ORIGINAL ARTICLE

An Open-Label Pilot Study Investigating Noninvasive High-Frequency Peripheral Nerve Fiber Stimulation in Chronic Pain

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■ **Abstract**

Objective: Providing sustained and effective treatment via the peripheral nervous system for the management of chronic pain is challenging. Application of noninvasive high-frequency stimulation at or near the painful area may benefit those with chronic pain. This open-label pilot survey examined the impact of this stimulation on pain intensity, activities of daily living, functional capacity, and medication consumption after 2 weeks of treatment.
Methods: Stimulation was administered at home using two high-frequency sinusoidal alternating signals at 3858 and 3980 Hz delivered between two electrodes placed directly over one or two locations of pain. Individuals completed a survey after 2 weeks to assess pain, activities of daily living (ADL), pain medication consumption, quality of life (QoL), mood, sleep, functional outcomes, and satisfaction.
Results: 463 individuals (372 males; 91 females) retuned the completed survey after 2 weeks of treatment. Pain and ADL scores significantly improved at follow-up compared with baseline (pain mean difference: 3.05; 95% confidence interval [CI]: 2.86, 3.24; ADL mean difference: 1.82; 95% CI: 1.60, 2.04). Corresponding improvements in QoL, sleep, mood, functional outcomes, and satisfaction were noted. On average, 8.00 ± 11.11 hours of pain relief were reported with 54% experiencing reductions in pain medication consumption. 98% would use the stimulation in the future.
Conclusion: Two weeks of noninvasive high-frequency peripheral nerve fiber stimulation appeared to confer positive effects in individuals with chronic pain. Future research employing a control group/arm is needed to establish the long-term impact of this bioelectric technique in specific pain cohorts. ■

Key Words: noninvasive, high frequency, peripheral nerve fiber stimulation, pain, activities of daily living

INTRODUCTION

The prevalence of chronic pain in the general population ranges from 35% to 51% in the U.K.[1] and from 19% to 43% in the U.S.A.[2] Chronic pain is recognized as a global health priority[3] and is characterized by severe pain continuing longer than 3 months despite medication or treatment.[4] It can negatively impact quality of life, sleep, physical mobility, employment, and mental health[5–9] and has economic implications.[10–12] Chronic pain is particularly prominent among former military personnel[13,14] and a contributing reason for medical discharge.[15] Indeed, it presents in 81.5% of veterans[16]

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and is closely tied to post-traumatic stress disorder (PTSD),[16–19] persistent postconcussive symptoms,[16] depression,[18,19] and alcohol misuse.[20]

The peripheral nervous system (PNS) offers clinicians the opportunity to treat both acute and chronic pain as it provides an accessible window into an integral pathway of communication between the body and the environment. Touch, proprioception, temperature, and nociception all influence our perception of the world. Pathological persistence of nociception from the PNS or peripheral nerve dysfunction can alter and amplify activity within pain pathways. This is termed peripheral sensitisation.[21,22] These pathophysiological sequences are driven by biochemical mediators that cause changes in the cell bodies of the somatosensory neurons which in turn can lead to central changes. Clinically, these changes result in ongoing pain, allodynia, hypersensitivity, or loss of function.[23]

At present, treatment options for chronic pain using the PNS may include physical therapy (eg, massage, desensitization, or acupuncture[24]), pharmacological management (eg, gabapentinoids, topicals, tricyclic antidepressants[25]), ablative therapy (thermal or chemical [24]), and/or neurostimulation (eg, spinal cord stimulation[26]). Recently, the term bioelectronic medicine applied to pain management has been used to describe the use of neurostimulation to modify the response of nerve tissue to reduce pain.[27] Examples include transcutaneous electrical nerve stimulation (TENS),[28,29] photobiomodulation,[30,31] and electromagnetic field,[32] all of which have been used in pain medicine. Bioelectronic medicine has an important advantage over other therapies, as it can employ electrical, magnetic, optical, and ultrasound technologies to deliver targeted, personalized therapy and eliminate the need for drug-centered therapy. The long-term objective is to improve clinical and economical outcomes.[33–35]

To have a meaningful sustained influence on the PNS, any noninvasive neuromodulation technology must bypass the impedance offered by the skin using a high-frequency electric field. It must also be able to provide a low-frequency electric field (1 to 180 Hz) to halt the propagation of action potentials that lead to the hyperpolarization required. This can be achieved by adding together two sinusoidal high-frequency signals, which pass into deep tissue and promote the further multiplication of these signals. This results in the formation of an active therapeutic low-frequency electrical field, focused in a 4- to 6-cm- (3.5-inch)-diameter hemisphere beneath and surrounding each electrode, not across the surface of the skin between the electrodes. This active electrical field is thought to hyperpolarize C-fibers inhibiting action potential propagation along these pain fibers (frequency conduction block theory). This technology is commercially available via a device called the BioWaveHome (BioWave Inc., Norwalk, CT, USA).

This open-label pilot survey was designed to quantify and understand the impact of this bioelectronic technology (BioWaveHOME) on individuals with chronic pain. The primary outcome measures were self-reported pain and activities of daily living (ADL). Secondary outcomes included medication consumption, quality of life (QoL), mood, sleep, physical function, satisfaction, and future usage. The study was exploratory to inform the protocols for future focused assessments.

METHODS

This was an open-label pilot survey that aimed to explore the efficacy of 2 weeks of BioWaveHOME in individuals with chronic pain in the U.S.A.

Participants

This was a retrospective review of anonymous data that were voluntarily returned by patients. Ethical approval was therefore not required. The therapy is a noninvasive treatment that is readily available in clinical practice. All adults who presented with a chronic lower-back, neck, upper- or lower-limb pain for more than 3 months were considered for inclusion. The individuals attended either a Veterans Affairs (VA) medical center, pain clinic, or orthopedic clinic between February 2019 and July 2020, where they were assessed by a healthcare professional for their suitability for treatment with a BioWaveHOME device as part of their treatment program. Some patients were treated with BioWavePRO during in-facility visits, while others were only provided the BioWaveHOME system for in-home use. Exclusion criteria included inability to read English and if the individual was not prepared to use the device consistently over a 2-week period. No a priori sample size calculation was conducted as responding to the survey was optional (see below for further details).

Treatment Protocol

All individuals were trained and advised on how to use the device and on the correct position of the skin pads.

The individuals were made aware of the option of responding to the voluntary and confidential evaluation survey within the first 2 weeks of use. Individuals were reminded this was optional and not a requirement of therapy. A prepaid envelope was provided. Data that were provided outside the 2-week initial treatment were not included in the final dataset.

Stimulation

Stimulation was delivered via the BioWaveHOME neurostimulator (BioWave, Norwalk, CT, U.S.A., see Figure 1A). A back-and-forth summation of two high-frequency sinusoidal alternating current signals at 3858 and 3980 Hz was administered. The current travelled between two electrodes which were placed directly over one or two locations of pain. The electrodes consisted of one of two types. B-set electrodes (see Figure 1B) were two 2.0-inch-diameter round electrodes for treating (1) two distinct locations of pain, (2) the origin of pain and most proximal location of pain to the origin (eg, in the case of a radiculopathy), or (3) one large area of pain (electrodes placed 1 inch apart from one another). E-set electrodes (see Figure 1C) comprised one 1.375-inch-diameter round electrode placed directly over a single location of pain and one 2-inch × 4-inch rectangular dispersive electrode placed over a bony prominence that was a comfortable location to receive stimulation. The stimulation elicited a deep, smooth sensation and was not in any way painful.

Data Collection

Figure 2 summarizes the study protocol. After 2 weeks of the stimulation, individuals were asked to complete a paper-based survey and return it via post. Briefly, the survey elicited responses on questions related to pain, ADL, medication consumption, QoL, sleep, functional outcomes, and satisfaction (see Table S1 for a summary of the survey).

Statistical Analysis

All statistical analyses were conducted in SPSS (version 25). Paired sample *t*-tests (or Wilcoxon signed-rank tests for non-normally distributed data) explored differences in pain and ADL between baseline and follow-up. Independent sample *t*-tests (or Mann–Whitney *U* tests) and one-way analyses of variance (ANOVAs; or Kruskal–Wallis tests) examined differences between groups. Normality was ascertained via the Shapiro–Wilk test, and all statistical tests were two-tailed. To control for multiple testing, the alpha level was adjusted using the Bonferroni correction. Change (Δ) between baseline and follow-up was calculated, and counts and percentages generated for categorical variables.

RESULTS

Demographics

In total, 463 individuals returned the survey over the 18-month period. There were 424 veterans (92%) and 39 members of the general public (8%). The predominant users were males (372 males; 91 females, see Table 1).

Most respondents suffered chronic pain alone with 21% reporting an acute pain during the 2-week period. Only a small percentage of the respondents were able to report the presence of different subtypes of pain (ie, neuropathic vs. nociceptive pain). Of the reported cases (n = 365), chronic back pain and chronic neck pain were reported in 295 respondents (81%). In general, pain in the periphery accounted for the remainder of the indication, but some overlap was noted (see Table 1 for a summary).

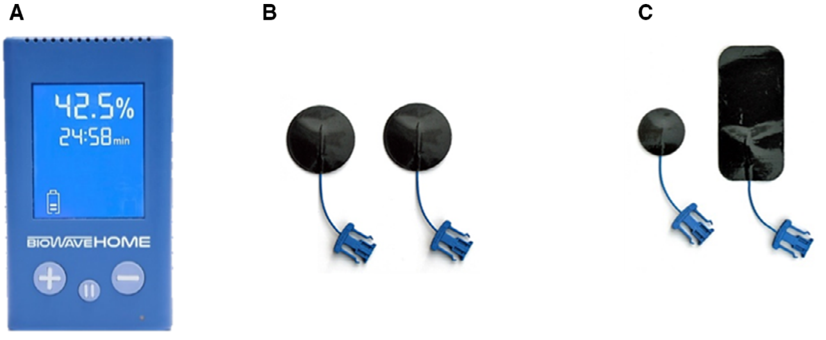

Figure 1. BioWaveHOME unit (A), B-set of electrodes (B), and E-set of electrodes (C).

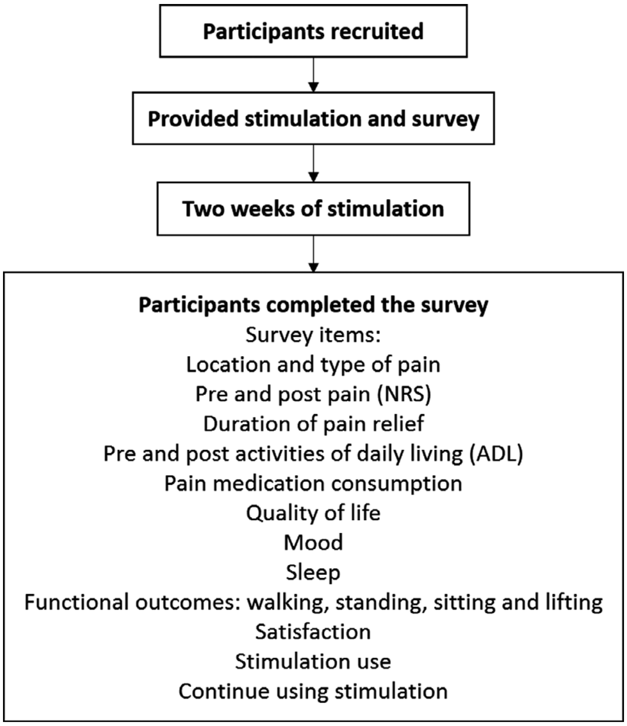

Figure 2. Summary of study protocol. ADL, activities of daily living; NRS, numerical rating scale.

Table 1. Summary of Characteristics of the Final Sample and Subgroups of Veterans and General Public

	Final Sample (n = 463)	Veterans (n = 424)	General Public (n = 39)
Gender			
Males	80%	83%	51%
Females	20%	17%	49%
Type of pain			
Chronic	91%	91%	97%
Acute	21%	22%	6%
Neuropathic	24%	23%	26%
Nociceptive	3%	3%	6%
Missing data (n)	37	32	5
Location of pain			
Back	70%	71%	69%
Neck	23%	24%	17%
Shoulder	25%	25%	20%
Ankle and/or foot	8%	8%	14%
Hand	2%	2%	9%
Leg, including sciatica	14%	15%	9%
Knee	16%	15%	17%
Missing data (n)	98	94	4

Data are presented as percentage apart from missing data which are presented nominally.

In the first 2-week period, survey responses revealed that just over half of the sample (51%) used the treatment daily, with 30% using the stimulation multiple times per day. The remaining participants reported using the treatment weekly (18%).

Pain and ADL Scores After 2 Weeks of Treatment

After 2 weeks of treatment, respondents reported an average reduction in pain of 3.05 (2.04) points. Pain was significantly lower following 2 weeks of treatment compared with baseline (mean difference: 3.05; 95% confidence interval [CI]: 2.86, 3.24; z-score = −17.37, $P < 0.001$, $r = 0.81$; Figure 3A). The average duration of pain relief reported by participants was 8.02 (11.11) hours (95% CI: 7.01, 9.04 hours).

Respondents also reported an average reduction in ADL scores of 1.82 (2.44) points following 2 weeks of the treatment. Compared with baseline, ADL scores were also significantly improved (mean difference: 1.82; 95% CI: 1.60, 2.04; z-score = −12.88, $P < 0.001$, $r = 0.60$; Figure 3b).

Intergroup analysis (ie, veterans, members of the general public) showed that significant improvements were seen in both pain and ADL scores. These improvements were universally noted across the multiple clinical indications (ie, pain types and pain locations, see Figures S1 to S5).

QoL, Mood, and Sleep

Improvements were also noted in the secondary outcome measures including QoL, mood, and enhanced sleep patterns (94%, 29%, and 33%, respectively, see Table S2).

Intergroup analysis (ie, veterans, members of the general public) showed the percentages of respondents reporting improvements in QoL, mood, and sleep were comparable in both groups. These improvements were also universally noted across the multiple clinical indications (ie, pain types and pain locations, see Table S2).

Respondents who reported improvements in QoL, mood, and sleep showed greater improvements in pain and ADL scores compared with those who reported little improvement in functional outcomes (see Tables 2 and 3).

Functional Outcomes

Improved functional capacity was reported by respondents. For example, 7% (33 of 463) could "lift more," 25% (115 of 463) could "sit for longer durations," 27% (125 of 463) could "walk farther," and 29% (133 of 463) could "stand for longer periods" of time (see Table S3).

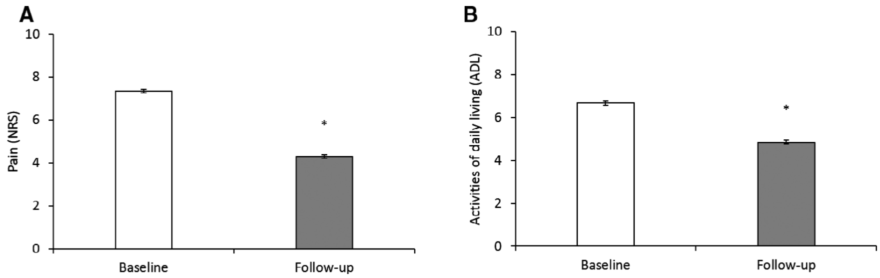

Figure 3. Pain (A) and ADL (B) scores during baseline and follow-up in the final sample. *Significantly different to baseline ($P < 0.001$). ADL, activities of daily living; NRS, numerical pain rating scale. Data are presented as mean ± 1 standard error of the mean (SEM).

Table 2. Summary of Differences in Improvements in Pain Scores Between Those Who Did and Did Not Report Improvements in QoL, Mood, and Sleep

	Pain Score				
	Z-Score	*P* Value	*r*	Mean Difference	95% CI
QoL	−5.25	< 0.001	0.25	2.19	1.40, 2.98
Mood	−3.01	0.003	0.14	0.68	0.27, 1.09
Sleep	−4.56	< 0.001	0.21	0.94	0.58, 1.31

CI, confidence interval; QoL, quality of life.

Table 3. Summary of Differences in Improvements in ADL Scores Between Those Who Did and Did Not Report Improvements in QoL, Mood, and Sleep

	ADL Score				
	Z-Score	*P* Value	*r*	Mean Difference	95% CI
QoL	−2.97	0.003	0.14	1.12	0.15, 2.09
Mood	−7.74	< 0.001	0.36	1.91	1.49, 2.33
Sleep	−9.22	< 0.001	0.43	2.15	1.75, 2.54

ADL, activities of daily living; CI, confidence interval; QoL, quality of life.

Intergroup analysis (ie, veterans, members of the general public) showed the percentages of respondents reporting improvements in functional outcomes were comparable in both groups. These improvements were universally noted across the multiple clinical indications (ie, pain types and pain locations, see Table S3).

Respondents who reported improvements in functional outcomes showed greater improvements in pain and ADL scores compared with those who reported little improvement in functional outcomes (see Tables 4 and 5).

Medication Consumption

The specific medication regime for each respondent was not recorded by the survey. The respondents were asked to report their oral medication consumption in one of three categories: "eliminated," "reduced," (ie, > 30%), or "stayed the same."

54% of respondents reported pain medication consumption was "reduced after treatment." In a small number of participants, 5% (21 of 405), pain medication was eliminated. Two of every five respondents reported medication consumption stayed the same in the 2 weeks of treatment.

Differences in change (Δ) in pain emerged according to type of change in pain medication ($H = 29.24$, $P < 0.001$, see Figure 4A). For respondents who reported pain medication consumption had been eliminated, they showed significantly greater reductions in pain compared with those who reported consumption had reduced (mean difference: −0.96; 95% CI: −2.17, 0.25; $P = 0.034$) or stayed the same (mean difference: −1.76; 95% CI: −2.98, −0.53; $P < 0.001$). Furthermore, pain relief was significantly greater for participants who reported reductions in pain medication consumption compared with those who stated consumption had stayed the same (mean difference: −0.80; 95% CI: −1.34, −0.25, $P < 0.001$).

There were no significant differences in change (Δ) in ADL scores between those who reported pain medication consumption had been eliminated, reduced, or stayed the same ($H = 1.82$, $P > 0.05$, see Figure 4B).

Table 4. Summary of Differences in Improvements in Pain Scores Between Those Who Did and Did Not Report Improvements in Functional Outcomes

	Pain Score				
	Z-Score	*P* Value	*r*	Mean Difference	95% CI
Lift	−3.51	< 0.001	0.16	1.25	0.54, 1.97
Sit	−2.86	0.004	0.13	0.70	0.27, 1.13
Walk	−6.07	< 0.001	0.28	1.31	0.91, 1.72
Stand	−4.64	< 0.001	0.22	1.02	0.62, 1.42

CI, confidence interval.

Table 5. Summary of Differences in Improvements in ADL Scores Between Those Who Did and Did Not Report Improvements in Functional Outcomes

	ADL Score				
	Z-Score	*P* Value	*r*	Mean Difference	95% CI
Lift	−4.58	< 0.001	0.21	2.02	1.18, 2.87
Sit	−6.73	< 0.001	0.31	1.71	1.27, 2.15
Walk	−8.49	< 0.001	0.39	2.10	1.68, 2.52
Stand	−8.62	< 0.001	0.40	2.08	1.66, 2.50

ADL, activities of daily living; CI, confidence interval.

Individual Satisfaction Scores

Overall, the level of satisfaction with the treatment was high with a mean score of 8.12 (1.84); where 0 was not satisfied and 10 was completely satisfied. For analysis, satisfaction scores were grouped into one of three bands (1 to 4, 5, or 6 to 10). Change in pain and ADL scores significantly differed between the three satisfaction groups ($H = 27.66$, $P < 0.001$ and $H = 8.08$, $P = 0.018$, respectively, see Figure 5). Respondents scoring 6 to 10 had significantly greater improvements in pain and ADL compared with those scoring 1 to 4 for satisfaction (pain mean difference: −2.12; 95% CI: −3.11, −1.12, $P < 0.001$; ADL mean difference: −0.98; 95% CI: −2.20, 0.25, $P = 0.042$).

Most respondents (98%, 449 of 460) stated they would continue using the stimulation after the 2-week period. Four participants reported indifference towards future usage, while seven said they would not continue with the stimulation. Data concerning future usage was missing in three instances. Similar patterns were observed across all subgroups (see Table S5).

DISCUSSION

The key findings of this article suggest that the noninvasive high-frequency neuromodulation used here can (1) significantly improve pain intensity and ADL and (2) positively impact QoL, mood, sleep, and functional outcomes following 2 weeks of treatment. The ability of this novel bioelectronic therapy to achieve these outcomes in such a short timeframe is a noteworthy observation. Respondents also reported high levels of satisfaction, and 98% of participants stated they would continue using the treatment. These findings are novel and timely, providing the initial evidence base needed to further assess this treatment's efficacy in chronic pain at a time when there is demand for pain treatments that are safe and cost-effective.

Noninvasive High-Frequency Neuromodulation in Pain

As chronic pain is characterized by increases in central and peripheral nerve activity,[36] electrical stimulation of the PNS may offer an alternative and effective way for reducing this hyperactivity. Noninvasive bioelectronic medical therapies, such as TENS,[28,29] photobiomodulation,[30,31] and electromagnetic field,[32] have been trialed in pain conditions to mixed effect. This pilot survey aimed to evaluate the impact of using a noninvasive neuromodulation device that can deliver high-frequency electrical stimulation to peripheral nerve fibers as a treatment option for chronic pain. Findings point to the benefits this stimulation can have on pain, ADL, QoL, mood, sleep, and physical ability after 2 weeks of use. Evidence from animals (see Ref. 37 for a review) suggests that high-frequency (kilohertz) nerve conduction blocks facilitate rapid, reversible, and localized blocks of nerve conduction. The stimulation employed in this study is based on the principle of a multiplication of two sine waves (ie, a Fourier Transform). In terms of potential mechanism of action, the electrical field generated from this stimulation may lead to hyperpolarized C-fibers, in

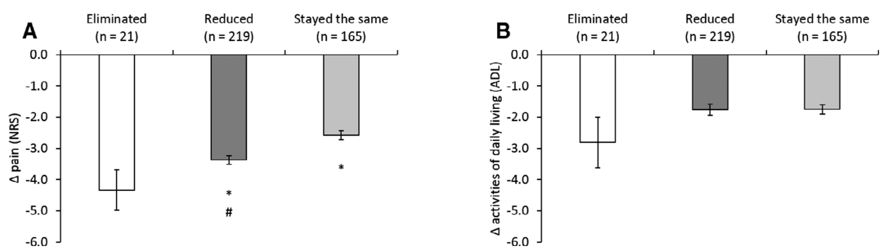

Figure 4. Change (Δ) in pain (A) and ADL (B) scores for participants who reported pain medication consumption had been eliminated, reduced, or stayed the same following 2 weeks of stimulation. *Significantly different to "eliminated" ($P < 0.05$); #Significantly different to "stayed the same" ($P < 0.001$). ADL, activities of daily living; NRS, numerical rating scale. Data are presented as mean ± 1 standard error of the mean (SEM).

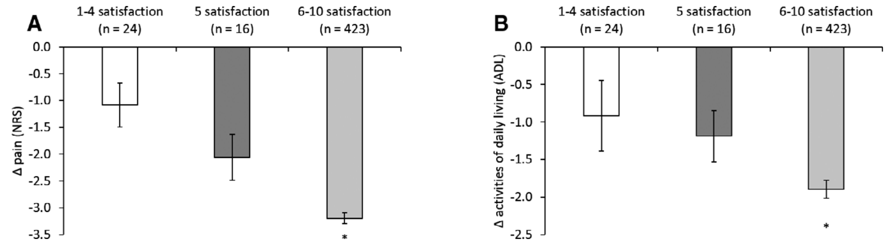

Figure 5. Change (Δ) in pain (A) and ADL (B) scores for participants who reported 1 to 4, 5, and 6 to 10 for satisfaction with the stimulation. *Significantly different to 1 to 4 satisfaction ($P < 0.05$). ADL, activities of daily living; NRS, numerical rating scale. Data presented as mean ± 1 standard error of the mean (SEM).

turn inhibiting action potentials from propagating along the pain fibers and therefore reducing pain sensations.

We acknowledge the design of this pilot survey was not perfect and that caution is needed when interpreting and generalizing the reported findings. However, the data were robust, given that findings consistently pointed to a relationship between improvements in pain and ADL when compared with baseline (pretreatment scores) and between groups after the treatment had taken place. Intriguingly, these improvements were correlated with improvements in a number of secondary outcomes, including QoL, mood, sleep, functional outcomes, medication consumption, and satisfaction with the treatment. Further research is needed to see whether these relationships can be extended beyond the initial 2-week treatment.

It is interesting to note that the observed improvements can be achieved with relatively little effort on the part of the individual. On average, two treatments per day, each lasting 30 minutes, are recommended in the initial stages of treatment. We found that 80% of respondents adhered to this regime. The average duration of relief reported was 8 ± 11 hours. This would therefore suggest that respondents found the requirement to commit to two 30-minute sessions each day, and this may have provided them with a sense of improvement to justify this commitment. We recognize that compliance was high among those who returned the survey. It is possible that improvements were noted as respondents had a focused plan for treatment and were motivated by the short-term goals. As this study was open-label, future research should employ a valid control to test the robustness of the findings. Although, a possible placebo effect may explain 30% improvement in pain and ADL, it would not explain the consistent improvements across all outcomes when the data were cross-analyzed.

Intergroup Analysis

The improvements reported in this pilot survey were independent of the clinical subgroups and the source of the chronic pain. Pain beliefs and coping strategies play a key role in modulating QoL and pain.[38] These modulatory effects are particularly strong in veterans, especially in those in whom chronic pain and PTSD are comorbid.[15,39] This sample comprised mainly veterans ($n = 424$) with findings showing that outcomes improved following 2 weeks of noninvasive high-frequency stimulation. Having a treatment that may offer this cohort a treatment option is an advantage. We recognize that the comorbidity of PTSD was not ascertained in this study rendering it unclear to what extent PTSD influenced responses to the noninvasive high-frequency peripheral nerve fiber neuromodulation. To better target treatment for this group, future research should assess for PTSD and pain coping strategies. Although there is little evidence to suggest that veterans suffer chronic pain differently than an individual who has not served in the armed forces,[40] the cause of the pain may be different (eg, polytrauma), military recruits may be drawn from a particular section of the population, and they may bring their own characteristics and comorbidities.[15]

As the sample comprised mainly veterans with males being the predominant gender in veteran groups,[41] the resulting sample had a minority of females. In the general population, the existence of gender differences in pain perception, pain severity, and response to analgesic treatment is acknowledged.[42] In veteran samples, there also seems to be differences between males and females in the prevalence, health care utilization, and severity of chronic pain.[43–46] Therefore, the role gender plays in modulating the magnitude of improvement in outcomes to noninvasive high-frequency peripheral nerve fiber stimulation in veterans should be explored in future research. This can be achieved by enlarging the cohort to include additional centers. The inability to classify the nature of the pain (neuropathic or nociceptive) resulted from the fact that the information was collected independently of medical input. Therefore, future research investigating the effects of chronic pain treatments in veterans should carefully take these factors into account.

Survey Limitations and Areas of Improvement

The survey design fulfilled the key objectives as a preliminary assessment tool. This simple survey was designed with the objective of having 12 questions or less and taking less than 5 minutes to complete in a paper format. The average response using a coordinated multimedia approach to any survey would be 30% when a combination of survey techniques, such as in-patient survey, online, direct email correspondence with the option of reminders, telephone calls, and/or app questionnaire, are used.[47] Although this level of data collection was not used in this pilot survey, the paper format was able to return enough clinically relevant data. Indeed, the completed survey set was high, ensuring the data recovered were of high quality. Also, statistical analysis established clinically significant improvements in the primary outcomes, which were associated with improvements in the secondary outcomes.

A digital marketing strategy could be used in future studies (eg, personalized text messages/emails, etc.). This would allow for an extension to the follow-up period and facilitate real-time data collection, providing added value. The data collected in this survey has generated the knowledge to design the long-term assessment plan that is required to evaluate this treatment. We accept that some aspects including the nature of the pain (acute, nociceptive, or neuropathic) and the analgesics used depended on the subjective report of individuals and could be improved. These aspects will be included in the next phase assessment. It is hoped that by extending the follow-up duration, including a control group, improving the mode of data collection, and ascertaining medication use (eg, opioid use) and pain diagnosis from medical professionals, data quality will be enhanced.

CONCLUSIONS

This open-label pilot survey highlighted the potential role of a novel bioelectronic technique to manage pain and improve ADL. With further research comparing the longer-term effects of this stimulation with a control arm/group in specific pain cohorts, the efficacy of noninvasive high-frequency neuromodulation in pain will become more established.

ACKNOWLEDGEMENTS

We would like to thank all of the individuals who gave their free time to reply to the survey.

CONFLICT OF INTEREST

In the past, D.H. has received speaker honorarium from Platform 14 to participate in cadaver workshops in the area of peripheral nerve stimulation techniques. B.B. has provided consultancy on medical writing and data analysis to Platform 14.

Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1. Summary of Survey Items.

Table S2. Participants Who Did and Did Not Encounter Improvements in Quality of Life, Mood, and Sleep.

Table S3. Participants Who Did and Did not Encounter Improvements in Functional Outcomes Including Lifting, Sitting, Walking, and Standing.

Table S4. Participants Who Reported Pain Medication Had been Eliminated, Reduced, or Stayed the Same After 2 Weeks of Treatment.

Table S5. Participant Satisfaction with the Stimulation and Future Use.

Figure S1. Pain (A) and activities of daily living (ADL) (B) scores during baseline and follow-up for the group of veterans and members of the general public.

Figure S2. Pain during baseline and follow-up in participants who reported chronic, acute, neuropathic, and nociceptive pain.

Figure S3. Pain during baseline and follow-up in participants who reported pain in the back, shoulder, neck, knee, leg, and ankle and/or foot.

Figure S4. Activities of daily living (ADL) scores during baseline and follow-up in participants who reported chronic, acute, neuropathic, and nociceptive pain.

Figure S5. Activities of daily living (ADL) scores during baseline and follow-up in participants who reported pain in the back, shoulder, neck, knee, leg, and ankle and/or foot.

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