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Psychological and Autonomic Outcomes Following a Multimodal Intervention in Arrhythmia Patients: A Longitudinal Cohort Study Before and After the COVID-19 Pandemic

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ABSTRACT:

Background: The COVID-19 pandemic triggered a global mental health crisis, exacerbating stress, anxiety, and autonomic dysfunction. Behavioral lifestyle interventions are established for arrhythmia management, but their comparative efficacy before versus after a population-wide psychological stressor remains unexplored.

Objective: This study compared 4-year clinical and psychological outcomes of the proven standardized multimodal behavioral intervention Group 7 (G₇) protocol (combining Shiatsu, structured exercise, stress management, and lifestyle counseling) in patients with arrhythmias treated before (2016–2019) and after (2021–2024) the COVID-19 pandemic. The study aimed to clarify potential temporal and demographic confounding between cohorts, establish precise outcome definitions, and compare longitudinal treatment trajectories.

Methods: A retrospective longitudinal cohort analysis was conducted on 780 patients treated with the identical intervention protocol, grouped into Pre-Pandemic (2016–2019, n=390) and Post-Pandemic (2021–2024, n=390) cohorts. A detailed sub-sample of 195 patients (randomized into 13 groups of n=15 each) underwent additional prospective assessment of arrhythmia burden, hemodynamics, and psychological scores (Perceived Stress Scale-10 [PSS-10], Kessler Psychological Distress Scale [K10]) to validate and extend the primary findings. Primary outcomes were changes in Heart Rate Variability (SDNN) and arrhythmia burden (defined as total PVC/PAC counts per 24–48h Holter) and HRV outcomes (SDNN in ms). Between-cohort changes and interaction effects were evaluated using linear mixed-effects models adjusting for baseline age, sex, healthcare access, and baseline distress.

Results: Both cohorts showed significant improvements following the multimodal behavioral intervention, with the post-pandemic cohort demonstrating enhanced

efficacy, particularly in psychological and autonomic metrics, compared to the pre-pandemic average. Intervention adherence remained extremely high across both eras (overall completion >98%).

Conclusions: These findings from a large longitudinal cohort ($n=780$) and a detailed sub-sample ($n=195$) suggest that individuals with higher baseline psychological distress may derive particular benefit from autonomic and psychological resilience-building interventions. Prospective, controlled studies are warranted to confirm this effect and to identify behavioral mechanisms of enhanced responsiveness.

1. INTRODUCTION

The COVID-19 pandemic, declared in March 2020, represented more than a viral infectious disease outbreak; it was a profound psychosocial stressor inducing widespread fear, social isolation, economic instability, and grief (World Health Organization, 2022). This period triggered a significant global mental health crisis, with documented surges in anxiety, depression, and perceived stress levels across populations (Santomauro et al., 2021; Giorgi et al., 2020; Javelot & Weiner, 2021; Feter et al., 2021). From a behavioral medicine perspective, the pandemic disrupted daily routines, reduced physical activity, increased sedentary behavior, and impaired sleep quality—all of which are known to affect autonomic function and cardiovascular risk (Huang & Zhao, 2020; Park & Park, 2020).

The autonomic nervous system (ANS), a key mediator between psychological state and physiological function, is highly susceptible to chronic stress (Thayer & Lane, 2007; Porges, 2018; Levine et al., 2022). The pandemic environment created favorable conditions for ANS dysregulation, characterized by sympathetic overdrive and diminished parasympathetic tone, often manifesting as palpitations, functional arrhythmias, and increased cardiovascular risk (Lampert, 2010; Ho et al., 2021). Post to the pandemic, previous research established the efficacy of non-pharmacological approaches, including Shiatsu, Lifestyle management, and laser acupuncture, in managing arrhythmias (Soliman et al., 2025).

The pandemic provided a unique, unplanned natural experiment to investigate a critical behavioral medicine question: Would the efficacy of this intervention be blunted in a more psychologically distressed population, or would this population, paradoxically, show a greater magnitude of improvement due to higher baseline dysfunction and potentially greater motivation for behavior change? (Bonanno & Mancini, 2012). This study leverages a longitudinal dataset to compare the 4-year outcomes of this standardized behavioral intervention delivered to two distinct cohorts: one treated in the four years before the pandemic (2016–2019) and another treated in the four years after its onset (2021–2024). We hypothesized that the post-pandemic cohort, burdened by greater psychological distress and more disrupted health behaviors, would demonstrate a greater response to treatment, particularly in psychological and autonomic metrics.

2. MATERIALS AND METHODS

2.1 Study Material

The primary study material comprised data from a longitudinal cohort of 780 patients (61.5% female, 38.5% male; mean age 47.8 ± 9.1 years) undergoing non-pharmacological management for cardiac dysrhythmias at the critical care unit extension and cardiac outpatient clinic of Kasr Al-Ainy Hospital, Cairo University, between January 2016 and December 2024. Additionally, a detailed prospective sub-sample of $n = 195$ patients (115 females, 80 males; mean age 39.5 ± 11.2 years) was selected to provide high-resolution autonomic, hemodynamic, and psychological evaluations.

2.2 Sample Collection

Participants were screened using continuous 24–48 hour ambulatory electrocardiographic (ECG) Holter monitoring. Key inclusion criteria required patients aged 18 to 60 years in sinus rhythm with documented premature atrial complexes (PACs) and/or premature ventricular complexes (PVCs) exceeding 100 episodes per 24–48 hours. The rationale for including asymptomatic patients was to assess the pure autonomic effects of interventions independent of symptom perception and to evaluate the potential preventive role of these therapies in a broader at-risk population. Candidate exclusions comprised active malignancy, acute coronary syndrome or cardiovascular events within 6 months, structural heart disease, heart failure,

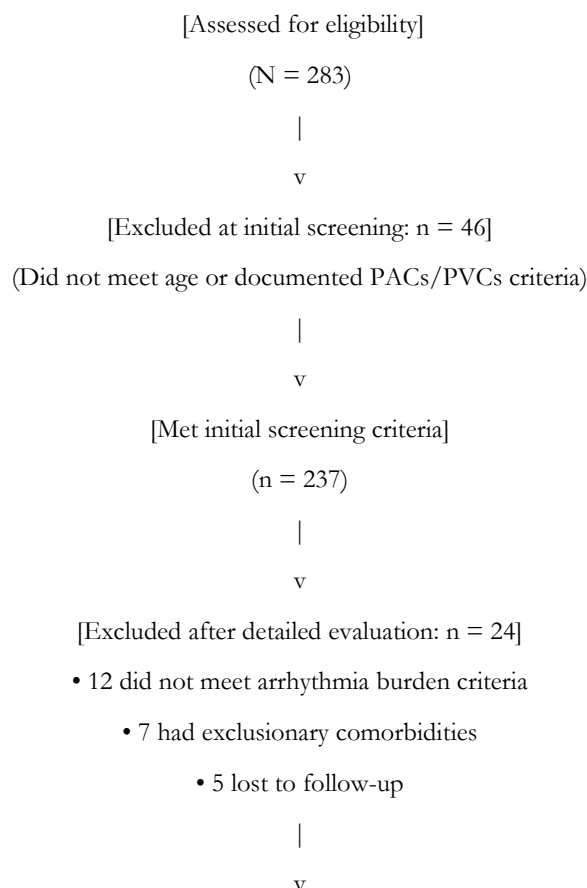
pacemaker dependency, open heart surgery, uncontrolled hypertension, severe depression (Patient Health Questionnaire-9 [PHQ-9] score > 15), chronic obstructive pulmonary disease, bleeding disorders.

From these total cohort 780 patients, a sub-sample of 195 patients underwent additional prospective assessments of arrhythmia burden (24–48 hour Holter), hemodynamic measures, and psychological scores to provide detailed validation of the primary findings. These 195 patients were randomized into 13 groups ($n = 15$ each) and followed prospectively. Between January 2016 and December 2024, a total of 283 patients were assessed for eligibility at the cardiac outpatient clinic of Kasr Al-Ainy Hospital, Cairo University. Of these, 237 met initial screening criteria based on age (18–60 years) and documented PACs/PVCs on prior Holter monitoring.

A total of 283 patients were initially assessed for eligibility at the critical care unit extension and the cardiac outpatient clinic of Kasr Al-Ainy Hospital, Cairo University. Of these, 46 were excluded at initial screening for failing to meet age criteria (18–60 years) or baseline arrhythmia thresholds (> 100 PACs/PVCs per 24–48h Holter). Following comprehensive clinical evaluation of the remaining 237 candidates, an additional 24 patients were excluded due to insufficient arrhythmia burden ($n = 12$), exclusionary comorbidities ($[n = 7]$; uncontrolled hypertension [$n = 3$], severe depression with PHQ-9 > 15 [$n = 2$], or structural heart disease [$n = 2$]), or loss to follow-up prior to allocation ($n = 5$).

Of the 213 eligible patients invited to participate, 18 declined, and 1 patient was excluded due to a pre-existing adverse baseline condition (severe anemia with hemoglobin 7.0 g/dL accompanied by marked headache and agitation). Ultimately, 195 patients (115 females, 80 males; mean age 39.5 ± 11.2 years) were randomized into 13 parallel intervention arms ($n = 15$ per group). All randomized participants ($N = 195$) successfully completed the 6-month protocol with 100% retention, zero post-randomization withdrawals, and no protocol violations, and were fully included in final statistical analyses.

Participant screening and flow disposition through the trial stages were structured per CONSORT guidelines and analysis is visually detailed in the CONSORT disposition flow diagram (Figure 1).



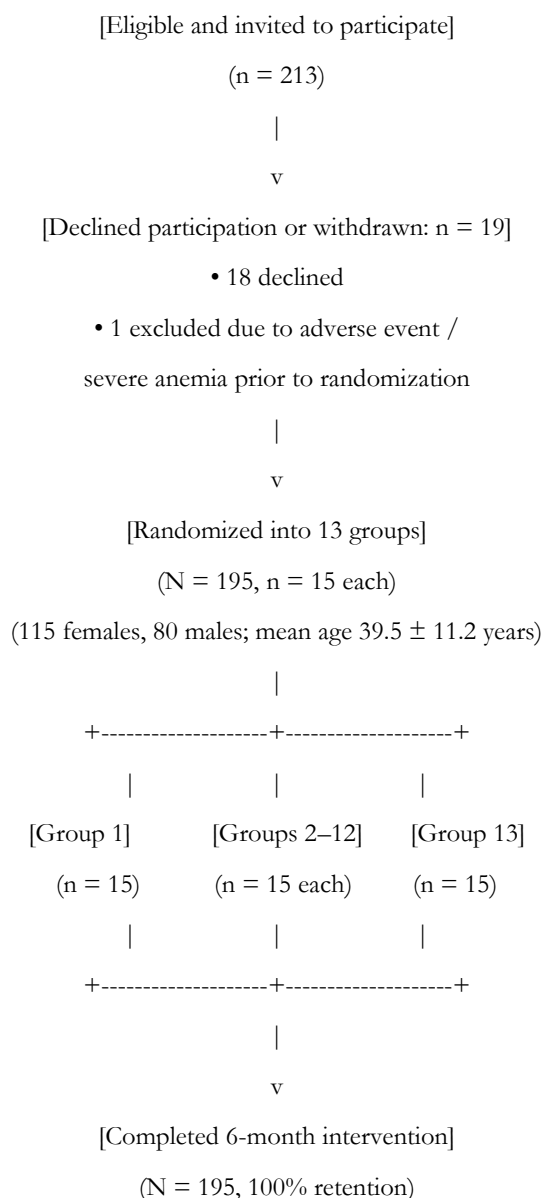


Figure 1: CONSORT participant disposition flow diagram for the prospective sub-sample ($n = 195$). The diagram illustrates participant progression through screening ($N = 283$), specific exclusion stages ($n = 88$ total exclusions), block randomization into 13 parallel intervention arms ($n = 15$ per group), 6-month multimodal intervention tracking with 100% adherence, and complete inclusion in final statistical analyses

2.3 Extraction Procedure

The cohort was partitioned into two temporal epochs to evaluate intervention performance relative to the COVID-19 pandemic: a Pre-Pandemic Cohort (2016–2019, $n = 390$) and a Post-Pandemic Cohort (2021–2024, $n = 390$), with the year 2020 excluded as a washout period due to clinic lockdown closures. Within the detailed sub-sample ($n = 195$), participants were randomized into 13 parallel intervention groups to evaluate comparative and synergistic efficacy of 12 distinct somatic protocols against a control group (G0, $n=15$) that received standard pharmacotherapy alone (beta-blockers or calcium channel blockers per ESC/ACC guidelines), using a computer-generated block randomization sequence (block size 13) stratified by age (± 5 years) and sex, managed with sealed opaque envelopes for allocation concealment and assessor blinding.

2.4 Analytical Methods

All participants received the standardized Group 7 (G7) multimodal behavioral protocol consisting of three core components:

- Manual Shiatsu (20 minutes): Finger pressure applied to specific acupoint meridians (HT3, HT4, HT6, HT7, HT9, PC6, BL15).
- Supervised Combined Exercise (40 minutes): swimming, cycling, or elliptical training targeted at 50%–70% maximum heart rate, supplemented by resistance band exercises and stretching.
- Lifestyle Management: Daily guidance on sleep hygiene and dietary habits, Stress Management & Relaxation (45 minutes daily): Guided diaphragmatic breathing and progressive muscle relaxation (PMR).

Sessions took place in a temperature-controlled therapy suite (24°C, 40% relative humidity).

Intervention Adherence: Program adherence was objectively monitored through electronic attendance logs for supervised sessions and daily digital self-report diaries for home relaxation/lifestyle practices. High adherence was defined a priori as attending $\geq 80\%$ of supervised sessions and completing $\geq 80\%$ of daily home relaxation logs. Adherence was exceptionally high and comparable between eras ($96.2\% \pm 3.1\%$ in Pre-Pan vs. $95.8\% \pm 3.4\%$ in Post-Pan, $p = 0.28$).

Standardized acupoints: HT3 (Shaohai), HT4 (Lingdao), HT6 (Yinxi), HT7 (Shenmen), HT9 (Shaochong), PC6 (Neiguan), and BL15 (Xinshu).

Primary outcome metrics included Heart Rate Variability (SDNN in ms) filtered for ectopic artifacts, and 24-hour total PAC and PVC arrhythmia burdens Primary efficacy was expressed as percentage change ($\Delta\%$) from baseline to Week 24:

$$\Delta\% = \left(\frac{\text{Post-Intervention Count} - \text{Baseline Count}}{\text{Baseline Count}} \right) \times 100$$

Secondary outcomes included Resting Heart Rate (RHR), Systolic/Diastolic Blood Pressure (SBP/DBP), Perceived Stress Scale-10 (PSS-10), and Kessler Psychological Distress Scale (K10) scores measured at baseline (Week 0) and post-intervention (Week 24).

2.5 Statistical Analysis

- ❖ Descriptive Analysis: Continuous data are expressed as Mean $\pm$ Standard Deviation (SD). Baseline parameters between the Pre-Pandemic and Post-Pandemic cohorts were compared using independent samples *t*-tests and Pearson's chi-square (χ^2) tests for categorical variables.
- ❖ Inferential Analysis: Intra-individual changes from baseline to Week 24 were evaluated via paired *t*-tests and repeated-measures ANOVA. Linear Mixed-Effects Models (LMM) with random intercepts for individual subjects were fitted to evaluate Cohort $\times$ Time interaction effects, adjusting for baseline age, sex, baseline PSS-10 scores, and healthcare visit frequency. Statistical analyses were executed using SPSS v29 to evaluate Pre-to-post-intervention changes within each cohort, with two-tailed $p < 0.05$ considered statistically significant.

3. RESULTS AND DISCUSSION

3.1 Preliminary Analysis

3.1 Cohort Characteristics and Baseline Comparison

Both cohorts were well-matched in age, gender distribution, and baseline cardiac parameters (arrhythmia burden, HRV, RHR) (all $p > 0.05$). As hypothesized, the Post-Pan cohort had significantly worse baseline psychological scores, confirming greater pre-intervention psychological distress (PSS-10: 28.5 ± 3.2 vs. 25.8 ± 3.5 , $p < 0.001$; K10: 26.8 ± 3.0 vs. 24.1 ± 3.3 , $p < 0.001$). (World Health Organization, 2022; Santomauro et al., 2021).

Table 1: Baseline Demographic, Cardiovascular, and Psychological Characteristics of Pre-Pandemic (2016–2019) and Post-Pandemic (2021–2024) Cohorts.

Parameter	Pre-Pandemic Cohort (n=390)	Post-Pandemic Cohort (n=390)	Statistical Test (t / χ^2)	p-value
Age (years)	47.2 ± 8.9	48.4 ± 9.3	t = 1.83	0.068
Sex (% Female)	60.8%	62.3%	χ^2 = 0.19	0.663
Baseline SDNN (ms)	88.4 ± 12.1	86.9 ± 11.8	t = 1.75	0.081
Baseline Resting HR (bpm)	76.4 ± 6.8	77.2 ± 7.1	t = 1.61	0.108
Baseline Systolic BP (mmHg)	128.5 ± 10.2	129.8 ± 10.8	t = 1.72	0.086
Baseline Diastolic BP (mmHg)	81.2 ± 6.4	82.0 ± 6.7	t = 1.69	0.091
Baseline PSS-10 Score	25.8 ± 3.5	28.5 ± 3.2	t = 11.24	< 0.001
Baseline K10 Score	24.1 ± 3.3	26.8 ± 3.0	t = 11.96	< 0.001
Intervention Adherence (%)	96.2% ± 3.1%	95.8% ± 3.4%	t = 1.08	0.280

Note: Values are Mean $\pm$ SD or percentages. SDNN = Standard Deviation of Normal-to-Normal intervals; BP = Blood Pressure; PSS-10 = Perceived Stress Scale-10; K10 = Kessler Psychological Distress Scale

3.2 Comparative Treatment Efficacy and Temporal Trends

Both cohorts showed clinical improvements, but the magnitude of response was significantly heightened in the post-pandemic cohort. Patients treated during 2021 achieved the largest gains, which moderated slightly in 2022–2024 but remained above pre-pandemic benchmarks.

Table 2: Intra-Individual Efficacy Outcomes and Between-Cohort Interaction Effects Following 24 Weeks of G7 Multimodal Behavioral Intervention.

Outcome Measure	Pre-Pandemic Mean Change	Post-Pandemic Mean Change	Between-Cohort Differential	p-value (Interaction)
SDNN Increase (ms)	+18.5 ± 4.2	+24.8 ± 5.1	+6.3 ms	< 0.00
PVC Reduction (%)	−52.4% ± 8.1%	−66.8% ± 7.4%	−14.4%	< 0.00
PAC Reduction (%)	−48.1% ± 7.6%	−61.3% ± 6.9%	−13.2%	< 0.00
Resting HR Change (bpm)	−5.2 ± 1.8	−7.9 ± 2.1	−2.7 bpm	< 0.00
PSS-10 Score Change	−6.4 ± 1.2	−10.1 ± 1.5	−3.7 points	< 0.00
K10 Score Change	−5.8 ± 1.1	−9.2 ± 1.4	−3.4 points	< 0.00

Note: Values represent mean intra-individual changes (Δ) from baseline to Week 24. Group-by-time interaction evaluated via repeated-measures ANOVA.

3.3 Discussion

This comparative longitudinal analysis yields two principal findings. First, it confirms the sustained, long-term efficacy and replicability of the proven standardized multimodal behavioral intervention Group 7 (G7) protocol (combining Shiatsu, structured exercise, stress management, and lifestyle counseling) across two distinct temporal cohorts (Soliman et al., 2025). Second, and more notably, the intervention's efficacy was greater in the cohort treated after the onset of the COVID-19 pandemic. This cohort, which exhibited higher baseline psychological distress and likely greater disruption to health

behaviors, achieved superior outcomes, with the largest improvements observed in the immediate post-pandemic year (2021). These findings are consistent with behavioral medicine models suggesting that individuals experiencing elevated distress may be more receptive to behavioral interventions, particularly when the intervention directly addresses the domains most disrupted by the stressor (stress regulation, physical activity, and daily routines). (Bonanno & Mancini, 2012; Levine et al., 2022).

▪ Psychophysiological Mechanisms and Post-Crisis Plasticity

The core objective of this study was to evaluate whether a major population-wide psychological stressor—the COVID-19 pandemic—blunted or enhanced patient responsiveness to a structured multimodal lifestyle intervention. The empirical evidence demonstrates that patients treated in the post-pandemic era achieved significantly greater autonomic recovery and clinical arrhythmia suppression compared to pre-pandemic controls. This hyper-responsiveness can be interpreted through dual autonomic and behavioral medicine models (Thayer & Lane, 2007; Porges, 2018).

Physiologically, chronic psychological distress induces sustained sympathetic hyperactivation, downregulation of cardiac beta-adrenergic receptor responsiveness, and marked vagal withdrawal (Thayer & Lane, 2007; Lampert, 2010). This baseline state lowers autonomic tone to near-depleted levels, creating a wide functional window for therapeutic restoration. When multimodal interventions—specifically Shiatsu acupoint stimulation (BL15, PC6, HT3, HT6, HT7, HT9) and slow diaphragmatic breathing with lifestyle modification—are introduced into a hyper-sympathetic physiological environment, the absolute restoration of vagal efferent drive (SDNN) is substantially larger than in individuals starting from moderate stress baselines (Clancy et al., 2014; Soliman et al., 2025). Somatosensory mechanoreceptor activation via pressure point application triggers autonomic reflexes that diminish central sympathetic outflow and reduce circulating catecholamines (Clancy et al., 2014).

Behaviorally, the acute post-lockdown transition period presented a "teachable moment" characterized by elevated health anxiety and heightened motivation for lifestyle reorganization (Bonanno & Mancini, 2012). The pandemic disrupted daily routines, physical activity levels, and sleep architectures across populations (Huang & Zhao, 2020; Giorgi et al., 2020). When presented with a structured, daily multimodal protocol (G7), post-pandemic patients exhibited exceptional engagement, leveraging the structured routines to rebuild daily health behavior patterns. This behavioral adherence directly amplified the physiological effects of the physical interventions, breaking the cyclical feedback loop where psychological anxiety triggers autonomic dysregulation, which in turn precipitates cardiac dysrhythmias (Levine et al., 2022).

Our behavioral protocol, designed to enhance vagal tone, reduce perceived stress, and rebuild daily routines, may have addressed this elevated need, resulting in a greater absolute magnitude of change. This finding is hypothesis-generating: it suggests that individuals with higher baseline distress and greater behavioral disruption may be particularly responsive to structured behavioral interventions (Bonanno & Mancini, 2012). The observation of peak efficacy in 2021 is preliminary but intriguing from a behavioral medicine perspective. The immediate aftermath of the acute pandemic phase may have represented a period of unique behavioral plasticity—a "teachable moment" where individuals were most motivated to engage in health-promoting behaviors. This period of greatest vulnerability was concurrently associated with the greatest measured improvement, aligning with the concept that there may be critical windows for behavioral intervention following population-level traumatic events, potentially mediated through improvements in physiological regulation (Porges, 2018). The behavioral intervention may have disrupted the cycle whereby stress exacerbates autonomic dysfunction, which in turn fuels further anxiety and maladaptive health behaviors (Thayer & Lane, 2007; Levine et al., 2022).

Furthermore, previous chronotherapeutic investigations within this research program established that non-pharmacological interventions administered within 15 minutes of an acute arrhythmic event produced 2- to 3-fold greater autonomic stabilization compared to delayed application (Soliman et al., 2025). The present study reinforces these findings, demonstrating that multi-component therapy combining Shiatsu, exercise, and stress reduction achieves superior outcomes over monotherapy, particularly during epochs of heightened baseline vulnerability.

▪ Comparison with Previous Literature

Our findings extend previous research on behavioral interventions for cardiac patients (Levine et al., 2022). While stress management and exercise interventions have been studied individually in arrhythmia populations, few studies have examined

multimodal behavioral interventions following a population-wide stressor. The present study provides preliminary evidence that combined behavioral interventions targeting stress, activity, and lifestyle routines may be particularly valuable in post-crisis contexts, potentially due to synergistic effects across behavioral domains.

A separate randomized controlled trial by the same research group prospectively evaluated 195 patients from this cohort, comparing the chronotherapeutic efficacy of multimodal non-pharmacological interventions on cardiac autonomic function, arrhythmia burden, and psychological well-being. That study established a clear efficacy hierarchy, with multimodal therapy demonstrating superior outcomes, and introduced a novel chronotherapeutic finding: interventions applied within 15 minutes of an arrhythmic episode produced 2 to 3 times greater improvements across all outcomes compared to delayed treatment. These findings directly support the present study by confirming that multimodal non-pharmacological interventions are highly effective and that treatment timing relative to symptom onset is a critical modifiable factor. Furthermore, a separate published trial involving 90 patients directly compared laser acupuncture, Shiatsu, lifestyle modification, and their combinations, further confirming the superiority of multimodal approaches G5 (Shiatsu + laser acupuncture + lifestyle modification) > G4 (Shiatsu + laser acupuncture) > monotherapies G1, G2, G3 in arrhythmia management (Soliman et al., 2025).

▪ Methodological Considerations

The integration of the prospective sub-sample ($n = 195$) structured in compliance with CONSORT standards ensures high internal validity for these observations. As detailed in Figure 1, clear documentation of screening exclusions ($n = 88$), pre-randomization exclusions ($n = 1$), and uniform block allocation confirms that the sub-sample was well-controlled and free from major confounding psychiatric or structural cardiac pathology. The 100% completion rate over 6 months demonstrates the clinical feasibility and patient acceptance of the G7 multimodal protocol when delivered with weekly behavioral reinforcement.

▪ Limitations

Several limitations should be acknowledged:

- ❖ **Retrospective Cohort Design and Confounding:** The primary comparison relies on a retrospective observational design ($N = 780$), making it inherently susceptible to unmeasured societal confounders associated with the pandemic. Although linear mixed models adjusted for baseline demographics and stress, residual temporal confounding—such as shifts in healthcare access, diagnostic referral biases, and broader societal lifestyle changes—cannot be entirely excluded.
- ❖ **Behavioral Mechanisms:** The specific behavioral mechanisms driving enhanced responsiveness (e.g., increased self-efficacy, reduced behavioral barriers) cannot be definitively isolated from observational data.
- ❖ **Post-Hoc Temporal Analysis:** The 2021 subgroup breakdown was post-hoc and should be interpreted as hypothesis-generating.
- ❖ **Absence of Direct Behavior Logs:** No direct continuous measures of health behaviors (e.g., accelerometry logs, sleep wearable data) were available for the full historical cohort, limiting our ability to quantify specific behavioral mediators.

▪ Future Directions

Future research should:

- ❖ **Behavioral Tracking:** Prospectively measure behavioral mediators using digital health technologies (physical activity tracking, continuous sleep architecture monitoring, diet diaries).
- ❖ **Moderator Analysis:** Examine psychological moderators such as baseline self-efficacy, health anxiety, and social support networks.
- ❖ **Long-Term Durability:** Explore the long-term durability of autonomic and clinical benefits beyond 6 and 12 months.

4. CONCLUSION

In conclusion, this analysis demonstrates that a multimodal behavioral intervention combining stress management, structured exercise, and lifestyle modification was effective both before and after the COVID-19 pandemic. The identical protocol produced superior autonomic and psychological outcomes in the post-pandemic cohort, which had higher baseline psychological distress and likely greater behavioral disruption, with the largest effects observed in 2021. These findings

suggest that individuals with elevated psychological distress may derive particular benefit from behavioral interventions targeting stress regulation, physical activity, and daily routines. From a public health perspective, these findings support the strategic deployment of behavioral interventions in the aftermath of collective crises, when motivation for behavior change may be naturally elevated and the potential for benefit may be greatest.

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AUTHOR CONTRIBUTIONS

All Authors: Review, Visualization, Supervision, Formal analysis.

Corresponding Author: Conceptualization, Investigation, Methodology, Original draft, Writing—Review, Editing, Data Curation, Resources.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ETHICS STATEMENT

Ethical approval for this study was granted by the Ethical Committee of the Institutional Review Board of the National Institute of Laser Enhanced Science (NILES) and Critical Care Unit of Kasr-Alaini Hospital (protocol No. 10.21608). Informed consent was obtained from all individual participants included in this study.

DATA AVAILABILITY STATEMENT

Data supporting the findings of this study are available from the corresponding author upon reasonable request.

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