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

Registration date
18/10/2023

Overall study status
Ongoing

Last Edited
15/07/2026

Condition category
Digestive System

[X] 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

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 January 2027

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

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United Kingdom
NW3 2PF
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT06223893

Integrated Research Application System (IRAS)
329173

Central Portfolio Management System (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

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

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.

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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.

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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

Phase
Not Applicable

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

Primary outcome(s)
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.

Key secondary outcome(s)
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

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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

Completion date
31/01/2027

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

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

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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.

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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
31/07/2026

Locations

Countries of recruitment
United Kingdom

England

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

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

Study participating centre
Derriford Hospital
Derriford Road
Plymouth
England
PL6 8DH

Study participating centre

Southampton General Hospital
Tremona Road
Southampton
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SO16 6YD

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

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

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

Study participating centre
Queens Medical Centre
Derby Road
Nottingham
England
NG7 2UH

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

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

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

Study participating centre
Torbay Hospital
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TQ2 7AA

Study participating centre
Queen Elizabeth Hospital
Queen Elizabeth Medical Centre
Edgbaston
Birmingham
England
B15 2TH

Study participating centre
Whittington Hospital
Magdala Avenue
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N19 5NF

Study participating centre
Royal Sussex County Hospital
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BN2 5BE

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Road
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AB25 2ZN

Sponsor information

Organisation
University College London

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

Individual participant data (IPD) sharing plan

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