

Cirrhosis Medical Home

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Table of Contents:

Study Schema

- 1.0 Background & Rationale**
- 2.0 Objective(s)**
 - 2.1 Primary Objective**
 - 2.2 Secondary Objective**
- 3.0 Study Measures**
 - 3.1 Primary Outcome Measure**
 - 3.2 Secondary Outcome Measures**
 - 3.3 Other Patient Measures**
 - 3.4 Other Caregiver Measures**
- 4.0 Eligibility Criteria**
 - 4.1 Patients**
 - 4.2 Caregivers**
- 5.0 Study Design**
- 6.0 Enrollment/Randomization**
- 7.0 Study Procedures**
- 8.0 Study Personnel**
- 9.0 Data Safety Monitoring**
- 10.0 Study Withdrawal/Discontinuation**
- 11.0 Statistical Considerations**
- 12.0 Data Management**
- 13.0 Privacy/Confidentiality Issues**
- 14.0 Follow-up and Record Retention**
- 15.0 References**
- 16.0 Appendices**
 - 16.1 Schedule of Events**
 - 16.2 Sample Care Plan**

1.0 Background & Rationale

Every year, 150,000 Americans are hospitalized for complications of liver cirrhosis.² These patients suffer from debilitating symptoms (ascites, gastrointestinal bleeding, infection, and hepatic encephalopathy).³ They also have impairments in physical, cognitive, psychological, and social functions leading to poor quality of life and long-term disability.^{1, 4-7} These impairments contribute to high utilization of health care resources; within 30 days of hospital discharge, 25% of patients are readmitted, and of these readmissions, 20-40% are preventable.⁸⁻¹⁰ This inpatient health care utilization is the largest driver of the \$30 billion spent annually on chronic liver disease.¹¹ These individual and societal burdens of cirrhosis could be improved with existing health care services, behavioral care, rehabilitation services, and community resources; but the current fragmented nature of the health care system does not allow for the necessary coordination to best care for this population.¹²

To address the health care system's lack of care coordination, the Institute of Medicine and Centers for Medicare and Medicaid Services recommend the development of collaborative care models (CCM) in a wide range of clinical settings.^{13, 14} CCMs are intended to provide coordinated, personalized care pragmatically using care coordinators. CCMs have successfully improved care in multiple patient populations, ranging from frail older adults to depression.¹⁵⁻²⁵ In contrast, for patients with cirrhosis, there is a paucity of data to support the benefit of CCM in this medically complex and vulnerable population.²⁶ At Indiana University, researchers have over 20 years of experience in developing, testing, and implementing CCMs successfully for patients living with dementia or depression.^{15, 16} Building on these successes, we have customized the CCM to best meet the unique and complex biopsychosocial needs of patients with cirrhosis: the Cirrhosis Medical Home.

In the Cirrhosis Medical Home, a care coordinator, supported by an interdisciplinary clinical team, will deliver a personalized intervention guided by a set of innovative tools: (i) patient-centered care protocols, (ii) a mobile office, (iii) care coordination support software, and (iv) dynamic feedback measures. The overall goal is to improve quality of life and to reduce acute health care utilization for patients with cirrhosis. In this pilot, randomized trial of 40 patients, we aim to refine our study processes in preparation for a large scale randomized controlled trial evaluating the efficacy of the Cirrhosis Medical Home in improving the quality of life of patients discharged from the hospital with cirrhosis. Additionally, up to 40 caregivers will be enrolled in the trial.

2.0 Objective(s)

- 2.1** The primary objective of this trial is to test the screening and enrollment processes for a randomized controlled trial of the Cirrhosis Medical Home compared to usual care for patients with decompensated cirrhosis and poor quality of life when discharged from the hospital
- 2.2** Secondary objectives are:

- 2.2.1 to assess the data collection process, outcome assessment, and the acceptability of the Cirrhosis Medical Home trial
- 2.2.2 to estimate the effect size of the Cirrhosis Medical Home intervention on quality of life at six months post hospital discharge

3.0 Study Measures

All primary and secondary outcomes measures will be obtained from study participants at baseline and at 3 and 6 months, per the schedule of events. Additionally, MELD and Child-Pugh scores will also be obtained at the 3 and 6 month assessments.

3.1 Primary Outcome (Feasibility) Measures

3.1.1. Enrollment rate: The enrollment rate is the number of patients/caregivers enrolled per month. We will further determine the number of patients/caregivers screened and approached for enrollment. Based on these numbers, we will calculate the proportion of screened patients/caregivers eligible for enrollment, the proportion of eligible patients/caregivers approached, and the proportion of approached patients/caregivers enrolled. Of those not eligible, we will record reasons for ineligibility. Of those eligible, but not approached, we will record reasons. For those approached, but not enrolled, we will record reasons.

3.1.2 Drop-out rate: The drop-out rate is the proportion of enrolled participants (patients and caregivers) who drop out of the study before completion.

3.1.3 Data completion: We will record the completeness of the data collection for enrolled subjects. For those with incomplete data, we will record reasons that data could not be collected.

3.2 Secondary Outcome Measures

3.2.1. Quality of Life: This outcome will be obtained from the patient only. Patient health-related QOL will be assessed using the Medical Outcome Study Short Form (SF-36).^{40, 48, 49} This scale has eight components (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health) that are aggregated into a Physical Component Summary (PCS) and a Mental Component Summary (MCS). Changes that differ by 2 or more points on a scale of 0 to 100 are clinically meaningful.⁴⁹

3.2.2 Physical Performance: Physical performance measures will be obtained from the patient only. Physical recovery will be assessed via the Short Physical Performance Battery (SPPB), a validated objective assessment.⁵⁰ The SPPB yields a performance score of 0-12 (0-4 poor, 5-7 intermediate, 8-12 good). A difference of 1 point indicates significant change in function. The SPPB has been validated in patients with decompensated cirrhosis.^{51, 52} Grip strength will also be obtained to calculate the Liver Frailty Index, <https://liverfrailtyindex.ucsf.edu>, which overlaps with the SPPB.

3.2.3 Depression and Anxiety Symptoms: Depression and anxiety symptoms will be obtained from the patient only. The Patient Health Questionnaire-9 (PHQ-9)^{53, 54} and Generalized Anxiety Disorder Scale (GAD-7)^{55, 56} will be used to measure patient mood and anxiety. The PHQ-9 is a nine-item depression scale with a total score from 0 to 27, and the GAD-7 is a seven-item anxiety scale with a total score from 0 to 21. Both of these scales are derived from the Patient Health Questionnaire, have good internal consistency and test-retest reliability as well as convergent, construct, criterion, procedural and factorial validity for the diagnosis of major depression and general anxiety disorder.

3.2.4 Cognitive Assessment: Cognitive assessment will be obtained from the patient only. 3D CAM and PHES are psychometric measures of hepatic encephalopathy. They are quick, simple paper tests that are easily interpreted. They are components of the gold-standard Psychometric Hepatic Encephalopathy Score.⁵⁷⁻⁶⁰

3.2.5 Caregiver Burden: Caregiver burden will be obtained from the caregiver only. The Zarit Burden Interview-12 (ZBI-12) is a validated instrument that has been utilized in various populations.⁶¹ It has excellent test characteristics when compared with the long form of the ZBI, and it has been used in other studies of cirrhosis.^{4, 62}

3.2.6 Acute Health Care Utilization: Health care utilization will be obtained from the patient only. In addition to patient-reported emergency room and admission data, we will use the Indiana University Health local data warehouse and the larger Indiana Network for Patient Care (INPC) to complement the utilization assessment. INPC is a large health information exchange in Indiana and provides data from all health care systems within the state.⁶³ We will determine the number of emergency room visits and the number of hospitalizations within 6 months of discharge as well as associated diagnoses. As part of this, we will also be tracking admissions specific to COVID-19, due to the large impact the pandemic has had on our healthcare system. We will do that by tracking whether patients are admitted with a COVID-19 diagnosis or die of COVID-19 while enrolled in the study.

3.2.7 CMH Interactions: In patients/caregivers randomized to the Cirrhosis Medical Home, we will record the numbers, timing, and types of interactions with the care coordinator (in-person, phone, video, other forms of communication). We will also record the use of interventions (e.g. care protocols, pharmacologic treatments).

3.2.8 Palliative Care outcomes: Palliative care referrals will be recorded, including presence of a referral order, successful attendance at a palliative care visit, completion of advanced directives, and place of death.

3.3 Other Patient Measures: At baseline, we will measure age, race, gender,

level of education, income, employment, family size and household composition, height, weight, etiology of cirrhosis, liver disease severity (Child-Pugh score,⁶⁴ MELD score⁶⁵), Charlson comorbidity index,⁶⁶ medications, prior health care utilization, and reason for hospital admission.

3.4 Other Caregiver Measures: At baseline, we will measure age, race, gender, location (living with the patient or elsewhere), relationship to patient, and length of time caring for the patient.

The results of this study will establish the feasibility of performing a randomized trial to evaluate the efficacy of the Cirrhosis Medical Home in improving QOL for patients with decompensated cirrhosis. The next step will be to conduct a large-scale efficacy trial.

4.0 Eligibility Criteria

4.1 Patients

4.1.1 Inclusion Criteria

- Age ≥ 18 years
- Cirrhosis based on:
 - biopsy
 - characteristic clinical, laboratory, and imaging findings
- Decompensated cirrhosis as denoted by any of the following:
 - active ascites requiring paracentesis during hospitalization
 - active overt hepatic encephalopathy requiring lactulose during hospitalization
 - active hepatic hydrothorax requiring thoracentesis during hospitalization
- Poor quality of life as defined by:
SF-36 Physical and/or Mental Component Summary scale <40 (1SD below the mean of healthy subjects)^{1, 40}
- Discharged to home, skilled nursing facility, sub-acute rehabilitation care, or long-term acute care
- Able to be consented, either in person or through legally authorized representative
- Access to a telephone

4.1.2 Exclusion Criteria

- Solid organ transplant of any organ
- History of dementing illnesses and other neurodegenerative diseases such as Alzheimer's disease, Parkinson's disease, or vascular dementia
- Unable to complete study questionnaire due to hearing loss
- Legally blind
- Pregnant or nursing
- Incarcerated

- Concurrent enrollment in a related interventional research study

4.2 Caregivers

4.2.1 Inclusion Criteria

- Age ≥ 18 years
- Identified caregiver of patient
- Able to be consented, either in person or through legally authorized representative
- Access to a telephone

4.2.2 Exclusion Criteria

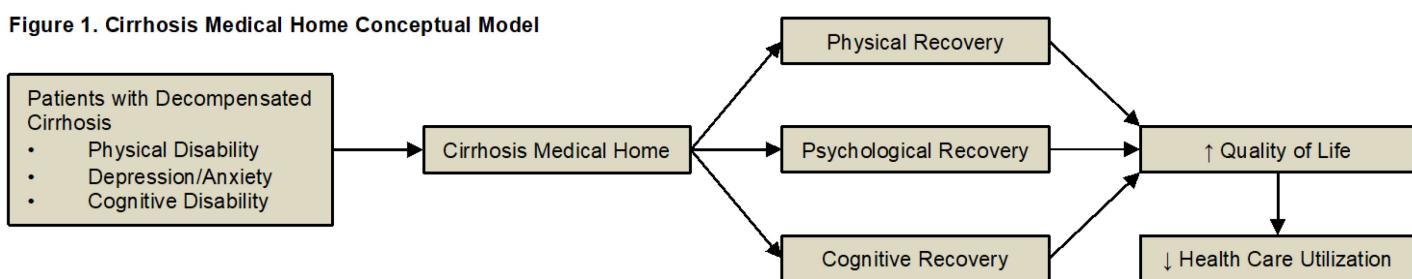
- Impaired cognitive function
- Unable to complete study questionnaire due to hearing loss
- Legally blind
- Incarcerated

5.0 Study Design

This is a pilot, randomized controlled trial to establish the feasibility of enrollment, data collection, and outcome assessment for a future efficacy trial. Participants will be enrolled and randomized to the Cirrhosis Medical Home or usual care at the time of hospital discharge and will be followed for 6 months.

The goal of this proposal is to establish the feasibility of a randomized controlled trial comparing the Cirrhosis Medical Home to usual care in improving QOL and health care utilization of patients with decompensated cirrhosis and poor QOL. To achieve this goal, we propose a feasibility study in which we will randomize 40 patients to the Cirrhosis Medical Home or usual care, assessing QOL; physical, cognitive, and psychological symptoms; and health care utilization. Figure 1 shows the conceptual model.³⁸ We hypothesize that the Cirrhosis Medical Home will improve QOL through its effects on physical, psychological, and cognitive recovery, and that this improvement in QOL will result in decreased health care utilization.

Figure 1. Cirrhosis Medical Home Conceptual Model



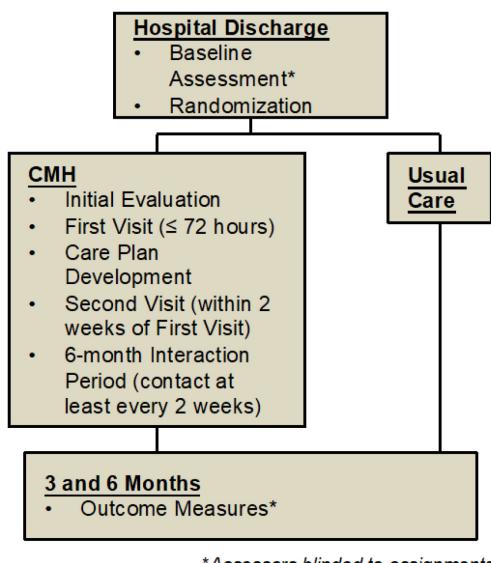
In addition, 40 caregivers of people with cirrhosis will be enrolled in the study. They will complete the Zarit Burden Interview-12 (ZBI-12) at baseline, 3 months and 6 months. For those caregivers who care for participants who are randomized into the CMH arm, the caregivers will complete the HABC-M Caregiver assessment during their interactions with the CMH care coordinator. The HABC-M for the Caregiver is not a study outcome but is an assessment that the care coordinator uses to help guide the individualized care plan for the patient.

6.0 Enrollment/Randomization

Research staff will review the hepatology inpatient census each day, and eligible patients will be approached during their hospital stay. On or close to the day of hospital discharge and after obtaining informed consent, research staff will complete the Baseline Assessment and obtain baseline measurements in all enrolled subjects in both intervention and control arms. Subjects will then be randomized via a computer-generated randomization scheme into the Cirrhosis Medical Home or usual care by separate personnel who will not be involved in outcomes assessments. Research staff who are completing study assessments will be blinded to the assignment. Research staff will be trained research study personnel in the Division of Gastroenterology who will be specifically trained in the study measures. Our research assistants will be trained not to inquire about study assignments. They will be conducting structured assessments that do not provide room for qualitative interviewing that should prevent unblinding. They will not be involved in study assignments and treatment administrations. Subjects will be instructed not to discuss their therapy with the research assistants.

7.0 Study Procedures

Figure 2. Study Flow



ARM 1: Cirrhosis Medical Home

Initial Evaluation: Prior to discharge, the care coordinator will review the hospital discharge plan, obtain the approval of the patient's physicians to co-manage the patient's care, and schedule a face-to-face, telephone, or virtual visit with the patient at their place of discharge. This step is important for relationship-building.

The First Visit: The care coordinator will conduct a face-to-face, telephone, or virtual visit at the patient's location (e.g. home, skilled nursing facility) within 72 hours of hospital discharge. The coordinator will assess the patient's physical, cognitive, and psychological status, and will complete a needs assessment for both the patient and family caregiver. All measures performed by the care coordinator will be used to guide the use of care protocols and development of the individualized care plan. These measures are different from the outcomes measures. The coordinator will also reconcile all medications. The Anticholinergic Cognitive Burden Scale will be completed by study staff. The coordinator will make note of scheduled and recommended appointments and will document initial and follow-up visits in the care coordination support software.

Individualized Care Plan: The care plan will be developed with an emphasis on coordinating services with the patient's providers. Using the assessments from the first visit, the coordinator will collaborate with the Cirrhosis Medical Home interdisciplinary team and the primary care providers to finalize the individualized care plan. This plan will be created through consultation and discussion between the care coordinator and interdisciplinary team using the assessments as guides. The assessments do not automatically trigger protocols or handouts, and there are no firm cutoffs on any of the assessments that would require any specific action. Rather, the assessments will be used to facilitate development of the care plan within the context of the patient's unique individual circumstances. The assessments will also be used to assess for response to any intervention provided, so that appropriate changes to the care plan can be made in a timely fashion. If a patient does not have a participating caregiver, then no caregiver protocols or handouts will be used. Finally, the care coordinator will schedule a second face-to-face, telephone, or virtual visit within two weeks of the first visit.

The Second Visit: During the second visit, the coordinator will review the individualized care plan with both the patient and the family caregiver. This process will include a) reviewing diagnoses; b) reviewing monitoring processes; c) implementation of care protocols; d) explanation of the corresponding educational handouts (patient and family caregiver); and e) connection to in-home services and community resources.

The 6-month Interaction Period: Follow-up includes a 6-month interaction period between the care coordinator, the patients, and the family caregivers via face-to-face visits, phone contact, email, fax, or mail. The minimum amount of contact will be every

two weeks. During these interactions, the coordinator will answer questions; collect patient and caregiver feedback; reconcile medications and discuss adherence; review appointments and care plans; have the patient and the caregiver complete the HABC Monitor to trigger the use of care protocols; and facilitate access to community resources. Additional measures, described in the schedule of events, may be repeated depending on the individualized care plan, active issues, and needs as determined by the study team. The plan will be amended through consultation and discussion between the care coordinator and interdisciplinary team using the assessments as guides. The assessments do not automatically trigger protocols or handouts and there are no firm cutoffs on any of the assessments that would require any specific action. Rather, the assessments will be used to facilitate development of the care plan within the context of the patient's unique individual circumstances. The assessments will also be used to assess for response to any intervention provided, so that appropriate changes to the care plan can be made in a timely fashion. Throughout the follow-up phase, the coordinator will work with patients, caregivers, the Cirrhosis Medical Home team, and the patient's physicians to monitor, implement, and revise the individualized care plan. Such revisions could include introducing discussions about hospice care for patients who develop indications for hospice referral during follow-up. The Cirrhosis Medical Home team and coordinator will meet weekly to discuss new patients and monitor progress. If a patient requires hospitalization, the team activates the acute care transition phase where the coordinator contacts the hospital team and provides relevant information about the patient's symptoms, as well as the patient's most updated medication list. Following any hospital discharge, the coordinator will conduct a home, telephone, or virtual visit within 72 hours to reconcile medications and coordinate the post-discharge care plan. At the end of 6 months, all patients will be transitioned to receive full care by their primary care and specialty physicians.

ARM 2: Usual Care

Prior to hospital discharge, the care coordinator will identify the primary care and/or hepatology provider of patients in the usual care group and will ensure follow up appointments at the time of hospital discharge. The coordinator will compose and send a letter to the primary care and/or hepatology provider summarizing the patient's diagnosis, hospital course, discharge medications, and the plan of follow-up care. If the patient does not already have a primary care or hepatology provider, the coordinator will work with the patient to identify a new provider. Subjects in this group will receive no further intervention.

Outcome Assessment (Both Arms)

Outcome measures will be obtained by blinded research staff from all enrolled subjects at baseline, 3 months, and 6 months. Baseline assessments will be completed in the hospital at the time of enrollment. Outcomes at 3 and 6 months will be completed in person. If participants are not able to attend in person, measures that can be performed remotely will be done via phone or videoconference.

8.0 Study Personnel

8.1 Research Staff

8.1.1. Recruitment Staff/Assessors: Trained research staff from the Division of Gastroenterology will be trained to administer the study measures in Section 3. They will recruit patients, obtain informed consent, complete the Baseline Assessment and measurements at the time of enrollment. They will be blinded to the study assignment as detailed in Section 6. They will also complete outcomes assessments at 3 and 6 months.

8.1.2. Randomization Staff: A separate member of the research team will be responsible for randomization so that the outcomes assessors will be blinded to the assignment.

8.2 Care Coordinator

The coordinator is a registered nurse whose scope of practice includes health coaching, case management, community organization, and nursing care. The coordinator will conduct home visits; collaborate with the interdisciplinary team; communicate with the patient's physicians; conduct root-cause analysis for unplanned acute care; implement individualized care plans; and monitor the care plans' effectiveness. The coordinator will be supervised by the interdisciplinary team. This person will conduct face to face, telephone, or virtual visit with those in the intervention arm in the hospital, within 72 hours of discharge, and again within 2 weeks (the first and second visits). They will meet with the CMH interdisciplinary team weekly throughout the study to review patients. They will assess patients using the several instruments detailed in the schedule of events, which will be used to help develop individualized care plans and which will be used to guide specific care protocols. They will interact with study participants at least every 2 weeks during the 6-month follow-up period. For those randomized to usual care, they will help ensure follow-up after discharged as detailed in Section 7, but will not have any further contact with study participants. The care coordinator will not perform any of the outcomes assessments. The coordinator will be trained in all study procedures and instruments.

8.3 CMH Interdisciplinary Team

The Cirrhosis Medical Home support team will consist of two hepatologists (Drs. Orman and Desai), a geriatrician with expertise in collaborative care (Dr. Boustani), a health services researcher (Dr. Fowler), and a pharmacist (Dr. Campbell). The team will meet weekly with the care coordinator. Dr. Orman will be accessible to the coordinator through phone or pager at all times. The team will supervise the care coordinator and ensure appropriate care.

9.0 Data Safety Monitoring

This is a minimal risk study and not a drug treatment trial. As such, adverse events are expected to be minimal in both number and nature. However, all such events or other subject problems/complications will be reported in accordance with federal, state, local, and university guidelines.

10.0 Study Withdrawal/Discontinuation

Participants who choose to withdraw from the study will do so by contacting the study coordinator or Dr. Orman directly at 317-278-1630. This information will be given to participants as part of the informed consent process and ongoing communication between participants and study staff.

11.0 Statistical Considerations

This is a pilot trial for feasibility and effect size estimation. The plan is to enroll 40 total patients and randomize in 1:1 ratio to the Cirrhosis Medical Home and usual care. As a pilot trial, the study is not powered to test efficacy, but is designed to generate preliminary data to support a larger future trial. The sample size of 40, enrolled over 9 months (see study timeline in section 13), will allow for recruitment of approximately one patient/caregiver dyad per week. Data collected from this pilot will be used to provide an estimate of intervention effect, i.e. the difference in the primary outcome measure (SF-36) between intervention and control groups. The pilot data will also provide estimates on variability in the outcome measures in this patient population. The effect and variability estimates from the pilot data will be used to power a large trial. The sample size of 40 will provide 80% probability that the 95% confidence interval for the estimated treatment difference with half-width of 0.7SD will contain the true treatment effect. The pilot sample size of 40 has also been shown to minimize the overall sample size of the pilot and the main trial together with 80% power in the main trial to detect effect sizes in the range of 0.1~0.3SD.⁶⁷

12.0 Statistical Data Management

Primary data will be collected from conversations with the participants, both in person and via the telephone, as well as direct data capture from study instruments and the EMR and stored electronically in REDCap. The storage location will be backed up automatically, manually every day per REDCap standard procedures. Other data sources include outside medical record and lab data, data from INPC that will be stored in separate electronic files and merged with the primary data as needed. Quality assurance steps will include built in range checks and testing of database by study team prior to moving to production mode. The following quality control methods will be used:

single entry with random checks of accuracy and extraction and cleaning of data that will be used for analysis approximately every 6 months.

13.0 Privacy/Confidentiality Issues

All study visits will be conducted in a private room with the door closed. Nonetheless, there is a risk of loss of confidentiality. Risks will be mitigated by conducting study visits in a private location. All paper data will be stored in locked cabinets in a locked area. Electronic data are entered and stored into a password protected database. Only authorized personnel will have access to the study data, in both paper and electronic format.

14.0 Follow-up and Record Retention

Subject participation will last 6 months and the entire duration of the study should take about 2 years. Study records and study data will be retained and destroyed in accordance with federal, state, local, and university guidelines.

	Year 1				Year 2			
	1	2	3	4	1	2	3	4
Start-up								
Enrollment								
Intervention								
Outcome measures								
Data entry								
Data analysis								
R01 Preparation								

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16.0 Appendices

16.1 Schedule of Events

16.2 Sample Care Plan

16.1 Schedule of Events

Assessment	Baseline	Initial Evaluation	First Visit	Second Visit	Week 4	CMH Interaction*					3 Month	CMH Interaction*					6 Month
Week [†]	0	0	72 hr	2		4	6	8	10	12		14	16	18	20	22	24
Demographics	X																
Height/weight	X																
Cirrhosis etiology	X																
MELD	X											X					X
Child-Pugh	X											X					X
CCI	X																
Medications	X		X	X		X	X	X	X	X		X	X	X	X	X	
Reason for admission	X																
SF-36	X				X							X					X
SPPB/LFI	X											X					X
C-SSRS				/		/	/	/	/	/		/	/	/	/	/	
PHQ-9	X											X					X
GAD-7	X											X					X
PHES	X											X					X
ZBI-12	X											X					X
Utilization	X																X
HABC-M Self		X ¹		X		X	X	X	X	X		X	X	X	X	X	
HABC-M Caregiver		X ¹		X		X	X	X	X	X		X	X	X	X	X	
MMSE		X ¹		/		/	/	/	/	/		/	/	/	/	/	/
TUG		X ¹		/		/	/	/	/	/		/	/	/	/	/	
HADS		X ¹		/		/	/	/	/	/		/	/	/	/	/	
PEG		X ¹		/		/	/	/	/	/		/	/	/	/	/	
3D CAM		X ¹		/		/	/	/	/	/		/	/	/	/	/	
Stroop		X ¹		/		/	/	/	/	/		/	/	/	/	/	
AUDIT-C		X ¹		/		/	/	/	/	/		/	/	/	/	/	
PACS		/ ¹		/		/	/	/	/	/		/	/	/	/	/	

*Interaction contacts may be in-person or via phone.

[†]Timing is approximate. The First Visit is within 72 hours of hospital discharge. The Second Visit is within 2 weeks of the First Visit. CMH Interactions occur a minimum of every 2 weeks.

X = required (HABC-M Caregiver only if caregiver enrolled)

/ = optional, depending on clinical circumstance

X¹ = can be performed at initial evaluation or first visit

 Performed by Blinded Research Staff for all enrolled subjects

 Performed by CMH Care Coordinator only for those randomized to the Cirrhosis Medical Home

 Patient assessments

 Caregiver assessments

Abbreviations: MELD, Model for End-Stage Liver Disease; CCI, Charlson Comorbidity Index; SF-36, Short Form Survey; SPPB, Short Physical Performance Battery; LFI, Liver Frailty Index; PHQ-9, Patient Health Questionnaire; GAD-7, Generalized Anxiety Disorder;; ZBI-12, Zarit Burden Interview; HABC-M, Healthy Aging Brain Care Monitor; MMSE, Mini-Mental Status Examination; TUG, Timed Up-and-Go; HADS, Hospital Anxiety and Depression Scale; PEG, Pain, Enjoyment, General Activity Scale; 3D CAM-, Confusion Assessment Method for the ICU

16.2 Sample Care Plan

Study ID #:	Age:									Gender:		
Occupation:	Educ:	3 m			6 m		9 m			12m	Ethnicity:	
Instrument		7/11	10/5	10/19	11/2	2/27	3/28	5/23	6/27	7/24	9/13	Targets
<u>MMSE</u>	-					-					-	-
Orientation Time	5/5					5/5					5/5	
Orientation Place	5/5					5/5					5/5	
Registration	3/3					3/3					3/3	
Attention &	5/5					5/5					5/5	
Calculation	3/3					3/3					3/3	
Recall	2/2					2/2					2/2	
Naming	1/1					1/1					1/1	
Repetition	3/3					3/3					3/3	
Comprehension	1/1					1/1					1/1	
Reading	1/1					1/1					1/1	
Writing	1/1					1/1					1/1	
Drawing	30					30					30	>27
Total												
<u>HADS</u>	-	-				-		-			-	-
Anxiety	13	9				7		0			0	<7
Depression	7	2				0		0			0	<7
TUG	UTC	UTC			UTC		UTC			UTC		<9 sec
PEG	4.33	3.33	2.3	2	1.66	2.33	2.66	2.33	0	2.33		<4
3D CAM	0	0	0	0	0	0	0	0	0	0		<20
Stroop												<190
<u>HABC-SRM</u>	-	-	-	-	-	-	-	-	-	-	-	-
Cognitive	2	0	0	0	0	0	0	0	0	0		<4
Functional	3	0	0	0	1	0	0	0	0	0		<3
Behavioral & Mood	8	8	5	2	1	0	0	0	0	0		<5
Total	13	8	5	2	2	0	0	0	0	0		<14
Score 1	0	0	0	0	0	0	0	0	0	0		
Score 2	0	0	0	0	0	0	0	0	0	0		
Score 3	0	0	0	0	0	0	0	0	0	0		
Total ACB	0	0	0	0	0	0	0	0	0	0		<2

Care Coordinator suggests implementing highlighted protocols below

Protocols:

1. Cognition
2. Exercise
3. Depression
4. Anxiety

5. Physical Health
6. Behavioral Care
7. Legal and Financial
8. Communication
9. Mobility
10. Personal Care
11. Sleep Disturbance
12. Pain
13. Stress
14. Acute Care Reduction/DELIRIUM
15. Medication Adherence
16. Ascites/Edema
17. Hepatic Encephalopathy
18. Alcohol and Substance Use Disorder Protocol

Care Plan:

1. Counseling (Prognosis & Natural History)
2. Enhancing Knowledge
3. Brain Exercises / Cognitive Rehabilitation
4. Physical Exercise / Physical Rehabilitation
5. Time-Off Caregiving Tasks (minimum of 8 hours per week)
6. Belonging to Support Group
7. Counseling (Coping with Disease Disability)
8. Respite Care
9. Medication Adherence Support
10. Referral or starting Cognitive Behavioral Therapy
11. Referral or starting Problem Solving Therapy
12. Referral for Family Therapy
13. Referral for Home Health Care Services
14. Referral to Adult Day Care
15. Referral for Driving Evaluation / Rehab
16. Recommend Residing in Assisted Living
17. Referral to Elder Law Attorney
18. Referral to Elder Abuse Agency Investigation
19. Referral for Guardianship
20. Counseling for Advance Directives
21. Prescribe ChEI
22. Prescribe Antidepressants
23. Prescribe Vascular Burden Reduction
24. Reduce Anticholinergic Burden
25. Prescribe Anxiolytics
26. Prescribe Sleep Medication
27. Prescribe Other