

THE PROBLEM

microglia -

dIPFC function

Cortisol curve

Cortisol curve



NEUROFIELD-SLE: PEMF Neuromodulation as a Next-Gen Treatment for Lupus Fatigue

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trial, Pros and Cons, Accessibility and Promotion

What Goes Wrong?

In SLE, fatigue is a consequence of chronic neuroinflammation and dysregulated brain functioning. Autoimmune activation in lupus triggers the release of inflammatory cytokines (e.g. IL-6, TNF-α) that cross the blood–brain barrier and disrupt normal brain function. These cytokines activate microglia, the brain's immune cells, shifting them into a pro-inflammatory state that interferes with neural communication. The inflammatory movement impairs the prefrontal cortex, a region critical for motivation, focus and executive function, leading to reduced activity of the dopamine system which is essential for maintaining mental energy and alertness. This forms a positive feedback loop as the reduced activity from the neuroinflammation causes more inflammation. In SLE, hypothalamic–pituitary–adrenal (HPA) axis dysfunction is common. Many patients show flattened diurnal cortisol curves, elevated nighttime cortisol, or blunted stress responses, which are all associated with chronic fatigue, immune imbalance, and poor sleep quality.

Fatigue in SLE is also partly driven by autonomic dysfunction, typically skewed toward sympathetic dominance (high resting heart rate, low HRV). HRV is a strong proxy for: Parasympathetic tone (especially vagal activity), Stress reactivity, and overall physiological resilience.

What Is SLE?

Systemic Lupus Erythematosus (SLE) is a chronic autoimmune disorder in which over 80% of patients experience debilitating fatigue, which is a pervasive cognitive and motivational exhaustion poorly correlated with disease or sleep quality. The disease is linked with chronic brain inflammation and disrupted dopamine signalling within prefrontal cortical circuits. Conventional treatments, including antidepressants, offer limited relief whilst posing risks such as insomnia and cardiovascular side effects.

Despite its prevalence, lupus fatigue remains a largely unmet clinical need.

To address this, we propose NEUROFIELD-SLE, a non pharmaceutical, wearable therapy that uses pulsed electromagnetic fields (PEMF) to modulate brain activity and restore neurochemical balance. By targeting the brain fatigue circuits directly, the approach offers a strategy to remove cognitive exhaustion without systemic drugs.

How Neurofield-SLE Works

Neurofield-SLE is a non pharmaceutical, wearable modulation device that is designed to reverse the neurological mechanisms underlying fatigue in Systemic Lupus Erythematosus. The headset delivers low intensity pulsed electromagnetic fields (PEMF) to the dorsolateral prefrontal cortex (dIPFC), a region critically involved in attention and motivation yet sensitive to the effects of neuroinflammation and dopaminergic disruption.

By applying theta frequency stimulation (5Hz) through paired electromagnetic coils, it induces transient activation of voltage gated calcium channels on cortical pyramidal neurons. This controlled calcium influx triggers dopamine release in the frontostriatal pathway, restoring cognitive drive and reducing mental fatigue. It also modulates microglial activity, shifting away from a pro inflammatory phenotype and suppressing the production of cytokines such as TNF-α and IL-6. Moreover, using PEMF stimulation on the prefrontal cortex can trigger signals through the vagus nerve which may then influence the spleen by adjusting its sympathetic nervous system activity. Inside the spleen, macrophages have α7 nicotinic acetylcholine receptors that, when activated (by PEMF), can suppress inflammation.

PEMF stimulation on the prefrontal cortex strengthens the brain's control over the body's stress response, helping to restore healthy cortisol patterns and shift the nervous system to a calmer, more balanced state. To measure progress the system tracks two key biomarkers: salivary cortisol tests which show whether the body's daily stress hormone rhythm is improving, while a wearable ECG patch continuously monitors heart rate variability (HRV).

SIDE VIEW

Theta-PEMF entited

prefrontal cortex

ISOLATED COMPONENTS

HPA Axis

Feedback chip

Overlays on ear

NEUROFIELD-SLE

TOP VIEW

SIDE VIEW

Electrode /

EXPLODED VIEW

Battery

PEMF emitter

ECG/Wearable

integration module

THE SOLUTION PEMF restores dopamine signaling PEMF coils Figure 1. Neurofield−SLE VS Lupus Fatigue Problem: Problem: Brain inflammation →

Theta-freg-

Vagus nerve

. Balanced tone

HRV metrics

- fatigue

 Stress system imbalance
- Microglia disrupt dopamine and focus

Solution:

- Gentle brain stimulation
- Boosts energy, reduces inflammation
- Restores natural rhythms

<u>Device Design & Manufacturing</u>

Sympathetic -

nervous system

Balanced tone

Cortisol curve

- NEUROFIELD-SLE is a lightweight, head-worn neuromodulation device shaped like a discreet halo headset. It features four embedded Helmholtz coil pairs aligned over EEG landmarks Fp1, Fp2, Fz, and AFz, targeting the dorsolateral prefrontal cortex (dIPFC). A silicone-coated polycarbonate frame ensures anatomical conformity, comfort, and biocompatibility during daily wear.
 Estimated Bill of Materials (BOM): ≈ £35-45 per unit
 - Projected Retail Production Cost: ≈ £70-90 including assembly, QA, packaging.

Component	<u>Specification</u>	Cost (Per Unit)
PEMF Coils (x4)	Copper wound, 6 cm diameter, 300 turns, ferrite core	£8
Microcontroller	ARM Cortex-M4, 120 MHz, BLE-enabled	£6
Power Supply	3.7 V Li-Ion battery (2000 mAh), 4-hour capacity	£4
Coil Drivers & Safety ICs	PWM amplifier + TI TPS2660 current limiter + temp cut-off	£5
Temperature Sensor (NTC Thermistor)	Max scalp temp: 40 °C; triggers auto-shutdown	£1.50
ECG Patch Connector (optional)	For HRV data sync (Bluetooth LE)	£3
Outer Housing	Polycarbonate + silicone liner (medical grade)	£6
Mobile App & Clinician Portal	iOS/Android (developed in-house or via SDK integration)	£2–3 (amortised)
Salivary Cortisol Kit (Optional)	3x/day sampling kit w/ cold storage	£10 (per kit)

Key Safety Features:

- **Thermal Monitoring:** Integrated NTC thermistors continuously measure surface coil temperature. Automatic shut-off above 40 °C to prevent skin burns or overheating.
- Current Limiting: Each coil driver uses hardware-based current control (TPS2660) to cap delivery at 500 mA.
 - Magnetic Field Compliance: Emissions stay within ICNIRP guidelines (<1 mT at scalp).
- Implant Contraindication Detection: A pre-use checklist prompts the user to confirm absence of cranial metal (e.g., aneurysm clips, DBS).
- Session Logging & Lockout: Firmware prevents >1 session/day unless clinician override is enabled.

Usability & Deployment:

- Setup: Intuitive mobile app guides the user through daily setup and automatic calibration.
- **Data Monitoring**: Daily HRV and session data are uploaded via BLE to a secure clinician portal; cortisol test kits are submitted weekly for lab analysis.
 - Training: Supplied with a QuickStart digital guide; optional in-clinic onboarding.

Figure 2: NEUROFIELD-SLE Headset

A clinically designed headset delivering targeted brain stimulation to alleviate lupus fatigue.

Key Features:

- Precision Coils 4
 electromagnetic coils stimulate
 fatigue-related brain regions
- Smart Monitoring Tracks cortisol rhythms and heart rate variability in real-time
- Optimized Treatment 30-minute theta-frequency (5Hz) PEMF sessions
- Safety Assurance Thermal controls and adaptive dosing
- Lightweight, adjustable, with medical-grade materials for comfort during use.
- Coil placement over brain's fatigue network.
- Integrated biometric sensors.
- Safety system components

Proposed clinical trial

HPA Axis Cortisol

Feedback

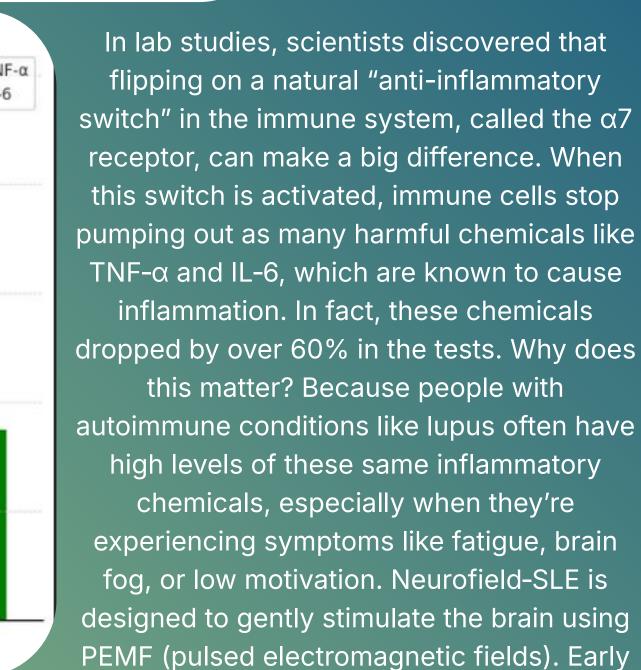
chip

- Objective: To evaluate whether the Neurofield headset can reduce fatigue levels in patients with SLE
 Type: Double-blind,randomised, placebo headset controlled trial
- Participants: 100 adult patients diagnosed with SLE and moderate to severe fatigue
 Intervention: Participants randomised to receive either an active EMF headset or a placebo headset, worn for 30 minutes daily over 8 weeks.
- Outcome: The main outcome will be measured using the Fatigue Severity Scale from the start to the end
 of the 8 weeks. However, the secondary outcome of the patients reported pain levels will also be
 analysed
- Results: If patients using the EMF headset showed a significant difference in fatigue scores from the beginning to the end of the trial compared to the placebo group, it would prove that the EMF headset has a direct effect on fatigue in SLE patients.
- Disclaimers: Although, EMF headsets may offer a viable non-pharmacological solution to reducing fatigue in SLE patients, further large-scale studies are required to confirm these results and evaluate long term safety of users of this device.

PEMF Reduces Brain Inflammation by ~50% After Injury 100 150% 150% 150% 150% 150% 150% Activation of α7nAChR Reduces Inflammatory Cytokines In lab studies

Does Neurofield-SLE Work?

In a 2022 study, gentle brain stimulation (PEMF) cut brain inflammation in mice by about 50%. It lowered two key immune chemicals linked to fatigue and brain fog—TNF-α and IL-1β. Neurofield-SLE uses a similar PEMF signal on the human brain. While this doesn't prove it works for lupus, it suggests this approach may help calm inflammation linked to lupus-related fatigue.



Unclear mechanism: The full extent about what parts will

be affected by the EMF headset to reduce fatigue is still

unclear, making it harder to to identify all the effects of

evidence suggests this may activate the same anti-inflammatory pathway in the brain and body, calming immune activity and potentially helping you feel more clear-headed, alert, and balanced, without the need for medication.

LPS + α7nAChR Agonist

Treatment Group

LPS Only

Accessibility and Promotion

To widen accessibility and to promote the EMF headset for SLE patients, efforts should be focused on increasing awareness for patients and among healthcare providers. This could be done via the use of educational campaigns and clinical evidence dissemination. In order to reduce costs, integrating the device into insurance coverage or subsidizing the costs, can ensure that the device is more accessible to the wider public. Furthermore, partnering with patient advocacy groups can help build trust between the public and this new type of treatment allowing for a much smoother transition from current treatment methods. This can be further supported if more trials involving more patients were conducted, which could help build scientific credibility and make the treatment seem more safe to the public. Notably, due to this being a new treatment which hasn't fully been explored yet, safety guidelines must be provided to ensure the device is used properly. Due to this, this device should be treated as a additional aid and tool in reducing fatigue with current reduction methods instead of being treated as a independent reduction method.

the device.

Challenges or Considerations <u>Advantages of Neurofield-SLE</u> Non-invasive and drug-free: This avoids additional Limitation on full extent of EMF treatment-Research on medications which is key due to many patients with how EMF devices affect SLE patients is still quite small. SLE already taking multiple drugs. Cost and accessibility: EMF headsets may be costly to Improvement in fatigue: Some emerging studies are starting to suggest that EMF devices might reduce purchase and therefore, may not be able to be accessed fatigue and improve energy levels. by all SLE patients. Safety concerns: The full extent of the side effects Easy usage: A headset is quite easy to use anywhere and might help regulate the usage of the device due to produced by long term, repeated exposure to EMF, have not fully been identified. Possible placebo effect: Some of the observed Improvements to quality of lifestyle: Even if the reduction in fatigue isn't too significant, the reduction improvements may be due to expectations rather than in fatigue will enable SLE patients to be able to engage | being induced by the EMF headset. more overall.

Lower risk of systemic side effects: EMF devices are

more targeted in their effect and don't affect multiple

organs such as the kidneys or liver like regular

medicine may be inclined to.