ISRCTN10842381 https://doi.org/10.1186/ISRCTN10842381

Supporting patients' adaption process in liver cirrhosis

Submission date 07/11/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/11/2025	**Overall study status** Ongoing	
Last Edited 28/11/2025	**Condition category** Digestive System	

Plain English summary of protocol
Background and study aims
In cases of liver cirrhosis, people need support in making adjustments in their daily lives. Adjustments can relieve symptoms or improve the outcome of medical treatment. Support is currently offered by a doctor and/or nurse at an outpatient clinic for Gastrointestinal Diseases. We want to investigate the benefits of patients also receiving support via an eHealth service called Care plan liver cirrhosis.

This study is the first-step evaluation of the person-centred eHealth tool, Care plan liver cirrhosis, which aims to facilitate patients' adaption process following LC disease. The feasibility of the Care plan liver cirrhosis will be studied for: acceptability, usability; whether the Care plan liver cirrhosis contribute to an improved infrastructure for the patients' healthcare support; and to study effects on intended outcome variables , i.e. Self-efficacy, patient perceived disability and patient-perceived health .

Who can participate?
Patients with liver cirrhosis with experience from the early to advanced disease stages. Registered nurses wo distribute the Care plan liver cirrhosis to patients.

What does the study involve?
All paticipants will receive the eHealth intervention 'Care plan liver cirrhosis' during a period of three months. Data will be collected before and after the intervention to study its effect on Self-efficacy, patient perceived disability and patient-perceived health.

What are the potential benefits and risks of participating?
The potential risks when participating in a research project are arising feelings and thoughts that may be difficult to prepare for in advance. The potential benefits is contribution to expanded knowledge and development of better support for people with liver disease.

Where is the study run from?
The County of Dalarna in Sweden.

When is the study starting and how long is it expected to run for?
Recruitment of participants will start 01/12/2025 and will preliminary continue until 31/12/2028.

Whos is funding the study?
The County of Dalarna and the Conuty of Linkoping (Sweden)

Whos is the main contact?
Maria Hjorth, maria.hjorth@regiondalarna.se

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Maria Hjorth

ORCID ID
https://orcid.org/0000-0002-0264-9992

Contact details
Centre for Clinical Research in Dalarna
County of Dalarna
Box 712
Falun
Sweden
791 29
+46 23492000
maria.hjorth@regiondalarna.se

Additional identifiers

Study information

Scientific Title
Supporting the patient’s adaption process by a person-centred eHealth tool: a feasibility study reflecting perspectives from patients and registered nurses in liver cirrhosis

Study objectives
The aim is to describe and explore:
1. Patients and registered nurses (RNs) acceptability and usability of carrying out activities in the Care plan liver cirrhosis
2. The fit of the Care plan liver cirrhosis in addition to the existing healthcare service to support the patients’ adaption process
3. Changes in patient-perceived disability and self-efficacy for disease management after receiving the Care plan liver cirrhosis
4. Associations and correlations between self-efficacy for disease management and patient-perceived disability before and after receiving Care plan liver cirrhosis
5. Content validity and internal consistency for the modified disability index

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/06/2025, The Swedish Ethical Review Authority (Box 2110, Uppsala, 750 02, Sweden; +46 10-4750800; registrator@etikprovning.se), ref: 2025-03997-01; 2025-06215-02

Study design
An explorative single arm experimental study design

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Outpatient management of liver cirrhosis in various disease stages.

Interventions
A single arm intervention with baseline and 3 month post-intervention measurement.
The person-centred eHealth tool, embraceing five modules, with sub-chapters. Each sub-chapter may be activated or deactivated, which facilitates individualised information to each patient.
- The first module, is active for all patients and contains seven chapters. The information is about liver disease and LC, physical examinations, and a field of notes where patients may share their thoughts for future communication with their healthcare provider.
- The second module, contains seven chapters with information relevant for patients in the early LC phase, which causes vague physical symptoms. The chapters covers medical treatment, self-care recommendations in order to prevent disease deterioration, psychological perspectives of a chronic illness, and information about future examinations.
- The third module, contains 13 chapters with information relevant to patients in the decompensated phase, which causes serious and distressing symptoms. The chapters covers information about bodily changes and common symptoms, i.e. fatigue, changed libido, sarcopenia, weight loss, loss of appetite, gastroesophageal variceal bleeding, ascites, hepatic encephalopathy, jaundice and itch. Furthermore, medical treatment, self-care recommendations and how to create a safe home environment and involve relatives.
- The fourth module, contains nine chapters with information relevant for patients that is under investigation for or waiting for a liver transplant. The chapters covers information about the process and decisions that needs to be considered during a liver transplant investigation process. Furthermore, self-care recommendations, juridical issues and practical information during the waiting time.
- The fifth module, contains five chapters relevant for patients and relatives during the palliative phase of LC. These chapters covers adapted information about the common late and advanced symptoms, i.e. fatigue, sleep disturbance, eating disability, nausea, constipation, gastrointestinal bleeding, infection, hepatic encephalopathy, itch, pain, dyspnoea and ascites. Furthermore, symptom-relieving treatment, psychological reactions, juridical and economic issues and being a relative.

In all modules of the Care plan liver cirrhosis, patients may interact by sending messages, direct to the responsible RN. In module 3 patients with ascites may report weight on a daily or weekly basis. The content of the Care plan liver cirrhosis is reviewed at ordinary RN consultations. If the LC disease progress, with new symptoms or needs, the content may be adjusted.

Intervention Type
Other

Primary outcome(s)
1. Self-efficacy for disease management measured using the Swedish version of the Self-efficacy for managing chronic disease (6 items) at baseline and after 3 months

Key secondary outcome(s))
1. Disability measured using a modified disability index (7 items) at baseline and after 3 months

2. Patient-perceived health measured using EQ5D (6 items) at baseline and after 3 months

3. Usability and accessibility of the Care plan liver cirrhosis (patient) measured using questionnaire (12 items) at 3 months

4. Usability and accessibility of the Care plan liver cirrhosis (registered nurse) measured using questionnaire (14 items) at 3 months

Completion date
31/12/2030

Eligibility

Key inclusion criteria
Patients:
1. Age ≥18 years
2. Diagnosis of liver cirrhosis
3. Planned follow-up at one of the two study clinics

Registered nurses:
1. Registered nurses that are users of the Care plan liver cirrhosis at Swedish hospitals

Participant type(s)
Health professional, 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
Patients:
1. Persistent overt hepatic encephalopathy

Date of first enrolment
01/12/2025

Date of final enrolment
31/12/2028

Locations

Countries of recruitment
Sweden

Study participating centre
County of Dalarna, Gastroenterology department, Falun hospital
Box 712
Falun
Sweden
791 29

Study participating centre
County of Ostragotaland, Gastroenterology department, Linkoping university hospital
Linkoping
Sweden
581 91

Sponsor information

Organisation
Centre for Clinical Research in Dalarna

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Centre for Clinical Research in Dalarna

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes