Rehabilitation after liver transplantation? A study into the applicability and feasibility of rehabilitation in liver transplant recipients.

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Aim of the preceding study is to explore the applicability and feasibility of a rehabilitation program for improvement of complaints of fatigue in liver transplant recipients.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Interventional

Summary

ID

NL-OMON29727

Source
ToetsingOnline

Brief title
Rehabilitation after liver transplantation?

Condition

- Hepatic and hepatobiliary disorders
- Hepatobiliary therapeutic procedures

Synonym
fatigue

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: active lifestyle, fatigue, liver transplantation, rehabilitation program

Outcome measures

Primary outcome

1. Severity of fatigue (patients)

(see also page 10)

Secondary outcome

2. Everyday physical activity (patients and healthy persons)

3. Cardiorespiratory fitness (patients and healthy persons)

4. Neuromuscular fitness (patients and healthy persons)

5. Health-related quality of life (patients)

6. Health-related functional status (patients)

7. Sleep quality (patients)

8. Anxiety en depression (patients)

9. Participation (epatients)

10. Self-efficacy (patients)

11. Coping (patients)

12. Satisfaction patient (patients)

13. Feasibility rehabilitation program

14. Costs rehabilitation program

(see also pages 10 to 13)

Study description

Background summary

Liver transplant recipients often experience severe complaints of fatigue and these complaints seem not to decrease over time. The cause of this fatigue is often not clear. However, there are indications that fatigue after liver transplantation is accompanied by a low level of daily physical activity and a low physical fitness.

Study objective

Aim of the preceding study is to explore the applicability and feasibility of a rehabilitation program for improvement of complaints of fatigue in liver transplant recipients.

Study design

The study concerns a longitudinal effect-study (pilot). We will explore whether liver transplant recipients who participated in the rehabilitation program have improved with respect to fatigue, level of everyday physical activity, physical fitness (cardiorespiratory, neuromuscular, body composition), health-related quality of life and a number of other factors. We will also explore to what extent there are relations between (changes in) severity of fatigue complaints on the one hand and (changes in) the level of everyday physical activity, physical fitness (cardiorespiratory, neuromuscular, body composition), health-related quality of life, and a number of other factors on the other hand. The rehabilitation program will be offered during three months and consists of 'physical fitness' module and 'active lifestyle' module. Fatigue questionnaires; Activity Monitor measurements; a progressive maximal aerobic test on a cycle ergometer; a 6-minute walk test; muscle strength measurements; body composition measurements; and a questionnaire concerning quality of life will be used to evaluate the applicability of the program. Furthermore, the feasibility of the rehabilitation program will be evaluated. This will be done using a semi-structered interview, in which the participants are asked to assess the content and organisation of the rehabilitation program.

Intervention

The rehabilitation program will be offered during three months and consists of a 'physical fitness' module (2 times a week 1 hour cardiorespiratory and neuromuscular exercise) and a 'active lifestyle' module (i.e. the subject will

be stimulated to improve his/her everyday physical activity by means of counseling (4 sessions)).

Study burden and risks

Patients:
The pre and post-treatment measurements consist of the collection of demographic data and medication use, functional measurements in the movement laboratory and some questionnaires. This will last approximately 5 hours, including rest periods. The instrumentation of the Activity Monitor and some questionnaires will last 2 hours; the time to remove the Activity Monitor will take 30 minutes. 3 months after the rehabilitation program the patients will be asked to fill in only the fatigue questionnaire (15 minutes) (follow-up).
The patients follow the parts 'physical fitness' and 'active lifestyle' during a period of 3 months. Duration of the part 'physical fitness': 2 hours a week, during 3 months. Duration of the part 'active lifestyle': 4 individual conversations of 1 hour each.
For the progressive maximal cycle ergometer test and the strength test subjects have to exert themselves maximally. Before the tests, there will be checked if it is safe to carry them out. During testing there will always be a doctor present. The other tests are not dangerous and are not a risk for the participants.

Healthy persons:
Collection of demographic data and functional measurements in the movement laboratory. This will last approximately 4 hours, including rest periods. The instrumentation of the Activity Monitor will last 1 hour; the time to remove the Activity Monitor will take 30 minutes.
For the progressive maximal cycle ergometer test and the strength test subjects have to exert themselves maximally. Before the tests, there will be checked if it is safe to carry them out. During testing there will always be a doctor present. The other tests are not dangerous and are not a risk for the participants.

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

Inclusion criteria patients:
- Sufficient knowledge of the Dutch language.
- Liver transplantation at least one year ago in the Erasmus MC.
- Age between 18 and 65 years.
- Persons must have complaints of fatigue: Fatigue Severity Scale (FSS) score> 4.
See also protocol page 10 and appendix 5.;Inclusion criteria healthy persons:
- Sufficient knowledge of the Dutch language.
- Age between 18 and 65 years.

Exclusion criteria

Exclusion criteria patients:
- Multiorgan transplant recipients.
- Severe comorbidity.
- Contra-indication for a progressive maximal cycle ergometer test.
- Contra-indication for exercise.;Exclusion criteria healthy persons:
- Disorders that may interfere with the measurements.
- Contra-indication for a progressive maximal cycle ergometer test.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-09-2006
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	13-07-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL11808.078.06