

# BMJ Open Advance care planning in patients with incurable cancer: study protocol for a randomised controlled trial

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## ABSTRACT

**Introduction:** There is limited evidence documenting the effectiveness of Advance Care Planning (ACP) in cancer care. The present randomised trial is designed to evaluate whether the administration of formal ACP improves compliance with patients' end-of-life (EOL) wishes and patient and family satisfaction with care.

**Methods and analysis:** A randomised control trial in eight oncology centres across New South Wales and Victoria, Australia, is designed to assess the efficacy of a formal ACP intervention for patients with cancer. Patients with incurable cancer and an expected survival of 3–12 months, plus a nominated family member or friend will be randomised to receive either standard care or standard care plus a formal ACP intervention. The project sample size is 210 patient–family/friend dyads. The primary outcome measure is family/friend-reported: (1) discussion with the patient about their EOL wishes and (2) perception that the patient's EOL wishes were met. Secondary outcome measures include: documentation of and compliance with patient preferences for medical intervention at the EOL; the family/friend's perception of the quality of the patient's EOL care; the impact of death on surviving family; patient–family and patient–healthcare provider communication about EOL care; patient and family/friend satisfaction with care; quality of life of patient and family/friend subsequent to trial entry, the patient's strength of preferences for quality of life and length of life; the costs of care subsequent to trial entry and place of death.

**Ethics and dissemination:** Ethical approval was received from the Sydney Local Health District (RPA Zone) Human Research Ethical Committee, Australia (Protocol number X13-0064). Study results will be submitted for publication in peer-reviewed journals and presented at national and international conferences.

**Trial registration number:** Pre-results; ACTRN12613001288718.

## INTRODUCTION

End-of-life (EOL) care is a key component of essential services for people with advanced

cancer.<sup>1</sup> Unfortunately, EOL care of patients with cancer has not kept pace with improvements in treatments directed at the cancer. While evidence shows that most patients with cancer prefer to die at home or in a hospice, hospital remains the most common place of death.<sup>2–3</sup> In a recent study, 65% of 28 000 patients with advanced solid tumours were found to have received at least one form of aggressive care within the last 30 days of life.<sup>4</sup> Aggressive care in this study was defined as either hospital admission, an intensive care unit (ICU) admission or an emergency room visit, as well as a chemotherapy or radiation treatment. Apart from the psychoemotional trauma, such late interventions have significant costs for the health system and the patient and their family.

Advance Care Planning (ACP) refers to the process by which patients, families and health professionals discuss and establish future goals of care in accordance with a patient's values and preferences. ACP is intended to support patients in receiving the care they would have chosen should they become too unwell to make their own EOL decisions near death. There is some evidence that complex ACP interventions may increase the frequency of out-of-hospital and out-of-ICU care and increase compliance with patients' EOL wishes.<sup>5</sup> However, the frequency of EOL discussions in cancer care is low<sup>6</sup> and limited research has been undertaken on the impact of complex ACP interventions in cancer. In a 2014 review of 113 studies on the effects of ACP, only 18% (20 studies) reported on complex ACP interventions and only two of these studies included patients with cancer.<sup>5</sup> Although ACP has the potential to improve the quality of death for patients with cancer, the effects of complex ACP interventions in this population are unknown. The present trial is designed to



evaluate whether the administration of a coordinated ACP intervention improves compliance with patient's EOL wishes, patient and family satisfaction with care, and the experience of death and dying.

## OBJECTIVE

The objective of the ACP study is to evaluate the efficacy of a formal ACP intervention for patients with incurable cancer who have received systemic therapy (chemotherapy, targeted therapy or endocrine therapy) and have an estimated survival of 3–12 months.

We hypothesise that patients randomised to intervention will be more likely to have family/friend report: (1) discussion with the patient about their EOL wishes and (2) perception that the patient's EOL wishes were met. For secondary outcomes, we hypothesise that patients participating in the intervention will be more likely to have their EOL preferences documented and complied with, have an improved quality of EOL care, have nominated family or friends who experience less mental ill health during bereavement, report improved quality of communication about EOL care, report greater satisfaction with care and value quality over quantity of life more than patients in the control arm.

We hypothesise that Advance Care Plans will reduce healthcare costs at the EOL; oncologists' predictions of expected survival time will be inaccurate; communication of expected survival time in terms of typical, best-case and worst-case scenarios will increase patient understanding of their prognosis; and that patients and nominated family/friends will report satisfaction with the intervention.

## METHODS AND ANALYSIS

### Study design

The ACP trial is a prospective, multisite, randomised control trial with two parallel groups receiving either usual care plus a coordinated ACP intervention or usual care without coordinated ACP. Participants enter the trial as dyads: a person diagnosed with cancer plus a nominated family member or friend. After recruitment, the patient and/or family will be contacted by telephone at 8-week and then 3-month intervals until the patient's death. Family members or friends will be contacted 3 months after bereavement to complete final questionnaires. Following the patient's death, a review of their medical record will assess documentation of EOL preferences and medical interventions received in the final 2 weeks of life.

The primary outcome measure is family or friend-reported: (1) discussion with the patient about their EOL wishes and (2) perception that the patient's EOL wishes were met.

The study is planned for a 3-year duration with a maximum 12-month follow-up period for patients and a maximum 15-month follow-up period for nominated family members or friends. The study is registered on

the Australia and New Zealand Clinical Trials Registry ACTRN12613001288718.

## Participants

To be eligible for the ACP study, patients must be 18 years or older, have a diagnosis of incurable cancer, have received systematic therapy to treat their cancer and have an expected survival time of 3–12 months. They must also be able to nominate a family member or friend who is willing to participate in the trial with them. All participants must be able to read and write English, and be capable of reading an information booklet and completing a series of questionnaires. Patients are excluded from the trial if they have previously completed formal ACP.

A total of seven oncology departments across two Australian states are actively recruiting to the trial: two oncology units in Melbourne (Austin and Box Hill Hospitals) and five in Sydney (The Chris O'Brien Life house, Campbelltown Hospital, Concord Repatriation General Hospital, The Royal North Shore Hospital and the Northern Cancer Institute).

## Intervention

Participants in the trial randomised to the intervention receive nurse-led (ACP clinician) ACP. Patients in the intervention group will be offered optional information about their likely life expectancy as part of the ACP intervention. Experienced oncology nurses or allied health professionals participate in a two-part training course and peer mentoring and shadowing in the clinical environment to learn to deliver the study intervention. The intervention is based on the Respecting Patient Choices model<sup>7</sup> with the addition of skills in EOL communication, and estimating and communicating typical, best-case and worst-case scenarios for survival. Treating oncologists will liaise with the ACP clinician to ensure patients understand their illness, treatment options and likely prognosis, and will be asked to sign any Advance Care Plans completed by the patient. The intervention is specifically targeted at patients with advanced cancer with input from the investigator team, including oncologists and palliative care physicians.

ACP clinicians complete Part 1 e-Learning Respecting Patient Choices education course to provide a broad introduction to ACP, and Part 2 Practical workshop at Austin Hospital, Australia, based on the Respecting Patient Choices education course.<sup>7</sup> ACP clinicians attend a focused 1-day workshop to learn additional skills in EOL communication and in delivering prognostic information. The workshop includes cancer-specific clinical information and role play with professional actors. Core components of the intervention are outlined in [figure 1](#).

The ACP meeting occurs within 2 weeks of enrolment into the study and includes the patient and their nominated family or friend. Patients are instructed that should their goals and wishes change at any stage, they

**Figure 1** Core components of the Advance Care Planning (ACP) intervention.

- I. Negotiate an agenda for the consultation
- II. Assess the patient's and/or family's readiness to discuss future care
- III. Explore the patient's understanding of their medical situation, any unmet information needs and provide information if appropriate
- IV. Explore the patient's values, goals, priorities, hopes, fears and concerns for the future
- V. Explore if there are any situations, treatments or health states the patient would find unacceptable
- VI. Summarise your understanding of the person's most important wishes for future care
- VII. Consider any other specific treatment options relevant to the person's circumstances
- VIII. Consider offering to make a recommendation for future medical care, if they were to become too sick to speak for themselves, based on their values and wishes
- IX. Help the patient to document their wishes

should contact their ACP nurse to arrange another meeting. All ACP meetings are audiotaped for quality and training purposes. Meetings will be audited to assess adherence and quality.

### Data collection and follow-up

Patients are assessed at baseline, 8 weeks (6 weeks post intervention), then every 3 months until death or the end of the study. Nominated family or friends are assessed at baseline, 8 weeks, every 3 months until the patient's death and at 3 months after the patient's death. [Figure 2](#) shows a schema of work flow throughout the study. The assessment schedule for patients and family/friends are summarised in [table 1](#) and [table 2](#). Following the patient's death, a review of their medical record will assess documentation of EOL preferences and medical interventions received in the final 2 weeks of life.

Study data will be collected and managed using Research Electronic Data Capture (REDCap) tools hosted at The University of Sydney. REDCap is a secure, web-based application designed to support data capture for research studies.<sup>8</sup>

### Primary outcome

There are no validated or 'gold-standard' procedures for measurement of compliance between patient's EOL wishes and the care provided.<sup>9</sup> To determine the extent to which the patient's EOL wishes were met, we will use family perception that the patients EOL wishes were met.

For the primary outcome of this study, we will assess family/friend-reported: (1) discussion with the patient about their EOL wishes and (2) perception that the patient's EOL wishes were met, assessed at 3 months

after bereavement. Specifically, family/friends will be asked:

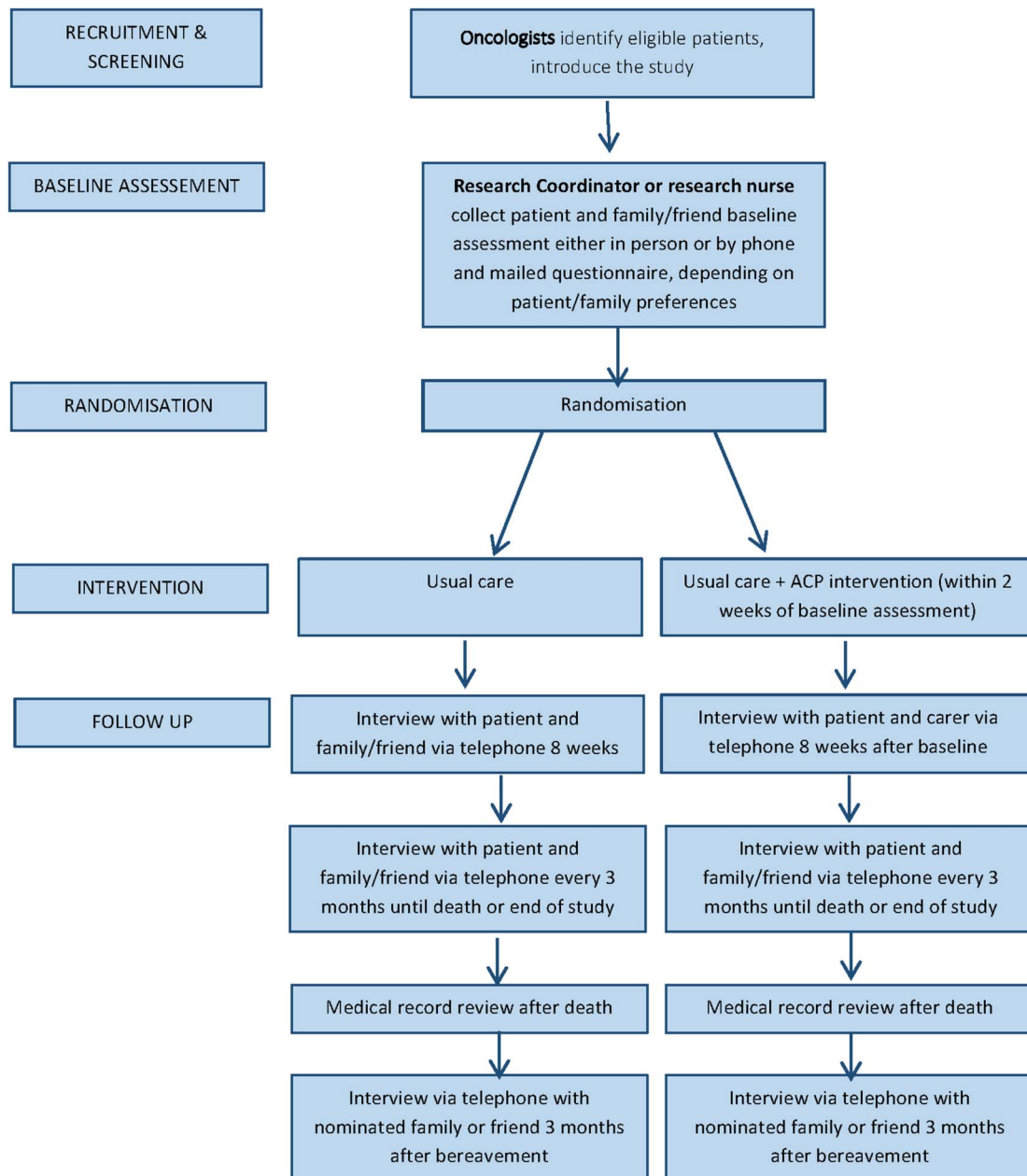
- ▶ 'Did the patient discuss with you any particular wishes he/she had about the care they would want to receive if they were dying?' Answers will be recorded on a 5-point Likert Scale from 0='Not at all' to 5='Very much'.
- ▶ 'I am satisfied that at the end of his/her life their wishes were met'. Answers will be recorded on a 5-point Likert Scale from 0 'Strongly disagree' to 5='Strongly agree'.

Agreement that EOL wishes were discussed (responses of 'Quite a bit' and 'Very much') AND that the patients EOL wishes were met (responses of 'Agree' or 'Strongly agree') will be scored as a positive outcome (ie, wishes known and complied with).

### Secondary outcomes

A. *The documentation of patient preferences for EOL care and concordance with care received at the EOL.*

Medical record review will assess concordance between documentation of preferences for care defined in the literature as important EOL care goals,<sup>10–12</sup> and medical interventions received in the last 2 weeks of life. As published papers used varied time frames (from a few days to a month) to assess medical interventions received at the EOL, we adopted a 2-week time point. We will identify documented patient preferences for place of death, cardiopulmonary resuscitation, ICU admission and any other significant intervention identified in a patient's medical record, including chemotherapy use within the last 4 weeks of life. Documented preferences will be compared with the care received in the last 2 weeks of life. Documentation of preferences and concordance



**Figure 2** Participant assessment and follow-up plan.

between preferences and care received are required to receive a positive score. Items will be scored individually.

B. *Prevalence, timing and location of EOL care documents.* Medical record review will assess the prevalence, timing and location of EOL care documents, as well as the documentation of substitute decision makers, at the hospital where patients received their oncology care.

C. *Place of death* will be verified with the caregiver at the 3-month bereavement interview by asking the nominated family or friends ‘Where did your loved one die?’

D. *Quality of EOL care* will be measured using a study-specific 27-item tool assessing the family/friend’s satisfaction with the quality of a patient’s death. The Assessment will be completed via an interview with

the family/friend at 3 months after bereavement and includes items adapted from Detering *et al*<sup>13</sup> and Engelberg *et al*<sup>14</sup> Quality about EOL Communication (QOC). For example, family/friends will be asked, ‘In your opinion, how would you rate the overall quality of the patient’s death/last week of life?’ And ‘How satisfied were you with the way in which the patient died?’

E. *The impact of death on surviving family members* will be measured using the Impact of Events Scale (IES)<sup>15</sup> at 3 months after bereavement. This is a validated 15-item tool that identifies risk of developing post-traumatic stress disorder. In addition, the well-validated and widely accepted 14-item Hospital Anxiety and Depression Scale (HADS)<sup>16</sup> will be used

**Table 1** Patient assessment schedule

Outcome	Measurement tool	Validated	Baseline	8 weeks	Every 3 months	After death
Demographics	Demographic questionnaire		✓			
Patient understanding of survival time	Prognosis survey and the iTool	✓	✓	✓		
Patient/family/healthcare provider communication about EOL care	EOL communication with family and healthcare providers questionnaire		✓	✓		
Quality of life	EQ-5D5L	✓	✓	✓	✓	
Preference for quantity or quality of life	Discrete choice experiment		✓	✓		
Patient satisfaction with care	Satisfaction with care survey			✓		
Costs of ACP	Costs of care survey		✓	✓	✓	
Satisfaction with intervention	Satisfaction with ACP intervention (intervention arm only)			✓		
The documentation of patient preferences for EOL care and concordance with care received at the EOL	Medical record review form					✓
Prevalence, timing and location of EOL care documents	Medical record review form					✓

at baseline, every 3 months until the patient's death and 3 months after bereavement.

- F. *Patient–family and patient–healthcare provider communication about EOL care* will be assessed using items adapted from Wright *et al.*<sup>12</sup>
- G. *Patient and caregiver satisfaction with care* will be assessed using a five-question survey used in a previous trial<sup>13</sup> focusing on satisfaction with information provision.
- H. *Quality of life (QOL)* will be measured using the EQ-5D-5L<sup>17</sup> for patients and the 12-item Short-Form Health Survey (SF-12)<sup>18</sup> for caregivers. QOL scores will be compared between groups and in the same group at different time intervals. Multivariate relationships between patients' QOL and different outcomes of the intervention will also be examined.
- I. *Patients' strength of preferences for QOL and length of future life* will be assessed using a Discrete Choice Experiment (DCE).<sup>19</sup> Patients are presented with a short description of a health state then asked to compare two descriptions and select which represents the better or more desired situation.
- J. *The cost of ACP* and the costs of healthcare used (for 3 months prior to trial entry until death) will be assessed. Costs of care will be assessed by data linkage using Commonwealth Medicare and Pharmaceutical Benefits Scheme (PBS) records, state-based records on hospital admissions and emergency department visits, as well as patient-reported out of pocket expenses and healthcare use of services and products that are beyond the scope of the administrative data sets. To determine the wider ramifications of the intervention, healthcare-use cost of the nominated family member or friend will also be obtained before and after the patient's death.
- K. *Accuracy of predictions of life expectancy* will be assessed by comparing the oncologist's estimate of each patient's life expectancy at baseline with the patient's

**Table 2** Family/friend assessment schedule

Domain	Measurement tool	Validated	Baseline	8 weeks	Every 3 months	3 months after bereavement
Demographics	Demographic questionnaire		✓			
Quality of life	SF-12	✓	✓	✓	✓	✓
Bereavement adjustment	Hospital Anxiety and Depression Scale	✓	✓	✓	✓	✓
The impact of death on surviving family members	Impact of Event Scale	✓				✓
Quality of end-of-life care	Quality of end-of-life and satisfaction with care questionnaire					✓

observed survival time using methods developed in a previous study.<sup>20</sup>

- L. *Patient understanding of life expectancy* will be assessed at baseline and at 8 weeks using an instrument developed in a previous study.<sup>21 22</sup> Patients in the intervention group who want information on life expectancy will be provided with individualised estimates of worst-case, typical and best-case scenarios for survival using the oncologist's estimate and a web-based tool (iTool) developed by Kiely *et al.*<sup>22</sup>
- M. *Patient and family satisfaction with the ACP intervention* will be assessed using a study-developed questionnaire.

**Box 1** Provides further details on the medical record review, data collection and assessment of intervention fidelity.

### Sample size

In a previous trial by the investigator group, EOL wishes were known and respected in 86% of the intervention group compared with 30% of controls.<sup>13</sup> Assuming the same baseline rate of EOL wishes known and respected in patients with cancer, and believing a doubling to 60% would influence clinical practice, two study groups that each include 56 patients who die within the 3-year follow-up period will result in the study having 90% power to detect a between-group difference with 95% certainty. A conservative estimate of mortality is 75%. To

allow for incomplete data on 20% of patients and a further 10% of their nominated family members or friends, we propose a sample size of 210 patients with advanced incurable cancer.

### Recruitment and randomisation

Oncologists at participating sites will be asked to identify patients who meet the study inclusion criteria and to inform patients about the study during their outpatient oncology visits. Potential participants will be introduced to a research team member in attendance at the clinic who will provide them with further details of the study. Family members or friends who are not in attendance at the clinic will receive a follow-up phone call from the research team. The information provided in the consent form will be the same for the intervention group and the control group. The information sheets will exclude naming the intervention (ACP) in order to avoid contamination of the control arm. Participants will be informed that the project is evaluating the effectiveness of a programme aimed at improving communication with patients with advanced cancer, their family and friends and their doctors. Participants will be informed that those randomised to the intervention group will meet with a specially trained nurse to talk through their goals, wishes and needs for care, now and in the future. Participants in this study will be advised before entry that participation is voluntary and they are free to withdraw at any time.

Participants will be randomised by minimisation with a 1:1 allocation of control group to intervention group. Participants will be stratified by site and sex, using the 24/7 Interactive Voice Response System (IVRS) telephone-based randomisation system at the National Health and Medical Research Council (NHMRC) Clinical Trials Centre.

The statistical analysis and preparation of tables and graphs for the report of the study by the statistician of the study will be blinded. Research staff completing follow-up assessment and medical record review will be blinded to the extent possible (participants will be identifiable by study ID only, but the 8-week assessment contains additional 'satisfaction with the intervention' questionnaire for intervention participants and the medical record may include study-specific documents). Participants and oncologists will be non-blinded.

### Statistical analysis

The study statistician performing the analysis will be blinded to group allocation. The effect of the ACP intervention will be assessed by using  $\chi^2$  tests for categorical outcomes and t-tests for continuous outcomes, if measured at one time point only and if there is no oncologist effect. Clustering by oncologist will be tested using mixed models, and if the intracluster correlation is estimated to be non-zero, outcomes will be analysed using mixed models and generalised linear mixed models with oncologist included as a random effect.

#### Box 1 Details of assessment of the medical record review and intervention fidelity

##### *Medical record review for deceased patients*

Trained members of the research team will consider all of a patient's available medical records (at the acute hospital where they receive their oncology care) to assess concordance between documentation of preferences for care and medical interventions received, place of death and timing and location of documentation of end-of-life (EOL) preferences (secondary outcomes A, B and C). Reviewers will receive 2 days of face-to-face group training, and be provided with a standard form and written guidelines. Ten per cent of records will be reabstracted by a second reviewer to assess for inter-rater reliability. Reviewers will have real-time consultation with medically trained staff if required. Where the abstractor is unsure of how to score, cases will be referred first to the study coordinator and then to the steering committee for additional review until consensus is reached.

##### *Intervention fidelity*

All intervention sessions will be audio recorded. This provides an opportunity to assess how the intervention was actually delivered in practice. There are currently no tools available which aim to measure the quality and consistency of Advance Care Planning (ACP) interventions. Additionally, there have been no published reports of auditing actual practice of ACP inside of a clinical trial setting. We will use the data from the recorded ACP conversations to: (1) design and evaluate a fidelity instrument, (2) describe variations in ACP intervention delivery and (3) analyse correlations between delivery and patient outcomes.

Outcomes which are measured repeatedly (eg, QOL) will be analysed with mixed models to assess patterns over time as well as differences between groups at specific time points. These models are valid for data that are missing completely and missing at random.<sup>23</sup> All analyses will follow the intention to treat. Mixed models are consistent with an intention to treat analysis in the presence of missing data.<sup>24</sup> A secondary per-protocol analysis will be performed along with an exploration of why any participants did not receive the treatment to which they were assigned. Accuracy of predictions of survival time will be investigated using descriptive statistics and Bland-Altman plots<sup>25</sup> for those patients who die within the follow-up period. Differences in survival will be explored with Kaplan-Meier plots.

Descriptive statistics will be used to describe the sample and to compare the characteristics of patients in the different groups.

### Interim analyses plan

Analysis of satisfaction with intervention and QOL data will be undertaken at midpoint of the study to ensure no adverse consequences.

### Data-monitoring plan

The study steering committee will monitor the course of the trial and provide ongoing oversight of the preliminary results. Investigators will review un-blinded results and, if necessary, will give a recommendation for discontinuation, modification or continuation of the study.

## DISCUSSION

The study has several strengths and limitations which are described as follows.

### Strengths

The study design follows that of a previous randomised controlled trial conducted by members of the investigator team.<sup>13</sup> Therefore, the study protocol and intervention have been proven to be feasible and successful in a different patient population. Furthermore, the ACP intervention used in the present study has a number of specific strengths. First, it includes patients and their family member or friend. Second, the ACP intervention is available to participants assigned to intervention for as many sessions as they request. Third, the ACP intervention has been adapted to be cancer-specific and finally, the intervention includes optional provision of and discussion of prognostic information. The study also has methodological strengths. The ACP study is a randomised controlled trial with allocation concealed using a computer-generated interactive voice system in order to prevent systematic bias.

### Limitations

The proportion of eligible patients who participate in the trial will be documented. It is likely that there will

be systematic differences between those who choose to participate in the ACP trial and those who choose not to participate. Second, it is likely that completing study questionnaires will prompt some participants in both arms of the study to consider and discuss their EOL wishes. Third, it is unavoidable that in conducting a longitudinal study involving patients with incurable disease, a number of participants will die before follow-up data can be collected, withdraw from the study or be lost to follow-up. Fourth, the study intervention is complex and requires skill, time and resources to deliver. It may be difficult to replicate consistently across institutions. Finally, as the ACP intervention requires the involvement of treating oncologists and documentation in the medical record, the oncologists and researchers working in the study cannot be blinded to group allocation.

Two other randomised controlled trials are underway, which also investigate the effects of ACP in cancer.<sup>26 27</sup> This presents an opportunity for meta-analysis of data on the effectiveness of ACP in cancer care. Data will be collected for almost 2000 patients with advanced cancer across Europe, the USA and Australia. Shared patient outcomes across all three studies include: concordance with EOL wishes and care received, quality of communication, quality of death/quality of EOL care, patient mental health outcomes and acceptability of the ACP intervention. Further details of each study are presented in [table 3](#). However, there are no gold-standard outcomes, or measures to assess the efficacy of ACP, and a variety of measures will be used across studies to assess similar outcomes. This presents a challenge to meta-analysis. [Table 3](#) presents details of study design, sample size, population, intervention and primary outcome measure for each study. Shared patient outcomes and a brief description of the distinguishing features between studies are also presented. A full list of the outcome measures used in each study can be found in the published study protocols.<sup>26 27</sup>

## ETHICS AND DISSEMINATION

This study is funded by the National Health and Medical Research (NHMRC) (grant number APP1050596) and is administered through the University of Sydney. There are no contractual agreements that limit data access for investigators. The study sponsor will have no role in the study design; collection, management and interpretation of data; writing of reports; and the decision to submit reports for publication.

The study will be conducted in accordance with the NHMRC's guidelines for the ethical conduct of human research. The study investigator team, which includes academics and clinicians with a broad range of skills and experience, has been established as a steering committee. The steering committee meet quarterly and will guide study procedures and dissemination of results.

**Table 3** Details and comparison between three randomised controlled trials (RCTs) of Advance Care Planning (ACP) in cancer care

Study name	Study design	Sample size	Population	Intervention	Primary outcome	Shared patient outcomes	Additional features of each study
ACTION Study <sup>27</sup>	Cluster RCT in 6 European countries (BE, DK, IT, NL, SI, UK)	1360	Patients with advanced lung or colorectal cancer with an average life expectancy of 12 months	Respecting Choices model	Quality of life and symptoms	Goal concordant care Quality of life Quality of death/quality of end-of-life (EOL) care Satisfaction with the intervention	Qualitative study of patients, relative's and professional caregivers' experiences of involvement in ACP
Bernacki <i>et al</i> <sup>26</sup>	Cluster RCT, USA	426	Patients with advanced incurable cancer and a life expectancy of <12 months	A multicomponent, structured communication intervention	Receipt of goal-concordant care, and peacefulness at the EOL	Timing, place and prevalence of documentation about EOL care Place of death	Clinician outcome data—attitudes, confidence, acceptability, prognostic evaluation
Australian ACP study	One-to-one randomisation RCT, Australia	210	Patients with advanced cancer, and a life expectancy of 3–12 months	Adapted Respecting Patient Choices model + prognostic information	Family/friend-reported: (1) discussion with the patient about their EOL wishes and (2) perception that the patient's EOL wishes were met	Resource use/cost analysis Bereavement outcomes in relatives	Estimating and discussing survival scenarios



Important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) will be communicated to relevant parties via regular study newsletters. The steering committee will also be responsible for assessing, reporting and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct.

All information collected during the course of the study will be kept strictly confidential and any information which would allow individual participants to be identified will not be released. Anonymised data will be compared; individual patients, family members or oncologists will not be identifiable. The results will be submitted for publication in peer-reviewed journals and will be presented at national and international conferences. The results of this study will provide evidence for the direction and development of quality EOL care for patients with advanced cancer.

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**Contributors** SJ drafted the manuscript, and is the study coordinator with responsibility for coordinating development of the study materials and collection of data. MHNT developed the Research Application in collaboration with WS, KD, JCI, PNB and MLB. JCI, WS, KD, PNB and BEK refined the research methods and developed the Advanced Care Planning (ACP) intervention for patients with cancer. SC, PB and JCe provided clinical leadership in recruitment of patients and protocol development. MS and BK developed the segment of the ACP relating to estimating and communicating patient life expectancy. JH proposed the inclusion of healthcare cost estimates in the data collected, and the inclusion of the discrete choice experiment. All authors reviewed and approved the manuscript.

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