Interventions for promoting the use of advance directives for end-of-life decisions in adults (Protocol)


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Interventions for promoting the use of advance directives for end-of-life decisions in adults (Protocol)
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Interventions for promoting the use of advance directives for end-of-life decisions in adults

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\textbf{ABSTRACT}

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effects of interventions for promoting the use of advance directives (ADs) about end-of-life decisions of adults.
BACKGROUND

**Conceptual background**

Advance directives (ADs) are written documents made by people in advance of a situation in which they may be incompetent to decide about their own care, stating their treatment preferences or authorizing a third party (proxy or substitute) to make decisions for them. Several types of AD documents exist:

- A ‘living will’ is a document that specifies treatments that would be desired/not desired if a person were unable to make his/her own choices. Living wills commonly address choices about cardiopulmonary resuscitation such as ‘do not resuscitate’ (DNR) orders, mechanical ventilation, artificial feeding and hydration, provision of blood and antibiotics, and surgical procedures.

- A ‘durable power of attorney for health care’ is an AD document in which the person specifies a proxy decision-maker to take decisions if s/he does not have decision-making capacity.

- A ‘values history’ (Doukas 1991) is a document that tries to collect those values which are important to the person, and which should be respected in end-of-life decision-making.

In this review we will use the term ‘advance directive’ in its broad sense, to refer to any written document in which an adult states in advance any preference about end-of-life decisions. This document may be a living will, a durable power of attorney, a values history or a complex written document that includes all of them. A person therefore can have one, two or all three of the above documents, depending on the circumstances. In fact, nowadays, most ADs are complex documents that include a living will, a durable power of attorney and a more or less complete values history. The ‘medical directive’ and the ‘health care directive’ are good examples of this kind of complex AD (Emanuel 1991).

The terms proxy, surrogate, substitute or healthcare agent will be considered synonyms in this review. They refer to the person appointed to make healthcare decisions for the patient when s/he becomes incompetent and is unable to make them for him or herself, and could be a family member, friend or appointed guardian. The proxy could be appointed previously by the patient using a durable power of attorney for health care. If a durable power of attorney does not exist when the patient becomes incompetent, they can be appointed at that time following legal provisions or court decisions. These proceedings depend on the regulations of each country or state.

For the purposes of this review, we will not consider oral statements or declarations by patients to be ADs. Nor will we include ADs referring to mental illness treatment decisions. Psychiatric ADs, also known as ‘Ulysses directives’, are written documents that enable people with mental illness to convey their treatment preferences if in the future they become incompetent. A Cochrane systematic review of this intervention is underway (Campbell 2006).

Advance care planning (ACP) is a term dating from the mid 1990s. It consists of a discussion or a set of encounters between people, their surrogates, and professionals about the goals and desired direction of the patient’s care, particularly end-of-life care, in the event that the patient is or becomes incompetent to make decisions (Teno 1994). ACP includes a set of interventions to promote communication or discussion, including structured interviews, meetings, use of videotapes, booklets or written ADs aiming to involve persons and surrogates in discussions about end-of-life decisions. A signed AD may be one component of ACP and it also may be one of the outcomes of an ACP process.

Our objective is to assess the effects of ADs, not ACPs. However, trials of ACP may include an intervention to promote the use of an AD, and if the effects of that intervention can be separated, that trial may be included. The literature is complex, though, and many terms are used to describe the same type of intervention. Therefore, all decisions about including and excluding studies will be carefully documented.

**Historical background**

ADs first appeared in the United States (US) in the late 1960s, to support respect for patient autonomy in the face of decision-making incapacity. Initially they were called ‘living wills’ (Kutner 1969). California was the first state to legalize ADs (Natural Death Act, 1976). Throughout the 1980s, after clear support from the President’s Commission Report (President 1983), most US states passed acts to legalize ADs, and the research field grew (McCarrick 1991). To the initially limited concept of ‘living will’ was added more sophisticated documents and legal terms like ‘advance directives’, ‘durable power of attorney’ and ‘health care proxy’.

ADs became even more common after the federal US Patient Self-Determination Act was passed in 1990. This generated extensive research about their clinical use, such as the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT) (Murphy 2000). SUPPORT involved 9105 patients in advanced stages of serious illnesses in five US teaching hospitals. The study found that physicians often ignore ADs, such as DNR orders. This was true even where efforts were made to improve physician-patient communication about the end of life. In SUPPORT, patients were randomised to receive or not receive an additional intervention consisting of education by a nurse practitioner trained to act as a communicator on issues relating to ADs (Teno 1997). The outcomes of neither the SUPPORT trial nor the Patient Self-Determination Act met the expectations that had been created around them.

In 1993, a prominent Hastings Center project reconsidered the role that ADs should play in clinical decisions. The researchers concluded that comprehensive communication between health professionals, patients and family members should be encouraged in order to improve the quality of end-of-life decisions; completion of an AD was less important than enhancing communication and participation. The Hastings Center project report named this...
new approach 'Advance care planning' (ACP) (Teno 1994). This approach has become the most prevalent in the North American literature (Prendergast 2001).

ADs have spread throughout the developed world, although with very different impacts and results. The ACP 'Let Me Decide' Project is having a considerable impact on the development of ADs in Canada (Molloy 2000). There is no federal law on ADs in Canada, but several provinces have developed their own regulations. Australia also has wide experience in the regulation of ADs (Taylor 2002). Several states have statutory schemes, while in the other states ADs are regulated by common law (Clayton 2007). New Zealand also has legal regulation of ADs (Wareham 2005), European countries are at different legislative stages. Spain is one of the most advanced, and laws regulating ADs have been enacted in each of the autonomous regions (Simon 2004). Germany is engaged in a long discussion about the best way to develop ADs (Sträling 2004), a question that has received attention from the German National Ethics Council (Nationaler 2005). A recent study estimated that almost 10% of German adults have completed an AD (Lang 2007). Denmark (Danish Council 2006) and France (Fournier 2005) are now developing legal regulations. The Dutch experience with ADs is different to that of other European countries, because it is linked to the euthanasia statutes (Rurup 2006). The Italian National Bioethics Committee supported ADs in 2003 and recommended legal regulation, which has not been approved to date (Advance 2003; Gambero 2007). In the United Kingdom, the Mental Capacity Act 2005 (which became law on 1 April 2007) newly regulated ADs in England and Wales (Johnston 2005). In Scotland, the Adults with Incapacity (Scotland) Act 2000 also has opened the door to regulation of ADs. But in general, there is a significant lack of research about the true impact of these regulations in European clinical settings.

Japan (Masuda 2003; Sass 1998) and Singapore (Leng 1997) lead Asia in terms of legislation and experience with ADs. In other countries like China (Hong Kong) ADs have no legal status although there are guidelines recommending their use and legal reform (Liu 2005).

**Effects of advance directives**

Public policies that promote the extensive use of ADs have been questioned, because of the scarcity of evidence about their effects on the care of people with impaired decision-making ability (NIH 2004; President 2005). Evidence about the impact of ADs on healthcare costs near the end of life is also weak (AHFMR 2005; Taylor 1999). According to several authors, living wills should not be offered to the general population at the level of public policy, but individualized to patients with imminent death or strong preferences. Durable powers of attorney for health care are far more useful than living wills for promoting shared decision making, because it is not possible to set out all of the decisions that should be taken in each possible clinical scenario (Fagerlin 2004). Several studies have highlighted the potential influence of socio-economic status, educational level or ethnicity on patients' intention to complete ADs (Bowman 2001; Carrese 1995; Waters 2001). Other authors maintain that the problem is that ACP and other strategies to promote AD completion have not been developed sufficiently (Hickman 2005).

Little is known about the potential adverse effects of interventions for promoting the use of ADs, or about the use of ADs themselves. Song's systematic review of the literature between 1980 and 2002 about the affective outcomes of end-of-life discussions on patients identified seven relevant studies (Song 2004). These suggested that end-of-life discussions helped to increase patient satisfaction with the caring process and that enhancing communication was perceived as an additional benefit. Song found no evidence of negative affective patient outcomes of end-of-life discussions.

**Relationship to other relevant reviews**

We have identified six relevant systematic reviews on the effects of interventions for promoting the use of ADs (Guo 2004; Hanson 1997; Jezewski 2007; Lorenz 2004, updated by Wilkinson 2007; Patel 2004; Ramsaroop 2007).

Hanson 1997 reviewed "clinical interventions designed to change medical care at the end of life". The authors identified 16 studies (of varying design) of interventions targeting patients or professionals (or both) published between 1990 and 1996. They concluded that for people at the end of life, educational interventions for both patients and physicians, combined with repeated treatment-preference discussions between physicians and patients as well as accessible documentation of the patient's treatment preferences, could reduce the use of life-sustaining interventions.

Guo's review (Guo 2004) aimed to explore both the evidence about the effects of different interventions for the delivery and completion of ADs, and the local use of ADs in Alberta, Canada. The authors identified one review (Hanson 1997) and ten randomised controlled trials (RCTs) published between 1993 and 2004, including participants aged 55 or more. This review found limited evidence that providing written materials about ADs alone or in combination with an educational videotape, or a physician-initiated discussion with patients, could increase AD completion rates by approximately 15%. The review assessed various other interventions (alone and in combination), and found that the most comprehensive education program increased AD completion rates by at least 45%, but the results could not be compared to other studies due to the difference in study design and reporting. Guo and colleagues concluded that "the optimal method to increase discussions with older persons about end-of-life health care issues and the completion of written directives depends upon various factors such as setting, target population, and the availability of resources". This important review has two problems, however. First, it does not separate interventions targeted at patients from interventions targeted at professionals, and second, there was no formal appraisal of the methodological quality of the included studies.
The third review focused on six topics around end-of-life care (Lorenz 2004). One of these was ACP. The authors included English-language studies published between 1990 and 2004, and targeted to patients or families. They assessed the methodological quality of intervention studies. The authors found four relevant systematic reviews, but only Hanson 1997 directly concerned ADs. In addition Lorenz and colleagues included 21 intervention studies and 22 prospective cohort studies that used various methodologies, including different instruments and respondents. The RCTs evaluated ACP, ADs, living wills and DNR orders in hospitals, outpatient settings and nursing homes. Eight of the cohort studies were drawn from the SUPPORT intervention study (Murphy 2000). Lorenz and colleagues concluded that “the usual practice of advance directives and advance care planning is supported by little reliable scientific evidence of efficacy in improving outcomes” and that “rigorous research in advance care planning is needed to understand how to best achieve patient and family goals (as opposed to evaluating resource allocation), and such research needs to address fundamental processes of care planning”. However the conclusions from the cohort studies suggested three additional insights. “First, the impact of efforts to increase AD communication, completion, and documentation was evaluated positively by participants, but has not been shown to be effective in altering treatment patterns. Second, patient preferences often change over time and as illness progresses. Third, communicating with families and involving them, as well as patients, in advance care planning is important when possible”. Recently Wilkinson 2007 updated Lorenz’s review of ADs and ACP (Lorenz 2004). Their update found that most people do not complete an AD, and that when ADs are completed they rarely affect care because they are narrow and legalistic. There is little connection between the completion of an AD and subsequent appropriate outcomes of care such as improved communication between patient and provider or caregiver, greater concordance between patient preferences and proxy reports of patient preferences, reductions in aggressive care, appropriate palliation, or preferred place of death.

Patel 2004 assessed the effects of ACP educational interventions on the AD completion rate in non-terminally ill adults. They identified and assessed the methodological quality of nine relevant RCTs published between 1981 and 2002, and concluded that AD completion rates may be increased by simple patient-directed educational interventions.

Ramsaroop 2007 reviewed interventions to increase AD completion in the primary care setting from 1991 to 2005. The authors included 18 studies of varying design, most of them assessing “multimodal interventions”, and showing statistically significant effects on completion rates. The most effective interventions involved direct interaction between patients and clinicians over multiple visits, with passive education using written materials found to be relatively ineffective.

Jezewski 2007 assessed the effectiveness of interventions to increase AD completion rates, and identified 25 studies (14 RCTs, 3 quasi-RCTs and 8 convenience samples). Interventions fell into two types: (a) didactic (information distributed through an educational program, clinical encounter or by post), and (b) interactive (person-to-person interaction where participants had the opportunity to ask questions and/or receive assistance completing the forms). In the didactic studies, the increase in completion rates was usually no higher than the predicted average completion rate for the general population (below 20%). In the interactive studies the AD completion rate post-intervention ranged from 23% to 71%. The most effective interventions included repeated contact or stimuli toward AD completion.

Why is it important to do this review?

More recent studies of ADs could challenge the conclusions of previous reviews. Our review will not limit studies by language, type of patient, publication date or setting; and it will include a wide range of interventions. We will include only high-quality study designs and will take a comprehensive approach to assessing the methodological quality of included studies. We will only use meta-analysis techniques if the included studies are sufficiently similar.

Objectives

To assess the effects of interventions for promoting the use of advance directives (ADs) about end-of-life decisions of adults.

Methods

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) (including cluster RCTs), quasi-RCTs, controlled before-and-after studies (CBAs) and interrupted time series (ITS) analyses. CBAs must meet two key criteria to be included: the intervention and control groups must be comparable on key characteristics and the timing of the periods for study in both groups must also be comparable. ITS studies must meet two key criteria to be included: there must be a clearly-defined point in time when the intervention occurred, and there must be at least three data points before and three after the intervention.

Types of participants
We will include studies of adults (where the majority of participants are aged 18 or over). Adult participants could include individuals who are the subject of the AD, and/or their family members (or friend or guardian) who are their proxy or surrogate decision maker. There will be no restrictions related to health status. Therefore, studies could include well people in the community, or patients with a diagnosed health problem, or people who are the final stages of their life. Studies could also include only those people who are the proxy or surrogate decision maker (for example, in situations where the patient is terminally ill, or has dementia, and no longer able to make decisions on their own behalf).

We will include studies where the intervention is directed to health professionals only, as long as data on one of the outcomes for this review is collected.

Types of interventions

We will include any type of communicative, educational or informational intervention for promoting the use of ADs. This could include a wide range of different intervention types, provided singly or in combination with others in a complex trial. Intervention types could include:

- Information provision;
- Information provision with follow up support or interaction;
- Education or training of members of the community, or patients and their families, or health professionals (eg workshops, groups sessions, individual educational sessions, role playing sessions);
- Simplified or more supportive materials or assistance, eg assistance with completing documentation;
- Administrative or medical record interventions, eg chart reminders;
- Counselling or consultations, including discussion of ADs;
- Public information campaigns, eg mass media campaigns;
- Regulation and legislation.

Interventions could be provided by any media and in any format. Interventions could be provided in any setting: a society/region, community; home, health service (any type).

Where interventions are delivered by a health professional, this could include any professional type, eg, nurse, a physician, a social worker, a religious representative or any other person qualified to provide the intervention.

Finally, we will consider the following main comparisons:

- Interventions to promote ADs versus no intervention;
- Interventions to promote ADs versus usual care;
- Interventions to promote ADs versus intervention on end-of-life care with no mention of ADs;
- One type of intervention to promote ADs compared with another such intervention;
- Single interventions versus complex interventions;
- Other relevant comparisons identified during the review process.

Exclusions

We will exclude studies where the intervention pertains only to the choice of resuscitation preferences for an individual patient, as these are the subject of another Cochrane review in progress. However, we will include studies which both promote the use of ADs, and include information on resuscitation preferences. We will exclude studies that promote decision making around euthanasia.

Types of outcome measures

We will report on the following outcomes:

Primary outcomes

- Completion of AD: ie any outcome that records data on the recording, completion, amendment or repeal of any aspect of an AD (including of any single or multiple documents included in the AD). For instance, this could include outcomes on preferences, goals, values, choices, wishes of the individual or congruence of wishes of the individual and surrogate decision maker, etc;
- Knowledge and understanding: any outcome related to knowledge and understanding of an AD, or of current or future health states and associated treatments, that would be the subject of an AD;
- Evaluation of the intervention: any outcome related to the quality of the intervention measured by patient, consumer, carer or health professional associated with the intervention.

We will collect and report separately outcomes for the patient and for the surrogate decision maker (family member or friend).

Secondary outcomes

- Communication and involvement in decision making: for example, frequency of information requests, discussions, involvement in decision making, skills associated with discussing issues;
- Health status and well being: including any psychosocial or physiological health outcome, for example, emotional outcomes, fear, anxiety or depression, confidence, quality of life, physical health status;
- Communication outcomes for health professionals: including satisfaction with communication;
- Use of AD within health setting: for example, whether enacted, used or acknowledged at admission or during stay;
- Costs: such as cost of the intervention, cost of completion of ADs, cost of care resulting from any increase in the use of ADs.

We will look for and report on any harms associated with the intervention.
Search methods for identification of studies

Database searching
We will search the following databases using specific search terms in combination with the search strategy for identifying clinical trials as detailed in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2005). We will search all databases from their start date. There will be no limits by date, language or publication status (published, unpublished, in press or in progress).

Electronic databases
- The Cochrane Library (Cochrane Database of Systematic Reviews (CDSR), Cochrane Central Register of Controlled Trials (CENTRAL), Database of Abstracts of Reviews of Effects (DARE), NHS Economic Evaluation Database (NHSEED), Health Technology Assessment database;
- MEDLINE (Ovid);
- CINAHL (Ovid);
- PsycINFO (Ovid);
- EMBASE (Embase.com)
- Social Sciences Citation Index;
- Science Citation Index;
- ERIC (Educational Resources Information Center).

Non-English and multilingual databases
- LILACS (Latin American and Caribbean health sciences literature);
- CSIC databases: (Spanish databases in health and social sciences);
- Scopus.

Clinical trials registers
- Current Controlled Trials (http://www.controlled-trials.com/);
- ClinicalTrials.gov (http://www.clinicaltrials.gov/);
- World Health Organisation International Clinical Trials Registry Platform (http://www.who.int/ictrp/en/).

Grey literature
- UMI ProQuest Dissertations & Theses Database (PQDT);
- Networked Digital Library of Theses and Dissertations.

We also will look for grey literature on the internet using the following crawlers or metasearchers: Metacrawler, Excite, Dogpile and Ixquick.

Reference lists
We will search reference lists of relevant studies and contact authors and research groups to check for more studies.

Search strategies
We will search MEDLINE (Ovid) with the search strategy presented at Appendix 1. We will adapt this strategy as necessary for the remaining databases.

For the search of grey literature and non-English databases we will use combinations of terms in different languages. The terms are as follows:
- French: Directives Préalables, Directives Anticipées (de volontés), Testament de Vie, Procuration, Procureur, Personne de confiance.
- German: Patientenverfügung, Patientenwillen, Patiententestaments, Vorsorgebevollmächtigter , Vorsorgevollmacht.
- Norwegian: Livstestament.
- Portuguese: Direitivas Antecipadas, Testamentos Quanto à Vida, Planejamento Antecipado de Cuidados.
- Spanish (South America): Directiva de Adelanto, Voluntad en Vida, Poder de Representación, Planificación Anticipada de Atención.
- Swedish: Livstestamente, Livsslutsdirektiv.

Using this strategy we will try to avoid publication bias.

Data collection and analysis

Selection of studies
Two review authors will assess independently the search results by title to identify potentially-relevant studies. We will retrieve in abstract or full text those studies that may be relevant, or which cannot be excluded on the basis of title alone. Two review authors will screen these studies independently, using the pre-specified selection criteria. Potentially-relevant studies that we exclude will be listed in the table 'Characteristics of Excluded Studies' with the reason for exclusion given. Any discrepancies between review authors during the selection process will be resolved by discussion and consensus, and if necessary, by seeking the advice of a third review author.

Data extraction and management
We will develop a data extraction form based on the Data Extraction Template of the Cochrane Consumers and Communication Review Group (Template 2007). We will extract data including...
details of study methods, number and characteristics of participants and settings, ethical considerations, consumer involvement, funding source for study and a detailed description of interventions and controls, study quality and outcomes, as follows:

- Setting: We will extract relevant information about the study setting, such as the country where the study took place, home versus healthcare settings, primary care setting versus hospital or nursing home, or rural versus urban setting. We will also extract data on the legal framework of ADs related to the study setting, if available.
- Participants: We will extract data on the characteristics of participants such as health status, socio-economic status, ethnicity, language, educational level, age, and any other factor that might influence the effects of interventions.
- Interventions: We will extract data on the interventions, in terms of their components, delivery, content, context, format, provider, provider training, timing and any other information that could affect the outcomes.
- Outcomes: We will extract data related to the primary or secondary outcomes of our review, and on any reported adverse outcome or harm produced by the intervention.

We will pilot the data extraction form with five included studies and refine it as needed.

Two review authors will extract data independently from included studies, using the data extraction form, entering data into separate Excel charts. Any discrepancies between review authors will be resolved by discussion and consensus, and if necessary, by seeking the advice of a third review author. We will contact the authors of included studies for missing data. One review author will transfer data from Excel software into RevMan 5 software, with a second review author checking the accuracy of data transfer.

Assessment of risk of bias in included studies

We will assess and report on the risk of bias of included studies in accordance with the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2008) which recommends the explicit reporting of the following individual domains for RCTs:

- Sequence generation;
- Allocation concealment;
- Blinding of participants, providers and outcome assessors (and also data analysts) (assessed for each main outcome or class of outcome);
- Incomplete outcome data (assessed for each main outcome or class of outcome);
- Selective outcome reporting;
- Other sources of bias (including baseline comparability; validation of outcome measures).

We will assess the risk of bias of cluster RCTs, quasi-RCTs, CBA and ITS studies using a modified version of the risk of bias tool, and in accordance with the guidelines of the Cochrane Consumers and Communication Review Group (Ryan 2007).

In all cases, two review authors will independently assess the risk of bias of included studies, with any disagreements resolved by discussion and consensus. This process will be blind in relation to the study authors, their institution and journals. We will use a template to guide the assessment of risk of bias, and will judge each domain as ‘yes’ (indicating a low risk of bias), ‘no’ (indicating a high risk of bias) or ‘unclear’ (indicating an uncertain risk of bias). We will present all included studies by study type and risk of bias level.

We will contact study authors for additional information about the included studies, or for clarification of the study methods as required. We will present the results of the risk of bias assessment in tables, and incorporate the results of this assessment into the review through systematic narrative description and commentary about each of the domains, leading to an overall assessment the risk of bias of included studies and a judgement about the internal validity of the review’s results.

Data analysis

We will begin the data analysis with a detailed narrative presentation and synthesis of included studies. We will present results separately for each study design. We will use tables to provide further details of studies, and include relevant quantitative and qualitative data. We will use visual tools (graphs and other plots) to organize and present results.

Depending on the number of trials and similarity of key features within trials, we will consider organising the studies and results by intervention type, population groups, intervention setting or outcomes. We will assess heterogeneity using the I² statistic, with a result of I² > 50% considered to be high heterogeneity. We will include a quality assessment in the narrative synthesis.

The results will be expressed as a risk ratio (RR) and 95% confidence interval (CI) for dichotomous outcomes and as a mean difference (MD) and 95% CI for continuous outcomes. If appropriate, we will pool the results of RCTs using a random-effects model with standardised mean differences (SMDs) for continuous outcomes and odds ratios (ORs) for dichotomous outcomes. We will conduct separate meta-analyses for different outcome types.

Primary analysis will be based on ‘intention to treat’. If the studies have not carried out this analysis, we will attempt to do so. We will conduct sensitivity analysis to evaluate the effect of trial quality, and to explore the reasons for heterogeneity if found. If studies have not accounted for the effects of clustering in trial designs, we will adjust standard deviations by the design effect, using intra-class coefficients if available.

We will use the generic inverse-variance method to incorporate cluster RCTs into meta-analysis (Higgins 2008).
**Consumer participation**

We will ensure consumer participation in the development and updating of the review. We sent a draft of this protocol, together with a user-friendly questionnaire in electronic format to guide the process, to a number of individuals and to patients'/consumers' organisations in several countries (on the advice of the Cochrane Consumer Network and the International Alliance of Patients' Organizations (IAPO)). We were pleased to receive consumer-oriented feedback from people associated with the following organisations:

- Unión de Consumidores de Andalucía-UCA/UCE, Spain;
- Laboratoire d'Étique Médicale et Biologique, Université René Descartes, Paris, France and Universidad de Salamanca, Spain;
- Cochrane Consumer Network;
- Annie Appleseed Project.

Their opinions helped us to clarify issues such as definitions of terms and the review objectives. We have ensured through this contribution that the aims of the protocol meet consumers' priorities. We will consult with this consumer advisory group at review stage in regard to the interpretation of quantitative data and the structure of the review text. We will also add to this advisory group other relevant organisations and individuals identified during the review process.

**ACKNOWLEDGEMENTS**

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**REFERENCES**

**Additional references**

*Advance 2003*


*AHFMR 2005*


*Bowman 2001*


*Campbell 2006*

Campbell LA, Kelsey SR. Advance treatment directives for people with severe mental illness. *Cochrane Database of Systematic Reviews* 2006, Issue 2. [DOI: 10.1002/14651858.CD005963]

*Carrese 1995*


*Clayton 2007*

Clayton JM, Hancock KM, Butow PN, Tattersall MHN, Currow DC. Clinical practice guidelines for communicating prognosis and end-of-life issues with adults in the advanced stages of a life-limiting...

Danish Council 2006


Doulkas 1991


Emanuel 1991


Fagerlin 2004


Fournier 2005


Gambaro 2007


Guo 2004


Hanson 1997


Hickman 2005


Higgins 2005


Higgins 2008


Jezewski 2007


Johnston 2005


Kutner 1969


Lang 2007


Leng 1997


Liu 2005


Lorencz 2004


Masuda 2003


McCarrick 1991


Molloy 2000


Murphy 2000


Nationaler 2005


NHI 2004


Patel 2004

Appendix 1. MEDLINE (Ovid) search strategy

1. exp Advance Directives/
2. wills/
3. right to die/
4. advance care planning/
5. patient self-determination act/
6. resuscitation orders/
7. advance directive adherence/
8. or/1-7
9. exp legal guardians/
10. health care agent$.tw.
11. power of attorney.tw.
12. proxy.tw.
13. or/9-12
14. end of life.tw.
15. (death or die or dies or dying).tw.
16. 14 or 15
17. 13 and 16
18. ((decision$ or planning or plan or plans or discuss$ or goal$ or directive$ or right$) adj3 (end of life or (death or die or dies or dying))).tw.
19. 8 or 17 or 18
20. randomized controlled trial.pt.
21. controlled clinical trial.pt.
22. randomized.ab.
23. placebo.sh.
24. clinical trials as topic.sh.
25. randomly.ab.
26. trial.ti.
27. or/20-26
28. humans.sh.
29. 27 and 28
30. clinical trial.pt.
31. exp clinical trials as topic/
32. (clin$ adj25 trial$).ti,ab.
33. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.
34. placebo$.ti,ab.
35. placebos.sh.
36. random$.ti,ab.
37. research design.sh.
38. (latin adj square).tw.
39. or/30-38
40. 39 and 28
41. prospective studies/
42. comparative study.sh.
43. exp evaluation studies/
44. follow up studies.sh.
45. prospective studies.sh.
46. (control$ or prospectiv$ or volunteer$).ti,ab.
47. cross-over studies.sh.
48. or/41-47
49. 48 and 28
50. 29 or 40 or 49

Interventions for promoting the use of advance directives for end-of-life decisions in adults (Protocol)  
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- Providing general advice on the review: FMP, RVP, PSL.
- Securing funding for the review: PSL.
- Performing previous work that was the foundation of the current review: PSL, IMBC.
DECLARATIONS OF INTEREST

None known

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