PROTOCOL TITLE:

Videos for Advance Care Planning in Young Adults

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Role of the Protocol Contributor:

Angelo Volandes at Massachusetts General Hospital (MGH) will serve as a protocol contributor to this study. He will assist the investigators with protocol development and analyses but will only receive de-identified data. Dr. Volandes is a co-founder of and receives income from ACP Decisions Nous, a nonprofit organization developing the advanced care planning video decision support tools being evaluated in this study. Dr. Volandes' financial interests have been reviewed and are managed by Massachusetts General Hospital and Partners HealthCare in accordance with their conflict of interest policies.

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1.0 Objectives

The Institute of Medicine report "Dying in America" called for the development of interventions to increase effective advance care planning (ACP) and shared decision making among adolescent and young adult (AYA) patients.(1-3) Such interventions aim to help AYAs and their caregivers discuss goals of care together to make sure patients receive medical care "consistent with their values, goals, and informed preferences."(1, 2) Communication surrounding preferences and goals of care and subsequent decision making is formalized in ACP, a process involving the provision of verbal or written information informing individuals about possible medical options such as cardiopulmonary resuscitation (CPR) or mechanical ventilation.(4-6) However, this ACP process is often inadequate as it is presently conducted, particularly for AYAs.(7-10)

Our research group has developed and studied video decision aids to assist patients with advanced cancer and their caregivers in making important decisions about their medical care.(11-25) Video can improve decision-making by providing visual information to present complex medical and emotional scenarios; a growing body of evidence supports the feasibility and effectiveness of using video aids in medical decision making.(2) Video enhances patients' and caregivers' understanding of complex health information by providing realistic visual images that can facilitate their education about hospitalizations, intensive care unit (ICU) admissions, and medical procedures, leading to greater concordance of preferences between patients and caregivers and improved caregiver outcomes in bereavement. Our work has shown that among adult patients, these videos can educate patients and family caregivers about their care options more effectively than verbal-only explanations, enhance their knowledge about medical interventions, and improve patient-caregiver concordance.(11-25)

We have developed a video decision aid for AYAs and their caregivers that reviews treatment options and begins to discuss goals and preferences for their care. The overall objective of this study is to conduct a randomized controlled trial of the video (vs. usual care) in 50 dyads of AYA with advanced cancer and their caregivers. Our hypothesis is that the video better informs patients and caregivers of their options, leads to more ACP conversations, engagement and documentation, and leads to more congruent decision making between AYA and caregivers (primary outcome). Demonstrating the effectiveness of using a video aid in this pilot provides evidence for conducting a larger trial integrating such a video into clinical practice. The

Specific Aims are:

Aim 1: To compare knowledge, preferences and decisional conflict among 50 dyads of AYA with advanced cancer and their caregivers randomly assigned to one of two ACP modalities: 1. The newly created video depicting various goals of care (intervention, 25 dyads), or 2. usual care (control, 25 dyads).

Hypothesis H1a: Patients and caregivers randomized to the video will have higher congruence of preferences between patient and caregiver dyads compared to dyads in the control group (primary outcome). H1b: Those randomized to the video group will have

higher knowledge, fewer preferences for life-prolonging interventions and lower decisional conflict than those randomized to the control group.

Aim 2: To compare ACP conversations between patients with their health care team and caregivers, and ACP documentation between intervention and control dyads. H2: Patients randomized to the video will have more ACP conversations and higher levels of engagement, and more ACP documentation after 3 months.

2.0 Background

AYA oncology patients often receive intensive medical services at the end of life (EOL).(26-28) Compared to younger children, AYA oncology patients have higher rates of hospitalization, more frequent ICU admissions, and receive more chemotherapy treatments during the last 30 days of life.(27, 28) To date, the majority of AYA cancer deaths occur in the hospital and minority race, Hispanic ethnicity, and hematological malignancy increased the odds of dying in the inpatient setting.(29) Palliative care has been associated with receipt of less intensive interventions at the EOL in hospitalized AYA patients with cancer, possibly due to the facilitation of greater AYA involvement in communication and decision-making.(26) A growing body of research suggests that AYA patients identified a spectrum of possible roles in medical decision-making, with the majority preferring an active role while still expressing a desire for parental presence in decision-making.(30) Fulfilling the roles of "good child" and "good patient" may impact AYA decision-making, adherence to medical treatment plans, and social interactions.(31) As a part of fulfilling these roles and in the absence of communication between patients and their caregivers around preferences and goals of care, AYAs may continue intensive therapies.(32, 33) ACP tools have been developed to facilitate ACP discussions between patients and their caregivers around preferences for care at the EOL,(32, 33) but these tools remain underutilized in the clinical setting. In the only randomized controlled trial of an ACP tool in AYA patients with cancer, patients randomized to receive the intervention (consisting of three, 1-hour family-centered ACP sessions and the Five Wishes tool), had statistically greater congruence to limit treatments in various clinical scenarios.

The lack of ACP is associated with greater use of intensive or burdensome interventions, more hospitalizations at the EOL, lower palliative care use, and worse family bereavement outcomes.(34-38) Unfortunately, ACP communication between AYA and their caregivers remains inadequate.(2) For the ACP process to lead to optimal decisions, AYA and caregivers require engaging, accurate, impartial and comprehensible information about treatment options, and a care setting where communication needs are addressed early in their illness.(39-42) However, studies show that traditional written and verbal ACP do not effectively engage or inform patients and their caregivers.(2) Patient understanding may also be clouded due to developmental needs and stage, psychological distress, and the inability to realistically envision accurate future health states.

The traditional approach to ACP, which primarily relies on *ad hoc* verbal descriptions of hypothetical clinical situations and treatment choices, is limited because complex scenarios are difficult for AYAs and caregivers to envision, clinician information is inconsistent, and verbal explanations are hampered by literacy, emotional and language barriers.(41, 43, 44) Over the past few years, investigators have recognized the shortcomings of prior efforts and have developed new interventions to better facilitate ACP in adult patients.(11-15, 17-23, 25, 45-47) The video intervention proposed for this study focuses on treatments for AYAs with advanced cancer. Video decisions aids to better educate and inform decision-making are commonly used. To the best of our knowledge, this is the first use of an ACP video decision aid in AYAs.

For AYAs and their caregivers to have informed ACP conversations about patient preferences, both patients and caregivers need accurate information presented in a standardized and easy to understand manner. Presently, clinicians do not provide any routine or standardized information about goals of care to AYAs or caregivers. AYAs and their caregivers often receive intensive interventions as a default option, without a shared decision-making conversation or awareness of different treatment options or blended goals of care. Poor ACP and communication about AYA preferences for end-of-life care contribute substantially to the receipt of intensive medical care and possibly increased suffering at the EOL. Therefore, improving ACP with a standardized video decision aid that accurately informs AYAs and their caregivers about ACP decisions may prove to be an effective strategy to enhance the delivery and quality of medical care for AYAs with advanced cancer and their caregivers. ACP video tools have shown promising efficacy in educating patients and caregivers about their options and informing their preferences for care. This study has the potential to improve the concordance of AYAs and caregiver preferences leading to better shared decision making and ultimately the delivery of AYA-centered care that is consistent with the patient's values.

Preliminary Studies in cancer: Over the last decade, the research team has focused on improving decision making for persons with serious illness by creating and studying innovative decision aids. The work cited below demonstrates the research team's experience, commitment, and ability to use effectively a wide array of clinical research methods to design, administer, and complete projects focused on serious illness.

The first video our team produced was a 5-minute decision aid depicting the goals of care for adults with cancer.(20) In a randomized controlled trial, patients with advanced cancer were randomized to either listen to a verbal description of the goals of care (N=27) or view the video decision aid (N=27), and then asked the level of care they would want. The three levels of care included: life-prolonging care (hospitalization, intensive care unit); limited care (hospitalization but no ICU); or, comfort care (symptom relief only). We also assessed uncertainty regarding decision making using the Decisional Conflict Scale with scores ranging from 3 (high uncertainty) to 15 (no uncertainty). End points were the selected goal of care in each arm of the study, uncertainty in decision making, and comfort viewing the video. Patients in the video arm (vs. control) were more likely to opt for comfort care, were more informed, and more certain of their decision. Among patients receiving the verbal narrative, 26% desired life-prolonging care, 52%

chose limited care, and 22% preferred comfort care. In the video group, none desired life-prolonging care, 4% chose limited care, 92% preferred comfort care, and, 4% were uncertain ($P < 0.001$). Participants in the video group had less uncertainty (mean uncertainty score, 13.7; [95% CI, 12.8 to 14.6]; $P = 0.002$) compared to participants randomized to the verbal group (mean uncertainty score, 11.5; [95% CI, 10.5 to 12.6]). Of the patients randomized to the video group, 82% felt "very comfortable" watching the video, and 82% would "definitely recommend" the video to other patients. Based on this work, the research team completed a larger NCI trial that was published in the *Journal of Clinical Oncology* and presented as an oral abstract at ASCO.(15) Dr. Volandes is leading a larger trial of this video decision aid in 4,500 patients with advanced cancer along with the adult palliative care team at Dana Farber Cancer Institute.

Overview of the Trial: This study is a randomized trial of the video in 50 AYAs with advanced cancer and their caregivers that will assess preferences for care in advanced cancer and concordance rate of preferences between dyad. We will randomly assign dyads to one of two ACP modalities: 1. the ACP video decision aid (intervention), or 2. Usual care. Patients' and caregivers' knowledge, preferences (goals of care, CPR, ventilation), and decisional conflict be assessed before and after exposure to the video or control ACP modality. Telephone-based interviews will be conducted at 3 months to assess patients' and caregivers' preferences, ACP conversations with caregivers and clinicians, and the medical record will be queried to examine ACP documentation. The primary outcome is AYA and caregiver concordance regarding treatment preferences for advanced cancer (Aim 1). Secondary outcomes include knowledge, preferences, decisional conflict, and ACP engagement (Aims 1 and 2). We will also explore the stability of preferences, presence of ACP conversations and documentation after 3 months (Aim 2). **We hypothesize that the video decision aid better informs patients and their caregivers and leads to more informed decision making.**

3.0 Inclusion and Exclusion Criteria

Subject Enrollment: All patients will be recruited from the outpatient clinics of Dana-Farber Cancer Institute (both pediatric and adult clinics),the inpatient settings of Boston Children's Hospital and Brigham and Women's Hospital, the inpatient or outpatient clinics of Massachusetts General Hospital, or virtually. Eligible study participants will give written consent to the primary investigator or study staff member before initiation of study procedures if recruited in-person. If participants are enrolled and complete study procedures virtually, they will provide verbal consent before initiating study procedures.

If in-person visits cannot be conducted, eligible participants will be still be mailed a pre-notice letter (Appendix B) that offers the chance for participants to opt-out or opt-in via email or phone call. After one week, we will call participants we have not heard from and ask if they would consider participating.

Patient Eligibility criteria will include patients who are:

i) Diagnosed with advanced cancer (i.e., initial first-line therapy is unsuccessful, marked by progression or relapsed disease)
ii) Aged between 18-39, which is the legal age for completing an ACP document (e.g., POLST/MOLST);
iii) Speak English; and
iv) Have a caregiver or identified surrogate decision maker who is able to participate.
~~iv)~~v) Treated at Dana-Farber Cancer Institute or Massachusetts General Hospital

Exclusion criteria will include:

i) A diagnosis of low-grade glioma given the fact that progressive or relapsed low grade may not be clinically characterized as advanced disease and associated poor prognosis.
ii) Visually impaired (note, hearing impaired is not an exclusion as the video is closed captioned);
iii) Psychological state not appropriate for ACP discussions as determined by the primary oncologist; and,
iv) Unable to participate in ACP discussions due to mental incapacity as determined by the Short Portable Mental Status Questionnaire(48).

Eligible patient participants will be asked to self-identify one caregiver or surrogate decision-maker that will also be approached for enrollment.

Caregiver eligibility criteria include:

(i) Speak English;
(ii) Aged 18 or older,
(iii) Not visually impaired, and
(iv) Have an associated patient with advancer cancer who is able to participate.

Only dyads will be enrolled, both patient and caregiver must consent to participation in the study.

4.0 Number and Selection of Subjects

We will conduct a pilot trial in 50 AYA with advanced cancer and their caregivers who will be randomized as dyads to either the video (intervention) or usual care (control). No exclusions by sex will be made.

Given the linguistic limitations of study personnel and materials (English-speaking only) who will be conducting structured interviews, the current study is limited to English-speaking patients only.

5.0 Study-Wide Recruitment Methods

5.1 Training of RAs

Each research assistant (RA) who works on the study will thoroughly review the protocol. Prior to approaching potential participants, the RA will be required to complete a practice consent with the study PI to ensure study procedures are being followed. The RA as well as associated personnel will complete the respective CITI training. In addition, all study staff will be familiar with the DF/HCC Operations and Policies library. In addition to the training mentioned above, new staff will observe a minimum of one consent led by the current RA.

5.2 Subject Recruitment

Participant recruitment: Potential participants will be identified by reviewing the monthly census for AYA with advanced cancer who meet our eligibility criteria from the inpatient and outpatient clinics. Additionally, information about this research study along with the study team's contact information may be included in patient-facing materials (i.e., the young adult program (YAP) newsletter, YAP phone app, fliers in waiting rooms, etc.) to help spread awareness and better identify eligible participants. If an interested patient and or family reaches out to the study team after hearing or reading about our study, we will inform the AYA that we will check to make sure they are eligible and their medical team believes it is appropriate for them to participate. The RA will then confirm the patient's eligibility and still afford the oncologist 72 hours (3 business AYAs) to opt their patient out of the study. Once a potential participant is identified from observing clinic lists, an email will be sent to the oncologist to seek permission to present the study to the patient. The email will detail information about the study, including eligibility and outlined protocol *(Appendix A*). The oncologist will have 72 hours (3 business days) to opt-out of their patient being approached. Three days will be a sufficient amount of time for providers to reply while not obstructing the progress of our study and is a similar timeframe used in other clinical studies by our research team using an opt-out approach. We may also ask providers if they have any patients that are eligible and would be good candidates for this study as a way to increase our eligible pool. The patient and caregiver will then be mailed a letter outlining the study. The letter will explain the goals of the study and inform the patients that a RA from DFCI will try to approach them at their next clinic visit *(Appendix* B) or over the phone. This letter includes the email address of the RA for this study and an option for patients to opt-out of being approached or called. All mailings, phone-based approaches, and consent meetings will be conducted by the research team at Dana-Farber.

If in-person enrollment cannot be conducted, eligible participants will still be mailed a pre-notice letter (Appendix B) that offers the chance for participants to opt-out or opt-in via email. After one week, we will call participants we have not heard from using and ask if they would consider participating. If there is no answer, the study team may leave a voicemail without identifying information but that includes a call-back number to contact

a study team member. For interested participants, we will email them a consent form and given the opportunity for them to read the form, ask questions, and consider participating. The research assistant will inform participants of an overview of the study, risks, and benefits, and the RA will also ask if participants wish to go through each section of the consent form together. If there are no further questions and the individual wishes to participate, the RA will ask for verbal consent. Following, the RA will document in the study team's tracking log the date of consent, where it occurred (zoom, phone call), and any important notes. If a dyad enrolls, we will set up a time for the study procedures to be completed via DFCI Zoom, which is HIPPA compliant. The Zoom meetings will be password protected and set up at a time that is convenient for the participant.

The RA will verify the ability of the patient and caregiver to provide consent by explaining the study and having the patient repeat (teach-back) the aims and risks. The clinical staff will not play any role in asking the patient to participate to minimize any coercion. However, the patient and caregiver may ask their clinician for additional details about the study.

Each study participant will receive a $20.00 gift card after the initial items are completed and a second $10.00 gift card for completing the follow-up interview 3 months later. Study visits will be coordinated to coincide with regularly scheduled clinical visits or lab draws to reduce out-of-pocket expenses.

6.0 Study Timelines

Participants enrollment in the study will last the course of 3 months with one in-person study visit and one phone-based interview. The study entails a one-time 30-40 minute in-person visit or over Zoom where participants will be randomized to the video aid intervention or information sheet control. Around three months following this initial visit, participants will complete a 5-10 minute follow-up phone-based interview. This follow-up interview will be audio recorded with the participants' knowledge and transcribed for analysis. Participants will have consented to be audio recorded during the informed consent process. All recordings will be de-identified. Given the number of AYA patients typically treated at this institution, we anticipate the study to span 2 years, including 3-month data collection tools preparation and survey training, 16 months rolling recruitment, surveying, and 3-month follow-up, 2 months data cleaning, analysis, and manuscript preparation. This timeline will continue to be updated given changes to recruitment/enrollment strategies in the setting of COVID-19.

7.0 Procedures Involved

Study design, randomization, intervention, and control arm: We will conduct a randomized controlled trial in 50 AYA with advanced cancer and their caregivers who

will be randomized as dyads to either the video (intervention) or usual care (control) (Figure 1). After enrollment, we will collect the following information from the caregiver: full name, date of birth, zip code, and gender for the purposes of reporting to the NCI and subject level registration.

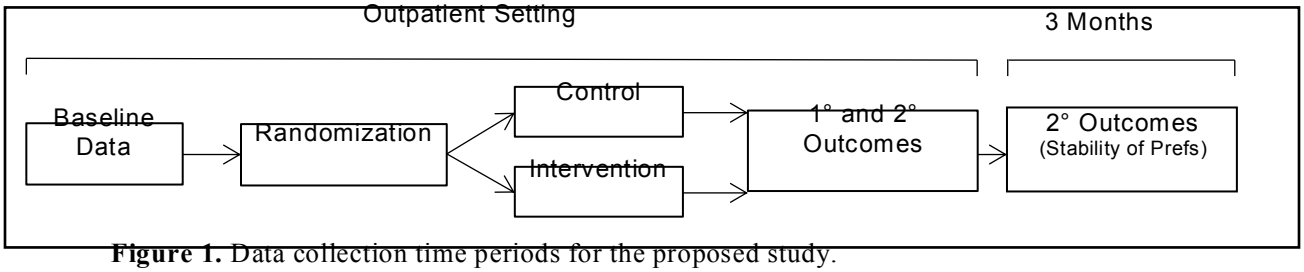

Figure 1. Data collection time periods for the proposed study.

The interview script for the encounter with participants is provided in Appendix C. Following completion of the pre-intervention questionnaire (Appendix D), the RA will provide a brief explanation of the three types of care (life-prolonging, selective, comfort) and the subjects will be randomized to intervention or usual care.
Patients and caregivers in the control group will only receive the verbal description of the three types of care (Appendix C, page 1).

Randomization: We will use a central, computer-generated simple randomization design stratified by race and ethnicity for even recruitment in both arms of the study.

Intervention: The intervention group will use the video decision aid describing the goals-of-care options. Patients and caregivers will review the video using an iPad and will have access to the video via a weblink to review the video on their own (Appendix E for video script, Appendix F for link to video). The development of the video followed a systematic approach, using an iterative process of reviews by oncologists, palliative care clinicians, AYA with advanced cancer and caregivers regarding the design, content, and structure of the video. The video decision aid was developed using the International Patient Decision Aid Standards with content that is intended to be objective and balanced.(49) It is scripted at a fourth-grade level of health literacy in English and has closed captioning (Appendix E). The video is available in English. The video is designed for AYAs with advanced cancer and their caregivers making future decisions. The goal of the decision aid is to use decision science to structure the decision in a way that support's the person's ability to make reasoned decisions by considering: 1). accurate information about each option; 2). the risks and benefits of each alternative; 3). to evaluate each choice within the context of their spiritual and emotional values, and their lifestyles; 4). to make a decision based on trade-offs among options; and, 5). to support ACP discussions with caregivers and clinicians about values, lifestyle, and medical history.

The video is narrated by an AYA who opens with an empathic statement regarding the situation any AYA finds themselves in. Then, there is a transition to contemplating what

the future might hold and decisions about medical care and introducing the concept of ACP. There is acknowledgment that these can often be difficult decisions and that the presence of caregivers often helps. There is an explicit statement regarding values and spiritual beliefs and how that might impact decision making. The video then attempts to translate the preceding conversation into actionable medical orders using the most common three-goal framework that is based on the MOLST paradigm: life-prolonging care (live as long as possible); selective care (live as long and as well as possible); and, and comfort care (live as comfortably as possible). The narrator then begins to describe the salient features of each of the three goals of care, reviewing the risks and benefits of each option, and then discussing the trade-offs among the three options. For each option, visual images illustrate the interventions (CPR, intubation, and hospice care) while discussing risks and benefits. The video was created using filming criteria formulated by this research team and used widely around the country.(50) The video was filmed without the use of prompts or stage directions (i.e., no actors; all real clinicians, patients, and caregivers) to convey a candid realism in the style known as cinema verite.(50, 51) At the conclusion of the video, each patient and caregiver in the intervention arm will receive a code to access the video at home and a printout version of the checklist (Appendix G)

Control arm: Patients and caregivers in the control group will only receive the verbal description of the three types of care (Appendix C, page 1).

Study staff will pull data from the patient's emergency medical record as a part of the baseline data collection and again after 3-month follow-up to determine ACP documentation.

8.0 Data Management and Confidentiality

~~**8.0**~~ The patient information sent by Massachusetts General Hospital (MGH) to Dana-Farber will be sent through a send secure email. No PHI will be sent to MGH.

Data elements of survey questionnaire: We are interested in studying the influence of the video compared to enhanced usual care on medical care options and concordance rate with 50 AYA with advanced cancer and their caregivers. To assess study outcomes, data will be collected, to the extent possible, using validated tools. Table 1 outlines the data elements that will be obtained from both patients and caregivers. The audio recording and de-identified transcripts will be stored in a stored location on a secured network only accessible to the study team. The audio recording and de-identified transcripts will be stored in a stored location on a secured network only accessible to the study team.

Sociodemographics: Data on sociodemographics will include age, gender, race, ethnicity, health insurance, education, marital status, religion, and religious attendance. (Appendix D, page 1-2, questions 1-8).

Preferences: Patients and caregivers will be asked for their goals-of-care preference (life-prolonging, selective, comfort, or Unsure), CPR preference (Yes, No, or Unsure), and ventilatory support (Yes, No, or Unsure) at baseline, and then again immediately after watching the video or reviewing the informational sheet (Appendix D, page 4, question 1-3; Appendix H, page 1, question 1-3) and then we will contact all patients after 3 months by telephone to ask for their preferences.(11, 13, 20) (Appendix I, page 2-3, question 1-3). We will also have an open-ended question for those patients who change their preferences from the initial post-video or control survey ("Can you explain why you have changed your preference from the one stated three months ago?"). AYAs and caregiver concordance of preferences (i.e., the same preference) is our primary outcome.

Knowledge: We will ask five true/false questions and one multiple choice question regarding knowledge of goals-of-care options which were used and validated in our previous studies.(11, 13, 20) (Appendix D, page 6; Appendix H, page 3).

Decisional conflict: We will measure decisional conflict, which attempts to measure uncertainty regarding decision making.(52) The Decision Conflict Scale is a well-validated and commonly used tool, we will use the 4-item SURE scale for ease of use and to reduce burden on the participant.(52) (Appendix D, bottom of page 4, questions 1-4; Appendix H, bottom of page 1, questions 1-4).

ACP engagement: We will ask four validated questions to patients only regarding ACP engagement (How ready are you to talk to your caregiver? To your doctor? To appoint a surrogate? To sign an ACP document?).(54) (Appendix D, page 4; Appendix H, page 2).

Comfort with the video: For those patients and caregivers randomized to the video, we will measure acceptability of the decision aid using four questions regarding comfort viewing the video, which we have validated in our prior work.(11, 13, 15, 17, 20-22, 25, 46) (Appendix H, page 4).

Additional outcomes: AYA-reported ACP conversations with caregivers and clinicians will be assessed after three months from baseline survey. Both patients and caregivers will be asked about ACP conversations (Appendix I, bottom of page 3).

Data collection protocol: Based on our prior work, data collection is estimated to take no longer than 40 minutes (10 minutes for informed consent and screening; 10 minutes for baseline assessment; 10 minutes for ACP modality; 10 minutes for immediate follow-up interview) and will be conducted in the outpatient setting. The relatively brief interviewing time (40 minutes) in which the survey is conducted should assure completion of the interview without burdening participants. We do not foresee the additional time to complete the survey to be a barrier to successful recruitment and completion of the protocol.

Participants will be provided written copies of the questions or the questions will be shared with them over zoom (using the “share screen” feature) in order to follow along

during the face-to-face or virtual interviews. The RA will collect baseline data, randomize patients and caregivers as a dyad to either the video or control arm via concealed envelopes, and administer the intervention. After this baseline interview and randomization, the RA will collect the remaining outcomes data regarding preferences, knowledge, and decisional uncertainty from both the patient and caregiver. For those participants randomized to the video intervention, they will also be asked questions regarding the usefulness of the video and their comfort with the video. If patients express interest in creating their own video, RA's may provide an information sheet to guide them through the process (Appendix J). Both patients and caregivers will be contacted at 3 months and assess their preferences and ACP conversations at that time. These phone-based interviews will be conducted independently to reduce influence on the outcome of concordance and will be audio recorded for later analysis.

Table 1: Data Element and Sources

Data Collected	Purpose	SOURCE				
		Tool	By Whom	From	When	Note
1. Eligibility screen						
Advanced Cancer	target sub-population identification, covariate		RA, PO	EHR	Daily	HIPAA waiver
Cognitive Assessment	screening	SPMSQ	RA	interview	Outpatient/Virtual	
2. Baseline Assessment						
Preferences	2º outcome		RA	interview	Outpatient/Virtual	
Knowledge	2º outcome		RA	interview	Outpatient/ Virtual	
Randomization followed by video intervention or enhanced usual care						
3. Post-video or informational sheet						
Preferences	2º outcome		RA	interview	Outpatient/ Virtual	
Preference concordance	1º outcome		RA	interview	Outpatient/ Virtual	
Knowledge	2º outcome		RA	interview	Outpatient/ Virtual	
Decisional conflict	2º outcome	DCS	RA	interview	Outpatient/ Virtual	
ACP engagement	2º outcome	ACPE	RA	interview	Outpatient/ Virtual	AYA only
Comfort with video	2º outcome		RA	interview	Outpatient/ Virtual	Video arm
4. Follow-up at 3 months						
Preferences	2º outcome		RA	telephone		
ACP conversations	2º outcome		RA	telephone		

KEY: RA: Research Assistant; PO: Primary Oncologist; EHR: Electronic Health Record; SPMSQ: Short Portable Mental Status Questionnaire; DCS: Decisional Conflict Scale; ACPE: Advance Care Planning Engagement Questionnaire.

DATA ANALYSES

Aim 1: ***H1:*** *AYA with advanced cancer and caregivers randomized to the video will have higher concordance between patients and caregivers (Primary Outcome), and more likely to have higher knowledge, make decisions for less burdensome care (i.e., limited or comfort care, no CPR, no ventilatory support), have lower decisional conflict, and engagement, than those randomized to the control group.* Preference concordance between patient and caregiver will be treated as a dichotomized variable and compared between the two study arms using a chi-square test. We will conduct separate analyses for patients and caregivers for secondary outcomes. Knowledge score, decision conflict scale, and ACP engagement will be considered as continuous variables. We will use two-sample t-tests or Wilcoxon rank sum tests, whichever more appropriate, to compare the distribution between the two study arms. Chi-square tests will be used to compare the proportion of patients/caregivers choosing less burdensome care between the two study arms. We will explore the effect of patient characteristics (age, sex, etc.) in choosing less invasive care using a logistic regression model. In this study, we will treat sex as self-reported gender and will conduct a sex-based analysis of intervention effects to explore sex as a biological variable. *Power analysis*: Assuming 50% of control arm achieve preference concordance between patients and caregivers, the study will have 80% power to detect a 41% difference (50% vs. 89%) in concordance. Assuming 68% of control patients/caregivers choose non-life prolonging care, the study will have 82% power to detect a 31% difference (68% vs. 99%) in preferences between the two arms. For the continuous outcomes (knowledge, decisional conflict, ACP engagement), the study will have 80% power to detect an effect size of 0.81 with 25 subjects per group.

Aim 2: ***H2.*** *Patients randomized to the video will have more ACP conversations and documentation after 3 months.* We will treat conversations and documentation as continuous variables. Assuming 50% of controls achieve ACP conversations/documentation between baseline and three-month follow-up, the study will have 81% power to detect a 27% difference (50% vs. 77%) between the two study arms.

Missing Data: We do not anticipate having substantial amounts of missing data on the initial survey; however, we expect some patients and caregivers to not complete the three-month follow-up surveys. The analyses will initially focus on the study completers (3 months) to estimate the effect of the video intervention on patients who completed the protocol as intended without imposing assumptions about missing data. We will also use the intention-to-treat principle, conducting sensitivity analyses to explore how various assumptions about missing data and differences between completers and non-completers affect the estimated outcomes. If data appear to be missing at random, we will employ multiple imputation methods,(55) maximum likelihood estimate approach with EM algorithm,(56) and mixed-effects modeling(57) that can adequately account for data missing at random. If we find that data are not missing at random, we will employ pattern

mixture modeling to handle incomplete data, and perform sensitivity analysis to assess the impact of missing data

9.0 Risks to Subjects

Limitations, potential problems, and alternative strategies: (1) We are limiting this study to English-speaking patients because our video is only available in this language presently. Should the study prove successful, we will adapt the video into other languages. (2) Another potential limitation we considered in developing this study proposal pertains to the lack of blinding of research investigators and clinicians to the intervention assignment, which may introduce bias. Blinding research staff to the intervention assignment is not practical and rarely accomplished in ACP trials. *We have implemented rigorous procedures to minimize the risk of bias.*

Subjects may feel uncomfortable while watching the video or during the interview. Subjects will always have the option of taking a break at any point during the study or not answering a question that may provoke anxiety or distress. Additionally, all subjects will also have the option of terminating the study at any point if feeling uncomfortable throughout the study.

Procedures to Minimize Risk: Subjects are informed that they may refuse to answer any questions if they wish and may choose to stop participating at any time. Effort is taken to identify and minimize the risk of emotional distress for study participants in a standardized fashion

10.0 Potential Benefits to Subjects

This project's results will investigate preferences that lead to decision-making in EOL care. AYAs and their caregivers may uniquely benefit from use of visual video technology to augment the ACP process. The minimal risk of potential psychological distress that may be provoked with discussing decision-making is clearly outweighed by the benefits and impact of this study's results.

11.0 Vulnerable Populations

Inclusion of Women and Minorities: This study does not focus on any race, ethnicity, or gender. No potential research subjects will be excluded from enrollment based on race, ethnic origin, or gender. Patients will be recruited from patients at DFCI/BCH/BWH that have advanced cancer and are expected to reflect the racial and ethnic diversity of this hospital-based population.

12.0 Setting

Research sites will include Dana-Farber/Boston Children's Hospital and Brigham and Women's Hospital as well as Massachusetts General Hospital.

13.0 Recruitment Methods

13.1 Patients will be recruited in the inpatient units, outpatient oncology clinics, or over the phone. The RA will approach or call the patient and ensure they have sufficient time to hear about the study and review the consent form if needed (Approach script, Appendix K). If potential participants are contacted virtually, the RA will call them up to three times approximately one week after the pre-notice letter is mailed. If the participant is interested, we will send them a consent form to review. Before the scheduled Zoom visit, we will ask if they have any questions and ask for verbal consent from the AYA.

13.2 Patients between the ages of 18-39 ~~0~~ on the inpatient and outpatient rosters of all sites will be screened on a regular basis, and additional potential participants will be identified through collaboration with the center for young adult oncology (CAYAO) and the Young Adult Program (YAP).

13.3 Information about the study and along with the study team's contact information may be included in patient-facing materials (newsletters, young adult program (YAP), ~~–~~ application, fliers) to help spread awareness and better identify eligible participants.

13.4 We may also ask providers if any of their patients would be good candidates for this study.

13.5 For any subject who is being seen in clinic on the day of screening or who is admitted to the oncology services and is between the ages of 18-39, the RA will open their record and review primary language, diagnosis, and disease status. These components will be noted in a tracking log with the patient's name, MRN, and date of birth. If the patient meets all eligibility requirements, an opt-out email will be sent to the primary oncology attending. If the oncologist has not responded within 72 hours or gives permission to approach, the RA will plan to approach the family. Additionally, the study team at DFCI will receive a list of eligible patients, who have passed the provider opt-out phase, from Massachusetts General Hospital for which the Dana-Farber staff will mail a letter to and approach for research participation.

13.6 The RA will plan to approach the patient at their next clinic appointment, or if they are inpatient, at their next available opportunity. If it is not possible to reach them in-person, the RA will

call them. Up to 3 attempts at contacting eligible participants will be made. They will be given a brief overview of the study.

13.7 Participants who complete all study materials will be given an $20 Amazon gift card. Participants that complete follow-up interview questions will receive an additional $10 Amazon gift card.

14.0 Consent Process

This study contains no more than minimal risk and written consent or verbal consent will be obtained from each study participant. Consent will be obtained by the RA in outpatient clinics, inpatients units at DFCI/BCH/BWH/MGH, or over the phone/Zzoom. Prior to explaining the study, the RA will ensure that the time and location are okay. Eligible patients will not be approached if the RA or provider considers them to be in a time of high stress. If inpatient, consent will be obtained in the patient's room. In the outpatient clinic, exam rooms, infusion suites, consult rooms, or quiet areas of the waiting area may be used. If the patient is interested in participating, consent may occur at the time of study introduction, or if they would like to take time to think about participating, a follow-up meeting will be scheduled. The RA will follow the processes outlined in "Policy: Informed Consent Process (CON-100)" to obtain informed consent (Appendix L).

We request a waiver of documentation of consent for participants that are accrued virtually because the study presents no more than minimal risk and all study procedures will be deidentified.

We also request a waiver of documentation of consent for oncology providers who participate given that their participations represent no more than minimal risk and their recordings/surveys will be deidentified.

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