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Original Article



# The Effect of Electrical Stimulation Using the Alpha Device as a New Pain Relief Technique in the Management of Low Back Pain

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**Abstract**

**Background:** Various electrical stimulation modalities help treat low back pain. This study aimed to determine whether the Alpha device could be utilized as an effective modality in treating non-specific chronic low back pain.

**Methods:** Twenty volunteers with low back pain were randomly enrolled in two groups: intervention (Alpha) and control. The patients in the Alpha group received five consecutive 20-minute treatment sessions with the Alpha device, and the control group just received the placebo treatment with this device. The visual analog scale (VAS), the Oswestry Disability Index (ODI), and the Tampa Scale of Kinesiophobia (TSK) were used to evaluate pain intensity, functional disability, and fear of movement, respectively, *in both groups after* five consecutive 20-minute sessions of treatment.

**Results:** The study results showed a reduction in the VAS ($P=0.019$), ODI ($P=0.012$), and TSK ($P=0.017$) scores in the intervention (Alpha) group compared to the control group after treatment.

**Conclusion:** The considerable effects of the Alpha device on pain reduction, improved function, and reduced fear of movement in patients with low back pain suggest that this modality could be utilized in physiotherapy centers.

**Keywords:** Physical therapy, Electrical stimulation therapy, Low back pain

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## Introduction

As one of the most prevailing reasons behind disability throughout the world, low back pain affects approximately 80 percent of the world's population at least once in their lifetime. This health problem creates numerous social, personal, and economic issues for those affected (1,2). Low back pain is categorized into two groups: specific and non-specific. Almost 90 percent of all backaches fall into the non-specific category, which means clinically, the cause is never detected (1), and there is no evidence of pathology with imaging (3). Different approaches to treating backache have been proposed, which include pharmacotherapy, kinesiotherapy, and physiotherapy. As one of the widespread treatments in physiotherapy, electrotherapy can help reduce or alleviate low back pain and other symptoms (4). For this purpose, there are different modalities, such as TENS (transcutaneous electric nerve stimulation) and IF (interferential), in physiotherapy.

In electrotherapy, electric nerve stimulation on the surface of the skin helps reduce the patient's pain through increasing morphine-like materials (stimulation with low frequencies) or through a gate control mechanism and blocking the ways to transmit pain signals (stimulation with high frequency) (5). Investigation of neural oscillations (or brain waves) changes has gained widespread attention as a new field of endeavor in the study of pain and the effects of electrical stimulation. Electroencephalography (EEG) is an electrophysiological technique for recording neural oscillations. Generally, this technique investigates the four neural oscillations of alpha, beta, theta, and delta waves. Studies show that pain leads to considerable changes in neural oscillations, and electrical stimulations also can affect the EEG. Yıldırım et al showed that electric nerve stimulation on the skin surface in young and healthy people could enhance alpha wave activity and increase the current intensity correlated with increased alpha wave activity (6). EEG analysis in resting position has shown that the brain activity of patients with chronic pain differs from those without pain, with the EEG showing increased delta,

theta, and beta waves and decreased alpha waves (7-9). The transmission of these neural oscillations (specifically alpha) leads to the relaxation of the body. As a result, a higher volume of blood and oxygen can reach the brain, contributing to pain control via endorphin release (10).

This information and developments in biomedical engineering drove us to develop a device to generate brain alpha waves. Such a device would improve brain waves, especially alpha waves. The whole process of general and technical tests on the machine was conducted in accordance with the ISO 9001 standard, and the device has been clinically tested (Figure 1).

Moreover, it should be noted that because the therapist is provided with various options for reducing the patient's pain, alternative methods can be used in case one physical factor fails to achieve the desirable pain alleviation or the process is beyond the patient's tolerance threshold. The present study aimed to determine whether the Alpha device could be utilized as a suitable and effective modality in treating non-specific chronic low back pain.

## Methods

The present study was a preliminary, single-masked clinical trial carried out in the clinic of the Faculty of Rehabilitation after the approval of the Ethics Committee of Shahid Beheshti University of Medical Sciences. Twenty patients suffering from chronic non-specific low back pain were randomly assigned to two groups of Alpha and control by convenient sampling. Participants were included if they were aged 20 to 70 years, experienced localized lower back pain, had recurrent or chronic pain for more than three months with a pain severity of 3 to 10 on the visual analog scale (VAS), had no prior surgery on the vertebrae or lower limb, and did not have diabetic neuropathy. Patients were excluded if they were unwilling to continue the treatment or did not attend all five daily therapy sessions. After matching the two groups, the eligible people were randomly divided into an Alpha and a control group using numbered pieces of paper inside sealed envelopes.

Initially, the patients were briefed about the study's aims and methodology. Afterward, once the patients had agreed to participate in the study, the written consent forms, which had been approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences, were distributed among the subjects. Then, the examiner recorded the demographic data of each subject. In this study, the VAS, the Oswestry Disability Index (ODI), and the Tampa Scale of Kinesiophobia (TSK) were used to evaluate Pain intensity, functional disability, and fear of movement, respectively. In the VAS, 0 represents no pain, 1–3 shows mild pain, 4–6 shows moderate pain, 7–9 shows severe pain, and 10 shows the worst pain. The subjects were asked to choose the number that best described the severity of their pain. The Persian version of the ODI Questionnaire contains questions covering functional activities, including the severity of the pain, personal care, lifting, walking, sleeping, sex life, social life, and travel. A range of 0 to 20 represents the lowest disability, 21–40 represents mild disability, 41–60 represents severe disability, 61–80 represents disabled people, and 81–100 represents those confined to bed (11). The Persian version of the TSK questionnaire contains 17 items, each answered on a four-point scale. On this scale, 1 shows total disagreement, and 4 shows total agreement. The final scoring in this questionnaire is between 17 and 68; the higher the score, the more severe the fear of movement, and hence their avoidance of daily activities (12).

### *Treatment plan*

Patients were randomly divided into an Alpha and a control group. The patients in the Alpha group received five consecutive 20-minute sessions of treatment. Electric stimulation in the Alpha group using the Alpha device was performed through four rubber electrodes (6×4 cm). A pair of electrodes were applied to the painful area, while another pair was used on the upper part of the area on either side of the spine in a way that covered the painful area. The Alpha device started working with the frequency of 95–96 Hz with pulse intervals of 89–104 μs and tolerable intensity for the patient.

In addition to its specific waveform, this device can cut the current on and off so that the maximum tolerable current is applied to the patient for five seconds, followed by a five-second. This cycle was repeated for 20 minutes. Since the current was tolerable for most patients, the stimulation was accompanied by mild muscle contractions. These mild contractions could help improve


**Figure 1.** The Alpha device (A) and electrode placement (B)

blood circulation and better oxygenation of the muscle and connective tissue, reducing pain and muscle tension.

In the control group, the working process was precisely similar to the method of the Alpha group, with the difference that the control group received the placebo treatment with the Alpha device, i.e., the current gradually increased over 5 seconds until the patient felt the current, and then the current was reduced to zero. In order to comply with ethical issues, all control group members were treated after the placebo treatment period was over. A physiotherapist conducted all measurements for different variables. The patients were unaware of their assigned group; therefore, this study was a single-masked clinical trial. Evaluations were done before the beginning of the treatment program and one day after the fifth session (the last session) for each patient.

### *Statistical analysis*

After the data were gathered, they were analyzed using SPSS software version 25. The Kolmogorov-Smirnov (K-S) test was done to ensure the normal distribution of the data. Paired *t*-test analysis was conducted to examine the differences between pre- and post-treatment in each group. The ANCOVA test was used to detect the difference in the means of the two independent groups. $P < 0.05$ was considered significant.

## Results

This study aimed to determine the effectiveness of the Alpha device in patients suffering from chronic low back pain. Twenty patients with the age range of 46.92 ± 14.14 participated in this study. Half of the participants were female. The demographic specifications of the participants in each group are provided in Table 1. The K-S test results showed that the age, height, weight, and body mass index (BMI) variables were normally distributed ($P > 0.05$). Comparing the means of variables in both groups showed that the age, height, weight, and BMI variables in the two groups did not have a meaningful difference ($P > 0.05$).

In order to investigate the effectiveness of the intervention on pain, functional disability, and fear of movement variables, a paired *t* test was conducted (Table 2). The mean of all indicators in the Alpha group significantly decreased after the intervention compared to the control group ($P < 0.05$).

The ANCOVA test showed that the mean values in the Alpha group generally decreased significantly compared to before treatment. Also, after five consecutive sessions, there was a significant difference between the intervention (Alpha) and the control groups regarding all variables (VAS, ODI, and TSK). Figures 2, 3, and 4 depict that the different mean values decreased in the Alpha group significantly after the intervention (following five consecutive treatment sessions). In contrast, there was no significant difference in the control group.

**Table 1.** Comparing the demographic characteristics of the two groups (mean ± SD)

| Variable | Control group ($n = 10$) Mean ± SD | Alpha group (n = 10) Mean ± SD | *P* value |
|---|---|---|---|
| Age (y) | 42.65 ± 19.38 | 51.20 ± 8.91 | 0.15 |
| Height (cm) | 165.50 ± 10.85 | 168.00 ± 10.87 | 0.67 |
| Weight (kg) | 64.32 ± 17.21 | 74.56 ± 9.90 | 0.15 |
| BMI (kg/m$^2$) | 23.24 ± 4.54 | 26.44 ± 2.32 | 0.07 |

## Discussion

The aim of the present study was to determine the effectiveness of the Alpha clinical device as a suitable and effective modality in reducing pain, improving functional disability, and reducing the fear of movement in patients who suffer from chronic non-specific low back pain. The results of this study showed that Alpha could improve all of the indicators, including VAS, ODI, and TSK, in the intervention (Alpha) group.

The Alpha device, as noted earlier, has two abilities:

1) generating electric stimulation in waves identical to natural neural brain waves. According to Yıldırım and colleagues' study, these stimulations can increase alpha activity. EEG analysis in resting position has shown that in patients with chronic pain, the activity of delta, theta, and beta waves increase while the alpha waves decrease (7-9). Increased alpha activity resulting from stimulation using the Alpha device can lead to the relaxation of the body with the increase in the blood and oxygen supply to the brain. This device also plays a role in pain control by producing endorphins (9). In addition to this potential mechanism, electrical stimulation, acting through gate control and blocking pain signal pathways (high-frequency stimulation), can alleviate patient pain (4).
2) Using the cutting off and turning on feature, which is among the specifications of the Alpha machine (five seconds of stimulation and five seconds of break), stimulation at the maximum tolerable current is possible, which is concurrent with mild contraction of back muscles. This feature can help improve the blood circulation and oxygen supply to the muscles, reducing muscle tension. Reducing the patient's pain

**Table 2.** Comparison of the mean ± SD and *P* value of study variables (VAS, ODI, and TSK) in both Alpha and control groups before and after treatment

| Intervention | Group | Before treatment Mean ± SD | After treatment Mean ± SD | *P* value |
|---|---|---|---|---|
| VAS | Control | 5.20 ± 2.09 | 5.40 ± 1.17 | 0.71 |
| | Alpha | 30 ± 1.63 | 3.80 ± 2.09 | 0.019* |
| ODI | Control | 12.03 ± 4.29 | 12.90 ± 4.58 | 0.239 |
| | Alpha | 13.10 ± 3.38 | 8.80 ± 5.45 | 0.012* |
| TSK | Control | 40.50 ± 7.90 | 40.60 ± 8.16 | 0.906 |
| | Alpha | 41.30 ± 2.05 | 35.90 ± 6.54 | 0.017* |

* Significant (based on paired *t* test).

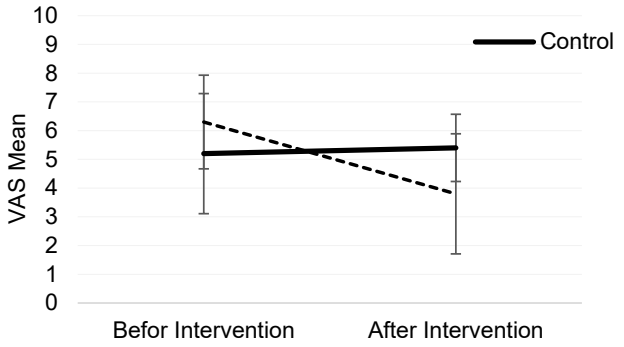


**Figure 2.** Changes in mean VAS (visual analog scale) before and after 5 sessions in the Alpha and control groups. Statistically significant for the Alpha group (*P* value=0.031) and significant between the two groups (*P* value=0.014) based on ANCOVA

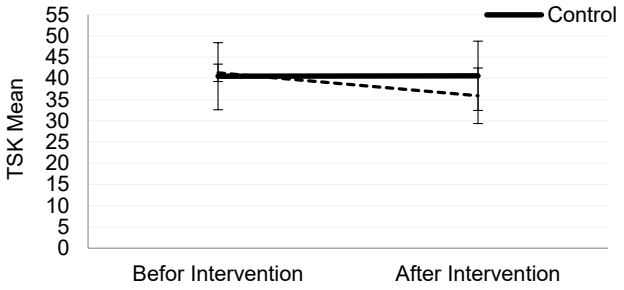


**Figure 4.** Changes in mean TSK (Scale of Kinesiophobia) before and after 5 sessions in the Alpha and control groups. Statistically significant for the Alpha group (*P* value=0.012) and significant between the two groups (*P* value=0.017) based on ANCOVA

can directly affect the patient's fear of movement, improve the patient's mobility and performance, and ultimately improve the patient's quality of life. The other advantages of this device are its small and portable size, low price, and minimal complications. Its contraindications are similar to those of the TENS device. Considering that the use of painkillers, especially in the long term, can have severe side effects, according to the specification of the Alpha device, we can suggest that this device can reduce the pain of patients and improve their activities of daily living without any side effects (13,14).

In the end, it is suggested that comparisons of the modalities available to physiotherapy should be conducted with larger sample populations to assess the effectiveness of the Alpha device. It should be noted that the Alpha device treatment method did not have any side effects for the patients. Considering that the Alpha device was examined for the first time in this study, one of the significant limitations of this study was that due to the lack of similar articles, it was not possible to compare the results of this study with other studies. Moreover, the sample was small because of time limitations, and a follow-up study was impossible. Due to these limitations, more research needs to be done on this matter.

## Conclusion

The considerable effects of the Alpha device on pain

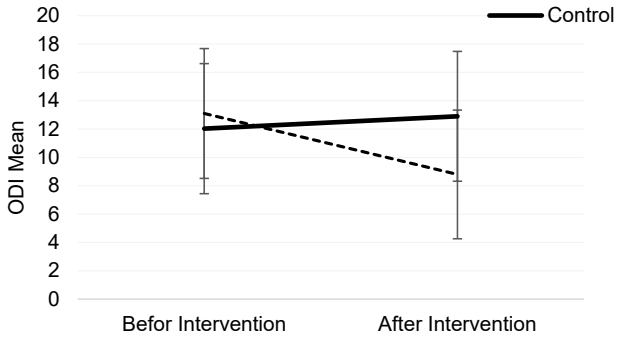


**Figure 3.** Changes in mean ODI (Oswestry Disability Index) before and after 5 sessions in the Alpha and control groups. Statistically significant for the Alpha group (*P* value=0.021) and significant between the two groups (*P* value=0.001) based on ANCOVA

reduction, improving performance, and reducing the fear of movement in low back pain patients make this modality suitable for use in physiotherapy centers.

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**Authors' Contribution**

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**Data curation:** Fatemeh Amiri.
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**Competing Interests**

The authors declare that they do not have any conflict of interest.

**Ethical Approval**

All subjects gave their informed consent before participating in the study. The protocol was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences (IR. SBMU. RETECH. REC.1401.146).

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