

A case study to assess the effects of the Exo-pulse neuromodulation suit on pain, fatigue and sleep patterns of an individual diagnosed with CFS/ME

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Abstract

The Exopulse suit was initially an approach to reduce spasticity and improve motor function in individuals with lesions in the CNS. Anecdotal findings from Exopulse users suggest that it could benefit people with pain syndromes, fatigue, and disturbed sleeping patterns. The Exopulse neuromodulation suit was programmed to apply multi-site afferent electrical stimulation and subsequently worn for one hour daily for thirty days. The one-hour session was done at the same time every morning, 9 AM to 10 AM, while the patient was lying in bed. One-hour Exopulse treatments consistently led to improvements in activity and sleep patterns. Diary records indicate that results carried over into the following day, which may indicate a training effect. All baseline scores were improved in self-assessments and objective measurements. The patient's parents commented on the increased interaction with friends and family, the increased planning ahead, and decreased agitation. CFS/ME is a condition in which performance and alertness can change due to environmental and internal factors. The results of this single Case Study design need to be approached cautiously.

Keywords: Chronic Pain; Fatigue; Electrical Stimulation; Neuromodulation

1. Introduction

Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) is a disabling and complex illness[1]. People with ME/CFS are often unable to do their usual activities. At times, ME/CFS may confine them to bed. People with ME/CFS have overwhelming fatigue that is not improved by rest. ME/CFS may get worse after any activity, whether it is physical or mental. This symptom is known as post-exertional malaise (PEM). Other symptoms can include problems with sleep, thinking and concentrating, pain, and dizziness.

People with ME/CFS may not look ill. However, they are not able to function the same way they did before they became ill. ME/CFS changes people's ability to do daily tasks, like taking a shower or preparing a meal. It often makes it hard to keep a job, attend school, and participate in family and social life. It can last for years and sometimes leads to severe disability. At least one in four patients are bed- or house-bound for long periods during their illness

While most common in people between 40 and 60 years old, the illness affects children, adolescents, and adults of all ages. Among adults, women are affected more often than men.

The Exopulse suit was initially an approach to reduce spasticity and improve motor function in individuals with lesions in the CNS [2]. This neuromodulation stimulation is non-invasive and non-pharmacological and has limited side effects compared to other known invasive or pharmacological treatments for spasticity and related chronic pain. Anecdotal findings on previous Exopulse users suggest that this approach could benefit people with pain syndromes, fatigue, and disturbed sleeping patterns. This could be attributed to the mechanisms affected by multi-site afferent electrical

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stimulation within the Central Nervous System [3]. These findings led to this case study to further assess possible improved outcome measures.



Figure 1 Exopulse suit

2. Case history

The patient, an 18-year-old woman, was diagnosed with CFS/ME after other differential diagnoses were ruled out eight months prior to this study. The onset had been quite sudden. Within 48 hours, she went from activities such as ballet, soccer, and socializing with friends to being bedridden for most of the day. Her main symptoms were severe tiredness, general pain, and disturbed sleeping patterns. She could only perform daily activities for around two and a half hours per day, preferably between her waking up and lunchtime. The general pain also prevented her from daily activities, worsening her symptoms. The symptoms were consistent from day to day with very little deviance.

3. Method

The Exopulse Suit features 58 embedded electrodes stimulating forty skin afference areas. It allows thirty different settings per area, using a sub-threshold neuromodulation stimulation. The suit was programmed to apply multi-site afferent electrical stimulation and subsequently worn for 1 hour daily for thirty days. The one-hour session was done at the same time every morning, 9 AM to 10 AM, while the patient was lying in bed. Outcome measures were recorded immediately before the treatment started and on day thirty.

4. Measurement tools

Sleep monitoring measuring REM and Deep Sleep using the Fitbit Alta H [4]. Self-Assessed Visual Analogue Scale for Pain [5]. Fatigue Severity Scale [6]. Multidimensional Assessment of Fatigue [7]. Timed Daily Active Hours [8]. The Karolinska Sleepiness Scale [9].

5. Results

One-hour Exopulse treatments consistently led to improvements in activity and sleep patterns. Diary records indicate that these benefits carried over into the following day, which may indicate a training effect. All baseline scores were improved in the subjective self-assessments and the objective measurements. The patient's parents commented on the increased interaction with friends and family, the increased planning ahead, and the decreased agitation.

Table 1 Measurements on Day 1 and Day 30

	Day 1	Day 30	% change
MAF (130 max score)	110	100	10
FSS (63 max score)	61	51	16.4
VAS (10 max score)	7.5	3.5	53.3
TDAH	2.5	7	200
REM/Deep sleep	2.5	5	100
KSS	7.5	4	46.7

6. Conclusion

The results in this single case study could be attributed to the mechanisms affected by multi-site afferent electrical stimulation within the Central Nervous System. The positive results suggest that further investigation is indicated to explore the nature, duration, and significance of the effects of this new treatment in the CFS/ME population.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest took place during this case study.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

References

- [1] Factors influencing the diagnosis of chronic fatigue syndrome Laura Solomon 1, William C Reeves PMID: 15534161 DOI: 10.1001/archinte.164.20.2241
- [2] Effects of 60 Min Electrostimulation With the EXOPULSE Mollie Suit on Objective Signs of Spasticity Gaia Valentina Pennati, Hanna Bergling, Loïc Carment, Jörgen Borg, Pável G. Lindberg, and Susanne Palmcrantz Front. Neurol. 15 October 2021. doi.org/10.3389/fneur.2021.706610
- [3] Electrical stimulation therapies for CNS disorders and pain are mediated by competition between different neuronal networks in the brain. Carl L.Faingol Medical Hypotheses. November 2008; 71(5): 668-681.
- [4] Performance of seven consumer sleep-tracking devices compared with polysomnography. Evan D Chinoy, Joseph A Cuellar, Kirbie E Huwa, Jason T Jameson, Catherine H Watson, Sara C Bessman, Dale A Hirsch, Adam D Cooper, Sean P A Drummond, Rachel R Markwald Sleep. May 2021; 44(5): 291.
- [5] Validation of digital visual analog scale pain scoring with a traditional paper-based visual analog scale in adults. Delgado DA, Lambert BS, Boutris N, McCulloch PC, Robbins AB, Moreno MR, Harris JD. Journal of the American Academy of Orthopaedic Surgeons. Global research & reviews. Mar 2018; 2(3).
- [6]] Measuring fatigue in Parkinson's: a psychometric study of two brief generic fatigue questionnaires. Hagell, P., Hoglund, A., et al. J Pain Symptom Manage. 2006; 32(5): 420-432
- [7] A Systematic Review of Studies Using the Multidimensional Assessment of Fatigue Scale Basia Belza, Christina E Miyawaki, Minhui Liu, Suparb Aree-Ue, Melissa Fessel, Kenya R Minott, Xi Zhang J Nurs Meas. 1 Apr 2018; 26(1): 36-75
- [8] Activity Logs as a Measure of Daily Activity Among Patients with Chronic Fatigue Syndrome Leonard A Jason 1, Phyllis Timpo, Nicole Porter, Joshua Herrington, Molly Brown, Susan Torres-Harding, Fred Friedberg J Ment Health. Dec 2009; 18(6).
- [9] Validation of the Karolinska sleepiness scale against performance and EEG variables Kaida M, Takahashi T, Åkerstedt A, Nakata Y, Otsuka T, Haratani K, et al. Clinical Neurophysiology. 2006; 117: 1574–81.