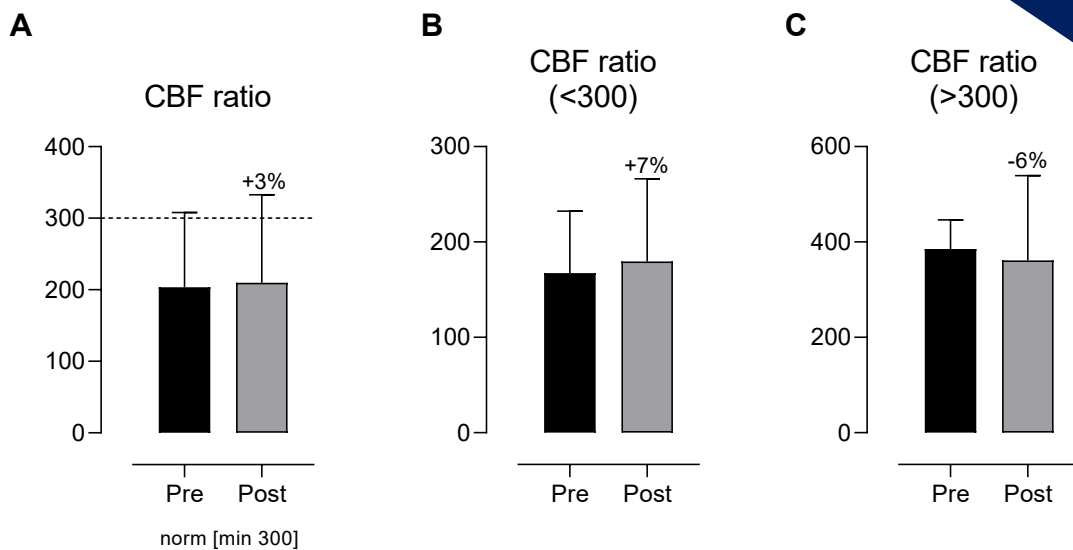


Figure 6. Cerebral Blood Flow changes.

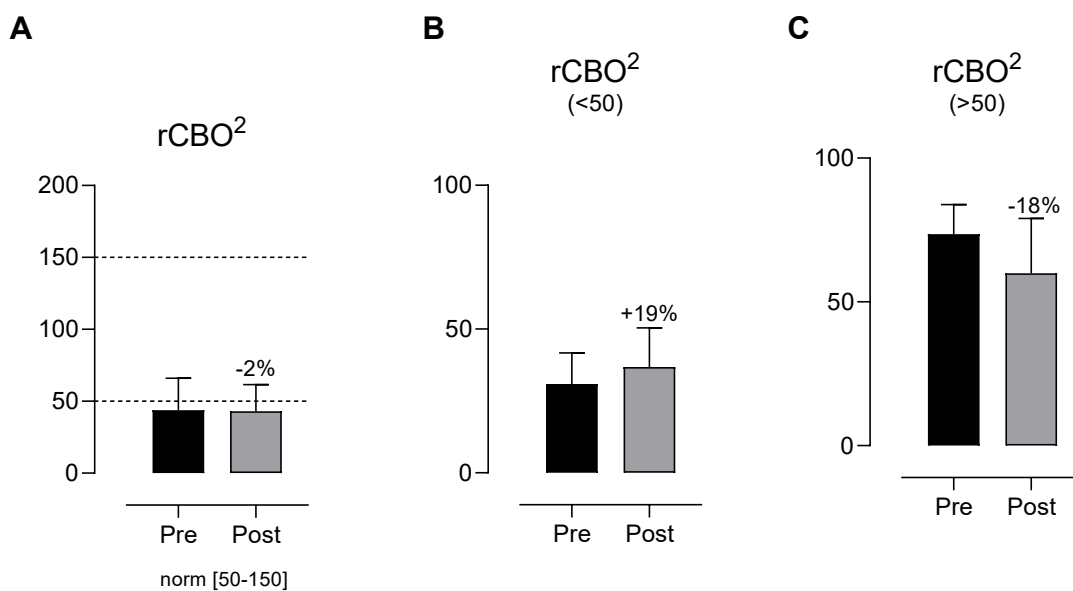


Figure 7. Regional Cerebral Blood Oxygenation changes.

Questionnaire Results

The self-reported questionnaire results indicated an overall improvement in wellness-related perceptions following the single 20-minute AVACEN session. For the positively scored outcomes, emotional balance increased by 4%, relaxation increased by 22% and was statistically significant ($p = 0.0001$), mental clarity increased by 1%, physical comfort increased by 11% ($p = 0.0273$), and energy increased by 17% ($p = 0.0027$).

For the negatively scored outcomes, all measures decreased after the session, reflecting improvement. Anxiety decreased by 23%, stress decreased by 40% and reached statistical significance ($p = 0.0028$), fatigue decreased by 26% ($p = 0.0336$), aches and pains decreased by 25% ($p = 0.0265$), and irritability decreased by 21%.

Overall, these changes were accompanied by a 15% increase in the total wellness score, which was also statistically significant ($p = 0.0004$), suggesting an overall improvement in self-perceived wellness immediately after the AVACEN session.

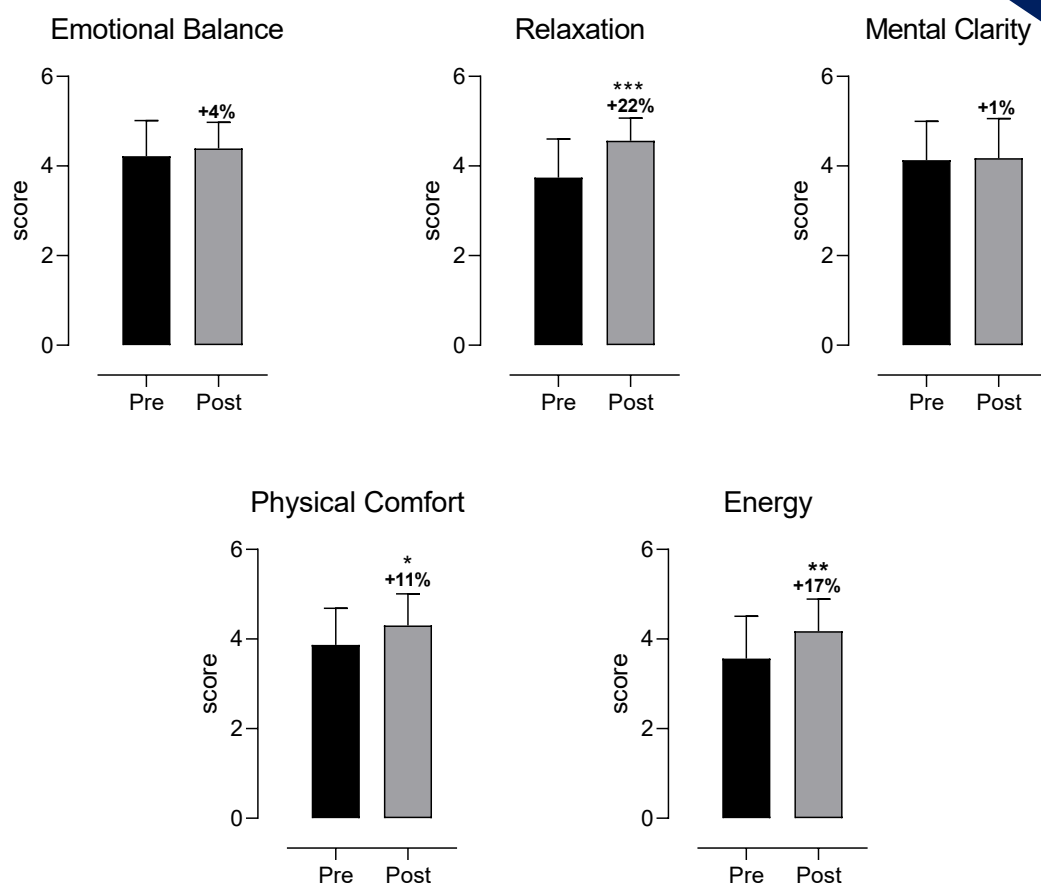


Figure 8. Positive Symptom Scores

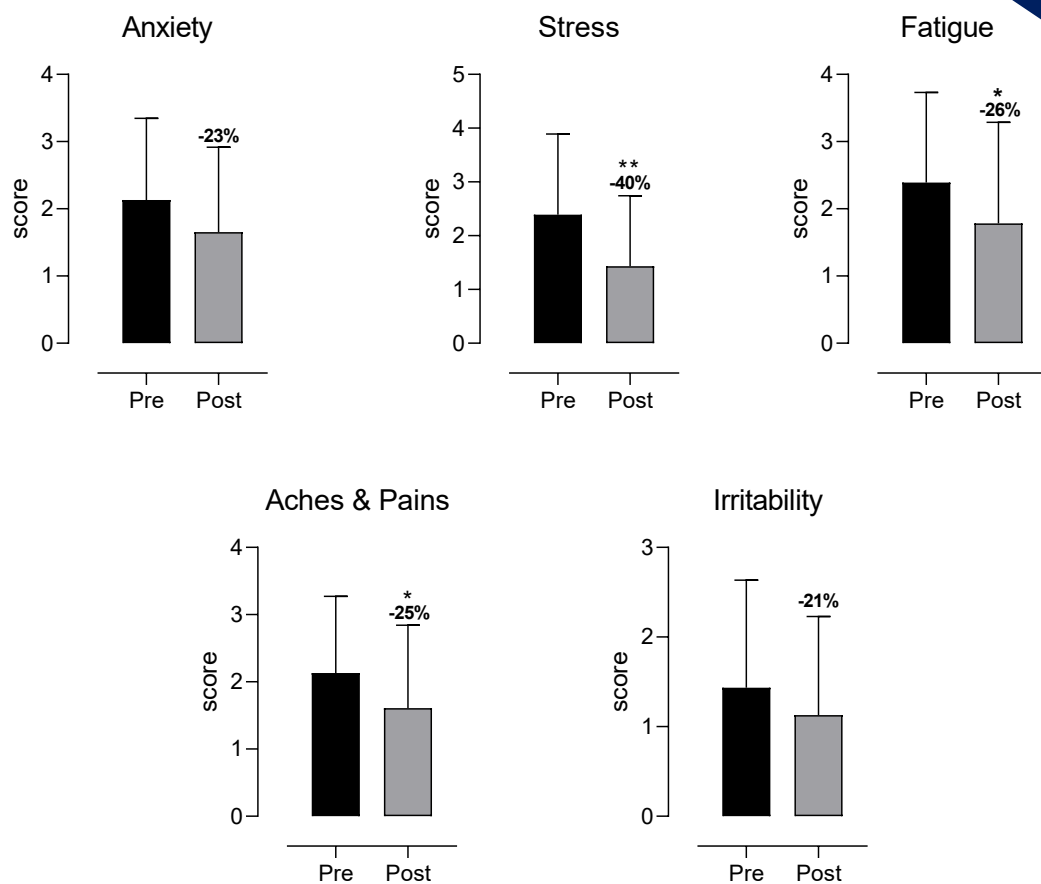


Figure 9. Negative Symptom Scores

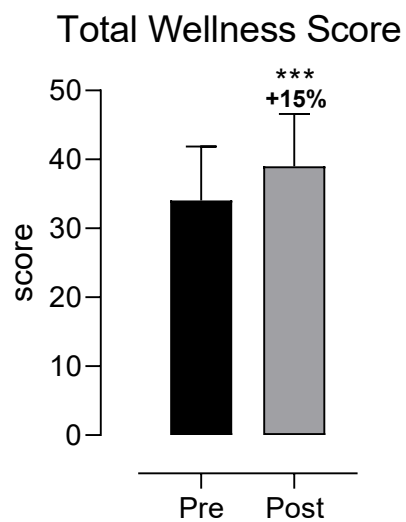


Figure 10. Total Wellness Score

Interpretation of the Results

Overall, the results of this pilot study suggest that a single 20-minute AVACEN session was linked to short-term changes in both body-based measurements and how participants said they felt afterward. In simple terms, the session appeared to be followed by signs of greater relaxation, better comfort, more energy, and lower stress-related feelings.

Looking at the physiological measures, some changes were small and may not be very meaningful on their own. For example, a few of the heart rhythm variability measures changed only slightly, so those results should not be overemphasized. However, the lower heart rate after the session may suggest a calmer physiological state. The circulation-related findings were also interesting. Even though the device was used on only one hand, changes in blood flow-related measures were seen in both hands. This may suggest that the response was not limited only to the exact area where the device was applied.

The brain oxygenation-related results were modest overall, but a useful pattern appeared when participants were separated by their starting values. Those who began with lower values tended to increase, while those who began with higher values tended to decrease. This may suggest that the session helped move some measures toward a more balanced range, rather than simply pushing everyone in the same direction.

The questionnaire results showed a clearer pattern. After the session, participants reported feeling more relaxed, more physically comfortable, and more energetic. They also reported less stress, less fatigue, and fewer aches and pains. The improvement in the total wellness score supports the idea that, overall, participants tended to feel better after the session.

Taken together, these early findings suggest that a single AVACEN session may provide short-term wellness-related benefits in this setting. Because this was a small pilot study looking only at immediate before-and-after changes, the results should be viewed as preliminary. Even so, the findings are encouraging and suggest that further research may be worthwhile.