Informed Consent Form

Dear Madam/Sir

We will invite you to participate in a clinical trial study on the application of Baduanjin to improve shoulder joint function in maintenance hemodialysis patients and explore its mechanism.

Before deciding whether to participate in this study, please read the following content carefully as much as possible. It can help you understand the study, why it was conducted, the procedures and duration of the study, and the benefits, risks, and discomforts that participating in the study may bring to you. If you are willing, you can also discuss with your relatives and friends, or ask your doctor for an explanation to help you make a decision.

1. Research Background and Purpose

This study has been approved by the Ethics Committee of Nantong University Affiliated Hospital, and is in accordance with the principles of the Helsinki Declaration and medical ethics.

The purpose of this study is to evaluate Baduanjin to improve shoulder joint function in maintenance hemodialysis（MHD） patients. The research results will be used to provide theoretical basis and data support for the exercise rehabilitation and personalized treatment of MHD patients.

This study will be conducted at the Blood Purification Center of Nantong University Affiliated Hospital, with an estimated 60 volunteers voluntarily participating.

2. Who is not suitable to participate in the study

If you are over the age range of 18-75 years old; History of cranial diseases caused by various other reasons; The vascular pathway is a tunnel catheter with a polyester sheath; The vascular pathway is a right arteriovenous fistula; Known infectious diseases; Individuals with primary or secondary muscle diseases (such as idiopathic inflammatory myopathy, progressive muscular

dystrophy, glycogen accumulation disease, etc.), mental abnormalities, limited autonomous behavior ability, and failure to cooperate with clinical observation and treatment are not eligible to participate in this study.

3.What will be required to participate in the research

(1) Before you are selected for the study, you will undergo the following examinations to determine if you are eligible to participate. The doctor will inquire and record your medical history, and conduct a comprehensive physical examination of you. Screen based on your blood routine, liver function (AST, ALT), kidney function (BUN, Cr) results, and electrocardiogram.

(2) If you pass the above inspection, you will follow the following steps for research.

During the study, the subjects in the Eight Section Brocade group were required to practice the entire set of Eight Section Brocade for no less than 3 days per week, while the control group received routine treatment. Both groups of patients received routine hemodialysis treatment and care during the research process. And blood tests, shoulder joint function scores, quality of life, and psychological test scores were completed at baseline, June, December, and 18 months, respectively.

(3) Other matters that require your cooperation

Vigorous exercise should be avoided, and prolonged bed rest is not allowed. Please schedule your daily routine, eat according to the prescribed diet, take your medication on time, and cooperate with medical staff to collect blood and observe at all times.

4. Possible benefits of participating in research

Your participation in this study may not directly benefit you financially, but it can provide useful information for your future treatment and follow-up. During your participation in the research, exercising with Ba Duan Jin can improve shoulder joint function, regulate psychology, improve cognition, and enhance quality of life.

5. Possible adverse reactions, risks, discomfort, and inconvenience associated with participating in research

Although the exercise prescription used in this study belongs to moderate intensity aerobic exercise and has been recommended as an exercise therapy for joint diseases, there may still be some unpredictable risks and discomforts.

If you experience any discomfort or unexpected situations during the study, regardless of whether it is related to the exercise plan, you should promptly notify your doctor, who will make a judgment and provide medical treatment.

Doctors will do their best to prevent and treat any harm that may arise from this study. If adverse events occur in clinical trials, the medical expert committee will determine whether they are related to the trial exercise protocol. The applicant will provide treatment costs and corresponding economic compensation for damages related to the trial.

6. Expenses

Your blood indicators during the clinical trial will be tested using excess blood samples taken during your regular follow-up, without increasing the frequency and volume of your blood collection.

If any damage related to the experiment occurs, the applicant will pay your medical expenses. If hospitalized due to serious adverse reactions, the

applicant will also provide appropriate compensation for nutrition, lost wages and bonuses.

7.Is personal information confidential?

Your medical records (research medical records/CRF, laboratory tests, etc.) will be kept intact in the hospital. Researchers, sponsor representatives, ethics committees, and drug regulatory authorities will be allowed to access your medical records. Any public reports related to the results of this research will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical data within the scope permitted by law.

In addition to this study, it is possible that your medical records will be reused in other future studies. You can now also declare that you refuse to use your medical records and blood samples for any research other than this one.

8. How to obtain more information?

You can raise any questions about this research at any time. Your doctor will leave you his/her phone number so that he/she can answer your question. If you have any complaints about participating in the study, please contact the Ethics Committee Office.

If there is any important new information during the research process that may affect your willingness to continue participating in the study, your doctor will notify you promptly.

9.Voluntary choice to participate in the study and withdrawal from the study midway

Whether to participate in the study depends entirely on your voluntary

choice. You may refuse to participate in this study, or withdraw from this study at any time during the research process.

Your doctor or researcher may suspend your participation in this study at any time for the best interests of you.

If you withdraw from the study for any reason, you may be asked about your use of the investigational drug. If the doctor deems it necessary, you may also be required to undergo laboratory and physical examinations.

10.What to do now?

Whether to participate in this study is up to you to decide. You can discuss with your family or friends before making a decision.

Before making a decision to participate in the study, please try to ask your doctor as many questions as possible until you fully understand the study.

Thank you for reading the above materials. If you decide to participate in this study, please inform your doctor or research assistant, and he/she will arrange all matters related to the study for you.

Please keep this information.

Informed Consent Form · Consent Signature Page

The Effect of Baduanjin on Shoulder Function

in Maintenance Hemodialysis Patients

Applicant: Yuan Li

Consent statement:

I have read the above introduction about this study and have the opportunity to discuss and raise questions with doctors regarding this research. All the questions I raised have received satisfactory answers.

I am aware of the potential risks and benefits associated with participating in this study. I know that participating in the study is voluntary, and I confirm that I have sufficient time to consider it and understand:

- I can consult a doctor for more information at any time.
- I can withdraw from this study at any time without discrimination or retaliation, and my medical treatment and rights will not be affected.

I am equally aware that if I withdraw from the study midway, especially due to medication reasons, if I inform the doctor of changes in my condition and complete corresponding physical and chemical examinations, it will be very beneficial for myself and the entire study.

If I need to take any other medication treatment due to illness, I will seek

the doctor's opinion in advance or truthfully inform them afterwards.

I agree that the drug regulatory department, ethics committee, or representative of the applicant can access my research materials.

I agree ☐ I refuse ☐

I will receive a signed and dated copy of the informed consent form.

Finally, I have decided to agree to participate in this study.

Signature of research participant: Date: YYYY-MM-DD

Contact phone number: Mobile number:

I confirm that I have explained the detailed information of this trial to the volunteer subjects, including their rights, potential benefits and risks, and provided them with a signed copy of the informed consent form.

Researcher's signature: Date: YYYY-MM-DD

Contact phone number: Mobile number:

Ethics Committee Office, 3rd Floor, Building 13, Nantong University Affiliated Hospital, 0513-85052390, Internal Line: 2390, Email: lunlib@126.com