PARTNERS HUMAN RESEARCH COMMITTEE
DETAILED PROTOCOL

PRICIPAL/OVERALL INVESTIGATOR

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PROTOCOL TITLE

A Randomized Controlled Trial of an Advanced Care Planning Video Decision Support Tool for Patients with End-Stage Liver Disease (Clinicaltrials.gov Identifier NCT03557086)

FUNDING

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SPECIFIC AIMS

The goal of this pilot randomized trial is to assess the feasibility and preliminary efficacy of an advanced care planning (ACP) video decision support tool for improving patients' knowledge regarding their goals of care options and end of life (EOL) decision-making in patients with end-stage liver disease (ESLD).

Aim 1: To assess the feasibility and acceptability of an ACP video decision support tool for patients with ESLD

- ***Hypothesis 1:*** *The intervention will be deemed feasible and acceptable if at least 60% of eligible patients are enrolled in the study and if at least 60% of patients randomly assigned to the video intervention report that the video is acceptable*

Aim 2: To assess the impact of an ACP video decision support tool on patients' knowledge about their EOL care options

- ***Hypothesis 2:*** *Patients randomly assigned to the video intervention will report improved knowledge of their EOL care options compared to those randomized to the verbal narrative control*

Aim 3: To assess the impact of an ACP video decision support tool on patients' preferences for EOL care

- ***Hypothesis 3:*** *Patients randomly assigned to the ACP video will be more likely to prefer comfort care compared to those randomized to the verbal narrative control arm*

- ***Hypothesis 4:*** *Patients randomly assigned to the video intervention will be more likely to forgo cardiopulmonary resuscitation (CPR) and intubation compared to those randomized to the verbal narrative control arm*

Aim 4: To assess the impact of an ACP video decision support tool on patients' documented EOL care preferences

- ***Hypothesis 5:*** *Patients randomly assigned to the video intervention will be more likely to have their code status documented in the electronic healthcare record compared to those randomized to the verbal narrative control arm*

BACKGROUND AND SIGNIFICANCE

End-stage liver disease (ESLD) is a terminal condition for which liver transplantation is the only cure. Heralded by the development of debilitating symptoms such as ascites, variceal bleeding, hepatic encephalopathy, or jaundice in patients with cirrhosis, ESLD is a state of limited life expectancy, with a median transplant-free survival of two years. Unfortunately, the diagnosis of ESLD is a terminal one for thousands of patients annually who are deemed ineligible for liver transplantation due to significant comorbid disease, substance use disorder, inadequate social support, or advanced age. However, despite their poor prognosis, patients with ESLD who are non-transplant candidates still receive aggressive medical care at the end of life (EOL). While most patients prefer to die at home, these patients are frequently hospitalized during the last month of

life and have high rates of in-hospital mortality.[1-5] Furthermore, these patients often receive aggressive life-sustaining therapies during their terminal hospitalizations, such as cardiopulmonary resuscitation (CPR) and intubation.[6,7] The Institute of Medicine report, *Dying in America,* highlighted substantial deficiencies in EOL care for patients with serious illness and identified intensive and costly care at the EOL as poor-quality care given its burden on patients, families, and the health care system.[8] Thus, there is a critical need to optimize the quality of EOL care for patients with ESLD who are not transplant candidates given their terminal diagnosis, poor prognosis, and the frequency with which they receive intensive and costly medical care at EOL.

Advance care planning (ACP) is the process by which patients discuss their goals and preferences for medical care at the EOL with their clinicians.[9-11] Patients who engage in advance care planning are better informed about their EOL care options, which improves their EOL decision-making.[12-18] Decisions about CPR and intubation are an integral part of advance care planning, and studies have shown that patients with life-limiting illnesses who discuss their EOL care preferences with their clinicians are less likely to opt for aggressive medical interventions.[18-23] Unfortunately, one retrospective analysis showed that only a minority (28%) of patients with ESLD ineligible for liver transplantation had documented advanced directives.[7] Another series revealed that the majority of hospitalized patients with cirrhosis were designated full code on admission[24], despite multiple studies showing dismal outcomes after cardiac arrest for this population, with rates of survival ranging from 0% to 16%.[25-29] Thus, interventions are needed to educate transplant-ineligible patients with ESLD of their care options at EOL in order enhance the frequency and quality of advance care planning for this vulnerable patient population.

Patients must receive accurate and understandable information about their medical options to make informed decisions about the care they would prefer to receive at the EOL.[9,10] However, verbal communication strategies do not effectively inform patients of their EOL care options as they are often too complex for patients to comprehend.[9-11,30-34] Patients frequently find it difficult to realistically envision care in the intensive care unit (ICU) or medical procedures such as CPR and intubation, especially given the variability in the quality of communication between patients and their clinicians.[9-11,30-37] Videos can enhance patients' comprehension of complex health information by providing realistic visual images that can facilitate education about medical procedures, such as CPR and intubation.[38,39] A video decision support tool offers an innovative strategy to educate transplant-ineligible patients with ESLD about CPR and intubation in order to empower them to make informed decisions regarding their EOL care.

RESEARCH DESIGN AND METHODS

Study Design and Schema:

Our proposed project is a single-center randomized controlled trial to assess the feasibility, acceptability and preliminary efficacy of an ACP video decision support tool versus a verbal narrative alone on EOL care preferences in transplant ineligible patients with ESLD in the outpatient setting. We will recruit up to 70 consecutive patients with ESLD who receive ambulatory care at the MGH Liver Center for this study. Patients will be randomized in a 1:1 fashion **(Figure 1)**. To ensure that patients in this sample received longitudinal care (ruling out

those being seen for second-opinion consultation), we will only include those patients who have had two or more visits to the MGH Liver Center.

Eligibility Criteria

Our proposed project is a single-center randomized controlled trial to assess the feasibility, acceptability and preliminary efficacy of an ACP video decision support tool versus a verbal narrative alone on EOL care preferences in transplant ineligible patients with ESLD. We will recruit up to 70 consecutive adult patients with ESLD who receive care at MGH for this study. Patients will be randomized in a 1:1 fashion **(see Schema for further details)**.

Eligibility Criteria

All patients with ESLD who are ≥ 18 years of age seen at the Massachusetts General Hospital will be screened for study participation. Our study population is defined as patients with cirrhosis complicated by at least one of the following clinically-evident decompensating events: 1) ascites; 2) hepatic encephalopathy; or 3) history of gastroesophageal variceal hemorrhage - which portends a poor prognosis.[40] Only patients who are deemed ineligible for liver transplantation by either their primary hepatologist or the inpatient hepatology consult service attending will be eligible for this study as this is a patient population for whom the diagnosis of ESLD is a terminal one.

Patients Inclusion Criteria:

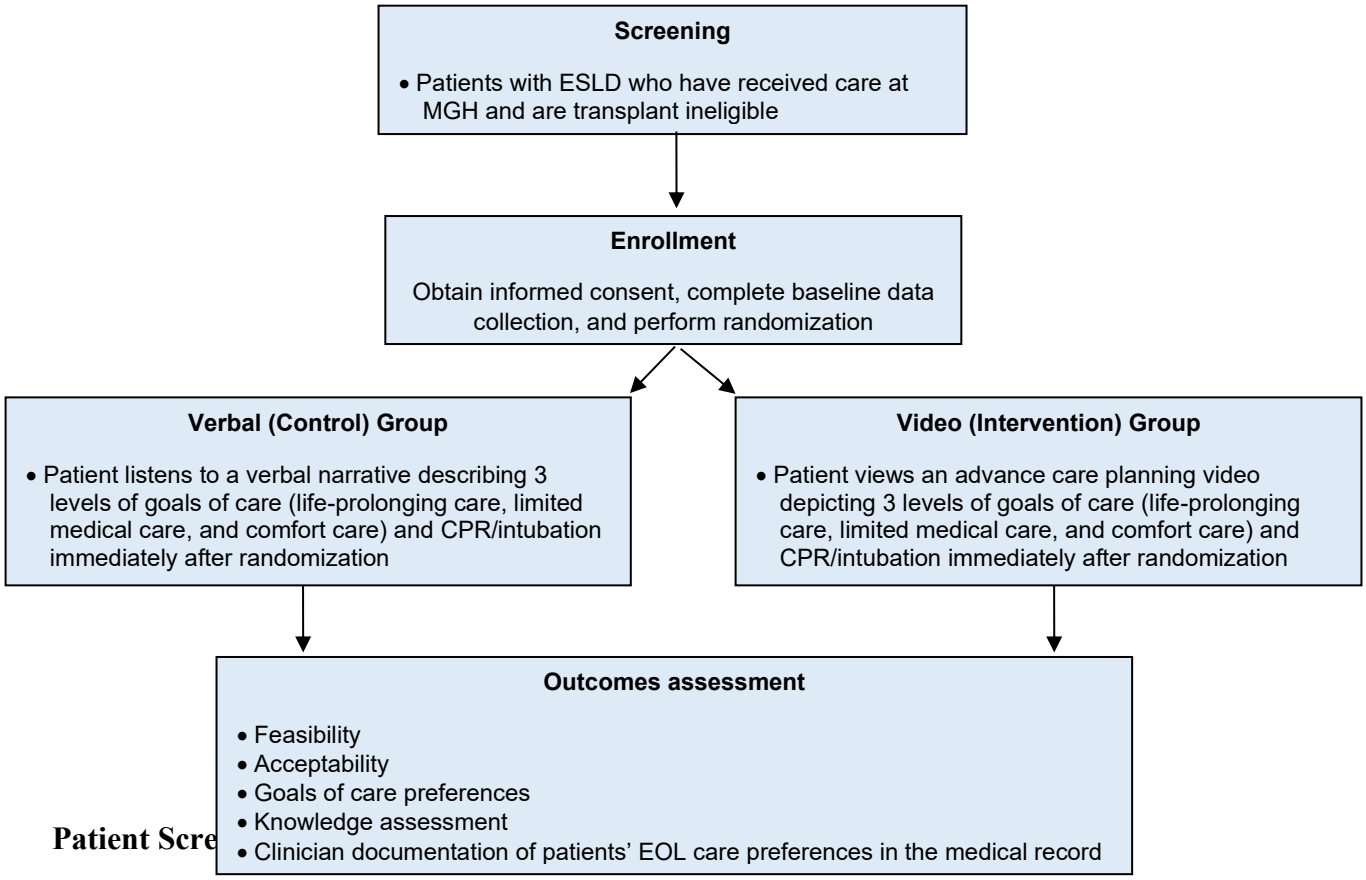
1. ≥ 18 years of age with an established diagnosis of ESLD
2. Patient must have either 1) primary hepatologist at the MGH Liver Center or an MGH-affiliated primary care physician, or 2) a previous inpatient admission at MGH
3. Deemed ineligible for liver transplantation as determined by the primary hepatologist or the inpatient hepatology consult service attending
4. Ability to communicate in English and provide informed consent
5. A score ≥ 7 on the Short Portable Mental Status Questionnaire[41] **(Appendix A)**

Patients Exclusion Criteria:

1. Severe hepatic encephalopathy which the primary hepatologist or the inpatient hepatology consult service attending believes prohibits informed consent or participation in the study
2. Significant uncontrolled psychiatric disorders (psychotic disorder, bipolar disorder, major depression) or other co-morbid disease (dementia, cognitive impairment), which the primary hepatologist believes prohibits informed consent or participation in the study
3. Prior history of liver transplantation
4. Patient has been referred to or enrolled in hospice care
5. Patient has been referred to palliative care

We have limited enrollment to patients able to comprehend English, as the video is only available in English at this time. If the intervention is effective in improving advance care planning and the delivery of EOL care for patients with ESLD, we will develop videos in additional languages for future trials.

Figure 1



Patient Scre

The research assistant (RA) will recruit patients with ESLD from the inpatient units at MGH or outpatient clinics at the MGH Liver Center. The RA will be trained by the principal investigator (PI, a gastroenterologist) to screen patients based on the eligibility criteria. The RA will be responsible for reviewing the inpatient hepatology consultation list, general medicine floors, and the outpatient MGH Liver Unit clinic schedule on a daily basis to ensure that we capture all potentially eligible patients for study participation. The PI will always be available on a daily basis to answer any screening questions regarding patients' eligibility. We have utilized these procedures in prior trials of patients with ESLD to identify all potentially eligible subjects.[42,43]

Once a potentially eligible patient is identified, the RA will send an email to the primary hepatologist in the outpatient setting, or the medicine attending and responding clinician in the inpatient setting (as well as the hepatology consult service if available) to notify them that their patient is eligible for study participation and inquire about any concerns regarding their particpiation. If the clinicians have objections to their patients' participation in the study, we will document the reason and not approach those individuals. If the clinicians do not have objections to their patients' participation in the study, we will ask the attendings to introduce the study to the eligible patient to obtain permission for the study staff to approach the patient. After obtaining permission from the primary hepatologist, inpatient hepatology consult attending and/or medicine attending, the RA will review the consent form with potential participants which will detail the nature of the study procedures. When obtaining informed consent, the RA will describe the goal

of the study: to better understand how much patients with ESLD know about ACP and EOL care preferences. The RA will also explain that the study requires completing a 15-minute baseline questionnaire asking participants about their CPR and intubation preferences, eliciting prior advance care planning discussions, and assessing their knowledge regarding CPR and intubation. The RA will undergo standardized training in all aspects of the research protocol, including the use of structured scripts to administer the questionnaires **(Appendix A)**. For patients agreeing to participate in the study, the RA will obtain written informed consent from the participants and provide them with a copy of the signed consent form.

After obtaining informed consent, the RA will administer the Short Portal Mental Status Questionnaire **(Appendix B)** to participants to confirm final eligibility. Immediately following enrollment, the RA will administer a 15-minute baseline questionnaire (see "Study Measures" below) that will include the following: demographics, self-reported health status, baseline EOL care preferences, CPR and intubation preferences, and a questionnaire assessing patients' knowledge of EOL care options.

Randomization

After enrollment and completion of the baseline questionnaires, participants will be randomized in 1:1 fashion without any stratification to either the control group (verbal narrative alone) or the intervention group (video decision support tool) using a random computed generated list, with assignments concealed in numbered envelops.

The Intervention Arm

Our group, the VIDEO Consortium (Video Images of Disease for Ethical Outcomes), has developed several video decision support tools to assist patients with advance care planning.[38,39,44] We have previously developed a five-minute advance care planning video for patients with advanced cancer[45], which has been adapted for this study.

We convened a panel of clinicians with expertise in hepatology, critical care, palliative care, medical ethics, and decision-making at our institution to develop a verbal narrative introducing the patient to advance care planning, a 3-part goals of care framework (life-prolonging care, limited medical care, and comfort care), and a description of medical procedures such as CPR and intubation that will outline the process, risks, and likelihood of successful resuscitation in patients with ESLD. This panel drafted and edit this narrative in an iterative process, which serves as the verbal script for our video decision support tool and the verbal narrative for our control group **(Appendix C)**. These experts also offered feedback about the representation of medical interventions, such as what care in the ICU is like and what CPR and intubation look like.

We designed the video to provide non-medical trained individuals a general understanding of the types of medical care patients may receive at the EOL and a description of medical interventions such as hospitalizations, ICU admission, CPR, and intubation. The video begins by addressing the importance of the patient's personal goals and perspectives by asking the viewer to reflect on their concerns about getting sick and their overall goals for their EOL care. The physician narrator then

introduces a framework for choices of medical care at the EOL including: 1) life-prolonging care; 2) limited medical care; and 3) comfort care. The visual images illustrating life-prolonging care include interventions that are available in a modern-day hospital such as CPR, mechanical ventilation, and treatment in the ICU. Scenes include an ICU with a ventilated patient being tended to by respiratory therapists, a simulated code conducted with clinicians illustrating chest compressions, CPR and intubation, and the administration of medications through a central venous catheter. For the second option, limited medical care, the narrator explains the goal of care is to pursue treatment for medical conditions, but avoid intensive medical interventions at the EOL. This type of care would include hospital care, intravenous medications, and antibiotics, but not CPR or ICU care. Visual images include a patient getting medicine via a peripheral venous catheter, scenes from a typical medical ward, and a patient wearing a nasal cannula to receive oxygen and breathing treatments. For the third option, comfort care, the narrator describes the goal of care as relieving symptoms and utilizing medical care that would only be used to provide comfort. Visual images include a patient on hospice care at home receiving pain medications, a patient with a respiratory face mask receiving oxygen at home, and an attendant assisting a patient with self-care. All three sequences of video images accompanying the narration attempt to help the viewer imagine the experience and likely outcomes of receiving these medical interventions at the EOL. The video was filmed and edited by the research team without the use of prompts or stage directions to convey a candid realism in the style known as cinema verité. All patients included in the video (or their proxies) gave consent to be filmed.

Immediately after completing the baseline assessment and randomization, patients assigned to the video intervention arm will view the 3-minute advance care planning video for patients with ESLD on an iPAD in the presence of the RA. We will use standardized procedures to minimize the interaction between the RA and patient while the patient is viewing the video. The RA will not be permitted to comment or answer questions while the patient views the video. Patients will be instructed to watch the video once without any interruption and will have no further exposure to the video. If patients have questions about the video or their EOL care options, the RA will instruct them to discuss their questions with their medical team.

The finalized video can be viewed by the IRB at the following link:
https://vimeo.com/269740750

Access Code: mghirb

The Control Arm

Immediately after completing the baseline assessment and randomization, patients assigned to the verbal narrative control arm will listen to the same description of the 3 goals of care used in the video arm read out loud by the RA **(Appendix C).** We will use standardized procedures to minimize interaction between the RA and patients during the interview. Specifically, the RA will not be permitted to comment or answer questions while the patients listen to the verbal narrative. Patients will be instructed to ask their physicians any questions they may have about goals of care.

Study Measures

We will administer the following study measures at baseline prior to randomization, and immediately after the video or verbal narrative in the intervention and control group, respectively according to the timeline displayed in **Table 1**:

- *Demographics:* Patients will complete a demographic questionnaire at baseline detailing their age, sex, race/ethnicity, religion, relationship status, educational level, living situation, employment status, and self-reported health status ("Relatively healthy", "Relatively healthy and terminally ill", "Seriously ill and not terminally ill", "Seriously ill and terminally ill")[46] **(Appendix D)**
- *EOL Care Preferences:* Patients will report their EOL care preferences as follows: life-prolonging care, limited medical care, comfort care, or unsure. **(Appendix E)**
- *CPR Preferences:* Patients will report their CPR preferences as follows: "Yes, attempt CPR", "No, do not attempt CPR", or "Not sure." **(Appendix E)**
- *Intubation Preferences:* Patients will report their intubation preferences as follows: "Yes, attempt intubation", "No, do not attempt intubation", or "Not sure." **(Appendix E)**
- *Knowledge Questionnaire:* We will assess patients' knowledge of goals of care as in previous studies using 5 true/false questions and 1 multiple choice question, each worth 1 point, for a summary score of 0 to 6 (higher score reflects greater knowledge)[45,47,48] **(Appendix F)**
- *Acceptability of the Video:* For the video intervention arm alone, we will administer 3-items assessing patients' comfort with watching the video, whether they find the video helpful in their understanding of the EOL care options, and whether they would recommend it to others.[49] **(Appendix G)**

We will also obtain the following important covariates and outcomes:

- *Disease-related variables:* We will collect variables from the EHR at the time of enrollment, including the etiology of ESLD, presence of clinically-evident decompensating events (ascites, esophageal variceal bleed, hepatic encephalopathy, or multiple), Model of End-Stage Liver Disease Sodium (MELD-Na) score, reason for transplant ineligibility, and clinical comorbidities using the modified Charlson Comorbidity Index.[50]
- *Code Status Documentation in the EMR:* The RA will review the EHR to collect whether clinicians' documented patients' code status in the EMR (yes: documented, no: not documented) 3 months after study enrollment.

Table 1: Data Collection Timeline

	Baseline	Post-intervention	3 months post-enrollment
Demographics	X		
Self-Reported Health Status	X		
EOL Care Preferences	X	X	
CPR Preferences	X	X	
Intubation Preferences	X	X	

Knowledge Questionnaire	X	X	
Comfort/Satisfaction with Video (Intervention group only)		X	
Disease-related variables	X		
Code status documentation			X

We will collect and enter all patient data electronically using Research Electronic Data Capture (REDCap). The REDCap Survey is a tool for building and managing online surveys. Vanderbilt University, in collaboration with a consortium of institutional partners, has developed this software and workflow methodology for electronic collection and management of research and clinical trial data. Our research team has extensive experience using REDCap and will create and design the surveys in a web browser, with institutional information technology support. The REDCap Survey system offers secure, HIPAA compliant, web-based applications that provide an intuitive interface for participants to enter data, with real-time validation rules at the time of entry.

Participants will use tablet computers to complete questionnaires in clinic. If any participants refuse or are unable to complete the questionnaires on the computer, they will be permitted to use hard-copy paper versions. In addition, the patient data collected from the electronic health record will be abstracted throughout the study and directly inputted into REDCap.

Study Outcomes

- **Primary Outcome:** The primary outcome is feasibility. The proposed video intervention will be deemed feasible if at least 60% of eligible patients are enrolled in the study. The 60% feasibility cut-off is commonly used in behavioral intervention studies.[51-53]
- **Secondary Outcomes:** The secondary outcomes will include patients' comfort/satisfaction with the video, patients' stated post-intervention EOL care preferences categorized as four options: Life-prolonging care, limited medical care, comfort care, or unsure; individual preferences for CPR and intubation before and after intervention in the verbal narrative and video groups; and change in knowledge scores after receiving the verbal narrative or video

Sample Size Calculation

We will randomize up to 70 patients with ESLD for this project. The primary endpoint of the study is feasibility. We chose the sample size of 70 patients based on the feasibility of completing the project during the proposed timeframe and the ability to assess the preliminary efficacy of the intervention. Consistent with the behavioral intervention literature, at least 20 patients are needed in each group in a pilot study to estimate a parameter.[54,55] Therefore, the proposed sample size will provide us with preliminary data that can be utilized to determine the effect size and adequately power future randomized trials. This is a commonly utilized study design for pilot testing of behavioral interventions and is consistent with the National Institute of Health Stage Model for Intervention Development. While the feasibility of the intervention can be assessed using a single-arm design, preliminary efficacy is better assessed utilizing a control group as we are proposing in this trial.

Analysis Plan

We will report baseline demographic and clinical characteristics of all study participants using means and proportions to describe continuous and categorical variables, respectively. Because this is a pilot study, we will use conservative (alpha = 0.05) and liberal (alpha = 0.20) critical values to assess statistical significance between the two arms in this pilot study.

Aim 1: The primary endpoint of the proposed study is feasibility. The proposed video intervention will be deemed feasible if at least 60% (95% CI +/- 13.6%) of eligible patients are enrolled in the study and complete at least 60% of the intervention sessions. The proposed video intervention will be deemed acceptable if at least 75% of patients randomized to the intervention arm report satisfaction and comfort with the video.

Aim 2: Changes in knowledge scores from before and after the intervention will be compared between the two groups using two-sample t-tests.

Aim 3: Post-intervention EOL care preferences (life-prolonging care, limited medical care, and comfort care), CPR preferences, and intubation preferences will be compared between the two groups using Fisher's exact tests. The change in CPR and intubation preferences before and after the intervention within each group will be compared using McNemar tests.

Aim 4: Code status documentation will be compared between the two groups using Fisher's exact tests.

Project Timeline	Table 1: Study Timeline and Study Procedures
Months 0-2	❖ Finalize protocol development and submit to Institutional Review Board for approval
Months 3-24 Months 3-15 Months 16-24	**Data Collection** ❖ Enroll up to 70 patients to participate in the prospective study ❖ Collect follow-up data on ACP documentation and prepare manuscript(s) for publication

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APPENDIX A: Script for Administering the Educational Methods

Introduction

Research staff member: My name is (state name) and I am a working on a project about what people prefer when receiving medical care at the end of life. The goal of this project is to understand what people think and what they like better when getting medical care for advanced liver disease. You are being asked to take part in this study because you have advanced liver disease. Taking part in the project is strictly up to you. You can decide to not answer any of the questions if you wish, and can stop the interview at any time. You may also see an educational video during this survey, and you can stop the video at any time. Taking part in this project will have no bearing on your current care. This interview will last about a half hour. Does this sound like a project you would like to participate in?

If YES: Research staff member will obtain written consent and administer the Short Portable Mental Status Questionnaire
If NO: Research staff member thank the patient and end the interview

Screening: Short Portable Mental Status Questionnaire (Appendix B)

Research staff member: First, I will ask you some general questions.

Administer Appendix B
If score is ≤ 6: Research staff member thank the patient and end the interview
If score is 7 or higher: Research staff member will continue to baseline questionnaires

Baseline Questionnaires (Appendices D, E, and F)

Here are some questionnaires to fill out on your own, which will help us to learn more about how people with advanced liver disease feel and what they like better when getting medical treatment. Please ask the interviewer if you need help at any time

Study Randomization - If randomized to VIDEO

Research staff member: I will now play an educational video tool about the different medical care options for patients with advanced liver disease. I will not be able to answer any questions about the content of the video. However, you should feel free to bring up any questions that you have about choices for medical care for patients with advanced liver disease to your care team. Do you have any questions about the study procedures before we begin?

If YES: Research staff member will address questions
If NO: Research staff member will play the educational video tool

Research staff member: You just watched an educational video tool about the different medical care options for patients with advanced liver disease. As a reminder, I will not be able to answer questions about the content of the video but again, you should feel free to bring up any questions that you have about choices for medical care for patients with advanced liver disease to your care team. You will now answer questions about choices for medical care for patients with advanced liver disease like those you answered before watching the video, as well as a few which specifically ask about the video itself.

Research staff member will administer post-assessment

Study Randomization - If randomized to NARRATIVE

Research staff member: I will now read to you a verbal narrative about the different medical care options for patients with advanced liver disease. I will not be able to answer any questions about the content of the narrative. However, you should feel free to bring up any questions that you have about choices for medical care for patients with advanced liver disease to your care team. Do you have any questions about the study procedures before we begin?

If YES: Research staff member will address questions
If NO: Research staff member will read the verbal narrative (Appendix C)

Research staff member: You just listened to a verbal narrative about the different medical care options for patients with advanced liver disease. As a reminder, I will not be able to answer questions about the content of the narrative but again, you should feel free to bring up any questions that you have about choices for medical care for patients with advanced liver disease to your care team. You will now answer questions about choices for medical care for patients with advanced liver disease like those you answered before listening to the narrative.

Research staff member will administer post-assessment

APPENDIX B: Short Portable Mental Status Questionnaire

Question	Response	Incorrect Responses
1. What are the date, month, and year?		
2. What is the day of the week?		
3. What is the name of this place?		
4. What is your phone number?		
5. How old are you?		
6. When were you born?		
7. Who is the current president?		
8. Who was the president before him?		
9. What was your mother's maiden name?		
10. Can you count backward from 20 by 3's?		

APPENDIX C: Verbal Narrative Transcript

I'd like to talk about choices for medical care when patients are very sick and in the hospital. I will explain 3 basic types of medical care. This is a way for you to start thinking now about the type of care you would want should you get very sick or not able to speak up for yourself. The reason that this is important is that people have very different ideas about what they want.

There are three basic types of medical care for people who are very sick. These are life prolonging care, limited medical care, and comfort care. Here is more to know:

Life prolonging care.

The first option is life prolonging care.

The goal of this type of care is to "prolong life," meaning that doctors will do everything they can to keep you alive. This can include trying cardiopulmonary resuscitation (or CPR) to restart your heart after it stopped beating. To do this, the doctor presses hard on your chest and uses a device to give your heart an electric shock.

If you want the doctor to try CPR, you must also agree to be on a ventilator (or breathing machine) if needed. When getting a ventilator, the doctor puts a tube down your throat. One end of the tube goes into your lungs and the other connects to a machine that pushes air into them. You cannot eat or talk while on a ventilator. You likely will also need such strong medicines that you must stay in the hospital's Intensive Care Unit (or ICU).

With life prolonging care, you agree to CPR and a ventilator in hopes for a longer life. But for most patients with advanced liver disease, CPR does not work. CPR also will not cure your liver disease or get you back to the level of health you had before your heart stopped.

Limited medical care.

The second option is limited medical care.

This is when people agree to just certain kinds of medical care. For instance, with limited medical care you might get medicine for treatable problems like fluid in the abdomen or infections around the stomach area. You might be admitted into the hospital and get fluids or medications through an IV tube that goes into your vein. But with limited medical care, you do not want doctors to try CPR or put you on a breathing machine--even if that means that without those treatments, you might die.

Comfort care.

The third option is comfort care.

The goal of this type of care is to increase comfort and reduce symptoms, but not to prolong life. People who choose this type of care might be at home, or in a hospice or nursing home. With comfort care the healthcare team can treat symptoms like breathing problems, nausea, and pain. But comfort care does not include CPR and breathing machines. It also does not include going to the hospital, unless the doctor thinks you will be more comfortable there. The goal of this type of care is to increase comfort and relieve pain.

I hope this helped you learn more about choices of medical care when people are very sick. Think about what matters to you. Discuss this with your family. Make sure to also talk with your doctor who may suggest a certain type of medical care for you. Once you decide what you want, tell your doctor and family. It is okay to later change your mind so long as you discuss that with your doctor and family. They can help protect your rights and wishes about medical care.

APPENDIX D: Demographics and Self-Reported Health Status

Please check the appropriate box or boxes.

1. Gender
   - ☐ Man
   - ☐ Woman
   - ☐ Other

2. Ethnicity
   - ☐ Hispanic or Latino
   - ☐ Not Hispanic or Latino

3. Race (please check all that apply)
   - ☐ American Indian or Alaskan native
   - ☐ Asian
   - ☐ African American or Black
   - ☐ Native Hawaiian or other Pacific Islander
   - ☐ White
   - ☐ Other (please specify) _____

4. Religion
   - ☐ Catholic Christian
   - ☐ Other Christian (such as Protestant, Orthodox, etc.)
   - ☐ Jewish
   - ☐ Muslim
   - ☐ Atheist
   - ☐ None
   - ☐ Other (please specify)_____

5. Current relationship status
   - ☐ Married or living with someone as if married
   - ☐ Non-cohabiting relationship
   - ☐ Single, never married
   - ☐ Divorced/Separated
   - ☐ Loss of long term partner/ Widowed

6. Please indicate your highest or current education level
   - ☐ 11th grade or less
   - ☐ High school graduate or GED
   - ☐ 2 years of college/AA degree/Technical school training
   - ☐ College graduate (BA or BS)
   - ☐ Masters degree
   - ☐ Doctorate/Medical degree/Law degree

7. What is your annual combined household income?
- ☐ Less than $25,000
- ☐ $25,000 – 50,000
- ☐ $50,000 -100,000
- ☐ $100,000 – 150,000
- ☐ Greater than $150,000

8. Please indicate who you live with (you may check more than one box)
- ☐ By myself
- ☐ Partner/Spouse
- ☐ Roommate/Friend
- ☐ Children under 18
- ☐ Children over 18
- ☐ Group home/assisted living/nursing home
- ☐ Parent
- ☐ Other (please specify) _____

9. Current employment status
(please check all that apply):
- ☐ Employed (full-time or part-time)
- ☐ Caring for home or family (not currently working and not looking for paid work)
- ☐ Unemployed and looking for work
- ☐ Unable to work due to illness or disability
- ☐ Retired
- ☐ Student
- ☐ Other (please specify) _____

10. How would you describe your current medical status?
- ☐ Relatively healthy
- ☐ Relatively healthy and terminally ill
- ☐ Seriously ill and not terminally ill
- ☐ Seriously ill and terminally ill

Please enter your email address
(will only be used if necessary):

_____

What is the best phone number to use if we needed to reach you?

_____

APPENDIX E: End of Life Care, Cardiopulmonary Resuscitation, and Intubation Preferences

1. Imagine that your liver disease became very advanced and that you became very ill and in need of medical treatment, which general approach would you want provided?
   - ☐ Life-prolonging care
   - ☐ Limited medical care
   - ☐ Comfort care
   - ☐ Unsure

2. If your liver disease were very advanced and you were to get so sick that your heart stopped beating, would you want doctors to do chest compressions and CPR to try to make your heart start again?
   - ☐ Yes, attempt CPR
   - ☐ No, do not attempt CPR
   - ☐ Not sure

3. If your liver disease were very advanced and you were to get so sick that you could not breathe on your own, would you want doctors to place you on a breathing machine to help you breathe?
   - ☐ Yes, attempt intubation
   - ☐ No, do not attempt intubation
   - ☐ Not sure

Appendix F: Knowledge Assessment Questionnaire

1. True or False: Cardiopulmonary resuscitation or CPR is a medical procedure that is done on patients whose heart stops beating in an attempt to restart their heart. **(True)**
2. True or False: Most patients with advanced liver disease that get CPR in the hospital survive and get to leave the hospital. **(False)**
3. True or False: Most patients with advanced liver disease who survive CPR and being placed on a breathing machine have very few complications from these procedures. **(False)**
4. True or False: Comfort care is a type of medical care that can only be provided for patients with advanced liver disease living in hospice. **(False)**
5. True or False: Once you tell your doctor what kind of medical care you want if your liver disease becomes very advanced, you cannot change your wishes in the future. **(False)**
6. Multiple Choice: How many patients with advanced liver disease that get CPR in the hospital survive and get to leave the hospital? a. almost all (more than 90%) b. about half (about 50%) c. very few (less than 10%) **(correct answer is c)**

Appendix G: Impression and acceptability of the video (intervention arm only)

1) Was the video <u>helpful</u> in improving your understanding about your choices for medical care?

__ 0 Very helpful
__ 1 Somewhat helpful
__ 2 A little helpful
__ 3 Not helpful

2) Did you feel <u>comfortable</u> seeing the video in order to help you answer the questions regarding medical care?

__ 0 Very comfortable
__ 1 Somewhat comfortable
__ 2 Not comfortable
__ 3 Don't know

3) Would you <u>recommend</u> the video to other patients with advanced liver disease who are facing a similar decision?

__ 0 I would definitely recommend it.
__ 1 I would probably recommend it.
__ 2 I would probably not recommend it.
__ 3 I would definitely not recommend it.