ISRCTN66295470 https://doi.org/10.1186/ISRCTN66295470

Effects of a personalized exercise prescription after kidney transplantation

Submission date
20/12/2016

Recruitment status
No longer recruiting

Registration date
19/01/2017

Overall study status
Completed

Last Edited
11/06/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] 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, such as dialysis (where the blood is cleaned by a machine). Kidney transplantation offers a more permanent treatment for kidney failure. Kidney transplant recipients (KTR) have a higher risk of developing cardiovascular disease (disease of the heart and blood vessels) than the general population, and often do not lead active lifestyles. The aim of this study is to find out whether taking part in a supervised exercise programme is a more effective way of helping KTR to exercise compared to voluntary physical activity carried out at home.

Who can participate?
Adults who received a kidney transplant six months ago.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in an exercise programme which takes place at a certified gym, supervised by trained exercise specialists. The programme is designed to help improve resistance (ability to exercise for longer) and strength.
Those in the second group are given general information about exercising and are asked to continue exercising at home as they normally would. At the start of the study and then after 6 and 12 months, participants in both groups have their exercise levels assessed as well as their health status and quality of life.

What are the possible benefits and risks of participating?
Participants in the exercise group could benefit from improved health and ability to exercise. There are no direct risks involved with participating.

Where is the study run from?
1. Policlinico S.Orsola-Malpighi (Italy)

2. Department of Biomedical & Neuromotor Sciences, University of Bologna (Italy)
3. Piazzale Bastia (Italy)
4. ULSS Company 9 (Italy)
5. Regional Hospital of Bologna (Italy)
6. University of Padua (Italy)
7. Regional Hospital of Modena (Italy)
8. Regional Hospital of Ravenna (Italy)
9. University of Florence (Italy)
10. Italian National Transplant Centre (Italy)

When is the study starting and how long is it expected to run for?
July 2010 to July 2015

Who is funding the study?
Istituto Superiore di Sanità (Italy)

Who is the main contact?
1. Dr Alessandro Nanni Costa (scientific)
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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2016-005093-35

Protocol serial number
118/2010/O/Sper

Study information

Scientific Title
Effects of tailored physical activity after kidney transplantation

Study objectives
The aim of this study is to evaluate the effects of prescribed physical activity in kidney transplant recipients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the S. Orsola-Malpighi Hospital’s Transplant Centre Bologna (Italy), 20 /07/2010, ref: 118/2010/O/Sper

Study design
Prospective multi-centre non-randomised controlled study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Kidney transplant recipients

Interventions
Patients recruited from different transplant centers are divided into two groups: the cases group (Group A), in which personalized physical activity is prescribed by the sports physicians, and the control group (Group B), in which some generic lifestyle indications are given without specific prescription and supervision. All participants (Groups A and B) receive individualized counseling by the transplant center about the protocol of the study, called “Transplant and Now it’s Time to Sports”.

Blood chemistry and urinalysis, complete blood count, and cardiac evaluation, are performed by the transplantation centers to assess the exclusion criteria and to check the function of the transplanted organ. After the administration of the SF-36 questionnaire to evaluate Health

Related Quality of Life (HRQoL), the patients who matched the inclusion criteria are sent to the sports medicine center to carry out the functional assessment tests for exercise capacity, muscle strength, and body composition. Based on the results of these tests, the sports physicians prescribe a tailored program of exercise only for patients in Group A. Then, patients in Group A are sent to a certified gym to start the prescribed physical activity under the supervision of a suitably trained exercise specialists.

In patients included in Group B general information are given in order to promote regular physical activities at home in line with the routine health recommendations of the transplant centres but no specific prescription is given. These patients are included in Group B mainly on logistic and organisational grounds (patients living in regions not taking part in the project, or living in areas without a sports centre or a gym). They are homogeneous with the patients of Group A for their clinical conditions and their willingness to participate in the study.

Patients in both groups are checked at baseline (T0), six months (T6) and 12 months (T12) from the time of enrollment, coming back to the transplantation and to the sports medicine centers at T6 and T12 to repeat both the clinical and the functional assessment tests performed at T0. In patients of Group B the level of physical activity is assessed at T6 and T12 by the International Physical Activity Questionnaire (IPAQ).

All physicians and exercise specialists involved in the study are required to participate in a 1-day course to implement and to share their knowledge on the clinical aspects of transplant recipients, on the effects of physical exercise, and on the protocol of the study.

Intervention Type
Behavioural

Primary outcome(s)
Type and modality of administration of physical exercise resulting more effective in terms of improving exercise capacity (cardiorespiratory fitness) in transplant recipients (related to preservation and graft function), measured during an incremental exercise and expressed as peak oxygen consumption (V'O2peak) that is demonstrated to be a strong predictor of CVD events, at baseline, 6 and 12 months.

Key secondary outcome(s))
1. Type and modality of physical exercise assessed by dynamic muscular strength tests (1RM measured using a leg press (Technogym, Cesena, Italy) for lower limb and free weights for upper limb), the power of the lower limbs measured indirectly from the fly time of a Counter Movement Jump (CMJ), at baseline, 6 and 12 months
2. Quality of life measured by the Medical Outcomes Study Short Form Questionnaire (SF-36) at baseline, 6 and 12 months
3. Morbidity and health status of kidney transplanted population measured by Creatinine (mg /dL) with Jaffè method, proteinuria (mg/1000 mL) with turbidimetry method at baseline, 6 and 12 months
4. Estimated Glomerular Filtration Rate (eGFR) with Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation at baseline, 6 and 12 months

Completion date
20/07/2015

Eligibility

Key inclusion criteria
1. Kidney recipients six months after organ transplantation
2. Clinically and functionally stable
3. Aged between 18 and 60 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Orthopaedic limitations
2. Psychiatric or neurological disorders
3. Proteinuria in nephrotic range
4. Low compliance to treatment
5. Any cardiovascular contraindication to exercise testing and training

Date of first enrolment
20/07/2011

Date of final enrolment
20/07/2014

Locations

Countries of recruitment
Italy

Study participating centre
Policlinico S.Orsola-Malpighi
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Study participating centre
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Sponsor information

Organisation
Istituto Superiore di Sanità

ROR
https://ror.org/02hssy432

Funder(s)

Funder type
Government

Funder Name
Istituto Superiore di Sanità

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 Valentina Totti (trapiantoesportcrter@gmail.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/02/2018		Yes	No
Results article	Longitudinal Analysis	16/04/2020	17/02/2023	Yes	No
Results article		17/01/2025	11/06/2025	Yes	No
Other publications		05/01/2024	11/06/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes