INFORMED CONSENT FORM

A Randomized Controlled Trial of Different Exercise Modalities in Patients With Chronic Kidney Disease: A Longitudinal Study of Renal Outcomes and Potential Mechanisms

ClinicalTrials.gov Identifier

NCT[not yet assigned]

Document Date

[October 18, 2026]

Dear Prospective Participant,

We are researchers from the China Institute of Sport Science, General Administration of Sport of China, and the Health Management Center of Beijing Aerospace General Hospital. We are conducting a project entitled “Exercise and Health Management in Chronic Kidney Disease.” Based on our assessment, you meet the eligibility criteria for this project, and we sincerely invite you to participate.

This informed consent form provides information about the purpose, procedures, potential benefits, risks, and possible inconveniences of the study. Please read it carefully. You may discuss the study with your family, friends, or healthcare professionals before making your own voluntary decision about whether to participate.

If you are currently participating in another clinical study, please inform the study staff promptly.

1. Study Purpose

This project primarily targets individuals at different stages of chronic kidney disease (CKD), as well as individuals who require weight management. Through follow-up assessments at multiple time points, the study aims to determine the effects of exercise on renal function and overall health status, thereby providing evidence to support exercise-based health management for chronic diseases.

2. Eligibility Requirements and Recruitment

2.1 Eligibility Requirements

Individuals who are Chinese citizens aged 30–60 years and have full civil capacity are welcome to participate in this study.

2.2 Exclusion Criteria

1．Individuals meeting any of the following criteria will be excluded from the study.

2．Poor adherence or an explicit unwillingness to comply with the study procedures.

3．Acute kidney failure, severe hypertension (systolic blood pressure ≥180 mmHg and diastolic blood pressure ≥110 mmHg), diabetes mellitus, heart failure, acute infection, malignancy, or active immune-mediated disease.

4．Participation in another clinical trial or a regular exercise intervention program within the

previous three months.

5．Severe edema, osteoarticular disease, or other physical impairments that interfere with exercise.

6．Body mass index (BMI) ≥35 kg/m².

7．Pregnancy or plans to become pregnant.

8．Severe cognitive impairment that prevents understanding or compliance with the intervention.

2.3 Recruitment Methods

Participants will be recruited through public recruitment channels, including on-site recruitment at the hospital, hospital announcements, and community outreach.

3. Study Procedures and Precautions

3.1 Group Assignment

You will be randomly assigned to an exercise intervention group or a waiting-list control group. Participants in the control group will maintain their usual lifestyle and receive regular health examinations. After the study ends, they will be offered the same exercise intervention program free of charge. Both groups will follow the same follow-up and assessment schedule during the study.

3.2 Study Duration and Assessments

The exercise intervention will last 12 months. During this period, you will be required to complete exercise training according to the study protocol and attend scheduled assessments at designated locations. These assessments will include physical and exercise-related measurements and questionnaires.

3.3 Data Use and Confidentiality

All your personal data and study-related information will be kept strictly confidential and used only for this study. Your data will be identified by a study identification number rather than your personal identity.

3.4 Exercise Precautions

Please follow the exercise instructions and do not change the exercise intensity or mode

without authorization. If you experience any discomfort, stop exercising immediately and contact the study staff.

4. Potential Benefits

4.1 Health Assessments and Education

Through regular assessments, you will receive examination results free of charge, health education resources such as disease management and dietary guidance, and regular health feedback. These may help strengthen your awareness of disease prevention and improve your quality of life.

4.2 Physical Fitness and Health Management

The intervention may help control body weight and body fat percentage and improve physical fitness, including cardiorespiratory endurance and muscle strength. It may also reduce the risk of complications and dependence on medication.

4.3 Exercise Guidance

You will receive professional exercise guidance and a health management plan, which may help improve renal function.

4.4 Multidisciplinary Support

You will have access to health management services provided by a multidisciplinary team, including physicians, exercise specialists, and health management professionals.

5. Risks and Risk Management

5.1 Risk of Privacy Breaches

Although the possibility of information disclosure cannot be completely eliminated, the research team will implement security measures, including encrypted data storage and access controls, to restrict access to information. Study results will be published using anonymized data to protect your privacy.

5.2 Exercise-Related Discomfort and Injury

You may experience temporary discomfort, such as muscle soreness or fatigue, after exercise. A small number of participants may experience exercise-related injuries. Physicians

and exercise specialists will monitor the exercise process and explain in advance how to reduce risks. If you experience any discomfort, your condition will be assessed promptly and the exercise program adjusted as necessary. Medical assistance will be provided when required.
If you experience any discomfort during the study, please contact the study staff immediately.

6. Privacy Protection

6.1 Protection of Personal Information

Your personal information, including examination results and questionnaire responses, will be identified using a study identification number rather than your real name. Information that could identify you will be accessible only to authorized members of the research team. Such information will not be disclosed to third parties without your permission.

6.2 Access to Study Records

Study records may be accessed for research purposes. Government regulatory authorities or ethics committees may review the records, as permitted by applicable regulations, to monitor compliance with research requirements. Confidentiality will be maintained.

6.3 Publication of Study Results

When the study results are published or made publicly available, no information that could identify you personally will be disclosed.

7. Discontinuation of Study Participation and Withdrawal

7.1 Voluntary Withdrawal

You may voluntarily withdraw from the study at any time. Withdrawal will not adversely affect your physical examinations, routine medical care, health examinations, medical insurance, or other rights and benefits. Please notify the study staff at least seven working days in advance before withdrawing.

7.2 Termination by the Investigator

The investigator may terminate your participation in the study under any of the following circumstances: you fail to comply with the study protocol, such as by repeatedly failing to complete the required exercise sessions or refusing assessments; you develop a serious

health problem that may make continued participation unsafe; or a major change is made to the study protocol and you no longer meet the eligibility criteria.

7.3 Use of Data After Withdrawal

Data collected before your withdrawal may be used by the investigators for subsequent analyses after anonymization.

8. Ethics Oversight

This study has been approved by the ethics committees of the China Institute of Sport Science, General Administration of Sport of China, and Beijing Aerospace General Hospital. These committees oversee the protection of your rights and safety.

9. Informed Consent and Signature

I have carefully read this entire informed consent form. The study staff have explained the study purpose, content, procedures, potential benefits, risks, and risk management measures to me in detail and have clearly answered all the questions I raised. I fully understand the relevant information about this study, voluntarily agree to participate, and consent to the research team using my study data in accordance with applicable requirements.

Participant Name: _____

Contact Number: _____

Date : _____