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Study protocol for Video Images about Decisions to Improve Ethical Outcomes with Palliative Care Educators (VIDEO-PCE): a pragmatic stepped wedge cluster randomised trial of older patients admitted to the hospital

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ABSTRACT

Introduction Despite the known benefit to patients and families, discussions about goals, values and preferences for medical care in advancing serious illness often do not occur. Many system and clinician factors, such as patient and clinician reticence and shortage of specialty palliative care teams, contribute to this lack of communication. To address this gap, we designed an intervention to promote goals-of-care conversations and palliative care referrals in the hospital setting by using trained palliative care educators and video decision aids. This paper presents the rationale, design and methods for a trial aimed at addressing barriers to goals-of-care conversations for hospitalised adults aged 65 and older and those with Alzheimer's disease and related Dementias, regardless of age.

Methods and analysis The Video Image about Decisions to Improve Ethical Outcomes with Palliative Care Educators is a pragmatic stepped wedge, cluster randomised controlled trial, which aims to improve and extend goals-of-care conversations in the hospital setting with palliative care educators trained in serious illness communication and video decision aids. The primary outcome is the proportion of patients with goals-of-care documentation in the electronic health record. We estimate that over 9000 patients will be included.

Ethics and dissemination The Institutional Review Board (IRB) at Boston Medical Center will serve as the single IRB of record for all regulatory and ethical aspects of this trial. BMC Protocol Number: H-41482. Findings will be presented at national meetings and in publications. This trial is registered at ClinicalTrials.gov.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Intervention is a novel combination of palliative care educators and video decision aid tools aimed to extend palliative care teams for those over 65 years old and with Alzheimer's disease and related dementias or cognitive impairment in the inpatient ward and intensive care unit settings.
⇒ Cluster randomised pragmatic trial provides more realistic data on implementation than an efficacy trial of the intervention.
⇒ Advances in natural language processing allow for accurate, rapid review of serious illness communication in clinical notes.
⇒ Stepped wedge trial subjected to underlying secular trends in outcomes and practices in the context of ongoing COVID-19 surges.
⇒ Elucidating goals-of-care outcome relies on clinician documentation of goals-of-care conversations in the clinical notes, rather than by capturing the conversation itself.

Trial registration number NCT04857060; ClinicalTrials.gov

INTRODUCTION

Conversations between clinicians and patients about prognosis, goals, values and preferences in the face of advancing serious illness are associated with improved patient and family outcomes, including decreased anxiety and

goal-concordant care.[1–5] Ideally, serious illness communication is an iterative process done by an interprofessional team of clinicians, which involves advance care planning (ACP) and in-the-moment decision-making during goals-of-care discussions as serious illness progresses.[6–9] Specialty palliative care teams add value to this process for complex patients through working alongside other clinicians to address symptoms, and psychosocial, spiritual and coordination-related barriers to serious illness care and communication.[10–12]

The absence of communication around serious illness care is associated with more intensive interventions and terminal hospitalisations, lower hospice use and worse bereavement outcomes.[1 3 13–18] Moreover, caregivers often suffer a great deal of burden and distress attempting to develop a comprehensive care plan, especially in illnesses in which cognitive impairment is a hallmark, such as Alzheimer's disease and related dementias (ADRD).[19] Without discussion about goals, values and preferences, caregivers are often poorly prepared to make medical treatment decisions for their loved ones, including whether or not to place a feeding tube, attempt cardiopulmonary resuscitation (CPR) or pursue other life-prolonging interventions.[20] Numerous studies have shown that caregiver decision-making is no better than chance at matching a patient's wishes and often lacks stability over time.[21–23] Thus, communication and decision-making needs of older adults and patients with ADRD and their caregivers are not currently met.

Over the past few years, investigators have recognised these shortcomings and have developed new interventions to better facilitate goals-of-care and ACP.[24] Studies have shown that traditional written and verbal ACP, which relies on ad hoc verbal descriptions of hypothetical clinical situations and treatment choices, does not effectively inform many patients and caregivers, and often occurs late in the disease process.[24] The traditional approach is limited because complex scenarios are difficult to envision, provider information is inconsistent, and verbal explanations are hampered by literacy, emotional and language barriers.[24–27] In addition, for those situations best served by specialty palliative care, staffing capacity to meet clinical needs poses a significant challenge.[11 28–32] Only a small proportion of patients are appropriately served by palliative care services in many hospitals.[33 34] This became especially evident during the first wave of the COVID-19 pandemic.[32] In this trial, we aim to assess the effect of combining video decision aid tools and proactive extension of the palliative care team on addressing prior challenges in goals-of-care conversations.

The COVID-19 pandemic has highlighted the importance for all patients to fully understand and engage in discussions about their goals, values and wishes for care; decision-making in serious illness is no longer hypothetical.[32] Rather than relying on traditional written and verbal ACP, the intervention in this study focuses on patient, caregiver and clinician communication for hospitalised and seriously ill patients. A palliative care educator (PCE), who is a nurse or social worker trained in serious illness communication and uses video decision aids, facilitates goals-of-care conversations. These aids, available in 30 different languages, are employed to overcome language and literacy barriers and present potential scenarios with a sense of reality that verbal descriptions alone usually lack.[35–37] The video tools have shown promising efficacy in educating patients about their options and informing their preferences for care.[36 38–41]

Given the intensity of illness experience for hospitalised patients, they may benefit from a PCE-led video intervention to help improve and extend serious illness communication in the hospital setting. The overall aim is to inform and empower patients and their caregivers in the decision-making process, improving the delivery of care that aligns with their wishes. This is the first trial we are aware of that employs PCEs trained in communication skills to engage hospitalised patients with a proven video intervention. In this manuscript, we present the protocol for the Video Images about Decisions to Improve Ethical Outcomes with Palliative Care Educators (VIDEO-PCE) study.

METHODS

Overview

The VIDEO-PCE study is a pragmatic stepped wedge cluster randomised trial (SW-CRT) that evaluates a PCE-led video intervention among older adults and those with ADRD hospitalised in the ward and Intensive Care Unit settings of two major hospitals. Patients' outcomes will be abstracted from electronic health records (EHR) with natural language processing (NLP) and caregiver outcomes will be assessed via survey (details about the NLP process and caregiver outcomes are found in online supplemental material 1). The study is funded by the National Institute on Aging (1 R01 AG072911). We used the Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines for this manuscript.[42]

Our primary aim is to assess the effects of the PCE-led video intervention on the documentation of goals-of-care and patient preferences for medical care. We will evaluate intervention effectiveness by comparing outcomes among 9000 hospitalised patients aged 65 and older. The hypothesis for this first aim is that a higher proportion of patients in the intervention periods has documentation in the EHR of discussions regarding: (1) goals-of-care, (2) surrogate decision-makers, (3) palliative care, (4) hospice and (5) time-limited trials. We will additionally be evaluating the presence and content of preferences for resuscitation, haemodialysis, and feeding tubes as documented in the EHR.

Our second aim is to characterise caregiver-centred outcomes of patients with ADRD and cognitive impairments, including: (1) knowledge of the goals-of-care, (2) confidence in future care, (3) communication satisfaction, (4) decisional satisfaction and (5) decisional

conflict. This will be achieved through interviewing 500 caregivers of patients with ADRD or cognitive impairments admitted to the hospital (survey tools described further in the Appendix, online supplemental material 1). The hypothesis for this second aim is that intervention phase caregivers of patients with ADRD will have higher knowledge, confidence, communication satisfaction, decisional satisfaction and lower decisional conflict as compared with control phase caregivers.

Patient and public involvement

Patients, families and the public were involved in the design, filming, editing and production of the video decision aid tools. Neither patients nor the public were involved in the design, conduct, reporting or dissemination plans of the research design.

Study timeline

The VIDEO-PCE trial is a 2-year study and is broken into the following time intervals: 2 months of initial data collection, tool preparation, staff training and site standardisation; 16 months of active study periods with rolling recruitment and data collection; 2 months of data cleaning and analysis and 4 months of manuscript preparation and dissemination of findings. During the intervention period, we will disseminate the intervention to 14 randomised inpatient units at our two hospital sites.

Sites and randomisation

We will draw participants from inpatient units at two hospitals: Boston Medical Center (BMC) in Boston, Massachusetts and North Shore University Hospital (NSUH), a part of Northwell Health, in Manhasset, New York. As per the design of SW-CRT, all study units will start in a control phase and transition stepwise to the intervention, where the unit will be exposed to the intervention. Step intervals are 2 months in length. With each new step period, one additional unit from each hospital (cluster) is exposed to the intervention. Therefore, there will be a total of eight steps at each hospital (figure 1).

Patients in a control unit will receive usual care, including any routine goals-of-care and shared decision-making processes. Eligible patients will contribute to control period data. Once a unit transitions to the intervention, patients in that unit are eligible to receive the intervention for the duration of the study. Prior to the collection of any data in the preintervention period, the study statistician will match units based on clinical attributes and will generate a set of uniform random numbers for each of the seven clusters to assign a starting period for the study intervention.

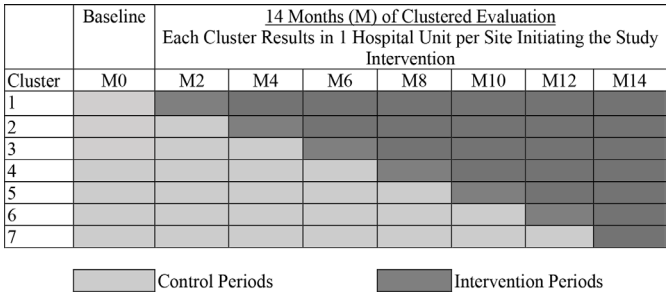

Figure 1 VIDEO-PCE study flow. VIDEO-PCE, Video Image about Decisions to Improve Ethical Outcomes with Palliative Care Educators.

Population

The study sample will consist of patients 65 years or older and any patient with ADRD, regardless of age, who are admitted to one of the 14 identified hospital units during the study time period for at least 8 weekday, daytime hours. Over the 2 years of the trial, we will examine data on approximately 9000 patients for the primary and secondary outcomes. Given the pragmatic nature of this trial, our inclusion criteria are quite broad and consistent with the goal of pragmatic trials. There are no exclusion criteria for patients in the study population. For the primary aim, the data needed to assess the outcomes for all patients aged 65 or over will be derived from each hospital's EHR.

For the second ADRD caregiver aim, we will enrol 500 caregivers (250 control surveys and 250 intervention surveys) for patients with ADRD or other cognitive impairments, regardless of age, who will be surveyed during the index hospitalisation to assess caregiver-centred outcomes. Caregivers may or may not be designated as the legal surrogate decision-maker for the patient. Any adult identified in the EHR as a patient's contact will be eligible to partake in the caregiver survey. Control surveys will be collected from caregivers of patients admitted to a study unit during a control period or collected from caregivers of a patient admitted to a non-study unit. Intervention surveys will be collected from caregivers of patients admitted to units during an intervention period. While some patients with ADRD or other cognitive impairments may still have decision-making capacity, the focus of this survey will be the experience of caregivers. The surveys will be administered to caregivers who speak either English or Spanish as the survey tools are validated in these two languages. We will not be including individuals who are not yet adults (ie, infants, children, teenagers) nor will we include incarcerated patients. For caregivers of patients in the control group, surveys will be completed during the patient's hospital stay or within 1 month of discharge. For caregivers of patients in the intervention group, the survey will be completed after the PCE intervention, and up to 1 month after discharge.

Intervention design, implementation and adherence monitoring

The intervention for VIDEO-PCE employs PCE-driven viewing of videos and engagement of patients and/or their decision-makers and clinical teams on intervention floors. For eligible patients, the PCEs will then serve in a triage function to manage cases that can be handled with educational support for shared decision-making and goals-of-care conversations or to stimulate a palliative care

consultation. Though the PCEs will see patients independent of a clinical team, they are members of and report to the palliative care team.

PCEs will receive Vital Talk intensive communication skills training via a highly structured series of Zoom conferences.[43] Additionally, the PCEs will engage in monthly coaching calls with two serious illness communication experts. Coaching calls will be designed to discuss and collectively debrief successes and challenges with clinical cases, identifying shared skills and language to deal with difficult patient situations.

The PCEs will also be trained on use of the certified video decision aids using the ACP Decisions video app. Video training will instruct PCEs on how to: (1) introduce the videos to patients and caregivers, (2) use the videos as adjuncts to clinician counselling, (3) select the appropriate video(s) from the entire suite according to patients' needs and (4) prescribe videos for patients and caregivers using the electronic platform. The suite of videos is designed to address common healthcare decisions confronting patients and their caregivers. The videos have been studied in multiple trials and are intended to be an adjunct to clinician counselling, not to replace it.[35 37–40 44–53] Suggested videos for clinicians to use with patients will include goals-of-care videos, general ACP videos, intervention-specific videos such as ventilatory support or CPR and hospice videos. The video library also includes content developed to address specific clinical needs. For example, additional videos that may be relevant to the patient population of this study are those covering decision points surrounding ADRD (eg, feeding tubes, resuscitation, etc), common questions and issues for caregivers and compassionate extubation.

Each day, PCEs will review a list of inpatients who are over the age of 65 or have a diagnosis of ADRD (regardless of age), prioritising patients who have not recently engaged in a goals-of-care conversation (as documented in the EHR). The PCEs will then proactively use the video decision aids and their training to provide educational support and assist in delivering services such as shared decision-making and goals-of-care conversations. The videos are only a few minutes in length and the PCE will watch the videos together with the patient and caregiver on a tablet (or remotely via telehealth with the caregiver). The PCEs will arrange all video showings to include patient and caregiver (when possible and acceptable to the patient). In cases when a patient is unable to view a video (eg, loss of capacity, delirium), the caregiver will view the video. Videos may also be shared with patients and caregivers via an email, text, weblink or Quick Response (QR) code provided by the PCE. This allows caregivers and patients access to videos outside of the clinic setting or when in-person clinical interactions are restricted. The PCE will encourage the patient to make their wishes known to their family or other caregiver (and will offer to facilitate a call/video call) and the attending physician. All encounters, including patients' wishes, will be documented in the EHR. As an integrated part of existing hospital practice, PCEs will communicate with the primary treating team and the palliative care team. When the PCE identifies specialty palliative care needs (eg, symptom control, complex communication needs, psychosocial and spiritual support around coping with serious illness), the PCE will recommend to the treating team to place the consult request.

For quality improvement and supervisory purposes, the PCEs will keep a tracking document of their activities (number of patients seen per day, amount of time spent with each patient, etc). These may be reviewed retrospectively by the research team and compared with research data. An amendment will be submitted to the Institutional Review Board (IRB) if such a scenario arises. PCEs will also track instances in which they view the video decision aids with a patient or provide a video code to a patient or family member. In addition, the number and playthrough rate of all video viewings will be tracked via the ACP decisions application.

Outcomes

The primary outcome of this trial is documentation of a goals-of-care conversation in the EHR at any time during the index hospitalisation, as ascertained by NLP-assisted review of clinical notes accumulated during that hospitalisation. Similar to our previous studies, documentation that will count towards the outcome will include a discussion with the patient regarding limitations of life-sustaining treatment, palliative care, hospice, goals-of-care, time-limited trial or surrogate decision-makers.[43 54] One secondary outcome of the trial is EHR documentation reflecting the presence and content of treatment preferences relating to resuscitation, feeding tubes and dialysis.

The other secondary outcomes of this trial will be ascertained from caregiver surveys for 500 patients with adults with ADRD or other cognitive impairments will be conducted via a survey administered electronically or over the telephone. These surveys will assess caregiver-centred outcomes (knowledge of ACP, confidence, communication satisfaction, decisional satisfaction and decisional certainty) in the month weeks following the index hospitalisation. We have included detailed descriptions of each survey instrument in the Appendix (online supplemental material 1). Table 1 outlines the purpose, source and cohort for each data element included in the study.

Data sources, data elements and linkage

Data for both the primary outcome and secondary outcome related to resuscitation and treatment preferences will be obtained via NLP-assisted chart review as we have done in prior studies.[43 54–56] The clinical data ware house representative from each of the two sites will extract EHR data, including inpatient clinical notes, from eligible patients at the conclusion of each 2-month step period. A dedicated REDCap[57] database housed at Boston University (BU) will be used to enter caregiver survey data entry across both sites. Each site will maintain and

Table 1 Data elements for the VIDEO-PCE trial

Data element	Purpose	Source	Cohort	Brief description
A.Patient level				
1. Demographics	Covariate (moderator)	EHR	Entire study sample	Age, gender, race/ethnicity (self-reported), language, religion, and diagnoses
2. Goals-of-care documentation	1° outcome	EHR (NLP extraction from inpatient clinical notes)	Entire study sample	Any documentation of a discussion pertaining to limitations of life sustaining treatment, palliative care, hospice, goals-of-care, time-limited trial or surrogate decision-makers
3. Resuscitation and treatment preferences (presence and content)	2° outcome	EHR (NLP extraction from inpatient clinical notes)	Entire study sample	Presence and content of resuscitation and treatment preferences including: Full code, DNR, DNI, DNH and documented preferences around feeding tubes, and dialysis
B.Caregiver level				
4. Caregiver-centred outcomes	2° outcome	Survey	Caregivers of patients with ADRD or other cognitive impairments who consent to participation in the survey	A brief survey assessing caregiver knowledge of ACP, confidence, communication satisfaction, decisional satisfaction and decisional certainty
C.System level				
5. Intervention/video decision aid use	Monitoring fidelity	Video App	Entire study sample	The playthrough rate, viewing medium, and view location for each video decision aid view will be tracked
6. PCE activity	Monitoring fidelity	Internal tracking sheets	Palliative care educators	The PCEs at each site will track encounters with patients, video views with patients, video code prescription and patient engagements

ACP, advance care planning; ADRD, Alzheimer's disease and related dementias; DNH, do-not-hospitalise; DNI, do-not-intubate; DNR, do-not-resuscitate; PCE, palliative care educator; POLST, physician order for life-sustaining treatment.

adhere to the processes and procedures for the protection of human subjects and protected health information (PHI) for their covered entities. All patients will be assigned a unique identifier, and each site will retain a linking file that will not be shared outside of the institution and will only be accessible to authorised study personnel. At Northwell Health, all data will be stored on an excel spreadsheet that is password protected on Microsoft OneDrive. OneDrive is a Health Insurance Portability and Accountability Act (HIPAA) compliant platform for data storage and sharing and has been vetted by Northwell Health's Research Information Technology and Research Compliance teams. BU will serve as the ultimate data repository for the study data repository, storing the demographic information obtained and caregiver survey data that BMC and Northwell collect. The NLP data ascertained by BMC and Northwell will be processed by Dana-Farber Cancer Institute (DFCI) and then transferred to BU/BEDAC. BU/BEDAC will be responsible for the creation of analytic data sets. At BU, all data will be stored securely on a network server located inside the BU firewall, with access restricted by username and password to authorised personnel, which complies with data storage requirements for PHI as defined by BU. Demographic and visit-level data from the EHR at each of the sites will be transferred as limited data sets directly to BU. NLP data from each of the sites will be processed locally and then a deidentified data set will be transferred via secure institutionally approved methods to DFCI for data quality assurance. The deidentified NLP data set will then be sent from DFCI to BU to be merged with the rest of the study data repository for the creation of analytic data sets. Data stored on the DFCI server will reside there only for the periods that are required to be there for study usage.

Data will be securely removed from the servers on a per-item basis. The data removed from DFCI's servers will be retained on BU long-term servers for storage.

Data will be stored and analysed on a HIPAA-secure cluster at each site and none of the data will be stored in paper form. The data and identifiers will be kept for 7 years after the end of the study period on the HIPAA-secure cluster computer at each site. After the 7 years, all HIPAA identifiers and all linking codes will be permanently destroyed in accordance with regulation. The study monitor or other authorised representatives of the sponsor may inspect all documents and records required to be maintained by the investigator.

Masking

Due to the nature of the intervention, participants and staff will not be blinded to the intervention. A series of steps will be taken to blind research staff to the outcomes; however, since the NLP outcome adjudication process is not fully automated in this study, perfect blinding will not be possible. The human-assisted NLP process requires that a staff member validates the text presented in the software as a possible outcome. The following steps will be taken to ensure blinding to study step assignment by the staff member doing the NLP outcome attribution: (1) annotation will be performed in large batches with all patients enrolled who have clinical notes to that point, (2) NLP notes for adjudication will be grouped at the hospital admission level when presented to annotators, (3) each note will be annotated at the hospital admission level to account for concepts contained in all notes documented over the course of the hospital stay and (4) when possible, staff members who perform the annotation will be those who have not previously engaged the participant in the intervention.

Sample size determination

All sample size estimates assume a minimum of 80% power and a two-sided alpha of 0.05. We employ the method for the computation of sample size for cross-sectional stepped wedge studies comparing intervention to usual care in two-group statistical analyses. This method incorporates information on the number of steps used in the SW-CRT, the number of subjects per time period and the degree of clustering via the intraclass correlation coefficient (ICC) to compute the design effect, the factor by which the sample size found to provide sufficient statistical power for a meaningful intervention difference in outcome assuming independent data are multiplied.

For the primary outcome of goals-of-care documentation in the medical record, a sample size of 440 records per group in a χ^2 test for independent data will provide 80% power at a two-sided alpha of 0.05 to detect a difference in the proportion of subjects with notation of 35% in the intervention group compared with 25% in the usual care group, values consistent with prior research and expectation based on clinical data from the two health systems estimated from recent data. Based on our planned number of steps (seven with one uniformly applied usual care period across all hospital units), enrolment per study period, and a reasonable ICC of 0.01, the design effect is 2.72. Thus, we will need to obtain outcome data from the records of at least 2394 subjects overall (1197 per health system) to provide 80% power for our analysis of intervention effectiveness. We anticipate, however, that as many as 9000 records will be available for analysis with respect to the documentation of goals-of-care. Thus, our planned sample size for our primary records-based analysis on 9000 records will, therefore, provide more than adequate power to test for differences in our primary outcome. We have set an absolute increase in 10%, that is, an increase in goals-of-care documentation during the index hospitalisation from 25% to 35%, as the benchmark for clinical significance. This inflated sample size is needed to support the power requirements of the caregiver interview survey. By establishing an absolute benchmark for the primary outcome, we protect from the risk of being overpowered (online supplemental material 1).

For the interview survey-derived outcomes (knowledge, confidence in future care, communication satisfaction, decisional satisfaction and decisional conflict) with approximately 500 subjects available across the eight 'clusters'/steps, the resulting design effect is 2.03 (again, assuming an ICC of 0.01). For this analysis sample size, the minimum effect size that can be detected for the uncertainty and knowledge scores separately with 80% power and alpha of 0.05 would be 0.36 after applying the design effect. In sum, our anticipated sample sizes for both our primary and secondary aims will provide adequate statistical power to detect moderately sized and clinically important effects of the intervention and account for the cluster-randomised nature of our stepped-wedge study design.

Statistical analysis methods

For the initial analyses of the primary and secondary outcomes, there will be no crossover of data for subjects from usual care to the intervention during the study; that is, subjects will only contribute data once during the course of the study, from their index hospitalisation. If a patient was transferred from a control unit to an intervention unit during their index hospitalisation, they will be assigned to contribute data to the intervention and should meet the inclusion criteria for both study units/wards. Accordingly, data being contributed by patients at each site during the preintervention period and data being contributed by patients after the initiation of the intervention will be kept separate for initial analyses. However, because we expect some patients to have multiple hospitalisations during different steps or to different units (ie, crossover design), we will perform secondary analyses on all outcomes, including data from the index hospitalisation. This will include stratified sensitivity analyses of patients who contribute data (a) only to control period; (b) only to intervention period or (c) to both control and intervention periods.

Given the randomised nature of the stepped wedge design, we will report our results according to Consolidated Standards of Reporting Trials guidelines. For aim 2 of the study, which requires patient/caregiver consent, we will record the number of people approached, screened, ineligible and refusing participation. We will record subject attrition and note all adverse events. We will employ the intent-to-treat principle in our comparative analyses between the intervention and usual care groups. All hypothesis tests will employ a two-sided alpha level of 0.05. Given that the primary aim will be addressed by the analysis of data obtained from available patient records for the study period, we will examine the distributions of relevant variables focusing on the data relating to the documentation of goals-of-care, the outcome of this aim. For the secondary aim caregiver-related aim of the study, we will examine the distributions of the uncertainty and knowledge scale scores, the outcomes of interest between intervention and control subjects as well as the distributional characteristics of all other salient study variables. We will generate descriptive statistics (means, SD, quantiles for continuous variables; counts and percentages for categorical variables) and schematic plots (Box-and-whisker, quantile-quantile plots).

Given the nature of the cluster randomisation employed, we will use statistical approaches that take the correlational nature of the data into account as well as the influence of time to account for secular trends. We will examine both the health system and hospital unit as clustering variables, with the hospital unit as the primary clustering variable. We will compare the intervention and usual care groups on salient variables in order to assess balance in the distributions of these variables. Variables found to differ between the study groups will be further evaluated to assess their confounding effects of intervention versus usual care differences on outcomes in multivariable analyses for correlated (clustered) data.

For aim 1, to formally estimate and test differences in the proportion of patients with documentation of goals of care between the intervention and control time periods, we will employ logistic regression models for correlated binary outcome data. These models will either involve the use of robust variance methods to account for the clustering of these data by hospital site via generalised estimating equations (GEE) or the inclusion of a random effect terms (in which case, the results will be interpreted as cluster specific). Other potential modifiers of the effect of intervention, confounding variables or covariates can be added to this model as fixed effects. Although we do not expect effect modification in the study data, we will examine the potential for such effects (interaction) through the use of stratified analyses and the inclusion of interaction terms with study group in our statistical models. Candidate effect modifiers specified *a priori* include age, gender, race/ethnicity, religion and language. We will also examine and incorporate secular trend effects, that is, the effect of time over the course of the study. Statistically significant interactions with the intervention will be retained and the nature of heterogeneous intervention effects will be estimated using the interaction model.

For aim 2, we will compare survey responses from intervention and control periods to account for clustering within clinical unit and hospital. We will include calendar time and any imbalance from caregiver characteristics in the model to adjust for the potential confounding factors. We will account for clustering using methods as described above but will employ linear models for correlated data fitted via GEE or in mixed models.

Missing data

We will impute missing data points using multiple imputation techniques. This approach assumes that data are missing either completely at random (MCAR) or at random (MAR) as a function of non-missing data on available variables in the data set. We will implement this process using PROC MI in SAS. We will generate 20 imputed data sets and will conduct our intent-to-treat analyses per our analysis plan, saving results across data sets, so they can be combined using PROC MIANALYZE in SAS. We will also consider the possibility that data are missing in a non-ignorable fashion. For example, should more or less symptomatic subjects be lost to follow-up as a result of treatment—and, thus, produce results that are biased in a manner not addressable by the above methods that assume MCAR or MAR data—we will randomly impute data in sensitivity analyses under various alternative scenarios employing multiple imputation with the combination of analytic results noted above. Additional details on sample size and statistical analysis considerations are presented in the Appendix (online supplemental material 1).

ETHICS AND DISSEMINATION

Regulatory considerations

This study will be conducted in compliance with the protocol, applicable regulatory requirements and BMC/BU Medical Campus Human Research Protection policies and procedures. It will be conducted according to applicable US federal regulations and institutional policies (which are based in federal regulations, guidance and Good Clinical Practice guidelines). This protocol and any amendments will be submitted to the BMC IRB, for formal approval of the study conduct. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator. A copy of the initial IRB approval letter will be provided to the sponsor before commencement of this study.

All caregiver subjects enrolled for aim 2 (caregiver survey) will provide verbal informed consent to a member of the research staff by phone prior to answering any survey questions. Subjects will be provided with sufficient information and time to make an informed decision about their participation in this study. A mailed copy of the consent form will be offered to these subjects to keep

for their records. The consent form will be submitted with the protocol for review and approval by the IRB (online supplemental file 1). Consent will be documented as required by the IRB. The trial is registered on ClinicalTrials.gov. Committees consisting of the various investigators oversee data safety and monitoring and the study includes an independent data safety and monitoring board.

Relevance and dissemination

We believe that the VIDEO-PCE study, as a pragmatic evaluation of the implementation of a PCE-guided video decision aid intervention for hospitalised older adults and those with ADRD, is a novel approach to goals-of-care conversations. A proactive programme to facilitate video decision support is a practical, evidence-based and innovative approach to assist patients facing such choices. If proven effective, this care model can be readily deployed across the country to improve the quality of care for millions of Americans. Given the urgent need for scalable interventions, this study is designed to generate evidence quickly and efficiently. We plan to publish and disseminate our primary and secondary outcomes rapidly after study completion and will also analyse and distribute learnings from areas such as the activities of the PCE teams and NLP chart review via publication and at national meetings.

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Contributors AV and MKPO designed and conceptualised the study, acquired data, drafted, and critically revised the manuscript, obtained funding, supervised the study, and provided administrative and technical support. ADD, LH, CL, EAB, MTC and SNZ designed and conceptualised the study, drafted and critically revised the manuscript and provided administrative and technical support. JL drafted and critically revised the manuscript and provided administrative and technical support. HC, MW, NW, JND and MG acquired data, critically revised the manuscript, provided statistical analysis, and provided administrative and technical support. SL, AD, LBC, KE, NJM, MA, TC, and MJ critically revised the manuscript and assisted the implementation of the study. ETM, SD, KS, SGK, and JI critically revised the manuscript and provided administrative, technical, and implementation support. SL, JP, AMR, KS, and QO critically revised the manuscript, collected caregiver surveys, and worked to annotate NLP data. SS critically revised the manuscript and acquired data.

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Competing interests Dr. Angelo Volandes has a financial interest in ACP Decisions, a non-profit organisation developing advance care planning video decision support tools. Dr. Volandes' interests were reviewed and are managed by MGH and Mass General Brigham in accordance with their conflict-of-interest policies. Aretha Delight Davis is an employee of ACPD and the spouse of Angelo Volandes. No other disclosures to report.

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Data availability statement Not applicable.

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MODEL RESEARCH CONSENT FORM
Caregiver Survey

Basic Information

TITLE:	Proactive Advanced Care Planning with Videos for the Elderly and all Patients with ADRD
PROTOCOL NO.:	[Number]
SPONSOR:	National Institutes of Health/National Institute on Aging
INVESTIGATOR:	Name Address City, State Zip Code Country
STUDY-RELATED PHONE NUMBER(S):	Name, Phone Number

Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you are a friend or family member for someone who may need your help making medical decisions in the future. We are doing the research to gather more information about the specific burden of caring for someone who may need your help making medical decisions. If you agree, you will complete a brief, one-time survey about the burden of being a caregiver/companion. You will be in the study for about 30 minutes, or as long as it takes you to complete the survey. You will find more information about what will happen in this study later in this form.

The main risk of being in the study are that some of the questions in the survey may make you sad or uncomfortable. You will find more information about risks later in this form.

Purpose

The goal of this project is to improve communication between patients and their health care team in the hospital, specifically around advance care planning.

What Will Happen in This Research Study

If you agree to be in this study we will ask you to complete a short survey, which can be done over the phone. The survey will ask questions about your experience in caring for someone who may need your

help making medical decisions. The survey will take about 30 minutes to complete. To help us understand your responses on this survey, in the context of the care that is provided to your friend/family member, we will be linking your survey responses with information from their medical record.

The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

Risks and Discomforts
The only risk to you in this study is that some of the questions may make you sad or uncomfortable. You may choose not to answer any questions that you do not want to.

Potential Benefits
You will receive no direct benefit from being in this study. The primary goal of this research is to collect information about the scientific questions asked in this study. Your being in this study may help the investigators learn about the experience of someone who cares for someone with dementia or Alzheimer's related disease

Costs
There are no costs to you for being in this research study.

Payment
You will receive $50 in the form of a pre-loaded debit card upon completion of the survey.

Confidentiality
We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. Only the people listed later in this section will be given access to your information. However, we cannot guarantee complete confidentiality.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information are covered by a CoC. The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

If you agree to be in the study, we will share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law.

- Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- Any people who you give us separate permission to share your information.

You should know that we are required to report certain information that we might learn in this study to state or other agencies. The information includes elder abuse and harm to others.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Re-Contact

We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please initial your choice below:

____Yes ____No You may contact me again to ask for additional information related to this study

____Yes ____No You may contact me again to let me know about a different research study

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get. You will only be paid for the study activities that you complete before withdrawing.

We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact [Name] at [Number]. Also call if you need to report an injury while being in this research.

Project Title: Proactive Advanced Care Planning with Videos for the Elderly and all Patients with ADRD
Principal Investigator: [Name]

You may also call [Number] or email [email]. You will be talking to someone at the IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

By agreeing to be in this research, you are indicating that you have read this form (or it has been read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study.

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Appendix

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Caregiver Survey Sources

Knowledge: We will measure caregiver knowledge of ACP using a 5-item ACP survey consisting of True/False questions that we have validated and used in our prior work.[1-3]

Confidence: We will ask caregivers how confident they are that their loved one with ADRD will get the type of medical care they want if they become seriously ill. This is a single question with Likert responses ranging from not at all to very confident. Although not psychometrically tested in large studies, it carries enormous face validity and is the closest approximation we can obtain of goal-concordant care prospectively.

Communication Satisfaction: We will use the 10-item communication subscale of the Consumer Assessment of Health Plans (CAHPS®) and ask caregivers to focus on recent ACP communication.

Decisional satisfaction: We will ask the six-item Satisfaction with Decision Scale (Cronbach's alpha = 0.86).[4] It includes items such as "The decision I made was the best decision possible for my loved one," and "I am satisfied that my decision was consistent with my loved one's values."

Decisional certainty: We will measure decisional conflict, which attempts to measure uncertainty regarding decision making. The Decision Conflict Scale is a well-validated and commonly used tool.[5]

Natural Language Processing

Software Specification

ClinicalRegex[6], which is a rule-based NLP software with text annotation capacities developed by the Lindvall Lab at Dana-Farber Cancer Insitute, will be used to assess goals of care documentation and resuscitation preferences. Clinical Regex has been applied in multiple studies to assess process-based quality measures.[7-21] The software presents all keywords and phrases associated with an outcome of interest, and identified using a pre-defined ontology, to a human who reviews the instance. Human reviewers determine whether the keyword or phrase instance appeared in a context that is indicative of goals of care/resuscitation preference documentation. All human reviewers will undergo multiple trainings with study investigators (Moseley, Das, Sciacca, Lindvall).

Outcome Ontology

The ontology for operationalizing the primary outcome of the trial, i.e., goals of care documentation, has six domains that encompass key aspects of goals of care: (1) goals of care conversations; (2) limitations of life-sustaining treatment; (3) palliative care involvement; (4) hospice conversations; (5) election of a surrogate decision maker; (6) time-limited trials. Four of these domains (with the exception of election of a surrogate decision maker and time-limited trials) have been refined and validated in a separate multisite clinical trial.[9]

To identify instances of this documentation associated with the primary and secondary outcomes, clinical experts will work with site teams to develop a list of keywords and phrases for each concept domain that represents, *a priori*, how the domain is believed to be represented within the clinical notes, when spontaneously written in the course of providing care (Table 1). Here, the goal is to capture the language which is most likely to be used when discussing the concepts we are seeking, and then to employ the ClinicalRegex software to search for the keywords and phrases and to point to this documentation in the clinical notes.

Annotator Training and Validation

Annotation guidelines will be developed within the framework of keyword searches to assist annotators in judging instances of document-embedded keywords from the keyword library as representing the primary or secondary outcome concepts. All research staff who will participate in clinical note review (henceforth refered to as 'operators') will have to undergo a two-part training process. The first part of the training involves review of software installation, application, and an in-depth review of concepts associated with the study outcome.

Prior to annotating, all operators must earn a passing score on a 'Calibration Test' developed by the Lindvall Lab. The 'Calibration Test' consists of mock clinical narratives and will test the reviewer's ability to judge goals of care documentation and resuscitation and treatment preferences. Results of the Calibration Test will be assessed across all concept domains, such that operatos may develop proficiency in each.

Operators who completed the Calibration Test (with an accuracy score of 70% or greater) will be considered to have learned the applicable concepts and passed the test. Operators who do not pass the Calibration Test will be re-trained and re-administered the calibration test one more time.

After the calibration tests are completed, at least two operators at each site will annotate a randomly sampled set of notes from 20 unique patients from the study's baseline period. The operators will annotate these notes three separate times: (1) for concepts associated with the primary outcome; (2) for concepts associated the secondary outcome; (3) for both types of concepts at the same time.

By having operators review notes multiple times, we will generate inter- and intra-operator error rates. Intra-operator error is expected to remain low to ensure that operators are consistent with their own annotation efforts over time. Inter-operator error should also remain low to ensure that annotators are consistent in their understanding of the concepts relative to other operators at the institution. If either intra- or inter operator error are deemed to be too high, re-training on those concepts associated with high rates of error will be performed.

During this validation process, we will also seek to ensure that our keyword library (which is used to search notes for terms and phrases) has as few off-target effects as possible. Specifically, we will seek to ignore keywords and phrases which are common in clinical notes, but are unlikely to be associated with study outcomes. These changes to the keyword libraries will be specific to each site to ensure we account for any site-specific terminology or peculiar documentation practices.

When new operators are onboarded to participate in the annotation effort, those individuals will also participate in the same trainings, and take the calibration test, before annotating the same validation note set. By annotating the same validation note set, we can ensure that new note annotators have similar note annotation practices to their peers.

Statistical Analysis

Sample Size Determination

Data for Aim 1 is derived from clinical notes recorded in the electronic health record (EHR) and as is typical for trials that integrate new initiatives within the workflow of large institutions in a SW-CRT that does not involve consent. We anticipate the sample size for Aim 1 to exceed what is required by a simple application of the power calculation presented above. However, this is warranted for eight reasons. First, the size of this observed sample gives us the opportunity to examine intervention effects for less common outcomes. Second, this sample size will allow us to evaluate potential heterogeneity in treatment effects for subpopulations as small as 20% of the larger study sample. Third, this sample size provides an experimental context in which we will be able to recruit a sample of 500 patients with ADRD or other cognitive impairments and their associated caregivers for survey. In order to sustain the activities of Aim 2, we need a large sample as many people in the sample for Aim 1 will not be eligible for participation in Aim 2. Fourth, the size of the sample for Aim 1 protects this trial from the potential that we will have significantly varying sizes of study clusters, as hospital units vary significantly in their numbers of available patients. This factor is often neglected in sample size assessments for SW-CRTs.[22] Fifth, there is minimal risk to human subjects presented by the expanded sample size for Aim 1. Indeed, this educational intervention is being spread across the clinical units of our two hospitals in a pragmatic manner as part of the standard of care.

The research activities of Aim 1 involve no direct burden to patients as there is no consent process and data for this activity will be derived from the EHR. The chief risk is the loss of confidentiality and robust protections are in place to protect patients from this potential risk. Sixth, we plan to extend this intervention as a new clinical initiative in our two health systems in a manner (time per cluster) that has been endorsed by leadership as a reasonable rate for dissemination (i.e., we are not adding more time). Seventh, we have devised an exceedingly efficient and accurate method for outcome assessment (i.e., we are not adding more cost). Eighth, we will protect against inappropriate conclusions. We understand that treatment effect sizes will be more relevant than p-values and that clinical significance is the goal (not simply statistical significance). In summary, the sample size for Aim 1 is needed to be able to address Aim 2 and we have taken appropriate measures to ensure that the research design for Aim 1 does not yield consequences for being overpowered.

Statistical Analysis Methods

Aim 1. To test the combined effects of a PCE-led, video-assisted palliative care intervention on rates of: goals of care documentation; medical orders for resuscitation preferences in the EHR; discussions of palliative care consults; and, discussions of hospice use.
Hypothesis: A higher proportion of patients in the intervention phase (vs. control) will: complete goals of care documentation (primary trial outcome), have documented orders for resuscitation preferences, have documentmantion of discussions regarding palliative care consults, and documentmantion of discussions regarding hospice.

Based on our prior work in which we exhibited the fact that African-American and Hispanic patients are at particularly high risk for lower level of knowledge related to ACP and goals of care, not discussing goals of care with family, not having a health care proxy, and not having goals of care documentation, we anticipate that this intervention may be particularly beneficial

for African-American and Hispanic patients.[23-25] Accordingly, we will evaluate heterogeneous treatment effects by race and ethnicity and anticipate having adequate diversity in our study population to make such assessments. All data regarding Aim 1 will come from the EHR. Our institutions maintain excellent self-report information regarding race and ethnicity.

We will conduct analyses related to potential effect modification as a step in our model validation process and to identify relationships that can be examined more fully in future research. Should interactions not be found to be statistically significant, we will fit a main effects-only model and use it to formally evaluate confounding by applying a change-in-estimates approach, with a 10% change in estimates being an initial screening criterion. Secondary outcomes: Similar procedures will be undertaken to assess intervention effects for the other EHR derived outcomes (documented of resuscitation preferences, palliative care consults, hospice enrollment, and health care proxies in the EHR).

For our primary analysis, we will consider our primary outcome (goals of care documentation) and our secondary outcomes (discussion of resuscitation preferences, palliative care, hospice use, and health care proxies) only for the patient's index hospitalization. However, because we expect some patients to have multiple rehospitalizations during the same step and may also include intervention time (i.e., crossover design), we will perform secondary analyses on all of our primary and secondary outcomes for each patient reviewing all EHR records from the index hospitalization of the patient until their death (or through study period). We will also perform stratified sensitivity analyses of patients who contribute only to control period vs. patients who contribute only to intervention period vs. those that contribute to both control and intervention periods.

We will conduct the above analyses on all patients 65 or over (regardless if they have ADRD) for our Aim 1 primary and secondary outcomes. Aim 1 outcomes will also be analyzed in the 500 patients with ADRD or other cognitive impairements from Aim 2 separately (since some of these patients will likely be younger than 65).

Aim 2. To characterize detailed caregiver-centered outcomes, including knowledge, confidence in future care, communication and decisional satisfaction, and decisional certainty in a subgroup of 500 patients with ADRD or other cognitive impairements and their caregivers admitted to the hospital. Hypothesis: Caregivers in the intervention phase (vs. control) will have higher knowledge, confidence in future care, improved communication and decisional satisfaction, and less decisional conflict.

Table 1: General NLP Keywords

Domain	General Keywords
Goals of Care	GOC, goals of care, goals for care, family meeting, family discussion, patient goals, patient values, quality of life, prognostic discussions, illness understanding, serious illness conversation, serious illness discussion, advance care planning, ACP, end of life, what matters most, poor prognosis, limited prognosis, prognosis, prognostic, terminal, dying, die, death, incurable, not curable, not curative, non curable, non-curable, non curative, non-curative, no cure, isn't a cure, is no cure, not reversible, non-reversible, treatments are palliative, treatment is palliative, palliative treatment, palliation, extend life, extending life, life-extending, life extending, lengthening life, lengthen life, life-lengthening, life lengthening, life limiting, life-limiting, does not wish to know, does not want to know, hours to days, days to weeks, weeks to months, months to years, prognostic understanding, month left, months left, years left, year left, weeks left, week left, unfortunate, regrettably, I am afraid, frank discussion, frank conversation, honest discussion, honest conversation, difficult conversation, difficult discussion, out of options, no remaining options, no more therapy, no further treatment, no further therapy, supportive care, comfort care, comfort approach, CMO, comfort directed care, prioritize comfort, end of life care, comfort measures, limiting invasive procedures, limit invasive procedures, what matters most
Code Status Limitations	Full code, FC, full intubation, full recusitation, Intubation, resuscitation, CPR, no intubation, no resuscitation, no CPR, declines CPR, do not intubate, do not resuscitate, DNR/DNI, DNR, DNI, declines intubation, declines cardiopulmonary resuscitation, no chest compressions, no compressions, no defibrillation, no mechanical intubation, refuses intubation, refuses CPR, code status discussion, discussed code status, life support, DNAR, do not attempt resuscitation
Hospice	Hospice, bridge to hospice, home hospice, inpatient hospice, hospice house, hospice at home
Palliative Care	Palliative care, palliative medicine, pall care, pal care, pallcare, palcare, PC
Surrogate Decision Maker	Health care agent, health care proxy, HCP, HCP agent, surrogate, surrogate decision maker, decision maker, proxy, health agent, power of attorney for health care, HCPOA, health care power of attorney, health care agent, HCA, guardian guardianship, court appointed guardian, affirmed proxy, POA, POAH
Time Limited Trial	Time-limited trial, time limited trial, limited trial, TLT
Resuscitation	Full code, FC, full intubation, full resuscitation, Intubation, resuscitation, CPR, no intubation, no resuscitation, no CPR, declines CPR, do not intubate, do not resuscitate, DNR/DNI, DNR, DNI, declines intubation, declines cardiopulmonary resuscitation, no chest compressions, no compressions, no defibrillation, no mechanical intubation, refuses intubation, refuses CPR, code status discussion, discussed code status, life support, DNAR, do not attempt resuscitation

Enteral Feeding	Artificial nutrition, feeding tube, supplemental nutrition, nutrition support, PEG, dobhoff, G tube, J tube, GJ tube, no artificial feeding, no feeding tube, declines feeding tube, refuses feeding tube, enteral feeding, gastrostomy tube, NG tube, nasogastric tube, OG tube, orogastric
Hemodialysis	Renal replacement therapy, hemodialysis, HD, iHD, CVVH, AVVH, RRT, hemodialysis not within goals, conservative management, medical management without dialysis, no dialysis

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