Human Research Protocol

Title: Randomized Trial of Text vs. Video Patient Educational Materials in Cirrhosis
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Background and Significance

Cirrhosis is a complex chronic disease, with several associated complications, numerous symptoms, and patients often require many medications. Cirrhosis is unfortunately linked to frequent hospitalizations and re-hospitalizations. Lack of medication compliance leads to hospitalizations, and increased disease understanding can improve medication compliance. Improved health literacy can prevent hospitalizations in other ways (preventing ED visits for ascites or HE). Based on internal QI data, we know that many patients with cirrhosis at U-M do not understand their medications and other aspects of their disease. Our essential purpose in this study is to compare the efficacy and patient satisfaction associated with traditional text cirrhosis education vs. recently-created educational videos on the same topics.

Specific Aims:

Aim 1: *Do educational materials improve patients' understanding of disease?*
Assess change in score for pre- and post-evaluations.

Aim 2: *Is one mode of patient education more effective than the other?*
Compare efficacy of educational materials when presented as text (Cirrhosis Toolkit) or video.

Aim 3: *Do patients prefer one mode of education over the other?*
Compare patients' preference for educational materials presented as text (Cirrhosis Toolkit) or video.

Aim 4: *How can these educational materials be improved?*
Collect feedback from patients on educational materials.

Research Design and Methods

Overview

We plan to enroll adult outpatients with cirrhosis who are evaluated at the University of Michigan Hepatology Clinic. We aim to enroll a maximum of 320 subjects with cirrhosis, into two main study arms. Arm 1 will include 160 responses from subjects who are newly diagnosed with cirrhosis, and Arm 2 will include 160 responses from subjects with history of cirrhosis.

After screening, and before being invited to respond to the study survey, participants will be randomized into one of 4 subgroups per each study arm, for a total of 8 possible subgroup assignments:

Arm 1: New Diagnosis		Arm 2: Previous Diagnosis	
1A: Cirrhosis Toolkit	1B: Cirrhosis Videos	2A: Cirrhosis Toolkit	2B: Cirrhosis Video
1A.1: General Cirrhosis Info	1B.3: General Cirrhosis Info	2A.1: General Cirrhosis Info	2B.3: General Cirrhosis Info
1A.2: Ascites Info	1B.4: Ascites Info	2A.2: Ascites Info	2B.4: Ascites Info

Subgroups 1and 2 will involve the presentation of educational materials in text-and-graphic format (Cirrhosis Toolkit), with each subgroup focusing on a single subject or section of the material. Subgroups 3 and 4 will be presented with similar material in video format, also focusing on a single subject per subgroup. Recruitment for this study will conclude once 40 subject-experiments have been completed for each subgroup.

Subjects will be given the option to be randomized into an additional study subgroup (For example: if they were randomized into subgroup 1A.1 in the first round, they would be randomized into 1A.2 or 1B.4 for their second round of participation) and participate in the study a second time. Enrollment will conclude once 160 subject-experiments have been completed for each study arm.

Inclusion Criteria

1. Age 18 years or older
2. Cirrhosis, as diagnosed by imaging, elastography, biopsy, or decompensation
3. Available email address
4. Arm 1: New patient visit for cirrhosis (and diagnosis within the last 6 months)
5. Arm 2: Previous cirrhosis diagnosis (>6 months)

Screening

For Arm 1, patients with a new diagnosis of cirrhosis will be identified by reviewing the University of Michigan Hepatology Clinic outpatient schedule and related notes in the Electronic Medical Record.

For Arm 2, Patients with >6 months history of cirrhosis diagnosis will be identified via Datadirect, previously established patient lists, and the University of Michigan Hepatology Clinic outpatient schedule.

Patients who meet the inclusion criteria will be randomized into one of the above subgroups and sent an email invitation to participate in the study. Potential participants will not be called or approached in person. The study invitation message will include contact information for study staff members in case these patients have any questions or would like to discuss the study in more detail before proceeding.

Procedures

The study will be conducted completely online, via REDCap. The initial study invitation email will include a link to the REDCap database, where participants will complete study questionnaires and activities. Informed consent for this study will be conducted online via REDCap.

Demographics Survey
Participants will be asked to report their age, sex, cause of cirrhosis, and any history of ascites, variceal bleeding, or HE.

Pre-Evaluation
Based on their randomly assigned subgroup, participants will complete a Pre-Evaluation, consisting of 5-6 content-specific questions, to determine each participants' baseline level of content knowledge. Pre-Evaluation scores will be recorded, but not presented to participants.

Educational Intervention
Participants will be prompted to review the educational material associated with their assigned subgroup. This will involve reading a specific section of the Cirrhosis Toolkit or watching videos. Participants will be given unlimited time to review and interact with educational materials and will be prompted to complete the Post-Evaluation when ready.

Post-Evaluation
Participants will be directed to respond to a set of content-specific questions identical to the Pre-Evaluation they completed earlier in the study, but in a randomized order. Post-Evaluation scores will be presented to participants after they complete the optional feedback survey (below).

The change in score between pre-and-post-evaluations for each participant will inform the results of aims 1 and 2. For questions with multiple correct answers, no partial credit will be awarded.

Debrief
Participants will be informed that all mandatory study activity has been completed and thanked for their time.
The study debrief will present participants with multiple optional study activities:

1) Complete the Feedback Survey
2) Contact study staff for further questions
3) Review their Post-Evaluation Score and complete a brief survey response
4) Re-enroll in the study to 'learn more'

1) The Feedback Survey will consist of questions related to aims 3 and 4.
   Questions:
   -Did you find this material helpful? (Likert scale)
   -Would you recommend this material to others? (yes/no)
   -Would you prefer further educational materials in text or video format?
   -Do you have any suggestions for improving these educational materials? (text box)

2) Participants will be given contact information for study staff members if they have any further questions.

3) Participants will have the option to review their post-evaluation scores only after all other activities have been completed, such as the feedback survey. Scores will be reported as [# correct]/[# of questions] Participants will be asked to reflect on their score:

-Are you satisfied with your score? (visual analog scale or Likert)

-What are your next steps for further education? (select all that apply: Nothing, talk to Hepatologist, talk to Nurse, talk to nutritionist, talk to other medical professional, internet search, talk to family and friends, other (please explain))

4) Participants will be given the option to 'learn more' and re-enroll in the study. If participants elect to re-enroll, they will be randomized into a different subgroup of the same study arm.

Statistical Analysis

Aim 1: Matched pair Wilcoxon comparing pre-test and post-test scores in the whole study population.

Aim 2: Matched pair Wilcoxon comparing score change (from pre to post) between video group and text group.

Aim 3: Descriptive statistics of Likert scale results.

Aim 4: Will report key themes from patient open-ended responses.

Foreseeable Risks and Discomforts

The risks of this study are primarily psychological. Subjects may become frustrated if performing poorly on the pre-or-post-evaluations. Patients may have privacy concerns about study communication via email or conducting study activities online or on their personal device.

Expected Benefits

A potential direct benefit for participants is the opportunity to learn something new about cirrhosis.

Privacy and Confidentiality

Redcap, a secure and HIPAA-compliant electronic program, will be used for all data collection and study activities. Once randomized, participants will be identified only by a study ID number. Results of the testing and any other information provided by the subject are available for analysis under the heading of this number only, not by name or other personally identifiable information. No names or personally identifiable information will be collected or used in any publications.

We will keep a separate password protected screening log on the University shared drive in a secured location. Only study personnel will have access to the electronic screening log that maps the Subject ID number and Screening ID number (if applicable) to the participant's email address. Only limited identifiable data will be collected for screening purposes.

Data and Safety Monitoring

There are no safety concerns in this study. We will store data on a secure U-M server. Study staff will proofread data weekly to verify accuracy. PI will complete a comprehensive review of all data prior to analysis.