

Real-World Effectiveness of a Novel AI-Software Dependent Neuromodulation (ASDN) with Remote Monitoring Capability Field Stimulation Device for Chronic Pain: A 24-Month Analysis of Over 2000 Patients

Maja Green¹, Adam Cabble¹, Michael Bailey², Maria L Kappell¹, Bart Billet³, Choll W Kim⁴, Jaspal R Singh⁵, Manish Suthar⁶, Hemant Kalia⁷, Shari Kappell¹, Krishnan Chakravarthy¹

¹Department of Pain Medicine, NXTSTIM Inc., San Diego, CA, USA; ²Department of Neuroscience, Monash University, Clayton, Victoria, Australia; ³Department of Anaesthesiology, AZ Delta Hospital, Roeselare, Belgium; ⁴Department of Orthopaedic Surgery, Scripps Memorial Hospital, La Jolla, CA, USA; ⁵Center for Global Health, Weill Cornell Medicine, New York, NY, USA; ⁶Pain Prevention and Rehabilitation Center, Chesterfield, MO, USA; ⁷Department of Pain Medicine, Invision Health, Rochester, NY, USA

Correspondence: Maja Green, Department of Pain Medicine, NXTSTIM Inc., 5362 Sweetwater Trails, San Diego, CA, 92130, USA, Tel +1 858 910-1778, Email mgreen@nxtstim.com

Importance: Chronic pain is a leading cause of disability worldwide, and conventional pharmacologic treatments are often limited by side effects, inadequate efficacy, and risk of dependency. Non-invasive neuromodulation therapies such as TENS and EMS offer alternatives but are traditionally constrained by fixed stimulation protocols and low user engagement.

Objective: To evaluate the 24-month real-world effectiveness of EcoAI™, an AI-driven wearable system delivering adaptive TENS and EMS for chronic pain management in community settings.

Design, Setting, and participants: This retrospective observational cohort study analyzed de-identified data from 2135 adult users across the United States between January 2023 and March 2025. All users completed at least one therapy session and submitted symptom data via a mobile application.

Intervention: EcoAI delivers transcutaneous electrical nerve stimulation (TENS) to modulate afferent pain signaling and electrical muscle stimulation (EMS) to improve local circulation and neuromuscular function. An embedded AI engine dynamically adjusts stimulation intensity, waveform, and duration based on user-reported outcomes and physiological markers.

Main Outcomes and Measures: Primary outcome: change in self-reported pain score (0–10 numeric scale). Secondary outcomes: mood, physical function, social engagement, work activity, and overall well-being. Session adherence and device usage patterns were also analyzed.

Results: Across 187,930 recorded sessions, median pain scores declined from 6.0 at baseline to 4.0 at 6 months and 3.0 at 24 months. Statistically significant improvements ($p < 0.001$) were also observed in secondary domains. Optimal outcomes were achieved with 2–4 sessions per day lasting 20–59 minutes. Older adults (≥ 60 years) demonstrated greater engagement and pain relief. No serious adverse events were reported.

Conclusions and Relevance: In this retrospective, decentralized study, the EcoAI platform demonstrated sustained, multidimensional benefit in adults with chronic pain. These findings support the potential of AI-driven TENS/EMS as a safe, scalable, and personalized adjunct to pharmacologic care.

Keywords: chronic pain, transcutaneous electrical nerve stimulation, TENS, electrical muscle stimulation, EMS, field stimulation, remote therapy monitoring, remote patient monitoring, artificial intelligence, digital therapeutics, real-world evidence

Introduction

Chronic pain remains a pervasive and costly public health concern, impacting over 50 million adults in the United States and contributing to significant personal and societal burden, including disability, lost productivity, increased healthcare utilization, and long-term opioid dependence.^{1–5} Conditions such as low back pain, neuropathy, fibromyalgia, and osteoarthritis collectively account for billions of dollars annually in direct and indirect costs. For many patients, chronic pain becomes a persistent, life-altering condition that is difficult to treat and often inadequately addressed by existing therapeutic approaches. Despite the broad range of pharmacologic options, including non-steroidal anti-inflammatory drugs (NSAIDs), anticonvulsants, antidepressants, and opioids, long-term efficacy remains modest, with diminishing returns over time, dose-limiting side effects, and risk of dependency or misuse.^{6–11} The ongoing opioid epidemic has further intensified the demand for safer, non-addictive treatment strategies that can be sustained in real-world settings and integrated into multimodal care. In this landscape, non-pharmacologic modalities have received growing attention. Among these, non-invasive neuromodulation technologies such as transcutaneous electrical nerve stimulation (TENS) and electrical muscle stimulation (EMS) have demonstrated potential in targeting peripheral and central pain pathways without pharmacologic exposure.^{12–15} TENS is thought to reduce pain through multiple mechanisms, including activation of large-diameter A β afferent fibers that inhibit nociceptive transmission at the spinal cord level (gate control theory), as well as stimulation of descending inhibitory pathways involving endogenous opioids and serotonergic systems. TENS may also reduce peripheral sensitization by modulating inflammatory mediators and nociceptor thresholds at the site of stimulation.¹²

However, traditional TENS/EMS systems are often hindered by fixed, generic programs that do not adapt to individual variability in pain mechanisms, symptom fluctuation, or body site response. These limitations, combined with low user engagement and lack of remote monitoring, have constrained their broader utility and clinical adoption. Spinal cord stimulation (SCS), a more advanced form of neuromodulation, has proven effective in certain pain syndromes and is widely used in refractory cases. Nevertheless, SCS requires surgical implantation, ongoing programming by specialists, and is associated with risks including infection, lead migration, hardware failure, and eventual explantation in up to 30% of cases.¹⁶ The financial cost and invasive nature of SCS make it impractical as a first-line or population-level solution, particularly when addressing chronic pain in broader, community-based cohorts. Consequently, there remains a critical unmet need for scalable, non-invasive, patient-centric solutions that combine the safety of TENS/EMS with the adaptability and precision typically seen in implantable systems.^{1,2,12,17,18}

EcoAI represents a novel approach to this challenge. Developed as an FDA-cleared, wearable neuromodulation platform, EcoAI integrates TENS and EMS technologies with artificial intelligence, enabling real-time, user-specific adjustments to therapy parameters based on individualized inputs. Unlike conventional devices, EcoAI operates as a closed-loop system, continuously analyzing user-reported outcomes, physiological markers (eg, heart rate variability, muscle activity), body location, and prior session performance to tailor stimulation frequency, intensity, and waveform on an ongoing basis¹⁹ ([Supplementary Figure 1](#)). While other digital platforms have begun exploring algorithmic personalization in pain management, most remain early in development and lack published real-world data at scale. To date, few AI-enhanced non-invasive systems have demonstrated sustained engagement or multidomain symptom improvement across diverse populations. This study presents the first large-scale evaluation of EcoAI in a real-world setting, examining its performance across 24 months of decentralized use. The platform's design allows patients to control session timing and body placement via a mobile interface, while the AI engine refines treatment recommendations to maximize effectiveness and maintain engagement. This 24-month real-world evaluation of EcoAI examines its performance in a decentralized cohort of 2135 adult users spanning over 187,000 device sessions. Primary outcomes include longitudinal changes in pain intensity and multidimensional functional scores, such as physical activity, mood, social and occupational function, and overall well-being. The study also analyzes usage behaviours, stimulation characteristics, and demographic correlates of response. By leveraging remote monitoring, large-scale patient-reported outcomes, and adaptive stimulation algorithms, this investigation aims to clarify the clinical utility, tolerability, and engagement dynamics of AI-driven, non-invasive neuromodulation in the management of chronic pain.

Methods

Design and Data Source

This retrospective observational study analyzed de-identified, real-world data collected through the EcoAI neuromodulation platform between January 2023 and March 2025. This study was determined to be exempt from ongoing IRB oversight under 45 CFR 46.104(d)(4) by WCG IRB (Work Order #1-1879470-1; IRB Tracking #20252405), based on the secondary use of fully de-identified data with no re-identification possible, in accordance with US federal regulations. EcoAI is a wearable, app-connected system that delivers TENS and EMS, enhanced by artificial intelligence (AI)-driven therapy personalization. The device is self-administered using surface electrodes and gel conductive pads, with real-time data captured via a mobile application that guides users through electrode placement, session setup, and parameter adjustment. All therapy session metadata, including anatomical treatment site, waveform selection, stimulation intensity, session frequency, and duration, were automatically logged through the app and transmitted to a secure, cloud-based platform equipped with remote patient monitoring (RPM) capabilities. This infrastructure enabled continuous data collection, storage, and integration of patient-reported outcomes with system-logged device usage. Weekly symptom data were submitted by users through the app using structured 0–10 numeric rating scales across six clinical domains. Pain locations included axial, appendicular, and peripheral regions, with frequent switching between sites by individual users. Each session was linked to a unique anonymized user identifier. The dataset encompassed all recorded therapy sessions conducted during the study period and underwent standardized quality assurance procedures, including range validation, de-duplication, timestamp verification, and preprocessing. The study adhered to all applicable regulatory and ethical guidelines for the secondary use of anonymized digital health data.

Setting

All data were generated under naturalistic conditions in real-world, home-based environments across the United States. Users engaged in self-managed therapy without in-clinic oversight, supported by app-guided interfaces and automated tracking through the cloud-based RPM platform.

Participants

This study analyzed a fully de-identified, retrospective dataset collected through self-directed use of the EcoAI system in community settings. As such, detailed clinical information—such as formal pain diagnoses, duration of symptoms, or medication use—was not captured. Inclusion criteria were intentionally broad to reflect real-world use, with no exclusions based on anatomical treatment site, underlying etiology, comorbidities, or concurrent therapies. Eligible users were adults (≥ 18 years) who completed at least one therapy session and submitted at least one weekly symptom report. The final analytic cohort comprised 2135 unique users (mean age 58.7 ± 15.6 years; 54% female) who completed 187,930 valid sessions across a wide range of pain conditions, as self-identified through the app interface.

Device Use and Engagement Metrics

The EcoAI system captured session-level metadata including frequency of use, stimulation intensity, session duration, and waveform selection. Users self-administered therapy via surface electrodes and had the ability to adjust stimulation parameters in real time through the mobile interface. All metadata were automatically logged and linked to a unique anonymized identifier. These data were used to assess engagement patterns, stimulation behaviors, and usage trends in the analytic cohort.

Outcome Measures

Patient-reported outcomes were collected weekly via the EcoAI app. Domains assessed included pain, mood, physical function, social engagement, work-related activity, and overall well-being. Each was rated on a 0–10 numeric scale, with lower scores indicating symptom improvement or reduced burden. Longitudinal outcome data were analyzed at approximately 1 (± 15 days), 3 (± 30 days), 6 (± 30 days), 12 (± 45 days), and 24 (± 15 days) months from each user's first recorded session.

Statistical Analysis

Descriptive statistics were used to summarize user demographics, device engagement metrics, and clinical outcomes. Continuous variables were expressed as means (SD) or medians (IQR), and categorical variables as frequencies and percentages. Longitudinal changes in symptom domain scores were evaluated using the Kruskal–Wallis test. Pairwise comparisons to baseline were conducted using Mann–Whitney *U*-tests with Bonferroni correction. Responder rates, defined as stability or improvement relative to baseline, were calculated at each time point using the Wilson method to generate 95% confidence intervals. Session frequency (1 to ≥ 9 /day) and session duration (<20, 20–59, ≥ 60 minutes) were compared using one-way ANOVA and Kruskal–Wallis tests with post hoc Tukey or Dunn’s correction as appropriate. Between-group comparisons by age (18–39, 40–59, and ≥ 60 years) were evaluated using ANOVA with Bonferroni adjustment. Variables with non-normal distributions, including treatment duration, were log-transformed prior to analysis. Multivariable linear regression was performed to identify independent predictors of session-level pain relief. The base model included age, sex, baseline pain score, anatomical treatment site, and dominant waveform program. Sequential models incorporated session frequency, cumulative treatment duration, waveform variability, and site-specific usage patterns. Final models included interaction terms between stimulation program and anatomical region. All continuous predictors were standardized. Model diagnostics included Shapiro–Wilk and Breusch–Pagan tests, and multicollinearity was assessed via variance inflation factors ($VIF < 2.0$). Model performance was evaluated using adjusted R^2 , Akaike information criterion (AIC), and likelihood ratio testing. Statistical analyses were conducted using R (version 4.2.2) and SPSS (version 28.0). Missing data, which accounted for <2% of observations, were assumed to be missing at random and were handled using complete-case analysis. Sensitivity analyses were performed using multiple imputation and confirmed the robustness of primary results. Session-level pain relief was calculated as the percentage reduction in pain score relative to each user’s first reported (baseline) value. For each session, users were prompted to rate their pain intensity (0–10 scale), and this was compared to their initial baseline entry. This allowed for standardized, within-user comparisons over time.

Results

Participants

Between January 2023 and March 2025, 2135 adult users (mean [SD] age, 58.7 [15.6] years; 54% female) completed a total of 187,930 valid EcoAI therapy sessions. The median number of sessions per user was 20 (interquartile range [IQR], 5–76), and the median treatment duration was 12 days (IQR, 4–30). Therapy was self-administered, and anatomical targeting was highly variable: the lower back (40%), upper back (13%), knee (10%), buttock (6%), and thigh (7%) were most commonly treated (Figure 1).

Primary and Secondary Outcomes

Pain and functional domain scores were assessed longitudinally using weekly in-app reporting. Of 1303 users who submitted baseline scores, follow-up data were available from 350 at 1 month, 216 at 3 months, 90 at 6 months, 34 at 12 months, and 10 at 24 months. Significant reductions from baseline were observed across all six domains. Median pain scores declined from 4.1 at baseline to 1.9 at 24 months ($p = 0.018$). Similarly, mood scores decreased from 3.7 to 1.4 ($p < 0.01$), and overall well-being scores improved from 3.9 to 2.0 ($p = 0.0081$). Gradual but statistically significant improvements were also observed in physical function (from 3.7 to 1.6; $p = 0.0055$), social engagement (from 3.4 to 1.4; $p < 0.05$), and work-related activity (from 3.3 to 1.6; $p < 0.01$) (Figure 2). Across domains, responder rates, defined as improvement or stability relative to baseline, ranged from 66.4% (pain) to 70.8% (mood) (Figure 3).

Session Frequency, Duration and Intensity

Among the 2135 users, the median number of sessions completed was 20 (IQR, 5–76), with a mean treatment duration of 74 days. Session frequency demonstrated a bimodal distribution: the majority of users performed 1–3 sessions per day, while a smaller subset used the device ≥ 5 times per day. Maximum reported benefit occurred among users completing 2–4 sessions daily. Session durations varied, with 20–59 minutes associated with the highest median pain relief. Short

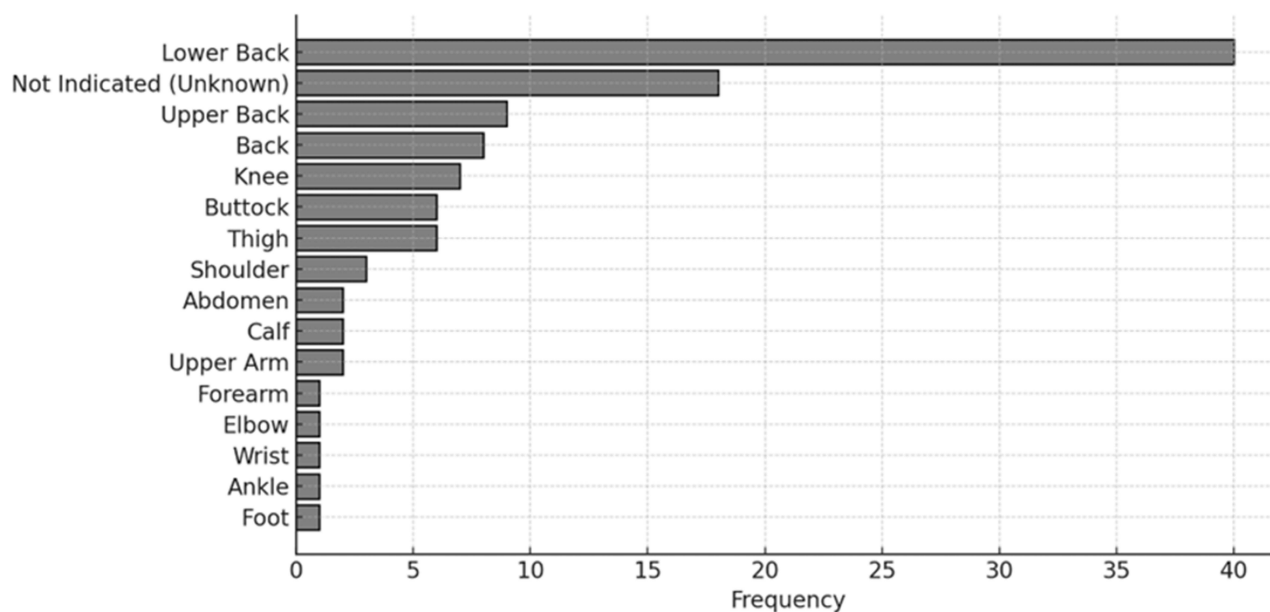


Figure 1 Distribution of anatomical regions targeted during 187,930 EcoAI sessions from 2135 users between January 2023 and March 2025. The lower back was the most frequently treated site, comprising 40% of all sessions, followed by the upper back, generalized back entries, knee, thigh, and buttock. Less common treatment areas included the upper arm, shoulder, calf, abdomen, foot, and distal extremities. A substantial proportion of sessions (~13%) lacked specific anatomical designation (“Not Indicated”). Data reflect user-reported entries through the EcoAI companion application.

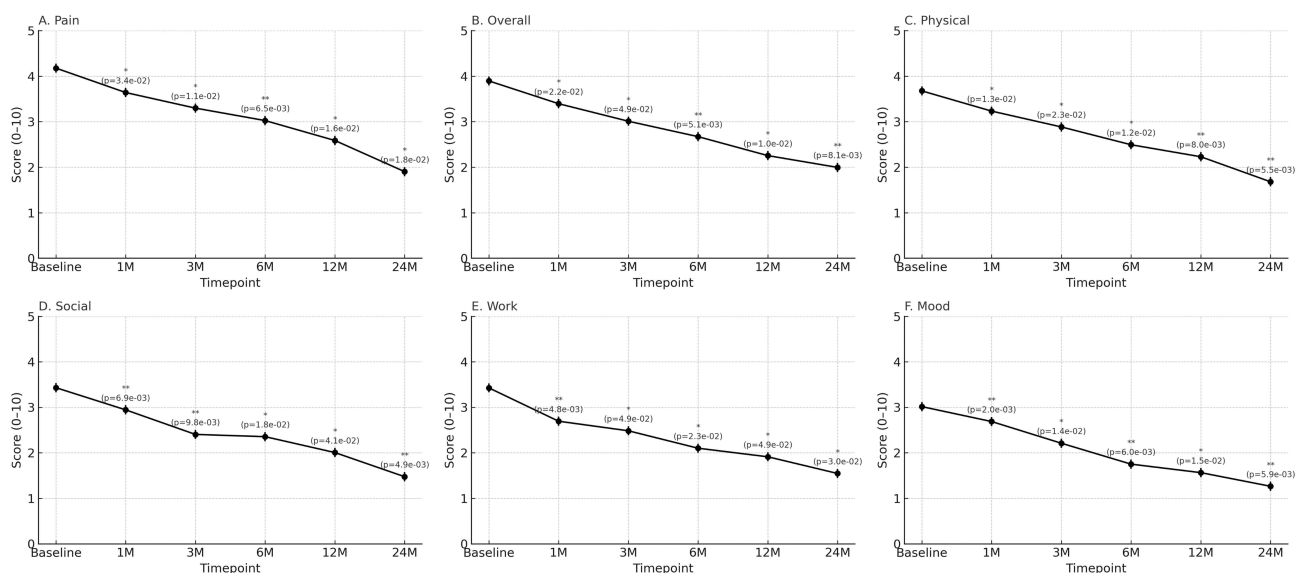


Figure 2 Line plots display median scores (0–10 scale) for pain (A), overall well-being (B), physical function (C), social engagement (D), work-related activity (E), and mood (F) from baseline through 1, 3, 6, 12, and 24 months. All outcomes were collected via the EcoAI mobile application’s structured survey, designed in collaboration with clinicians and patient advisors to capture multidimensional impact of chronic pain. In all domains, lower scores indicate reduced symptom burden or improved function, with 0 representing the best possible outcome. Error bars denote interquartile ranges. Statistical comparisons between each follow-up timepoint and baseline were conducted using the Mann–Whitney *U*-test with Bonferroni correction. P-values are shown above each timepoint; significance thresholds are indicated as **p* < 0.05, ***p* < 0.01, and ****p* < 0.001. Substantial improvements were observed across all domains, with the greatest absolute reductions in pain and mood. Gains in physical and social function occurred more gradually but were sustained through 24 months.

sessions (<20 minutes) were less effective, while extended sessions (>60 minutes) showed reduced efficacy and increased variability. Users also engaged dynamically with the system, frequently rotating among stimulation programs and modifying intensity based on feedback and symptom response. These findings are further illustrated in Figure 4.

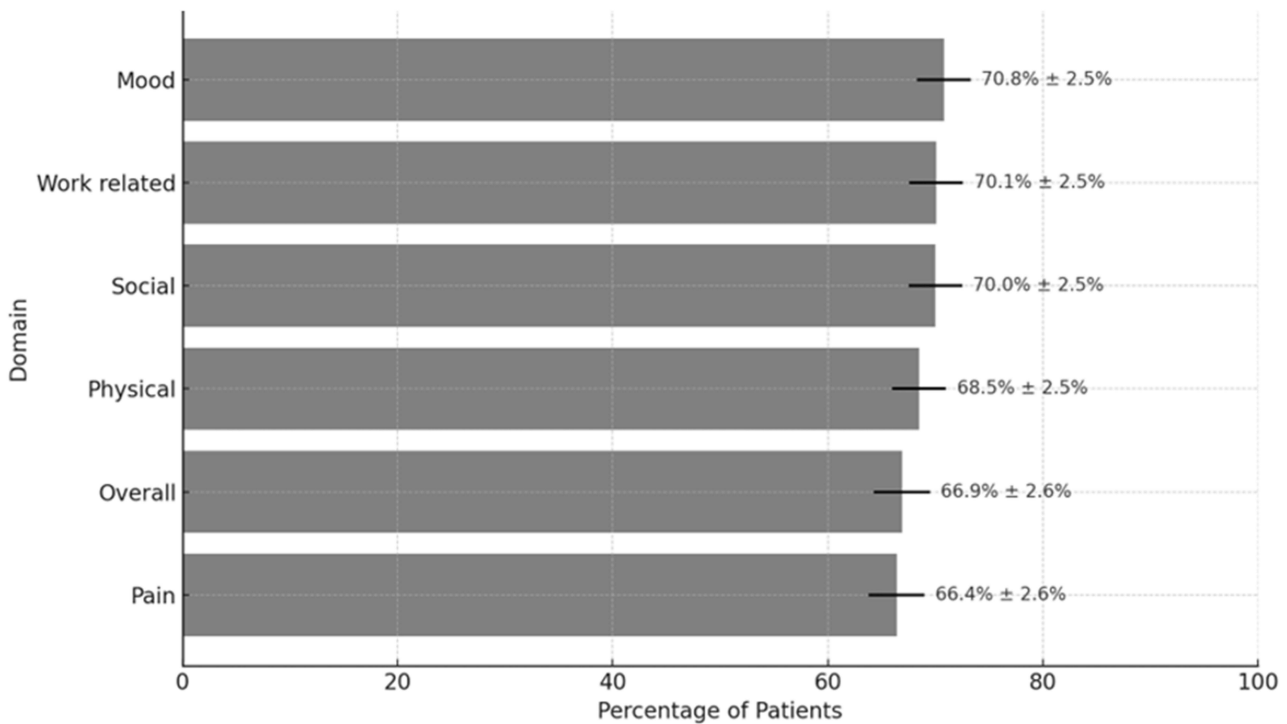


Figure 3 Responder rates by domain with 95% Confidence Intervals. This bar chart displays the percentage of patients who reported improvement or stability (no worsening from baseline) across six domains: pain, overall well-being, physical function, social engagement, work-related activity, and mood. Data were collected through weekly opt-in surveys within the EcoAI mobile application. Error bars represent 95% confidence intervals calculated using the Wilson method. Responder rates ranged from 66.4% (pain) to 70.8% (mood), indicating broad multidimensional benefit in a real-world cohort using AI-guided TENS/EMS therapy.

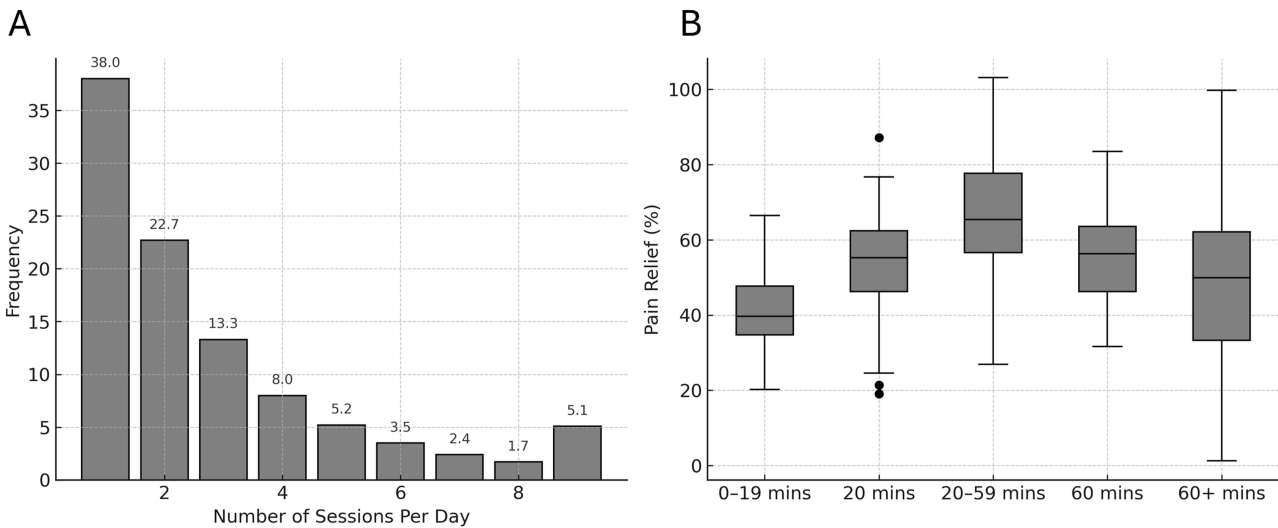


Figure 4 (A) Frequency of daily device usage categories. Bar chart showing the percentage distribution of users by number of sessions per day. The majority (38%) used the device once daily, with declining frequency at higher usage rates. The optimal range for therapeutic engagement, 2–4 sessions per day, was used by approximately 41% of the cohort. **(B)** Pain relief by session duration. Box plot illustrating the distribution of session-level pain relief (%) across five predefined session duration categories. Sessions lasting 20–59 minutes were associated with the highest median pain relief. Short sessions (<20 minutes) produced lower median benefit, while prolonged sessions (>60 minutes) showed greater variability and reduced efficacy. Box plots represent interquartile ranges with whiskers denoting the full range, and outliers plotted as individual points.

Session Characteristics and Usage Patterns

A non-linear association was found between session frequency and pain relief. Users performing 2 to 4 sessions per day reported the highest mean reduction in pain (46–48%), outperforming both lower-frequency (1/day, 40%) and high-

frequency users (>5/day, 42%). Optimal session duration ranged from 20 to 59 minutes (Figure 4A). Pain relief was significantly lower in sessions under 20 minutes (32%) or over 60 minutes (40%) ($p < 0.001$ for both) (Figure 4B).

User behavior followed a bimodal distribution, with most users discontinuing within 30 days, while a distinct subgroup engaged in long-term use (≥ 80 days) (Figure 5A and B). Older adults (≥ 60 years) reported higher mean pain relief (48%) and used the device longer (mean, 83 days) compared with younger adults (mean, 26 days; 42% relief; $p < 0.001$) (Figure 5C). Responder rates increased with cumulative use: 74.2% in users with <1 month of therapy versus 86.3% in those exceeding 12 months ($p = 0.0012$) (Figure 5D).

Anatomical Targeting and Effectiveness

Pain relief varied by stimulation site. The greatest benefit was reported from sessions targeting the foot and ankle (52–55%), followed by the knee (48%) and hip (46%). Lower and upper back sessions yielded intermediate relief (44% and 42%, respectively), while elbow and wrist sites produced the least improvement (30–35%) ($p < 0.001$ for between-site comparisons) (Table 1).

Predictors of Pain Relief

Multivariable linear regression identified several independent predictors of greater session-level pain relief, including older age ($\beta = 0.13$; $p < 0.001$), longer treatment duration ($\beta = 0.09$; $p = 0.002$), and moderate session frequency (2–4/day; $\beta = 0.11$; $p < 0.001$). Stimulation intensity was inversely correlated with pain scores, suggesting a dose-responsive

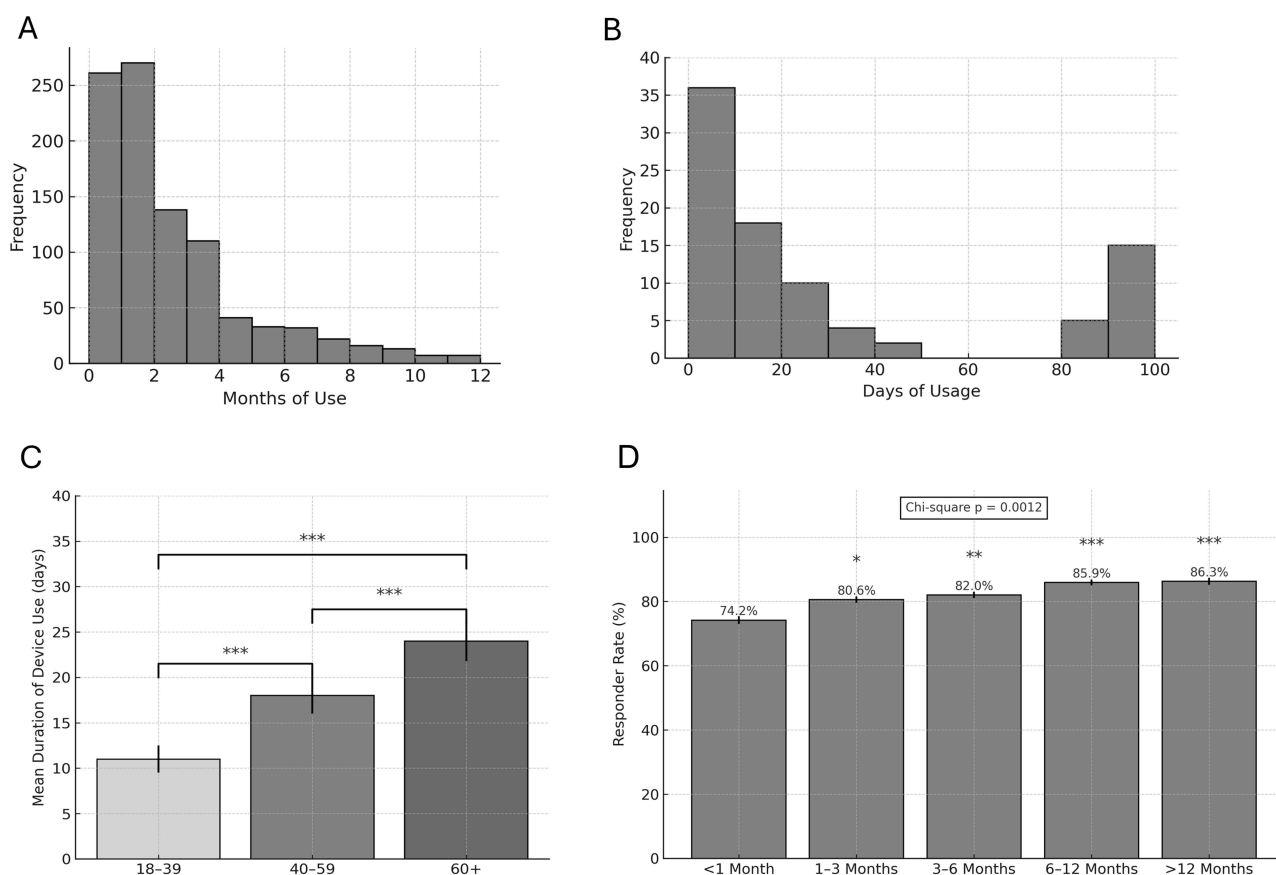


Figure 5 (A) Histogram of months of use showing a right-skewed distribution, with most users engaging for 1–3 months and a smaller subset extending usage beyond 6 months. (B) Histogram of actual days of usage indicating a bimodal distribution, with peaks at short-term (<30 days) and long-term (>80 days) engagement. (C) Mean duration of device use by age group. Older users (≥ 60 years) demonstrated significantly longer use than younger age groups, with pairwise comparisons between all groups reaching statistical significance ($***p < 0.001$). (D) Responder rate ($\geq 30\%$ pain reduction) stratified by total duration of use. A clear upward trend in response rates is observed with longer engagement, ranging from 74.2% for <1 month to 86.3% for >12 months. Chi-square test confirmed a significant association between duration of use and response rate ($p = 0.0012$). Significance annotations: * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.

Table 1 Mean Percentage Pain Relief by Anatomical Treatment Location

Body Location	Percentage Pain Relief
Ankle	67
Foot	58
Knee	50
Calf	47
Abdomen	43
Shoulder	41
Back	40
Lower Back	37
Thigh	37
Not Indicated (Unknown)	37
Upper Back	33
Forearm	33
Upper Arm	32
Buttock	30
Elbow	30
Wrist	25

Notes: This table summarizes the average pain relief reported by users following sessions targeting specific body regions. The highest levels of pain relief were observed at the ankle (67%) and foot (58%), followed by knee (50%) and calf (47%). Lower-extremity and distal treatment areas generally produced greater analgesia than upper-extremity or proximal regions. Sites such as the wrist, elbow, and buttock demonstrated the lowest average relief (25–30%), possibly reflecting anatomical sensitivity, electrode placement challenges, or underlying pain etiology. Data are derived from session-level entries across the 24-month study period using the EcoAI platform.

relationship. The strongest predictors were anatomical location and stimulation program, particularly when analyzed as interaction terms. Certain program-site combinations produced average pain reductions exceeding 60%. The final model explained 28% of the variance in session-level pain relief (adjusted $R^2 = 0.28$) and passed all model diagnostic checks (variance inflation factors <2.0 ; assumptions of linearity and homoscedasticity met) (Figure 6A–E).

Discussion

This 24-month real-world evaluation provides robust and clinically significant evidence supporting the use of EcoAI, an AI-guided, non-invasive neuromodulation system, as an effective and scalable digital therapeutic for chronic pain. Among 2135 adult users completing 187,930 self-directed therapy sessions, statistically and clinically meaningful improvements were observed across six key domains: pain, mood, physical function, social engagement, work-related activity, and overall well-being. These gains were not only durable, persisting through 12 and 24 months, but were achieved in fully decentralized, self-managed environments without in-clinic programming or procedural intervention. This real-world implementation model adds critical ecological validity to a field historically dominated by short-term trials or tightly controlled implantable device studies. EcoAI's performance reflects a foundational distinction from conventional TENS and EMS systems: its closed-loop, adaptive architecture. While traditional TENS/EMS systems deliver fixed stimulation protocols with limited patient personalization, EcoAI dynamically adjusts stimulation parameters in real time using AI algorithms trained on prior user sessions, physiological data, and self-reported symptoms. These adaptations include modulation of stimulation intensity, waveform frequency and shape, session duration, and anatomical targeting. This flexibility allows for greater inter-individual and intra-individual responsiveness, critical in a clinical landscape where pain perception and response are highly heterogeneous and influenced by neuroplastic, psychosocial, and comorbid factors.

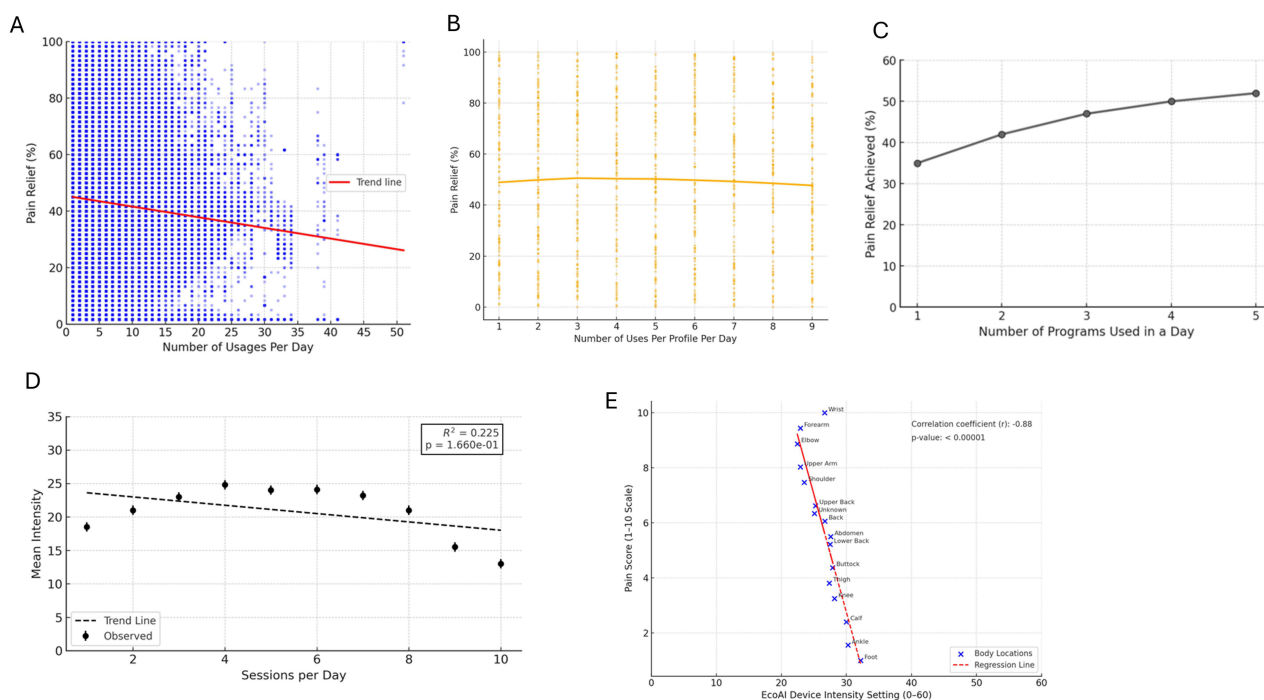


Figure 6 (A) Inverse correlation between mean pain score and average intensity setting across anatomical locations ($r = -0.88$, $p < 0.00001$), indicating that higher stimulation intensities were associated with lower pain scores. (B) Pain relief by number of daily usages, showing a negative association beyond 20+ sessions/day; heatmap density and a red trend line illustrate this relationship. (C) Pain relief by number of uses per profile per day, with a bell-shaped curve peaking at moderate use frequencies (2–4 uses). (D) Positive association between number of stimulation programs used per day and pain relief achieved, indicating improved outcomes with greater variation in program use. (E) Relationship between daily session frequency and mean stimulation intensity, with a slight decline in intensity at higher session counts ($R^2 = 0.225$, $p = 0.166$). Together, these subplots highlight how usage frequency, variety, and stimulation intensity influence pain outcomes in real-world EcoAI device use.

Central to EcoAI’s architecture is the dual-source data model, integrating patient-reported outcomes via a mobile app with remote nursing oversight. This hybrid approach enhances validity, mitigates safety risks, and facilitates continuous engagement, factors rarely achieved at scale in non-invasive pain management. The app-based interface empowers users to select stimulation parameters while the backend AI adapts these inputs in accordance with evolving response profiles. Such personalization, combined with remote monitoring, represents a paradigm shift in chronic pain treatment, moving from episodic, clinic-centered care to intelligent, continuous self-management supported by data science.

The analysis revealed a reproducible and clinically actionable dose–response relationship. Maximum analgesia was achieved with 2 to 4 sessions per day, each lasting 20 to 59 minutes. Interestingly, diminishing returns were observed with overuse (defined as >25 sessions per day), suggesting a threshold beyond which neural desensitization or attentional fatigue may undermine therapeutic efficacy. This phenomenon is consistent with preclinical studies of neuromodulatory tolerance and reinforces the importance of structured dosing, even in self-directed settings. From a translational standpoint, these findings support the integration of adaptive stimulation schedules that can maintain efficacy while preventing habituation, an ongoing challenge in both TENS and implantable neuromodulation therapies. Beyond frequency and duration, stimulation intensity and waveform diversity emerged as independent predictors of pain relief. Higher intensity stimulation was associated with greater analgesic outcomes, a finding that aligns with evidence from gate control theory and descending inhibitory pathway activation. Meanwhile, greater waveform variability appears to prevent receptor fatigue and may enhance neuroplastic adaptation, echoing strategies employed in high-frequency and burst spinal cord stimulation. Together, these data suggest that stimulation “richness” not just amplitude or frequency, plays a pivotal role in achieving sustained pain control. Anatomical treatment location also significantly influenced response. Lower-extremity and distal sites, such as the ankle (67% mean pain relief), foot (58%), and knee (50%), were associated with the highest analgesic gains. In contrast, upper-extremity areas like the wrist (25%) and elbow (30%) showed more modest responses. Several mechanisms may underlie this disparity. First, lower-limb regions may have a higher density of large-diameter afferent fibers amenable to TENS-induced gate control. Second, deeper musculature

and greater nerve exposure in distal regions may facilitate more effective current penetration. Finally, pain phenotypes common in upper-extremity syndromes (eg, radial neuropathy, lateral epicondylitis) may be less responsive to electrical neuromodulation due to their multifactorial origins or proximity to joint structures. Multivariable modeling further demonstrated that optimal outcomes resulted not from any single variable but from the interaction between anatomical targeting, session intensity, and waveform programming. This underscores the clinical importance of personalization, not just at the outset, but dynamically throughout the therapeutic course. Static protocols, by contrast, risk under-dosing, overuse, or loss of engagement, particularly in populations with complex or fluctuating symptoms. One of the most important and practice-relevant findings was the system's effectiveness in older adults, a population often excluded from device trials due to assumptions about digital literacy, cognitive decline, or comorbid frailty. Users aged ≥ 60 years experienced greater mean pain reduction (48%) than younger counterparts and maintained longer cumulative engagement with the device. These results challenge prevailing biases about older adults' capacity to use digital therapeutics and suggest that intuitive, user-friendly design, when combined with meaningful symptom relief, can drive sustained adoption even in high-risk populations. Given the high prevalence of chronic pain and polypharmacy in this demographic, EcoAI offers a compelling alternative or complement to medication-based management, particularly in settings where procedural interventions are contraindicated or impractical. Responder rates increased steadily over time, with 86.3% of users achieving $\geq 30\%$ pain reduction after 12 months of consistent use. This delayed but progressive therapeutic effect highlights the importance of long-term adherence and supports the hypothesis that neuromodulation may promote sustained neuroplastic remodeling of pain networks. While short-term gains are valuable, long-term responders are the true benchmark for success in chronic pain management. The ability to monitor these outcomes longitudinally through passive data capture is a unique strength of the EcoAI system and a necessary tool for evaluating durability of effect in decentralized care. Importantly, the safety profile was favorable, with no serious adverse events reported over nearly 188,000 sessions. This reinforces the non-invasive, low-risk nature of TENS/EMS when guided by adaptive dosing and integrated safety checks. Given the increasing scrutiny over neuromodulation-related complications, particularly with implanted devices, EcoAI's risk profile makes it suitable for broad outpatient deployment, including among populations with medical complexity or limited access to specialty care. Despite being decentralized and patient-managed, EcoAI seamlessly integrates into daily routines without disrupting function or requiring provider programming. Its real-time adaptability promotes engagement, while its backend analytics provide both the patient and clinician with actionable insight over time. This positions EcoAI not merely as a tool for symptom suppression but as a longitudinal therapeutic platform capable of addressing the chronicity, variability, and multidimensionality of pain. The ability to capture both behavioral engagement and symptom trajectories offers an unprecedented opportunity to tailor digital therapeutics at scale, improving not only individual outcomes but informing population-level strategies for pain care delivery. EcoAI exemplifies a broader transformation underway in chronic disease management: the convergence of wearable technology, artificial intelligence, and patient-reported outcomes to enable dynamic, remote, and precision-guided care. As this ecosystem evolves, integration with electronic medical records, payer infrastructure, and regulatory frameworks will be critical to scaling impact. However, the foundational elements, efficacy, safety, engagement, and adaptability, are already established in this 24-month dataset. Future directions may include integration with biometric sensors, predictive flare modeling, or reinforcement learning to further individualize stimulation patterns based on real-time physiology and behavior.

This large-scale, real-world evaluation establishes EcoAI as a clinically effective, user-friendly, and scalable solution for managing chronic pain. By combining non-invasive neuromodulation with AI-driven personalization, passive data collection, and remote monitoring, EcoAI addresses critical gaps in current treatment paradigms. It supports not only symptom relief but sustainable engagement, care continuity, and therapeutic precision. As the field of pain management shifts toward decentralization and digital integration, EcoAI offers a model of what the future can, and arguably should, look like: intelligent, personalized, and built around the patient.

While this study was designed as a retrospective, app-based analysis of de-identified real-world data, it offers unique insights that are often inaccessible in tightly controlled trials. Although formal diagnostic classifications, medication history, and clinician-confirmed outcomes were not available, as is typical in large-scale decentralized datasets, the breadth and granularity of self-reported information enable a rich understanding of patient behaviour,

engagement, and therapeutic response in naturalistic settings. Additionally, the study design did not include a control or comparator group, which limits the ability to attribute observed improvements directly to the intervention. Without a randomized comparison, the possibility of confounding variables, such as natural pain fluctuations, placebo effect, or self-selection bias, cannot be excluded. We acknowledge that this limitation impacts the interpretability of causal effects and should be addressed in future prospective or controlled studies. The absence of a control group does limit causal inference; however, the large sample size, real-world design, and high volume of longitudinal data across diverse user profiles enhance the ecological validity of the findings. Attrition over time is a recognized feature of real-world digital health studies, yet valuable outcomes were captured even among long-term users, providing important perspectives on sustained engagement and effectiveness. While outcomes were collected via structured numeric rating scales rather than standardized research instruments, this approach was deliberately chosen to enable scalable, low-burden symptom monitoring in self-managed environments, reflecting how patients actually interact with digital therapeutics outside the clinic.

TENS is among the most widely used non-invasive modalities for chronic pain, but its broader impact has historically been constrained by fixed, non-personalized protocols and inconsistent adherence. Compared to traditional TENS and EMS systems, EcoAI offers a significant advancement by integrating real-time algorithmic adjustment and user-specific personalization, features not commonly available in earlier-generation neuromodulation technologies. Further, the EcoAI platform addresses these limitations by integrating AI-driven personalization, closed-loop feedback, and remote monitoring into a wearable, self-guided system. This evolution of traditional TENS and EMS expands their clinical utility and relevance, particularly for populations underserved by pharmacologic or invasive interventions. The consistent, multi-domain improvements observed over 24 months highlight not only the feasibility but also the potential scalability of intelligent neuromodulation in real-world care. These findings support a reappraisal of TENS-based therapies when delivered through modern, adaptive, user-centered frameworks like EcoAI.

Conclusion

EcoAI represents a scalable and patient-centered therapeutic platform that has demonstrated sustained, multidomain benefit in the management of chronic pain under real-world conditions. By integrating adaptive algorithms, real-time patient-reported outcomes, and remote oversight, the system offers a level of personalization that extends beyond conventional TENS/EMS and approximates the responsiveness of implantable neuromodulation, without the procedural risks or clinical overhead. The consistently observed improvements in pain, function, mood, and overall well-being, paired with high engagement and favorable safety, support its potential role as both a first-line and adjunctive therapy, particularly for individuals underserved by pharmacologic or interventional approaches. Its intuitive design, decentralized delivery, and demonstrated usability in older adults position it well for broad application in everyday clinical practice. While these results are encouraging, future prospective trials and biomarker-integrated studies will be important to further validate and optimize its therapeutic impact. As healthcare increasingly shifts toward non-invasive, personalized, and patient-directed solutions, EcoAI reflects a promising model for the next generation of digital pain care.

Disclosure

Dr Maja Green is an employee of NXTSTIM. Professor Michael Bailey reports personal fees for statistical consulting from Solaris Research Institute Inc., outside the submitted work. Dr Bart Billet reports personal fees for consultancy from Medtronic, Abbott, Salvia BioElectronics, and Saluda, outside the submitted work. Dr Hemant Kalia is a consultant for Abbott, Nervonik, Nalu, Curonix, and Equanimity, during the conduct of the study. Dr Krishnan Chakravarthy is the founder of NXTSTIM. The authors report no other conflicts of interest in this work.

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