

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Utilizing Advance Care Planning Videos to Empower Perioperative Cancer Patients and Families: A Study Protocol of a Randomized Controlled Trial
AUTHORS	Aslakson, Rebecca; Isenberg, Sarina; Crossnohere, Norah; Conca-Cheng, Alison; Yang, Ting; Weiss, Matthew; Volandes, Angelo; Bridges, JF; Roter, Debra

VERSION 1 - REVIEW

REVIEWER	Clare O'Callaghan Cabrini Health Australia
REVIEW RETURNED	19-Feb-2017

GENERAL COMMENTS	<p>The protocol outlines the rationale and research design for a randomized controlled trial which evaluates the impact of an advance care planning (ACP) video intervention on “patient-centredness” of the patient-surgeon (consent) conversation before the cancer patient’s major surgery, and related outcomes. Control group patients view a surgical program information video. The study is well designed and the findings should provide helpful information which address a knowledge gap related to ACP with people with advanced cancer needing major surgery. I only have a few minor comments.</p> <p>Page 4, line 12. I suggest you remove “particularly” here. My understanding is that ACP’s purpose is always only be intended to be operated on if the person is unable to make decisions.</p> <p>Page 4, lines 50-51. The following should be in the Method section. “Patients will be randomized to (1) an intervention arm that views the ACP intervention video, or (2) a control arm that views a control video.”</p> <p>Page 5, Line 1. Please explain PCORI (and you don’t need to abbreviate it if you do not use it again).</p> <p>You introduce and explain “companion” on page 6 yet first mention the term on page 5. Please clarify “companion” when the term is introduced.</p> <p>I think it would be helpful to emphasize the cancer surgical nature of this study in the title and Introduction. I also think you need to mention that your study focusses on people having major surgery for advanced cancer (and their companions) in the Objective section.</p> <p>One editing concern: Page 3, line 20. Regarding: “... final video address surgery, but not specifically” Do you mean “... final video addresses surgery, but not specifically”</p>
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REVIEWER	Dr Maryann Street Deakin University, Australia
REVIEW RETURNED	28-Feb-2017

GENERAL COMMENTS	<p>Thank you for the opportunity to review this manuscript which is a protocol for a RCT to examine the use of Advance Care Planning videos with patients undergoing major non-emergency surgery by one of nine oncology surgeons.</p> <p>This is a well-designed study with four hypotheses: that patients who view the intervention video will 1) engage in more patient-centred communication with their surgeons; 2) be less anxious and depressed; 3) find the intervention video more helpful and 4) will watch the intervention video more often than those who viewed the control video. The primary outcome is the surgeon-patient conversation, analysed using the Roter Interaction Analysis System (RIAS) for patient satisfaction, utilization and adherence to patient centred care.</p> <p>I congratulate the authors on a clearly written manuscript of the study protocol which adequately describes the methodology to be used.</p> <p>I do have some minor comments and suggestions;</p> <p>1 Study population: In the section on Study Design, Study Sample Population (page 5), the number of surgeons is described and that recruitment will be through nine oncology clinics. However, the number of patients to be recruited is not included and is not detailed until page 11 (Sample size calculation). Randomization is stratified by surgeon, to reduce any confounders due to 'surgeon demeanour', which is a legitimate method. However, it is not clear if the number of patients per surgeon is intended to be equal or sequential, allowing for practice size variations. Please include this detail.</p> <p>2 The timing of watching the video is standardised for all surgeons, such that it occurs immediately after the surgeon recommends that the patient be scheduled for surgery. This seems a surprising time as many patients will be suffering from information and emotional overload at that time. Please comment on the implications of when the video is viewed.</p> <p>3 The referencing is consistent in style. It was noted that there are several references for the use of Advance Care Planning videos for educational purposes, but these are all from the same team of researchers. This suggests a lack of comparative research is available, which perhaps highlights the need for this RCT.</p>
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VERSION 1 – AUTHOR RESPONSE

Response to Reviewer Comments

- Page 4, line 12. I suggest you remove “particularly” here. My understanding is that ACP’s purpose is always only be intended to be operated on if the person is unable to make decisions.
 - o Thank you for this comment. We have removed the word “particularly” (Page 4).

- Page 4, lines 50-51. The following should be in the Methods section. “Patients will be randomized to (1) an intervention arm that views the ACP intervention video, or (2) a control arm that views a control video.”
 - o Thank you for the recommendation. We have removed this sentence from the importance/background section (Page 4). The Methods section contains other language indicating the presence of the two videos and detailed descriptions of each of them.

- Page 5, Line 1. Please explain PCORI (and you don't need to abbreviate it if you do not use it again).
 - o Thank you for this comment. We have added a description of PCORI: "The trial is funded by the Patient Centered Outcomes Research Institute, which supports comparative effectiveness research to help patients and other stakeholders make informed medical decisions" (Page 5).

- You introduce and explain "companion" on page 6 yet first mention the term on page 5. Please clarify "companion" when the term is introduced.
 - o Thank you for indicating that we had not explicitly defined the term "companion." We have added a definition of "companion" on page five before its first mention. It states, "Of note, accompanying family members or friends (i.e., "companions") are often present during the audiorecording of the presurgical visit" (Page 5).

- I think it would be helpful to emphasize the cancer surgical nature of this study in the title and Introduction. I also think you need to mention that your study focuses on people having major surgery for advanced cancer (and their companions) in the Objective section.
 - o We have altered the title to be "Utilizing Advance Care Planning Videos to Empower Perioperative Cancer Patients and Families: The Protocol for a Patient-Centered Outcomes Research Institute-funded Study," which acknowledges that the study involves cancer patients (Page 1). We have similarly revised our objective sentence to explicitly mention that the study focuses on cancer patients: "The objective of this study is to evaluate whether, compared to a control video, an ACP video developed for patients and families pursuing aggressive surgical treatment for cancer impacts the patient centeredness of the patient-surgeon conversation during the audiorecorded presurgical consent visit" (Page 4). Our introduction has been similarly updated to emphasize the role of cancer patients: "As patients with advanced cancer undergoing major surgery often experience conditions that may increase their risk for both complications during surgery and post-operative outcomes (e.g., functional decline, frailty, comorbidities, and polypharmacy)¹⁸⁻²², it is likely beneficial for them to initiate ACP prior to surgery" (Page 4).

- One editing concern: Page 3, line 20. Regarding: "... final video address surgery, but not specifically ...". Do you mean "... final video addresses surgery, but not specifically ...".
 - o Thank you. As this is in the 'Strengths and Limitations' portion, we will change the sentence to read "the final video addresses surgery, but not specifically pancreatic cancer or cancer surgery" upon resubmission.

- Study population: In the section on Study Design, Study Sample Population (page 5), the number of surgeons is described and that recruitment will be through nine oncology clinics. However, the number of patients to be recruited is not included and is not detailed until page 11 (Sample size calculation). Randomization is stratified by surgeon, to reduce any confounders due to 'surgeon demeanour', which is a legitimate method. However, it is not clear if the number of patients per surgeon is intended to be equal or sequential, allowing for practice size variations. Please include this detail.
 - o Thank you. We have added a sentence to the Study Sample Population section to note the number of patients we intended to recruit: "Based on sample size calculations, explained in the Design Justification section below, we aimed to recruit 90 patients for the study" (Page 5).
 - o Regarding the number of patients recruited from each surgeon, we have added the following sentence detailing our expectations, "We do not anticipate surgeons to recruit an equal number of patients given differences in practice type and volume; however, each surgeon was encouraged to recruit at least three patients to allow for clustering by surgeon in our analysis" (Page 6).

- The timing of watching the video is standardised for all surgeons, such that it occurs immediately

after the surgeon recommends that the patient be scheduled for surgery. This seems a surprising time as many patients will be suffering from information and emotional overload at that time. Please comment on the implications of when the video is viewed.

o Thank you for your comment regarding the timing of the video. The surgeon stakeholders who assisted with the design of our study suggested that the proposed timing for patients viewing the video was the most appropriate time given their outpatient interactions with patients prior to surgery. While we acknowledge that some patients may indeed be experiencing information and emotional overload during this period, it is difficult to otherwise facilitate a study that aims to change patient behavior during this period in the care trajectory.

o We have added a sentence when describing the rationale behind the timing of the video viewing: “Surgeon stakeholders involved in the design of the study recommended this timing for the video viewing” (Page 7).

- The referencing is consistent in style. It was noted that there are several references for the use of Advance Care Planning videos for educational purposes, but these are all from the same team of researchers. This suggests a lack of comparative research is available, which perhaps highlights the need for this RCT.

o We acknowledge that most studies to date have been done by Dr. Angelo Volandes and his team, which encompasses references 36-50. We agree this highlights the need for this RCT. Volandes has done ACP video research on several clinical conditions and diverse inpatient vs outpatient settings; however, there is a need for studies on this field from other research teams. We want to also acknowledge that Dr. Volandes is a co-author on this manuscript and was instrumental in helping us to create this video. This video was designed as an ACP video for surgical patients specifically and believe that this feature is a contribution of our work to the literature.

VERSION 2 – REVIEW

REVIEWER	Clare O'Callaghan Cabrini Health Australia
REVIEW RETURNED	10-Apr-2017

GENERAL COMMENTS	This is now a very well presented protocol of an RCT examining Advance Care Planning videos for perioperative patients and families. I only have a few comments. Why are there numbers in Figure 2 (trial enrolment diagram)? A few typos: In Abstract (Participants). Should this be 'clinics'? Page 12, line 47. Delete a “talked” in “... but we have not talked specifically talked about this ...”
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REVIEWER	Dr Maryann Street Deakin University, Australia
REVIEW RETURNED	15-Apr-2017

GENERAL COMMENTS	Thank you for responding to the reviewers comments and addressing suggested changes. The manuscript for the study protocol for a RCT to examine the use of Advance Care Planning videos with patients undergoing major is clearly written and I look forward to reading the findings when they are published.
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VERSION 2 – AUTHOR RESPONSE

Response to Reviewer Comments

- Why are there numbers in Figure 2 (trial enrolment diagram)?
 - o Thank you for this comment. We have removed participant counts from Figure 2.

- A few typos: In Abstract (Participants). Should this be 'clinics'?
 - o Thank you for this comment. The typo has been corrected to 'clinics.'

- Page 12, line 47. Delete a "talked" in "... but we have not talked specifically talked about this ..."
 - o Thank you for this comment. The word 'talked' has been deleted.