ISRCTN11380842 https://doi.org/10.1186/ISRCTN11380842

CirrhoCare - using smart-phone technology to enhance care and access to treatment for cirrhosis

Submission date 08/09/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 18/10/2023	**Overall study status** Ongoing	
Last Edited 08/07/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims

Cirrhosis, progressive scarring of the liver, has many causes, principally, excessive alcohol intake, fatty liver and viral infections. Unlike many chronic diseases, cirrhosis deaths are increasing rapidly year on year. It is the third most common cause of premature, UK working-age deaths, with 62,000 years of working life lost each year and NHS care costs of £4.53bn annually. One-quarter of all UK cirrhosis patients are at risk of acute decompensation. This describes the development of acute complications such as fluid overload, confusion and infections, requiring hospital admissions and often urgent treatment. Currently, cirrhosis patients deemed at risk of decompensation require regular hospital clinical assessments to detect these new complications. Even following hospital discharge, readmission with new decompensating complications approaches 37% in 4 weeks. This disease burden, compounded by increasing alcohol and obesity-driven liver disease, means demand for specialist liver services outweighs current capacity in a resource-stretched healthcare system. Moreover, regional variation of specialist liver services also impacts illness and deaths, leading to a postcode lottery of care access and geographical inequity. The CirrhoCare trial addresses this urgent clinical need through an innovative cirrhosis management system, including home monitoring of decompensated cirrhosis patients, measuring vital signs such as heart rate and blood pressure (using low-cost, sensing technology), assessing weight (smart-scale) and mental ability (smartphone app), all of which are impacted as cirrhosis progresses. By efficiently and securely collecting data on CyberLiver's management system (platform), CirrhoCare provides a decision-facilitating tool, incorporating individual patient data, helping liver physicians to optimise and personalise treatment in the community. The study will also assess the clinical and cost-effectiveness of CirrhoCare management and seek regulatory approvals. This innovative aspect of cirrhosis management will be more acceptable and convenient for patients. It will also deliver community care with environmental, sustainable benefits, through reduced hospital visits. The cost-effectiveness analysis will generate value-for-money evidence of CirrhoCare management, and the clinical evidence needed to inform future adoption into the NHS.

Who can participate?
Advanced liver cirrhosis patients who have been hospitalised for decompensation who fulfil the trial eligibility criteria and can participate in the trial.

What does the study involve?
The study is a multi-centre, randomised controlled trial, comparing CirrhoCare digital-remote management with standard care for high-risk cirrhosis patients (at risk of new complications) being discharged from the hospital.

What are the possible benefits and risks of participating?
Participants in both arms will receive care as per the standard of care. As a result, taking part in this trial may or may not benefit the participants directly. However, participants on the CirrhoCare management system arm may have greater contact time with their clinician through the app system and notifications from the convenience of their own home. This management system will proactively seek signs of early deterioration in their condition (i.e., decompensated), such that patients with these signs can be prioritised for early assessment. Thus participants in this arm may benefit from a reduction in hospital admissions, reduced hospital intervention and liver disease severity scores in comparison to patients in the standard-of-care arm.

There is no foreseen risk to the participant, though they may have greater contact time with their clinician through the app system and notifications, although this will be from the convenience of their own home.

Where is the study run from?
The University College London with sponsor responsibilities delegated to the Comprehensive Clinical Trials Unit (CCTU).

When is the study starting and how long is it expected to run for?
December 2022 to November 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) Invention for Innovation (i4i) (ref: NIHR204223)

Who is the main contact?
All public queries should be sent to cctu.cirrhocare@ucl.ac.uk
The main contact for scientific queries is Prof Rajeshwar Mookerjee, r.mookerjee@ucl.ac.uk

Contact information

Type(s)
Public

Contact name
Dr CirrhoCare Trial

Contact details
-
-
United Kingdom
-

None available
cctu.cirrhocare@ucl.ac.uk

Type(s)
Scientific, Principal Investigator

Contact name
Prof Rajeshwar Mookerjee

ORCID ID
https://orcid.org/0000-0002-6275-9384

Contact details
Royal Free Hospital
Rowland Hill St
London
United Kingdom
NW3 2PF
+44 (0)207 794 0500
r.mookerjee@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
329173

ClinicalTrials.gov number
NCT06223893

Secondary identifying numbers
CPMS 57442

Study information

Scientific Title
CirrhoCare, A real-world, randomised controlled study, to determine the clinical and cost-effectiveness of CirrhoCare digital home monitoring and management in patients with decompensated cirrhosis

Acronym
CirrhoCare

Study objectives
CirrhoCare management system can reduce liver-related complications and the necessity for hospital intervention over 12 weeks post hospitalisation, for decompensation of liver cirrhosis, compared to the standard of care pathway.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/09/2023, Wales Research Ethics Committee 5 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 2922 941106; Wales.REC5@wales.nhs.uk), ref: 23/WA/0211

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Complications of cirrhosis

Interventions
Current interventions as of 05/02/2025:

Trial Design and methodology of the randomised controlled trial:
1. Phase IIb
2. Open-label: participants and physicians treating the patient will be informed of their randomisation arm. However, an adjudication committee will assess all decompensation events by a group of clinicians not aware of the intervention allocation.

Health Condition(s) or Problem(s) Studied:
Advanced liver cirrhosis patients who have been hospitalised for decompensation.

Target Sample Size: 214

Intervention and Control Arms:

Intervention: 107 patients randomised to receive the CirrhoCare management system.

Control: 107 patients randomised to receive the standard of care.
Participants will be randomised into one of two groups: Intervention (CirrhoCare management system) or Control (standard of care). Each participant will have an equal chance of being

assigned to either of the groups. Participants and their physicians will not be blinded to study arm allocation, which means they will know the group they are randomised to.

Trial Setting:
The trial will recruit 214 patients from at least 12 sites across the UK. The aim is to recruit patients with advanced liver cirrhosis who have been hospitalised for decompensation. The recruitment period is 1 year.

Visits and assessments:
Pre-screening/randomisation visit (72 hours prior to discharge)

All potential participants will be properly informed and made aware of the trial objectives and activities. Each participant will be made aware that they have an equal chance of being allocated to the CirrhoCare Management system or standard of care group. Participants will be informed of the length of the trial and what trial visits will involve.

Eligibility will be determined as per the eligibility criteria in the protocol and all participants must provide written informed consent before any trial-specific procedures take place.

The participant will provide demographic and socio-economic data and will take the participant's medical history and perform a physical examination. The participant will have blood tests (e.g. full blood count, INR, Urea and electrolytes, and liver function tests) and a microbial swab which are part of the standard of care. The participant will also complete the other assessment tests (e. g. MELD score, CLIF-AD score, Liver Frailty Index) and EQ-5D-5L Quality of Life questionnaire. Once confirmed as eligible, the participant will be randomised to receive either the CirrhoCare management system or Standard of care.

Participants randomised to the Standard of Care will follow the hospital’s care management once discharged.

Participants randomised to the CirrhoCare management system:
Participants on this arm will be asked to complete the hand grip strength and the Royal Free Hospital – Nutritional Prioritising Tool. The participants will also be shown and trained on how to use the CirrhoCare kit. Part of the CirrhoCare Management system is to collect data on their BP, temperature, weight, ECG/heart rate well-being (including food and fluid intake) and their adherence to taking their liver-related medications.

Once the participant is discharged from the hospital, the CirrhoCare app will prompt the participant on what assessments to collect daily at home. Participants will also be handed an appointment reminder card of when they will be seen by the clinical team (either face-to-face or by telephone, depending on the visit).

All participants, regardless of which intervention group they are randomised to will be followed up at 28, 56 and 90 days after randomisation. Day 28 visit will ideally be a face-to-face visit, Day 56 can be conducted over the telephone, and Day 90 must be a face-to-face visit.
• Assessment of concomitant medications, study outcomes, SAEs and hospital admissions.
• Quality of life questionnaire.
• (for participants who are randomised on the CirrhoCare management system) Complete the CirrhoCare usability questionnaire and return of CirrhoCare kit at the Day 90 follow-up visit.

Trial Design and methodology of the qualitative research:

This research will take part in three parts:

Part 1: Perceptions of current care and digital home monitoring and management
As part of this design, a web-based questionnaire will be developed, tailored to three different audiences:
a) healthcare professionals delivering care for this decompensated cirrhosis patient group (minimum of 25 respondents)
b) patients or carers (min of 25 respondents)
c) simplified questionnaire for a third 'other group' to cover people not identifying as either healthcare professionals or patients/carers (this group is not a targeted group, so no minimum respondents).
A minimum of ten (10) semi-structured interviews will be conducted with healthcare staff and patients/carers, recruited through participating sites, questionnaire responses or communication from targeted emails using networks shared by British Liver Trust or known clinical networks.

Part 2: Socio-demographics of participants in the CirrhoCare RCT
This part is designed to assess variation in participation and experience of using CirrhoCare within the RCT compared to the socio-demography of the population. To assess this, the following information will be obtained as part of the RCT:
- Location of residence (outbound postcode area, e.g., AN1)
- Demographic factors: Ethnicity, age, gender, and level of education
- Social or economic factors: Employment status, and English as a first language
- Health status: Learning disability; Physical disability
This data will be collected during the RCT and only from participants who are randomised on the CirrhoCare management system arm.

Part 3: Experience and perceptions towards CirrhoCare
In this part, perspectives will be sought from clinicians, patients and carers, and other stakeholders (such as commissioners and policymakers) on the main barriers and facilitators to improving clinical care through the implementation of the CirrhoCare management system.
A second web-based questionnaire (called Questionnaire 2) will be developed, tailored to the three main audiences:
a) healthcare professionals delivering care for this patient group (minimum of 3 responders per site)
b) patients or carers (min of 5 responders per site)
c) other stakeholders, including commissioners and policymakers (targeting a min of 10 responses)
A minimum of ten (10) semi-structured interviews will be conducted with individuals from these groups, recruited through participating sites, questionnaire responses or communication from targeted emails using networks shared by British Liver Trust or known clinical networks.

Two focus groups will be carried out with patients and carers from participating sites.

Participants will only be involved in this part of the research if they have finished their active involvement in the RCT.

———

Previous interventions:

Trial Design and methodology of the randomised controlled trial:
1. Phase IIb
2. Open-label: participants and physicians treating the patient will be informed of their randomisation arm. However, an adjudication committee will assess all decompensation events by a group of clinicians not aware of the intervention allocation.

Health Condition(s) or Problem(s) Studied:
Advanced liver cirrhosis patients who have been hospitalised for decompensation.

Target Sample Size: 214

Intervention and Control Arms:

Intervention: 107 patients randomised to receive the CirrhoCare management system.

Control: 107 patients randomised to receive the standard of care.
Participants will be randomised into one of two groups: Intervention (CirrhoCare management system) or Control (standard of care). Each participant will have an equal chance of being assigned to either of the groups. Participants and their physicians will not be blinded to study arm allocation, which means they will know the group they are randomised to.

Trial Setting:
The trial will recruit 214 patients from at least 12 sites across the UK. The aim is to recruit patients with advanced liver cirrhosis who have been hospitalised for decompensation. The recruitment period is 1 year.

Visits and assessments:
Pre-screening/randomisation visit (72 hours prior to discharge)

All potential participants will be properly informed and made aware of the trial objectives and activities. Each participant will be made aware that they have an equal chance of being allocated to the CirrhoCare Management system or standard of care group. Participants will be informed of the length of the trial and what trial visits will involve.

Eligibility will be determined as per the eligibility criteria in the protocol and all participants must provide written informed consent before any trial-specific procedures take place.

The participant will provide demographic and socio-economic data and will take the participant's medical history and perform a physical examination. The participant will have blood tests (e.g. full blood count, INR, Urea and electrolytes, and liver function tests) and a microbial swab which are part of the standard of care. The participant will also complete the other assessment tests (e. g. MELD score, CLIF-AD score, Liver Frailty Index) and EQ-5D-5L Quality of Life questionnaire. Once confirmed as eligible, the participant will be randomised to receive either the CirrhoCare management system or Standard of care.

Participants randomised to the Standard of Care will follow the hospital’s care management once discharged.

Participants randomised to the CirrhoCare management system:
Participants on this arm will be asked to complete the hand grip strength and the Royal Free Hospital – Nutritional Prioritising Tool. The participants will also be shown and trained on how to use the CirrhoCare kit. Part of the CirrhoCare Management system is to collect data on their BP,

temperature, weight, ECG/heart rate well-being (including food and fluid intake) and their adherence to taking their liver-related medications.

Once the participant is discharged from the hospital, the CirrhoCare app will prompt the participant on what assessments to collect daily at home. Participants will also be handed an appointment reminder card of when they will be seen by the clinical team (either face-to-face or by telephone, depending on the visit).

All participants, regardless of which intervention group they are randomised to will be followed up at 4, 8 and 12 weeks after randomisation. Week 4 will ideally be a face-to-face visit, Week 8 can be conducted over the telephone, and Week 12 must be a face-to-face visit.
• Assessment of concomitant medications, study outcomes, SAEs and hospital admissions.
• Quality of life questionnaire.
• (for participants who are randomised on the CirrhoCare management system) Complete the CirrhoCare usability questionnaire and return of CirrhoCare kit at the 12-week follow-up visit.

Trial Design and methodology of the qualitative research:

This research will take part in three parts:

Part 1: Perceptions of current care and digital home monitoring and management
As part of this design, a web-based questionnaire will be developed, tailored to three different audiences:
a) healthcare professionals delivering care for this decompensated cirrhosis patient group (minimum of 25 respondents)
b) patients or carers (min of 25 respondents)
c) simplified questionnaire for a third 'other group' to cover people not identifying as either healthcare professionals or patients/carers (this group is not a targeted group, so no minimum respondents).
A minimum of ten (10) semi-structured interviews will be conducted with healthcare staff and patients/carers, recruited through participating sites, questionnaire responses or communication from targeted emails using networks shared by British Liver Trust or known clinical networks.

Part 2: Socio-demographics of participants in the CirrhoCare RCT
This part is designed to assess variation in participation and experience of using CirrhoCare within the RCT compared to the socio-demography of the population. To assess this, the following information will be obtained as part of the RCT:
- Location of residence (outbound postcode area, e.g., AN1)
- Demographic factors: Ethnicity, age, gender, and level of education
- Social or economic factors: Employment status, and English as a first language
- Health status: Learning disability; Physical disability
This data will be collected during the RCT and only from participants who are randomised on the CirrhoCare management system arm.

Part 3: Experience and perceptions towards CirrhoCare
In this part, perspectives will be sought from clinicians, patients and carers, and other stakeholders (such as commissioners and policymakers) on the main barriers and facilitators to improving clinical care through the implementation of the CirrhoCare management system.
A second web-based questionnaire (called Questionnaire 2) will be developed, tailored to the three main audiences:
a) healthcare professionals delivering care for this patient group (minimum of 3 responders per

site)
b) patients or carers (min of 5 responders per site)
c) other stakeholders, including commissioners and policymakers (targeting a min of 10 responses)
A minimum of ten (10) semi-structured interviews will be conducted with individuals from these groups, recruited through participating sites, questionnaire responses or communication from targeted emails using networks shared by British Liver Trust or known clinical networks.

Two focus groups will be carried out with patients and carers from participating sites.

Participants will only be involved in this part of the research if they have finished their active involvement in the RCT.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
CirrhoCare management system

Primary outcome measure
Current primary outcome measure as of 05/02/2025:

To investigate whether the CirrhoCare management system leads to a reduction in the requirement for hospital intervention from new-liver-related complications (ascites, overt hepatic encephalopathy, infection or portal hypertensive bleeding and renal impairment) over 90 days from randomisation. This will be measured by collecting the data on hospital interventions of patients, (predominantly readmissions) on the CirrhoCare management system arm compared with the standard arm over 90 days from randomisation.

_____

Previous primary outcome measure:

To investigate whether the CirrhoCare management system leads to a reduction in the requirement for hospital intervention from new-liver-related complications (ascites, overt hepatic encephalopathy, infection or portal hypertensive bleeding and renal impairment) over 12 weeks from randomisation. This will be measured by collecting the data on hospital interventions of patients, (predominantly readmissions) on the CirrhoCare management system arm compared with the standard arm over 12 weeks from randomisation.

Secondary outcome measures
Current secondary outcome measures as of 05/02/2025:

1. Determine the effects of the CirrhoCare management system on the liver disease severity as assessed by reduction in CLIF-C AD score, or Model for End-stage Liver. This will be measured

using the CLIF-C AD score at baseline and follow-up visits at Day 28, Day 56 and Day 90.
2. Assess healthcare resource use and cost analysis over 90 days from randomisation
3. Assessment of user experience and engagement through questionnaires and interviews
4. Health-related Quality of Life (EQ-5D-5L) and frailty assessment (Liver Frailty Index) at Day 90
5. Mortality (overall survival) over 90 days
6. Length of hospital stay and number of hospital readmissions over 90 days from randomisation
7. Assessment of the effects of the individual components making up the primary outcome measure over 90 days
8. The longitudinal effects of all secondary outcomes will be investigated by using an appropriate model that incorporates the Day 28 and Day 56 visits in addition to the Day 90 visit
9. Assessment of the number of hospital readmissions for a given participant and the length of stay of each hospitalisation, over 90 days of follow-up

_____

Previous secondary outcome measures:

1. Determine the effects of the CirrhoCare management system on the liver disease severity as assessed by reduction in CLIF-C AD score, or Model for End-stage Liver. This will be measured using the CLIF-C AD score at baseline and follow-up visits at 4, 8 and 12 weeks.
2. Assess healthcare resource use and cost analysis over 12 weeks from randomisation
3. Assessment of user experience and engagement through questionnaires and interviews
4. Health-related Quality of Life (EQ-5D-5L) and frailty assessment (Liver Frailty Index) at 12 weeks
5. Mortality (overall survival) over 12 weeks
6. Length of hospital stay and number of hospital readmissions over 12 weeks from randomisation
7. Assessment of the effects of the individual components making up the primary outcome measure over 12 weeks
8. The longitudinal effects of all secondary outcomes will be investigated by using an appropriate model that incorporates the week 4 and week 8 visits in addition to the week 12
9. Assessment of the number of hospital readmissions for a given participant and the length of stay of each hospitalisation, over 12 weeks follow-up

Overall study start date
01/12/2022

Completion date
30/11/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 01/05/2025:
1. Adults ≥18 years and diagnosed with cirrhosis of any aetiology.
2. Cirrhosis defined by standard clinical criteria, ultrasonographic findings and/or histology. Cirrhosis of any aetiology may be included. However, participants with cirrhosis due to autoimmune hepatitis must be on stable corticosteroid dose for ≥3-month period before study inclusion (to be recorded on concomitant log).
3. Cirrhosis severity-risk defined by European-Foundation Consortium Liver Failure – Acute Decompensation score (CLIF-C AD score) ≥42 points but ≤65 points at the time of screening.
4. Hospitalisation for acute decompensation [determined as one or more of the following:

increasing ascites, variceal haemorrhage, overt hepatic encephalopathy, spontaneous bacterial peritonitis (SBP) or hepatorenal syndrome – acute kidney injury (HRS-AKI)].
5. Participants able to give informed consent.

_____

Previous inclusion criteria:
1. Adults >= 18 years diagnosed with cirrhosis of any aetiology.
2. Cirrhosis, defined by standard clinical criteria, ultrasonographic findings and/or histology. Cirrhosis of any aetiology may be included. However, participants with cirrhosis due to autoimmune hepatitis must be on stable corticosteroid dose for >=3-month period before study inclusion.
3. Cirrhosis severity risk defined by the European-Foundation Consortium Liver Failure - Acute Decompensation score (CLIF-C AD score) >=45 points but <60 points at the time of screening.
4. Hospitalisation for acute decompensation (determined as one or more of the following: increasing ascites, portal hypertensive-related bleeding, overt hepatic encephalopathy, new infection).
5. Participants who are able to give informed consent.

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 214; UK Sample Size: 214

Key exclusion criteria
Current exclusion criteria as of 01/05/2025:
1. Participants with ACLF grade 2 and above according to the criteria published by Moreau
2. Participants with CLIF-C AD score ≥66, who have a high mortality similar to ACLF ≥2 participants
3. Current overt hepatic encephalopathy, defined as grade II-IV hepatic encephalopathy according to the West-Haven classification, unable to give consent
4. Participants with active hepatocellular carcinoma (HCC) or a history of HCC that is in remission for less than 6 months for uninodular HCC or for less than 12 months for multinodular HCC within Milan criteria
5. Participants with a history of significant extrahepatic disease with impaired short-term prognosis, including congestive heart failure New York Heart Association Grade III/IV 5, COPD GOLD >2, chronic kidney disease with serum creatinine >2 mg/dL or under renal replacement therapy
6. Participants with documented refractory ascites - added 23/05/2025: on a palliative pathway
7. Participants who are active on the transplant waiting list
8. Participants with current extrahepatic malignancies, including solid tumours and hematologic

disorders.
9. Participants with mental incapacity, significant language barrier, or any other reason considered by the investigator precluding adequate understanding, cooperation or compliance in the study
10. Participants with active viral infections, or yet to achieve a clear response to anti-viral therapy
11. Any disorders likely to impact on study engagement, including severe frailty, severe addiction history (including opioids) with evidence of multiple recent relapses
12. Any other reason that the PI considers would make the participant unsuitable to enter CirrhoCare (e.g., participants on an end-of-life palliative care pathway)
13. Participants enrolled in other interventional trials

_____

Previous exclusion criteria as of 05/02/2025:

1. Participants with ACLF grade 2 and above according to the criteria published by Moreau.
2. Participants with CLIF-C AD score ≥ 66, who have a high mortality similar to ACLF ≥2 participants.
3. Current overt hepatic encephalopathy, defined as grade II-IV hepatic encephalopathy according to the West-Haven classification, unable to give consent.
4. Participants with active hepatocellular carcinoma (HCC) or a history of HCC that is in remission for less than six months for uninodular HCC or for less than 12 months for multinodular HCC within Milan criteria.
5. Participants with a history of significant extrahepatic disease with impaired short-term prognosis, including congestive heart failure New York Heart Association Grade III/IV, COPD GOLD >2, chronic kidney disease with serum creatinine >2mg/dL or under renal replacement therapy.
6. Participants with documented refractory ascites
7. Participants who are active on the transplant waiting list.
8. Participants with current extrahepatic malignancies including solid tumours and hematologic disorders.
9. Participants with mental incapacity, significant language barriers, or any other reason considered by the investigator precluding adequate understanding, cooperation or compliance in the study.
10. Participants with active viral infections, or yet to achieve clear response to anti-viral therapy.
11. Any disorders likely to impact on study engagement, including severe frailty, severe addiction history (including opioids) with evidence of multiple recent relapses.
12. Any other reason that the PI considers would make the participant unsuitable to enter CirrhoCare (e.g., participants on an end-of-life palliative care pathway).
13. Participants enrolled in other interventional trials.

_____

Original exclusion criteria:

1. Participants with acute-on-chronic liver failure (ACLF) grade 2 and above according to the criteria
2. Participants with CLIF-C AD score > = 60, who have a mortality similar to ACLF > = 2 participants
3. Current overt hepatic encephalopathy, defined as grade II-IV hepatic encephalopathy according to the West-Haven classification, unable to give consent
4. Participants with active hepatocellular carcinoma (HCC) or a history of HCC that is in remission

for less than six months for uninodular HCC or for less than 12 months for multinodular HCC within Milan criteria
5. Participants with a history of significant extrahepatic disease with impaired short-term prognosis, including congestive heart failure New York Heart Association Grade III/IV (New York Heart Association Criteria Committee, 1979), COPD GOLD > 2, chronic kidney disease with serum creatinine > 2mg/dL or under renal replacement therapy
6. Refractory ascites, and who are being considered for liver transplantation listing
7. Participants with current extrahepatic malignancies, including solid tumours and hematologic disorders
8. Participants with mental incapacity, language barrier, or any other reason considered by the investigator precluding adequate understanding, cooperation or compliance in the study (e.g., severe addiction and relapse history)
9. Participants with active viral infections, or yet to achieve clear response to anti-viral therapy.
10. Any disorders likely to impact on study engagement, including severe frailty, and severe addiction history (including opioids) with evidence of multiple relapses.
11. Any other reason that the PI considers would make the participant unsuitable to enter CirrhoCare (e.g. participants on an end-of-life palliative care pathway)
12. Refusal or inability to give informed consent
13. Participants enrolled in other interventional trials

Date of first enrolment
31/10/2023

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Derriford Hospital
Derriford Road
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
King's College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
The Royal London Hospital
80 Newark street
London
United Kingdom
E1 2ES

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre

Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
St George’s Hospital, St George’s University Hospitals NHS Foundation Trust
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre
Royal Liverpool University Hospital
Mount Vernon St
Liverpool
United Kingdom
L7 8YE

Study participating centre
St Thomas Hospital, Guy's and St Thomas' NHS Foundation Trust
Westminster Bridge Rd
London
United Kingdom
SE1 7EH

Study participating centre
Torbay Hospital
Newton Road
Torquay
United Kingdom
TQ2 7AA

Study participating centre
Queen Elizabeth Hospital
Queen Elizabeth Medical Centre
Edgbaston

Birmingham
United Kingdom
B15 2TH

Study participating centre
Whittington Hospital
Magdala Avenue
London
United Kingdom
N19 5NF

Study participating centre
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Sponsor information

Organisation
University College London

Sponsor details
Comprehensive Clinical Trials Unit
Gower Street
London
England
United Kingdom
WC1E 6BT
+44 (0)20 3108 6833
cctu-enquiries@ucl.ac.uk

Sponsor type
Hospital/treatment centre

Website
http://www.london.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal, 18 months after the anticipated trial end date and following statistical and health economic analysis.

Intention to publish date
31/10/2026

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made 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		06/07/2025	08/07/2025	Yes	No