

STUDY PROTOCOL

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

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STUDY SUMMARY

Background

Patients with advanced chronic kidney disease (CKD) awaiting deceased-donor kidney transplantation frequently experience progressive deterioration in functional capacity, mobility, and quality of life during the waiting-list period. Frailty, sarcopenia, physical inactivity, and reduced cardiorespiratory reserve are highly prevalent in this population and have been associated with worse perioperative outcomes and postoperative recovery.

Multimodal prehabilitation programs combining exercise training, nutritional optimization, and psychological support have demonstrated benefits in several major surgical populations. However, implementation in kidney transplant candidates remains limited because of barriers including dialysis burden, transportation difficulties, fatigue, reduced mobility, and limited access to hospital-based programs.

Remote and home-based prehabilitation supported by digital platforms may improve accessibility, adherence, and scalability while maintaining clinical effectiveness.

Study Objectives

Primary Objective

To evaluate the effectiveness of a multimodal prehabilitation program on functional capacity in patients with advanced CKD awaiting deceased-donor kidney transplantation, comparing an in-person supervised model with a remote home-based model.

Secondary Objectives

1. To compare adherence between both intervention models.
2. To evaluate the impact on physical activity and mobility.
3. To assess changes in kidney disease-specific quality of life.
4. To evaluate postoperative recovery quality in transplanted patients.
5. To analyze postoperative complications and healthcare utilization.
6. To identify barriers and facilitators influencing participation and adherence.
7. To explore sustainability and accessibility associated with remote delivery models.

STUDY DESIGN

This study is a prospective, randomized, single-center, parallel-group clinical trial.

Participants will be randomized in a 1:1 ratio to:

- In-Person Multimodal Prehabilitation
- Remote Multimodal Prehabilitation

Randomization will be performed using a computer-generated sequence with variable block sizes.

Due to the nature of the intervention, participant blinding is not feasible. Whenever possible, outcome analyses will be performed blinded to treatment allocation.

STUDY POPULATION

Adult patients with advanced chronic kidney disease listed for deceased-donor kidney transplantation at Hospital Clínic de Barcelona will be screened for eligibility.

Potential participants will be identified during routine pre-anesthetic outpatient assessment.

INTERVENTIONS

In-Person Multimodal Prehabilitation

Participants assigned to the in-person group will receive an 8-week supervised multimodal prehabilitation program conducted at the hospital gym.

The intervention includes:

- Moderate-to-high intensity aerobic exercise
- Resistance and strength training
- Mobility and balance exercises
- Individualized nutritional counseling
- Psychological support focused on stress management and motivation

Exercise sessions will be supervised by physiotherapists three times per week.

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

Remote Multimodal Prehabilitation

Participants assigned to the remote group will receive an 8-week home-based multimodal prehabilitation program delivered through the Surgifit® digital platform.

The intervention includes:

- Supervised online aerobic exercise
- Resistance and strength training
- Mobility and balance exercises
- Individualized nutritional counseling
- Psychological support focused on stress management and motivation

Exercise sessions will be supervised remotely three times per week in small groups.

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

DIGITAL PLATFORM

All participants will have access to the Surgifit® platform.

The platform provides:

- Exercise guidance and supervision

- Educational materials
- Nutritional recommendations and healthy recipes
- Mindfulness and psychological support activities
- Monitoring of adherence and physical activity

The platform is hosted on secure cloud-based servers with encrypted data storage.

OUTCOME MEASURES

Primary Outcome

Change in Functional Capacity

Functional capacity will be assessed using the 6-Minute Walk Test (6MWT).

The primary endpoint is the change in walking distance (meters) from baseline to 8 weeks.

Secondary Outcomes

Secondary outcomes include:

- Kidney disease-specific quality of life (KDQOL-36)
 - Program adherence
 - Physical activity level (IPAQ-short and YPAS)
 - Functional mobility (Timed Up and Go Test)
 - Frailty measures
 - Nutritional status
 - Body composition assessed by bioimpedance
 - Anxiety and depression symptoms
 - Postoperative quality of recovery (QoR-15)
 - Postoperative complications
 - Intensive care unit admission
 - Hospital length of stay
 - Barriers and facilitators influencing adherence
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STUDY PROCEDURES

Baseline Assessment (T0)

Participants will undergo:

- 6-Minute Walk Test
- Functional mobility assessment
- Frailty assessment
- Nutritional assessment
- Bioimpedance analysis
- Quality-of-life questionnaires

- Anxiety and depression assessment
- Physical activity questionnaires

Demographic and clinical variables will also be collected.

Week 8 Assessment (T1)

Participants will repeat baseline functional and questionnaire assessments.

Adherence to the intervention and adverse events will be recorded.

Month 6 Assessment (T2)

Participants who have not undergone transplantation will repeat functional and questionnaire assessments.

Postoperative Assessments

For participants undergoing transplantation during the study period:

- QoR-15 will be assessed on postoperative day 5 and day 30.
- Postoperative complications and length of stay will be recorded.

SAMPLE SIZE

The study was designed to detect a clinically relevant difference of 30 meters in the 6-Minute Walk Test between groups.

Assuming a standard deviation of 60 meters, a two-sided alpha level of 0.05, and 80% statistical power, and considering baseline adjustment using ANCOVA with an assumed pre-post correlation coefficient of $r = 0.6$, 35 evaluable participants per group are required.

Assuming a dropout rate of 15–20%, 42 participants per group will be included, for a total sample size of 84 participants.

STATISTICAL ANALYSIS

The primary analysis will follow the intention-to-treat principle.

Continuous variables will be described as mean $\pm$ standard deviation or median and interquartile range according to data distribution.

Categorical variables will be described as frequencies and percentages.

The primary endpoint will be analyzed using analysis of covariance (ANCOVA), including post-intervention 6MWT as the dependent variable, treatment group as the independent variable, and baseline 6MWT as a covariate.

Secondary outcomes will be analyzed using appropriate parametric or non-parametric methods according to variable type and distribution.

Sensitivity analyses using repeated-measures mixed models may be performed.

Missing data will be evaluated and handled using multiple imputation when appropriate.

A two-sided p-value <0.05 will be considered statistically significant.

SAFETY ASSESSMENT

Adverse events related to exercise or study participation will be recorded throughout the intervention period.

Exercise interventions will be individualized according to participant functional status and supervised by qualified healthcare professionals.

Participants presenting clinical instability or contraindications during follow-up may discontinue the intervention according to medical judgment.

ETHICAL CONSIDERATIONS

The study will be conducted in accordance with the Declaration of Helsinki and Good Clinical Practice principles.

Written informed consent will be obtained from all participants before enrollment.

The protocol has been submitted for approval to the Research Ethics Committee of Hospital Clínic de Barcelona.

Participant confidentiality and data protection will be guaranteed in accordance with applicable regulations.

All study data will be coded and stored in secure databases.

DATA MANAGEMENT

Study data will be collected and managed using REDCap electronic data capture tools.

Only authorized study personnel will have access to identifiable participant information.

De-identified data may be shared upon reasonable request following publication of the primary results and according to institutional policies.

EXPECTED IMPACT

This study aims to generate clinically applicable evidence regarding the implementation, feasibility, adherence, and effectiveness of multimodal prehabilitation in patients with advanced CKD awaiting kidney transplantation.

The findings may contribute to the development of scalable and patient-centered perioperative optimization strategies incorporating remote and digital healthcare solutions.

REFERENCES

1. McAdams-DeMarco MA, Ying H, Van Pilsum Rasmussen S, et al. Prehabilitation prior to kidney transplantation: results from a pilot study.
2. Cheng XS, Myers JN, Han J, et al. Prehabilitation for kidney transplant candidates: is it time?
3. Ma X, He M, Wang J, et al. Home-based prehabilitation exercise intervention for patients with end-stage renal disease awaiting kidney transplantation.
4. Perry R, Herbert G, Atkinson C, et al. Pre-admission interventions (prehabilitation) to improve outcomes after major elective surgery.
5. Carli F, Scheede-Bergdahl C. Prehabilitation to enhance perioperative care.
6. Ting SMS, Iqbal H, Kanji H, et al. Functional cardiovascular reserve predicts survival pre- and post-kidney transplantation.
7. Ricardo AC, Hacker E, Lora CM, et al. Validation of the Kidney Disease Quality of Life Short Form 36 (KDQOL-36).
8. Myles PS, Stark PA, Bissett IP. Validation of the Quality of Recovery-15 questionnaire in surgical patients.