Research Proposal

(Version number: 1.0; Version date: 2022.09.03)

Project Name: External diaphragm pacing therapy and correlation study on trunk balance and respiratory function in stroke patients

Organization: The First Affiliated Hospital of Anhui Medical University

Department: Department of Rehabilitation Medicine

Researchers: ZHANG liqiong

1.Integrity statement

This study ensures that the operation is strictly in accordance with the test procedures and the authenticity of the data records; there is no conflict of interest in this study.

2. Research topic

External diaphragm pacing therapy and correlation study on trunk balance and respiratory function in stroke patients

3. Research background:

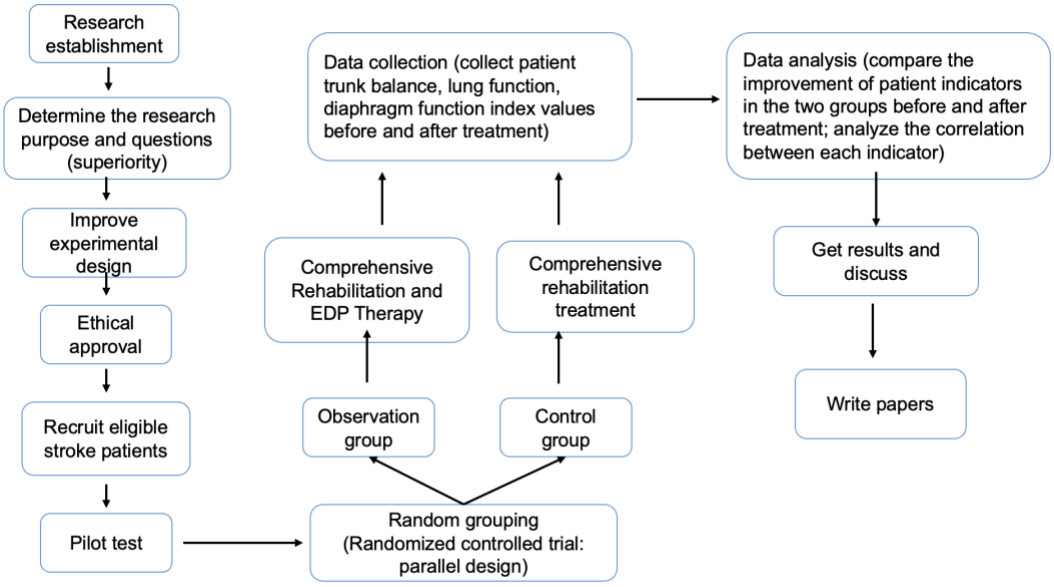
Stroke is a common neurological disease in clinical practice and is the leading cause of death and disability worldwide. Post-stroke patients are often left with multiple functional impairments. Although most people return to walking independently 6 months after stroke, balance and trunk control problems persist in the chronic stage of the disease, which has a significant impact on patients' quality of life. Impact. Post-stroke patients not only have functional impairments in limb movement and balance, but their respiratory function is also significantly lower than that of normal people. Clinical studies report that respiratory muscle training can not only improve respiratory function, but also promote the recovery of the body's balance function and trunk control ability. Some studies have pointed out that human trunk control also involves interaction with key respiratory muscles. When the activation of respiratory muscles is damaged, core stability decreases, affecting normal trunk balance. However, the correlation between trunk balance ability and respiratory function in stroke patients has not yet been clarified, which may provide new ideas for clinical rehabilitation evaluation and treatment of stroke patients. There are many clinical methods to evaluate the respiratory function of stroke patients. The commonly used quantitative evaluation methods are pulmonary ventilation function assessment and diaphragm ultrasound imaging. The diaphragm is the main respiratory muscle of the human body. Extracorporeal diaphragm pacing (EDP) therapy applies neuromuscular electrical stimulation of appropriate intensity and frequency to the phrenic nerve, which can improve the patient's respiratory movement by affecting the passive activity of the diaphragm and is beneficial to the treatment. Respiratory muscle weakness has significant effects. At present, clinical studies mostly use EDP for pulmonary function rehabilitation in patients with central nervous system diseases. It is believed that it can enhance the strength of respiratory muscles and improve patients' breathing exercises and quality of life. Studies have pointed out that EDP can not only improve the respiratory function of stroke patients, but also enhance trunk control ability. However, such reports are rare and limited to clinical observations. There are few studies on EDP's promotion of trunk balance function recovery and its specific mechanism of action. Based on this, the purpose of this study is to apply EDP to treat stroke patients, observe the improvement of trunk balance ability, lung function and

diaphragm function in stroke patients, and analyze the correlation between trunk balance ability and respiratory function indicators.

4. Research purpose

Apply EDP to treat stroke patients, observe the improvement of trunk balance ability, lung function and diaphragm function in stroke patients, and analyze the correlation between trunk balance ability and respiratory function indicators.

5. Design plan



6. Research matters execution process

2023.01.01 to 2023.08.01 , and relevant data before and after the intervention will be entered and sorted. Continue to review relevant domestic and foreign literature related to this topic and make a summary.

2023.08.02-2023.09.30 The first stage of data analysis, discussion of results, and writing of the paper.

2023.09. 3 0-2024.09.30 Continue to recruit subjects , conduct second-stage data analysis, discuss results, and write papers .

7. Recruitment of participants

30 stroke patients admitted to the Department of Rehabilitation Medicine of the First Affiliated Hospital of Anhui Medical University from January 2023 to August 2023 were randomly selected in the first phase .

8. Ethical considerations

This study has been approved by the Ethics Committee of the First Affiliated Hospital of Anhui Medical University. In accordance with the ethical principles of the "Ethical Review Methods for Biomedical Research Involving Humans", WMA's "Declaration of Helsinki" and CIOMS's "International Ethical Guidelines for Biomedical Research Involving Humans", after review and approval by the chief review committee, the review results will be reported to the ethics committee. Agree It carried out this research and published the research results publicly. Approval time is September 20, 2023, approval number: PJ2023-11-49.

9. Inclusion and exclusion criteria

Inclusion criteria: ①Patients who meet the diagnostic criteria for stroke for the first time; ②Patients whose disease duration is within 6 months, have received specialist and standardized treatment, and have stable vital signs; ③are informed of this study, voluntarily accept rehabilitation treatment, and sign an informed consent form; ④no chronic breathing before and after stroke History of systemic and circulatory diseases. ⑤ The patient can maintain the starting posture evaluated by the mTIS scale for 10 seconds. The standard for the starting posture is: sitting on the edge of the bed without any support for the back and arms, with the thighs in full contact with the bed surface, and with the feet flat and the same width as the hips. On the ground, bend your knees 90° and place your arms on your thighs.

Exclusion criteria: ① People with severe heart, lung and other organ function diseases, such as pulmonary embolism, pacemaker placement, etc.; ② People with severe cognitive impairment and abnormal hearing and understanding; ③ People who are not suitable for electrical stimulation treatment Other reasons include sudden instability of vital signs, malignant tumors, combined mental illness, etc.

10. Grouping method

Eligible patients were recruited by members of the project team and divided into experimental groups and control groups through a random number table method . Subjects were randomly enrolled and were unaware of their grouping , and only some researchers were informed of the grouping .

1 1. Intervention methods

The control group received routine rehabilitation training: with the help of rehabilitation therapists, corresponding muscle strength training, comprehensive training of hemiplegic limbs, balance function training, limb neuromuscular electrical stimulation, acupuncture and other comprehensive rehabilitation treatments were carried out according to the patient's functional injury site. On this basis, the observation group added an EDP-D2 external diaphragm pacemaker (Zhongke Tyco (Guangzhou) Electronic Technology Co., Ltd.) for treatment. The specific operation steps are as follows: After

disinfecting the skin, place the small electrode pads on the lower 1/3 of the outer edge of the sternocleidomastoid muscles on the left and right sides, and place the large electrodes on the surface of the pectoralis major muscles on both sides, and fix them with medical tape. The pacing frequency and stimulation intensity are adjusted by the degree of stimulation. Each treatment time is 20 minutes, once a day, 5 days a week, and the treatment course is 4 weeks.

12. Measurement indicators

(1) Pulmonary function measurement: Use an exercise cardiopulmonary testing system (Nanjing Hanya Smax58ce) to test the patient's lung function before treatment and 4 weeks after treatment, including forced vital capacity (FVC), forced expiration in 1 second Forced Expiratory Volume in 1 second (FEV1), FEV1/FVC (%), standing and supine vital capacity (Position vital capacity, VC), and calculate the change percentage of vital capacity from standing to supine position [ΔVC (%) : (upright vital capacity - supine vital capacity) / supine vital capacity (%)].

(2) Diaphragm function evaluation: The American Sonosonic portable color ultrasound (M-Turbo) was used to measure the diaphragmatic excursion of quiet breath (DE-QB) on the hemiplegic side of the two groups of patients before treatment and 4 weeks after treatment. and forced breathing diaphragm mobility (Diaphragmatic excursion of deep breath, DE-DB), and measure the thickness of the hemiplegic side diaphragm (The thickening of the diaphragm, Tdi) at the end of expiration and end of inhalation to calculate the diaphragm thickening rate [Thickening fraction, TF: (diaphragm thickness at end-inspiration - diaphragm thickness at end-expiration) / diaphragm thickness at end-expiration (%)].

(3) The Modified Trunk Impairment Scale to Norwegian Version (mTIS) is used to evaluate the patient's trunk balance ability before treatment and after 4 weeks of treatment.

1 3. Definition of effective identification of test participants

Effective: The patient's intervention time is 4 weeks, and the patient's treatment is basically completed . The measurement indicators are completed according to standards and the data is complete .

Withdrawal: Due to personal reasons, incompatibility with treatment, dissatisfaction with the research process or other reasons.

Exclusion: Patients with severe comorbidities or complications who do not participate in the study.

Loss to follow-up: The patient was suddenly discharged from hospital or transferred to another department during the trial, resulting in the continuation of the study.

Confounding (confounding): A situation in which external factors or indicators have a false influence on the research results.
Suspension: Refers to the premature termination of a study, which may be due to unpredictable safety issues, poor treatment efficacy, or other serious problems that have to stop the trial.
Suspension: Suspension may occur due to safety issues, concerns about treatment efficacy, or other reasons that require further investigation.

14. Statistical analysis methods

All data were analyzed using spss26.0, count data were expressed as frequencies, and Fisher's exact probability method was used; for measurement data that conformed to normal distribution, the independent sample t test was used for comparison between groups, and Pearson correlation analysis was used for correlation; if it did not conform to normality Rank sum test was used for comparison of distribution between groups, and Spearman correlation analysis was used for correlation. $P<0.05$ was considered as a statistically significant difference.

15. Expected results

EDP therapy contributes to the restoration of respiratory function and trunk balance in stroke patients. Additionally,the trunk balance ability in stroke patients displays a correlation with Respiratory function.