

Kidney Transplantation 360°

Submission date 03/05/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 05/05/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/06/2025	Condition category Surgery	<input type="checkbox"/> 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

Study website

<http://www.ntx360grad.de>

Contact information

Type(s)

Scientific

Contact name

Prof Lars Pape

ORCID ID

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Contact details

Hannover Medical School

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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/cardiovascular assessments 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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

<http://www.ntx360grad.de>

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.

Psychosocial 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

Exercise capacity reduced (<60% of normal values): Initial duration 15-20min with 25-40% of maximum exercise capacity

Exercise 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 measure

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

Secondary outcome measures

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

Overall study start date

01/03/2016

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

Age group

All

Sex

Both

Target number of participants

1411

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

Sponsor details

Carl-Neuberg-Straße 1

Hannover

Germany

D-30625

Sponsor type

University/education

Website

www.mh-hannover.de

ROR

<https://ror.org/00f2yqf98>

Funder(s)

Funder type

Government

Funder Name

Federal Joint Committee of the Federal Republic of Germany

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

01/06/2022

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

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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
Protocol article		23/08/2017	27/10/2022	Yes	No
Results article	Graft failure	25/05/2024	11/06/2024	Yes	No

