PREhabilitation of CAndidates for REnal Transplantation: A Hybrid Study

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To examine the effect of a multi-modal prehabilitation program on frailty and other indicators of physical and psychological fitness of KTCs during the waiting-list period and its optimal implementation in a real-world situation.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nephropathies
Study type	Interventional

Summary

ID

NL-OMON53460

Source
ToetsingOnline

Brief title
PreCareTx-study

Condition

- Nephropathies

Synonym
chronic kidney disease, End-stage renal disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Nierstichting

Intervention

Keyword: Frailty, Kidney transplant candidates, Prehabilitation

Outcome measures

Primary outcome

Frailty will serve as a proxy for overall health status. Therefore, the primary endpoint of this study is change in frailty status as measured by the Tilburg Frailty Indicator. Endpoints will be measured at T0 (baseline assessment), T1 (13 weeks after T0) and T2 (26 weeks after T0).

Secondary outcome

Secondary endpoints include changes in physical fitness (hand grip strength, leg muscle strength, functional capacity, nutritional status (BMI, Fat free mass, psychological well-being (fatigue, symptoms of anxiety and depression) and quality of life. Endpoints will be measured at T0 (baseline assessment), T1 (13 weeks after T0) and T2 (26 weeks after T0).

Study description

Background summary

The health status of kidney transplant candidates (KTCs) is often compromised due to their chronic kidney disease, comorbidities and/or dialysis. To be able to handle the stress of the upcoming transplant surgery and enhance post-operative recovery, it is important for KTCs to be in an optimal physical and psychological condition. Prehabilitation, the enhancement of a person*s functional capacity in order to improve the ability to withstand a future stressor, may be an effective intervention to improve the overall health status of KTCs. Although research investigating prehabilitation in transplant populations is limited, studies showed that prehabilitation during the waiting-list period is safe and feasible, and may have a positive effect on pre- and postoperative outcomes. We hypothesized that, compared to usual care, a prehabilitation program tailored to individual patients* needs will improve

the overall health status of KTCs.

Study objective

To examine the effect of a multi-modal prehabilitation program on frailty and other indicators of physical and psychological fitness of KTCs during the waiting-list period and its optimal implementation in a real-world situation.

Study design

An effectiveness-implementation hybrid type 1 study design comprised of a randomized controlled trial to test the effectiveness of prehabilitation to improve the overall health status of KTCs, and a mixed-methods study to gather information on its potential for further implementation.

Intervention

A twelve-week prehabilitation program consisting of physical exercises, nutritional measures and psychosocial interventions based on the KTCs personal needs as indicated by an assessment consisting of questionnaires and physical tests. The prehabilitation program will be followed by a twelve-week consolidation program, in which the intensity and frequency of the interventions will be lower, in order to enhance the incorporation of the interventions into the daily life of the KTC. During the intervention period, participants will receive counseling by a lifestyle coach. Progress in physical activity will be monitored using an online platform.
The control group will recieve care as usual

Study burden and risks

The burden for all participants (intervention and control group) will consist of filling out questionnaires (T0, 60 minutes), T1 (30 minutes) and T2 (30 minutes), completing at all three measurement points a food diary (45 minutes per measurement), to wear an activity tracker for three days, and three study visits at the UMCG in which physical tests will be performed (50-60 minutes per measurement). In total this will take *7 hours of their time during the 26 weeks of the study. In addition, participants in the intervention group will be asked to exercise *30 minutes a day and will have a weekly 10-to-15-minute counselling session by (video)call with the lifestyle coach. Efforts will differ per patient as the prehabilitation program will be tailor-made. Although the risk that patients may get injured during exercise is negligible, this will be monitored weekly by the lifestyle coach. We believe it is justified to perform the proposed study given the scarcity of data on the effectiveness of prehabilitation in KTCs and the potential of major improvements in physical functioning and psychological well-being and transplantation outcomes in this

vulnerable patient group.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Adult kidney transplant candidates (>=18 years)
2. Listed for kidney transplantation on the UMCG kidney transplant waiting list at the start of the study or wait listed during the inclusion period (November 2022 - March 2025).

Exclusion criteria

1. Inability to read and/or speak Dutch
2. Combined organ transplantation (e.g., kidney+pancreas, kidney+liver)
3. In case of living donor kidney transplant: a transplantation planned within 3 months
4. Involved in a lifestyle intervention program

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2023
Enrollment:	176
Type:	Actual

Ethics review

Approved WMO Date:	07-12-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-10-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05489432
CCMO	NL82273.042.22