The following protocol information is provided solely to describe how the authors conducted the research underlying the published report associated with the following article:

Randomized Controlled Trial of a Video Decision Support Tool for CPR Decision-Making in Advanced Cancer

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Data Supplement

A Pilot Study of Using Video Images in Advance Care Planning in Advanced Cancer

A. Selection of patients, eligibility and ineligibility criteria

This is a pilot prospective randomized study with a goal to enroll 150 subjects with established diagnosis of advanced cancer recruited from oncology clinics. These subjects will be randomly assigned to one of two ACP modalities:
1. A video visually presenting CPR after a verbal narrative (intervention) or
2. A verbal narrative describing CPR (control)

Subject recruitment:
The proposed study will be conducted at oncology clinics. Potential consecutive subjects will be identified by the oncologist at the time of their scheduled clinic visit. Only returning patients (i.e., not new consults) will be considered. Given the delicate nature of the study, the oncologist will decide whether the patient is a potentially appropriate subject based on their knowledge of the patient's clinical status, decision-making capacity, demeanor, and family involvement.

The specific eligibility criteria include:

1. A diagnosis of cancer that falls under one of the following:

    A. All patients with brain cancer, inoperable hepatocelluar/bile duct/gallbladder cancer, incurable non-small cell lung carcinoma (wet IIIb or IV), extensive stage small cell lung cancer, inoperable mesothelioma, inoperable pancreatic cancer or; metaststatic gastric or esophageal cancer, metastatic melanoma, *OR*

    B. Patients with the following cancers, if first-line therapy has failed and limited response is expected to second-line therapy: breast cancer, colorectal cancer, head and neck cancer, leukemia, ovarian cancer, prostate cancer, renal cancer, sarcoma, lung cancer, myeloma, or lymphoma, *OR*

    C. Less than one year prognosis

2. ability to provide informed consent,
3. cognitive ability to participate in the study, and
4. ability to communicate in English.

Patients who are unable to make decisions (as determined by the oncologist or RA), non-English speakers, and new patients will be excluded.

The potential subject will be given a flyer outlining the study and then he/she will be approached by the PI or RA at the conclusion of the scheduled appointment to further explain the study and obtain verbal informed consent. Ability to provide informed consent will be confirmed with the oncologist. The PI/RA is aware of the sensitivity of the recruitment of cancer patients and will verify the ability to provide consent by explaining the nature of the study and having the subject repeat the aims and risks of the study. If family members are with the patient, they will be involved in the decision to participate, although the subject will provide informed consent (i.e., according to eligibility criteria, subjects must have decision-making capacity).

B. Treatment plan and administration schedule

Subjects will be exposed to either the video after hearing a verbal description (intervention arm) or verbal description (control arm) once, at the same clinic visit immediately following consent.

Intervention arm : The three-minute digital video presents CPR, Intubation, IV medication administration, ICU care, and nursing care. CPR and Intubation are conducted on a simulator rather than a real patient. Images of a real patient on a ventilator in the ICU setting as well as a patient receiving IV medications are shown. A three-minute verbal narrative accompanies the video, and is the same verbal narrative that is used in the control arm of the study. The verbal narrative describes CPR. In its development, the video's design, content, and structure were reviewed for accuracy by oncologists, palliative care, and medical ethics experts. Consent to film the video and for its use in research was obtained from all the filmed patients and their families. The video will be shown to study participants on a portable computer.

Control arm: The aforementioned verbal narrative accompanying the video in the intervention arm will be used verbatim in the control arm, and will be read out loud to the subject by the PI or RA.

C. Rules for dose modification

N/A; "Dose modification' is not a possibility in this trial of a single exposure to a video.

D. Measurement of treatment effect including response criteria, definitions of response and survival, and methods of measurement

As described below, preferences for CPR will be established at baseline and then compared after exposure to the video after verbal description (intervention) or verbal description (control) ACP modalities. Subjects' knowledge regarding CPR will be ascertained and compared after exposure to the video (intervention) and verbal narrative (control) arms. Subject's stability of preferences after 6-8

weeks will also be obtained by telephone in the video (intervention) and verbal narrative (control) arms.

Data collection protocol: Data collection is estimated to take no longer than 30 minutes per patient (13 minute baseline interview, 3 minutes for the ACP modality, 13 minute follow-up interview) and will be conducted immediately following the scheduled oncology appointment. At that time, subjects will be brought to a separate private room where the PI or RA will obtain verbal informed consent and conduct the interview. All survey interviews will be conducted by the PI or RA in a structured script in each arm of the study. The RA will clarify any points made in the video or verbal narrative but there will be no open interactions. The PI/RA will read the structured script verbatim.

Before the subject is randomized to either the video or verbal narrative arm, a pre-interview (baseline) assessment will be conducted to obtain the following data: 1. self-reported socio-demographics (age, gender, race/ethnicity, education, marital status, religion, religious attendance and health status); 2. a pre-intervention knowledge assessment questionnaire, and 3. CPR preference.

After the PI or RA administers the pre-test assessment, all subjects will be read a verbal description of CPR. Subjects will then be randomized to either the video (intervention) or verbal narrative (control) arm of the study using a list generated by a computer randomization scheme. Randomization assignment will be placed in sealed envelopes. Those randomized to the video intervention will then see the video on a portable laptop.

Then, the identical 13 minute follow-up interview will be administered to subjects in both arms of the study. This follow-up interview will include the following components: 1. CPR preferences; 2. a post-intervention knowledge assessment questionnaire, and 3. comfort with the video (intervention arm only). A Likert question will also be included at the end of the interview to elicit the degree to which they felt comfortable experiencing the ACP modality and participating in this study. Health literacy will be assessed at the end of the interview using the Rapid Estimate of Adult Literacy in Medicine tool.

All subjects will be contacted by telephone 6-8 weeks after the survey to obtain their CPR preference again.

Data elements: To assess study outcomes, data will be collected, to the extent possible, using established and validated survey instruments and questionnaires with which the PI has experience from earlier studies.

1. CPR preferences:
   The patients will be asked to identify their preferences for CPR with the following question: If your cancer were very advanced and you were to get

so sick that your heart stopped beating, would you want doctors to shock your heart and do chest compressions as part of CPR to try to make your heart start again?

2. Knowledge Assessment:
We will be utilizing 3 True or False Questions and 1 multiple choice question to assess patients overall understanding of CPR options pre and post intervention.

3. Other variables:
Subjects will have demographic data obtained during the baseline interview including age, gender, race, ethnicity and marital status. We will also obtain level of education completed, religious affiliation and frequency attending services, family history of cancer, and self-reported health status using the first question of the Short Form (SF) 12. We will also assess health literacy at the end of the interview using the Rapid Estimate of Adult Literacy in Medicine tool. Finally, subjects will be telephoned 6-8 weeks after the initial survey to ask the same question regarding CPR.

E. Reasons for early cessation of therapy
N/A

F. Objectives and Statistical Section (including endpoints)

Data analysis plan by study aim:

Aim 1: To recruit 150 subjects and randomly assign them to a video after verbal description (intervention) group or verbal narrative (control) group. The baseline variables (demographic characteristics and care preferences) will be described and compared for the 150 subjects randomized to the study arms. Means and proportions will be used to describe continuous and categorical variables, respectively. T-tests will be used to compare continuous variables, and Fisher's Exact tests will be used to compare categorical variables. Non-parametric tests (i.e., Wilcoxon signed rank test) will also be used as appropriate based on the distribution of the variables.

Aim 2: To compare the care preferences of 150 subjects for CPR randomized to the video or verbal narrative group. The distribution of CPR preferences between the two groups will be compared post-randomization using the Pearson chi-squared test.

Aim 3: To compare the knowledge assessment of 150 subjects randomized to video or verbal narrative group. Cochran-Mantel-Haenszel tests will be used to

compare subjects' mean change in knowledge scores from baseline to post-intervention questionnaires between the two groups.

Aim 4: To compare the stability of preferences between the two arms of the study after 6-8 weeks. Follow-up CPR preferences will be compared between subjects in the two arms using Pearson chi-squared tests.

Sample size calculations.

In our prior work, we found that 91% of subjects who used the video decision aid did not want CPR. In the usual care arm of the study, 59% of subjects did not want CPR. Below is a table explaining our rationale for our sample size.

Verbal Arm	Video Arm		
Percent who do not want CPR	Percent who do not want CPR	Power	Total sample size (both arms)
59%	91%	90%	68
49%	91%	90%	86
69%	91%	90%	150
59%	84%	90%	150