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## Audio-visual presentation of information for informed consent for participation in clinical trials (Review)

Synnot A, Ryan R, Prictor M, Fetherstonhaugh D, Parker B

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[Intervention Review]

# Audio-visual presentation of information for informed consent for participation in clinical trials

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## ABSTRACT

### Background

Informed consent is a critical component of clinical research. Different methods of presenting information to potential participants of clinical trials may improve the informed consent process. Audio-visual interventions (presented, for example, on the Internet or on DVD) are one such method. We updated a 2008 review of the effects of these interventions for informed consent for trial participation.

### Objectives

To assess the effects of audio-visual information interventions regarding informed consent compared with standard information or placebo audio-visual interventions regarding informed consent for potential clinical trial participants, in terms of their understanding, satisfaction, willingness to participate, and anxiety or other psychological distress.

### Search methods

We searched: the Cochrane Central Register of Controlled Trials (CENTRAL), *The Cochrane Library*, issue 6, 2012; MEDLINE (OvidSP) (1946 to 13 June 2012); EMBASE (OvidSP) (1947 to 12 June 2012); PsycINFO (OvidSP) (1806 to June week 1 2012); CINAHL (EbscoHOST) (1981 to 27 June 2012); Current Contents (OvidSP) (1993 Week 27 to 2012 Week 26); and ERIC (Proquest) (searched 27 June 2012). We also searched reference lists of included studies and relevant review articles, and contacted study authors and experts. There were no language restrictions.

### Selection criteria

We included randomised and quasi-randomised controlled trials comparing audio-visual information alone, or in conjunction with standard forms of information provision (such as written or verbal information), with standard forms of information provision or placebo audio-visual information, in the informed consent process for clinical trials. Trials involved individuals or their guardians asked to consider participating in a real or hypothetical clinical study. (In the earlier version of this review we only included studies evaluating informed consent interventions for real studies).

## Data collection and analysis

Two authors independently assessed studies for inclusion and extracted data. We synthesised the findings using meta-analysis, where possible, and narrative synthesis of results. We assessed the risk of bias of individual studies and considered the impact of the quality of the overall evidence on the strength of the results.

## Main results

We included 16 studies involving data from 1884 participants. Nine studies included participants considering real clinical trials, and eight included participants considering hypothetical clinical trials, with one including both. All studies were conducted in high-income countries.

There is still much uncertainty about the effect of audio-visual informed consent interventions on a range of patient outcomes. However, when considered across comparisons, we found low to very low quality evidence that such interventions may slightly improve knowledge or understanding of the parent trial, but may make little or no difference to rate of participation or willingness to participate. Audio-visual presentation of informed consent may improve participant satisfaction with the consent information provided. However its effect on satisfaction with other aspects of the process is not clear. There is insufficient evidence to draw conclusions about anxiety arising from audio-visual informed consent. We found conflicting, very low quality evidence about whether audio-visual interventions took more or less time to administer. No study measured researcher satisfaction with the informed consent process, nor ease of use.

The evidence from real clinical trials was rated as low quality for most outcomes, and for hypothetical studies, very low. We note, however, that this was in large part due to poor study reporting, the hypothetical nature of some studies and low participant numbers, rather than inconsistent results between studies or confirmed poor trial quality. We do not believe that any studies were funded by organisations with a vested interest in the results.

## Authors' conclusions

The value of audio-visual interventions as a tool for helping to enhance the informed consent process for people considering participating in clinical trials remains largely unclear, although trends are emerging with regard to improvements in knowledge and satisfaction. Many relevant outcomes have not been evaluated in randomised trials. Triallists should continue to explore innovative methods of providing information to potential trial participants during the informed consent process, mindful of the range of outcomes that the intervention should be designed to achieve, and balancing the resource implications of intervention development and delivery against the purported benefits of any intervention.

More trials, adhering to CONSORT standards, and conducted in settings and populations underserved in this review, i.e. low- and middle-income countries and people with low literacy, would strengthen the results of this review and broaden its applicability. Assessing process measures, such as time taken to administer the intervention and researcher satisfaction, would inform the implementation of audio-visual consent materials.

## PLAIN LANGUAGE SUMMARY

### Audio-visual presentation of information used in the informed consent process for people considering entering clinical trials

#### Review question

We reviewed the evidence about the effect of audio-visual presentation of information used in the informed consent process for people considering entering a clinical trial. We compared this with the usual informed consent information (either written and/or verbal) and placebo (sham) audio-visual information.

#### Background

Before taking part in a clinical trial, potential participants must be provided with detailed information, such as what they will be asked to do and any possible benefits or harms. Once they understand what is involved, and if they are happy to take part, they usually sign a consent form. This process is known as 'informed consent'. The problem is that consent forms use technical language that can be hard to for the average person to understand. Sometimes people agree to take part in a clinical trial even though they are unsure what is involved. Presenting the consent form information in an audio-visual format (for example, on a computer or DVD) might improve the informed consent process.

#### Study characteristics

We searched for studies of audio-visual informed consent interventions which allocated people to an experimental or control group by a random or quasi-random process, published up until June 2012. We found 16 studies, involving a total of 1884 people. Nine studies included people considering real clinical trials, eight included people asked to imagine participating in a clinical trial (a hypothetical trial), with one including both. Most of the studies were conducted in the United States.

People were considering (or imagined considering) participation in a range of different clinical trials, including those testing cancer treatments and drugs for mental health problems. The audio-visual informed consent information was presented on computers, DVDs,

videos and CD-ROMs. They included voice overs by professional actors, real patients talking about their experiences and a combination of words, pictures and audio to explain the technical concepts. In some studies, people also received the usual written informed consent forms and/or a face-to-face explanation by the study staff.

### **Key results**

There is low to very low quality evidence that audio-visual consent interventions may slightly improve knowledge or understanding of the parent trial, but may make little or no difference to rate of participation or willingness to participate. Audio-visual presentation may improve participation satisfaction with the information provided. However its effect on satisfaction with other aspects of the process is not clear. There is not enough evidence to draw conclusions about anxiety arising from audio-visual informed consent. There is conflicting, very low quality evidence about whether audio-visual interventions take more or less time to administer, and no study measured researcher satisfaction with the informed consent process, nor ease of use.

We do not believe that any studies were funded by organisations with a vested interest in the results.

### **Quality of the evidence**

The quality of evidence from real clinical trials was low, and from hypothetical clinical studies, very low. This is because of the small number of people in the studies, and some issues in the way they were conducted. If the next update of this review includes more studies of audio-visual informed consent presentation, it could change the results of this review.

## SUMMARY OF FINDINGS

### Summary of findings for the main comparison. Summary of findings (Comparison 1)

**Audio-visual informed consent interventions compared with standard (written and/or verbal) informed consent interventions for people considering clinical trial participation**

**Patient or population:** People with a health condition or nominally 'well' considering real clinical trial participation (across a range of topic areas)

**Settings:** Hospitals or medical centres in the United States

**Intervention:** Audio-visual informed consent presentation

**Comparison:** Standard (written and/or verbal) informed consent presentation

Outcomes	Narrative summary of findings	No of Participants (studies)	Quality of the evidence (GRADE)
<b>Knowledge (Single intervention)</b> [mean number of correct questionnaire responses, assessed immediately post-intervention]	We are uncertain whether single audio-visual informed consent improves knowledge <sup>1</sup>	155 (1 study)	⊕○○○ <b>very low</b> <sup>2</sup>
<b>Knowledge (Multi-component intervention)</b> [mean number of correct questionnaire responses, assessed immediately post-intervention]	We are uncertain whether multi-component audio-visual informed consent improves knowledge <sup>3</sup>	126 (1 study)	⊕○○○ <b>very low</b> <sup>4</sup>
<b>Satisfaction with the information provided (Single and multi-component intervention)</b>	No studies were found that measured this outcome		
<b>Rate of participation (Single intervention)</b>	No studies were found that measured this outcome		
<b>Rate of participation (Multiple intervention)</b> [questionnaire, measured immediately post-intervention]	We are uncertain whether multi-component audio-visual informed consent improves rate of participation <sup>5</sup>	110 (1 study)	⊕○○○ <b>very low</b> <sup>6</sup>
<b>Anxiety, or other psychological distress</b>	No studies were found that measured this outcome		



<b>(Single and multi-component intervention)</b>			
<b>Retention of knowledge</b>	No studies were found that measured this outcome		
<b>(Single and multi-component intervention)</b>			
<b>Satisfaction with the decision-making process (single intervention)</b>	No studies were found that measured this outcome		
<b>Satisfaction with the decision-making process (multi-component intervention)</b>	We are uncertain whether multi-component audio-visual informed consent improves satisfaction with the decision-making process <sup>7</sup>	126 (1 study)	⊕⊕⊕⊕ <b>very low</b> <sup>8</sup>
[questionnaire, assessed immediately post-intervention]			

\*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).  
**CI:** Confidence interval; **RR:** Risk Ratio;

GRADE Working Group grades of evidence

**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low quality:** We are very uncertain about the estimate.

- 1 Two audio-visual intervention groups in one study (Agre 2003a) were pooled, showing no evidence of an effect on knowledge (result not presented due to very low quality evidence)
- 2 Very low evidence quality (small, single study; lack of allocation concealment; confidence interval includes crosses the line of no effect and includes appreciable benefits and harms)
- 3 The results of the sole study (Kass 2009) were difficult to interpret (result not presented due to very low quality evidence).
- 4 Very low evidence quality (very serious risk of bias limitations; small, single study; uncertain results)
- 5 The results of the sole study (Kass 2009) showed no difference in rate of participation (result not presented due to very low quality evidence)
- 6 Very low evidence quality (very serious risk of bias limitations; small, single study; confidence intervals cross the line of no effect)
- 7 The results of the sole study (Kass 2009) showed no difference in satisfaction with the decision-making process (result not presented due to very low quality evidence)
- 8 Very low quality evidence (serious risk of bias limitations; small, single study; likely imprecision)

## Summary of findings 2. Summary of findings (Comparison 2)

### Audio-visual plus standard informed consent interventions compared with standard informed consent interventions for participants considering clinical trial participation

**Patient or population:** people with a health condition (or pregnant) considering real clinical trial participation (across a range of topic areas)

**Settings:** hospital or medical centre in a developed country (predominantly United States)

**Intervention:** audio-visual plus standard (written and/or verbal) informed consent intervention

**Comparison:** standard (written and/or verbal) informed consent intervention

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
	Assumed risk	Corresponding risk			
	with standard informed consent	with audio-visual plus standard informed consent			
<b>Knowledge - continuous</b> [mean number of correct questionnaire responses, measured immediately post-intervention]		Knowledge in audio-visual plus standard group was <b>0.04 standard deviations</b> higher (-0.03 to 0.38)		143 (2 studies) <sup>1</sup>	⊕⊕○○ <b>low</b> <sup>2</sup>
<b>Knowledge - dichotomous</b> [> 80% of knowledge questions correct, measured immediately post-intervention]	We are uncertain whether audio-visual plus standard informed consent interventions affect knowledge <sup>3</sup>			290 (2 studies)	
<b>Satisfaction with the information provided</b>	No studies were found that measured this outcome				
<b>Rate of participation</b> [case notes or questionnaire, measured immediately or up to four weeks post-intervention]	Audio-visual plus standard informed consent may make little or no difference to rate of participation <sup>4</sup>			258 (2 studies)	⊕⊕○○ <b>low</b> <sup>5</sup>
<b>Anxiety (or other psychological stress)</b> [Spielberger State and Trait Anxiety score, measured immediately post-intervention]	We are uncertain whether audio-visual informed consent interventions affect anxiety (or other psychological stress) <sup>6</sup>			142 (1 study)	⊕⊕○○ <b>low</b> <sup>7</sup>
<b>Retention of knowledge</b> [> 80% of knowledge questions correct, measured two to four weeks post-intervention]	<b>64 per 100</b> <sup>8</sup> participants	<b>88 per 100</b> participants (68 to 113)	<b>RR 1.38</b> (1.07 to 1.77)	85 (1 study)	⊕⊕○○ <b>low</b> <sup>9</sup>
<b>Satisfaction with the decision-making process</b>	No studies were found that measured this outcome				

\*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**CI:** Confidence interval; **RR:** Risk Ratio;

GRADE Working Group grades of evidence

**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low quality:** We are very uncertain about the estimate.

- 1 A third study ([Hutchison 2007](#)) measured knowledge but was not able to be pooled due to skewed data. They found the mean change and median knowledge change scores between groups favoured the intervention.
- 2 Evidence quality was low (some inconsistency; confidence intervals mostly demonstrate appreciable benefit, one (just) crosses the line of no effect)
- 3 Due to high statistical heterogeneity (and somewhat inconsistent findings) these results were not pooled. One showed an improvement in knowledge and the but the other did not.
- 4 Due to high statistical heterogeneity (and inconsistent findings) these results were not pooled but neither showed evidence of an effect on rate of participation
- 5 Evidence quality was low (some inconsistency; confidence intervals cross the line of no effect, one study more precise around the line of no effect, the other includes appreciable benefits)
- 6 The results of the single study ([Hutchison 2007](#)) are difficult to interpret due to a significant baseline imbalance and possibly skewed results
- 7 Evidence quality was low (baseline imbalance; small, single study)
- 8 Assumed risk calculated based on control group risk in [Weston 1997](#)
- 9 Evidence quality was moderate (few participants/events, some imprecision - lower confidence interval crosses the appreciable benefit)

### Summary of findings 3. Summary of findings (Comparison 3)

#### Audio-visual informed consent intervention compared with placebo audio-visual informed consent intervention for people considering clinical trial participation

**Patient or population:** people with a health condition or nominally 'well' considering real or hypothetical clinical trial participation in cancer or psychiatric medication trials

**Settings:** hospital/medical centre or university

**Intervention:** audio-visual informed consent intervention

**Comparison:** placebo informed consent intervention

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
	Assumed risk	Corresponding risk			
	with placebo audio-visual informed consent	with audio-visual informed consent			
<b>Knowledge</b> [questionnaire (scored out of 80), measured immediately post-intervention]	Audio-visual informed consent may make little or no difference to knowledge <sup>1</sup>			93 (1 study)	⊕⊕⊕⊕ <b>low</b> <sup>3</sup>
<b>Knowledge</b>	<b>81 per 100</b> <sup>2</sup> participants	<b>95 per 100</b> participants	<b>RR 1.17</b>	49	

[scored correct answer to single question, measured immediately post-intervention]	(78 to 100)	(0.96 to 1.43)	(1 study)	
<b>Satisfaction with the information provided</b>	<b>17 per 100<sup>2</sup></b> participants	<b>56 per 100</b> participants	<b>RR 3.30</b>	44 ⊕⊕○○ <b>low<sup>4</sup></b>
[single question, measured immediately post-intervention]	(21 to 100)	(1.24 to 8.78)	(1 study)	
<b>Rate of participation</b>	<b>33 per 100<sup>2</sup></b> participants	<b>14 per 100</b> participants	<b>RR 0.41</b>	49 ⊕⊕○○ <b>low<sup>5</sup></b>
[case notes, measured immediately post-intervention]	(4 to 44)	(0.13 to 1.33)	(1 study)	
<b>Anxiety, or other psychological distress</b>	No studies were found that measured this outcome			
<b>Retention of knowledge</b>	No studies were found that measured this outcome			
<b>Satisfaction with the decision-making process</b>	No studies were found that measured this outcome			

\*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**CI:** Confidence interval; **RR:** Risk Ratio

GRADE Working Group grades of evidence

**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low quality:** We are very uncertain about the estimate.

1 The results of the single study ([Wirshing 2005](#)) are incomplete but the mean scores between groups are similar and there is minimal difference in mean change scores between groups

2 Assumed risk was calculated from the control group of [Strevel 2007](#)

3 Evidence quality was low (small sample size; at least one confidence interval crosses the line of no effect and includes appreciable benefits)

4 Evidence quality was low (small study, imprecise result but includes only appreciable benefits)

5 Evidence quality was low (small study, confidence interval crosses the line of no effect and includes appreciable benefits and harms)

## BACKGROUND

Informed consent is a critical stage in the conduct of clinical research. It is ethically imperative that potential trial participants are properly informed and understand that their initial and continuing participation is voluntary (Sugarman 1998). Participants should be told of the aims of the research, the methods that are to be used, the anticipated benefits and potential harms of participation for them as individuals, any anticipated discomfort associated with participation, sources of funding, potential and actual conflicts of interest and the institutional affiliations of the researchers (WMA 2008). In addition, potential participants should be informed of their right to refuse participation or withdraw their consent at any time, without affecting the care they receive. They should also be advised about any costs that they may incur, such as additional travel associated with attending hospital more often.

It is commonly reported that people who have given their 'informed consent' do not fully understand their rights as participants, or the methods of their treatment allocation in trials (Chuppuy 2010; Harth 1995; Hietanen 2000; Williams 2003). Terminology used in the consent process for trials may be challenging, with concepts such as randomisation, blinding of treatment allocation and equipoise (a state of genuine uncertainty as to the potential benefits and harms of interventions in the trial) needing to be conveyed. Misconceptions about the purpose of a trial and the treatment that will be received are common (Joffe 2001a), and a significant proportion of people do not recall consenting to participation on their own or their child's behalf (Ballard 2004; Chappuy 2006; Schats 2003; Tait 2003). Despite the imperative for the informed consent process to meet regulatory guidelines for clinical research, poor participant understanding of the research has been demonstrated across clinical areas (Chuppuy 2010; Joffe 2001a; Williams 2003). As a result there have been calls for research into innovations to improve the informed consent process for clinical research (Flory 2004; Joffe 2001a; Tait 2003; Williams 2003).

### Description of the intervention

Different strategies have been tried to improve the informed consent process. These include written information materials and consent forms modified with simple language, added illustrations, and altered layout to highlight important points (Enama 2012; Kruse 2000). Other studies have included additional detailed oral and/or written information (Stanley 1998) and computer-based enhancement of information provision (Dunn 2001a) in attempts to improve the process. The use of audio-visual interventions such as informational DVDs and computer presentations may enhance the process. Audio-visual presentations can ensure the clear delivery of information that is complete, consistent and unbiased, to supplement or reduce staff time spent in seeking informed consent. A study of the feasibility of using multimedia technology during the informed consent process for clinical research reported that consumers felt the multimedia tool allowed them to control the pace at which they viewed the information, and that the use of the video "made information more understandable" (Jimison 1998).

Using a visual format to present information on clinical research may complement the informed consent process and audio-visual presentation may be used to provide a dramatic representation of what participation in the study involves. In addition, complex concepts such as randomisation may be explained using visual examples. An audio-visual format may also enable subgroups of

potential research participants, such as those who have difficulty reading complex information, to access and better understand complex concepts (Campbell 2004). Audio-visual information presented via the Internet, computer or DVD may promote interactivity, with viewers being able to access specific information, or lay definitions of terms, via interactive menus.

Despite the potential benefits of using audio-visual interventions in the informed consent process, harms may also be associated with their use. In many situations, such as in cancer trials or where parents' consent is sought for a child's participation, informed consent is associated with difficult treatment decisions (Miller 2005; Ruccione 1991; Stryker 2006). Such situations may be inherently distressing, and the information disclosed in the informed consent process may increase people's anxiety or sense of powerlessness (Miller 2005; Ruccione 1991; Simon 2001). People's satisfaction with the informed consent process and with their decision about participating in the research, and their level of decisional regret may also be affected (Franck 2007; Kupst 2003; Pope 2003; Stryker 2006).

With informed consent for trial participation, as for screening and treatment decisions, there is tension between ensuring consumers are informed and ensuring participation (Edwards 2013; Raffle 2001). In other health arenas, enhancing the structure and content of healthcare information has led to consumers adopting more conservative screening or treatment choices (Stacey 2014). The effect of audio-visual interventions for informed consent on outcomes such as rates of trial participation and willingness to participate is important in this context. For individuals, trial participation may be a benefit or a harm, depending on the trial and its particular risks and benefits to them, as well as on their understanding of these underlying risks and benefits. Trialists seeking ethically to provide high-quality evidence in order to genuinely benefit society through improved healthcare policy and practice have a legitimate interest in promoting trial participation; while in the context of poorly or unethically-conducted trials, willingness to participate should be considered a harm. In this review we considered it important to capture the audio-visual intervention's effects on people's decision or willingness to participate in the subsequent trial. We emphasise, however, that these outcomes may be either beneficial or harmful to participants and should be considered in the context of the particular trial.

### Hypothetical trials

In this review update we newly included hypothetical clinical trials. These are trials in which the participants may be healthy volunteers or people with a health condition who are asked to consider taking part in an imaginary clinical trial. Hypothetical trials may allow greater internal validity than clinical trials, for example they are not necessarily constrained by the same inclusion and exclusion criteria (Jeste 2009) and they allow for pre-testing of novel consent formats without adversely affecting a real clinical trial (Llewellyn-Thomas 1995). However, they are considered to reduce external validity, as participants may not make the same choices in a real-world as in a hypothetical situation. We include these trials in this update for two reasons. First, hypothetical trials of audio-visual information in informed consent continue to be conducted (Jeste 2009; Karunaratne 2010) and second, there has been limited systematic comparison of the value of hypothetical trials in this area. Our inclusion of hypothetical trials allows for such a comparison, albeit informally.

## Terminology

This review uses the terms 'clinical trial' and 'clinical research' interchangeably. In the original review (Ryan 2008), these terms were not defined explicitly but both referred to randomised controlled trials of healthcare interventions. However as clinical and informed consent research have grown, it is necessary to define our use of these terms. A clinical trial is usually described as one kind of clinical research, but the explicit differences between the terms are poorly defined. Research into screening tests, diagnostic procedures, the natural history of disease, in addition to healthcare treatments or interventions have all been described as both clinical research and a clinical trial (NHMRC, ARC and AVCC 2007; NIH 2012). Yet, the definition of a clinical trial tends to refer to a trial of health-related interventions, and is often preceded by a description of the four phases of a clinical trial (NIH 2012; WHO 2013). WHO 2013 refers to clinical research as including drug, surgical and behavioural treatments, cells and other biological products, radiologic procedures, devices, process of care changes and preventative care. In this review we use the two terms interchangeably to mean a clinical research study involving humans who are prospectively assigned to receive a healthcare intervention, including treatments, or diagnostic or monitoring procedures and devices.

## Relationship to other relevant reviews

This review relates to a number of Cochrane and non-Cochrane reviews. Four recent systematic reviews have focused on aspects of the informed consent process for clinical trial participation, and are directly relevant to this review (Cohn 2007; Flory 2004; Palmer 2012; Nishimura 2013). Recently, Palmer 2012 systematically reviewed the effects of multimedia informed consent interventions on knowledge, identifying 20 studies. The authors used a broad definition of a multimedia intervention as one in which the information was 'computer-based', and considered knowledge as their sole outcome. This review also focused on the degree to which the interventions were underpinned by theoretical concepts. The three other systematic reviews (Cohn 2007; Flory 2004; Nishimura 2013) have also considered the effects of multimedia informed consent interventions within systematic reviews that also include other kinds of enhanced consent interventions, such as simplified written materials. Nishimura 2013 identified 13 trials of video and computer multimedia interventions and considered their effects on understanding, satisfaction, accrual and retention. Flory 2004 identified 12 video and multimedia interventions assessed in 9 studies. In addition to the effect of the intervention on understanding, they also considered participant satisfaction and willingness to participate. Despite the fact that Cohn 2007 was conducted after Flory 2004, its authors found only two studies that assessed multimedia consent interventions, and only considered the effect on knowledge.

A recent Cochrane review by Kinnersley and colleagues (Kinnersley 2013), examining interventions to promote informed consent for people considering treatment decisions, such as surgery, is complementary to this review. They identified 25 studies that assessed non-interactive audio-visual or interactive multimedia interventions, allowing a pooled analysis of these interventions' effects on knowledge, satisfaction and anxiety. Another Cochrane review (Trewick 2010) considered the effects of interventions to improve recruitment to randomised controlled trials, finding three trials of educational video interventions.

## Why it is important to do this review

Although several systematic reviews exist in this area, we searched extensively and used rigorous methods to assemble and evaluate the evidence on the effects of these interventions. With the exception of Nishimura 2013, this is the only recent systematic review to consider the effect of audiovisual presentation of consent information on outcomes other than knowledge.

## OBJECTIVES

To assess the effects of audio-visual information interventions regarding informed consent, compared with standard information interventions regarding informed consent for potential clinical trial participants, in terms of their understanding, satisfaction, willingness to participate and anxiety or other psychological distress.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

Randomised controlled trials (RCTs) and quasi-RCTs (trials in which randomisation is attempted but subject to potential manipulation, for example using day of week, hospital record number, date of birth or sequence of entry into trial).

#### Types of participants

Individuals or the guardians of individuals who were asked to participate in a clinical trial. Studies involving children, or people who were not competent to provide informed consent, and in which parents or surrogates would have provided informed consent on their behalf, were eligible for inclusion.

We defined a clinical trial as a clinical research study involving humans who are prospectively assigned to receive a healthcare intervention, including treatments, or diagnostic or monitoring procedures and devices. This did not include studies in which there were no interventions or procedures, such as donating genetic samples, as potential participants were not involved in the research as participants themselves.

We also included studies in which participants were asked to participate in a hypothetical clinical trial: that is, where participants (such as students asked to imagine participating in a trial) were not potential research subjects; or the trial itself was hypothetical (for example, multiple sclerosis vaccine). We excluded hypothetical studies from the original version of this review (Ryan 2008) but included them in this update for the reasons outlined in the Background and to increase the usefulness of the review.

#### Types of interventions

We included studies using audio-visual presentation of information in the process of seeking informed consent. We defined audio-visual presentation as any pre-recorded audio-visual material presented on the Internet, by DVD or by other means.

We included studies in which the audio-visual intervention either alone, or in addition to standard forms of information provision (such as written or oral information as usually employed in the particular service setting) was compared with standard forms of information provision or with a placebo audio-visual intervention.

## Types of outcome measures

The following outcome measures were considered to address the needs of both consumers and clinical researchers.

### Primary outcomes

- Participant/guardian knowledge and understanding of the parent study. This may include knowledge and understanding of:
  - \* concepts related to the research design and conduct of the parent study (for example the concept of randomisation, and how data will be collected);
  - \* concepts related to the condition or intervention involved in the parent study (for example potential benefits or harms of the intervention).
- Participant/guardian satisfaction with the information provided about the parent study
- Rate of participation or willingness to participate in the parent study
- Anxiety (or other psychological stress) of participant/guardian associated with the informed consent process

### Secondary outcomes

- Participant/guardian retention of knowledge and understanding of the parent study for at least two weeks post intervention
- Participant/guardian satisfaction with the decision-making process including:
  - \* satisfaction with decision to participate or decline participation;
  - \* feeling of coercion;
  - \* decisional conflict and decisional regret.
- Clinical researcher satisfaction with the informed consent process
- Clinical researcher ease of use of informed consent process
- Time taken to administer the consent procedure
- Level of adherence to study protocol for participants who entered the parent study
- Rate of withdrawal from the parent study following consent
- Participant/guardian satisfaction with the media used to convey the information

## Search methods for identification of studies

### Electronic searches

For the previous version of this review (Ryan 2008), we searched in April 2004 and updated searches in June 2006. Due to changes in the review's inclusion criteria (see [Differences between protocol and review](#)), and in relevant terminology, we revised these strategies and ran them in June 2012 (see [Appendices 1 to 7](#)). We did not limit the latest searches by year of publication, to ensure all references were screened according to the review's amended inclusion criteria. The search strategies for the previous version of this review are not reported here as they have been replaced by the 2012 search strategies; however they can be viewed in [Ryan 2008](#). There were no language restrictions.

In June 2012 we searched the following databases:

- Cochrane Central Register of Controlled Trials (CENTRAL), *The Cochrane Library*, issue 6, 2012;
- MEDLINE (Ovid) (1946 to 13 June 2012);
- EMBASE (Ovid) (1947 to 12 June 2012);
- PsycINFO (Ovid) (1806 to June Week 1 2012);
- CINAHL (EBSCO) (1981 to 27 June 2012);
- Current Contents (Ovid) (1993 Week 27 to 2012 Week 26); and
- ERIC (Proquest) (searched 27 June 2012).

A number of additional databases were specified in the review protocol that we planned to search for the original review (Ryan 2008), but we decided that complete coverage of the area was already ensured by the databases above. Accordingly, they were not searched for any iteration of the review. These databases were: PsycLIT and Psychological abstracts (covered by PsycINFO); Healthstar (covered by MEDLINE); CONSUMER; Consumer Sciences Index; Consumer reports on health; Current index to journals in education (CIJE); Resources in education (RIE); Institute for Scientific Information; ISI Web of Science (searched only as secondary citation index). We did not search the Cochrane Consumers and Communication Review Group Specialised Register as it is a sub-set of CENTRAL and is currently out of date.

### Searching other resources

We searched reference lists of included studies and relevant review articles. We also checked the excluded studies table from [Ryan 2008](#) to ensure that any studies previously excluded on the basis they were a hypothetical trial were assessed for inclusion in this update.

After the original searches (in 2004 and 2006) and again between October 2012 and April 2013 we contacted authors of included and some possibly-eligible studies, and experts in informed consent, in order to: gather additional information on the included studies; confirm inclusion/exclusion of eligible studies; and identify other potentially-relevant studies both published and in progress. We present details of author contact in [Appendix 8](#).

## Data collection and analysis

### Selection of studies

Two review authors (AS/MP/DF/BP) independently screened the titles/abstracts of studies identified by the searches against the inclusion criteria. We retrieved in full text all studies identified from their titles as being potentially relevant, and the same two authors assessed them for eligibility. Discrepancies were resolved by discussion with a third team member. Key studies excluded at this stage are listed in the table [Characteristics of excluded studies](#), with reasons given.

### Data extraction and management

For included studies, two authors (AS/DF/BP/RR/MP) independently extracted data, with discrepancies resolved by discussion and consensus. Categories of data were based on the Cochrane Consumers and Communication Review Group Data Extraction Template, and included the following components: details of the study, participant characteristics, interventions, outcomes and study conclusions. This information is reported for each included study in the [Characteristics of included studies](#) tables.

Where details were not included in the published study, or were unclear, we contacted authors requesting further information (see [Appendix 8](#)). In this update we only extracted and reported on outcomes that were pre-specified in the [Types of outcome measures](#), with those outcomes new to this update listed at [Differences between protocol and review](#). As a result, some outcomes that were included in [Ryan 2008](#) (for example, perceived worth of the trial and quality of research information disclosed) are not reported in this update.

### Assessment of risk of bias in included studies

We assessed and reported on the methodological characteristics of included studies in accordance with the guidelines of the *Cochrane Handbook for Systematic Reviews of Interventions*, which recommends using the Cochrane 'Risk of Bias' tool ([Higgins 2011a](#); see also [Ryan 2013](#)). The 'Risk of bias' tool includes seven domains: sequence generation; allocation concealment; blinding of participants and personnel; blinding of outcome assessors; incomplete outcome data; selective outcome reporting; and other sources of bias. Under 'other sources of bias' we examined baseline imbalance between groups, inappropriate administration of an intervention and contamination between intervention and control groups. We judged each item as being at 'high', 'low' or 'unclear' risk of bias, as set out in the *Cochrane Handbook* ([Higgins 2011a](#)).

For the sequence generation domain, we rated quasi-randomised studies as 'high risk'. For the blinding of outcome assessors we considered the type of outcome (objective or self-reported); and the role of the participants in measuring the outcome and/or the providers of the outcome assessment measure (i.e. self-administered questionnaire or provider-administered interview). For objective outcome measures, blinding of the participants was not judged as key to the 'Risk of bias' assessment. Studies were judged to be at a low risk of bias if personnel were blinded; and at an unclear risk of bias if they were not, or it was unclear.

For self-reported outcomes, which comprised the majority of outcomes in the review, we considered whether outcomes were self-administered or personnel-administered. For self-administered outcomes, blinding of personnel was not judged as key to the 'Risk of bias' assessment. Studies were judged at low risk of bias if participants were blinded, high if they were unblinded and low if it was unclear. For self-reported outcomes that were personnel-administered, we considered both the blinding of participants and personnel. Studies in which both personnel and participants were blinded were judged at low risk or bias and studies in which both personnel and participants were unblinded were judged at high risk of bias. If either the personnel or participants were unblinded it was judged at unclear risk of bias.

Two authors (AS/DF/BP/RR/MP) independently assessed the risk of bias of included studies, with any disagreements resolved by discussion and consensus. Where possible we contacted study authors for clarification of the study methods (see [Appendix 8](#)). We incorporated the results of the 'Risk of bias' assessment into the review through standard tables (see [Characteristics of included studies](#)) and systematic narrative description and commentary about each of the elements, leading to an overall assessment the risk of bias of included studies and a judgement about the internal validity of the review's results, at the outcome level where possible.

### Measures of treatment effect

For dichotomous outcomes, we sought to analyse data based on the number of events and the number of people assessed in the intervention and comparison groups, presenting the risk ratio (RR) and 95% confidence interval (CI). For continuous measures, we sought to analyse data based on the mean, standard deviation (SD) and number of people assessed for both the intervention and comparison groups, presenting the mean difference (MD) and 95% CI. Where meta-analysis of continuous data was possible, we calculated the standardised mean difference (SMD) and 95% CI as the studies used different tools for the same outcome. Where there were insufficient data provided to present the results in this way (for example the total number of participants in the intervention and control groups not provided), we report the data as presented by the authors.

Some of our outcomes are outcome categories, whereby a single study may contribute multiple outcomes to a category. An example of this is the knowledge and understanding outcome. If a study had multiple outcomes in the same category, we identified the main outcome for the study using the following approach ([Brennan 2009](#)):

1. Selecting the primary outcome as identified by the publication authors;
2. If no primary outcome was specified, selecting the one specified in the sample size calculation;
3. If there were no sample size calculations, ranking the effect estimates and selecting the median effect estimate.

### Unit of analysis issues

In the event that studies collected outcome measures more than once, for example, measuring intention to participate immediately after the intervention and some weeks later, we took the longest follow up time point from each study. In the case of the 'knowledge' outcome however, we report two separate outcome measures: 'knowledge', and 'recall of knowledge at least two weeks later'. The 'knowledge' outcome was taken as the knowledge measured in the period immediately after delivery of the intervention. If knowledge was measured more than once (i.e. at two weeks and at three months), we took the longer follow-up measurement for the 'recall of knowledge' outcome measure.

### Dealing with missing data

In the case of missing outcome data, missing summary data or missing study-level participant characteristics, we contacted the authors for more information. Where this was provided, we included the data in the review. We report any data that were not provided, identified this as a source of bias and considered its implications in interpreting the results. We imputed missing summary data where possible and report any assumptions made.

Where studies did not state that results were calculated using an intention-to-treat approach, we contacted study authors to request data to enable us to conduct such an analysis. As we did not receive any further study data, we analysed the results as reported.

### Assessment of heterogeneity

Where we meta-analysed data, we assessed heterogeneity by a visual inspection of the forest plot and the  $\text{Chi}^2$  test of

heterogeneity. We quantified heterogeneity using the  $I^2$  statistic (Higgins 2011a).

### Assessment of reporting biases

We assessed reporting bias qualitatively, based on the characteristics of the included studies (e.g. if only small studies were identified that indicate positive findings in favour of audio-visual interventions, or if the larger trials were multi-centre trials), and on any information we obtained from contacting experts in the area and study authors suggesting the existence of unpublished studies. We were not able to combine sufficient RCTs (at least 10) to construct a funnel plot to investigate small study effects or publication bias.

### Data synthesis

To synthesise the results, we reviewed the interventions and comparisons in each study and used this to create our overarching comparisons for the review. Keeping the real and hypothetical studies separate, we report the available data for each of our primary and secondary outcomes within each comparison. Where possible, we pooled the data meta-analytically. We describe the results for each outcome narratively and, where there were sufficient data, graphically. For each outcome we considered the impact of the quality of the evidence on the strength of the result, the degree of heterogeneity and its possible sources and the relevance of the results to research practice. We used the GRADE system (Schünemann 2011) to determine the quality of the evidence using GRADEpro software.

The decision to meta-analyse the data was based on an assessment of whether the included trials were similar enough (in terms of comparisons, interventions and outcomes) to enable meaningful conclusions to be drawn from a statistically-pooled result. It was also dependent on there being data from two or more primary studies available for inclusion. We did not take into account the similarity of study populations in the decision to meta-analyse the data, as we were seeking to determine the effect of the intervention across populations. However, we considered the study population as a possible source of heterogeneity in the pooled result. Due to the variability in the populations and interventions of included studies, we used a random-effects model for all meta-analyses.

### 'Summary of findings' tables

For this update, we prepared 'Summary of findings' tables of the main results for each comparison. We used the methods outlined in the *Cochrane Handbook* (Higgins 2011a) to present meta-analysed data and referred to the format used in a recent Cochrane review (Chan 2011) to present narrative findings. We pre-specified the following outcomes for inclusion in the 'Summary of findings' tables:

- participant/guardian knowledge and understanding of the parent study,
- participant/guardian satisfaction with the information provided about the parent study,
- rate of participation or willingness to participate in the parent study,
- anxiety (or other psychological stress) of participant/guardian associated with the informed consent process,

- participant/guardian retention of knowledge and understanding of the parent study for at least two weeks post intervention, and
- participant/guardian satisfaction with the decision-making process.

### Subgroup analysis and investigation of heterogeneity

Due to a lack of studies, we did not conduct the planned subgroup analyses on participants' education level and literacy. In future updates of the review, if sufficient data are available, we will investigate potential differences between particular subsets of participants visually (for example by using box plots), and then by subgroup analyses or, if the number of trials permit (i.e. greater than 10), by using random-effects meta-regression. The latter will be preferred because it will allow us to estimate the relative change and 95% confidence intervals.

### Sensitivity analysis

There were insufficient studies to conduct sensitivity analyses to investigate the influence of the included studies' risk of bias on effect estimates obtained from meta-analyses. If sufficient studies are available in future updates, we plan to group studies according to their 'Risk of bias' ratings (high/unclear risk of bias or low risk of bias). A study will be categorised as being at high/unclear risk of bias if it was rated as being at high or unclear risk of bias on one or more of the following domains: sequence generation, allocation concealment or selective outcome reporting. The remaining studies will be considered at low risk of bias. These three domains were selected as the limited but growing empirical evidence from methodological studies suggests they can most strongly influence intervention effect estimates (Higgins 2011a), although these decisions may be revised in light of most recent methodological advice. We will exclude studies at high/unclear risk of bias in a sensitivity analysis to determine whether risk of bias has substantially influenced review findings.

### Consumer participation

For each included study, we collected information (from the trial report and from author contact where possible) about the involvement of consumers in the development and evaluation of the interventions. We also sought literature on consumers' views of informed consent for clinical studies, and their needs from the informed consent process. This literature helped to inform the review, particularly the Discussion, and the Implications for research. In addition, consumer advocates assessed the protocol (McLaughlin 2002), and the original review (Ryan 2008), to ensure that consumers' needs and views were represented appropriately.

## RESULTS

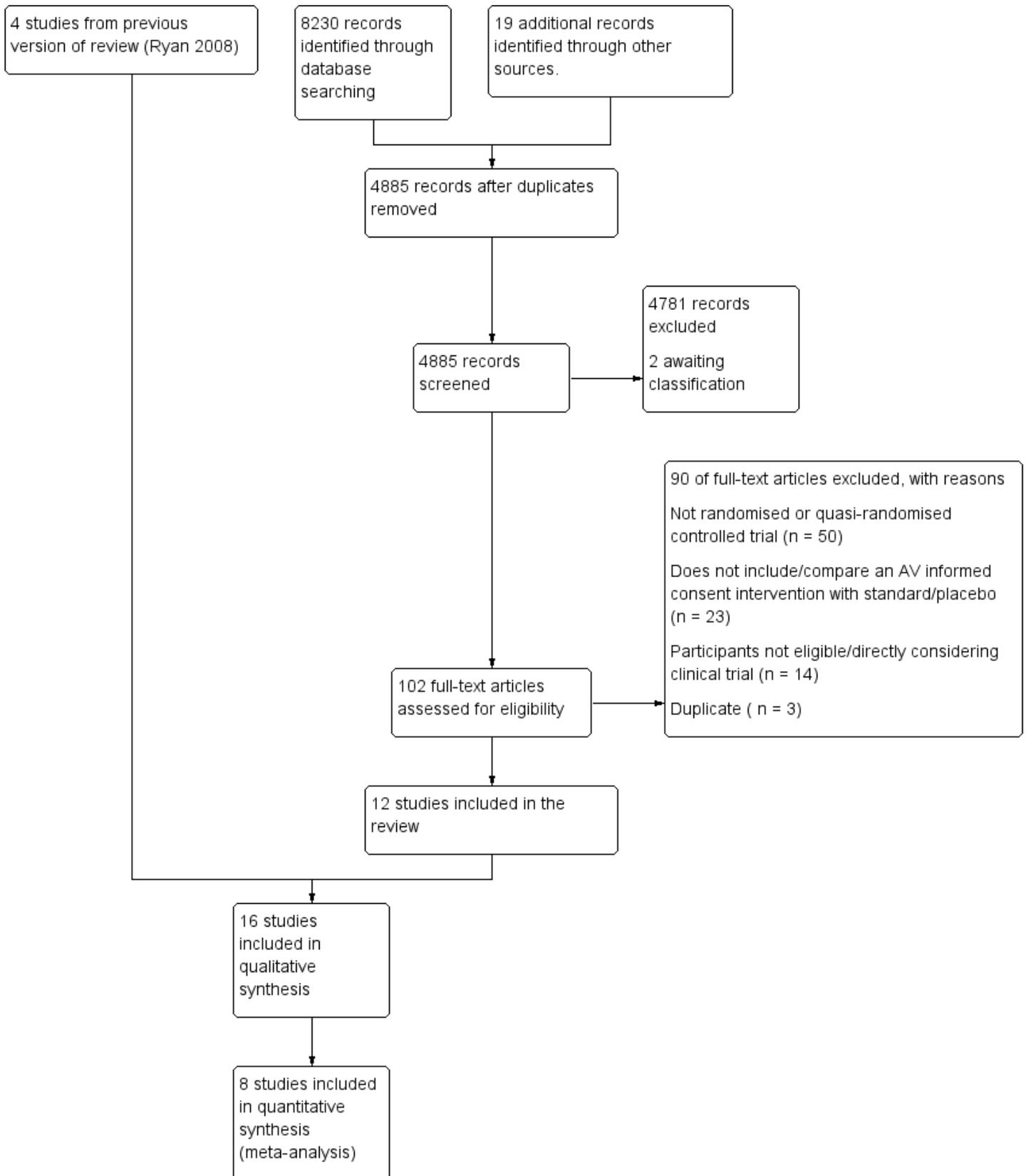
### Description of studies

#### Results of the search

We identified 8279 records from electronic database searches and 18 records through other sources (see flow chart of study selection in Figure 1). After removing duplicates, we screened 4883 records by title and abstract, excluding 4781 records. We obtained 102 records in full text, excluding 90 records. The reasons for exclusion of the key excluded studies are listed in the Characteristics of excluded studies table. As the review update was being finalised, two recent

studies were identified which will be assessed for inclusion in a future update ([Rowbotham 2013](#); [Sonne 2013](#)).

**Figure 1. Study flow diagram**



## Included studies

Twelve new studies (Campbell 2004; Harmell 2012; Hoffner 2012; Hutchison 2007; Jeste 2009; Karunaratne 2010; Kass 2009; Klein 2012; Mittal 2007; O'Lonegan 2011; Strevel 2007; Wirshing 2005) met the review's inclusion criteria and were added to the four studies (Agre 2003a; Benson 1988; Norris 1990; Weston 1997) included in the previous version of this review (Ryan 2008). The 16 studies were reported in 24 papers.

Type of trial	Study ID
Real clinical trial	Agre 2003a; Benson 1988; Hoffner 2012; Hutchison 2007; Kass 2009; Norris 1990; Strevel 2007; Weston 1997; Wirshing 2005
Hypothetical clinical trial	Agre 2003a; Campbell 2004; Harmell 2012; Jeste 2009; Karunaratne 2010; Klein 2012; Mittal 2007; O'Lonegan 2011

Detailed information about all studies is presented in the [Characteristics of included studies](#) tables. Key information is summarised below.

### Study design

Eight of the nine real clinical trial studies were described as randomised controlled trials (RCTs) (Agre 2003a; Hoffner 2012; Hutchison 2007; Kass 2009; Norris 1990; Strevel 2007; Weston 1997; Wirshing 2005) but in three of these studies the random sequence generation method was not fully described, so they may be quasi-RCTs (Hoffner 2012; Kass 2009; Norris 1990). The ninth study (Benson 1988) was a quasi-RCT which allocated participants sequentially.

Seven of the eight hypothetical clinical trial studies were described as RCTs (Agre 2003a; Campbell 2004; Jeste 2009; Harmell 2012; Klein 2012; Mittal 2007; O'Lonegan 2011), but four of these trials (Campbell 2004; Jeste 2009; Klein 2012; O'Lonegan 2011) did not fully describe their random sequence generation method so they could be quasi-RCTs. Karunaratne 2010 was a quasi-RCT, sequentially allocating participants to groups.

### Sample size

Studies ranged in size from 35 (Harmell 2012; Mittal 2007) to 441 participants (Agre 2003a); in total 2330 people participated in the 16 studies.

We excluded some participants from three studies as they did not meet our inclusion criteria (Agre 2003a; O'Lonegan 2011; Wirshing 2005 - see [Characteristics of included studies](#)). We also excluded participants in additional study arms that did not meet our inclusion criteria, or we could not be sure the study arm met our inclusion criteria (Agre 2003a; Benson 1988; Campbell 2004 - see [Characteristics of included studies](#)).

Overall, we included data from 1884 participants in this review; 1023 participants considering real clinical trial studies and 861 participants considering hypothetical clinical trial studies.

As shown below, nine studies included participants considering participation in a real clinical trial and eight studies included participants considering participation in a hypothetical clinical trial. Agre 2003a included both patients and 'surrogates' (people ineligible for the trial who were having day surgery) to consider, or imagine considering, participation in a real trial and as such, contributes to both the real and hypothetical study results.

### Setting

Twelve of the 16 studies were conducted in the United States, with 2 of the real clinical trial studies being conducted in Canada (Strevel 2007; Weston 1997) and 1 in the United Kingdom (Hutchison 2007). The sole hypothetical clinical trial study conducted outside of the United States was Karunaratne 2010, undertaken in Australia.

The studies were predominantly conducted in hospitals/medical centres (where specified). Of the real clinical trials, Wirshing 2005 was conducted in both a health centre and university. Of the hypothetical clinical trial studies, Campbell 2004 was conducted in a community facility.

### Participants

While the participants were diverse across the 16 studies, half of the studies focused on cancer drug trials or psychiatric treatments (predominantly medications). Most of the people considering real trial participation had cancer and were considering participation in one of multiple phase I to III oncology trials being offered (Agre 2003a; Hoffner 2012; Hutchison 2007; Kass 2009; Strevel 2007). Two studies (Benson 1988; Wirshing 2005) included people with psychiatric disorders (predominantly schizophrenia) considering one of many trials of psychiatric treatments (predominantly medication). Weston 1997 included pregnant women considering a trial for the management of pre-labour rupture of membranes (PROM) at term. Norris 1990 did not specify the study inclusion criteria but participants were considering a clinical trial of a duodenal ulcer drug.

The hypothetical clinical trials included nominally 'well people' (Agre 2003a; Campbell 2004; Klein 2012; O'Lonegan 2011), people with a health condition (Karunaratne 2010; Mittal 2007) or both populations (Harmell 2012; Jeste 2009). Campbell 2004 also created two population groups by using two different hypothetical studies (high risk and low risk study protocol) on which to base their consent materials. We included the data from both population groups in all three studies. Participants with actual health conditions had Alzheimer's disease, schizophrenia or diabetes (Karunaratne 2010; Harmell 2012; Jeste 2009; Mittal 2007). Campbell 2004 and O'Lonegan 2011 were the only studies

to include guardians (parents imagining clinical trial participation for their children).

In all studies, it was either explicitly stated, or implied, that the interventions were conducted in English. Half the trials specified English competency in their inclusion criteria (Agre 2003a; Hoffner 2012; Hutchison 2007; Jeste 2009; Karunaratne 2010; Klein 2012; Strevel 2007; Weston 1997). Only one study (Campbell 2004) specifically sampled for people with low health literacy, by conducting the study in a low-income community.

Of all studies in which ethnicity was reported, four included less than 15% of participants from ethnic minorities (Agre 2003a; Hoffner 2012; Klein 2012; O'Lonegan 2011) while three studies had between 22% and 32% of participants from ethnic minorities (Jeste 2009; Klein 2012; Mittal 2007). The education level of participants across the studies was generally high (see [Characteristics of included studies](#)).

### Interventions

Despite the focus of this review on studies that include just one kind of informed consent intervention (audio-visual), there was considerable heterogeneity between both the interventions and comparisons in this review. Across studies, the interventions varied widely in terms of the format, content and interactivity of the audio-visual component and the presence of additional elements such as written materials or face-to-face discussion. So too the control groups varied between written materials, face-to-face interaction and placebo audio-visual presentation, either alone or in combination.

Based on the interventions and control groups included in the studies, three comparisons were possible:

1. Audio-visual informed consent interventions versus standard informed consent procedures
2. Audio-visual plus standard informed consent interventions versus standard informed consent procedures
3. Audio-visual informed consent interventions versus placebo audio-visual interventions

We provide a description of the interventions and control groups of the studies included in each of these comparisons.

While the majority of studies included two arms, providing a single comparison, there were a number of studies with more than two arms. For the real clinical trials, we pooled the two intervention arms in Agre 2003a and Benson 1988 (See [Characteristics of included studies](#)), in line with *Cochrane Handbook* (Higgins 2011b) as we could determine very little difference between the intervention components. For the same reasons, we pooled the two intervention arms in the hypothetical studies Agre 2003a and Campbell 2004 (see [Characteristics of included studies](#)). We elected not to pool the intervention arms in Klein 2012 as the differences in the intervention components and results were more stark.

#### Comparison 1: Audio-visual informed consent interventions versus standard informed consent interventions

Two real clinical trials (Agre 2003a; Kass 2009) and seven hypothetical clinical trials (Agre 2003a; Campbell 2004; Harmell 2012; Karunaratne 2010; Klein 2012; O'Lonegan 2011; Mittal 2007) compared an audio-visual informed consent intervention with a

standard informed consent intervention. The studies within this comparison either made the simple comparison of audio-visual intervention versus written information or the more complex comparison of audio-visual + face-to-face intervention versus written information + face to face intervention. Because the face-to-face component in the more complex comparison is present in the both the intervention and control groups, it is effectively controlled for in the analysis. Thus, the underlying comparison in both the simple and complex comparisons in the same, namely an audio-visual informed consent intervention versus a standard informed consent intervention.

#### Single intervention (audio-visual intervention alone versus written information)

One real (Agre 2003a) and four hypothetical clinical trials (Agre 2003a; Campbell 2004; Karunaratne 2010; O'Lonegan 2011) compared a single audio-visual intervention with written consent information.

#### Real clinical trials

The audio-visual interventions in Agre 2003a consisted of a computer and video program. Little information is provided about the format of each, other than the fact both had scripts (implying there was audio) and the video used actors. Both interventions were non-interactive, were delivered by a research assistant on site and took between 10 and 20 minutes to view. The audio-visual interventions were professionally produced but it is unclear whether their development was informed by relevant theory or user testing. The pooled audio-visual arms were compared to a written consent form. It is unclear whether participants read the form independently or were guided through it. The content of both the audio-visual intervention and written forms was based on 1 of 18 specific consent forms and included the standard elements of a consent document (for example purpose, risks, participant rights) and was written at 8th-grade level.

#### Hypothetical clinical trials

The audio-visual interventions in Agre 2003a consisted of a computer and video program (as described above).

Campbell 2004 included video and computer interventions. These were almost identical except that the video had no text (no reading required) and was not interactive while the computer program had bulleted text and participants could advance the slides. Both interventions had video and still pictures with narration. The intervention was self-directed and the entire intervention took around one hour to complete. Minimal information about the interventions' development was provided beyond that they were based on readability research. For the purposes of the analysis, we pooled the results of the two intervention groups together. The intervention was compared with a written consent form. Two different consent forms were used (for a low risk and high risk study). The basic content for both consent forms and all intervention groups included standard consent information about one of the two trials, using simplified language.

In Karunaratne 2010 the audio-visual intervention was a computer program. It used text and hyperlinks to key words and diagrams, video clips of procedures and online quizzes. The intervention was interactive and took on average 19 minutes to complete. The program encouraged participants to re-read sections when they incorrectly answered quiz questions. The development and theory

behind the computer program was not reported. It was compared to a paper-based consent form. The content of both presentations was identical and covered standard consent information.

O'Lonegan 2011 used a computer-based intervention. It was shown as a PowerPoint slide with embedded hyperlinks to video clips showing footage of the procedures. The interaction was interactive, was delivered to the parent-child dyad together and took from 7 to 10 minutes to complete. The audio-visual intervention was informed by relevant theory (learning-objective approach) and extensive user testing with parents and children. The control group received the standard written consent form. The content of both consent materials covered standard consent concepts.

#### Multi-component intervention

One real (Kass 2009) and three hypothetical (Harmell 2012; Klein 2012; Mittal 2007) clinical trials compared a multi-component audio-visual consent intervention (audio-visual plus face to face) with a multi-component informed consent control (written information plus face to face).

#### Real clinical trials

The audio-visual intervention in Kass 2009 consisted of a computer program which was followed by a discussion with an oncologist. The program consisted of written and narrated information, with video clips of actors portraying patients making decisions about trial participation. It was self-directed and interactive, and about 20 minutes long. The computer program was based on extensive consultation with patients and other stakeholder groups, but no theoretical basis is described. The intervention was compared to the standard National Cancer Institute (NCI) consent form and a discussion with an oncologist. The content of both arms was based on the NCI Clinical Trials Pamphlet (including phases of drug testing and the voluntary nature of participation) about clinical trials in general.

#### Hypothetical clinical trials

The audio-visual intervention in Harmell 2012 was a web-based multimedia intervention delivered with face-to-face guidance and clarification from a research assistant. The intervention used a mix of video clips, static images/graphics and bulleted text. Questions were included at the end of each section; the length was not reported. The intervention was delivered by the research assistant, who participants could ask to pause and

replay sections. The development and theoretical basis for the intervention is not described but the authors refer to using the same hypothetical protocol as their previous study (Jeste 2009). This was compared with a standard written consent form plus face-to-face guidance and clarification from a research assistant. The content was identical in both groups, and included standard consent information for a specific trial.

Klein 2012 used two audio-visual presentations (multimedia and interactive multimedia) combined with a researcher available to answer questions. Both presentations used text, graphics and narration of text, and could be stopped and resumed. In the interactive multimedia arm, participants could also advance the screen and replay content and had to answer questions correctly to progress. These took about 20 minutes to complete. The authors described a strong theoretical basis but development of the interventions was otherwise not described. These arms were compared to a standard consent document that was read out by a research assistant. The content was identical in all groups and based on standard consent documents.

The audio-visual intervention used in Mittal 2007 consisted of a computer slide show along with a research assistant highlighting the key points. The slide show consisted of graphics, narration and video clips and took on average 25 minutes to complete. It was only interactive in the sense that the research assistant advanced the slides. The content described standard informed consent information and was identical to the written information to which it was compared. Participants in the control group received a written consent form, and a research assistant read along with the information and highlighted key points. The development and theoretical basis of the intervention is not reported.

#### Comparison 2: Audio-visual plus standard informed consent interventions versus standard informed consent interventions

Five real clinical trials (Benson 1988; Hoffner 2012; Hutchison 2007; Norris 1990; Weston 1997) and no hypothetical clinical trials compared audio-visual plus standard informed consent interventions with standard informed consent interventions. The interventions and comparisons in these studies differ from comparison 1 in that the interventions and control groups received identical consent materials, with the exception of the addition of the audio-visual materials in the intervention group. Thus the underlying comparison becomes audio-visual intervention versus no intervention (as the additional materials are controlled in both groups). These studies made the following comparisons:

Study ID	Intervention	Comparison
Benson 1988	audio visual + face to face	face to face
Hoffner 2012	audio visual + written consent	written consent
Hutchison 2007; Norris 1990; Weston 1997	audio visual + face to face + written consent	face to face + written consent

#### Real clinical trials

Benson 1988 had two audio-visual intervention arms that consisted of non-interactive videos and both were supplemented by

information provided by a researcher. Limited information is provided about how the videos differed, but both appeared to contain footage of research staff describing the parent studies. Both

were developed 'in house' by the research team. No theoretical basis is described. The content is described as the 'usual' information provided about clinical trials. The length of the audio-visual interventions is unclear. Due to the similarities between the intervention groups these results were pooled for the analysis. The pooled interventions were compared to the 'unassisted disclosure' group, in which subjects received the consent information (exact content unclear) from a researcher in a 'customary' manner. It is unclear if either the intervention or control groups included written information.

In [Hoffner 2012](#) the intervention group received a DVD presentation plus the written consent form. The DVD was non-interactive and consisted of footage of clinical trial participants and healthcare providers providing unscripted perspectives on trial participation. Participants were given the 20-minute DVD to watch at home. The authors describe an extensive development process involving multi-disciplinary stakeholder groups including consumers. This was compared with the written consent form that participants also took home to read. The content of the written consent form was not stated, but it is implied that it covered standard consent form topics.

Participants in intervention group in [Hutchison 2007](#) initially met with a doctor and received the written consent form for 1 of 18 trials for which they were eligible, then took the audio-visual presentation home with them. They returned a week later to discuss their trial participation with the doctor. The audio-visual presentation could be viewed on a DVD, CD-ROM or video, was non-interactive and took 10 minutes to watch. It covered general information about clinical trials (including randomisation, voluntariness, benefits/risks) and video of participants undergoing treatment. The audio-visual materials were overseen by an advisory committee and expert consumer panel. This was compared with control participants who also received the same components (minus the audio-visual intervention). The written consent form contained the same information as the audio-visual presentation but was more specific to the trial itself.

In [Norris 1990](#) the intervention group received a written consent form and had a discussion with a study nurse, followed by viewing the audio-visual presentation (in the form of a video). The video included information on the study protocol, procedures used and possible adverse reactions. Being a video, it is unlikely to have been interactive and the length is unspecified. The development and any theoretical basis are unclear. This was compared with the control group participants who received the written consent form and discussion with the study nurse.

Participants in the intervention group in [Weston 1997](#) viewed a 10-minute, non-interactive video and then received the written consent form and had any questions answered by a study nurse. Participants could watch the video at home or on site (most chose on site). The video was narrated by the principal investigator and discussed standard elements of informed consent and showed video footage of actual patients receiving the treatment. It was developed by a professional production company. No theoretical basis is described. This was compared to participants in the control group who received the written consent form and had any questions answered by the study nurse.

### Hypothetical clinical trials

No hypothetical clinical trials were included in this comparison.

### Comparison 3: Audio-visual informed consent interventions versus placebo informed consent interventions

Two real clinical trials ([Strevel 2007](#); [Wirshing 2005](#)) and one hypothetical clinical trial ([Jeste 2009](#)) compared an audio-visual informed consent intervention with a placebo audio-visual informed consent intervention. Both [Jeste 2009](#) and [Strevel 2007](#) compared an audio-visual intervention with a placebo intervention. [Jeste 2009](#) compared an audio visual + face-to-face intervention with a placebo DVD + face-to-face intervention. Because the face-to-face components in [Jeste 2009](#) are present in both the intervention and control groups, they effectively cancel each other out for the purposes of the analysis. Thus, the underlying comparison in the three studies is audio-visual informed consent intervention versus placebo audio-visual informed consent intervention.

### Real clinical trials

[Strevel 2007](#) used a non-interactive DVD presentation covering standard informed consent topics. It was created in a documentary style, with graphics and text to augment the dialogue and enacted scenes. It was eight minutes long and delivered on site in a private room. The information was not specific to a single trial. The DVD was informed by an understanding of common knowledge deficits for potential trial participants and reviewed by oncologists. No theoretical basis was described. This was compared with a placebo DVD that covered general information about the accomplishments of the researchers. No clinical trial specific content was included. Participants then consulted a doctor to discuss their trial participation but the outcomes were measured before this appointment, so there was no face-to-face element to the intervention when considering the outcomes measured.

In [Wirshing 2005](#) the audio-visual presentation consisted of a video covering standard consent information plus a discussion about good decision-making. The information was not specific to a single trial but about research in general. The video was 16 minutes long, non-interactive and consisted of bulleted text, narration and brief vignettes with actors playing study staff and patients discussing participation. The development and any theoretical basis were not described. This was compared to a control group which received a placebo video. This contained information about the history of research with no clinical trial specific information. Both [Strevel 2007](#) and [Wirshing 2005](#) do not explicitly state that participants received a copy of the written consent form with the DVD or placebo DVD, but it would seem likely that they did at some point, as they were making a decision about participation in one of several real clinical trials.

### Hypothetical clinical trials

The intervention in [Jeste 2009](#) consisted of a DVD, a copy of the written consent form and face-to-face explanation from a researcher. The DVD content was based on the consent form and included standard informed consent information. It was interactive, in that participants could ask the research assistant to stop and repeat sections, and contained narration, still pictures, graphics and animation, and summary text. Participants could also ask the researcher questions. On average, it took 22 minutes to complete. The authors report that the intervention drew heavily

on multimedia learning theory, but gave no further information about its development. This was compared with a placebo DVD that contained 'general research information' and the written consent form that participants could read along with the researcher.

## Outcomes

### Primary outcomes

#### Participant/guardian knowledge and understanding of the parent study

Participant/guardian knowledge and understanding of the parent study was measured in all real and hypothetical studies.

#### Real clinical trials

The real clinical trials measured:

- knowledge of the parent clinical trial(s) (Hoffner 2012; Hutchison 2007; Strevel 2007; Weston 1997),
- retention or knowledge of consent information (Agre 2003a; Norris 1990),
- understanding of trial purpose (Kass 2009), and
- understanding of the consent process (Benson 1988; Wirshing 2005).

Knowledge was predominantly assessed by an author-devised questionnaire (Agre 2003a; Hutchison 2007; Kass 2009; Strevel 2007; Weston 1997; Wirshing 2005). Hoffner 2012 used the a modified version of the Questionnaire of Informed Consent (QuiC) (Joffe 2001b). Benson 1988 assessed knowledge via semi-structured interview. Knowledge was measured immediately following the intervention (Agre 2003a; Benson 1988; Kass 2009; Norris 1990; Strevel 2007; Weston 1997; Wirshing 2005) or within one week of it (Hoffner 2012; Hutchison 2007). All real clinical trials measured knowledge once, with the exception of Hutchison 2007 and Wirshing 2005 which also measured knowledge at baseline (not reported in this review).

Two studies (Hoffner 2012; Strevel 2007) measured multiple knowledge outcomes. The QuiC (used in Hoffner 2012) has two component scores; objective knowledge and self-reported knowledge. As the authors identified the objective knowledge component as their primary outcome, we extracted and report on this measure in the review. Strevel 2007 asked participants nine separate knowledge-related questions. Three of these questions had more than one correct response and could not be included. We ranked the effect estimates of the remaining six questions and selected the median: knowledge of goals of clinical trials - safety. Additionally, the results of the knowledge questionnaire in Norris 1990 were reported as the percentage of participants who scored between 0 and 10 questions correct. To be able to use these scores, we converted them to a dichotomised outcome (adequate/inadequate knowledge) and determined the cut off for adequate knowledge at 80% (as per Weston 1997).

#### Hypothetical clinical trials

The hypothetical clinical trials measured:

- knowledge or retention of knowledge of the consent information (Agre 2003a; Klein 2012),
- comprehension of consent/assent process (O'Lonegan 2011),

- knowledge of protocol-specific information, and knowledge of research in general (Campbell 2004),
- knowledge of the procedure and clinical trial (Karunaratne 2010), and
- three related knowledge measures: understanding, reasoning and appreciation (Harmell 2012; Jeste 2009; Mittal 2007).

Five studies assessed knowledge using an author-devised questionnaire (Agre 2003a; Karunaratne 2010; Klein 2012; O'Lonegan 2011). O'Lonegan 2011 also assessed comprehension of the same elements of consent process in children using an interview that was later scored (data not included in the review). Campbell 2004 used a modified version of the Deaconess Informed Consent Comprehension Test (Miller 1996). Three studies (Harmell 2012; Jeste 2009; Mittal 2007) administered the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR) (Dunn 2006). All studies, with the exception of Jeste 2009 and Mittal 2007 (described below) assessed knowledge once, immediately following the intervention.

Four hypothetical studies (Campbell 2004; Harmell 2012; Jeste 2009; Mittal 2007) measured multiple knowledge outcomes. In addition to measuring 'prompted recall', Campbell 2004 also assessed 'free recall', whereby participants were asked to describe all they could remember about the study and then were scored on how many pieces of information they recalled. Because prompted recall was measured in a way that was consistent with other studies (by questionnaire), we selected and extracted data for this outcome measure. The MacCAT-CR (used by Harmell 2012, Jeste 2009 and Mittal 2007) measures three sub-scales that all met our criteria for knowledge and understanding: 1) understanding, 2) appreciation and 3) reasoning. These were measured immediately after the intervention (Harmell 2012), again after re-explanation of initially-misunderstood information (Mittal 2007) and once again after a second re-explanation (Jeste 2009). Harmell 2012 reported the three relevant sub-scales at one time point. As such, we calculated the effect size between groups for each sub-scale, ranked them and used the median effect size in our review. This was the 'reasoning' sub-scale for both the people with schizophrenia and the healthy comparison participants. In the case of Mittal 2007, all sub-scales were presented at both time points. As a result we took the longest time point (after re-explanation of consent information) and ranked the effect estimates. The median effect estimate was the understanding sub-scale, so this was used as the knowledge outcome measure. In the case of Jeste 2009, only one sub-scale (understanding) was presented at all three time points. It was unclear at which time point the other two sub-scales were taken. As a result, we could not rank the effect estimates and instead took the longest time point (after two re-explanations of the consent information) for the understanding sub-scale and used this as the knowledge outcome measure. By taking the longest time point it means the intervention effectively includes more face-to-face exposure, however participants in this trial already received significant input from a research assistant (to answer questions etc) so this does not change the components of the intervention in a meaningful way.

#### Participant/guardian satisfaction with the information provided about the parent study

One real clinical trial study (Strevel 2007) and two hypothetical studies (Harmell 2012; Klein 2012) assessed aspects of participants' satisfaction with the information provided about the parent study.

[Strevel 2007](#) asked four questions that related to satisfaction with the information provided about the study. We ranked the effect estimates and selected the median: whether the intervention helped in deciding whether or not to participate in a clinical trial (and reported the percentage of those who agreed or strongly agreed). This was assessed once immediately after the intervention. [Harmell 2012](#) asked participants to rate their satisfaction with the quality of the consent procedure relative to past experience using a three-point Likert scale. However, this question was only asked of participants who had taken part in previous research (approximately 80% of participants). This was assessed once immediately after the intervention. [Klein 2012](#) included three questions to measure satisfaction on a five-point Likert scale (satisfaction with consent length, difficulty and importance of the information). In line with our methods, we calculated the mean effect estimate for each question, ranked them and took the median measure; satisfaction with the length of the consent process. This was assessed once immediately after the intervention.

While two studies ([Hoffner 2012](#); [Karunaratne 2010](#)) assessed participant perceptions of the audio-visual intervention, including their satisfaction related to the intervention and the overall process, we did not include these data in the review. Data from [Hoffner 2012](#) could not be included as the authors sought participant feedback after the completion of the RCT portion of their study, inviting control participants to also view the video and provide their perceptions. [Karunaratne 2010](#) used qualitative methods to explore participant perceptions, which was not included in this review.

#### **Rate of participation or willingness to participate in the parent study**

Rate of participation or willingness to participate was measured in four real clinical trial studies ([Hutchison 2007](#); [Kass 2009](#); [Strevel 2007](#); [Weston 1997](#)) and four hypothetical studies ([Campbell 2004](#); [Jeste 2009](#); [Karunaratne 2010](#); [O'Lonergan 2011](#)).

Of the four real clinical trials, two studies ([Kass 2009](#); [Weston 1997](#)) assessed rate of participation by asking participants whether they intended to participate and two ([Strevel 2007](#); [Hutchison 2007](#)) assessed participants' case notes. [Hutchison 2007](#) reported the clinical trial refusal rate, which we converted into a clinical trial participation rate in line with our outcome measure. [Strevel 2007](#) assessed initial consent to participate and then actual entry into the trial after consent. We took the second measure (entry into the trial) as it was a more concrete measure of participation. [Hutchison 2007](#), [Kass 2009](#) and [Strevel 2007](#) all measured this outcome once, within approximately one week of the intervention. [Weston 1997](#) measured willingness for future trial participation immediately after the intervention and two to four weeks later. As pre-specified in our methods, we selected the later measurement point.

The hypothetical clinical trials variously assessed participants' likelihood to enrol ([Campbell 2004](#)), agreement to participate ([Kass 2009](#); [O'Lonergan 2011](#)) and interest in taking part ([Karunaratne 2010](#)) in the hypothetical trial. Two of the four studies ([Jeste 2009](#); [Karunaratne 2010](#)) assessed this via an item in the knowledge questionnaires and two studies ([Campbell 2004](#); [O'Lonergan 2011](#)) asked participants orally. All studies collected this outcome once, immediately after the intervention. It is unclear if the measure reported by [Jeste 2009](#) was taken immediately post-intervention or after the re-explanation of consent documents. [O'Lonergan 2011](#)

does not report the rate of participation either as a main finding, or in results tables, but simply state that 'all participants agreed (to participate)'.  
 '.

#### **Anxiety (or other psychological stress) of participant/guardian associated with the informed consent process**

Only one study ([Hutchison 2007](#)) measured participant anxiety or other psychological stress. Using the Spielberger State and Trait Anxiety Inventory-S, [Hutchison 2007](#) measured anxiety at baseline and one week after the intervention. We selected the post-intervention measure only.

#### **Secondary outcomes**

##### **Participant/guardian retention of knowledge and understanding of the parent study for at least two weeks post intervention**

[Benson 1988](#) and [Weston 1997](#) were the only studies to measure participant/guardian retention of knowledge. [Benson 1988](#) did this by re-interviewing participants two weeks after the intervention but did not report the results. [Weston 1997](#) re-administered the knowledge questionnaire to participants two to four weeks after the intervention.

##### **Participant/guardian satisfaction with the decision-making process**

One real clinical trial study ([Kass 2009](#)) and no hypothetical clinical trial studies assessed participant satisfaction with the decision-making process. [Kass 2009](#) asked participants whether they felt like they had the option to refuse to take part, assessing this outcome once via a questionnaire item.

##### **Time taken to administer the consent procedure**

No real clinical trial studies and four hypothetical studies ([Jeste 2009](#); [Karunaratne 2010](#); [Klein 2012](#); [Mittal 2007](#)) measured time taken to administer the consent procedure. Some additional studies ([Agre 2003a](#); [Benson 1988](#); [Campbell 2004](#)) reported the length of the audio-visual component of their intervention but did not formally compare the time taken to administer the consent procedures between intervention and control groups. [Strevel 2007](#) reported physicians' perceptions of the time taken to inform participants, and their satisfaction with this, but not the length of time it took to administer the intervention itself.

Only [Klein 2012](#) addressed this outcome in any detail, reporting that participants were timed from the moment they began the consent intervention until all of their questions had been answered by study personnel. In [Mittal 2007](#) it was unclear if the trialists timed participants until they completed the consent intervention or until they had completed the outcome measures (which also required re-explanation of misunderstood information).

##### **Participant/guardian satisfaction with the media used to convey the information**

One real clinical study ([Strevel 2007](#)) assessed satisfaction with the media used to convey information, by asking participants if 'DVD viewing is a useful way to provide education' with a Likert-scale item in a questionnaire. This was measured immediately after the intervention.

##### **Outcomes for which there were no data**

No study assessed the following secondary outcomes:

- Clinical researcher satisfaction with the informed consent process;
- Clinical researcher ease of use of informed consent process;
- Level of adherence to study protocol for participants who entered the parent study;
- Rate of withdrawal from the parent study following consent.

### Consumer involvement

A number of the real clinical trials involved consumers extensively in the development of the audio-visual intervention. [Kass 2009](#) undertook a qualitative study with consumers to develop the video scripts and invited 18 people with cancer and cancer survivors to review the video. They also included consumers in the video itself. [Hutchison 2007](#) included two 'expert patients' from early in the script and video development, and included footage in the video of real patients receiving treatment. [Hoffner 2012](#) included patients and family members in the range of stakeholders consulted during video development, and invited consumers to appear in the video to provide their own (unscripted) perceptions of trial involvement. [Weston 1997](#) included consumers in the production of the video intervention. The video included dialogue with an actual trial participant discussing her reasons for participating. Authors of the remaining four real trial studies either reported that the development of their intervention did not involve consumers ([Agre 2003a](#); [Benson 1988](#)), or did not provide sufficient information to assess whether consumers were involved ([Strevel 2007](#); [Wirshing 2005](#)).

The hypothetical clinical studies were quite different; only one described consumer involvement in intervention development. [O'Lonegan 2011](#) pre-tested 3 consent formats with 24 parent-child dyads and incorporated their feedback into the design of both the intervention and control consent presentations. The other nine hypothetical studies either did not involve consumers ([Agre 2003a](#)) or did not provide sufficient information to assess whether consumers were involved ([Campbell 2004](#); [Harmell 2012](#); [Jeste 2009](#); [Karunaratne 2010](#); [Klein 2012](#); [Mittal 2007](#); [Strevel 2007](#)).

### Funding sources

Four studies did not report their source of funding ([Agre 2003a](#); [Karunaratne 2010](#); [Norris 1990](#); [Strevel 2007](#)). The remaining 12 reported funding from government, philanthropic and other

health/research funding bodies. There is no indication that any studies received industry funding.

### Excluded studies

In the previous version of this review, one study ([Hougham 2003b](#)) was listed in the [Characteristics of studies awaiting classification](#) table. [Hougham 2003b](#) was cited in [Hougham 2003a](#), but the reference provided was incomplete. We sought unsuccessfully to contact the author during the preparation of [Ryan 2008](#) to request the full reference. As such, this study still awaits assessment. Another two studies identified during the final stages of this review update will be assessed in a future update ([Rowbotham 2013](#); [Sonne 2013](#)).

We excluded 90 studies at the full-text stage (see [Figure 1](#)). The main reasons for exclusion were:

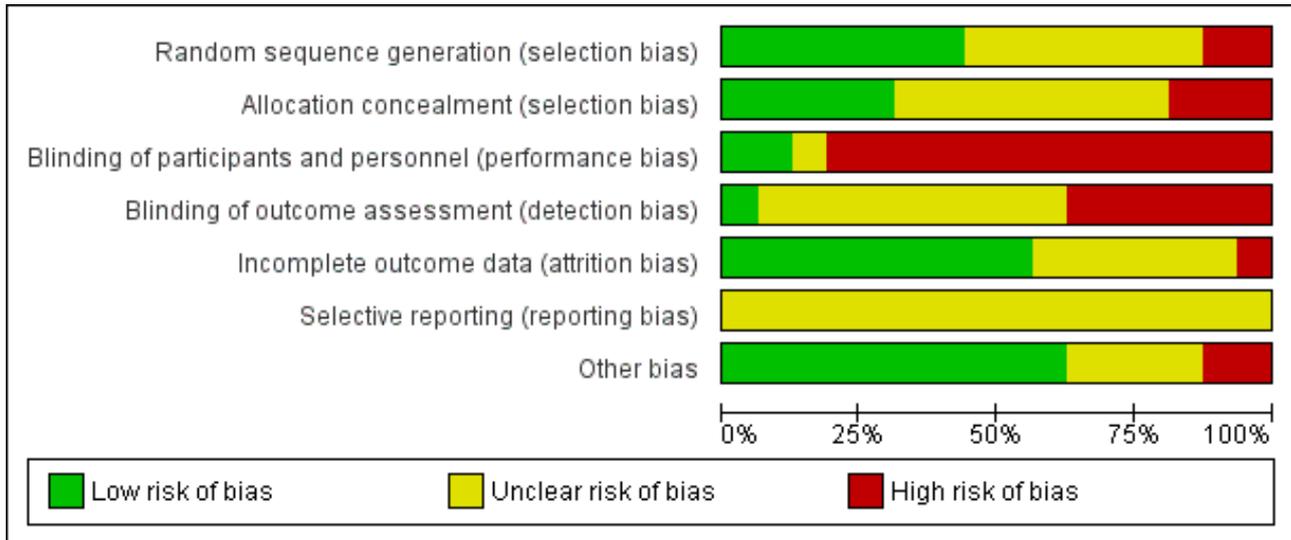
- the study was not a randomised or quasi-randomised controlled trial (n = 50),
- the study did include/compare an audio-visual informed consent intervention with a standard or placebo intervention (n = 23),
- the participants were not eligible for or directly considering participation in a real or hypothetical clinical trial (n = 14), and
- the study was a duplicate publication (n = 3).

A selection of the more relevant excluded studies (with reasons) is listed in the [Characteristics of excluded studies](#) table.

### Risk of bias in included studies

Overall, studies were judged to be at moderate to high risk of bias (see [Characteristics of included studies](#); [Figure 2](#); [Figure 3](#)). Many studies provided insufficient information about study design and execution, and hence were judged as unclear for a number of domains. This may be a reflection of inadequate reporting rather than poor conduct of the trials themselves. Risk of bias was highest in the domain of blinding of participants and personnel (performance bias), reflecting the difficulty of achieving blinding in studies of information provision. Studies fared better with regard to completeness of outcome data (attrition bias) and other sources of bias, with more than half the included studies rated as low risk for these domains.

**Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.**



**Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.**

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Agre 2003a	+	-	-	-	+	?	+
Benson 1988	-	-	-	-	+	?	+
Campbell 2004	?	+	-	?	+	?	+
Harmell 2012	+	?	-	?	?	?	+
Hoffner 2012	?	?	-	-	?	?	+
Hutchison 2007	+	+	+	?	+	?	-
Jeste 2009	?	?	-	?	+	?	+
Karunaratne 2010	-	-	-	?	?	?	?
Kass 2009	?	?	-	?	-	?	-
Klein 2012	?	?	-	?	?	?	?

**Figure 3. (Continued)**

Klein 2012	?	?	-	?	?	?	?
Mittal 2007	+	+	-	?	+	?	+
Norris 1990	?	?	-	-	?	?	?
O'Lonegan 2011	?	?	-	-	+	?	+
Strevel 2007	+	+	+	+	+	?	+
Weston 1997	+	+	-	-	+	?	+
Wirshing 2005	+	?	?	?	?	?	?

**Allocation**

**Random sequence generation**

Five of the nine real clinical studies (Agre 2003a; Hutchison 2007; Strevel 2007; Weston 1997; Wirshing 2005) described using a truly random number sequence and were rated as at low risk of bias. The remaining real trials reported their assignment of participants as 'random', however, Benson 1988 described quasi-random sequence generation (high risk) and the rest did not provide a description of randomisation, being rated as at unclear risk of bias (Hoffner 2012; Kass 2009; Norris 1990).

Similarly, all eight hypothetical clinical trials reported using 'random' assignment but only three (Agre 2003a; Harmell 2012; Mittal 2007) described a truly number sequence generation method (low risk). Karunaratne 2010 provided further information, describing a quasi-random sequence generation method (high risk) with the remaining studies rated as unclear due to insufficient information (Campbell 2004; Jeste 2009; Klein 2012; O'Lonegan 2011).

**Allocation concealment**

Three of the nine real clinical trials (Hutchison 2007; Strevel 2007; Weston 1997) described adequate allocation concealment (low risk). Authors of two studies (Agre 2003a; Benson 1988) confirmed that they did not conceal allocation (high risk) and the four remaining trials (Hoffner 2012; Kass 2009; Norris 1990; Wirshing 2005) were judged as being at unclear risk due to insufficient information.

Two of the eight hypothetical trials (Campbell 2004; Mittal 2007) described adequate allocation concealment (low risk). Authors of Karunaratne 2010 and Agre 2003a confirmed they did not conceal allocation (high risk) and the remaining four hypothetical studies (Harmell 2012; Jeste 2009; Klein 2012; O'Lonegan 2011) were ranked as unclear due to insufficient information.

**Blinding**

**Blinding of participants and personnel**

The overt nature of audio-visual interventions makes blinding of participants and providers particularly difficult, unless a placebo audio-visual intervention is used. As such, the majority of real clinical trials and all hypothetical clinical trials were ranked as being at high risk of bias for blinding of participants and personnel.

Two real trials (Hutchison 2007; Strevel 2007) were able to blind or partially blind participants and personnel (low risk). Wirshing 2005 used a placebo DVD (making blinding possible), but provided insufficient information about blinding (unclear risk). Hutchison 2007 blinded personnel, but not participants (unclear risk).

One hypothetical clinical study (Jeste 2009) also used a placebo DVD, but the personnel watched this with participants and as such were unblinded.

**Blinding of outcome assessment**

Similarly, the nature of the outcomes measured in informed consent trials limits investigators' ability to blind the outcome assessment. The majority of outcomes (such as knowledge and satisfaction) are self-reported, making blinding difficult when participants are not themselves blind to their allocation. In fact, the only outcome included in this review able to be measured objectively (by case notes, for example) is rate of participation in the parent trial. In determining the risk of detection bias for each study, we considered whether the outcome was objective or self-reported, and the role of participants and personnel in administering the outcome measure. For studies with more than one outcome we rated the risk of bias for each outcome before combining the ratings.

Only one of the nine real studies (Strevel 2007) was judged to be at low risk of bias for blinded outcome assessment; the outcomes were self-reported but participants were blind to group allocation. Hutchison 2007 was judged at low risk of bias for the objective primary outcome (rate of participation) but at unclear risk of bias

overall when considering the remainder of self-reported outcomes. A further two real trials were at unclear risk of bias due to insufficient information about how the outcomes were assessed and by whom (Wirshing 2005), and whether personnel conducting interviews with participants were blinded (Kass 2009), while the remaining five studies were at high risk of bias (Agre 2003a; Benson 1988; Hoffner 2012; Norris 1990; Weston 1997).

Hypothetical trials fared somewhat better. Only Agre 2003a and O'Lonegan 2011 were judged at high risk of bias, with the remaining seven studies at unclear risk of bias. Four studies (Campbell 2004; Harmell 2012; Jeste 2009; Mittal 2007) used an interview or questionnaire administered by a blinded assessor. The remaining two studies provided insufficient information about how the outcomes were assessed and by whom (Karunaratne 2010), and whether some of the participants who completed the self-administered questionnaire may have been blinded (Klein 2012).

### Incomplete outcome data

Most studies accounted for all or nearly all participants. Four real clinical trials (Agre 2003a; Benson 1988; Strevel 2007; Weston 1997) achieved 100% (or close to 100%) follow up of participants for all relevant outcomes (low risk). Hutchison 2007 was also rated at low risk of bias, as the primary outcome was complete and missing data for some outcomes were accounted for appropriately in the analysis. Three real clinical trials were rated as unclear risk of bias due to around 15% loss to follow up that was not accounted for in the analysis (Hoffner 2012), or insufficient/inconsistent information (Wirshing 2005; Norris 1990). Kass 2009 was rated as being at high risk of bias as numbers of participants randomised and those analysed varied substantially.

Five of the eight hypothetical trials achieved 100% (or close to 100%) follow up for all relevant outcomes (low risk of bias) (Agre 2003a; Campbell 2004; Jeste 2009; Mittal 2007; O'Lonegan 2011). A further two studies also achieved close to 100% follow up but were rated as unclear risk of bias as they: excluded a small number of questionnaire items from analysis (Karunaratne 2010); and excluded 20% of participants for one outcome (Harmell 2012). Klein 2012 was rated as unclear as it did not explicitly state how many participants were randomised to each group, with a small loss to follow up.

### Selective reporting

No studies mentioned published protocols against which their completed reports could be assessed, so it was not possible to determine whether selective outcome reporting had occurred. All sixteen studies were rated as unclear risk of bias for this domain.

### Other potential sources of bias

Five of the nine real clinical studies (Agre 2003a; Benson 1988; Hoffner 2012; Strevel 2007; Weston 1997) were rated at low risk of other bias as they reported that groups were comparable on key characteristics at baseline, and reported no other issues likely to increase the risk of bias (such as inappropriate administration of an intervention or contamination). Two studies (Norris 1990; Wirshing 2005) were rated at unclear risk of bias as they did not provide baseline demographic characteristics by group, with the remaining two studies (Hutchison 2007; Kass 2009) at high risk of other bias for baseline imbalance and other issues.

Six of the eight hypothetical studies (Agre 2003a; Campbell 2004; Harmell 2012; Jeste 2009; Mittal 2007; O'Lonegan 2011) were rated as low risk of other bias, as groups were comparable at baseline and authors reported no other issues likely to increase the risk of bias. Karunaratne 2010 and Klein 2012 were rated as at unclear risk of other bias, for baseline imbalance, and lack of demographic data by intervention arm respectively.

We found no evidence to suggest publication bias. Although we had insufficient included studies to undertake funnel plots, a qualitative assessment of included studies revealed that the larger studies tended to be the ones that showed a positive effect of the intervention on the most commonly-reported outcomes; knowledge and rate of participation.

## Effects of interventions

See: **Summary of findings for the main comparison** Summary of findings (Comparison 1); **Summary of findings 2** Summary of findings (Comparison 2); **Summary of findings 3** Summary of findings (Comparison 3)

### Comparison 1: Audio-visual informed consent interventions versus standard informed consent interventions

#### Primary outcomes

#### Participant/guardian knowledge and understanding of the parent study

##### Single intervention (audio-visual intervention alone versus written information)

One real clinical study (Agre 2003a) assessed participant knowledge of the parent study in 155 participants. The pooled intervention arms showed evidence of no effect on knowledge (SMD 0.05 (95% CI -0.28 to 0.39)), (see Analysis 1.1 (sub-analysis 1.1.1)).

Based on the evidence from real clinical trials, we are uncertain about the effect of a single audio-visual intervention (versus written information) on participant knowledge and understanding of the parent study. The quality of this evidence is very low (small, single study; lack of allocation concealment; confidence interval includes possible benefits and harms but does include minimally important difference (effect size of 0.5)), meaning any effect estimate is very uncertain.

Four hypothetical studies measured participant/guardian knowledge of the parent study (Agre 2003a; Campbell 2004; Karunaratne 2010; O'Lonegan 2011) in 499 participants. We pooled the results of the two audio-visual interventions in both Agre 2003a and Campbell 2004, and then meta-analysed their results with those of O'Lonegan 2011. The pooled result showed a small improvement in knowledge with the audio-visual intervention (SMD 0.26 (95% CI 0.06 to 0.45)) and low statistical heterogeneity ( $\text{Chi}^2 = 0.91$ ,  $P = 0.82$ ,  $I^2 = 0\%$ ) (see Analysis 1.1 (sub-analysis 1.1.2)). We note however the effect size and confidence interval do not include a clinically important effect (when using the minimally important difference 'rule of thumb' of an effect size of 0.5). While we did not formally include the child data from O'Lonegan 2011 we note that the authors reported that the children's knowledge scores reflected the parents' knowledge scores. The remaining hypothetical study (Karunaratne 2010) was not included in the meta-analysis as these data appeared skewed. The authors reported that knowledge was significantly improved in

the intervention group compared with the control group (correct answers 82% versus 73%,  $P = 0.005$ ), however they may have used an inappropriate test to determine statistical significance.

Based on the evidence from hypothetical clinical trials, we are uncertain about the effect of a single audio-visual intervention (versus written information) on participant knowledge and understanding of the parent study. While the results suggest a small effect on knowledge, the quality of this evidence is very low (very serious risk of bias limitations; hypothetical study suggesting indirectness), making the effect estimate very uncertain.

#### **Multi-component intervention (audio-visual plus face-to-face intervention versus written information plus face to face)**

[Kass 2009](#) was the sole real clinical trial to assess knowledge (in 126 participants), however the authors used a question with five multiple-choice responses and it was unclear how many of the response options they considered to be correct. While the difference between the intervention and control group answers in 4 out of 5 response options was not statistically significant, the authors reported that participants "in the intervention group were significantly more likely to correctly state that the purpose of an early phase trial related to safety (34.4%) compared to 16% of control participants ( $P = 0.03$ )".

Based on the evidence from real clinical trials, we are uncertain about the effect of a multi-component audio-visual intervention (versus written information) on participant knowledge and understanding of the parent study. The result was difficult to interpret and the quality of the evidence was very low (small study with uncertain results; serious risk of bias issues), meaning the effect estimate is very uncertain.

Three hypothetical studies measured participant knowledge of the parent study ([Harmell 2012](#); [Klein 2012](#); [Mittal 2007](#)) in 165 participants. We pooled the results of both participant groups in [Harmell 2012](#) (well people and people with schizophrenia) with [Mittal 2007](#). The pooled result showed no effect on knowledge (SMD 0.24 (95% CI -0.23 to 0.71)) with low statistical heterogeneity ( $\text{Chi}^2 = 0.25$ ,  $P = 0.88$ ,  $I^2 = 0\%$ ) (see [Analysis 1.1](#) (sub-analysis 1.1.3)). We note however that the confidence interval includes a range of effects including a potentially clinically-important benefit (effect size greater than 0.5). We were unable to include the results of [Klein 2012](#) in the meta-analysis as the authors did not state the overall number of participants in each group. [Klein 2012](#) reported a statistically-significant improvement in understanding with the interactive multimedia intervention (mean number of correct responses 15.9/18, SD 0.93) compared with the control group (mean number of correct responses 14.9/18, SD 1.34) ( $P < 0.05$ ), but not between the non-interactive multimedia intervention and control (mean number of correct responses (15.2/18, SD 1.51).

Based on the evidence from hypothetical clinical trials, we are uncertain about the effect of a multi-component audio-visual intervention (versus written information). While all studies showed a consistent improvement in knowledge, none reached statistical significance (unlikely due to their small sample sizes). In addition, the quality of the evidence was very low (very serious risk of bias limitations; small, hypothetical studies suggesting indirectness; confidence intervals crossed the line of no effect and clinically important benefit but not harm) meaning these effect sizes are very uncertain.

#### **Participant/guardian satisfaction with the information provided about the parent study**

##### **Single intervention (audio-visual intervention alone versus written information)**

No real or hypothetical clinical trials measured participant/guardian satisfaction with the information provided about the parent study in this comparison.

##### **Multi-component intervention (audio-visual plus face-to-face intervention versus written information plus face to face)**

No real clinical trials measured participant/guardian satisfaction with the information provided about the parent study in this comparison.

Two hypothetical studies ([Harmell 2012](#); [Klein 2012](#)) measured satisfaction with the information provided about the parent study in 122 participants. We did not pool these studies because:

1. they used very different satisfaction measures,
2. [Klein 2012](#) included two different audio-visual intervention groups that we could not pool, and
3. [Harmell 2012](#) did not include all participants in the satisfaction measure.

[Klein 2012](#) found that participants who received the interactive audio-visual intervention were more satisfied with the consent process length than those in the control group (mean score 3.58/5, SD 0.56 versus mean score 4.03/5, SD 0.65,  $P < 0.05$ , lower score equates to more satisfied). The difference in satisfaction scores between the non-interactive audio-visual intervention group and the control group was not statistically significant (mean score 3.74/5, SD 0.82 versus mean score 4.03/5, SD 0.64).

[Harmell 2012](#) measured participant satisfaction with 'consent quality', compared with past experience. However, due to the nature of the question, they only asked participants who had previously taken part in research (80% of their sample). For this sub-set of participants, they report that those who received the audio-visual intervention were more likely to report 'better' consent quality compared to past experience when compared with those who received the written consent form (60% versus 17% of healthy control participants and 44% versus 25% of people with schizophrenia). This result is difficult to interpret as those who had participated in research before may have had a reasonably positive experience to warrant considering signing up for more research.

Based on the evidence from hypothetical clinical trials, we are uncertain about the effect of multi-component audio-visual interventions (versus written plus face to face information) on participant/guardian satisfaction with the information provided about the parent study. Despite the limitations of the data for this outcome, both studies showed an improvement in satisfaction with the intervention. However, the quality of the evidence was very low (serious risk of bias limitations; hypothetical studies suggesting indirectness; small sample with unclear precision) meaning the effects are very uncertain.

## Rate of participation or willingness to participate in the parent study

### Single intervention (audio-visual intervention alone versus written information)

No real clinical trials measured rate of participation for this comparison.

Three hypothetical studies involving 463 participants measured willingness to participate in the parent study (Campbell 2004; Karunaratne 2010; O'Lonergan 2011). These studies were not pooled as Campbell 2004 reported the rate of participation in the low risk (107/117) and high risk (77/116) protocol groups but did not report these data broken down by intervention and control groups. O'Lonergan 2011 did not provide any numerical data, only stating that 'all participants agreed' to participate. Karunaratne 2010 reported that participants who received the audio-visual intervention were more likely to indicate they would (hypothetically) participate in the study (23/30 versus 17/30,  $P = 0.01$ ). However, when we re-calculated this as a relative risk it did not show evidence of an effect (RR 1.35 (95% CI 0.93 to 1.96)) (see Analysis 1.2).

Based on the evidence from hypothetical clinical trials, we are uncertain about the effect of single audio-visual interventions (versus written plus face to face information) on rate of participation or willingness to participate in the parent study. Due to limitations in the data for this outcome and very low quality evidence (uncertain risk of bias issues; small, single study; hypothetical study suggesting indirectness; confidence interval includes benefits and harms) we are very uncertain about the effect estimate.

### Multi-component intervention (audio-visual plus face-to-face intervention versus written information plus face to face)

One real clinical study (Kass 2009) assessed participants 'decision to enrol' in the parent study in 110 participants. Kass 2009 reported the percentage of participants in each group who agreed to participate in the parent study, but not the overall number of participants included in each group for this outcome. They report that there was no difference in agreement to participate between the intervention and control groups (78.3% versus 74.0%,  $P = 0.59$ ).

Based on the evidence from real clinical trials, we are uncertain about the effect of multi-component audio-visual interventions (versus written plus face-to-face information) on rate of participation or willingness to participate in the parent study. The single study appears to show there is no difference in rate of participation but the evidence is very low quality (serious risk of bias limitations; small study; confidence intervals likely to be imprecise) and as such, any estimate of the effect is very uncertain.

No hypothetical clinical trials measured rate of participation for this comparison.

## Secondary outcomes

### Participant/guardian satisfaction with the decision-making process

#### Single intervention (audio-visual intervention alone versus written information)

No real or hypothetical clinical trials measured satisfaction with the decision-making process for this comparison.

### Multi-component intervention (audio-visual plus face-to-face intervention versus written information plus face to face)

One real clinical study (Kass 2009) assessed whether participants were satisfied with the decision-making process (specifically, whether they felt they had the option to refuse) in 126 participants. Again, Kass 2009 reported the percentage of participants who were satisfied in each group but not the overall number of participants in each group for this outcome. They reported that satisfaction was high in the intervention and control groups, with no difference between groups (95.6% versus 93.1%,  $P = 0.54$ ).

Based on the evidence from real clinical trials, we are uncertain about the effect of multi-component audio-visual interventions (versus written plus face-to-face information) on participant satisfaction with the decision-making process. The quality of the evidence is very low (serious risk of bias limitations; small study; confidence intervals would cross the line of no effect) and as such, any estimate of the effect is very uncertain.

No hypothetical clinical trials measured participant satisfaction with the decision-making process.

### Time taken to administer the consent procedure

#### Single intervention (audio-visual intervention alone versus written information)

No real clinical trials measured time taken to administer the consent procedure.

One hypothetical trial (Karunaratne 2010) measured time taken to administer the consent procedure. The authors did not report the standard deviation so we calculated this using the intervention and control group means, number of participants and the  $P$  value ( $P = 0.001$ ). Karunaratne 2010 found that the audio-visual intervention took 6 minutes longer to complete the written information (MD 6.0 minutes (95% CI 5.08 to 6.92 minutes); see Analysis 1.3, sub-analysis 1.3.1).

Based on the evidence from a hypothetical clinical trial, we are uncertain about the effect of single audio-visual intervention (versus written information) on the time taken to administer the consent procedure. While the single study suggests that audio-visual interventions take longer to administer, the quality of the evidence is very low (very serious risk of bias limitations; hypothetical study suggesting indirectness; few participants) meaning the estimate of the effect is very uncertain.

#### Multi-component intervention (audio-visual plus face-to-face intervention versus written information plus face to face)

Two hypothetical studies (Mittal 2007; Klein 2012) measured time taken to administer the consent procedure, with conflicting results. We could not pool these results as Klein 2012 did not report the number of participants in each group. Mittal 2007 found that the audio-visual intervention took less time than the written and face-to-face consent procedure (MD -9.4 minutes (95% CI -14.34 to -4.46 minutes), see Analysis 1.3, sub-analysis 1.3.2). Klein 2012 found that their interactive audio-visual intervention took slightly more time than their non-interactive multimedia intervention, which took slightly more time than their written and face-to-face consent procedure (M 20.8 minutes SD 5.38 versus M 19.2 minutes, SD 1.49 versus M 18.7 minutes, SD 2.32). Despite these small differences, the authors reported that the difference between both the intervention

groups and the control group was statistically significant (P values not reported).

Based on the evidence from hypothetical studies, we are uncertain about the effect of a multi-component intervention (versus written information plus face to face) on the time taken to administer the consent procedure. The results of the two studies conflict and the quality of the evidence is very low (inconsistent results; hypothetical studies suggesting indirectness; small sample size; wide confidence intervals) meaning the estimate of the effect is very uncertain.

#### Outcomes for which there are no data in this comparison

No study in this comparison measured the following outcomes:

- Anxiety (or other psychological stress) of participant/guardian associated with the informed consent process
- Participant/guardian retention of knowledge and understanding of the parent study for at least two weeks post intervention
- Clinical researcher satisfaction with the informed consent process
- Clinical researcher ease of use of informed consent process
- Level of adherence to study protocol for participants who entered the parent study
- Rate of withdrawal from the parent study following consent
- Participant/guardian satisfaction with the media used to convey the information

#### Comparison 2: Audio-visual plus standard informed consent interventions versus standard informed consent interventions

This comparison included only real clinical studies; no hypothetical study assessed this comparison.

#### Primary outcomes

##### Participant/guardian knowledge and understanding of the parent study

Three real studies (Benson 1988; Hoffner 2012; Hutchison 2007) measured knowledge of the parent study as a continuous outcome (287 participants) and two real studies (Norris 1990; Weston 1997) measured knowledge as a dichotomous outcome (290 participants). For the continuous data, we pooled the results of the two audio-visual intervention groups in Benson 1988 and meta-analysed this with the results of Hoffner 2012. We did not include Hutchison 2007 in this meta-analysis as the data appeared to be skewed on inspection of the box and whiskers plot. The combined result showed evidence of no effect on knowledge (SMD 0.04 (95% CI -0.30 to 0.38) (see Analysis 2.1). Statistical heterogeneity was low ( $\text{Chi}^2 = 0.60$ ,  $P = 0.44$ ,  $I^2 = 0\%$ ). Hutchison 2007 compared the difference in the change in percentage knowledge score and the difference in median knowledge change scores between groups and found that knowledge scores in the intervention group were higher. The authors reported that the percentage mean change favoured the intervention group ( $P > 0.05$ ) and the median knowledge change score between groups was 5.0 (95% CI 0.0 to 16.7).

For the dichotomous data, Weston 1997 measured the percentage of participants scoring at least 80% on their knowledge questionnaire. We dichotomised the categorical results of Norris

1990 into this same format to allow for statistical comparison. Due to high statistical heterogeneity ( $\text{Chi}^2 = 67.75$ ,  $P < 0.001$ ,  $I^2 = 99\%$ ) we have presented the results graphically without the pooled result (see Analysis 2.2). Considered separately, Norris 1990 found that participants in the intervention group had greater knowledge than those in the control group (82/100 versus 30/100, RR 2.73 (95% CI 2.0 to 3.74)), whereas Weston 1997 demonstrated evidence of no effect, with a result that included no clinically important benefit or harm (using the 'rule of thumb' for dichotomous outcomes of an effect size of 0.25) (40/42 versus 42/48, RR 1.09 (95% CI 0.96 to 1.24)).

Based on the evidence from real clinical trials, we are uncertain about the effect of audio-visual plus standard interventions (versus standard information) on knowledge and understanding of the parent study. Some studies demonstrated evidence of an effect while others did not. Because the quality of this evidence is low (inconsistency; some confidence intervals cross the line of no effect), further research is very likely to change the effect estimate, or our confidence in this estimate.

##### Rate of participation or willingness to participate in the parent study

Two real studies (Hutchison 2007; Weston 1997) measured rate of participation in 258 participants. Due to moderate statistical heterogeneity when we attempted to pool the results ( $P = 0.08$ ,  $I^2 = 68\%$ ), we present these results separately (see Analysis 2.3). Neither study found evidence of an effect of audio-visual interventions on rate of participation (Hutchison 2007: 62/86 versus 66/87, RR 0.95 (95% CI 0.8 to 1.13); Weston 1997: 23/41 versus 17/44, RR 1.45 (95% CI 0.92 to 2.30)).

Based on the evidence from real clinical trials, audio-visual plus standard interventions (versus standard information) may make little or no difference to the rate of participation or willingness to participate in the parent study. While neither study showed an effect on rate of participation, the quality of the evidence is low (somewhat inconsistent results; confidence intervals includes appreciable benefits and harms) meaning further research is very likely to change the effect estimate, or our confidence in this estimate.

##### Anxiety (or other psychological stress) of participant/guardian associated with the informed consent process

One real study (Hutchison 2007) measured the anxiety of 142 participants, but the results are difficult to interpret. Not only do the results appear skewed but also the authors report that there was a statistically-significant difference in baseline anxiety scores between the two groups (participants in the intervention arm appeared more anxious). The authors report that the difference in median anxiety change score between the two groups favours the intervention group (-4.6 (95% CI -7.0 to -2.0)) but the post-intervention median anxiety scores between groups are similar (owing to the greater anxiety in the intervention group at baseline).

Based on the evidence from a single real clinical trial, we are uncertain whether audio-visual plus standard interventions (versus standard information) affect anxiety (or other psychological stress) of participants associated with the informed consent process. The result of the single study is difficult to interpret and the quality of the evidence is low (baseline imbalance; small, single study), meaning further research is very likely to change the effect estimate, or our confidence in this estimate.

## Secondary outcomes

### Participant/guardian retention of knowledge and understanding of the parent study for at least two weeks post intervention

One real clinical study ([Weston 1997](#)) assessed retention of knowledge at least 2 weeks post-intervention in 85 participants. Defining adequate knowledge as having at least 80% correct knowledge questionnaire answers, the authors found the audio-visual intervention improved knowledge two to four weeks post-intervention (36/41 versus 28/44, RR 1.38 (95% CI 1.07 to 1.77), see [Analysis 2.4](#)).

Based on the evidence from real clinical trials, audio-visual plus standard interventions (versus standard information) probably improves participant knowledge and understanding of the parent study for at least two weeks post intervention. The quality of the evidence was low (few participants/events, some imprecision, lower confidence interval crosses the line of no effect and includes appreciable benefits) meaning further research is very likely to change the effect estimate, or our confidence in this estimate.

### Outcomes for which there are no data in this comparison

No study in this comparison measured the following outcomes:

- Participant/guardian satisfaction with the information provided about the parent study
- Participant/guardian satisfaction with the decision-making process
- Clinical researcher satisfaction with the informed consent process
- Clinical researcher ease of use of informed consent process
- Time taken to administer the consent procedure
- Level of adherence to study protocol for participants who entered the parent study
- Rate of withdrawal from the parent study following consent
- Participant/guardian satisfaction with the media used to convey the information

## Comparison 3: Audio-visual informed consent interventions versus placebo informed consent interventions

### Primary outcomes

#### Participant/guardian knowledge and understanding of the parent study

Two real clinical trials ([Strevel 2007](#); [Wirshing 2005](#)) measured participant knowledge of the parent study in 132 participants. The data could not be pooled as [Strevel 2007](#) used a dichotomous knowledge measure whereas [Wirshing 2005](#) used a continuous measure. [Strevel 2007](#) found there was no evidence of an effect on knowledge (21/22 versus 22/27, RR 1.17 (95% CI 0.96 to 1.43), see [Analysis 3.1](#)). The authors of [Wirshing 2005](#) report the mean knowledge scores for the intervention and controls groups (mean score 69.2/80 SD 8.2 versus mean score 65.1/80 SD 9.5) but do not comment on the statistical significance of the difference between groups (nor do they provide the total number of participants in each group, which would allow us to calculate the RR). Instead, they calculate the difference in mean change scores, reporting this is as statistically significant, in favour of the intervention group ( $P = 0.002$ ).

Based on the evidence from real clinical trials, audio-visual interventions (versus placebo) may make little or no difference to participant knowledge and understanding of the parent study. The results from both studies suggest there was no difference in knowledge, however the quality of the evidence is low (small sample size, at least one confidence interval crosses the line of no effect and includes appreciable benefits) meaning further research is very likely to change the effect estimate, or our confidence in this estimate.

The sole hypothetical study measuring knowledge in this comparison ([Jeste 2009](#)), including 188 participants, found an improvement in knowledge between the schizophrenia patients' intervention and control groups (intervention mean scores 23.7/26, SD 4.4 versus control mean score 21.1/26, SD 6.2, MD 2.60 (95% CI 0.75 to 4.45)). However they reported no difference in knowledge between the healthy comparison participants' intervention and control groups (intervention mean score 25.9/26, SD 0.2 versus control mean scores 25.8/26, SD 0.7, MD 0.10 (95% CI -0.16 to 0.36)) (see [Analysis 3.2](#)).

Based on the evidence from a hypothetical clinical trial, we are uncertain about the effect of audio-visual interventions (versus placebo) on knowledge and understanding of the parent study. While the results of the single study suggest that there is no difference in 'well' people, but a potential improvement with audio-visual interventions with people with schizophrenia, the quality of the evidence is very low (serious risk of bias limitations; hypothetical study suggesting indirectness; small single study; some imprecision) meaning any effect estimate is very uncertain.

#### Participant/guardian satisfaction with the information provided about the parent study

The sole real clinical study to assess participant satisfaction with the information provided about the parent study in 44 participants was [Strevel 2007](#), whose authors found that participants who viewed the intervention were more likely to agree or strongly agree that the DVD helped them decide whether to participate in a clinical trial (11/20 versus 4/24, RR 3.30 (95% CI 1.24 to 8.78), see [Analysis 3.3](#)).

Based on the evidence from a real clinical trial, audio-visual interventions (versus placebo) may improve participant satisfaction with the information provided about the parent study. While the results of the single study suggest a large improvement in satisfaction, the quality of the evidence is low (small study, imprecise result but includes only appreciable benefits) meaning further research is very likely to change the effect estimate, or our confidence in this estimate.

No hypothetical study assessed this outcome.

#### Rate of participation or willingness to participate in the parent study

One real clinical study ([Strevel 2007](#)) measured rate of participation in the parent study in 49 participants. They found no evidence of an effect between groups, but a range of appreciable benefits and harms (3/22 versus 9/27, RR 0.41 (95% CI 0.13 to 1.33)), (see [Analysis 3.4](#) (sub-analysis 3.4.1)).

Based on the evidence from a single real clinical trial, audio-visual interventions (versus placebo interventions) may make little or no difference to willingness to participate in the parent study.

The quality of the evidence is low (small, single study; confidence intervals include benefits and harms), meaning further research is very likely to change the effect estimate, or our confidence in this estimate.

One hypothetical study (Jeste 2009) also measured this outcome in 188 participants. The results in both participant groups (people with schizophrenia and healthy comparison participants) were very similar and showed no difference between rate of participation in the intervention and control groups (pooled results: 64/93 versus 66/95, RR 0.99 (95% CI 0.82 to 1.19), see [Analysis 3.4](#) (sub-analysis 3.4.2)).

Based on the evidence from a hypothetical clinical trial, we are uncertain about the effect of audio-visual interventions (versus placebo interventions) on rate of participation or willingness to participate in the parent study. The results from the single study suggest there is no difference but the quality of the evidence is very low (serious risk of bias limitations; hypothetical study suggesting indirectness; single study; confidence intervals cross the line of no effect and include appreciable benefits and harms) meaning the effect estimate is very uncertain.

### Secondary outcomes

#### Participant/guardian satisfaction with the media used to convey the information

One real clinical trial (Strevel 2007) assessed participant satisfaction with the media used to convey the information in 44 participants. They found a similar number of participants reported being satisfied with the DVD intervention (RR 1.20 (95% CI 0.87 to 1.65), see [Analysis 3.5](#)).

Based on the evidence from a real clinical trial, audio-visual interventions (versus placebo interventions) may make little to no difference on satisfaction with the media use to convey the information. The results of the single study suggest there is no effect on satisfaction but the result includes a range of appreciable effects and the quality of the evidence is low (small, single study; confidence interval crosses the line of no effect and includes appreciable benefits), meaning further research is very likely to change the effect estimate, or our confidence in this estimate.

#### Time taken to administer the consent procedure

One hypothetical clinical study (Jeste 2009) assessed the time taken to administer the consent procedure in 188 participants. The authors reported that on average the audio-visual intervention took 4 minutes less than the placebo audio-visual intervention to administer (M 22 minutes versus M 26 minutes). They did not report the standard deviation (nor a P value from which we could calculate a standard deviation) to allow us to present this result graphically.

Based on the evidence from a hypothetical clinical trial, we are uncertain about the effect of audio-visual interventions (versus placebo) on the time taken to administer the consent procedure. The results from the single study are incomplete and the quality of the evidence is very low (serious risk of bias limitations; hypothetical study suggesting indirectness; small, single study), meaning the effect estimate is very uncertain.

#### Outcomes for which there are no data in this comparison

No study in this comparison measured the following outcomes:

- Anxiety (or other psychological stress) of participant/guardian associated with the informed consent process
- Participant/guardian retention of knowledge and understanding of the parent study for at least two weeks post intervention
- Participant/guardian satisfaction with the decision-making process
- Clinical researcher satisfaction with the informed consent process
- Clinical researcher ease of use of informed consent process
- Level of adherence to study protocol for participants who entered the parent study
- Rate of withdrawal from the parent study following consent

## DISCUSSION

### Summary of main results

We found 12 new studies that were added to the 4 studies in the original review (Ryan 2008), allowing us to draw somewhat firmer conclusions about the effects of audio-visual presentation of information for informed consent for people considering clinical trial participation (see [Effects of interventions](#); [Summary of findings for the main comparison](#); [Summary of findings 2](#); [Summary of findings 3](#)). Of the 16 studies, including 1884 participants, 9 studies were conducted with people considering real clinical trial participation, and 8 were conducted with people considering hypothetical clinical trial participation, with 1 study including participants considering both types of trials. For the majority of studies, the parent trial was investigating novel cancer treatments or psychiatric medications. The participants in these studies were varied; including people with a range of health conditions and 'nominally well' people. All studies were conducted in high-income countries, primarily the United States.

Despite the fact that this review focused on only one type of enhanced consent intervention, there was considerable heterogeneity in the audio-visual presentations tested. The presentations varied from simple audio-visual interventions, such as non-interactive videos, viewed independently, to computer programs with quizzes and hyperlinks, viewed under supervision. Many audio-visual interventions (and comparisons) included additional elements, such as written materials and/or face-to-face explanation.

The results from nine real clinical trials suggest that audio-visual presentation of informed consent information may slightly improve knowledge of the parent study but may make little or no difference to rate of participation or willingness to participate. There is low to very low quality evidence that audio-visual presentation of informed consent may improve participant satisfaction with the consent information provided, but the effect on other aspects of satisfaction, such as satisfaction with the decision-making process, is unclear. There is insufficient evidence to draw conclusions about anxiety (or other psychological distress) arising from audio-visual informed consent. The real clinical studies tell us very little about the experience of study personnel in providing audio-visual informed consent information. We found very low quality and conflicting evidence about whether audio-visual informed consent took more or less time to administer, and no study measured researcher satisfaction with the informed consent process nor ease of use.

In addition, there is insufficient evidence about whether particular aspects of audio-visual presentation of informed consent information (such as interactivity) are more important than others, or whether additional elements, such as written materials or face-to-face explanation, have a benefit over and above the audio-visual component alone. It is important to note that for most of the real clinical studies, the quality of the evidence is low, meaning further research is likely to change the findings; it may strengthen the results or change the direction of effect.

The evidence from eight hypothetical clinical trials is broadly consistent with that of the real trials, but the very low quality evidence makes it difficult to draw any conclusions from these studies when considered in isolation. We note that many studies (in particular the hypothetical trials) are very small and likely to be underpowered, making it unlikely they could demonstrate an effect of the intervention, even if such an effect exists.

## Overall completeness and applicability of evidence

### Population and setting

The evidence in this review is drawn exclusively from high-income countries. In addition, half the studies in this review excluded participants with inadequate English comprehension. Only one study (Campbell 2004) explicitly sampled for participants with low literacy, and only three studies included more than 20% of participants from minority backgrounds (Jeste 2009; Klein 2012; Mittal 2007). These are important limitations since comprehension and satisfaction with informed consent processes tend to be lower among people with low literacy, including culturally and linguistically diverse groups and those with limited education (Breese 2007; Fink 2010). Studies have suggested that miscomprehension of information about clinical trials may reach very high levels among potential participants in low- and middle-income countries, and that these levels are substantially higher than those in high-income countries (Krosin 2006; Moodley 2005; Verástegui 2006). Because the determinants of informed consent are complex and are not readily generalisable from high-income to low-and-middle income countries (Krosin 2006; Verástegui 2006), the effects of audio-visual interventions in other settings remain unclear.

Sheridan 2011, in a recent systematic review, concluded that enhanced consent interventions have differential effects in people with low and high health literacy. The authors identified a number of design features of information interventions that mitigate the effects of low health literacy. Several of these are relevant to audio-visual informed consent, such as: the addition of a video to oral narrative, using tables for numerical information rather than text and adding icons to numerical information. This suggests that people with low literacy might find audio-visual informed consent interventions to be of greater benefit than those with high literacy, however this would need to be borne out in future research.

People with poor cognition are also particularly at risk of poor comprehension during the informed consent process (Appelbaum 2010). In this review, two studies (Harmell 2012; Jeste 2009) compared the effects of audio-visual informed consent information in people with and without schizophrenia. These studies found a relatively greater improvement in knowledge with the audio-visual intervention in participants with schizophrenia, compared with participants without schizophrenia (see Analysis 1.1; Analysis

3.2). However, Jeste 2009 found no difference in the effect of the intervention on rate of participation between these groups. Mittal 2007 also considered the effect of audio-visual presentation of informed consent information in people with poor cognition, sampling only participants with mild Alzheimer's Disease or mild cognitive impairment. However, their results are consistent with most other studies in this review, and do not suggest a relatively greater beneficial effect in the intervention group. Finally, we note that these three studies had small ( $n = 188$  for Jeste 2009) or very small ( $n = 35$  for Harmell 2012 and Mittal 2007) sample sizes for these outcomes, limiting the strength and applicability of this finding.

### The control intervention

The decision by most study authors to include additional written (sometimes simplified) consent documents (i.e. Campbell 2004) and/or in-depth face-to-face discussion or support (i.e. Mittal 2007) in the intervention and often the control groups, muddies the water somewhat when assessing the effects of the audio-visual component of the intervention. While written consent materials and the opportunity to ask questions are standard elements of the consent process, they may not always be delivered as optimally in practice as under 'study conditions'.

In fact, there is evidence from a recent Cochrane review to suggest that the addition of these enhanced consent formats may favour the null hypothesis. In the context of people providing informed consent to have surgery, simplified written consent materials and detailed face-to-face discussion were both found to be effective in improving knowledge (Kinnnersley 2013). The idea that both the intervention and control groups benefited from the consent materials with which they were provided is supported by the results of studies in this review. In all but five included studies, the post-intervention knowledge scores in both the audio-visual and comparison groups were at least 80% of the possible maximum score. In a further three studies (Agre 2003a; Benson 1988; Campbell 2004) the knowledge scores in both groups were between 50% to 65%. This suggests either that participants in both audio-visual and comparison groups had high baseline knowledge scores or that both benefited from an enhanced informed consent intervention.

### Study design

There is limited literature directly comparing the degree to which the results of hypothetical clinical trials mimic real clinical trials of informed consent interventions. We note that other reviews of these interventions which include both types of studies do not draw distinctions between them in describing the results (Flory 2004; Palmer 2012). One study (Buchbinder 2004) of people considering enrolment in an HIV vaccine trial found that only 20% of those who indicated hypothetical willingness to participate subsequently enrolled in the trial. While there is insufficient evidence in this review to draw firm conclusions about how successfully hypothetical research can inform real-life clinical trial consent procedures, we note that the results of hypothetical studies in this review broadly reflect the real studies' results.

A number of subtle differences in interpretation of terms such as 'clinical trial' and 'potential participant' between our review and other systematic reviews published on this topic (Flory 2004; Palmer 2012) have meant there are a small number of studies in those reviews that are excluded from this review. For example,

we excluded two studies (Bickmore 2009; McGraw 2012) as they asked people to consider donating genetic samples to a repository, rather than to participate in a clinical trial per se. As the field of informed consent research grows, we expect more studies to be published on seeking consent for new types of research, such as bio-banking (McGraw 2012). In future updates of this review, the authors should consider whether the definition of a 'clinical trial' used in this review needs to be expanded to incorporate these newer kinds of studies. We also excluded studies in which participants were asked about future clinical research participation in general (Fureman 1997; Ishii 2007) and those in which a specific trial was discussed but not all participants would have been eligible to take part (Jacobsen 2012; Quinn 2011). However, now that hypothetical clinical trials have been included in this review, these distinctions become more difficult to clearly define. The authors of future updates of this review may consider whether the inclusion criteria should be expanded further to include such studies. How the exclusion of these studies from this review may have affected the results is unclear.

### Outcomes

Outcome assessment for informed consent for research is problematic. Even for a seemingly uncomplicated outcome like knowledge/understanding, for example, there is not a 'gold standard' assessment method (Cohn 2007; Flory 2004). What constitutes 'adequate' knowledge or understanding with regard to clinical trial participation remains contentious (Stead 2005). For example, is a certain percentage of correct responses considered adequate? Where does this threshold lie? Is understanding of some components essential while of others less so? Is there agreement between researchers and participants in terms of what is most important? (Agre 2003b; Dunn 2006; Guarino 2006; Joffe 2001b; Robinson 2005). These issues require further research.

Understanding or comprehension is, however, only one of several components of meaningful informed consent (Sugarman 1998). Researchers and ethicists refer to 'decisional capacity' - an individual's ability to use information when deciding whether to undertake a particular treatment or to participate in research - to describe how meaningful the informed consent for clinical treatment or research is (Dunn 2006). Decisional capacity includes at least four domains: understanding or comprehension of the relevant information; appreciation of the significance of the information and application to an individual's own situation; the ability to use the information in decision-making; and the ability to express a consistent choice or decision (Dunn 2006; Palmer 2005). Each of these components need to be addressed for consent to be well informed. In a systematic review of tools to assess decisional capacity for both treatment and research, Dunn and colleagues noted that only a minority of tools assessed all four domains of decisional capacity, with most focusing solely or primarily on understanding or comprehension (Dunn 2006). A few tools assessing decisional capacity more comprehensively, such as the validated MacArthur Competence Assessment Tool for Clinical Research, were identified, but the authors noted that clear consensus and definition of the range of relevant outcomes is required in informed consent research.

### Quality of the evidence

The evidence from real clinical trials was rated as low quality for most outcomes, and for hypothetical studies, very low. We

note, however, that this was in large part due to questionable study quality (that may reflect poor reporting rather than poor conduct), low participant numbers and the hypothetical nature of some studies, rather than inconsistency between study results or confirmed poor trial quality. While there is limited empirical evidence suggesting the decisions of participants in hypothetical clinical trials do not reflect those made in real clinical trials (Buchbinder 2004), we took a cautious approach and downgraded the evidence from these studies for indirectness. Basic improvements in future trials, such as using and reporting random sequence generation and allocation concealment and ensuring the study is sufficiently powered to achieve statistical significance, would greatly improve the quality of this evidence base and may alter the results of this review.

We note that the majority of studies in this review did not report a theoretical base underpinning their interventions, nor whether consumers were involved in the interventions' development. While these factors are not captured in Cochrane 'Risk of bias' domains (Higgins 2011a), nor in considerations of evidence quality using GRADE (Guyatt 2008), they are important considerations for consumer health information interventions (Nilsen 2006; Palmer 2012). Sheridan 2011 suggests that the common features of information interventions that improve comprehension include being 'high intensity', theory-based, pilot-tested and delivered by a health professional with an emphasis on skill building. We echo the call by Palmer 2012, in his recent systematic review on this topic, for a stronger theoretical base underpinning audio-visual informed consent development, and add that consumers should be more involved in an iterative development process.

### Potential biases in the review process

We utilised standard methods for Cochrane reviews that are designed to minimise bias. Where possible, we contacted authors of included studies and key articles, and thus obtained additional information to supplement published trial reports. At least two authors extracted data, assessed risk of bias, synthesised the results, and determined the GRADE ratings (Guyatt 2008). We sought to ensure the wider applicability of the review by engaging consumer input throughout its development, and by consulting relevant consumer literature. Despite these strengths, it is possible that we did not identify all relevant published or unpublished studies. We welcome contact from anyone knowing of a potentially-eligible study not assessed for inclusion in this review. We did not conduct any handsearching, or any electronic searching of databases in languages other than English, although there were no language restrictions on the studies eligible for inclusion.

There were some outcomes in the included studies, such as perceived importance of the trial (Benson 1988) and capacity to consent (Harmell 2012; Jeste 2009; Mittal 2007), that were not captured in this review as they did not reflect any of our pre-specified outcomes. In addition, to minimise the risk of selective outcome reporting, we collected one outcome per outcome category. This meant that although some studies (for example Strevel 2007 and Kass 2009) reported multiple outcomes of interest to this review, not all were extracted. In addition, rate of participation or willingness to participate in a trial was a primary outcome specified for this review. We recognise, however, that this is a complex outcome that may be affected by a range of factors, such as knowledge and/or understanding, satisfaction, anxiety and others. We note the recent Cochrane review assessing informed

consent interventions for people considering surgery (Kinnersley 2013) includes 'informed consent' as its primary outcome measure, incorporating a number of other outcomes such as knowledge, anxiety and satisfaction. Further refinement of the outcomes of this review may be warranted in future updates.

### Agreements and disagreements with other studies or reviews

The findings of this review are broadly consistent with other evidence about the effects of audio-visual interventions used in the informed consent process for potential trial participants, although only one other review has meta-analysed results (Nishimura 2013) and none considered the effects in real and hypothetical studies separately. Previous studies have noted, for example, the relative scarcity of rigorous research on informed consent for research in comparison with that on informed consent for clinical treatment (Sugarman 1998). Flory 2004's systematic review of various interventions to improve both real and hypothetical trial participants' understanding of information disclosed during the informed consent process identified 12 video and computer multimedia interventions assessed in 9 studies (8 of which were described as randomised). Flory identified 6 of the 16 studies that are included in our review (Agre 2003b; Benson 1988; Campbell 2004; Kass 2009; Weston 1997; Wirshing 2005). The other three studies identified by Flory 2004 were excluded from our review due to: having no audio component (Dunn 2001; Llewellyn-Thomas 1995), and having no specific informed consent intervention (Fureman 1997). Flory's review assessed the quality of included studies in a minimal fashion and did not apply the quality rating to the discussion of the review's results.

Nine of the interventions identified by Flory and colleagues resulted in no significant improvement in participants' understanding, although two did show improved retention of information at follow up. Overall, the authors concluded that "multimedia and enhanced consent form interventions do not consistently improve research participants' understanding. Person-to-person interactions, especially the extended discussion interventions, may be more effective" (Flory 2004). As our review has identified ten additional studies since Flory 2004 was published, we can draw slightly firmer conclusions as to the impact of audio-visual interventions on participants' knowledge.

A broadly-framed review by Cohn 2007 only identified two studies of multimedia interventions (Agre 2003b; Weston 1997) and similarly concluded that no single approach (of simplified written consent forms, use of trained professionals and multimedia interventions) appeared universally effective.

More recently, Palmer 2012 reviewed the effects of multimedia tools on people's understanding of the information conveyed during the research consent process. Palmer's review was more limited in scope and methodology than this review, selecting only studies that were published in peer-reviewed English language journals, and only those measuring comprehension. They conducted a minimal search, and did not separate the studies into comparisons, nor meta-analyse the findings. Palmer 2012 identified 20 relevant comparative studies, of which 13 are included in our review and 7 studies are excluded for reasons including lack of random or quasi-random sequence generation, having no audio component, and having no specific informed consent intervention. Palmer and colleagues' conclusions were similar to those of our review

regarding the knowledge outcome; specifically they found that multimedia tools have positive but inconsistent effects on knowledge, with the diversity of populations, interventions and assessment tools in the included studies making the identification of clear trends difficult. Common methodological limitations identified by Palmer 2012, with which our review agrees, included the lack of a guiding theory for intervention development, and the lack of structured, blinded outcome assessment.

A more rigorous systematic review (Nishimura 2013) investigated the effect of a range of enhanced consent interventions on knowledge, satisfaction, accrual and retention. The authors identified eight of the studies included in this review (Agre 2003a; Campbell 2004; Hutchison 2007; Karunaratne 2010; Kass 2009; Mittal 2007; Weston 1997; Wirshing 2005) but this overlap was reduced to three studies (Agre 2003a; Hutchison 2007; Mittal 2007) in their meta-analysed results. This lack of overlap is partly explained by the fact that our searches are more recent (2012 compared to 2010) and that we excluded five of their included studies (Bickmore 2009; Dunn 2001; Fureman 1997; Hack 2007; Llewellyn-Thomas 1995) for reasons explained in the Characteristics of excluded studies table. They included 7 of their 13 studies in a meta-analysis of knowledge, finding no evidence of an effect (SMD 0.32 (95% CI -0.20 to 0.85)). The authors note this result had high heterogeneity ( $I^2 = 90%$ ) suggesting the result should be interpreted with caution. The authors investigated the observed heterogeneity through sub-group analysis but were not able to explain the variability. They investigated the effect of all enhanced consent intervention types on satisfaction and accrual. Similar to this review, they found a mixed picture of effectiveness for satisfaction and generally no effect on accrual (described in this review as 'rate of participation').

Finally, a recent Cochrane review by Kinnersley 2013 assessed the effects of informed consent interventions for patients undergoing surgery in 65 trials. The authors conclude that informed consent interventions for people undergoing surgical and other invasive procedures generally improve knowledge and satisfaction with decision-making, reduce decisional conflict and have no effect on anxiety or satisfaction with the consent process. The effects of audio-visual and interactive multimedia consent interventions, as a sub-set of enhanced consent interventions, were broadly similar, improving knowledge, with no effect on satisfaction or anxiety.

## AUTHORS' CONCLUSIONS

### Implications for practice

The value of audio-visual interventions as a tool for helping to improve the informed consent process for people considering participating in clinical trials remains largely unclear.

There is now some low to very low quality evidence that such interventions may slightly improve knowledge or understanding of the parent trial, but may make little or no difference to rate of participation or willingness to participate. It is unclear whether audio-visual presentation improves participant satisfaction with various aspects of the informed consent process. There is insufficient evidence to draw any conclusions about anxiety arising from audio-visual informed consent interventions. There is very low quality and conflicting evidence about whether audio-visual interventions took more or less time to administer, and no

study measured researcher satisfaction with the informed consent process, nor ease of use.

In the absence of clear results, triallists should continue to explore innovative methods of providing information to potential trial participants during the informed consent process, mindful of the range of outcomes that the intervention should be designed to achieve, and balancing the resource implications of intervention development and delivery against the purported benefits of any intervention. We note the findings of [Kinnersley 2013](#) relating to consent for surgery, that suggest that any enhanced consent intervention is generally equally as effective. However, the applicability of these findings to the area of clinical trial consent remain unclear.

### Implications for research

More real clinical trials with a sufficiently powered sample size would enhance our understanding of the effects of audio-visual informed consent interventions for people considering clinical trial participation. Triallists should seek to minimise the risk of bias in their studies by ensuring adequate randomisation and allocation concealment, and by blinding (where possible) participants, intervention providers and outcome assessors. Study reporting in this field also requires improvement; trial authors should adhere to the recommendations of the CONSORT statement ([www.consort-statement.org](http://www.consort-statement.org)), particularly in terms of the methods they use to minimise the risk of bias, and in terms of participant numbers and the flow of participants through each stage of the trial.

Future trials in low-and-middle income countries, and with people with low literacy or poor cognition, would strengthen this field of research and increase the applicability of this evidence. Triallists may wish to consider the principles of consumer participation, underlying theory, and design aspects that mitigate the effects of low health literacy, in the development of audio-visual informed consent interventions. Equally, separating the additional consent elements, such as simplified written materials and in-depth discussion, from the audio-visual and comparison groups may allow for effective comparisons that are not conflated with the effects of other enhanced consent interventions. A qualitative systematic review of consumer perspectives of interventions to enhance informed consent could inform the development of future interventions and the selection of relevant outcomes.

Relevant outcomes which should be assessed in future trials include: knowledge and its retention over time, satisfaction with the information provided, participation rate, anxiety, satisfaction with the decision-making process, adherence to the parent study protocol and post-consent withdrawal from the parent study.

Informed consent as a unified outcome measure incorporating elements such as knowledge and satisfaction with decision-making could also be considered ([Kinnersley 2013](#)). The MacArthur Competence Assessment Tool for Clinical Research ([Dunn 2006](#)) could be a useful measure for future triallists, allowing greater consistency in the measurement of knowledge, in addition to an assessment of whether the decision whether to consent was truly informed. Process measures, such as time taken to administer and/or develop the audio-visual intervention and researcher-specific outcomes such as satisfaction and ease of use would inform the implementation of audio-visual consent materials.

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**CHARACTERISTICS OF STUDIES**
**Characteristics of included studies [ordered by study ID]**
**Agre 2003a**

Methods	<p>Aim of study: To measure the effectiveness of three consent tools - videotape, computer and booklet formats - against the standard written consent form; and to compare different methods of delivering consent information across different phases of trials and in different patient populations.</p> <p>Study design: RCT.</p> <p>Number of arms: four: videotape, computer instruction (CD) and standard information provision (control) and booklet. Note that we excluded the booklet arm (see notes).</p> <p>Real or hypothetical trial: Real and hypothetical (included patients and surrogates).</p> <p>Ethics approval: Yes.</p> <p>Informed consent: Yes.</p> <p>Funding: Not specified.</p> <p>Time span of trial: January 1999 to November 2001.</p> <p>Consumer involvement: No.</p>
Participants	<p>Description: Patients considering participation in 18 existing oncology trials; family and friends accompanying patients; and non-patient surrogates recruited from hospital waiting room. Only patients considering trial participation and surrogates were included in this review (we excluded family and friends as they were not guardians nor imagining participation for themselves).</p> <p>Methods of recruitment of participants: recruited during consent discussion for trials.</p> <p>Inclusion/exclusion criteria for participation:                  Inclusion criteria: Able to speak and read English; 18 years or older.</p> <p>Geographic location: United States (exact location not provided)</p> <p>Setting: Hospital outpatient department.</p> <p>Pretrial calculation of sample size: Yes; pre-trial calculation of sample size determined 600 participants were needed overall, assuming a type I error rate of <math>P &lt; 0.05</math> and accounting for 20% of the variance.</p> <p>Eligible (total number approached to participate): Unclear.</p>

**Agre 2003a** (Continued)

Number excluded: n = 0.

Number agreeing to participate/number refusing to take part: n = 249 patients agreed to participate. Number of people refusing to participate was not recorded but authors note that the number of refusals was low.

Number randomised to intervention: Video: n = 53 (patients), n = 32 (surrogates), Computer: n = 53 (patient), n = 31 (surrogates).

Number randomised to control: n = 49 (patients), n = 31 (surrogates)

Number excluded post-randomisation: n = 0

Total: n = 249 (note: n = 192 participants were excluded from the review (family and friends of patients and the patients and surrogates who received the booklet intervention)).

Number withdrawn: n = 0.

Number lost to follow-up: n = 0.

Number died: n = 0.

Number included in final analysis: n = 249.

Number included for each outcome:  
 Knowledge: n = 249 [80 control, 85 video, 84 computer].

Age: mean age 59.5 years (patients), 45.3 years (surrogates).

Gender: n = 53 (26%) female (patients), n = 63 (49%) (surrogates).

Ethnicity: Ethnicity of participants overall provided only: 12% of total sample (n = 441) was of ethnic minority status, predominantly African American and Latino.

Principal health problem or diagnosis: Patients - cancer. Details of type of cancer not given, although patients were enrolled in clinical oncology trials (therapeutic and non-therapeutic) of different phases. Surrogates - not applicable.

Other health problem/s: Not reported.

Stage of problem/illness: Not reported.

Treatment in parent trial: 18 different clinical oncology trial protocols were offered to patients, including therapeutic (phase I, II or III) (15/18 trials) and non-therapeutic (3/18 trials). Surrogates were limited to the three trials that were accruing the most patients.

Other social/demographic details:

Educational range was assessed on 1-9 scale [1 = < 8th grade; 2 = 8th grade graduate; 3 = some high school; 4 = high school graduate; 5 = business or technical college; 6 = some college; 7 = college degree; 8 = some graduate school; 9 = professional degree].

Patients: mean score 6.51. Surrogates: mean score 7.14.

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**Interventions**

Aim of intervention: To improve people's knowledge and understanding of trials to which they are considering consenting to participate.

Theoretical basis: not reported.

Development: The consent document for each of the 18 oncology protocols was assessed for reading level, and amended to fall at the 8th grade reading level. Language for the basic consent tools was identical, with summary/review sections added to the video and computer interventions. The consent form was used as the basis for scripts produced by the researchers.

Components: All interventions were given alone (i.e. with no additional material).

**Agre 2003a** (Continued)

AV Format (media): Video: video, Computer: computer-assisted instructional program delivered on a CD. Both the video and computer interventions had scripts which implies that there was audio.

AV Interactivity: All interventions were not interactive.

Content: Was based on the trials for which consent was being sought. Included description of the purpose of the research and research procedures; side-effects, risks, benefits and alternatives; confidentiality/privacy; and the right to refuse/withdraw from the study.

Length: Length of video/computer intervention was dependent on the oncology trial: the shortest was 10.24 minutes, the longest 21.39 minutes.

Language: English.

Number of times viewed: Once. Authors note that none of the participants viewed/read the intervention more than once, although a small number of patients reviewed sections.

Intervention quality: Video and computer intervention were professionally produced; the videos used professional talent (no further details available).

Viewing setting: Interventions were delivered in private consultation rooms.

Target audience: Patients and/or their family members/friends considering enrolling in oncology trials. Unrelated non-patient subjects waiting for patients in Surgical Day Hospital waiting area.

Recipient: Patients and family members; unrelated participants.

Delivery of the intervention: No details provided.

Details of providers: All interventions were delivered by the principal investigator, or by one of two trained study research assistants.

Fidelity/integrity: The authors advised that all interventions were delivered as intended but not how this was assessed. Yes; all interventions were always delivered as intended.

Components of usual care/control: written information.

Format of usual care/control: Participants were given the written material (no further information provided).

Content of usual care/control: The standard consent document for each of the 18 oncology protocols was assessed for reading level, and amended if necessary to fall at the 8th grade reading level.

Delivery of control: Not reported.

Quality of usual care/control: Not reported.

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**Outcomes**

Outcome: Knowledge/understanding.

Definition used by authors: retention of consent information.

Method of assessment: Proportion of correct responses on a 12- to 15-item multiple choice knowledge quiz (created for each of the 18 oncology protocols). Self-completed by participants.

Methods for follow-up of non-respondents: Not applicable.

Number of times measured: once.

Timing of outcome assessment: immediately post-intervention.

Authors' conclusions: "Media consent tools are not a panacea for improving informed consent knowledge. Moreover these tools cannot simply be a conversion of standard consent information to another format....An important finding... is that on average, no one in any group or demographic correctly answered more than two-thirds of the knowledge questions. There is great potential for using the computer as an interactive learning tool that could engage patients and accommodate different styles of learning and different preferences for information."

**Agre 2003a** (Continued)

Notes                      The booklet intervention arm was excluded from this review because it was an enhanced written intervention and was therefore neither an audio-visual intervention nor a standard consent intervention. Knowledge test construction for specific oncology protocols/trials may have yielded test of uneven difficulty for different trial protocols.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated randomisation sequence.
Allocation concealment (selection bias)	High risk	Allocation not concealed.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel not blinded.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Sole outcome was self-reported (knowledge) was assessed by questionnaire. This was self-administered by participants, who were unblinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants accounted for in analysis. No exclusions or withdrawals.
Selective reporting (reporting bias)	Unclear risk	The outcome reported in the methods section was subsequently reported in the results however no published protocol is available.
Other bias	Low risk	Groups were assessed as comparable on demographic characteristics at baseline.

**Benson 1988**

Methods                      Aim of study: To determine if research participants' understanding can be improved. Specifically, this study aimed to determine whether, and to what extent, innovative disclosure techniques can improve the amount and quality of information delivered to participants, and whether participants' understanding of the research can be improved.

Study design: Quasi-RCT.

Number of arms: four: unassisted disclosure (routine informed consent)(control), unassisted disclosure plus videotape (routine informed consent + instructional video), assisted disclosure and 'improved' videotape (second instructional video + additional information deemed appropriate to disclose by psychiatric investigator), neutral educator. Note neutral educator arm not included in this review (see notes).

Real or hypothetical trial: Real.

Methods of recruitment of participants: Potential participants for the current trial were participants in four existing psychiatric research studies (on depression, schizophrenia, social skills and borderline personality disorder). People were recruited as they were identified as prospective research participants by psychiatric investigators.

Inclusion/exclusion criteria for participation:  
 Included: participants in one of four psychiatric research studies.

**Benson 1988** (Continued)

Excluded: none stated.

Ethics approval: Yes.

Informed consent: Yes.

Funding: Supported by the Foundations Fund for Research in Psychiatry.

Time span of trial: Approximately 1981 to 1982. The four component psychiatric research studies ran for variable time periods (eg 6 weeks, 10 weeks) but data not provided for all studies.

Consumer involvement: No.

**Participants**

Description: Psychiatric patients enrolled in psychiatric research studies.

Geographic location: United States, urban.

Setting: Two of four studies were conducted at a major university medical centre; the remaining two were conducted at a government psychiatric facility.

Number of participants:

Pretrial calculation of sample size: Unclear; authors state that the initial research design required 24 disclosure sessions per study (ie. with each disclosure method group containing six subjects from each of the four psychiatric studies). Delays in recruitment for the social skills and bipolar disorder studies meant that numbers were decreased to 20 in each of these two studies.

Eligible (total number approached to participate): Unclear.

Number excluded: Unclear. Note that author reply indicated that they did not recall any participants being excluded due to ineligibility, but that they could not be certain due to the length of time elapsed since the trial was conducted.

Number agreeing to participate/number refusing to take part: n = 66 agreed to participate. Number of people refusing to take part: n = 12 refused participation: n = 1 from each of the depression and schizophrenia studies; n = 7 from the social skills study; and n = 3 from the bipolar disorder study.

Number randomised to intervention: Unassisted disclosure + videotape group: n = 22, Assisted disclosure + improved videotape group: n = 22.

Number randomised to control: n = 22.

Number excluded post-randomisation: n = 0.

Total: n = 66.

Number withdrawn: n = 0.

Number lost to follow-up: n = 0.

Number died: n = 0.

Number included in final analysis: n = 66.

Number included for each outcome: n = 66.

Age: mean age 40.89 years (SD 16.43, range 18 to 76 years) (for overall study population).

Gender: 29.5% female (for overall study population).

Ethnicity: white 69.9%; other 30.1% (for overall study population).

Principal health problem or diagnosis: Overall study population: schizophrenia 50%, depression 27.3%, borderline personality disorder 22.7%.

Other health problem/s: None stated.

**Benson 1988** (Continued)

Stage of problem/illness: Variable, as participants of four separate psychiatric research studies were included.

Depression study (n = 24): participants were elderly people with major depression, randomly assigned to receive treatment with one of two antidepressant drugs for 10 weeks.

Schizophrenia study (n = 24): participants were community-based people with chronic schizophrenia, randomly assigned to treatment with a low or moderate dose of antipsychotic drug for several years.

Social skills training study (n = 20): participants were chronic schizophrenic outpatients, randomly assigned to control (normal day hospital) or to one of two experimental social skills training groups.

Borderline personality disorder study (n = 20): participants had a diagnosis of borderline personality disorder and were randomly assigned to treatment with placebo or one of two different psychotropic drugs for six weeks.

Treatment in parent trial: See above.

Other social/demographic details: Not reported.

Education in years: mean 11.9 years (SD 2.16, range = 6 to 18 years).

**Interventions**

Aim of intervention: To improve the amount and quality of the information given to prospective participants in psychiatric research trials, and to improve their understanding of research.

Theoretical basis: Not reported

Development: The intervention was developed in-house, by the research team.

Components: instructional videotapes (standard and improved) were delivered with standard informed consent (unassisted disclosure) or additional information disclosed by investigator (assisted disclosure).

AV format (media): Videotape: 'standard' and 'improved' videotape versions.

AV interactivity: Both video interventions were non-interactive.

Content: The videotapes employed were described as 'instructional' (standard) and 'improved' for the two different intervention components. The standard video format involved the principal investigator or other designated project staff from the psychiatric trials describing the study as he/she chose to do so. This typically reflected the usual presentation made to subjects at the time of consent. The improved video format included feedback from the research team about areas of the disclosure that could be improved or required greater emphasis. Following this feedback, the second 'improved' video format was produced.

Length: Unclear.

Language: English.

Number of times viewed: Unclear.

Intervention quality: Video quality was assessed as adequate by the research team. The videos were not professionally produced.

Viewing setting: Unclear.

Target audience: Potential psychiatric research participants.

Recipient: Potential psychiatric research participants.

Delivery of the intervention: Unclear, no details provided.

Details of providers: Investigator (psychiatric researcher); no further details.

Fidelity/integrity: The study design was such that interventions were intended to reflect what the researchers involved in the four psychiatric trials wished to communicate to potential trial participants. The differences between the two video intervention groups was solely whether feedback was provided to the researchers presenting information to participants or not.

Components of usual care/control: Routine disclosure by psychiatric researcher; disclosures were independently rated for adequacy using a structured format.

**Benson 1988** (Continued)

Format of usual care/control: Face-to-face disclosure by researcher.

Content of usual care/control: Unclear, authors state that subject consent was obtained in the researcher's usual manner.

Delivery of control: Not reported.

Quality of usual care/control: Not reported.

Outcomes	<p>Outcome: Knowledge/understanding</p> <p>Definition used by authors: Subject understanding of research</p> <p>Method of assessment: Subject interview; unclear who conducted interview. Subject understanding assessed based on 15 items, each rated on a 3-point scale (0 = poor to 2 = fair).</p> <p>Methods for follow-up of non-respondents: Unclear.</p> <p>Number of times measured: twice.</p> <p>Timing of outcome assessment: Immediately following informed consent disclosure session, and at approximately 2 weeks after disclosure session. Note that only data from interviews immediately after the disclosure session were presented (no data at 2 week follow-up reported).</p> <p>Methods for follow-up of non-respondents: Unclear.</p> <p>Authors' conclusions: "Findings indicate that the use of experimental techniques generally increases the quality of information delivered to prospective subjects...Subject understanding was also found to be significantly associated with the quality of information provided... Innovative methods of information delivery...were generally superior to unassisted investigator disclosures in transmitting high-quality research information to prospective subjects. However, our research also indicates that the impact of increased information on subject understanding may vary substantially across studies using different patient populations."</p>
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Notes	<p>As it was unclear what the 'neutral educator' intervention arm consisted of it was unclear whether this constituted a type of 'standard informed consent' presentation and was excluded from the review. The main outcome measure for this study, 'quality of research information disclosed', was reported on in the original review but did not clearly fit the pre-specified outcomes for this review and is not included in the results.</p>
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**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quasi-random allocation: sequential allocation to study groups.
Allocation concealment (selection bias)	High risk	Allocation not concealed.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel not blind.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Sole outcome (knowledge) was assessed by interview. While the participants were unblinded, it is unknown if those conducting the interview were blinded.
Incomplete outcome data (attrition bias)	Low risk	100% follow up achieved. All participants accounted for in the analysis.

**Benson 1988** (Continued)

## All outcomes

Selective reporting (reporting bias)	Unclear risk	The outcome reported in the methods section was subsequently reported in the results however no published protocol is available.
Other bias	Low risk	Groups were comparable on demographic factors and psychopathology ratings at baseline.

**Campbell 2004**

Methods	<p>Aim of study: To compare comprehension of consent information as a function of the medium of presentation while controlling for reading skill. An additional aim was to learn whether degree of knowledge gained from consent materials influenced parental acceptance of research that was to (hypothetically) involve their children.</p> <p>Study design: RCT.</p> <p>Number of arms: Four-arms (standard print (control), enhanced print, video and computer-based) across two different hypothetical consent documents (low risk and high risk). Note we did not include the enhanced print intervention in this review (see notes).</p> <p>Real or hypothetical trial: Hypothetical.</p> <p>Ethics approval: Not stated.</p> <p>Informed consent: Yes.</p> <p>Funding: National Institutes of Child Health and Human Development.</p> <p>Time span of trial: 11 months (late 1999 to late 2000).</p> <p>Consumer involvement: Not reported.</p>
Participants	<p>Description: Parents of young children from low income families (taking part in Head Start programs).</p> <p>Inclusion/exclusion criteria: Person must be the parent or primary caregiver to a child younger than 10 years old.</p> <p>Methods of recruitment of participants: Two head start programs 'publicised' the study amongst enrolled families. Participants were offered a \$US25 gift certificate.</p> <p>Geographic location: United States, region not reported.</p> <p>Setting: Community (Head Start child well being program facilities).</p> <p>Pretrial calculation of sample size: Authors note that "the design called for 30 participants in each of the eight cells for a total of 240" but this was based on the author's assessment of what would provide reliable regression figures, not a power calculation.</p> <p>Eligible (total number approached to participate): Not reported.</p> <p>Number excluded: Not reported.</p> <p>Number agreeing/refusing to take part: n = 181 agreed to take part, number refusing to take part not reported.</p> <p>Number randomised to intervention: Total number randomised to intervention not reported but participant numbers for final analysis (after exclusion of n = 5 from sample overall post-randomisation) were; Low Risk study n = 29 (video), n = 29 (laptop) (Total n = 117), High risk study: n = 29 (video), n = 27 (laptop) (Total n = 116).</p>

**Campbell 2004** (Continued)

Number randomised to control: Total number randomised to control not reported but participant numbers for final analysis (after exclusion of n = 5 from sample overall post-randomisation) were, n = 31 (low risk protocol), n = 31 (high risk protocol) (Total participants n = 62).

Number excluded post-randomisation: n = 5 excluded post-randomisation and post-intervention due to possible contamination (not reported which group they were originally allocated).

Number withdrawn: No participants withdrew from the study.

Number lost to follow-up: No loss to follow up.

Number died: n = 0.

Number included in final analysis: n = 176.

Number included for each outcome: For both outcomes (knowledge and rate of participation), Low Risk study n = 29 (video), n = 29 (laptop) (Total n = 117), n = 31 (control) High risk study: , n = 29 (video), n = 27 (laptop), n = 31 (control) .

Age: Overall participants: 32.1 years (9.7 years). Range not reported. Not broken down by study group or intervention group but the authors report this was similar between groups.

Gender: Low Risk study: video n = 26 females (90%), laptop n = 25 females (86%) control n = 26 females (84%), ; High risk study: video n = 24 females (83%), laptop n = 23 females (85%), control n = 24 females (77%).

Ethnicity: Overall participants (n = 224 collected only): African-American n = 188 (84%), white n = 29 (13%), other n = 7 (3%).

Principal health problem or diagnosis: Not applicable.

Other health problem/s: Not applicable.

Stage of problem/illness: Not applicable.

Treatment in parent trial: Low risk protocol ("Premie" study) is a longitudinal examination of outcomes among very low birth weight infants. The study did not pose any known risks but infants required multiple observations (i.e. EEGs) in multiple settings (hospital and home). High risk protocol ("Heart") involved the implantation of an experimental mechanical ventricular assist device in a young person awaiting a heart transplant. The study had a high risk of death.

Other social/demographic details: Education level not provided by study group or intervention but for overall participants (n = 228 collected), 6-9 years n = 8 (3.5%), 9-11 years n = 46 (20.2%), high school graduates n = 92 (40.3%), some college or vocational school n = 59 (25.9) college graduates n = 23 (10.1%). The average reading level of participants overall was between 7th and 8th grade.

**Interventions**

Aim of intervention: Not explicitly stated but inferred aim (from aim of study) was to improve comprehension for people with low literacy.

Theoretical basis of intervention: Not reported.

Development of intervention: Both interventions (video and computer) were based on previous research about readability, the use of video and computerised presentations to improve recall. No further information about development provided.

Components of intervention: Video: video intervention alone; Computer: computer-based intervention alone.

AV format (media): Written consent form with simplified text, headings, white space and pictures Video: video images with voice narration, with no reading required Computer: video and still pictures with simplified bulleted text that was simultaneously narrated, making reading unnecessary.

AV interactivity: Video: no interactivity Computer: participants could control the advancement or review of each frame.

**Campbell 2004** (Continued)

**Content:** Content for all three interventions closely matched the original consent forms that were used for the control group. Each one contained sections on purposes of the research, procedures, risks, expected benefits, rights of participants, contact information and costs.

**Length:** Entire time required for each intervention group was approximately one hour.

**Language:** English.

**Number of times viewed:** Intervention delivered once, however participants were able to view/read the interventions 'at whatever pace was personally comfortable'. This may have included repeating segments.

**Intervention quality:** Local data collectors were hired for both study facilities and trained by project staff. The data collectors arranged appointments, allocated participants, administered the interventions and the outcome measures. Quality of intervention materials not reported.

**Viewing setting:** Viewed at one of two Head Start facilities in the community. Intervention was administered individually.

**Target audience:** Parents of young children from low income families with a range of literacy skills.

**Recipient:** Parents (guardians).

**Delivery of the intervention:** All participants were first asked to visualise an actual child and to pretend that the relevant medical event was affecting them and that they had been asking to participate in a study. Participants then read or watched the consent materials. The data collector did not give any more additional material, such as answering questions

**Details of providers:** Trained data collectors (recruited for the project) at both sites delivered the intervention. No number reported.

**Fidelity/integrity:** Not reported. However, authors suspected contamination in n = 5 cases due to participants being able to hear other interventions being simultaneously delivered to other participants.

**Components of usual care/control:** Written materials only.

**Format of usual care/control:** Written consent form.

**Content of usual care/control:** Actual consent form from one of two research studies ("Premmie" or "Heart") used. Length not described (other than 'long and complicated', however overall intervention length (for all groups) was one hour.

**Delivery of control:** Delivery process the same as for the intervention. Delivered by trained data collectors. Delivered once but participants were able to read at 'whatever pace was comfortable'.

**Quality of usual care/control:** Not reported.

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**Outcomes**

**Outcome:** Knowledge.

**Definition used by authors:** Prompted recall.

**Method of assessment:** Questions adapted from the Deaconess Informed Consent Comprehension Test (questions covering procedures, risks, benefits, alternatives and the rights of study participants). Administered orally, responses scored later via audiotapes.

**Methods for follow-up of non-respondents:** Not applicable.

**Number of times measured:** Once.

**Timing of outcome assessment:** Immediately post-intervention.

**Authors' conclusions:** No statistically-significant main effects were found for the amount of information demonstrated through either free or prompted recall. Stronger trends towards media effects were found when less skilled readers alone were considered. Findings support idea that simplified print benefits comprehension for those with most limited reading skills.

**Campbell 2004** (Continued)

Outcome: Rate of participation

Definition used by authors: Likelihood of agreeing to enrol one's child in the described study.

Method of assessment: Verbal question from data collector to participants including reasons why the stated choice was made.

Methods for follow-up of non-respondents: Not applicable.

Number of times measured: Once.

Timing of outcome assessment: Immediately post-intervention.

Authors' conclusions: Neither apparent comprehension, reading level, nor format experienced significantly affected hypothetical decision to enrol. Simulated agreement to participate varied as a function of risk; almost four times as many would have declined higher risk Heart study than low risk Preemie study. (8.5% would decline low risk study, 34% would not enrol child in high risk study).

Notes	The enhanced written intervention arm was excluded from this review because it was neither an audio-visual intervention nor a standard consent intervention. The authors report two knowledge measures, free recall and prompted recall. Free recall was measured by asking participants to describe all they could remember about the study and participants were scored on how many pieces of information they recalled. Due to the fact that prompted recall was measured in a way that was consistent with other studies (by questionnaire) this outcome measure was selected for the purposes of this review.
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**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The authors provided detailed information about a restricted randomisation scheme but insufficient information was provided to determine if the actual sequence generation was truly random.
Allocation concealment (selection bias)	Low risk	Data collectors were given manila envelopes with pre-numbered codes attached, showing the risk level, format to be experienced and the temporal order in which they were to be received. These were only opened immediately prior to administering the intervention.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel were unable to be blinded.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Both outcomes (knowledge and rate of participation) were assessed via an audio-recorded interview. Both the participants and those conducting the interview were unblinded. However those who scored the interview were blinded, and did so by listening to the transcripts, so the impact of the unblinded interviewer may be lessened.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Five participants (out of 238, less than 1%) were excluded post-randomisation due to concerns about contamination (not reported by intervention status). This is unlikely to have affected the overall results. The authors report that the remaining participants were included in the analysis.
Selective reporting (reporting bias)	Unclear risk	The outcome reported in the methods section was subsequently reported in the results however no published protocol is available.
Other bias	Low risk	Authors report no systemic differences between groups at baseline. N = 5 participants withdrawn due to concerns about contamination (the audiotapes implied the participant may have overheard another intervention being conduct-

**Campbell 2004** (Continued)

ed). But the authors reported that the interventions rarely overlapped with another session so the chance of further contamination is very low.

**Harmell 2012**

Methods	<p>Aim of study: To assess the feasibility and potential effectiveness of a web-media approach to consent.</p> <p>Study design: RCT.</p> <p>Number of arms: 2-arms.</p> <p>Real or hypothetical trial: Hypothetical.</p> <p>Ethics approval: Yes.</p> <p>Informed consent: Yes.</p> <p>Funding: NIH and the Stein Institute for Research on Aging.</p> <p>Time span of trial: Not reported.</p> <p>Consumer involvement: Not reported.</p>
Participants	<p>Description: People with schizophrenia and well people from the community.</p> <p>Inclusion/exclusion criteria: People with schizophrenia inclusion: DSM-IV-TR diagnosis of schizophrenia (established through review of research records. Healthy controls inclusion: a lifetime absence of psychiatric illness (established with the Mini International Neuropsychiatric Interview). Exclusion criteria: diagnosis of dementia or other neurological/medical conditions known to affect cognition.</p> <p>Methods of recruitment of participants: Participants were recruited through a university research registry. No information about how they were approached to participate or whether they were compensated.</p> <p>Geographic location: United States, implied that it's urban.</p> <p>Setting: Not reported.</p> <p>Pretrial calculation of sample size: Not reported, 'the small sample size was dictated by the intent of the present study' [ie. a pilot].</p> <p>Eligible (total number approached to participate): n = 38.</p> <p>Number excluded: n = 1 excluded prior to randomisation (did not meet inclusion criteria).</p> <p>Number agreeing/refusing to take part: n = 1 declined to participate, n = 37 agreed to participate.</p> <p>Number randomised to intervention: n = 18 (Schizophrenia: n = 8, healthy controls: n = 10).</p> <p>Number randomised to control: n = 18 (Schizophrenia: n = 10, healthy controls: n = 8).</p> <p>Number excluded post-randomisation: n = 1 excluded (did not meet inclusion criteria) from the control group (from the schizophrenia patients). Therefore n = 18 randomised to intervention (schizophrenia n = 8, healthy controls n = 10) and n = 17 randomised to the control group (schizophrenia n = 9, health controls n = 8).</p> <p>Number withdrawn: n = 0.</p> <p>Number lost to follow-up: n = 0.</p> <p>Number died: n = 0.</p> <p>Number included in final analysis: n = 35 (schizophrenia: n = 16, healthy controls: n = 19).</p>

**Harmell 2012** (Continued)

Number included for each outcome: For both understanding  $n = 35$  [schizophrenia  $n = 10$  intervention and  $n = 9$  control and healthy controls  $n = 8$  intervention,  $n = 8$  control]. For satisfaction they excluded participants who had not taken part in research before (see notes under outcome measure) therefore  $n = 29$  [schizophrenia  $n = 9$  intervention and  $n = 8$  control, health controls  $n = 5$  intervention and  $n = 6$  control].

Age: schizophrenia: 57.9 (8.9) years (intervention), 57.0 (10.0) years (control). Healthy controls: 48.6 (15.9) years (intervention), 52.5 (12.1) years (control).

Gender: Schizophrenia:  $n = 4$  women (40%) (intervention),  $n = 1$  (11%) (control) Healthy controls:  $n = 5$  women (62.5%) (intervention),  $n = 4$  women (50%) (control).

Ethnicity: Ethnic minorities in Schizophrenia:  $n = 3$  (30%) (intervention),  $n = 2$  (22.2%) (control), Healthy Controls:  $n = 2$  (25%) (intervention),  $n = 2$  (25%) (controls).

Principal health problem or diagnosis: Schizophrenia group: schizophrenia. Healthy controls: not applicable.

Other health problem/s: Not reported.

Stage of problem/illness: Not reported.

Treatment in parent trial: Experimental cognition-enhancing medication.

Other social/demographic details: Years of education (mean +/- SD). Schizophrenia: 11.8 years (1.9) (intervention), 12.4 years (0.9) (control). Healthy controls: 16.0 years (1.9) (intervention), 14.9 years (1.6) (control).

**Interventions**

Aim of intervention: Hypothesis was that the intervention would result in better comprehension and greater satisfaction.

Theoretical basis of intervention: Not reported (see notes).

Development of intervention: The AV intervention was based on that used by the authors in a previous study, also included in this review (Jeste 2009). They modified the video (replacing graphics, video segments and images with new material) based on their experience of using the video in the previous trial.

Components of intervention: Web-based media plus face-to-face guidance and clarification/response to questions from research assistant.

AV format (media): Computer-aided presentation mixed with video clips, static images/graphics and bulleted text to explain the main points. Links and graphics were provided on important points. Questions with corrective feedback were included after each key thematic section.

AV interactivity: Interactive. The video could be paused or replayed (via the research assistant).  
 Content: Introduction, a time-line showing when risks would take place, a description of procedures during each visit, risks/discomforts, possible benefits, compensation, who to contact if injured, and voluntary participation information.

Length: On average, the intervention took 32.5 minutes to complete among healthy control subjects and 42.3 minutes among schizophrenia patients.

Language: Not explicitly reported but assumed that it is English.

Number of times viewed: Not reported but participants could request sections be replayed.

Intervention quality: No discussion of AV or intervention quality.

Viewing setting: Viewed individually but where it as viewed was not reported.

Target audience: People considering hypothetical clinical trial participation with and without schizophrenia (cognitive deficits).

Recipient: Participants.

**Harmell 2012** (Continued)

Delivery of the intervention: Participants met with a research associate and used a web-media prototype with the research associate in attendance.

Details of providers: Described as 'research associates' only.

Fidelity/integrity: Not reported.

Components of usual care/control: Written consent form with face-to-face input from research associate.

Format of usual care/control: Printed consent form plus an RA reviewed the form with the participant, stopped after major conceptual units and checked if participants had questions.

Content of usual care/control: Introduction, a time-line showing when risks would take place, a description of procedures during each visit, risks/discomforts, possible benefits, compensation, who to contact if injured, and voluntary participation information.

Delivery of control: Delivered by a research assistant. Number of times not reported.

Quality of usual care/control: Not reported.

**Outcomes**

Outcome: Understanding

Definition used by authors: Reasoning (see notes).

Method of assessment: 8-item sub-scale within the MacCAT-CR (MacArthur Competence Assessment Tool for Clinical Research) questionnaire.

Methods for follow-up of non-respondents: Not applicable.

Number of times measured: Once.

Timing of outcome assessment: Immediately after the intervention.

Authors' conclusions: None of the differences on the Mac-CAT-CR sub-scales reaches statistical significance but the overall trend was towards better performance in patients who received the web-media consent. Note the fact that study was most likely underpowered so ability to determine statistical significance of results unlikely but a trend was seen.

Outcome: Satisfaction with the information provided.

Definition used by authors: Satisfaction with the quality of the consent procedure relative to past experience.

Method of assessment: Self-administered question with a three-point Likert scale (better, worse or equivalent) where participants were asked to compare the quality of the procedure relative to past research experiences. Note this outcome was only collected for participants who had previously taken part in research, therefore only 17/18 schizophrenia patients and 11/17 healthy control subjects were included in this outcome.

Methods for follow-up of non-respondents: Not applicable.

Number of times measured: Once.

Timing of outcome assessment: Immediately after the intervention.

Authors' conclusions: many participants rated the quality of the enhanced consent procedure as "better" and no participant reported their current experience as worse.

**Notes**

The authors state that "We investigated participants' comprehension of consent information in reference to a hypothetical clinical trial of an experimental cognition enhancing medication that was developed for our earlier study of DVD-aided consent ([Jeste 2009](#))" however it is unclear whether it was the informed consent form itself or the multimedia intervention that was the same as the Jeste study.

This also study measured capacity to consent (as measured by the UCSD Brief Assessment of Capacity to Consent (UBACC) however it was not included as capacity to consent was not an outcome included

**Harmell 2012** (Continued)

ed in this review. Three of the four sub-scales used in the MacCAT-CR meet our criteria for the knowledge outcome. The fourth sub-scale (expression of a choice was excluded from the review). These include: Understanding (including understanding of purpose, potential benefits and risks), appreciation (recognise the difference between treatment and research and the voluntary nature of participation) and reasoning (being able to describe potential study consequences). We ranked the effect estimates of the three outcomes measures to determine the median effect estimate, reasoning. As such, we used this sub-scale as the measure of understanding for the purposes of this review.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The authors confirmed that the random number sequence was generated using a computer algorithm by a biostatistician. Two lists were generated (one for schizophrenia patients and one for the healthy controls).
Allocation concealment (selection bias)	Unclear risk	The authors advised that each participant was consecutively enrolled by a research assistant who checked their allocation on a spreadsheet with the randomisation list outlined. It does not appear the allocation of subsequent participants was concealed from the research assistant. While the chance of the list being subverted is low, the risk of bias remains unclear.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel were not blinded to the intervention status.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The sole outcome (knowledge) was assessed by an interview over the phone. While participants were unblinded, the personnel who administered the outcome assessments were blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	n = 1 participant withdrawn after randomisation (did not meet inclusion criteria). This was unrelated to study participation and unlikely to affect the results. For the knowledge outcome there was no further loss to follow up but for the satisfaction outcome, n = 7 participants (20% of participants) were not included in the analysis as they had not participated in research before. Thus the overall risk rating is unclear.
Selective reporting (reporting bias)	Unclear risk	The outcome reported in the methods section was subsequently reported in the results however no published protocol is available.
Other bias	Low risk	Within the schizophrenia participants there was an imbalance in gender (11% female in the control group and 40% in the intervention group) but this was not statistically significant and both schizophrenia participants and healthy controls were otherwise well balanced. The authors report that between these two participant groups the healthy controls had higher education levels but considering these groups were not directly compared this is not a particular issue.

**Hoffner 2012**

Methods	<p>Aim of study: To assess the impact of viewing the Clinical Trials Video on patients' understanding of clinical trials and to evaluate how that understanding contributed to the informed consent process.</p> <p>Study design: RCT.</p> <p>Number of arms: 2.</p>
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**Hoffner 2012** (Continued)

Real or hypothetical trial: Real.

Ethics approval: Yes.

Informed consent: Yes.

Funding: NIH grant (amount not stated).

Time span of trial: Not reported.

Consumer involvement: The intervention (Clinical Trials Video) was developed with, and reviewed by, a range of stakeholders, including patients and family members. Clinical trial participants appeared in the video and provided their own perspectives (unscripted).

**Participants**

Description: Patients.

Inclusion/exclusion criteria: Confirmed cancer diagnosis, age 18 years or older, able to understand English, and considering participation in a phase I, II or III clinical trial (treatment trial).

Methods of recruitment of participants: Eligible patients were identified and referred by oncology care providers from the Phase I, Thoracic Oncology, Gastrointestinal Oncology, Lymphoma and Sarcoma Clinics at cancer treatment centre.

Geographic location: United States, urban.

Setting: Specialist cancer research hospital and treatment centre.

Pretrial calculation of sample size: Initial design: 128 patients required to provide 80% power to detect 5-point difference in mean QuIC Section A scores between the 2 arms using 2-sided t test and assuming standard deviation of 10. Preliminary data suggested SD of QuIC closer to 8, and only 82 patients (41 per arm) needed to achieve similar power.

Eligible (total number approached to participate): n = 110.

Number excluded: n = 8.

Number agreeing/refusing to take part: n = 90 agreed to participate, therefore n = 12 refused to take part.

Number randomised to intervention: n = 45.

Number randomised to control: n = 45.

Number excluded post-randomisation: n = 2 (became ineligible for a treatment trial).

Number withdrawn: n = 6 (changed mind), n = 1 (too sick).

Number lost to follow-up: n = 4.

Number died: n = 0.

Number included in final analysis: n = 77.

Number included for each outcome: Understanding (measured as objective knowledge and self-reported understanding of clinical trials): n = 39 control, n = 38 intervention.

Age: Intervention: 57 +/- 10 years, control: 55 +/- 12 years. Range not reported.

Gender: Intervention: n = 16 females (42.1%), Control: n = 17 females (43.6%).

Ethnicity: Intervention: n = 34 white (94.7%), n = 2 Black or African American (5.3%), n = 0 Asian, Control: n = 36 white (92.3%), n = 2 Black or African American (5.1%), n = 1 Asian (2.6%).

Principal health problem or diagnosis: Cancer (various kinds, predominantly sarcoma (n = 23, 29.9%), colon (n = 15, 19.5%), lung (n = 10, 13.0%) and other gastrointestinal (n = 9, 11.7%), missing (n = 8, 10.4%) (overall participant numbers).

**Hoffner 2012** (Continued)

Other health problem/s: Not reported.

Stage of problem/illness: Not reported.

Treatment in parent trial: Phase I, II or III treatment trial offered but specific treatment offered not reported.

Other social/demographic details: Education level: Intervention: n = 0 unknown, n = 16 (42.1%) some college or less, n = 22 (57.9%) college graduate or advanced degree. Control: n = 2 (5.1%) unknown, n = 16 (41.0%) some college or less, n = 21 (53.8%) college graduate or advanced degree. Previous clinical trial participation: intervention n = 14 (36.8%), control n = 13 (33.3%)

**Interventions**

Aim of intervention: to help dispel patients' misconceptions by explaining clinical trials in a clear, simple and balanced way.

Theoretical basis of intervention: Not stated.

Development of intervention: Developed by a multi-disciplinary team (health care professionals, an ethicist, health communication experts, institutional review board specialists and patient and family advisors). It was then extensively reviewed by health care providers, patients and families.

Components of intervention: DVD plus consent form.

AV format (media): DVD in which clinical trial participants and healthcare providers provide their own (unscripted) perspectives on clinical trial participation.

AV interactivity: Not interactive.

Content: Not reported.

Length: 20 minute DVD.

Language: English.

Number of times viewed: Not reported. Participants took the DVD home so may have watched it more than once. Participants were followed up for outcome measurements within one week.

Intervention quality: Video developed by a range of stakeholders but production quality of DVD not described.

Viewing setting: Intervention was viewed at home. After the video was watched by all participants, authors report "approximately" 50% viewed it with family/friends.

Target audience: Cancer patients considering participation in a clinical (treatment) trial.

Recipient: Participants.

Delivery of the intervention: Participants were given The Clinical Trials Video to take home with the written trial consent form. Portable DVD players were provided to participants who did not have a DVD player at home.

Details of providers: DVD was self-administered. No details of any training provided to participants in how to use borrowed DVD player.

Fidelity/integrity: Participants were asked if they had watched the DVD before the outcome measure was administered.

Components of usual care/control: Written consent form.

Format of usual care/control: Written.

Content of usual care/control: Clinical trial consent form, length and content of form not stated.

Delivery of control: Consent form given to participants to read at home. May have been read more than once.

Quality of usual care/control: Not reported.

**Hoffner 2012** (Continued)

Outcomes

Outcome: Knowledge.

Definition used by authors: Understanding of the information conveyed regarding the clinical trial.

Method of assessment: A modified version of the Quality of Informed Consent (QuiC) questionnaire was administered over the phone. This assessed objective understanding (primary outcome identified by authors). Self-reported understanding was also assessed but is not reported in the review.

Methods for follow-up of non-respondents: Not reported.

Number of times measured: Once.

Timing of outcome assessment: Within one week of taking administering the intervention.

Authors' conclusions: No significant difference in clinical trial understanding found between groups, both scored approximately 87% on section A and approximately 90% on section B of QuiC. Previous clinical trial participation had no significant effect on QuiC scores. Results do not suggest an increase in knowledge among those randomised to view the video.

Notes

First published as a conference abstract (Hitchcock-Bryan 2007). After outcome measurement between groups, the control group was then given the video and the perceptions of both groups about the clinical trials video was recorded. As both groups received the intervention prior to measuring perceptions, these outcomes are not included in the review. The authors reported two knowledge outcomes: objective knowledge and self-reported knowledge. As the authors identified objective knowledge as their primary outcome we only collected this outcome for purposes of the review.

Additionally, the authors report on participants 'perceptions of the Clinical Trials Video', including outcomes that matched the outcomes included in this review, such as whether the video assisted participants to make a decision about clinical trial participation and whether watching the video was worthwhile. However, these perceptions were captured after the RCT element of the trial was completed, and control participants had also watched the video, meaning there was no comparison between groups. As such, these data were not included in the outcomes reported in this review. The authors also measured rate of participation, but only report this for the participants overall, and this appears to have been assessed after the control participants also viewed the video.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The authors outline that randomisation was conducted via permuted blocks stratified by disease speciality clinic, however the method of generating the random number sequence was not described.
Allocation concealment (selection bias)	Unclear risk	Described as central randomisation but no further information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel unable to be blinded to intervention status.
Blinding of outcome assessment (detection bias) All outcomes	High risk	The sole outcome (knowledge) was assessed via questionnaire over the phone. Participants were unblinded and it is likely that those administering the questionnaire were also unblinded as before they administered the questionnaire they asked participants whether they watched the video.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	n = 7 (out of 45, 16%) excluded/withdrawn in control group post-randomisation and n = 6 (out of 45, 13%) excluded/withdrawn from intervention group post-randomisation. Reasons for attrition across groups, n = 2 (became ineligible), n = 1 (too sick), n = 6 (changed mind), n = 4 (lost to follow up). Attrition

**Hoffner 2012** (Continued)

		balanced across groups but these participants were not accounted for in the analysis and it is unclear whether their absence affected the overall results.
Selective reporting (reporting bias)	Unclear risk	The outcome reported in the methods section was subsequently reported in the results, however no published protocol is available.
Other bias	Low risk	Groups were balanced on demographic factors at baseline.

**Hutchison 2007**

Methods	<p>Aim of study: To determine the effect of an audio-visual patient information intervention (AVPI) on refusal rates to randomised cancer trials and on knowledge and anxiety and to investigate patients' perceptions of the AVPI.</p> <p>Study design: RCT.</p> <p>Number of arms: 2.</p> <p>Real or hypothetical trial: Real.</p> <p>Ethics approval: Yes.</p> <p>Informed consent: Yes.</p> <p>Funding: Chief investigator received funding from the Chief Scientist's Office.</p> <p>Time span of trial: January 2005 to August 2006.</p> <p>Consumer involvement: 2 expert patients involved from early in the script and video development. The video included pictures of patients receiving treatment.</p>
Participants	<p>Description: Patients with cancer who were eligible for a clinical trial.</p> <p>Inclusion/exclusion criteria: diagnosis of colorectal, breast or lung cancer and were clinically eligible for entry into a cancer treatment RCT, or best supportive care, access to a video-recorder, CD-ROM or DVD player, could understand English.</p> <p>Methods of recruitment of participants: Potential participants were approached by their clinician during the explanation of the clinical trial.</p> <p>Geographic location: United Kingdom, urban.</p> <p>Setting: Cancer centre outpatient department.</p> <p>Pretrial calculation of sample size: Based on previous literature, the authors assumed a 40% refusal rate. They determined that a sample size of 164 patients in total was required in order to have an 80% chance of detecting a 20% difference in refusal to participate and a standardised difference of 0.45 between continuous variables such as knowledge and anxiety scores.</p> <p>Eligible (total number approached to participate): n = 231 (a further n = 13 were identified but not approached as they were considered to be particularly distressed).</p> <p>Number excluded: n = 2 (no access to video, computer or DVD player).</p> <p>Number agreeing/refusing to take part: n = 173 agreed to participate, n = 56 declined to participate.</p> <p>Number randomised to intervention: n = 86.</p> <p>Number randomised to control: n = 87.</p> <p>Number excluded post-randomisation: n = 0.</p> <p>Number withdrawn: n = 0.</p>

**Hutchison 2007** (Continued)

Number lost to follow-up: Loss to follow up varies by outcome. For the primary outcome (clinical trial refusal rate) no loss to follow up. For knowledge outcome, n = 9 (intervention), n = 10 (control) were lost to follow up, for anxiety outcome n = 13 (intervention) n = 18 (control) lost to follow up.

Number died: n = 0.

Number included in final analysis: Clinical trial refusal rate (primary outcome measure) n = 173.

Number included for each outcome: Clinical trial refusal rate (rate of participation) n = 173 [n = 86 intervention, n = 87 control], knowledge (knowledge and understanding) n = 154 [n = 77 intervention, n = 77 control], anxiety (anxiety or other psychological distress) n = 142 [n = 73 intervention, n = 69 control].

Age: Intervention group - < 50 years n = 19 (22.1%), 50 to 59 years n = 20 (23.3%), 60 to 69 years n = 34 (39.5%), > 69 years n = 13 (15.1%), Control group - < 50 years n = 18 (20.7%), 50 to 59 years n = 21 (24.1%), 60 to 69 years n = 33 (37.9%), > 69 years n = 15 (16.2%).

Gender: Intervention group - 66 females (76.7%), Control group - 67 females (77.0%).

Ethnicity: Not reported.

Principal health problem or diagnosis: Colorectal, breast or lung cancer.

Other health problem/s: Not applicable.

Stage of problem/illness: Intervention group - limited stage of cancer n = 59 (68.6%), advanced stage of cancer n = 27 (31.4) , Control group - limited stage of cancer n = 58 (66.7%), advanced stage of cancer n = 29 (33.3%)

Treatment in parent trial: Randomised cancer treatment trial. Patients were entered into a total of 18 different randomised trials (mainly phase III) of chemotherapy and hormone drugs.

Other social/demographic details: Deprivation status: Affluent n = 23 (27.4%) intervention, n = 24 (27.6%) control, Middle n = 39 (46.4%) intervention, n = 33 (37.9%) control, deprived n = 22 (26.2%) intervention, n = 30 (34.5%) control, Educational qualifications: none n = 18 (22.2%) intervention, n = 21 (26.3%) control, Below degree level n = 39 (48.1%) intervention, n = 36 (45.0%) control, degree level or higher n = 24 (29.6%) intervention, n = 23 (28.8%) control.

**Interventions**

Aim of intervention: To inform patients about randomised controlled trials, as a supplement to their trial-specific written information sheet.

Theoretical basis of intervention: Not reported.

Development of intervention: Video development informed by the literature and overseen by an advisory group (nurse, doctor, psychologist and researcher) and an expert panel (2 current patients). Other expertise was sought from health, ethics and clinical trial experts. An operational project team (consisting of nurses experienced in directing and script writing, a professional actress and the hospital's medical illustration department) created the video.

Components of intervention: DVD/CR-ROM/video plus a discussion with a doctor plus written information.

AV format (media): Intervention created in different formats (participants able to choose their preferred format). N = 48 (56%) chose DVD, n = 37 (43%) chose video and n = 1 (1%) chose CD-ROM.

AV interactivity: Not interactive.

Content: Topics include how drugs/treatments are developed, importance of clinical trials, what randomised trials are and when they are carried out, criteria for taking part, benefits/disadvantages of taking part in a randomised trial, funding issues, voluntariness of decision and freedom to withdraw at any time. Randomisation is described by an actress using flip charts with pictures. The video includes pictures of patients receiving treatment.

Length: 10 minutes.

Language: English.

**Hutchison 2007** (Continued)

Number of times viewed: Not reported. Patients watched the AV intervention at home, so they may have watched it more than once.

Intervention quality: AV intervention quality: used nursing staff who had experience with directing and script writing. Professional actress used in the video. The medical illustration department edited the video. No mention of intervention quality of other staff involved in delivering the standard care element of the intervention.

Viewing setting: At home. Not reported if they viewed it individually or with family members.

Target audience: Colorectal, breast or lung cancer patients.

Recipient: Participants.

Delivery of the intervention: Patients initially discussed the clinical trial and were given the trial specific information sheet and consent form by a registrar or consultant (visit 1). They were given the AV intervention at this time (in a format of their choosing) and instructed to watch it at home. Participants returned to their doctor (visit 2) and discussed whether they wanted to participate in the trial.

Details of providers: Registrar or consultant from the tumour site team delivered the discussion/written information. No further information reported about other providers involved in delivering DVD etc.

Fidelity/integrity: Not reported for the intervention group as a whole, however of the 73 participants in the intervention group who completed the questions about their perceptions of the AVPI in the Clinical Trials Decision Questionnaire, n = 70 (96%) had watched the video.

Components of usual care/control: Face-to-face explanation of the trial specific information sheet and consent form.

Format of usual care/control: A consultant or registrar from the tumour site team discussed the treatment trial and administered a trial-specific information sheet and consent form.

Content of usual care/control: Trial specific information sheet and consent form covered the same basic principles as the AV intervention but while the consent forms covered broad information about randomisation as a process, it focused more on the specific details of the trial itself. The AVPI gave more details and examples to explain about randomisation. The 18 different consent forms contained different (trial-specific) information but contained the same type of information as they were developed with guidance from the same ethics committee.

Delivery of control: Delivered by registrar or consultant from the tumour site team at the first visit. Information delivered by clinician in visit 1 and discussed again (re decision to participate) at visit 2.

Quality of usual care/control: Not reported.

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**Outcomes**

Outcome: Knowledge.

Definition used by authors: Knowledge.

Method of assessment: A 12-item questionnaire was developed by the research team A 12-item questionnaire was developed by the research team, assessing knowledge of trial aims, randomisation and rights of participants.

Methods for follow-up of non-respondents: Not reported.

Number of times measured: Twice.

Timing of outcome assessment: At visit 1 (explanation of treatment trial) and visit 2 (return visit, usually one week later, to discuss decision). Outcome measures were both assessed after the patient had visited the doctor and the timing was consistent between groups.

Authors' conclusions: The findings support the use of AVPI as useful in terms of improving patient knowledge and understanding before decision making. In both groups, patients were more knowledgeable following the information-giving process. Improvements in the knowledge score tended to be higher in the AVPI arm. An increase in knowledge did not make people more likely to participate in the clinical trial.

**Hutchison 2007** (Continued)

Outcome: Rate of participation.

Definition used by authors: Clinical trial refusal rate (see notes).

Method of assessment: Review of case notes.

Methods for follow-up of non-respondents: Not reported.

Number of times measured: Once.

Timing of outcome assessment: At visit 2 (one week post intervention).

Authors' conclusions: AVPI had no effect on refusal rates to the randomised cancer trials that the patients were offered. The observed refusal rate for clinical trials in this study, approximately 20%, is substantially less than that reported in the literature. There were no significant differences in consent rates associated with rates of disease. AVPI was not shown to have any effect on refusal rates to randomised cancer trials.

Outcome: Anxiety or other psychological harm.

Definition used by authors: Anxiety.

Method of assessment: Spielberger State and Trait Anxiety Inventory .

Methods for follow-up of non-respondents: Not reported.

Number of times measured: Twice.

Timing of outcome assessment: At visit 1 (explanation of treatment trial) and visit 2 (return visit, usually one week later, to discuss decision).

Authors' conclusions: There was a statistically-significant difference in anxiety score at baseline; patients in the AVPI arm appeared to be more anxious than in the control arm. The change in anxiety scores over time was also significant between groups. Anxiety improved in the AVIP arm more than in the control arm. The change from pre- to post- intervention in the AVPI group was highly significant. There was no significant change in the control group. AVPI was effective in improving knowledge and understanding without raising anxiety.

**Notes**

The results for the clinical trial refusal rate were reversed to show the results as rate of participation. The authors reported the following response options to this question yes, no (refused), no (not eligible) and no (other). We dichotomised these responses to yes and no only.

Additionally, the authors collected participants perceptions of the audio-visual intervention, including the effect of the video on decision-making. These data were not included in the review as this questionnaire was only provided to intervention participants and there was no comparison to the control group.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer database used to generate a stratified random number sequence.
Allocation concealment (selection bias)	Low risk	The randomisation sequence was obtained by contacting a central clinical trials unit.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants were unaware of their intervention status until after the first part of the intervention (discussion with medical staff) was completed. The registrars/consultants who gave the face-to-face discussion and administered the written information were blinded to the intervention status.
Blinding of outcome assessment (detection bias)	Unclear risk	Primary outcome measure (rate of participation) was assessed via case notes and the outcome assessors were blinded (low risk of bias). The remaining out-

**Hutchison 2007** (Continued)

All outcomes		comes (knowledge and anxiety) were assessed by questionnaires administered by study personnel. It seems likely that personnel were unblinded as they has to ask whether participants watched the video prior to administering the questionnaire (high risk of bias). Overall unclear risk of bias.
Incomplete outcome data (attrition bias) All outcomes	Low risk	The primary outcome (clinical trial refusal rate) was complete. For the knowledge outcome (intervention), n = 9 (out of 86, 10%) did not complete follow up assessment. For knowledge (control) n = 10 (out of 87, 11%) did not complete follow up assessment. For anxiety (intervention), n = 13 (out of 86, 15%) did not complete follow up assessment. For anxiety (control) n = 18 (out of 87, 21%) did not complete follow up assessment. The numbers were balanced between groups and the reasons for missing data were mainly unrelated to the trial (continued treatment at another cancer centre, treatment options changed, declined to complete or did not post back questionnaires. Missing data were taken into account using multiple imputation methods in the analysis of knowledge and anxiety.
Selective reporting (reporting bias)	Unclear risk	The outcome reported in the methods section was subsequently reported in the results however no published protocol is available.
Other bias	High risk	Baseline imbalance: intervention and control group similar across demographic characteristics but there was a statistically-significant difference between anxiety scores at baseline that the authors were unable to explain.

**Jeste 2009**

Methods	<p>Aim of study: To compare effectiveness of a multimedia vs routine consent procedure (augmented with a 10-minute control video presentation) as a means of enhancing comprehension among middle-aged and older persons with schizophrenia and healthy comparison subjects.</p> <p>Study design: RCT.</p> <p>Number of arms: 2 arms (with two different population groups).</p> <p>Real or hypothetical trial: Hypothetical.</p> <p>Ethics approval: Yes.</p> <p>Informed consent: Yes.</p> <p>Funding: National Institutes of Health, The Department of Veteran Affairs.</p> <p>Time span of trial: Not reported.</p> <p>Consumer involvement: Not reported.</p>
Participants	<p>Description: Community dwelling outpatients with schizophrenia and well people in the community.</p> <p>Inclusion/exclusion criteria: People with schizophrenia inclusion: aged over 40 years, diagnosed with schizophrenia (by their treating physician using DSM-IV criteria), fluency in English, absence of a substance abuse disorder, dementia or other condition likely to influence decisional capacity. Healthy comparison controls inclusion criteria; age comparable to schizophrenia patients, absence of major neuropsychiatric disorders.</p> <p>Methods of recruitment of participants: People with schizophrenia were recruited from hospital outpatient departments, local board-and-care facilities and through private physicians. Healthy control comparisons were recruited through newspaper advertisements, flyers and word of mouth. Description of those recruiting not reported. Compensation not reported.</p> <p>Geographic location: United States, urban.</p>

**Jeste 2009** (Continued)

Setting: Not reported.

Pretrial calculation of sample size: Authors used previously published data to determine that a sample size of 120 people with schizophrenia and 60 healthy comparison subjects would be needed to detect a 'medium' effect size with 80% power.

Eligible (total number approached to participate): n = 248 screened for inclusion.

Number excluded: n = 36 excluded prior to enrolment, n = 8 withdrawn prior to randomisation (did not meet inclusion criteria).

Number agreeing/refusing to take part: n = 196 agreed to participate, n = 16 refused to take part.

Number randomised to intervention: n = 93 (n = 31 healthy subjects, n = 62 schizophrenia patients).

Number randomised to control: n = 95 (n = 29 healthy subjects, n = 66 schizophrenia patients).

Number excluded post-randomisation: n = 0.

Number withdrawn: n = 0.

Number lost to follow-up: n = 0.

Number died: n = 0.

Number included in final analysis: n = 188.

Number included for each outcome: For outcomes of knowledge and rate of participation, it would appear to be n = 188 (healthy comparison subject, intervention n = 31, control n = 29, for schizophrenia patients intervention n = 62, control n = 66) but final numbers for schizophrenia patients are not provided.

Age: Schizophrenia patients: intervention 52.4 years (8.0), control 51.2 years (6.5). Healthy comparison subjects: intervention 54.7 years (7.3), 54.2 years (9.3). Range not stated.

Gender: Schizophrenia patients: intervention n = 17 females (55%), control n = 14 females (48%). Healthy comparison subjects: intervention n = 22 females (35%), control n = 24 females (36%).

Ethnicity: Schizophrenia patients: intervention n = 40 (65%) Caucasian, n = 10 (16%) African American, n = 7 (11%) Latino, n = 5 (8%) other, control n = 40 (61%), n = 12 (18%), n = 7 (11%), n = 7 (11%). Healthy comparison subjects: intervention n = 23 (74%) Caucasian, n = 2 (6%) African American, n = 2 (6%) Latino, n = 4 (13%) other, control n = 24 (83%) Caucasian, n = 1 (3%) African American, n = 2 (7%) Latino, n = 2 (7%) other.

Principal health problem or diagnosis: Schizophrenia for n = 128, not applicable for healthy comparison subjects (n = 60).

Other health problem/s: Not reported.

Stage of problem/illness: Not reported.

Treatment in parent trial: Hypothetical 14-week RCT of a cognition-enhancing medication for cognitive deficits associated with schizophrenia or with normal ageing.

Other social/demographic details: Number of years of education - schizophrenia patients: intervention 12.4 years (2.1), control 12.2 years (1.9), healthy comparison subjects: intervention 14.1 years (1.8), control 14.3 years (2.3)

**Interventions**

Aim of intervention: Not explicitly stated but the authors hypothesised that the intervention would improve understanding, appreciation, reasoning, and expression of choice.

Theoretical basis of intervention: Informed by the principles of multimedia learning theory: learning is facilitated when information is simultaneously provided through both verbal and visual-spatial/pictorial channels (Baddeley, A. *Working Memory, Thought, and Action*. New York, NY: Oxford University Press).

**Jeste 2009** (Continued)

Development of intervention: The development of the DVD was heavily informed by the principles of learning theory but no user-testing, stakeholder input was described. Authors refer to previous pilot data but no reference for this work is reported.

Components of intervention: DVD plus written information.

AV format (media): DVD presentation that included audio of narrator verbally explaining key points, simultaneous visual presentation using graphics, still pictures and animation, and summary text.

AV interactivity: Not interactive but participants were able to ask RA to stop and repeat segments of the DVD at any stage.

Content: The content of the DVD was based on the written consent form. Information was broken into 13 chapters, including: description of the purpose and procedures of the study, the potential risks from study procedures and medications (those typical of cholinomimetics), potential benefits (including possible lack of direct personal benefits), the limits of payment for treatment for research-related injuries, the voluntary nature of participation, procedures for withdrawal from the study, confidentiality (and procedures to foster it), and means of addressing any questions or concerns.

Length: Unclear how long actual DVD was, average time for multimedia consent procedure was 22 minutes.

Language: English.

Number of times viewed: Participants were encouraged to stop the DVD and repeat any segments that were unclear.

Intervention quality: AV intervention informed by theory and a previous pilot is mentioned. The simulated consent form was based on the consent form for an actual pilot study being conducted at UCSD and was similar to a simulated consent form used in the authors' prior research. Two IRB members reviewed the form during development to help ensure content validity.

Viewing setting: The AV intervention was viewed individually with an RA but the setting was not described.

Target audience: Individuals with serious mental illness (SMI).

Recipient: Participants.

Delivery of the intervention: A research assistant gave participants a written consent form and administered the AV intervention. Participants were encouraged to ask the research assistant to repeat sections of the DVD, or to stop and discuss any questions.

Details of providers: Delivered by a research assistant, but no details of the number involved, nor any training provided.

Fidelity/integrity: Not reported.

Components of usual care/control: written informed consent plus control DVD.

Format of usual care/control: Participants met individually with a research assistant and watched the 10-minute control DVD. They were then provided with the written informed consent and were encouraged to read the form as it was read out by the research assistant.

Content of usual care/control: Content of written consent form as per the content of the AV intervention. Content of control DVD: general research information. Length of DVD 10 minutes, average time taken for whole consent process was 26 minutes.

Delivery of control: Delivered once, by a research assistant. Participants were asked to stop and ask for clarification at any time.

Quality of usual care/control: Not reported.

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**Outcomes**

Outcome: Knowledge.

Definition used by authors: Understanding (see notes).

**Jeste 2009** (Continued)

Method of assessment: MacCAT-CR questionnaire.

Methods for follow-up of non-respondents: Not applicable.

Number of times measured: Three (we used the third time point only - see notes).

Timing of outcome assessment: After any initially misunderstood information presented in the intervention had been re-explained to participants by study personnel.

Authors' conclusions: Among schizophrenia patients, those in the multimedia group had significantly better scores on MacCAT-CR understanding at trial 1, 2 and 3. Among healthy subjects, the only significant difference was higher MacCAT-CR understanding at trial 2 in the multimedia group. Overall conclusion of the authors, schizophrenia outpatients provided with a multimedia-aided consent procedure demonstrated better comprehension of a research protocol, compared with those presented with an enhanced consent procedure.

Outcome: Rate of participation.

Definition used by authors: Rate of agreement to participate (although presented as % who declined to participate - see notes).

Method of assessment: MacCAT-CR questionnaire, sub-scale 4 rated whether participants were able to clearly state whether they were willing to participate in the study. The authors used the response to this item to compare whether or not they agreed or declined to participate

Methods for follow-up of non-respondents: Not applicable

Number of times measured: The MacCAT-CR was measured three times but the authors only report a single rate of participation.

Timing of outcome assessment: Unclear if the reported rate of participation was taken from the first, second or third MacCAT-CR results (therefore could have been before or after the re-explanation - see notes).

Authors' conclusions: There was no significant difference in the rates of agreement to participate vs not participate in the hypothetical protocol between the two consent conditions within each subject group.

Outcome: Time taken to administer the consent procedure.

Definition used by authors: Average time for the consent procedure.

Method of assessment: Not reported.

Methods for follow-up of non-respondents: Not applicable.

Number of times measured: Once.

Timing of outcome assessment: Not reported.

Authors' conclusions: The average time for the 2 consent procedures was similar.

**Notes**

The primary outcome measure was capacity to consent which is not a pre-specified outcome in this review and hence is not included.

We pooled the two population sub-groups, healthy subjects and schizophrenia patients, together.

Three of the four sub-scales used in the MacCAT-CR meet our criteria for the knowledge outcome. The fourth sub-scale (expression of a choice) was excluded from the review. These include: Understanding (including understanding of purpose, potential benefits and risks), appreciation (recognise the difference between treatment and research and the voluntary nature of participation) and reasoning (being able to describe potential study consequences). These outcomes were measured at three time points (after intervention, after re-explanation of initially misunderstood concepts and after a second re-explanation of misunderstood concepts) but only the understanding sub-scale was reported at all three time points. The other two scores were only presented for one time point but the authors did not speci-

**Jeste 2009** (Continued)

fy which time point this was. As a result, we used the understanding outcome and took the longest time point (trial 3). This outcome measure was recorded after participants had had any misunderstood information re-explained to them twice.

The authors present their results in a table that outlines the total number of participants included in the analysis for the healthy control subjects but not for the schizophrenia patients. The number of participants in the healthy subjects intervention and control groups matches the number randomised and the authors report that all subjects randomised "completed the study described". For this reason we assume that the total number of participants in the schizophrenia intervention and controls groups matches the number randomised for the knowledge and rate of participation outcomes.

The authors reported the percentage of people who declined to participate in the study. We reversed these numbers (i.e. 100% - the given %) so that they represented the % of participants of agreed to participate in the study. We multiplied the percentages by the total number of participants in each group to obtain number of people, rather than % of people for the rate of participation outcome.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation method not reported.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not reported.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants unable to be blinded. While the control group used a placebo DVD (making blinding possible) the personnel sat with participants while they were viewing it, making blinding impossible.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Both outcomes (knowledge and rate of participation) were assessed by a questionnaire administered by semi-structured interview. While participants were unblinded those who administered and scored the questionnaires were blinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	It would appear that all participants were accounted for in the analysis, however it is not explicitly stated by the authors for the schizophrenia participants, beyond the authors stating that 'all participants completed the study as described'.
Selective reporting (reporting bias)	Unclear risk	The outcome reported in the methods section was subsequently reported in the results however no published protocol is available.
Other bias	Low risk	Considering the patients and healthy controls separately, there was no baseline imbalance within groups.

**Karunaratne 2010**

## Methods

Aim of study: To assess the efficacy, with respect to participants understanding of information, of a computer-based approach to communication about complex, technical issues that commonly arise when seeking informed consent for clinical research trials.

Study design: quasi-RCT.

Number of arms: 2 arms.

Real or hypothetical trial: Hypothetical.

**Karunaratne 2010** (Continued)

Ethics approval: Yes.

Informed consent: Yes.

Funding: Not reported.

Time span of trial: August 2006 to October 2007 (14 months).

Consumer involvement: Not reported.

**Participants**

Description: Patients.

Inclusion/exclusion criteria: Inclusion criteria: people with diabetes, aged 18 to 70 years with self-defined English literacy and competency in computer use, who could travel to the hospital to take part in the study.

Methods of recruitment of participants: Participants were recruited from a range of hospital and research institutes. Patients were contacted via telephone and had the study explained over the phone. The information sheet was subsequently mailed to all interested participants.

Geographic location: Australia, urban.

Setting: Hospital.

Pretrial calculation of sample size: Initial power calculation have an estimated sample size of 100. After the first 10 participants had enrolled, this was re-calculated and re-estimated as 60 to attain the same difference in means and power.

Eligible (total number approached to participate): n = 148.

Number excluded: n = 26 did not meet inclusion criteria, n = 39 did not take part for other reasons.

Number agreeing/refusing to take part: n = 60 agreed to participate (n = 23 declined to take part).

Number randomised to intervention: n = 30.

Number randomised to control: n = 30.

Number excluded post-randomisation: n = 0.

Number withdrawn: n = 0.

Number lost to follow-up: n = 0.

Number died: n = 0.

Number included in final analysis: n = 60 .

Number included for each outcome: Knowledge and rate of participation. For both outcomes n = 60 (30 intervention, 30 control).

Age: Intervention: 52.6 years, range 27 to 67 years, Control: 51.0 years, range 27 to 70 years.

Gender: Intervention: n = 12 females (40%), Control: n = 6 females (20%).

Ethnicity: Not reported.

Principal health problem or diagnosis: Diabetes.

Other health problem/s: Not reported.

Stage of problem/illness: Not reported.

Treatment in parent trial: Hypothetical trial of right heart catheterisation to monitor heart attack complications in diabetic patients. The trial involved the catheterisation procedure, insulin testing and blood sampling for genetic testing.

**Karunaratne 2010** (Continued)

Other social/demographic details: Education level; intervention: secondary n = 15 (50%), tertiary n = 15 (50%), control: secondary n = 9 (30%), tertiary n = 21 (70%) (note slight imbalance in favour of higher education level in control group). Fluency in written English; intervention n = 30 (100%), control n = 29 (97%), fluency in spoken English: intervention n = 30 (100%), control n = 30 (100%).

**Interventions**

Aim of intervention: To improve participant understanding.

Theoretical basis of intervention: Not reported.

Development of intervention: Not reported.

Components of intervention: AV intervention alone.

AV format (media): Computer-based presentation with explanatory features, hyperlinks to diagrams, video clips and online quizzes displayed on a 17-inch computer monitor.

AV interactivity: Interactive (including text boxes linked to key words, hyperlinks to diagrammatic and pictorial representations of procedures, and a video clip of a live right heart catheterisation). Participants could move forward and backwards through each page or skip to a specific page.

Content: The content was identical to paper-based version and contained sub-sections including: introduction, study sponsor, purpose and background, procedures, possible benefits, possible risks, other treatments, privacy, confidentiality and disclosure of information, new information arising during project, results, further information, other issues or complaints, reimbursement for your costs, ethical guidelines, injury, compensation and termination of study. The presentation was broken up into sections, separated at intervals by a quiz (multiple choice or true/false format). If participants answered correctly they were transferred to the next section.

Length: Average time taken to complete the computer-based task was 19 minutes (range 9 to 33 minutes).

Language: English.

Number of times viewed: Participants were encouraged to re-read sections when they incorrectly answered the quiz questions at the end of that section.

Intervention quality: Not reported.

Viewing setting: Intervention was viewed in a room with a computer in the hospital. As the same room was used for intervention and control participants it is implied that the intervention was viewed individually.

Target audience: People with diabetes.

Recipient: Participants.

Delivery of the intervention: Participants attended the hospital and were given either the paper-based or computer-based intervention in a single room within the hospital. No further information reported. Details of providers: Not reported. Intervention was self-directed.

Fidelity/integrity: Not reported.

Components of usual care/control: Paper-based information statement was based on a typical information statement approved by the institution's ethics committee.

Format of usual care/control: Paper-based information statement.

Content of usual care/control: Contained the same content as the computer-based presentation (without the interactive elements). It was five pages (2044 words) long and took on average 13 minutes (range 6 to 32 minutes) to read.

Delivery of control: Participants were given the written materials in a single room. The number of times it was read and who delivered the intervention are not reported.

Quality of usual care/control: Not reported.

**Karunaratne 2010** (Continued)

Outcomes	<p>Outcome: Knowledge.</p> <p>Definition used by authors: Understanding.</p> <p>Method of assessment: A questionnaire was developed that had 26 assessment questions (true/false, multiple-choice and yes/no format). Only 23 questions were used in the analysis as &gt;90% of participants from both groups answered 3 questions correctly.</p> <p>Methods for follow-up of non-respondents: Not applicable.</p> <p>Number of times measured: Once.</p> <p>Timing of outcome assessment: Immediately after the intervention.</p> <p>Authors' conclusions: The average percentage of correct answers for the group that completed the computer-based task was significantly higher than that completing the paper-based task. The group that completed the computer-based task answered several questions significantly better including questions about procedures, the site of catheter insertion, privacy, methods of disclosing study results, contact persons and compensation in the event of possible injury.</p> <p>Outcome: Rate of participation.</p> <p>Definition used by authors: Same outcome described as both 'interest in taking part in the mock study' and 'willingness to participate'.</p> <p>Method of assessment: Final question in the knowledge questionnaire.</p> <p>Methods for follow-up of non-respondents: Not applicable.</p> <p>Number of times measured: once.</p> <p>Timing of outcome assessment: immediately after the intervention.</p> <p>Authors' conclusions: Significantly more participants in the group that completed the computer-based task expressed interest in taking part in the mock study, if it were real.</p> <p>Outcome: Time taken to administer the consent procedure.</p> <p>Definition used by authors: The time taken to complete each reading task.</p> <p>Method of assessment: Not reported.</p> <p>Methods for follow-up of non-respondents: Not applicable.</p> <p>Number of times measured: Once.</p> <p>Timing of outcome assessment: Not reported.</p> <p>Authors' conclusions: The average time taken to read the information for those who completed the computer-based task was 6 minutes longer than that for the group that completed the paper-based task.</p>
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Notes	The authors also undertook a qualitative exploration of participants understanding and sought feedback about the informed consent interventions themselves however these results were not included in the review.
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**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Participants were sequentially allocated to the intervention and control groups, in blocks of 10. The first five participants were allocated to the intervention group and the second five to the control group, and so on.

**Karunaratne 2010** (Continued)

Allocation concealment (selection bias)	High risk	Allocation sequence not able to be concealed.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants unable to be blinded. Personnel were unblinded.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Both outcomes (knowledge and rate of participation) were assessed by questionnaire. It is unclear whether participants self-administered the questionnaire or it was administered by study personnel. While participants were unblinded it is unclear if study personnel were blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	100% follow up achieved. However, the authors excluded 3 out of the 26 knowledge questions from the analysis because both > 90% of groups answered them correctly.
Selective reporting (reporting bias)	Unclear risk	The outcome reported in the methods section was subsequently reported in the results however no published protocol is available.
Other bias	Unclear risk	Baseline imbalance: control group was better educated than intervention group (70% versus 50% tertiary educated), otherwise comparable.

**Kass 2009**

Methods	<p>Aim of study: Not explicitly stated.</p> <p>Study design: RCT.</p> <p>Number of arms: 2-arm study.</p> <p>Real or hypothetical trial: Real.</p> <p>Ethics approval: Yes.</p> <p>Informed consent: Yes.</p> <p>Funding: National Institutes of Health.</p> <p>Time span of trial: Not reported.</p> <p>Consumer involvement: 18 people with cancer and cancer survivors reviewed the AV intervention and provided detailed feedback. A prior study involving in-depth interviews formed the basis of scripts for actors portraying consumers to read out.</p>
Participants	<p>Description: Patients.</p> <p>Inclusion/exclusion criteria: Inclusion: a patient at one of three medical centres that had been referred for evaluation with an oncologist regarding possible clinical trial participation and if they and their oncologists were willing to have their appointments audio taped. Patients at one of the medical centres were eligible if they were being treated in the Advanced Solid Tumour Clinic.</p> <p>Methods of recruitment of participants: At two of the medical centres, patients were referred by their oncologist when because of their clinical history, clinical trial participation might be discussed.</p> <p>Geographic location: Urban, United States.</p> <p>Setting: Hospital clinics.</p> <p>Pretrial calculation of sample size: Not reported.</p>

**Kass 2009** (Continued)

Eligible (total number approached to participate): Not reported.

Number excluded: Not reported.

Number agreeing/refusing to take part: n = 288 initially randomised to the study.

Number randomised to intervention: Not reported.

Number randomised to control: Not reported.

Number excluded post-randomisation: n = 158 did not complete the outcome assessment and were therefore excluded. N = 70 in the intervention group and n = 60 were in the control group.

Number withdrawn: Not reported.

Number lost to follow-up: Not reported.

Number died: Not reported.

Number included in final analysis: Unclear. The authors report that n = 130 participants completed the survey however many outcomes do not include 130 participants.

Number included for each outcome: Rate of participation (n = 126 overall but not broken down by intervention arm), satisfaction with the decision-making process (n = 110 overall but not broken down by intervention arm).

Age: Not reported.

Gender: Not reported.

Ethnicity: Not reported.

Principal health problem or diagnosis: Cancer (no further information reported).

Other health problem/s: Not reported.

Stage of problem/illness: Not reported.

Treatment in parent trial: Phase I, II or III clinical cancer trial.

Other social/demographic details: Not reported.

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**Interventions**

Aim of intervention: Not reported.

Theoretical basis of intervention: Not reported.

Development of intervention: The content was based on the NCI Clinical Trials Pamphlet (used in the control group) and discussions with oncologists. Scripts were drawn from in-depth interviews with patients. The computer-based tool was reviewed by patients, oncologists and nurses and changes made as a result of this.

Components of intervention: Computer-based tool alone. Participants then had an appointment with their oncologist after viewing the intervention.

AV format (media): Computer-based tool with written and narrated information and video clips of actors portraying patients.

AV interactivity: Participants could click on the video clips to play them but no further interactivity is reported

Content: The intervention described the three phases of drug testing, including the different purposes of each, ways in which patients might benefit from trial participation other than medically, urged patients to discuss risks and benefits with their oncologist, and emphasized voluntary nature of participation. It also included embedded video clips of five actors portraying patients who decided to enrol in a clinical trial (three) or not to enrol (two) and clips of two oncologists (one actual, one actor) describing the purpose and benefits of early phase clinical trials. At relevant points, pictures of patients or on-

**Kass 2009** (Continued)

oncologists would appear on the screen. Patients could then start a clip by touching a picture. After each section, patients were provided a suggested question to ask their doctors. The last screen listed all the questions, and the patients could receive the entire list to take to an appointment with the oncologist.

Length: 20 minutes.

Language: English.

Number of times viewed: Not reported.

Intervention quality: Actors used to portray patients. Other aspects of intervention quality not described.

Viewing setting: In an empty room or private area.

Target audience: People with cancer who were eligible for clinical trial participation.

Recipient: Participants.

Delivery of the intervention: The intervention was self-directed and viewed privately.  
Details of providers: Not reported.

Fidelity/integrity: Not reported.

Components of usual care/control: Informational Pamphlet developed by the National Cancer Institute called "Taking Part in Clinical Trials: What Cancer Patients Need to Know". Participants had an appointment with their oncologist after reading the pamphlet.

Format of usual care/control: Written information plus appointment with oncologist.

Content of usual care/control: The pamphlet covered similar topics to the intervention, including information about the three phases of clinical drug testing. It covered the process of randomisation, common protections for participants, benefits and harms. The pamphlet included information on post marketing trials, which the intervention did not. It provided a set of suggested questions that participants might want to ask their doctors.

Delivery of control: Participants reviewed the pamphlet on their own with no further engagement by research staff.

Quality of usual care/control: Not reported.

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**Outcomes**

Outcome: Knowledge (see Notes).

Definition used by authors: Understanding of trial purpose.

Method of assessment: Assessed by single multiple choice item on a questionnaire.

Methods for follow up of non-respondents: Assessed by questionnaire, or within one week by telephone.

Timing of outcome assessment: Phone call.

Number of times measured: Once.

Authors' conclusions: Respondents in the intervention group were significantly more likely to correctly state that the purpose of an early phase trial related to safety (34.4%) compared to 16% of control participants ( $P = 0.03$ ).

Outcome: Rate of participation.

Definition used by authors: Likelihood of enrolment.

Method of assessment: Assessed by questionnaire, or within one week by telephone.

Methods for follow-up of non-respondents: Phone call.

**Kass 2009** (Continued)

Number of times measured: Once.

Timing of outcome assessment: After the oncologist appointment (which followed the administration of the intervention or control) or 1-2 weeks later in phone call if participants were undecided after appointment.

Authors' conclusions: There were no significant differences in the likelihood of enrolment between groups.

Outcome: Satisfaction with the decision-making process.

Definition used by authors: Did you feel like you had the option to refuse to take part?

Method of assessment: Questionnaire.

Methods for follow-up of non-respondents: Not applicable.

Number of times measured: Once.

Timing of outcome assessment: After the oncologist appointment (which followed the administration of the intervention or control).

Authors' conclusions: Not reported in the text.

**Notes**

We obtained no useable data for this study and the authors were not able to provide any more information. There was one outcome related to knowledge (understanding the purpose of the investigational study) that could potentially have been included in the review however the response options were multiple choice and it is unclear whether there was one or more correct answer. The included outcomes (rate of participation and satisfaction with the decision-making process) reported the percentage of participants who responded with yes/no but not the overall number of participants in this group. Additionally, the authors reported on a number of outcomes that did not meet the pre-specified outcomes of this review, including, "Why do you think the physician talked to you about joining the study", perceptions about how taking part in the study may affect their prognosis and reasons for declining to participate.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Method of generating random number sequence not reported. However, recruitment was undertaken at different sites in stages. The first two sites resulted in an over-sampling of control participants. The authors used a different random number scheme that favoured the intervention arm in a 2:1 ratio.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unable to blind participants. Participants subsequently met with their oncologists. Authors report that they have no data on whether oncologists were made aware of participants' intervention status during consultation.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Both outcomes (rate of participation and satisfaction with decision-making) were assessed by questionnaire or over the phone. While participants were unblinded, it is unclear whether personnel were also blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	n = 288 randomised but only n = 130 completed the outcome assessment (n = 158/288 missing, 55%). Outcome data appears incomplete for all relevant outcomes (Satisfaction with decision-making process n = 126 (4/130 missing, 3%), rate of participation n = 110 (20/130 missing, 15%). No discussion of reasons for attrition. Did not appear to perform intention-to-treat analysis.

**Kass 2009** (Continued)

Selective reporting (reporting bias)	Unclear risk	The outcome reported in the methods section was subsequently reported in the results, however no published protocol is available.
Other bias	High risk	Both groups received a doctor's visit after the video or pamphlet, but there is no information on whether informed consent was discussed. This could either inflate or deflate the effect size. Additionally there was a baseline imbalance: authors report that control participants reported slightly higher family income and intervention participants were more likely to report prior trial participation. Trial results also differed by source of recruitment; to balance the number of participants in each group the authors recruited more intervention participants from their final recruitment site.

**Klein 2012**

Methods	<p>Aim of study: The authors hypothesized that multimedia and interactivity would improve participant understanding of information presented in informed consent when compared to the standard, researcher reviewed paper-document process.</p> <p>Study design: RCT.</p> <p>Number of arms: 3 arms (multimedia, interactive multimedia, control).</p> <p>Real or hypothetical trial: Hypothetical.</p> <p>Ethics approval: Not reported.</p> <p>Informed consent: Not reported.</p> <p>Funding: National Institutes of Health.</p> <p>Time span of trial: Not reported.</p> <p>Consumer involvement: Not reported.</p>
Participants	<p>Description: Students and staff at a Midwestern state university, USA [well people in the community].</p> <p>Inclusion/exclusion criteria: All English-speaking students, staff and faculty at a US university were eligible to participate.</p> <p>Methods of recruitment of participants: Mass email to students, faculty and staff; news releases to university personnel; and posted flyers Participants were compensated \$10 for their time.</p> <p>Geographic location: United States (specific location not reported).</p> <p>Setting: Hospital.</p> <p>Pretrial calculation of sample size: Not reported.</p> <p>Eligible (total number approached to participate): Not reported.</p> <p>Number excluded: Not reported.</p> <p>Number agreeing/refusing to take part: Not reported.</p> <p>Number randomised to intervention: Authors state that overall n = 95 participants randomised to one of the three groups but only n = 94 accounted for in the analysis (n = 31 in the multimedia group, n = 31 in the interactive multimedia group)</p> <p>Number randomised to control: Authors state that overall n = 95 participants randomised to one of the three groups but only n = 94 accounted for in the analysis (n = 32 in the control group).</p> <p>Number excluded post-randomisation: Not reported.</p>

**Klein 2012** (Continued)

Number withdrawn: Not reported.

Number lost to follow-up: n = 1/95 not accounted for in the analysis but not explicitly reported as a loss to follow up.

Number died: Not applicable.

Number included in final analysis: Authors report n = 95 "completed the study" but final numbers not always reported (n = 94 for one outcome).

Number included for each outcome: Knowledge (number of participants not reported). Satisfaction (interactive multimedia n = 31, multimedia n = 31, control n = 32).

Age: Not reported by group. Overall mean age was 34 years (SD not reported).

Gender: Not reported by group. Overall 73% (n = 69) of participants were female.

Ethnicity: Not reported by group. Overall 90% of participants were Caucasian.

Principal health problem or diagnosis:

Other health problem/s: Not applicable.

Stage of problem/illness: Not applicable.

Treatment in parent trial: Study of a cholesterol lowering drug.

Other social/demographic details: Not reported by group. Overall, 35% were had a graduate or professional degree, 23% had some college, 19% had graduated from college and 16% had some graduate or professional classes.

**Interventions**

Aim of intervention: Not explicitly stated but hypothesised to improve understanding.

Theoretical basis of intervention: Pavaio's (1990) dual coding system, the principles of cognitive load theory (Sweller et al 1998, Verhoeven et al 2009), theories of interactivity (various authors).

Development of intervention: Not reported.

Components of intervention: Both intervention groups (multimedia and interactive multimedia included a computer program alone).

AV format (media): Multimedia - Text presented on screen with relevant graphics and narration of text. Presentation ran automatically but participants could pause and resume the presentation. Participants could seek out the researcher to ask questions during or after the presentation. Interactive multimedia - was identical to the multimedia presentation except that participants had to click to progress the screens and could replay content. In addition participants were asked 10 multiple-choice questions throughout the presentation and were provided with feedback on their responses. Participants could only progress to the next screen once they had answered the question correctly. Participants could asked questions during or after the presentation.

AV interactivity: Multimedia - not interactive. Interactive multimedia - interactive (as outlined under AV Format)

Content: Both interventions contained the same content. This was based on an IRB approved informed consent document. The information covered: the purpose of the study, expected duration of participation, a description of study procedures, identification of experimental procedures, risks, benefits, alternative treatments, confidentiality, costs and compensation, the voluntary nature of the study, and contact information.

Length: Multimedia (mean time 19 minutes), Interactive multimedia (mean time 21 minutes).

Language: English.

Number of times viewed: Multimedia: not stated but appears to be once; Interactive multimedia: not stated (participant could return to previous screens and replay narrative).

**Klein 2012** (Continued)

Intervention quality: Not reported. The multimedia interventions were on a platform provided by the Patient Education institute, screen shots appear professional.

Viewing setting: The intervention was viewed individually, in an examination room of the hospital.

Target audience: Potential participants considering a medical study.

Recipient: Participants.

Delivery of the intervention: Researchers accompanied participants to the room, started the presentation, demonstrated how to use it, and then left the room. The researchers remained close by. Participants could pause the presentation and ask the researcher to respond to their questions part way through.

Details of providers: "researchers" (no further information provided).

Fidelity/integrity: Not reported.

Components of usual care/control: Written copy of the informed consent form plus face-to-face explanation and answering of questions by researcher.

Format of usual care/control: Written and face to face.

Content of usual care/control: The content was identical to the intervention groups.

Delivery of control: Researchers provided the participant with a paper copy of the informed consent document and summarized each sentence of the document for the participant, pausing after each section to ask if the participant had any questions. Researchers answered any questions that the participant asked.

Quality of usual care/control: The consent form used was IRB-approved but no further information reported.

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Outcomes

Outcome: Knowledge.

Definition used by authors: Knowledge of information presented in the informed consent.

Method of assessment: An 18-item knowledge questionnaire devised by the authors, tested on computer. Questions covered the key elements in the consent form.

Methods for follow-up of non-respondents: Not applicable.

Number of times measured: Once.

Timing of outcome assessment: immediately post-intervention.

Authors' conclusions: Average number of correct answers significantly higher in interactive multimedia than control; neither were significantly different from multimedia.

Outcome: Participant satisfaction with the information provided.

Definition used by authors: Satisfaction with the length of the informed consent process.

Method of assessment: 5-point Likert scale (excessively short to excessively long).

Methods for follow-up of non-respondents: Not applicable.

Number of times measured: Once.

Timing of outcome assessment: Immediately post-intervention.

Authors' conclusions: Interactive multimedia participants rated the process as significantly shorter than those in the control condition; neither differed significantly from participants in the multimedia condition.

Outcome: Time taken to administer the consent procedure.

**Klein 2012** (Continued)

Definition used by authors: Time to complete the consent condition.

Method of assessment: Participants were timed from the point they began the process to when they had their questions answered.

Methods for follow-up of non-respondents: Not applicable.

Number of times measured: Once.

Timing of outcome assessment: From beginning to end of consent procedure.

Authors' conclusions: Participants significantly spent more time in the Interactive Multimedia Condition (approximately 2 minutes more than the paper-based condition) compared to the Control condition. Neither of those two groups differed significantly from the Multimedia Condition results. Results fell between Interactive Multimedia and Paper-based Control.

Notes	The authors measured time as an outcome however this was not included as an outcome in this review. The authors also measured three elements of satisfaction (satisfaction with length, difficulty and the importance of the information). We calculated the mean difference between the two intervention and control arms for each question and ranked the effect estimates. The median effect estimate was 'satisfaction with length of the informed consent process' and as such this was the outcome included in the review.
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**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	The study reports that "Participants were randomly assigned", no further details provided.
Allocation concealment (selection bias)	Unclear risk	Allocation method not described.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not explicitly described but participants were unable to be blinded to the audio-visual or control status (but may have been blinded to their intervention status between multimedia and interactive multimedia). Personnel unlikely to be able to be blinded as they orientated participants to the intervention and they answered questions or summarised information.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Both outcomes (knowledge and satisfaction) were assessed by questionnaire that was self-administered by participants on a computer. While blinding of participants is unclear, it is possible that participants in the two intervention groups were blinded to which intervention they were receiving.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The authors do not report how many participants were randomised to each group. They report that n = 95 completed the study but do not provide the final number of participants in each group.
Selective reporting (reporting bias)	Unclear risk	The outcome reported in the methods section was subsequently reported in the results however no published protocol is available.
Other bias	Unclear risk	Unable to assess baseline incompatibility between groups, as demographic characteristics not broken down by study group.

**Mittal 2007**

Methods	Aim of study: To evaluate the feasibility, acceptability, and preliminary efficiency of two enhanced consent procedures.
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**Mittal 2007** (Continued)

Study design: RCT.

Number of arms: 2 arms.

Real or hypothetical trial: Hypothetical.

Ethics approval: Yes.

Informed consent: Yes.

Funding: University of Arkansas for Medical Sciences Alzheimer's Disease Center, National Institute on Aging and National Institute of Mental Health and John A. Hartford Foundation's Center of Excellence in Geriatric Psychiatry at the University of California.

Time span of trial: Not reported.

Consumer involvement: Not reported.

**Participants**

Description: People with possible or probably mild Alzheimer's Disease (AD) or mild cognitive impairment (MCI).

Inclusion/exclusion criteria: Diagnosis of mild AD or MCI, mini-mental state examination (MMSE) score greater than or equal to 19 and absence of uncompensated hearing or visual deficits.

Methods of recruitment of participants: Patients were recruited from those attending two separate health care facilities. How potential participants were invited to participate is not reported.

Geographic location: United States, urban.

Setting: Health Service.

Pretrial calculation of sample size: Not reported.

Eligible (total number approached to participate): n = 86 (at one site) and n = 5 or less (at second site, author estimation).

Number excluded: Not reported.

Number agreeing/refusing to take part: Not reported.

Number randomised to intervention: AV intervention (n = 17), Enhanced written (n = 18).

Number randomised to control: For the purposes of this review there is no control group (intervention A vs intervention B).

Number excluded post-randomisation: n = 0.

Number withdrawn: Not reported.

Number lost to follow-up: n = 0.

Number died: n = 0.

Number included in final analysis: n = 35.

Number included for each outcome: Knowledge (n = 17 AV intervention, n = 18 enhanced written).

Age: AV intervention: 77.5 years (7.2 years), Enhanced written: 73.9 years (8.0 years).

Gender: AV intervention: n = 8 females (47.1%), Enhanced written: n = 7 females (38.9%).

Ethnicity: AV intervention, n = 14 white people (82.4%), Enhanced written: n = 12 white people (70.6% of 17 participants, n = 1 missing).

Principal health problem or diagnosis: Possible or probable mild Alzheimer's disease or mild cognitive impairment.

**Mittal 2007** (Continued)

Other health problem/s: Not reported.

Stage of problem/illness: Mild.

Treatment in parent trial: Hypothetical clinical trial of a cognitive-enhancing drug with potentially serious side-effects.

Other social/demographic details: Number of years of education: AV intervention: 14.0 years (3.5 years), Enhanced written: 15.0 years (3.0 years), MMSE: AV intervention 26.5/30 (3.3), Enhanced written: 25.9/30 (3.5).

**Interventions**

Aim of intervention: Both interventions were designed to improve understanding.

Theoretical basis of intervention: Not reported.

Development of intervention: Not reported.

Components of intervention: AV intervention: computer slide show plus research assistant explanation. Enhanced written: written consent form plus research assistant explanation (see note).

AV format (media): AV intervention: Computer slide show with graphics, narration and video clips. Enhanced written: written consent form printed in 14-point font, read aloud by the study coordinator while the participant read along.

AV interactivity: AV intervention: not interactive. The study coordinator advanced the slides.

Content: Both interventions described: testing procedures, possibility of no benefit, medication risks, study purpose, procedures, voluntary nature of participation, withdrawal procedures, alternatives and contacts in case of questions

Length: AV intervention average length: 24.9 minutes (7.2 minutes), Enhanced consent average length: 34.3 minutes (7.7 minutes).

Language: Not reported (but English is implied).

Number of times viewed: Not explicitly reported but it is implied that the intervention was viewed/read once.

Intervention quality: Not reported.

Viewing setting: The intervention was viewed individually but the setting was not reported.

Target audience: People with mild Alzheimer's or mild cognitive impairment.

Recipient: Participants.

Delivery of the intervention: AV intervention: The study coordinator facilitated the slide show by advancing slides, reviewing the information with participants and highlighting essential items. The participants didn't receive a copy of the consent form. Enhanced written: The study coordinator reviewed information with participants and highlighted essential items. Participants received a copy of the consent form and read along with the study coordinator.

Details of providers: Study coordinator delivered the intervention. No description of any training provided.

Fidelity/integrity: Not reported.

Components of usual care/control: Not applicable.

Format of usual care/control: Not applicable.

Content of usual care/control: Not applicable.

Delivery of control: Not applicable.

Quality of usual care/control: Not applicable.

**Mittal 2007** (Continued)

Outcomes	<p>Outcome: Knowledge.</p> <p>Definition used by authors: Understanding (see notes).</p> <p>Method of assessment: MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR).</p> <p>Methods for follow-up of non-respondents: Not applicable.</p> <p>Number of times measured: Twice (we are using the second time point only - see notes).</p> <p>Timing of outcome assessment: Immediately after intervention and then again after the key information had been re-summarised by a research assistant.</p> <p>Authors' conclusions: There were no significant differences in understanding between groups at the first or second trial. Participants improved their understanding scores after re explanation.</p> <p>Outcome: Time taken to administer the consent procedure.</p> <p>Definition used by authors: Time to administer consent.</p> <p>Method of assessment: Not reported.</p> <p>Methods for follow-up of non-respondents: Not applicable.</p> <p>Number of times measured: Once.</p> <p>Timing of outcome assessment: Not reported.</p> <p>Authors' conclusions: We found that the SSP (AV intervention) took significantly less time to administer.</p>
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**Notes**

Three of the four sub-scales used in the MacCAT-CR meet our criteria for the knowledge outcome. The fourth sub-scale (expression of a choice was excluded from the review). These include: Understanding (including understanding of purpose, potential benefits and risks), appreciation (recognise the difference between treatment and research and the voluntary nature of participation) and reasoning (being able to describe potential study consequences). These outcomes were measured at two time points (after intervention and after re-explanation of initially misunderstood concepts). We ranked the effect estimates of the three outcomes measures taken at the longer time point (trial 2, after re-explanation). The median effect estimate was for the understanding sub-scale. As such, we used this measure for the knowledge outcome.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated random number sequence.
Allocation concealment (selection bias)	Low risk	The allocation sequence was kept centrally by an administrative assistant. The research assistant who delivered the intervention called the administrative assistant to find out which intervention to deliver.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel were unable to be blinded to their intervention status.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Sole outcome (knowledge) was assessed by questionnaire, administered by study personnel. While participants were unblinded, study personnel were blinded.
Incomplete outcome data (attrition bias)	Low risk	All participants accounted for in the analysis.

**Mittal 2007** (Continued)

## All outcomes

Selective reporting (reporting bias)	Unclear risk	The outcome reported in the methods section was subsequently reported in the results, however no published protocol is available.
Other bias	Low risk	No baseline imbalance.

**Norris 1990**

Methods	<p>Aim of study: To study the effectiveness of videotape instruction in promoting the understanding of study conduct to potential study participants.</p> <p>Study design: RCT.</p> <p>Number of arms: two: video (consent form + speak with study nurse + videotape); control (consent form + speak with study nurse).</p> <p>Real or hypothetical trial: Real.</p> <p>Ethics approval: Unclear.</p> <p>Informed consent: Unclear.</p> <p>Funding: Not stated.</p> <p>Time span of trial: 1 May 1988 to 30 June 1989.</p> <p>Consumer involvement: Not reported.</p>
Participants	<p>Description: People invited to participated in study of duodenal ulcer monitoring in response to study medication designed to promote ulcer healing.</p> <p>Methods of recruitment of participants:          Unclear: dates (1 May 1988 to 30 June 1989) refer to study duration, not specifically to the recruitment period. Unclear with respect to source of potential participants and to the process of invitation to participate.</p> <p>Inclusion/exclusion criteria for participation in study: Not stated explicitly; potential participants were individuals invited to participate in study of duodenal ulcer medication (short duration study, up to 8 weeks in duration).</p> <p>Geographic location: Unclear, although likely to be the United States.</p> <p>Setting: Unclear.</p> <p>Pretrial calculation of sample size: No.</p> <p>Eligible (total number approached to participate): Unclear.</p> <p>Number excluded: Unclear.</p> <p>Number agreeing to participate/number refusing to take part: n = 200 agreed to participate, * Number of people refusing to participate was unclear.</p> <p>Number randomised to intervention: n = 100*</p> <p>Number randomised to control: n = 100*</p> <p>Number excluded post-randomisation: Unclear.</p> <p>Total: Unclear.</p> <p>Number withdrawn: Unclear.</p>

**Norris 1990** (Continued)

Number lost to follow-up: Unclear.

Number died: Unclear.

Number included in final analysis: n = 200\*

Number included for each outcome: Knowledge: n = 200\* [100 video, 100 control].

Age: Not reported.

Gender: Not reported.

Ethnicity: Not reported.

Principal health problem or diagnosis: Not reported directly but participants were potential participants for duodenal ulcer study.

Other health problem/s: Not reported.

Stage of problem/illness: Not reported.

Treatment in parent trial: Duodenal ulcer drug - Sucralfate (Carafate).

Other social/demographic details: Not reported.

**Interventions**

Aim of intervention: To promote knowledge and understanding of study conduct to potential study participants in the process of obtaining informed consent.

Theoretical basis: not reported.

Development: unclear.

Components: Both groups were able to ask questions of the study nurse.

AV format (media): Videotape: video.

AV Interactivity: unclear whether interactive or non-interactive.

Content: Information on the study protocol and adherence to the study protocol, including the following: compliance with dosing schedules; maintenance of diary cards; adherence to specific antacid limitations; presence at scheduled follow-up visits; procedures to be used; possible adverse reactions; study consent forms; and who to call for information.

Length: Unclear.

Language: Unclear (but English is implied).

Number of times viewed: Unclear.

Intervention quality of video: Unclear.

Viewing setting: Video was viewed as part of a group.

Target audience: Potential study participants.

Recipient: Potential study participants.

Delivery of the intervention: Video group (group 1): Participants studied the consent form and discussed it with the study nurse. They then viewed the video, before consent being sought (ie prior to signing the consent form).

Details of providers: Research nurse; no further detailed provided.

Fidelity/integrity: Not reported.

Components of usual care/control: Standard information provision (consent form) and questions answered by study nurse.

Format of usual care/control: Written consent form plus face-to-face discussion,

**Norris 1990** (Continued)

Content of usual care/control: Standard written consent form; no further details provided.

Delivery of control: Not reported.

Quality of usual care/control: Not reported.

Outcomes	<p>Outcome: Knowledge.</p> <p>Definition used by authors: Patient consent quiz (knowledge of information in study patient information sheet).</p> <p>Method of assessment: Numbers of correct responses on a 10-item patient consent quiz (questionnaire). Self-completed by participant.</p> <p>Methods for follow-up of non-respondents: Not reported.</p> <p>Number of times measured: once.</p> <p>Timing of outcome assessment: immediately post-intervention.</p> <p>Authors' conclusions: "Utilization of audio-visual techniques, specifically videotape instruction, has been shown to increase a participant's understanding of the study and his/her role in it. While instructive videotapes can never supplement the role of the investigator or study nurse in communicating with the study participant, they can be extremely useful tools in making study participants 'truly informed,' thereby giving literal meaning to the term 'informed consent'."</p>
Notes	<p>* Note that the trial reports inconsistent participant numbers: stating initially that 278 participants signed consent forms and were randomised; and later, that 200 participants were randomised to two groups. We have used n = 200 participants, assuming 100 were allocated to each of two groups, for this review.</p> <p>For the knowledge outcome measure, the authors report the percentage of participants who scored 10 correct, 1-2 incorrect, 3-6 incorrect, 6-9 incorrect and 10 incorrect questions. We converted this to a dichotomous outcome (adequate knowledge, inadequate) knowledge. We set the cut off for adequate knowledge at 80% as this is the value used in <a href="#">Weston 1997</a>. Therefore, adequate knowledge includes participants who scored 10 correct and 1-2 incorrect responses. We also assumed n = 100 participants in each group as the table of results presents percentage of participants only.</p>

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Study is described as randomised but method not described.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants unable to be blinded. Unclear if personnel were blinded.
Blinding of outcome assessment (detection bias) All outcomes	High risk	The sole outcome (knowledge) was assessed by questionnaire. It was self-administered by participants, who were unblinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Authors report that 278 participants signed consent forms and were randomised; and later, that 200 participants were randomised to two groups. Outcome was assessed immediately post-intervention but number of participants included in the outcome are not reported.

**Norris 1990** (Continued)

Selective reporting (reporting bias)	Unclear risk	The outcome reported in the methods section was subsequently reported in the results however no published protocol is available.
Other bias	Unclear risk	No baseline characteristics reported.

**O'Lonegan 2011**

Methods	<p>Aim of study: To develop audio-visual descriptions about research procedures and rights, for incorporation into a multimedia permission/assent (P/A) process and then to determine if incorporation of these media improved child and/or parent comprehension.</p> <p>Study design: RCT.</p> <p>Number of arms: two.</p> <p>Real or hypothetical trial: Hypothetical.</p> <p>Ethics approval: Yes.</p> <p>Informed consent: Yes.</p> <p>Funding: Children's Hospital Research Institute, National Institutes of Health/National Center for Research Resources.</p> <p>Time span of trial: Not reported.</p> <p>Consumer involvement: 24 parent-child dyads were involved in a pre-study testing the informed consent intervention and assessments for preferences and comprehension (to develop the intervention and control documents for assessment in the RCT).</p>
Participants	<p>Description: Children and their parents (child-parent dyads). For the purposes of this review we included the data from parent participants only (see notes).</p> <p>Inclusion/exclusion criteria: Inclusion: parents of children aged 11-14 years; Exclusion: parents of children with known cognitive, vision or hearing deficits, or having previously undergone DXA (dual energy radiograph absorptiometry) or ultrasound.</p> <p>Methods of recruitment of participants: Participants were recruited from a large metropolitan area served by an urban medical campus with a tertiary care paediatric facility and several regional chronic care centres. No further details provided.</p> <p>Geographic location: United States (urban).</p> <p>Setting: Not reported.</p> <p>Pretrial calculation of sample size: Power calculation based on total comprehension scores, assuming a standard deviation of 13.6. n = 82 participants per group were calculated to provide 80% power to detect an overall 6-point difference.</p> <p>Eligible (total number approached to participate): Not reported.</p> <p>Number excluded: Not reported.</p> <p>Number agreeing/refusing to take part: n = 170 parents (as part of n = 170 parent-child dyads). Number refused to participate not reported.</p> <p>Number randomised to intervention: n = 83.</p> <p>Number randomised to control: n = 87.</p> <p>Number excluded post-randomisation: n = 0.</p>

**O'Lonegan 2011** (Continued)

Number withdrawn: n = 0.

Number lost to follow-up: n = 1 for each outcome except n = 4 for parental understanding assessed by VAS.

Number died: n = 0.

Number included in final analysis: n = 169.

Number included for each outcome: Knowledge n = 169 [n = 83 intervention, n = 86 control], knowledge assessed by visual analogue scale n = 166. Rate of participation: no data provided but authors note that 'all participants agreed' to take part in the hypothetical study.

Age: Children: Intervention 12.6 +/- 1.1 years, control 12.7 +/- 1.1 years, range 11 - 14 years. Parents: intervention n = 23 (29%) less than 40 years, control n = 22 (25%) less than 30 years.

Gender: In the parents group, the sample included n = 5 guardians (gender not described) however both intervention (86%) and control groups (84%) contained a similar percentage of mothers.

Ethnicity: Parents: intervention non-Hispanic n = 77 (95%), control non-Hispanic n = 78 (93%).

Principal health problem or diagnosis: Children with 'medical diagnosis': intervention n = 51 (61%) intervention, n = 58 (67%) control. Description of medical diagnosis not provided.

Other health problem/s: Not applicable.

Stage of problem/illness: Not applicable.

Treatment in parent trial: Not 'treatment': participants consenting to scans to determine body composition of children; no further intervention in parent study.

Other social/demographic details: Parents education level: less than high school intervention n = 8 (10%), control n = 8 (10%), some college intervention n = 30 (37%), n = 22 (26%), college degree intervention n = 18 (22%), control n = 23 (27%), any graduate school intervention n = 25 (31%), control n = 31 (37%).

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**Interventions**

Aim of intervention: To provide audio-visual descriptions of research procedures and rights.

Theoretical basis of intervention: The multimedia consent procedure was developed using the learning-objective approach (no reference provided).

Development of intervention: Authors performed a pre-study which developed and assessed the intervention for evaluation in the RCT that followed. Three groups of 8 parent-child dyads were recruited to the pre-study: each group separately viewed 3 versions of the procedure descriptions in different orders. Participants' preferences and comprehension were assessed and compared for each of the three presentation methods. Video versions were rated as most preferred over paper versions and a trend towards improved comprehension, therefore the video format was selected for assessment in the RCT.

Components of intervention: Computer slide alone.

AV format (media): Powerpoint document with 5 embedded hyperlinks to video content embedded within the document.

AV interactivity: Interactive: the parent-child dyads could click on the hyperlinks.

Content: Included three hyper linked sections on research rights : what research is; what assent means; the right to refuse participation or withdraw at any time. Two hyper linked sections about the study-specific procedures (DXA and ultrasound): video showing an adolescent male being prepared for an having each of the procedures with narrative voice-over explaining the risks and purpose of each procedure. The text was created using short declarative sentences and using age-appropriate examples. Explanatory text used in both intervention and control arms was identical.

Length: 7 to 10 minutes.

Language: English, using 3rd grade language.

**O'Lonegan 2011** (Continued)

Number of times viewed: once; each hyper linked section was accessed once by each parent-child dyad.

Intervention quality: The intervention was based on developmental work undertaken in the pre-study. All interactions between participants and researchers were scripted to ensure consistency.

Viewing setting: Not reported.

Target audience: Potential child participants and their parents.

Recipient: Participants and guardians.

Delivery of the intervention: Parent-child dyads were seated next to each other with either a laptop computer (multimedia) or paper form in front of them.

Details of providers: Not reported.

Fidelity/integrity: There was an error in delivery of one intervention component meaning that the learning objectives for question 1 (study purpose) was not delivered as designed for the intervention (this question was therefore removed from post-process assessment questions).

Components of usual care/control: Written information.

Format of usual care/control: Paper-based assent document.

Content of usual care/control: The paper-based assent document contained the same information (explanatory text) as the multimedia assent tool and took a similar time to complete (7 to 10 minutes).

Delivery of control: Parent and child were seated next to each other with the paper-based document in front of them.

Quality of usual care/control: Not reported.

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Outcomes

Outcome: Knowledge/understanding.

Definition used by authors: PPCI (Parental Post-consent Comprehension Interview) (total parental comprehension).

Method of assessment: Paper-based form (questionnaire) based around 8 questions; study purpose, study procedures, study risk, direct and indirect benefit, alternatives to research, right to withdraw and voluntariness of the research (see notes).

Methods for follow-up of non-respondents: Not reported.

Number of times measured: Once.

Timing of outcome assessment: Immediately post-intervention.

Authors' conclusions: 'We observed significantly better overall comprehension of the hypothetical study and its research procedures for children and parents exposed to the multimedia P/A process compared with text.'

Outcome: Rate of participation.

Definition used by authors: Not specifically defined by authors, appears to have been a somewhat informal assessment.

Method of assessment: At the completion of the formal outcome measures, participants were asked if they would allow their child to take part in the study, if it was real.

Methods for follow-up of non-respondents: Not reported.

Number of times measured: Once.

Timing of outcome assessment: Immediately post-intervention.

**O'Lonegan 2011** (Continued)

Authors' conclusions: The authors report that "all participants agreed".

**Notes**

This study included parent-child dyads, who viewed the intervention together and then provided their answers to the collected outcomes. As the participants were correlated we couldn't include both sets of data. We therefore selected parents as the participants in our review, as they were the only group who provided true consent to participate (the children instead providing assent). The authors reported overall comprehension scores, self-rated comprehension by visual analogue scale and the results of 1-2 specific questions within the comprehension questionnaire. Because the overall comprehension score was used in the sample size calculation, we took this as the primary outcome measure.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Each parent-child dyad was randomly assigned to either the paper-based or the multimedia process group'; no further details reported.
Allocation concealment (selection bias)	Unclear risk	No details reported.
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding of participants or personnel was stated and seems likely that participants knew they were receiving the intervention (i.e. laptop viewing rather than paper-based form).
Blinding of outcome assessment (detection bias) All outcomes	High risk	The parental outcome (knowledge) was assessed by questionnaire that was self-administered by participants. Blinding of participants seems unlikely.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Follow-up was almost complete; n = 1/170 responses missing. No reasons for missing data were provided but this seems unlikely to substantially influence effects.
Selective reporting (reporting bias)	Unclear risk	The outcome reported in the methods section was subsequently reported in the results, however no published protocol is available.
Other bias	Low risk	No baseline imbalance: groups were balanced for demographic variables.

**Strevel 2007**
**Methods**

Aim of study: To assess the impact of an educational DVD reviewing phase I clinical trials in oncology patients who are potentially eligible for participation in such trials.

Study design: RCT.

Number of arms: 2.

Real or hypothetical trial: Real.

Ethics approval: Yes.

Informed consent: Yes.

Funding: Not reported.

Time span of trial: Patients recruited from August 2005 until January 2006; no other details reported.

Consumer involvement: Not reported.

**Strevel 2007** (Continued)

**Participants**

Description: Patients, newly referred to phase I clinic.

Inclusion/exclusion criteria: Aged 18 years or older; possession of a general understanding of the English language for reading, writing and listening; and initial eligibility assessment for a phase I clinical trial due to metastatic disease for which standard treatment approaches have failed, have low expectations, or do not exist.

Methods of recruitment of participants: Newly referred patients to a phase I clinic were prospectively and consecutively eligible for trial enrolment.

Geographic location: Canada (urban).

Setting: Weekly phase I trials hospital clinic.

Pretrial calculation of sample size: Yes, estimated to require a sample size of 50 for a power of 80% to detect a difference of at least 40% between study arms (clinically relevant difference).

Eligible (total number approached to participate): n = 70.

Number excluded: n = 0.

Number agreeing/refusing to take part: n = 21 (refused).

Number randomised to intervention: n = 22.

Number randomised to control: n = 27.

Number excluded post-randomisation: n = 0.

Number withdrawn: n = 0.

Number lost to follow-up: n = 0.

Number died: n = 0.

Number included in final analysis: n = 49.

Number included for each outcome: Participant knowledge and understanding (patient knowledge; different sub scales n = 49 [n = 22 intervention, n = 27 control except for two sub scales with n = 1 missing from the intervention and control groups respectively); participant satisfaction with the information provided (satisfaction with the educational DVD intervention n = 44 [n = 20 intervention, n = 24 control]); rate of participation (phase I study consent/enrolment n = 49 [n = 22 intervention, n = 27 control]).

Age: mean 56.3 years (SD 12.1).

Gender: Intervention group n = 7 females (32%); Control group n = 12 females (44%).

Ethnicity: Not collected.

Principal health problem or diagnosis: Cancer; various types.

Other health problem/s: Not applicable.

Stage of problem/illness: Initial eligibility assessment for a phase I clinical trial due to metastatic disease for which standard treatment approaches have either failed, have low expectations, or do not exist.

Treatment in parent trial: Consenting to participate in phase I oncology trial.

Other social/demographic details: Previous clinical trial participation reported: Intervention group n = 2 patients (9%); Control group n = 5 patients (19%).

**Interventions**

Aim of intervention: To provide general information on phase I clinical trials.

Theoretical basis of intervention: Not reported.

**Strevel 2007** (Continued)

Development of intervention: Educational DVD was developed by the researchers based on knowledge deficits described for phase I clinical trial populations. Script content was reviewed by medical oncologists involved in drug development at the hospital in which the clinic was located.

Components of intervention: DVD alone.

AV format (media): DVD filmed in a documentary style with inclusion of graphics and/or text to augment dialogue and enacted scenes.

AV interactivity: Non-interactive.

Content: Content included: types of clinical trials, goals of phase I trials, early phase drug development, frequency of diagnostic testing, requirement for research-related tests such as pharmacokinetic sampling, eligible patient populations, toxicity and side effects, likelihood of a positive clinical outcome, and appropriate patient expectations.

Length: 8 minutes.

Language: English.

Number of times viewed: Once.

Intervention quality: Not reported; no details of intervention development other than the above. No additional components of intervention delivery were involved other than the DVD itself so quality of the intervention itself is high.

Viewing setting: Viewed individually, alone in a private room on a laptop with earphones.

Target audience: Potential phase I oncology trial participants, patients newly referred to phase 1 clinic.

Recipient: Participants.

Delivery of the intervention: Patients viewed the DVD alone in a private room.

Details of providers: Self: intervention delivered as DVD; no other components.

Fidelity/integrity: Not reported.

Components of usual care/control: Placebo DVD which described research accomplishments of scientists and investigators at Princess Margaret Hospital.

Format of usual care/control: DVD.

Content of usual care/control: No information relevant to phase I clinical trials, described research accomplishments of scientists and researchers at the health institute. Duration 8 minutes.

Delivery of control: Self: patients viewed the DVD alone in a private room.

Quality of usual care/control: DVD delivered without additional components.

**Outcomes**

Outcome: Knowledge.

Definition used by authors: Knowledge of phase I trials.

Method of assessment: Self-administered questionnaire, 4 true/false questions, 1 multiple choice question; 1 question requiring true/false for multiple options (4 sub-questions).

Methods for follow-up of non-respondents: Not applicable (0 missing for majority of sub scales; n = 1 missing from two sub scales with no methods of follow-up reported).

Number of times measured: Once.

Timing of outcome assessment: Immediately following the intervention.

Authors' conclusions: Most patients (86%) had previously heard of clinical trials but only 49% had previously heard of phase I studies before the phase I clinic visit. Compared with patients viewing the placebo DVD, those viewing the educational DVD were significantly less likely to believe that the goal of

**Strevel 2007** (Continued)

phase I clinical trials was to decide if a new drug was more effective than an old one, significantly more likely to know that the drug had been tested in animals but not thoroughly in humans and significantly less likely to believe phase I drugs have proven anti-cancer effects in humans.

Outcome: Satisfaction with information provided.

Definition used by authors: Satisfaction with information provided.

Method of assessment: Self-administered questionnaire, 5 items scored on Likert scale (1 to 5).

Methods for follow-up of non-respondents: Not reported.

Number of times measured: Once.

Timing of outcome assessment: Immediately following the intervention.

Authors' conclusions: Compared with those viewing the placebo DVD, participants viewing the educational DVD were significantly more likely to: agree or strongly agree that they had good knowledge of phase I trials, that the DVD prompted them to have more questions for their physicians, and that the DVD helped them to decide whether or not to enter a phase I trial.

Outcome: Rate of participation.

Definition used by authors: Phase I study consent/enrolment.

Method of assessment: Chart review to determine whether consent was obtained and reasons for non-entry to phase I trial.

Methods for follow-up of non-respondents: Not applicable (all accounted for).

Number of times measured: Once.

Timing of outcome assessment: Outcome collected once participants had decided whether they were going to participate (often immediately post-intervention to up to a few weeks later).

Authors' conclusions: There was no significant difference between educational and placebo DVD in terms of numbers of participants consenting to participate; nor were reasons for non-participation significantly different between the two groups. Reasons cited included concern of toxicity and the highly investigational nature of the trial, availability of other approved treatment options, poor functional status excluding trial participation, and incapacity to provide informed consent.

Outcome: Satisfaction with the media used.

Definition used by authors: Satisfaction - usefulness of the DVD format.

Method of assessment: Self-administered questionnaire; 1 of the 5 items on the satisfaction questionnaire; scored on Likert scale (1 to 5).

Methods for follow-up of non-respondents: Not reported.

Number of times measured: Once.

Timing of outcome assessment: Immediately following the intervention.

Authors' conclusions: Compared with those viewing the placebo DVD, participants viewing the educational DVD were significantly more likely to: agree or strongly agree that the DVD provided useful information.

Notes

The authors reported a number of individual response options related to knowledge and satisfaction. No primary outcome was reported; nor any sample size calculation. Therefore we ranked the effect estimates and selected the median effect estimate for outcomes with multiple measures (where this was an even number we chose the n/2 outcome). For knowledge and satisfaction with the information provided outcomes we calculated the difference in mean percentages between intervention and control groups to calculate effect sizes.

**Strevel 2007** (Continued)

For knowledge outcomes: of sub scales reported we only counted correct response items on 6 of the 9 reported sub scales (we did not include the 3 negatively scored sub scales of item 4). The median effect estimate chosen was 6/2 (3rd): knowledge of goals of clinical trials – safety.

For satisfaction with the information provided measures the 4/2 (2nd) ranked effects estimate was selected: Satisfaction - helpfulness of DVD in deciding on trial participation. Note that 1 of the 5 satisfaction sub scales (Satisfaction - usefulness of DVD format) was reported separately under Satisfaction with the media used (participation).

The authors report physician's perceptions of the time taken to inform participants, and their satisfaction with this, but not the length of time it took to administer the intervention itself. As such these data were not included in the time outcome.

Additionally, the authors reported the treating physicians' perceptions of participant knowledge after the intervention and the reasons for participants declining to participate. Neither of these outcomes met the inclusion criteria for the review.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Patients were randomly assigned based on a computer-generated randomisation scheme.
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes containing the allocation sequence were provided to project staff who only opened them prior to administering the intervention. [Information provided by study authors].
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Authors state that patients were blinded and use of a placebo DVD should have allowed blinding to group status. Personnel (clinic physicians, nurses) were all blinded to intervention group.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Two outcomes (knowledge and satisfaction) were assessed by self-administered questionnaires and participants were blinded (low risk of bias). Rate of participation was determined by chart review; unclear if the study coordinators (who were unblinded) assessed this outcome (unclear risk of bias), however this outcome was objectively measured so lack of blinding appears unlikely to influence the results.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcomes were complete for rate of participation and for most knowledge outcome sub scales, with n = 1 missing from the intervention and control groups respectively on two subscales. For satisfaction measures 2/22 and 3/27 failed to complete these items; loss is small and balanced across groups, unlikely to bias the results.
Selective reporting (reporting bias)	Unclear risk	The outcome reported in the methods section was subsequently reported in the results, however no published protocol is available.
Other bias	Low risk	Baseline imbalance: groups were balanced in demographic and other factors at baseline.

**Weston 1997**

Methods	Aims of study:  1. To evaluate the effect of the video on: (1) women's willingness to participate; (2) their views that the Term PROM Study was worthwhile; and (3) their ability to understand and retain information about:
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**Weston 1997** (Continued)

(a) pre labour rupture of the membranes at term; (b) the risks and benefits associated with the options for their care; and (c) various aspects of the study protocol.

2. To evaluate the effect of a patient information video during the informed consent process of a perinatal trial.

Study design: RCT.

Number of arms: two: video group (written information + video), control group (written information only).

Real or hypothetical trial: Real.

Ethics approval: Yes.

Informed consent: Yes.

Funding: Medical Research Council of Canada (MRC) grant # MA-11392.

Time span of trial: 28 June to 22 December 1994. Note that the study enrolled women during this period; actual time span of the trial not specified.

Consumer involvement: Actual patients were involved in the production of the video intervention.

**Participants**

Description: Women potentially eligible to participate in the Term PROM study (the term pre labour rupture of membranes study) - a Multicentre RCT comparing management policies of induction of labour versus expectant management for pregnant women with pre labour rupture of membranes at term, in terms of serious fetal/neonatal infection, caesarean section and patient satisfaction with care (ie pregnant women considering enrolling in perinatal trial).

Methods of recruitment of participants: Women were recruited from physicians' offices and clinics. Unclear of the process of invitation to participate.

Inclusion/exclusion criteria for participation in study:

Inclusion criteria: English speaking; between 19 to 33 weeks' gestation; informed written consent.

Exclusion criteria: Women who had previously watched the Term PROM video. Note that the population for study was purposely chosen from gestational age groups that were not eligible for the TermPROM study so that recruitment would not interfere with or be confounded by the recruitment efforts of the TermPROM study.

Geographic location: Toronto, Ontario, Canada.

Setting: Most women watched video following baseline assessment and completed questionnaire 1 on the day of enrolment (in doctor's office) (83.3% of video group; 95.8% of control group). The remainder of women watched the video at home and completed questionnaire 1 at home.

Number of participants

Pretrial calculation of sample size: Yes; to find an increase in willingness to participate (primary outcome) of 30%, a sample size of  $n = 45$  was required for each group ( $\alpha = 0.05$ , 2-tailed  $\beta = 0.2$ ).

Eligible (total number approached to participate): Data were not collected.

Number excluded: Data were not collected.

Number agreeing to participate/number refusing to take part:  $n = 90$  people agreed to participate. Number of people refusing to participate was not collected.

Number randomised to intervention:  $n = 42$ .

Number randomised to control:  $n = 48$ .

Number excluded post-randomisation:  $n = 0$ .

Total:  $n = 90$ .

Number withdrawn:  $n = 0$ .

**Weston 1997** (Continued)

Number lost to follow-up: n = 5 (1 in video group [non-responder]; 4 in control group [2 preterm births and 2 non-responders]).

Number died: n = 0.

Number included in final analysis: n = 90 women for questionnaire 1, n = 85 women for questionnaire 2.

Number included for each outcome:

Knowledge: n = 90 at baseline [42 video, 48 control]; n = 85 at follow-up [41 video, 44 control].

Willingness for future participation: n = 90 at baseline [42 video, 48 control]; n = 85 at follow-up [41 video, 44 control].

Age: median age (video) median 31.4 years (range 21.8 to 39.5), control 31.8 years (range 18.0 to 31.3).  
Gender: All female.

Ethnicity: Not reported.

Principal health problem or diagnosis: All pregnant women of gestational age range such that would not interfere with actual Term PROM study. All 19 to 33 weeks gestation at enrolment.

Other health problem/s: Not reported.

Stage of problem/illness: Not reported.

Treatment in parent trial: Not reported.

Other social/demographic details

- Schooling: video: n = 2 (4.8%) high school or lower; n = 40 (95.2%) college or higher; control: n = 4 (8.3%) high school or lower; n = 44 (91.7%) college or higher.
- Parity: video group: n = 23 (54.8%) nulliparous; n = 19 (45.2%) one or more; control group: n = 26 (54.2%) nulliparous; n = 22 (45.8%) one or more.
- Gestational age: video group: median 25 weeks (range 20.3 to 33.0); control group: median 27.3 weeks (range 19.6 to 32.9).

**Interventions**

Aim of intervention:

1. To describe the objectives of the Term PROM study and to outline the care provided to participants in the different randomised groups.
2. To increase willingness to participate in, feelings of worth of and knowledge of a perinatal trial.

Theoretical development: Not reported

Development: The video was professionally produced by Edwin Medical Communications Inc., a video production house specialising in medical education videos. Patient information video used patients and their families, nurses, the study's principal investigator and study staff.

Components: Both groups received written information and were able to ask the study nurse questions. All consenting women were given the written information used during the consent process for the TermPROM study.

AV format (media): Videotape.

AV Interactivity: Non interactive.

Content: Included description of the medical condition, pre labour rupture of membranes at term (Term PROM); and description of the study, including: the manoeuvre - showing actual patients receiving each treatment, the risks and benefits of all study groups, the benefits of participating in clinical research and important aspects of the trial protocol, described by the principal investigator.

An actual trial participant also described why she had participated in the study, the contribution she felt it made to medical science and to future women. An invitation to participate in the study and instructions on where to obtain further information on study participation were also included.

Length: 10 minutes.

**Weston 1997** (Continued)

Language: English (Not stated directly but assume English as study inclusion criteria specifies participants English speaking).

Content: Included description of pre labour rupture of membranes at term; description of the study; personal account of trial participant; and invitation to participate in trial.

Number of times viewed: Once.

Intervention quality: Professionally narrated and commercially produced, 'very high quality'.

Viewing setting: Intervention was delivered in doctor's office or at home. Most women watched video following baseline assessment and/or completed questionnaire 1 on the day of enrolment (in doctor's office) (83.3% of video group; 95.8% of control group); the remainder watched the video at home and/or completed questionnaire 1 at home.

Target audience: Potential study participants.

Recipient: Pregnant women, potential study participants.

Delivery of the intervention: Video group: Video intervention was delivered following routine information and discussion with study nurse. Baseline information (demographics etc) were collected; women were given the written information sheet and questions were answered by the study nurse. Women then watched the video (duration 10 minutes).

Details of providers:

The information contained in the video was presented by patients, families, nurses, the study's principal investigator and study staff, with narration by the professional narrator. Personal characteristics unclear.

Study nurse was also involved in delivering information; no further details provided.

Fidelity/integrity: Yes; the research assistant was present when participants viewed the video. All mothers stayed to watch the video.

Components of usual care/control: written information.

Format of usual care/control: Participants were given the written material, with questions answered by the study nurse.

Content of usual care/control: The standard written information was provided, written to be understood by women with 8th grade education, with questions answered by the study nurse.

Delivery of control: Baseline information (demographics etc) was collected; women were then given the written information sheet and questions were answered by the study nurse.

Quality of usual care/control: Not reported.

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Outcomes

Outcome: Knowledge/understanding.

Definition used by authors: Content knowledge (knowledge of study protocol and knowledge of PROM).

Method of assessment: Number of correct responses on an 11-item questionnaire. Self-completed by participant.

Methods for follow-up of non-respondents: After assessment 1, arrangements were made by the study nurse for each woman to complete the questionnaire again in 2 to 4 weeks.

Follow-up for non-respondents: unclear.

Number of times measured: once.

Timing of outcome assessment: immediately post-intervention.

Outcome: Recall of knowledge/understanding.

Definition used by authors: Content knowledge (knowledge of study protocol and knowledge of PROM).

**Weston 1997** (Continued)

Method of assessment: Number of correct responses on an 11-item questionnaire. Self-completed by participant.

Methods for follow-up of non-respondents: After assessment 1, arrangements were made by the study nurse for each woman to complete the questionnaire again in 2 to 4 weeks.

Follow-up for non-respondents: unclear.

Number of times measured: once.

Timing of outcome assessment: 2 to 4 weeks following recruitment (video group: median 17 days, range 9 to 15 days; control group: median 16.5 days, range 10 to 56 days).

Authors' conclusions: There was no statistically-significant difference initially in the number of women in the two groups that answered at least 9 of 11 content questions correctly. Two to four weeks later the number of correct content questions was lower in both groups but the video group had retained more information than the control group.

Outcome: Rate of participation.

Definition by authors: willingness for future participation.

Method of assessment: 1-item questionnaire. Self-completed by participant.

Timing: After assessment 1, arrangements were made by the study nurse for each woman to complete the questionnaire again in 2 to 4 weeks.

Follow-up for non-respondents: unclear.

Number of times measured: twice.

Timing of outcome assessment: immediately post-intervention (assessment 1); 2 to 4 weeks following recruitment (video group: median 17 days, range 9 to 15 days; control group: median 16.5 days, range 10 to 56 days) (assessment 2).

Authors' conclusions: "The showing of a patient information video may increase the willingness of women to participate in a research trial, and may have the additional effect of educating them about the health problem and specifics of the trial. This willingness to participate seems to decrease over time and therefore a patient information video may be most helpful at the time informed consent is requested."

**Notes**

Note study was duplicate publication: same study included in Weston (1995) abstract. Author reply (J. Weston, first author) confirmed the studies were the same.

The effects of the video in women of different cultural or educational backgrounds is not clear. The sample studied included a high proportion of highly educated women, and authors note that the results may not be generalisable for these reasons.

The outcome, 'importance of the study' was collected and reported on in the original review but did not clearly fit any of the pre-specified outcomes and so was not included in this update.

The outcome, 'content knowledge' is described as consisting of knowledge or PROM (6-item questionnaire) and knowledge of study protocol (5-item questionnaire), however the results are presented as one outcome, content knowledge (11-item questionnaire).

Rate of participation was measured at two time points, immediately post-intervention and two to four weeks later. As outlined in our protocol we took the longer time period, two to four weeks.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A randomisation list was generated using a random number table.

**Weston 1997** (Continued)

Allocation concealment (selection bias)	Low risk	Allocations held centrally, each participant's assignment obtained by phone.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and personnel not blind.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Both outcomes (knowledge and rate of participation) were assessed by questionnaire. The questionnaire was self-administered by participants, who were unblinded.
Incomplete outcome data (attrition bias) All outcomes	Low risk	n = 1 (2%) of participants in control and n = 4 (8%) of participants in intervention group lost to follow up, due to pre-term delivery or non-response. Intention to treat analysis conducted. Unlikely to affect the results.
Selective reporting (reporting bias)	Unclear risk	The outcome reported in the methods section was subsequently reported in the results however no published protocol is available.
Other bias	Low risk	Groups were assessed as comparable at baseline.

**Wirshing 2005**

Methods	<p>Aim of study: To evaluate a brief educational video designed to enhance the informed consent process for people with serious mental and medical illnesses who are considering participating in treatment research.</p> <p>Study design: RCT.</p> <p>Number of arms: 2.</p> <p>Real or hypothetical trial: Real (also other participant groups but they did not meet our criteria for a hypothetical participant - see notes).</p> <p>Ethics approval: Not reported.</p> <p>Informed consent: Yes.</p> <p>Funding: National Institute of Mental Health (NIMH).</p> <p>Time span of trial: Not reported.</p> <p>Consumer involvement: Not reported.</p>
Participants	<p>Description: Patients with schizophrenia (also included university students and medical patients but these were excluded from the review - see notes. Only the information regarding patients with schizophrenia was extracted and presented below).</p> <p>Inclusion/exclusion criteria: Patients were contemplating medication treatment trials. Exclusion: patients with acute psychotic symptoms.</p> <p>Methods of recruitment of participants: Not reported.</p> <p>Geographic location: United States, urban.</p> <p>Setting: Veteran's Affairs Healthcare Centre, University aftercare program.</p> <p>Pretrial calculation of sample size: Not reported.</p> <p>Eligible (total number approached to participate): Not reported.</p>

**Wirshing 2005** (Continued)

Number excluded: Not reported.

Number agreeing/refusing to take part: n = 83.

Number randomised to intervention: Not reported (only overall number of participants reported).

Number randomised to control: Not reported.

Number excluded post-randomisation: Not reported.

Number withdrawn: Not reported.

Number lost to follow-up: Not reported.

Number died: Not reported.

Number included in final analysis: Not reported.

Number included for each outcome: For the single outcome in this study, knowledge, the authors do not report the number of participants included in the intervention and control group however they confirmed that all participants were included in the results.

Age: Overall mean 37.2 years (SD 13.9 years) (group breakdown not provided).

Gender: Overall participants 15 (18%) female (group breakdown not provided).

Ethnicity: Not reported.

Principal health problem or diagnosis: Schizophrenia.

Other health problem/s: Not reported.

Stage of problem/illness: Considering maintenance therapy treatment options for stabilised schizophrenia symptoms.

Treatment in parent trial: Maintenance therapy in one of 10 possible treatment trials; no further details reported.

Other social/demographic details: Years of education mean 13.2 years (SD 1.7 years) (group breakdown not provided).

---

**Interventions**

Aim of intervention: To enhance the consent process for medical and psychiatric treatment by alerting potential participants to their rights, informing them of requisite elements of the informed consent process, modelling active participation and discussing good decision making.

Theoretical basis of intervention: Not reported.

Development of intervention: Not reported.

Components of intervention: Educational video.

AV format (media): Within the video, each point is presented in three modalities—text bullets, voiceover narration, and brief enacted vignettes with professional actors playing a doctor/recruiter and a patient reviewing major consent topics.

AV interactivity: Not interactive.

Content: The videotape was written to be generic and applicable to a wide range of conditions, protocols, and treatments. Addresses three areas: 1) optimal behavior during the recruitment session, 2) the content that the informed consent session covers, and 3) good decision making. The videotape repeatedly emphasizes the need for the patient to be active, open about any failure to understand, and assertive in seeking information. Major consent topics covered included the purpose of the study, the benefits, the risks and voluntariness. A final section emphasizes the need to consider pros and cons and to weigh costs and benefits of participation in the decision-making process.

Length: 16 to 18 minutes.

**Wirshing 2005** (Continued)

Language: English; written at 5th grade reading level.

Number of times viewed: Once.

Intervention quality: Professional actors were used for enacted vignettes within the video. Otherwise little information reported on quality.

Viewing setting: Not reported.

Target audience: Any participants (with or without psychiatric issues) considering medical or psychiatric clinical trial participation.

Recipient: Participants.

Delivery of the intervention: Not reported.

Details of providers: Not reported.

Fidelity/integrity: Not reported.

Components of usual care/control: Control educational video.

Format of usual care/control: Video.

Content of usual care/control: General information about the history of human subject research and the role of institutional review boards. Contains no specific information related to the consent process. Length 16 to 18 minutes.

Delivery of control: Not reported.

Quality of usual care/control: Not reported.

**Outcomes**

Outcome: Knowledge/understanding.

Definition used by authors: Knowledge of informed consent process.

Method of assessment: 80-item quiz on key elements of the informed consent process.

Methods for follow-up of non-respondents: Not applicable.

Number of times measured: Twice.

Timing of outcome assessment: Before (baseline) and after viewing the video (note we used the second assessment).

Authors' conclusions: There was a significant main effect of videotape condition, indicating far more improvement in knowledge for those viewing the experimental videotape in each subject group. Our brief videotape is a valid teaching tool for a broad range of prospective clinical research participants, including those with schizophrenia.

**Notes**

Three participant groups took part in the trial; schizophrenia patients, medical patients and university students. The authors confirmed that the consent material was generic and only the schizophrenia patients were considering a specific trial. The medical patients and university students were not asked to imagine clinical trial participation. The authors do not provide the number of participants in the intervention and control groups, only the mean and SD of the knowledge score in each group.

**Risk of bias**

**Bias**

**Authors' judgement**

**Support for judgement**

Random sequence generation (selection bias)

Low risk

In the published paper the authors state that 'subjects were randomly assigned' but with no further details were reported. In their response to our queries, the authors advised that this most likely occurred by a computer generated numbers table.

**Wirshing 2005** *(Continued)*

Allocation concealment (selection bias)	Unclear risk	This was not reported in the papers and remained unclear after consultation with the authors.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants and personnel could have been blinded to their intervention status (as both watched a video) but this is not reported. After consultation with the authors, it appeared that personnel were not blinded to the intervention status of participants.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The sole outcome (knowledge) was assessed by an 80-item quiz. It is unclear whether participants self-administered the questionnaire or it was administered by study personnel. It is also unclear if participants and/or study personnel were blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The final number of participants included in the intervention and control groups is not reported in the paper. The authors reported that all participants who completed the outcome measures were analysed, but it is unclear if all participants completed the outcome measures.
Selective reporting (reporting bias)	Unclear risk	The outcome reported in the methods section was subsequently reported in the results however no published protocol is available.
Other bias	Unclear risk	The authors do not provide the demographic details between groups (only overall).

**Characteristics of excluded studies** *[ordered by study ID]*

Study	Reason for exclusion
<a href="#">Barbour 1978</a>	Not randomised/quasi-randomised controlled trial: no comparison group
<a href="#">Benitez 2002</a>	Does not include an audio-visual informed consent intervention
<a href="#">Benson 1985</a>	Does not include an audio-visual informed consent intervention: recording interaction only
<a href="#">Bickmore 2009</a>	Participants not directly considering clinical trial: considering donating genetic samples only
<a href="#">Campbell 2008</a>	Does not include an audio-visual informed consent intervention
<a href="#">Curbow 2004</a>	Not randomised/quasi-randomised controlled trial
<a href="#">Dobscha 2005</a>	Does not include an AV informed consent intervention
<a href="#">Du 2008</a>	Participants not eligible for clinical trial: Not all participants were eligible for clinical trial participation
<a href="#">Dunbar 1989</a>	Not randomised/quasi-randomised controlled trial
<a href="#">Dunlop 2011</a>	Not randomised/quasi-randomised controlled trial
<a href="#">Dunn 2001</a>	Does not include an AV informed consent intervention: no audio component
<a href="#">Flory 2004</a>	Not randomised/quasi-randomised controlled trial: systematic review

Study	Reason for exclusion
<a href="#">Fureman 1997</a>	Does not include AV informed consent intervention: the intervention included education about clinical trials in general, it was not a specific informed consent intervention
<a href="#">Gesualdo 2012</a>	Not randomised/quasi-randomised controlled trial: no randomisation to AV and non-AV intervention; historical control
<a href="#">Goldberger 2011</a>	Participants not directly considering clinical trial: Informed consent for a (single) diagnostic test, not for a research study of any kind
<a href="#">Hack 2007</a>	Does not include an AV informed consent intervention
<a href="#">Harzstark 2001</a>	Does not include AV informed consent intervention: Intervention not associated with process of obtaining informed consent for research
<a href="#">Hazen 2010</a>	Not randomised/quasi-randomised controlled trial
<a href="#">Hendrikson 2007</a>	Not randomised/quasi-randomised controlled trial
<a href="#">Henry 2009</a>	Not randomised/quasi-randomised controlled trial
<a href="#">Hougham 2003a</a>	Not randomised/quasi-randomised controlled trial: overview of research
<a href="#">Hultgren 2009</a>	Not randomised/quasi-randomised controlled trial: no mention of allocation procedure or the term "random(ised)"
<a href="#">Ishii 2007</a>	Does not include an AV informed consent intervention: Intervention was related to education for future possible clinical trial participation
<a href="#">Jacobsen 2012</a>	Participants not eligible/directly considering clinical trial: Not all participants eligible/asked to participate in a clinical trial
<a href="#">Jimison 1998</a>	Not randomised/quasi-randomised controlled trial: interactive audio-visual tool development
<a href="#">Joseph 2006</a>	Not randomised/quasi-randomised controlled trial: no comparison group
<a href="#">Kim 2008</a>	Not randomised/quasi-randomised controlled trial: reports the development of an audio-visual information consent tool
<a href="#">Llewellyn-Thomas 1995</a>	Does not include an AV informed consent intervention: no audio component
<a href="#">McGraw 2012</a>	Participants not directly considering clinical trial: participants were considering taking part in a biobank, not clinical research
<a href="#">Moseley 2006</a>	Participants not directly considering clinical trial: participants consenting to surgery
<a href="#">Moser 2006</a>	Not randomised/quasi-randomised controlled trial
<a href="#">Palmer 2012</a>	Not randomised/quasi-randomised controlled trial: systematic review
<a href="#">Quinn 2011</a>	Not all participants invited/eligible to take part in clinical trial
<a href="#">Sahai 2007</a>	Participants not directly considering clinical trial: Informed consent intervention for surgery
<a href="#">Simes 1986</a>	Does not include an AV informed consent intervention

Study	Reason for exclusion
<a href="#">Tindall 1994</a>	Does not include an AV informed consent intervention
<a href="#">Varnhagen 2005</a>	Does not include an AV informed consent intervention
<a href="#">Wells 2012</a>	Not randomised/quasi-randomised controlled trial
<a href="#">Wragg 2000</a>	Does not compare an audio-visual informed consent intervention with standard/enhanced consent intervention: Audio-visual intervention provided to both groups. The comparison was different framing messages used in a multi-component intervention

### Characteristics of studies awaiting assessment *[ordered by study ID]*

#### [Hougham 2003b](#)

Methods	Paper not found
Participants	
Interventions	
Outcomes	
Notes	

#### [Rowbotham 2013](#)

Methods	Study design: Randomised controlled trial
Participants	Patients drawn from a variety of clinical practices at California Pacific Medical Center
Interventions	IRB-approved standard paper consent form or the same consent form via an iPad based interactive system
Outcomes	Knowledge/understanding, participant satisfaction with the media used to convey the information, willingness to participate in the clinical trial, time taken to administer the consent procedure
Notes	Fourth author declared a potential conflict of interest as Chair of the company producing the iPad based system

#### [Sonne 2013](#)

Methods	Study design: Quasi-randomised controlled trial Real or hypothetical: hypothetical
Participants	Description: Students were asked to imagine participating in one of three trials with invasive procedures
Interventions	AV format: video and ipad with images, instructional text and scripted voice-overs, professionally produced. Five videos per mock trial were viewed.

**Sonne 2013** (Continued)

Outcomes Knowledge/understanding (subjective and objective assessment), participant satisfaction with the media used to convey the information

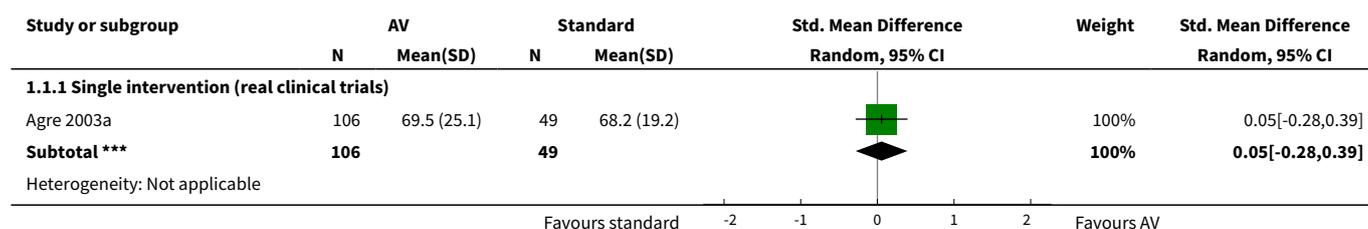
Notes

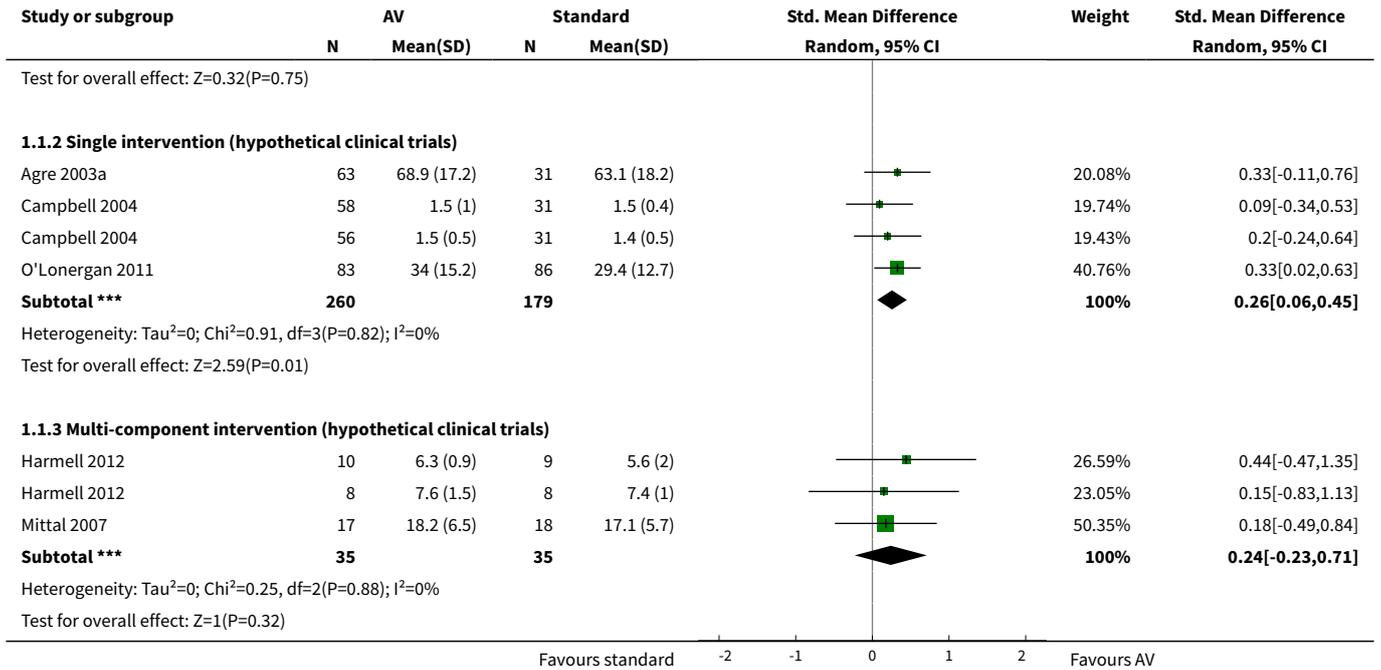
**DATA AND ANALYSES**

**Comparison 1. Audio-visual informed consent versus standard informed consent**

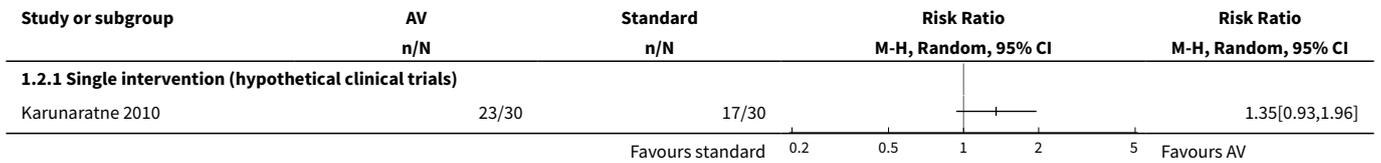
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
<b>1 Knowledge</b>	5		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Single intervention (real clinical trials)	1	155	Std. Mean Difference (IV, Random, 95% CI)	0.05 [-0.28, 0.39]
1.2 Single intervention (hypothetical clinical trials)	3	439	Std. Mean Difference (IV, Random, 95% CI)	0.26 [0.06, 0.45]
1.3 Multi-component intervention (hypothetical clinical trials)	2	70	Std. Mean Difference (IV, Random, 95% CI)	0.24 [-0.23, 0.71]
<b>2 Rate of participation</b>	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
2.1 Single intervention (hypothetical clinical trials)	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
<b>3 Time taken to administer</b>	2		Mean Difference (IV, Random, 95% CI)	Totals not selected
3.1 Single intervention (hypothetical clinical trials)	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
3.2 Multi-component intervention (hypothetical clinical trials)	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]

**Analysis 1.1. Comparison 1 Audio-visual informed consent versus standard informed consent, Outcome 1 Knowledge.**

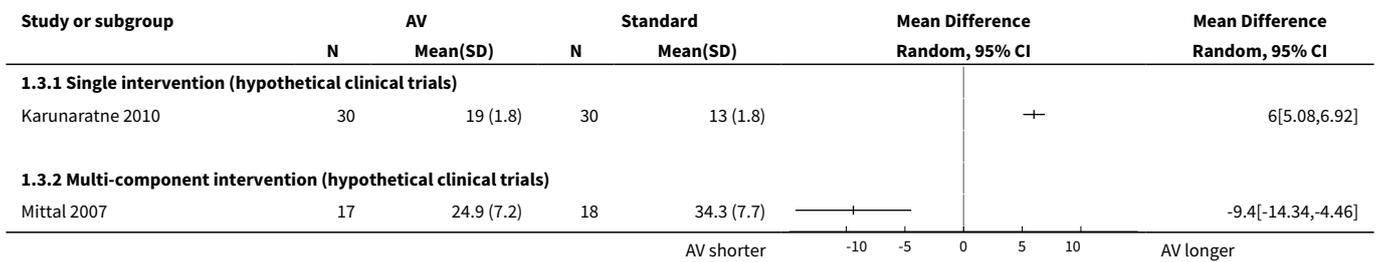




**Analysis 1.2. Comparison 1 Audio-visual informed consent versus standard informed consent, Outcome 2 Rate of participation.**



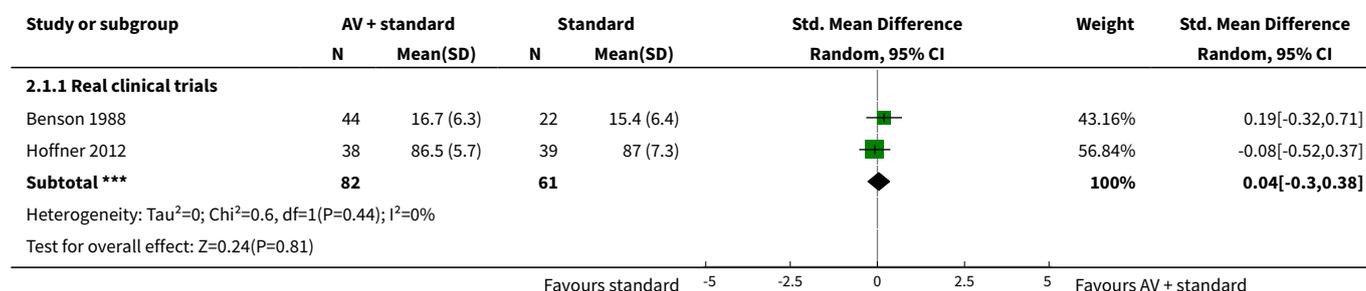
**Analysis 1.3. Comparison 1 Audio-visual informed consent versus standard informed consent, Outcome 3 Time taken to administer.**



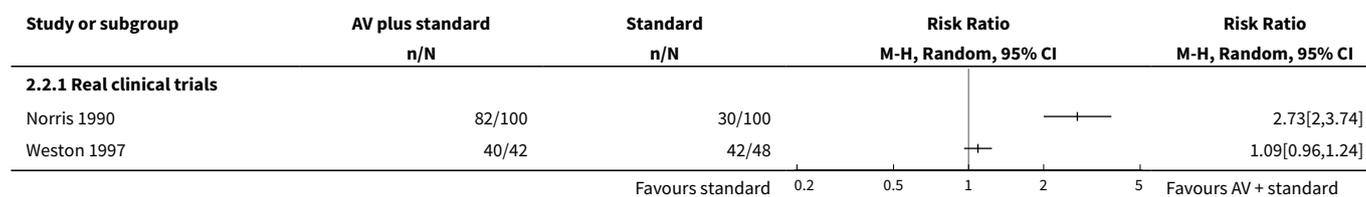
**Comparison 2. Audio-visual plus standard informed consent versus standard informed consent**

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Knowledge	2		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1 Real clinical trials	2	143	Std. Mean Difference (IV, Random, 95% CI)	0.04 [-0.30, 0.38]
2 Knowledge	2		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
2.1 Real clinical trials	2		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
3 Rate of participation	2		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
3.1 Real clinical trials	2		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
4 Retention of knowledge	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
4.1 Real clinical trials	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]

**Analysis 2.1. Comparison 2 Audio-visual plus standard informed consent versus standard informed consent, Outcome 1 Knowledge.**



**Analysis 2.2. Comparison 2 Audio-visual plus standard informed consent versus standard informed consent, Outcome 2 Knowledge.**



**Analysis 2.3. Comparison 2 Audio-visual plus standard informed consent versus standard informed consent, Outcome 3 Rate of participation.**

Study or subgroup	AV plus standard n/N	Standard n/N	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
<b>2.3.1 Real clinical trials</b>				
Hutchison 2007	62/86	66/87		0.95[0.8,1.13]
Weston 1997	23/41	17/44		1.45[0.92,2.3]
Favours standard    0.2    0.5    1    2    5    Favours AV + standard				

**Analysis 2.4. Comparison 2 Audio-visual plus standard informed consent versus standard informed consent, Outcome 4 Retention of knowledge.**

Study or subgroup	AV + standard n/N	Standard n/N	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
<b>2.4.1 Real clinical trials</b>				
Weston 1997	36/41	28/44		1.38[1.07,1.77]
Favours standard    0.2    0.5    1    2    5    Favours AV + standard				

**Comparison 3. Audio-visual informed consent versus placebo informed consent**

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
<b>1 Knowledge</b>	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
1.1 Real clinical trials	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
<b>2 Knowledge</b>	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
2.1 Hypothetical clinical trials	1		Mean Difference (IV, Random, 95% CI)	0.0 [0.0, 0.0]
<b>3 Satisfaction with the information provided</b>	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
3.1 Real clinical trials	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
<b>4 Rate of participation</b>	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
4.1 Real clinical trials	1	49	Risk Ratio (M-H, Random, 95% CI)	0.41 [0.13, 1.33]
4.2 Hypothetical clinical trials	1	188	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.82, 1.19]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5 Satisfaction with the media used	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
5.1 Real clinical trials	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]

**Analysis 3.1. Comparison 3 Audio-visual informed consent versus placebo informed consent, Outcome 1 Knowledge.**

Study or subgroup	AV n/N	Placebo n/N	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
<b>3.1.1 Real clinical trials</b>				
Strevel 2007	21/22	22/27		1.17[0.96,1.43]

Favours placebo      Favours AV

**Analysis 3.2. Comparison 3 Audio-visual informed consent versus placebo informed consent, Outcome 2 Knowledge.**

Study or subgroup	AV N Mean(SD)	Placebo N Mean(SD)	Mean Difference Random, 95% CI	Mean Difference Random, 95% CI
<b>3.2.1 Hypothetical clinical trials</b>				
Jeste 2009	31 25.9 (0.2)	29 25.8 (0.7)		0.1[-0.16,0.36]
Jeste 2009	62 23.7 (4.4)	66 21.1 (6.2)		2.6[0.75,4.45]

Favours placebo      Favours AV

**Analysis 3.3. Comparison 3 Audio-visual informed consent versus placebo informed consent, Outcome 3 Satisfaction with the information provided.**

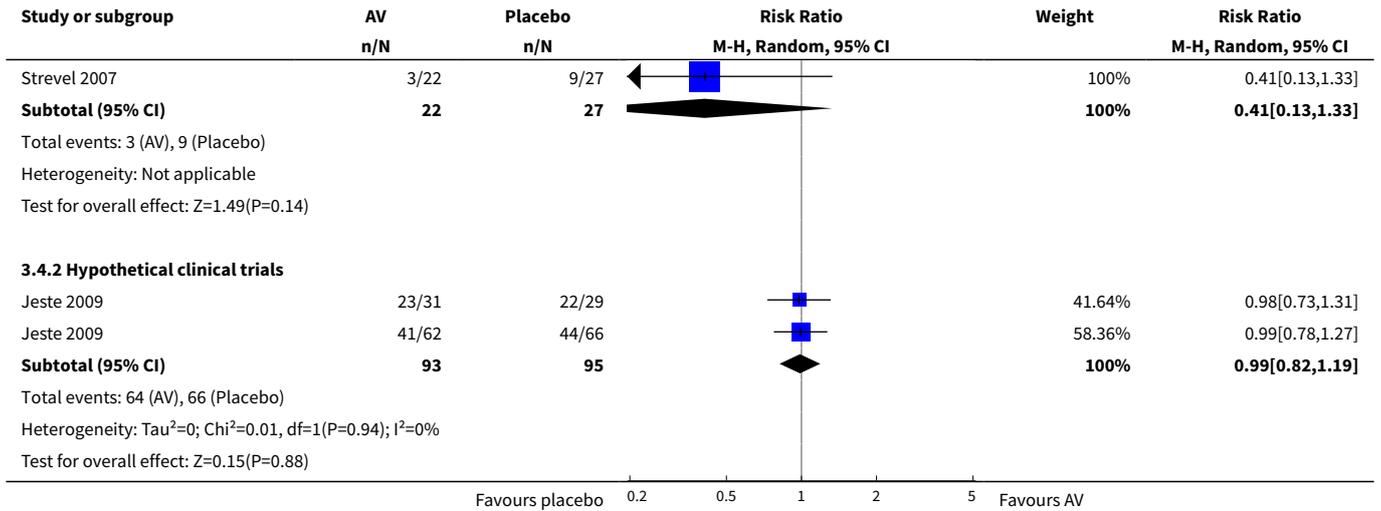
Study or subgroup	AV n/N	Placebo n/N	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
<b>3.3.1 Real clinical trials</b>				
Strevel 2007	11/20	4/24		3.3[1.24,8.78]

Favours placebo      Favours AV

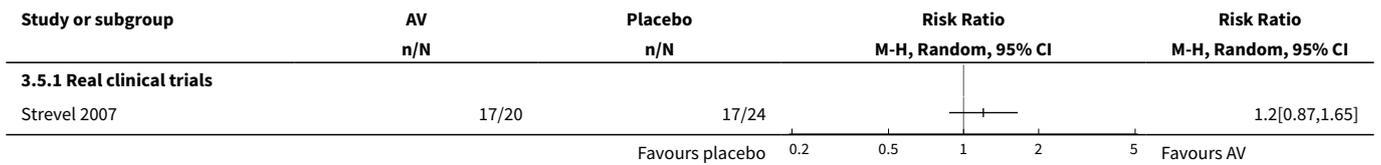
**Analysis 3.4. Comparison 3 Audio-visual informed consent versus placebo informed consent, Outcome 4 Rate of participation.**

Study or subgroup	AV n/N	Placebo n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
<b>3.4.1 Real clinical trials</b>					

Favours placebo      Favours AV



**Analysis 3.5. Comparison 3 Audio-visual informed consent versus placebo informed consent, Outcome 5 Satisfaction with the media used.**



**APPENDICES**

**Appendix 1. MEDLINE search strategy**

1. communications media/
2. exp educational technology/
3. exp audiovisual aids/
4. video recording/
5. exp videoconferencing/
6. video games/
7. (video\* or dvd\* or film\* or cd-rom\* or audiovisual\* or audio-visual\* or multimedia or multi-media).tw.
8. information systems/
9. online systems/
10. exp computers/
11. software/
12. hypermedia/
13. user computer interface/

14. computer assisted instruction/
15. computer graphics/
16. (computer\* and (sound or audio\* or graphic\* or imag\* or game\* or gaming)).tw.
17. computeri#ed.tw.
18. (interactive or animation\*).tw.
19. internet/
20. (internet or web or website\* or webcast\*).tw.
21. (computer adj (assisted or aided or based or mediated or generated)).tw.
22. medical informatics/
23. decision support techniques/
24. decision-making computer assisted/
25. ((decision\* or decid\*) adj4 (tool\* or technolog\* or technique\* or system\* or program\*)).tw.
26. or/1-25
27. exp informed consent/
28. consent\*.tw.
29. (informed adj2 (decision\* or choice\*)).tw.
30. therapeutic misconception/
31. exp disclosure/
32. disclos\*.tw.
33. ((improv\* or increas\* or enhanc\* or patient) adj3 (understanding or comprehension or knowledge)).tw.
34. or/27-33
35. 26 and 34
36. exp clinical trials as topic/
37. exp longitudinal studies/
38. evaluation studies as topic/
39. pilot projects/
40. (trial? or experiment? or research stud\*).tw.
41. ((clinical or intervention or evaluation or comparative or longitudinal or follow-up or followup or prospective or multi-center or multicenter or double blind or pilot or random\* or control\*) adj2 stud\*).tw.
42. exp human experimentation/
43. research subjects/
44. ((research or study) adj (subject\* or participant\*)).tw.
45. ((participa\* or tak\* part or enrol\* or recruit\*) adj7 (research or stud\*)).tw.
46. researcher subject relations/
47. or/36-46

48. 35 and 47
49. randomized controlled trial.pt.
50. controlled clinical trial.pt.
51. randomized.ab.
52. placebo.ab.
53. drug therapy.fs.
54. randomly.ab.
55. trial.ab.
56. groups.ab.
57. or/49-56
58. exp animals/not humans.sh.
59. 57 not 58
60. 48 and 59

## Appendix 2. EMBASE search strategy

1. educational technology/
2. exp audiovisual equipment/
3. videorecording/
4. videoconferencing/
5. (video\* or dvd\* or film\* or cd-rom\* or audiovisual\* or audio-visual\* or multimedia or multi-media).ti,ab,kw.
6. information system/
7. online system/
8. exp computer/
9. exp computer program/
10. hypermedia/
11. computer interface/
12. computer graphics/
13. (computer\* and (sound or audio\* or graphic\* or imag\* or game\* or gaming)).ti,ab,kw.
14. computeri#ed.ti,ab,kw.
15. (interactive or animation\*).ti,ab,kw.
16. internet/
17. (internet or web or website\* or webcast\*).ti,ab,kw.
18. (computer adj (assisted or aided or based or mediated or generated)).ti,ab,kw.
19. medical information system/
20. decision support system/
21. ((decision\* or decid\*) adj4 (tool\* or technolog\* or technique\* or system\* or program\*)).ti,ab,kw.

22. or/1-21
23. informed consent/
24. parental consent/
25. consent\*.tw.
26. (informed adj2 (decision\* or choice\*)).ti,ab,kw.
27. therapeutic misconception/
28. disclos\*.ti,ab,kw.
29. ((improv\* or increas\* or enhanc\* or patient) adj3 (understanding or comprehension or knowledge)).ti,ab,kw.
30. or/23-29
31. 22 and 30
32. exp controlled study/
33. exp clinical study/
34. exp comparative study/
35. evaluation/
36. pilot study/
37. (trial? or experiment? or research stud\*).ti,ab,kw.
38. ((clinical or intervention or evaluation or comparative or longitudinal or follow-up or followup or prospective or multi-center or multicenter or double blind or pilot or random\* or control\*) adj2 stud\*).ti,ab,kw.
39. human experiment/
40. research subject/
41. ((research or study) adj (subject\* or participant\*)).ti,ab,kw.
42. ((participa\* or tak\* part or enrol\* or recruit\*) adj7 (research or stud\*)).ti,ab,kw.
43. or/32-42
44. 31 and 43
45. randomized controlled trial/
46. controlled clinical trial/
47. single blind procedure/ or double blind procedure/
48. crossover procedure/
49. random\*.tw.
50. placebo\*.tw.
51. ((singl\* or doubl\*) adj (blind\* or mask\*)).tw.
52. (crossover or cross over or factorial\* or latin square).tw.
53. (assign\* or allocat\* or volunteer\*).tw.
54. or/45-53
55. 44 and 54

**Appendix 3. CINAHL search strategy**

#	Query	Limiters/Expanders
S50	S38 and S48	Limiters - Exclude MEDLINE records Search modes - Boolean/Phrase
S49	S38 and S48	Search modes - Boolean/Phrase
S48	S39 or S40 or S41 or S42 or S43 or S44 or S45 or S46 or S47	Search modes - Boolean/Phrase
S47	TI (singl* or doubl* or tripl* or trebl*) and TI (blind* or mask*)	Search modes - Boolean/Phrase
S46	AB (singl* or doubl* or tripl* or trebl*) and AB (blind* or mask*)	Search modes - Boolean/Phrase
S45	AB (random* or trial or placebo*) or TI (random* or trial or placebo*)	Search modes - Boolean/Phrase
S44	MH Quantitative Studies	Search modes - Boolean/Phrase
S43	MH Placebos	Search modes - Boolean/Phrase
S42	MH Random Assignment	Search modes - Boolean/Phrase
S41	MH Clinical Trials+	Search modes - Boolean/Phrase
S40	PT Clinical Trial	Search modes - Boolean/Phrase
S39	PT randomized controlled trial	Search modes - Boolean/Phrase
S38	S31 and S37	Search modes - Boolean/Phrase
S37	S32 or S33 or S34 or S35 or S36	Search modes - Boolean/Phrase
S36	(participa* N6 research*) or (participa* N6 stud*) or ("tak* part" N6 research*) or ("tak* part" N6 stud*) or (enrol* N6 research*) or (enrol* N6 stud*) or (recruit* N6 research*) or (recruit* N6 stud*)	Search modes - Boolean/Phrase
S35	"research* subject*" or "human subject*" or "human experiment*"	Search modes - Boolean/Phrase
S34	(clinical N1 stud*) or (intervention N1 stud*) or (evaluation N1 stud*) or (comparative N1 stud*) or (longitudinal N1 stud*) or ("follow-up" N1 stud*) or (followup N1 stud*) or (prospective N1 stud*) or ("multi-center" N1 stud*) or (multicenter N1 stud*) or ("double blind" N1 stud*) or (pilot N1 stud*) or (random* N1 stud*) or (control* N1 stud*)	Search modes - Boolean/Phrase
S33	trial* or experiment* or "research stud*"	Search modes - Boolean/Phrase
S32	MH experimental studies+	Search modes - Boolean/Phrase
S31	S25 and S30	Search modes - Boolean/Phrase
S30	S26 or S27 or S28 or S29	Search modes - Boolean/Phrase

(Continued)

S29	(improv* N2 understanding) or (improv* N2 comprehension) or (improv* N2 knowledge) or (increas* N2 understanding) or (increas* N2 comprehension) or (increas* N2 knowledge) or (enhanc* N2 understanding) or (enhanc* N2 comprehension) or (enhanc* N2 knowledge) or (patient* N2 understanding) or (patient* N2 comprehension) or (patient* N2 knowledge)	Search modes - Boolean/Phrase
S28	disclos*	Search modes - Boolean/Phrase
S27	(informed N1 decision*) or (informed N1 choice*)	Search modes - Boolean/Phrase
S26	consent*	Search modes - Boolean/Phrase
S25	S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24	Search modes - Boolean/Phrase
S24	(decision* N3 tool*) or (decision* N3 technolog*) or (decision* N3 technique*) or (decision* N3 system*) or (decision* N3 program*)	Search modes - Boolean/Phrase
S23	"risk communication tool*" or "risk information tool*" or "risk presentation tool*" or "risk graphic* tool*" or "risk visuali*ation tool*"	Search modes - Boolean/Phrase
S22	computer* and (sound or audio* or graphic* or imag* or game or gaming)	Search modes - Boolean/Phrase
S21	multimedia or "multi media" or video* or dvd* or film* or television or "cd-rom*" or animation or audiovisual* or "audio visual*"	Search modes - Boolean/Phrase
S20	interactive	Search modes - Boolean/Phrase
S19	"computer assisted" or "computer based" or "computer generated" or "computer mediated" or computeri?ed	Search modes - Boolean/Phrase
S18	hypertext or hypermedia	Search modes - Boolean/Phrase
S17	internet or web or website* or webcast*	Search modes - Boolean/Phrase
S16	"user computer interface"	Search modes - Boolean/Phrase
S15	"computer graphics"	Search modes - Boolean/Phrase
S14	"computer terminals"	Search modes - Boolean/Phrase
S13	MH software	Search modes - Boolean/Phrase
S12	"computer program**"	Search modes - Boolean/Phrase
S11	MH computer systems+	Search modes - Boolean/Phrase
S10	MH health information networks	Search modes - Boolean/Phrase
S9	"online system**"	Search modes - Boolean/Phrase

(Continued)

S8	MH health information systems	Search modes - Boolean/Phrase
S7	MH information systems	Search modes - Boolean/Phrase
S6	MH health informatics+	Search modes - Boolean/Phrase
S5	"communication* media"	Search modes - Boolean/Phrase
S4	"educational technology"	Search modes - Boolean/Phrase
S3	MH "computers and computerization"	Search modes - Boolean/Phrase
S2	MH informatics	Search modes - Boolean/Phrase
S1	MH audiovisuals+	Search modes - Boolean/Phrase

#### Appendix 4. PsycINFO search strategy

1. exp audiovisual communications media/
2. multimedia/
3. exp audiovisual instruction/
4. instructional media/
5. communications media/
6. telecommunications media/
7. exp electronic communication/
8. hypermedia/
9. exp information systems/
10. exp computers/
11. computer software/
12. exp human computer interaction/
13. teleconferencing/
14. computer games/
15. (video\* or dvd\* or film\* or cd-rom\* or audiovisual\* or audio-visual\* or multimedia or multi-media).ti,ab,id.
16. computer assisted instruction/
17. (visual display or graphical display).ti,ab,hw,id.
18. (computer\* and (sound or audio\* or graphic\* or imag\* or game\* or gaming)).ti,ab,id.
19. (interactive or animation\*).ti,ab,id.
20. internet/
21. (internet or web or website\* or webcast\*).ti,ab,hw,id.
22. (computer adj (assisted or aided or based or mediated or generated)).ti,ab,id.

23. computeri#ed.ti,ab,id.
24. computer applications/
25. decision support systems/
26. ((risk communication or risk assessment or risk information) adj4 tool\*).ti,ab,id.
27. ((decision\* or decid\*) adj4 (tool\* or technolog\* or technique\* or system\* or program\*)).ti,ab,id.
28. or/1-27
29. informed consent/
30. consent\*.ti,ab,id.
31. (informed adj2 (decision\* or choice\*)).ti,ab,id.
32. disclos\*.ti,ab,id.
33. ((improv\* or increas\* or enhanc\* or patient) adj3 (understanding or comprehension or knowledge)).ti,ab,id.
34. or/29-33
35. 28 and 34
36. exp experimental methods/
37. treatment effectiveness evaluation/
38. (trial? or experiment? or research stud\*).ti,ab,id.
39. ((clinical or intervention or evaluation or comparative or longitudinal or follow-up or followup or prospective or multi-center or multicenter or double blind or pilot or random\* or control\*) adj2 stud\*).ti,ab,id.
40. exp experimentation/
41. experimental subjects/
42. ((research or study) adj (subject\* or participant\*)).ti,ab,id.
43. ((participa\* or tak\* part or enrol\* or recruit\*) adj7 (research or stud\*)).ti,ab,id.
44. or/36-43
45. 35 and 44
46. random\*.ti,ab,hw,id.
47. trial\*.ti,ab,hw,id.
48. controlled stud\*.ti,ab,hw,id.
49. placebo\*.ti,ab,hw,id.
50. ((singl\* or doubl\* or trebl\* or tripl\*) and (blind\* or mask\*)).ti,ab,hw,id.
51. (cross over or crossover or factorial\* or latin square).ti,ab,hw,id.
52. (assign\* or allocat\* or volunteer\*).ti,ab,hw,id.
53. treatment effectiveness evaluation/
54. mental health program evaluation/
55. exp experimental design/
56. "2000".md.

57. or/46-56

58. 45 and 57

### **Appendix 5. Current Contents search strategy**

1. communications media.mp.

2. educational technology.mp.

3. (video\* or dvd\* or film\* or cd-rom\* or audiovisual\* or audio-visual\* or multimedia or multi-media).mp.

4. software.mp.

5. hypermedia.mp.

6. computer\*.kw,kp,ti.

7. (computer\* and (sound or audio\* or graphic\* or interface\* or interaction or imag\* or game\* or gaming)).mp.

8. computer#ed.mp.

9. (interactive or animation\*).mp.

10. (internet or web or website\* or webcast\*).mp.

11. (computer adj (assisted or aided or based or mediated or generated)).mp.

12. medical informatics.mp.

13. ((decision\* or decid\*) adj4 (tool\* or technolog\* or technique\* or system\* or program\*)).mp.

14. or/1-13

15. consent\*.mp.

16. (informed adj2 (decision\* or choice\*)).mp.

17. therapeutic misconception.mp.

18. disclos\*.mp.

19. ((improv\* or increas\* or enhanc\* or patient) adj3 (understanding or comprehension or knowledge)).mp.

20. or/15-19

21. 14 and 20

22. (trial? or experiment? or research stud\*).mp.

23. ((clinical or intervention\* or evaluation or comparative or longitudinal or follow-up or followup or prospective or multi-center or multicenter or double blind or pilot or random\* or control\*) adj2 stud\*).mp.

24. ((research or study) adj (subject\* or participant\*)).mp.

25. ((participa\* or tak\* part or enrol\* or recruit\*) adj7 (research or stud\*)).mp.

26. or/22-25

27. 21 and 26

28. (random\* or trial\* or placebo\* or assign\* or allocat\* or volunteer\* or ((singl\* or doubl\* or tripl\* or trebl\*) and (blind\* or mask\*)) or crossover or cross over or factorial\* or latin square).mp.

29. 27 and 28

30. (beha or clin).sb.

31. 29 and 30

**Appendix 6. CENTRAL (Cochrane Central Register of Controlled Trials) search strategy**

#1	(*communication*-media or instructional-media or educational-technology):ti,ab,kw
#2	MeSH descriptor Educational Technology explode all trees
#3	MeSH descriptor Audiovisual Aids explode all trees
#4	(video* or dvd or film or cd-rom or audiovisual* or audio-visual* or multimedia or multi-media):ti,ab,kw
#5	((information or online) next system) or medical-informatics):kw
#6	(computer next (program or interface or system or network or terminal or graphics or assisted or aided or based or mediated or generated)):ti,ab,kw
#7	(computer* and (sound or audio* or graphic* or imag* or game or gaming)):ti,ab,kw
#8	MeSH descriptor Computers explode all trees
#9	MeSH descriptor Software, this term only
#10	hypermedia:ti,ab,kw
#11	computeri*ed:ti,ab,kw or ("computers" or microcomputer):kw
#12	(interactive or animation*):ti,ab,kw
#13	(internet or web or website or webcast):ti,ab,kw
#14	(risk-information or risk-communication or risk-presentation or risk-graphic* or risk-visuali*ation) next tool
#15	((decision* or decid*) near/4 (tool or technolog or technique or system or program*)):ti,ab,kw
#16	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15)
#17	consent*:ti,ab,kw
#18	(informed near/2 (decision or choice)):ti,ab,kw
#19	disclos*:ti,ab,kw
#20	therapeutic-misconception:kw
#21	((improv* or increas* or enhanc* or patient) near/3 (understanding or comprehension or knowledge)):ti,ab,kw
#22	(#17 OR #18 OR #19 OR #20 OR #21)
#23	(#16 AND #22)
#24	MeSH descriptor Clinical Trials as Topic explode all trees
#25	MeSH descriptor Longitudinal Studies explode all trees

(Continued)

#26	MeSH descriptor Human Experimentation explode all trees
#27	(research*-subject or research-participant or study-participant or human-subject):ti,kw
#28	pilot-project:ti,ab,kw
#29	(trial or experiment or research-study):ti,ab,kw
#30	((clinical or intervention or evaluation or comparative or longitudinal or follow-up or followup or prospective or multi-center or multicenter or double-blind or pilot or random* or control*) next study):ti,ab,kw
#31	((participa* or tak*-part or enrol* or recruit*) near/7 (research or study)):ti,ab,kw
#32	(#24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31)
#33	(#23 AND #32)

## Appendix 7. ERIC search strategy

(Command Line Search)

all(multimedia OR "multi media" OR video\* OR dvd\* OR film\* OR television OR "cd-rom\*" OR animation\* OR audiovisual\* OR "audio visual\*" OR interactive\* OR computer\* OR software OR media OR hypermedia OR internet OR web OR website\* OR webcast\* OR portal\* OR online OR "on-line" OR informatics OR "information system\*" OR ((decision\* OR decid\*) NEAR/4 (tool\* OR technolog\* OR technique\* OR system\* OR program\*)) OR "risk information tool\*" OR "risk communication tool\*" OR "risk presentation tool\*" OR "risk graphic\*" OR "risk visuali\* tool\*") AND all(consent\* OR disclos\* OR "informed decision\*" OR "informed choice\*" OR ((improv\* OR increas\* OR enhanc\* OR patient\*) NEAR/3 (understanding OR comprehension OR knowledge))) AND all(trial\* OR experiment\* OR "research stud\*" OR ((clinical OR intervention OR evaluation OR comparative OR longitudinal OR "follow-up" OR followup OR prospective OR "multi-center" OR multicenter OR "double blind" OR pilot OR random\* OR control\*) NEAR/2 stud\*) OR "research\* subject\*" OR "research participant\*" OR "study participant\*" OR "human subject\*" OR "human experiment\*") AND all(random\* OR trial\* OR placebo\* OR assign\* OR allocat\* OR volunteer\* OR ((single\* OR double\* OR triple\* OR treble\*) AND (blind\* OR mask\*)) OR crossover OR "cross over" OR factorial\* OR "latin square")

## Appendix 8. Details of author/expert contact

Study ID/Expert Name	Contact person	Response?	Information obtained
<b>TRIAL AUTHORS</b>			
<a href="#">Agre 2003b</a>	P. Agre	Yes	Confirmed that Mintz et al trial (cited in Agre et al 2003) was published as Wirshing et al 2005. Also provided contact details to N. Kass, author of second queried trial cited in Agre et al 2003. Provided confirmation that Agre et al 1994 paper was informed consent for therapeutic decision-making (and excluded from review). Provided detailed information about the <a href="#">Agre 2003a</a> study September 12 2006. Contacted for more information for current update and provided this.
<a href="#">Benson 1988</a>	P.S. Appelbaum	Yes	Provided details requested on author form.
<a href="#">Benson 1988</a>	P. Benson	No	-
<a href="#">Bickmore 2009</a>	T. Bickmore	No	-

(Continued)

<a href="#">Campbell 2004</a>	F. Campbell	Yes	Provided further trial information.
<a href="#">Dunn 2001</a>	L. Dunn	Yes	Confirmed that intervention did not contain audio-visual material; study excluded based on this information.
<a href="#">Fureman 1997</a>	I. Fureman	No	-
<a href="#">Harmell 2012</a>	B. Palmer		Provided further trial information.
<a href="#">Hazen 2010</a>	R. Noll	Yes	Confirmed that no RCT had been conducted with the audio-visual intervention described in the paper.
<a href="#">Hoffner 2012</a>	B. Hoffner	No	-
<a href="#">Hougham 2003a</a>	G. Sachs	Yes	Provided up to date contact details for G. Hougham; also provided additional papers and contact details for several researchers working in the field of informed consent.
<a href="#">Hougham 2003a</a>	G. Hougham	Yes	Initial response agreed to find information on trials contained in paper. No further response.
<a href="#">Hultgren 2009</a>	F. Fregni	No	No response received so made determination that it was not an RCT based on the fact that allocation was not described and the word random(isation) was not used.
<a href="#">Hutchison 2007</a>	C. Hutchison	Yes	Confirmed that she has undertaken no further RCTs that would meet the inclusion criteria for this review. Further contact made and author provided further trial information.
<a href="#">Jeste 2009</a>	D. Jeste	No	-
<a href="#">Karunaratne 2010</a>	A. Karunaratne	Yes	Confirmed that the intervention met the inclusion criteria and provided further trial information.
<a href="#">Kass 2009</a>	N. Kass E. Emanuel C. Daugherty	Yes	Initially contacted in 2007 about Kass et al trial that was yet to be published. The authors confirmed it meets review criteria. Contacted N Kass in 2013 (no response). Contacted in C. Daugherty in 2013 - advised that Daugherty 2003 and Hlubocky 2004 described the same study as <a href="#">Kass 2009</a> but he was not able to provide further information about the <a href="#">Kass 2009</a> trial.
<a href="#">Kim 2008</a>	J. Baker	Yes	Confirmed that no RCT had been conducted with the audio-visual intervention described in the paper.
<a href="#">Klein 2012</a>	D. Klein	No	-
<a href="#">Llewellyn-Thomas 1995</a>	H. Llewellyn-Thomas	Yes	Confirmed there was no audio component to the intervention.
<a href="#">Mittal 2007</a>	D. Mittal	Yes	Provided further trial information.
<a href="#">Norris 1990</a>	Authors not traceable		-
<a href="#">O'Lonegan 2011</a>	T. O'Lonegan	No	Email addresses no longer accurate, new email addresses not traceable.

(Continued)

J. Foster-Harwood

<a href="#">Quinn 2011</a>	K. Wells	Yes	Advised that manuscript is being considered for publication but that not all participants were offered/eligible for clinical trial participation.
<a href="#">Strevel 2007</a>	L. Siu	Yes	Provided further trial information.
<a href="#">Wells 2012</a>	K. Wells	Yes	Provided the details of an RCT published after this paper (Jacobson 2012) that was subsequently excluded.
<a href="#">Weston 1997</a>	J. Weston	Yes.	Confirmation of duplication of study (Weston 1995, abstract); provision of all requested additional trial details.
<a href="#">Wirshing 2005</a>	D. Wirshing J. Mintz M. Sergi	Yes	Contacted Wirshing for original review and provided full text paper and additional references. Contacted for 2013 update, J. Mintz provided some additional trial information.

### EXPERTS

J. Karlawish re informed consent research (expert)	J. Karlawish	No	-
S. Kim re informed consent research (expert)	S. Kim	Yes	Referred to other experts in research on interventions to alter informed consent.

### WHAT'S NEW

Date	Event	Description
8 April 2014	New citation required and conclusions have changed	<p>The conclusions of this review are based on a much larger number of studies than the original version. While the updated review's findings were largely consistent with those of the previous version, we found some low to very low quality evidence of slight improvements in knowledge or understanding of the parent trial, but with little or no difference in the effect on rate of participation or willingness to participate.</p> <p>The authorship was changed for this update.</p>
13 June 2012	New search has been performed	<p>We ran new searches in June 2012. To the original 4 included studies we added 12 new studies, bringing the total number of included studies to 16.</p> <p>The inclusion criteria and some other aspects of the review methods were revised for this update. The original review (<a href="#">Ryan 2008</a>) had only included people considering participating in a real trial. For this update, we included studies in which participants were asked to consider taking part in a real or a hypothetical</p>

Date	Event	Description
		ical clinical trial. We expanded the comparator interventions to include standard and placebo audio-visual interventions. We revised the structure of the outcomes, added several new outcomes and broadened the scope of the 'anxiety' outcome. We assessed all studies using the Cochrane 'Risk of bias' tool, and added 'Summary of findings' tables.

## HISTORY

Protocol first published: Issue 3, 2002

Review first published: Issue 1, 2008

Date	Event	Description
9 April 2009	Amended	<a href="#">Mittal 2007</a> added to excluded studies list.
8 November 2007	New citation required and conclusions have changed	Substantive amendment

## CONTRIBUTIONS OF AUTHORS

Kristen McLaughlin and Caroline Crowther (see [Acknowledgements](#)) participated in the conceptualisation of the review and Kristen McLaughlin, Annie Brindley (see [Acknowledgements](#)) and Caroline Crowther prepared the protocol ([McLaughlin 2002](#)).

Rebecca Ryan, Megan Prictor, Kristen McLaughlin and Sophie Hill prepared the original version of this review ([Ryan 2008](#)).

For this update:

AS revised the methods, undertook the searches, assessed studies for inclusion, extracted data, contacted authors, entered data into Revman, led the data synthesis and interpretation, contributed to review text and addressed feedback.

RR revised the methods, assessed studies for inclusion, extracted data, led the data synthesis and interpretation, and contributed to the review text, performed final data checks and addressed feedback.

MP revised the methods, assessed studies for inclusion, contacted authors, contributed to data synthesis and interpretation and contributed to the review text and performed final data checks.

DF revised the methods, assessed studies for inclusion, extracted data, contributed to data synthesis and interpretation and performed final data checks.

BP extracted data, contributed to data synthesis and interpretation and performed final data checks.

## DECLARATIONS OF INTEREST

Authors included staff of the Cochrane Consumers and Communication Review Group (AS, MP, RR), based at La Trobe University and funded by the National Health and Medical Research Council (AS, RR) and the Department of Health (Victoria) (MP). The decision whether or not to publish the updated review did not involve these staff.

## SOURCES OF SUPPORT

### Internal sources

- La Trobe University, Melbourne, Australia.

All authors were employees of La Trobe University and received office space, and IT and library support, from the University.

## External sources

- NHMRC, Australia.

Cochrane Collaboration infrastructure funding to Australian Cochrane Review Groups. Salary of RR, AS

- Department of Health, Victoria, Australia.

Funding and service agreement with La Trobe University for Cochrane Consumers and Communication Review Group. Salary of MP

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Before this review update was commenced, we made a number of changes to methods derived from the previous version of this review (Ryan 2008):

- Objectives: we re-worded the objectives to better reflect the change in outcome order
- Types of participants: we included studies in which participants were asked to consider taking part in a hypothetical clinical trial situation (see background section for justification). We include a definition of 'clinical trial'
- Types of interventions: we expanded the types of interventions we included for comparison with audio-visual interventions to include standard and placebo audio-visual interventions
- Types of outcomes measures: we structured the outcomes according to primary and secondary outcomes and re-ordered them. The outcome 'Anxiety' was broadened to include 'Anxiety (or other psychological stress)' and two clinical researcher-related outcome measures, along with time taken to administer the intervention, were added, to increase the relevance of the findings to this stakeholder group
- Search methods for identification of studies: to account for the change in inclusion criteria we revised the search strategies and conducted the searches without date restriction. This search yield replaces the original search yield for this review
- Data extraction and management - small changes were made to the type of data extracted. Additionally we incorporated detailed information about the interventions and outcomes that was provided in two tables in the previous version of the review, into the Characteristics of Included Studies tables
- Assessment of risk of bias of included studies - we replaced the original assessment of study bias with the Cochrane 'Risk of bias' tool as outlined in the *Cochrane Handbook*.
- We added 'Summary of findings' tables

In addition, we expanded the methods relating to the analysis of data to better reflect current headings and methodological guidance for Cochrane reviews. These changes are outlined under the following sections of this review; Measures of treatment effect, Unit of analysis issues, Dealing with missing data, Assessment of heterogeneity, Assessment of reporting biases, Data synthesis, Subgroup analysis and investigation of heterogeneity and Sensitivity analysis.

The text in these sections replaces the following text that was included in an appendix of the previous version of the review (Ryan 2008) for application in future updates:

"Analysis would include calculation of relative risk (RR) and 95% confidence intervals (CI) for dichotomous outcomes and weighted mean difference (WMD) and 95% CI for continuous outcomes, using Cochrane Review Manager (RevMan) software. The Chi-squared test would be used to test for heterogeneity in outcomes. A fixed effects model would be used unless heterogeneity was found, in which case a random effects model would be used. Primary analyses would be on an 'intention to treat' basis.

Sensitivity analyses (to evaluate the effects of trial quality on meta-analysis results) and subgroup analyses (to assess the effects of the timing of the video intervention delivery relative to the informed consent process; the timing of outcome assessment with reference to the video intervention delivery; the use of the video intervention for the guardians of individuals asked to participate in a clinical study; and the effects on people with low literacy or people from other language groups) would be conducted if possible.

These methods will be retained for application in a future update of the review, if statistical pooling becomes possible."

## INDEX TERMS

### Medical Subject Headings (MeSH)

\*Audiovisual Aids; \*Clinical Trials as Topic; \*Informed Consent; \*Patient Selection; Patient Education as Topic [\*methods]; Randomized Controlled Trials as Topic

### MeSH check words

Humans