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Kidney Transplantation 360°

Submission date
03/05/2017

Recruitment status
No longer recruiting

Registration date
05/05/2017

Overall study status
Completed

Last Edited
27/06/2025

Condition category
Surgery

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The kidneys are responsible for filtering out the waste products and excess water in the blood, and converting them into urine. If the kidneys stop working properly, then the body is unable to get rid of the waste products building up in the blood. Eventually, the kidneys are no longer able to support the body's needs (kidney failure) and so a treatment to replace the work of the failed kidneys is needed. Having a kidney transplant can transform the life of a patient whose kidneys have failed through disease. Follow-up care after kidney transplantation is performed in transplant centers as well as in nephrologist's (kidney specialist) offices in Germany without organised integrated care of these different sectors of the German health care system. This lack of organization can lead to cardiovascular (heart and blood vessel) complications and patients not properly sticking to follow up care plans. The aim of this study is to find out whether adding case management and a range of mental health and heart and blood vessel (cardiovascular) assessments and treatments can lead to an improvement in quality of life and transplant survival in kidney transplant patients.

Who can participate?
Patients receiving a kidney transplant between 2010 and 2019 in lower Saxoney.

What does the study involve?
In addition to normal care, all participants have a case manager monitor their care for two years. This involves taking part in regular mental health and physical assessments as well as taking part in regular exercise as well as referral to a psychologist to treat them for any mental health issues they may have. They are also regularly contacted by telephone to further monitor their care and have access to their case notes online. The number of appointments participants receive depends on their individual needs. At the start and end of the program, participants complete a range of questionnaires and assessments to determine their physical and mental wellbeing.

What are the possible benefits and risks of participating?
Patients benefit from taking part in the study as it could lead to an improvement in their quality of live, to longer graft survival, less hospitalizations and better exercise capacity. There are no notable risks involved with participating.

Where is the study run from?
1. Hannover Medical School (Germany)
2. Nephrologisches Zentrum Niedersachsen (Germany)

When is the study starting and how long is it expected to run for?
March 2016 to July 2021

Who is funding the study?
Federal Joint Committee of the Federal Republic of Germany (Germany)

Who is the main contact?
Dr Lars Pape

Contact information

Type(s)
Scientific

Contact name
Prof Lars Pape

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
1.0

Study information

Scientific Title
The Kidney Transplantation 360° study: A multicenter, multisectoral, multimodal telemedicine-based follow-up care model to improve care and reduce health-care costs after kidney transplantation in children and adults

Acronym
NTX360°

Study objectives

After kidney transplantation, case management and psychosomatic/cardoivascular assesments and interventions prolong patient and graft survival, reduce co-morbidities and health care costs and to enhance quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board of Hannover Medical School, 10/02/2017, ref: 3464-2017

Study design
Multi-centre non-randomized interventional study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Kidney transplantation

Interventions
In addition to routine care, the patients receive the following interventions that are not included in routine care:

Case management:
This takes place over two years and involves continuous organization of KTX related health care by a case manager.

Psychosocial assessments:
These take place twice yearly over two years and involve assessment of adherence in personal interviews using the Basel Assessment of Adherence with Immunosuppressive Medication Scale (BAASIS©). A collaborative rather than confrontational interview style will be used in order to elicit honest replies and to avoid social desirability. We will assess the following potential barriers of adherence using established instruments: cognitive dysfunctions, lack of resources, lack of knowledge regarding IS, experience of adverse events, mental disorders, psychological distress, low quality of life, and low social support.

Psychococial intervention:
Patients in need of more information about IS will be referred to an educational group offered by the case manager. Patients can also be referred to a psychologist within the psychosocial team who will offer up to eight treatment sessions per year without waiting period. This intervention can be conducted face-to-face or over the internet and will deal with psychosocial correlates of non-adherence (e.g., social or work problems, psychological distress) and offer behavioral interventions.

Cardiovascular assessment:
This takes place twice yearly over two years and involves a physical examination and an incremental exercise testing on an ergometer including blood lactate measurements for determination of cardiovascular and skeletal muscle function. Furthermore a 30 minute constant

load test on a cycle ergometer with ECG, blood pressure, blood lactate and glucose monitoring, a Timed up and go test, a Sit-to-Stand-test and measurement of steps per day will be performed initially and every 6 months for evaluation of second outcome parameters.

Training program:
This takes place continuously over two years. Exercise training recommendations are derived from exercise intervention studies with heart and renal transplant patients and include moderate endurance training or moderate resistance training every other day:
Exercise capacity near to normal (>80% of normal values): Initial duration 15-30min with 35-60% of maximum exercise capacity
Exercise capacity reduced (60-80% of normal values): Initial duration 10-20min with 30-50% of maximum exercise capacity
Excercise capacity reduced (<60% of normal values): Initial duration 15-20min with 25-40% of maximum exercise capacity
Excercise training will be monitored by an exercise physiologist via a wearable system to measure physical activities and the respective heart rates. A regular feed–back, based on continuous training data interpretation, will be given by monthly by video/phone conference in order to motivate the patient and adapt the training prescriptions. In the first year after KTX patients will be seen 4 times face to face (later 2 times a year), and during these occasions patients will be monitored during a 30 minute endurance exercise training.

Telemedical visits:
Tele-visits will take place in cooperation between the transplant center and the (pediatric) nephrologist in private practice reducing the amount of visits necessary at the transplant center. At the time of the patient's visit to the nephrologist's office, an experienced physician from the transplant center will be connected with both via telephone in order to discuss treatment. In case of unexpected medical problems, unscheduled tele-visits are possible.

Intervention Type
Mixed

Primary outcome(s)
Health care costs due to hospitalization are measured using health insurance data at end of all interventions (12 or 24 months).

Key secondary outcome(s))
In all patients all endpoints will be evaluated 24 months after study start, taking into account that some patients will only have 12 months of interventions.

1. Adherence for outpatient visits is measured by actual visits/scheduled visits at end of all interventions
2. Adherence to immunosuppressive therapy is measured by BAASIS-Scale at each psychosocial assessment
3. Cardiovascular fitness and stabilization of weight is measured by different parameters at each CV-assessment
4. Quality of life is measured by Peds-QL and/or SF35 at each psychosocial assessment
5. Implementation of an internet-based case file including all sectors of care is assessed using case file at end of all interventions
6. Implementation and acceptance of telemedicine visits are measured using case file at end of all interventions

Completion date
31/01/2021

Eligibility

Key inclusion criteria
Patients receiving a kidney transplant between 2010 and 2019 in lower Saxony.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment
1010

Key exclusion criteria
Insurance company does not take part in KTX360°

Date of first enrolment
03/05/2017

Date of final enrolment
30/11/2019

Locations

Countries of recruitment
Germany

Study participating centre
Hannover Medical School
Carl-Neuberg-Straße 1
Hannover
Germany
D-30625

Study participating centre

Nephrologisches Zentrum Niedersachsen
Vogelsang 105
Hannoversch Münden
Germany
D-34346

Study participating centre
University Hospital of Erlangen
Ulmenweg 18
Erlangen
Germany
D-91054

Sponsor information

Organisation
Hannover Medical School

ROR
https://ror.org/00f2yqf98

Funder(s)

Funder type
Government

Funder Name
Federal Joint Committee of the Federal Republic of Germany

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from ntx360grad@mh-hannover.de

IPD sharing plan summary
Available on request

Study outputs

	Date	Date	Peer	Patient-

Output type	Details	created	added	reviewed?	facing?
Results article	Graft failure	25/05/2024	11/06/2024	Yes	No
Results article		12/06/2025	27/06/2025	Yes	No
Protocol article		23/08/2017	27/10/2022	Yes	No
Other publications	Results of sub-study on prevalence of mental disorders	23/02/2022	24/02/2022	Yes	No
Other publications	Results of sub-study on cognitive impairment	31/10/2019	27/10/2022	Yes	No
Other publications	Results of sub-study on influence of officially ordered restrictions during the first wave of COVID-19 pandemic on physical activity and quality of life	07/12/2020	27/10/2022	Yes	No
Other publications	Results of sub-study on knowledge about immunosuppressant medication	25/09/2020	27/10/2022	Yes	No
Other publications	Results of sub-study on organ integration	25/03/2021	27/10/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes