1. PROTOCOL INFORMATION

Study Title: To evaluate the preliminary efficacy of our digitally enhanced CHW-led intervention in newly diagnosed PDAC with a pilot randomized controlled trial of 60 PDAC patients comparing the intervention to attention control with usual care
Date: 9/1/2025
Funding Source: DOD/CDRMP
Phase of Study: N/A
Version Date of Protocol: 1.0

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2. PRINCIPAL INVESTIGATOR'S INFORMATION

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3. STUDY PERSONNEL INFORMATION

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4. STUDY INFORMATION

Location(s) of Research Activity: Loma Linda University Medical Center
Expected Start/Stop Dates of Research: 07/1/2025 to 07/01/2027
Special Time Sensitivities: Funded through a 2-year grant from the DOD.
Type of Research: Prospective
Anticipated Enrollment number: 60
Patient Population: Patients with pancreatic ductal adenocarcinoma

5. PURPOSE

The purpose of this study is to obtain a preliminary estimate of the impact of a community health worker-led intervention by understanding the variance of the primary outcomes (symptom burden and quality of life) using a pilot randomized controlled trial.

6. OBJECTIVES AND PURPOSE

Objective: To evaluate the preliminary efficacy and the variance of primary outcomes (symptom burden and quality of life) of our digitally enhanced CHW-led intervention in newly diagnosed PDAC with a pilot randomized controlled trial of 60 PDAC patients comparing the intervention to attention control with usual care.

1 Hypothesis H1: Compared to attention control with usual care the digitally enhanced CHW-led intervention is expected to decrease NCCN-FACT Hepatobiliary-Pancreatic Symptom Index scores and improve HRQoL compared to baseline.

7. STUDY DESIGN

a. Background Information

Pancreatic Ductal Adenocarcinoma (PDAC) has become the 3rd most common cause of cancer mortality and is projected to become the 2nd largest contributor to cancer mortality by 2030.[1] The overall 5-year survival is 12%, with poor survival (44%) even in patients with local-stage disease.[2]

There are significant racial and ethnic disparities in PDAC, with Non-Hispanic Blacks and Hispanics having lower survival than non-Hispanic whites.[3] These disparaties were driven by lower socioeconomic status and delays in receiving chemotherapy, radiotherapy, and germline mutation testing with targeted novel therapies.[4, 5] Hispanics Reasons cited include lack of access to supportive medical care, language barriers, and rural location.

These racial and ethnic disparities in PDAC patients extend to participation in clinical trials, representing the only avenue to improve the prognosis of patients with advanced-stage disease substantially.[6] There is a 53% lower enrollment of Hispanics in clinical trials for PDAC, with no Hispanic patients enrolled among the ten Phase I clinical trials that reported ethnicity.[7] *Patient-reported barriers included mistrust or fear, lack of comfort, information and awareness of the clinical trial process, and, time and resource constraints.*[8] Clinical trials using digital health interventions in PDAC have also been studied to improve healthcare delivery[9], but Hispanics have the lowest rates of healthcare technology adoption.[10] Reasons for this disparity in Hispanics include lack of access, lack of trust (privacy concerns), lack of comfort with technology, and lack of motivation to use technology to support health.[11] Clearly, Hispanics with PDAC are underrepresented in both therapeutic and digital engagement clinical trials due to cultural, socioeconomic, and information factors, which are addressable.

PDAC patients have low health-related QoL (HRQoL), around the initiation of treatment.[12] For patients receiving palliative chemotherapy, baseline QoL was significantly impaired, and 39% had deterioration in QoL by 3 months and 59% by 6 months.[13] We conducted a prospective cohort study that followed 111 patients with newly diagnosed PDAC.[14] We demonstrated that 72% of patients had a clinically significant decrease in the physical and mental well-being domains of HRQoL at 30 days. In particular, Hispanics with PDAC were found to have significantly lower physical and mental HRQoL than other ethnic groups.[15]

Early initiation of palliative care has been shown to improve HRQoL and overall survival in patients with different solid tumors.[16, 17] Palliative care also increases advanced care planning (ACP) and reduces overall healthcare costs. Regarding PDAC, SEER-based

analyses demonstrated that most palliative care encounters for PDAC occurred near the end of life and were not associated with lower costs.[18] Nevertheless, palliative care encounters within 30 days of diagnosis reduced the number of ED visits, rate of ICU admission, and overall healthcare costs.[19] Multiple clinical trials have demonstrated that early palliative care within 2-4 weeks of diagnosis can improve physical, social, emotional, and functional HRQoL.[20, 21] However, Hispanic PDAC patients are less likely to receive palliative care or hospice referrals than non-Hispanic Whites.[22] Despite evidence that palliative care initiation may benefit PDAC patients, there is limited data on the impact of initiating palliative care at the time of diagnosis in this population.

PDAC patients report critical misconceptions about the treatment of PDAC. They overestimated the effectiveness of aggressive treatments, including surgery.[23] Furthermore, 50% of patients believed that undergoing every possible treatment was the only approach to their disease. Patients with metastatic PDAC expressed that the goal of treatment was improving their survival, and were unsure that palliative care could address symptoms and improve their quality of life.[24] These studies illustrate significant patient misconceptions regarding treatment options, the goal of treatment, and the availability of palliative care.

PDAC is diagnosed with endoscopic ultrasound (EUS)-guided biopsy and delays in establishing care with oncology and palliative care are common. Indeed, one study reported an interval of 26 days from diagnosis to discussing treatment and that there was almost a 2-month delay between the onset of symptoms and treatment initiation.[25] Another study demonstrated a two-week delay from diagnosis to being seen in the oncology clinic and another two-week delay before treatment initiation in the era of neoadjuvant chemotherapy for PDAC.[26] Palliative care has traditionally been delivered after oncologic care initiation, usually late in the course of disease, to patients who are hospitalized units or as a consultative service for patients with uncontrolled symptoms.[27, 28] Since palliative care interventions are typically initiated after establishing care with Oncology, patients' symptom burden and lower QoL are not addressed during these delays in care initiation.

Hispanic patients have very different perspectives than non-Hispanic Whites regarding end-of-life care. Focus groups identified that cultural values of denial, secrecy about prognosis, and a collectivistic, family-centered system influenced Hispanic treatment and hospice decisions, while Non-Hispanic Whites valued more direct discussions.[29] Furthermore, 85% of Hispanic patients with terminal cancer, expressed that their cancer was not terminal and that ACP was unnecessary. They also expressed that communication should involve their family to be effective. Prior studies have not explored the perspectives of Hispanic patients with PDAC. Important cultural differences in approaching terminal cancer and death among Hispanics highlight the need for culturally sensitive patient interventions, including the importance of familial caregivers in communication.

Community health workers (CHWs) are frontline, public health workers who are trusted members of the community served.[30] They bridge the gap between individuals and healthcare systems. Interventions facilitated by CHWs (promotores in Hispanic communities) have improved cancer screening and diagnosis rates, particularly in racial and ethnic minorities.[31] In patients with metastatic cancers receiving treatment, CHW-led interventions focused on ACP reduced acute care costs and improved palliative care engagement.[32] However, this study included a small number of PDAC and Hispanic patients. While CHWs represent a promising workforce for engaging patients, it is unclear if they can address HRQoL and low rates of early palliative care engagement among Hispanic PDAC patients.

b. **Rationale**

Specific Aim: To evaluate the preliminary efficacy of our digitally enhanced CHW-led intervention in newly diagnosed PDAC with a pilot randomized controlled trial of 60 PDAC patients comparing the intervention to usual care with attention control.

Hypothesis H1: Compared to usual care with attention control, the digitally enhanced CHW-led intervention is expected to decrease NCCN-FACT Hepatobiliary-Pancreatic Symptom Indexscores and improve HRQoL compared to baseline.

c. **Endpoints**

The primary endpoint will be change in the symptom burden, measured by the NCCN-FACT Hepatobiliary-Pancreatic Symptom Index and quality of life, measured by the FACT-HEP instrument.

Secondary endpoints include the change in the PCAS-9, ACP Engagement Survey, and ACP completion rates Other secondary outcomes include direct healthcare costs, ER/urgent care utilization, and response/usage rates to the SMS questions.

d. **Overall study design**

This will be a pilot randomized controlled trial where we will plan on randomizing patients with PDAC in a 1:1 fashion to receive a digitally-enhanced community health worker intervention that will involve visits with the CHW and digital communication to facilitate care navigation and provide early palliative care engagement or usual care with attention control.

e. **Study Procedures and Schedule**

Recruitment of subjects for the study

To recruit patients for the interviews, we will screen all of the patients who present for endoscopic ultrasound (with biopsy) to the endoscopy unit or pre-procedure clinic at Loma Linda, as well as patients referred to the medical or surgical oncology clinics with a new diagnosis of pancreatic adenocarcinoma. We will recruit patients from our gastroenterology clinic and endoscopic unit and the oncology clinic (the researcher's patients) both in person and over the phone via a telephone call. We will not contact patients outside our clinical practice but will distribute an IRB-approved flyer with our number to oncology clinics that patients can call and leave a voicemail or email us at our secure HIPPA-complaint Loma Linda email address assigned to our study (cancerresearch@llu.edu). We will also distribute an IRB-approved letter to other oncologists informing them of the study so they can distribute the flyer to their patients and inform patients who may be candidates for this study. The reason we are including patients with suspected PDAC is to eliminate delays once they receive a diagnosis as patients previously reported a flurry of medical visits in the 2 weeks after diagnosis. However, patients will need to undergo a biopsy and have pathology confirmation before study initiation. Patients found to have other pathology on biopsy than pancreatic adenocarcinoma will be excluded. We will explain the study inperson

or over the phone when they are referred for a pancreatic biopsy or for oncologic care for a new diagnosis of pancreatic cancer. We will explain that we are recruiting them because they have pancreatic cancer and want to study if a community health worker can help patients like themselves navigate care and engage with palliative care better than the current care that patients receive. If they are interested, they will then be consented using written informed consent at their clinic visit in the clinic or prior to their in-person study visit.

When a patient is diagnosed with PDAC, they receive the diagnosis over the phone and follow-up in clinic. They are referred to medical and surgical oncology and to palliative care for supportive care..

Study Intervention

Usual Care consists as follows:
An attention control where patients are provided handouts from PANCAN and videos from the NPF and study staff contact them monthly over video to administer the surveys for the outcomes but also answer any questions.
After a PDAC diagnosis is made, referrals are made to Medical and Surgical Oncology and Palliative Care, and the patient follows up in the Gastroenterology clinic to discuss the diagnosis and related symptoms. Baseline surveys will be completed at the time of enrollment in both the usual care and CHW-led intervention arms.

The CHW-led intervention arm will receive the same care/referrals as usual care but in addition work with a CHW as follows:

The study visits will take place in person in the clinic, School of Behavioral Health conference room, or the patient's home or virtually using Microsoft Zoom (depending on the patient's preference).

Randomization

The intervention each patient will receive will be randomized using a uniform random number generator (https://www.randomize.net/) with stratification by either metastatic PDAC or resectable/borderline resectable PDAC.

2 PANCREATIC CANCER CHW INTERVENTION

I. PRESURVEY AND INTRODUCE PATIENTS TO DIGITAL APPLICATIONS

When? Within 7 days of diagnosis
Setting: in person or by phone. Format: 1 on 1 or in small groups
Duration: 1 hr.
Goal: Administer surveys before the intervention and introduce patients to the Twillio-SMS and educational videos.

II. SESSION 1. Basic information and emotional resources

Goal: To develop trust and address immediate reactions/needs

When? During week 2

Setting: In-person ideally or over Zoom if preferred by the patient. Involves the patient and their caregiver.

Duration: 60-120 minutes

A. MEDICAL INFORMATION

1. Provide basic information and prognosis about pancreatic cancer – types, stages, procedures and treatment options (surgery, chemotherapy by mouth or IV, radiotherapy, experimental?)
2. Discuss patient and caregiver(s) expectations and possible physical challenges over the next weeks
3. Discuss support at home during and after visits to the clinic or treatments
4. Nutritional advice specific to patients following pancreatic cancer treatment plan
5. Recommended physical activity / physiotherapist according to the patient's Abilities

B. EMOTIONAL AND MENTAL HEALTH:

1. Tips to address new cancer diagnosis
2. Tips to adapt everyday life to the reality of pancreatic cancer and f/up
3. How to face inability to engage in more physical activity (for those that were used to exercise frequently)
4. Share with patient and caregiver(s) possible emotional and spiritual needs over the next weeks
5. Discuss support at home during and after visits to the clinic or treatments
6. How to talk to Friends and family members about your diagnosis
7. Asking for help
8. Reconnecting strained relationships (family, friends, spiritual)

9. Recognizing and and managing anxiety, depression and stress (mindfulness, meditation, relaxation techniques)
10. Tips to developing a positive and resilient approach to life
11. Professional psychological support (individual or family therapy)

C. REVIEW OF TWILLIO AND DOCOLA APPS USE

D. Palliative care and other resources

- Connecting with palliative team
- Caregiver selection
- Intro to Support groups
  - LLUC support groups for caregivers meet on Sundays (English only)
  - California Caregiver Resource Center online and in person.
  - Identifying meaningful new skills, hobbies, social activities

III. SESSION 2. Practical resources and addressing new questions

Goal: win trust and address immediate reactions/needs
When? During week 3 (*or week 4 if intervention is 3 months long)*
Setting: In-person ideally or over Zoom if preferred by the patient. Involves the patient and their caregiver.
Duration: 60-120 minutes

A. MEDICATIONS AND SIDE EFFECTS

1. Information and management of side effects.
2. Meds and tips information based on patient needs
3. Importance of adhering to treatment?

B. LEGAL DOCUMENTS

1. Patient rights and legal help
2. Other available resources and services
3. Advance Directives and other legal documents: health insurance and coverage, how to appeal or submit applications, how to request supplies, tools and durable mobile equipment

C. Palliative care (continued)

D. PRACTICAL SKILLS/WORKSHOPS

1. Tips to reduce the time burden (too many MDs?/appts?) with MyChart or other tools
2. Complementary therapies: massage, aromatherapy, music, art therapy, etc….
3. Cooking classes and recipes.
4. Physical activities: yoga, Tai chi or other easy exercises

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IV. TELEHEALTH VISIT with resource person of choice (facilitated by CHWs).

Goal: provide customized resources based on patients' needs

When? During week 3-6

Setting: In groups (online or in-person?) patients and caregiver(s)

Duration: 1 hr

(Optional) According to patients' desires or interests, information can be provided about end of life plans (community resources, estate planning, finances, funeral homes, funeral services, etc..)

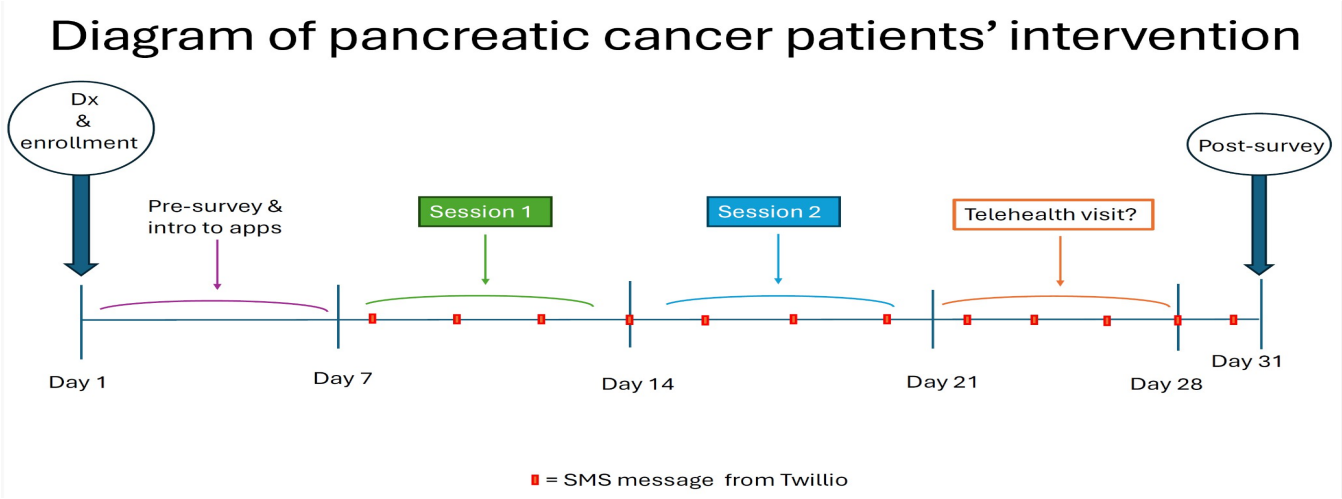
V. FOLLOW-UP PERIOD – patients and caregivers (*if program lasts 3 months*)

Goal: CHWs weekly calls providing help to problem solve & provide support and if needed can meet the patient in person.

When? During weeks 7 to 12

Setting: Telephone and if needed virtual or in-person.

Duration: varie



Use of Digital Applications

Patients will be provided access to web-based educational modules through Docola and Youtube that provide general information about pancreatic cancer, palliative care, and treatment options.

In between the study visits, the patients will receive the Edmonton Symptom Assessment Scale via Twillio-RedCap SMS once a week (an integrated short message system platform in Loma Linda's implementation of RedCap). A positive ESAS is defined as three symptoms with > 7/10 scores. If the CHW receives a positive ESAS, they will call the patient to ask how they are doing and then forward the responses to the Palliative care team, which will triage the patient as needed clinically to respond to these symptoms. The CHW will also ask the patient if they have questions or concerns twice a week using Twillio-RedCap SMS messages.

f. **Alternative procedures**.

There are no alternative procedures.

8. INCLUSION / EXCLUSION CRITERIA

Inclusion criteria:

- Age 18 to 90
- English or Spanish-Speaking
- Diagnosed with Newly-Diagnosed Pancreatic Adenocarcinoma or has a pancreatic mass on CT/MRI with suspected PDAC and is awaiting biopsy.
- Able to communicate verbally to allow for audio recording to complete an exit-interview
- Must be able to consent

Exclusion criteria:

- Biopsy Does not Confirm Adenocarcinoma of the Pancreas

9. RECRUITMENT AND RETENTION

Dr. Thiruvengadam and the clinical research coordinator (who will be hired and then added to the IRB prior to starting the study) will recruit patients with suspected or newly diagnosed pancreatic cancer from the gastroenterology, oncology and surgical oncology clinics and endoscopy unit (the researcher's patients) No patients outside of the researcher's clinical practice will be contacted regarding the study unless they contact the study investigators first when responding to the study flyer. Pancreatic cancer is diagnosed by endoscopic ultrasound, and patients have a pre-procedure and post-procedure visit where the diagnosis is given and discussed with the patient, and referral to oncology, etc., are made. This is the setting where patients will be included.

Recruitment Method: Study investigators will recruit patients from the endoscopy unit or clinic after a patient is referred with suspected pancreatic cancer or confirmed pancreatic cancer. This method involves recruiting the researcher's own patients.

We will also distribute IRB-approved letters to community oncologists along with an IRB-approved flyer that can be provided to patients which contains a phone number and email that the patient can use to contact the study team. If a patient contacts us expressing interest, then we will recruit them over the phone and then enroll them in the study after obtaining consent.

10. INFORMED CONSENT PROCESS

Prior to conducting any study-related activities, written informed consent or electronic informed consent using the MyChart platform will be obtained from the patient either in the clinic, endoscopy unit or prior to the first study visit. The patient will be provided with a signed and dated copy of the informed consent form.

Dr. Thiruvengadam, Dr. Joachim-Celeste, Dr. Montgomery or the clinical research coordinator (who will be hired and then added to the IRB before starting the study) will be responsible for obtaining consent. First the study will be explained to the patient along with its risks and benefits when the patient is first contacted in the clinic or endoscopy unit. After the patient has had any questions answered, if they agree to participate, consent will be obtained in the clinic or endoscopy unit or in the conference room prior to an in-person interview or small focus group.

Authorization for HIPAA will also be obtained as part of the intervention is communicating with the patients medical team and study data may be shared with the Sponsor (DOD/CDMRP).

11. SCREENING

Screening procedures will be performed in the seven days prior to enrollment for the researcher's own patients and occur as the investigator reviews the patient's chart to perform a clinical visit to inform or obtain the diagnosis of pancreatic

adenocarcinoma. We will not screen any patients not under the care of the study investigators.

If any patients outside of our care are interested in the study and contact us via phone or email, we will only screen them for the study after they are consented with HIPAA authorization obtained and if they meet the inclusion criteria, at that point they will be enrolled.

12. POTENTIAL RISKS

- Anxiety or stress related to talking about pancreatic adenocarcinoma.
- Loss of confidentiality.

To mitigate the risk of anxiety and stress, we will let patients guide the conversation with the CHWs so that they can redirect the conversation and what resources they want based on their anxiety/stress level or if some topic is difficult for them to talk about. We also will have their palliative care provider engage with them if they experience any anxiety or stress.

To mitigate the loss of confidentiality, we will de-identify all study documents except the informed consent document (which will be stored either electronically in LLEAP or in a secure locked drawer in the office of Dr. Thiruvengadam). We will use a unique patient ID number on all other study documents. All protected health information collected will be securely stored in an encrypted LLU computer and will not be shared with anyone electronically. Any paper records will be stored in the same locked drawer in Dr. Thiruvengadam's office at LLU.

13. POTENTIAL BENEFIT(S)

Patients assigned to the CHW intervention may benefit from it as community health workers are providing care navigation and connecting patients to resources that they may need.

14. SUBJECT WITHDRAWAL OR TERMINATION

At any time before or after the interview or focus group, a patient may withdraw participation, and their transcribed and recorded interview will be destroyed.

15. COMPENSATION

We will provide $10 Amazon gift cards to compensate patients for their time in participating in each study visit. They will receive this gift card regardless of how much of the interview/focus group they complete.

16. CONFIDENTIALITY AND PRIVACY

The primary way we will maintain confidentiality and privacy is by not including any identifying information on any study documents except for the informed consent document (which will be stored either electronically in LLEAP or in a secure locked drawer in the office of Dr. Thiruvengadam). We will use a unique patient ID number on

all other study documents. All protected health information collected will be securely stored in an encrypted LLU computer and will not be shared with anyone electronically. Any paper records will be stored in the same locked drawer in Dr. Thiruvengadam's office at LLU. All research data will be on a secure, encrypted LLU computer and will not be transmitted or shared with anyone else.

17. DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data Collection

We will collect baseline demographics data (age, gender, race/ethnicity, date of diagnosis, stage of diagnosis, and treatments) from the patient's chart. We will also administer the following surveys before the first study visit, at 4 weeks and 3 months.

•FACT-HEP (measures HRQoL) - 30 questions
NCCN-FACT Hepatobiliary-Pancreatic Symptom Index – 18 questions
Palliative Care Attitude Survey (PCAS-9) – 9 questions
ACP (Advanced care planning engagement) survey – 4 questions
Acceptability of intervention measure (AIM) survey – 4 questions
Technology Comfort (our survey) – 12 questions

Storage

At the time of patient enrollment each patient will be given a unique identification number. The key that corelates the unique identification number will be stored on a secure encrypted computer at Loma Linda. Apart from the informed consent, all other documents will not have any patient information written on them. They will only have the unique identification number.

RedCap will be used to store all the study data for this study. As described above this data is deidentified and the RedCap ID serves as the unique identification number. After the patient fills out the paper version of the questionnaire the data will be entered in RedCap by a study investigator and then those paper form which do not contain any identifiable information will be shredded.

Then after the data collection is completely entirely for all patients and the study is completed, we will destroy the electronic copy correlating names to keys which was stored on a secure computer at Loma Linda. At this point all the study data will be deidentified and stored in RedCap. When the study analysis is completed then all the data will be deleted from the computer.

Record Retention

Records of data generated in the course of this study will be de-identified and will be kept for at least 6 years and then destroyed. Prior to destruction, data can be used for other IRB approved research.

18. STATISTICAL ANALYSIS

Quantitative Analysis. We will first determine the distribution of the primary and secondary outcomes for the usual care and CHW arms by using a Shapiro–Wilk test to assess the normality for these outcomes. Then accordingly we will report either a mean (standard deviation) or a median (95% confidence interval) for both arms for the NCCN-FACT Hepatobiliary-Pancreatic Symptom Index and FACT-Hep scores and then use the standard deviation or variance for the power analyses for a larger definitive subsequent RCT. We will also use a t-test and Wilcoxon rank-sum test to compare the differences between these measures between the two groups at different time points. To assess a preliminary pre/post effect, we will compare survey data between baseline and 4 weeks using generalized linear models to compute contrasts for continuous variables from the FACT-Hep subscores, NCCN-FCAT HPBSI, PCAS-9, and ACP Engagement Survey scores.

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