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Fit for kidney transplantation through comprehensive rehabilitation

Submission date	Recruitment status	[_] Prospectively registered
19/07/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/06/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
22/01/2025	Urological and Genital Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Elderly patients on the kidney transplant waiting list often experience a decline in physical and mental performance and an increase in frailty over time, potentially jeopardizing their transplant eligibility. A comprehensive rehabilitation program with ongoing support aims to help these patients remain active, independent, and optimally prepared for transplantation. This study seeks to evaluate whether such a program can enhance physical and mental performance while reducing cardiac events and other comorbidities before transplantation.

Who can participate?
Adults aged 65 years or older with a diagnosis of dialysis-dependent end-stage renal disease (ESRD) who are registered on the kidney transplant waiting list at the Transplantation Center Erlangen-Nuremberg are eligible for participation.

What does the study involve?
Participants will receive an informational sheet and an appointment for the baseline visit. During this visit, they will provide informed consent and sign a privacy agreement. Subsequently, they will undergo physical fitness tests, blood sampling, a micro-CT scan to assess bone density, and an evaluation of their nutritional status. Following this baseline assessment, participants will engage in a three-week inpatient comprehensive rehabilitation program. Upon completion of the program, their physical fitness and nutritional status will be reassessed, and they will receive a personalized training regimen and dietary recommendations. Baseline assessments will be repeated every six months.

What are the possible benefits and risks of participating?
Participants may benefit from improved physical function, quality of life, body composition, bone density, and laboratory parameters. Additional potential benefits include enhanced post-transplant recovery, reduced wound healing complications, and a lower incidence of delayed graft function. Furthermore, the findings from this study may inform future care strategies for patients with similar conditions.

There are no additional risks for the patients.

Where is the study run from?
University of Erlangen-Nuremberg, Department of Medicine, Medicine 4 (Germany)

When is the study starting and how long is it expected to run for?
June 2020 to May 2025

Who is funding the study?
Bavarian State Office for Health and Food Safety (Germany)

Who is the main contact?
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Study website
https://fit-für-transplantation.fau.de/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
GE8-2496-IMV-19-V2

Study information

Scientific Title
A controlled clinical trial of an interdisciplinary treatment approach in elderly dialysis patients on the waitlist for transplantation

Acronym
Fit4KTX

Study objectives
An interdisciplinary treatment approachment (exercise, nutrition, psychosomatics) compared to the control group
1. leads to a permanent “transplantable” waitlist-status
2. improves the physical performance and self-sufficiency
3. improves blood parameters, bone volume and bone mineral density
4. reduces cardiovascular events
5. improves the patients quality of life and adherence
6. before KTx reduces wound healing disturbances and the incidence of a delayed graft function after KTx

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 19/11/2020, University of Erlangen-Nuremberg (Department of medicine, Krankenhausstraße 12, 91054 Erlangen, Germany; +49 9131 85 22270; ethikkomission@fau.de) ref: 438_20 B

Study design
Single-center non randomized and non controlled longitudinal interventional trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic kidney disease stage 5 on dialysis

Interventions
Current interventions as of 22/01/2025:

Patients in the intervention group undergo a baseline assessment followed by a three-week inpatient rehabilitation program tailored to an individualized treatment plan. This plan encompasses medical care, sports therapy, physiotherapy, occupational therapy, nutritional education, and psychological support. Upon completion of the intensive three-week program, patients receive exercise and nutritional recommendations designed for implementation at home and/or during dialysis sessions. Follow-up assessments conclude at the end of the study period, with evaluations of physical performance and frailty conducted semiannually post-intervention.
Patients in the control group are assessed only at baseline and during follow-up assessments conducted every six months. The total study duration per patient is 2 years.

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Previous interventions:

The patients, who are in the intervention group, get a baseline assessment and take part in a three week inpatient rehabilitation with an individual plan of treatment, which includes medical care, sports therapie, physiotherapie, ergotherapie, nutritional education and psychological care. After these three weeks of intensive care, the patients get exercise and nutritional advices, which they can implement at home and/or at the dialysis. The follow up ends at the end of the trial. Every half year after the intervention, the assessment of physical performance and frailty will be repeated.
The patients who are in the control group are only examined at the beginning and in the follow up after every 6 months

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 22/01/2025:

Body composition measured using InBody 270 and waist circumstance at baseline and after every 6 months until the end.

Previous primary outcome measure:

Transplantability status (transplantable, not transplantable, pre-waiting list, removed) measured using patient records over the entire duration of the study

Secondary outcome measures
Current secondary outcome measures as of 22/01/2025:

1. Physical performance measured using the sit to stand Test (60), the 6-Minute-Walking-Test, the Berg-Balance-Scale, the frailty scale (Fried) and the timed up and go Test at baseline and after every 6 months until the end.
2. Degree of independence measured by the Barthel Index at baseline and after every 6 months until the end.
4. Nutritional status measured using blood parameters (HbA1c, potassium, calcium, phosphate, vitamin D, parathyroid hormone, erythrocytes, albumin, CRP, CK, ferritin,) at baseline and after every 6 months until the end.
5. Bone health measured using high-resolution peripheral quantitative CT at baseline and after every 12 months until the end.

Previous secondary outcome measures:

1. Physical performance measured using the sit to stand Test (60), the 6-Minute-Walking-Test, the Berg-Balance-Scale, the frailty scale (Fried) and the timed up and go Test at baseline, after three weeks and after every 6 months until the end.
2. Body composition measured using InBody 270 and waist circumstance at baseline, after three weeks and after every 6 months until the end.
3. Quality of life measured using Sf-12 at baseline and after every 6 months until the end.
4. Nutritional status measured using blood parameters (HbA1c, cholesterol, LDL, HDL triglycerides, potassium, sodium, chloride, magnesium, gGT, GOT, GPT, AP, calcium, phosphate, vitamin D, parathormone, erythrocytes, reticulocytes, ferritin, total protein, albumin, vitamin B12, folic acid and protein electrophoresis) at baseline and after every 6 months until the end.
5. Bone health measured using high-resolution peripheral quantitative CT at baseline and after every 6 months until the end.

Overall study start date
01/06/2020

Completion date

31/05/2025

Eligibility

Key inclusion criteria
1. Diagnosis of dialysis-dependent chronic kidney disease
2. Being on the waiting list for a kidney transplant at the Erlangen-Nuremberg Transplant Centre
3. Aged 65 years or older
4. Agrees to participate in the trial and signs the participation

Participant type(s)
Patient

Age group
Senior

Lower age limit
65 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Not listed on the waiting list for a kidney transplant at the Erlangen-Nuremberg Transplant Centre
2. Severe disease or dysfunction that make participation impossible

Date of first enrolment
20/11/2020

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
Germany

Study participating centre
University of Erlangen-Nuremberg
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Bavarian State Office for Health and Food Safety

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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
Bavarian State Ministry of Health and Care

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/08/2025

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		25/03/2021	29/07/2021	No	Yes