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ORIGINAL RESEARCH ARTICLE

Wearable low back trainer combined with massage in the treatment of chronic nonspecific low back pain

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ABSTRACT

Objective: To observe the clinical effect of wearable low back trainer combined with massage in the treatment of chronic non-specific low back pain. **Methods:** A total of 56 chronic nonspecific low back pain patients were randomly assigned to three groups. The observation group (n=19) was treated with wearable device treatments based on massage for two weeks, once a day, eight minutes each time, five times a week, while the control group (n=19) received massage only for two weeks, once a day, 20 minutes each time, and the blank group (n=18) rest only with closely observation. The therapeutic effect of three groups were evaluated by VAS and ODI scores before the treatment, one week after treatment and two weeks after treatment respectively. **Results:** There was no significant difference in the VAS score between the observation group and the control group before treatment ($P>0.05$) while the VAS score difference between the three groups after one week and two weeks of treatment were statistically significant ($P<0.05$). The VAS scores of the observation group and the control group showed a downward trend with time. After 2 weeks of treatment, the VAS value of the observation group decreased significantly more than the control group, and the difference was statistically significant ($P<0.05$). The decrease of VAS value in the group was significantly greater than that in the blank group, and the difference was statistically significant ($P<0.05$). There was no significant difference in the ODI score between the observation group and the control group before treatment and after 1 week of treatment ($P>0.05$). However, there was a statistically significant difference in the ODI score between the three groups after 2 weeks of treatment ($P<0.05$). The changing trends of ODI values in the three groups were different and both the observation group and the control group showed a downward trend. After two weeks of treatment, the ODI values of the observation group decreased significantly more than the control group with statistically significant differences ($P<0.05$). However, the ODI value of the blank group decreased after 1 week of treatment and increased again after two weeks of treatment. **Conclusion:** The use of the wearable low back trainer combined with massage therapy has a better therapeutic effect on chronic non-specific low back pain and can relieve pain more effectively than just simple massage therapy alone.

Keywords: chronic nonspecific low back pain; wearable low back trainer; massage; visual pain analogue scale; Oswestry disability index

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1. Introduction

Chronic non-specific low back pain is a group of pain-based syndromes that occur in the lumbar spine and lumbosacral region[1] and is one of the most common clinical symptoms of musculoskeletal-related diseases. Studies have shown that 80% of adults will experience low back pain at different times in their lives with an incidence rate of 7.6% to 37%, and it is the first cause of activity limitation in people under the age of 45[2]. The treatment of chronic non-specific low back pain includes surgery, drug therapy and rehabilitation[3]. Presently, some scholars have advocated that exercise therapy is the first choice in the treatment of chronic non-specific low back pain[4,5], and that massage is also one of the treatment methods recommended by evidence-based medicine[6,7]. In addition, studies have also found that exercise therapy combined with other methods to treat non-specific low back pain can achieve the best recovery effect[8]. Due to the complex pathological mechanism of low back pain and the large individual differences of patients, it is very difficult to accurately choose the mode, intensity, frequency and time of exercise therapy[9]. Wearable low back trainers utilise a pair of sensors and an app to provide therapeutic exercise via video games. The trainer completes 17 movements through more than 50 games and trains the core muscles to achieve the purpose of treatment, and to a certain extent solve the problem of large individual differences in traditional sports therapy treatment methods and effects. This study intends to use a wearable low back trainer combined with massage therapy to treat patients with chronic non-specific low back pain and evaluate the improvement of low back pain symptoms in patients before and after treatment to provide a basis for the clinical application of wearable low back trainer.

2. Clinical data

2.1. Case selection criteria

Diagnostic criteria

Referring to chronic nonspecific low back pain federal guidelines and European guidelines[10,11]:

(1) Low back pain or discomfort refers to the pain area located between the lower angle of the scapula and the buttocks with symptoms that persist for more than 3 months with or without radiating pain in the lower extremities. (2) Tenderness and/or muscle tension in and around the pain area. (3) Repeated episodes or chronic progressive exacerbations. (4) No low back pain caused by other systemic diseases.

Inclusion criteria

(1) Meet the above diagnostic criteria. (2) 18-65 years old. (3) Clear consciousness and stable vital signs. (4) Imaging and biochemical examinations have ruled out tumours, infections, fractures and other specific pains not caused by the spinal system. (5) Subjects and their family members agree to participate in this study and sign the informed consent form voluntarily.

Exclusion criteria

(1) There are obvious abnormalities in imaging examination including vertebral body compression fracture, sacral fissure, intervertebral disc herniation, spondylolisthesis, etc. (2) Severe cardiovascular and cerebrovascular diseases, diabetes, ankylosing spondylitis, rheumatoid arthritis, etc. (3) Pregnant women and lactating women. (4) Those who received drugs, surgery and other treatments at the same time and affected the effect indicators of this study (5) Those who had poor compliance and gave up treatment in the middle of the study.

2.2. General information

Fifty-six patients were selected with chronic non-specific low back pain that has met the inclusion criteria in the Department of Rehabilitation Medicine, Pearl River Hospital of Southern Medical University from October 2016 to February 2018. The selected patients were then further divided into a blank group of 18 cases, a control group of 19 cases and an observation group of 19 cases according to the random number table method.

This study was approved by the Ethics Committee of Zhujiang Hospital, Southern Medical University. There was no significant difference in age, gender, course of the disease and lumbar spine mobility among the three groups (P>0.05), which were comparable, as shown in **Table 1**.

Table 1. Comparison of general data of three groups **($\bar{x} \pm s$)**

Group	n	Gender		Age/ years old	Course of illness /month	Lumbar spine mobility					
		Male	Female			Forward bending	Back stretch	Left bending	Right bending	Left rotation	Right rotation
Blank	18	10	8	41.4±12.4	28.7±51.0	66.5±20.7	20.2±11.1	26.4±8.8	24.4±10.0	31.8±10.3	33.7±9.8
Control	19	10	9	41.8±13.8	31.3±55.1	56.9±21.3	24.3±16.0	24.6±13.7	25.3±16.4	34.3±8.7	32.1±10.9
Observation	19	10	9	44.7±13.8	36.4±49.5	59.4±18.9	24.3±11.3	29.1±14.9	32.2±16.8	30.9±10.4	31.8±8.4

3. Methods

3.1. Treatment methods

The blank group

Bed rest for 2 weeks without any treatment, and the changes in the condition were closely observed.

The control group

Take massage therapy. In the session, the patient was placed in the prone position while the therapist uses the rubbing method to relax the muscles of the patient's lower back and the muscle fibre spasm with nodular or cord-like changes in the waist, buttocks or legs was pressed or plucked until it softens or disappears. Then the patient took the lateral recumbent position and performed the left and right oblique pulling method to adjust the facet joints. Thereafter, the patient was then adjusted to the prone position again where the meridian joints were adjusted by backward extension and waist rotation method. Finally, the patient was instructed to lie flat and the passive straight legs were raised and muscles were pulled following which the rolling, kneading, pressing, pointing and other techniques were used to sort out the techniques. Each massage session was performed for 20 minutes each time, once a day, 5 times a week for a total of 2 weeks as a course of treatment.

The observation group

On the basis of traditional massage therapy, combined with waist and back trainer training. The patients first received the massage therapy of which the massage method was the same as that of the control group. Following the massage, the group was then given the wearable waist and back trainer for training. Place Valedo Bluetooth sensors at sternum handle and lumbar spine 2 before training, and then enter the game interface. Before the game starts, lumbar spine activities were first performed in all directions to calibrate the sensors in the wearable trainer. As the game begins, the movements made by the waist and back correlates with the game level by controlling a flying bird in the game which moves to advance in a certain route to carry out the movement of the lumbar spine in all directions. In total, there are 17 types of movements in the game and more than 50 kinds of therapeutic exercises were carried out. Each training session was 8 minutes carried out once time a day, 5 times a week with a total of 2 weeks as a course of treatment.

3.2. Statistical methods

EmpowerStats and R software were used for statistical processing. The measurement data were expressed as ($\bar{x} \pm s$). Variance analysis was used for comparison among the three groups, and LSD-t test was used for pairwise comparison within the three groups. The enumeration data were expressed as percentage, and $\chi 2$ test or Fisher exact test was used for comparison among the three groups. A generalised additive mixed model was used to analyse the trends of the three sets of measurement data. P<0.05 was considered statistically significant.

4. Results

4.1. Efficacy criteria

All assessments were completed by the same professionally trained and qualified therapist before treatment and after one and two weeks of treatment.

Assessment of pain intensity

A visual analogue scale (VAS) was used to assess patients' pain intensity. Specific method: On the 10 cm line segment, write 0 points for "no pain" at the left endpoint, and 10 points for "severe pain" at the right endpoint and the patient gives the corresponding score value according to their pain degree. For the scoring system, the higher the pain intensity, the higher the score. VAS is a one-dimensional assessment scale with good sensitivity, reliability and validity[2].

Assessment of functional impairment

The modified Chinese version of the Oswestry Disability Index (ODI) questionnaire was used to evaluate the functional impairment of patients. The questionnaire contains a total of 9 items[12,17], including pain, single function (lifting, sitting, sleeping, standing, walking) and personal comprehensive function (daily activities, social activities and outings) as three major areas of assessment. The minimum score for each item is 0 and the maximum score is 5. For the scoring system, a higher score indicates higher severity for the degree of dysfunction. After the corresponding scores of the 9 items were accumulated, the percentage of the maximum total score (45 points) was calculated with high calculated scores indicating a more seriousness of the patient's dysfunction.

4.2. Treatment outcomes

Analysis of variance of the VAS and ODI scores of the three groups

There was no significant difference in the VAS scores among the 3 groups before treatment (P>0.05). The difference was statistically significant (P<0.05) between the VAS scoring groups and before and after treatment after 1 week and 2 weeks of treatment in the 3 groups (P<0.05). There was no significant difference in ODI score between the three groups before treatment and after 1 week of treatment (P>0.05) while there was a statistically significant difference in ODI score between the three groups after 2 weeks of treatment (P<0.05). See **Table 2**.

Table 2. Comparison of VAS and ODI scores in three groups before and after treatment **($\bar{x} \pm s$)**

Group	VAS score/point			ODI score/%		
	Before treatment	1 week after treatment	2 weeks after treatment	Before treatment	1 week after treatment	2 weeks after treatment
Blank	5.3889±2.2000	4.7222±1.8726	4.9375±2.1125	28.6667±17.0949	25.7778±12.8684	27.6250±15.4612
Control	5.5789±2.1938	3.7895±2.2504	3.4118±2.2655 1)	38.4211±17.5319	30.6316±15.6070	28.9412±17.8342
Observation	5.4211±1.5024	3.1579±1.2589 1) 2)	1.8000±1.1464 1) 2)	36.5263±14.0292	24.4211±12.1029	15.2000±15.1714 1)

Note: Compared with before treatment, 1) P<0.05; compared with the blank group, 2) P<0.05.

The trend analysis of the VAS and ODI scores in the three groups before and after treatment

The generalised additive model analysis showed that there was no significant difference in the baseline values of VAS between the three groups before treatment (P>0.05). After treatment, the observation group was compared with the control group and the VAS scores showed a downward trend over time. After 2 weeks of treatment, the decrease in VAS values of the observation group was found to be significantly greater than that of the control group where the difference was statistically significant (P<0.05). However, the difference was not statistically significant (P>0.05). The decrease in VAS values in the observation group after 1 week and 2 weeks of treatment were significantly greater than that in the blank group with a statistically significant difference (P<0.05). See **Figure 1**. On the other hand, there was no statistically significant difference (P>0.05) between the 3 groups of ODI baseline values before treatment and 1 week after treatment (P>0.05) with statistically significant difference (P<0.05) was only seen after 2 weeks of treatment in the 3 groups. However, during the treatment process, the ODI values of the 3 groups were different and the ODI values of the observation group showed a downward trend. The decrease in the ODI values of the observation group after 2 weeks of treatment was significantly greater than that of the control group and the difference was statistically significant (P<0.05). Meanwhile, the ODI values of the blank group decreased after 1 week of treatment and increased again after 2 weeks of treatment. See **Figure 2**.

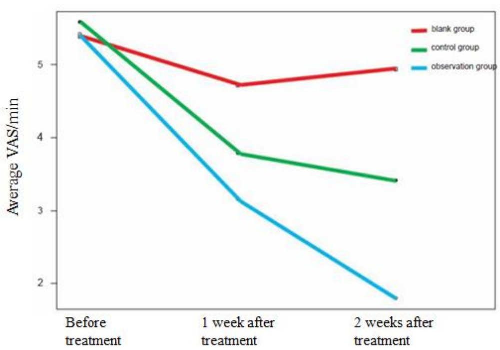

Figure 1. Comparison of VAS score at different times among three groups.

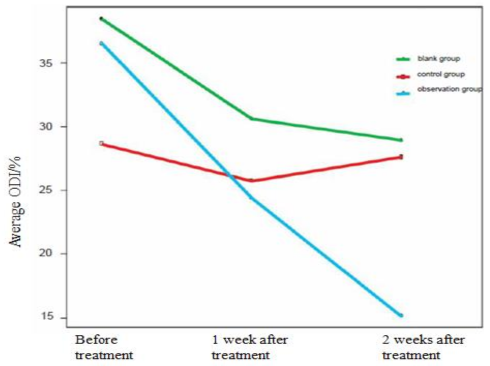

Figure 2. Comparison of ODI score at different times among three groups.

5. Discussion

Wearable devices are safe, stable, smart and miniature technology products or closely-fitting or implanted into the human body as monitor indicators in real-time through bio-sensing and other technologies and transmit the collected indicators to mobile terminals or the cloud through wireless communication. After statistical analysis such as modelling and data mining, exclusive medical information data is then formed for doctors to use as a benchmark to provide users with accurate medical services. It has the characteristics of wearable, intelligent mobile and human-computer interaction[18]. As a product of contemporary information technology, the market size of wearable devices is gradually expanding[19]. In the field of health care, wearable devices are mainly used in five aspects: Health monitoring, safety monitoring, family rehabilitation, curative effect evaluation, and early disease detection[20]. The sensor represents the technical performance of the wearable device, and its main function is to input data into the wearable device, which is the premise of subsequent data processing and feedback[21]. The application of sensors can simplify the process of rehabilitation evaluation and can also improve the objectivity and accuracy of evaluation, thereby improving the effectiveness of rehabilitation treatment[22]. At present, the sensors used in wearable devices mainly include motion sensing, environment sensing and physiological parameter detection sensors[23].The waist and back trainer used in this observation uses wireless motion sensors to send data back to mobile phones or computer terminals in real-time. The wireless motion sensors use Bluetooth technology to capture the smallest movements of the upper body in 3D. Its motion tracking components include a 3D gyroscope, a 3D accelerometer and a 3D magnetometer for continuous and accurate calculation of the axial vector of the motion angle and acceleration. Based on various technologies of sensors, the wearable low back trainer uses a designed interactive game. The sensor reads the body posture to determine whether the required operation is performed and then dynamically adjusts to achieve the purpose of treating low back pain. Exercising through wearable devices can control the movements and time as well as to conduct evaluations and recommend exercise prescriptions based on the evaluation results, which is more advantageous than traditional exercise therapy. The wearable devices can carry out an in-depth analysis of the collected data for big data, providing evidence-based medicine for clinical diagnosis and treatment activities. Wearable technology has the characteristics of convenience and intelligence and provides new ideas for the development and progress of the field of rehabilitation medicine[24].

As a new wearable medical device, the safety and effectiveness of the wearable low back trainer are the key links in determining its clinical application. To test the improvement of patients' symptoms after treatment, this study design combines massage therapy with a wearable low back trainer and compared it with massage therapy alone. The study found that as exercise therapy for the treatment of chronic non-specific low back pain, the wearable low back trainer combined with massage therapy can significantly relieve the pain symptoms of patients with chronic low back pain with better effect than that of a simple massage.

Patients who received rest without any treatment had unclear efficacy and their ODI scores were found to be worse at the end of 2 weeks of treatment as compared to before treatment. In Van Tulder's[25] study, it was also found that bed rest is ineffective. The wearable low back trainer uses virtual technology and games to monitor various information of the limbs in real-time and provides a dynamic trajectory of the athlete. At the same time, the trainer corrects the posture in real-time, which improves the effect of rehabilitation training. Its stimulating game environment can provide rehabilitation guidance and improve compliance for patients with low back pain[26]. In this study, the observation has a small sample size, a limited number of treatments and a short follow-up time and the long-term efficacy is unclear. Therefore, there are certain limitations and further research is needed in the future.

The application of wearable devices in patients with chronic non-specific low back pain is still in its infancy and most wearable devices tend to be intelligent for health monitoring and rehabilitation aids, while relatively few products are for remote rehabilitation for disease prevention and treatment[27].

6. Conclusions

The wearable back trainer also needs to be further developed in the treatment of diseases. Firstly, the game design needs to be further integrated with clinical practice. At the beginning of the game and after a period of use, a variety of methods can be used to evaluate and select or adjust according to the evaluation results. In different training games, the game design needs to take into account factors such as lumbar spine mobility, muscle strength, muscle endurance and fun. Secondly, patients and doctors can be distinguished in the App design. With the consent of patients, the patient's treatment and evaluation information can be fed back to the doctor in time. It is convenient for doctors to understand the patient's training in time, track and adjust the treatment methods, strengthen supervision, and provide a new way for remote rehabilitation. According to the information collected, the Internet of Things big data platform is constructed. Through data processing, a more scientific, reasonable and personalized treatment plan is formulated[28]. In terms of health management, important and trivial data such as wearable devices, personal activity location and living habits can be more completely run through, which will greatly help personal health management and environmental adaptation. Through the interactions with life scenarios, health education can be better carried out[29] where wearable devices can be directly worn on the body, and the design should be beautiful and generous while meeting the user's comfort experience[30]. Thirdly, it should be more convenient and faster to wear and consider environmental protection and reusability. As a new method for the treatment of chronic non-specific low back pain, the wearable device low back trainer has a certain clinical application value. However, there are still many aspects that limit its wide clinical promotion such as price-friendly and privacy issues[31]. The rationality and validity of the exercise prescription remains to be further improved, and its long-term efficacy still needs further observation.

Conflict of interest

The authors declare no conflict of interest.

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