

The effectiveness of a lifestyle intervention program on physical capacity and movement behaviour in recipients of solid organ transplantation

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To assess the additional value of a five day comprehensive assessment and intervention program on exercise and lifestyle followed by a six months maintenance program in primary care compared to the usual care program after solid organ...

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

Summary

ID

NL-OMON49489

Source

ToetsingOnline

Brief title

Rehabilitation after transplantation

Condition

- Other condition

Synonym

organ transplantation

Health condition

patienten na een orgaantransplantatie (long, nier, lever, hart)

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W, Goede doel 4 mijl en 4 mijl for you

Intervention

Keyword: Exercise training, Lifestyle, Rehabilitation, Transplantation

Outcome measures

Primary outcome

Endurance time as measured bij a Constant Workrate Test. This is a measure of exercise capacity. The test is done on a stationary bike at 70% op peak workrate.

Secondary outcome

- Physical Activity (ActivePAL movement monitor, Short questionnaire to assess health-enhancing physical activity (SQUASH))
- Physical Fitness (Six minute walking test, cardio pulmonary exercise test (maximal oxygen consumption capacity, maximal load cycled, anaerobic threshold), peripheral muscle strength tests (biceps, quadriceps, grip))
- Metabolic syndrome and new onset diabetes after transplantation (Bioelectrical impedance analysis, body mass index, Cholesterol, HbA1C, blood pressure measurement)
- Psychological status (State-Trait Anxiety Inventory-6 (STAI-6, anxiety), Patient Health Questionnaire 9 (PHQ9, depression), Exercise self-efficacy (LIVAS-scale/exercise self-efficacy scale), Six-Dimensional EuroQol instrument)

(EQ6D, quality of life), Visual Analogue Scale (VAS, quality of life))

Study description

Background summary

The majority of patients after solid organ transplantation does not meet the recommended amount and type of physical activity. A more sedentary and inactive lifestyle is reported when compared to the general population. Transplant recipients have a maximal rate of oxygen consumption (VO₂peak) below the normal range and this reduction in VO₂peak is present despite the restoration of near normal organ function after transplantation. Beside a reduced exercise capacity around 30-50% of patients develop comorbid conditions such as osteoporosis, hyperlipidemia and diabetes in the years after transplantation.

We hypothesize that rehabilitation after transplantation will improve the amount and type of physical activity and reduce comorbidity in patients after transplantation.

Study objective

To assess the additional value of a five day comprehensive assessment and intervention program on exercise and lifestyle followed by a six months maintenance program in primary care compared to the usual care program after solid organ transplantation on exercise capacity, physical activity, physical fitness, health related quality of life, anxiety and mood and metabolic parameters.

Study design

The study design is an open label randomized controlled trial.

Intervention

Before a five day comprehensive assessment and intervention program on exercise and lifestyle all patients have to fill in some questionnaires about health related quality of life and wear a body monitoring system.

The five day intervention program consists of intakes of a dietician, psychologist, physiotherapist and physician assistant, testing (2 walking tests, 1 maximal and 1 endurance cycling tests, Peripheral Muscle Strength Test of legs, arms and handgrip), training (endurance training and muscle strength training in the fitness, swimming), exercise (in the sportcomplex and outside), education by the nurse, dietician, psychologist and physiotherapist.

All patients will receive a personal training schedule for training six months in primary care or at home. They will all receive a training diary in which

they will log all there training activities and the experienced intensity.

Patients in the control group visit the University Medical Centre Groningen, Centre of Rehabilitation, location Beatrixoord for one day. They undergo the before mentioned tests. Before this day, they wil fill in some questionnaires and wear a movemonitor for one week.

Six months after T0 all physical tests and questionnaires will be repeated in both the control and rehabilitation group. A body monitoring system will be worn for one week to obtain information on physical activity. This is for both groups the same.

Intervention will take place on top of usual medical care.

Study burden and risks

Participation in this study means for the patients in the intervention group two visits to the University Medical Centre Groningen, Centre of Rehabilitation, location Beatrixoord, one visit of one day, one visit of five days.

Patients in de control group will visit the University Medical Centre Groningen, Centre of Rehabilitation, location Beatrixoord two times a day. The main risk for patients in this study is to get an injury as a result of taking blood form the vein. This risk is small however. We expect the benefits of training will be of more value, than the risk of an injury.

Deelname aan de studie betekent dat patiënten in de interventiegroep 2 keer het UMCG CVR locatie Beatrixoord moeten bezoeken: een bezoek van een dag en een bezoek van vijf dagen met eerder beschreven programma.

Patiënten in de controlegroep komen 2x een dag naar het UMCG CVR locatie Beatrixoord

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 > 18 years old
- Lung, liver, kidney or heart transplantation
- About 6 months after discharge after transplantation

Exclusion criteria

- Dependence in terms of activity of daily life
- Failure of the transplanted organ < 4 weeks before start of the study
- Impossibility to attend group sessions, such as deafness
- Co-morbidity that interferes with the program
- Unstable cardiac co-morbidities (coronary disease/heart failure)
- Debilitating joint or limb problems/complaints of the musculoskeletal system interfering with the program
- Drug abuse
- Alcohol abuse
- Analphabetism

Study design

Design

| | |
|---------------------|-----------------------------|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

Primary purpose: Prevention

Recruitment

| | |
|---------------------------|---------------------|
| NL | |
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 17-06-2019 |
| Enrollment: | 106 |
| Type: | Actual |

Ethics review

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|--------------------|---|
| Approved WMO | |
| Date: | 25-01-2019 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO | |
| Date: | 18-11-2020 |
| 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 | ID |
|----------|----------------|
| CCMO | NL67525.042.18 |