

INFORMED CONSENT FORM

Official Title

Implementation of a Multimodal Prehabilitation Program in Patients With Advanced Chronic Kidney Disease Awaiting Deceased-Donor Kidney Transplantation: Comparison of an In-Person and Remote Model

NCT Number

Pending assignment

Protocol Version

Version 3.0

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Sponsor

Fundació de Recerca Clínic Barcelona – Institut d'Investigacions Biomèdiques August Pi i Sunyer (FRCB-IDIBAPS)

Study Site

Hospital Clínic de Barcelona, Spain

Principal Investigator

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PATIENT INFORMATION SHEET

Introduction

You are being invited to participate in a research study. Before you decide whether to participate, it is important that you understand why the research is being conducted and what your participation will involve.

Please read the following information carefully and ask the study team any questions you may have. You may discuss participation with family members, friends, or your healthcare providers before making your decision.

Participation in this study is entirely voluntary.

Purpose of the Study

The purpose of this study is to evaluate the feasibility and effectiveness of a multimodal prehabilitation program in patients with advanced chronic kidney disease awaiting deceased-donor kidney transplantation.

The study will compare two different models of delivering prehabilitation:

- An in-person supervised program
- A remote home-based program supported by a digital platform

The program combines physical exercise, nutritional counseling, and psychological support with the goal of improving mobility, functional capacity, quality of life, and postoperative recovery after kidney transplantation.

Why Have I Been Invited?

You are being invited because you are an adult patient with advanced chronic kidney disease currently awaiting deceased-donor kidney transplantation.

Approximately 84 participants will take part in this study.

Do I Have to Participate?

No. Participation is completely voluntary.

If you decide not to participate, or if you withdraw from the study at any time, your medical care, transplant eligibility, and relationship with your healthcare providers will not be affected in any way.

You may withdraw your consent at any time without giving a reason.

What Will Happen if I Participate?

If you agree to participate, you will undergo:

Baseline Assessment

You will complete an initial assessment lasting approximately 2 hours, including:

- Functional capacity testing (6-Minute Walk Test)
- Physical activity questionnaires
- Quality-of-life questionnaires
- Emotional well-being assessment
- Nutritional assessment
- Clinical evaluation

Prehabilitation Program

You will participate in an 8-week personalized prehabilitation program while awaiting kidney transplantation.

You will be randomly assigned to one of two groups:

In-Person Program

Supervised exercise sessions at the hospital gym.

Remote Program

Supervised online exercise sessions through the Surgifit® digital platform.

Both programs include:

- Aerobic exercise
- Strength training
- Mobility and balance exercises
- Nutritional counseling
- Psychological support focused on stress management and motivation

After the initial supervised phase, participants will continue a personalized physical activity program until transplantation.

Digital Platform

All participants will receive access to the Surgifit® digital platform, which includes:

- Exercise guidance
- Nutritional advice and healthy recipes
- Mindfulness activities
- Educational materials

The platform requires registration using your name and email address.

Follow-Up Assessments

You will undergo follow-up evaluations at:

- 8 weeks
- 6 months (if transplantation has not yet occurred)

If you receive a kidney transplant during the study period, postoperative clinical information related to your recovery will be collected from your medical records. A follow-up visit approximately 30 days after transplantation will also be performed.

Participation in the study will not delay or modify your kidney transplantation process or standard medical care.

Focus Group Participation (Optional)

You may also be invited to participate in a focus group discussion with other participants and healthcare professionals.

The purpose is to better understand participant experiences, barriers, facilitators, and suggestions for improving the prehabilitation program.

Participation in the focus group is optional and not required to participate in the main study.

Possible Benefits

Participation may help improve:

- Functional capacity
- Mobility
- Physical activity levels
- Quality of life
- Postoperative recovery after transplantation

However, you may not receive direct personal benefit from participation.

The study may also help improve future prehabilitation programs for patients awaiting kidney transplantation.

Possible Risks and Discomforts

Potential risks are mainly related to physical exercise and may include:

- Fatigue
- Shortness of breath
- Muscle soreness
- Joint discomfort

The risk of serious adverse events is considered low because exercise programs are individualized and supervised by qualified professionals.

Participation in focus groups does not involve physical risks. Although confidentiality will be encouraged among participants, complete confidentiality of group discussions cannot be guaranteed.

Alternatives to Participation

If you decide not to participate, you will continue to receive standard medical care and routine recommendations regarding physical activity, nutrition, and healthy lifestyle habits while awaiting transplantation.

Confidentiality and Data Protection

Your privacy and confidentiality will be protected in accordance with applicable data protection regulations, including the European Union General Data Protection Regulation (GDPR).

Your study data will be coded so that you cannot be directly identified in research databases or publications.

Only authorized members of the study team, regulatory authorities, ethics committees, and authorized monitors may access identifiable information when necessary for study oversight or verification.

Your identity will never appear in publications or scientific presentations resulting from this study.

De-identified data may be shared with other researchers for scientific purposes following institutional approval and applicable regulations.

What Happens if I Withdraw?

You may withdraw your consent at any time.

No new data will be collected after withdrawal. However, information already collected before withdrawal may continue to be used to preserve the scientific validity of the study and comply with legal requirements.

Costs and Compensation

Participation in this study will not involve any additional costs to you.

No financial compensation will be provided for participation.

Contact Information

If you have questions about the study or experience any study-related problems, you may contact the study team at Hospital Clínic de Barcelona.

For questions regarding your rights as a research participant, you may contact the local Research Ethics Committee.

CONSENT FORM

By signing below:

- I confirm that I have read and understood the information provided in this document.
- I have had the opportunity to ask questions and received satisfactory answers.
- I understand that participation is voluntary.
- I understand that I may withdraw at any time without affecting my medical care.
- I voluntarily agree to participate in this study.

Participant Name: _____

Participant Signature: _____

Date: ____ / ____ / ____

Person Obtaining Consent: _____

Signature: _____

Date: ____ / ____ / ____

OPTIONAL CONSENT FOR FOCUS GROUP PARTICIPATION

By signing below, I voluntarily agree to participate in focus group discussions related to this study.

Participant Name: _____

Participant Signature: _____

Date: ____ / ____ / ____

Investigator Signature: _____

Date: ____ / ____ / ____