# Group rehabilitation for renal patients

Published: 02-07-2010
Last updated: 06-05-2024

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Metabolism disorders NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON37964

**Source**
ToetsingOnline

**Brief title**
Group rehabilitation for renal patients

### Condition

- Metabolism disorders NEC
- Muscle disorders
- Renal disorders (excl nephropathies)

**Synonym**
renal failure, renal insufficiency

**Research involving**
Human

### Sponsors and support

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

## Intervention

**Keyword:** randomised controlled trial, rehabilitation, renal patients

## Outcome measures

### Primary outcome

The primary outcome parameters in the GRN-study are: quality of life , (maximal) exercise capacity, (maximal) skeletal muscle strenght, physical activity level and costeffectiveness. In the GRN-ACT substudy also adiposity.

### Secondary outcome

Secundary study parameters in the GRN-study are nutritional status (SGA), blood pressure, fatigue and labor participation. In the GRN-ACT substudy, additional secundary parameters are: metabolic complications (insuline sensitivity, bloodglucoselevels, lipidprofile and metabolic syndrome), nutritional habits and knowledge of nutrition, fear of movement and copingstyle.

# Study description

### Background summary

Exercise intolerance and skeletal muscle weakness are common in dialysis and renal transplant patients and severely compromise quality of life. In the earlier study ''Body composition and muscle dysfunction in renal patients: underlying mechanisms and the response to exercise training* (performed at the department of internal medicine at the Maastricht University Medical Center, funded by the Dutch Kidney Foundation (Projectcode C99.1825), the short-term effectiveness of an intensive, supervised exercise training program (twice weekly during a period of 12 weeks; combination of endurance and resistance training) has been investigated in a natural groups cohort study. Exercise training seemed to have beneficial effects on exercise capacity, skeletal muscle strength and quality of life of renal transplant and hemodialysis patients. Quality of life (in particular scores related to physical functioning) is a strong predictor of morbidity and mortality in dialysis patients. In renal transpalnt patients, the beneficial effects of exercise

training may prevent the development of new medical problems such as obesity, abnormalities in the lipid profile, posttransplant diabetes mellitus, and cardiovascular disease. The long-term effectiveness and cost-effectiveness of exercise training programs for renal transplant and dialysis patients have, however, not yet been established. Therefore, the long-term effectiveness and cost-effectiveness of an intensive, supervised exercise training program will be investigated in a randomised controlled design in renal transplant and dialysis patients. Results of such a study are important to convince health care insurers that exercise training is (cost)effective and has to be considered as a structural part of the routine treatment of renal transplant and dialyis patients and therefore should be routinely reimbursed.

**Study objective**

The purpose of GRN-study is: 1. to determine the long-term effectiveness of a 12 weeks lasting physical exercise training program. 2. to determine the costeffectiveness of the 12 weeks lasting physical exercise training program. In aim of the GRN-ACT substudy is to study the prevention of posttransplant adiposity and its adverse cardiometabolic effects by a combined diet-and-physical activity program or exercise intervention in renal transplant patients starting in the first year after transplantation.

**Study design**

Randomised controlled trial

**Intervention**

Dialysis patients in the study are randomised into two groups: The exercise intervention group (I): Patients assigned to the intervention group participate in a 12 weeks lasting, intensive, standardized and supervised physical training program (twice weekly a session of 2 hours) which consists of a combination of endurance and strength training. The training sessions will be performed in mixed groups of renal transplant and dialysis patients (n = 10-12). After completion of the training program, patients receive an individual sport- and physical activity advice. Subsequently, patients will receive usual care in the 12 months lasting follow-up period. During the follow-up period patients is offered the possibility to schedule three consultations with a lifestyle coach (facultative). The usual care group (II): Patients assigned to the usual care group receive the standard medical care (usual care) during the 15 months lasting study period. Physical training does not form a part of the usual care of renal transplant and dialysis patients. After randomisation, patients assigned to the usual care group receive the advice to meet the 'Nederlandse Norm Gezond Bewegen (NNGB), i.e. the advice to perform 30 minutes of moderately intense physical activity at at least five but preferably all days of the week. In both groups, measurements performed at baseline (measurement of quality of

life, exercise capacity, muscle strength, physical activity level, subjective global assessment, bloodpressure, fatigue and labor participation) will be repeated at t = 12 weeks, t = 6 months and t = 15 months. In group I, maximal exercise capacity and maximal skeletal muscle strength will be measured at t = 6 weeks too. Besides, patients in both groups will complete (retrospective) cost-questionnaires at t = 0, 3, 6, 9, 12 and 15 months. After baseline measurements of quality of life, exercise capacity, muscle strength, physical activity level, subjective global assessment, bloodpressure, fatigue, labor participation and health care costs, renal transplant patients in the GRN-ACT substudy are randomised into three groups: The exercise intervention group (I): patients assigned to the exercise intervention group will follow the same exercise intervention program (intervantion and follow-up) as dialysis patients which will be assigned to the exercise intervention group (see above). The usual care group (II): Patients assigned to the usual care group receive the standard medical care (usual care) during the 15 months lasting study period. Physical training does not form a part of the usual care of renal transplant and dialysis patients. After randomisation, patients assigned to the usual care group receive the advice to meet the 'Nederlandse Norm Gezond Bewegen (NNGB), i.e. the advice to perform 30 minutes of moderately intense physical activity at at least five but preferably all days of the week. The combined exercise and diet intervention group (group III): Patients assigned to the combined exercise and diet intervention group (group III) follow the same program as group I but extended with a dietary intervention. Patients will be consulted by a dietitian who will discuss the dietary habits of the patients. During these consultations personal goals will be set for maintenance of healthy dietary habits. During the first 12 weeks of the intervention program consultations will take place every 2 weeks (6x), after this period every 3 months. In all groups of transplant patients in the GRN-ACT substudie, measurements performed at baseline (measurement of quality of life, exercise capacity, muscle strength, physical activity level, subjective global assessment, bloodpressure, fatigue and labor participation) will be repeated at t = 12 weeks, t = 6 months and t = 15 months. In group I and III, maximal exercise capacity and maximal skeletal muscle strength will be measured at t = 6 weeks too. Insulin sensitivity will be performed in all groups (OGTT) at t= 0, 3 and 15 months. Blood measurements will be performed in all groups at t= 0, 3, 6 and 15 months. Bloo

d sampling will take place at the same time as a regular care consult, so no extra blood sampling will be needed. Besides, patients in all groups will complete (retrospective) cost-questionnaires at t = 0, 3, 6, 9, 12 and 15 months. In group I en group II nutritional habits will be measured at t= 0, 3, en 15 months. In group III nutritional habits will also be measured at t= 6 months. In group I en group II nutritional knowledge will be measured at t= 0 and 15 months. In group III this will also be measured at t= 6 months. Fear of movement will be measured at t=0, 3 en 15 months in groups I, II and III. Copingstyle will be measured in all groups only at t=0.

**Study burden and risks**

The follow-up period of the study is 15 months. Patients assigned to the exercise intervention group (group I) participate in a 12 weeks lasting, intensive, standardized and supervised physical training program (twice weekly a session of 2 hours). After completion of the training program, patients receive an individual sport- and physical activity advice. Subsequently, patients will receive usual care in the 12 months lasting follow-up period. During the follow-up period patients is offered the possibility to schedule three consultations with a lifestyle coach (facultative). Patients assigned to the usual care group (group II) receive the standard medical care (usual care) during the 15 months lasting study period. Physical training does not form a part of the usual care of renal transplant and dialysis patients. After randomisation, patients assigned to the usual care group receive the advice to meet the 'Nederlandse Norm Gezond Bewegen (NNGB), i.e. the advice to perform 30 minutes of moderately intense physical activity at at least five but preferably all days of the week. Patients assigned to the combined exercise and diet intervention group (group III) follow the same program as group I but extended with a dietary intervention. Patients will be consulted by a dietitian who will discuss the dietary habits of the patients. During these consultations personal goals will be set for maintenance of healthy dietary habits. During the first 12 weeks of the intervention program consultations will take place every 2 weeks (6x), after this period every 3 months. In both groups, measurements performed at baseline (measurement of quality of life, exercise capacity, muscle strength, physical activity level, subjective global assessment, bloodpressure, fatigue and labor participation) will be repeated at t = 12 weeks, t = 6 months and t = 15 months. In group I, maximal exercise capacity and maximal skeletal muscle strength will be measured at t = 6 weeks too. Besides, patients in both groups will complete (retrospective) cost-questionnaires at t = 0, 3, 6, 9, 12 and 15 months. In all groups of transplant patients in the GRN-ACT substudie, measurements performed at baseline (measurement of quality of life, exercise capacity, muscle strength, physical activity level, subjective global assessment, bloodpressure, fatigue and labor participation) will be repeated at t = 12 weeks, t = 6 months and t = 15 months. In group I and III, maximal exercise capacity and maximal skeletal muscle strength will be measured at t = 6 weeks too. Insulin sensitivity will be performed in all groups (OGTT) at t= 0, 3 and 15 months. Blood measurements

will be performed in all groups at t= 0, 3, 6 and 15 months. Blood sampling will take place at the same time as a regular care consult, so no extra blood sampling will be needed. Besides, patients in all groups will complete (retrospective) cost-questionnaires at t = 0, 3, 6, 9, 12 and 15 months. In group I en group II nutritional habits will be measured at t= 0, 3, en 15 months. In group III nutritional habits will also be measured at t= 6 months. In group I en group II nutritional knowledge will be measured at t= 0 and 15 months. In group III this will also be measured at t= 6 months. Fear of movement will be measured at t=0, 3 en 15 months in groups I, II and III. Copingstyle will be measured in all groups only at t=0. The protocol provides in strict precautions to warrant patient's safety during exercise tests and exercise training. Prior to the baseline measurements, the nephrologist assesses whether or not a patient is able to participate in the study based on medical-technical grounds (eg based on medical history, auscultation of heart and lungs, measurement of blood pressure and possibly an ECG). If indicated, the nephrologist calls the cardiologist in consult to take this decision. For each patient, an individual (standardized) training program based on the results of the cycle and strenght tests at baseline will be developed. Exercise tests, skeletal muscle strenght tests and trainingsessions will be

performed under (medical) supervision. Furthermore, a solid warming-up will be performed before each exercise test, skeletal muscle strength test and trainingsession in order to reduce the risk of exercise-related injuries.
Maximal exercise tests will be performed under medical supervision and ECG and blood pressure monitoring and will be terminated if changes in ECG occur, systolic blood pressure exceeds 250 mmHg, diastolic blood pressure is 120 mmHg or higher, or blood pressure decreases 20 mmHg or more. There are detailed instructions on how to act when problems occur during the trainingprogram. The physical training program and exercise tests do not have adverse effects on renal function. The OGTT for measurement of insuline sensitivity could cause some nausea. Blood samples will be taken by educated and experienced laboratory employees.

# 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

General: - age >= 18 years; - informed consent. Renal transplant patients: - stable renal function; - time after transplantation at the start of the study: at least 3 months, maximum 9 months; Hemodialysis and peritonealdialysis patients: - at least 3 months dependent on renal replacement therapy;

### Exclusion criteria

General: 1. psychopathology / severe cognitive impairment 2. negative result of the screening by the nephrologist and / or cardiologist. Renal transplant patients: - type 1 diabetes mellitus Remark: The nephrologist takes care for the inclusion of patients in the study. The nephrologist assesses whether or not a patient is able to participate in the study based on medical-technical grounds (eg based on medical history, auscultation of heart and lungs, measurement of blood pressure and possibly an ECG). If indicated, the nephrologist calls the cardiologist in consult to take this decision.

## Study design

### Design

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

### Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 25-10-2010 |
| Enrollment: | 400 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 02-07-2010 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 18-07-2011 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 02-02-2012 |
| Application type: | Amendment |
| Review commission: | MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht) |
| Approved WMO Date: | 13-02-2012 |
| Application type: | Amendment |
| Review commission: | MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht) |
| Approved WMO Date: | 14-03-2012 |
| Application type: | Amendment |
| Review commission: | MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht) |
| Approved WMO Date: | 26-03-2012 |
| Application type: | Amendment |
| Review commission: | MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht) |
| Approved WMO Date: | 17-04-2012 |
| Application type: | Amendment |
| Review commission: | MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht) |
| Approved WMO | |

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| Date: | 20-06-2012 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 24-10-2012 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 15-01-2013 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

# 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 | ID |
|---|---|
| ClinicalTrials.gov | NCT01047410 |
| CCMO | NL27231.068.09 |