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Home-based exercise and motivational programme before and after liver transplantation: ExaLT Trial

Submission date
12/05/2022

Recruitment status
No longer recruiting

Registration date
07/06/2022

Overall study status
Ongoing

Last Edited
06/10/2025

Condition category
Surgery

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Liver disease is the 3rd commonest cause of death in adults of working age and liver transplantation (LT) remains the only cure for liver failure. LT exerts a huge stress on the body and mind, especially in people who are already physically and mentally frail because of their liver disease. We know that being physically frailty prior to surgery results in a longer hospital stay because of postoperative complications and contributes to 1 in 10 patients either dying whilst still on the waiting list or shortly after LT. Exercise is one of the most powerful medical therapies available, with numerous proven benefits to patients with diseases like diabetes, heart disease and cancer. Despite this, exercise is not currently used in patients with liver failure or recovering from LT, due to a lack of robust evidence. Exercise may have the potential to improve the lives of people with liver disease and reduce the side-effects of LT surgery. The current standard of care for NHS patients awaiting LT is an advice leaflet. Evidence-based exercise programmes around the time of transplantation do not exist. Only a few small studies have indicated that supervised, hospital-based exercise can improve physical function and quality of life.
We aim to determine the effect of a home-based exercise and motivation-support programme in patients undergoing LT on their quality of life after surgery. We would also like to understand if exercise results in improvements in intricate measures of physical fitness and muscle function that account for changes in quality of life, and how the motivation-support component of the intervention enhances uptake and ongoing engagement of exercise pre and post LT.

Who can participate?
Patients with end-stage liver disease who are on the liver transplant waiting list.

What does the study involve?
We intend to perform a clinical trial, in which patients will be randomly allocated to receive either the home-based exercise/motivation support programme (intervention group) or a patient advice leaflet (control group) whilst on the LT waiting list. The intervention will begin whilst patients are on the LT waiting list and end 6 months after LT. The intervention will consist of regular strength and endurance exercises, tailored to each patient's level of fitness. During clinic visits and via telephone calls a physiotherapist will provide motivational support

throughout the exercise programme. The trial will involve recruiting 266 patients over two years from two LT hospitals in
England. We shall assess the effectiveness of the intervention by measuring quality of life before and after the study period in both groups of patients. The intervention will be deemed effective if quality of life scores are higher with the intervention than the control group.

What are the possible benefits and risks of participating?
We do not know how this trial will directly help participants, but it will help improve the care of patients with liver failure (and/or liver cancer), who are waiting or who have had a liver transplant. Participants may feel the indirect benefits of being part of this trial such as receive care which is not standard, improve the patient's experience and knowledge of the liver disease process and receive closer monitoring and follow up. Participants may also feel empowered knowing that they contribution to clinical research will help advance new and improved treatments/services for patients undergoing a liver transplant.
The exercises that participants will be given to do will be matched to their ability and individualised to their needs, however there is still the possibility of sprains or injuries if the exercise are not carried out correctly. Participants can experience temporary pain/discomfort when they have blood taken and may develop a bruise at the site where the needle has sampled blood. To minimise this, additional blood tests for trial purposes will be taken (when possible) at the same time as blood tests as part of their routine clinical care.
In relation to an ongoing COVID pandemic, current government guidelines will be adhered to and local NHS and University procedures will be followed to minimise the risk of exposure to the virus.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
June 2021 to May 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
295426

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 52211, NIHR129318, IRAS 295426

Study information

Scientific Title
A phase IIb, randomised-controlled, two-centre clinical trial (ExaLT) on the efficacy of a home-based exercise and motivational programme in patients before and after liver transplantation

Acronym
ExaLT

Study objectives
A remotely monitored ‘home-based exercise and theory based motivation support programme’ delivered by physiotherapists before and after liver transplantation (LT) (intervention group) improves the quality of life (physical component score of SF-36v2) in LT recipients compared to a control group using a patient ‘exercise’ advice leaflet (control group).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/04/2022, Hampshire A REC Board (Temple Quay House, 2 The Square, Temple Quay, Bristol, BS1 6PN, United Kingdom; +44 207 104 8196; hampshirea.rec@hra.nhs.uk), ref: 22/SC/0067

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Exercise before and after liver transplant

Interventions
Eligible participants will be randomised 1:1 to receive either:
Group 1: Intervention group. Remotely-monitored home-based exercise and theory-based motivation support programme whilst on the LT waiting list (max. 12 months) through to 24 weeks post-LT.
OR
Group 2: Control group. Patient exercise advice leaflet before and after LT.
The study intervention will be variable due to the unpredictable nature of the timing of Liver transplant (median waiting time 72 days (95% CI 64-80) registered between 2018-2021).
All patients that are transplanted within 52 weeks of randomisation will receive a fixed 24 week intervention after Liver transplant (LT.)

The visits are summarised below:

Phase 1. Participants will attend the hospital (QEUHB or RFH) in line with their routine waiting list clinic appointment (where possible), at baseline line (visit 1), weeks 6 (visit 2), 12 (visit 3), 24 (visit 4), 36 (visit 5) and 48 (visit 6). At these visits, a repeat of the baseline assessment, including LFI and DASI, will be undertaken. The results of these assessments, review of the participant exercise diary and discussions with the participant themselves will be used to progress exercises and revise goals of their Home-based exercise programme (HBEP) if they are in the intervention arm.
The end of the study intervention will be at 52 weeks if the participant has not undergone LT. At this stage, they will be asked if they wish to continue in the study (data collection).

Post Liver Transplant: Phase 2
The trial physiotherapists will review the participant on the post-LT ward, within 48 hours of discharge from ICU. Within 48 hours prior discharge from hospital (or day 10 post-LT if not discharged by this point), a repeat of the baseline assessments, including LFI and DASI, will be undertaken on the ward

Participants will then attend the hospital (QEUHB or RFH), in line with their routine post-LT follow-up clinic appointment (where possible), at weeks 6 post LT (visit 7), week 12 (visit 8), week 24 weeks (visit 9), 48 weeks (visit 10). At these visits, a repeat of the baseline assessment, including LFI and DASI, will be undertaken. Of note, Phase 2 of the HBEP will commence on day 1 of admission to the post-LT ward (i.e. within 24 hours of discharge from ICU) and end 24 weeks after the date of the LT surgery (visit 9).

Intervention Type
Behavioural

Primary outcome(s)
Physical component score (PCS) from the short form-36 version 2.0 (SF-36v2) health-related QoL questionnaire at 24 weeks post LT (scale 0-100).

Key secondary outcome(s))
Key secondary outcome measure:
1. Comprehensive Complication Index at 24 weeks post LT (scale 0-100).

Other secondary outcome measures to be assessed at 24 weeks post LT (unless stated):
2. Mental Component Score (MCS) of SF-36v2 health-related QoL questionnaire
3. Liver Frailty Index (LFI), Duke Activity Score Index (DASI)
4. Pre-LT morbidity (UKELD, MELD-Na, hospital admissions) and mortality (*assessed up to day of LT)
5. Post-LT length of ICU/hospital stay and hospital re-admissions (frequency, duration [days])
6. Post-LT 30, 90, 180 and 365 day mortality
7. Habitual physical activity levels (daily time spent in light, moderate and vigorous intensity physical activity) using Actigraph accelerometers
8. “Dose” of exercise completed (measure of the frequency, intensity and duration of exercise)
9. Adherence to Home-based exercise program (HBEP - intervention arm only)
10. Perceptions of the health care climate (how need supportive/empowering the physiotherapist is), measured using the Health Care Climate Questionnaire (HCCQ)
11. Basic psychological need satisfaction (i.e. feelings of autonomy, relatedness, competence), measured using the Basic Psychological Need Satisfaction in Exercise Scale (PNSE)
12. Self-determined motivation to exercise, using Behavioural Regulation in Exercise Questionaire-2 (BREQ-2)

Completion date
31/05/2026

Eligibility

Key inclusion criteria
1. Adult Patients (aged 18 years or over)
2. Patients listed for a cadaveric, primary liver transplantation (LT) at QEUHB or the RFH
3. Being an out-patient at the time of baseline trial visit (consent)

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
269

Key exclusion criteria
1. Patient listed for Liver Transplant for any of the following reasons:
1.1. Super-urgent Liver Transplant (according to the Kings College criteria)
1.2. Multi-organ transplantation (e.g. combined liver and kidney transplant)
1.3. Live-related donor Liver Transplant
1.4. Re-graft Liver Transplant
2. Patients with an inability to safely comply with the exercise intervention due to the following conditions:
2.1. Severe hepatic encephalopathy (defined as grade 3 or 4; as judged by the principal or nominated co-investigators)
2.2. Oxygen-dependent hepato-pulmonary syndrome
3. Patients without liver failure, including:
3.1. Liver cancer in the absence of cirrhosis
3.2. Polycystic liver disease
3.3. Rare metabolic/genetic conditions (e.g. glycogen storage disorders)
4. Refusal or lacks capacity to give informed consent to participate in the trial, at the point of study visit 1

Date of first enrolment
03/05/2022

Date of final enrolment
28/05/2024

Locations

Countries of recruitment
United Kingdom

Study participating centre
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Queen Elizabeth Hospital Birmingham
Mindelsohn Way
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United Kingdom
B15 2TH

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/09/2024	10/09/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes