

Effects of a personalized exercise prescription after kidney transplantation



CrossMark [#]

Condition category

Urological and Genital Diseases

Date applied

20/12/2016

Date assigned

19/01/2017

Last edited

18/01/2017

Prospective/Retrospective

Retrospectively registered

Overall trial status

Completed

Recruitment status

No longer recruiting

Plain English Summary

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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2. Professor Valentina Totti
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Trial website



Contact information

Type

Scientific

Primary contact

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Additional identifiers

EudraCT number

2016-005093-35

ClinicalTrials.gov number

Protocol/serial number

118/2010/O/Sper

Study information

Scientific title

Effects of tailored physical activity after kidney transplantation

Acronym

Study hypothesis

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

Ethics approval

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

Secondary study design

Non randomised study

Trial setting

Other

Trial type

Quality of life

Patient information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Condition

Kidney transplant recipients

Intervention

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

Phase

Drug names

Primary outcome measures

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'O_{2peak}) that is demonstrated to be a strong predictor of CVD events, at baseline, 6 and 12 months.

Secondary outcome measures

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

Overall trial start date

20/07/2010

Overall trial end date

20/07/2015

Reason abandoned**Eligibility****Participant inclusion criteria**

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

Participant type

Patient

Age group

Adult

Gender

Both

Target number of participants

120

Participant 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

Recruitment start date

20/07/2011

Recruitment end date

20/07/2014

Locations**Countries of recruitment**

Italy

Trial participating centre

Policlinico S.Orsola-Malpighi
U.O. Nephrology and Dialysis via Massarenti 9
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Trial participating centre

University of Bologna
Department of Biomedical & Neuromotor Sciences Via del Pilastro 8
Bologna
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Trial participating centre

Sports medicine, Cardiovascular Department
Piazzale Bastia, 1
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Trial participating centre

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Trial participating centre

Regional Hospital of Bologna
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Trial participating centre

University of Padua
Sports Medicine Unit DIMED, Department of Medicine Via Tiziano Aspetti 106
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Trial participating centre

Regional Hospital of Modena
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Trial participating centre

University of Florence
Sports Medicine Center School of Sports Medicine Department of Experimental and Clinical Medicine Largo
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Trial participating centre

Italian National Transplant Centre
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Sponsor type

Government

Website



Funders

Funder type

Government

Funder name

Istituto Superiore di Sanità

Alternative name(s)

Funding Body Type

Funding Body Subtype

Location**Results and Publications****Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal (Plos One).

IPD Sharing plan:

The datasets generated during and/or analysed during the current study are/will be available upon request from Valentina Totti (trapiantoesporterter@gmail.com).

Intention to publish date

30/06/2017

Participant level data

Available on request

Results - basic reporting**Publication summary****Publication citations****Additional files****Editorial Notes**