BMJ Open

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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To cite: Lakin JR, Zupanc SN, Lindvall C, *et al*. 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. *BMJ Open* 2022;**12**:e065236. doi:10.1136/bmjopen-2022-065236

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-065236).

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Received 31 May 2022
Accepted 11 July 2022

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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.

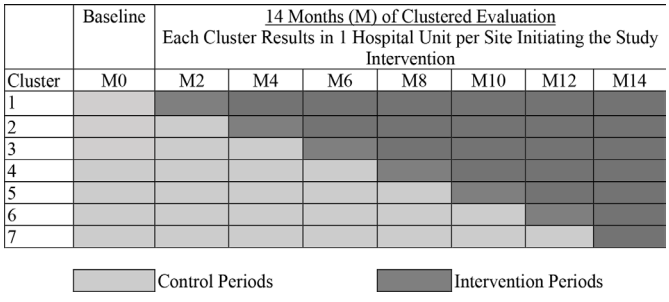

Figure 1 VIDEO-PCE study flow. VIDEO-PCE, Video Image about Decisions to Improve Ethical Outcomes with Palliative Care Educators.

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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Acknowledgements We would like to thank the participating teams at each of our sites for their involvement in this study.

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.

Funding Research reported in this publication was supported by the National Institute On Aging of the National Institutes of Health under Award Number R01AG072911. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Data availability statement Not applicable.

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REFERENCES

1 Detering KM, Hancock AD, Reade MC, *et al*. The impact of advance care planning on end of life care in elderly patients: randomised controlled trial. *BMJ* 2010;340:c1345.
2 Bernacki R, Paladino J, Neville BA, *et al*. Effect of the serious illness care program in outpatient oncology: a cluster randomized clinical trial. *JAMA Intern Med* 2019;179:751–9.
3 Bernacki RE, Block SD, American College of Physicians High Value Care Task Force. Communication about serious illness care goals: a review and synthesis of best practices. *JAMA Intern Med* 2014;174:1994–2003.
4 Paladino J, Bernacki R, Neville BA, *et al*. Evaluating an intervention to improve communication between oncology clinicians and patients with life-limiting cancer: a cluster randomized clinical trial of the serious illness care program. *JAMA Oncol* 2019;5:801–9.
5 Mack JW, Weeks JC, Wright AA, *et al*. End-of-life discussions, goal attainment, and distress at the end of life: predictors and outcomes of receipt of care consistent with preferences. *J Clin Oncol* 2010;28:1203–8.
6 Sudore RL, Fried TR. Redefining the "planning" in advance care planning: preparing for end-of-life decision making. *Ann Intern Med* 2010;153:256–61.
7 Izumi S, Fromme EK. A model to promote clinicians' understanding of the continuum of advance care planning. *J Palliat Med* 2017;20:220–1.
8 Jacobsen J, Bernacki R, Paladino J. Shifting to serious illness communication. *JAMA* 2022;327:321–2.
9 Lakin JR, Benotti E, Paladino J, *et al*. Interprofessional work in serious illness communication in primary care: a qualitative study. *J Palliat Med* 2019;22:751–63.
10 Temel JS, Greer JA, Muzikansky A, *et al*. Early palliative care for patients with metastatic non-small-cell lung cancer. *N Engl J Med* 2010;363:733–42.
11 Meier DE, Back AL, Berman A, *et al*. A national strategy for palliative care. *Health Aff* 2017;36:1265–73.

12 Quill TE, Abernethy AP. Generalist plus specialist palliative care--creating a more sustainable model. *N Engl J Med* 2013;368:1173–5.
13 Brinkman-Stoppelenburg A, Rietjens JAC, van der Heide A. The effects of advance care planning on end-of-life care: a systematic review. *Palliat Med* 2014;28:1000–25.
14 Leung JM, Udris EM, Uman J, *et al*. The effect of end-of-life discussions on perceived quality of care and health status among patients with COPD. *Chest* 2012;142:128–33.
15 Wright AA, Zhang B, Ray A, *et al*. Associations between end-of-life discussions, patient mental health, medical care near death, and caregiver bereavement adjustment. *JAMA* 2008;300:1665–73.
16 Mitchell SL, Kiely DK, Hamel MB. Dying with advanced dementia in the nursing home. *Arch Intern Med* 2004;164:321–6.
17 Mitchell SL, Teno JM, Kiely DK, *et al*. The clinical course of advanced dementia. *N Engl J Med* 2009;361:1529–38.
18 Thorne SE, Bultz BD, Baile WF, *et al*. Is there a cost to poor communication in cancer care?: a critical review of the literature. *Psychooncology* 2005;14:875–84.
19 Wendler D, Rid A. Systematic review: the effect on surrogates of making treatment decisions for others. *Ann Intern Med* 2011;154:336–46.
20 Givens JL, Kiely DK, Carey K, *et al*. Healthcare proxies of nursing home residents with advanced dementia: decisions they confront and their satisfaction with decision-making. *J Am Geriatr Soc* 2009;57:1149–55.
21 Shalowitz DI, Garrett-Mayer E, Wendler D. The accuracy of surrogate decision makers: a systematic review. *Arch Intern Med* 2006;166:493–7.
22 Covinsky KE, Fuller JD, Yaffe K, *et al*. Communication and decision-making in seriously ill patients: findings of the support project. the study to understand prognoses and preferences for outcomes and risks of treatments. *J Am Geriatr Soc* 2000;48:S187–93.
23 Phipps E, True G, Harris D, *et al*. Approaching the end of life: attitudes, preferences, and behaviors of African-American and white patients and their family caregivers. *J Clin Oncol* 2003;21:549–54.
24 Institute of Medicine. *Dying in America: improving quality and honoring individual preferences near the end of life*. Washington, D.C, 2014.
25 Tulsky JA. Improving quality of care for serious illness: findings and recommendations of the Institute of medicine report on dying in America. *JAMA Intern Med* 2015;175:840–1.
26 Tulsky JA. Interventions to enhance communication among patients, providers, and families. *J Palliat Med* 2005;8 Suppl 1:s-95–s-101.
27 Gillick MR. Advance care planning. *N Engl J Med* 2004;350:7–8.
28 Lupu D, American Academy of Hospice and Palliative Medicine Workforce Task Force. Estimate of current hospice and palliative medicine physician workforce shortage. *J Pain Symptom Manage* 2010;40:899–911.
29 O'Mahony S, Levine S, Baron A, *et al*. Palliative workforce development and a regional training program. *Am J Hosp Palliat Care* 2018;35:138–43.
30 Pawlow P, Dahlin C, Doherty CL, *et al*. The hospice and palliative care advanced practice registered nurse workforce: results of a national survey. *J Hosp Palliat Nurs* 2018;20:349–57.
31 Dudley N, Chapman S, Spetz J. Community-based palliative care leader perspectives on staffing, recruitment, and training. *J Hosp Palliat Nurs* 2018;20:146–52.
32 Lopez S, Finuf KD, Marziliano A, Weiss-Domis S, *et al*. Palliative care consultation in hospitalized patients with COVID-19: a retrospective study of characteristics, outcomes, and unmet needs. *J Pain Symptom Manage* 2021;62:267-276.
33 Szekendi MK, Vaughn J, Lal A, *et al*. The prevalence of inpatients at 33 U.S. hospitals appropriate for and receiving referral to palliative care. *J Palliat Med* 2016;19:360–72.
34 Spetz J, Dudley N, Trupin L, *et al*. Few hospital palliative care programs meet national staffing recommendations. *Health Aff* 2016;35:1690–7.
35 Volandes AE, Mitchell SL, Gillick MR, *et al*. Using video images to improve the accuracy of surrogate decision-making: a randomized controlled trial. *J Am Med Dir Assoc* 2009;10:575–80.
36 Volandes AE, Paasche-Orlow M, Gillick MR, *et al*. Health literacy not race predicts end-of-life care preferences. *J Palliat Med* 2008;11:754–62.
37 Volandes AE, Paasche-Orlow MK, Barry MJ, *et al*. Video decision support tool for advance care planning in dementia: randomised controlled trial. *BMJ* 2009;338:b2159.
38 El-Jawahri A, Podgurski LM, Eichler AF, *et al*. Use of video to facilitate end-of-life discussions with patients with cancer: a randomized controlled trial. *J Clin Oncol* 2010;28:305–10.
39 El-Jawahri A, Mitchell SL, Paasche-Orlow MK, *et al*. A randomized controlled trial of a CPR and intubation video decision support tool for hospitalized patients. *J Gen Intern Med* 2015;30:1071–80.
40 Volandes AE, Paasche-Orlow MK, Mitchell SL, *et al*. Randomized controlled trial of a video decision support tool for cardiopulmonary resuscitation decision making in advanced cancer. *J Clin Oncol* 2013;31:380–6.
41 Volandes AE, Ariza M, Abbo ED, *et al*. Overcoming educational barriers for advance care planning in Latinos with video images. *J Palliat Med* 2008;11:700–6.
42 Chan A-W, Tetzlaff JM, Altman DG, *et al*. Spirit 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158:200–7.
43 Volandes AE, Zupanc SN, Paasche-Orlow MK, *et al*. Association of an advance care planning video and communication intervention with documentation of advance care planning among older adults: a nonrandomized controlled trial. *JAMA Netw Open* 2022;5:e220354.
44 Eneanya ND, Percy SG, Stallings TL, *et al*. Use of a supportive kidney care video decision aid in older patients: a randomized controlled trial. *Am J Nephrol* 2020;51:736–44.
45 Volandes AE, Lehmann LS, Cook EF, *et al*. Using video images of dementia in advance care planning. *Arch Intern Med* 2007;167:828–33.
46 Volandes AE, Levin TT, Slovin S, *et al*. Augmenting advance care planning in poor prognosis cancer with a video decision aid: a preintervention-postintervention study. *Cancer* 2012;118:4331–8.
47 El-Jawahri A, Paasche-Orlow MK, Matlock D, *et al*. Randomized, controlled trial of an advance care planning video decision support tool for patients with advanced heart failure. *Circulation* 2016;134:52–60.
48 Volandes AE, Barry MJ, Wood F, *et al*. Audio-video decision support for patients: the documentary genré as a basis for decision AIDS. *Health Expect* 2013;16:e80–8.
49 Volandes AE, Kennedy WJ, Davis AD, *et al*. The new tools: what 21st century education can teach us. *Healthc* 2013;1:79–81.
50 Volandes AE, Paasche-Orlow MK, Davis AD, *et al*. Use of video decision aids to promote advance care planning in hilo, Hawai'i. *J Gen Intern Med* 2016;31:1035–40.
51 Epstein AS, Volandes AE, Chen LY, *et al*. A randomized controlled trial of a cardiopulmonary resuscitation video in advance care planning for progressive pancreas and hepatobiliary cancer patients. *J Palliat Med* 2013;16:623–31.
52 Volandes AE, Brandeis GH, Davis AD, *et al*. A randomized controlled trial of a goals-of-care video for elderly patients admitted to skilled nursing facilities. *J Palliat Med* 2012;15:805–11.
53 Volandes AE, Barry MJ, Chang Y, *et al*. Improving decision making at the end of life with video images. *Med Decis Making* 2010;30:29–34.
54 Lindvall C, Deng CY, Moseley E. Natural language processing to identify advance care planning documentation in a multisite pragmatic clinical trial. *J Pain Symptom Manage* 2021.
55 Brizzi K, Zupanc SN, Udelsman BV, *et al*. Natural language processing to assess palliative care and end-of-life process measures in patients with breast cancer with leptomeningeal disease. *Am J Hosp Palliat Care* 2020;37:371–6.
56 Lee KC, Udelsman BV, Streid J, *et al*. Natural language processing accurately measures adherence to best practice guidelines for palliative care in trauma. *J Pain Symptom Manage* 2020;59:225–32.
57 Harris PA, Taylor R, Thielke R, *et al*. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.