FIT4Cirrhotics@Home: Effects of a home-based, bimodal lifestyle intervention in patients with liver cirrhosis awaiting orthotopic liver transplantation.

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

Summary

ID

NL-OMON53348

Source
ToetsingOnline

Brief title
FIT4Cirrhotics@Home

Condition

- Hepatic and hepatobiliary disorders

Synonym
Liver cirrhosis, liver scarring

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

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

Intervention

Keyword: Aerobic capacity, Exercise, Home-based, Prehabilitation

Outcome measures

Primary outcome

The main study parameter/endpoint is the progression in aerobic capacity after 6 weeks. Hereto, before and after the first training period a CPET will performed to determine the difference in VO2 at the VAT and VO2peak in ml/kg/min.

Secondary outcome

A secondary parameter/endpoint of this study is the progression in aerobic capacity after the second training period, and six weeks after termination of the program. Hereto, after 12 and 18 weeks another CPET will be performed. Other secondary parameters/endpoints are the evaluation of differences in sarcopenia, anthropometry, functional mobility, quality of life, perceived fatigue, incidence of hepatic encephalopathy, number of unplanned hospital admissions, change in liver frailty index score and change in microbiome composition at six, 12 and 18 weeks, or until transplantation. Furthermore, postoperative outcomes up to twelve months post-OLT will be collected.

Study description

Background summary

Patients with liver cirrhosis who are on the waiting list for orthotopic liver transplantation (OLT) encounter all key components of physical frailty, i.e.,

decreased functional capacity, impaired aerobic capacity and sarcopenia, which all lead to fatigue, diminished quality of life, increased hospitalization and pre- and post-transplantation morbidity and mortality. An exercise program in combination with nutritional support has proven to improve all key components of physical frailty and quality of life in various surgical patient populations. Although small studies have demonstrated similar positive effects of exercise training in patients on the waiting list for OLT, to date no large studies supported the effects of exercise training and nutritional support on (the longevity of) the increase in aerobic capacity in OLT patients.

Study objective

The primary objective of this study is to assess the individual patients* response to an exercise program on aerobic capacity at six weeks by measuring the VO2 at the VAT and VO2peak before and after a homebased bimodal lifestyle program in non-fit patients with liver cirrhosis awaiting OLT.

Secondary objectives are to assess individual differences in sarcopenia, anthropometry, functional mobility, quality of life, perceived fatigue, incidence of hepatic encephalopathy, number of unplanned hospital admissions, change in liver frailty index score and change in microbiome composition at six, 12, and 18 weeks. The aerobic capacity will also be re-evaluated at 12 and 18 weeks. Furthermore, the feasibility of a semi-supervised home-based bimodal lifestyle program in patients with liver cirrhosis awaiting OLT will be evaluated.

Study design

This study is an investigator-initiated, single center, single arm, prospective clinical trial. It will take place at the University Medical Center Groningen, the Netherlands. Eligible patients will participate in the bimodal lifestyle program, which comprises two home-based training periods of six-weeks each (12 weeks training in total, or until transplantation). After 18 weeks (i.e., six weeks after termination of the program) a final assessment will take place to evaluate the longevity of the expected effects of the lifestyle program on predefined study outcomes.

Intervention

Patients will participate in a home-based bimodal lifestyle program. The program comprises semi-supervised high intensity interval and endurance training on an advanced cycle ergometer (Lode Corival Home+, Lode BV, Groningen, The Netherlands), combined with nutritional support consisting of protein, vitamin and mineral supplementation. Moreover, to improve functional mobility and muscle function patients will perform peripheral resistance training of the large muscle groups of the upper and lower extremities.

Finally, to improve respiratory performance after surgery and potentially reduce pulmonary complications, patients will perform breathing exercises. The program will be patient personalized and compromises three training sessions per week. The cycle ergometer used for this program will upload training results to an online platform, enabling remote monitoring of patients* adherence and training progress. Furthermore, a community physical therapist will visit the patient at least weekly to monitor progress and to optimize the training intensity.

Study burden and risks

Because the exercise program is situated at home (both the cycle ergometer as the community physiotherapist will come to the patient) the investigators make things as accessible as possible for the patient to participate. Supervision by the physiotherapist during the training sessions is arranged three times in the first week and at least once a week thereafter. At the start of the program a CPET with continuous ECG monitoring will be executed under guidance of trained employees to assess baseline cardiorespiratory fitness, as well as to rule out strain related cardiac ischemia and other contraindications for physical exercise training during the consecutive exercise program. Hence, patient*s safety in the exercise program is guaranteed.

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

• Diagnosed with end-stage liver disease / liver cirrhosis (regardless of etiology);
• On the waiting list for OLT;
• VO2 at the VAT <=13 ml/kg/min and/or VO2peak <=18 ml/kg/min;
• Speaks the Dutch language;
• Aged at least 18 years;
• Understands the purpose of the study and has given written informed consent to participate in the
study.

Exclusion criteria

• Experienced a MACE (e.g., myocardial infarction) in the past six months;
• Experienced a cerebrovascular incident in the past six months;
• Medical history of an uncontrolled heart rhythm disorder;
• Hepatic encephalopathy grade 3 or 4;
• Acute liver failure;
• Acute on chronic liver failure;
• Hospitalization at start of the study;
• Non-treated esophageal varices (i.e., variceal eradication endoscopy and/or adequately dosed NSBB);
• Not capable of cycling on a cycle ergometer
• No available community physical therapist in the living area of the patient.
Patients refusing or unable to sign informed consent

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2023
Enrollment:	16
Type:	Anticipated

Ethics review

Approved WMO

Date:	02-08-2023
Application type:	First submission
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	NL83612.042.23