# Active Care After Transplantation: ACT for the future

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The proposed randomized controlled lifestyle intervention studies the effects of an exercise and nutrition intervention in the first year after transplantation on: 1. Exercise capacity, muscle strength, diet, quality of life and social participation...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

# Summary

## ID

NL-OMON40892

**Source** ToetsingOnline

**Brief title** ACT for the future

## Condition

- Other condition
- Appetite and general nutritional disorders
- Muscle disorders

**Synonym** post transplantation overweight

#### **Health condition**

overgewicht en deconditionering na niertransplantatie

#### **Research involving**

Human

## **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Groningen **Source(s) of monetary or material Support:** Nierstichting Nederland en Innovatiefonds Zorgverzekeraars

## Intervention

Keyword: Rehabilitation, Renal transplantation

### **Outcome measures**

#### **Primary outcome**

- Quality of life;
- Exercise capacity;
- Muscle strength and muscle mass.
- Cardio Metabolic risk (body composition, metabolic syndrome and insulin

resistance).

#### Secondary outcome

- Daily physical activity;
- Nutritional intake, nutritional status and nutritional knowledge;
- · Barriers and success factors for intervention effect on patient level;
- Psychological factors.

# **Study description**

#### **Background summary**

The patient and graft survival in the first year after renal transplantation have improved considerably in recent decades . However the long -term outcomes, are still not optimal for the patient. Cardiovascular diseases are the primary cause of death after renal transplantation , and also a major cause of morbidity .The adverse cardio metabolic risk profile after kidney transplantation plays an important role in this increased risk. A healthy lifestyle can reduce the cardio metabolic risk after transplantation, by prevention of post-transplant obesity, metabolic syndrome and post-transplant diabetes . Lifestyle changes aiming to improve endurance , muscular strength and a healthy diet can also contribute to a higher quality of life after transplantation.

Obesity is a well-known problem after transplantation. In the first year after transplantation, patients gain on average of 6 kilogram. This gain in weight entirely consists of an increase in fat mass. The weight gain appears to be related to both unhealthy diet and lack of exercise, and leads to a less favorable cardio metabolic risk profile. Lack of exercise after renal transplantation is a strong predictor of cardiovascular mortality. Previous research shows that low muscle mass and exercise intolerance are important determinants of guality of life in renal transplant patients . Change in lifestyle can improve muscle mass and exercise tolerance, and thereby the quality of life . Healthy diet and physical activity are important targets for intervention after renal transplantation. Sustainable changes of lifestyle habits require specific expertise. Experience in other high-risk groups such as pre-diabetes patients is valuable. The promising finding in pre-diabetes patients show that lifestyle measures are effective in the prevention of diabetes. In renal transplant patients, the greatest weight gain occurs in the first year after transplantation : the first year after transplantation

therefore offers a ' window of opportunity ' for preventing obesity .

## Study objective

The proposed randomized controlled lifestyle intervention studies the effects of an exercise and nutrition intervention in the first year after transplantation on:

1. Exercise capacity, muscle strength, diet, quality of life and social participation.

2. The development of obesity and metabolic risk factors in the first year after renal transplantation.

## Study design

This study is an applied randomized controlled intervention. Participants will be randomized into three groups: standard care, exercise, exercise and nutritional intervention.

#### Intervention

Participants will be randomized over the three research groups : standard care , exercise group, exercise and nutritional intervention group. The standard care group receives regular care and advice to be physically active. The exercise intervention group (3 months exercise program with 15 months lifestyle counseling) aims to improve muscle strength and fitness. The exercise and nutritional intervention group receives the exercise intervention supplemented by a nutritional intervention ( 3 months exercise program with 15 months lifestyle counseling, plus nutritional counseling for 15 months). The lifestyle counseling is based on the theory of behavioral change. Motivational interviewing techniques are used to improve self-management skills of the participants .

#### Study burden and risks

Participation in the study does not imply any health risks. The research protocol provides strict precautions to ensure patient safety. Prior to baseline measurements participants will be medically evaluated by a nephrologist to decide whether the patient is medically able to participate in the research (eg on the basis of medical history, listen to your heart and lungs, measurement of blood pressure and possibly an ECG ). If indicated, the nephrologist will consult the cardiologist. Furthermore, prior to all exercise testing and training sessions, an extended warm-up will be performed in order to keep the risk of sport related injuries as small as possible. Maximal exercise tests will take place under medical supervision and ECG monitoring and blood pressure will be recorded during the test. The test will be stopped immediately when changes or abnormalities in the ECG occur , systolic blood pressure is higher than 250 mmHg , diastolic blood pressure is higher than 120 mmHg or blood pressure will drop more than 20 mmHg. There are detailed instructions on how to act when problems would occur during the intervention program.

When (sports ) injuries occur during the intervention , participants will be referred to their GP. The nephrologist will be informed if any injury will occur. In case of any cardiac and / or pulmonary problems the nephrologist .will be contacted.

# Contacts

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# **Trial sites**

## **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

## **Inclusion criteria**

• Age over 18 years;

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- Informed Consent;
- < 1 year after transplantation;
- Approval for participation in the study by the nephrologist based on a clinical evaluation

## **Exclusion criteria**

- Psychopathology or severe cognitive impairment
- Combined organ transplantation
- Physical or clinical limitations that prevent participation to the intervention program.
- Negative results of medical screening by the nephrologist or cardiologist.\*
- Pregnancy

# Study design

## Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

## Recruitment

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NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	11-07-2014
Enrollment:	219
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	10-07-2014
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-02-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

# **Study registrations**

# Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

**Register** CCMO **ID** NL49084.042.14