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Efficacy of Qigong Baduanjin on nutritional status and quality of life in patients on haemodialysis: study protocol for a prospective randomised controlled trial

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ABSTRACT

Introduction Haemodialysis (HD) patients usually engage in a low level of physical activities, which could impact the prognosis and mortality of this group. Fitness Qigong Baduanjin, a physical exercise from traditional Chinese Medicine, is known to have benefit in chronic heart failure patients and peritoneal dialysis patients. However, researches about Baduanjin in HD patients are currently limited. So, the aim of the study is to investigate the current exercise intensity of HD patients and its influencing factors, and to explore the effects of Baduanjin on HD patients.

Methods and analysis This prospective, non-blinded, randomised controlled trial will enrol patients with end-stage kidney disease who were stable on HD for more than 3 months. All eligible participants will be randomly divided into the intervention group undergoing Baduanjin and the control group without Baduanjin in a 1:1 ratio. The intervention group is required to perform Baduanjin two times per day, starting 30 min after breakfast and dinner, 45 min per session for a total of a 6 month, starting from 10 June 2024. Information such as laboratory biochemical examination indicators, radiological examination results and related scales and questionnaires will be collected at baseline, 1 month follow-up, 3 month follow-up and 6 month follow-up. All statistical tests are conducted through the two-tailed test, and a p-value≤0.05 will be considered statistically significant for the difference being tested. The description of quantitative indicators will be used in calculating the number of cases, mean, SD, median and IQR method. The classification indicators will be used to describe the number of cases and percentages (frequency and frequency rate).

Ethics and dissemination The study protocol was approved by the Ethics Committee of the First Affiliated Hospital of Zhejiang Chinese Medical University (V20230521). The results will be reported in a peer-reviewed journal and a relevant academic conference.

Trail registration ChiCTR2300074659.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study is the first non-blinded, randomised controlled trial focused on the efficacy of Fitness Qigong Baduanjin on nutritional status and quality of life in haemodialysis (HD) patients.
⇒ This study is designed to explore the effects of Baduanjin on physiological function, exercise ability, nutritional status, dialysis quality, social rehabilitation and quality of life of HD patients and will provide relevant reference for daily Baduanjin exercise of HD patients.
⇒ The limitations of the study including small sample size, difficult to quantify the intensity of Baduanjin exercise and short Baduanjin intervention period.

INTRODUCTION

Haemodialysis (HD) is one of the most important replacement therapies for end-stage kidney disease (ESKD).[1] Researches have suggested that HD patients usually engage in a low level of physical activities due to renal failure, cardiovascular risk, reduced or insufficient protein intake as well as metabolic acidosis, resulting in low motivation, frailty, malnutrition and inflammation, leading to the changes of muscle structure and decrease in muscle strength or even sarcopenia.[2–4] Related studies have shown that poor physical activity engagement could increase the occurrence of certain adverse events, such as depression, fatigue, acid–base disturbance, myoatrophy or even heart failure, which perhaps is the most pervasive disturbance in HD patients, impacting the prognosis and mortality of this group, and appropriate amount of exercise can have positive effects on HD patients.[5–7] One study asked HD patients to attend an outpatient cardiac rehabilitation programme on their off-dialysis days, those who attended more than 50% of the sessions experienced improved exercise capacity of 45%, while the others did not see any changes in their

exercise capacity.[5] Therefore, researchers believed that exercise is one of the best non-medication therapies to improve dialysis patient's condition.[8 9] For instance, Korean dialysis patients showed that high physical activity was associated with favourable results in improving frailty, disability and exhaustion.[8] Another exercise programme for peritoneal dialysis (PD) patients in the USA believed that resistance and aerobic exercise programme using exercise bands appears feasible and safe for PD patients.[10]

The 2012 KDIGO CKD clinical practice guideline encouraged HD patients to engage in physical activity that is compatible with their cardiovascular health condition and tolerance, with a goal of at least 30 min per week, 5 times per week.[11] However, the tolerance of HD patients in exercise is limited, it is urgent to seek for suitable exercise methods for this group.

As a core part of traditional Chinese medicine (TCM) therapy, Fitness Qigong Baduanjin has a history of more than 2000 years,[4] which is an aerobic exercise with moderate intensity and easy operation.[12] Powerful evidence has been provided that the use of home-based Baduanjin exercise could significantly improve the cardiopulmonary function in chronic heart failure patients,[13] physical function and health-related quality of life in PD patients.[14] Another study has provided powerful evidence for the use of home-based Baduanjin exercise in anterior ST Elevation Myocardial Infarction (STEMI) patients in improving the cardiopulmonary function.[15]However, the effect of Baduanjin in HD patients is not yet clear. So, this study intends to explore the efficacy of Fitness Qigong Baduanjin on nutritional status and quality of life in maintenance HD patients.

METHODS AND ANALYSIS

Study setting

We performed a prospective, non-blinded, randomised controlled trial with participants identified from the Blood Purification Centre of the First Affiliated Hospital of Zhejiang Chinese Medical University. All eligible participants will be enrolled and randomly divided into the intervention group undergoing Baduanjin and the control group without Baduanjin in a 1:1 ratio. And patients were followed regularly at the outpatient clinic in 1 month, 3 months and 6 months unless loss to follow-up. The flow chart of the study is shown in figure 1.

Study objectives

The aim of the study is to investigate the current exercise intensity of HD patients and its influencing factors, and to explore the effects of Baduanjin on physiological function, exercise ability, nutritional status, dialysis quality, social rehabilitation and quality of life of HD patients.

Eligibility criteria

Patients with ESKD on HD from the Blood Purification Centre of the First Affiliated Hospital of Zhejiang Chinese Medical University will be recruited. The recruitment

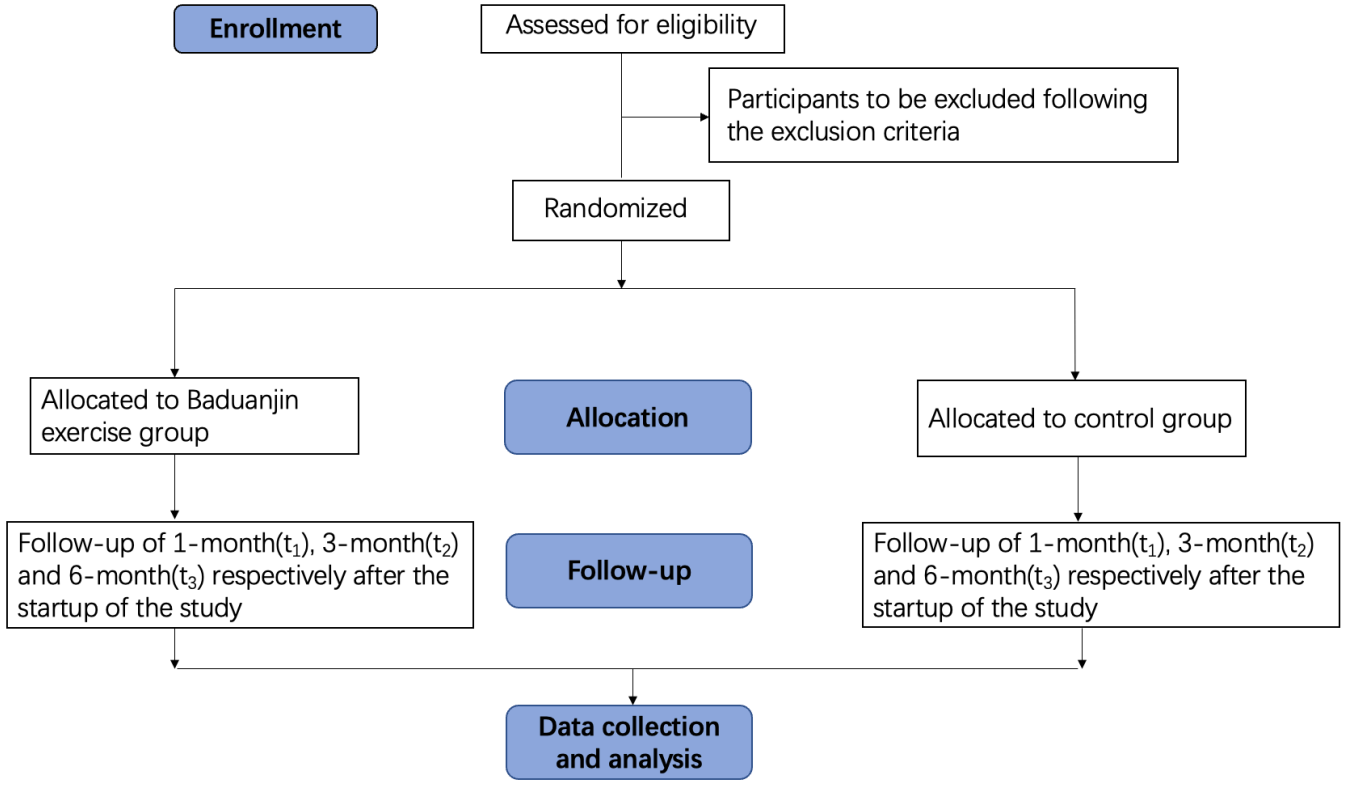

Figure 1 The flow chart of the study. Screening, randomisation and follow-up according to the CONSORT diagram. CONSORT, Consolidated Standards of Reporting Trials.

period will start from 1 May 2024 to 1 June 2024. The detailed inclusion and exclusion criteria are outlined below.

Inclusion criteria

Patients undergoing maintenance HD will be selected when:

- They are from the Blood Purification Centre of the First Affiliated Hospital of Zhejiang Chinese Medical University.
- They are stable on HD for at least 90 days.
- Age≥18 years.

Exclusion criteria

Patients with the following characteristics will be excluded:

- When they are not from the Blood Purification Centre of the First Affiliated Hospital of Zhejiang Chinese Medical University.
- When they are undergoing a regular HD programme less than 90 days.
- When they are with serious acute comorbidities.
- When they are suffering from central and peripheral nervous system diseases or limb deficiencies that cannot tolerate exercise.
- When they are undergoing the acute phase of newly developed cardiovascular or cerebrovascular event.
- When they are with mental illness or intellectual disability who cannot understand the informed content.
- Other HD patients who have been evaluated by the researchers as unsuitable for participation in this study.

Patient and public involvement

Patients did not participate in the design of the study, and the intervention phase of the research process is the first stage in which patients participate in. Patients from the intervention group are required to perform Baduanjin for a total of 6 months, and we will follow-up on all the participants at 1 month (t_1), 3 months (t_2) and 6 months (t_3) after the startup of the study. Participants will get personal test results immediately after each assessment.

Sample size

This is a full-scale, prospective, non-blinded, randomised controlled trial. Due to the specific subjects of the study in a single-centre setting, no sample size was calculated because the aim was to include all patients available. All eligible participants will be enrolled.

Informed consent

For any HD patient who meets the inclusion and exclusion criteria, they will be approached to participate in the study. Each patient will be provided with a written informed consent form (ICF) covering the purpose and procedure of the study, the foreseeable benefits and potential risks of participation, compensation for any potential harm, data protection procedures and the option to withdraw from the study at any time without any reason, which should be read carefully by each patient. The study team will answer any questions the patient may have, and both the patient and study team will sign the ICF to indicate the patient's full understanding of the protocol. Written informed consent must be obtained from all participants prior to any intervention.

Intervention

After fully understanding the objectives and method of the study and signing the ICF, participants will be randomly allocated to either the intervention or control group. While participants in the control group only undergoing HD, participants in the intervention group will be taught how to play Baduanjin, which includes the Preparation Form, the first form of Pressing the Heavens with Two Hands, the second form of Drawing the Bow and Letting the Arrow Fly, the third form of Separating Heaven and Earth, the fourth form of Wise Owl Gazes Backward, the fifth form of Big Bear Turns from Side to Side, the sixth form of Touching Toes then Bending Backwards, the seventh form of Punching with Angry Gaze and the eighth form of Bouncing on the Toes. Before the intervention, the study team will coach the participants how to play Baduanjin, correct their non-standard movements and ask them to practice five times a week. After the patients have mastered the complete set of Baduanjin techniques, the effects will be officially observed. Each form is required to perform two times per day, starting 30 min after breakfast and dinner, 45 min per session, for a total of a 6 month Baduanjin exercise. Detailed descriptions of Baduanjin are as follows.

As one of the Qigong exercise therapies with traditional Chinese characteristics, Baduanjin is composed of eight forms with moderate intensity. The main points of each form are quite clear and easy to memorise, involving different body parts and organs at the same time.

The first form optimises body flexibility by stretching tendons and pulling bones, 'the liver governs the sinew, favours the free flow of qi and free activity', resulting in freeing the liver qi. The second form helps free the flow of liver qi and alleviates rib-side pain. The third form can regulate the spleen-stomach through the stimulation of the foot yangming stomach channel and the foot taiyin spleen channel in the chest and rib-side regions. The fourth form stimulates the dazhui acupoint on the neck by rotation. Movements such as squatting are used in the fifth form to stimulate the bladder channel and the foot shaoyin kidney channel to relieve the exuberance of heart fire. In the sixth form, acupoints such as weizhong, yangguan and mingmen are stimulated through bending and stretching to secure the kidneys and strengthen the waist. Through gazing angrily, the seventh form can stimulate the liver channel, help liver qi flow freely and liver blood run full. As for the eighth form, the qi-blood can be regulated and yin-yang balanced through the stimulation of du mai on the back.

Outcome measures

Primary outcomes

The primary outcomes for the study are as follows:

- Laboratory biochemical examination indicators: biochemical examination (including albumin, prealbumin, total cholesterol, total triglyceride and low density lipoprotein), haemoglobin, erythrocyte, packed cell volume, hypersensitive C-reactive protein, HD adequacy indexes (including spKt/V, URR).
- Radiological examination (muscles of the waist and lower limbs), cardiac function evaluation, etc.
- Somatology: Body Max Index, skinfold thickness, hand grip strength, body composition analysis.
- Adverse events or serious adverse events: cardiovascular and cerebrovascular events, events related to vascular access, hospital admissions (infection-related, non-infection-related, cardiovascular and cerebrovascular events), dialysis withdrawal events, death events

Secondary outcomes

The secondary outcomes for the study are as follows:

- Nutrition Assessment Subjective Global Assessment (SGA) scale.
- Pittsburgh Sleep Quality Index (PSQI).
- SF-36 Kidney Disease Quality of Life Short Form (SF-36 KDQOL).
- 6 min Walk Test (SMWT).
- Dominant Hand Grip Strength.

Study timeline

The specific timeline of the study is presented in table 1.

Data management

Data collection

Required sociological, clinical and laboratory information will be obtained from the hospital information system. Relevant questionnaires will be handed out to participants and all the results will be collected.

Data management

All data are stored securely in our hospital network, and will be recorded into the Excel database and be checked on a regular basis to ensure its integrity and accuracy and will be accessed for research purposes after the trial is completed, which is 1 December 2024. The study team members, ethics committees and government departments affiliated with the study will be allowed to access the data. If the participants are infringed due to data disclosure in the study, the research team will provide them with appropriate compensation if necessary.

Date usage

The use of the information collected is only for academic purposes and the results will be published in appropriate scientific journal and presented at relevant national and international meetings.

Confidentiality

The collected information will remain anonymous. Participants will be allocated a participant number for deidentification purposes. All the original questionnaires, records and ICFs will be stored properly in locked cabinets and the Excel database will be coded and will only be accessed by the study team.

Statistical analysis

All statistical tests are conducted through the two-tailed test, and a p-value≤0.05 will be considered statistically significant for the difference being tested. The description of quantitative indicators will be used in calculating the number of cases, mean, SD, median and IQR method. The classification indicators will be used to describe the number of cases and percentages (frequency and frequency rate).

This study will compare baseline demographics, clinical data, laboratory biochemistry, HD data and follow-up observations to endpoint events or the end of the follow-up period for each group of patients. The results are expressed as follows: mean±SD for normal distribution continuous variables, median (quartile method, 25%–75%) for non-normal distribution continuous variables, and frequency (n) and frequency rate (%) for categorical variables. Demographic, clinical and laboratory data of patients in each group will be compared, using independent sample t-test or analysis of variance (ANOVA) based on variable attributes. Mann Whitney U test or Kruskal Wallis test will be selected as non-parametric tests and χ^2 test or Fisher's exact test is to be used in comparing frequency (frequency rate) between the two groups.

For laboratory biochemistry, HD adequacy and scale evaluation results at multiple follow-up points observed in the study, both mixed two-way repeated measure ANOVA and linear mixed models will be used at the same time to compare the intervention characteristics at different time points. In the preparation stage, extreme outliers will be detected, Shapiro-Wilk normality test and Levene variance homogeneity test will be performed to check whether the model hypothesis is satisfied. The intergroup factor is whether the Fitness Qigong Baduanjin intervention is used, and the intragroup factor is the follow-up time of repeated measurements. The post-tests for important bidirectional interactions are divided into two models: (1) treatment effect: A simple one-way model is used to evaluate the effect of Fitness Qigong Baduanjin intervention at different time point levels and to compare pairwise comparisons between groups at each time point; (2) time effect: A simple one-way model is used to evaluate the influence of the time effect in the intervention group and the control group, and to compare the two groups in pairs at different time points. And based on different data types and distribution, Tukey HSD test or Dunn's test will be selected and the Bonferroni method will be applied in adjusting the P-value.

Table 1 Timetable of planned activities during the study directly related to participants

	Study period						
Timepoint	**Enrolment**	**Allocation**	**Baseline**	**1 month follow-up**	**3 months follow-up**	**6 months follow-up**	**Close-out**
	0	0	t_0	t_1	t_2	t_3	t_4
Registration							
Informed consent	√						
Eligibility screen	√						
Eligibility check	√						
Allocations	√	√					
Interventions							
Fitness Qigong Baduanjin training		√					
Fitness Qigong Baduanjin during haemodialysis	×	×	×	√	√	√	×
Evaluation indicators	×	×					
Baseline demographic clinical data			√				
Nutrition Assessment SGA scale			√	√	√	√	×
Body composition analysis			√	√	√	√	×
Dominant hand grip strength			√	√	√	√	×
Laboratory biochemical examination			√	√	√	√	×
Radiological examination (muscles of the waist and lower limbs)			√	×	√	√	×
Cardiac function evaluation (Ultrasound Cardiogram, UCG)			√	×	√	√	×
Haemodialysis adequacy test			√	×	√	√	×
PSQI			√	×	√	√	×
KDQOL-SF-36			√	×	√	√	×
SMWT			√	×	√	√	×
Endpoint events							
Vascular access complications			√	√	√	√	×
Cardiovascular and cerebrovascular events			√	√	√	√	×
Hospitalisation events			√	√	√	√	×
Death events			√	√	√	√	×
Dialysis withdrawal events, including choosing abdominal dialysis, transplantation and giving up treatment			√	√	√	√	×

PSQI, Pittsburgh Sleep Quality Index ; SF-36 KDQOL, Kidney Disease Quality of Life Short Form; SGA, Subjective Global Assessment ; SMWT, 6 min Walk Test.

The linear hybrid model will select the autocorrelation structure according to the optimal Akaike information criterion. For survival data, Kaplan-Meier curves will be used to estimate survival (for primary outcomes and adverse events), and log-rank test to compare differences between the two groups. For the analysis of various outcome prognostic factors in the intervention group and the control group, Proportional Cox hazard model and Anderson-Gill model are to be used to calculate the HR (95% CI). Counting outcome data (multiple events) will be using the Poisson generalised linear model.

Statistical analysis will be performed through R project V.4.1.1., rstatix and nlme packages are to be selected for repeated measurements of ANOVA and linear mixed models. Survival, rms, mgcv packages will be used in survival analysis. A p-value≤0.05 is considered statistically significant.

Ethics and dissemination

This research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. Patients enrolled in our study have given their written informed consent, and the study protocol was approved by the Ethics Committee of the First Affiliated Hospital of Zhejiang Chinese Medical University. The results of this study will be reported in a peer-reviewed journal and a relevant academic conference.

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Contributors JZ and SH contributed to the study conception and design, writing (including draft, review and editing) and finalisation of the manuscript. XZ and CX collected the data and review the manuscript. SW and XY collected and organised the data. YY and HC validated and supervised the data. HC contributed to conceptualisation, supervision, article drafting and final approval of the version to be published.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

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