The Effect of Baduanjin on Physical Fitness and Bone Density in Maintenance Hemodialysis Patients

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1.Research Background

Chronic kidney disease bone mineral metabolism disorders exist in maintenance dialysis (MHD) patients, with a high incidence of bone and joint pain of 58.7%. At the same time, the motor ability of patients with chronic kidney disease decreases as the disease progresses, and MHD patients gradually experience muscle atrophy, decreased upper limb motor ability, slow walking, and slow sitting and standing. Long term lack of exercise further exacerbates bone and joint lesions. Functional fitness refers to the comprehensive physiological functions of the body's cardiopulmonary, skeletal muscle system and the quality of softness and balance, and is now mainly targeted at the elderly and the frail; it evaluates the level of daily life activities, reflects the decline of body functions, and is an important indicator of health.

Studies have shown that exercise can improve joint function, alleviate joint pain, increase muscle strength, and improve inflammation in MHD patients. However, due to the lack of relevant evidence-based evidence, exercise rehabilitation has not yet been included in routine clinical care plans.Clinical research data on rehabilitation exercises for MHD patients are needed to recommend reasonable, feasible and acceptable exercise modalities for the national population. Baduanjin is an ancient health art that combines breathing and exhaling with physical exercise, and it is a multifactorial intervention that integrates physical, mental, emotional, spiritual and behavioral elements, with moderate exercise volume, which belongs to the category of aerobic exercise. Although studies have suggested that Baduanjin has a good therapeutic effect on people with physical fitness disorders, and clinical studies on the prevention of bone loss and the improvement of bone mineral density have also been conducted gradually. However, there is still a lack of information on the application of Baduanjin in MHD patients.However, there is still a lack of information on the application of Baduanjin in MHD patients.

In this study, physical fitness measures were chosen as indicators of physical functioning and health status of MHD patients. The study is intended to follow the method of evidence-based medicine and observe the improvement of physical fitness and bone density in maintenance dialysis patients by applying Baduanjin, so as to

provide theoretical basis and data support for the exercise rehabilitation and individualised treatment of MHD patients.

References

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2.Research Content

2.1 Research Purpose

Main objective: To observe the effect of Baduanjin on physical fitness and bone density of maintenance dialysis patients.

Secondary objective: To observe the effect of Baduanjin on the quality of life and emotions of MHD patients.

2.2 Study Description

The aim of this study is to observe the therapeutic effect of Baduanjin on improving physical fitness and bone density in MHD patients. A total of 50 MHD patients will be included and randomized into an intervention group of 25 cases and a control group of 25 cases. The intervention group undergo a 30 minute Baduanjin exercise under the guidance of a professional doctor before the dialysis day, including a 5-minute warm-up exercise, a 20 minute Baduanjin exercise, and a 5-minute relaxation exercise. The intervention group practice three days a week, while the control group maintain routine treatment and daily activities. Measure the indicators of each group at baseline, months 6, 12. The evaluation of physical fitness is based on the scores (which include muscle strength measurement; five-times sit-to-stand test; timed "up and go" test; sitting forward flexion test; standing on one-leg with eyes closed test). The bone mineral density test is based on the result of the double-energy DXA line. The quality of life score is based on the SF-36 score, and the emotional

score is based on the anxiety and depression scale.

2.3 Grouping Criteria

Inclusion Criteria:

- Age>18 years old, ≤ 75 years old
- Having received MHD treatment in this dialysis center for more than 3 months and maintaining stable condition
- Having normal comprehension ability, clear verbal expression, informed consent and willingness to participate in this study
- Having free movement ability, and being able to tolerate Baduanjin exercise after cardiopulmonary exercise test
- Right-handed, with fistula in the non-dominant hand

Exclusion Criteria:

- Patients who usually practice traditional Chinese medicine exercises such as tai chi;
- Patients who are recently complicated with severe infections, active malignant tumors, severe cardiopulmonary insufficiency, gastrointestinal bleeding, nervous system diseases and cannot tolerate exercise;
- Patients with various orthopedic, neurological, and other diseases that cause muscle and joint deformities that affect grip strength measurement;
- Patients with senile dementia, hearing impairment, comprehension abnormalities, mental disorders, unclear verbal expression or unwilling to participate in this study;
- Patients with hemoglobin <70g/L, carbon dioxide binding capacity <13mmol/L, and blood potassium >6.5mmol/L in laboratory tests and no significant improvement after treatment;
- Patients who are participating in other clinial studies.

2.4 Outcome Measures

Primary Outcome Measure:

1) Muscle strength measurement

Grip strength can reflect the strength of hand muscles. The grip strength of both hands of patients was measured using a domestic gripper.The patient took an upright position and grasped the handle with the maximum force. When the display on the machine stopped changing, the value was recorded. The test was repeated three times, and the maximum value was taken to record the results.

2) Five-times Sit-to-Stand Test (FTSST)

The five-times sit-to-stand test is used to evaluate the functional strength of the lower

limbs. MHD patients sat on a 46cm chair without armrests, with their feet on the ground and their backs not resting on the chair. Their hands were crossed on their shoulders. They stood up from the chair as quickly as possible without arm support. They completed five sitting and standing movements, and the completion time was recorded.During the test, the patient kept his hands crossed and his knees completely straightened.Three tests were completed, with a one-minute rest between tests. The average value of the three tests was statistically analyzed.

3) Timed "up and go" test (TUGT)

The timed "up and go" test is often used to evaluate functional mobility such as balance and walking required in daily life.MHD patients were seated in a back chair with armrests (the seat was about 46cm high, and the armrest was about 21cm high). A guide line was placed on the ground 3m away from the chair. After the test began, the patient left the chair, stood firmly and walked forward for 3m as fast as possible, crossed the guide line, turned around, and returned to the chair to sit down. The walking aids were not allowed during the test.The test was conducted 3 times in total, with a 1-minute rest between adjacent tests. The average value of the 3 tests was taken for statistical analysis.

4) The sitting forward flexion test

The sitting forward flexion test is often used to evaluate the flexibility of the lower limbs of patients.The patient straightened the knee joint, sat on the flat ground with both feet flat on the test board, bent forward, straightened both arms forward, and gradually pushed the cursor with both middle fingertips to the farthest possible distance.The measuring device was 0 point along the plane of the foot pedal board, negative inward, positive forward, in centimeters. The knee joint could not be bent during the test, and sudden force could not be applied.The test was conducted 3 times in total, and the best result was taken for statistical analysis.

5) The Standing on one-leg with eyes closed test (SOLECT)

The Standing on one-leg with eyes closed test evaluates the stability of the static posture by quantitative measurement, reflecting the balance ability of patients.The patient spread both hands, closed his eyes, and stood on one leg, with the other leg bent so that the angles between the two legs were 90 degrees. Time was recorded from the time when the foot left the ground, and the shaking stopped when the foot left the ground or stood up. The average of the three times was used for statistical analysis.

6) Bone mineral density test

The signals received by the scanning system after the double-energy DXA line penetrated the body were transmitted to the supporting software to calculate the average bone mineral density content (g/cm2) of the whole body, the left femur Ward triangle area, and the lumbar spine (L2~L4).

Secondary Outcome Measures:

1) Changes in the Short Form-36 (SF-36)

Changes from the Short Form-36 (SF-36) and European Quality of Life Five Dimension （EQ-5D-5L） scale at 0 months, 6 months, 12 months. The SF-36 score is used to evaluate an individual's health status and quality of life. The SF-36 score expressed as a number between 0 and 100, with higher numbers indicating better health. EQ-5D-5L evaluate quality of life from five aspects: action ability, self-care, daily activities, pain or discomfort, anxiety or depression. The score range generally ranges from less than 0 to 1, and the higher the score, the better the state; The VAS score range is 0-100, with higher scores indicating better health status.

2) Changes in the Hospital Anxiety and Depression Scale （HADS）

Changes from HADS Index at at 0 months, 6 months, 12 months. HADS consists of 14 items, of which 7 items assess depression and 7 items assess anxiety. The scores for anxiety and depression range from 0 to 21, with higher scores indicating more severe symptoms.

2.5 **Statistical analysis, confidentiality plan**

In terms of statistical analysis, SPSS 27.0 statistical software is used to establish a database and perform statistical processing. Descriptive statistical analysis, qualitative indicators are described as percentages, and quantitative indicators are described as mean ± standard deviation. The data is subjected to normality testing and corresponding testing methods are adopted based on whether it follows a normal distribution. Qualitative data comparison adopts chi square test. Quantitative data conforms to normal distribution, t-test is used for comparison between two groups, and nonparametric test is used for abnormal distribution and $P<0.05$ is considered statistically significant.

2.6 **Preservation and Confidentiality of Information**

The researcher preserves all research data, including confirmation of all participants (able to effectively verify different record materials, such as hospital original records), all original informed consent forms with subject signatures, all case

observation forms, detailed records of evaluation indicators, etc.

The results of this project may be published in medical journals, but we will keep the information of the subjects confidential in accordance with legal requirements. Unless required by relevant laws, the personal information of the subjects will not be disclosed. When necessary, research supervision and management departments, hospital ethics committees and their relevant personnel may access patient information in accordance with regulations.

3. Exit and Termination Criteria

1. patients with adverse reactions such as trauma, surgery or serious infection, cardiopulmonary failure, who cannot continue to perform exercise during the trial;
2. Patients who underwent kidney transplantation or disappeared or died for various reasons during the trial;
3. Patients with poor compliance during the trial, unwilling to continue to exercise or requesting to withdraw from the trial for various reasons.

4 **Ethical issues**

4.1 Ethical Approval

This clinical research protocol complies with the relevant provisions of the Helsinki Declaration regarding the protection of subject rights.This protocol, written informed consent form, and materials directly related to the subjects must be submitted to the ethics committee for written approval before the study can be officially conducted. If this protocol has been revised during the clinical research implementation process, it must be submitted to the ethics committee for approval before implementation, and these changes cannot be implemented without the approval of the ethics committee, unless they are made to eliminate obvious and direct risks to the subjects. When such situations occur, they will be reported to the ethics committee. If important new information related to the study is found, the informed consent form must be modified in writing and submitted to the ethics committee for approval before obtaining the consent of the subjects again. Each clinical research center agrees that before the start of this research project, the ethics committee of the team leader unit shall review the research plan. The ethics committees of each sub center may choose to file or review it themselves. If necessary (such as serious adverse events or protocol violations), the ethics committees of each center shall convene a meeting in a timely manner for review and report the review conclusions to the ethics committees of other

centers.

4.2 Informed consent

The researcher must provide the subject or their legal representative with an easily understandable and approved informed consent form by the ethics committee, providing the subject or their legal representative with a complete and comprehensive explanation of the detailed information related to the clinical study, including the research purpose, research procedures, potential benefits and risks, subject rights and obligations and letting the patient know that they have the right to withdraw from the study at any time. After ensuring that patients fully understand and have sufficient time to consider and receive satisfactory responses to the questions raised, they agree and sign an informed consent form before starting clinical research. During the participant period, all updated versions of the informed consent form and written information will be provided to the participants. The informed consent form should be kept as an important document in clinical research for future reference.

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